

PUBLICATION SUMMARY PERTAINING TO ABBOTT RIATA™ LEADS

(WITH >100 PATIENTS OR RIATA™ LEADS UNLESS NOTED)



2018–2019 PUBLICATIONS

CITATION	SAMPLE SIZE	STUDY NOTE	SUMMARY/CONCLUSION
<p>San Antonio R, Guasch E, Chipa-Ccasani F, et al. Failure-free survival of the Riata™ implantable cardioverter-defibrillator lead after a very long-term follow-up. Indian Pacing and Electrophysiology Journal. https://doi.org/10.1016/j.ipej.2019.02.005. published Feb 19, 2019. accessed Aug 19, 2019.</p>	50	Single Center	13 patients (26%) observed to have had lead malfunction: three (23%) due to cable externalization, six (46%) due to electrical failure and four (31%) due to both complications. Of malfunctioning leads, 77% failed after 7 years follow up. Incidence rate of overall malfunction per 100 patients was 0.9 during first 7 years post-implantation and more than doubled (to 16.7) after 10 years.
<p>Lam A, Buehler S, Goulouti E, et al. Comparison of lead failure manifestation of Biotronik Linx+ with St. Jude Medical Riata™ and Medtronic Sprint Fidelis+ lead. J Interv Card Electrophysiol. 2019;54(2):161-170. doi:10.1007/s10840-018-0486-0.</p>	260	Single Center	Analysis of 93 Linx+, 86 Riata™, and 81 Fidelis+ leads, 11 (12%), 22 (26%), and 25(31%) leads failed during a median follow-up of 46, 61, and 84 months, respectively. Lead survival at 5 years was 88%, 92%, and 71% for Linx+, Riata™, and Fidelis+ leads respectively.
<p>Escudero CA, Mah DY, Miyake CY, et al. Riata™ lead failure in pediatric and congenital heart disease patients. Journal of Cardiovascular Electrophysiology. 2019;30(3):320-325. doi:10.1111/jce.13812</p>	58/63	Multi-center	58 patients and 63 leads from seven centers were included. Electrical failure occurred in 43% and conductor coil externalization in 16% of leads at median lead ages of 4.7 (3.4-7.5) and 4.3 (3.9-7.0) years, respectively.
<p>Watanabe M, Yokoshiki H, Mitsuyama H, et al. Long-term reliability of the defibrillator lead inserted by the extrathoracic subclavian puncture. Journal of Arrhythmia. 2018;34(5):541-547. doi:10.1002/joa3.12107.</p>	324	Single Center	Lead survival for Medtronic Fidelis+ and St. Jude Medical Riata™ leads were 94.7% and 80.7% (90.4% and 75.9% in 6949 Fidelis+ leads) at 5 and 10 years post implantation.

2016 – 2017 PUBLICATIONS

CITATION	SAMPLE SIZE	STUDY NOTE	SUMMARY/CONCLUSION
<p>Stöker, De Asmundis, Vanduynhoven, et al.</p> <p>Long-Term Performance of the Riata™/ST Implantable Cardioverter-Defibrillator Lead.</p> <p><i>American Journal of Cardiology.</i> 2016;117(5):807-812. doi:10.1016/j.amjcard.2015.12.013</p>	154	Single Center Belgium	A retrospective review of Riata™ lead 8F (n = 72), Riata™ ST lead 7F (n = 52), and Riata™ ST Optim™ lead (n = 30) lead performance using three management approaches: monitoring, capping, or extracting. Electrical failure (EF) was identified in 14 Riata™/ST leads (13%) and none (0) of the ST Optim™ leads.
<p>Parkash R, Thibault B, Mangat I, et al.</p> <p>Canadian Registry of Implantable Electronic Device Outcomes Surveillance of the Riata™ lead Under Advisory.</p> <p><i>Heart Rhythm.</i> 2017;2017(11):033.</p>	1352	Nationwide (Canada)	The 12-year rate of electrical failure for the 8F lead was 9.45% while the 10-year failure rate for the 7F lead was 7.25%. No significant differences were observed between the 2 lead models with respect to electrical failure. 76% of the leads revised were abandoned and 24% were extracted with power tools. The rate of major complications in each group was 5.6% and 5.9% respectively. After a dwell time of 10 years the risk of failure exceeds the risk of peri-procedural major complications, indicating that risk-benefit is favorable to revise the lead in appropriate clinical scenarios.
<p>Gwag HB, Hwang JK, Park KM, et al.</p> <p>The Incidence of Riata™ Defibrillator Lead Failure: a Single-Center Experience.</p> <p><i>J Korean Med Sci.</i> 2017;32(10):1610-1615. doi: 10.3346/jkms.2017.32.10.1610.</p>	44	Single Site (South Korea)	All patients implanted with Riata™ defibrillator leads between January 2003 and December 2010 were investigated for externalized conductor (EC) and electrical dysfunction (ED). There was no difference in ED-free survival rate between patients with and without EC (P=0.628).
<p>Theuns DAMJ, Van Erven L, Kimman GP, et al.</p> <p>Nationwide Longitudinal Follow-up of Riata™ Leads Under Advisory at 3 Annual Screenings.</p> <p><i>JACC.</i> 2017;3(8):887-893. doi: 10.1016/j.jacep.2016.12.011.</p>	882	Nationwide (Netherlands)	The development of conductor externalization (CE) is progressive with an incidence rate of 4.9 per 100 patient-years (7.0 for 8F Riata™ lead and 3.2 for 7F Riata™ ST lead). There no association observed between CE and electrical failure.
<p>Parkash R, Thibault B, Mangat I, et al.</p> <p>Canadian Registry of Implantable Electronic Device Outcomes: Surveillance of the Riata™ Lead Under Advisory.</p> <p><i>Circ Arrhythm Electrophysiol.</i> 2016;9(10):1-9.</p>	3763	Nationwide (Canada)	The overall electrical failure rate was 5.2% at 8 years with no difference between 7F and 8F models. Cable externalization was found to be more common in the 8F model (12.3% vs 5.2%, P<0.0001). Predictors of electrical lead failure include cable externalization, higher left ventricular ejection fraction, younger age, higher body mass index and a passive fixation lead. These predictors can assist with clinical decisions as to whether lead revision should be performed prophylactically.

