St. Jude Medical ICD Lead Design and Long-Term Performance

January 2014

ST. JUDE MEDICAL

Outline

- Lead design and common mechanical lead failures
- Externalized conductors
  - Clinical presentation, relevance, incidence, and timing
- Why has the performance of newer generation leads improved?
  - Riata™ 8F silicone to Optim™ insulated lead design improvements
  - Summary of design evolution and performance
- Clinical Data and Publications
  - Riata Lead Evaluation Study results
  - St. Jude Medical Cardiac Lead Assessment Study
  - Riata Silicone Lead Patient Management Recommendations
  - Combined Optim™ lead registry data
  - ICD leads reliability and survival probability data

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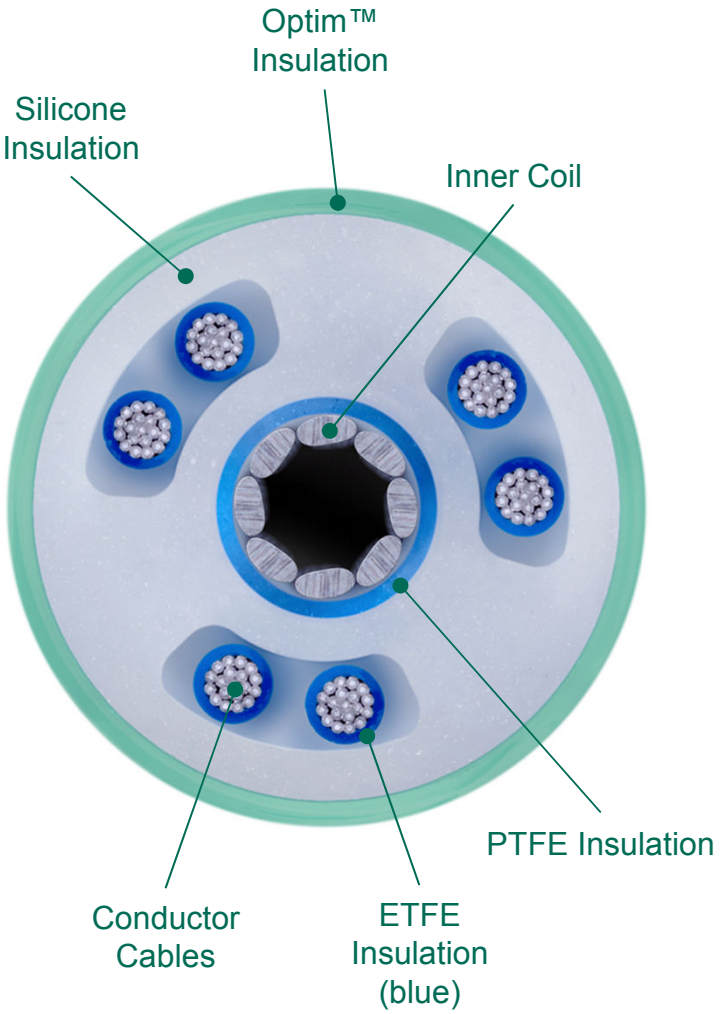
Main Components of an ICD Lead

- Carries electric current to the distal pace/sense electrode (helix in active fixation leads)

- Carry electric current to the anode pace/sense electrode, high voltage RV coil and high voltage SVC coil

- Isolates electrical components from each other as well as from the bloodstream
- Types include: silicone, polyurethane, Optim insulation



Optim Insulated Durata™ lead

Types of Mechanical Lead Failures

Conductor Fracture

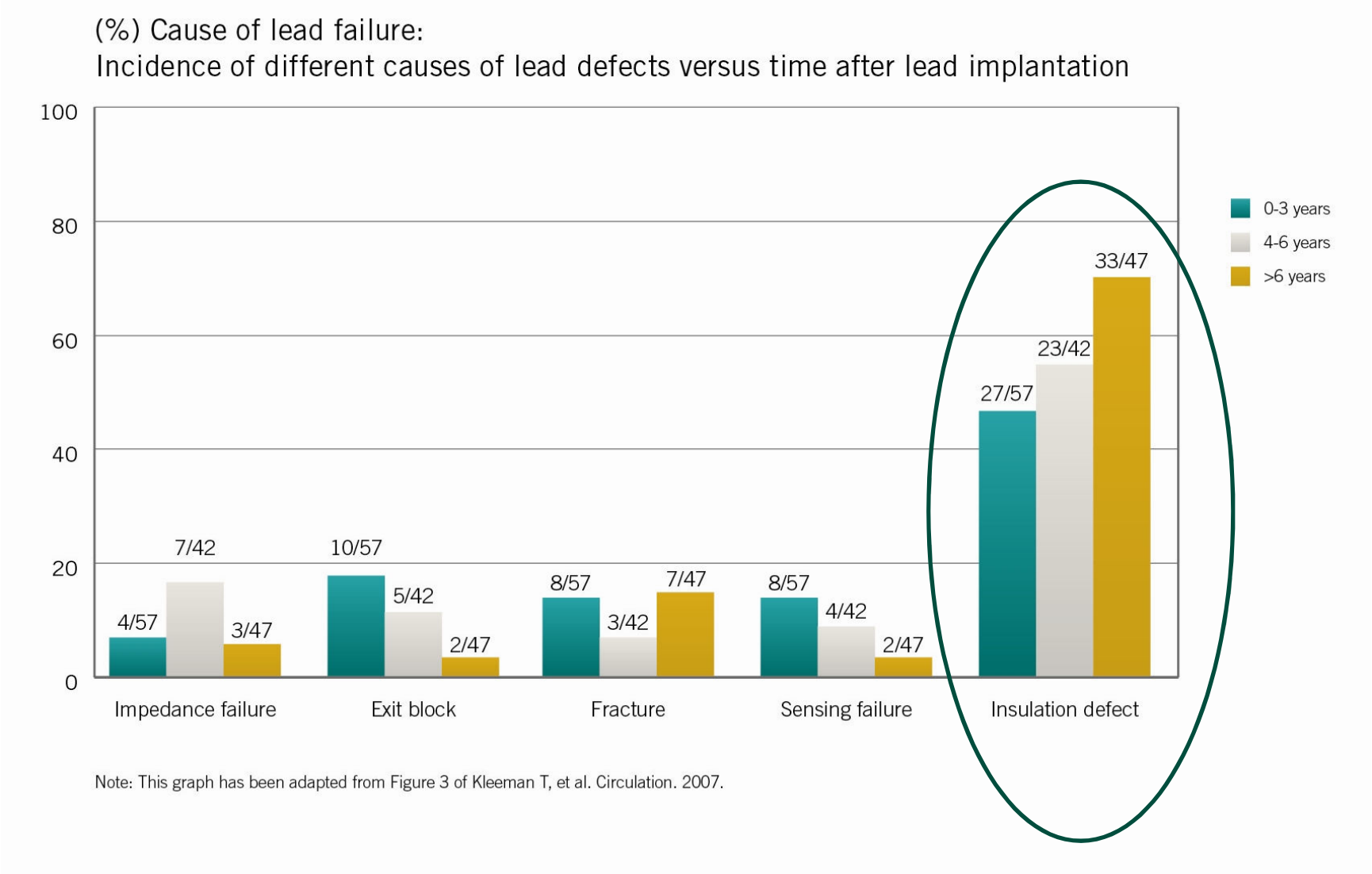
- A break within a lead conductor (includes connectors, coils, cables and/or electrodes)
- Mechanisms include: clavicular crush, pocket fracture, intravascular fracture

Insulation Breach

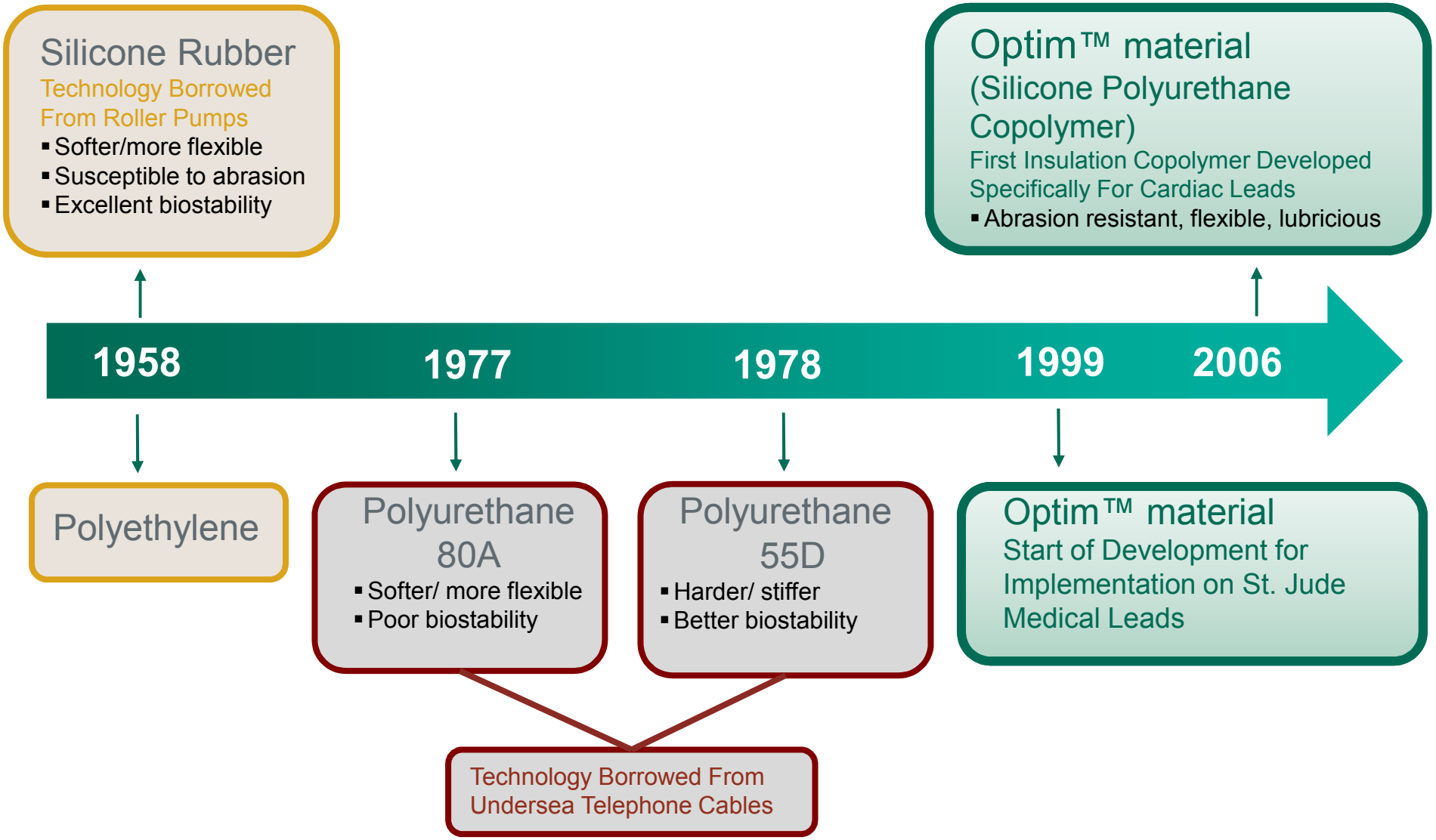
- A disruption or break in lead insulation
- Mechanisms include insulation breach due to:
  - External interactions: lead-to-can, lead-to-lead, clavicular crush, or contact with anatomical structures
  - Internal interactions: Conductor-to-insulation
- Externalized conductors – may be a result of external or internal interactions

