

Riata™ Case Reports

Citation	Mean follow-up	Data From	Results
Jacob M. Larsen, Dominic A.M.J. Theuns, and Anna M. Thøgersen. Paradoxical thromboembolic stroke during extraction of a recalled St Jude Medical Riata defibrillator lead with conductor externalization. <i>Europace</i> eut164 first published online August 9, 2013 doi:10.1093/europace/eut164	5.5 years	Case report, Riata 1582, N = 1.	Fluoroscopic screening revealed two externalizations. An asymptomatic man with Brugada syndrome undergoing lead extraction had a left-sided cerebral infarction but was discharged with only minor cognitive dysfunction. The authors suggest that thromboembolism may be avoided if extraction is guided by comprehensive pre-procedure imaging such as transesophageal echocardiography.
Rubenstein D, Weston LT, Kneller J, Wright C, Yin H. Safe extraction of Riata looped extruding filler cables. <i>J Cardiovasc Electrophysiol.</i> 2013;24(8): 942-946. doi: 10.1111/jce.12196	5 years	Case report, Riata 1590, N=1	The paper described a technique that reduced extruded loops of FC and allowed safe extraction of the lead. Filler cables (FC) are fixed at their ends only with a silicone adhesive compared to mechanical crimps for active cables (AC). This glue bond can break allowing a progressive migration of the filler cable to extrude out the insulation breach forming profound loops of cables.
Orlov MV. WikiLeaks of lead extraction: do we know the truth about Fidelis and Riata?. <i>Heart Rhythm.</i> 2013.	N/A	Editorial commentary	The author restated the results published by Brunner MP's lead extraction paper with a discussion on implications and limitations of Brunner's retrospective lead extraction study. (1) Removal of recalled ICD leads was associated with similar rates of procedural success, failure and major complications compared to non-recalled leads. (2) The presence of an externalized conductor was not associated with a higher incidence of procedural complications.
Webber MR, Allen RF, Stiles MK. Unheralded failure of Riata defibrillator lead identified at defibrillation threshold testing, <i>Journal of Arrhythmia.</i> 2013;29(3): 187-189. Available at: http://dx.doi.org/10.1016/j.joa.2013.04.003 .	N/A	Case report. N = 1.	A case of Riata lead with normal lead fluoroscopic appearances failed to deliver effective therapy for VF.
Choi K, Kim JH, Kim HJ, Lee SO, J EY, Kim JS. A case of Riata dual coil defibrillator lead failure in a patient with ventricular fibrillation. <i>Korean Circ J.</i> 2013;43(5): 336-339. Available at: doi: 10.4070/kcj.2013.43.5.336	3 years	Case report of Riata 1570 (N=1)	Insulation breach observed under fluoroscopic evaluation after Riata advisory. Before Riata advisory, ICD interrogation revealed recurrent shock due to high frequency of noise.
Greenslade J, Crozier I, Melton I, Matthewson S. Failure to Shock – A Riata Lead Case Study. <i>Heart, Lung and Circulation.</i> 2013;22: 548-593. Available at: http://dx.doi.org/10.1016/j.hlc.2013.04.030 .	Implanted Jan 2006. Device failed to shock 12/10/2012. Therefore, follow-up = 6 years.	Case report of Riata 1570 (N = 1)	Device failed to shock when VT was detected. HVLI = 0 W. Inspection of the lead post extraction revealed that a portion of the superior vena cava shock coil had 'melted'. At this site the underlying right ventricular conductor insulation and ETFE coating were abraded.
Gunaruwan P, Barlow M. Diathermy-induced ventricular fibrillation with Riata high-voltage lead insulation failure. <i>Europace.</i> 2013;15(4):473. Available at: doi: 10.1093/europace/eus227. Epub 2012 Aug 7.	N/A	Case report of Riata 1570 (N=1)	Riata 1570 failed to deliver therapy. Insulation defect was noticed during lead replacement case. During the replacement case, VF was induced when the diathermy was knife was < 1 cm from the lead.

