

Medical Device Advisory
Riata[®] and Riata[®] ST Silicone Endocardial Defibrillation Lead Performance

Dear St. Jude Medical Patient:

St. Jude Medical is committed to keeping you and your doctor informed of all important product information. As such, St. Jude Medical recently provided doctors with important information about our Riata and Riata ST silicone insulated family of defibrillation leads (Models: 1560, 1561, 1562, 1570, 1571, 1572, 1580, 1581, 1582, 1590, 1591, 1592, 7000, 7001, 7002, 7010, 7011, 7040, 7041, 7042).

As you know, your defibrillation lead is the wire that connects the defibrillator device (implanted near the shoulder) to the heart. We have informed doctors who manage patients with these leads that breaches in the outer silicone insulation that protects the inner wires have been identified in a small percentage of patients. This information applies only to these specific models of Riata silicone insulated defibrillation leads listed above. No other St. Jude Medical leads or devices are affected by this issue.

In most of the patients who have had a lead insulation breach detected, the lead has continued to operate normally to deliver the needed therapy due to a second insulation on the lead wires themselves. We encourage patients with these leads who have not already heard from their doctor's office regarding this matter to contact them with any questions or concerns they may have. The information we have provided to doctors is more detailed since they are in the best position to know how to manage your individual care.

We sincerely apologize for any concerns that this may cause you or your family. We are dedicated to providing the most reliable medical products for doctors and patients and deeply regret when an issue like this happens. We are committed to helping doctors manage this issue by continuing to provide them with all the latest information and necessary support. If you have any additional questions or would like to inquire if you have an affected Riata silicone lead, please contact St. Jude Medical Technical Services at 1-800-722-3774.

Sincerely,



Mark Carlson, M.D.
Chief Medical Officer & Sr. Vice President
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Philip Tsung
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