

Update on St. Jude Medical Defibrillation Lead Performance



ST. JUDE MEDICAL

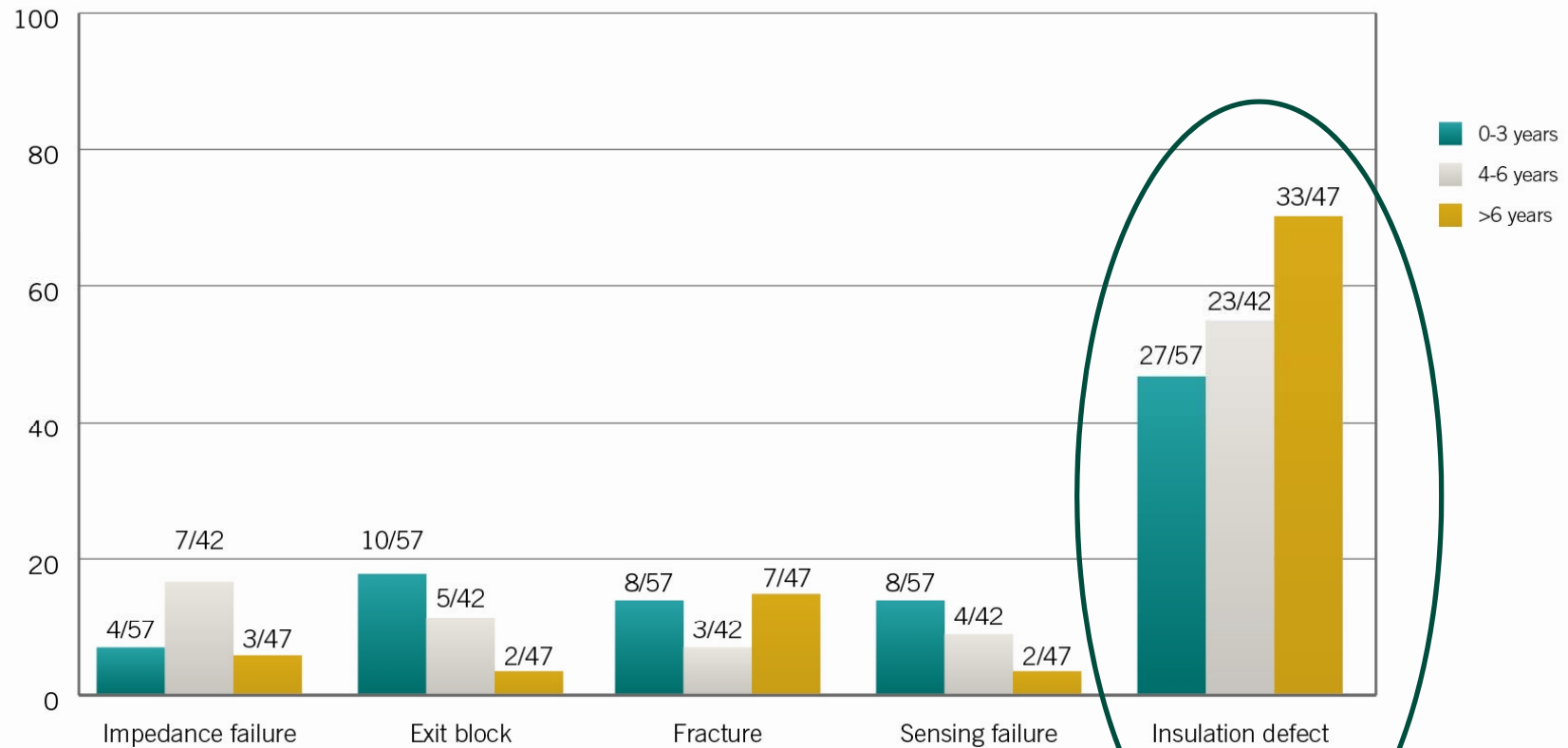
MORE CONTROL. LESS RISK.

Insulation Failure

Most Common Industry-Wide Lead Failure

(%) Cause of lead failure:

Incidence of different causes of lead defects versus time after lead implantation



Note: This graph has been adapted from Figure 3 of Kleemann T, et al. *Circulation*. 2007.

Kleemann T, et al. Rate of Transvenous Defibrillation Lead Defects in Implantable Cardioverter-Defibrillators over a Period > 10 years. *Circulation*. 2007;115:2474-2480.