2015 PUBLICATIONS

CITATION	SAMPLE SIZE	STUDY NOTE	SUMMARY/CONCLUSION
<p>Cohen TJ, Asheld WJ, Germano J, Islam S, Patel D.</p> <p>A Comparative Study of Defibrillator Leads at a large-Volume Implanting Hospital: Results From the Pacemaker and Implantable Defibrillator Leads Survival Study (“PAIDLESS”).</p> <p>Journal of Invasive Cardiology. 2015;27(6):292-300.</p>	703	Single Center (Winthrop U.)	Recalled St. Jude Medical leads performed better than recalled Medtronic leads in our study. Recalled St. Jude Medical leads had no significant difference in lead failure when compared with the other manufacturer’s non-recalled leads.
<p>Parkash, Tung, Champagne, et al.</p> <p>Insight into the mechanism of failure of the Riata™ lead under advisory.</p> <p>Heart Rhythm. 2015;12(3): 574-579. doi:10.1016/j.hrthm.2014.12.002.</p>	263	Nationwide (Canada)	Lead-can abrasion is the most common form of insulation defect in the Riata™ group of leads under advisory. Management of this group of leads under advisory should not neglect the issue of lead-can abrasion, in addition to detection of cable externalization.
<p>Lovelock JD, Premkumar A, Levy MR, et al.</p> <p>Pulse Generator Exchange does not accelerate the rate of the electrical failure in a recalled small caliber lead.</p> <p>Pacing Clin Electrophysiol. 2015;38(12):1434-8. doi:10.1111/pace.12734.</p>	153	Single Center (Emory)	Conductor externalization was seen frequently in our cohort of patients. ICD generator exchange did not accelerate the rate of Riata™ lead failure at 1 year. Although both the control and the change-out cohorts failed at a rate much greater than non-recalled leads, generator exchange did not appear to add to the problem.
<p>McKeag N, Hodkinson EC, Noad RL, et al.</p> <p>Assessment of implantable cardioverter defibrillator leads with evidence of conductor externalization: An observational study.</p> <p>2015;36(1):47.</p>	202	Single Center (N. Ireland)	Between 2010 and 2014, 47 of 202 (23%) Riata™ leads had evidence of conductor externalization. During four years of follow-up, 10.6% of patients with a Riata™ ICD lead and evidence of conductor externalization developed an electrical abnormality of the lead (5 of 47).
<p>Singh G, Lahiri MK, Khan A, Fang KD, Schuger CD.</p> <p>Fluoroscopic investigation of Riata™ transvenous defibrillator leads.</p> <p>Cardiology Journal. 2015;22(1):57-67. doi:10.5603/CJ.a2014.0039.</p>	90	Single Center (Michigan)	Prevalence of insulation failure exhibiting as conductor externalization is high (26.7%) among large diameter 8F Riata™ leads with a significant proportion of patients manifesting electrical failure. High resolution 3 view fluoroscopy is a reasonable approach to screen for this unique type of insulation failure.

2015 PUBLICATIONS (CONTINUED)

CITATION	SAMPLE SIZE	STUDY NOTE	SUMMARY/CONCLUSION
<p>Pokorney SD, Zhou KE, Matchar DB, et al.</p> <p>Optimal Management of Riata™ Leads with No Known Electrical Abnormalities or Externalization: A Decision Analysis.</p> <p>Journal of Cardiovascular Electrophysiology. 2015;226(2):184-191. doi:10.1111/jce.12563.</p>	n/a	n/a	Overall there were minimal differences in survival with monitoring versus active lead management approaches. There is no evidence to support fluoroscopic screening for externalization of Riata™ or Riata™ ST leads.
<p>Steinberg C, Sarrazin JF, Philippon F, et al.</p> <p>PA/Lateral Chest X-Ray is Equivalent to Cine Fluoroscopy for the Detection of Conductor Externalization in Defibrillation Leads.</p> <p>PACE. 2015;38(1):77-83. doi:10.1111/pace.12504.</p>	78	Single Center (Quebec)	PA/lateral CXR with zooming is equivalent to cine-fluoroscopy for the detection of Riata™ lead insulation defects and should be considered as the preferred screening method.
<p>El-Chami, Merchant, Levy, et al.</p> <p>Outcomes of Sprint Fidelis‡ and Riata™ lead extraction: Data from 2 high-volume centers.</p> <p>Hearth Rhythm. 2015;12(6):1216-1220. doi:10.1016/j.hrthm.2015.02.031.</p>	102	Multi-center (Emory and UPMC)	Our data from two high-volume centers suggest that extraction of Sprint Fidelis‡ and Riata™ leads is associated with excellent clinical success and a similar rate of major procedural complications.
<p>Bongiorni, Di Cori, Segreti, et al.</p> <p>Transvenous extraction profile of Riata™ leads: Procedural outcomes and technical complexity of mechanical removal.</p> <p>Heart Rhythm. 2015;12(3):580-587. doi:10.1016/j.hrthm.2014.12.013.</p>	134	Single Center (Pisa, IT)	Extraction of Riata™ leads is feasible and effective. However, extraction of Riata™ leads is more complex than that of Sprint Fidelis‡ leads. Lack of coil backfilling and cable externalizations in the Riata™ group may account for these differences.
<p>Zeitler, Pokorney, Zhou, et al.</p> <p>Cable externalization and electrical failure of the Riata™ family of implantable cardioverter-defibrillator leads: A systematic review and meta-analysis.</p> <p>Heart Rhythm. 2015;12(6):1233-1240. doi:10.1016/j.hrthm.2015.03.005.</p>	n/a	Meta-analysis, multi-studies	In clinical practice, rates of conductor externalization (CE) in Riata™ leads are substantial. While CE is associated with significant increase in the risk of electrical failure (EF), the incidence of EF without externalization is not trivial.

