

QuickSite® & QuickFlex® CRT Lead Update

Silicone Insulated Left Ventricular Lead Advisory, April 3, 2012



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QuickSite® and QuickFlex® LV Lead Update

- St. Jude Medical is proactively informing clinicians of the potential for visual observations of externalized conductors in QuickSite and QuickFlex leads with silicone insulation
- There have been no reports of death or serious injury associated with the externalized conductors; likewise there have been no electrical dysfunctions attributable to the externalized conductors.
- St Jude Medical and its Medical Advisory Board recommend continuing to monitor patients at regularly scheduled intervals
 - X-ray and fluoroscopy is not recommended, replacement is not recommended
- As a conservative measure, the sale of QuickSite and QuickFlex leads is being discontinued immediately.
- The unipolar version of the QuickSite lead, model 1056K, and the QuickFlex μ model 1258T and Quartet® model 1458Q leads are not subject to this communication as their construction is different than the subject leads and the QuickFlex μ and Quartet leads utilize Optim® insulation rather than silicone insulation



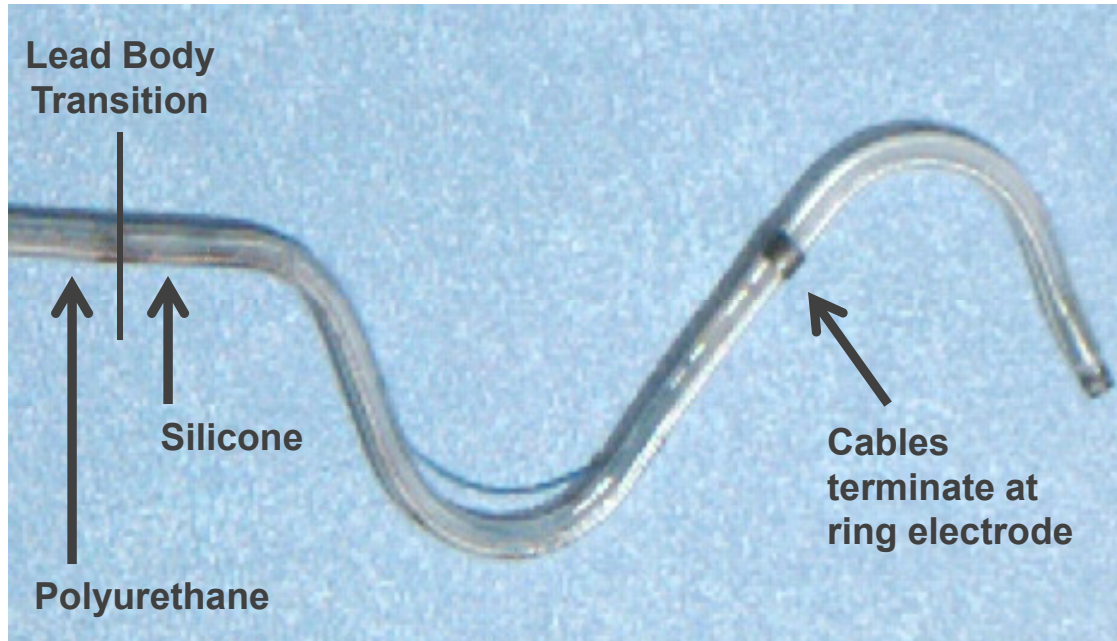
QuickSite® and QuickFlex® LV Lead Update

- Silicone insulated bipolar CRT Leads
 - This voluntary advisory includes the QuickSite models 1056T and 1058T, and QuickFlex models 1156T and 1158T.
 - Since 2004, approximately 171,000 of these leads have been implanted worldwide (82,000 QuickSite and 89,000 QuickFlex).
 - Approximately 101,000 QuickSite and QuickFlex bipolar leads are estimated to be currently in service worldwide (59,000 in the US and 42,000 Internationally).
- Externalized Cable Observations
 - SJM has confirmed a total of 39 cases of externalized conductors (11 through field reports and 28 through laboratory analysis).
 - The reported externalization rate is 0.023% (2.3 per 10,000 leads)
 - No electrical dysfunctions have been attributable to externalized conductors
 - Based on a review of 1,219 leads returned for any reason and available fluoroscopic and x-ray images, it is estimated that 3 to 4% of QuickSite and QuickFlex leads may demonstrate this anomaly.



