An ICD lead study without equal

Over five years ago, St. Jude Medical (SJM) began to actively monitor the post-market performance of all SJM Optim™ insulated leads. With over 10,000 leads enrolled—spanning more than a 60-month period—Optim-insulated ICD leads continue to show outstanding performance.

Performance of SJM Optim-insulated Leads

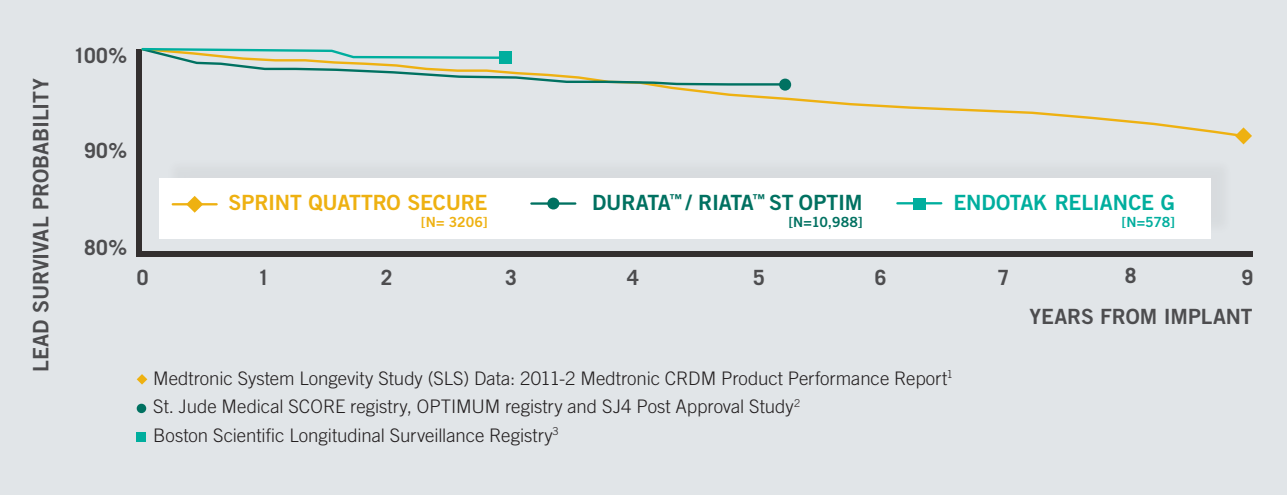
	St Jude Medical OPTIMUM/SCORE/ SJ4 PAS[1]	Medtronic™ System Longevity Study[2]	Boston Scientific Longitudinal Surveillance Registry[3]
Number of Leads Enrolled in Study	10,987	3,206	578
Cumulative Months of Follow-up	306,048	121,001	12,484
Number of Leads Active in Study	7,667	1,584	495

Optim ICD Leads* Continue to Show Outstanding Performance

- More than **10,000 Optim leads**, 3X more than the closest competitive ICD lead study, enrolled in active post-market registries: OPTIMUM, SCORE and SJ4
- **Approximately 30,000 patient years** of surveillance spanning more than a 60-month period
- Independent analysis of these registry data by the Population Health Research Institute (PHRI) of McMaster University/Hamilton Health Science continue to confirm and support the safety and reliability of our Durata and Optim leads."

*Durata™ and Riata™ ST Optim leads

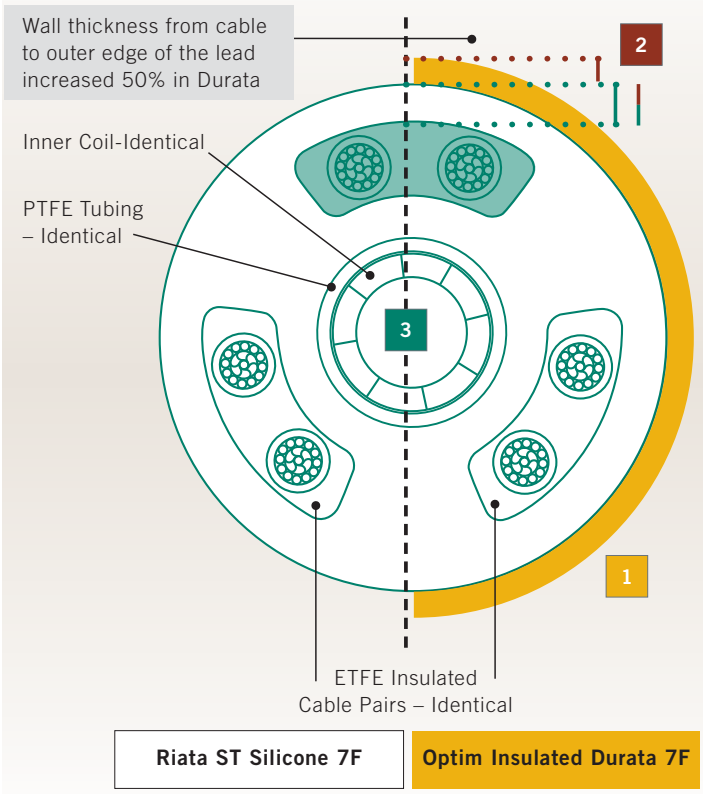
Optim-insulated ICD leads Compare Favorably to Competitive ICD Leads



