MAUDE ENTRIES (377 TOTAL DEATHS) FOR SPRINT QUATTRO SECURE IMPLANTABLE DEFIBRILLATION LEAD MODEL 6947

Search Criteria:

1. **Go to MAUDE URL -> Tools and Resources -> Medical Device Databases and select MAUDE Database**
2. **Clear all default data in the fields (the 510K and PMA fields may have some default values so those need to be cleared before doing the search)**
3. **In Brand Name, type in Quattro**
4. **In Manufacturer, type in Medtronic**
5. **In Event Type, type in Death**
6. **In Date Report range, type in 1/1/2001 to 2/10/2012**
7. **Select Search. A list of all Quattro model numbers will be generated. The user will need to select each individual MAUDE report to identify a specific model number (e.g. model 6947). Also, duplicate records may exist and they would need to be individually removed to arrive at a total number.**

#	MDR Report Key	MDR TEXT
		Note 1: The term "ASKU" is used where a field is left blank or N/A. **Note 2: There are some "Events Types" that are initially injury or malfunction but it is death due to patient outcome. Hence these are included in the 377.** **Note 3: The MAUDE search can result in duplicate records since sometimes a MEDWATCH form is submitted in addition to the MDR submitted by the manufacturer. Duplicate records have been removed in this table below.** **Note 4: Some records show repeated text for Event Description and Manufacturer's Narrative. This is a result of updates provides by the manufacturer.** **Note 5: Some records show Device Problems indicated as "No Known Device Problem." These records could be updated with additional text should there be further information provided on the case.**
001	**386786**	**Model Number** 6947 **Device Problem** Other (for use when an appropriate device code cannot be identified) **Event Date** 01/23/2002 **Event Type** Death **Patient Outcome** Death,Other **Event Description** Rv lead perforation. **Manufacturer Narrative** Follow-up with the user facility revealed that this event did not meet their mdr reporting threshold.
002	**411665**	**Model Number** 6947 **Device Problem** Difficult to insert **Event Date** 07/11/2002 **Event Type** Death **Patient Outcome** Death **Event Description** During procedure to implant icd, pt coded and died. Possibly due to perforation of right ventricle by lead insertion activity.
003	**418710**	**Model Number** 6947

		Device Problem Difficult to insert **Event Date** 07/11/2002 **Event Type** Death **Patient Outcome** Death; **Manufacturer Narrative** Attempts were made to obtain additional information from the user facility regarding this event. The information submitted reflects all relevant data received. Notification that this event does not meet the user facility's reporting criteria will be filed internally if it is received after this report is submitted. D. 1 brand sprint quattro, d. 2 implantable tachy lead, d. 7/8 implant/explant 11jul02. - d. 1 brand sprint quattro d. 2 implantable tachy lead d. 7/8 implant/explant 11jul02.
004	**1964240**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 04/01/2009 **Event Type** Death **Patient Outcome** Death **Event Description** The device and leads were returned to the manufacturer after the patient's death. The cause of death and date of death have been requested and not received. **Manufacturer Narrative** Without a lot number or device serial number, the manufacturing date cannot be determined. Analysis of the device is in process; the results will be forwarded when available. **Event Description** The device and leads were returned to the manufacturer after the patient's death. The cause of death and date of death have been requested and not received. Follow up revealed patient had been seen in clinic only once and that was 2 months before death. The nurse reported no device issues were noted. **Manufacturer Narrative** This event occurred outside the us. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient information is not generally available due to confidentiality concerns. Evaluation summary (b)(4) no anomalies found. (b)(4) no anomalies found, outer insulation breached cut and cosmetic depression, apparent explant damage. Proximal segment returned and analyzed. (b)(4) - no anomalies found. Proximal segment returned and analyzed. Corrected serial number of (b)(4) lead from none to (b)(4). Analysis of the device is in process; the results will be forwarded when available. Evaluation summary (b)(4) no anomalies found, outer insulation breached cut and cosmetic depression, apparent explant damage. Proximal

		segment returned and analyzed. (b)(4) - no anomalies found. Proximal segment returned and analyzed. Corrected serial number of (b)(4) lead from none to (b)(4).
005	**487519**	**Model Number** 6947 **Device Problem** Other (for use when an appropriate device code cannot be identified) **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** User facility follow-up is not initiated on reported infection as it is related to a patient condition and not device performance. No information was received to suggest a causal relationship between the device performance and the patient death. We are unable to determine if explant occurred prior to patient death because no explant date information was provided. - evaluation summary - tdg039492v no anomalies found; full lead returned. **Event Description** Infection.
006	**630098**	**Model Number** 6947 **Event Date** 03/26/2003 **Event Type** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. - evaluation summary - pjl237946h no anomalies found - tdg007539r no anomalies found; proximal segment returned for analysis. - evaluation summary - pjl237946h no anomalies found - tdg007539r no anomalies found; proximal segment returned for analysis. **Event Description** Did not detect vf; information received with follow-up indicates the patient expired.
007	**632562**	**Model Number** 6947 **Device Problem** Other (for use when an appropriate device code cannot be identified)

		Event Date 03/29/2004 **Event Type** Death **Patient Outcome** Death; **Manufacturer Narrative** This event occurred outside the us where the same model is distributed and is based solely on analysis. The user facility has no responsibility to file a 3500a. All information provided is included in this report. Patient information is not generally available due to confidentiality concerns. - evaluation summary - tdg066460v full lead returned; continuity on the pin cap was intermittent. **Event Description** Tested out of specification during analysis.
008	**633006**	**Model Number** 6947 **Device Problem** Other (for use when an appropriate device code cannot be identified) **Event Date** 05/04/2004 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** This report is based solely on device return and analysis. - evaluation summary - tdg096830v connector intermittent continuity full lead received. **Event Description** 6947 tested out of specification during analysis. There was no allegation that the patient death was device related.

009	**1041089**	**Model Number** 6947 **Device Problem** Other (for use when an appropriate device code cannot be identified) **Event Date** 05/17/2005 **Event Type** Death **Patient Outcome** Other **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Our records indicate the patient expired more than one year ago. We have no information to suggest the death was device related. Evaluation summary battery - battery depletion-normal. **Event Description** Asku.
010	**714012**	**Model Number** 6947 **Device Problems** High impedance; Oversensing; Inappropriate shock **Event Date** 02/04/2006 **Event Type** Death **Patient Outcome** Other; **Manufacturer Narrative** This information was received from a competitor. All data pertinent to the event is provided. **Event Description** It was reported that the patient was getting shocks, so patient went to er. Pacing impedance > 3000 ohms. Oversensing noted on ventricular egm causing inappropriate shocks. At doctor's order, device was turned off. Patient coded on gurney while going from er to or and died.
011	**784883**	**Model Number** 6947 **Device Problem** Other (for use when an appropriate device code cannot be identified) **Event Date** 05/31/2006

		Event Type Death **Patient Outcome** Other; Death **Manufacturer Narrative** This device is in litigation concerning the event. No further follow up will be done due to its proprietary nature. **Event Description** It was alleged by an attorney that the device 'caused massive infection in (the patient's) body' and had to be removed, along with the leads, 33 months post implant. A further allegation was made that 'the damage caused by the device prevented (the patient) from having another pacemaker/defibrillator installed and eventually caused his death. ' further information was requested, but given the pending litigation, no further information was attainable.
012	**803312**	**Model Number** 6947 **Device Problem** Other (for use when an appropriate device code cannot be identified) **Event Date** 06/28/2006 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The infection was previously reported through easr, however, further information was received that the patient died. Evaluation summary: prn105067h no anomalies were found. **Event Description** It was reported that the patient expired due to sepsis caused by streptococcus. The physician's office stated it was uncertain where the infection came from. They said that the patient works with horses as a hobby and also had a knee injection the week before the patient developed a fever. It is also of note that the patient had a lead revision on june 2, 2006
013	**825641**	**Model Number** 6947 **Device Problem** Other (for use when an appropriate device code cannot be identified) **Event Date** 01/11/2007

		Event Type Death **Patient Outcome** Death **Manufacturer Narrative** This information was received from a competitor. All data pertinent to the event is provided. If additional relevant information is received, a supplemental report will be submitted. Cause of death was requested but not received. **Event Description** It was reported the lv lead was removed due to a fracture and the rv lead was removed due to a 'failure' of the y adaptor. The proximal pins were jammed in the y adaptor header and both leads had to be removed. It was also reported that the patient died during the lead extraction. No further details are available on the circumstances surrounding the pt's death. Cause of death is not known.
014	**826075**	**Model Number** 6947 **Device Problem** Failure to capture **Event Date** 11/13/2006 **Event Type** Death **Patient Outcome** Other **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Cause of death information was requested but not received. Evaluation summary: prm127215h the actual device was not received for evaluation. We did receive performance data collected from the device and have analyzed the data which indicates no anomalies found. **Event Description** It was reported that the device was interrogated after the patient expired. The patient was a heart failure patient who was non-compliant. He was feeling poorly but refused to go to the hospital when his device started firing. The medtronic field person, after evaluation of the post-mortem device interrogation, concluded that the atrium was at a standstill, there was loss of an atrial channel signal, and there was some ventricular non-capture after a shock. Cause of death information was requested but not received.

015	**941988**	**Model Number** 6947 **Device Problems** Oversensing; Low impedance **Event Date** 08/21/2007 **Event Type** Death **Patient Outcome** Death,Required Intervention **Event Description** It was reported the lead was explanted due to low impedance, less than 200 ohms, & oversensing. Additional information was subsequently received reporting during laser extraction to remove the lead, onset of vt occurred. Lab staff defibrillated the patient with 200joules externally & converted back to sinus rhythm for a brief period. The patient's rhythm deteriorated to intermittent heart block, followed by incessant vt/vf, despite multiple external shocks & cpr. During resuscitation efforts, the dr. Attempted to place a new competitor lead to provide stable pacing support. A new lead was implanted, & resuscitation continued, but was unsuccessful. The model 6947 lead was not extracted. **Manufacturer Narrative** This information was received from a competitor. All data pertinent to the event is provided. If additional relevant information is received, a supplemental report will be submitted. Cause of death reported by physician was cardiac; acute death during lead extraction, as a result of extraction procedure, leading to cardiopulmonary arrest. The autopsy report stated cause of death as "hemopericardium & hemothorax during pacemaker placement," with hypertensive arteriosclerotic cardiovascular disease" as contributory factor. Other: it was reported the lead was explanted due to low impedance, less than 200 ohms, & oversensing. Additional information was subsequently received reporting during laser extraction to remove the lead, onset of vt occurred. Lab staff defibrillated the patient with 200joules externally & converted back to sinus rhythm for a brief period. The patient's rhythm deteriorated to intermittent heart block, followed by incessant vt/vf, despite multiple external shocks & cpr. During resuscitation efforts, the dr. Attempted to place a new competitor lead to provide stable pacing support. A new lead was implanted, & resuscitation continued, but was unsuccessful. The model 6947 lead was not extracted. No conclusion can be drawn; oversensing, impedance, low.
016	**1044820**	**Model Number** 6947 **Device Problem** Defective item **Event Date** 01/19/2007

		Event Type Death **Patient Outcome** Death,Other **Event Description** A lawsuit alleges the patient was injured and died, and further states the icd and leads were 'defective'. Additional information was received reporting that there was no performance issue with the device, that the icd and leads were explanted due to infection, and the patient died during the explant procedure. There was no allegation from a health care professional that the death was device related. **Manufacturer Narrative** A lawsuit alleges the patient was injured and died, and further states the icd and leads were 'defective'. Additional information was received reporting that there was no performance issue with the device, that the icd and leads were explanted due to infection, and the patient died during the explant procedure. There was no allegation from a health care professional that the death was device related. No conclusion can be drawn defective device.
017	**1061589**	**Model Number** 6947 **Device Problems** Oversensing; Pacing intermittently; Noise **Event Date** 04/30/2008 **Event Type** Death **Patient Outcome** Death,Other **Manufacturer Narrative** This information was received from a competitor. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. It is not known if the device was explanted post-mortem. It was reported that oversensing of diaphragmatic noise and rv (right ventricular) pacing inhibition occurred. The manufacturer's patient device registration system indicates the patient died five days after the reported event. There is no allegation that the death was device related. Follow-up information received indicated the patient had been admitted with respiratory failure, stroke, aspiration pneumonia, and cardiomyopathy. The death certificate indicates the manner of death to be natural causes. No conclusion can be drawn oversensing pacing intermittently noise. **Event Description**

		It was reported that oversensing of diaphragmatic noise and rv (right ventricular) pacing inhibition occurred. The manufacturer's patient device registration system indicates the patient died five days after the reported event. There is no allegation that the death was device related. Follow-up information received indicated the patient had been admitted with respiratory failure, stroke, aspiration pneumonia, and cardiomyopathy. The death certificate indicates the manner of death to be natural causes.
018	**1288775**	**Model Number** 6947 **Device Problem** Other (for use when an appropriate device code cannot be identified) **Event Date** 11/28/2008 **Event Type** Death **Patient Outcome** Death,Other **Event Description** The patient's doctor reported the pt's wife said the incision site was red, but not open, and there was no drainage. She sent pictures to the doctor, which showed a dark red color, the length of the incision. The pt was admitted to a hospital to 'treat conservatively. ' a doctor who saw the pt 10 days later stated "concerns of icd infection", reporting the pt had developed a rash three weeks earlier and went to the er. At that time, the family said there was no apparent infection. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary no anomalies found. The wife was reportedly concerned the icd had eroded through the skin and was exposed. Examination noted device erosion, with mild inflammatory changes around the exposed leads. Assessment included 'device erosion' and 'possible infection'. The pt's history described 'advanced dementia, dnr status, completely dependent. ' the plan was to remove the device & provide comfort care. The patient died while in the hospital. Additional information from a physician stated the cause of death was chronic heart failure/ pea (pulseless electrical activity). Cpr was started, but the patient's wife chose to stop the efforts. The physician said there is 'no allegation of the device or infection relating to the patient's death. Other: the patient's doctor reported the pt's wife said the incision site was red, but not open, and there was no drainage. She sent pictures to the doctor, which showed a dark red color, the length of the incision. The pt was admitted to a hospital to 'treat conservatively. ' a doctor who saw the pt 10 days later stated

		"concerns of icd infection", reporting the pt had developed a rash three weeks earlier and went to the er. At that time, the family said there was no apparent infection. No conclusion can be drawn.
019	**1414160**	**Model Number** 6947 **Device Problem** High impedance **Event Date** 06/13/2009 **Event Type** Death **Patient Outcome** Death; **Manufacturer Narrative** This event occurred outside the us where the same model is distributed. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient information is not generally available due to confidentiality concerns. The ipg model number (d234vrc) is not approved for distribution in the united states, however, it is similar to a device marketed in the u. S. Evaluation summary: no anomalies found; proximal segment returned and analyzed. Analysis of the ipg is in process; the results will be forwarded when available. Disclaimer: submission of information by medtronic under the medical device reporting regulation does not constitute an admission that the device (s) has malfunctioned or that there is any causal connection between the performance of the device and any injury that may have occurred. Cause of death was requested but not received. **Event Description** It was reported that in 2009, the patient called an ambulance after becoming nauseated. The patient died in spite of a resusitation attempt. Interrogation of the device revealed power on reset occurred the day before, and two lead impedances warnings on original date. Cause of death has been requested and not received. Follow up revealed there was no autopsy, and the phyisician stated he doesn't know if the device had anything to do with the patient's death. **Manufacturer Narrative** This event occurred outside the us where the same model is distributed. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient information is not generally available due to confidentiality concerns. The ipg model number (d234vrc) is not approved for other text : trueisprint quattro

		secureimplantable tachy lead. It was reported that in 2009, the patient called an ambulance after becoming nauseated. The patient died in spite of a resusitation attempt. Interrogation of the device revealed power on reset occurred the day before, and two lead impedances warnings on original date. Cause of death has been requested and not received. Follow up revealed there was no autopsy and the phyisician stated he doesn't know if the device had anything to do with the patient's death. No conclusion can be drawn. Impedance, high. **Manufacturer Narrative** The ipg model number (d234vrc) is not approved for distribution in the united states, however, it is similar to a device marketed in the u. S. Cause of death was requested but not received. Evaluation summary: no anomalies found; proximal segment returned and analyzed. A power on reset was confirmed at preliminary analysis. Attempts to repeat the por were unsuccessful. Examination of the device during separation of the major components revealed two points between the hybrid and an adjacent component that had apparently been penetrated by a probe or some instrument. No conclusive evidence was found associating these probe marks with the unexplained por event. Due to the inability in reproducing the por, a cause for the reset was not determined.
020	**1414162**	**Model Number** 6947 **Device Problem** Other (for use when an appropriate device code cannot be identified) **Event Date** 03/25/2009 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis of the ipg (model 154awg) is in process; the results will be forwarded when available. Evaluation summary: no anomalies found. Proximal segment returned and analyzed. **Event Description**

		It was reported the patient died with cause of death sepsis, multiple organ failure, probable cytomegalovirus pneumonitis with secondary bacterial infection, and complications of multiple myeloma. There is no indication this death was device related.
021	**1414165**	**Model Number** 6947 **Device Problem** Defective item **Event Date** 01/22/2008 **Event Type** Death **Patient Outcome** Death **Event Description** Lawsuit alleges that the patient "sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress. " review of the manufacturer's database revealed the patient had died. The cause of death has been requested and not received. There is no allegation from a health care professional that the death was device related. **Manufacturer Narrative** This event involves a legal case in progress or potential litigation. The proprietary nature of the event may affect follow up efforts. If additional relevant information is received, a supplemental report will be submitted. Our records indicate the patient expired more than one year ago. We have no information to suggest the death was device related. The cause of death has been requested but has not been received. It is not known if the device was explanted post-mortem.
022	**1434260**	**Model Number** 6947 **Device Problem** Other (for use when an appropriate device code cannot be identified) **Event Date** 01/12/2009 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Without a lot number or device serial number, the manufacturing date cannot be determined. **Event Description**

		It was reported that during placement of an rv lead, an occlusion was noted between the subclavian and superior vena cava and the procedure was abandoned. The patient subsequently became combative and hypotensive. A chest xray was done that demonstated a left sided hemothorax. The patient became bradycardic in the 40s with no detectable blood pressure. A chest tube was placed and drained about one liter of blood. The patient was intubated and noted to have a biventricular paced rhythm that became agonal without blood pressure. Treatment with numerous medications was done, however the patient died. Additional information received from the manufacturer's representative reported the cause of death to be "blood in the lungs. ".
023	**1438305**	**Model Number** 6947 **Device Problems** Dislodged; Interference; Oversensing; Undersensing **Event Date** 07/07/2009 **Event Type** Death **Patient Outcome** Death,Other **Event Description** It was reported the rv lead appeared to have dislodged in 2009 which is when short interval counts began to register. Four days later, rv lead integrity alert triggered, due to oversensing and noise which corresponded to onset of first episode of atrial fibrillation. Atrial lead integrity reported to be sound. Rv sensing reported to be inconsistent which made it "extremely difficult to distinguish exactly when the patient was in simultaneous af and vf and when/if the rv lead was purely sensing the atrial fibrillation. " no evidence of any vf in the absence of af and vice versa. Four days later, patient received 5 shocks from device and an external shock soon after one of these internal shocks. Then the sensing on the rv lead reportedly became completely non-diagnostic, due to the prevalence of undersensing. The patient died. The cause of death was requested and not received. No allegation from hcp that death was device related. **Manufacturer Narrative** This event occurred outside the us where the same model is distributed. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient information is not generally available due to confidentiality concerns. There was no indication the death was device related; the cause of death has been requested, but has not been received. It is not known if the lead was explanted post mortem.
024	**1492396**	**Model Number** 6947

		Device Problem Defective item **Event Date** 07/19/2006 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** This event involves a legal case in progress or potential litigation. The proprietary nature of the event may affect follow up efforts. If additional relevant information is received, a supplemental report will be submitted. Our records indicate the patient expired more than one year ago. We have no information to suggest the death was device related. It is not known if the device was explanted post-mortem. The cause of death has been requested, but has not been received. **Event Description** A lawsuit alleged that the patient had a sprint fidelis lead implanted, and that unknown to the patient, the lead was "defective and unreasonably dangerous and or was negligently designed or manufactured and malfunctioned due to manufacturing and or design defects, and as a result of the same, [patient] suffered injuries up until the time of his death. " it is further alleged that as a result of the lead, the patient died. Review of manufacturer's database verified patient death and also that the patient did not have a sprint fidelis lead model implanted. There is no allegation from a healthcare professional that the death was device related. The cause of death has been researched and not received.
025	**1493484**	**Model Number** 6947 **Device Problem** Defective item **Event Date** 09/15/2008 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** This event involves a legal case in progress or potential litigation. The proprietary nature of the event may affect follow up efforts. If additional relevant information is received, a supplemental report will be submitted. The device is part of the advisory for this model. We have no information to suggest the death was device related. It is not known if the device was explanted post-mortem. The cause of death has been researched but has not been received.

		Event Description A lawsuit alleged that the patient had a sprint fidelis lead implanted, and that unknown to the patient, the lead was "defective and unreasonably dangerous and or was negligently designed or manufactured and malfunctioned due to manufacturing and or design defects, and as a result of the same, [patient] suffered injuries, up until the time of his death. " it is further alleged that as a result of the lead, the patient died. Review of manufacturer's database verified patient death and also that the patient did not have a sprint fidelis lead model implanted. There is no allegation from a health care professional that the death was device related. The cause of death has been researched and not received.
026	**1495711**	**Model Number** 6947 **Device Problem** Defective item **Event Date** 09/08/2008 **Event Type** Injury **Patient Outcome** Death,Required Intervention **Event Description** The device was returned for analysis after being explanted for normal battery depletion indicators. The device subsequently tested out of specification during manufacturer's analysis. No patient complications have been reported as a result of this event. It was later alleged by the attorney that the patient "suffered physical and other injury as a result of the recalled lead. " it is further alleged the patient "died as a direct and proximate result of defects" in the sprint fidelis lead. Review of public database verified patient death. It is noted the sprint fidelis lead was capped due to the advisory during a routine device replacement for normal battery depletion. Manufacturer's representative reported 6949 lead was in the patient at time of death, but not in use. The 6947 was the active lead at time of death. There is no allegation from a health care professional that the death was device related. The cause of death has been researched and not received. **Manufacturer Narrative** This report is based solely on device return and analysis. No information to suggest a device-related adverse event or product problem was received. If additional relevant information is received, a supplemental report will be submitted. This event involves a legal case in progress or potential litigation. The proprietary nature of the event may affect follow up efforts. It is not

		known if the lead was explanted post-mortem. The cause of death has been requested but has not been received. Evaluation summary: actual longevity is < 80% of 99. 9% longevity limit. The device was fully functional, with no high current drain or evidence of battery problems. Without the history of the programmed settings throughout its service life, there is no way to determine why the longevity did not match the predicted model.
027	**1523151**	**Model Number** 6947 **Device Problem** Performance **Event Date** 02/07/2008 **Event Type** Death **Patient Outcome** Other **Manufacturer Narrative** This report is based on device return and analysis. Evaluation summary - distal conductor fractured. Proximal segment returned and analyzed. No anomalies found. No anomalies found. Proximal segment returned and analyzed. Additional analyst comment - both the svc and rv defib conductor filars are fractured - apparent explant damage. Proximal segment. **Event Description** The lead was returned to the manufacturer and subsequently tested out of specification. It was determined the patient had died. The hcp reported the patient had been having some chest discomfort sometimes when he is resting or sitting or after he has eaten. He had developed at least 2 episodes of similar pain when walking. The physician expressed concern about these intermittent symptoms of chest discomfort. Cause of death has been requested and not received. Additional information was received from the hcp who reported the cause of death was ventricular fibrillation, "a shockable rhythm. Unclear if the device fired. " physician is reporting the death was possibly related to a device or lead malfunction.
028	**1524656**	**Model Number** 6947 **Device Problem** Other (for use when an appropriate device code cannot be identified) **Event Date** 08/12/2009 **Event Type** Death **Patient Outcome** Death,Other **Event Description** The lead was returned to the manufacturer, analyzed, and tested out of specification. Review of

		the manufacturer's database indicated the patient had died. It had been reported by the patient's daughter that the patient had called her with complaints of shortness of breath. The patient was unresponsive by the time the daughter arrived at his home 10 minutes later. She did cpr, and "he began breathing on his own. But passed very shortly after. " it was also reported by the daughter that the cause of death was congestive heart failure. Follow up with the clinic reported the last device check was remote in 2009, and everything was fine. The hcp stated the probable cause of death was known non-ischemic cardiomyopathy. There is no allegation from the hcp that the death was device related. **Manufacturer Narrative** This report is based solely on device return and analysis. No information to suggest a device-related adverse event or product problem was received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: distal conductor fractured. Full lead returned and analyzed.
029	**1534476**	**Model Number** 6947 **Device Problem** Oversensing **Event Date** 10/27/2009 **Event Type** Death **Patient Outcome** Death,Other **Event Description** It was reported the patient died "out of hospital," and oversensing was questioned. The manufacturer's representative reported "there is no suspicion that oversensing was the cause" of the patient's death. An autopsy was going to be performed. The cause of death has been requested but not received. There is no allegation from a healthcare professional that the death was device related. **Manufacturer Narrative** This event occurred outside the us. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient's information is not generally available due to confidentiality concerns. The cause of death has been requested but has not been received. There was no indication that the death was device related. The icd model number is not approved for distribution in the united states, however, it is similar to a device marketed in the u. S. The event is being reported due to an alleged or

		confirmed malfunction. Evaluation summary: (b) (4) no anomalies were found. (b) (4) no anomalies found. Proximal segment returned and analyzed.
030	**1542955**	**Model Number** 6947 **Device Problems** Lead(s), fracture of; Defective item **Event Date** 06/15/2006 **Event Type** Death **Patient Outcome** Death **Event Description** Attorney alleges patient "suffered physical and other injury, including, but not limited to, implantation of a now recalled device, increased medical monitoring and treatment, failure, fracture, inappropriate shocking, capping, and/or explantation, as a result of the recalled lead" and as result of lead, patient "sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, mental anguish, economic losses and other damages. " alleges patient "suffered physical injuries and various physical manifestations of emotional distress associated with one or more of the following: the implantation, recall, failure, removal/replacement, and/or inability to have the defective sprint fidelis lead removed or replaced. " review manufacturer's database verified patient death and patient did not have sprint fidelis lead implanted at time of death. No allegation from health care professional that death device related. Cause death researched and not received. **Manufacturer Narrative** This event involves a legal case in progress or potential litigation. The proprietary nature of the event may affect follow up efforts. If additional relevant information is received, a supplemental report will be submitted. The device is part of the advisory for this model. Our records indicate the patient expired more than one year ago. We have no information from a health care professional to suggest the death was device related. It is not known if the device was explanted post-mortem. The cause of death has been researched, but has not been received.
031	**1551570**	**Model Number** 6947 **Device Problem** Dislodged **Event Date** 11/09/2009 **Event Type** Death **Patient Outcome** Death

		Manufacturer Narrative This event occurred outside the us. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient's information is not generally available, due to confidentiality concerns. **Event Description** It was reported that during the lv lead implant, the rv lead "popped back and was dislodged. " the physician assumes this dislodgement caused a pericardial effusion. The patient's blood pressure is reported to have dropped and the patient died. There was no autopsy, however, the physician "doesn't think that our products were the cause of death. " the cause of death was reported to be the pericardial effusion and considered to be procedure related.
032	**1554915**	**Model Number** 6947 **Device Problems** High impedance; Lead(s), fracture of; Oversensing; Sensitivity; Inappropriate shock **Event Date** 09/10/2009 **Event Type** Injury **Patient Outcome** Death,Other,Required Intervention **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: distal conductor fractured; full lead in segments returned and analyzed. Full lead in segments. **Event Description** It was reported that there was sensing difficulty, oversensing, high impedance, an apparent lead fracture, and that the patient received inappropriate therapy. The lead was explanted and replaced. No further patient complications have been reported as a result of this event. Follow up information from the clinic reported there were no device issues related to the patient's death, but the svc lead extraction in 2009 was difficult. A "laceration occurred on the innominate vein in the svc due to all the adhesions. " patient was hospitalized a couple extra days and was doing fine until suddenly two days later, while sitting in a chair, the patient's pulmonary status began to deteriorate. The patient arrested and was not able to be resuscitated. A pulmonary embolus was suspected, though the clinic does not know the exact cause of death.

033	**1560003**	**Model Number** 6947 **Device Problem** Other (for use when an appropriate device code cannot be identified) **Event Date** 11/15/2009 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. There is no allegation from a health care professional that the death was device related. The cause of death has been requested and not received. Evaluation summary - battery depletion-normal. No anomalies found. Proximal segment returned and analyzed. No anomalies found. Proximal segment returned and analyzed. No anomalies found. Proximal segment returned and analyzed. **Event Description** It was reported the patient had a septic shoulder joint replacement and rheumatoid arthritis. The patient died. There is no allegation from a health care professional that the death was device related. Death certificate was later received and reported the cause of death to be septic shoulder joint replacement and rheumatoid arthritis. The patient had a total shoulder replacement done in 2008, a shoulder joint relocation in 2009, and irrigation of infected shoulder joint nine months later.
034	**1579543**	**Model Number** 6947 **Device Problems** Oversensing; Other (for use when an appropriate device code cannot be identified) **Event Date** 11/05/2009 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** Corrected information received reported the lead (b)(4) is actually model 6947 and not 6949 as was originally reported. Corrected lead model from 6949 to 6947. **Event Description** It was reported that the patient had a cardiac arrest in 2009 and cardiopulmonary resuscitation (cpr) was given. An aed was used but advised not to shock the patient. When the patient arrived

		at the emergency unit, asystole was determined. An er consultant stated "the rhythm seemed to be asystole from the start". The patient expired. Device history reports did not register any tachyarrythmia episodes for that day. It was reported the patient had suffered frequent similar types of episodes since two months prior to event. A consultant in emergency medicine stated that a technical check of the device suggests a possible fault. It was further reported that even though the v-v counter was high at 2500, "that at no point, had inappropriate therapy been delivered. ". **Manufacturer Narrative** This event occurred outside the us. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient's information is not generally available due to confidentiality concerns. The lead is part of the advisory for this model. Cause of death was requested but not received. Evaluation summary: (b) (4) no anomalies found. (b) (4) no anomalies found. Partial lead in segments returned and analyzed. Corrected information received reported the lead (b) (4) is actually model 6947 and not 6949 as was originally reported.
035	**1581663**	**Model Number** 6947 **Device Problems** Device remains activated; High sensing threshold **Event Date** 01/07/2010 **Event Type** Death **Patient Outcome** Death **Event Description** It was reported the pace/sense portion of the rv lead was capped and replaced with a new pace/sense lead due to high thresholds. While in recovery, the staff noted the patient received one shock. Device interrogation detected 2 episodes and one shock. Testing noted there was no capture with the new rv lead, normal impedances, and no rv sensing signal. Lead dislodgement was suspected and an xray was done to evaluate lead position. It was reported, the patient was stable and externally monitored in the cardiac care unit and while discussing situation with physician, patient became unconscious. Resusitation was attempted, but patient died. It was reported the physician does not think the device contributed to the patient's death. An autopsy was performed. The results are not yet available. **Manufacturer Narrative**

		This event occurred outside the us. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient's information is not generally available due to confidentiality concerns. Additional information received reported the autopsy was done and showed the lead placement was "positioned accordingly" in the right ventricle. The autopsy diagnosis are listed as "dilated cardiomyopathy - status post pm-implantation. State post postoperative fibrillation with frustrating cpr. Suspicion on acute myocardial ischemia of the posterior wall of the left ventricle. ".
036	**1611124**	**Model Number** 6947 **Device Problem** Other (for use when an appropriate device code cannot be identified) **Event Date** 01/29/2010 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** This event occurred outside the us. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient information is not generally available due to confidentiality concerns. This model number is not approved for distribution in the united states, however, it is similar to a device marketed in the u. S. The event is being reported due to an alleged or confirmed malfunction. Evaluation summary (b) (4) no anomalies found. (b) (4) no anomalies found. Full lead returned and analyzed. (b) (4) no anomalies found. Full lead returned and analyzed. (b) (4) no anomalies found. Full lead returned and analyzed. **Event Description** It was reported the patient had a device system implant. At implant, the patient was not induced into ventricular fibrillation, so the device was not tested intraoperatively. 9 days later, the patient required pericardial puncture due to pericardial effusion. Shortly after this procedure, the patient developed ventricular fibrillation. The device gave the patient 3 shocks that were reported to be ineffective. Resusitation efforts were attempted. The patient was intubated and in the intensive care unit and subsequently died. An autopsy was performed. The cause of death has been requested and not received.
037	**1611127**	**Model Number** 6947 **Device Problem** Other (for use when an appropriate device code cannot be identified)

		Event Date 02/04/2010 **Event Type** Death **Patient Outcome** Death **Event Description** It was reported that during implant of a crt-d device system with a 6947 and 5554 lead, an lv (left ventricular) lead could not be implanted, so the physician opted for a dual chamber icd. After the implant, the patient's blood pressure dropped and an echocardiogram determined there was cardiac bleeding. 800 ml of blood was removed from patient's chest, but the patient died the day after implant procedure. There is no allegation from a health care professional that the death was device related. It was later reported there was no suspicion about the device system, "which was working fine. " the cause of death was reported to be worsening heart failure. **Manufacturer Narrative** This event occurred outside the us. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient's information is not generally available due to confidentiality concerns.
038	**1640003**	**Model Number** 6947 **Device Problem** No Information **Event Date** 01/17/2010 **Event Type** Death **Patient Outcome** Death **Event Description** It was reported patient was discharged from hospital 3 days after device implant with no signs of pericardial effusion, pleural effusion, or bleeding in device pocket. Patient started on anticoagulation therapy (b) (6) 2010 due to reduced lv function, previous stroke, (b) (6), and paroxysmal atrial fibrillation. Patient admitted to intensive care unit (b) (6) 2010 due to dyspnea. Chest xray showed left lung "completely shadowed with fluid. " echocardiogram showed "small, hemodynamically not relevant pericardial effusion. " bleeding in the device pocket also reported - ct of thorax showed hemothorax on left. "thoracal drain" inserted and removed 750ml hemorrhagic fluid. Patient improved temporarily, but again worsened requiring 2nd drainage. Patient did not improve with this and emergency thoracotomy performed. Even with catecholamine support, patient worsened, required 2nd thoracotomy, but died intraoperatively.