Insulation Failure

Most Common Industry-Wide Lead Failure[1]

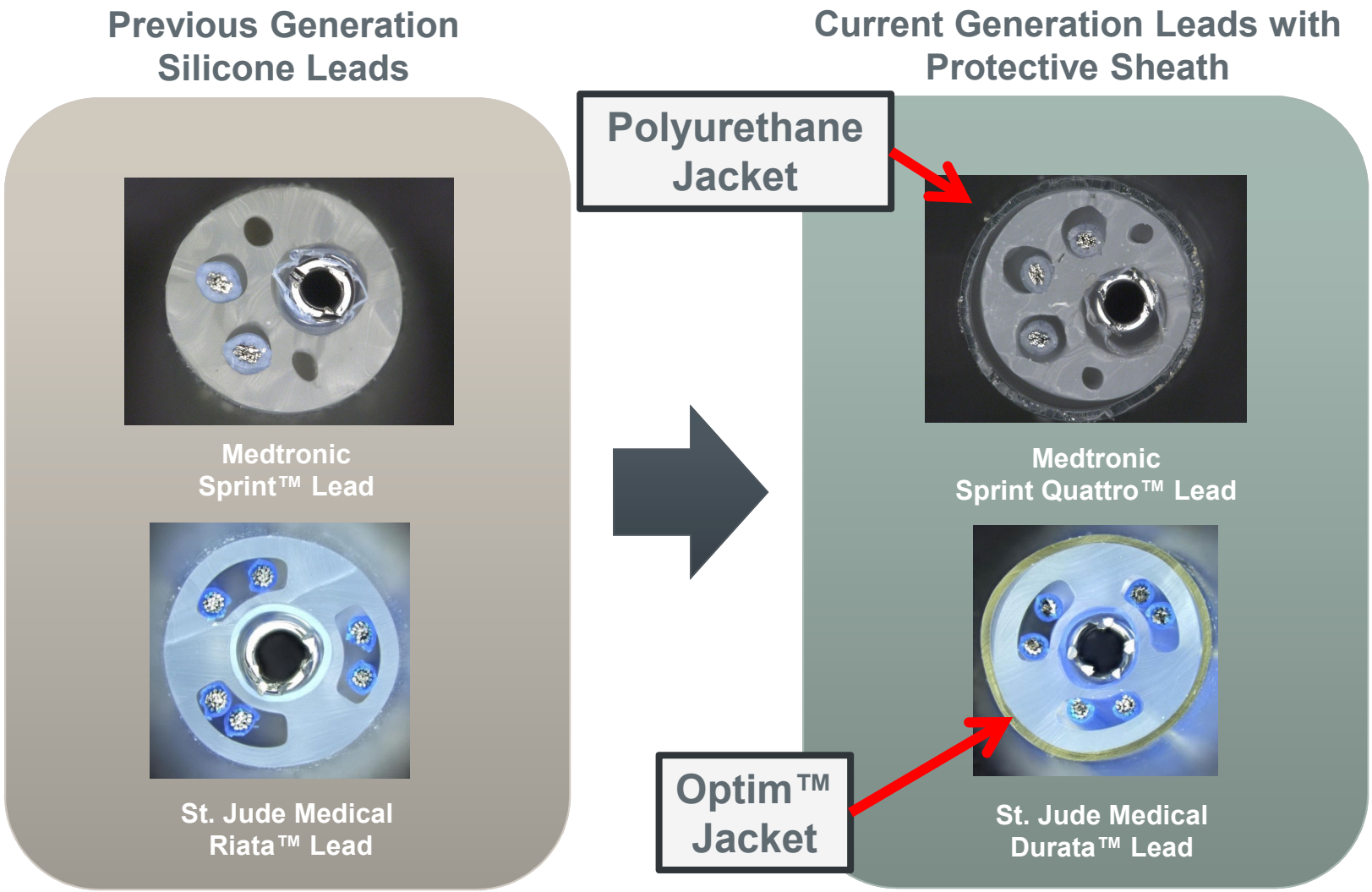


Lead Insulation Timeline



Insulation Failure

Adding a *protective insulation jacket* has resulted in a large reduction in all cause insulation failures compared to early generation silicone ICD leads



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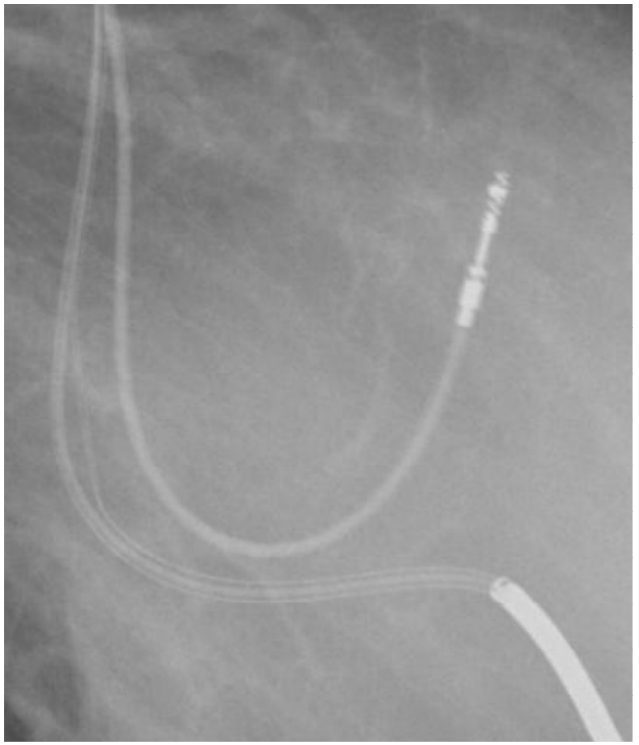
What Are Externalized Conductors?

Definition:

- The appearance on x-ray or fluoroscopy of conductors outside of the lead body due to an abrasion-related breach of the outer insulation

Clinical Presentation: Visual vs. Electrical

- Externalized conductors have been observed in SJM Riata™ and Riata™ ST silicone leads
- Most externalized conductors present as an observation on X-ray or fluoroscopy without functional abnormalities due to the ETFE coating



Multiple Studies Show That Externalized Conductors Are More Common in 8F Models Compared to 7F, Even When Accounting For Implant Duration

Published literature

Studies demonstrating rates of externalized conductors in 7F and 8F models:

		Riata™ (8F) Silicone	Riata™ (7F) Silicone
Author/ Study	Patients Screened	Externalized Conductors	Externalized Conductors
SJM Riata™ LES	724	24.0%	9.3%
Abdelhadi et al.[2]	110	32.1%	3.4%
Larsen et al.[3]	298	21.4%	5.5%
Theuns et al.[4]	1029	21.4%	8.0%
Kodoth, et al.[5]	165	26.9%	4.6%
Erkapic, et al.[6]	357	2.6%	0.9%
Parvathaneni et al.[7]	87	37.8%	10%

The Majority of Leads with Externalized Conductors Do NOT Exhibit Functional Abnormalities

SJM returned leads analysis

- The overwhelming majority of leads returned with externalized conductors have not had electrical abnormalities as a result of externalized conductors

Published literature

- Multiple studies have shown no correlation between externalized conductors and electrical abnormalities[3,8,9,10,11]
  - "From our study and others, it is clear that there is a rate of electrical failure that is distinct from structural failure." -Parkash, et al.[11]
    "Prevalence of externalized cables in St. Jude Riata family ICD leads... did not impact electrical lead integrity in majority probably because externalized cables remained insulated by ethylene tetrafluoroethylene" -Kumar, et al.[10]

ETFE Conductor Cable Insulation provides redundant insulation

- Ethylenetetrafluoroethylene (ETFE) insulation
  - Is a polymer coating applied to the outer surface of defibrillation lead conductor cables across industry
  - Provides adequate dielectric strength for the lead to continue to function normally without the silicone covering
  - ETFE coated cables have undergone the full suite of biocompatibility tests as is typical for other blood tissue contacting materials
- ETFE coating is extremely resilient to cardiac motion, as confirmed by standardized 10 year simulated tests, and have strong abrasion resistance
- Testing of ETFE coated conductors demonstrated that externalized cables with compromised ETFE continued to provide sufficient insulation to effectively deliver HV therapy, even after 100 shocks[12]
- There have been no reports of failure to pace or deliver a shock that have been solely attributable to the presence of an externalized conductor

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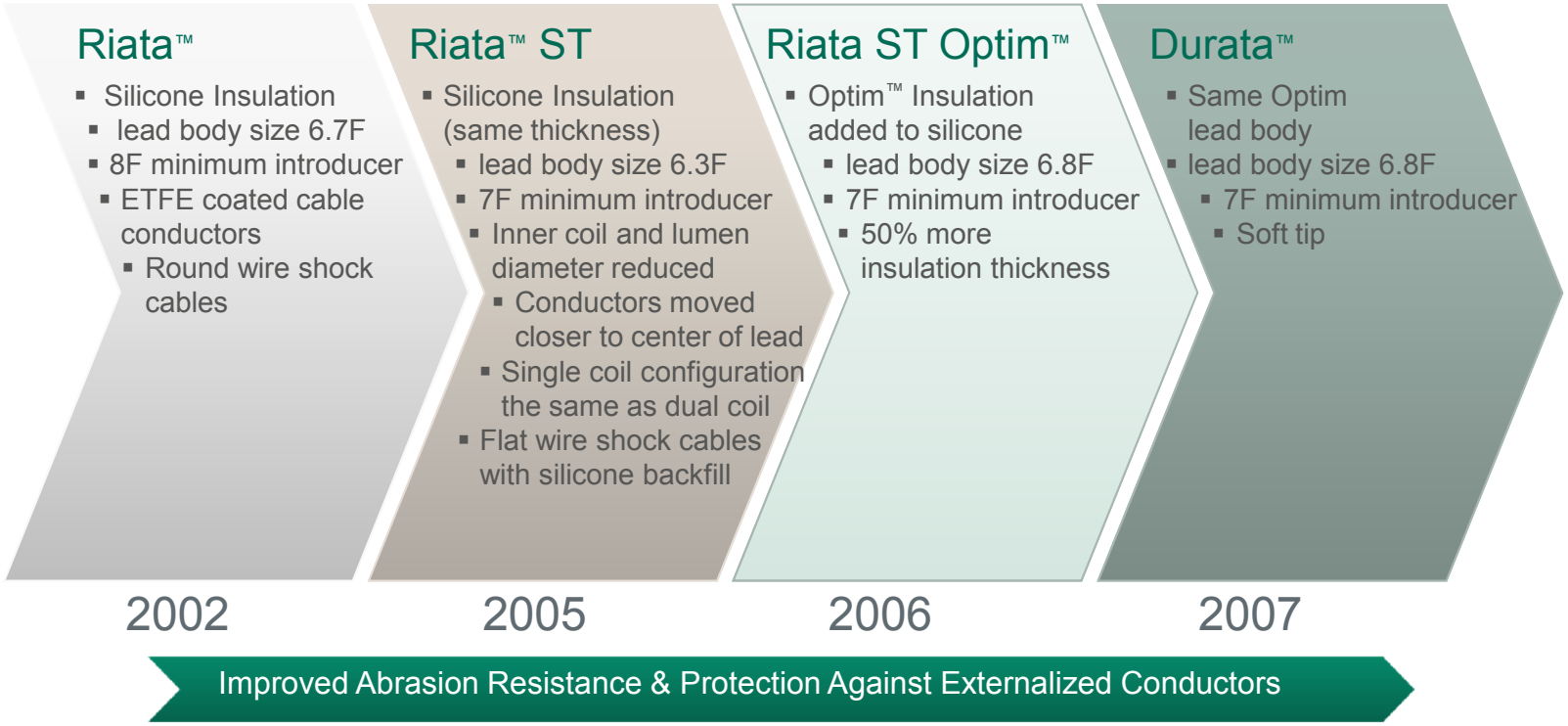
Why Has the Performance of Newer Generation Leads Improved?

