



Why Should We Trust Durata?



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Disclosures

- I receive honoraria, research support and/or consult with:
 - Boston Scientific
 - Cook Medical
 - Medical Interconnect
 - LEADEXX
 - Medtronic
 - QRS Systems
 - Spectranetics
 - St. Jude Medical

No off label uses of devices or drugs will be part of this presentation.



St. Jude ICD Leads After Riata



Can we renew our trust?

What are our concerns?

- Will there be "inside out" erosion of the conductors?
- Will there be "outside in" erosion from device on lead or lead on lead interaction
- Will there be internal shorting
- Isn't it really just the same construction as RIATA??



Aren't they all really the same?



- All Silicone rubber
- <u>Concentric design</u>, <u>8 Fr introducer</u>
- Redundant cable conductors
- Non-backfilled / round shock coils
- All silicone rubber
- <u>Silicone backfilled Flat wire coils</u>
- Cables moved closer to central axis
- <u>7 Fr introducer</u>

Optim outer insulation

- Soft silicone tip
- Pre-curved RV shock coil
- DF4 Connecter option



Aren't they all really the same?



Fundamental Text Book Engineering With Flexible Shaft Neutral Stress Axis

Since neither (E/ρ) nor A is zero, \overline{y} must equal zero. Thus, for flexural loading and linearly elastic action, the neutral axis passes through the centroid of the cross section. Instances in which the neutral axis (the

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During bending, the <u>shear stress</u> <u>increases</u> linearly from the central axis to the edge of the shaft and is <u>greatest</u> <u>at the farthest distance from the</u> central axis

Riata Concentric Lead Body Design

Coil (most fragile component) is in central axis to minimize shear stress during severe bending

ETFE

PTFE

Redundant cable pairs to shock & ring electrodes provide protection to the coil

Silicone Rubber Only

Large cable lumen allow cables to move to help absorb external forces which helps minimize fracture risk

6.7 Fr Body

<u>Green</u> Coil Insulation: PTFE (Polytetrafluoroethylene) – a tubing placed over the coil <u>Blue</u> Cable Insulation: ETFE (Ethylene tetrafluoroethylene) – extruded over the cable



<u>Riata 8Fr</u> Silicone to <u>Riata ST 7 F</u>r Silicone Lead Design Changes

Conductor Configuration

- <u>Conductors are closer</u> to the lead body's central axis in 7F compared to 8F Riata[®] silicone leads
 - <u>Reduces tension</u> on conductors and risk of externalized conductors¹
- Flat wire shock coil made the 7 Fr introducer size possible



Riata Silicone 8F Riata ST Silicone (7F)

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



<u>Riata ST 7 Fr</u> To The <u>Riata ST Optim</u> <u>& Durata</u> Optim Insulated Leads

Optim Insulation

- Over 50x more <u>abrasion</u> <u>resistant</u> than silicone¹
- Much greater lubricity between Optim insulation and the ETFE cables than Silicone and the ETFE cables

Wall thickness from the cable lumen to the outer edge of the lead increased 50% in Durata Optim Insulation Tubing

1. Jenney C, Tan J, Karicherla A, Burke J, Helland J. A New Insulation Material for Cardiac Leads with Potential for Improved Performance, Heart Rhythm, 2, S318-S319 (2005)



Riata ST 7 Fr Silicone

Optim Insulated Riata ST Optim & Durata 7F

Center

Optim Introduced On The Riata ST Optim And Durata Lead Bodies (Cross-Section)

Biostable Optim Insulation Tubing Protective Jacket

All Riata ST Optim & Durata leads have 6.8 Fr quad-lumen lead bodies

All Models Are Quad-Lumen

Silicone Rubber



MDT Quattro ICD Lead Body Design

Sense

Defib

Pace

80A Polyurethane Outer Jacket

Compression

PTFE

HP Silicone

<u>Second ICD lead</u> with a protective insulation jacket (using 80A polyurethane) over the silicone rubber insulation <u>done to</u> <u>significantly reduce</u> <u>insulation failures</u> that were <u>very common</u> in the previous MDT Sprint lead family

