U.S. Recall of Riata Leads

On December 14, 2011, the U.S. Food and Drug Administration (FDA) classified St. Jude Medical Inc.'s voluntary medical device advisory letter to physicians regarding the performance of Riata and Riata ST Silicone Defibrillator Leads as a Class I Recall.

FDA Classifies Voluntary Physician Advisory Letter on Riata and Riata ST Silicone Defibrillation Leads as Class I Recall

The FDA has classified this recall as Class I because of the potential risk of serious injury or patient death if affected devices malfunction. As communicated in the November 28 Physician Advisory Letter, the clinical implications of externalized conductors in a defibrillation lead without electrical anomalies are not fully known or understood at this time. In some cases, the wires inside some leads can penetrate the insulation, resulting in inappropriate shocks. In other cases, the wires fail to deliver necessary shocks.

Any adverse reactions experienced with the use of this product should be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088 or at www.fda.gov/medwatch.

While St. Jude Medical discontinued distribution of the Riata and Riata ST family of silicone leads in December 2010, an estimated 79,000 Riata and Riata ST family of silicone leads remain active in patients in the United States. The affected model numbers are:

- Riata (8F) Silicone Endocardial Defibrillation Leads (Models 1560, 1561, 1562, 1570, 1571, 1572, 1580, 1581, 1582, 1590, 1591, and 1592)
- Riata ST (7Fr) Silicone Endocardial Defibrillation Leads (Models 7000, 7001, 7002, 7010, 7011, 7040, 7041, and 7042)

As detailed in the advisory letter to physicians, St. Jude Medical and its Medical Advisory Board recommend the following related to patient monitoring:

- For leads that do not exhibit externalized conductors, continue to monitor the patient's implanted system at regularly scheduled visit intervals every three to six months as per the Heart Rhythm Society (HRS)/European Heart Rhythm Association (EHRA) consensus statement with particular attention to diagnostic information related to defibrillation lead performance.
- For leads that exhibit externalized conductors with no electrical abnormality, continue to monitor lead and system performance as per HRS/EHRA guidelines. The value of screening x-ray or fluoroscopy for patients with leads that exhibit no electrical abnormalities is unknown at this time and therefore, the risk of increased radiation exposure for monitoring should be weighed against using remote monitoring and in-clinic follow-up for detection of electrical anomalies. Prophylactic explant or replacement of a lead without electrical dysfunction is not recommended.
- For leads that exhibit externalized conductors with an associated electrical abnormality, management of the patient may include x-ray, fluoroscopy (cine), or additional testing including provocative methods such as shoulder and arm movements and deep respiration while looking at the surface ECG and intracardiac electrograms. Consideration should be given to prophylactically replacing leads with observed electrical abnormalities. If the leads are replaced, the risks and benefits of removing the old leads, or leaving them in place, should be carefully considered.
- Currently there is no expert consensus regarding whether patients undergoing pulse generator replacement should undergo fluoroscopy or lead replacement if an externalized conductor without electrical anomalies is present. This is, in part, because the risk versus benefit of replacing a lead in such a patient may vary from patient to patient and center to center. Consideration of fluoroscopy and lead replacement at time of pulse generator replacement should be individualized based on specific patient conditions and circumstances.

St. Jude Medical strongly encourages that, when possible, remote monitoring and patient alerts are used to detect electrical changes that may be associated with externalized conductors.