		Cause of death requested and not received. **Manufacturer Narrative** This event occurred outside the us. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient information is not generally available due to confidentiality concerns. Follow up revealed that a subclavian puncture had been the introduction technique for accessing the veins for lead introduction. No autopsy was performed; however, there is no allegation from the physician against the device or leads as regards the patient's death.
039	**1649173**	**Model Number** 6947 **Device Problems** Oversensing; Inappropriate shock **Event Type** Death **Patient Outcome** Death,Required Intervention **Event Description** A journal article was reviewed that contained information regarding this device and these leads. It was reported that ventricular oversensing occurred for a patient with wide qrs complexes and increased potassium levels. The patient received inappropriate shocks due to "triple counting. " the patient was brought to the hospital and became "respiratory insufficient and lost consciousness. " the author indicated that "due to electro-mechanical dissociation and echocardiographic findings, the resuscitation was aborted. " subsequently, the patient expired. There are no device-related death allegations. Further follow-up did not yield any additional relevant information regarding this event. **Manufacturer Narrative** This information is based entirely on journal literature. This event occurred outside the us. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient information is limited due to confidentiality concerns. Since no device id was provided, it is unknown if this event has been previously reported. Without a lot number or device serial number, the manufacturing date cannot be determined. Referenced article: "a rare type of ventricular oversensing in icd therapy-

		inappropriate icd shock delivery due to triple counting. " pace pacing clin. Electrophysiol. February 1;33(2):e17-e19.
040	**1654710**	**Model Number** 6947 **Device Problems** Retraction problem; Failure to advance; High sensing threshold **Event Date** 12/30/2009 **Event Type** Death **Patient Outcome** Death **Event Description** It was reported that, during implant procedure, after a few minutes, the rv (right ventricular) capture threshold increased up to 8 v. During repositioning, the helix did not come out of lead tip and was stuck. Lead removed and replaced with a new one. The patient outcome was reported to be okay. The next day, 500 cc of blood was removed from patient's thorax, "likely because of a cardiac tamponade. " patient died the day after implant procedure. The cause of death has been requested and not received. There is no allegation from a health care professional that the death was device related. **Manufacturer Narrative** This event occurred outside the u. S. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient information is not generally available due to confidentiality concerns. Evaluation summary (b) (4)v distal conductor blood/body fluid (not obstructed). Full lead returned and analyzed. Additional analyst comment - helix will not extend at this time due to dried blood in the tip end of the distal conductor preventing torque transfer when the is-1 pin is rotated. It cannot be determined at this time if this contributed to the inability of the helix to function correctly at the implant attempt.
041	**1660652**	**Model Number** 6947 **Device Problem** No Information **Event Date** 06/11/2005 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** This event involves a legal case in progress or potential litigation. The proprietary nature of the

		event may affect follow up efforts. If additional relevant information is received, a supplemental report will be submitted. Our records indicate the patient expired more than one year ago. We have no information from a health care professional to suggest the death was device related. It is not known if the device was explanted post-mortem. The cause of death has been researched but has not been received. **Event Description** Attorney alleges patient "implanted with medtronic's sprint fidelis leads, was injured and died as a result. As a direct and proximate result of medtronic's design, manufacture, assembly, marketing and sales of the sprint fidelis leads, (patient has)sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, and economic losses and consequential damages. " further alleges that as a result of "the implantation of medtronic's sprint fidelis leads, (patient) suffered fatal injuries. " there is no allegation from a health care professional that the death was device related. Review of manufacturer's database verified patient's death and also that the patient did not have a sprint fidelis lead model implanted. The cause of death has been researched and not received.
042	**1663220**	**Model Number** 6947 **Device Problem** No Information **Event Date** 03/24/2010 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. (b) (4) no anomalies found. (b) (4). Proximal segment returned and analyzed. **Event Description** It was reported the patient died of asphyxiation due to extrication of tracheostomy tube with complications thereof. Significant contributing factors were reported to be congestive heart failure due to cardiomyopathy with implanted pacemaker/defibrillator, history of hypertension, chronic obstructive pulmonary disease, alcoholism, psoriasis, and recent aspiration pneumonia with septic shock. There is no allegation from a health care professional that the death was device related.

043	**1678416**	**Model Number** 6947 **Device Problems** Difficult to position; Failure to advance **Event Date** 01/28/2009 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary (b) (4) no anomalies found. Full lead returned and analyzed. **Event Description** It was reported this lead was an implant attempt and not implanted as the helix would not extend and there was positioning difficulty. "no adverse patient event was noted. " it was determined the patient died 5 days after this procedure. There is no allegation from a health care professional that the death was device related. The cause of death has been requested and not received.
044	**1720686**	**Model Number** 6947 **Device Problems** Device remains activated; No Information **Event Date** 01/14/2010 **Event Type** Injury **Patient Outcome** Death,Other **Event Description** It was reported the patient, with a complex medical history was admitted to the hospital with respiratory failure. The patient was found to be septic, with fever. He was transferred to icu and was on ventilator support. The source of the infection could not be identified. The patient was positive for (b)(6). He also had 'bouts' of sinus tachycardia and atrial fibrillation with rapid ventricular response. He also had multiple short bursts of ventricular tachycardia but was asymptomatic and was given rate control medications. After 18 days, patient was taken off the ventilator, and one week later ((b)(6) 2010) he was discharged to a skilled nursing facility in stable condition. It was later reported the patient died (b)(6) 2010 from complications of heart failure. There is no allegation from a health care professional that the death was device related. **Manufacturer Narrative**

		The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary (b)(4) no anomalies found. (b)(4) no anomalies found, several conductors blood/body fluid (not obstructed). Proximal segment returned and analyzed. (b)(4) no anomalies found, proximal conductor stretched, apparent explant damage. Proximal segment returned and analyzed.
045	**1737621**	**Model Number** 6947 **Device Problem** No Information **Event Date** 05/18/2010 **Event Type** Death **Patient Outcome** Death **Event Description** It was reported the patient died with cause of death noted to be multi-organ system failure, sepsis syndrome, pneumonia, and ischemic cardiomyopathy. There is no allegation from a health care professional that the death was device related. **Manufacturer Narrative** Proximal segment returned and analyzed. (b)(4) no anomalies found. Proximal segment returned and analyzed. (b)(4) no anomalies found. Proximal segment returned and analyzed. (b)(4) battery depletion-normal. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis of the device is in process; the results will be forwarded when available. Evaluation summary (b)(4) no anomalies found. Proximal segment returned and analyzed. (b)(4) no anomalies found. Proximal segment returned and analyzed. (b)(4) no anomalies found. Proximal segment returned and analyzed.
046	**1760409**	**Model Number** 6947 **Device Problem** Failure to sense **Event Date** 06/16/2010 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** This event occurred outside the us. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient

		information is not generally available due to confidentiality concerns. Evaluation summary (b) (4) the actual device was not received for evaluation. We did receive performance data collected from the device and have analyzed the data. No anomalies found. **Event Description** It was reported the patient was admitted to the hospital at 4am on (b) (6)2010, collapsed, and resuscitated externally. At 1306 that same day, the device detected a vf (ventricular fibrillation) and gave the patient one shock. The patient "was almost on the verge of death" at that time. At 1314, it detected vf again, but aborted the shock. The patient subsequently died. The physician is wanting to check why the device was "not able to sense the vt/vf which happened in the early morning hrs of (b) (6) 2010. " the cause of death has been requested and not received. It was determined the patient was not pacemaker dependent.
047	**1784426**	**Model Number** 6947 **Device Problem** No Information **Event Date** 04/15/2010 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** This event occurred outside the us. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient information is not generally available due to confidentiality concerns. Evaluation summary: (b)(4) no anomalies found, all conductors distorted. Proximal segment returned and analyzed. **Event Description** It was reported the patient died a "sudden death" 11 days after implant. The patient's death is "unknown, does not appear to be" device related. The cause of death "appears" to be acute coronary syndrome (acs). No autopsy was performed. There is no allegation from a health care professional that the death was device related. The exact cause of death has been requested and not received.
048	**1810598**	**Model Number** 6947

		Device Problem No Information **Event Date** 07/01/2010 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. (b)(4) no anomalies found. **Event Description** It was reported the patient had been admitted to the hospital for lead extraction due to endocarditis, sepsis, and vegetation on valves. The device and leads were all extracted "rather easily and did not require laser extraction. " upon transfer to the patient room, the patient became pale, had difficulty breathing, and subsequently had a ventricular fibrillation arrest and died. There is no allegation from a health care professional that the death was device related. The cultures were reported to have been cancelled due to the patient death.
049	**1840742**	**Model Number** 6947 **Device Problem** No Information **Event Date** 08/31/2010 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** It was reported that during the third test of implant dft testing, the patient "went into a pulseless electrical activity. Electrical activity was seen on the monitor but the patient had no pulse. " resuscitation attempts were unsuccessful and the patient expired. There is no allegation from a health care professional that the death was device related. Follow up revealed the cause of death was pea related to aicd shock related to chf. No autopsy was done. An echocardiogram had shown no evidence of effusion. It was also reported that multiple shocks were performed by the implanted device throughout the resusitation code.

		The cause of death has been requested and not received.
050	**1857424**	**Model Number** 6947 **Device Problem** No Information **Event Date** 12/17/2008 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. There is no allegation from a health care professional that the death was device related. Evaluation summary: (b)(4) the proximal segment returned for analysis. No anomalies found; proximal conductor distorted, apparent explant damage noted. **Event Description** The patient called approx 2 weeks post implant to report a "tapping in device at different times over the past two to three days. Reported that tapping was felt over the implant area". The system was later returned to the manufacturer with no information and it was noted in the manufacturer's database that the patient had died 27 days after the implant. There is no allegation from a health care professional that the death was device related. The cause of death has been requested and not received.
051	**1858457**	**Model Number** 6947 **Device Problem** No Information **Event Date** 08/14/2010 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary (b)(4) no anomalies found. (b)(4) no anomalies found. Proximal segment returned and analyzed. **Event Description**

		It was reported patient was found unresponsive, cyanotic and pale by his wife. When ambulance arrived, patient was pulseless, apneic and cyanotic, and in pea (pulseless electrical activity). Patient was intubated and en route to hospital, "they shocked 3 times for possible defibrillation. " patient did not respond to resuscitation efforts and died. Cause of death reported to be cardiac dysrhythmia, coronary artery disease, along with hypertension, cardiomyopathy, myocardial infarction, and tobacco use. There is no allegation from a health care professional that the death was device related. Per the emergency room report, physician reported diagnostic impression of cardiac arrest likely secondary to acute myocardial infarction.
052	**1868738**	**Model Number** 6947 **Device Problem** No Information **Event Date** 08/10/2010 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** It was reported by the patient's wife that the patient died with cause of death cardiac arrest. Follow up revealed the patient had last been seen in the clinic (b)(6) 2009 and the clinic received 2 transtelephonic reports on (b)(6) 2010 and (b)(6) 2010, both revealing device system function fine. There is no allegation from a health care professional that the death was device related. Additional information has been requested and not received.
053	**1875987**	**Model Number** 6947 **Event Date** 09/20/2010 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description**

		It was reported the patient died due to respiratory arrest. When the device was implanted in (b)(6) 2010, the r waves were 8mv, and one month later were 2. 3mv. Reprogramming had been done and 3 days before patient died, the "r waves were better. " patient was in the hospital at the time of the check with stable impedances and capture thresholds reported. It was also reported that a few months prior, the patient "received atp and shocks for vt (all appropriate). " there is no allegation from a health care professional that the death was device related. Additional information has been requested and not received.
054	**1879279**	**Model Number** 6947 **Event Date** 10/04/2010 **Event Type** Death **Patient Outcome** Death,Required Intervention,Hospitalization,Life Threatening **Event Description** There is no allegation from a health care professional that the death was device related. The cause of death has been requested and not received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Follow up revealed that towards the end of the surgery, patient developed hypotension and was admitted to coronary care unit in critical condition. Transesophageal electrocardiogram showed no pericardial tamponade or pleural effusion. The patient continued to decompensate and eventually died. The cause of death was presumed to be advanced congestive heart failure and cardiogenic shock. Medical examiner determined the death to be natural and no autopsy was done. **Event Description** It was reported the patient had a device system replacement surgery to upgrade to a biventricular system. Approximately 1. 5 hours after the end of the procedure, the patient coded and died. Follow up revealed the physician reported patient death was not procedure-related, that it was due to the patient's heart failure. Manufacturer's representative reported the patient was not pacemaker dependent and there was nothing wrong with the device system.

055	**1879303**	**Model Number** 6947 **Device Problem** No Information **Event Date** 09/25/2010 **Event Type** Death **Patient Outcome** Death **Event Description** It was reported by the patient's son that the patient died with cause of death noted as sudden cardiac death. An autopsy is being done. The son reported he was told "device did not go off. " there is no allegation from a health care professional that the death was device related. The cause of death has been requested and not received. Review of public database revealed obituary reported the patient died "after suffering sudden cardiac arrest. ". **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
056	**1882286**	**Model Number** 6947 **Event Date** 05/17/2010 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** This event occurred outside the us. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient information is not generally available due to confidentiality concerns. This model number is not approved for distribution in the united states, however, it is similar to a device marketed in the u. S. The event is being reported due to an alleged or confirmed malfunction. Evaluation summary: (b)(4) device was returned and analyzed. No anomalies found. (b)(4) proximal segment of the lead returned and visual analysis was performed. No anomalies found. **Event Description** It was reported that the patient died on (b)(6)-2010 in the hospital. The death was reported as an unexplained death. There is no allegation from a health care professional that the death was device or lead related. The cause of death has been requested and not received.
057	**1882293**	**Model Number** 6947

		Event Date 06/06/2010 **Event Type** Death **Patient Outcome** Death; **Event Description** It was reported that there were "episodes which occurred on (b)(6)". Patient's family and hospitals have no record of any episodes that this may relate to. It was further reported that the patient received an inappropriate shock from his device on (b)(6) 2010 causing him to jump, resulting in a fall, and breaking his ankle. He was admitted to the hospital and discharged shortly after to rehabilitation hospital. The patient didn't have surgery for the ankle fracture. On (b)(6) 2010, patient was re-admitted to the hospital with a chest infection, agitation and confusion. The patient was treated with antibiotics and improved but suffered a cardiac arrest and died on (b)(6) 2010. **Manufacturer Narrative** This event occurred outside the us. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient information is not generally available due to confidentiality concerns. (b)(4) no anomalies found. Performance data indicates nst activity between 31 may 2010 and time of explant ((b)(6) 2010) appears to be physiologic with v-v cycles at > or = 300ms. Impedance trends appear stable. The main concern from the coroner is "the device was downloaded after the post mortem and there was nothing to suggest any activation after the 25/5 but there was no information recorded prior to that date suggesting that it had been downloaded on that date thereby deleting the information held. " the doctors could not rule out the possibility that the patient had received another shock from the device. It was reported by the coroner that the cause of death was bronchopneumonia, as well as stroke and ischemic heart disease. There is no allegation from a health care professional that the death was device related
058	**1887108**	**Model Number** 6947 **Event Date** 08/19/2010 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.

		Event Description It was reported by physician the patient died with cause of death cardiac arrest. Patient last seen in the device clinic (b)(6) 2010. Had been pacemaker dependent. No autopsy was done. There is no allegation from a health care professional that the death was device related.
059	**1890578**	**Model Number** 6947 **Event Date** 11/14/2009 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** It was reported that the patient died. The relatedness of the death to the device system was reported as "unknown". The cause of death has been requested and not received.
060	**1891574**	**Model Number** 6947 **Event Date** 08/13/2010 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary (b)(4) the actual device was not received for evaluation. We did receive performance data collected from the device and have analyzed the data. Impedance - no anomalies found. Trends appear stable. Oversensing - multiple short v-v sensed events of < 220 ms are observed on the (b)(6) 2010. (11 episodes nst, 2 episodes vf). **Event Description** It was reported the patient died and had significant history of both atrial and ventricular arrhythmias based on episode counters. Prior to death, there were 3 ventricular

		tachycardia/ventricular fibrillation episodes that appear to have been detected and treated appropriately. "post shock there appeared to be transient loss of capture. " there is no allegation from a health care professional that the death was device related. The cause of death has been requested and not received.
061	**1894590**	**Model Number** 6947 **Device Problem** No Information **Event Date** 09/25/2009 **Event Type** Malfunction **Patient Outcome** Death,Required Intervention,Hospitalization,Life Threatening **Event Description** It was reported there was elevated thresholds at implant. The lead use continued based on medical judgement despite "difficult venous anatomy. " no patient complications were reported related to the event. Follow up revealed patient was later taken to a local hospital after a syncopal episode and was "in shock. " had left ventricular assist device implanted and was pacemaker dependent. Post operative couse was complicated by multisystem organ failure and requiring of dialysis. Bacteremia and septic shock also reported. The family opted to withdraw care and the patient died (b)(6) 2010. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
062	**1898011**	**Model Number** 6947 **Device Problem** No Information **Event Date** 10/06/2010 **Event Type** Injury **Patient Outcome** Death,Required Intervention,Hospitalization,Life Threatening **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The initial reported event was received on (b)(6) 2010. Of note, the reportable serious injury is normally submitted via a bimonthly

		medwatch report submission that would have been due on (b)(6) 2010. Information was subsequently received on (b)(6) 2010 and revealed patient died. As there is new information that reasonably suggests the device has or may have caused or contributed to a death, this event no longer qualifies for bimonthly reporting and is therefore being submitted as a 30-day report. Evaluation summary (b)(4) no anomalies found. **Event Description** Infection and erosion were reported. The patient was treated for a possible staph infection with vancomycin and santyl. The device system was explanted (b)(6) 2010. It was later reported the patient was found unresponsive and died (b)(6) 2010. There were no allegations of any device performance concerns. The cause of death has been requested and not received. Follow up later revealed the patient had been discharged to hospice care and had been seen by home health aide the day prior to death with vital signs reported to be within normal limits. Spouse reported patient had died after returning from dialysis.
063	**1902632**	**Model Number** 6947 **Event Date** 07/02/2010 **Event Type** Death **Patient Outcome** Death **Event Description** It was reported by emergency medical service records that the patient was found down at home. Family member attempted cpr, but the patient was unresponsive, pulseless and in pulseless electrical activity. Ems attempted resuscitation at the patient's home and during transportation to the hospital emergency room. During transportation the rhythm changed to asystole and remained in asystole at the emergency room. The patient died on (b)(6) 2010. No autopsy was performed and the clinical impression/diagnosis was cardiac arrest. Patient last seen in clinic approximately one month prior to death and was not pacemaker dependent. There were "no device issues they are aware of" and "no episodes, no abnormal findings, device check was good". The device was not explanted. "they do not know what the official cause of death was". **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
064	**1903762**	**Model Number** 6947

		Device Problem No Information **Event Date** 11/11/2010 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The initial reported event was received on (b)(6) 2010. Of note, the reportable malfunction is normally submitted via a bimonthly medwatch report submission that should have been submitted on (b)(6) 2010. Information was subsequently received on (b)(6) 2010 and revealed patient died. As there is new information that reasonably suggests the device has or may have caused or contributed to a death, this event no longer qualifies for bimonthly reporting and is therefore being submitted as a 30-day report. (b)(4) no anomalies found, blood in/on helix/lobe mechanism. Full lead returned and analyzed. **Event Description** It was reported that the physician had difficulties trying to position the lead in the patient's right atrium. It was also reported that the lead had high pacing thresholds. The lead was removed and a new lead was implanted which also had high thresholds. Later review of manufacturer database revealed the patient died approximately 10 weeks later. The cause of death has been requested and not received.
065	**1904178**	**Model Number** 6947 **Device Problem** No Information **Event Date** 10/13/2010 **Event Type** Malfunction **Patient Outcome** Death **Event Description** It was reported that the patients device was sounding an alert. Patient was in hospice and was reported to have died approximately 5 weeks after this reported event. The cause of death has been requested and not received. Follow up did reveal the patient had last been seen by the (b)(6) clinic in (b)(6) 2007. Later reported a transtelephonic report had been sent and eventually able to rectify the beeping sound. Patient on hospice for end stage renal disease, chronic kidney failure, hypertensive heart disease, & chronic obstructive bronchitis. On (b)(6) 2010, the patients device

		was turned off and he died three days later. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The initial reported event was received on (b)(6) 2010. Of note, the reportable serious injury is normally submitted via a bimonthly medwatch report submission that would have been due on (b)(6) 2010. Information was subsequently received on (b)(6) 2010 and revealed patient died. As there is new information that reasonably suggests the device has or may have caused or contributed to a death, this event no longer qualifies for bimonthly reporting and is therefore being submitted as a 30-day report.
066	**1904945**	**Model Number** 6947 **Event Date** 12/04/2009 **Event Type** Malfunction **Patient Outcome** Required Intervention **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis of the device is in process; the results will be forwarded when available. **Event Description** It was reported the lead was capped due to high thresholds. The lead was not replaced. The device was replaced due to eri. No patient complications have been reported as a result of this event. It was later reported the patient died (b)(6) 2009 with unknown relatedness "to both the system and an arrhythmic event. " the cause of death has been requested and not received.
067	**1905454**	**Model Number** 6947 **Device Problem** Defective item **Event Date** 08/08/2009 **Event Type** Death **Patient Outcome** Death,Required Intervention,Hospitalization,Life Threatening **Event Description** It was reported by patients life partner that she questioned if the device provided therapy at the time of the patient death and that the "lead wire fried. " the patient had recently completed testing

		for heart transplant and "all good. " the patient had complained of "buzzing in my chest" but not pain the night before he died and "can't breath" in the early am. 911 was called and the medics arrived. The cause of death has been requested and not received. Follow up with clinic revealed there was no "fried lead. " device interrogation after death showed device functioning fine, delivered shocks, but patient's heart did not respond. Clinic has "no concerns about the patient's device system performance prior to or at the time of death. " patient had not been pacemaker dependent. Last device check was one month prior to death and there were no rhythm issues and device was functioning fine within normal parameters. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary (b)(4) battery depletion-normal. (b)(4) no anomalies found, outer insulation cosmetic depression. Proximal segment returned and analyzed. (b)(4) no anomalies found, outer insulation cosmetic depression. Proximal segment returned and analyzed. (b)(4) no anomalies found, outer insulation cosmetic depression. Proximal segment returned and analyzed.
068	**1909127**	**Model Number** 6947 **Event Date** 09/26/2010 **Event Type** Death **Patient Outcome** Death,Hospitalization **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** It was reported that the patient was implanted with a device and lead and died approximately nine months after the procedure. The cause of death has been requested and not received. It was reported that the patient was implanted with a device and lead and died approximately nine months after the procedure. The cause of death has been requested and not received. Based on follow-up received, the patient was admitted to the hospital for biliary sepsis from cholangitis complicated by atrial fibrillation in which the high ventricular rates were difficult to control. The death was unrelated to the device/lead system. The cause of death was sepsis.

069	**1911830**	**Model Number** 6947 **Event Date** 05/01/2010 **Event Type** Death **Patient Outcome** Death **Event Description** It was reported the patient died approximately six months after device replacement. The cause of death has been requested and not received. It was further reported by the physician's nurse that the circumstances of the patient's death are unknown. The patient's was at the (b)(6) hospital for approximately six months prior to the patient's death. The cause of death and device relatedness is unknown. The patient had extensive cardiac history and the patient's son stated the death was due to coronary disease. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) no anomalies found. (b)(4), proximal segament of the lead was returned and analyzed. No anomalies found. Distal conductor cut, outer insulation breached cut, outer insulation cosmetic depression, apparent explant damage, and visual analysis performed only. (b)(4), proximal segment of the lead was returned and analyzed. No anomalies found. All conductors blood/body fluid (not obstructed), outer insulation cosmetic cut and depression, apparent explant damage, and visual analysis performed only.
070	**1911848**	**Model Number** 6947 **Device Problem** No Information **Event Date** 10/13/2010 **Event Type** Death **Patient Outcome** Death; **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The initial reported event was received on 10/30/2010. Of note, the reportable malfunction is normally submitted via a bimonthly medwatch report submission that would have been due on 12/10/2010. Information was

		subsequently received on 11/24/2010 and revealed patient died. As there is new information that reasonably suggests the device has or may have caused or contributed to a death, this event no longer qualifies for bimonthly reporting and is therefore being submitted as a 30-day report. Evaluation summary (b)(4) connector other, defib conductor fracture (overstress), outer insulation cosmetic esc and depression. Analyst visual comment - the lead was returned wit the svc and the rc defib cables fractured at the connector. Also, intermittency between the connector pin and cap. Proximal segment returned and analyzed. **Event Description** The lead was returned to the manufacturer, analyzed, and subsequently tested out of specification. Follow up later revealed the patient had died in (b)(6). The death certificate noted the cause of death to be congestive heart failure. There had been no indication of any device performance issues or concerns. The device had been turned off 12 days prior to death. No autopsy was performed. Unknown to the clinic if the patient had been pacemaker dependent.
071	**1911850**	**Model Number** 6947 **Event Date** 09/14/2010 **Event Type** Death **Patient Outcome** Death **Event Description** It was reported the patient died one month and seventeen days post implant of a device and two leads. The cause of death has been requested and not received. Follow up with clinic reported she does not think the patient death had anything to do with the device. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) no anomalies found. (b)(4): proximal segment of the lead returned and analyzed. Visual analysis performed only.
072	**1912173**	**Model Number** 6947 **Event Date** 10/19/2009

		Event Type Death **Patient Outcome** Death **Event Description** It was reported the patient died approximately four months after device and lead replacement. The cause of death has been requested and not received. Based on follow-up received, the patient declined aggressive treatment in the hospital and was admitted into hospice care with a diagnosis of congestive heart failure. The patient was dyspneic and distressed. Implantable cardiovertor defibrillator therapies were turned off ten days prior to the patient's death. Pacemaker therapies remained on. There is no allegation from a health care professional that the patient's death was device and/or lead related. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) no anomalies found. (b)(4) proximal segment of the lead returned and analyzed. No anomalies found. All conductors stretched, outer insulation breached cut and cosmetic depression, and visual analysis performed only. (b)(4) proximal segment of the lead returned and analyzed. No anomalies found. Proximal conductor stretched, outer insulation cosmetic depression, apparent explant damage, and visual analysis performed only. (b)(4) proximal segment of the lead returned and analyzed. No anomalies found. All conductors stretched, outer insulation cosmetic depression, apparent explant damage, and visual analysis performed only.
073	**1912175**	**Model Number** 6947 **Event Date** 05/01/2010 **Event Type** Death **Patient Outcome** Death,Other **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) no anomalies found. (b)(4) proximal segment of the lead was returned and analyzed. No anomalies found. Proximal conductor distorted, all conductors blood/body fluid (not obstructed), outer insulation cosmetic depression, apparent explant damage, and visual analysis performed only. (b)(4) proximal segment of the lead was returned and analyzed. No anomalies found. All conductors blood/body fluid (not obstructed), outer insulation cosmetic depression, visual analysis

		performed only. (b)(4) proximal segment of the lead was returned and analyzed. No anomalies found. All conductors blooc/body fluid (not obstructed), outer insulation cosmetic depression, and visual analysis performed only. **Event Description** It was reported the patient died approximately six months after device replacement. The cause of death has been requested and not received. Based on follow up received from the physician's office, the patient fell approximately three months prior to the patient's death and no complications were reported. It was also reported that while waiting in the physician's office after an office visit, the patient died of respiratory failure. There is no allegation from a health care professional that the death was device and/or lead related.
075	**1913390**	**Model Number** 6947 **Event Date** 09/09/2010 **Event Type** Death **Patient Outcome** Death **Event Description** It was reported the patient died approximately four months after implant of a device and lead. The cause of death has been requested and not received. Based on follow-up with the funeral home, it was further reported that the patient died at home and the cause of death was respiratory failure with secondary causes of hypoxia, end-stage coronary artery disease (ecad) and end-stage congestive heart failure (echf). **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) no anomalies found. (b)(4) no anomalies found, outer cosmetic depression. Proximal segment returned and analyzed. **Event Description** **Manufacturer Narrative**

		The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned and analyzed. No anomalies were found. (b)(4) the proximal segment of the lead was returned and analyzed. No anomalies were found. It was noted there was outer insulation cosmetic depression. **Event Description** It was reported the patient died approximately four months after implant of a device and lead. The cause of death has been requested and not received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) no anomalies found. Analysis of the lead is in process; the results will be forwarded when available.
076	**1917401**	**Model Number** 6947 **Event Date** 08/01/2008 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** It was reported the patient received a replacement device and later died. The date of death and cause of death has been requested and not received.
077	**1918614**	**Model Number** 6947 **Event Date** 08/02/2009 **Event Type** Death **Patient Outcome** Death **Event Description**

		It was noted the patient died approximately 10 months after device implant. Follow up with the clinic reported the patient died from respiratory failure. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** It was noted the patient died approximately 10 months after device implant. The cause of death has been requested and not received.
078	**1919852**	**Model Number** 6947 **Event Date** 11/28/2010 **Event Type** Death **Patient Outcome** Death,Required Intervention,Life Threatening **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** It was reported the patient had a history of vf and an ejection fraction of 10%. The patient's wife reported the patient also had seizure like episodes. "the paramedics came to the home and performed cpr. " it was reported the patient died. The cause of death has been requested and not received.
079	**1919859**	**Model Number** 6947 **Event Date** 11/15/2010 **Event Type** Death **Patient Outcome** Death **Event Description** It was reported the patient had a stroke "sometime after the next day check" and died. Follow up with clinic reported cause of death was acute cva and dilated cardiomyopathy. Patient had presented to hospital nine days prior to death with atrial fibrillation and symptoms suggestive of transient ischemic attack (tia). Placed on medical management for atrial fibrillation. Underwent

		placement of icd, was cardioverted to sinus rhythm, and was doing well. However, did suffer an acute right-sided cerebrovascular accident (cva) later that same day. Treated medically and continued to do poorly and died two days later with final death diagnoses: acute right cva; dilated cardiomyopathy; atrial fibrillation converting to sinus rhythm with electrical cardioversion. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** It was reported the patient had a stroke "sometime after the next day check" and died. The cause of death has been requested and not received.
080	**1923511**	**Model Number** 6947 **Event Date** 12/03/2009 **Event Type** Death **Patient Outcome** Death **Event Description** It was reported the patient died on (b)(6) 2009 approximately eight months after device and lead replacement. Follow up with the clinic reported the device therapies were turned off "as patient was in hospice" and the patient died the following day. The cause of death is unknown to the clinic. **Manufacturer Narrative** The information submitted reflects all relevant data known at the time of this report. However, the cause of death has been requested. If additional relevant information is received, a supplemental report will be submitted.
081	**1923518**	**Model Number** 6947 **Event Date** 11/18/2010 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative**

		The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary (b)(4) the actual device was not received for evaluation. We did receive performance data collected from the device and have analyzed the data. Lead integrity alert triggered - patient alert for lead failure predictor on (b)(4)-2010 23:48:53. **Event Description** It was reported the patient died approximately 6 weeks after device implant. The cause of death has been requested and not received.
082	**1923535**	**Model Number** 6947 **Device Problems** Failure to capture; Impedance issue **Event Date** 11/22/2010 **Event Type** Death **Patient Outcome** Death **Event Description** It was reported that the patient died 8 months after device was implanted. The clinic reported that there was a carealert notification transmission but the after hours notification method was not setup. When the transmission was seen by the clinician they called the patient but were informed that the patient had passed away. The cause of death has been requested and not received. Follow up with clinic later revealed carelink check was done on patient night before and was fine. Nephew saw patient at around 9 pm. Patient died next morning sometime between 6 am and 930 am. The device was unable to capture at 5 v at 1ms - patient's heart would not respond. The clinic reported "the device did everything that it could. ". **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Additional information received indicated the carealert was related to a lead warning and out of range lead impedance.
083	**1924922**	**Model Number** 6947 **Event Date** 09/15/2010 **Event Type** Death **Patient Outcome** Death **Event Description**

		Information identified in the manufacturer's database noted the patient died less than a month after a new system was implanted. Cause of death has been requested and not received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
084	**1925221**	**Model Number** 6947 **Device Problem** Device alarm system issue **Event Date** 09/23/2010 **Event Type** Death **Patient Outcome** Death,Other **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the actual device was not received for evaluation. We did receive performance data collected from the device and have analyzed the data. Quick look window shows lead integrity alert triggered on (b)(6) 2010 based on short interval count (sic) incrementing, and 2 or more ventricular tachycardia-non sustained episodes less than 220 ms although the record only shows 1 ventricular fibrillation(vf) episode less than 220 ms on (b)(6) 2010. One short v-v sensed event of less than 220 ms is observed on the (b)(6) 2010. (15 episodes non sustained tachycardia, 5 episodes vf). Lifetime ventricular-sic counts are observed at 57 counts on the lifetime counter, with 22 of these counts occurring since the (b)(6) 2010. High sic can indicate the presence of noise or intermittency in the system. **Event Description** It was reported that a lead integrity alert was triggered due to short r-r events. The episode was classified as a ventricular fibrillation event and the question was raised of why did it take longer to detect the vf rhythm. The device and lead remain in use. No patient complications were reported as a result of this event. It was further reported that the patient died two and a half months post implant. The cause of death has been requested but not received.
085	**1935593**	**Model Number** 6947

		Event Date 11/07/2010 **Event Type** Death **Patient Outcome** Death,Required Intervention,Hospitalization,Life Threatening **Event Description** It was noted that the patient died just over two months post implant. The cause of death has been requested and not received. **Manufacturer Narrative** Follow up information received from the funeral home indicated the cause of death was dilated cardiomyopathy. No autopsy was completed. Circumstances surrounding patient death as reported on ambulance record and hospital records indicate the patient yelled out to spouse for help, was found sliding down the wall onto the floor and spouse attempted resuscitation. Emergency services arrived, resuscitation efforts were continued including intubation, therapy for ventricular fibrillation, pulseless electrical activity, therapy received for ventricular tachycardia but patient was declared dead at the emergency room. Last device report approximately six weeks prior to the patient's death indicated atrial pacing of 50. 15%, ventricular pacing of 98. 41%, normal device function. The last visit with the primary cardiologist four weeks before death indicated an abnormal optivol reading and fluid levels had been increasing since (b)(4) of 2010. A visit to the congestive heart failure clinic three weeks before death indicated the patient received a dobutamine infusion and labs showed an elevated creatinine. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
086	**1936647**	**Model Number** 6947 **Event Date** 08/17/2010 **Event Type** Death **Patient Outcome** Death,Other **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** It was noted the patient died approximately 6 months after device implant. The cause of death

		has been requested and not received. Follow up revealed the patient died of unknown causes in his sleep. There was no autopsy performed. The records note the patient had a history of renal failure, coronary artery disease, hypertension, and atrial fibrillation.
087	**1937179**	**Model Number** 6947 **Event Date** 11/05/2010 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** It was reported that the patient died three days post implant of the implantable cardiac defibrillator and right atrial pacing lead. It was further reported that two days after the implant the patient went in for follow-up and the system checked out ok and the patient was given the ok to fly home. On the plane the patient had an emesis and "slumped over" and passed out. The cause of death has been requested but not received.
088	**1937189**	**Model Number** 6947 **Event Date** 11/14/2010 **Event Type** Death **Patient Outcome** Death **Event Description** It was reported under the system longevity study, approximately three months post implant, the patient died. The relationship to the device system is unknown. The cause of death and confirmation of the date of death has been requested and not received. Patient's friend reported the patient passed away at home "in his sleep. " based on follow-up received, the patient was one hundred percent paced. The patient was last seen by their physician two days prior to death and showing recent signs and symptoms of congestive heart failure. There is no allegation from a health professional that the death was device/and or lead related. **Event Description** It was reported under the system longevity study, approximately three months post implant, the patient died. The relationship to the device system is unknown. The cause of death and

		confirmation of the date of death has been requested and not received. Patient's friend reported the patient passed away at home "in his sleep. ".
089	**1938233**	**Model Number** 6947 **Event Date** 12/09/2010 **Event Type** Death **Patient Outcome** Death,Required Intervention,Hospitalization,Life Threatening **Event Description** It was reported that the patient died the day after system implant. The device was interrogated the morning of the patients's death and it was reported by the manufacturer's representative that the device was working within normal limits. The patient was discharged to home and was later returned to the hospital where resuscitation efforts were not successful. Interrogation during the resuscitation efforts revealed that the number of intervals to detect was higher than previously that day and that oversensing was present which had not been in prior interrogation. A hospital physician stated that cause of death may have been a pulmonary embolus. Cause of death has been requested but not received. **Manufacturer Narrative** Device system was returned to the manufacturer from the medical examiner post autopsy and information received indicated cause of death was arteriosclerotic cardiovascular disease. Additional information received indicated that the patient walked in door of house one day after device implant and "dropped dead". No arrhythmias were present on interrogation. Cause of death provided as sudden death- electromechanical disassociation/pulseless electrical activity. A statement from the physician indicated death was not related to the device or lead system. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned, analyzed and no anomalies were found. (b)(4) no anomalies found, defib conductor distorted, several conductors blood/body fluid (not obstructed), inner tubing kinked/buckled, all insulators breached cut, blood in/on helix/lobe mechanism (sleeve head), blood in/on helix/lobe mechanism, apparent explant damage. Full lead returned and analyzed. (b)(4) no anomalies found, proximal conductor blood/body fluid (not obstructed), outer insulation breached cut, apparent explant damage. Full lead returned and analyzed. (b)(4) no anomalies found, proximal conductor blood/body fluid (not obstructed), outer insulation breached cut, blood in/on helix/lobe mechanism (sleeve head), blood in/on helix/lobe mechanism, apparent explant damage. Full lead

		returned and analyzed.
090	**1938271**	**Model Number** 6947 **Event Date** 08/04/2009 **Event Type** Death **Patient Outcome** Death,Other **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The initial reported event was received on 29-november-2010. Of note, the reportable malfunction is normally submitted via a bimonthly medwatch report submission that would have been due on 10-february-2011. Information was subsequently received on 23-december-2010 and revealed the patient died. As there is new information that reasonably suggests the device has or may have caused of contributed to a death, this event no longer qualifies for bimonthly reporting and is therefore being submitted as a 30-day report. Evaluation summary: (b)(4) the full lead was returned, analyzed and no anomalies were found. It was noted that the proximal conductor was distorted, there was blood/body fluid on the distal conductor (not obstructed) and the lead appeared damage at implant. (b)(4) the full lead was returned, analyzed and no anomalies were found. It was noted that the proximal conductor was distorted, there was blood in/on the helix/lobe mechanism and the lead appeared damage at implant. There was blood in/on the helix/lobe mechanism and the lead appeared damage at implant. **Event Description** It was reported that the leads were attempted to be implanted but failed due to bad valve regurgitation. The leads were not implanted and were returned to the manufacturer. It was later found that the patient had died two weeks after implant. The cause of death has been requested but not received.
091	**1944506**	**Model Number** 6947 **Event Date** 12/16/2010 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative**