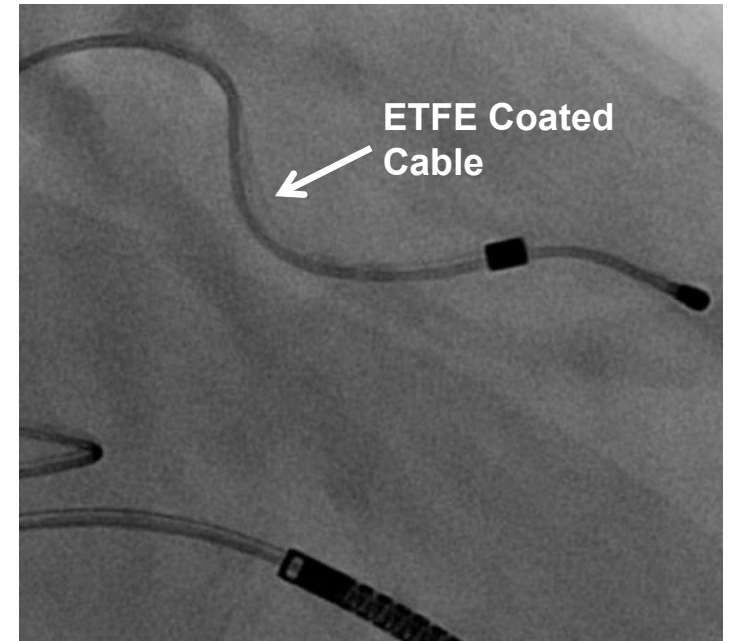
Examples of Externalization in Silicone Insulated LV Leads