2014 PUBLICATIONS

CITATION	SAMPLE SIZE	STUDY NOTE	SUMMARY/CONCLUSION
Larsen J, Nielsen J, Johansen J, et al. Prospective nationwide fluoroscopic and electrical longitudinal follow-up of recalled Riata™ defibrillator leads in Denmark. Heart Rhythm. 2014;11:2141-2147.	239	Nationwide	The development of externalized conductors (EC) is a dynamic process despite long lead dwell time. ECs are associated with a higher risk of electrical abnormalities. Therefore, lead replacement should be considered, especially in patients with a long life expectancy.
Larsen J, Riahi S, Johansen J, et al. The patient perspective on the Riata™ defibrillator lead advisory: A Danish nationwide study. Heart Rhythm. 2014.11:2148-2155.	256	Nationwide	The Riata™ lead advisory is associated with a persistent small reduction in device acceptance and a small increase in device-related concerns with minimal improvement over time. Female sex is a predictor of a high negative advisory impact on general well-being. A need for counseling may arise in vulnerable subsets of patients.
Parkash R, Tung S, Champagne J, et al. Insight into the mechanism of failure of the Riata™ lead under advisory. Heart Rhythm. 2014;12(3):574-579. doi:10.1016/j.hrthm.2014.12.002.	263	Nationwide	Lead-can abrasion is the most common form of insulation defect in the Riata™ group of leads under advisory. Management of this group of leads under advisory should not neglect the issue of lead-can abrasion, in addition to detection of cable externalization.
Steinberg C, Sarrazin JF, Philippon F, et al. Longitudinal follow-up of Riata™ leads reveals high annual incidence of new conductor externalization and electrical failure. J Interv Card Electrophysiol. 2014;41(3):217-22.	147	Single Center	The annual incidence of new insulation defects in Riata™ leads is much higher than previously reported. Lead models 1580, 1582, and 1590 are at highest risk for new conductor externalization. Electrical dysfunction in Riata™ leads is also much higher than reported and is associated with conductor externalization.
McKeag N, Hodkinson E, Noad R, et al. Fluoroscopic and Electrical Assessment of Implantable Cardioverter Defibrillator Leads: A Prospective Observational Study. Pacing and Clinical Electrophysiology. 2014;37(11):1538-1543. doi:10.1011/pace.12473	147	Single Center	Conductor externalization (CE) was observed at a rate of 3.6 per 100 patient-years of follow-up, in 140 individuals with a Riata™ ICD lead and no definite evidence of CE at baseline.
Maytin M, Wilkoff BL, Brunner M, et al. Multicenter experience with extraction of the Riata™/Riata™ ST ICD lead. Heart Rhythm. 2014;11(9):1613-1318. doi:10.1016/j.hrthm.2014.05.014.	577	Multi-center Extraction	Extraction of the Riata™/Riata™ ST leads can be challenging, and leads with externalized cables may require specific extraction techniques. Extraction of the Riata™/Riata™ ST leads can be performed safely by experienced operators at high-volume centers with a complication rate comparable to published data.
Cutts E, Paulsen J, Jones P, Shein MJ, Simms J, Faris O. Value of Active Surveillance in Collecting Lead Adverse Event Data. Heart Rhythm. 2014;11(5):S489.	n/a	Other	Externalized conductor (EC) rates from Lead Evaluation Study (LES) and Product Performance Reports (PPR) are vastly disparate. Actively collected LES data are likely to be more representative of actual EC rate. PPRs are helpful tools in evaluating clinical performance of leads, but reliance on passive reporting limits their utility. Underreporting is not limited to one manufacturer of another, but rather an industrywide challenge that deserves discussion. These observations reinforce the need for industrywide effort to perform active surveillance and to improve voluntary reporting.

2014 PUBLICATIONS (CONTINUED)

CITATION	SAMPLE SIZE	STUDY NOTE	SUMMARY/CONCLUSION
<p>Cunnane R, Anshuman D, Moss JD, et al.</p> <p>Single Chest X-Ray Versus Multi-Angled Fluoroscopy in Identifying Structural Abnormalities in Riata™ Leads.</p> <p>Heart Rhythm. 2014;11(5):S505.</p>	128	Single Center	Chest x-ray, though helpful, appears not to be as sensitive as multi-angle fluoroscopy for identifying structural dysfunction of the Riata™ lead. Serial examination of Riata™ leads annually by fluoroscopy is supported by these findings. Examining zones within the heart has the highest yield.
<p>Hayes DL, Freedman R, Niebauer MJ, et al.</p> <p>Incidence of New Externalized Conductors and Electrical Dysfunction in Riata™ and Riata™ ST Silicone ICD Leads: 1 year Results from a Prospective, Multicenter Study.</p> <p>Heart Rhythm. 2014;11(5):S11</p>	776	Multi-center	<p>Through 1 year of follow-up, the incidence of new externalized conductors in 8F Riata™ and 7F Riata™ ST silicone leads is low.</p> <p>The presence of externalized conductors is not associated with an increased risk for electrical dysfunction.</p>
<p>Larsen JM, Nielsen JC, Johansen JB, et al.</p> <p>Conductor Externalization is Strongly Associated with Electrical Abnormality in Recalled Riata™ Defibrillator Leads - A Danish Nationwide Perspective Follow-up Study.</p> <p>Heart Rhythm. 2014;11(5):S12.</p>	298	Nationwide	Riata™ lead conductor externalization is strongly associated with electrical abnormalities. The rates of new electrical abnormalities and externalizations are relatively high. This emphasizes the need to consider lead replacement in case of externalization especially in patients with long life expectancy.
<p>Zhao X, Thomann S, Alfalasi O, et al.</p> <p>Riata™ Silicon Defibrillation leads failure: increase in prevalence after 5 years of Follow-up. European</p> <p>Heart Journal. 2014;35:690.</p>	198	Single Center	Riata™ leads had a high rate of malfunction in different period after implantation. Insulation defects of leads are especially higher after 5 years that implies a very careful and strict follow-up on the long run.
<p>Demirel F, Adiyaman A, Delnoy PPHM, et al.</p> <p>Mechanical and electrical dysfunction of Riata™ Implantable cardioverter-defibrillator leads.</p> <p>EP Europace. 2014;16(12):1787-1794.</p>	273	Single Center	Riata™ leads show progressive and high externalization rates without correlation between externalization and electrical lead failure. Non-ischaemic cardiomyopathy and impaired LVEF are independent predictors of structural lead failure in cross-sectional analysis, whereas 7F lead is a predictor of electrical lead failure.
<p>Liu J, Brumberg G, Rattan R, et al.</p> <p>Longitudinal Follow-Up of Implantable Cardioverter Defibrillator Leads.</p> <p>American Journal of Cardiology. 2014;113(1):103-103-6. doi:10.1016/j.amjcard.2013.08.046.</p>	5,288	Single Center	This study represents a comprehensive retrospective review of ICD lead survival rate from major US lead manufacturers. Our data demonstrate that failure-free survival curves of recalled ICD leads diverge from those of non-recalled leads 2 years after implantation. Furthermore, an overall ICD lead survival rate on the order of 90% is seen at 5 years.
<p>Richardson TD, Kolek MJ, Goyal SK, et al.</p> <p>Comparative Outcomes of Transvenous Extraction of Sprint Fidelis‡ and Riata™ Defibrillator Leads: A Single Center Experience.</p> <p>Journal of Cardiovascular Electrophysiology. 2014;25(1):36-42. doi:10.1111/jce.12265.</p>	192	Single Center	Despite differences in baseline characteristics, this study indicates that Medtronic Sprint Fidelis‡ and St. Jude Medical Riata™ ICD leads have similar procedural outcomes with transvenous lead extraction.