		The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary (b)(4) no anomalies found. (b)(4) no anomalies found, distal and defib conductors distorted, several conductors blood/body fluid (not obstructed), inner tubing kinked/buckled, outer insulation cosmetic cut, all insulators breached cut, helix/lobe distorted/bent, blood in/on helix/lobe mechanism, apparent explant damage. Full lead returned and analyzed. **Event Description** It was reported by the patient's daughter that the patient died and "there was a question about his heart rate at the time of his death and we want to get the device checked. " the cause of death has been requested and not received. It was later reported that, according to the clinicians, the device is not suspect in the patient's death. Follow up later reported the patient's family questioned "whether there was a device malfunction causing his collapse. ". Patient discharged from hospital to nursing facility 13 days prior to death. Last office visit was five days after hospital discharge. An echocardiogram showed ejection fraction of 30%.
092	**1944512**	**Model Number** 6947 **Event Date** 03/29/2010 **Event Type** Death **Patient Outcome** Death; Life Threatening Hospitalization Required Intervention **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The patient recovered fully and was discharged from the hospital. No further complications were reported as a result of this event. It was later reported that approximately 8 months later, the patient had one arrhythmia that was successfully treated, but patient was later found unresponsive on the couch. Patient was reported to be "brain dead. " review of manufacturer's database revealed the patient died 13 days later. The cause of death has been requested and not received. Evaluation summary: (b)(4) the actual

		device was not received for evaluation. We did receive performance data collected from the device and have analyzed the data. That data showed interference/noise and ventricular oversensing. The lifetime ventricular sensing integrity counter is 94 and all counts occured over five days previous to interrogation. A high value of this count can indicate a possible intermittency in the system. **Event Description** It was reported that the patient had arrhythmias in the car while driving to the er. The patient never received therapy because the treatment aborted in vf episode #24. The device "was pacing at the upper sensing rate=130 bpm, which may have compromised detection. Atrial undersensing and activity pacing caused ventricular safety pacing as several of the fibrillation sensed events to be sensed as cross-talk. " it was also reported the ventricular sensed intervals were as long as 360 ms. Short intervals before fibrillation detection disabled anti-tachycardia pacing during charge which caused the therapy to abort during the charge. Some of the intervals were at 190 ms which were too short to program around. Additionally, the hospital personnel tried to resuscitate the patient, but he was pronounced dead. An hour later, family went into his room and discovered movement.
093	**1964293**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 12/24/2010 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary (b)(4) no anomalies found. (b)(4) no anomalies found, outer insulation cosmetic depression. Proximal segment returned and analyzed. (b)(4) no anomalies found, outer insulation breached cut, apparent explant damage. Proximal segment returned and analyzed. (b)(4) no anomalies found, outer insulation breached cut, apparent explant damage. Proximal segment returned and analyzed. **Event Description**

		It was reported the patient died approximately 7 weeks after device system implant. The death certificate notes the cause of death to be sudden cardiac arrest, coronary artery disease, atherosclerotic heart disease, and diabetes mellitus with contributing factors of hypertension and chronic renal failure. Follow up determined patient admitted to hospital six days prior to death with severe chest pain while undergoing dialysis. Myocardial infarction ruled out. Patient in paced rhythm. Chest xray noted persistant right pleural effusion. The day prior the death, severe chest pain with acute respiratory failure requiring intubation. Patient subsequently deteriorated and code blue called, but resusitation was unsuccessful. No allegation of any device/lead issues. **Manufacturer Narrative**
094	**1966071**	**Model Number** 6947 **Event Date** 06/23/2004 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis summary - (b)(4) battery depletion-normal. (b)(4) no anomalies found, outer insulation cosmetic depression. Proximal segment returned and analyzed. (b)(4) no anomalies found, outer insulation cosmetic depression. Proximal segment returned and analyzed. (b)(4) no anomalies found. Proximal segment returned and analyzed. **Event Description** A cardiac resynchronization therapy defibrillator (crt-d) and three leads were returned from an unknown source with no information. Information identified in the manufacture's data base indicated the patient died approximately five and a half months post the implant of the crt-d system. **Manufacturer Narrative** The device(s) associated with this adverse outcome was/were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. The information

		submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis summary - (b)(4) battery depletion-normal. (b)(4) no anomalies found, outer insulation cosmetic depression. Proximal segment returned and analyzed. (b)(4) no anomalies found, outer insulation cosmetic depression. Proximal segment returned and analyzed. (b)(4) no anomalies found. Proximal segment returned and analyzed.
095	**1972029**	**Model Number** 6947 **Event Date** 12/24/2010 **Event Type** Death **Patient Outcome** Death **Event Description** A cardiac resynchronization therapy-defibrillator (crt-d) system was received and returned with no information. Per the manufacture data base the patient had died approximately nine months post implant of the crt-d and left ventricular lead. Through the follow-up process it was revealed that the patient had been seen in the clinic one month prior to the day of death for management of congestive heart failure. They had developed shortness of breath, cough, and increased weight gain. These symptoms were being managed by diuretic therapy. The patient was seen in the clinic the day before death where the symptoms had improved and diuretic management seemed under control. The patient died the next day. Cause of death was requested but not known by the cardiology clinic or primary clinic. No funeral home contact is available. The last interrogation of the crt-d was three months prior to death which only showed that the optivol fluid index was increasing, which would be consistent. **Manufacturer Narrative** Analysis of the device and leads are in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Manufacturer Narrative** Analysis of the leads are in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned and analyzed and no anomalies were found.

		The last interrogation of the crt-d was three months prior to death which only showed that the optivol fluid index was increasing, which would be consistent with symptomatic congestive heart failure. Otherwise the device measurements were with in normal limits. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned and analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the proximal conductor was cut, there was blood/body fluid on the proximal conductor (not obstructed), the outer insulation was breached cut, the outer insulation had a cosmetic depression and there was apparent explant damage. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the distal conductor was distorted, there was blood/body fluid on the distal conductor (not obstructed), there was blood/body fluid on the outer tubing overlay, the outer insulation was breached cut, outer tubing overlay was breached cut and there was apparent explant damage. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that all the insulators were breached cut, the outer insulation had a cosmetic depression and there was apparent explant damage.
096	**1972039**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 09/28/2010 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** It was noted the patient died 7 weeks after device implant. Follow up later revealed that per the death certificate, cause of death was congestive heart failure due to atherosclerotic cardiovascular disease. Follow up later revealed patient admitted to hospital for endstage coronary artery disease with gradual deterioration. Poor response to diuretics and eight days prior to death, spouse requested no further aggressive treatments. No autopsy was performed. It was reported the death was not related to the device or leads.

097	**1972043**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 01/31/2009 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis summary - (b)(4) no anomalies found. (b)(4) no anomalies found, several conductors blood/body fluid (not obstructed). Partial lead in segments returned and analyzed. **Event Description** It was reported the patient died. Follow up with clinic later reported patient had chest discomfort the day prior to death after having received one appropriate shock. Went to hospital and started on medications when found to be in polymorphic ventricular tachycardia. Later became diaphoretic and very hypotensive. Determined to be in cardiogenic shock, admitted to icu and treated medically, but by the next morning was made a do not resuscitate by the daughter, device was turned off, and patient died with cause of death noted to be cardiogenic shock due to severe ischemic cardiomyopathy. "the device was functioning appropriately prior to her death. " patient was not pacer dependent.
098	**1977126**	**Model Number** 6947 **Device Problems** Fracture; High impedance **Event Date** 12/03/2010 **Event Type** Death **Patient Outcome** Death,Required Intervention,Hospitalization,Life Threatening **Event Description** It was reported that there was high impedance and an apparent lead fracture on the right ventricular lead. Through follow up, it was reported that during a lead extraction, the patient had an atrial perforation and died in the operating room. **Manufacturer Narrative**

		The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The initial reported event was received on (b)(6) 2010. Of note, the reportable malfunction and/or serious injury (high impedance and possible lead fracture) is normally submitted via a bimonthly medwatch report submission that should have been submitted on (b)(6) 2011. Information was subsequently received on (b)(6) 2010 and revealed the patient died. As there is new information that reasonably suggests the device has or may have caused or contributed to a death, this event no longer qualifies for bimonthly reporting and is therefore being submitted as a 30-day report.
099	**1977134**	**Model Number** 6947 **Device Problems** No Known Device Problem; No Information **Event Date** 01/10/2011 **Event Type** Death **Patient Outcome** Death,Required Intervention,Hospitalization,Life Threatening **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis of the device is in process; the results will be forwarded when available. Without a lot number or device serial number, the manufacturing date cannot be determined. **Event Description** It was reported that during a system implant, the left ventricular lead dislodged and the vessel was too large for the lead. The lead was successfully replaced. After the implant, the patient returned to the intensive care unit intubated. The patient was later extubated and, per follow up, eating and talking when the patient arrested and died. It was further reported that the device was "pacing fine in icu after implant" and the patient's left arm was swollen. Additional follow up determined the cause of death to be cardiomyopathy. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Without a lot number or device serial number,

		the manufacturing date cannot be determined. Additional information was received that reported that after implantation, the patient had a severe desaturation when laid flat and a chest xray showed a small right pneumothorax. That evening, the patient suffered a respiratory arrest and as the patient was a dnr, no resuscitative efforts were undertaken per the family and patient's wishes. There was not noted to be any change in the patient's cardiac rhythm at the time of his demise. Evaluation summary: (b)(4) the device was returned, analyzed and no anomalies were found. (b)(4): the full lead was returned, analyzed and no anomalies were found. It was noted that the inner tubing was kinked/buckled, the helix/lobe was distorted/bent, there was blood in/on the helix/lobe mechanism and there was apparent explant damage. (b)(4): the full lead was returned, analyzed and no anomalies were found. It was noted that there was blood/body fluid on the proximal conductor (not obstructed), the outer insulation was breached cut, the helix/lobe was distorted/bent, there was blood in/on the helix/lobe mechanism and there was apparent explant damage. (b)(4): the full lead was returned, analyzed and no anomalies were found. It was noted that there was blood/body fluid on the distal conductor (not obstructed).
100	**1977136**	**Model Number** 6947 **Device Problem** No Information **Event Date** 01/12/2011 **Event Type** Death **Patient Outcome** Death,Required Intervention,Hospitalization,Life Threatening **Manufacturer Narrative** This event occurred outside the us. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient information is not generally available due to confidentiality concerns. **Event Description** It was reported that during the implant procedure, a tamponade occurred with a pericardial effusion. Paracentesis was performed without success and the patient experienced a cardiac arrhythmia and died. Physician has no allegation against the device or lead in regards to the patient's death. Physician later reported cpr (cardiopulmonary resusitation) was started due to cardiogenic shock due to the narcotic medications and severe ischemic cardiomyopathy. Further reports the echocardiography showed evidence of the pericardial effusion of two to three

		hundred ml, but no signs of hemodynamic impairment - "no evidence of a cardiac tamponade. " autopsy refused by family, but physician reported the very probable cause of death was the severe ischemic cardiomyopathy in combination with a relatively high dose of a narcotic medication needed during the procedure. **Manufacturer Narrative**
101	**1977138**	**Model Number** 6947 **Device Problem** No Information **Event Date** 11/26/2010 **Event Type** Death **Patient Outcome** Death **Event Description** It was reported by the patient's daughter in regards to the device that "it messed up on her" and patient died due to heart failure. Reported patient had been "doing good until the defibrillator messed" up on the patient. Verification of cause of death will be requested. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. This one of two reports that are reporting the death of this patient, note report number 2649622000-2011-07673.
102	**1980116**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 12/09/2010 **Event Type** Death **Patient Outcome** Death **Event Description** It was noted the patient died 22 days following device implant. Follow up with the clinic later reported the patient died with cause of death noted to be infection.

		Manufacturer Narrative The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** It was noted the patient died 22 days following device implant. Follow up with the clinic later reported the patient died with cause of death noted to be infection/(b)(6). Nurse later reported that patient was recovering well at last office visit, but one week later, patient reported to spouse that not feeling well. Spouse noted a mental status change in patient and brought to er. Patient found to be (b)(6) and device explant was scheduled. Patient died before this could be done. The patient had not been pacemaker dependent. Unknown to clinic if autopsy was done.
103	**1984194**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 05/21/2010 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis of the device is in process; the results will be forwarded when available. Analysis summary - (b)(4) no anomalies found. Proximal segment returned and analyzed. (b)(4) - no anomalies found. Proximal segment returned and analyzed. **Event Description** It was noted the patient died approximately eight months following device system implant. The cause of death is being requested.

		Manufacturer Narrative The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis summary - (b)(4) no anomalies found. Proximal segment returned and analyzed. (b)(4) - no anomalies found. Proximal segment returned and analyzed. (b)(4) no anomalies found.
104	**1988733**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 01/24/2011 **Event Type** Death **Patient Outcome** Death **Event Description** It was noted the patient died one month following device implant. The cause of death is being requested. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted
105	**1988748**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 02/02/2011 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description**

		It was noted the patient died approximately nine months following device implant. The cause of death is being requested.
106	**1992244**	**Model Number** 6947 **Device Problem** No Information **Event Date** 10/31/2010 **Event Type** Death **Patient Outcome** Death **Event Description** It was reported the patient died approximately ten months from system implant. The cause of death has been requested and not received. Based on follow-up received, the patient went into hospice care and device therapies were turned off approximately three months prior to death. The patient was not pacemaker dependant. The cause of death is complications of human immunodeficiency virus. There are no allegations from a health care professional that the death was device and/or lead related. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned and analyzed. No anomalies were found. (b)(4) the proximal segment of the lead was returned and analyzed. No anomalies were found. It was noted there were outer insulation cosmetic depression and visual analysis was performed. (b)(4) the proximal segment of the lead was returned and analyzed. No anomalies were found. It was noted that visual analysis was performed. (b)(4) the proximal segment of the lead was returned and analyzed. No anomalies were found. It was noted there were outer insulation cosmetic depression and visual analysis was performed. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant

		information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned and analyzed. No anomalies were found. (b)(4) the proximal segment of the lead was returned and analyzed. No anomalies were found. It was noted there were outer insulation cosmetic depression and visual analysis was performed only. (b)(4) the proximal segment of the lead was returned and analyzed. No anomalies were found. It was noted that visual analysis was performed only. (b)(4) the proximal segment of the lead was returned and analyzed. No anomalies were found. It was noted there were outer insulation cosmetic depression and visual analysis was performed only.
107	**1992248**	**Model Number** 6947 **Device Problems** No Known Device Problem; No code available **Event Date** 01/02/2011 **Event Type** Death **Patient Outcome** Death,Other **Manufacturer Narrative** Analysis of the leads are in process; the results will be forwarded when available. Evaluation summary: (b)(4): the device was returned and analyzed and found to have no anomalies. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Manufacturer Narrative** Evaluation summary: (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression. (b)(4): the device was returned and analyzed and found to have no anomalies. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description**

		It was reported that the after the patient died the device was given to the family. The device was active, reporting shocks delivered and sending carelink transmissions. The caller was instructed to have the family bring in the device to have it turned off. Per the manufacture database the patient died seven months post implant of a biventricular defibrillator and two leads. Cause of death has been requested and not received.
108	**1994132**	**Model Number** 6947 **Device Problem** No Information **Event Date** 02/28/2008 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis of the device is in process; the results will be forwarded when available. Evaluation summary: (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the proximal conductor was distorted, the outer insulation was breached cut and there was apparent explant damage. It was noted that visual analysis was performed only. (b)(4) the partial lead was returned in segments, analyzed and no anomalies were found. It was noted that the proximal conductor was distorted and there was apparent explant damage. It was noted that visual analysis was performed only. **Event Description** A device system was returned to the manufacturer with no information. Information obtained indicates the patient died approximately two weeks after system implant. The cause of death has been requested, but not received.
109	**1994151**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 02/10/2010

		Event Type Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis of the 6947 lead is in process; the results will be forwarded when available. Evaluation summary - (b)(4) no anomalies found. (b)(4) no anomalies found, all conductors blood/body fluid (not obstructed), outer insulation cosmetic depression. Proximal segment returned and analyzed. **Event Description** It was noted the patient died 55 days following device implant. The cause of death is being requested. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis of the device is in process; the results will be forwarded when available. **Manufacturer Narrative** Evaluation summary - (b)(4) no anomalies found. (b)(4) no anomalies found, all conductors blood/body fluid (not obstructed), outer insulation cosmetic depression. Proximal segment returned and analyzed. (b)(4) no anomalies found, all insulators breached cut, apparent explant damage. Proximal segment returned and analyzed.
110	**1995370**	**Model Number** 6947 **Device Problem** No code available **Event Date** 06/26/2004 **Event Type** Death **Patient Outcome** Death

		Event Description Information identified in the manufacturer's database noted the patient died four months post implant of the implantable cardiac defibrillator. The patient was last seen one month prior to the day of death in the cardiology clinic. An echocardiogram was performed that day which revealed a large right atrium with high pressures, an ejection fraction of thirty five percent, and an atrial lead in a high position. The patient had no complaints and had been feeling good. The physician chose not to take the patient back to surgery and risk the complications of an additional surgery. Cause of death was requested and not received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
111	**1997103**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 07/20/2003 **Event Type** Death **Patient Outcome** Death **Event Description** It was noted the patient died approximately 5 months following device system implant. The cause of death was requested and not received. Follow up with the patient's clinic reported they do not have any information on the cause of death. There is no indication of any device or lead issues at or around the patient's date of death. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
112	**1998227**	**Model Number** 6947

		Device Problem No Known Device Problem **Event Date** 10/08/2010 **Event Type** Death **Patient Outcome** Death; Life Threatening Required Intervention **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** It was reported an ambulance was called to the patient's home, patient was unresponsive, cardiopulmonary resusitation was begun. Patient was taken to hospital in cardiac arrest with ventricular fibrillation and was pronounced dead on arrival. The patient's last clinic visit was two months prior to death. "appears patient was not very compliant with device checks. " the cause of death is being requested. The physician had called manufacture's technical services to report dissatisfaction with the device memory being overwritten with more recent episodes. "the tone of the call was not that the device was suspect in any way or that the device should have done anything differently. It was just regarding episode storage. ".
113	**2001208**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 10/29/2010 **Event Type** Death **Patient Outcome** Death **Event Description** It was noted the patient died 44 days following implant of device and lead. The cause of death is being requested. **Manufacturer Narrative**

		The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
114	**2001220**	**Model Number** 6947 **Device Problem** No Information **Event Date** 06/19/2009 **Event Type** Death **Patient Outcome** Death,Other **Manufacturer Narrative** Correction made to section: evaluation summary: (b)(4): the device was returned and analyzed and no anomalies were found. (b)(4):the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Manufacturer Narrative** Evaluation summary: (b)(4):the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis of the device is in process; the results will be forwarded when available. **Event Description** An implantable cardiac defibrillator system was returned from an unknown source with no information. Per the manufacture data base, the patient died five months post implant of the system. Cause of death has been requested and not received.
115	**2001757**	**Model Number** 6947

		Device Problem No Known Device Problem **Event Date** 08/04/2010 **Event Type** Death **Patient Outcome** Death **Event Description** The device system was returned from a competitor with no information. Per the manufacturer database, the patient died approximately 5. 5 months post implant of the system. Cause of death is being requested. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. This information was received from a competitor. All data pertinent to the event is provided. Analysis of the device is in process; the results will be forwarded when available. Evaluation summary - (b)(4) no anomalies found, outer insulation cosmetic depression. Proximal segment returned and analyzed. (b)(4) no anomalies found. Proximal segment returned and analyzed. (b)(4) no anomalies found, outer insulation cosmetic depression. Proximal segment returned and analyzed. Evaluation summary - (b)(4) no anomalies found, outer insulation cosmetic depression. Proximal segment returned and analyzed. (b)(4) no anomalies found. Proximal segment returned and analyzed. (b)(4) no anomalies found, outer insulation cosmetic depression. Proximal segment returned and analyzed. (b)(4) no anomalies found.
116	**2003387**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 08/30/2010 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative**

		The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis of the leads is in process; the results will be forwarded when available. (b)(4) no anomalies found. Evaluation summary (b)(4) no anomalies found. (b)(4) no anomalies found. Proximal segment returned and analyzed. (b)(4) no anomalies found, all conductors blood/body fluid (not obstructed). Proximal segment returned and analyzed. (b)(4) no anomalies found. Proximal segment returned and analyzed. **Event Description** It was noted the patient died 26 days following device system implant. Follow up with the cardiology clinic reported there were no complications with the implant and no device or lead issues after implant as far as they know. The cause of death was requested, but not available.
117	**2009345**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 12/08/2010 **Event Type** Death **Patient Outcome** Death,Required Intervention,Hospitalization **Event Description** An implantable cardiac defibrillator system was returned to the manufacturer with no information. Review of the database indicates that the patient died one week after device replacement. The cause of death has been requested, but not received. **Manufacturer Narrative** Additional information received from this hospital indicates the patient was admitted with progressive pain, had a device replacement due to elective replacement indicator and following a workup to determine if the patient was a candidate for a mechanical device or

		transplant the patient had a cardiac arrest with successful resuscitation. A palliative care conference was completed with the patient expressing a desire to discharge to home and to not die in the hospital. The patient became a do not rescuscitate and plans were made to discharge with hospice. The discharge summary did not note disposition and patient's date of death was five days after the care conference. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned, analyzed and no anomalies were found. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer tubing overlay cosmetic stress cracking, the outer insulation had a cosmetic depression and visual analysis only was completed. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found.
118	**2014182**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 09/12/2010 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4): the device was returned and analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that there was blood/body fluid on the distal conductor (not obstructed). **Event Description** A bi-ventricular defibrillator system was returned. Information identified in the manufacturer's database noted the patient died six months post the implant of the bi-ventricular device. Cause of death was requested and not received.

		Manufacturer Narrative Analysis of the device is in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that there was blood/body fluid on the distal conductor (not obstructed).
119	**2016437**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 01/25/2011 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** Evaluation summary: (b)(4): the device was returned, analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** A bi-ventricular defibrillator system was returned from an unknown source with no information other than the system was removed from the patient prior to cremation. Information identified in the manufacturer's database noted the patient died three months post the implant of the bi-ventricular system. Cause of death has been requested and not received.

120	**2016463**	**Model Number** 6947 **Device Problems** Failure to shock or properly shock; Low impedance; Device-device incompatibility **Event Date** 02/17/2011 **Event Type** Death **Patient Outcome** Death; Life Threatening Hospitalization Required Intervention **Manufacturer Narrative** The device has been returned to the manufacturer. This event occurred outside the us. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient information is not generally available due to confidentiality concerns. This is one of two reports that includes device implanted at the time of the patient death. See manufacture report number: 2649622-2011-13602. Evaluation summary: (b)(4) full lead was returned, analyzed and no anomalies were found. It was noted that the defibrillation coil was distorted, blood/body fluid was on several conductors (not obstructed), inner tubing was kinked/buckled, outer insulation had cosmetic environmental stress cracking, a cosmetic cut, and a cosmetic depression. The outer tubing overlay was breached cut, there was blood in/on the helix/lobe mechanism (sleeve head) and in/on the helix/lobe mechanism, and there was apparent explant damage. There was dried tissue on the helix. (b)(4) the device was returned, analyzed and no anomalies were found. Performance data was collected from the device and have analyzed the data. All therapies exhausted and max shocks delivered alerts are observed on (b)(6) 2011. Multiple short ventricle-ventricle (v-v) sensed events of < 220 ms are observed on the (b)(6) 2011. (3 episodes non-sustained tachycardia (nst), 1 episode ventricular fibrillation-vf) there are also many episodes of < 220 ms on the same day (27 nst, 2 vf). High ventricular sensing integrity counter (v-sic) counts are observed with 920 counts occurring since the (b)(6) 2011. High sic can indicate the presence of noise or intermittency in the system. **Event Description**

		It was reported that the device detected ventricular fibrillation and delivered three therapies. It was also reported that the device charged to 35joules but delivered charges were between 0. 6joules and 1. 5joules, there was a decreased impedance, and the patient died. The cause of death has been requested but not received. Additional information was received suggesting the previously capped defibrillation lead may have had an interaction with the active defibrillation lead resulting in the deceased joule output.
121	**2019519**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 09/24/2010 **Event Type** Death **Patient Outcome** Death **Event Description** Review of the manufacturer's database indicated that the patient had died approximately nine months post the implant of the replacement system. **Manufacturer Narrative** All information known was provided per the complainant. Therefore, no attempts for additional information will be made. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
122	**2019539**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 04/15/2008 **Event Type** Death **Patient Outcome** Death **Event Description** Review of the manufacturer's database indicated that the patient had died eight months

		post implant of the replacement bi-ventricular system. **Manufacturer Narrative** All information known was provided per the complainant. Therefore, no attempts for additional information will be made. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
123	**2020895**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 12/03/2009 **Event Type** Death **Patient Outcome** Death **Event Description** Review of the manufacturer's database indicated that the patient had a system replacement and died five months later. **Manufacturer Narrative** All information known was provided per the complainant. Therefore, no attempts for additional information will be made. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
124	**2020898**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 08/30/2008 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative**

		All information known was provided per the complainant. Therefore, no attempts for additional information will be made. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** Review of the manufacturer's database indicated that the patient had died approximately five and half months post implant of the replacement device and defibrillation lead.
125	**2020903**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 11/17/2008 **Event Type** Death **Patient Outcome** Death **Event Description** Review of the manufacturer's database indicated that the patient had died approximately six months post the implant of the replacement implantable cardiac defibrillator and defibrillation lead. **Manufacturer Narrative** All information known was provided per the complainant. Therefore, no attempts for additional information will be made. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
126	**2020906**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 08/17/2008 **Event Type** Death **Patient Outcome** Death

		Manufacturer Narrative All information known was provided per the complainant. Therefore, no attempts for additional information will be made. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** Review of the manufacturer's database indicated that the patient had a lead replacement and died seven months later.
127	**2020930**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 11/04/2010 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** All information known was provided per the complainant. Therefore, no attempts for additional information will be made. Information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** Review of the manufacturer's database indicated that the patient had died approximately six months post the implant of the replacement system.
128	**2020934**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 02/10/2010 **Event Type** Death **Patient Outcome** Death

		Event Description Review of the manufacturer's database indicated that the patient had a system replacement and died nine months later. **Manufacturer Narrative** All information known was provided per the complainant. Therefore, no attempts for additional information will be made. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
129	**2020945**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 10/02/2009 **Event Type** Death **Patient Outcome** Death **Event Description** Review of the manufacturer's database indicated that the patient had a implantable cardiac defibrillator replacement and died approximately five months later. **Manufacturer Narrative** All information known was provided per the complainant. Therefore, no attempts for additional information will be made. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
130	**2020949**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 05/24/2009 **Event Type** Death **Patient Outcome** Death

		Manufacturer Narrative All information known was provided per the complainant. Therefore, no attempts for additional information will be made. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** Review of the manufacturer's database indicated that the patient had a device and lead replacement and died five months later.
131	**2020955**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Type** Death **Patient Outcome** Death **Event Description** Review of the manufacturer's database indicated that the patient had a device and lead replacement and died within one year of implant. **Manufacturer Narrative** All information known was provided per the complainant. Therefore, no attempts for additional information will be made. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Additional information was received correcting the device and model number from (b)(4) to (b)(4).
132	**2020959**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 06/14/2010 **Event Type** Death **Patient Outcome** Death

		Event Description Review of the manufacturer's database indicated that the patient had a system replacement and died one month later. **Manufacturer Narrative** All information known was provided per the complainant. Therefore, no attempts for additional information will be made. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
133	**2020965**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 07/09/2010 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** All information known was provided per the complainant. Therefore, no attempts for additional information will be made. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** Review of the manufacturer's database indicated that the patient had a lead replacement and died ten months later.
134	**2020968**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 04/29/2008 **Event Type** Death **Patient Outcome** Death

		Event Description Review of the manufacturer's database indicated that the patient had a system replacement and died five months later. **Manufacturer Narrative** All information known was provided per the complainant. Therefore, no attempts for additional information will be made. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
135	**2020974**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 12/13/2010 **Event Type** Death **Patient Outcome** Death **Event Description** Review of the manufacturer's database indicated that the patient had a system replacement and died four months later. **Manufacturer Narrative** All information known was provided per the complainant. Therefore, no attempts for additional information will be made. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
136	**2020978**	**Model Number** 6947

		Device Problem No Known Device Problem **Event Date** 09/11/2009 **Event Type** Death **Patient Outcome** Death **Event Description** Review of the manufacturer's database indicated that the patient had a system replacement and died nine months later. **Manufacturer Narrative** All information known was provided per the complainant. Therefore, no attempts for additional information will be made. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
137	**2020984**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 06/25/2009 **Event Type** Death **Patient Outcome** Death **Event Description** Review of the manufacturer's database indicated that the patient had a lead and device replacement and died three weeks later. **Manufacturer Narrative** All information known was provided per the complainant. Therefore, no attempts for additional information will be made. The information submitted reflects all relevant data

		received. If additional relevant information is received, a supplemental report will be submitted.
138	**2020987**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 01/18/2009 **Event Type** Death **Patient Outcome** Death **Event Description** Review of the manufacturer's database indicated that the patient had a lead replacement and died five months later. **Manufacturer Narrative** All information known was provided per the complainant. Therefore, no attempts for additional information will be made. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
139	**2020991**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 07/19/2010 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** All information known was provided per the complainant. Therefore, no attempts for additional information will be made. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.

		Event Description Review of the manufacturer's database indicated that the patient had a device and lead replacement and died eleven months later.
140	**2024329**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 11/05/2010 **Event Type** Death **Patient Outcome** Death,Other **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis of the device is in process; the results will be forwarded when available. Evaluation summary - (b)(4) no anomalies found. Proximal segment returned and analyzed. (b)(4) no anomalies found. Proximal segment returned and analyzed. (b)(4) no anomalies found. Partial lead in segments returned and analyzed. **Event Description** Review of manufacturer's database indicated the patient died seven months following device system implant. The cause of death has been requested and not received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary - (b)(4) no anomalies found. Proximal segment returned and analyzed. (b)(4) no anomalies found. Proximal segment returned and analyzed. (b)(4) no anomalies found. Partial lead in segments returned and analyzed. (b)(4) no anomalies found.
141	**2024351**	**Model Number** 6947 **Device Problem** No Known Device Problem

		Event Date 05/24/2010 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. All information known was provided and no further information is available. Therefore, no attempts for additional information will be made. **Event Description** Review of manufacturer's database indicated that the patient died approximately three months following implant of defibrillator and right ventricular lead.
142	**2025526**	**Model Number** 6947 **Device Problem** Oversensing **Event Date** 02/19/2011 **Event Type** Death **Patient Outcome** Death; **Manufacturer Narrative** The device is part of the advisory for this model. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** It was reported that the device on the day of death recorded a patient alert, ventricular fibrillation/tachycardia, non sustained ventricular tachycardia episodes, short ventricle to ventricle intervals, and oversensing. The cause of death was requested and not received. No autopsy was performed.

		Manufacturer Narrative Evaluation summary: (b)(4): the actual device was not received for evaluation. We did receive performance data (b)(4) collected from the device and have analyzed the data. There was oversensing. Multiple short ventricular-ventricular sensed events of greater than 220 ms are observed on the (b)(6) 2011 at approx. 03:35. (8 episodes non sustained tachycardia). In addition there was interference/noise observed as seen in a high short interval count (sic). Sic counts are observed with 359 counts on the lifetime counter, all of these counts occurring since the (b)(6) 2011. High sic can indicate the presence of noise or intermittency in the system. There was also high resistance/impedance with an out of trend sub threshold lead impedance patient alert observed on (b)(6) 2011. The device is part of the advisory for this model. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
143	**2025535**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 01/25/2011 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** A call to technical services came in on (b)(4) 2011 to report a por. Of note, the reportable injury is normally submitted via bimonthly med watch report submission that would have been submitted on (b)(4) 2010. Information was subsequently received on (b)(4) 2011 and revealed the patient died. As there is new information that reasonably suggests the device has or may have caused or contributed to a death this event no longer qualifies for the bimonthly reporting and is therefore being submitted as a 30-day report. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description**

		It was reported that a power on reset (por) occurred. The device was checked, and software was reinstalled and manual changes were made. Information gathered through follow-up revealed the patient died approximately three weeks after the por. The cause of death was a myocardial infarction secondary cause arteriosclerotic heart disease. **Manufacturer Narrative** Evaluation summary: the actual device was not received for evaluation. We did receive performance data collected from the device and have analyzed the data. A power on reset parameter occurred on (b)(6) 2010 08:52:32 for write to locked ram, addr=129e. In addition there was a patient alert for por on (b)(6) 2010 08:52:32. A call to technical services came in on (b)(6) 2011 to report a por. Of note, the reportable injury is normally submitted via (b)(6) report submission that would have been submitted on (b)(6) 2010. Information was subsequently received on 28feb2011 and revealed the patient died. As there is new information that reasonably suggests the device has or may have caused or contributed to a death this event no longer qualifies for the bimonthly reporting and is therefore being submitted as a 30-day report. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
144	**2025543**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 11/10/2009 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis of the device is in process; the results will be forwarded when available. Evaluation summary (b)(4) no anomalies found, outer insulation cosmetic depression. Proximal segment returned and analyzed. (b)(4) no anomalies found, distal conductor blood/body fluid (not obstructed). Proximal segment returned and analyzed. (b)(4) no anomalies found, all insulators breached cut, outer insulation cosmetic depression, apparent explant damage. Proximal

		segment returned and analyzed. **Event Description** Review of manufacturer's database revealed the patient died approximately eight months after device implant. The cause of death has been requested and not received.
145	**2025815**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 12/21/2009 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** Evaluation summary - (b)(4) no anomalies found. Proximal segment returned and analyzed. (b)(4) no anomalies found, all conductors blood/body fluid (not obstructed). Proximal segment returned and analyzed. (b)(4) no anomalies found. Proximal segment returned and analyzed. **Event Description** Review of manufacturer's database indicated that the patient died approximately four weeks following device system implant. The cause of death has been requested and not received. Follow up with manufacturer's representative reported his notes do not list the patient as pacemaker dependent. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary - (b)(4) no anomalies found. Proximal segment returned and analyzed. (b)(4) no anomalies found, all conductors blood/body fluid (not obstructed). Proximal segment returned and analyzed. (b)(4) no anomalies found. Proximal segment returned and analyzed. (b)(4) no

		anomalies found.
146	**2027247**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 02/22/2011 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis of the device is in process; the results will be forwarded when available. Evaluation summary (b)(4) no anomalies found, all conductors stretched. Proximal segment returned and analyzed. (b)(4) no anomalies found, all conductors stretched, apparent explant damage. Proximal segment returned and analyzed. **Event Description** It was reported the patient died with cause of death noted to be ischemic cardiomyopathy. Additional circumstances surrounding death included recent acute stroke and moderate aortic stenosis. It was unknown if the device was suspected in the patient death. Additional information has been requested and not received.
147	**2032081**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 03/18/2011 **Event Type** Death **Patient Outcome** Death,Other **Event Description** It was reported the patient died with cause of death pending and unknown if device was suspect in the patient's death. "stated removed leads and device ok - with 'some shocks'. Device not interrogated after death. " the cause of death has been requested and not received. Follow up with clinic reported they did know the patient had died, but had no

		further information as to cause of death. The patient was pacemaker dependent and had medical history of seizures since childhood. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary - (b)(4) no anomalies found. (b)(4) no anomalies found, defib conductor distorted and cut, all conductors blood/body fluid (not obstructed), outer tubing overlay cosmetic esc, outer insulation breached cut and cosmetic depression, blood in/on helix/lobe mechanism, apparent explant damage. Partial lead in segments returned and analyzed. (b)(4) no anomalies found, all conductors blood/body fluid (not obstructed), outer insulation breached cut, blood in/on helix/lobe mechanism, apparent explant damage. Full lead in segments returned and analyzed. **Event Description** It was reported the patient died with cause of death pending and unknown if device was suspect in the patient's death. "stated removed leads and device ok - with 'some shocks'. Device not interrogated after death. " the cause of death has been requested and not received. Follow up with clinic reported they did know the patient had died, but had no further information as to cause of death. The patient was pacemaker dependent and had medical history of seizures since childhood. It was later reported there was a potential performance issue with the device.
148	**2032087**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 03/04/2008 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.