Visual Example



Source: SJM Product Returns
QuickFlex® lead model 1158T/86

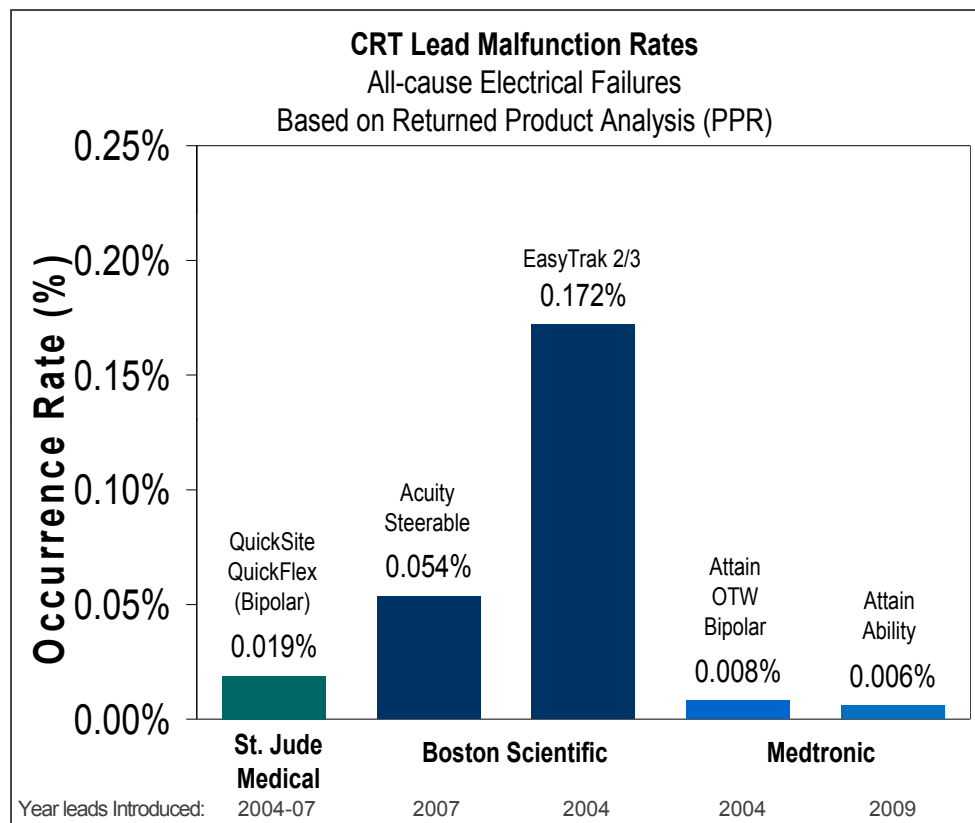
Fluoroscopic Example



Source: SJM Technical Services
QuickSite® lead model 1056T/86

Confirmed Electrical Failure Rates of Industry CRT Leads

- No electrical dysfunctions have been attributable to the externalized conductors
 - Conductor cables are coated with ETFE insulation, which provides adequate dielectric strength for the lead to continue to function normally
 - The ETFE coating on the cables has remained intact in all analyzed cases
 - All-cause electrical failure rate for QuickSite and QuickFlex leads is 0.019% (1.9 per 10,000 leads).
 - Data from returned product analysis and Product Performance Reports (PPR) show all-cause electrical failure rates for these leads compares favorably to the other LV leads on the market



Sources: St Jude Medical worldwide returned product analysis data in April 3, 2012 Medical Device Advisory Letter (US data in Nov 2011 PPR and supplemental US and International data on file). Boston Scientific worldwide data in Q4 2011 PPR, Medtronic US data in 2011-2 PPR.
Definitions: For St Jude Medical, all-cause electrical failure rate is calculated as fractures, crimp/weld/bond failures, and insulation breaches not resulting in externalized conductors (All-cause electrical