> The 80A Polyurethane jacket must be thick to compensate for <u>ESC degradation</u> <u>since it has known</u> biostability issues

MDT's Quattro Lead – A Sprint Lead Body With An <u>80A PolyU Protective Insulation</u>





MDT Sprint <u>Silicone Only</u> <u>Lead Body Size</u>: <u>7.8 Fr</u> Introducer size: <u>10 Fr</u>

MDT Sprint Quattro With <u>80A Polyurethane</u> Insulation Protective Outer Jacket Protective Outer 80A PU Tubing Adds ~ 0.8 Fr <u>Lead Body Size</u>: <u>8.6 Fr</u> / Introducer Size: <u>9 Fr</u>



How Did MDT's Sprint (All Silicone) Leads Compare To The Quattro 80A PU Jacketed Leads ? Product Performance Report <u>Returned Malfunctions</u> Data

Lead	US Registered Implants (Approx)	All Cause Conductor Fractures	All Cause Insulation Failures	Total
MDT Sprint Silicone Only Lead Family (10.5 Fr Intro / 7.8 Fr Body)	95,900	201 <u>(0.210%)</u>	97 <u>(0.100%)</u>	298 (0.310%)
MDT Sprint Quattro PU 80 Jacketed Lead Family (9 Fr Intro / 8.6 Fr Body)	382,100	340 (0.089%)	17 <u>(0.004%</u>)	357 (0.093%)

(Sprint leads marketed March, 1996 & 1997; Quattro leads marketed December, 2001)

Data is from the MDT PPR, 1st ED., 2012, Returned, confirmed malfunction lead data chart



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Optim Insulation:

Silicone Rubber – Polyurethane Chemical Copolymer

• A new <u>copolymer</u> chemical structure – <u>not a physical mixture</u>



<u>A 15 year projec</u>t – 8 to develop the chemistry & 7 to qualify the material for implantable cardiac lead use



Optim Insulation:

Silicone Rubber – Polyurethane Chemical Copolymer

A new <u>copolymer</u> chemical structure – <u>not a physical mixture</u>

The Optim Chemistry

- Kept the "<u>Hard segment</u>" polyurethane 55D chemistry (~40%)
- Replaced the "<u>soft segment</u>" (polyether) polyurethane chemistry (degrades easily) with a new very inert segment (~12%)
 - Balance of the chemistry is <u>silicone rubber</u> (~ 48%)



Optim ESC Biostability

24 month biostability (ESC) in sheep
Strained tubing (150%) over "dumbells"
Cracking: Optim & PU55D <<< PU80A



Optim™ (Silicone Rubber – Polyurethane Copolymer) Insulation

¹ Jenney C, Tan J, Karicherla A, Burke J, Helland

J. A New Insulation Material for Cardiac Leads with Potential for Improved Performance, HRS 2005, Heart Rhythm, 2, S318-S319 (2005). of Insulatio 600000 >500000 >500000 (Turned-Off Tester – Only minor surface wear) 500000 Ī 400000 Рег The Optim insulation is at 300000 Failure F least 50X more resistant to 200000 abrasion than silicone rubber C ycles to 00000 9976 **Presented at:** 0 Optim **55D Polyurethane HP Silicone** • HRS - 2005 & 2006 Cardiostim - 2006 Cyclic Compression Results EuroPace - 2005 3500 Cycles to Failure Per Mil of Insulatio >3125 >3125 (Turned-Off Tester – Only minor surface wear) 3000 2500 The Optim insulation is <u>at</u> 2000 least 60X more resistant to 1500 cyclic compression than 1000 silicone rubber 500 48.7 0 Optim **55D Polyurethane** Device-on-lead abrasion test results: HP Silicone Same as lead-on-lead testing

Lead-to-Lead Abrasion Results

Why not just use 80A?