		Event Description It was reported the patient died and the relatedness of the death to the device is unknown. The last office visit had been approximately five weeks prior to death "and there is nothing noted. " follow up with the cardiologist reported the cause of death was congestive heart failure due to ischemic cardiomyopathy.
149	**2032929**	**Model Number** 6947 **Device Problem** Failure to shock or properly shock **Event Date** 09/21/2010 **Event Type** Death **Patient Outcome** Death **Event Description** It was reported by the patient's adult child that the patient died from ventricular fibrillation. It was reported that the rhythm went into "v-fib and the device shocked and then it went into v-fib again and shocked and then it went asystole" and that the device "only shocked (the patient) twice. " cause of death has been requested and not received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
150	**2032945**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 10/16/2004 **Event Type** Death **Patient Outcome** Death **Event Description** It was reported that a patient who had an implantable cardiac defibrillator and two leads died eleven months post implant of the devices. Cause of death is unknown and will be

		requested. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
151	**2032951**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 12/20/2007 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** Evaluation summary: (b)(4): the device was returned and analyzed and found to have no anomalies. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** A bi-ventricular device and three leads were returned from an unknown source with no information. Information identified in the manufacturer's database noted the patient died ten months post the implant of the device. Cause of death was requested and not received. **Manufacturer Narrative**

		Evaluation summary: (b)(4): the device was returned and analyzed and found to have no anomalies. Analysis of the leads are in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
152	**2032954**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 03/28/2008 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** Evaluation summary: (b)(4): the device was returned, analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** An implantable cardiac defibrillator (icd) and two leads were returned from an unknown source with no information. Information identified in the manufacturer's database noted the patient died approximately six weeks post the implant of the icd system. Cause of death was requested and not received. **Manufacturer Narrative** Analysis of the device and leads are process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
153	**2032966**	**Model Number** 6947

		Device Problem No Known Device Problem **Event Date** 11/13/2010 **Event Type** Death **Patient Outcome** Death **Event Description** Review of manufacturer's database revealed the patient died 12 days after device system implant. Follow up with the clinic reported the cause of death was respiratory failure due to intertrial lung disease. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary - (b)(4) no anomalies found. (b)(4) no anomalies found. Proximal segment returned and analyzed. (b)(4) no anomalies found. (b)(4) no anomalies found. Proximal segment returned and analyzed. (b)(4) no anomalies found. (b)(4) no anomalies found. Proximal segment returned and analyzed. Evaluation summary - (b)(4) no anomalies found.
154	**2034365**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 01/10/2011 **Event Type** Death **Patient Outcome** Death **Event Description** An implantable cardiac defibrillator was returned to the manufacturer with no information. Review of the manufacturer's database indicates the patient died six days after the device system was explanted and approximately ten months post initial implant. The cause of death has been requested but not received. **Manufacturer Narrative**

		The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned, analyzed and no anomalies were found.
155	**2035406**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 03/21/2011 **Event Type** Death **Patient Outcome** Death; **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** It was reported the patient had an lv (left ventricular) lead revision and expired approximately five weeks later due to "lv lead complications. " follow up with the clinic reported the patient had a history of congestive heart failure, nonischemic cardiomyopathy, non hodgins lymphoma, and acute renal insufficiency. Unknown if patient was pacemaker dependent. Additional information as to cause of death was requested and not received.
156	**2036975**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 02/01/2010 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned, analyzed and no anomalies were found. (b)(4) the

		proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that visual analysis only was performed. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that visual analysis only was performed. **Event Description** An implantable cardiac defibrillator system was returned to the manufacturer with no information. Further review of the manufacturer's database indicated the patient is deceased and died approximately four months after device replacement. The cause of death has been requested but not received.
157	**2036987**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 06/06/2010 **Event Type** Death **Patient Outcome** Death **Event Description** An implantable cardiac defibrillator (icd) system was returned from an unknown source with no information. Information identified in the manufacturer's database noted the patient died approximately five months post the implant of the icd system. Cause of death will be requested. **Manufacturer Narrative** Evaluation summary: (b)(4): the device was retuned and analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary (b)(4) no anomalies found. (b)(4) no anomalies found. (b)(4) proximal segment.

		Manufacturer Narrative Evaluation summary: (b)(4): the device was retuned and analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
158	**2036992**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 04/12/2010 **Event Type** Death **Patient Outcome** Death **Event Description** An implantable cardiac resynchronization therapy defibrillator (crt-d) and three leads were returned from an unknown source with no information. Information identified in the manufacturer's database noted the patient died ten months post the implant of the crt-d and defibrillation lead. Cause of death was requested and not received. **Manufacturer Narrative** Without a lot number or lead serial number, the manufacturing date cannot be determined. Evaluation summary: (b)(4): the device was returned and analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned and analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that there was blood/body fluid on the distal conductor (not obstructed). Lead/mdtr: the proximal segment of the lead was returned, analyzed and no anomalies were found. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
159	**2037000**	**Model Number** 6947 **Device Problem** No Known Device Problem

		Event Date 11/17/2010 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** All follow up efforts have been completed and no further information will be available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned, analyzed and no anomalies were found. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that visual analysis only was performed. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation was breached cut, there was apparent explant damage and visual analysis only was performed. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that visual analysis only was performed. **Event Description** An implantable cardiac defibrillator system was returned to the manufacturer with no information. Further review of the manufacturer's database indicated the patient is deceased and died approximately seven months after system implant. The cause of death has been requested, but not received.
160	**2037002**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 08/04/2010 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.

		Event Description Information identified in the manufacturer's database noted the patient died approximately three and a half months post the implant of an implantable cardiac defibrillator. Cause of death has been requested and not received.
161	**2037010**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 11/25/2010 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** Analysis of the leads are in process; the results will be forwarded when available. Evaluation summary: (b)(4): the device was returned and analyzed. Preliminary results revealed that the device had no telemetry and no pacing output. Visual inspection of the grommet, setscrew, and connector revealed no anomalies. There were tool marks on the shield. The device lost telemetry and function due to battery depletion. The cause of the depletion cannot be determined. The device was fully functional and operated under normal current drain when powered with an external supply. The residual voltage and impedance indicates that the battery was not internally shorted. Since no save to disk data could be retrieved from the device and no other data was provided from the field there is no way to confirm this result. The result of analysis is inconclusive. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** An implantable cardiac defibrillator (icd) system was returned to the manufacture after it was removed for the autopsy. The cause of death is listed as coronary artery obstruction and addition circumstances surrounding the death was respiratory infection. The patient died ten months post implant of the icd system. **Manufacturer Narrative** Evaluation summary: (b)(4): the proximal segment of the lead was returned, analyzed and

		no anomalies were found. It was noted that the outer insulation had a cosmetic depression. (b)(4):the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that all conductors distorted, all of the insulation was breached cut, outer tubing overlay was breached cut, the outer insulation had a cosmetic depression and there was apparent explant damage. (b)(4): the device was returned and analyzed. Preliminary results revealed that the device had no telemetry and no pacing output. Visual inspection of the grommet, setscrew, and connector revealed no anomalies. There were tool marks on the shield. The device lost telemetry and function due to battery depletion. The cause of the depletion cannot be determined. The device was fully functional and operated under normal current drain when powered with an external supply. The residual voltage and impedance indicates that the battery was not internally shorted. Since no save to disk data could be retrieved from the device and no other data was provided from the field there is no way to confirm this result. The result of analysis is inconclusive. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
162	**2037032**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 10/14/2010 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned, analyzed and no anomalies were found. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that visual analysis only was performed. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that visual analysis only was performed. **Event Description**

		An implantable cardiac defibrillator system was returned to the manufacturer with no information. Further review of the manufacturer's database indicated the patient is deceased and died approximately two months after system implant. The cause of death has been requested but not received.
163	**2038342**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 06/01/2010 **Event Type** Death **Patient Outcome** Death **Event Description** An implantable cardiac defibrillator (icd) and lead were returned from an unknown source with no information. Information identified in the manufacturer's database noted the patient died approximately six months post the implant of the icd system. Cause of death was requested and not received. **Manufacturer Narrative** Evaluation summary: (b)(4): the device was returned and analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned and analyzed and no anomalies were found. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
164	**2038389**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 02/10/2011 **Event Type** Death **Patient Outcome** Death,Required Intervention,Hospitalization,Life Threatening **Event Description** It was reported that the patient died two days after implant. It was further reported that the patient fell down the steps at home, tried to stand up, became unresponsive and

		subsequently died. The cause of death has been requested, but not received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned, analyzed and no anomalies were found. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. (b)(4) the partial lead was returned in segments, analyzed and no anomalies were found. **Manufacturer Narrative** Additional information received from hospital medical records indicated the patient's spouse heard and noise and found patient who had fallen down the stairs and was unresponsive. Emergency services arrived and patient was found at the bottom of the stairs, unresponsive, pulseless and had agonal respirations. A paced rhythm was noted but was pulseless and pulseless electrical activity was reported. The patient was transferred to the hospital where resuscitation efforts were continued but were unsuccessful and the patient was declared deceased. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned, analyzed and no anomalies were found. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. (b)(4) the partial lead was returned in segments, analyzed and no anomalies were found.
165	**2040593**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 02/27/2011 **Event Type** Death **Patient Outcome** Death **Event Description**

		Review of manufacturer's database indicated the patient died 19 days after a device implant. The cause of death has been requested and not received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
166	**2042661**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 03/08/2011 **Event Type** Death **Patient Outcome** Death; **Manufacturer Narrative** Analysis of the device is in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** It was reported that a patient who had an implantable cardiac defibrillator died. There was a report that there was oversensing that occurred resulting in a non sustained tachycardia episode. The t-wave oversensing resolved and the patient returned to pacing. This episode occurred twelve days prior to the day of death. On the day of death an agonal rhythm was recorded. Cause of death had been requested and not received.
167	**2042668**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 05/17/2010 **Event Type** Death **Patient Outcome** Death **Event Description**

		An implantable cardiac defibrillator system was returned from an unknown source with no information. Further review of the manufacturer's database indicated the patient is deceased and died approximately seven months after system implant. The cause of death has been requested and not received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned, analyzed and no anomalies were found. Analysis of the device is in process; the results will be forwarded when available. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression.
168	**2042687**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 11/09/2010 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned, analyzed and no anomalies were found. Analysis of the device is in process; the results will be forwarded when available. **Event Description** An implantable cardiac defibrillator system was returned from an unknown source

		indicating the patient is deceased. Further review indicated the patient died approximately four months post system implant. The cause of death has been requested and not received. **Manufacturer Narrative** Additional information received from physician indicated cause of death was due to hypertension and gastrointestinal bleed. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned, analyzed and no anomalies were found. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression and visual analysis only was performed. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that visual analysis only was performed. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression and visual analysis only was performed.
169	**2042691**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 12/19/2010 **Event Type** Death **Patient Outcome** Death **Event Description** **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. All follow up efforts have been completed, no further information will be available. Evaluation summary: (b)(4) the device was returned, analyzed and no anomalies were found. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that there was blood/body fluid on several conductors (not obstructed), the

		inner tubing was kinked/buckled and there was apparent explant damage. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that there was blood/body fluid on the outer tubing overlay. **Event Description** An implantable cardiac defibrillator system was returned from an unknown source with no information. Further review of the manufacturer's database indicated the patient is deceased and died approximately six weeks after system implant. The cause of death has been requested and not received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. All follow up efforts have been completed, no further information will be available. Evaluation summary: (b)(4) the device was returned, analyzed and no anomalies were found. Analysis of the device is in process; the results will be forwarded when available.
170	**2044425**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 02/19/2011 **Event Type** Death **Patient Outcome** Death; Life Threatening Hospitalization Required Intervention Other **Event Description** It was reported that the patient presented to the emergency room unconscious and in persistent ventricular fibrillation. The patient's spouse reported that the patient had been shocked multiple times the previous day, while alert, aware and conscious and was rescued / converted by external defibrillation the previous day. During the device interrogation it was determined that the patient was in an sinus ventricular tachycardia with rapid ventricular response and that the patient had received additional shocks since

		being transferred to the intensive care unit. The physician requested that the icd be programmed off. The patient subsequently died. Cause of death was requested and not received. **Manufacturer Narrative** A call to technical services came in on (b)(4) 2011 to report a ask a question regarding the performance/reliability of an icd. Of note, the reportable injury is normally submitted via bimonthly med watch report submission that would have been submitted on (b)(4) 2010. Information was subsequently received on (b)(4) 2011 and revealed the patient died. As there is new information that reasonably suggests the device has or may have caused or contributed to a death this event no longer qualifies for the bimonthly reporting and is therefore being submitted as a 30-day report. Evaluation summary: (b)(4): the actual device was not received for evaluation. We did receive performance data collected from the device and have analyzed the data. The data revealed no anomalies found. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
171	**2044433**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 12/10/2010 **Event Type** Death **Patient Outcome** Death,Other **Event Description** A cardiac resynchronization therapy defibrillator (crt-d) and three leads were returned from an unknown source with no information. Information identified in the manufacture's data base indication the patient died approximately five months post the implant of the crt-d. Cause of death has been requested and not received. **Manufacturer Narrative** Evaluation summary: (b)(4): the device was returned and analyzed and no anomalies

		were found. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that there was a white substance on the outer insulation, the inner tubing was kinked/buckled, the outer insulation had a cosmetic depression and there was apparent explant damage. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic cut, all of the insulators were breach cut, there was a white substance on the outer insulation, there was apparent explant damage and the lead was stretched. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that there was blood/body fluid on the distal conductor (not obstructed) and the outer insulation had cosmetic environmental stress cracking. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. (b)(4) no anomalies found (b)(4) no anomalies found (b)(4) proximal segment (b)(4) no anomalies found (b)(4) proximal segment (b)(4) no anomalies found (b)(4) proximal segment.
172	**2046599**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 06/02/2007 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The device(s) associated with this adverse outcome was/were reported from a medtronic mdr specialist after discovering the patient had died via the manufacture's data base. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** Information identified in the manufacture's data base indicated that the patient died approximately one month post implant of an implantable cardiac defibrillator and two

		leads.
173	**2048997**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 09/29/2008 **Event Type** Death **Patient Outcome** Death **Event Description** An implantable cardiac defibrillator (icd) system was returned to the manufacturer from an unknown source with no information. Further review of the manufacturer's database indicated the patient is deceased and died approximately five months after device system was implanted. **Manufacturer Narrative** The device(s) associated with this adverse outcome was/were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned, analyzed and no anomalies were found. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation was breached cut, the outer insulation had a cosmetic depression and there was apparent explant damage. Visual analysis only was performed.
174	**2052305**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 11/30/2010 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** Evaluation summary: (b)(4): the device was returned and analyzed and no anomalies

		were found. (b)(4): the proximal segment of the lead was returned and analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that all the conductors were stretched and there was apparent explant damage. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** An implantable cardiac defibrillator (icd) and two leads were returned from an unknown source with no information. Information identified in the manufacture's data base indication the patient died approximately six months post the implant of the icd system. Cause of death has been requested and not received.
175	**2052313**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 03/05/2011 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned, analyzed and no anomalies were found. **Event Description** An implantable cardiac defibrillator was returned following the patient's death. Further review of the manufacturer's database indicated that patient died approximately nine months after device replacement. The cause of death has been requested and not received.
176	**2052318**	**Model Number** 6947 **Device Problem** No Known Device Problem

		Event Date 01/24/2011 **Event Type** Death **Patient Outcome** Death **Event Description** An event received indicated a patient was deceased and died approximately nine and one half months after device and lead replacement. The cause of death has been requested and not received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
177	**2055036**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 12/04/2010 **Event Type** Death **Patient Outcome** Death **Event Description** An implantable cardiac defibrillator (icd) and two leads were returned from a crematory with patient identification and date of death. Information identified in the manufacture's data base indication the patient died approximately eight months post the implant of the icd. Cause of death has been requested and not received. **Manufacturer Narrative** Evaluation summary: (b)(4): the device was returned and analyzed and no anomalies were found. Analysis of the leads are in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.

		Manufacturer Narrative Evaluation summary: (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that there was blood/body fluid on the distal conductor (not obstructed), the inner tubing was kinked/buckled and the outer insulation had a cosmetic depression. (b)(4): the device was returned and analyzed and no anomalies were found. Analysis of the leads are in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
178	**2055049**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 11/21/2010 **Event Type** Death **Patient Outcome** Death **Event Description** It was reported the patient died with death certificate noting cause of death to be cardiopulmonary arrest due to myocardial infarction, due to cardiomyopathy. Other significant conditions include diabetes mellitus, type 2. Manner of death was natural and no autopsy was performed. Follow up with clinic revealed last device check they have for this patient is a remote transmission approximately six weeks prior to death. Patient was in atrial fibrillation and there is no indication of any malfunction of the device. Unknown if patient was pacer dependent. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
179	**2055054**	**Model Number** 6947 **Device Problem** Dislodged or dislocated

		Event Date 02/15/2011 **Event Type** Death **Patient Outcome** Death,Required Intervention,Hospitalization,Life Threatening **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. This is one of two reports associated with this patient's death. Reference report # 264922000-2011-07132. **Event Description** It was reported that the patient was deceased. It was further reported that the lead had dislodged and an external pacemaker was needed as there were periods of asystole. The lead was repositioned and then dislodged a second time. The patient developed congestive heart failure, electromechanical dissociation, had a cardiac arrest, was unable to be revived and died.
180	**2055068**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 02/07/2011 **Event Type** Death **Patient Outcome** Death **Event Description** Review of manufacturer's database revealed the patient died approximately six weeks following device implant. The cause of death has been requested and not received. Follow up with manufacturer's representative revealed the patient was not pacemaker dependent and representative was not aware of any device/lead related issues related to the patient's death. **Event Description** Review of manufacturer's database revealed the patient died approximately six weeks

		following device implant. The cause of death has been requested and not received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary - (b)(4) no anomalies found. (b)(4) no anomalies found, outer cosmetic depression. Proximal segment returned and analyzed. (b)(4) no anomalies found, outer insulation cosmetic esc and breached cut and cosmetic depression. Proximal segment returned and analyzed. (b)(4) no anomalies found. Outer insulation breached cut and cosmetic depression, apparent explant damage. Proximal segment returned and analyzed.
181	**2055074**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 06/22/2008 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The device(s) associated with this adverse outcome was/were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Analysis of the device is in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** A cardiac resynchronization therapy defibrillator (crt-d) and three leads were returned from an unknown source with no information. Information identified in the manufacture's data base indication the patient died approximately one month post the implant of the crt-d system. **Manufacturer Narrative**

		Evaluation summary: (b)(4): the device was returned, analyzed and no anomalies were found. The device(s) associated with this adverse outcome was/were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Analysis of the leads are in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Manufacturer Narrative** Evaluation summary: (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that there was blood/body fluid on the distal conductor (not obstructed). (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that there was blood/body fluid on the distal conductor (not obstructed). (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the proximal conductor was distorted, the outer insulation was breached cut and there was apparent explant damage. (b)(4): the device was returned, analyzed and no anomalies were found. The device(s) associated with this adverse outcome was/were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Analysis of the leads are in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
182	**2058105**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 02/09/2011 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative**

		The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** It was reported that there was a care alert transmission for right ventricular pacing impedance out of range, high voltage defibrillation impedance out of range, and fast ventricular rate during atrial tachycardia/atrial fibrillation. Information obtained through follow up revealed the patient had died on the day that the care alerts were being transmitted. The patient was found dead at home. The device was last checked in the clinic one month prior to the death and found to have normal function. The patient had a history of atrial fibrillation. The cause of death was requested and not received.
183	**2061610**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 03/19/2011 **Event Type** Death **Patient Outcome** Death **Event Description** It was reported that the patient died approximately four months after an upgrade to a bi-ventricular implantable cardiac defibrillator system. Cause of death is not determined, but noted to be possible myocardial infarction. No autopsy performed. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
184	**2063537**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 01/20/2010

		Event Type Death **Patient Outcome** Death **Event Description** A cardiac resynchronization therapy defibrillator (crt-d) and three leads were returned from an unknown source with no information. Information identified in the manufacture's data base indication the patient died approximately six months post the implant of the icd and two leads. Cause of death was requested and not received. **Manufacturer Narrative** Evaluation summary: (b)(4): the device was returned and analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had cosmetic environmental stress cracking and the outer insulation had a cosmetic depression. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression. The device is part of the advisory for this model. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
185	**2065006**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 10/15/2009 **Event Type** Death **Patient Outcome** Death **Event Description** It was reported that the patient died two days after upgrade to bi-ventricular defibrillator system. Follow up indicated the cause of death was ischemic cardiomyopathy, prolonged qt and polymorphic ventricular tachycardia. Also reported was that the patient had terminal and/or refractory dysrhythmias. **Manufacturer Narrative**

		This death event was timely reported under mfg report numbers 2647346000-2010-00732, 2649622000-2010-12088 on (b)(6) 2011. However, the devices associated with the death were incorrect. Therefore, these reports are being submitted to accurately report the devices involved with the event. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
186	**2065020**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 03/21/2011 **Event Type** Death **Patient Outcome** Death **Event Description** It was reported that the recommended replacement time (rrt) was projected to be less than one year from implant. Review of manufacturer's database revealed the patient had died 25 days after device implant. Follow up revealed the cause of death was septic shock and there were no device or lead issues related to the patient's death. **Event Description** It was reported that the recommended replacement time (rrt) was projected to be less than one year from implant. Review of manufacturer's database revealed the patient had died 25 days after device implant. The cause of death has been requested and not received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
187	**2066376**	**Model Number** 6947 **Device Problem** No Known Device Problem

		Event Date 02/27/2011 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** Analysis of the lead is in process; the results will be forwarded when available. Evaluation summary: (b)(4): the device was returned and analyzed and no anomalies were found. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** An implantable cardiac defibrillator (icd) and lead were returned from a competitor with no information. Information identified in the manufacture's data base indication the patient died approximately eight months post the implant of the icd and lead. Cause of death will be requested. **Manufacturer Narrative** It was further reported by the patient's physician that seven months prior to death the interrogation showed a normal icd function, with 0% pacing, and no episodes of ventricular tachycardia/ventricular fibrillation (vt/vf). Two months prior to death on the physician indicated that there were no episodes of vt/vf or a-fib. The patient had a recent hospitalization for congestive obstructive pulmonary disease (copd), congestive heart failure (chf) and atrial-fibrillation (a-fib). The patient had a pmh of ischemic cardiomyopathy, chf, copd, and a-fib. The patient is not pacemaker dependent. No autopsy was performed. The physician indicated that the death was not related to the device or leads. The physician did not no the cause of death. Evaluation summary: (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression. (b)(4): the device was returned and analyzed and no anomalies were found. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.

		Event Description An implantable cardiac defibrillator (icd) and lead were returned from a competitor with no information. Information identified in the manufacture's data base indication the patient died approximately eight months post the implant of the icd and lead. Cause of death will be requested. An implantable cardiac defibrillator (icd) and lead were returned from a competitor with no information. Information identified in the manufacture's data base indication the patient died approximately eight months post the implant of the icd and lead. Cause of death will be requested. **Manufacturer Narrative** Evaluation summary: (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression. (b)(4): the device was returned and analyzed and no anomalies were found. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
188	**2067457**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 02/24/2011 **Event Type** Death **Patient Outcome** Death,Required Intervention,Hospitalization,Life Threatening **Event Description** It was reported that the patient was deceased and died six days after implantable cardiac defibrillator replacement and three days after lead implant. The cause of death has been requested and not received. **Manufacturer Narrative**

		The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Manufacturer Narrative** Additional information received indicated that the patient was admitted to the hospital due to repeated defibrillator firings. The patient had a generator changed due to limited number of shocks remaining on device. An epicardial lead was placed (b)(6) 2011. On (b)(6) 2011 the patient had episodes of ventricular tachycardia which progressed to sustained ventricular tachycardia. Resuscitation efforts were utilized and the patient was stabilized. On (b)(6) 2011, the patient developed sustained ventricular tachycardia again with pulseless electrical activity. Resuscitation efforts were utilized again and were subsequently discontinued at the family's request. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
189	**2067474**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 05/10/2010 **Event Type** Death **Patient Outcome** Death,Required Intervention **Event Description** It was reported that there was lead dislodgement. The right atrial lead (and device) were repositioned and remain implanted and in use. There were no further patient complications reported as a result of this issue. It was later noted the patient died approximately ten months after device implant. Follow up with the clinic reported the patient had last been seen by them (b)(6) 2010 with no problems noted. The cause of death has been requested and not received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant

		information is received, a supplemental report will be submitted.
190	**2068942**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 06/10/2008 **Event Type** Death **Patient Outcome** Death **Event Description** Review of the manufacturer's database indicated that the patient had two leads replaced and died approximately five months later. **Manufacturer Narrative** All information known was provided per the complainant. Therefore, no attempts for additional information will be made. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
191	**2068943**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 12/10/2008 **Event Type** Death **Patient Outcome** Death **Event Description** Review of manufacturer's database revealed the patient died approximately six months after device system implant. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The device(s) associated

		with this adverse outcome was/were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made.
192	**2068986**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 03/27/2011 **Event Type** Death **Patient Outcome** Death; **Event Description** It was reported that the patient was deceased and died approximately seven months after implantable cardiac defibrillator was replaced. Further information received indicated that the patient had laid down for a nap and was later found by family. The cause of death has been requested and not received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Manufacturer Narrative** Additional information received from physician indicated that interrogation of device had been reviewed and the patient had recurrent ventricular tachycardia, was shocked appropriately but died due to terminal ventricular tachycardia. No known device performance problem noted by physician. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4): the actual device was not received for evaluation. We did receive performance data collected from the device and have analyzed the data. All lead impedances rise on the noted day of death, (b)(6) 2011. (vpace rises to 1482 ohms from 475 ohms; superior vena cava lead rises from 46 ohms to 114 ohms, the defib active can rises from 38 ohms to 104 ohms). A lead integrity alert triggered on the noted date of death (b)(6) 2011; this, along with the rises of impedance may be attributed to

		post-mortem measurements. Multiple short v-v sensed events of < 220 ms are observed on the (b)(6) 2011, the noted date of death. (5 episodes non-sustained tachycardia) 49 short v-v counts are observed since the (b)(6) 2011, the noted date of death. High sensing integrity counts can indicate the presence of noise or intermittency in the system.
193	**2068989**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 03/19/2011 **Event Type** Death **Patient Outcome** Death; **Event Description** It was reported that a patient with an implantable cardiac defibrillator died approximately one year and four months after implant. On the day of death there were very fine fibrillation waves, due to the low amplitude of the waves there was some undersensing which prevented the detection of ventricular tachycardia/ventricular fibrillation. Cause of death will be requested. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Manufacturer Narrative** Cause of death was requested and not received. The actual device was not received for evaluation. We did receive performance data collected from the device and have analyzed the data. Oversensing was observed with two short ventricular-ventricular sensed events of greater than 220 ms are observed on the (b)(4) 2011, the noted day of death. There were two episodes on non-sustained tachycardia. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.

194	**2068995**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 02/05/2008 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary - (b)(4) no anomalies found. (b)(4) no anomalies found. Proximal segment returned and analyzed. (b)(4) no anomalies found. Proximal segment returned and analyzed. (b)(4) no anomalies found. Proximal segment returned and analyzed. **Event Description** Review of manufacturer's database indicated patient had died approximately three months following device system implant. The cause of death has been requested and not received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis of the device is in process; the results will be forwarded when available.
195	**2069005**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 06/18/2009 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.

		Event Description Review of manufacturer's database indicated the patient died approximately two months following device implant. The cause of death has been requested and not received. **Event Description** Review of manufacturer's database indicated the patient died approximately two months following device implant. The cause of death has been requested and not received. Follow up revealed the patient had a heartrate in the 40s, so reported was probably not pacer dependent. Patient had been admitted to a rehab/nursing center 27 days prior to death.
196	**2069924**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 09/14/2010 **Event Type** Death **Patient Outcome** Death; **Manufacturer Narrative** The patient is involved in a settlement involving the sprint fidelis lead model captured in e1062853. Per legal, all information known was provided per the complainant and no further information is available. Therefore, no attempts for additional information will be made. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** Review of the manufacturer's database indicated that the patient had died approximately two months post the implant of the replacement device and lead.
197	**2069964**	**Model Number** 6947 **Device Problem** No Known Device Problem

		Event Date 05/14/2009 **Event Type** Death **Patient Outcome** Death; **Manufacturer Narrative** The device is part of the advisory for this model. Evaluation summary: (b)(4): the device was returned and analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that all the conductors were stretched and there was apparent explant damage. (b)(4): the proximal segment of the lead was returned and analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned and analyzed and no anomalies were found. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** A cardiac resynchronization therapy defibrillator (crt-d) and three leads were returned from an unknown source with no information. Information identified in the manufacture's data base indication the patient died approximately eight months post the implant of the crt-d system.
198	**2069981**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 05/17/2006 **Event Type** Death **Patient Outcome** Death **Event Description** A cardiac resynchronization therapy defibrillator (crt-d) and two leads were returned from an unknown source with no information. Information identified in the manufacture's data base indication the patient died approximately six months post the implant of the crt-d system.

		Manufacturer Narrative Analysis of the device and leads are in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Manufacturer Narrative** Evaluation summary: (b)(4): the device was returned, analyzed and no anomalies were found. Analysis of the leads are in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Manufacturer Narrative** Evaluation summary: (b)(4): the device was returned, analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that all the insulators were breach cut, the outer insulation had a cosmetic depression and there was apparent explant damage. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that there was blood/body fluid on the distal conductor (not obstructed). The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
199	**2071213**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 12/15/2009 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The patient is involved in a settlement involving the sprint fidelis lead model captured in e896708. Per legal, all information known was provided per the complainant and no further information is available. Therefore, no attempts for additional information will be made. The information submitted reflects all relevant data received. If additional relevant

		information is received, a supplemental report will be submitted. **Event Description** Review of the manufacturer's database indicated that the patient had died approximately eight months post the implant of the replacement device.
200	**2072241**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 12/04/2010 **Event Type** Death **Patient Outcome** Death **Event Description** It was reported the patient received six successful shocks for ventricular fibrillation (vf) with rhythm returning to sinus after each shock. Rhythm reverted back to vf within 4 - 5 beats of these shocks. The episode did not meet the current termination criteria thereby rendering the device unavailable for additional shocks. Further reported "device has functioned within specifications. " the patient subsequently died. The cause of death has been requested and not received. **Manufacturer Narrative** This event occurred outside the u. S. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient information is not generally available due to confidentiality concerns. Evaluation summary: (b)(4): analysis unknown/not analyzed. (b)(4): no anomalies found. Proximal segment returned and analyzed. (b)(4): no anomalies found. Proximal segment returned and analyzed.

201	**2073309**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 04/01/2011 **Event Type** Death **Patient Outcome** Death **Event Description** It was reported by the patient's spouse that the patient had "another heart attack" and died. The spouse further reported that the defibrillator the patient had did not defibrillate "very well". Cause of death has been requested and not received. **Manufacturer Narrative** The device is part of the advisory for this model. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
202	**2076962**	**Model Number** 6947 **Device Problem** No code available **Event Type** Death **Patient Outcome** Death; Life Threatening Hospitalization Required Intervention **Manufacturer Narrative** Evaluation summary: (b)(4): the device was returned, analyzed and no anomalies were found. (b)(4): the full lead was returned, analyzed and the helix disengaged from the helical channel. It

		was noted that the inner tubing was kinked/buckled, the outer insulation had a cosmetic cut, and the helix was distorted/bent. (b)(4): the full lead was returned, analyzed and no anomalies were found. It was noted that there was blood/body fluid on the distal conductor (not obstructed), there was blood/body fluid on the outer tubing overlay, the helix/lobe was distorted/bent and there was blood. This report is based solely on device return and analysis. No information to suggest a device-related adverse event or product problem was received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** The implantable cardiac resynchronization therapy-defibrillator (crt-d) system was returned and the right ventricular lead subsequently tested out of specification. Further information obtained indicated the patient died of heart failure. The physician stated that the patient developed a hematoma after the crt-d system was implanted that became infected. The entire crt-d system was removed, and "about a week later" the patient died of heart failure.
203	**2076974**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 12/31/2010 **Event Type** Death **Patient Outcome** Death **Event Description** Review of manufacturer's database indicated the patient died approximately three months after device implant. The cause of death has been requested and not received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
204	**2077008**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 03/10/2011

		Event Type Death **Patient Outcome** Death; **Event Description** It was reported that the patient had a urinary tract infection/issue and was admitted a few days later. Then the patient was admitted to the care of hospice with a slight fever and not very responsive. The patient later died. Information identified in the manufacture data base revealed the patient died seven days post implant of the crt-d. **Manufacturer Narrative** The patient is involved in a settlement involving the sprint fidelis lead model captured in e912827. Per legal, all information known was provided per the complainant and no further information is available. Therefore, no attempts for additional information will be made. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
205	**2077038**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 02/01/2009 **Event Type** Death **Patient Outcome** Death,Other **Event Description** The implantable cardiac defibrillator system was returned with no information. A database search revealed that the patient expired approximately 5 month after implant. No complaints, allegations, or contacts regarding the system or any of the individual components have been received. Follow up on cause of death was inconclusive as the date of death was (b)(6) 2009. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The device(s) associated with this adverse outcome was/were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Analysis of the device is in process; the results will be forwarded

		when available. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The device(s) associated with this adverse outcome was/were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Evaluation summary: (b)(4) the proximal segment of the lead was returned, analyzed, and primary analysis results revealed no anomalies found. (b)(4) the device was returned, analyzed, and primary analysis revealed no anomalies found. **Event Description** **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The device(s) associated with this adverse outcome was/were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Evaluation summary: (b)(4): the proximal segment of the lead was returned, analyzed, and primary analysis results revealed no anomalies found. Analysis of the device is in process; the results will be forwarded when available.
206	**2079293**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 09/27/2010 **Event Type** Death **Patient Outcome** Death **Event Description** An implantable cardiac defibrillator (icd) system was returned to the manufacturer from an unknown source with no information. Further review of the manufacturer's database indicated the patient is deceased and died approximately three months after device system implanted. The cause of death has been requested and not received.