Riata™ Case Reports (continued)

<p>Ricciardi D, La Meir M, de Asmundis C, Brugada P. A case of <i>in vivo</i> thrombogenicity of an externalized Riata ST lead. <i>Europace</i>. 2013 Mar;15(3):428. doi: 10.1093/europace/eus395.</p>	<p>Implanted in 2007. Paper published in Mar 2013. Follow-up = 6 years.</p>	<p>Lead: Riata 7020 (N=1). Center = 1.</p>	<p>Case report. Riata 7020 showed conductor externalization during coronary angiography. The patient underwent a coronary artery bypass surgery. At the opening of the right atrium the lead showed a longitudinal thrombus measuring 3.5 and 1.5 cm in maximal width around the segment of the insulation failure, together with a strong fibrotic tissue surrounding the lead attached to the tricuspid valve.</p>
<p>Ellis CR. Extinction of small-caliber transvenous ICD leads: Downsizing in a race to a recall. <i>Heart Rhythm</i>. 2013;10(2): 191-193. Available at: http://dx.doi.org/10.1016/j.hrthm.2012.10.026.</p>	<p>N/A</p>	<p>Editorial commentary</p>	<p>The author suggested that inadequacy of current postmarketing surveillance and lack of mandatory returned product analysis partially contribute to the delay of FDA's recalls on Riata.</p>
<p>Lakshmanadoss U, Lahoda D, Deshmukh P. Riata lead failure with normal electrical lead parameters and normal fluoroscopic appearance. <i>J Interv Card Electrophysiol</i> 2013;36(1): 87–89. Available at: doi: 10.1007/s10840-012-9739-5. Epub 2012 Oct 19.</p>	<p>Case 1: 68 months (at replacement) Case 2: 47 months (at replacement)</p>	<p>Case 1: Riata 1581. Case 2: Riata 1581. Center = 1.</p>	<p>Two case reports. Riata 1581 demonstrated normal lead parameters before ICD replacement. During ICD replacement, 1581 failed to deliver shock (because of over current detected by device) during replacement, although high-resolution fluoroscopy of the lead showed normal Riata leads without any fluoroscopically apparent separation. Case 1 analysis: revealed that the proximal superior vena cava (SVC) shocking coil was melted 24.8 cm from the tip of the lead, and internal insulation abrasions were also present in the same area, 24.2 to 27.1 cm from the lead tip. Case 2 analysis: Upon visual inspection of the extracted Riata lead, charring and significant damage were apparent proximal to the SVC coil. Performing meaningful analysis was not possible as per the manufacturer.</p>
<p>Shah P, Singh G, Chandra S, Schuger CD. Failure to deliver therapy by a Riata Lead with internal wire externalization and normal electrical parameters during routine interrogation. <i>J Cardiovasc Electrophysiol</i>. 2013 Jan;24(1): 94-6. Available at: doi: 10.1111/j.1540-8167.2012.02361.x. Epub 2012 May 21.</p>	<p>Implanted in 2004. Case occurred in Feb 2012. Therefore, follow up = 8 years.</p>	<p>Lead: Riata 1581 (N=1). Center = 1.</p>	<p>Case report. Riata 1581 failed to deliver shock (because of HVLI of < 10 ohms) upon therapy delivery.</p>
<p>Cronin EM, Baranowski BJ, Martin DO. Failure of fluoroscopy to detect “inside- out” insulation failure and externalized conductors in a Riata ICD lead. <i>Heart Rhythm</i>. 2012 Nov 30. pii: S1547-5271(12)01379-3. Available at: http://dx.doi.org/10.1016/j.hrthm.2012.11.022.</p>	<p>Implanted in 2006. Extracted date unclear.</p>	<p>Case report. Riata 1580 = 1.</p>	<p>Due to infection, the Riata lead was extracted (in 2012?). Externalized conductor was revealed in the extracted lead, despite the absence of conductor externalization on fluoroscopy. The Riata lead did demonstrate poor sensing and high capture threshold shortly after implant in 2006.</p>
<p>Chan CW, Chiang CS. An ICD lead with failure of outer insulation goes undetected by regular measurements. <i>Pacing Clin Electrophysiol</i>. 2012 Sep;35(9): e261-2. doi: 10.1111/j.1540-8159.2011.03164.x. Epub 2011 Jul 11.</p>	<p>20 mos</p>	<p>Case report. Riata ST 7041 = 1.</p>	<p>Structural abnormality 20 months after implantation, confirmed with fluoroscopy. No preceding lead measurement abnormality was reported is there to arouse earlier fluoroscopic screening.</p>

Riata™ Case Reports (continued)