- 80A Poly U <u>would not and could not</u> <u>be used by SJM</u> due to the 80A failures seen in the SJM biostability testing.
 - The FDA would not have allowed it.

 Other manufacturers that had been using it, continue to use it as it was already approved for them in the past



Externalized Conductor Incidence Based On Field Reported Complications <u>Plus</u> Returned Confirmed Malfunctions

SJM Product Performance Database WW Data through <u>Feb 29, 2012</u>

SJM Lead Family	All Cause Abrasion	Externalized Conductors
Riata [®] Silicone (8F)	1.05%*	0.37%*
Riata ST Silicone (7F)	0.56%*	0.13%*
Riata ST Optim & Durata	0.04%	0.0%

This internal data reflect all reported or confirmed cases and is <u>very</u> useful to compare relative incidence levels across lead models and lead families

* Product line phase-out completed in Dec. 2010

Optim Leads' Performance In Surviving <u>All</u> <u>Cause Insulation Abrasion Failures</u> vs Riata

Silicone Leads

<u>NEW DATA</u> (SJM PPR, April, 2012)

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

• Analysis includes <u>all cause</u> <u>conductor fractures</u>, <u>all cause</u> <u>insulation breaches</u>, and <u>all</u> <u>cause mechanical connection</u> failures (i.e. crimps, welds, bonds)

 Durata with Optim insulation has shown <u>outstanding</u>
 <u>reliability</u> as of <u>62 months</u> of implant duration



<u>Riata & Riata ST vs Quattro 6947</u> Independent Mult-Center Study Results

A multicenter (<u>7 sites</u>) independent analysis was conducted that compared survival of SJM's Riata[®] Family silicone leads (<u>n = 773</u>) and Riata ST Family silicone leads (<u>n = 287</u>) to MDT's Quattro Secure[®] Model 6947 lead (<u>n = 1668</u>)*



Presented by Dr. Abdelhadi (Mpls Heart Center, Abbott Northwestern Hospital) at the "Riata Summit", Jan 20, 2012



St. Jude Medical Post-Market Registries and Studies

<u>10,950 Optim ICD lead patients*</u> are currently enrolled at <u>292 sites*</u>, in active monitoring post-market registries, with <u>> 27,000 pt-yrs</u> & FU to-date of <u>> 5 years</u>

Registry	Launch	# ICD Leads	# of	Purpose	Data Through March 31, 2012
Studies			Sites		
Riata Lead Evaluation Study	December 2011	> 600 (Enrollment Ongoing) <i>Riata & Riata ST</i>	18	Prospective, multi-center study to e incidence of externalized conductor Riata ST silicone leads and determin of leads with externalized conductor	evaluate the rs in Riata [®] and ne the performance ors
OPTIMUM (Optim)	August 2006	5997 Durata and Riata ST Optim	214	Prospective, multi-center, actively r to evaluate the long-term performa insulated leads	monitored registry Ince of all Optim [®]
SCORE (Optim)	September 2007	3458 Durata and Riata ST Optim	58	Prospective, multi-center, actively monitored, long- term data collection and evaluation registry to eval long term performance of CRM devices	
DF4 PAS (Optim)	June 2009	1743 Durata DF4	58	Prospective, multi-center, actively monitored study characterize the chronic performance of the St. Jude Medical SJ4 connector and RV high voltage SJ4 lead	

*A few patients at a few sites are in two different registries



Performance of Optim Insulated ICD Leads In <u>Combined</u> Prospective Registries

SJM Post-Market Registries and Studies Data- March 31st Cutoff Date

- In Optim[®] insulated leads (<u>N = 10,950*</u>), zero externalized conductors and a very low incidence of all-cause abrasion have been observed in over 27,000 patient-years and follow-up to date over 5 years @ 292 sites*
 - All-cause mechanical failure rate is <u>extremely low</u> on Optim ICD leads