		Manufacturer Narrative The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4): the device was returned, analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that visual analysis only was performed. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that visual analysis only was performed.
207	**2079304**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 10/14/2006 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** Evaluation summary: (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that there was blood/body fluid on the distal conductor (not obstructed) and the outer insulation had a cosmetic depression. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that there was blood/body fluid on the distal conductor (not obstructed) and the outer insulation had a cosmetic depression. Analysis of the device is in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Manufacturer Narrative** Evaluation summary: (b)(4): the device was returned, analyzed and analysis of the device revealed normal battery depletion. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that there was blood/body fluid on the distal conductor (not obstructed) and the outer insulation had a cosmetic depression. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that there was blood/body fluid on

		the distal conductor (not obstructed) and the outer insulation had a cosmetic depression. Analysis of the device is in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** A cardiac resynchronization therapy defibrillator (crt-d) and three leads were returned from an unknown source with no information. Information identified in the manufacture's data base indicated the patient died approximately eleven months post the implant of the crt-d and one lead. **Manufacturer Narrative** Analysis of the device and leads are in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
208	**2082921**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 03/30/2011 **Event Type** Death **Patient Outcome** Death **Event Description** An implantable cardiac defibrillator (icd) system was returned to the manufacturer from an unknown source with no information. Further review of the manufacturer's database indicated the patient is deceased and died approximately six weeks after device system implanted. Follow up information obtained indicated the cause of death was cardiac arrest with a secondary cause of end stage heart failure. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned, analyzed and no anomalies were found. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a

		cosmetic depression and visual analysis only was completed. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression and visual analysis only was completed.
209	**2083039**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 09/11/2010 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary - (b)(4) no anomalies found. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis of the device is in process; the results will be forwarded when available. **Event Description** An implantable icd system was returned to the manufacturer from an unknown source with no information. Review of manufacturer's database indicated the patient is deceased and died approximately six weeks after device system implant. The cause of death has been requested and not received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary - (b)(4) no anomalies found. (b)(4) no anomalies found, outer insulation cosmetic depression. Proximal segment returned and analyzed. (b)(4) no anomalies found, outer insulation cosmetic depression. Proximal segment returned and analyzed. (b)(4) no anomalies found, outer insulation cosmetic depression. Proximal segment returned and analyzed.

		Event Description
210	**2083047**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 09/15/2009 **Event Type** Death **Patient Outcome** Death **Event Description** It was reported the patient died approximately four months after device implant. The relatedness of the death to the device is reported as unknown. The cause of death has been requested and not recevied. Follow up revealed the patient was not pacemaker dependent. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
211	**2083684**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Type** Death **Patient Outcome** Death; Other **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** It was reported by a study that the patient expired of "cardiopulmonary collapse" approximately 10 months after implant. No further details surrounding the death are available. There are no complaints or allegations against the device or any part of the system.
212	**2083714**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 11/05/2008 **Event Type** Death **Patient Outcome** Death

		Event Description An implantable icd system was returned to the manufacturer from an unknown source with no information. Review of manufacturer's database indicated the patient is deceased and died approximately 11 months after device system implant. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The device(s) associated with this adverse outcome was/were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Analysis of the device is in process; the results will be forwarded when available. **Event Description** **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The device(s) associated with this adverse outcome was/were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Analysis of the device is in process; the results will be forwarded when available. Evaluation summary - (b)(4) no anomalies found. Proximal segment returned and analyzed. (b)(4) no anomalies found. Proximal segment returned and analyzed. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The device(s) associated with this adverse outcome was/were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Evaluation summary: (b)(4): the device was returned and analyzed

		and found to have normal battery depletion. (b)(4): no anomalies found. Proximal segment returned and analyzed. (b)(4): no anomalies found. Proximal segment returned and analyzed. **Event Description**
213	**2086042**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 11/05/2008 **Event Type** Death **Patient Outcome** Death **Event Description** An implantable icd system was returned to the manufacturer from an unknown source with no information. Review of manufacturer's database indicated the patient is deceased and died approximately 11 months after device system implant. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The device(s) associated with this adverse outcome was/were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Analysis of the device is in process; the results will be forwarded when available. Evaluation summary - (b)(4) no anomalies found. Proximal segment returned and analyzed. (b)(4) no anomalies found. Proximal segment returned and analyzed.
214	**2086060**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 06/29/2006 **Event Type** Death **Patient Outcome** Death **Event Description** A lead was returned from an unknown source with no information. Information identified in the manufacture's data base indicated the patient died approximately the eight days after the lead was

		implanted and capped. **Manufacturer Narrative** The device(s) associated with this adverse outcome was/were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Evaluation summary: (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
215	**2087714**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 04/06/2011 **Event Type** Death **Patient Outcome** Death **Event Description** An implantable icd system was returned to the manufacturer from a funeral home. Review of manufacturer's database indicated the patient died approximately one year after device system implant. The cause of death has been requested and not received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis of the device is in process; the results will be forwarded when available. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary - (b)(4): no anomalies found. (b)(4): no anomalies found, several conductors distorted, lead stretched, apparent explant damage. Proximal segment returned and analyzed. Analyst comment - rv and svc conductors were not returned. (b)(4): no anomalies found, outer insulation pulled apart (overstress), lead stretched, apparent explant damage. Proximal segment returned and analyzed.
216	**2088985**	**Model Number** 6947

		Device Problem No Known Device Problem **Event Date** 12/16/2009 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis of the leads is in process; the results will be forwarded when available. Evaluation summary: (b)(4): no anomalies found. **Event Description** An implantable icd system was returned to the manufacturer from an unknown source with no information. Review of manufacturer's database indicated the patient is deceased and died approximately eleven months after device system implant. The cause of death has been requested and not received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4): no anomalies found. (b)(4): no anomalies found. Proximal segment returned and analyzed. (b)(4): no anomalies found. Proximal segment returned and analyzed. **Event Description**
217	**2088991**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 10/20/2010 **Event Type** Death **Patient Outcome** Death **Event Description** An implantable icd system was returned to the manufacturer from an unknown source with no information. Review of manufacturer's database indicated the patient is deceased and died approximately (b)(6) after device system implant. The cause of death has been requested and not

		received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary (b)(4): no anomalies found. (b)(4): no anomalies found, proximal conductor distorted, blood in/on helix/lobe mechanism (sleeve head), blood in/on helix/lobe mechanism, apparent explant damage. Full lead returned and analyzed. (b)(4): no anomalies found, defib conductor distorted, inner tubing kinked/buckled, outer insulation cosmetic cut, blood in/on helix/lobe mechanism (sleeve head), blood in/on helix/lobe mechanism, apparent explant damage. Full lead returned and analyzed. **Event Description** An implantable icd system was returned to the manufacturer from an unknown source with no information. Review of manufacturer's database indicated the patient is deceased and died approximately four months after device system implant. The cause of death has been requested and not received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis of the leads is in process; the results will be forwarded when available. Evaluation summary: (b)(4): no anomalies found.
218	**2090435**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 02/04/2011 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.

		Event Description Information identified in the manufacture's data base indicated the patient died approximately three months post the implant of the cardiac resynchronization therapy defibrillator (crt-d) system. Cause of death has been requested and not received.
219	**2092041**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 12/21/2008 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The devices associated with this adverse outcome were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Analysis of the device is in process; the results will be forwarded when available. Evaluation summary: (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that visual analysis only was performed. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that visual analysis only was performed. **Event Description** An implantable cardiac defibrillator (icd) system was returned to the manufacturer from an unknown source with no information. Further review of the manufacturer's database indicated the patient is deceased and died approximately six months after the right ventricular lead was replaced.
220	**2092071**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Type** Death **Patient Outcome** Death,Other **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis of the device is in process; the results

		will be forwarded when available. **Event Description** The implantable cardiac defibrillator was returned with no information. A database search revealed that the patient had expired approximately 7 months after implant. Follow up has been inconclusive, cause of death was requested and not yet received. No complaints or allegations have been made against the system or any of the individual components. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4): analysis of the device revealed normal battery depletion. (b)(4): the proximal segment of the lead was returned, analyzed, and primary analysis revealed no anomalies found. (b)(4): the proximal segment of the lead was returned, analyzed, and primary analysis revealed no anomalies found. (b)(4): the proximal segment of the lead was returned, analyzed, and primary analysis revealed no anomalies found. **Event Description** **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis of the device is in process; the results will be forwarded when available. Evaluation summary: (b)(4) the proximal segment of the lead was returned, analyzed, and primary analysis revealed no anomalies found. (b)(4) the proximal segment of the lead was returned, analyzed, and primary analysis revealed no anomalies found. (b)(4) the proximal segment of the lead was returned, analyzed, and primary analysis revealed no anomalies found. **Event Description**
221	**2094306**	**Model Number** 6947

		Device Problem No Known Device Problem **Event Date** 01/22/2011 **Event Type** Death **Patient Outcome** Death,Required Intervention,Hospitalization,Life Threatening **Event Description** An event was received that indicated the patient with an implantable cardiac defibrillation system had died. Manufacture's representative went to the funeral home to interrogate the device and shut it off so it could be given to the family. Reported by the family the patient was outside shoveling and collapsed. The paramedics came patient was taken to the hospital where they was pronounced dead. The interrogation showed that the patient went into ventricular tachycardia and ventricular fibrillation the device shocked the patient appropriately, however the patient's rhythm was very erratic and was unable to be rescued. The representative stated two doctors who were involved in the case and had no allegations toward the device. The patient was cremated, no autopsy was performed and the family received the device. Upon analysis of the save to disk from the interrogated right ventricular lead subsequently tested out of specifications. **Manufacturer Narrative** Evaluation summary: (b)(4): the actual lead was not received for evaluation. We did receive performance data collected from the device and have analyzed the data. The analysis revealed the lead had oversensing. Five ventricular non sustained tachycardia episodes less than 220 ms average the ventricular cycle on (b)(6) 2011 in the timeframe between 15:46:28 and 15:47:13. Please note this is the day of death as well. This report is based solely on device return and analysis. No information to suggest a device-related adverse event or product problem was received. If additional relevant information is received, a supplemental report will be submitted.
222	**2094380**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 12/21/2010 **Event Type** Death **Patient Outcome** Death,Other **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is

		received, a supplemental report will be submitted. Evaluation summary: (b)(4): the device was returned, analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that visual analysis only was performed. (v)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that visual analysis only was performed. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that visual analysis only was performed. **Event Description** An implantable icd system was returned to the manufacturer from an unknown source with no information. Review of manufacturer's database indicated the patient is deceased and died approximately two months after device system implant. The cause of death has been requested and not received.
223	**2096742**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 06/11/2008 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The device(s) associated with this adverse outcome was/were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4): the device was returned, analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that visual analysis only was performed. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that visual analysis only was performed. **Event Description**

		An implantable cardiac defibrillator (icd) system was returned to the manufacturer from an unknown source with no information. Further review of the manufacturer's database indicated the patient is deceased and died approximately five months after device replaced. **Manufacturer Narrative** The device(s) associated with this adverse outcome was/were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis of the device is in process; the results will be forwarded when available.
224	**2101278**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 02/19/2011 **Event Type** Death **Patient Outcome** Death; **Event Description** It was reported that the patient was deceased and died two days after lead replacement. The cause of death has been requested and not received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. All follow up efforts have been completed. No further information is available.
225	**2101280**	**Model Number** 6947 **Device Problem** Loose or intermittent connection **Event Date** 03/29/2010 **Event Type** Death **Patient Outcome** Death,Required Intervention,Hospitalization **Event Description** It was reported that lead integrity alert triggered. It was determined that the lead had not been

		screwed in tight enough in the connector. The setscrew was retightened and impedance was found to be in range. The device remains in use. No patient complications have been reported as a result of this event. **Manufacturer Narrative** Additional information obtained indicated the patient was deceased and died approximately one year after lead/header connection was modified. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Information was subsequently received on (b)(6) 2011 and revealed the patient was deceased. As there is new information that reasonably suggests the device has or may have caused or contributed to a death, this event no longer qualifies for bimonthly reporting and is therefore being submitted as a 30-day report.
226	**2104232**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 01/19/2010 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** Evaluation summary: (b)(4): the device was returned and analyzed and found to have normal battery depletion. (b)(4): the proximal segment of the lead was returned and analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned and analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned and analyzed and no anomalies were found. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** A cardiac resynchronization therapy defibrillator and three leads were returned from an unknown source with no information. Information identified in the manufacture database indicated the patient died two months after implant to the crt-d device and one lead. Cause of death was requested and not received.

227	**2104237**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Type** Death **Patient Outcome** Death; Hospitalization Required Intervention Other **Event Description** A save to disk data report was sent in and analyzed from a patient who had expired. The report showed an out of specification finding on the ventricular lead. No complaints or allegation have been made against the system. The cause of death was congestive heart failure and respiratory failure. **Manufacturer Narrative** This event occurred outside the u. S. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient information is not generally available due to confidentiality concerns. Evaluation summary: the lead was received for testing as well as data from the associated device. One episode of 190 ms vf on (b)(6) 2011 was shown, oversensing. The lead was returned in segments, analyzed, and primary analysis results revealed no anomalies found.
228	**2108439**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 04/15/2011 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** It was reported by the patient's spouse that the device "didn't work" and the patient died. Cause of death has been requested and not received.

229	**2108463**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 11/22/2010 **Event Type** Death **Patient Outcome** Death **Event Description** A cardiac resynchronization therapy defibrillator (crt-d) and two leads were returned from an unknown source with no information. Information identified in the manufacture's data base indicated the patient died approximately five months post the implant of the crt-d system. Cause of death was requested and not received. **Manufacturer Narrative** Evaluation summary: the device was returned and analyzed and found to have normal battery depletion. (b)(4): the proximal segment of the lead was returned and analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned and analyzed and no anomalies were found. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Manufacturer Narrative** The patient died of acute myocardial infarction that led to cardiogenic shock and death. The patient was admitted to the hospital nine days prior to death for hip fracture, ischemic cardiomyopathy, hypotension due to low ejection fraction, chronic renal insufficiency and diabetes. During the hospital course the ejection fraction was measured at 30%. The patient went to surgery for hip repair and had a decrease in blood pressure and went into cardiogenic shock. Cardiac enzymes were positive and a cardiac catherization was performed. At that time it was discover the patient had significant coronary artery dieses with 80% blockage, circumflex 95%, a right carotid artery 100% blocked. The patient had a stent placed. The patient's prognosis remained guarded and do not resuscitated order was put in place. The patient died two days later. Evaluation summary: the device was returned and analyzed and found to have normal battery depletion. (b)(4): the proximal segment of the lead was returned and analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned and analyzed and no anomalies were found. The information submitted reflects all relevant data received. If additional

		relevant information is received, a supplemental report will be submitted. **Event Description**
230	**2108476**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 02/09/2008 **Event Type** Death **Patient Outcome** Death,Other **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The device(s) associated with this adverse outcome was/were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Analysis of the leads is in process; the results will be forwarded when available. Evaluation summary: (b)(4): the device was returned, analyzed and no anomalies were found. **Event Description** **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The device(s) associated with this adverse outcome was/were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Analysis of the device is in process; the results will be forwarded when available. **Event Description** The implantable cardiac defibrillator system was returned with no information. The system had been implanted for less than 1 month. The patient expired (b)(6) ago. No complaints or

		allegations have been made. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The device(s) associated with this adverse outcome was/were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Evaluation summary: (b)(4) the device was returned, analyzed and no anomalies were found. (b)(4) the proximal segment of the lead was returned, analyzed and primary analysis results reveal no anomalies found. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that inner tubing kinked/buckled and there was apparent explant damage. **Event Description**
231	**2108479**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 07/06/2010 **Event Type** Death **Patient Outcome** Death,Other **Event Description** The implantable cardiac defibrillator system was returned with no information. A database search revealed the patient had expired approximately 5 months post implant. Follow up has been inconclusive. No complaints or allegations have been made against the device or any of the individual components. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Follow up has been attempted but inconclusive as the patient moved between the time of death and implant, the only contacts available were the implanter who had no contact number for the patient's new physician.

		Analysis of the device is in process; the results will be forwarded when available. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Follow up has been attempted but inconclusive as the patient moved between the time of death and implant, the only contacts available were the implanter who had no contact number for the patient's new physician. Evaluation summary: (b)(4): the device was returned, analyzed, and primary analysis results revealed no anomalies found. Analysis of the leads are in process; the results will be forwarded when available. **Event Description** **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Follow up has been attempted, but inconclusive as the patient moved between the time of death and implant, the only contacts available were the implanter who had no contact number for the patient's new physician. Evaluation summary: (b)(4) the device was returned, analyzed, and primary analysis results revealed no anomalies found. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that inner tubing kinked/buckled, the outer insulation had a cosmetic depression and there was apparent explant damage. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression. **Event Description**
232	**2111131**	**Model Number** 6947 **Device Problem** No Known Device Problem

		Event Date 01/23/2011 **Event Type** Death **Patient Outcome** Death **Event Description** An implantable cardiac defibrillator (icd) system was returned to the manufacturer from a crematory indicating the patient was deceased. Further review of the manufacturer's database indicated the patient died approximately three months after device system was replaced. The cause of death has been requested and not received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned, analyzed and no anomalies were found. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression and visual analysis only was performed. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that visual analysis only was performed.
233	**2111240**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 09/02/2008 **Event Type** Death **Patient Outcome** Death,Required Intervention,Hospitalization **Manufacturer Narrative** Evaluation summary: (b)(4): the device was returned and analyzed and no anomalies were found. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis of the leads are in process; the results will be forwarded when available. **Event Description** It was reported that the patient with a cardiac resynchronization therapy defibrillator (crt-d) system died approximately three days after implant. The implant itself was unremarkable. An allegation from an attorney states that "following the defibrillator implantation the patient had a

		spontaneous episode of ventricular tachycardia. " the crt-d "went off and shocked" the patient, who called emergency responders. In addition, it was alleged that the crt-d "went off" several times en route to the hospital. Cause of death was requested and never received.
234	**2112711**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 11/16/2004 **Event Type** Death **Patient Outcome** Death **Event Description** An implantable cardiac defibrillator (icd) system was returned to the manufacturer from an unknown source with no information. Further review of the manufacturer's database indicated the patient is deceased and died approximately eight months after device system implanted. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis of the device is in process; the results will be forwarded when available. The device is part of the advisory for this model. The devices associated with this adverse outcome were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. **Event Description** Asku. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The device is part of the advisory for this model. The devices associated with this adverse outcome were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Analysis of the leads is in process; the results will be forwarded when available. Evaluation summary (b)(4) battery

		depletion-normal. **Event Description** **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The device is part of the advisory for this model. The devices associated with this adverse outcome were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Evaluation summary (b)(4) battery depletion-normal. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that there was blood/body fluid on the distal conductor (not obstructed), the outer insulation had a cosmetic cut, the outer insulation had a cosmetic depression, there was apparent explant damage and visual analysis only was performed. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that there was blood/body fluid on the distal conductor (not obstructed), the outer insulation had a cosmetic depression, there was apparent explant damage and visual analysis only was performed.
235	**2114547**	**Model Number** 6947 **Event Date** 12/10/2010 **Event Type** Death **Event Description** It was reported that the patient with a cardiac resynchronization therapy defibrillator (crt-d) died seven months after the implant. Cause of death is unknown and will be requested. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description**

		Manufacturer Narrative Additional information was received. The cause of death as reported by a friend of the patient is congestive heart failure. The patient died at home. The device was not explanted according to the funeral home. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
236	**2114607**	**Model Number** 6947 **Event Type** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The initial reported event was received on (b)(6) 2011. Of note, the reportable malfunction and/or serious injury of helix unable to redeploy is normally submitted via a bimonthly medwatch report submission that would have been due on (b)(6) 2011. Information was subsequently received on (b)(6) 2011 and revealed the patient died. As there is new information that reasonably suggests the device has or may have caused or contributed to a death, this event no longer qualifies for bimonthly reporting and is therefore being submitted as a 30-day report. Evaluation summary: (b)(4) the full lead was returned, analyzed and no anomalies were found. It was noted that the defibrillation coil was distorted, there was blood/body fluid on the outer tubing overlay, the inner tubing was kinked/buckled, the outer tubing overlay was melted, the outer tubing overlay was breached cut, there was blood in/on the helix/lobe mechanism (sleeve head), there was blood in/on the helix/lobe mechanism and there was apparent explant damage. **Event Description** It was reported that the lead had sensing difficulties and was attempting to be repositioned. It was further reported that the screw would not extend after retracting. After removal of the lead, the patient's blood pressure decreased, the pulse was difficult to detect and the patient's respirations deteriorated. An endotracheal tube was placed; an ultrasound was completed showing a pericardial effusion and a pericardial drain was placed. The patient's blood pressure improved and the patient remained stable. The patient developed cardiogenic shock and anoxic encephalopathy. Care was subsequently withdrawn at the families request and the patient died.

		Manufacturer Narrative The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. This event is one of two reporting the death of this patient. See manufacture report numbers: 249622-2011-07738. The initial reported event was received on (b)(6) 2011. Of note, the reportable malfunction and/or serious injury of helix unable to redeploy is normally submitted via a bimonthly medwatch report submission that would have been due on (b)(6) 2011. Information was subsequently received on (b)(6) 2011 and revealed the patient died. As there is new information that reasonably suggests the device has or may have caused or contributed to a death, this event no longer qualifies for bimonthly reporting and is therefore being submitted as a 30-day report. Evaluation summary: (b)(4) the full lead was returned, analyzed and no anomalies were found. It was noted that the defibrillation coil was distorted, there was blood/body fluid on the outer tubing overlay, the inner tubing was kinked/buckled, the outer tubing overlay was melted, the outer tubing overlay was breached cut, there was blood in/on the helix/lobe mechanism (sleeve head), there was blood in/on the helix/lobe mechanism and there was apparent explant damage. **Event Description**
237	**2114624**	**Model Number** 6947 **Event Date** 03/08/2011 **Event Type** Death **Event Description** It was reported that the patient was deceased and died (b)(6) after lead placement. Additional information received indicated that the lead had sensing difficulties with multiple positioning attempts. The lead was successfully implanted with stable r waves when the patient's blood pressure decreased, the pulse was difficult to detect and the patient's respirations deteriorated. An endotracheal tube was placed; an ultrasound was completed showing a pericardial effusion and a pericardial drain was placed. The patient's blood pressure improved and the patient remained stable. The patient developed cardiogenic shock and anoxic encephalopathy. Care was

		subsequently withdrawn at the families request and the patient died. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. This event is one of two reporting the death of this patient. See manufacture report numbers: 2649622-2011-07729. **Event Description**
238	**2114649**	**Model Number** 6947 **Event Date** 05/10/2011 **Event Type** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Additional follow up information has been requested and not yet received. **Event Description** It was reported that the patient implanted with these devices had expired. Upon a post-mortum interrogation no ventricular fibrillation or ventricular tachycardia episodes were seen. No complaints or allegations have been made, the device was implanted for less than 1 year.
239	**2114654**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 01/06/2010 **Event Type** Death **Patient Outcome** Death,Other

		Event Description The implantable cardiac defibrillator system was returned with no information from a (b)(6). A database search revealed that the patient had died less than (b)(6) from implant. Follow up has been inconclusive on device involvement. Cause of death has been requested and not yet received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis of the device is in process; the results will be forwarded when available. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned, analyzed and no anomalies were found. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that there was a white substance on the outer insulation and the outer insulation had a cosmetic depression. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. **Event Description** **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis of the device is in process; the results will be forwarded when available. Evaluation summary: (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that there was a white substance on the outer insulation and the outer insulation had a cosmetic depression. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. **Event Description**

240	**2117350**	**Model Number** 6947 **Device Problem** No code available **Event Type** Death **Patient Outcome** Death,Required Intervention,Hospitalization **Event Description** It was reported that the device system was removed due to infection. The suspected organism was (b)(6). Further review of the manufacturer's database indicated that the patient is deceased and died (b)(6) after the system was removed. The cause of death has been requested and not received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The initial report of infection was received on (b)(6) 2011 and is normally submitted via an alternative summary reporting (asr) that would have been due on (b)(6) 2011. Information was subsequently received on (b)(6) 2011 that revealed the patient was deceased. As there is new information that reasonably suggests the device has or may have caused or contributed to a death, this event no longer qualifies for asr and is therefore being submitted as a 30-day report. Evaluation summary: (b)(4): the device was returned, analyzed and no anomalies were found. **Manufacturer Narrative** Additional information received indicated the patient was admitted with fatigue and malaise and was initially treated for a community acquired pneumonia and became severely septic. Two weeks prior to admission, the patient had completed an eight week course of intravenous vancomycin. A transesophageal echocardiogram demonstrated a small vegetation on the atrial lead. The hospital course was complicated by acute hypoxic respiratory failure. The patient self-extubated and decided to be a do not resuscitate/do not intubate. After a consult with palliative care, the patient was placed on comfort care. The patient died secondary to ischemic cardiomyopathy and no autopsy was performed. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The initial report of infection was received on (b)(6) 2011 and is normally submitted via an alternative summary reporting (asr) that would have been due on (b)(6) 2011. Information

		was subsequently received on (b)(6) 2011 that revealed the patient was deceased. As there is new information that reasonably suggests the device has or may have caused or contributed to a death, this event no longer qualifies for asr and is therefore being submitted as a 30-day report. Evaluation summary: (b)(4) the device was returned, analyzed and no anomalies were found. **Event Description**
241	**2119127**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 07/15/2010 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** It was reported that the patient was deceased and died approximately three months post device system replacement. The cause of death has been requested and not received.
242	**2119149**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 09/03/2009 **Event Type** Death **Patient Outcome** Death,Required Intervention,Hospitalization,Life Threatening **Event Description** An implantable cardiac defibrillator (icd) system was returned to the manufacturer from an unknown source with no information. Further review of the manufacturer's database indicated the patient is deceased and died approximately two days after the device system was replaced. The cause of death has been requested and not received. **Manufacturer Narrative**

		The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis of the device is in process; the results will be forwarded when available. Evaluation summary: (b)(4): the device was returned, analyzed and no anomalies were found. **Event Description** **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned, analyzed and no anomalies were found. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that visual analysis only was performed. **Manufacturer Narrative** Additional information received included an emergency room report indicating the patient had not been feeling well for several hours at home and then collapsed. Emergency services was contacted and resuscitation efforts were initiated. The patient arrived to the emergency room in ventricular fibrillation and it was reported that in the fifty minutes of down time prior to arrival, the majority of the time the patient was in asystole. Due to prolonged downtime, resuscitation efforts were halted and the patient was declared deceased. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned, analyzed and no anomalies were found. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that visual analysis only was performed. **Event Description**
243	**2122388**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 03/05/2011

		Event Type Death **Patient Outcome** Death,Other **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Additional information has been requested and not yet received. As information will be sent as it is made available. Analysis of the device is in process; the results will be forwarded when available. **Event Description** The implantable cardiac defibrillator was recieved from a hospital with information that the patient had expired. Limited information has been made available regarding the circumstances of the death. Additional information has been requested and not yet recieved. No complants or allegations have been made. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Additional information has been requested and not yet received. As information will be sent as it is made available. Evaluation summary: (b)(4) analysis of the device revealed normal battery depletion. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that there was blood/body fluid on all conductors (not obstructed) and the outer insulation had a cosmetic depression. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that inner tubing kinked/buckled, the outer insulation had a cosmetic depression and there was apparent explant damage. **Event Description** **Event Description** **Manufacturer Narrative**

		The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Additional information has been requested and not yet received. As information will be sent as it is made available. Evaluation summary: (b)(4) analysis of the device revealed normal battery depletion. Analysis of the leads is in process; the results will be forwarded when available.
244	**2123978**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 11/04/2010 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** Evaluation summary: (b)(4): the device was returned and analyzed and no anomalies were found. Analysis of the leads is in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** A cardiac resynchronization therapy defibrillator (crt-d) and three leads were returned from a competitor with no information. Information identified in the manufacture's data base indicated the patient died approximately eleven months post the implant of the crt-d and one lead. Cause of death was requested and not received. **Event Description** **Manufacturer Narrative** Evaluation summary: (b)(4): the device was returned and analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned and analyzed and no anomalies were found. It was noted that all the conductors were distorted and stretched, the inner insulation was pulled apart due to overstress, and the outer insulation had cosmetic depression. In addition there was apparent explant damage. (b)(4): the proximal segment of the lead was returned and analyzed and no anomalies were found. It was noted that the proximal conductor was distorted,

		the outer insulation had a cosmetic cut, and there was apparent explant damage. (b)(4): the proximal segment of the lead was returned and analyzed and no anomalies were found. It was noted the distal conductor was stretched, the outer insulation had cosmetic depression, and there was apparent explant damage. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
245	**2124049**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 10/31/2008 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** Analysis of the device and leads are in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Manufacturer Narrative** Evaluation summary: (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had cosmetic environmental stress cracking and the outer insulation had a cosmetic depression. Analysis of the device is in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** **Event Description** A cardiac resynchronization therapy defibrillator (crt-d) and three leads were returned from an unknown source for disposal. Information identified in the manufacture's data base indicated the

		patient died approximately six months post the implant of the crt-d and two leads. **Manufacturer Narrative** Evaluation summary: (b)(4): the device was returned and analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had cosmetic environmental stress cracking and the outer insulation had a cosmetic depression. Analysis of the device is in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description**
246	**2127531**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 11/11/2010 **Event Type** Death **Patient Outcome** Death **Event Description** A cardiac resynchronization therapy defibrillator (crt-d) and three leads were returned from a competitor with no information. Information identified in the manufacture's data base indicated the patient died approximately eight months post the implant of the crt-d system. **Manufacturer Narrative** Analysis of the device is in process; the results will be forwarded when available. Evaluation summary: (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that all conductors distorted. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that all the conductors were

		stretched, the outer insulation was breached depression and there was apparent explant damage. Information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Manufacturer Narrative** Evaluation summary: (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that all conductors distorted. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that all the conductors were stretched, the outer insulation was breached depression and there was apparent explant damage. (b)(4): the device was returned, analyzed and analysis of the device revealed normal battery depletion. Information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description**
247	**2130867**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** Without a lot number or device serial number, the manufacturing date cannot be determined. This event occurred outside the us. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient information is not generally available due to confidentiality concerns. **Event Description** It was reported that a patient with an implantable cardiac defibrillator system died less than a month after implant. The death was listed as an arrhythmic event. More specific cause of death has been requested and not received. **Manufacturer Narrative**

		Evaluation summary: (b)(4): the actual device was not received for evaluation. We did receive performance data collected from the device and have analyzed the data. The save to disk was reviewed and no anomalies were found. Without a lot number or device serial number, the manufacturing date cannot be determined. This event occurred outside the us. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient information is not generally available due to confidentiality concerns. **Event Description**
248	**2134493**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 05/01/2005 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** Analysis of the device and leads are in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** Asku. **Event Description** An implantable cardiac defibrillator (icd)and two leads were returned from a medical examiner's office for disposal. Information identified in the manufacture's data base indicated the patient died approximately six months post the implant of the icd system. Cause of death was requested and not received. **Manufacturer Narrative** Analysis of the device and leads are in process; the results will be forwarded when available.

		(b)(4): the full lead was returned and analyzed and the primary finding was that no anomalies were found. It was noted that the outer tubing was kinked/buckled, the outer tubing overlay had cosmetic environmental stress cracking, the outer insulation had a cosmetic cut, the inner tubing was kinked/buckled, there was blood/body fluid in the outer tubing overlay and all the insulators were breached cut. In addition the outer tubing overlay was breached cut, there was a white substance on the exposed defibrillation coil, the outer insulation had cosmetic depression, there was blood in/on the helix mechanism and sleeve, and apparent explant damage was observed. (b)(4): the full lead was returned and analyzed and the primary finding was that no anomalies were found. It was noted that all the conductors were distorted and the distal conductor was cut. The proximal conductor had blood/body fluid not obstructing, the outer insulation had a cosmetic cut, all the insulators had a breach cut, the outer insulation had cosmetic depression, and there was blood in /on the helix mechanism and the sleeve head. In addition there was apparent explant damage. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** **Manufacturer Narrative** Evaluation summary: (b)(4): the device was returned and analyzed and found to have normal battery depletion. The device met 80% of its expected longevity. (b)(4): the full lead was returned and analyzed and the primary finding was that no anomalies were found. It was noted that the outer tubing was kinked/buckled, the outer tubing overlay had cosmetic environmental stress cracking, the outer insulation had a cosmetic cut, the inner tubing was kinked/buckled, there was blood/body fluid in the outer tubing overlay and all the insulators were breached cut. In addition the outer tubing overlay was breached cut, there was a white substance on the exposed defibrillation coil, the outer insulation had cosmetic depression, there was blood in/on the helix mechanism and sleeve, and apparent explant damage was observed. (b)(4): the full lead was returned and analyzed and the primary finding was that no anomalies were found. It was noted that all the conductors were distorted and the distal conductor was cut. The proximal conductor had blood/body fluid not obstructing, the outer insulation had a cosmetic cut, all the insulators had a breach cut, the outer insulation had cosmetic depression, and there was blood in /on the helix mechanism and the sleeve head. In addition there was apparent explant damage.

		The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
249	**2134497**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 03/01/2011 **Event Type** Death **Patient Outcome** Death,Other **Event Description** The implantable cardiac defibrillator system was returned with very little information. A database search showed the patient had expired less than one year after implant of the system. Additional information has been requested and not yet received. No complaints or allegations have been made against the system or any of the individual components at this time. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4): the device was returned, analyzed, and analysis results revealed no anomalies found. (b)(4): the proximal segment was returned, analyzed, and primary analysis results revealed no anomalies found.
250	**2134507**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 09/05/2010 **Event Type** Death **Patient Outcome** Death,Required Intervention,Hospitalization,Life Threatening **Event Description** An implantable cardiac defibrillator (icd) was returned from an unknown source. Information identified in the manufacture's data base indicated the patient died approximately six weeks post the implant of the icd system. Cause of death was requested and not received. **Manufacturer Narrative** Additional information was received by the patient's cardiologist, which included the death

		summary. The patient died of electro mechanical disassociation due to recurrent ventricular tachycardia. The patient was not pacemaker dependent and the cardiologist indicated the device and death were not related. The patient was admitted to the hospital three months prior to death on (b)(6) 2010 with severe coronary artery disease and underwent a triple vessel bypass and placement of a porcine aortic valve and mitral valve on (b)(6) 2010. The patient had a difficult and slow recovery which was complicated by ventricular fibrillation in the hospital and was successfully resuscitated. (b)(6) 2010 patient received an icd system and discharged to home on (b)(6) 2010 on chronic dialysis. (b)(6) 2010 the patient arrived in the emergency room after receiving three shocks from the defibrillator. The device was thoroughly interrogated and functioning normally, sensing appropriately and capturing appropriately in both chambers, per the physician. The patient had six episodes of monomorphic supraventricular tachycardia that were successfully converted by the shocks the device delivered. The physician had a discussion with the patient who expressed not wanting to live like this and receive anymore shocks and wanted the device turned off. Comfort care status was requested. Prior to the device being turned off the patient had another episode of vt and received a shock, went unresponsive, never woke up, stopped breathing and expired. Evaluation summary: (b)(4): the device was returned and analyzed and no anomalies were found. The information submitted reflects all relevant data received. **Event Description** **Manufacturer Narrative** Evaluation summary: (b)(4): the device was returned and analyzed and no anomalies were found. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
251	**2136065**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 05/21/2011 **Event Type** Death **Patient Outcome** Death,Other **Event Description**

		It was reported that the patient expired approximately one month after implant. No complaints or allegations against the device have been made. Information regarding the cause of death and circumstances surrounding the death have been requested and not yet received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis of the device is in process; the results will be forwarded when available. **Event Description** **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) analysis of the device found normal battery depletion. Analysis of the leads is in process; the results will be forwarded when available. The device(s) associated with this adverse outcome was/were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) analysis of the device found normal battery depletion. (b)(4) the proximal segment of the lead was returned, analyzed, and analysis results revealed no anomalies found. It was further noted that the outer insulation had a cosmetic depression. (b)(4) the proximal segment of the lead was returned, analyzed, and analysis results revealed no anomalies found the device(s) associated with this adverse outcome was/were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made.

		Event Description
252	**2137122**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 01/12/2011 **Event Type** Death **Patient Outcome** Death,Required Intervention,Hospitalization,Life Threatening **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned, analyzed and no anomalies were found. **Event Description** **Event Description** **Manufacturer Narrative** Additional information obtained from the hospital indicated the patient was admitted after presenting to the emergency room with symptoms of fevers, chills, nausea, vomiting and diarrhea. Admitting diagnosis: severe sepsis with shock and multiorgan failure of questionable source- most probably secondary to gastroenteritis and right foot ulcer. Hypoxic respiratory failure. Acute renal failure. The patient continued to deteriorate requiring intravenous fluids, resuscitation and vasopressor support. The patient was intubated due to respiratory failure. Blood cultures grew gram-positive cocci clusters. The patient had been treated as an outpatient for a right foot ulcer and had been receiving antibiotics. As the patient continued to deteriorate, the family decided to withdraw support and the patient passed away. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned, analyzed and no anomalies were found.