Lead Design Evolution Overview

- Extensive lead design improvements have been made in newer generation leads
- Optim insulation was introduced in 2006
  - The first and only insulation (silicone and polyurethane copolymer) designed specifically for cardiac leads

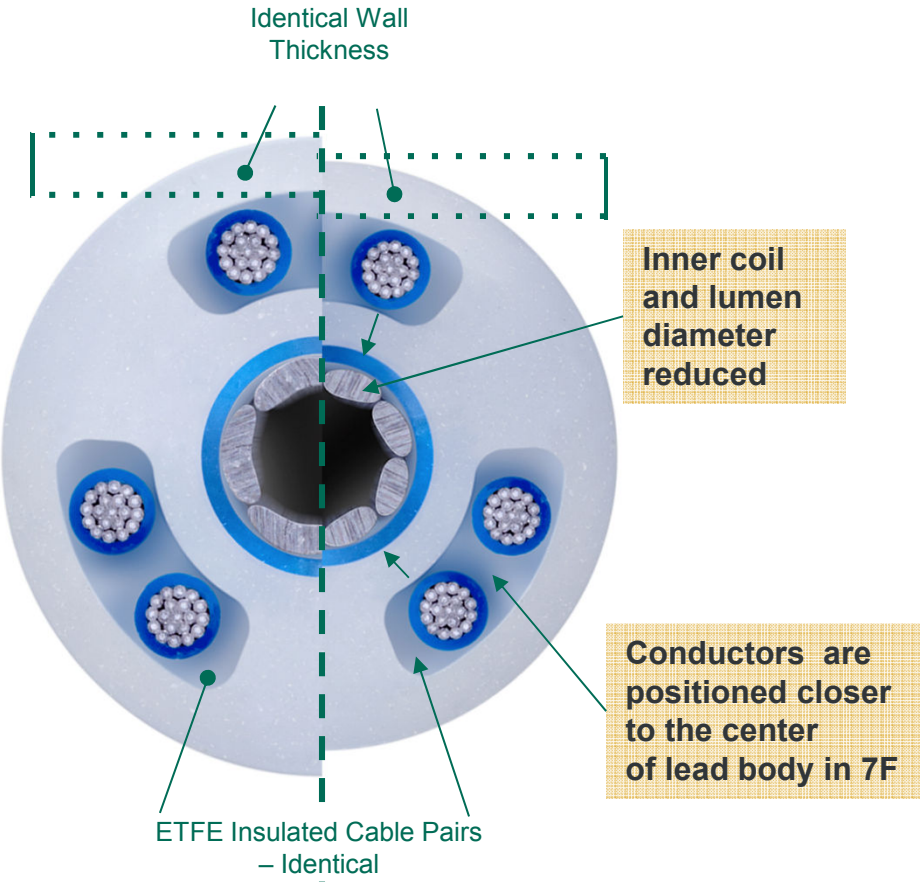


Riata™ 8F Silicone to 7F Silicone Lead Design Improvements

- Conductors closer to the center of the lead body in 7F compared to 8F Riata™ silicone leads
  - Reduces tension on conductors and risk of externalized conductors[13]

- Same in 7F and 8F Riata silicone leads

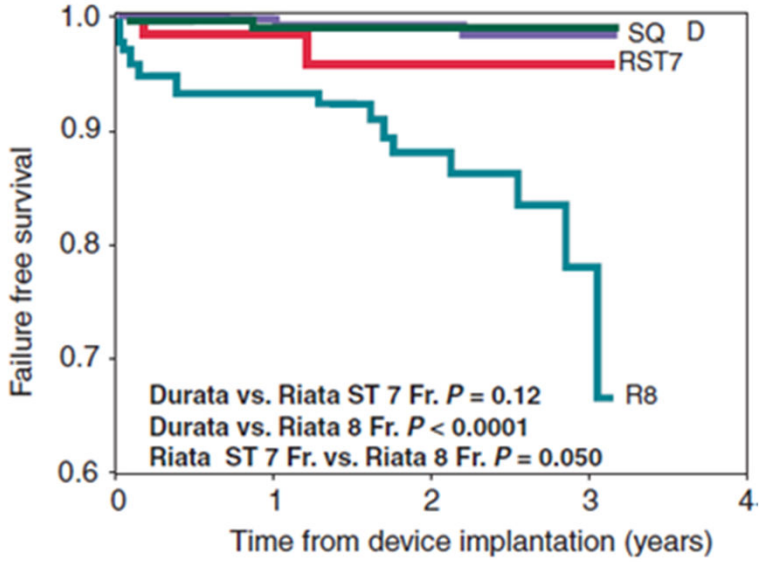
- Reduced diameter in 7F compared to 8F leads



Design Improvements in Riata™ ST Silicone

Comparable performance to St. Jude Medical Durata™ lead

- The University of Pittsburgh Medical Center retrospectively analyzed the failure rates and failure-free survival of Durata Optim™ insulated leads (N = 828), Riata™/Riata ST silicone leads (N = 627) and Quattro™ (N = 1,020) at the hospitals of the University of Pittsburgh Medical Center[14]
  - Lead failure was defined as electrical malfunction or abnormality resulting in lead extraction or replacement with a new ICD lead, excluding dislodgements or perforations
- Riata ST silicone lead vs. Durata lead vs. Sprint Quattro lead
  - The Riata ST silicone lead survival was comparable to that of the Durata lead (p = 0.12)
- Riata silicone lead vs. Riata ST silicone lead
  - 7 Fr. Riata ST lead survival was significantly better compared to that of the 8 Fr. Riata lead (p=0.050)



Sprint Quattro (SQ)	1020	820	660	465
Durata (D)	828	684	491	290
Riata 8 Fr. (R8)	472	318	279	236
Riata ST 7 Fr. (RST7)	155	98	79	60

Design Improvements in Riata™ ST Silicone

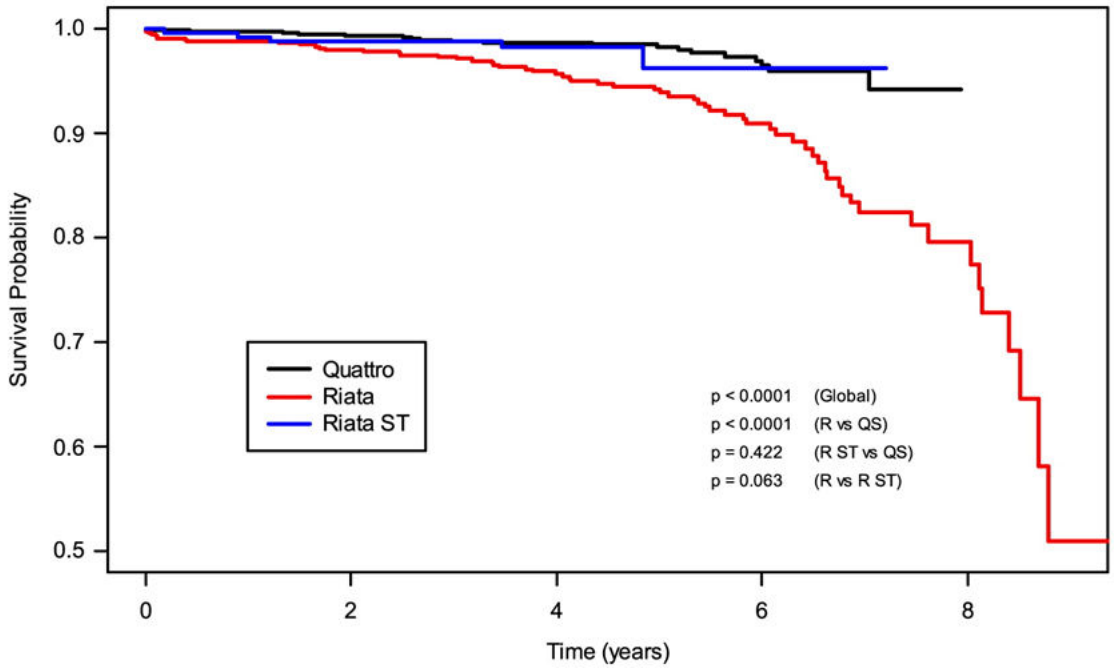
Comparable performance to Medtronic Sprint Quattro™ lead

- A prospective multicenter (7 sites) independent analysis was conducted to compare the survival of St. Jude Medical Riata™ silicone leads (N = 774) and Riata ST silicone leads (N = 307) to Medtronic Quattro™ Secure leads (N = 1668)[2]

- Riata ST 7F silicone lead survival was comparable to that of Medtronic Quattro leads (p = 0.422)[2]

- Riata ST lead failure (electrical malfunction): 0.40% per patient year vs. Quattro lead failure: 0.43% per patient year[2]