<p>Dorman HG, van Opstal JM, Stevenhagen J, Scholten MF. Conductor externalization of the Riata internal cardioverter defibrillator lead: tip of the iceberg? Report of three cases and review of literature. <i>Europace</i>. 2012 Aug;14(8): 1161-4. Available at: doi: 10.1093/europace/eus064. Epub 2012 Mar 19. Review.</p>	<p>N/A</p>	<p>Three case reports. Riata 1580 = 1. Riata 1582 = 2.</p>	<p>Case 1: Riata 1580. Appropriate therapy, normal follow up parameters, yet fluoroscopy revealed conductor externalization. Case 2: Riata 1582. Decreasing impedance trend observed during follow up. Fluoroscopy revealed conductor externalization. Case 3: Riata 1582. Noise on EGM. Fluoroscopy revealed conductor externalization.</p>
<p>Kneller J, Delacey W, Wood MA, Ellenbogen KA. Detection of a Riata insulation failure by the Medtronic Lead Integrity Alert. <i>Europace</i>. 2012 Aug;14(8):1215-6. Available at: doi: 10.1093/europace/eus021. Epub 2012 Feb 26.</p>	<p>Implanted in July 2004. Paper published in 2012. Therefore, follow up = 7 years.</p>	<p>Case report. Riata 1580 = 1.</p>	<p>LIA triggered oversensing alert for the Riata lead. Lead revision revealed conductor externalization.</p>
<p>Israel CW, Bänsch D, Böcker D, <i>et al.</i> [Recommendations of the Working Group of Arrhythmias of the German Society of Cardiology on the approach to patients with Riata® and Riata ST® leads (St. Jude Medical). Nucleus of the Working Group of Arrhythmias of the German Society of Cardiology]. <i>Herzschrittmacherther Elektrophysiol</i>. 2012 Jun;23(2):107-15. doi: 10.1007/s00399-012-0186-x. [Article in German]</p>	<p>N/A</p>	<p>Editorial commentary</p>	<p>Recommendations: 1) Activation of automatic ICD alerts, 2) remote monitoring with automatic daily alerts whenever possible, 3) monthly ICD controls in patients at high risk (pacemaker dependency, history of ventricular tachyarrhythmias) and high or moderate lead-related risk (8F, 7F single coil), 3-monthly controls in moderate patient and lead-related risk, 3 to 6-monthly controls in low patient and lead-related risk (no bradycardia, no history of ventricular tachyarrhythmia).</p>
<p>Gelder RN, Gunderson BD. Prevention of inappropriate ICD shocks due to lead insulation failure by continuous monitoring and automatic alert. <i>Pacing Clin Electrophysiol</i>. 2012 Jun;35(6):e150-3. doi: 10.1111/j.1540-8159.2011.03316.x. Epub 2012 Feb 6.</p>	<p>Implanted in 2007. Paper published in Mar 2013. Follow-up = 6 years.</p>	<p>Case report. Riata 7002 = 1.</p>	<p>LIA triggered oversensing alert for the Riata lead. Lead revision revealed conductor externalization.</p>
<p>Leong DP, Van Erven L. Unrecognized failure of a narrow caliber defibrillation lead: the role of defibrillation threshold testing in identifying an unprotected individual. <i>Pacing Clin Electrophysiol</i> 2012;35:e154–e155.</p>	<p>Implanted in 2003. Paper accepted in 2011. Therefore, follow up = 8 years.</p>	<p>Case Report. Riata 1570 = 1.</p>	<p>Case report of a short circuit in the Riata 1570 defibrillator lead (Riata 1570, St. Jude Medical, St. Paul, MN, USA) that was unsuspected owing to normal lead parameters until defibrillator threshold testing at the time of elective generator change. The short circuit manifested as unsuccessful defibrillation of ventricular fibrillation with immediate battery depletion.</p>
<p>Krebsbach A, Alhumaid F, Henrikson CA, Calkins H, Berger RD, Cheng A. Premature failure of a Riata defibrillator lead without impedance change or inappropriate sensing: a case report and review of the literature. <i>J Cardiovasc Electrophysiol</i>. 2011 Sep;22(9):1070-2. doi: 10.1111/j.1540-8167.2011.02042.x. Epub 2011 Mar 8.</p>	<p>2 months</p>	<p>Case Report. Riata 1570 = 1.</p>	<p>Patient complained of intermittent hiccups 2 months after implant. Interrogation revealed elevated pacing threshold and diaphragmatic stimulation. Pacing and shock lead impedances remained stable. No inappropriate sensing was noted. Fluoroscopic examination of the lead revealed conductor externalization.</p>