		Event Description An implantable cardiac defibrillator (icd) was returned to the manufacturer from an unknown source with no information. Further review of the manufacturer's database indicated the patient is deceased and died approximately five weeks after device system replaced. Additional information received indicated the cause of death was severe septic shock. The patient presented to the hospital with symptoms of weakness, nausea and shortness of breath three days in duration and subsequently died the following day. No cause of the sepsis was noted. The patient had a post procedure check two weeks after replacement and pocket, wound and device interrogation were normal. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis of the device is in process; the results will be forwarded when available.
253	**2138587**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 03/26/2011 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** It was reported that the patient died approximately three weeks after implantable cardiac defibrillator replacement. Additional information obtained indicated the cause of death was sudden cardiac arrest with contributing causes of chronic kidney disease, congestive heart failure and hypothyroidism.
254	**2138625**	**Model Number** 6947

		Device Problem No Known Device Problem **Event Date** 10/07/2010 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** Information identified in the manufacture's data base indicated the patient died approximately two months post implant of the a cardiac resynchronization therapy defibrillator (crt-d) system. A cause death has been requested and not received.
255	**2139917**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 04/09/2011 **Event Type** Death **Patient Outcome** Death,Other,Life Threatening **Event Description** It was reported that the patient expired 4 days after implant. The reporter stated that the patient "passed away from respiratory arrest that lead to sudden cardiac arrest. " follow up has been attempted to confirm cause of death and gain any details surrounding the event. Further information has not been received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Follow up indicated that the cause of death was sudden cardiac arrest and respiratory arrest. The patient had many other health problems and this is thought to be the cause of the arrest. Leads (b)(4) and (b)(4) were returned attached to/with the device and other registered lead. Follow up with medtronic records indicate that these two leads were shipped to the same implanting hospital as the previously reported lead and device. This device requires these leads and so it is reasonable that the leads were infact implanted in this patient. The implant date is unknown. No allegations have been made against

		the device. Analysis of the device is in process; the results will be forwarded when available.
256	**2139935**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 03/14/2011 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** Analysis of the device and leads are in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** **Event Description** Information identified in the manufacture's data base indicated the patient died approximately six months post implant of an implantable cardiac defibrillator (icd) system. A cause of death has been requested and not received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Manufacturer Narrative** Evaluation summary: (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation was breached cut and there was apparent explant damage. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the distal conductor was distorted, the defibrillation conductor had fracture due to overstress, all the conductors were stretched, the outer insulation was breached cut, there was apparent explant damage and the lead was stretched. (b)(4): the device was returned, analyzed and analysis of the device revealed normal battery depletion. The

		information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** **Event Description** **Manufacturer Narrative** Evaluation summary: (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation was breached cut and there was apparent explant damage. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the distal conductor was distorted, the defibrillation conductor had fracture due to overstress, all the conductors were stretched, the outer insulation was breached cut, there was apparent explant damage and the lead was stretched. Analysis of the device is in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
257	**2157865**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 04/08/2010 **Event Type** Death **Patient Outcome** Death **Event Description** An implantable cardiac defibrillator (icd) and two leads were returned from an unknown source with no information. Information identified in the manufacture's data base indicated the patient died approximately one month post the implant of the icd system. Cause of death was requested and not received. **Manufacturer Narrative** Evaluation summary: (b)(4): the device was returned and analyzed and no anomalies were found.

		(b)(4): the proximal segment of the lead was returned and analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned and analyzed and no anomalies were found. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
258	**2160385**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 06/03/2011 **Event Type** Death **Patient Outcome** Death; Life Threatening Other **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** It was reported that the patient expired due to a cardiac arrest. The event was captured on the carelink monitor which transmitted an alert for "all therapies exhausted" 3 hours after the event due to the phone line being busy at the time the event occurred. The patient recieved 30 appropriate shocks and the device failed to shock 14 times before the therapies were exhausted.
259	**2162694**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 02/05/2009 **Event Type** Death **Patient Outcome** Death,Other **Event Description** The implantable cardiac defibrillator system was returned with no information. A database search by serial number revealed the patient had expired 2 years ago. The death occured less than one year after implant of the device. No previous contacts, complaints, or allegations have been made against the device system or any of it's individual components. **Manufacturer Narrative**

		The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The device(s) associated with this adverse outcome was/were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Evaluation summary: (b)(4): the device was returned, analyzed, and analysis results revealed no anomalies found. (b)(4): the proximal section of the lead was returned, analyzed, and analysis results revealed no anomalies found. (b)(4): the proximal section of the lead was returned, analyzed, and analysis results revealed no anomalies found. (b)(4): the proximal section of the lead was returned, analyzed, and analysis results revealed no anomalies found.
260	**2165656**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 03/26/2011 **Event Type** Death **Patient Outcome** Death,Other **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Additional follow up is still pending. **Event Description** It was found during investigation of an unrelated event that the patient had expired 25 days after implant. Information regarding the circumstances surrounding the death have been requested and not yet received. No complaints or allegations against the system or any of the individual components have been received.
261	**2171969**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 06/20/2011 **Event Type** Death **Patient Outcome** Death,Other **Event Description** It was reported that the patient developed slow ventricular tachycardia which was in and out of the detection zone. The device did not detect the arrhythmia and therapy was delayed. The

		patient expired due to cardiac arrest. Further details surrounding the death have been requested and not recieved. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
262	**2176122**	**Model Number** 6947 **Device Problem** No code available **Event Date** 05/25/2011 **Event Type** Death **Patient Outcome** Death **Event Description** **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4): the device was returned, analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that there was blood/body fluid on the outer tubing overlay, the outer insulation had a cosmetic depression and visual analysis only was performed. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that there was blood/body fluid on the proximal conductor (not obstructed), the outer insulation had a cosmetic depression and visual analysis only was performed. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression and visual analysis only was performed. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis of the device is in process; the results will be forwarded when available. Evaluation summary: (b)(4) the device was returned, analyzed and no anomalies were found.

		Event Description An implantable cardiac defibrillator (icd) system was returned to the manufacturer from an unknown source with no information. Further review of the manufacturer's database indicated the patient is deceased and died approximately three months after icd replacement. Additional information received indicated the cause of death was septic shock, acute on chronic cardiomyopathy, withdrawal of support per patient, severe hypotension, lactic acidosis and end stage renal disease.
263	**2178088**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 08/14/2008 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The device(s) associated with this adverse outcome were identified when the system that was explanted was returned with no information. The patient died three years prior to the return of that system. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** Information identified in the manufacture's data base indicated the patient died approximately four months post the implant of the cardiac resynchronization therapy defibrillator (crt-d). Cause of death is unknown.
264	**2178716**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 03/31/2010

		Event Type Death **Patient Outcome** Death **Event Description** An implantable cardiac defibrillator (icd) and two leads were returned from an unknown source with no information. Information identified in the manufacture's data base indicated the patient died approximately four months post the implant of the icd. Cause of death was requested and not received. **Manufacturer Narrative** Analysis of the leads are in process; the results will be forwarded when available. Evaluation summary: (b)(4): the device was returned and analyzed and no anomalies were found. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Manufacturer Narrative** Evaluation summary: (b)(4): returned, analyzed and no anomalies were found. It was noted that the inner tubing was kinked/buckled, the outer insulation had a cosmetic cut, there was blood in/on the helix/lobe mechanism (sleeve head), there was blood in/on the helix/lobe mechanism and there was apparent explant damage. (b)(4): analyzed and no anomalies were found. It was noted that the proximal conductor was distorted, there was blood/body fluid on the proximal conductor (not obstructed), the outer insulation was breached cut, the outer insulation had a cosmetic depression, there was blood in/on the helix/lobe mechanism (sleeve head), there was blood in/on the helix/lobe mechanism and there was apparent explant damage. (b)(4): the device was returned and analyzed and no anomalies were found. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description**
265	**2178726**	**Model Number** 6947 **Device Problem** No code available **Event Date** 03/17/2011

		Event Type Death **Patient Outcome** Death,Required Intervention,Hospitalization **Event Description** **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The is one of two events reporting the death of this patient. See manufacture report numbers: 2649622000-2011-10882, 2647346000-2011-00958, 2649622000-2011-10883. Analysis of the device is in process; the results will be forwarded when available. Evaluation summary: (b)(4) the device was returned, analyzed and no anomalies were found. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The is one of two events reporting the death of this patient. Analysis of the device is in process; the results will be forwarded when available. Evaluation summary: (b)(4): the device was returned, analyzed and no anomalies were found. **Event Description** An implantable cardiac defibrillator (icd) system was returned to the manufacturer from an unknown source with no information. Further review of the manufacturer's database indicated the patient is deceased and died approximately one month after the device system was replaced. Additional information received indicated the device system was removed due to infection. The cause of death has been requested and not received. **Event Description** **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The is one of two events reporting the death of

		this patient. See manufacture report numbers: 2649622-2011-10882, 2647346-2011-00958, 2649622-2011-10883. Evaluation summary: (b)(4) the device was returned, analyzed and no anomalies were found. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer tubing overlay was breached cut, the outer insulation had a cosmetic depression and there was apparent explant damage. (b)(4) the full lead was returned in segments, analyzed and no anomalies were found. (b)(4) the full lead was returned in segments, analyzed and no anomalies were found. It was noted that there was blood/body fluid on all conductors (not obstructed). Reporting regulation does not constitute an admission that the device (s) has malfunctioned or that there is any causal connection between the performance of the device and any injury that may have occurred.
266	**2178749**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 04/22/2011 **Event Type** Death **Patient Outcome** Death **Event Description** It was reported that the patient is deceased and died approximately one month after device system implant. The cause of death has been requested and not received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. This is one of two events reporting the death of this patient. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. This is one of two events reporting the death of this patient. See manufacture report numbers: 2647346-2011-00957, 2182208-2011-01071, 2649622-2011-10880, 2649622-2011-10881. **Event Description**

267	**2181956**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 01/01/2011 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** Evaluation summary: (b)(4): the device was retuned and analyzed and found to have normal depletion, the device meets expected longevity. Analysis of the leads are in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** **Event Description** A cardiac resynchronization therapy defibrillator (crt-d) and three leads were returned from a facility were funeral service and cremation preparation are completed. Information identified in the manufacture's data base indicated the patient died approximately eleven months post the implant of the crt-d. Cause of death has been requested and not received. **Manufacturer Narrative** Analysis of the device and leads are in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Manufacturer Narrative** Evaluation summary: (b)(4): the device was retuned and analyzed and found to have normal depletion, the device meets expected longevity. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that all conductors were distorted, the outer insulation was breached cut, the outer insulation had a cosmetic depression, there was

		apparent explant damage, the lead was stretched and visual analysis only was performed. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that all conductors were distorted, the distal conductor was cut, the outer insulation was breached cut, there was apparent explant damage and visual analysis only was performed. (b)(4) the distal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the proximal conductor was distorted, there was blood/body fluid on the proximal conductor (not obstructed), the outer insulation had a cosmetic depression, there was apparent explant damage and visual analysis only was performed. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description**
268	**2183308**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 05/26/2010 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** Evaluation summary: (b)(4): the device was returned and analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned and analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned and analyzed and no anomalies were found. It was also noted that the outer insulation had cosmetic depression. (b)(4): the proximal segment of the lead was returned and analyzed and no anomalies were found. It was also noted that the outer insulation had cosmetic depression. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** A cardiac resynchronization therapy defibrillator (crt-d) and three leads were returned from a facility were funeral service and cremation preparation are completed. Information identified in the manufacture's data base indicated the patient died approximately three months post the

		implant of the crt-d system. Cause of death has been requested and not received.
269	**2184916**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 05/01/2011 **Event Type** Death **Patient Outcome** Death **Event Description** It was reported that the patient was deceased and died approximately seven months post implantable cardiac defibrillator system implant. The cause of death has been requested and not received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: the actual device was not received for evaluation. We did receive performance data collected from the device and have analyzed the data. No anomalies were found. **Event Description**
270	**2189804**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Type** Injury **Patient Outcome** Death; Hospitalization Required Intervention **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The initial reported event was received on (b)(6) 2011. Of note, the reportable malfunction and/or serious injury of high impedance, possible lead dislodgement and pocket stimulation is normally submitted via a bimonthly

		medwatch report submission that would have been due on (b)(6) 2011. Information was subsequently received on (b)(6) 2011 and revealed the patient died. As there is new information that reasonably suggests the device has or may have caused or contributed to a death, this event no longer qualifies for bimonthly reporting and is therefore being submitted as a 30-day report. **Event Description** It was reported that the left ventricular (lv) lead impedance is greater than 3000s ohms. It was also reported that the lead dislodged back into the pocket and the patient complained of pocket stimulation. The device was reprogrammed to disable the lv lead and it was further reported there was a possible lead fracture. Additional information was received indicating the patient was deceased. The patient had been discharged from the hospital one week prior to death after being admitted with acute on chronic renal failure and acute on chronic heart failure. The patient requested to leave against medical advice and died one week later. The day of the patient's death, the patient called the clinic with complaints of not feeling well and was directed to go to the hospital. The cause of death has been requested and no further information is available.
271	**2192074**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 04/16/2011 **Event Type** Death **Patient Outcome** Death **Event Description** It was reported that the patient was deceased and died eight days after device implant. The cause of death has been requested and not received. **Manufacturer Narrative** Additional information was received indicating the leads implanted at the time of the patient death. This event occurred outside the u. S. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient information is not generally available due to confidentiality concerns. This model number is not approved for distribution in the united states, however, it is same/similar to a device marketed in

		the u. S. Analysis of the device is in process; the results will be forwarded when available.
272	**2192115**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 06/21/2011 **Event Type** Death **Patient Outcome** Death **Event Description** A cardiac resynchronization therapy defibrillator (crt-d) and three leads were returned from an unknown source with no information. Information identified in the manufacture's data base indicated the patient died approximately one month post the implant of the icd. Cause of death was requested and not received. **Manufacturer Narrative** Evaluation summary: (b)(4): the device was returned and analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned and analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned and analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned and analyzed and no anomalies were found. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
273	**2194007**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 07/08/2011 **Event Type** Death **Patient Outcome** Death; **Event Description** It was reported that a patient died. A trans telephonic transmission alert and notified the clinic that the patient had an arrhythmia storm and received multiple defibrillation therapies, and eventually did not survive. The medical examiner stated that the patient's most likely cause of death was arrhythmia storm. No further information was able to be obtained.

		Manufacturer Narrative Of note, was unable to contact/find a (b)(6) at (b)(6) or at any branch of (b)(6). The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
274	**2195938**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 05/04/2011 **Event Type** Death **Patient Outcome** Death,Required Intervention,Hospitalization,Life Threatening **Event Description** It was reported initially that the patient had the implantable cardiac defibrillator and lead removed due to infection. The patient was admitted to the hospital the day before and on the returned paperwork it states the patient had a diagnosis of a large pulmonary embolism, hyponatremia, and thrombocytopenia. Information identified in the manufacture's database indicated the patient is deceased, and died the day after the system was explanted. Follow up revealed the patient's cause of death was sepsis and recurrent ventricular arrhythmias. Further information has been requested and not yet received. **Manufacturer Narrative** Returned paper work with a report of infection and a large pulmonary embolis, hyponatremia, and thrombocytopenia came in on (b)(6) 2011. Of note, the reportable injury is normally submitted via bimonthly med watch report submission that would have been submitted on (b)(6) 2011. Information was subsequently received on (b)(6) 2011 and revealed the patient died. As there is new information that reasonably suggests the device has or may have caused or contributed to a death this event no longer qualifies for the bimonthly reporting and is therefore being submitted as a 30-day report. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4): the device was returned and analyzed and no anomalies were found. **Event Description**

		Manufacturer Narrative Additional information: the patient was hospitalized (b)(6) 2011 - (b)(6) 2011 for right lung community acquired pneumonia and leukocytosis. Discharged diagnosis included thrombocytopenia with a history of idiopathic thrombocytopenic purpura, system lupus erythematosus, and pulmonary embolus status post inferior vena cava filter. On (b)(6) 2011 patient was admitted again for shortness of breath pulmonary embolus. A ct on (b)(6) 2011 showed what looked like a massive amount of thrombus in the left main pulmonary artery and right ventricle causing little perfusion of the left lung. A right lower lobe pulmonary embolism was also seen on ct. An echo revealed thrombus mass located in the septal portion of right ventricle. Exploration revealed a large load of unusual appearing material that was fibrinous in appearance and not consistent with thrombus. The physician indicated that the right atrium was opened and the icd was "intimately" involved with a large amount of the same material and this material was removed from the right ventricle. The icd system was removed during the same procedure and pocket debridement was done. The patient was place in intensive care. Post-op xrays showed good expansion of both lungs. Cause of death and death summary were not provided. Returned paper work with a report of infection and a large pulmonary embolis, hyponatremia, and thrombocytopenia came in on (b)(6) 2011. Of note, the reportable injury is normally submitted via bimonthly med watch report submission that would have been submitted on (b)(6) 2011. Information was subsequently received on (b)(6) 2011 and revealed the patient died. Evaluation summary: (b)(4): the device was returned and analyzed and no anomalies were found. **Event Description** **Manufacturer Narrative** Additional information: the patient was hospitalized (b)(6) 2011 - (b)(6) 2011 for right lung community acquired pneumonia and leukocytosis. Discharged diagnosis included thrombocytopenia with a history of idiopathic thrombocytopenic purpura, system lupus erythematosus, and pulmonary embolus status post inferior vena cava filter. On (b)(6) 2011 patient was admitted again for shortness of breath pulmonary embolus. A ct on (b)(6) 2011

		showed what looked like a massive amount of thrombus in the left main pulmonary artery and right ventricle causing little perfusion of the left lung. A right lower lobe pulmonary embolism was also seen on ct. An echo revealed thrombus mass located in the septal portion of right ventricle. Exploration revealed a large load of unusual appearing material that was fibrinous in appearance and not consistent with thrombus. The physician indicated that the right atrium was opened and the icd was "intimately" involved with a large amount of the same material and this material was removed from the right ventricle. The icd system was removed and pocket debridement was done. The patient was place in intensive care. Post-op xrays showed good expansion of both lungs. Cause of death and death summary were not provided. Returned paper work with a report of infection and a large pulmonary emboli, hyponatremia, and thrombocytopenia came in on (b)(6) 2011. The lab work on the leads showed no anaerobes recovered and no growth over 5 days. The pulmonary artery contents that were removed grew curvularia which is a fungus;. Blood cultures were negative. Urine culture was negative. The death summary was dictated on (b)(6) 2011. The death summary included that after icd and the pulmonary artery thrombus were removed the patient deteriorated, went into dic, multiorgan failure and respiratory failure. The patient became hemodynamically unstable and died. Evaluation summary: (b)(4): the device was returned and analyzed and no anomalies were found.
275	**2195947**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 05/29/2009 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** Evaluation summary: (b)(4): the device was returned and analyzed and found to have no anomalies. (b)(4): the full lead was returned, analyzed and no anomalies were found. It was noted that the inner tubing was kinked/buckled, outer tubing overlay with cosmetic environmental stress crack, the outer insulation had a cosmetic depression, the helix was distorted/bent, there was blood in/on the helix mechanism and there was apparent explant damage. (b)(4): the full lead was returned, analyzed and no anomalies were found. It was noted that there was blood/body fluid on the distal conductor (not obstructed), the outer insulation had cosmetic environmental stress cracking and the outer insulation had a cosmetic depression. (b)(4): the full lead was returned, analyzed and no anomalies were found. It was noted that there was blood/body fluid on the proximal conductor (not obstructed), the outer insulation was

		breached cut, the outer insulation had a cosmetic depression, there was blood in/on the helix mechanism (sleeve head), there was blood in/on the helix mechanism and there was apparent explant damage. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** **Event Description** A cardiac resynchronization therapy defibrillator (crt-d) and three leads were returned from a medical examiner with no information regarding the death. Information identified in the manufacture's data base indicated the patient died approximately ten months post the implant of the crt-d system. Cause of death was requested and not received. **Manufacturer Narrative** Evaluation summary: (b)(4): the device was returned and analyzed and found to have no anomalies. Analysis of the leads are in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
276	**2198164**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 12/22/2008 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis of the device is in process; the results will be forwarded when available. The devices associated with this adverse outcome were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made.

		Event Description An implantable cardiac defibrillator (icd) system was returned to the manufacturer from an unknown source with no information. Further review of the manufacturer's database indicated the patient is deceased and died approximately three months after device replacement. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis of the device is in process; the results will be forwarded when available. The devices associated with this adverse outcome were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Evaluation summary: (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that visual analysis only was performed. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression and visual analysis only was performed. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that visual analysis only was performed. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The devices associated with this adverse outcome were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Evaluation summary: (b)(4) the device was returned, analyzed and no anomalies were found. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that visual analysis only was performed. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression and visual analysis only was performed. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that visual analysis only was performed.

		Event Description **Event Description**
277	**1960525**	**Model Number** 6947 **Device Problems** Failure to deploy; Difficult to position **Event Date** 01/04/2010 **Event Type** Death **Patient Outcome** Death,Required Intervention,Hospitalization,Life Threatening **Event Description** It was reported that during the implant attempt, the first 6947 lead was attempted but required multiple repositioning attempts to gain "satisfactory electrical values. " after the multiple repositioning attempt the helix would no longer extend. A second 6947 lead was attempted. During the implant of this lead the patient went into an episode of ventricular tachycardia. Anti-tachycardia pacing via the newly implanted lead as well as external cardioversion were attempted but were unsuccessful resulting in the patient's death. **Manufacturer Narrative** This event occurred outside the us. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient information is not generally available due to confidentiality concerns. **Event Description** **Manufacturer Narrative** This event occurred outside the us. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient information is not generally available due to confidentiality concerns. Evaluation summary (b)(4) helix disengaged from helical channel, blood in/on helix/lobe mechanism (sleeve head), blood in/on helix/lobe mechanism. Full lead returned and analyzed. **Manufacturer Narrative** **Event Description** It was reported that during the implant attempt, the first 6947 lead was attempted, but required multiple repositioning attempts to gain "satisfactory electrical values. " after the multiple repositioning attempt the helix would no longer extend. A second 6947 lead was attempted. During the implant of this lead the patient went into an episode of ventricular tachycardia. Anti-tachycardia pacing via the newly implanted lead as well as external cardioversion were attempted but

		were unsuccessful resulting in the patient's death. Additional information reported it was not believed the death was device related. The lead appeared to enter the right ventricle which caused brief run of ectopics. This immediately became sustained ventricular tachycardia.
278	**2210780**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 07/29/2009 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The device(s) associated with this adverse outcome was/were reported when identified in the manufacture database. The patient died two years ago. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** Information identified in the manufacture's data base indicated the patient died approximately nine months post the implant of an implantable cardiac defibrillator (icd) two years ago. Cause of death is unknown.
279	**2212247**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 05/23/2011 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description**

		Information identified in the manufacture's data base indicated the patient died approximately one month post implant of two leads. A cause of death has been requested and not received.
280	**2212275**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 05/01/2011 **Event Type** Death **Patient Outcome** Death **Event Description** A cardiac resynchronization therapy defibrillator (crt-d) and three leads were returned from a funeral home after the patient died. Information identified in the manufacture's data base indicated the patient died approximately four months post the implant of the crt-d system. Cause of death was requested and not received. **Manufacturer Narrative** Evaluation summary: (b)(4): the device was returned and analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned and analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned and analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned and analyzed and no anomalies were found. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
281	**2215369**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 07/13/2011 **Event Type** Death **Patient Outcome** Death,Required Intervention,Hospitalization,Life Threatening **Event Description** It was reported by the patient's family that the patient is deceased and "your device was supposed to save him, it didn't he fell". It was also reported that "he died, it must be defective or something. " additional information obtained indicated the patient had reported not feeling well, had difficulty walking at home, slumped over by a wall and became unresponsive. Emergency

		medical services were notified and the patient was found to be in asystole. Resuscitation efforts were initiated, the patient was transported to the hospital where remained in asystole and resuscitation efforts continued. However, the patient died. It is unknown if an autopsy was completed. The cause of death has been requested and not received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
282	**2215383**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 07/05/2011 **Event Type** Death **Patient Outcome** Death **Event Description** **Manufacturer Narrative** Additional information received noted the cause of death to be myocardial infarction with ventricular fibrillation. Last device check one month before death noted normal device function. Past medical history provided as ventricular tachycardia and ischemic cardiomyopathy. An autopsy was performed and the death is noted to not be related to the device system. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the actual device was not received for evaluation. We did receive performance data collected from the device and have analyzed the data. One ventricular non-sustained tachycardia =190 ms average ventricular-cycle on (b)(4)-2011. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.

		Manufacturer Narrative The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the actual device was not received for evaluation. We did receive performance data collected from the device and have analyzed the data. One ventricular non-sustained tachycardia =190 ms average ventricular-cycle on (b)(6) 2011. **Event Description** It was reported that the patient was deceased and died approximately six weeks after implant. It was also reported that several ventricular fibrillation/ventricular tachycardia events were treated. The cause of death has been requested and not received. **Event Description**
283	**2216557**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 03/25/2008 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Attempts to obtain additional information were unsuccessful. Evaluation summary: (b)(4) the device was returned, analyzed and no anomalies were found. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that visual analysis only was performed. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that visual analysis only was performed. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that visual analysis only was performed. **Event Description** An implantable cardiac defibrillator (icd) system was returned to the manufacturer from a funeral home with no information. Further review of the manufacturer's database indicated the patient

		died the day of device system implant. The cause of death was requested and not received.
284	**2219334**	**Model Number** 6947 **Device Problems** High impedance; Failure to shock or properly shock; Low impedance; Electrical shorting; Impedance issue **Event Date** 07/23/2011 **Event Type** Death **Patient Outcome** Death,Other,Life Threatening **Manufacturer Narrative** This event occurred outside the us. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient information is not generally available due to confidentiality concerns. Further information has been requested but not yet received. Evaluation summary: (b)(4) the device was returned, analyzed, and analysis results revealed no anomalies found. **Event Description** **Event Description** **Manufacturer Narrative** This event occurred outside the us. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient information is not generally available due to confidentiality concerns. Further information has been requested, but not yet received. Evaluation summary: (b)(4) the device was returned, analyzed, and analysis results revealed no anomalies found. We did receive performance data collected from the device and have analyzed the data. No anomalies were found. Save to disk pdd file bri concerto (b)(6) 2011. Pdd provided was not useable, no s2d analysis data was reviewed. S2d file (b)(4) shows during the 6 - defib episode 18, (b)(6) to 6 defib, with pathway b to ax and ax to b, impedance= 0 ohms, on (b)(6) 2011 in the timeframe between 01:54:23 and 01:54:53. Daily hv-lead impedance trend data shows svc defib=63 to 76 ohms range between on (b)(6) 2011 and (b)(6) 2011. Sensing - oversensing1 - ventricular nst=211 ms on (b)(6) 2011

		02:03:40. 1 - vf=170 ms average v-cycle on (b)(6) 2011 01:54:12. Sensing - interference/noise. **Manufacturer Narrative** This event occurred outside the u. S. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient information is not generally available due to confidentiality concerns. Further information has been requested but not yet received. **Event Description** It was reported that the patient expired due to a cardiac arrest. The patient received 6 shocks which were partial therapy and not effective followed by a 35j shock for ventricular fibrillation episode. High pacing impedances were noted as well as low high voltage impedances. Further information has been requested and not yet received.
285	**2219348**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 07/09/2003 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The devices associated with this adverse outcome were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Evaluation summary: (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that there was a cosmetic depression on the outer insulation. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that there was a cosmetic depression on the outer insulation. (b)(4) the device was returned to the manufacturer and analyzed. Normal depletion was noted and meets expected longevity. **Event Description**

		Event Description **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The devices associated with this adverse outcome were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Analysis of the device is in process; the results will be forwarded when available. Evaluation summary: (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that there was a cosmetic depression on the outer insulation. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that there was a cosmetic depression on the outer insulation. **Event Description** An implantable cardiac defibrillator (icd) and two leads were returned from an unknown source with no information. Information identified in the manufacture's data base indicated the patient died approximately six months post the implant of the icd system, and approximately eight years ago. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The devices associated with this adverse outcome were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Analysis of the device and leads are in process; the results will be forwarded when available.
286	**2220876**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 08/13/2010

		Event Type Death **Patient Outcome** Death **Event Description** It was reported that the patient is deceased and died approximately six weeks after device and lead replacement. The cause of death has been requested and not received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
287	**2222134**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 07/11/2011 **Event Type** Death **Patient Outcome** Death **Event Description** An implantable cardiac defibrillator (icd) system was returned to the manufacturer from a medical examiner. Further review of the manufacturer's database indicated the patient died approximately seven weeks after device system implanted. The cause of death has been requested and not received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned, analyzed and analysis results revealed normal battery depletion. (b)(4) the proximal segment of the lead was returned, analyzed and analysis results revealed no anomalies found. It was noted that there was blood/body fluid on the distal conductor (not obstructed). (b)(4) the proximal segment of the lead was returned, analyzed and analysis results revealed no anomalies were found. It was noted that visual analysis only was performed.
288	**2222139**	**Model Number** 6947 **Device Problem** No Known Device Problem

		Event Date 05/28/2011 **Event Type** Death **Patient Outcome** Death **Event Description** **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned, analyzed and analysis results revealed no anomalies were found. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression and visual analysis only was performed. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the proximal conductor was distorted, the outer insulation had a cosmetic depression, there was apparent explant damage and visual analysis only was performed. **Manufacturer Narrative** A correction has been made on the device (b)(4). The recall code has been removed as there is no remedial action code for these devices. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned, analyzed and analysis results revealed no anomalies were found. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression and visual analysis only was performed. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the proximal conductor was distorted, the outer insulation had a cosmetic depression, there was apparent explant damage and visual analysis only was performed. **Event Description** **Event Description** An implantable cardiac defibrillator (icd) system was returned to the manufacturer from a funeral

		home with no information. Further review of the manufacturer's database indicated the patient died approximately five months after device system implanted. The cause of death has been requested and not received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis of the device is in process; the results will be forwarded when available. Evaluation summary: (b)(4) the device was returned, analyzed and analysis results revealed no anomalies were found.
289	**2222147**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 08/05/2011 **Event Type** Death **Patient Outcome** Death,Required Intervention,Hospitalization,Other,Life Threatening **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned, analyzed, and analysis results revealed no anomalies found. Analysis of the leads is in progress. Results will be forwarded when analysis is completed. **Event Description** It was reported that the device system was removed for infection. The patient expired 2 days later. The cause of death was listed as spesis. Additional follow up information has been requested to determine the cause of the sepsis and infection if available and no further information has been made available at the time of the report. No complaints or allegations against the essential functions of the device system have been made. **Manufacturer Narrative**

		Event Description **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4): the device was returned, analyzed, and analysis results revealed no anomalies found. (b)(4): the full lead was returned, analyzed and no anomalies were found. It was noted that there was blood/body fluid on the distal conductor (not obstructed), there was blood/body fluid on the proximal conductor (not obstructed), the outer insulation was melted, the outer insulation had cosmetic environmental stress cracking, the outer insulation had a cosmetic depression and there was apparent explant damage. (b)(4): the distal portion of the lead was returned, analyzed and no anomalies were found. It was noted that there was blood/body fluid on the proximal conductor (not obstructed), inner tubing kinked/buckled, the outer insulation was breached cut, there was a white substance on the outer insulation, the outer insulation had a cosmetic depression and there was blood in/on the helix/lobe mechanism. (b)(4): the distal portion of the lead was returned, analyzed and no anomalies were found. It was noted that the defibrillation coil was distorted, there was blood/body fluid on several conductors (not obstructed), inner tubing kinked/buckled, outer tubing overlay cosmetic environmental stress cracking, the outer insulation was torn, exposed defib coil white substance, there was blood in/on the helix/lobe mechanism (sleeve head), there was blood in/on the helix/lobe mechanism and there was apparent explant damage. **Event Description**
290	**2227861**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 04/30/2011 **Event Type** Death **Patient Outcome** Death,Other **Manufacturer Narrative** Evaluation summary: (b)(4): the device was returned and analyzed and no anomalies were found. Analysis of the lead is in process; the results will be forwarded when available. The information

		submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** An implantable cardiac defibrillator (icd) system was returned from a funeral home for disposal. Information identified in the manufacture's data base indicated the patient died approximately eight months post of the icd. Cause of death has been requested and not received. **Event Description** **Manufacturer Narrative** Evaluation summary: (b)(4): the proximal segment of the lead was returned and analyzed and no anomalies were found. (b)(4): the device was returned and analyzed and no anomalies were found. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
291	**2230039**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 07/02/2010 **Event Type** Death **Patient Outcome** Death; Life Threatening Required Intervention **Manufacturer Narrative** Evaluation summary: (b)(4): the device was returned and analyzed and found to have normal battery depletion. Analysis of the leads is in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** An implantable cardiac defibrillator (icd) system was returned from an unknown source with no information. Information identified in the manufacture's data base indicated the patient died approximately three months post of the system. Additional information received indicated the

		cause of death was cardiac arrest. The patient was found at home unresponsive, emergency medical services were called. The patient was in asystole and unable to be revived. The patient was not pacemaker dependent. **Manufacturer Narrative** Evaluation summary: (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. (b)(4): the device was returned and analyzed and found to have normal battery depletion. Analysis of the leads is in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description**
292	**2230068**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 07/30/2011 **Event Type** Death **Patient Outcome** Death **Event Description** It was reported by the clinic that they did not receive an alert from the remote monitor until approximately two days after the patient had died, as reported by the patient's family member. Information identified in the manufacture's data base indicated the patient died approximately eleven months post of the implantable cardiac defibrillator (icd) system. A cause of death was requested and not received. **Manufacturer Narrative** The device (b)(4) and the monitor (b)(4). There is no remedial action code for these products. Further investigation regarding the complaint of the missed carealert was completed. Review of the icd device information for the patient revealed although the patient had a vt/vf episode, the alert for vt/vf episode was programmed off, which means even though the patient had episodes, the monitor would not transmit because the alert is not enabled. Of further note regarding the

		alert received on (b)(6) 2011, the patient had a lia alert trigger which was timely. Consequently this has prompted a change in the device analysis results. Conclusion: attempt(s) for additional information were unsuccessful. However, if requested additional information is subsequently received it would be process and considered accordingly. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** It was reported by the clinic that they did not receive an alert from the remote monitor until approximately two days after the patient had died, as reported by the patient's family member. Information identified in the manufacture's data base indicated the patient died approximately eleven months post of the implantable cardiac defibrillator (icd) system. A cause of death was requested and not received. **Manufacturer Narrative** Attempt(s) for additional information were unsuccessful. However, if requested additional information is subsequently received it would be process and considered accordingly. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
293	**2235711**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 08/06/2011 **Event Type** Death **Patient Outcome** Death; **Manufacturer Narrative** Evaluation summary: (b)(4) the actual device was not received for evaluation. We did receive performance data from (b)(4) collected from the device and have analyzed the data. One patient alert was observed for lead failure predictor on (b)(4)-2011 16:15:20. Attempt(s) for additional information were unsuccessful. However, if requested additional information is subsequently received it would be process and considered accordingly. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will

		be submitted. **Event Description** **Event Description** It was reported that a patient died two months after the implant of a cardiac resynchronization therapy defibrillator (crt-d) system. The manufacture representative was asked to interrogate the device post mortem. No details regarding the death were known by the representative. A cause of death has been requested and not received. **Manufacturer Narrative** Attempt(s) for additional information were unsuccessful. However, if requested additional information is subsequently received it would be process and considered accordingly. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
294	**2192104**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Type** Death **Patient Outcome** Death **Event Description** An implantable cardiac defibrillator (icd) and two leads were returned from a pacemaker clinic for analysis after a patient death. The cause of death was cardiac arrest. **Manufacturer Narrative** There have been requests made for the date of death and additional circumstances around the patient's death and they have not been received. Evaluation summary: (b)(4): the device was returned and analyzed and no anomalies were found. Analysis of the leads are in process; the results will be forwarded when available. This event occurred outside the u. S. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient information is not generally available due to confidentiality concerns.
295	**2247255**	

		Model Number 6947 **Device Problem** No Known Device Problem **Event Date** 08/10/2010 **Event Type** Death **Patient Outcome** Death **Event Description** Asku. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned, analyzed and analysis revealed normal battery depletion. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression and visual analysis only was performed. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression and visual analysis only was performed. **Event Description** An implantable cardiac defibrillator (icd) system was returned to the manufacturer from an unknown source with no information. Further review of the manufacturer's database indicated the patient is deceased and died approximately eight months after device system implant. The cause of death has been requested and not received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis of the device is in process; the results will be forwarded when available. Evaluation summary: (b)(4): the device was returned, analyzed and analysis revealed normal battery depletion.
296	**2247261**	**Model Number** 6947 **Device Problem** No Known Device Problem

		Event Date 03/22/2010 **Event Type** Death **Patient Outcome** Death **Event Description** **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned, analyzed and analysis revealed normal battery depletion. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the inner tubing was kinked/buckled and there was apparent explant damage. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression. **Event Description** An implantable cardiac defibrillator (icd) system was returned to the manufacturer from an unknown source with no information. Further review of the manufacturer's database indicated the patient is deceased and died approximately two months after device and lead implant. Additional information obtained indicated the cause of death was ischemic cardiomyopathy. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis of the device is in process; the results will be forwarded when available. Evaluation summary: (b)(4): the device was returned, analyzed and analysis revealed normal battery depletion.
297	**2247310**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 03/01/2011 **Event Type** Death **Patient Outcome** Death **Event Description**

		Manufacturer Narrative Evaluation summary: (b)(4): the proximal segment of the lead was returned and analyzed and no anomalies were found. It was also noted that the outer insulation had cosmetic depression. (b)(4): the proximal segment of the lead was returned and analyzed and no anomalies were found. It was also noted that the outer insulation had cosmetic depression. (b)(4): the proximal segment of the lead was returned and analyzed and no anomalies were found. (b)(4): the device was returned and analyzed and no anomalies were found. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** A cardiac resynchronization therapy defibrillator (crt-d) system was returned from an unknown source with no information. Information identified in the manufacture's data base indicated the patient died approximately eight months post the implant of the crt-d system. Cause of death has been requested and not received. **Manufacturer Narrative** Evaluation summary: (b)(4): the device was returned and analyzed and no anomalies were found. Analysis of the leads is in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
298	**2248689**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 06/27/2011 **Event Type** Death **Patient Outcome** Death,Required Intervention,Hospitalization **Manufacturer Narrative** The initial reported event was received on (b)(6) 2011 of note, the report of infection is normally submitted via an asr that would have been due on (b)(6) 2011. Information was subsequently received on (b)(6) 2011 and revealed the patient died. It is unclear how long after the infection and explant that the patient died as there are no dates listed for either. As there is new

		information that reasonably suggests the device has or may have caused or contributed to a death this event no longer qualifies for asr reporting and is therefore being submitted as a 30-day report. Attempt(s) for additional information were unsuccessful. However, if requested additional information is subsequently received it would be process and considered accordingly. Evaluation summary: (b)(4): the device was returned and analyzed and no anomalies were found. (b)(4): the full lead in segments was returned and analyzed and no anomalies were found. (b)(4): the lead was returned in segments, analyzed and the distal conductor fractured. It was noted that the defibrillation coil was distorted, there was blood/body fluid on the distal conductor (not obstructed), there was blood/body fluid on the outer tubing overlay, the outer tubing overlay was melted, the outer insulation had cosmetic cut, the inner tubing was kinked/buckled, outer tubing overlay with cosmetic environmental stress crack, outer tubing overlay was breached cut, the outer insulation had a cosmetic depression, there was blood in/on the helix mechanism and the lead was flexed, within five centimeters of the anchoring sleeve. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** An implantable cardiac defibrillator (icd) was returned from an unknown source. The device system was removed due to infection. Information identified in the manufacture's data base indicated the patient is deceased and died. It is unknown how long after the system was removed that the patient died. In addition the right ventricular lead was returned, analyzed, and subsequently tested out of specification. A cause of death has been requested and not received.
299	**2248714**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 06/26/2011 **Event Type** Death **Patient Outcome** Death **Event Description** It was reported that the patient is deceased and died approximately four months after implantable cardiac defibrillator replacement. The cause of death has been requested and not received.