All-cause failure-free survival curves

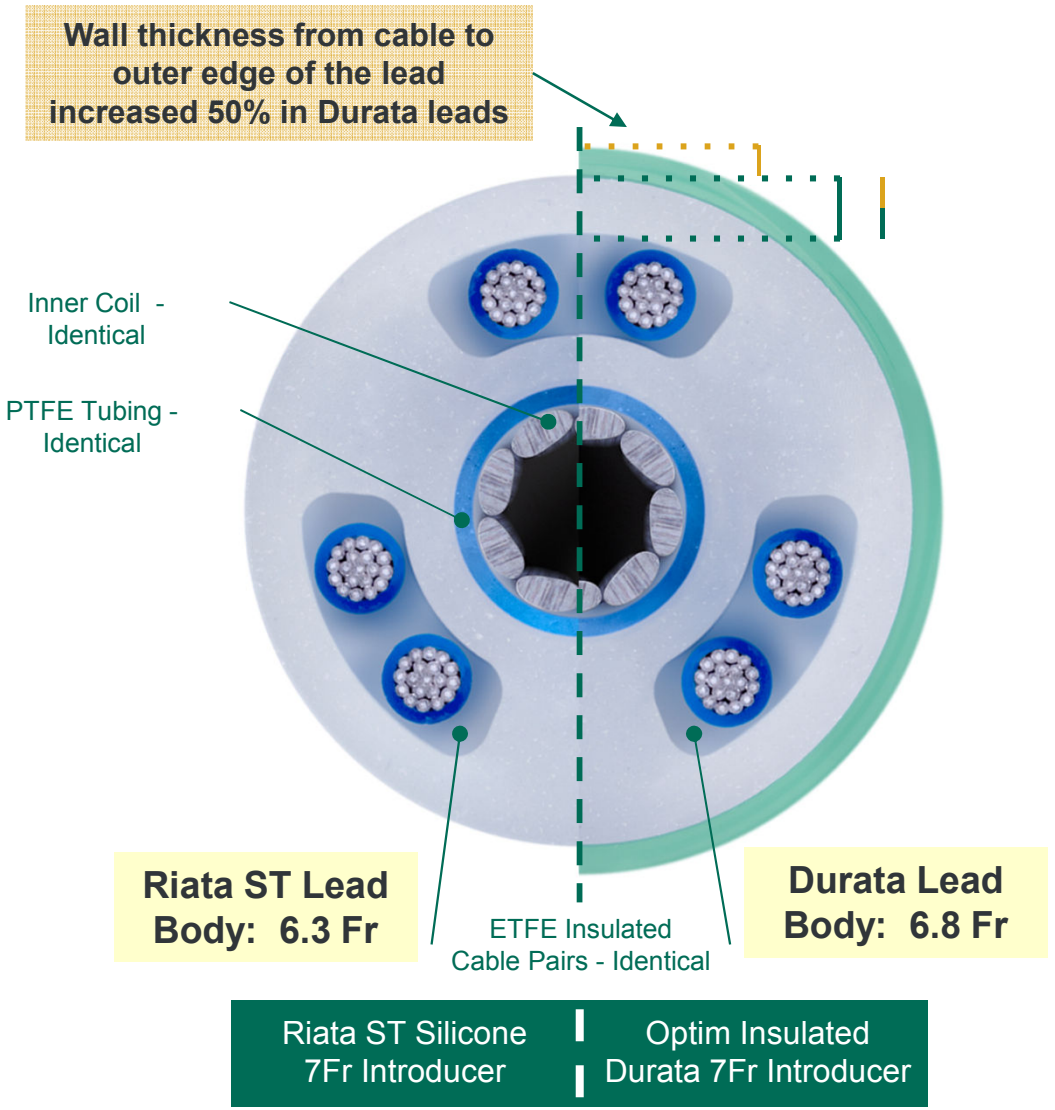


Optim™ Insulated Lead Design Improvements

Differences Between Riata™ ST Silicone and Optim™ Insulated Durata™ Leads

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

- 50x more abrasion resistant than silicone[15]
- Greater lubricity between Optim insulation and ETFE than Silicone and ETFE



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Summary of Lead Design Evolution and Differences

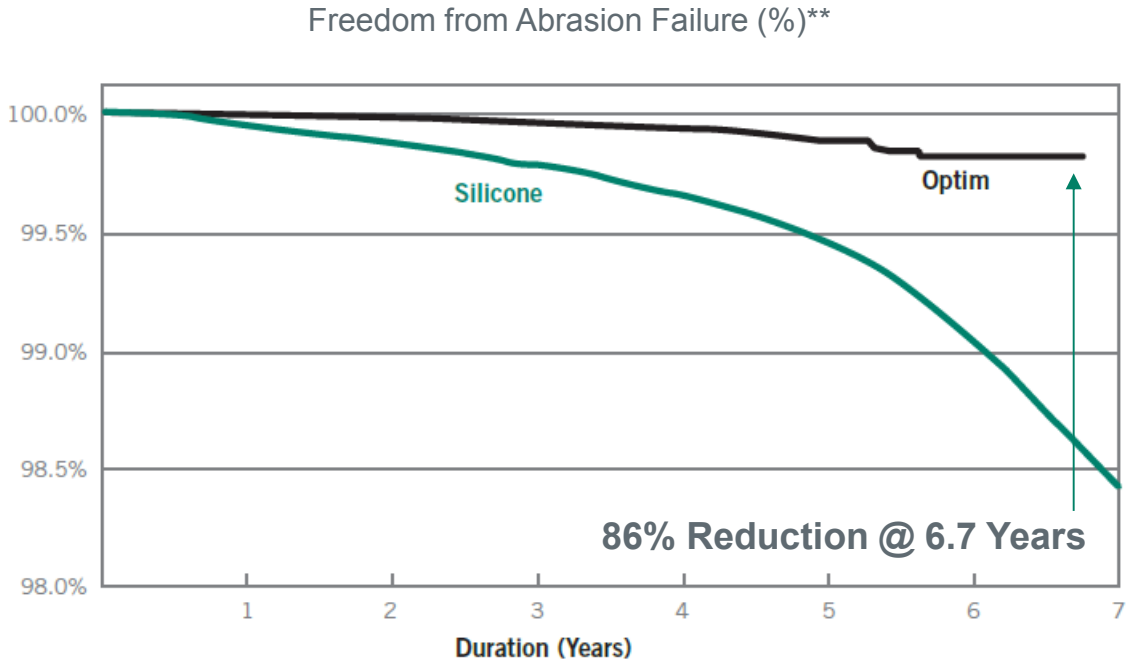
The Durata™ lead is significantly different in design than the Riata™ lead in many components.

Key Design Element	Riata™ lead	Riata™ ST lead	Durata™ lead (Includes Riata ST Optim™ unless noted otherwise)
Lead Body Insulation Thickness	Identical in Riata and Riata ST		50% increase relative to Riata and Riata ST
Lead Body Insulation Material	Silicone Only		Optim sheath (with 50X the abrasion resistance of Silicone) over Silicone
General Lead Body Design	Larger inner center lumen	Smaller inner central lumen	
Inner Coil Design	Larger diameter 5 filar coil	8 filar coil with smaller diameter stylet lumen and smaller diameter	
Inner Coil Profile	Round wire	Flat wire in all Passive models; Round wire in Active models	
Single Coil Lead Body Design	Three total lumens (two cable & 1 coil)	Four total lumens (3 cable & 1 coil)	
Distal Cable Terminations at Electrodes	Precise cable alignment during manufacturing required with a potential to introduce cable tension or compression		Process technology change allowing cables to reside in a neutral stress state
Shock Coils	Round wire with no silicone backfill	Flat wire shock coil with a unique process that fills gaps with Silicone	
Use of PTFE	Insulation tubing over inner coil for helix performance and insulation integrity		
Use of ETFE	Insulation coating over each cable for insulation integrity		
Connectors	Standard DF-1 and IS-1 connectors with Silicone legs		Standard IS-1 and DF-1 lead connectors plus DF4 connector added; full Optim insulation also added to IS-1 and DF-1 connector tails
Cable Conductors	MP35N® DFT material*		Low Titanium (LT) material removes material defects for better fatigue life (10X) on 1X19 MP35N-LT DFT
Distal tip	Metal collar		Atraumatic soft silicone rubber tip (Not in Riata ST Optim)
RV Shock Coil	Straight		Curved slightly during manufacturing (Not in Riata ST Optim)

* MP35N is a trademark of SPS Technologies, Inc

Performance Improvements Due To Optim™ Insulation
Reduction in Abrasion Failures

- Post-market surveillance of Optim insulated defibrillation leads at 6.7 years after market release*:
  - **99.805% abrasion-free**
    - **86% reduction in abrasion** rates compared to Riata™/ Riata ST™ silicone leads (p<0.0001)
    - Optim insulated leads provide significant protection against abrasion failures compared to silicone insulated leads



Complaints and Returns Data through August 31, 2013. Data on file, St. Jude Medical, 2013.[16]

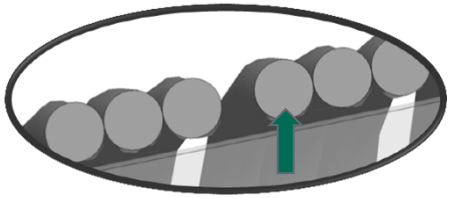
*U.S. Data Only. Failure is defined as a reported or confirmed case of abrasion.

**Kaplan-Meier/Log-Rank analysis takes into account differences in follow-up duration between the lead models

Additional Design Improvement
Flat Wire Shock Coils With Silicone Backfill

- Flat wire shock coils with silicone backfill designed to prevent tissue in-growth were introduced in 7F Riata™ silicone leads and replaced the round wire shock coils of 8F leads
- Distributes pressure evenly along the length of the shock coil and eliminates movement of the shock coil wires relative to the lead body
- Based on the product performance report, these additional design improvements resulted in a 94% reduction in abrasion under the shock coil[16]

Round Wire Cross Section

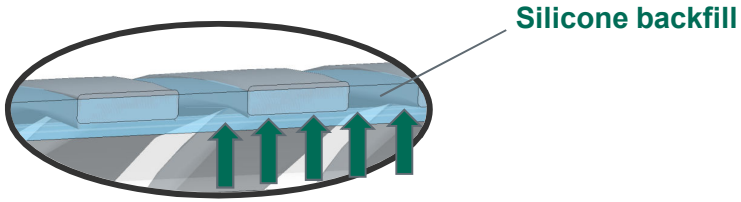


Single Point Load

Exterior View

Riata Silicone 8F

Flat Wire Cross Section

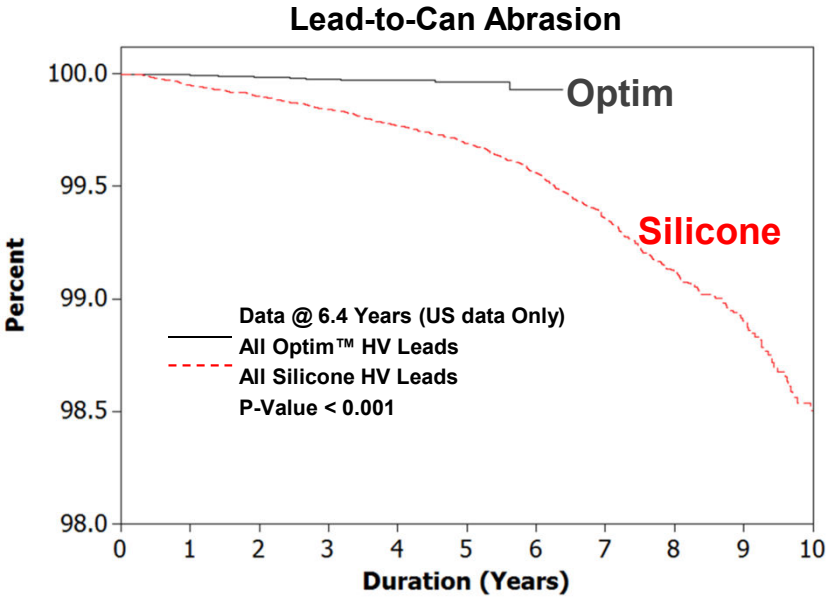


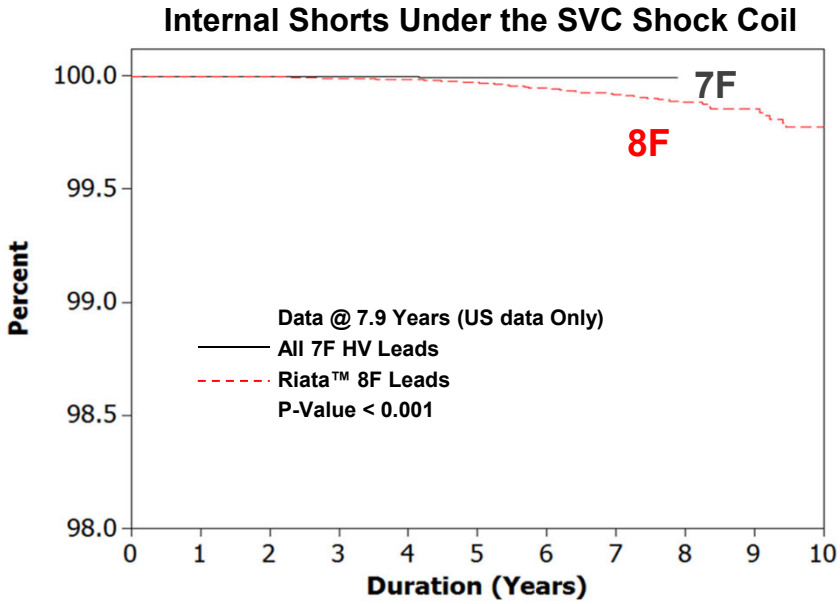
Distributed Load

Exterior View

Riata™ ST Optim (7F) & Durata™

Lead-to-Can Abrasion versus Internal Abrasion





Lead-to-Can Abrasion		
SJM Leads	**Worldwide Sales**	**Total Incidence**
Silicone Models (Riata™ and Riata™ ST)	226,700	0.581%
Optim™ Models (Riata ST Optim & Durata™)	425,300	0.030%

