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
- **Concentric design, 8 Fr introducer**
- Redundant cable conductors
- Non-backfilled / round shock coils

6.7 Fr Body / 7.6 Fr for Model 1582

- All silicone rubber
- **Silicone backfilled Flat wire coils**
- Cables moved closer to central axis
- 7 Fr introducer

6.3 Fr Body

- **Optim outer insulation**

6.8 Fr Body

- **Soft silicone tip**
- **Pre-curved RV shock coil**
- DF4 Connector option

6.8 Fr Body
Aren’t they all really the same?

- All Silicone rubber
- **Concentric design, 8 Fr introducer**
- Redundant cable conductors
- Non-backfilled / round shock coils

**Over 85% of the Durata lead’s B.O.M. (bill of materials) components were changed from the original Riata**

- **Optim outer insulation**
- **Soft silicone tip**
- **Pre-curved RV shock coil**
- DF4 Connector option
Since neither \((E/\rho)\) nor \(A\) is zero, \(\bar{y}\) 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}

**Pg 212, Ch. 4, Flexural Loading Stresses**
During bending, the shear stress increases linearly from the central axis to the edge of the shaft and is greatest at the farthest distance from the central axis.

“Take Homes”
- Concentric design
- Keep components close to the central axis
- Place most fragile component in the central axis
Riata *Concentric* Lead Body Design

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

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

**Green Coil Insulation**: PTFE (Polytetrafluoroethylene) – a tubing placed over the coil

**Blue Cable Insulation**: ETFE (Ethylene tetrafluoroethylene) – extruded over the cable
Conductor Configuration

- **Conductors are closer to the lead body’s central axis in 7F compared to 8F Riata® silicone leads**
  - Reduces tension on conductors and risk of externalized conductors

- **Flat wire shock coil** made the 7 Fr introducer size possible

Riata ST 7 Fr To The Riata ST Optim & Durata Optim Insulated Leads

Optim Insulation

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

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

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

All Models Are Quad-Lumen
MDT Quattro ICD Lead Body Design

80A Polyurethane Outer Jacket

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

The 80A Polyurethane jacket must be thick to compensate for ESC degradation since it has known biostability issues.
MDT’s Quattro Lead – A Sprint Lead Body With An 80A PolyU Protective Insulation Jacket

MDT Sprint Silicone Only

Lead Body Size: 7.8 Fr
Introducer size: 10 Fr

MDT Sprint Quattro With 80A Polyurethane Insulation Protective Outer Jacket

Protective Outer 80A PU Tubing Adds ~ 0.8 Fr

Lead Body Size: 8.6 Fr / Introducer Size: 9 Fr
How Did MDT’s Sprint (All Silicone) Leads Compare To The Quattro 80A PU Jacketed Leads?
Product Performance Report *Returned Malfunctions* Data

<table>
<thead>
<tr>
<th>Lead</th>
<th>US Registered Implants (Approx)</th>
<th>All Cause Conductor Fractures</th>
<th>All Cause Insulation Failures</th>
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<tr>
<td><strong>MDT Sprint Silicone Only Lead Family</strong></td>
<td>95,900</td>
<td>201 (0.210%)</td>
<td>97 (0.100%)</td>
<td>298 (0.310%)</td>
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<td>(10.5 Fr Intro / 7.8 Fr Body)</td>
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(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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A 90+ % Reduction
Optim Insulation:
Silicone Rubber – Polyurethane Chemical Copolymer

• A new copolymer chemical structure – not a physical mixture

Combines The Most Desired Cardiac Lead Characteristics

- Strength / Tear Resistance
  - Abrasion Resistance
  - Lubricity
- Flexibility
- Bio-stability

From “Hard Segment” Poly U 55D
(From undersea telephone cables)

From Silicone Rubber
(From roller pumps)

A 15 year project – 8 to develop the chemistry & 7 to qualify the material for implantable cardiac lead use
Optim Insulation:
Silicone Rubber – Polyurethane Chemical Copolymer

• A new **copolymers** chemical structure – *not a physical mixture*

**The Optim Chemistry**

• Kept the “**Hard segment**” polyurethane 55D chemistry (~40%)

• Replaced the “**soft segment**” (polyether) polyurethane chemistry (degrades easily) with a new very inert segment (~12 %)
  
  • Balance of the chemistry is **silicone rubber** (~ 48%)
Optim ESC Biostability

- 24 month biostability (ESC) in sheep
- Strained tubing (150%) over “dumbbells”
- Cracking: Optim & PU55D << PU80A
The Optim insulation is at least 50X more resistant to abrasion than silicone rubber.