failure rate is also described as the all-cause mechanical failure rate less the externalized conductor rate). For Boston Scientific and Medtronic, data shown represents lead conductor fractures reported in PPRs.

Perspective from Medical Advisory Board

- The clinical implications are much different from, and should not be viewed as similar to, the Riata® lead externalized conductor issue
- LV CRT leads are not used to deliver immediate life-saving therapy (defibrillation, anti-tachycardia pacing, or primary pacing for pacemaker-dependent patients).
- LV CRT leads are used to provide resynchronization therapy for heart failure
 - Long term loss of biventricular pacing could lead to heart failure exacerbation
 - No electrical dysfunction attributable to externalized conductors has been reported to date and the rate of occurrence of an electrical anomaly for these leads is expected to be low
 - If an electrical abnormality were to occur, it can potentially be corrected with reprogramming to an alternative configuration at a follow-up clinic visit
- Therefore, the risk of a clinically significant event is low
- The MAB provided input to the Dear Doctor Letter and have concurred with its contents.



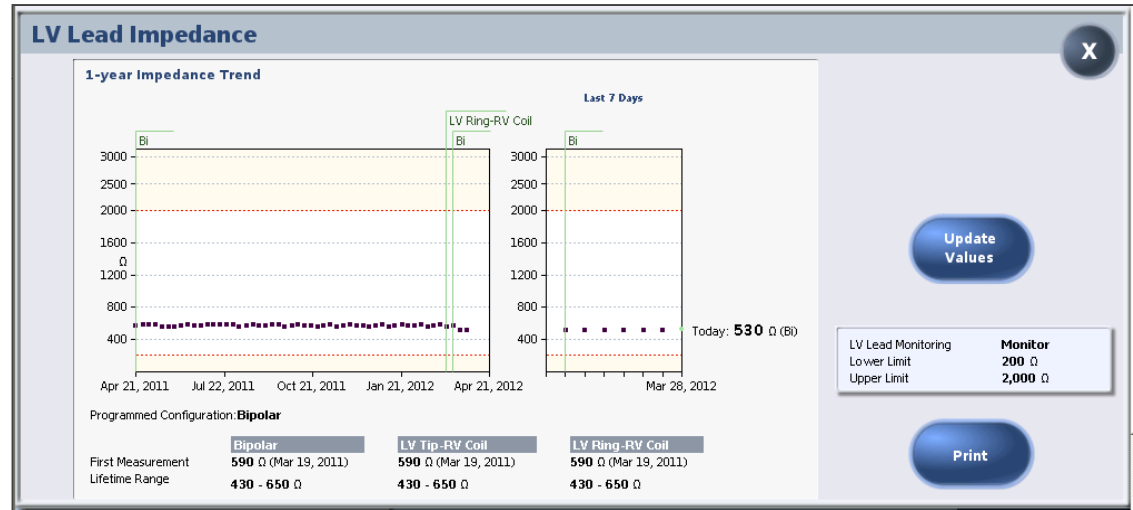
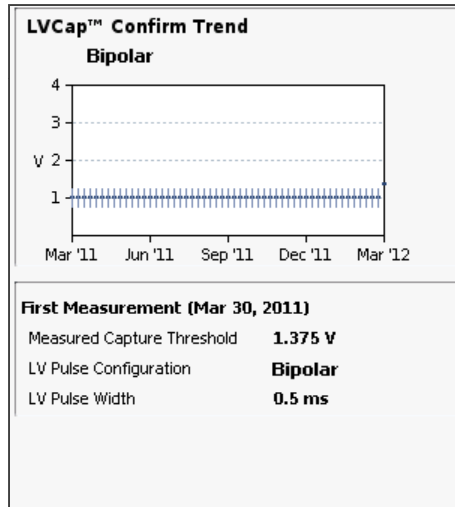
Recommendations from Medical Advisory Board