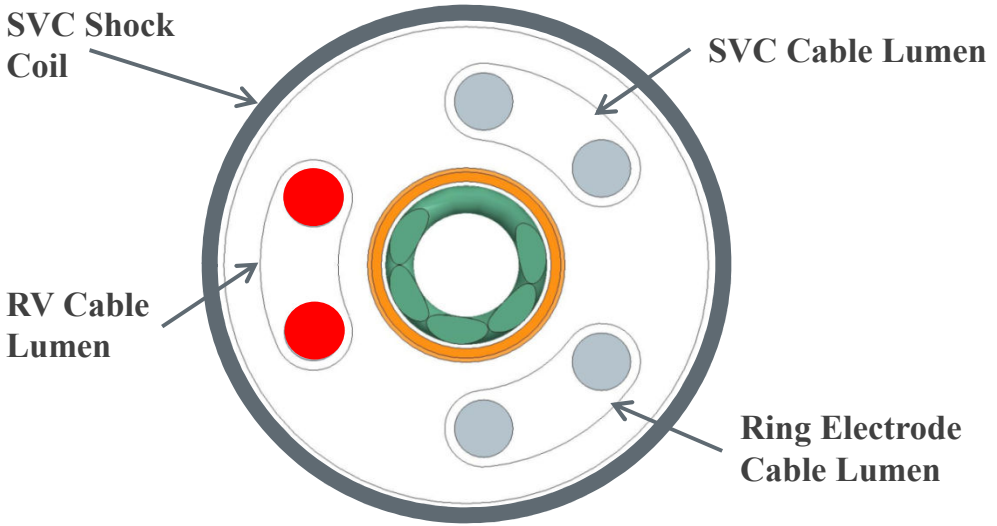
Internal Shorts Under the SVC Shock Coil		
SJM Leads	**Worldwide Sales**	**Total Incidence**
8F Riata	156,100	0.0546%
7F Models (Riata ST, Riata ST Optim & Durata)	495,900	0.0034%

Kaplan-Meier/Log-Rank analysis takes into account differences in follow-up duration between the lead models

Calculated from Complaints and Returns Data Included in the SJM Product Performance Report (Dec 2013).

SVC Under the Shock Coil Abrasion Shorts

When inside-out abrasion occurs underneath an SVC shock coil, a risk for compromised HV therapy exists only when the RV cables short circuit against the SVC shock coil (no compromise of HV therapy can occur underneath the RV shock coil because the SVC cable is not present).

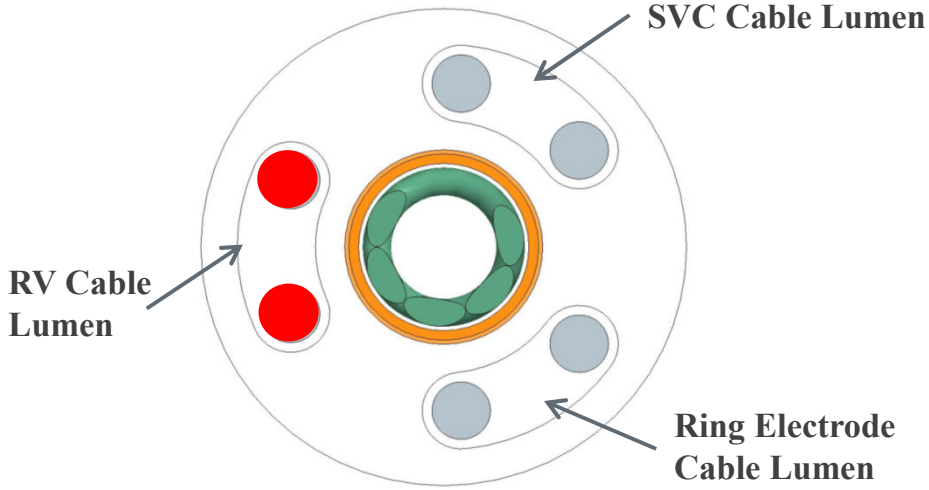


Internal Shorts Under the SVC Shock Coil (Worldwide Data Confirmed by Returned Product Analysis)			
SJM Leads	**Worldwide Sales**	**Total Incidence**	**HV Therapy Potentially Affected**
8F Riata™	156,100	0.0546%	0.0315%
7F Models (Riata™ ST, Riata™ ST Optim™ & Durata™)	495,900	0.0034%	0.0028%

Calculated from Complaints and Returns Data Included in the SJM Product Performance Report (Dec 2013).[16]

Lead-to-Can Abrasion

When lead-to-can abrasion occurs, a risk for compromised HV therapy exists only when the RV cables are involved and the ETFE coating is also breached.



Lead-to-Can Abrasion (Worldwide Data Confirmed by Returned Product Analysis)			
SJM Leads	**Worldwide Sales**	**Total Incidence**	**HV Therapy Potentially Affected**
Silicone Models (Riata™ and Riata™ ST)	226,700	0.578%	0.092%
Optim™ Models (Riata ST Optim & Durata™)	425,300	0.030%	0.005%

Calculated from Complaints and Returns Data Included in the SJM Product Performance Report (Dec 2013).[16]

Insulation Failures Rates Based on Failure Mechanism

Insulation Failure Mechanism	Abrasion Source	Riata™ Silicone 8F Worldwide Incidence Rate (N = 156,100)	Riata™ ST Worldwide Incidence Rate (N = 70,600)	Riata ST Optim™ & Durata™ Worldwide Incidence Rate (N = 425,300)
Intravascular – External Abrasion (e.g., Lead-to-Lead, Lead-to-Anatomical Structure)*	External Abrasion	0.28%	0.24%	0.011%
Externalized Conductors – External Source of Abrasion**	External Abrasion	0.25%	0.12%	0.004%
Lead-to-Can Abrasion*	External Abrasion	0.60%	0.53%	0.030%
Insulation Damage (e.g., Clavicular Crush, Suture Sleeve Tie Down)*	External Abrasion	0.07%	0.04%	0.013%
Intravascular – Inside Out Abrasion*	Internal Abrasion	0.30%	0.14%	0.0002%***
Externalized Conductors – Inside-Out**	Internal Abrasion	1.62%	0.61%	0.0002%***
Internal Abrasion short under RV shock coil*	Internal Abrasion	0.07%	0.02%	0.003%
Internal Abrasion short under SVC shock coil*	Internal Abrasion	0.05%	0.004%	0.003%

* Determined by returned product analysis.

** Includes cases determined by returned product analysis as well as cases identified only by fluoroscopy or visualization of explanted leads.

*** The Riata ST Optim lead design included short lengths (0.5” nominal) adjacent to the shock coils which were not covered by the Optim sheath. These values reflect a total of two cases of silicone insulation breach due to inside-out abrasion in the short region not protected by Optim.

As a result of continuous improvements since the Riata ST Optim lead was introduced, Durata leads manufactured today have no significant non-Optim regions adjacent to the shock coils.

Product Performance Report ,St. Jude Medical, Dec 2013.

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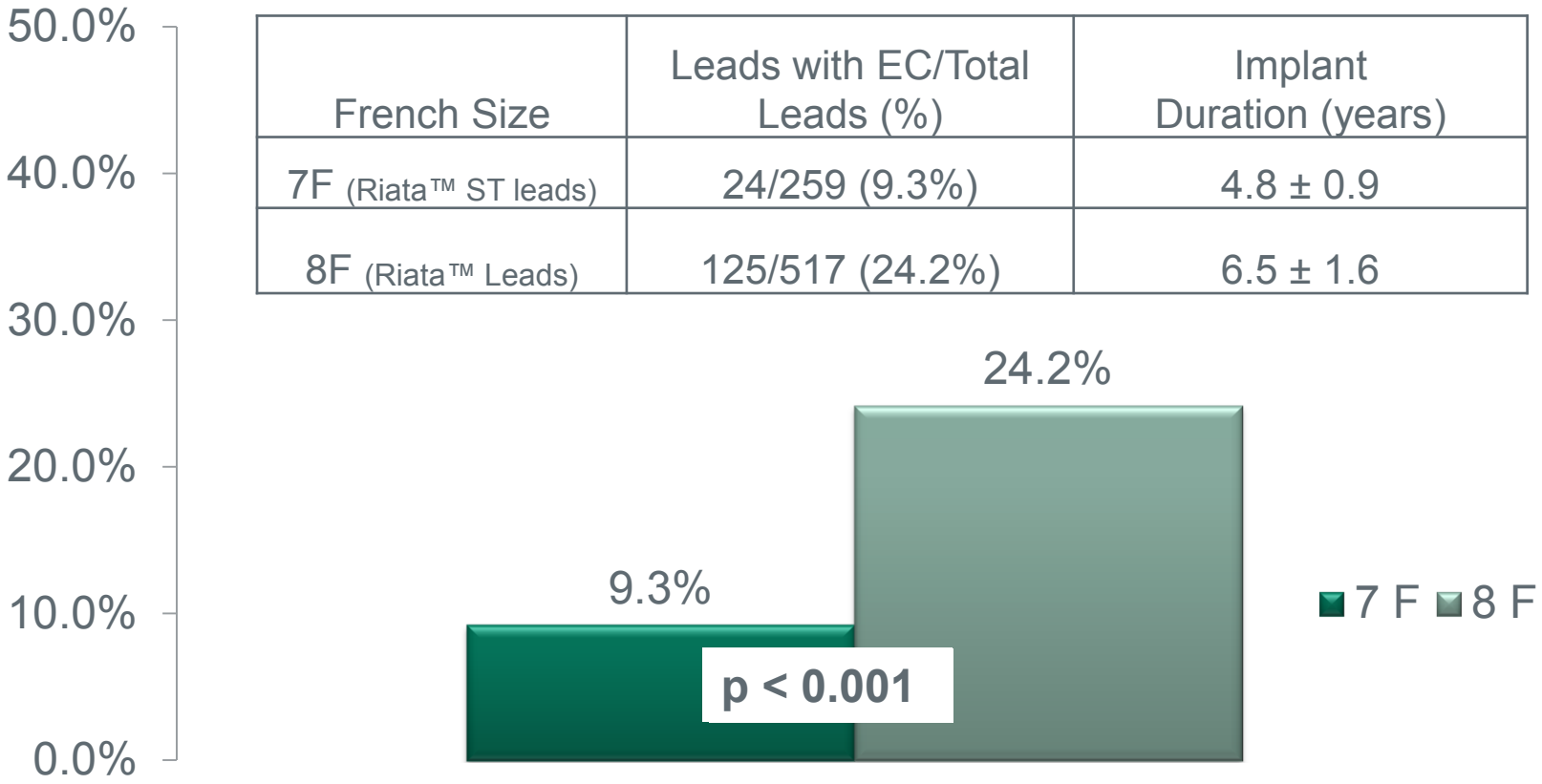
Riata™ Lead Evaluation Study