MORE CONTROL LESS RISK

Timeline

- June 2001: Riata[®] Silicone leads approved
- Dec 2010: Physician communication on Riata Silicone lead performance and completion of phase-out
- Nov 2011: Physician advisory on Riata Silicone leads
 - Approximately 79,000 remaining in US

Clinical Presentation of Externalized Conductors: Visual vs. Electrical

- Most externalized conductors present as just a visual observation on X-ray or fluoroscopy without functional abnormalities
- Large majority (over 80%) of externalized conductors are electrically intact and function normally
- There have been no reports of loss of therapy due to externalized conductors

Externalized Conductors: 8F vs. 7F Silicone leads

	Shock Coil Configuration	Incidence Rate	Remaining Population
Riata 8F	Dual Coil	0.096%	48,000
	Single Coil	0.64%	2,000
Riata 7F	Dual Coil	0.024%	27,000
	Single Coil	0.081%	2,000

- Riata 8F Silicone leads have a significantly higher rate of externalized conductors than Riata 7F Silicone leads ($p=0.006$)
- Riata 8F Single Coil leads have a significantly higher rate of externalized conductors than all other Riata Silicone lead models combined ($p<0.001$)

Riata Silicone Lead Patient Management Recommendations

- Normal follow up as per HRS/EHRA consensus
- Remote monitoring strongly encouraged
- No prophylactic screening x-ray or fluoroscopy
- No explantation of normally functioning leads with or without externalized conductors
- HRS Webinar (Dec 21, 2011) participants recommend the same

Prospective Riata Lead Evaluation Study

- Minimum of 500 patients with Riata or Riata ST silicone leads of varying implant duration will undergo proactive fluoroscopy to determine if a conductor is externalized
- In externalized conductors, electrical performance of the leads will be assessed every three months for two years
- Objectives
 - To determine the incidence of externalized conductors
 - To determine the incidence of lead electrical problems in patients who have leads with externalized conductors
- First enrollment: Dec 2011

Optim[®] Insulated Leads: Riata ST Optim and Durata

- July 2006: Optim 7F Defibrillation Leads approved
- As of Nov 2011:
 - ~280,000 Optim defibrillation leads implanted (~250,000 Durata leads)
 - Over 5 years of clinical experience
- Significant design changes made between Silicone and Optim defibrillation leads
- No reports of externalized conductors in our Optim Defibrillation leads and they continue to demonstrate excellent performance by any measure

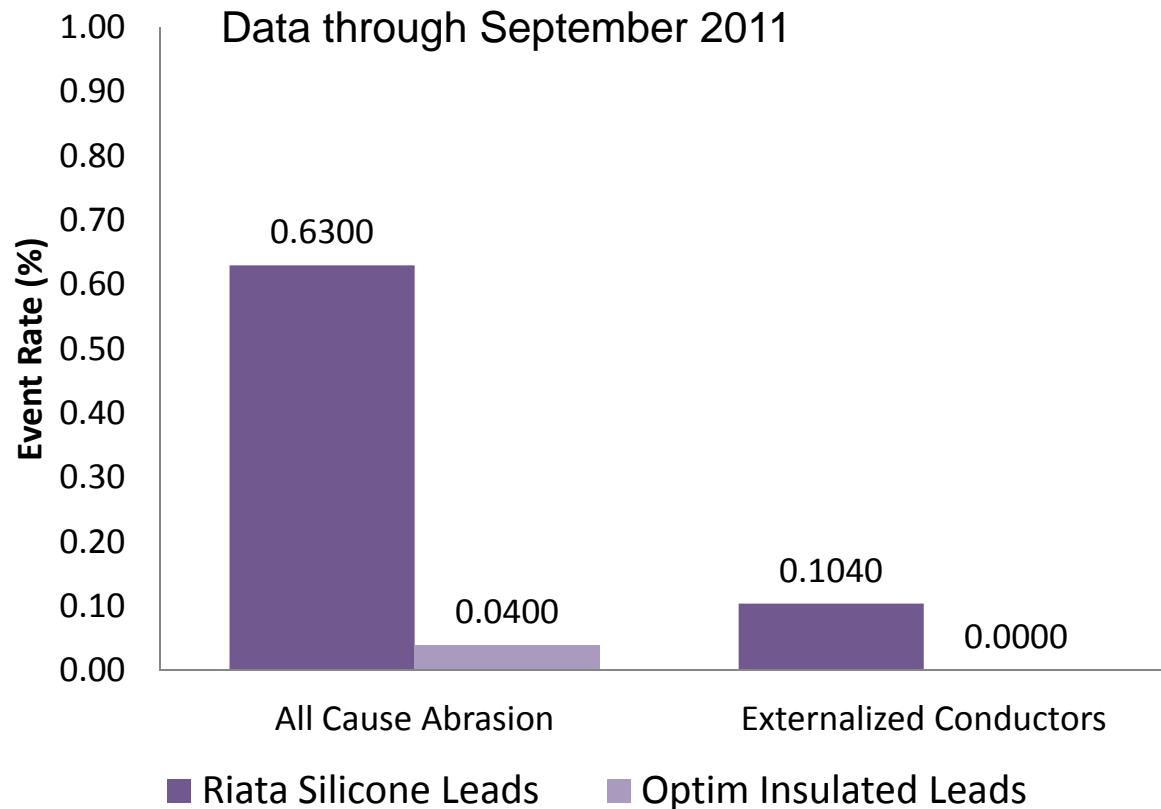
Significant Design Improvements: Riata Silicone to Optim Leads

- Smaller inner coil and stylet lumen brings conductors closer to the center of the lead body reducing conductor tension
- 50% increase in overall wall thickness
- Addition of Optim insulation; 50x more abrasion resistant than silicone

