St. Jude Medical, Riata and Riata ST Silicone Endocardial Defibrillation Leads: Class 1 Recall - Failures with Lead Insulation

U.S. Food & Drug Administration

AUDIENCE: Cardiology, Emergency Medicine, Risk Manager

ISSUE: FDA notified healthcare professionals of a Class I Recall of the St. Jude Medical Riata and Riata ST Silicone Endocardial Defibrillation Leads. The silicone insulation covering these defibrillation leads is at risk of premature abrasion. When abrasion occurs, the conductors inside the leads can come out (externalized) of the insulation. Leads with externalized conductors may develop electrical dysfunction and not work as intended. In the event the device does not work as intended, should a life-threatening heart rhythm occur, pacing or defibrillation therapy may not be delivered as intended. This may result in serious adverse events, including death.

The recall includes the following model numbers:

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

BACKGROUND: The leads connect an implantable cardioverter defibrillator (ICD) or cardiac resynchronization therapy defibrillator (CRT-D) to cardiac tissue in order to monitor and regulate a patient’s heart rate by providing pacing and delivery of high voltage therapy for ventricular arrhythmias.

RECOMMENDATION: On November 28, 2011, St. Jude Medical sent a Medical Device Advisory letter to physicians via certified mail. The letter is an update to St. Jude Medical’s Important Product Information letter, dated December 15, 2010. The current Medical Device Advisory letter provides an update on the failure rates associated with externalized conductors of Riata and Riata ST leads. The letter also includes updated recommendations and mitigations for patients implanted with Riata and Riata ST leads.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm [1]
- Download form [2] or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[12/20/2011 - Recall Notice [3] - FDA]

SOURCE [4]

Source URL (retrieved on *01/25/2015 - 7:35pm*):
http://www.mdtmag.com/news/2011/12/st-jude-medical-riata-and-riata-st-silicone-endocardial-defibrillation-leads-class-1-recall-failures-lead-insulation

Links:
[1] http://www.fda.gov/MedWatch/report.htm
[2] http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
[3] http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm284360.htm
[4] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm284390.htm