Presented at:
- HRS - 2005 & 2006
- Cardiostim - 2006
- EuroPace - 2005

The Optim insulation is at least 60X more resistant to cyclic compression than silicone rubber.

Device-on-lead abrasion test results: Same as lead-on-lead testing.

Why not just use 80A?

- 80A Poly U *would not and could not be used by SJM* 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 Plus Returned Confirmed Malfunctions**

<table>
<thead>
<tr>
<th>SJM Lead Family</th>
<th>All Cause Abrasion</th>
<th>Externalized Conductors</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Riata® Silicone (8F)</strong></td>
<td>1.05%*</td>
<td>0.37%*</td>
</tr>
<tr>
<td><strong>Riata ST Silicone (7F)</strong></td>
<td>0.56%*</td>
<td>0.13%*</td>
</tr>
<tr>
<td><strong>Riata ST Optim &amp; Durata®</strong></td>
<td>0.04%</td>
<td>0.0%</td>
</tr>
</tbody>
</table>

This internal data reflect all reported or confirmed cases and is very 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 All Cause Insulation Abrasion Failures vs Riata Silicone Leads

NEW DATA
(SJM PPR, April, 2012)

- Analysis includes all cause conductor fractures, all cause insulation breaches, and all cause mechanical connection failures (i.e. crimps, welds, bonds)

- Durata with Optim insulation has shown outstanding reliability as of 62 months of implant duration

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

Data @ 5.2 Years:
- Optim: 99.96%
- Silicone: 99.56%

P < 0.0001

Combined data from returned lead malfunctions PLUS field reported complications / observations
Riata & Riata ST vs Quattro 6947
Independent Mult-Center Study Results

- A multicenter (7 sites) independent analysis was conducted that compared survival of SJM’s Riata® Family silicone leads (n = 773) and Riata ST Family silicone leads (n = 287) to MDT’s Quattro Secure® Model 6947 lead (n = 1668)*
### St. Jude Medical Post-Market Registries and Studies

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

<table>
<thead>
<tr>
<th>Registry Studies</th>
<th>Launch</th>
<th># ICD Leads</th>
<th># of Sites</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Riata Lead Evaluation Study</td>
<td>December 2011</td>
<td>&gt; 600</td>
<td>18</td>
<td>Prospective, multi-center study to evaluate the incidence of externalized conductors in Riata® and Riata ST silicone leads and determine the performance of leads with externalized conductors</td>
</tr>
<tr>
<td></td>
<td>(Enrollment Ongoing)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Riata &amp; Riata ST</td>
<td></td>
<td>Riata &amp; Riata ST</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OPTIMUM (Optim)</td>
<td>August 2006</td>
<td>5997</td>
<td>214</td>
<td>Prospective, multi-center, actively monitored registry to evaluate the long-term performance of all Optim® insulated leads</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Durata and Riata ST Optim</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SCORE (Optim)</td>
<td>September 2007</td>
<td>3458</td>
<td>58</td>
<td>Prospective, multi-center, actively monitored, long-term data collection and evaluation registry to evaluate long term performance of CRM devices</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Durata and Riata ST Optim</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DF4 PAS (Optim)</td>
<td>June 2009</td>
<td>1743</td>
<td>58</td>
<td>Prospective, multi-center, actively monitored study to characterize the chronic performance of the St. Jude Medical SJ4 connector and RV high voltage SJ4 leads</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Durata DF4</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Data Through March 31, 2012

*A few patients at a few sites are in two different registries*
Performance of Optim Insulated ICD Leads In *Combined* Prospective Registries