- Prospective, multi-center, international study
- Study Objectives
  - Phase I: To determine the prevalence of externalized conductors in patients implanted with Riata and Riata ST silicone leads
  - Phase II: To determine the incidence of electrical malfunction in leads with and without externalized conductors

Prevalence of Externalized Conductors in the Total Cohort

Overall prevalence of externalized conductors in 7F leads is significantly lower than 8F leads ($p < 0.001$)[17]

French Size	Leads with EC/Total Leads (%)	Implant Duration (years)
7F (Riata™ ST leads)	24/259 (9.3%)	4.8 ± 0.9
8F (Riata™ Leads)	125/517 (24.2%)	6.5 ± 1.6



NUMERATOR: Total number of leads with externalized conductors
DENOMINATOR: Total number of leads

Prevalence of Externalized Conductors: Leads with Implant Duration < 6 Years

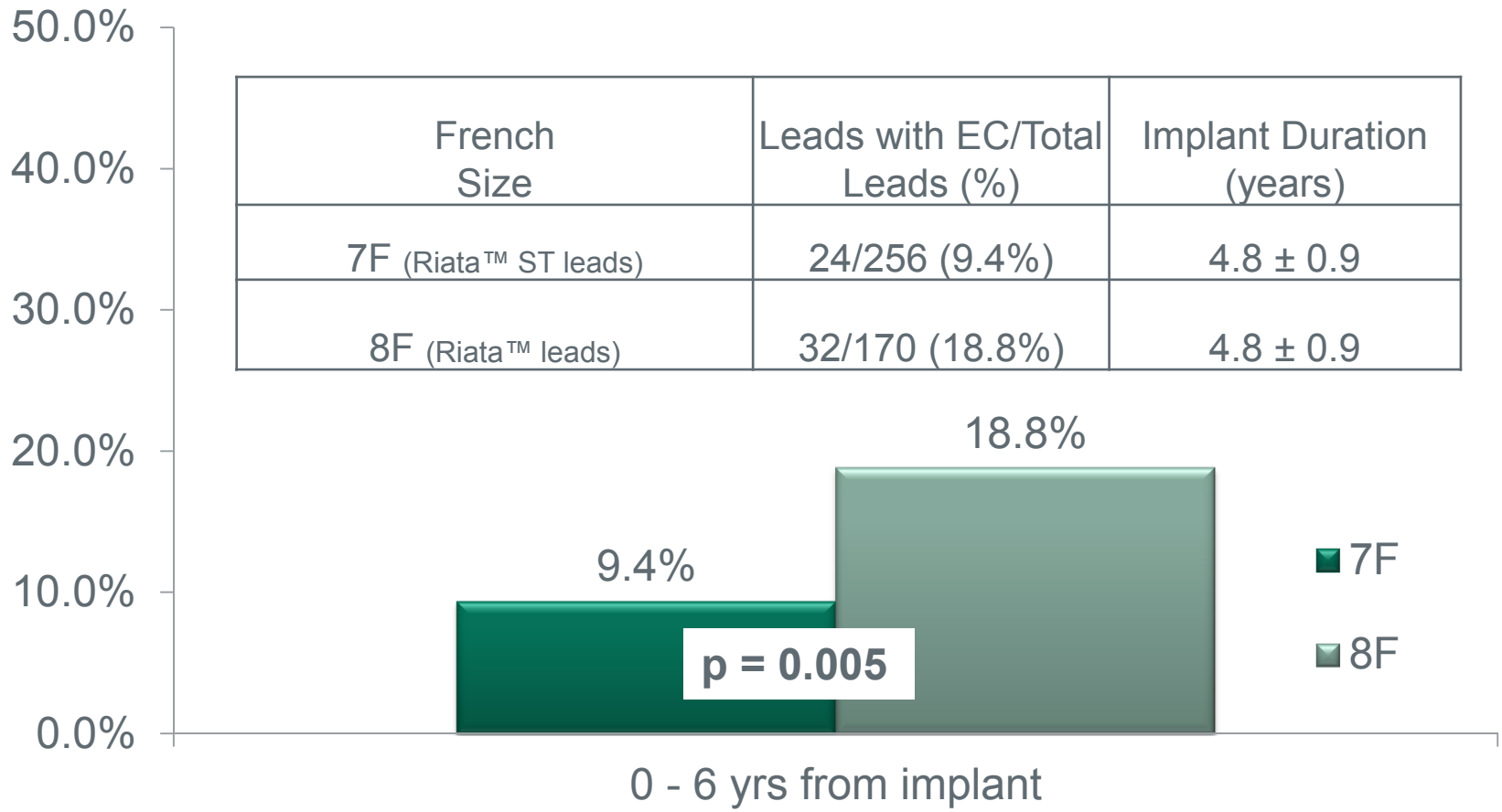
To account for differences in implant duration between the 7F and 8F lead cohorts, an analysis was performed for leads with implant durations up to 6 years (includes 256 of 259 7F leads)[17]

French Size	Number of Leads	Implant Duration (years)*
7F (Riata™ ST leads)	256	4.8 ± 0.9 years
8F (Riata™ leads)	170	4.8 ± 0.9 Years

* Difference in implant duration not significant (p = NS)

Prevalence of Externalized Conductors: Leads with Implant Duration ≤ 6 Years[17]

French Size	Leads with EC/Total Leads (%)	Implant Duration (years)
7F (Riata™ ST leads)	24/256 (9.4%)	4.8 ± 0.9
8F (Riata™ leads)	32/170 (18.8%)	4.8 ± 0.9



NUMERATOR: Total number of leads with externalized conductors aged ≤ 6 years
DENOMINATOR: Total number of leads with implant duration ≤ 6 years

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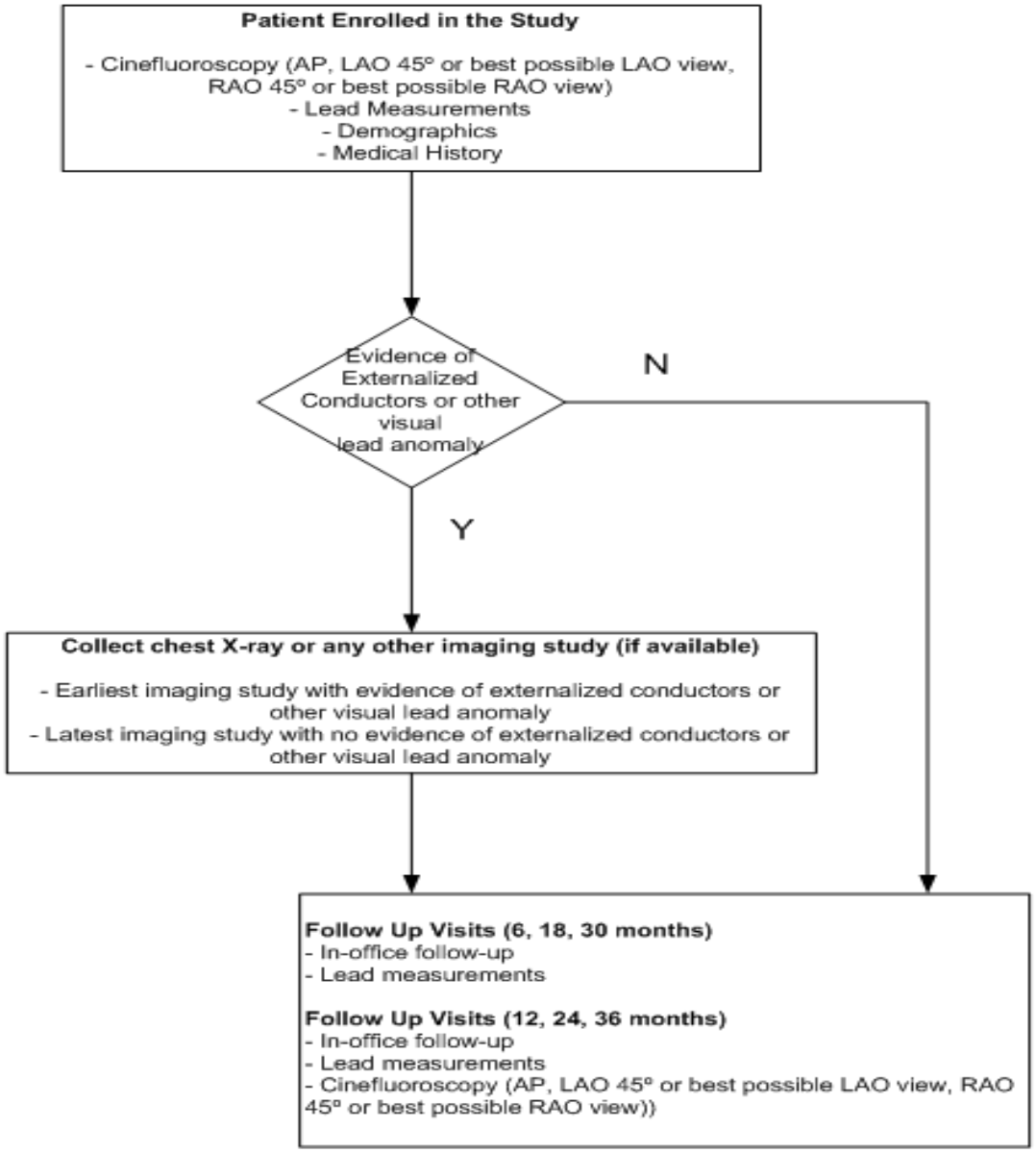
St. Jude Medical Cardiac Lead Assessment Study (CLAS)

Objective:

Evaluate the performance of Riata™, Riata™ ST Silicone, QuickSite™/ QuickFlex™ and Durata™ leads.

Enrollment began: December 2011



Riata™ and Riata™ ST CLAS Summary
Data as of Nov 19, 2013*

- As mentioned in previous slides, the prevalence of externalized conductors (EC) at enrollment (from a total of 776 patients across 23 centers) was significantly lower in 7F Riata ST leads compared to 8F Riata leads (9.3% vs. 24.0%, $p<0.0001$)

- The incidence of new EC at 1 year post-enrollment is 1.4% in 7F leads and 3.9% in 8F leads ($p=0.21$)

- During a mean follow-up period of 16.7 ± 5.2 months, a total of 14 leads (5 with EC, 9 without EC) were identified as having electrical dysfunction

- There was no significant difference in the proportion of electrical failures in leads with and without EC (3.2% vs. 1.5%, respectively, $p=0.18$), suggesting that electrical dysfunction is not associated with EC

* Reported in the "Focus on Clinical Performance" section of the December 2013 Product Performance Report[16]

Durata™ Lead Fluoroscopy Update: CLAS summary
Data as of Nov 19, 2013*

- The Durata lead family was added to the CLAS registry study in 2013 to determine the prevalence and incidence of lead compromise evidenced by imaging and electrical dysfunction

- In CLAS, there has been no evidence of EC in Durata leads (total of 507 patients implanted with Durata leads at 26 centers underwent fluoroscopic evaluation with a mean implant duration of 3.9 ± 0.8 years)
- In addition, during a mean follow-up period of 3.5 ± 1.8 years, there have been no cases of electrical dysfunction

* Reported in the "Focus on Clinical Performance" section of the December 2013 Product Performance Report[16]

Outline

- Lead design and common mechanical lead failures
- Externalized conductors
  - Clinical presentation, relevance, incidence, and timing
- Why has the performance of newer generation leads improved?
  - Riata™ 8F silicone to Optim™ insulated lead design improvements
  - Summary of design evolution and performance
- Clinical Data and Publications
  - Riata Lead Evaluation Study results
  - St. Jude Medical Cardiac Lead Assessment Study
  - **Riata Silicone Lead Patient Management Recommendations**
  - Combined Optim™ lead registry data
  - ICD leads reliability and survival probability data

Riata™ Silicone Lead Externalized Conductors Patient Management Recommendations

- St. Jude Medical MAB (Nov 2011 Advisory)
  - 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
  - No expert consensus regarding fluoroscopy at the time of pulse generator replacement
- HRS Webinar (Dec 21, 2011) participants' recommendations were similar
- Riata Lead Management Webinar (July 2012) participants' recommendations were similar
- St. Jude Medical MAB (Nov 2012) reaffirmed its previous recommendations
- FDA Safety Communication (August 16, 2012)
  - Physicians should image Riata and Riata ST leads implanted in patients to assess for externalization or other visible insulation abnormalities
  - Other FDA recommendations were consistent with the recommendations in our Nov 2011 advisory
- For updates on programming and alerting considerations, please visit www.riatacommunication.com.