2013 PUBLICATIONS

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<p>Greenslade J, Crozier I, Melton I, Mattewson S.</p> <p>Single Centre Experience with Riata™ Defibrillator Leads.</p> <p>Heart, Lung and Circulation. 2013;22(7):560. doi:10.1016/j.hcl.2013.04.031.</p>	100	Single Center	9% electrical failure rate with Riata™ leads which is higher than published data.
<p>Greenberg SM, Schechter SO, Hoch DH, et al.</p> <p>Does the Riata™ lead Deliver Adequate Defibrillation Shocks? A Single Center Experience in 289 Patients.</p> <p>Heart Rhythm. 2013;10(5):S25.</p>	289	Single Center	Externalized conductors was observed in 13.1% of 8F leads and 4.8% in 7F; failure of defibrillation efficacy only occurred in one patient; in 99% of this cohort, sensing and HV function remained intact.
<p>Lindemann J, Betts J, Davidson O, et al.</p> <p>The Role of Lead Integrity Alerts and Remote Monitoring in Reducing Morbidity Associated With the St Jude Medical Riata™ ICD Lead.</p> <p>Heart, Lung and Circulation. 2013;22:S123. doi:10.1016/j.hlc.2013.05.295.</p>	103	Single Center Medtronic Sponsored	Despite a normally functioning Riata™ lead at generator change, 8% of leads failed at a median of 17 months post generator change. The Lead Integrity alert and Remote Monitoring appear to be helpful in preventing inappropriate shocks.
<p>Lorvidhaya P, Mendoza I, Sehli S, Atalay M, Kim M.</p> <p>Prospective evaluation of cinefluoroscopy and chest radiography for Riata™ lead defects: implications for future lead screening.</p> <p>Journal of Interventional Cardiac Electrophysiology. 2013;38(2):131-135. doi:10.1007/s10840-013-9822-6.</p>	102	Single Center	Cinefluoroscopy appears to be more sensitive than CXR for the detection of Riata™ cable extrusion. Interpretation of CXR by a radiologist with education in lead defects correlates highly with cinefluoroscopy with very high specificity. Depending on available resources for screening, CXR may be a reasonable alternative to cinefluoroscopy. Multidisciplinary collaboration across specialties (radiology and electrophysiology) can lead to improved diagnostic capability and thus the potential for enhanced quality of care.
<p>Rordorf R, Possio L, Savastano S, et al.</p> <p>Failure of implantable cardioverter-defibrillator leads: A matter of lead size?</p> <p>Heart Rhythm. 2013;10(2):184-190. doi:10.1016/j.hrthm.2012.10.017.</p>	890	Single Center	<p>During a median follow-up of 33 months, the overall failure rate was 6.3%. The failure rate was significantly higher in Sprint Fidelis‡ leads than in both standard-diameter (4.8%/year vs 0.8%/year; P<.001) and Riata™/Riata™ ST (4.8%/year vs 2.6%/year; P = .03) leads.</p> <p>Compared with standard-diameter leads, both Sprint Fidelis‡ and Riata™/Riata™ ST small-diameter ICD leads are at an increased risk of failure, although the incidence of events is significantly lower in the Riata™ than in the Sprint Fidelis‡ group.</p>
<p>Ellenbogen KA, Gunderson BD, Stromberg KD, Swerdlow CD.</p> <p>Performance of Lead Integrity Alert to Assist in the Clinical Diagnosis of Implantable Cardioverter Defibrillator Lead Failures.</p> <p>Circ Arrhythm Electrophysiol. 2013;6(6):1169-1177. doi:10.1161/CIRCEP.113.000744.</p>	12,793	CareLink™ data	<p>Analyzed data 6123 St. Jude Riata™ or Durata™, 5114 Boston Scientific Endotak‡, and 1556 Fidelis‡ combinations followed in the Medtronic CareLink‡ remote monitoring network for Lead system events and lead failures.</p> <p>The Lead Integrity Alert (Medtronic) markedly increased the detection rate of lead system events compared with conventional impedance monitoring.</p>

2013 PUBLICATIONS (CONTINUED)

CITATION	SAMPLE SIZE	STUDY NOTE	SUMMARY/CONCLUSION
<p>Hayes, Freedman, Curtis, et al.</p> <p>Prevalence of Externalized Conductors in Riata™ and Riata™ ST Silicone Leads: Results from the Prospective, Multicenter, Riata™ Lead Evaluation Study.</p> <p>Heart Rhythm. 2013;10(12):1778-1782. doi:10.1016/j.hrthm.2013.08.030.</p>	776	Multi-center	Larger-diameter Riata™ leads were more prone to EC than smaller-diameter Riata™ ST leads. The prevalence of electrical dysfunction was not associated with EC.
<p>Marcus GM, Keung E, Scheinman MM.</p> <p>The Year in Review of Clinical Cardiac Electrophysiology.</p> <p>J Am Coll Cardiol. 2013;62(25):2433-2447. doi:10.1016/j.jacc.2013.09.050.</p>	n/a	Review paper	Summarizes results from the VA, Abdelhadi, and Canadian HRS studies.
<p>Liu J, Qin D, Rattan R, et al.</p> <p>Longitudinal Follow-Up of Externalized Riata™ Leads.</p> <p>Am J Cardiol. 2013;112(10):1616-1618. doi:10.1016/j.amjcard.2013.07.044.</p>	329	Single Center	Prospective follow-up data on externalized Riata™ leads suggest an electrical failure rate in excess of 6% per year. This high failure rate warrants consideration of prophylactic replacement of externalized Riata™ leads. Further studies examining the natural history of Riata™ leads are warranted.
<p>Cheung JW, Al-Kazaz M, Thomas G, et al.</p> <p>Mechanisms, Predictors and Trends on Electrical Failure of Riata™ Leads.</p> <p>Heart Rhythm. 2013;10(10):1453-1459. doi:10.1016/j.hrthm.2013.06.015.</p>	314	Single Center	Younger age and female gender are independent predictors of Riata™ lead failure. Loss of integrity of conductor cables with ethylene tetrafluoroethylene coating is an important mode of electrical failure of the Riata™ lead. Further study of Riata™ lead failure trends is warranted to guide lead management.
<p>Hauser RG, Kallinen RLM.</p> <p>Early fatigue fractures in the IS-1 connector leg of a small-diameter ICD lead: Value of returned product analysis for improving device safety.</p> <p>Heart Rhythm. 2013;10(10):1462-1468. doi:10.1016/j.hrthm.2013.07.001.</p>	n/a	MAUDE database (April 11, 2013)	Search found 59 leads with fractures in the IS-1 leg. Most fractures were in leads implanted in 2008–2009; no fractures were found in leads implanted after 2010. St. Jude Medical’s small diameter leads that were manufactured before 2011 are prone to early outer coil fatigue fractures in the IS-1 leg. The failure mechanism appears to have been mitigated by a design change. Returned Product Analysis is important for improving device safety.
<p>Swerdlow CD, Ellenbogen KA.</p> <p>Implantable cardioverter-defibrillator leads: Design diagnostics, and management.</p> <p>Circulation. 2013;128(18):2062-71. doi:10.1161/CIRCULATIONAHA.113.003920.</p>	n/a	Review paper about device design	Addresses design issues with both Sprint Fidelis† and Riata™ leads, as well as potential signs of lead failure and management.