OPTIMUM, SCORE and DF4	All Optim ICD Lead Incidence
Externalized Conductors	0.0% (<u>NONE</u>)
All-Cause Insulation Abrasion	0.04%
All-Cause Mechanical Failures*	0.16%

*A few patients at a few sites are in two different registries

* All-cause mechanical failures include: conductor fracture, insulation failures, welds, crimps

<u>Combined</u> Prospective, Active, Audited <u>Registry</u> Data: Riata ST Optim and Durata



WW Riata & Riata ST Silicone Leads With Confirmed Externalized Cables



What About The Two MAUDE Database Durata Reports That Competitors Have Been Showing Physicians ?

MAUDE abrasion case reports to imply that Durata leads have the same issues with <u>externalized conductors</u> as do the all silicone rubber Riata leads

SJM reported this information to the FDA and has the details of each case

NONE of these cases involve externalized conductors due to inside-out abrasion. The few cases cited are variations on a rare but known type of failure where two conductors short within the lead body, under a shock coil

These events are captured in the SJM product performance report

SJM's Riata ST Optim and Durata leads with Optim insulation continue to demonstrate excellent performance with <u>NO reports of</u> <u>externalized conductors</u>

All manufacturers have cases of lead failure – including shorting underneath the shock electrodes – that are reported in the MAUDE database – SJM overall lead reliability compares very favorably to other "reliable" lead models



Design Improvement: Non Tissue In-Growth Shock Coils <u>Flat Wire Shock Coils With Silicone Backfill</u>

- Flat wire technology distributes pressure evenly along the length of the shock coil which results in improved abrasion resistance
- Field data shows this design improvement resulted in an <u>95% reduction in abrasion</u> and resultant shorting under the shock coil¹
- <u>Bench testing</u> shows a <u>> 10X improvement in cycles to failure</u> for abrasion under the Shock Coil



enter

1. St. Jude Medical data on file. Not yet published.

Design Improvement: Non Tissue In-Growth Shock Coils

Flat Wire Shock Coils With Silicone Backfill

			All-Cause Internal Shorts		Internal Shorts Under Shock Coils	
SJM Lead Family	Year Introduced	Worldwide Sales	Qty	Rate	Qty	Rate
Riata [®] Silicone 8F	2001	156,308	124	0.079%	115	0.074%
Riata ST®	2005	70,665	15	0.021%	9	0.013%
Riata ST Optim	2006	33,030	4	0.012%	2	0.006%
Durata®	2007	276,021	9	0.003%	4	0.001%

Data through February 29, 2012



Can Product Performance Reports Be Used To Compare Companies' Lead Performance ?





How Do SJM's Durata & Riata ST Optim Leads Compare To BSI's Reliance G/SG Leads ?

Product Performance Report <u>Adverse Observations</u> Data

Lead	US Registered Implants (Approx)	All Cause Conductor Fractures	All Cause Insulation Failures	Total
BSI Endotak Reliance G & SG Family 9F	211,000	211 (0.100%)	66 (0.031%)	277 (0.130%)
SJM Durata & Riata ST Optim Families 7F	153,300	50 (0.033%)	15 (0.010%)	65 (0.042%)

(Reliance G Leads marketed March, 2004; Riata ST Optim & Durata leads marketed July, 2006)

• All leads are <u>active fixation</u>

Complaint data is from the Customer "<u>Acute</u>" & "<u>Chronic</u>" Observations charts

Durata / Riata ST Optim data is from the SJM April, 2012 PPR

Reliance G & SG data is from the BSI Q1, 2012 PPR





PPR Total Complaints of <u>ALL CAUSE</u> Fractures (Acute & Chronic)





PPR Comparison of ALL Cause Mechanical Failures



Medical Center

So... Should we Trust Durata?

- Though Durata has some of the same design characteristics as Riata, they are truly different leads
- Data that we have available (OK, it is from St. Jude) indicates that Durata is at least as reliable as any other lead on the market

