April 3, 2012

St. Jude Medical
Cardiac Rhythm Management Division
15900 Valley View Court
Sylmar, CA 91342-3577 USA
Tel 818 362 6822
Fax 818 364 5814

IMPORTANT MEDICAL DEVICE INFORMATION
St. Jude Medical QuickSite® and QuickFlex® Left Ventricular CRT Leads
Models 1056T, 1058T, 1156T and 1158T

Dear Doctor,

This letter provides important information regarding the potential for externalization of the ETFE coated cable conductors in St. Jude Medical QuickSite and QuickFlex Left Ventricular (LV) CRT bipolar leads listed above that utilize silicone insulation in the distal portion of the lead. St. Jude Medical is providing this information to proactively inform clinicians of the existence of visual observations of externalized conductors due to abrasion of the silicone insulation in the distal portion of these QuickSite and QuickFlex leads. 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. Although the reported rate of this visual anomaly is low, based on a review of returned leads and available fluoroscopic and x-ray images, it is estimated that 3 to 4% of QuickSite and QuickFlex leads may exhibit this anomaly. As a conservative measure, the sale of QuickSite and QuickFlex leads is being discontinued as of the date of this letter. Approximately 101,000 QuickSite and QuickFlex leads are estimated to be currently in service worldwide.

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® rather than silicone insulation.

Clinical and Non-Clinical Observations
There have been 39 confirmed cases of externalized conductors in the QuickSite and QuickFlex leads, as summarized below:

- St. Jude Medical has received 7 field reports (6 QuickSite, 1 QuickFlex) from clinicians who have observed externalized conductors at the distal, silicone insulation portion of the subject leads after lead extraction for lead dislodgement, infection, change in capture threshold, or change in lead impedance. Failure analysis of these returned leads demonstrated that none of the reported clinical observations were attributable to the externalized conductors.
- St. Jude Medical has received reports of an additional 4 QuickSite leads that had a visual observation of externalized conductors but continued to function normally; those leads remain in service.
- There have been no other field reports of a visual observation of an externalized conductor; however, laboratory analysis of returned product with or without an associated complaint identified 19 additional QuickSite and 9 additional QuickFlex leads which exhibited an externalized conductor in the distal silicone insulation area.

In none of these cases was the externalization determined to be the root cause for the product return.

Root Failure Cause
The cable conductors are connected to the pacing ring electrode of the lead, whereas a central coil conductor is connected to the pacing tip. Cable conductors can become externalized and seen outside the lead body when abrasion results in a breach to the silicone insulation in the distal section of the lead allowing the cable conductors to exit the lead body. The root failure mechanism of externalized conductors observed on QuickSite and QuickFlex leads has been identified as mechanical stress at the distal silicone insulation portion of the lead leading to the insulation abrasion.

Rate of Occurrence
The reported rate of externalized conductors in the QuickSite and QuickFlex leads is 0.023% (2.3 per 10,000 leads). The reported rate is based on 39 confirmed cases of externalized conductors in a population of approximately 82,000 QuickSite and 89,000 QuickFlex leads sold worldwide since the first introduction of the leads in 2004. However, St. Jude Medical understands that this issue is under-detected because these cases are visual observations without any signs of electrical dysfunction and fluoroscopic/x-ray imaging is not routine. Based on the existing data, the exact rate of externalized cables is unknown. St.

Jude Medical has performed a review of returned leads and available fluoroscopic and x-ray images of patients with QuickSite and QuickFlex leads (1,219 leads). It is estimated that the incidence of externalization on these leads may be at 3 to 4%. Although this estimate is based on limited available information and the actual rate may be higher or lower, a higher rate would not change the recommendations for follow up due to the very low clinical risk.

For point of comparison between CRT lead models, the table below summarizes the worldwide reported and laboratory identified rates of all-cause abrasion, all-cause mechanical failures (includes all-cause abrasions, fractures and crimp/weld/bond failures), and electrical dysfunction rates due to a lead malfunction. The externalized conductor rate is included in the all-cause abrasion rate and externalized conductors are the predominant source of the all-cause abrasions. Since the externalized conductors have not been found to be the cause of electrical dysfunction, the all-cause electrical failure rate is the all-cause mechanical failure rate (0.042%) less the externalized conductor rate (0.023%), which is 0.019% (1.9 per 10,000) for QuickSite and QuickFlex combined.

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%

The newer QuickFlex μ and the Quartet LV CRT leads introduced starting in 2008 employ Optim insulation along the entire length of the lead, including the distal portion, without the use of silicone insulation material throughout the lead body. Over 65,000 of these LV CRT full body Optim insulated leads have been sold worldwide since 2008 with no reports or laboratory observations of externalized conductors and therefore, are not subject to this communication.

Clinical Implications, Recommendations and Mitigations
In the event that a QuickSite or QuickFlex LV CRT lead experiences an externalized conductor, the likelihood of an electrical anomaly or adverse clinical event is low. There are no known risk factors for cable externalization. If externalization of the cable conductor were to occur, the ETFE coating on the cables is designed to provide adequate dielectric strength for the lead to continue to function normally without the silicone covering. The system also provides for multiple alternative pacing configurations that can be programmed, if needed. Although no electrical dysfunction attributable to these external conductors has been observed to date, in the case that all of these redundancies were to fail, the inability of the LV CRT lead to pace could affect biventricular pacing and result in exacerbation of heart failure.

St. Jude Medical and its Medical Advisory Board recommend that physicians continue to monitor their patient's implanted system at regularly scheduled intervals with attention paid to diagnostic information related to LV 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. A special X-ray or fluoroscopic imaging is not recommended for LV CRT leads with normal electrical function. CRT pacing functionality should be evaluated during routine device checks and only leads exhibiting electrical anomalies that cannot be reprogrammed to deliver effective CRT pacing should be considered for replacement.

St. Jude Medical is committed to keeping customers informed about product performance so that they can make the best patient care decisions. We regret any inconvenience this may cause you and your patients. If you have any questions or concerns, please do not hesitate to contact your local St. Jude Medical representative or our European Technical Support Department at +46 8 474 4147 or US Technical Services Department at +1 800 722-3774.

Sincerely,

Vice President, Quality Assurance

Attachment:

Device List