St. Jude Medical™

Differences Between Riata ST Silicone and Durata Optim-insulated Leads

Lead Design Enhancements



1 Optim Insulation

- 50X more abrasion resistant than silicone[5]

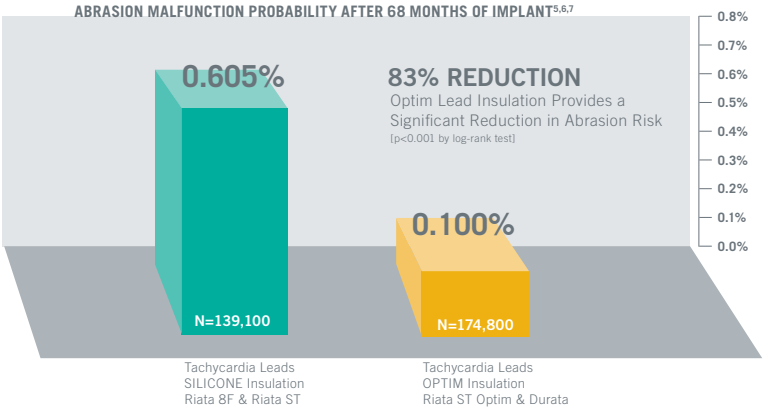
2 Wall Thickness

- Increased by 50% in Durata lead compared to Riata 7F silicone lead due to addition of Optim insulation

3 Conductor Configuration

- Conductors closer to the center of the lead body in 7F leads reduces tension on conductors and risk of internal abrasion.*

* St. Jude Medical Engineering Report: Tension and Cable Shortening Comparison.



REFERENCES

1. Medtronic System Longevity Study (SLS) Data: 2012-2 Medtronic CRDM Product Performance Report.
2. St. Jude Medical SCORE registry, OPTIMUM registry and SJ4 Post Approval Study data through August 31, 2012.
3. Boston Scientific Longitudinal Surveillance Registry data, Boston Scientific PPR – Q3 2012 edition
4. http://www.forbes.com/sites/larryhusten/2012/02/22/guestpost-more-lessons-from-the-riata-icd-lead-recall
5. C. Jenney, J. Tan, A. Karicherla, J. Burke, and J. Helland, "A New Insulation Material for Cardiac Leads with Potential for Improved Performance," HRS 2005, HeartRhythm, 2, S318-S319 (2005).
6. J. Tan and C. Jenney, "Comparative In Vivo Biostability Study of A New Lead Insulation Material Versus Polyurethanes," HRS2006, Heart Rhythm, 3, S146 (2006).
7. T. Kleemann, T. Becker, K. Doenges, M. Vater, J. Senges, S. Schneider, W. Saggau, U. Weisse, and K. Seidl, "Annual Rate of Transvenous Defibrillation Lead Defects in Implantable Cardioverter-Defibrillators Over a Period of >10 Years," Circulation, 115, 2474-2480 (2007).

Global Headquarters
One St. Jude Medical Drive
St. Paul, Minnesota 55117
USA
+1 651 756 2000
+1 651 756 3301 Fax

Implantable Electronic Systems Division
15900 Valley View Court
Sylmar, California 91342
+1 818 362 6822
+1 818 364 5814 Fax

St. Jude Medical Coordination Center BVBA
The Corporate Village
Da Vincilaan 11 Box F1
B-1935 Zaventem
Belgium
+32 2 774 68 11
+32 2 772 83 84 Fax

St. Jude Medical Brasil Ltda.
Rua Itapeva, 538
5º ao 8º andar
01332-000 – São Paulo – SP
Brazil
+55 11 5080 5400
+55 11 5080 5423 Fax

St. Jude Medical Japan Co., Ltd.
Shiodome City Center 15F
1-5-2, Higashi-Shinbashi
Minato-ku
Tokyo 105 7115
Japan
+81 3 6255 6370
+81 3 6255 6371 Fax

SJMprofessional.com

ST. JUDE MEDICAL™

Products registered are approved for CE Mark. Devices depicted may not be available in all countries. Check with your St. Jude Medical representative for product availablility in your country

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

DURATA, RIATA, RIATA ST, OPTIM, ST. JUDE MEDICAL, the nine-squares symbol and MORE CONTROL. LESS RISK. are registered and unregistered trademarks and service marks of St. Jude Medical, Inc. and its related companies. Sprint Quattro is a registered or unregistered trademark of Medtronic. Endotak Reliance is a registered or unregistered trademark of Boston Scientific Corporation.

Item GMCRM1023EN Rev B

GMCRM1023EN