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

- In Optim® insulated leads (N = 10,950*), 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 extremely low on Optim ICD leads

<table>
<thead>
<tr>
<th>OPTIMUM, SCORE and DF4</th>
<th>All Optim ICD Lead Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Externalized Conductors</td>
<td>0.0% (<em>NONE</em>)</td>
</tr>
<tr>
<td>All-Cause Insulation</td>
<td></td>
</tr>
<tr>
<td>Abrasion</td>
<td>0.04%</td>
</tr>
<tr>
<td>All-Cause Mechanical</td>
<td></td>
</tr>
<tr>
<td>Failures*</td>
<td>0.16%</td>
</tr>
</tbody>
</table>

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

* All-cause mechanical failures include: conductor fracture, insulation failures, welds, crimps and bonds
**Combined** Prospective, Active, Audited **Registry** Data: Riata ST Optim and Durata

- **a)** Freedom from **Externalized Conductors**: 100% (*none*)
- **b)** Freedom from **All-Cause Insulation Abrasion**: 99.9%
- **c)** Freedom from **All-Cause Mechanical Failures**: 99.6%
- **d)** Freedom from **All-Cause Lead Related Complications**: ~98.5%
  (Includes All-Cause Mechanical Failures, plus Lead Dislodgments, Lead Perforations, etc.)

**Kaplan-Meier Analysis**

- **N = 10,950 leads**

**Survival Probability**

**Follow-up Duration (Years)**

**MDT SLS**: 4,168 Q Leads (2nd Ed, 2012)
**BSI’s LSR**: 537 REL G Leads (Q1, 2012)
**MDT + BSI Combined Total**: 4705

**DATA Through March 31, 2012**
Within 1 Year: 2% of EC cases
Within 2 Years: 9% of EC cases
Within 3 Years: 20% of EC cases

Optim® insulated ICD leads have over 5 years of clinical experience with no reports of externalized conductors.
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 externalized conductors 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 NO reports of externalized conductors
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**

**Flat Wire Shock Coils With Silicone Backfill**

- **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 *95% reduction in abrasion and resultant shorting* under the shock coil\(^1\).

- Bench testing shows a *> 10X improvement in cycles to failure* for abrasion under the Shock Coil.

---

\(^1\) St. Jude Medical data on file. Not yet published.
## Design Improvement: Non Tissue In-Growth Shock Coils

**Flat Wire Shock Coils With Silicone Backfill**

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

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 *Adverse Observations* Data

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<tr>
<td><strong>BSI Endotak</strong> Reliance G &amp; SG Family</td>
<td>211,000</td>
<td>211 (0.100%)</td>
<td>66 (0.031%)</td>
<td>277 (0.130%)</td>
</tr>
<tr>
<td>9F</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>SJM Durata &amp; Riata ST Optim Families</strong></td>
<td>153,300</td>
<td>50 (0.033%)</td>
<td>15 (0.010%)</td>
<td>65 (0.042%)</td>
</tr>
<tr>
<td>7F</td>
<td></td>
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(Reliance G Leads marketed March, 2004; Riata ST Optim & Durata leads marketed July, 2006)

- All leads are *active fixation*
- Complaint data is from the Customer “*Acute*” & “*Chronic*” 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 **ALL CAUSE** Insulation Breaches
(Acute & Chronic)

Data from:
SJM’s April 2012 PPR
BSI Q1 2012 PPR
PPR Total Complaints of **ALL CAUSE** Fractures (Acute & Chronic)

*Data from:*
SJM’s April 2012 PPR
BSI Q1 2012 PPR
PPR Total Complaints of *ALL CAUSE Mechanical Failures* (Insulation Breach & Fracture – Acute & Chronic)

Data from:
SJM’s April 2012 PPR
BSI Q1 2012 PPR
PPR Comparison of **ALL Cause Mechanical Failures**

Data from:
- SJM’s April 2012 PPR
- BSI Q1 2012 PPR
- MDT 2nd Ed, 2011 PPR

Note that BSX Malfunction Data represents their Worldwide experience while MDT and SJM report U.S. Malfunctions only. The effect of this difference is not known.
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.