2013 PUBLICATIONS (CONTINUED)

CITATION	SAMPLE SIZE	STUDY NOTE	SUMMARY/CONCLUSION
<p>Fazal IA, Shepherd EJ, Tynan M, Plummer CJ, McComb JM. Comparison of Sprint Fidelis[‡] and Riata[™] defibrillator lead failure rates. Int J Cardiol. 2013;168(2):848-852. doi:10.1016/j.ijcard.2012.10.015.</p>	219	Single Center	Sprint Fidelis [‡] and Riata [™] leads have a significant but comparable failure rate at 2.60% per year and 2.71% per year of follow-up respectively. The number of deaths in both groups is similar and no deaths have been identified as being related to lead failure in either cohort.
<p>Badenco N, Himbert C, Dinanian S, et al. Riata[™] and Riata[™] ST defibrillator leads failure: cable externalization is one problem, but other electrical failures seem more preoccupant. Eur Heart J. 2013;34(1):1396. doi:10.1093/eurheartj/eh308.P1396.</p>	181	Two Centers	Riata [™] lead failure mostly concerns 8-French leads. Attention is especially paid to conductor externalization risk, but global failure rate with electrical complications seems more preoccupant and needs to be emphasized.
<p>Kouraki K, Strauss M, Skarlos A, Zahn R, Kleeman T. Incidence of Riata[™] lead failure in clinical practice: a single center experience. Eur heart J. 2013;34(1):1405. doi:10.1093/eurheartj/eh308.P1405.</p>	680	Single Center	Ten percent of implanted Riata [™] leads had to be replaced due to lead failure after a median time of 1056 days after first implantation. One fourth of these patients presented Riata [™] lead groups with an inadequate shock. Rate of lead failure did not differ between the various Riata [™] lead groups.
<p>Mahajan D, Perschbacher D, Jones P, Reddy S, Sharma A. Different manifestations of right ventricular ICD advisory leads using impedance and noise. Eur Heart J. 2013;34(1):1393. doi:10.1093/eurheartj/eh308.P1393.</p>	995	Boston Scientific sponsored	Fidelis [‡] patients had more noise episodes and RV Z \geq 2000 Ω consistent with early Pace/Sense conductor malfunctions. Riata [™] leads had more abrupt changes in RV impedance and Shock impedance \leq 20 Ω consistent with the insulation and HV conductor malfunctions. Riata [™] lead noise episodes tend to be more variable in rate than Fidelis [‡] noise episodes.
<p>Segreti L, Zucchelli G, Soldati E, et al. Transvenous removal of recalled ICD leads: Riata[™] vs. Sprint Fidelis[‡]. Eur Heart J. 2013;34(1):3654. doi:10.1093/eurheartj/eh309.P3654.</p>	513	Single Center Extraction	Experience shows that the extraction of recalled Sprint Fidelis [‡] and Riata [™] ICD leads is feasible and effective. However, extraction of Riata [™] leads is more complex than Sprint Fidelis [‡] leads. Lack of coil backfilling and cable externalization in Riata [™] lead group may account for these differences. The decision to extract or not to extract Riata [™] leads should be individualized.
<p>Liu J, Patel D, Rattan R, et al. Failure-free survival of the Durata defibrillator lead. EP Europace. 2013;15(7):1002-1006. doi:10.1093/europace/eut010.</p>	2,475	Single Center	The Durata [™] lead failure-free survival is significantly better than the 8F Riata [™] lead, albeit at a shorter follow-up time. Riata [™] lead and comparable with that of the 7F Riata [™] ST and the Sprint Quattro [‡] ICD leads. These data provide an insight into the mechanism of electrical failure of Riata [™] leads and have implications for patient management.
<p>Brunner MP, Cronin EM, Jacob J, et al. Transvenous extraction of implantable cardioverter-defibrillator leads under advisory - A comparison of Riata[™], Sprint Fidelis[‡], and non-recalled implantable cardioverter-defibrillator leads. Heart Rhythm. 2013;10(10):1444-1450. doi:10.1016/j.hrthm.2013.06.021.</p>	1,079	Single Center Extraction	ICD lead extraction procedures were performed in 1079 patients, including 430 patients with recalled leads (121 Riata [™] , 308 Sprint Fidelis [‡] , and 1 Riata [™] and Sprint Fidelis [‡]) and 649 patients with non-recalled ICD leads. Recalled ICD leads were extracted with safety and efficacy comparable to that of non-recalled ICD leads.