		Manufacturer Narrative The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
300	**2248728**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 07/24/2011 **Event Type** Death **Patient Outcome** Death **Event Description** Information identified in the manufacture's data base indicated the patient died approximately two months post the implant of the implantable cardiac defibrillator (icd). Cause of death has been requested and not received. **Manufacturer Narrative** Attempt(s) for additional information were unsuccessful. However, if requested additional information is subsequently received it would be process and considered accordingly. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
301	**2248764**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 07/25/2010 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** Evaluation summary: (b)(4): the device was returned, analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the distal conductor fractured due to overstress, the outer insulation was breached cut, the outer insulation had a cosmetic depression and there was apparent explant damage. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It

		was noted that the outer insulation had a cosmetic depression. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression and cut, and there was apparent explant damage. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** **Manufacturer Narrative** Analysis of the device and leads is in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** A cardiac resynchronization therapy defibrillator (crt-d) was returned from an unknown source with no information. Information identified in the manufacture's data base indicated the patient died approximately five months post the implant of the crt-d. A cause of death has been requested and not received. **Event Description** **Manufacturer Narrative** Evaluation summary: (b)(4): the device was returned, analyzed and no anomalies were found. Analysis of the leads is in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
302	**2250327**	**Model Number** 6947

		Device Problem No Known Device Problem **Event Date** 01/31/2010 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis of the device is in process; the results will be forwarded when available. Evaluation summary: (b)(4) the device was returned, analyzed and no anomalies were found. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that all conductors were distorted, there was blood/body fluid on all conductors (not obstructed) there was apparent explant damage and visual analysis only was performed. **Event Description** An implantable cardiac defibrillator (icd) system was returned to the manufacturer from an unknown source with no information. Further review of the manufacturer's database indicated the patient is deceased and died approximately five months after device system implanted. The cause of death has been requested and not received. **Event Description** Asku. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned, analyzed and no anomalies were found. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that all conductors were distorted, there was blood/body fluid on all conductors (not obstructed) there was apparent explant damage and visual analysis only was performed. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression and visual analysis only was performed.

303	**2252234**	**Model Number** 6947 **Device Problems** Failure to sense; Undersensing **Event Date** 08/24/2011 **Event Type** Death **Patient Outcome** Death,Required Intervention,Hospitalization,Life Threatening **Event Description** It was reported that the patient presented to the emergency room in cardiac arrest and expired a few days later. The implantable cardiac defibrillator was undersensing the r-wave and since the patient's last follow up appointment the rate setting on the device was 40 beats per minute. The physician questions if the detections were set right on the device, as the patient had several ventricular fibrilation episodes while in the hospital before the death. **Manufacturer Narrative** This event occurred outside the us. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient information is not generally available due to confidentiality concerns. Further information has been requested. The device and lead have been returned, analysis is in progress and will be forwarded when completed. Data from the device has been sent and is being analyzed, results will be forwarded when complete.
304	**2264641**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 09/01/2009 **Event Type** Death **Patient Outcome** Death,Other **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The device(s) associated with this adverse outcome was/were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Evaluation summary: (b)(4) the device was returned, analyzed and

		analysis results revealed normal battery depletion. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression. **Event Description** **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis of the device is in process; the results will be forwarded when available. The device(s) associated with this adverse outcome was/were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Evaluation summary: (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression. **Event Description** The system was returned with no information. A database search by serial number showed the patient expired less than 1 year after implant. The death occurred 2 years ago. No complaints, allegations, or, previous contacts, regarding the system or any individual components has been received.
305	**2271054**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 05/11/2008 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis of the device is in process; the results will be forwarded when available. The device and leads associated with this adverse outcome

		were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Evaluation summary: (b)(4) the device was returned to the manufacturer and analyzed. No anomalies were found. **Event Description** **Event Description** **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The device and leads associated with this adverse outcome were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Evaluation summary: (b)(4) the device was returned to the manufacturer and analyzed. No anomalies were found. (b)(4) - the proximal segment of the lead was returned to the manufacturer and analyzed. No anomalies were found. There was an outer insulation breach cut and outer insulation cosmetic depression. (b)(4) - the proximal segment of the lead was returned to the manufacturer and analyzed. There was an outer insulation cosmetic cut and a breached cut. The outer insulation had cosmetic depression. **Event Description** A dual chamber implantable cardioverter defibrillator (icd) system was returned to the manufacturer from an unknown source with no information. Further review of the manufacturer's database indicated the patient is deceased and died approximately (b)(6) after the device system was implanted. **Manufacturer Narrative**

		The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis of the device is in process; the results will be forwarded when available. The device and leads associated with this adverse outcome were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made.
306	**2278027**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 09/16/2009 **Event Type** Death **Patient Outcome** Death **Event Description** **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The devices associated with this adverse outcome were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Analysis of the device is in process; the results will be forwarded when available. Evaluation summary: (b)(4) the device was returned to the manufacturer, analyzed and no anomalies were found. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The devices associated with this adverse outcome were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Evaluation summary: (b)(4) the device was returned to the manufacturer, analyzed and no anomalies were found. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted the outer insulation had a

		cosmetic depression. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that all conductors were distorted, the outer insulation was torn, the outer insulation had a cosmetic depression, there was apparent explant damage and visual analysis only was performed. **Event Description** **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The devices associated with this adverse outcome were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Analysis of the device is in process; the results will be forwarded when available. **Event Description** An implantable cardiac defibrillator (icd) system was returned to the manufacturer from an unknown source with no information. Further review of the manufacturer's database indicated the patient is deceased and died approximately (b)(6) after device system implant.
307	**2280888**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 07/10/2009 **Event Type** Death **Patient Outcome** Death **Event Description** An implantable cardiac defibrillator (icd) system was returned to the manufacturer from a funeral home with no information. Further review of the manufacturer's database indicated the patient died approximately three months after device system implant. The cause of death has been requested and will not be received.

		Manufacturer Narrative The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Attempts to obtain additional information were unsuccessful. Evaluation summary: (b)(4) the device was returned to the manufacturer, analyzed and no anomalies were found. (b)(4) the proximal segment of the lead was returned to the manufacturer, analyzed and no anomalies were found. It was noted that visual analysis only was performed. (b)(4) the proximal segment of the lead was returned to the manufacturer, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression and visual analysis only was performed. **Event Description** **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Attempts to obtain additional information were unsuccessful. Analysis of the leads is in process; the results will be forwarded when available. Evaluation summary: (b)(4) the device was returned to the manufacturer, analyzed and no anomalies were found.
308	**2284934**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 08/23/2011 **Event Type** Death **Patient Outcome** Death **Event Description** An implantable cardiac defibrillator (icd) system was returned from a competitor with no information. Information identified in the manufacture's database indicated the patient died approximately (b)(6) post the implant of the icd system. Follow up revealed the patient was not pacemaker dependant. (b)(6) prior to death the patient was seen in the cardiology clinic and the device had normal function. A cause of death has been requested and not received.

		Manufacturer Narrative Evaluation summary: (b)(4): the full lead was returned, analyzed and no anomalies were found. It was noted that there was blood/body fluid on the proximal conductor (not obstructed), the outer insulation was breached cut, the outer insulation had a cosmetic depression, (b)(4): the device was returned and analyzed and no anomalies were found. (b)(4): the full lead was returned, analyzed and no anomalies were found. It was noted that the defibrillation coil was distorted, the defibrillator conductor was cut, there was blood/body fluid on the distal conductor (not obstructed), the inner tubing was kinked/buckled, outer tubing overlay with cosmetic environmental stress crack, the outer insulation was torn, outer tubing overlay was breached cut, there was exposed defibrillator coil with a white substance, all insulators were breached cut, there was a white substance on the outer insulation, the outer insulation had a cosmetic depression, the helix/lobe was distorted/bent, there was blood in/on the helix/lobe mechanism (sleeve head) and there was apparent explant damage.
309	**2286851**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 02/03/2009 **Event Type** Death **Patient Outcome** Death; Other **Event Description** **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The device(s) associated with this adverse outcome was/were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Evaluation summary: (b)(4) the device was returned, analyzed, and analysis results revealed no anomalies found. (b)(4) the full lead was returned, analyzed and no anomalies were found. It was noted that all conductors distorted, all conductors are stretched, there was blood/body fluid on the proximal conductor (not obstructed), the outer insulation was breached cut, there was blood in/on the helix/lobe mechanism, there was apparent explant damage and the lead was stretched. (b)(4) the proximal segment of the lead was returned,

		analyzed and no anomalies were found. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The device(s) associated with this adverse outcome was/were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Evaluation summary: (b)(4) the device was returned, analyzed, and analysis results revealed no anomalies found. Analysis of the lead is in process; the results will be forwarded when available. **Event Description** **Event Description** The implantable cardiac defibrillator system was returned with no information. A database search by serial number showed the patient expired less than 1 year after implant. The death occurred greater than 2 years ago. No complaints, allegations, or, previous contacts, regarding the system or any individual components has been received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The device(s) associated with this adverse outcome was/were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Analysis of the device is in process; the results will be forwarded when available.
310	**2298895**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 03/07/2011

		Event Type Death **Patient Outcome** Death; **Event Description** **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis of the device is in process; the results will be forwarded when available. Evaluation summary: (b)(4) the device was returned to the manufacturer and analyzed. No anomalies were found. **Event Description** An implantable cardioverter defibrillator (icd) system was returned to the manufacturer from an unknown source with no information. Further review of the manufacturer's database indicated the patient is deceased and died approximately two months after the device system implanted. The cause of death has been requested and not received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned to the manufacturer and analyzed. No anomalies were found. (b)(4) - the proximal segment of the lead was returned to the manufacturer and analyzed. A visual analysis was performed only. No anomalies were found.
311	**2301396**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 04/10/2011 **Event Type** Death **Patient Outcome** Death; **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.

		Event Description It was reported that the patient is deceased and died approximately (b)(6) post device and lead replacement. The cause of death has been requested and not received.
312	**2303239**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 09/23/2010 **Event Type** Death **Patient Outcome** Death; Life Threatening Hospitalization Required Intervention Other **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned, analyzed, and analysis results revealed no anomalies found. Analysis of the leads is in process; the results will be forwarded when available. **Event Description** **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned, analyzed, and analysis results revealed no anomalies found. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the defibrillation coil was distorted, the defibrillation conductor was fractured (overstress), the outer tubing was kinked/buckled, and the outer insulation had a cosmetic depression. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that there was blood/body fluid on the outer tubing overlay.

		Event Description **Event Description** Asku. **Manufacturer Narrative** Asku. **Event Description** The implantable cardiac defibrillator system was returned with the information of a patient death. Further investigation has found that the patient had a cardiac arrest during strenuous exercise. Further information has not been made available and has been requested. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis of the device system is in process; the results will be forwarded when available.
313	**2303974**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 08/05/2011 **Event Type** Death **Patient Outcome** Death; **Event Description** A cardiac resynchronization therapy defibrillator (crt-d) was returned from an unknown source for disposal. Information identified in the manufacture's database indicated the patient died approximately (b)(6) post of the system. Follow up revealed the patient died of ventricular arrhythmia, cardiomyopathy, and coronary artery disease. The patient was seen in the cardiology clinic one month prior to death and the device function was normal.

		Manufacturer Narrative Evaluation summary: (b)(4): the device was returned and analyzed and no anomalies were found. Analysis of the leads is in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Manufacturer Narrative** Evaluation summary: (b)(4): the proximal segment of the lead was returned and analyzed and no anomalies were found. It was noted that the outer insulation had cosmetic depression. (b)(4): the proximal segment of the lead was returned and analyzed and no anomalies were found. It was noted that the outer insulation had cosmetic depression and the distal conductor had blood/body fluid (not obstructing). (b)(4): the device was returned and analyzed and no anomalies were found. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
314	**2307099**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 07/08/2011 **Event Type** Death **Patient Outcome** Death; **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The cause of death has been requested and not received. Analysis of the device is in process; the results will be forwarded when available. **Event Description** A cardiac resynchronization therapy w/defibrillator (crt-d) system was returned to the manufacturer from an unknown source with no information. Further review of the manufacturer's database indicated the patient is deceased and died approximately eleven months after the crt-d device was replaced. **Manufacturer Narrative**

		The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The cause of death has been requested and not received. Evaluation summary: (b)(4)-the device was returned to the manufacturer and analyzed. No anomalies were found; miscellaneous-reduced or no analysis/ok. (b)(4)-the proximal segment of the lead was returned to the manufacturer and analyzed. A visual analysis was performed only. No anomalies were found. (b)(4)-the proximal segment of the lead was returned to the manufacturer and analyzed. A visual analysis was performed only. No anomalies were found. (b)(4)-the proximal segment of the lead was returned to the manufacturer and analyzed. A visual analysis was performed only. No anomalies were found.
315	**2307110**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 09/29/2011 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** Evaluation summary: (b)(4): the device was returned and analyzed and no anomalies were found. (b)(4): the full lead in segments was returned and analyzed and no anomalies were found. It was noted that the outer insulation had cosmetic depression. (b)(4): the full lead in segments was returned and analyzed and no anomalies were found. (b)(4): the full lead in segments was returned and analyzed and no anomalies were found. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** **Event Description** **Manufacturer Narrative** Evaluation summary: (b)(4): the device was returned and analyzed and no anomalies were found.

		Analysis of the leads is in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Manufacturer Narrative** Analysis of the device and leads is in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** A cardiac resynchronization therapy defibrillator (crt-d) system was returned from an unknown source with a note that the device was explanted post (b)(6) and there were no device issues. Information identified in the manufacture's database indicated the patient died approximately (b)(6) post the implant of the crt-d system. A cause of death has been requested and not received.
316	**2320759**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 07/11/2011 **Event Type** Death **Patient Outcome** Death; Other **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. All possible reasonable contacts have been contacted and no further information has been made available. Any further information made available will be sent on a supplemental report. **Event Description** It was reported by the patient's family that at the time of the patient's death the patient's "heart was beating over 227 beats a minute and the device didn't go off. " several attempts were made to find additional information about patient's death and no further information has been made available. The device system has not been returned.
317	**2323759**	**Model Number** 6947

		Device Problem No Known Device Problem **Event Date** 12/01/2009 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** Evaluation summary: (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that there was blood/body fluid on all conductors (not obstructed), the outer insulation had cosmetic environmental stress cracking and the outer insulation had a cosmetic depression. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that there was blood/body fluid on the proximal conductor (not obstructed) and the outer insulation had a cosmetic depression. (b)(4): the device was returned and analyzed and no anomalies were found. Attempt(s) for additional information were unsuccessful. However, if requested additional information is subsequently received it would be process and considered accordingly. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** **Manufacturer Narrative** Evaluation summary: (b)(4): the device was returned and analyzed and no anomalies were found. Attempt(s) for additional information were unsuccessful. However, if requested additional information is subsequently received it would be process and considered accordingly. Analysis of the leads is in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description**

		Event Description A cardiac resynchronization therapy defibrillator (crt-d) system was returned from an unknown source with no information. Information identified in the manufacture's database indicated the patient died approximately (b)(6) post the implant of the crt-d. A cause of death has been requested and has not be received. **Manufacturer Narrative** Attempt(s) for additional information were unsuccessful. However, if requested additional information is subsequently received it would be process and considered accordingly. Analysis of the device system is in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
318	**2323771**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 10/12/2011 **Event Type** Death **Patient Outcome** Death; Other **Event Description** It was reported that the patient expired at home. The physician's office was unaware of any problems since the new implant approximately 4 months before death. Additional follow up was attempted but all leads have been exhausted. No complaints, allegations, or previous contacts regarding the device system or any of its individual components have been made. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
319	**2325506**	**Model Number** 6947 **Device Problem** No Known Device Problem

		Event Date 01/24/2010 **Event Type** Death **Patient Outcome** Death; **Manufacturer Narrative** Attempt(s) for additional information were unsuccessful. However, if requested additional information is subsequently received it would be process and considered accordingly. Evaluation summary: (b)(4) the device was returned and analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that there was blood/body fluid on the distal conductor (not obstructed). The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** **Manufacturer Narrative** Attempt(s) for additional information were unsuccessful. However, if requested additional information is subsequently received it would be process and considered accordingly. Evaluation summary: (b)(4): the device was returned and analyzed and no anomalies were found. Analysis of the lead is in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** An implantable cardiac defibrillator (icd) system was returned from an unknown funeral home. Information identified in the manufacture's data base indicated the patient died approximately (b)(6) post the implant of the icd system. A cause of death has been requested and not received.
320	**2237610**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 01/06/2009 **Event Type** Death **Patient Outcome** Death,Other **Event Description** **Manufacturer Narrative**

		The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned, analyzed, and analysis findings revealed no anomalies found. (b)(4) the proximal lead was returned, analyzed, and analysis results revealed no anomalies found. It was also noted that the inner tubing was kinked/buckled. (b)(4) the proximal segment of the lead was returned, analyzed, and analysis results revealed no anomalies found. It was also noted that the proximal conductor had blood/body fluid present. (b)(4) the proximal segment of the lead was returned, analyzed, and analysis results revealed no anomalies found. It was also noted that the proximal conductor had blood/body fluid present. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4): the device was returned, analyzed, and analysis findings revealed no anomalies found. **Event Description** The system was returned with no information. A database search by serial number showed the patient expired less than 1 year after implant. The death occurred great than 2 years ago. No complaints, allegations, or, previous contacts, regarding the system or any individual components has been received.
321	**2337431**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 10/19/2011 **Event Type** Death **Patient Outcome** Death; Life Threatening Hospitalization Required Intervention **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Attempts to obtain additional information were unsuccessful.

		Event Description A patient death was reported by the clinic nurse per a call to technical services. The event indicated that the patient received a shock from the patient's cardiac resynchronization therapy w/defibrillator (crt-d) system, then called 911 and was taken to the emergency department where the patient died. A cause of death has been requested and not received.
322	**2337447**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 11/19/2010 **Event Type** Death **Patient Outcome** Death; **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis of the device is in process; the results will be forwarded when available. **Event Description** **Event Description** An implantable cardiac defibrillator (icd) system was returned to the manufacturer from an unknown source with no information. Further review of the manufacturer's database indicated the patient is deceased and died approximately ten months after device system implant. The cause of death has been requested and not received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned, analyzed and no anomalies were found. (b)(4) the

		proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted the outer insulation had a cosmetic cut and cosmetic depression and there was apparent explant damage.
323	**2247293**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 04/08/2011 **Event Type** Death **Patient Outcome** Death,Other **Event Description** The implantable cardiac defibrillator system was returned with no information. A database search by serial number revealed the patient to be deceased. The death occurred less than one year after implant. Follow up has been inconclusive and no further contacts are known. No complaints, allegations, or previous contacts have been received in regards to the device system or any of the individual components. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4): the device was returned, analyzed, and analysis results revealed no anomalies found. Analysis of the leads is in progress and results will be forwarded once completed. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned, analyzed, and analysis results revealed no anomalies

		found. Analysis of the leads is in progress and results will be forwarded once completed. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression.
324	**2344223**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 03/10/2011 **Event Type** Death **Patient Outcome** Death; **Event Description** It was reported that the patient in a study with an implantable cardiac defibrillator (icd) system died within a year of the implant. The cause of death and date of death are unknown and have been reported as unavailable. **Manufacturer Narrative** It was reported that no further information regarding the date of death and cause of death was available. This event occurred outside the us. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient information is not generally available due to confidentiality concerns.
325	**2344464**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 03/25/2010 **Event Type** Death **Patient Outcome** Death; Other **Event Description** The implantable pulse generator system was returned with no information. A database search by serial number revealed the patient to be deceased. The death occurred less than one year after implant. Follow up has been inconclusive and no further contacts are known. No complaints, allegations, or previous contacts have been received in regards to

		the device system or any of the individual components. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned, analyzed, and analysis results revealed no anomalies found. Analysis on the leads is in process and will be forwarded when complete. **Event Description** Asku. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned, analyzed, and analysis results revealed no anomalies found. (b)(4) the proximal segment of the lead was returned, analyzed, and analysis results revealed no anomalies found. It was also noted that there was an outer insulation cosmetic depression.
326	**2346442**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 03/17/2009 **Event Type** Death **Patient Outcome** Death **Event Description** It was reported that the patient is deceased. Further review of the manufacturer's database indicated the patient died approximately (b)(6) post lead replacement.

		Manufacturer Narrative The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The devices associated with this adverse outcome were identified upon review of the manufacturer's database. No further information is available. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made.
327	**2346461**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 10/31/2011 **Event Type** Death **Patient Outcome** Death **Event Description** An implantable cardiac defibrillator (icd) system was returned from a medical examiner's office for disposal. Information identified in the manufacture's database indicated the patient died approximately (b)(6) post implant of the system. A cause of death is pending and has been requested when complete. **Manufacturer Narrative** Attempt(s) for additional information were unsuccessful. However, if requested additional information is subsequently received it would be process and considered accordingly. Analysis of the device and leads is in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description**

		Manufacturer Narrative Analysis of the leads is in process; the results will be forwarded when available. Attempt(s) for additional information were unsuccessful. However, if requested additional information is subsequently received it would be process and considered accordingly. Evaluation summary: (b)(4): the device was returned, analyzed and analysis of the device revealed normal battery depletion. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** **Manufacturer Narrative** Attempt(s) for additional information were unsuccessful. However, if requested additional information is subsequently received it would be process and considered accordingly. Evaluation summary: (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that there was blood/body fluid on the outer tubing overlay, the distal conductor cut, the inner tubing cut, the outer tubing overlay was breached cut, the outer insulation was breach cut and the outer insulation had a cosmetic depression. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression. (b)(4): the device was returned, analyzed and analysis of the device revealed normal battery depletion. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
328	**2347903**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 10/27/2011 **Event Type** Death **Patient Outcome** Death; Life Threatening Hospitalization Required Intervention

		Event Description **Manufacturer Narrative** This event occurred outside the us. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient information is not generally available due to confidentiality concerns. Without a lot number or device serial number, the manufacturing date cannot be determined. Evaluation summary: (b)(4) the actual device was not received for evaluation. We did receive performance data collected from the device and have analyzed the data. Time of recommended replacement time (rrt) in save to disk on (b)(6) 2011, device rrt<=2. 6251 volt. Save to disk data in file (b)(4) shows last battery measurement = 2. 55 v on (b)(6) 2011. Patient alert for low battery voltage on (b)(6) 2011. Lead failure predictor high rate-non sustained <= 197 milliseconds (ms) average ventricular-cycle on (b)(6) 2011. Ventricular non-sustained tachycardia=160 milliseconds on (b)(6) 2011. Ventricular fibrillation=200 ms average ventricular-cycle on (b)(6) 2011. **Manufacturer Narrative** This event occurred outside the us. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient information is not generally available due to confidentiality concerns. Without a lot number or device serial number, the manufacturing date cannot be determined. **Event Description** It was reported that the patient is deceased and died eight days post device system implant. The patient is reported to have had a ventricular tachycardia storm and the death is reported to be due to medical reasons. It was further reported there was premature battery depletion. The cause and circumstances of the patient death were requested and

		will not be received.
329	**2351936**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 10/26/2011 **Event Type** Death **Patient Outcome** Death **Event Description** It was reported that the remote transmission showed oversensing and there were two non-sustained tachycardia episodes. These events took place twelve days prior to the patient's death. A cause of death has been requested and reported as unrelated to the device; however a specific cause of death has not been received. The patient died (b)(6) post implant of the cardiac resynchronization therapy defibrillator. **Manufacturer Narrative** Attempt(s) for additional information were unsuccessful. However, if requested additional information is subsequently received it would be process and considered accordingly. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
330	**2351950**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 07/01/2008 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** This event occurred outside the us. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient information is not generally available due to confidentiality concerns. Without a lot number or device serial number, the manufacturing date cannot be determined. This

		model number is not approved for distribution in the united states, however, it is same/similar to a device marketed in the u. S. **Event Description** It was reported that the patient, who was part of a study, is deceased and died approximately three weeks post device system implant. Further information related to the cause of death was requested and is not available.
331	**2351974**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 09/24/2009 **Event Type** Death **Patient Outcome** Death; **Manufacturer Narrative** This event occurred outside the us. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient information is not generally available due to confidentiality concerns. Without a lot number or device serial number, the manufacturing date cannot be determined. **Event Description** It was reported that the patient, who was part of a (b)(6) study, is deceased and died approximately ten months after device system implant. Further information related to the cause of death was requested and is not available.
332	**2351981**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 09/20/2009 **Event Type** Death **Patient Outcome** Death; **Event Description**

		It was reported the patient, who was part of a study, is deceased and died approximately ten months post system implant. Further information related to the cause of death was requested and is not available. **Manufacturer Narrative** This event occurred outside the u. S. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient information is not generally available due to confidentiality concerns. Without a lot number or device serial number, the manufacturing date cannot be determined. This model number is not approved for distribution in the united states, however, it is same/similar to a device marketed in the u. S.
333	**2353562**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 05/17/2009 **Event Type** Death **Patient Outcome** Death; **Event Description** Asku. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The products associated with this adverse outcome were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Evaluation summary: (b)(4)-the device was returned to the manufacturer and analyzed. No anomalies were found. (b)(4)-the proximal segment of the lead was returned and analyzed. No anomalies were found. All conductors, including the defibrillation conductor had blood/body fluid

		(not obstructed). The outer tubing overlay had blood/body fluid and was melted. There was apparent explant damage. (b)(4)-the proximal segment of the lead was returned and analyzed. No anomalies were found. All conductors had blood/body fluid (not obstructed). The outer insulation was melted and had cosmetic depression. There was apparent explant damage. **Event Description** Asku. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The products associated with this adverse outcome were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Analysis of the leads is in process; the results will be forwarded when available. Evaluation summary: (b)(4) - the device was returned to the manufacturer and analyzed. No anomalies were found. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The products associated with this adverse outcome were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Analysis of the device is in process; the results will be forwarded when available. **Event Description**

		A dual chamber implantable cardioverter defibrillator (icd) system was returned to the manufacturer from an unknown source with no information. Further review of the manufacturer's database indicated the patient died approximately three months post the device system implant.
334	**2355565**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 04/12/2008 **Event Type** Death **Patient Outcome** Death,Other **Event Description** It was reported by a study that the patient had expired less than one year after implant. Follow up has been inconclusive. No specific complaints or allegations have been reported. **Manufacturer Narrative** This event occurred outside the us. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Follow up was done by the study and no additional information has been made available regarding the cause of death or circumstances surrounding the death. Patient information is not generally available due to confidentiality concerns.
335	**2358912**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 02/03/2011 **Event Type** Death **Patient Outcome** Death; **Event Description** **Manufacturer Narrative**

		A correction has been made on the device (b)(4). Evaluation summary: (b)(4): the device was returned and analyzed and no anomalies were found. Analysis of the lead is in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** An implantable cardiac defibrillator (icd) system was returned from an unknown source after removal due to cremation. Information identified in the manufacture's data base indicated the patient died approximately eight months post implant of the icd and lead. A cause of death has been requested and not be received. **Manufacturer Narrative** Analysis of the device and lead is in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Manufacturer Narrative** The recall code has been removed as there is no remedial action code for this device. Evaluation summary: (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. (b)(4): the device was returned and analyzed and no anomalies were found. Analysis of the lead is in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description**

		Asku.
336	**2360354**	**Model Number** 6947 **Device Problems** High impedance; Oversensing; Retraction problem **Event Date** 09/16/2011 **Event Type** Death **Patient Outcome** Death,Required Intervention,Hospitalization,Other,Life Threatening **Event Description** It was reported that a patient died after a difficult extraction of a right ventricular (rv) lead. The rv lead had a high impedance of greater than 3000 ohms and oversensing and the plan was for removal of both the rv and right atrial leads. The atrial lead was removed without difficulty. The rv lead would not retract and was cut and laser was started for removal. Within one minute of removal of the rv lead the patient's blood pressure dropped and almost nonexistent. The physician opened the sternum and discovered the superior vena cava was shredded. The patient was cross clamped, placed and bypass and was coded. Pressure was reestablished on a balloon pump. Despite efforts the patient died the next day. The manufacture representative stated the death is suspect to be related to the extraction of the rv lead. An official cause of death has been requested and not received. **Manufacturer Narrative** Attempt(s) for additional information regarding the circumstances surrounding the death were unsuccessful. However, if requested additional information is subsequently received it would be process and considered accordingly. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
337	**2360409**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 09/15/2011

		Event Type Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Analysis of the device is in process; the results will be forwarded when available. **Event Description** **Event Description** It was reported by the patient's family that the patient is deceased. Further review of the manufacturer's database indicated the patient died approximately nine months after implantable cardiac defibrillator replacement. It was further reported by the family that the patient had received therapy days before passing away. The cause of death has been requested and not received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4): the device was returned to the manufacturer, analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted there was a fracture of the defib conductor (overstress), the outer insulation was breached cut, had a white substance and a cosmetic depression; the

		lead was stretched and there was apparent explant damage. The lead was returned with both the right ventricular and the super vena cava defib cables fractured. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted there was blood/body fluid on the distal conductor (not obstructed), the outer insulation had cosmetic environmental stress cracking, was breached cut and had cosmetic depression; there was apparent explant damage. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted there was blood/body fluid on the distal conductor (not obstructed), the inner insulation was kinked/buckled, the inner insulation was pulled apart (overstress), the outer insulation had cosmetic depression, the lead was stretched and there was apparent explant damage. **Event Description** (b)(4).
338	**2364051**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 08/13/2009 **Event Type** Death **Patient Outcome** Death,Other **Event Description** The system was returned with no information. A database search by serial number showed the patient expired less than 1 year after implant. The death occurred 2 years ago. No complaints, allegations, or, previous contacts, regarding the system or any individual components has been received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The device(s) associated with this adverse outcome was/were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably

		known. Therefore, attempts for additional information cannot be made. Analysis of the device is in process; the results will be forwarded when available. **Event Description** (b)(4). **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The device(s) associated with this adverse outcome was/were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Evaluation summary: (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the proximal conductor was distorted, there was blood/body fluid on all conductors (not obstructed) and there was apparent explant damage. (b)(4): the device was returned, analyzed, and analysis results revealed no anomalies found. **Event Description** **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The device(s) associated with this adverse outcome was/were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Evaluation

		summary: (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the proximal conductor was distorted, there was blood/body fluid on all conductors (not obstructed) and there was apparent explant damage. Analysis of the device is in process; the results will be forwarded when available.
339	**2367840**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 02/24/2011 **Event Type** Death **Patient Outcome** Death; **Manufacturer Narrative** Analysis of the device and leads is in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** An implantable cardiac defibrillator (icd) was returned from an unknown source with no information. Information identified in the manufacture's data base indicated the patient died approximately eleven months post implant of the system. A cause of death has been requested and not be received. **Event Description** **Manufacturer Narrative** (b)(4). There is no remedial action code for the device. Analysis of the leads is in process; the results will be forwarded when available. Evaluation summary: (b)(4): the device was

		returned and analyzed and no anomalies were found. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Manufacturer Narrative** A correction has been made on the device (b)(4). The recall code has been removed as there is no remedial action code for the device. Evaluation summary: (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression. (b)(4): the device was returned and analyzed and no anomalies were found. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
340	**2370730**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 06/30/2008 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The devices were returned from an unknown source with no information and further this patient died tens years ago. Contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Evaluation summary: (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression. Analysis of the device is in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.

