

IMPORTANT MEDICAL DEVICE ADVISORY

Extended Charge Time on St. Jude Medical Ellipse™/Ellipse™ ST VR/DR
Implantable Cardioverter Defibrillators (ICDs)
Model Numbers: CD1309, CD1311, CD1409, CD1411, CD2277, CD2309, CD2311, CD2409, CD2411
(all -36, -36Q, -36C and -36QC suffixes)

August 19, 2014

Dear Doctor:

This letter provides you with information regarding a potential anomaly in the Ellipse family of Implantable Cardioverter Defibrillator (ICD) devices that St. Jude Medical has identified during review of field complaints and product returns. This anomaly may result in delayed delivery of high voltage therapy or prevent delivery of part or all of a programmed high voltage therapy shock. The anomaly most commonly presents as a vibratory patient notification and upon interrogation, a programmer or Merlin.net™ alert indicating a “Capacitor Charge Time Limit reached” message. This may occur during a capacitor maintenance or charging for high voltage therapy. There have been no serious injuries or patient deaths reported to St. Jude Medical as a result of this anomaly. No other St. Jude Medical device models are affected.

The anomaly occurs as a result of internal damage to the capacitors used in the high voltage charging circuitry of the subject devices, which may result in an extended charge time. As designed, the device will deliver the available energy on the capacitors once the charge time limit of 32 seconds is reached, even if the energy is less than the programmed value. This condition is detectable as the device will initiate a vibratory patient alert and, for patients enrolled and actively being followed, a Merlin.net notification. Additionally, upon device interrogation, an alert message will indicate “Capacitor Charge Time Limit reached” on a specific date. Approximately 97% of Ellipse extended charge time events reported to St. Jude Medical have been detected during capacitor maintenance with the remainder detected during defibrillation threshold (DFT) testing. There have been no reported cases of an Ellipse device failing to deliver high voltage therapy to a patient when needed.

Clinical Implications

The clinical implications of capacitors experiencing internal damage during a charging sequence, for either capacitor maintenance or for a diagnosed tachyarrhythmia, are:

1. During a device diagnosed tachyarrhythmia, the patient may receive full or partial high voltage therapy; however, delivery of high voltage therapy may take up to 32 seconds.
2. In the majority of cases where data were available to make an assessment, the capacitors did recover to perform normally during subsequent charges.

Root Cause

The capacitor geometry used in Ellipse ICDs is unique and therefore only Ellipse ICDs are impacted by this capacitor anomaly. Capacitors consist of individual layers of anodes (positive plates), cathodes (negative plates) and papers (insulation) which are stacked and aligned via a “front alignment hole.” The completed stack is enclosed in a capacitor case which is then filled with electrolyte and sealed. Evidence of arcing has been observed between the anode and cathode at the front alignment hole in returned Ellipse devices that exhibited this anomaly.

Additionally, as a result of implementing a standard manufacturing process operation, Ellipse ICDs with capacitors manufactured since August 2012 have demonstrated a lower likelihood of experiencing persistent damage to the capacitors after an initial extended charge time event compared to those manufactured prior to August 2012.

Rate of Occurrence

There have been no serious injuries or patient deaths reported to St. Jude Medical as a result of this anomaly. As of July 31, 2014, there have been 179 extended charge time events associated with this anomaly reported on Ellipse devices, equivalent to an incidence rate of 0.42% (179 out of approximately 43,000 worldwide sales).

There is a low probability of delayed therapy or insufficient therapy resulting from this anomaly. In accordance with our Health Hazard Evaluation process, the probability of serious injury due to delayed therapy is estimated to be 0.0032% (less than 1 in 31,000) and the probability of death due to insufficient therapy is estimated to be 0.00042% (less than 1 in 238,000).

Recommendations and Mitigations

St. Jude Medical recommends that patients with affected devices be enrolled in Merlin.net so that any extended charge time alert (“Capacitor Charge Time Limit reached” message) will be transmitted to Merlin.net for patients being actively monitored and can be viewed by your clinic staff.

If your patient has received a vibratory notification and/or if a programmer or Merlin.net alert for an extended charge time has been observed:

1. Schedule your Ellipse ICD patient for an in-office follow-up evaluation as soon as possible.
2. Interrogate the Ellipse ICD and perform a manual capacitor maintenance charge. Note the charge time to full charge; it should be approximately 15 seconds or less.
3. Contact St. Jude Medical’s Technical Services Department at 800-722-3774 to review the results of the capacitor maintenance test and discuss if additional evaluation is required.
4. A device that has experienced repeated extended charge time out warnings should be considered for replacement.

As the large majority of the extended charge time events have presented at the routine 6 month automatic capacitor maintenance interval, programming the interval to every 4 months at your patient’s next scheduled follow up visit may provide an earlier indication of this potential anomaly. It should be noted that changing the device programming to a 4 month capacitor maintenance interval will reduce device longevity by approximately 9%.

Device replacement is not recommended for an Ellipse device exhibiting normal charge times, and patients should continue to be followed at routine follow up intervals.¹

St. Jude Medical has reviewed these recommendations with its Medical Advisory Board (MAB) who support the above recommendations.

The U.S. Food and Drug Administration (FDA) and Competent Authorities outside the U.S. have been notified of this issue. A redesigned high voltage capacitor eliminating the source of capacitor damage at the front alignment hole has received regulatory approval. Ellipse ICDs with serial numbers beginning with the number “1” and starting at 1132470, as well as Ellipse ICDs with serial numbers beginning with the number “7” and starting with 7126267, incorporate the new capacitors.

All Ellipse devices with the original capacitor design will be removed from field inventory, including product that may be in your hospital inventory. These devices should not be implanted and should be returned to St. Jude Medical. Your St. Jude Medical representative will work with you and your hospital administration to retrieve all of the potentially affected Ellipse ICDs that remain on your hospital shelves. We apologize for any inconvenience that this may cause you and your patients. If you have any questions or concerns, please do not hesitate to contact your local St. Jude Medical representative or St. Jude Medical’s Technical Services Department at 800-722-3774.

Sincerely,



Mark Carlson, MD
Vice President, Global Clinical Affairs and Chief Medical Officer



Jeff Fecho
Vice President, Global Quality

Attachment: Physician Device Advisory Notice

¹ HRS/EHRA Expert Consensus on Monitoring Cardiovascular Implantable Electronic Devices (CIED), April 2008.