2013 PUBLICATIONS (CONTINUED)

CITATION	SAMPLE SIZE	STUDY NOTE	SUMMARY/CONCLUSION
<p>Larsen JM, Riahi S, Nielsen JC, et al.</p> <p>Nationwide Fluoroscopic Screening of Recalled Riata™ Defibrillator Leads in Denmark.</p> <p>Heart Rhythm. 2013;10(6):821-827. doi:10.1016/j.hrthm.2013.02.010.</p>	299	Nationwide	The prevalence of externalization in a nationwide screening is at the same level as reported in previous studies with similar lead dwell times. The degree of externalization is time dependent, and location seems to differ between single and dual coil leads. Long-term lead performance and association with electrical failure need further clarification. Fluoroscopy has a good diagnostic performance in clinical practice.
<p>Parkash R, Exner D, Champagne J, et al.</p> <p>Failure rate of the Riata™ lead under advisory: A report from the CHRS Device Committee.</p> <p>Heart Rhythm. 2013;10(5):692-695. doi:10.1016/j.hrthm.2013.01.018.</p>	5,043	Nationwide	The overall rate of lead failure in the Riata™ 8F and Riata™ ST 7F leads is higher than previously reported by using passive surveillance data. The impact of recent advisories related to these leads is not yet apparent.
<p>Kremers MS, Hammill SC, Berul CI, et al.</p> <p>The National ICD Registry Report Version 2.1 including leads and pediatrics for years 2010 and 2011.</p> <p>Heart Rhythm. 2013;10(4):e59-e65. doi:10.1016/j.hrthm.2013.01.035.</p>	n/a	National ICD Registry	<p>There were 23,234 Medtronic Sprint Fidelis[±] leads tracked in the registry. Of the assessed Fidelis[±] leads, about 1 in 5 (19.6%) were found to be functioning abnormally. The lead was removed or abandoned in 7910 (34.1%), and reused in 15,072 (64.9%).</p> <p>There were 8755 St Jude Medical Riata™ 8F leads and 3213 Riata™ ST 7F leads identified. Of those functionally assessed, 715 (8.2%) 8F leads and 236 (7.4%) 7F leads functioned abnormally. These leads were extracted or abandoned in 929 (10.6%) and 345 (10.7%), respectively.</p>
<p>Patel D, Adelstein E, Nemeč J, et al.</p> <p>Extraction of defibrillator leads recalled for cable externalization and failure.</p> <p>J Interv Card Electrophysiol. 2013;36(3):273-278. doi:10.1007/s10840-012-9751-9.</p>	627	Single Center Extraction	<p>From a total of 627 patients implanted with the Riata™ lead, 20 patients underwent lead extraction.</p> <p>Extraction of the Riata™ lead seems to be successful and safe and frequently requires the use of powered sheaths.</p>
<p>Abdelhadi RH, Saba SF, Ellis CR, et al.</p> <p>Independent multicenter study of Riata™ and Riata™ ST implantable cardioverter-defibrillator leads.</p> <p>Heart Rhythm. 2013;10(3):361-365. doi:10.1016/j.hrthm.2012.10.045.</p>	2,749	Multi-center	The survival of Riata™ (but not Riata™ ST) leads was lower than Quattro [±] leads; however, Riata™ ST leads had significantly shorter follow-up than Riata™ leads. ECs were common in Riata™ leads, and more than a quarter of Riata™ leads that had ECs were malfunctioning.
<p>Steinberg C, Sarrazin JF, Philippon F, et al.</p> <p>Detection of high incidence of Riata™ lead breaches by systematic postero-anterior and lateral chest X-ray in a large cohort.</p> <p>EP Europace. 2013;15(3):402-408. doi:10.1093/europace/eus339.</p>	284	Single Center	The incidence of insulation breach in Riata™ leads is much higher than quoted by the manufacturer or reported by most of the literature. A PA and lateral CXR with zooming appears adequate to identify lead breaches when reviewed by an electrophysiologist. Riata™ lead breaches without electrical abnormalities present a management dilemma and will require further studies.
<p>Bohn SVL, Valk S, Theuns D, Jordaens L.</p> <p>Long-term performance of the St Jude Riata™ 1580-1582 ICD lead family.</p> <p>Neth Heart J. 2013;21(3):127-134. doi:10.1007/s12471-012-0341-3.</p>	374	Single Center	A high incidence of insulation defects associated with conductor externalization in the Riata™ ICD lead family is observed. The mode of presentation is diverse. This type of insulation failure can lead to failure of therapy delivery.

2012 PUBLICATIONS

CITATION	SAMPLE SIZE	STUDY NOTE	SUMMARY/CONCLUSION
<p>Cohen TJ, Maltempi W, Cohen BA, et al. The Pacemaker and Defibrillator Lead Survival and Malfunctions Study: Which Core Lead Design Elements Influence Leads Failure? Heart Rhythm. 2012;9(5):S14.</p>	2,967	Single Center	Improved survival with Boston Scientific compared to Medtronic or St. Jude Medical: Boston Scientific vs Medtronic [Hazard ratio (HR) = 0.36 (95% CI: 0.21–0.60)]; St. Jude Medical vs Medtronic [HR = 0.47 (0.29–0.76)]; Boston Scientific vs St. Jude Medical [HR = 0.54 (0.26–1.13)].
<p>Corbisiero R, Armbruster R. Incidence of Externalized Conductors in ICD Leads Using PA and Lateral Chest X-Ray Imaging. Heart Rhythm. 2012;9(5):S236.</p>	389	Single Center	After review of the most recent PA/LAT CXR, externalized conductors were observed in 6 leads (5 Riata™, 1 Riata™ ST, 0 Durata™). The mean time to externalized conductors was 3.86 years, up to 5.4 years. One lead with an EC had decreased shock impedance 1.5 years after externalized conductors noted. All other leads are functioning normally 1.61 years post observation of externalized conductors.
<p>Hauser R. Performance of Riata™ leads: results from an independent multicenter study. European Heart Journal. 2012;33:539.</p>	1,060	Multi-center	62 out of 1060 (5.8%) of Riata™ and Riata™ ST leads failed, including 45 electrical malfunctions (7 with externalized conductors) and 17 normally functioning leads with externalized conductors.
<p>Johansen JB, Joergensen OD, Nielsen JC, et al. Defibrillator Lead Diameter as a Predictor of Lead Survival Time. Heart Rhythm. 2012;9(5):S61.</p> <p>Johansen JB, Joergensen OD, Nielsen JC, et al. Poor Survival of Defibrillator Leads with Small Diameter. EP Europace. 2012;14(1):133.</p>	4,251	Nationwide	All groups < 9F had lower survival compared to 9F. 7F and 8F leads had lower survival than 9F leads.
<p>Ng J, Bashir J, Karim S, et al. St Jude Medical Riata™ High Voltage ICD Lead Long Term Performance Report a Single Centre Experience. Heart, Lung and Circulation. 2012;21:S139-S139. doi:10.1016./jhlc.2012.05.350.</p>	171	Single Center	Our local experience with the Riata™ HV leads suggests a much higher incidence of lead related adverse events requiring invasive intervention. This is in contrast to recently published data as well as the performance report from St. Jude Medical.
<p>See VY, Beck H, Saliaris A, et al. Variable pattern of Lead Defects in Riata™ Family ICD Leads. Heart Rhythm. 2012;9(5):S454.</p>	105	Single Center	4 leads (3.7%) had evidence of compromise requiring invasive management (extraction or lead implant). Insulation breach resulting in inappropriate therapy was observed in 2 leads. Externalized conductors were observed in one lead on fluoro without any electrical issues.
<p>Steinberg C, Sarrazin JF, Phlippon F, et al. High Incidence of Riata™ Lead Breaches - A Single Center Experience. Heart Rhythm. 2012;9(5):S60.</p>	106	Single Center	PA and lateral chest x-ray showed 21.7% leads with externalized conductors. Abnormal CXR was more frequent with 8F leads compared to 7F leads (28% vs. 7%).

