### Riata® Case Studies

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<tr>
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| Krebsbach A, et al.                                                       | **63 year old woman with SJM 8F Riata 1570 Silicone right ventricular lead**  
* Sensing, pacing and shock lead impedances were all normal  
* Fluoroscopy revealed externalized conductors between the 2 defibrillator coils away from the main body of the lead  
* The area proximal to the right ventricular defibrillator coil near the region where the lead traverses the tricuspid valve was affected  
* Post-explantation analysis revealed insulation abrasion with externalized conductors |
| Richards MW, Warren CE, Anderson MH:                                    | **CASE 1**  
| Late failure of a single-coil transvenous implantable cardioverter defibrillator lead associated with conductor separation. Europace 2010;12:1191-1192. | * 43 year old woman with SJM 8F Riata 1582 defibrillator lead  
* At follow-up, 44 months post-implant, high pacing threshold and impedance  
* Lateral chest radiograph showed externalized conductors of the ICD lead proximal to the defib coil in the right atrium (not evident in the posteroanterior radiograph)  
* Lead was fully removed via thoracotomy  
**CASE 2**  
| 60 year old woman with SJM 8F Riata 1582 Silicone single coil defib lead | * At follow up, 63 months post-implant, two short episodes of noise oversensing each detecting VF were noted (patient was using electrical equipment)  
* Lead impedance, shock circuit impedance, and pacing thresholds were stable  
* Posteroanterior chest radiograph was obtained but no abnormality  
* 6 weeks later during which the patient avoided use of electrical equipment, device check revealed 6 more short episodes of noise triggering VF detection  
* Conductor externalization proximal to the defib coil was observed  
* Lead was abandoned and new lead was placed |
| Duray G, Ireal C, Schmitt J, Hohnloser S:                                | **64 year old man with SJM 8F Riata 1580 single coil RV shock lead**  
| Implantable cardioverter-defibrillator lead disintegration at the level of the tricuspid valve. Heart Rhythm 2008;5:1224-1225. | * SJM 8F Riata 1580 ICD Silicone lead  
* ICD shock delivery demonstrated inappropriate ICD shock therapy elicited by artifacts leading to detection of presumed VF episode  
* Earlier nonsustained episodes without shock delivery demonstrated similar double potentials in the V channel leading to detection of presumed VF  
* Fluoro revealed: approx 6-cm long portion insulation breach at the level of the tricuspid valve with externalized conductors  
* Lead was abandoned and new lead was placed |
| Valk S, Luijten R, Jordansen L:                                          | **64 year old man with SJM 8F Riata 1580 silicone single coil RV shock lead**  
| Insulation damage in a shock wire: An unexpected fluoroscopic image. Pacing Clin Electrophysiol 2010:33:770-772. | * Patient had increase in HV lead impedance, detected with home monitoring and inappropriate shocks due to noise in ECG  
* Chest X-ray revealed no abnormality  
* Fluoro revealed insulation failure with externalized conductors  
* Lead was removed and replaced with a new shock lead |
## Riata® Case Studies (Continued)

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* 2 years post-implant, patient received device warning for VF, triggering a charge that was aborted after arrhythmia interruption  
* Remote transmission of EGMs revealed irregular non-physiological signals suggesting lead insulation failure  
* Chest radiograph revealed unusual lead profile in the right atrium with externalized conductors  
* Lead was removed and replaced  
* Post-explantation analysis confirmed 5cm insulation breach with externalized conductors |
* 71 year old woman with BiV SJM ICD and SJM 8F Riata 1580 RV dual-coil lead, implanted in 2005  
* Patient received several appropriate ICD therapies due to VT, routine device check-ups showed no signs of malfunction of device or leads  
* During end-of-life device replacement procedure 6 years post-implant, fluoroscopy revealed insulation defect and conductor externalization  
* Because there was no electrical lead failure and extensive thrombotic occlusion of the subclavian vein, the lead was not replaced  
* A new MDT device with lead integrity alert and lead noise algorithm was implanted and patient was put on remote monitoring  
CASE 2  
* 71 year old woman with SJM single chamber ICD and SJM 8F Riata 1582-65 single coil lead, implanted in 2006  
* On routine device check-ups, a decreasing trend was seen for lead impedance and R-wave sensing  
* Fluoroscopy showed an insulation defect and conductor externalization  
* The lead was extracted and a new lead and device were implanted (manufacturer unknown)  
CASE 3  
* 61-yr old man with a MDT single-chamber ICD and SJM 8F Riata 1582-65 single active coil lead, implanted in 2007  
* Patient received appropriate VT therapy in 2008  
* Interrogation of the device in 4 years post-implant revealed noise on the iEGM, which was interpreted by the device as short V-V intervals, all other parameters were normal  
* ICD was switched off and scheduled for replacement  
* During replacement procedure, fluoroscopy showed an extensive insulation defect, Riata lead was disconnected but not removed, and a new ICD lead was implanted |
| Leong DP, et al. Unrecognized Failure of a narrow caliber defibrillation lead: The role of defibrillation threshold testing in identifying and unprotected individual. PACE. 2012. | * 78 year old man scheduled for elective BiV ICD replacement for battery depletion of his SJM ICD. Patient had 8F Riata 1570 RV lead, implanted in 2003  
* Lead measurements since implantation had been within normal range and stable  
* During device replacement DFT testing, patient remained in VF after 23 J shock was delivered  
* Second shock was not delivered due to a programmer alert of a fault in the “pulse generator or lead”  
* Patient was defibrillated externally and device was replaced  
* During repeat DFT testing with the new device, the same sequence of events occurred and an alert of depleted battery capacity was observed  
* Despite normal lead measurements during interrogation, physicians hypothesized a short circuit within the RV lead  
* New Guidant lead was implanted and old lead was capped  
* Product analysis report of the two depleted new generators indicated structural device damage by a short circuit in the RV lead |
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* 11 months later, patient received lead integrity alert for 390 short V-V intervals sensed  
* RV pacing impedance and RV and SCV oil impedances were stable  
* Fluoroscopy of the lead showed two potential areas of disruption  
* The lead was successfully extracted, outside-in and inside-out abrasions were observed |
* Patient received several appropriate therapies for VF episodes  
* 3 years post-implant, patient received lead integrity alert due to oversensing  
* RV lead was partially explanted and insulation abrasion with intermittent conductor externalization was observed; this abrasion was not observed on fluoroscopy |
* 4 years post implant, non-reproducible episodes of oversensing when patient pressed hands together was observed  
* 5 years post-implant, intermittent episodes of noise oversensing during interrogation was observed  
* ICD lead profile appeared normal, though, lead impedance had gradually reduced  
* Chest x-ray and fluoroscopy revealed externalized conductors |
* Appropriate therapies for VT were delivered  
* Pacing, sensing, and impedance measurements were stable  
* Recurrent appropriate shocks for VT prompted physicians to do a coronary angiogram to rule out any new coronary stenosis  
* During this procedure, an outer insulation lead failure in the Riata lead was observed |