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St. Jude Medical Post-Market Registries

Over 11,000 Optim™ insulated leads are currently enrolled in active monitoring post-market registries and studies with approximately 30,000 lead implant years and **follow-up to date over 5 years**

Registries and Studies	Launched	ICD Leads	Number of Sites	Purpose
OPTIMUM	**August 2006**	**6037** *Durata and Riata ST Optim*	**216**	Prospective, multi-center, actively monitored registry to evaluate the long-term performance of all Optim™ insulated leads
SCORE	**September 2007**	**3481** *Durata and Riata ST Optim*	**58**	Prospective, multi-center, actively monitored, long-term data collection and evaluation registry to evaluate long term performance of CRM devices
SJ4 PAS	**June 2009**	**1743** *Durata DF4*	**58**	Prospective, multi-center, actively monitored study to characterize the chronic performance of the St. Jude Medical SJ4 connector and RV high voltage SJ4 leads

Long term Optim™ High Voltage Lead Function

Combined Registry Data

Data cut off August 31, 2013

For Optim HV leads implanted for over 5 years,
99.7% continue to function normally

No. of leads functioning normally at ≥ 5 years from implant	**1025 /1028 leads (99.7%)**

Optim™ Insulation Registry

Independent Analysis Confirms strong performance of Optim HV Leads

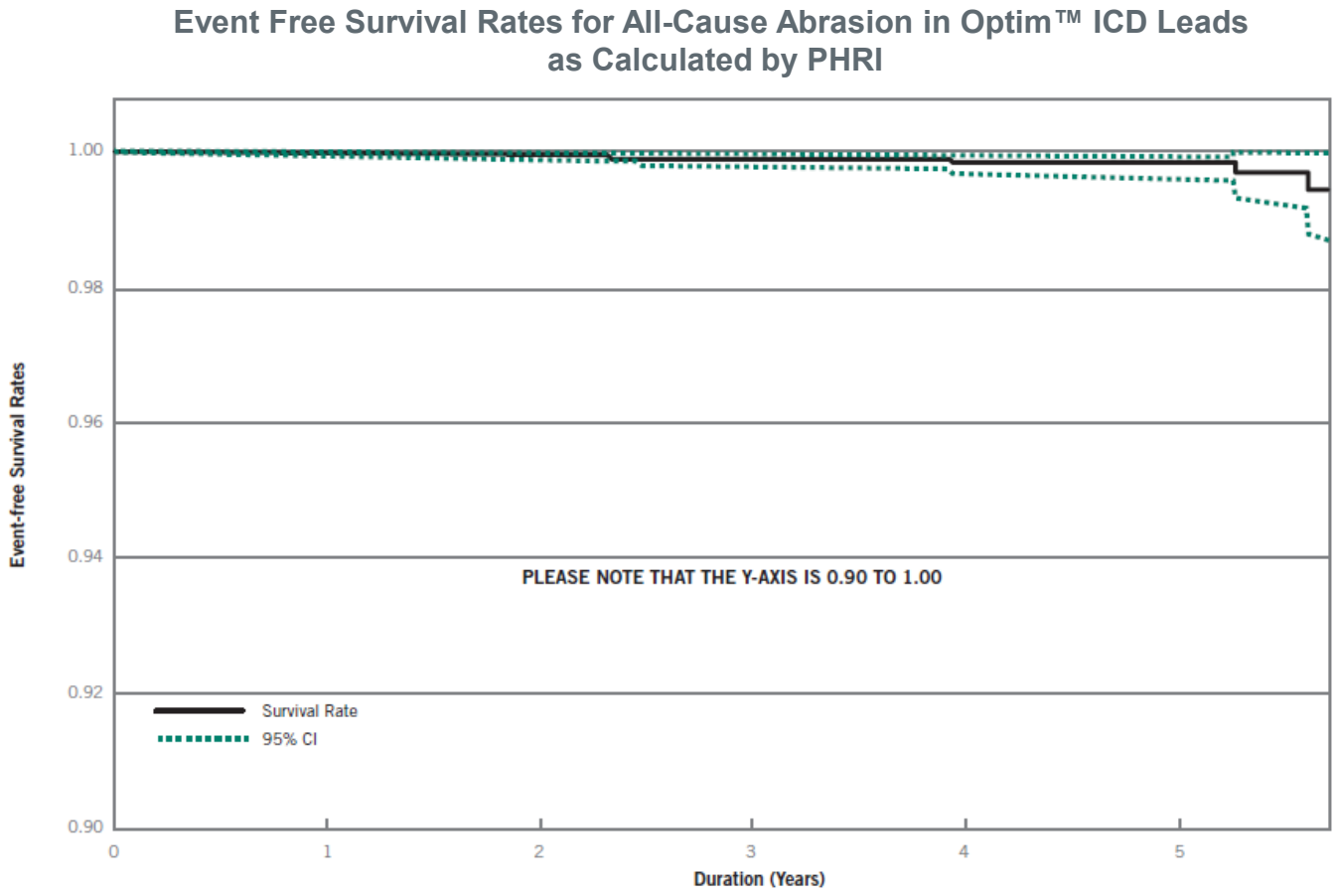
- An Independent analysis by Population Health Research Institute (PHRI) of Durata™ and Riata™ ST Optim leads in actively monitored post market surveillance registries with 11,016 Optim insulated HV leads in approximately 300 centers with nearly six years of follow-up (data through August 31, 2013)[16]

OPTIMUM, SCORE and SJ4	
Freedom from All-Cause Insulation Abrasion (at 5 years)	99.8%
Freedom from All-Cause Mechanical Failures* (at 5 years)	99.3%

*** All-cause mechanical failures include: conductor fracture, insulation abrasion, welds, crimps and bonds.**

Optim™ Insulation Registry Independent Analysis (PHRI)[16]

SJM Post-Market Registries and Studies Data - August 31, 2013 Cutoff Date

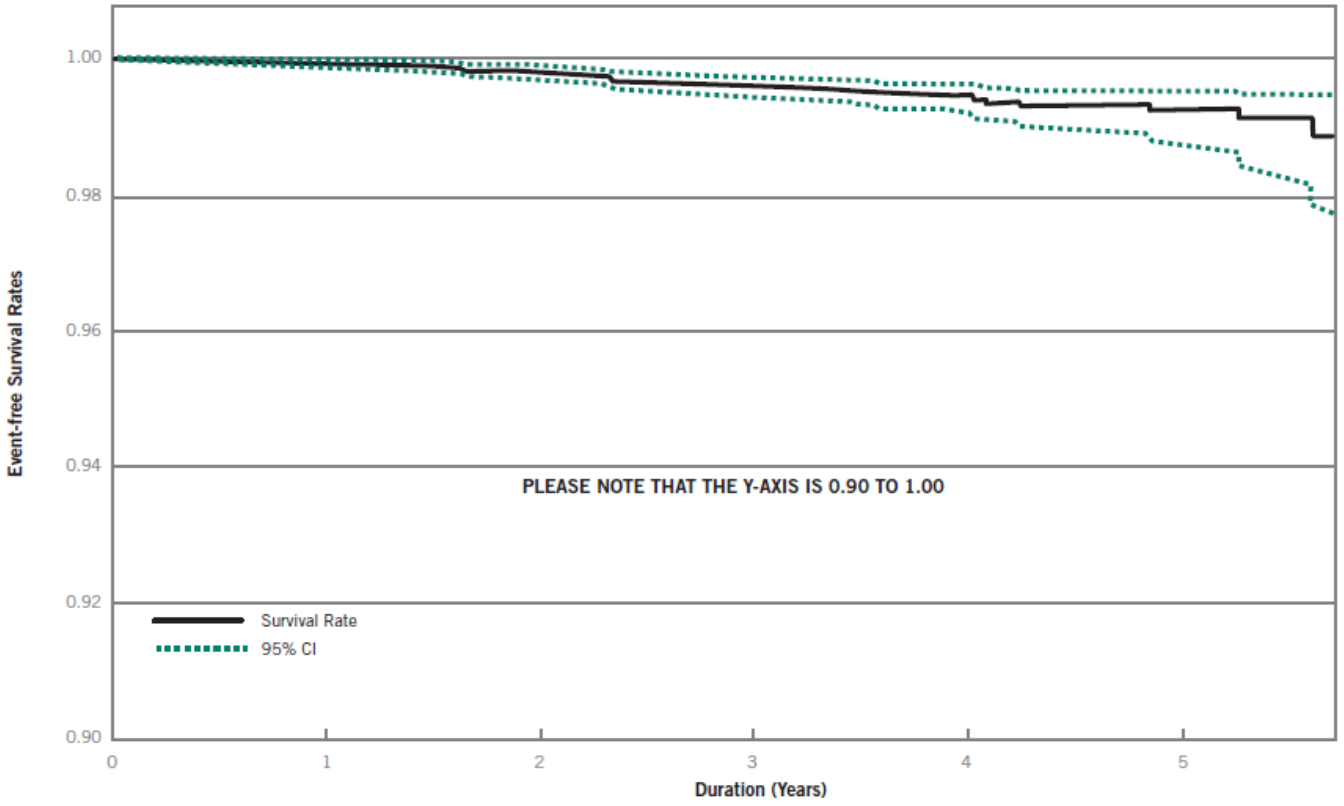


Year	0	1	2	3	4	5
Leads at Risk	11016	9971	8407	6426	3391	1131

Optim™ Insulation Registry Independent Analysis (PHRI)[16]