2012 PUBLICATIONS (CONTINUED)

CITATION	SAMPLE SIZE	STUDY NOTE	SUMMARY/CONCLUSION
<p>Steinberg C, Sarrazin J, Bouchard M, et al.</p> <p>High Prevalence of Riata™ Insulation Defects Detected by Systematic PA/Lateral Chest X-Ray - A Single Center Experience.</p> <p>Canadian Journal of Cardiology. 2012;28(5):S393-S394. Doi:10.1016/j.cjca.2012.07.690.</p>	269	Single Center	There is a high frequency of cable externalization in Riata™ leads, which can be detected in up to 24.1% in a larger cohort. The prevalence of insulation breaches in Riata™ leads is much higher than quoted by the manufacturer or reported in the literature. Careful analysis of a PA/lateral CXR with zooming has a high diagnostic yield to detect lead extrusion making fluoroscopy probably unnecessary. Cable externalizations are associated with subtle, but significant electrical abnormalities over time and there is a strong association between cable externalization and clinical lead failure.
<p>Swerdlow CD, Gunderson BD, Stromberg KD, Ellenbogen KA.</p> <p>Performance of ICD Lead Integity Alert for Diagnosis of Riata™ Lead Failures.</p> <p>Circulation. 2012;126.</p>	1,944	CareLink™ data	<p>Lead Integrity Alert (LIA) follow-up resulted in 30 alerts, 21 lead events (70%) and 9 false positives (30%). Lead events included 20 lead failures (LF) and 1 dislodgment. The 9 false positive alerts were caused by T-wave oversensing, electromagnetic interference, and ventricular fibrillation.</p> <p>Riata™ LFs identified by LIA are detected primarily by transient oversensing, often of distinctive spikey signals. Impedance is usually stable. The rate of inappropriate shocks is low for LIAenabled ICDs. Rare false-positive LIA alerts identify clinically-significant events.</p>
<p>Wright JF, Santos M, Betts J, et al.</p> <p>Long Term Outcomes of ICD Leads: A Difference in Failure Mechanisms.</p> <p>Heart Rhythm. 2012;9(5):S297.</p>	758	Single Center	6.2% leads failed during 57 +/- 28 months.
<p>Wright J, Lindermann J, Betts J, et al.</p> <p>Varying Modes of Presentation of Lead Failure in the 8F Silicone Riata™ ICD Lead.</p> <p>Heart, Lung and Circulation. 2012;21(1):S142. doi:10.1016/j.hlc.2012.05.359.</p>	432	Single Center	<p>Lead failure resulted in 10% of Riata™ leads undergoing revision during long term follow up. Noise and changes in impedance related to insulation failures being the most common abnormality.</p> <p>Inappropriate shocks occurred in 23%. DFT testing should be routinely performed at generator change to ensure normal function. Remote monitoring may be of value to allow earlier detection of potential lead problems.</p>
<p>Kodoth VN, Hodkinson EC, Noad RL, et al.</p> <p>Fluoroscopic and Electrical Assessment of a Series of Defibrillation Leads: Prevalence of Externalized Conductors.</p> <p>Pacing and Clin Electrophysiol. 2012;35(12):1498-1504. doi:10.1111/pace.12010.</p> <p>Kodoth V, Cromie N, Lau E, Mceneany D, Wilson C, Robert MJ. Riata™ lead failure;A report from Northern Ireland Riata™ lead screening programme. Euro Heart J. 2011;32(1):310.</p>	212	Single Center	A significant proportion (15%) of patients with a Riata™ lead had an insulation breach 4 years after implantation. High-resolution fluoroscopic imaging in at least two orthogonal views is required to identify this abnormality.

2012 PUBLICATIONS (CONTINUED)

CITATION	SAMPLE SIZE	STUDY NOTE	SUMMARY/CONCLUSION
<p>Sung RK, Massie BM, Varosy PD, et al. Long-term electrical survival analysis of Riata™ and Riata™ ST silicone leads: National Veterans Affairs experience. Heart Rhythm. 2012;9:1954-1961.</p> <p>Sung et al. Survival Analysis of St. Jude Medical Riata™ and Riata™ ST High-Voltage Leads in Comparison to Medtronic Sprint Quattro, Fidelis† and Boston Scientific Endotak Leads. Heart Rhythm. 2012;9(5):S13.</p>	14,968	Nationwide	There is decreased survival probability of Riata™/ST leads compared to other contemporary high-voltage leads, with decreased survival of Riata™ ST silicone compared to Riata™ lead series.
<p>Theuns D, Elvan A, De Voogt W, De Cock C, Van Erven L, Meine M. Prevalence and presentation of externalized conductors and electrical abnormalities in Riata™ defibrillator leads after fluoroscopic screening: Report from the Netherlands Heart Rhythm Association device advisory committee. Circ Arrhythm Electrophysiol. 2012;5:1059-1063.</p>	1,029	Nationwide	The prevalence of externalized conductors in Riata™ leads is significantly high (14.3%) using fluoroscopic screening. The majority of externalized conductors are not detectable with standard ICD interrogation. Screening with fluoroscopy is reasonable.
<p>Hauser RG, Abdelhadi R, McGriff D, Retel LK. Deaths Caused by the Failure of Riata™ and Riata™ ST Implantable Cardioverter-Defibrillator Leads. Heart Rhythm. 2012;9:1227-1235.</p> <p>Hauser et al. Deaths Caused By Riata™ ICD Lead Failure: Analysis of the U.S. FDA Device Database. European Heart Journal. 2012;33(1):540.</p>	n/a	MAUDE Database (Feb. 2012)	<p>Over 8 years, 133 deaths associated with these leads were identified in the MAUDE database: 71 involving Riata™ silicone and Riata™ ST silicone leads and 62 involving Quattro+ Secure leads.</p> <p>Riata™ and Riata™ ST ICD leads are prone to failures that have resulted in death. These failures appeared to have been caused by insulation defects that resulted in short circuiting between high-voltage components. Externalized conductors were not a factor in these deaths.</p>
<p>Liu J, Brumberg G, Rattan R, Jain S, Saba S. Class I recall of defibrillator leads: a comparison of the Sprint Fidelis† and Riata™ families. Heart Rhythm. 2012;9:1251-1255.</p>	2,270	Single Center	In this study, a comparative analysis of the failure-free survival of 2 recalled leads (Medtronic Sprint Fidelis† and St. Jude Medical Riata™) demonstrates discrepancies in the timing of the recall despite comparable failure-free survival patterns leading to the recall. The causes of these discrepancies are unclear and raise questions regarding the consistency of postmarketing surveillance and manufacturers' reporting of malfunctions of medical devices.
<p>Liu J, Rattan R, Adelstein E. et al. Fluoroscopic screening of asymptomatic patients implanted with the recalled Riata™ lead family. Circ Arrhythm Electrophysiol. 2012;5:809-814.</p>	245	Single Center	The Riata™ lead exhibits time-dependent high rates of cable externalization exceeding 20% at >5 years of dwell time. Externalized leads are associated with a more pronounced decrease in R-wave amplitude, which may be an early marker of future electric failure. The use of fluoroscopic and electric screening of asymptomatic patients with the Riata™ lead remains controversial in the management of patients affected by the recent Food and Drug Administration recall.