		Event Description **Event Description** **Manufacturer Narrative** The devices were returned from an unknown source with no information and further this patient died tens years ago. Contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Evaluation summary: (b)(4): the device was returned and analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation had a cosmetic depression. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Manufacturer Narrative** The devices were returned from an unknown source with no information and further this patient died tens years ago. Contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Analysis of the device and leads is in process; the results will be forwarded when available. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description**

		An implantable cardiac defibrillator (icd) was returned from an unknown source with no information. Information identified in the manufacture's data base indicated the patient died approximately five months post implant of the icd three years ago.
341	**2379856**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 11/24/2011 **Event Type** Death **Patient Outcome** Life Threatening,Required Intervention,Hospitalization **Manufacturer Narrative** This event occurred outside the u. S. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient information is not generally available due to confidentiality concerns. Evaluation summary: (b)(4) the actual device was not received for evaluation. We did receive performance data collected from the device and have analyzed the data. A patient alert for lead failure predictor occurred on (b)(4) 2011. Ventricular short interval count (v-sic) equals 31 counts, in 0. 50 days, on (b)(4) 2011. **Event Description** Asku. **Event Description** It was reported that the patient is deceased and died approximately five weeks after device and lead replacement. Additional information reported that the day after having shoulder surgery, the patient developed slow ventricular tachycardia (vt) and atrial flutter/atrial fibrillation. The patient collapsed, resuscitation efforts were initiated, external defibrillation was performed and asystole was noted. The vt is reported to have been below the detection rate and no therapy was given for some time. Anti-tachycardia

		pacing and therapy was received from the device once detection rates were met. The patient was resuscitated, intubated and on medications and an intra-aortic balloon pump. Frequent non-sustained vt and atrial fibrillation were noted. Device interrogation revealed atrial non-capture and loss of sensing, potentially due to fine atrial fibrillation. The patient later had a cardiac arrest, asystole was noted and resuscitation efforts were initiated. However, the patient died. **Manufacturer Narrative** This event occurred outside the us. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient information is not generally available due to confidentiality concerns.
342	**2381682**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 11/16/2010 **Event Type** Death **Patient Outcome** Death; Other **Event Description** The implantable cardiac defibrillator system was returned with no information. A database search by serial number revealed the patient to be deceased. The death occurred less than one year after implant. Follow up has been inconclusive and no further contacts are known. No complaints, allegations, or previous contacts have been received in regards to the device system or any of the individual components. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned, analyzed, and analysis results revealed no anomalies found. (b)(4) the proximal segment of the lead was returned, analyzed, and analysis results revealed no anomalies found. (b)(4) the proximal segment of the lead was

		returned, analyzed, and analysis results revealed no anomalies found.
343	**2383169**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 11/09/2011 **Event Type** Death **Patient Outcome** Death; **Event Description** (b)(4). **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Additional comorbidities noted on autopsy: the aorta had mild atherosclerosis and coronary arteries had mild calcific arteriosclerosis. Evaluation summary: (b)(4)-the device was returned to the manufacturer and analyzed. The device experienced normal battery depletion, and met the expected longevity. **Event Description** It was reported that the patient is deceased and died approximately two years and five months after implant of a single chamber implantable cardioverter defibrillator (icd) and defibrillation lead. Both products were returned to the manufacturer from a pathologist status post autopsy. The preliminary report lists the cause of death (cod) as cardiomegaly (eight hundred-twenty grams) with dilated ventricles, left greater than the right and a pericardial effusion; secondary causes listed were bilateral pleural effusions and hepatomegaly. A final cod was obtained from the funeral home, and per the certificate of death the cod was lethal arrhythmia due to dilated cardiomyopathy, secondary to congestive heart failure.

		Manufacturer Narrative The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Additional comorbidities noted on autopsy: the aorta had mild atherosclerosis and coronary arteries had mild calcific arteriosclerosis. Evaluation summary: (b)(4) - the device was returned to the manufacturer and analyzed. The device experienced normal battery depletion, and met the expected longevity. (b)(4) - the proximal segment of the lead was returned to the manufacturer and analyzed. No anomalies were found. The outer insulation had a breached cut and cosmetic depression. There was apparent explant damage. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Additional comorbidities noted on autopsy: the aorta had mild atherosclerosis and coronary arteries had mild calcific arteriosclerosis. **Event Description** It was reported that the patient is deceased and died approximately two years and five months after implant of a single chamber implantable cardioverter defibrillator (icd) and defibrillation lead. Both products were returned to the manufacturer from a pathologist status post autopsy. The preliminary report lists the cause of death (cod) as cardiomegaly (eight hundred-twenty grams) with dilated ventricles, left greater than the right and a pericardial effusion; secondary causes listed were bilateral pleural effusions and hepatomegaly. A final cod was obtained from the funeral home, and per the certificate of death, the cod was lethal arrhythmia due to dilated cardiomyopathy, secondary to congestive heart failure.
344	**2385330**	**Model Number** 6947 **Device Problem** No Known Device Problem

		Event Date 10/31/2011 **Event Type** Death **Patient Outcome** Death; **Event Description** It was reported by the patient's relative that the implantable cardiac defibrillator (icd) was to be programmed off the day before the patient died. When the relative came into the patient's room that day the nurse stated that the implantable cardiac defibrillator (icd) was shocking the patient and magnets had been to stop the unwanted therapy. The relative wanted to know if the wrong part was turned off. In addition it was noted that the patient died seven months after implant of the cardiac resynchronization therapy defibrillator (crt-d). A cause of death has been requested and not received. **Manufacturer Narrative** Attempt(s) for additional information were unsuccessful. However, if requested additional information is subsequently received it would be process and considered accordingly. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
345	**2385337**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 11/21/2011 **Event Type** Death **Patient Outcome** Death; Other **Event Description** A cardiac resynchronization therapy defibrillator (crt-d) system was returned from the funeral home with no additional information. Information identified in the manufacture's data base indicated the patient died approximately three months post implant of the system. The cause of death was obtained by the funeral home. The cause of death is cardiac dysrhythmia with cardiac rhythm disturbance as a condition leading to the cause of death. Addition information regarding the device system and circumstances surrounding the death were requested and not received.

		Manufacturer Narrative Evaluation summary: (b)(4): the device was returned and analyzed and no anomalies were found. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** Asku. **Manufacturer Narrative** Evaluation summary: evaluation summary: (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation was breach cut, the outer insulation had a cosmetic depression and there was apparent explant damage. (b)(4): the device was returned and analyzed and no anomalies were found. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
346	**2388192**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 11/16/2011 **Event Type** Death **Patient Outcome** Death; Life Threatening Hospitalization Required Intervention **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4): the device was returned, analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that there was a cosmetic depression on the outer insulation. (b)(4): the

		proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted there was blood/body fluid on the distal conductor (not obstructed) and a cosmetic depression on the outer insulation. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4): the device was returned, analyzed and no anomalies were found. **Event Description** An implantable cardiac defibrillator (icd) system was returned to the manufacturer from a funeral home for disposal with information indicating the patient is deceased. The cause of death is reported to be respiratory arrest due to hypoxic encephalopathy, ventricular tachycardia and ischemic cardiomyopathy. The circumstances of death have been requested and not received. **Event Description** (b)(4).
347	**2388199**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 08/24/2011 **Event Type** Death **Patient Outcome** Death; **Event Description** Asku.

		Manufacturer Narrative The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Attempts to obtain additional information related to the cause of death were unsuccessful. Evaluation summary: (b)(4) - the device was returned to the manufacturer and analyzed. The device experienced normal depletion, and met expected longevity. **Event Description** (b)(4). **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Attempts to obtain additional information related to the cause of death were unsuccessful. **Event Description** A cardiac resynchronization therapy w/defibrillator, a defibrillation lead and left ventricular pacing lead were returned to the manufacturer from an unknown source with no information. Further review of the manufacturer's database indicated the patient died approximately two months post the device system implant. A cause of death has been requested and will not be received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Attempts to obtain additional information related to the cause of death were unsuccessful. Evaluation

		summary: (b)(4) - the device was returned to the manufacturer and analyzed. The device experienced normal depletion, and met expected longevity. (b)(4) - the proximal segment of the lead was returned to the manufacturer and analyzed. No anomalies were found. A visual analysis was performed only. (b)(4) - the proximal segment of the lead was returned to the manufacturer and analyzed. No anomalies were found. All insulators were breached cut, there was apparent explant damage. A visual analysis was performed only.
348	**2395854**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 12/07/2011 **Event Type** Death **Patient Outcome** Death; **Manufacturer Narrative** Attempt(s) for additional information were unsuccessful. However, if requested additional information is subsequently received, it would be process and considered accordingly. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** It was reported by the manufacturer representative that a patient with a cardiac resynchronization therapy defibrillator died. The representative was called to the emergency room to check the device status post sudden cardiac arrest of the patient. The patient was unresponsive. The physician made programming changes. Once the changes were made, the representative noticed undersensing. Attempts were made to contact the physician. The representative was instructed by the physician to adjust the sensitivity in the morning. The representative left the hospital when in the early morning hours was called to turn off therapies, as the patient had died. When the representative re-interrogated, there continued to be possible undersensing of ventricular tachycardia/ventricular fibrillation.
349	**2395868**	**Model Number** 6947

		Device Problem No Known Device Problem **Event Date** 10/19/2011 **Event Type** Death **Patient Outcome** Death; **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. All reasonable known contacts have been contacted and all known information regarding the death has been reported. Further information has been requested and not yet made available. **Event Description** The implantable cardiac defibrillator system was returned with no information. A database search by serial number revealed the patient to be deceased. The death occurred less than one year after implant. Follow up has been inconclusive and no further contacts are known. No complaints, allegations, or previous contacts have been received in regards to the device system or any of the individual components. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. All reasonable known contacts have been contacted and all known information regarding the death has been reported. Further information has been requested and not yet made available. Evaluation summary: (b)(4) the device was returned, analyzed, and analysis results revealed no anomalies found. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that there was blood/body fluid on the proximal conductor (not obstructed).

		Event Description Asku. **Event Description** Asku. **Manufacturer Narrative** Asku. **Event Description** (b)(4). **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. All reasonable known contacts have been contacted and all known information regarding the death has been reported. Further information has been requested and not yet made available. Evaluation summary: (b)(4): the device was returned, analyzed, and analysis results revealed no anomalies found.
350	**2397874**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 09/21/2011 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative**

		Attempt(s) for additional information were unsuccessful. However, if requested additional information is subsequently received it would be process and considered accordingly. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** A cardiac resynchronization therapy defibrillator (crt-d) system was returned from an unknown source with no information. Information identified in the manufacture's data base indicated the patient died approximately three months post implant of the system. A cause of death was requested and will not be received. **Manufacturer Narrative** Evaluation summary: (b)(4): the device was returned and analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned and analyzed and no anomalies were found. It was noted that the outer insulation had cosmetic depression. (b)(4): the proximal segment of the lead was returned and analyzed and no anomalies were found. It was noted that the outer insulation had cosmetic depression. (b)(4): the proximal segment of the lead was returned and analyzed and no anomalies were found. It was noted all the conductors had blood/body fluid that was not obstructing. Attempt(s) for additional information were unsuccessful. However, if requested additional information is subsequently received it would be process and considered accordingly. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** (b)(4).
351	**2397944**	**Model Number** 6947

		Device Problem No Known Device Problem **Event Date** 04/07/2010 **Event Type** Death **Patient Outcome** Death; Other **Manufacturer Narrative** Evaluation summary: (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. The device(s) associated with this adverse outcome was/were returned from an unknown source. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** An implantable cardiac defibrillator (icd) system was returned from a competitor with no information. Information identified in the manufacture's data base indicated the patient died approximately three months post implant of the system. A cause of death was requested and will not be received. **Event Description** (b)(4). **Manufacturer Narrative** Evaluation summary: (b)(4): the device was returned and analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. The device(s) associated with this adverse outcome

		was/were returned from an unknown source. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
352	**2397965**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 12/06/2011 **Event Type** Death **Patient Outcome** Death; **Manufacturer Narrative** Attempt(s) for additional information were unsuccessful. However, if requested additional information is subsequently received it would be process and considered accordingly. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** It was reported by the patient's spouse that the patient with an implantable cardiac defibrillator (icd) had died. Information identified in the manufacture's data base indicated the patient died approximately eleven months post implant of the system. A cause of death was still pending.
353	**2399991**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 09/25/2003 **Event Type** Death **Patient Outcome** Death **Event Description** A dual chamber implantable cardioverter defibrillator (icd) system was returned to the manufacturer from an unknown source with no information. Further review of the

		manufacturer's database indicated the patient died approximately two months post the icd and defibrillation lead implant. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The products associated with this adverse outcome were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. A cause of death will not be received. **Event Description** Asku. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The products associated with this adverse outcome were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. A cause of death will not be received. Evaluation summary: (b)(4) - the device was returned to the manufacturer and analyzed. The device experienced normal depletion and met expected longevity. (b)(4) - the proximal segment of the lead was returned to the manufacturer and analyzed. No anomalies were found. (b)(4) - the proximal segment of the lead was returned to the manufacturer and analyzed. No anomalies were found.
354	**2402888**	**Model Number** 6947 **Device Problem** No Known Device Problem

		Event Date 01/12/2010 **Event Type** Death **Patient Outcome** Death **Event Description** A single chamber implantable cardioverter defibrillator (icd) system was returned to the manufacturer from an unknown source with no information. Further review of the manufacturer's database indicated the patient died approximately twelve days post the device system implant. **Manufacturer Narrative** This event occurred outside the us. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient information is not generally available due to confidentiality concerns. Attempts to obtain additional information were unsuccessful. A cause of death has been requested and will not be received. Evaluation summary: (b)(4)-the device was returned to the manufacturer and analyzed. No anomalies were found. **Event Description** (b)(4). **Manufacturer Narrative** This event occurred outside the us. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient information is not generally available due to confidentiality concerns. Attempts to obtain additional information were unsuccessful. A cause of death has been requested and will not be received. Evaluation summary: (b)(4): the device was returned to the manufacturer and analyzed. No anomalies were found. (b)(4): the proximal segment of the lead was returned to the manufacturer and analyzed. No anomalies were found.

		Visual analysis performed only.
355	**2403022**	**Model Number** 6947 **Device Problem** No code available **Event Date** 12/03/2011 **Event Type** Death **Patient Outcome** Death; Life Threatening Hospitalization Required Intervention **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** It was reported by a patient family member that the patient recieved blunt force trauma to the chest area. Soon after the patient began receiving shocks, multiple shocks were deleivered and the patient required surgery and a transfer to another facility where she expired. The cause of death is listed as natural causes. There had been no previous complaints or allegations on the implantable cardiac defibrilator or any of the 2 associated leads.
356	**2405355**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 01/04/2007 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The devices associated with this adverse outcome were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Evaluation summary:

		(b)(4) the device was returned, analyzed and revealed normal battery depletion. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted there was cosmetic environmental stress cracking and a cosmetic depression of the outer insulation. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted there was cosmetic depression of the outer insulation. **Event Description** Asku. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The devices associated with this adverse outcome were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. **Event Description** An implantable cardiac defibrillator (icd) system was returned to the manufacturer from an unknown source with no information. Further review of the manufacturer's database indicated the patient is deceased and died approximately four months after device replacement.
357	**2408761**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 08/11/2011 **Event Type** Death **Patient Outcome** Death; **Event Description**

		An implantable cardioverter defibrillator (icd) system was returned to the manufacturer from the hospital. Review of the manufacturer's database indicated the patient died approximately four months post the icd system implant. **Manufacturer Narrative** This event occurred outside the us. All information provided is included in this report. This event will be processed with the information at hand. If additional relevant information is received, a supplemental report will be submitted. Patient information is not generally available due to confidentiality concerns. A cause of death has been requested and not received. **Manufacturer Narrative** This event occurred outside the us. All information provided is included in this report. This event will be processed with the information at hand. If additional relevant information is received, a supplemental report will be submitted. Patient information is not generally available due to confidentiality concerns. A cause of death has been requested and not received. Additional information: this model number is not approved for distribution in the united states, however, it is same/similar to a device marketed in the u. S. Evaluation summary: (b)(4) - the device was returned to the manufacturer and analyzed. No anomalies were found. (b)(4) - the proximal segment of the lead was returned to the manufacturer and analyzed. No anomalies were found. A visual analysis was performed only. (b)(4) - the proximal segment of the lead was returned to the manufacturer and analyzed. No anomalies were found. A visual analysis was performed only. **Event Description** An implantable cardioverter defibrillator (icd) system was returned to the manufacturer from the hospital. Review of the manufacturer's database indicated the patient died

		approximately four months post the icd system implant. **Event Description** Asku. **Manufacturer Narrative** This event occurred outside the us. All information provided is included in this report. This event will be processed with the information at hand. If additional relevant information is received, a supplemental report will be submitted. Patient information is not generally available due to confidentiality concerns. A cause of death has been requested and not received. Additional information: this model number is not approved for distribution in the united states, however, it is same/similar to a device marketed in the u. S. Evaluation summary: (b)(4) - the device was returned to the manufacturer and analyzed. No anomalies were found.
358	**2408767**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 06/18/2010 **Event Type** Death **Patient Outcome** Death; Other **Event Description** A cardiac resynchronization therapy defibrillator (crt-d) system was returned from an unknown source with no information. Information identified in the manufacture's data base indicated the patient died approximately nine months post implant of the crt-d. A cause of death has been requested and not be received. **Manufacturer Narrative** Attempt(s) for additional information were unsuccessful. However, if requested

		additional information is subsequently received it would be process and considered accordingly the information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** Asku. **Manufacturer Narrative** Evaluation summary: (b)(4): the device was returned and analyzed and no anomalies were found. (b)(4): the device was returned and analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned and analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned and analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned and analyzed and no anomalies were found. Attempt(s) for additional information were unsuccessful. However, if requested additional information is subsequently received it would be process and considered accordingly the information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Manufacturer Narrative** Evaluation summary: (b)(4): the proximal segment of the lead was returned and analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned and analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned and analyzed and no anomalies were found. Attempt(s) for additional information were unsuccessful. However, if requested additional information is subsequently received it would be process and considered accordingly. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.

		Event Description Asku.
359	**2418675**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 10/06/2011 **Event Type** Death **Patient Outcome** Death **Event Description** The implantable cardiac defibrillator system was returned with no information. A database search by serial number revealed the patient to be deceased. The death occurred less than one year after implant. Follow up has been inconclusive and no further contacts are known. No complaints, allegations, or previous contacts have been received in regards to the device system or any of the individual components. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. All known reasonable contacts have been contacted and no further information has been made available but has been requested. Evaluation summary: (b)(4) the proximal segment of the lead was returned, analyzed, and analysis results revealed no anomalies found. (b)(4) the proximal segment of the lead was returned, analyzed, and analysis results revealed no anomalies found. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. All known reasonable contacts have been contacted and no further information has been made available but has

		been requested. Evaluation summary: (b)(4) the device was returned, analyzed, and analysis results revealed no anomalies found. (b)(4) the proximal segment of the lead was returned, analyzed, and analysis results revealed no anomalies found. (b)(4) the proximal segment of the lead was returned, analyzed, and analysis results revealed no anomalies found. **Event Description** Asku.
360	**2420581**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 11/01/2011 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The cause of death was requested and not received. Attempts to obtain additional information were unsuccessful. **Event Description** It was reported that the patient is deceased, and died approximately three months post the dual chamber implantable cardioverter defibrillator (icd) system implant. The patient died at home and no icd interrogation was performed. Additional information shows the patient was seen in the clinic six days prior to death. Icd interrogation showed the patient had had an episode of ventricular tachycardia (vt) which deteriorated into ventricular fibrillation (vf), and was terminated. Another episode of vt was found to have occurred four days after the previous event; it was also terminated with a shock. The patient thought to have tripped and fallen while out mowing and walking to the house, but may have "blacked out. ".

361	**2425576**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 10/08/2011 **Event Type** Death **Patient Outcome** Death **Event Description** An implantable cardiac defibrillator (icd) system was returned to the manufacturer from an unknown source with no information. Further review of the manufacturer's database indicated the patient is deceased and died approximately nine months after device was replaced. The cause of death has been requested and not received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** Asku. **Manufacturer Narrative** Additional information received indicated the cause of death was congestive heart failure and manner of death: natural. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned and analyzed which revealed normal battery depletion. **Manufacturer Narrative** Additional information received indicated the cause of death was congestive heart failure

		and manner of death: natural. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) the device was returned and analyzed which revealed normal battery depletion. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that several conductors were stretched, there was a defibrillation conductor fracture (overstress), a proximal conductor fracture (overstress), the outer insulation was torn and had cosmetic depression, the lead was stretched, there was apparent explant damage and the superior vena cava pin plug was pulled out from the connector leg. (b)(4) the full lead was returned, analyzed and no anomalies were found. It was noted that all conductors were stretched, all insulation's torn, the outer insulation was breached cut and had a white substance, the helix/lobe was distorted/bent, there was blood in/on the helix/lobe mechanism, the lead was stretched and there was apparent explant damage.
362	**2428142**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Type** Death **Patient Outcome** Death; **Event Description** It was reported that the patient is deceased. The date of death is unknown. The hospital clinic was trying to get in touch with the patient, a participant in the shock-less study, for a twelve month follow-up and found out from a family member that the patient had "died suddenly in the car. " the hospital clinic asked the family about the patient's cause of death, but the family refused to talk about the death. **Manufacturer Narrative** This event occurred outside the us. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient information is not generally available due to confidentiality concerns. This model number, (b)(4) is not approved for distribution in the united states, however, it is same/similar to a device marketed in the u. S. Additional attempts to obtain information

		were unsuccessful. The cause of death will not be received.
363	**2432306**	**Model Number** 6947 **Device Problems** Artifact; Fracture; Oversensing; Inappropriate shock **Event Type** Death **Patient Outcome** Death,Required Intervention,Hospitalization,Life Threatening **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The initial reported event was received on (b)(4) 2012. Of note, the reportable serious injury is normally submitted via a bimonthly medwatch report submission that would have been due on (b)(4) 2012. Information was subsequently received on (b)(4) 2012 and revealed patient died. As there is new information that reasonably suggests the device has or may have caused or contributed to a death, this event no longer qualifies for bimonthly reporting and is therefore being submitted as a 30-dayreport. **Event Description** It was reported that the right ventricular lead was oversensing, showed noise, and had an apparent fracture. The patient recieved multiple inappropriate shocks. During extraction of the lead by laser, a peice of the inner conductor was noted have came out. The patient died later that day due to cardiac tamponade.
364	**2433735**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 12/22/2011 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Follow up has been

		requested and not yet made available. **Event Description** During the investigation of a separate event, the death of a patient implanted with this implantable cardiac defibrillator system was discovered. The death occurred less than one year after implant. Follow up on the cause of death and circumstances surrounding the death have been inconclusive. Further information has been requested and not yet made available. No complaints, allegations, or previous contacts regarding this device system or any of the individual components have been received.
365	**2433745**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 02/27/2006 **Event Type** Death **Patient Outcome** Death; **Event Description** A cardiac resynchronization therapy w/defibrillator (crt-d) system was returned to the manufacturer from an unknown source with no information. Further review of the manufacturer's database indicated the patient died approximately three months post the device system implant. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The devices associated with this adverse outcome were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. A cause of death will not be received.

		Manufacturer Narrative The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The devices associated with this adverse outcome were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. A cause of death will not be received. Evaluation summary: (b)(4)-the proximal segment of the lead was returned to the manufacturer and analyzed. No anomalies were found. The outer insulation had a breached cut. There was apparent explant damage. A visual analysis was performed only. (b)(4) - the proximal segment of the lead was returned to the manufacturer and analyzed. No anomalies were found. The distal conductor had blood/body fluid (not obstructed). A visual analysis was performed only. (b)(4)-the partial lead was returned in segments to the manufacturer and analyzed. No anomalies were found. The distal conductor had blood/body fluid (not obstructed). The outer insulation had a breached cut. There was apparent explant damage. A visual analysis was performed only. (b)(4)-the device was returned to the manufacturer and analyzed. The device experienced normal depletion and met expected longevity. **Event Description** A cardiac resynchronization therapy w/defibrillator (crt-d) system was returned to the manufacturer from an unknown source with no information. Further review of the manufacturer's database indicated the patient died approximately three months post the device system implant. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The devices associated with this adverse outcome were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known.

		Therefore, attempts for additional information cannot be made. A cause of death will not be received. Evaluation summary: (b)(4) - the proximal segment of the lead was returned to the manufacturer and analyzed. No anomalies were found. The outer insulation had a breached cut. There was apparent explant damage. A visual analysis was performed only. (b)(4) - the proximal segment of the lead was returned to the manufacturer and analyzed. No anomalies were found. The distal conductor had blood/body fluid (not obstructed). A visual analysis was performed only. (b)(4) - the partial lead was returned in segments to the manufacturer and analyzed. No anomalies were found. The distal conductor had blood/body fluid (not obstructed). The outer insulation had a breached cut. There was apparent explant damage. A visual analysis was performed only.
366	**2435466**	**Model Number** 6947 **Device Problem** Defective item **Event Type** Death **Patient Outcome** Death **Event Description** It was reported that the patient's device reached elective replacement indicator (eri) prematurely with concern of lead integrity. Additional information received from the patient's family indicated the patient is deceased and stated the cause may be due to the battery. Information obtained from the mortuary reported the cause of death to be sudden cardiac death, ventricular fibrillation, coronary artery disease and device at end of life and battery depletion. The patient died at home and no autopsy was performed. **Manufacturer Narrative** The initial reported event was received on (b)(4) 2011. Of note, the reportable malfunction and/or serious injury of premature battery depletion is normally submitted via a bimonthly medwatch report submission that would have been due on (b)(4) 2012. Information was subsequently received on (b)(4) 2012 and revealed the patient died. As there is new information that reasonably suggests the device has or may have caused or contributed to a death, this event no longer qualifies for bimonthly reporting and is therefore being submitted as a 30-day report. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental

		report will be submitted. Evaluation summary: (b)(4) the actual device was not received for evaluation. Performance data collected from the device was analyzed, and revealed that battery voltage had battery depletion indicated/eri (elective replacement indicator) and patient alerts for low battery voltage between (b)(4) 2010 and (b)(4) 2011. Time of eri in save to disk on (b)(4) 2010, device eri less than or equal to 2. 62 volts. Weekly battery voltage trend data shows minimum battery voltage equal to 2. 64 to 2. 59 volts minimum between (b)(4) 2010 and (b)(4) 2011.
367	**2435482**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 12/21/2004 **Event Type** Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The device(s) associated with this adverse outcome was/were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Evaluation summary: (b)(4) - the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the proximal conductor was stretched and there was apparent explant damage. (b)(4) - the proximal segment of the lead was returned, analyzed and no anomalies were found. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The device(s) associated with this adverse outcome was/were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Evaluation summary: (b)(4) analysis of the device revealed normal battery depletion. (b)(4) the

		proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the proximal conductor was stretched and there was apparent explant damage. (b)(4) the proximal segment of the lead was returned, analyzed and no anomalies were found. **Event Description** The system was returned with no information. A database search by serial number showed the patient expired less than 1 year after implant. The death occurred great than 2 years ago. No complaints, allegations, or, previous contacts, regarding the system or any individual components has been received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The device(s) associated with this adverse outcome was/were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made.
368	**2435517**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 02/01/2009 **Event Type** Death **Patient Outcome** Death **Event Description** An implantable cardiac defibrillator (icd) system was returned from an unknown source with no information. Information identified in the manufacture's data base indicated the patient died approximately four months post implant of the ipg three years ago. **Manufacturer Narrative**

		Evaluation summary: (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that there was blood/body fluid on the distal conductor (not obstructed). The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Manufacturer Narrative** Evaluation summary: (b)(4): the device was returned and analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that there was blood/body fluid on the distal conductor (not obstructed). The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
369	**2437153**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 12/21/2011 **Event Type** Death **Patient Outcome** Death; **Event Description** A dual chamber implantable cardioverter defibrillator (icd) system was returned to the manufacturer from an unknown source with no information. Further review of the manufacturer's database indicated the patient died nineteen days post the device system implant. A cause of death was requested and will not be received. Additional information obtained includes the patient had four in-patient hospital stays for congestive heart failure exacerbations over the past year, and was seen in clinic two weeks prior to death where his medical condition was stable and device function normal. One day prior to death, the

		patient was placed on palliative care for symptom management and comfort care. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Occurred. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. Evaluation summary: (b)(4) - the device was returned to the manufacturer and analyzed. No anomalies were found. (b)(4) - the proximal segment of the lead was returned to the manufacturer and analyzed. No anomalies were found. The outer insulation had cosmetic depression. A visual analysis was performed only. (b)(4) - the proximal segment of the lead was returned to the manufacturer and analyzed. No anomalies were found. The outer insulation had cosmetic depression. A visual analysis was performed only.
370	**2438729**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 04/25/2004 **Event Type** Death **Patient Outcome** Death **Event Description** A single chamber implantable cardioverter defibrillator system was returned to the manufacturer from an unknown source with no information. Further review of the manufacturer's database indicated the patient died approximately four months post the device system implant. **Manufacturer Narrative**

		The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The products associated with this adverse outcome were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. A cause of death will not be received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The products associated with this adverse outcome were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. A cause of death will not be received. Evaluation summary: (b)(4) -the device was returned to the manufacturer and analyzed. The device experienced normal depletion and met expected longevity. (b)(4) - the proximal segment of the lead was returned to the manufacturer and analyzed. No anomalies were found. A visual analysis was performed only.
371	**2438731**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 05/11/2009 **Event Type** Death **Patient Outcome** Death; **Manufacturer Narrative** Evaluation summary: (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the proximal conductor was distorted, the outer insulation had a cosmetic cut, the outer insulation was breach cut, there was apparent explant damage and the lead was stretched. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. The device(s) associated with this adverse outcome was/were returned from an unknown source.

		Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Event Description** A cardiac resynchronization therapy defibrillator (crt-d) system was returned from an unknown source with no information. Information identified in the manufacture's data base indicated the patient died approximately five months post implant of the crt-d approximately three years ago. **Manufacturer Narrative** Evaluation summary: (b)(4): the device was returned and analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the proximal conductor was distorted, the outer insulation had a cosmetic cut, the outer insulation was breach cut, there was apparent explant damage and the lead was stretched. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. The device(s) associated with this adverse outcome was/were returned from an unknown source. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
372	**2438740**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 02/19/2010 **Event Type** Death **Patient Outcome** Death; **Event Description**

		A cardiac resynchronization therapy defibrillator (crt-d) system was returned from an unknown source with no information. Information identified in the manufacture's data base indicated the patient died approximately two months post implant of the crt-d system approximately two years ago. **Manufacturer Narrative** The device(s) associated with this adverse outcome was/were returned from an unknown source. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Manufacturer Narrative** Evaluation summary: (b)(4): the device was returned, analyzed and analysis of the device revealed normal battery depletion. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. The device(s) associated with this adverse outcome was/were returned from an unknown source. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. **Manufacturer Narrative** Evaluation summary: (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. (b)(4): the proximal segment of the lead was

		returned, analyzed and no anomalies were found. The device(s) associated with this adverse outcome was/were returned from an unknown source. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.
373	**2438747**	**Model Number** 6947 **Device Problems** High impedance; Oversensing; Inappropriate shock **Event Date** 01/13/2012 **Event Type** Death **Patient Outcome** Death; Life Threatening Hospitalization Required Intervention **Manufacturer Narrative** This event occurred outside the us. All information provided is included in this report. If additional relevant information is received, a supplemental report will be submitted. Patient information is not generally available due to confidentiality concerns. **Event Description** It was reported that the patient is deceased. Additional information reported that a patient alert was triggered and that during device interrogation, which noted oversensing and pacing impedance greater than 3000 ohms, the patient received five inappropriate shocks. Prior to lead extraction, the physician noted visible damage in the lead near the anchoring sleeve. During the extraction procedure via laser, the innominate artery was damaged and the patient went into cardiac arrest. The patient was placed on an extracorporeal pump while an emergency surgery repair was performed. The patient died the following day and the cause of death was idiopathic ventricular fibrillation.
374	**2438767**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 01/13/2010

		Event Type Death **Patient Outcome** Death **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The device(s) associated with this adverse outcome was/were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Evaluation summary: (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the proximal conductor was distorted, the outer insulation was breached cut and there was apparent explant damage. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation was breached cut and there was apparent explant damage. **Event Description** The system was returned with no information. A database search by serial number showed the patient expired less than 1 year after implant. The death occurred great than 2 years ago. No complaints, allegations, or, previous contacts, regarding the system or any individual components has been received. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The device(s) associated with this adverse outcome was/were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant

		information is received, a supplemental report will be submitted. The device(s) associated with this adverse outcome was/were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. Evaluation summary: (b)(4): the device was returned, analyzed, and analysis results revealed no anomalies found. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the proximal conductor was distorted, the outer insulation was breached cut and there was apparent explant damage. (b)(4): the proximal segment of the lead was returned, analyzed and no anomalies were found. It was noted that the outer insulation was breached cut and there was apparent explant damage.
375	**2440123**	**Model Number** 6947 **Device Problems** Failure to capture; Electrical issue **Event Date** 01/11/2012 **Event Type** Death **Patient Outcome** Death; Life Threatening Hospitalization Required Intervention **Event Description** It was reported that the patient is deceased, that the patient had presented to the emergency room and had received therapy from device. Resuscitation efforts were attempted and at the end of the code the cardiologist questioned why the pacemaker was not working. Additional information received from the manufacturer's representative noted that the patient had presented to the emergency room in a ventricular tachycardia storm and that all therapies were appropriate. It was further reported that rhythm strips from the emergency room noted intermittent pacing spikes without capture. However, the electrophysiologist believed the issue to be due to the patient's acidotic state. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted.

376	**2440163**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 10/28/2008 **Event Type** Death **Patient Outcome** Death; **Event Description** A dual chamber implantable cardioverter defibrillator (icd) system was returned to the manufacturer from an unknown source with no information. Further review of the manufacturer's database indicated the patient died approximately ten months post the icd generator implant. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The products associated with this adverse outcome were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. A cause of death will not be received. **Event Description** A dual chamber implantable cardioverter defibrillator (icd) system was returned to the manufacturer from an unknown source with no information. Further review of the manufacturer's database indicated the patient died approximately ten months post the icd generator implant. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The products associated

		with this adverse outcome were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. A cause of death will not be received. Evaluation summary: (b)(4) - the device was returned to the manufacturer and analyzed. No anomalies were found. (b)(4) - the proximal segment of the lead was returned to the manufacturer and analyzed. No anomalies were found. The outer insulation had a breached cut and cosmetic depression. There was apparent explant damage. A visual analysis was performed only. (b)(4) - the proximal segment of the lead was returned to the manufacturer and analyzed. No anomalies were found. A visual analysis was performed only.
377	**2440176**	**Model Number** 6947 **Device Problem** No Known Device Problem **Event Date** 10/21/2004 **Event Type** Death **Patient Outcome** Death; **Event Description** A dual chamber cardiac resynchronization therapy w/defibrillator system was returned to the manufacturer from an unknown source with no information. Further review of the manufacturer's database indicated the patient died approximately seven months post the device system implant. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The products associated with this adverse outcome was/were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. A cause of death will not be received. **Manufacturer Narrative**

		The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The products associated with this adverse outcome was/were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. A cause of death will not be received. Evaluation summary: (b)(4) - the proximal segment of the lead was returned to the manufacturer and analyzed. No anomalies were found. (b)(4) - the proximal segment of the lead was returned to the manufacturer and analyzed. No anomalies were found. (b)(4) - the proximal segment of the lead was returned to the manufacturer and analyzed. No anomalies were found. (b)(4) - the device was returned to the manufacturer and analyzed. The device experienced normal depletion and met the expected longevity. **Manufacturer Narrative** The information submitted reflects all relevant data received. If additional relevant information is received, a supplemental report will be submitted. The products associated with this adverse outcome was/were returned from an unknown source with no information. Consequently, contact information to complete follow-up is not reasonably known. Therefore, attempts for additional information cannot be made. A cause of death will not be received. Evaluation summary: (b)(4) - the proximal segment of the lead was returned to the manufacturer and analyzed. No anomalies were found. (b)(4) - the proximal segment of the lead was returned to the manufacturer and analyzed. No anomalies were found. (b)(4) - the proximal segment of the lead was returned to the manufacturer and analyzed. No anomalies were found.