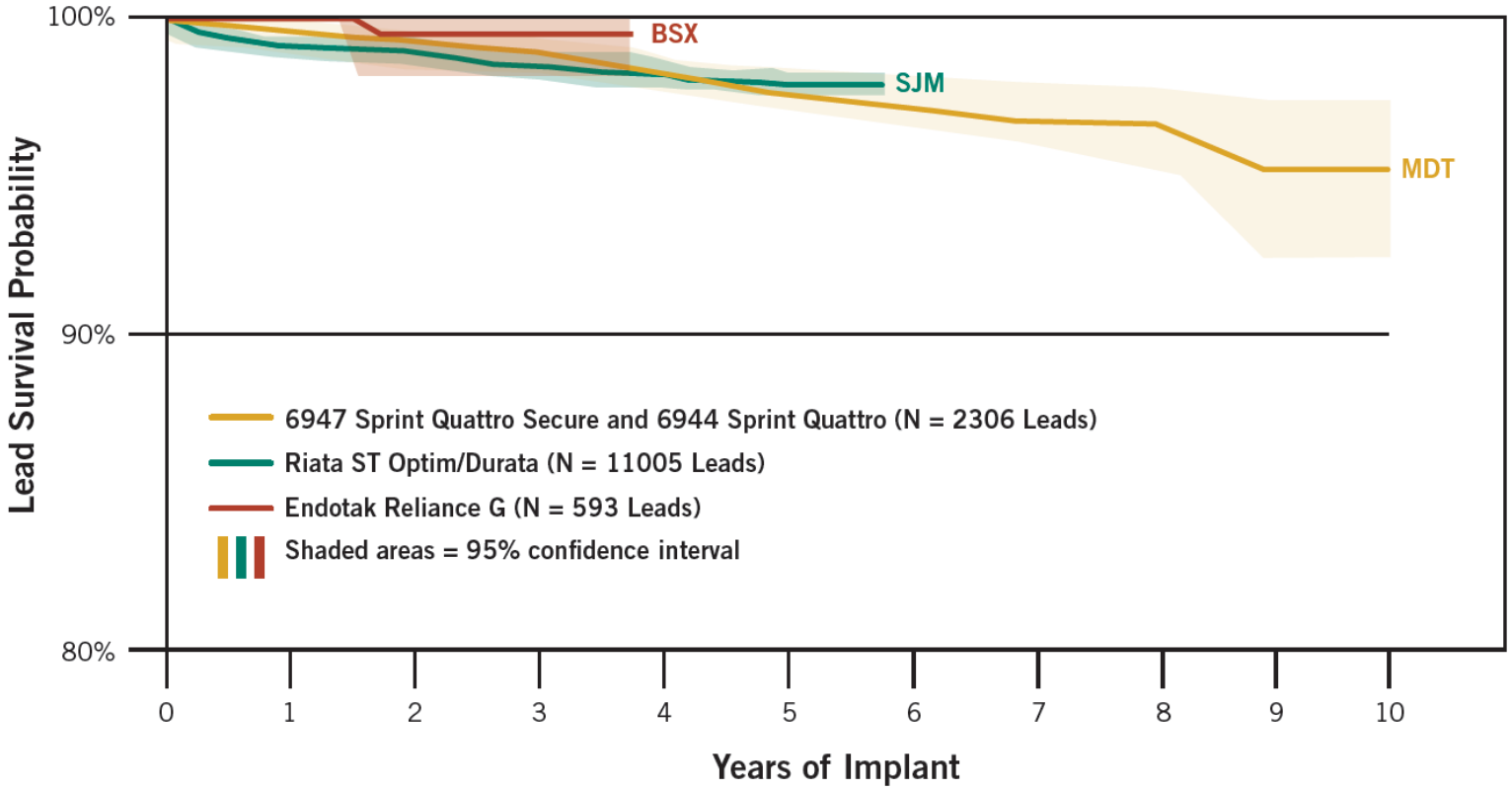
SJM Post-Market Registries and Studies Data - August 31, 2013 Cutoff Date

Event Free Survival Rates for All-Cause Mechanical Failure in Optim™ ICD Leads as Calculated by PHRI



Year	0	1	2	3	4	5
Leads at Risk	11016	9965	8397	6408	3380	1127

ICD Leads Survival: From Active Lead Registries[19,20]



	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Optim ICD leads	9398	7445	4858	2066	498	85 @ 69 months				
Sprint Quattro leads	2751	2117	1304	830	648	495	327	223	105	48 @ 117 months
Endotak Reliance leads	492	339	138	50 @ 45 months						

Differences in registry protocols mean direct comparisons between lead performances cannot be made. Data presented here is not intended to draw comparisons between manufacturers, but to communicate the rates of survival that have been reported in these registries. Sprint Quattro and Sprint Quattro Secure are trademarks of Medtronic, Inc.

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Reliability of Durata™ leads: Canadian Experience

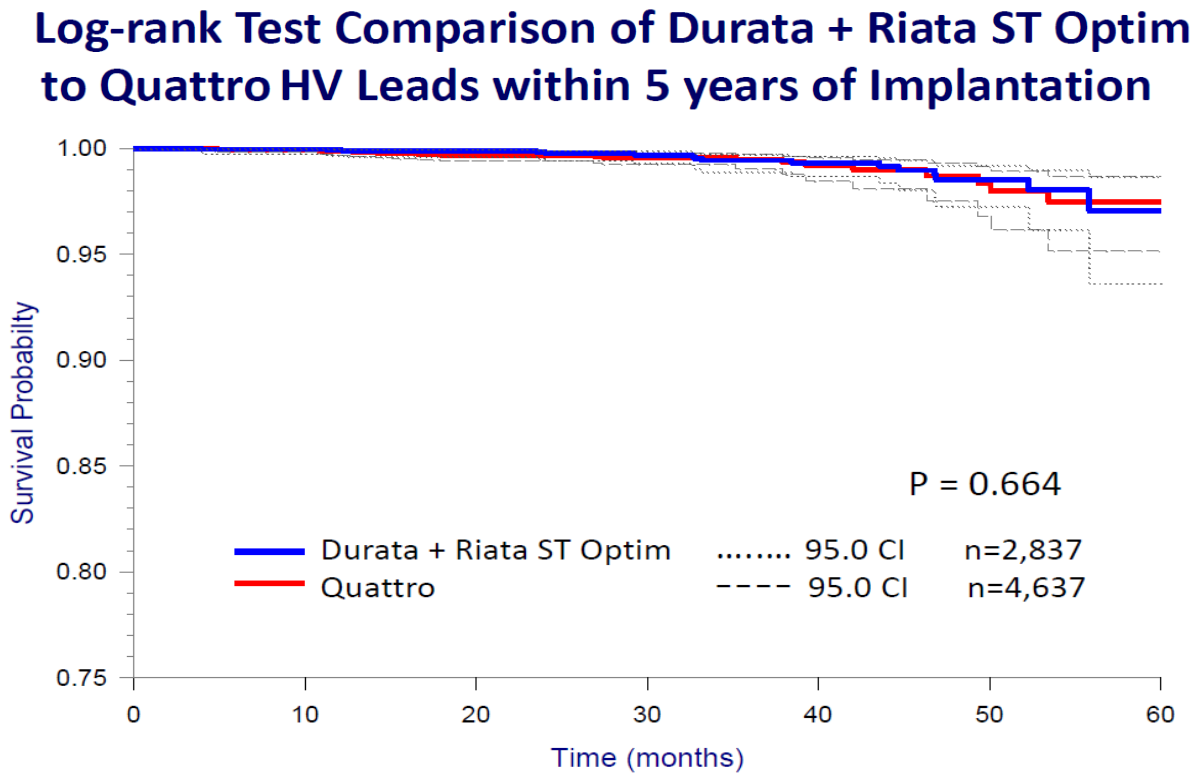
- Retrospective study of Riata™ST Optim™ insulated lead (n=504) and Durata™ (n=3477) lead failure rates from 14 Canadian centers[21].
- Electrical failure rates*:
  - Durata leads: 0.49% (0.24% per year)
  - Riata ST Optim leads: 1.18% (0.27% per year)
- Mean follow up for Durata leads was shorter than that for Riata ST Optim leads (2.0± 1.1 years vs. 4.5± 0.5 years).
- There were no instances of externalized conductors (not all leads underwent fluoroscopy or x-ray imaging).
- Two patients experienced inappropriate shocks but no deaths were attributed to lead failure.

*increased impedance, increased pacing threshold, over-sensing due to noise

Independent studies support strong reliability of Durata™ leads

An analysis of almost 3,000 Durata/ Riata™ ST lead patients from the VA National Cardiac Device Surveillance Program shows[22]

- 98.1% Electrical Failure-Free Survival at 5 years
- Comparable failure-free survival rates to Medtronic Sprint Quattro™ leads



Fluoroscopic and electrical assessment confirm Durata™ reliability

- This single-site study was the first systematic fluoroscopic and electrical assessment of Optim-coated leads (n=413).[23]
  - Analysis included high voltage leads (n=225) as well as low voltage leads (n=188)
  - Lead failure was defined as an electrical malfunction or abnormality resulting in lead replacement, excluding infections, dislodgements, or perforations

- Average follow-up time was 25.7 ± 14.1 months

- During the total follow-up of 10,036 lead-months, there were 7 Optim-lead failures.

- Fluoroscopic screening detected no cases of externalized conductors

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19. A 95% confidence interval reflects a significance level of 0.05 and represents 95% confidence in the true value of the parameter lying within the confidence limits. Sample size, and number of failures relative to sample size, both impact the confidence interval bounds. A larger sample size normally will lead to a better estimate of the population parameter. The survival estimates and confidence intervals for the individual Medtronic models were provided in their PPR. Combined Survival estimates for the two models are calculated using the survival estimates and number of leads at risk for each lead models at time points i and i+1. Standard error of the pooled survival estimate at time point i+1 is based on the survival estimate at that time point, number of leads at risk, the number of leads with event, and the number of leads withdrawn for time prior to ti+1. Log-log method is then used to produce the 2-sided 95% confidence bounds. For St Jude Medical leads were Greenwood's formula is used to calculate the standard errors, and the log-log method is used to produce the 2-sided 95% confidence bounds.
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Durata® Defibrillation Lead
Indications for Use
The Durata™ Models 7120, 7121, and 7122 transvenous leads are indicated for use with compatible pulse generators (refer to the applicable defibrillator manual for system indications). They provide pacing and sensing and deliver cardioversion/defibrillation therapy to the heart. A transvenous lead system may offer the patient the benefit of avoiding a thoracotomy for lead implantation. If the initial lead configuration is not effective, repositioning of the lead or other lead configurations should be attempted. In some patients, a nonthoracotomy lead configuration may not provide reliable conversion of arrhythmias, and the use of subcutaneous or epicardial patch defibrillation leads should be considered.
Contraindications
Contraindications for use of the Durata leads with an implantable pulse generator include ventricular tachyarrhythmias resulting from transient or reversible factors such as drug toxicity, electrolyte imbalance, or acute myocardial infarction. Transvenous lead systems are contraindicated for patients with tricuspid valvular disease or a mechanical heart valve. Durata leads are contraindicated for patients for whom a single dose of 1.0 mg of dexamethasone sodium phosphate is contraindicated. The Durata 7120/7121/7122 leads are contraindicated for extra firm (red color knob) stylets. The lead is not designed, sold, or intended for use other than as indicated.
1. St. Jude Medical DF-1 lead connectors conform to theinternational connector standard ISO 11318/Amd. 1.
2. St. Jude Medical IS-1 lead connectors conform to the internationalconnector standard ISO 5841-3.
Potential Complications
Possible complications of the use of transvenous lead systems include, but are not limited to, supraventricular or ventricular arrhythmias, conduction disturbances, cardiac perforation, cardiac tamponade, loss of contractility, air embolism, heart wall rupture, myocarditis, post-operative heart failure, chronic mechanical stimulation of the heart, tricuspid valve dysfunction, lead fracture necessitating surgical removal, pneumothorax, hemothorax, infection, tissue necrosis, and erosion of the skin. Specific events and effects are summarized below:
WARNINGS
Implanted cardiac leads are subjected to a hostile environment within the body due to constant, complex flexural and torsional forces, interactions with leads and/or the pulse generator, or other forces associated with cardiac contractions and patient physical activity, posture, and anatomical influences. Cardiac leads' functional lifetimes can be affected by these and other factors. Refer to the defibrillator manual for additional complications and precautions specific to the pulse generator