2012 PUBLICATIONS (CONTINUED)

CITATION	SAMPLE SIZE	STUDY NOTE	SUMMARY/CONCLUSION
<p>Theuns DAMJ, Van Malderen S, Dabiri-Abkenari L, Chaitising RS, Szili-Torok T, Jordaens L.</p> <p>Impact of fluoroscopic screening on failure rates of the Riata™ high-voltage implantable defibrillator lead.</p> <p>European Heart Journal. 2012;33(1):540.</p>	452	Leads: Riata™ (N = 374), Riata™ ST (N = 78)	The failure rate of the Riata™ high-voltage lead is low when physicians rely solely on electrical abnormalities. The extent of externalized conductors is much higher when we screen Riata™ high-voltage leads using fluoroscopy, with a failure rate up to 39.7% at 8 years. The definitive management of patients with Riata™ high-voltage leads and externalized conductors needs to be clarified soon as the failure rate of this specific lead will increase.
<p>Van Rees JB, Van Welses GH, Borleffs CJW, et al.</p> <p>Update on small-diameter implantable cardioverter-defibrillator leads performance.</p> <p>PACE. 2012;35:652-658.</p>	591	Single Center	The current update demonstrates that the risk of lead failure during long-term follow-up is significantly increased for both the Sprint Fidelis† and the 7F Riata™ lead in comparison to the benchmark cohort.
<p>Hauser RG, McGriff D, Retel LK.</p> <p>Riata™ implantable cardioverter-defibrillator lead failure: analysis of explanted leads with a unique insulation defect.</p> <p>Heart Rhythm. 2012;9:742-749.</p>	n/a	MAUDE Database (Sep 2011)	A total of 226 insulation defects were found in 105 Riata™ and Riata™ ST leads. 32 leads were reported to show exposed cables or externalized conductors. 43 out of 105 leads which were reported to have been assessed for integrity of ETFE cable coating of which 51.2% were found to be abraded, exposing the conductor.
<p>Hauser RG, Kallinen L.</p> <p>Riata™ ICD Lead Failure: Results of the Manufacturers Analysis of Returned Leads.</p> <p>JACC. 2012;59(13):E584. doi:10.1016/S0735-1097(12)60585-3.</p>	n/a	MAUDE Database	Explanted Riata™ and Riata™ ST leads were found to have multiple inside-out insulation defects which often involved the low voltage conductors. Thus lead noise and inappropriate shocks were common. High voltage cable insulation abrasion also occurred. These observations suggest that Riata™ leads may have more widespread damage than can be detected by fluoroscopic examination.
<p>Hodkinson E, Kodoth V, Ashfield K, et al.</p> <p>Follow-up Riata™ Screening in Northern Ireland.</p> <p>JACC. 2012;59(13). doi:10.1016/S0735-1097(12)60586-5.</p>	165	Nationwide	Riata™ lead population found to have a lead failure incidence of 2.6%/year and a prevalence of 19%. This exceeds the manufacturer quoted 0.47%. Our data suggests that insulation failure is progressive over time. Therefore interval lead screening by fluoroscopy, in addition to the advised lead parameter checks, is justified. Lead screening programmes & strategies for dealing with lead failure should be developed & agreed.

2011 PUBLICATIONS

CITATION	SAMPLE SIZE	STUDY NOTE	SUMMARY/CONCLUSION
<p>Wilkoff B, Freedman R, Hayes D, Kalbfleisch S, Kutalek S, Schaerf R.</p> <p>Decreased Incidence of Lead Abrasion with Optim™ Insulation.</p> <p>EP Europace. 2011;13(3):381.</p>	616,000	Multi-center	138,000 Silicone HV leads and 96,000 Optim™ HV leads. The abrasion failure probability of Optim™ defibrillation leads was lower than that for silicone defibrillation leads (0.045% vs. 0.27%, p < 0.0001).

BENCH TESTING

CITATION	SAMPLE SIZE	STUDY NOTE	SUMMARY/CONCLUSION
<p>Lau EW.</p> <p>Differential lead Component Pulling as a Possible Mechanism of Inside-Out Abrasion and Conductor Cable Externalization.</p> <p>Pacing and Clin Electrophysiol. 2013;36(9):1072-1089. doi:10.1111/pace.12185.</p> <p>Lau EW. Compression-bending of multi-component semi-rigid columns in response to axial loads and conjugate reciprocal extension-prediction of mechanical behaviours and implications for structural design. J Mech Behav Biomed Mater. 2013;17:112-125. doi:10.1016/j.jmbbm.2012.08.015.</p>	n/a	Bench testing	The Durata™ lead, Riata™ ST Optim™ lead, QuickFlex™ lead, and Quartet™ lead should be relatively immune to conductor cable externalization with protrusion CCE. The Durata™ leads are extremely resistant to longitudinal deformation and probably cause mediastinal displacement rather than differential pulling in response to pectoral movements in vivo. Implantation techniques and lead designs can be used to minimize the risk of CCE. A bench test for CCE can be constructed.
<p>Fischer A, Klehn R.</p> <p>Contribution of ethylenetetrafluoroethylene (ETFE) insulation to the electrical performance of Riata™ silicone leads having externalized conductors.</p> <p>J Interv Card Electrophysiol. 2014;37(2):141-145. doi:10.1007/s10840-013-9790-x.</p>	n/a	Bench testing	Testing of ETFE-coated conductors following multiple preconditioning steps showed that ETFE serves as a redundant layer of insulation. In the event that the ETFE coating is breached, the potential gradient seen resulting from a high-voltage defibrillation shock was similar to a lead with no breach to the ETFE, even after 100 shocks.

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