Optim[®] Insulated Leads: No Externalized Conductors

Complaints Plus Returns Analysis Data

Reduced All Cause Abrasion and Externalized Conductor Event Rates in Optim Insulated Leads



Performance Improvements Due To Optim[®] Insulation

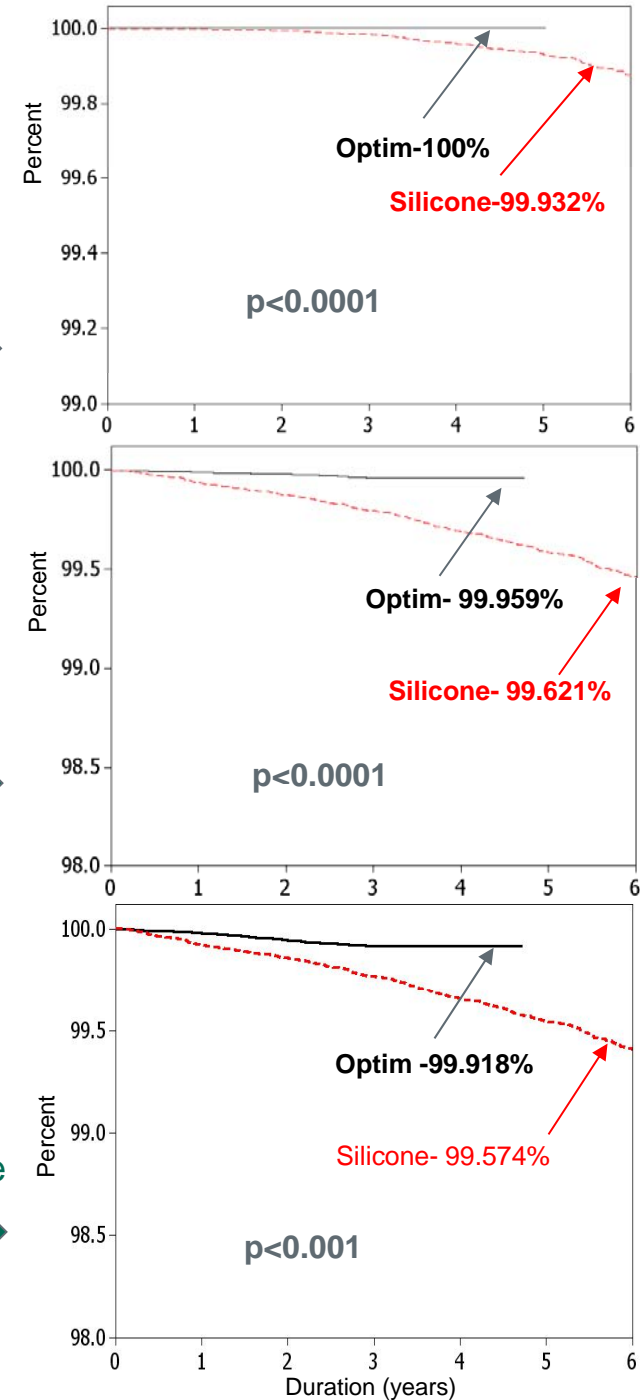
Freedom from Externalized Conductors:
Optim insulation: No Reports of Externalized Conductors



Freedom from All-Cause Abrasion:
Optim insulation: Significant Reduction in All-Cause Abrasions



Freedom from All-Cause Mechanical Failures:
Optim insulation: Significantly Higher Overall Lead Survival Rate



Proven Performance of Riata ST Optim and Durata 7F Optim Leads in SJM Registries and 3rd Party Publications

- OPTIMUM Registry
 - Prospective, multi-center, active follow-up registry
 - A total of 21,393 Optim leads (15,392 LV and 6,001 HV) were implanted in 13,989 pts at 224 sites
 - The all-cause abrasion free survival rate for high voltage Optim insulated leads was 99.98% in 6,001 OPTIMUM registry patients with Durata® and Riata ST Optim® leads during 61 months of follow-up
 - **No cases of externalized conductors**
- Wilkoff, et. al (HRS 2011)
 - Analysis of over 96,000 Optim ICD leads vs. 138,000 silicone ICD leads showed a significant reduction ($p < 0.0001$) of abrasion related failures at 44 months post implant
 - **No cases of externalized conductors**
- SCORE Registry
 - No insulation failures in 2,952 Durata and Riata ST Optim leads with over 30 months of follow-up
 - **No cases of externalized conductors**
- Epstein, et. al (HRS 2008)
 - No insulation failures in ICD leads with Optim insulation in 1,093 Optim ICD leads during 22-month of follow-up at publication
 - **No cases of externalized conductors**

Key Takeaways

- Most externalized conductors present as just a visual observation on X-ray or fluoroscopy without functional abnormalities
- St. Jude Medical communicated recommendations and HRS Webinar (December 21, 2011) participants recommend the same
- Prospective Riata Lead Evaluation Study will guide future management of patients with these leads
- There have been no reports of externalized conductors in Optim leads and they continue to demonstrate excellent performance by any measure