- Continue to monitor patient's implanted system at regularly scheduled intervals
 - Review diagnostic information related to CRT pacing performance, in particular LV lead impedance and capture thresholds.
 - Programming of alerts that monitor lead impedance changes outside of the nominal range and enabling the patient notifier should be considered if available.
- X-ray or fluoroscopic imaging is not recommended for leads with normal electrical function.
- Only leads that exhibit electrical anomalies and cannot be reprogrammed to deliver effective CRT pacing should be considered for replacement.



Available Pacing and Impedance Diagnostics

- LVCap™ Confirm automatically measures pacing threshold every 8 or 24 hours (programmable), and displays 1-year capture threshold trend
- LV lead impedance diagnostic measures the programmed pacing vector daily, and displays 1-year impedance trend
- Alerts can be set and transmitted if impedance goes outside specified range



LVCap™ Confirm Trend is available on Promote Accel®, Unify® CRT-Ds and on Anthem® RF and Anthem CRT-Ps.

Daily LV Lead Impedance Trend is available on all St Jude Medical® CRT-Ds. Programmable alert range and automatic alert transmissions are available on Promote RF/+Accel, Unify CRT-Ds and on Anthem RF CRT-Ps.

QuickFlex[®] μ and Quartet[®] CRT Lead Reliability

Next Generation Optim[®] Insulated Left Ventricular Leads

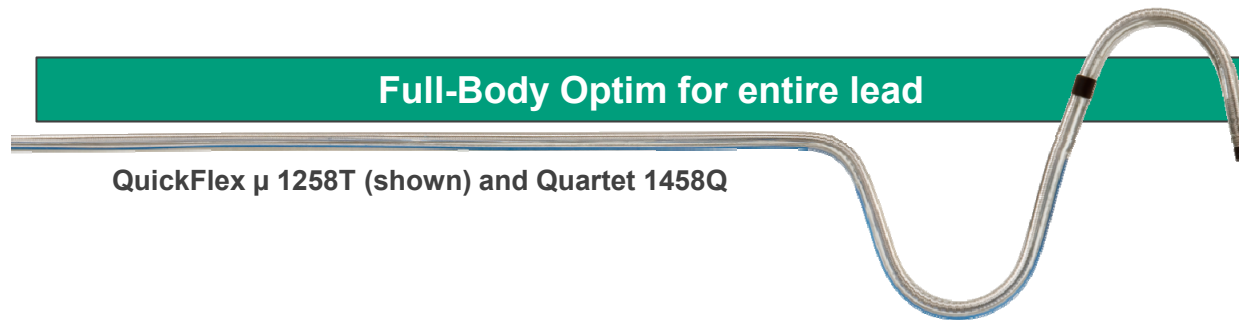


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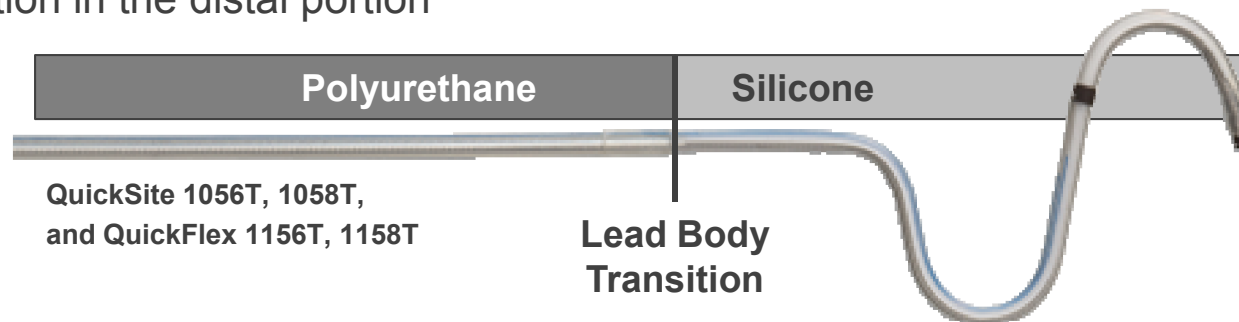
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Optim Insulated QuickFlex[®] μ and Quartet[®] Lead Reliability

- QuickFlex μ and Quartet are made with all Optim[®] insulation in the entire lead body and distal section (i.e. they are full body Optim leads).
- Optim insulation has been shown to be greater than 50 times more abrasion resistant than silicone¹



- QuickSite[®] and QuickFlex leads are made with silicone insulation in the distal portion



1. Helland J, et al. Heart Rhythm, 2005.



QuickFlex[®] μ and Quartet[®] Lead Clinical Performance

- With 65,000 Optim insulated QuickFlex μ and Quartet leads implanted starting in 2008, there are no reports or laboratory observations of externalized conductors in Optim insulated QuickFlex μ and Quartet LV leads
- Extensive testing on new and returned Optim leads shows no signs of abrasion in cable lumens

| Name | Model | Year Introduced | Rate of All-Cause Abrasions | Rate of All-Cause Mechanical Failures | Rate of All-Cause Electrical Dysfunction |
|-----------------------------------|--------------|-----------------|-----------------------------|---------------------------------------|--|
| QuickSite | 1056T | 2004 | 0.043% | 0.063% | 0.025% |
| QuickSite XL | 1058T | 2006 | 0.033% | 0.047% | 0.020% |
| QuickFlex | 1156T | 2007 | 0.012% | 0.023% | 0.012% |
| QuickFlex XL | 1158T | 2007 | 0.014% | 0.028% | 0.017% |
| Combined QuickSite/QuickFlex | | | 0.026% | 0.042% | 0.019% |
| Name | Model | Year Introduced | Rate of All-Cause Abrasions | Rate of All-Cause Mechanical Failures | Rate of All-Cause Electrical Dysfunction |
| QuickFlex μ | 1258T | 2008 | 0.000% | 0.013% | 0.013% |
| Quartet | 1458Q | 2009 | 0.000% | 0.008% | 0.008% |

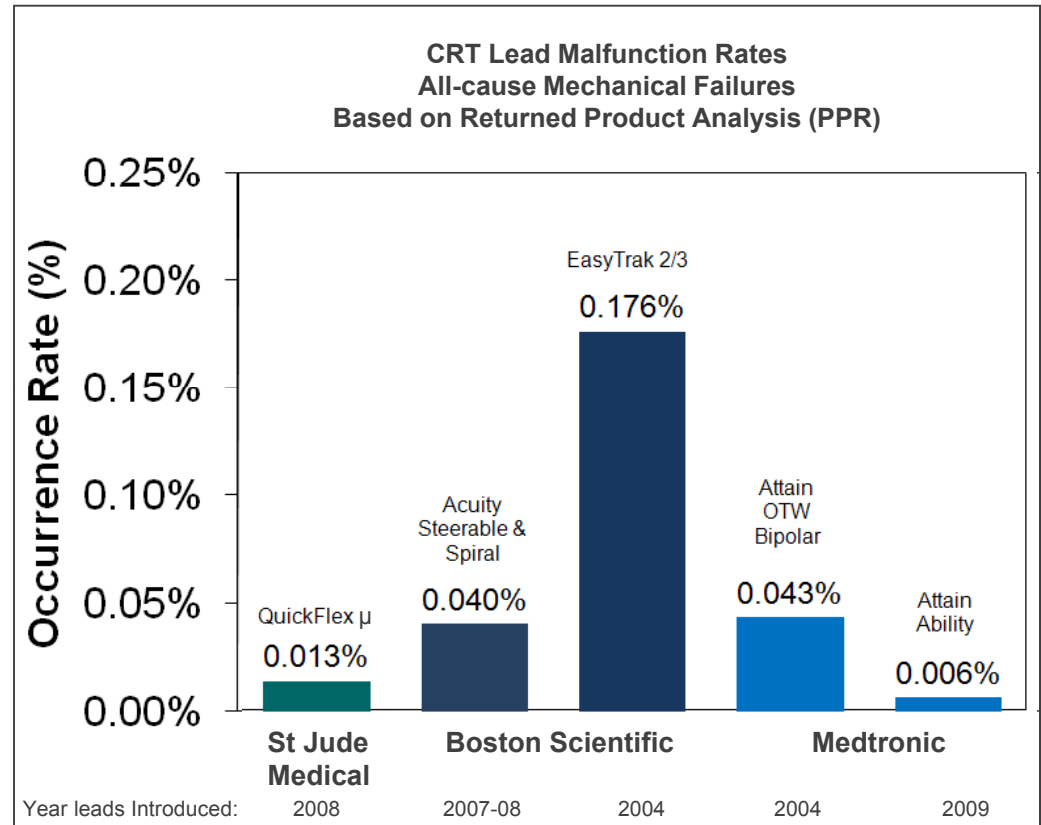
Sources: St Jude Medical worldwide returned product analysis data (US data in Nov 2011 PPR and supplemental US and International data on file).

Definitions: All-cause mechanical failure rate includes all-cause abrasions, fractures, and crimp/weld/bond failures. All-cause electrical failure rate is calculated as fractures, crimp/weld/bond failures, and insulation breaches not resulting in externalized conductors (All-cause electrical failure rate is also described as the all-cause mechanical failure rate less the externalized conductor rate).



Confirmed Mechanical Failure Rates of Industry CRT Leads

- Data from returned product analysis and Product Performance Reports (PPR) show the all-cause mechanical failure rate (includes electrical and insulation failures) of QuickFlex® μ leads compares favorably to the other LV leads on the market
- SCORE Registry data on QuickFlex μ leads through 40 months of follow-up show excellent performance
- The PPR represents US field experience, so Quartet leads data are not yet available
- St Jude Medical is also tracking performance of these leads in the OPTIMUM registry and post-approval studies



Sources: St Jude Medical worldwide returned product analysis data (US data in Nov 2011 PPR and supplemental US and International data on file). Boston Scientific worldwide data in Q4 2011 PPR, Medtronic US data in 2011-2 PPR.
Definitions: Category of all-cause mechanical failures includes all-cause abrasions, fractures, and crimp/weld/bond failures.

Summary

- QuickSite® and QuickFlex® silicone insulated leads
 - We are proactively informing clinicians of the existence of visual observations of externalized conductors despite the low potential for clinical consequences and the low reported incidence
 - All-cause electrical failure rates are low, and to date no instances of electrical dysfunction have been attributable to externalized conductors
 - Recommendation is to monitor according to normal follow-up practice
- QuickFlex μ and Quartet® Optim® insulated leads
 - QuickFlex μ and Quartet leads are made with all Optim insulation, which is greater than 50 times more abrasion resistant than silicone
 - No reports of externalized conductors in over 65,000 Optim insulated QuickFlex μ and Quartet LV leads implanted worldwide
 - St Jude Medical has active, prospective registries and post-approval studies to track performance of Optim insulated CRT leads



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

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