Premature Battery Depletion of St. Jude Medical ICD and CRT-D Devices: FDA Safety Communication

Date Issued:

October 11, 2016

Audience:

- Patients with a St. Jude Medical Implantable Cardioverter Defibrillator (ICD) and Cardiac Resynchronization Therapy Defibrillator (CRT-D) device
- Caregivers of patients with a St. Jude Medical ICD and CRT-D device
- Cardiologists, electrophysiologists, cardiac surgeons, primary care physicians treating patients with heart failure or heart rhythm problems

Medical Specialties:

Cardiac Electrophysiology, Cardiology, Cardiac Surgery, Heart Failure

Device:

St. Jude Medical Implantable Cardioverter Defibrillators (ICDs) and Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are devices that provide pacing for slow heart rhythms, and electrical shock or pacing to stop dangerously fast heart rhythms.

ICDs and CRT-Ds are both implanted under the skin in the upper chest area with connecting insulated wires called “leads” that go into the heart. Patients need an ICD or CRT-D if their heart beat is too slow (bradycardia), too fast (tachycardia), or needs coordination to treat heart failure.

The devices addressed in this communication are the following St. Jude Medical ICD and CRT-D models manufactured before May 2015:

- Fortify VR
- Fortify ST VR
- Fortify Assura VR
- Fortify Assura ST VR
- Fortify DR
- Fortify ST DR
- Fortify Assura DR
- Fortify Assura ST DR
- Unify
- Unify Quadra
- Unify Assura
- Quadra Assura
- Quadra Assura MP

Purpose:

FDA is providing information and recommendations regarding St. Jude Medical's advisory on ICD and CRT-D batteries that may fail earlier than expected. FDA and St. Jude Medical are alerting patients, patient-caregivers, and physicians to respond immediately to Elective Replacement Indicator (ERI) alerts. Due to problems with these batteries, patients do not have the normal 3-month lead time for device replacement. Some batteries have run out within 24 hours of the patient receiving an ERI alert. St. Jude Medical has initiated a recall and correction of the affected devices.

Summary of Problem and Scope:

Implanted defibrillators (ICDs and CRT-Ds) are powered by lithium-based batteries. Deposits of lithium, known as "lithium clusters," can form within the battery and create abnormal electrical connections leading to rapid battery failure.

St. Jude Medical has reported that in some cases, full battery drainage can occur within a day to a few weeks after the patient receives an ERI alert. If the battery runs out, the ICD or CRT-D will be unable to deliver life-saving pacing or shocks, which could lead to patient death. The patients most at risk are those with a high likelihood of requiring life-saving shocks and those who are pacemaker dependent.

To date, of the 398,740 affected devices sold worldwide, 841 were returned for analysis due to premature battery depletion caused by lithium clusters.

- 2 deaths (1 in the U.S.), have been associated with devices that could not provide needed shock therapy due to premature battery depletion.
- 10 patients (9 in the U.S.), have reported fainting from devices that could not provide needed pacing therapy due to premature battery depletion.
- 37 patients (30 in the U.S.), have reported dizziness from devices that could not provide needed pacing therapy due to premature battery depletion.

Battery depletion may not always be reported to the manufacturer, therefore the true number of devices with premature battery depletion due to lithium clusters is not known. At this time, 349,852 affected devices remain actively implanted worldwide.

Devices may be programmed to deliver a vibratory patient alert when the battery has reached ERI. In addition, St. Jude Medical's home monitoring system may be used to monitor battery status and provide health care provider notifications. Due to the low frequency of device failure, these are likely appropriate mitigations for most patients, as patients could be at greater risk of complications from the surgical procedure required to replace the device.

However, because battery depletion may occur rapidly after an ERI, and some patients may not detect the device alert, these mitigations may not be sufficient for all patients, such as those that are dependent upon their device for pacing with an untolerated or absent intrinsic heart rate. Health care providers should consider whether elective device replacement is warranted for their pacemaker dependent patients.

Ultimately, health care providers should individualize the care of their patients based on the patients' medical history, comorbidities and condition.

Recommendations for Health Care Providers:

- Do not implant unused affected devices. Premature battery depletion due to lithium clusters has only been observed in devices manufactured prior to May 2015. At this time, there is no information indicating that this issue affects devices manufactured after this date.
- Communicate with all patients who have an affected device that their device has a battery that may run out earlier than expected. Consider giving patients the Dear Patient letter provided by St. Jude Medical.

- Continue to conduct follow-up on patients with affected devices using in-office visits in addition to remote monitoring once they have been notified of the battery issue. Increased in-office surveillance is not necessary for patients who are also followed with remote monitoring.
- Immediately replace the device at the time of an ERI alert. Currently, there is not a factor, method, or test to identify when devices with this form of premature battery depletion are approaching ERI, or to accurately predict remaining battery life once ERI appears.
- Pacemaker-dependent patients with a device that has reached ERI should be treated as a medical emergency.
- Health care providers should consider whether elective device replacement is warranted for their pacemaker dependent patients. Ultimately, health care providers should individualize the care of their patients based on the patients' medical history, comorbidities and condition.
- Most patients will not require prophylactic device replacement prior to ERI, as the rate of complications following replacement surgery are higher than those associated with premature battery depletion. However, the FDA and St. Jude Medical recognize the need to weigh individual clinical considerations. If the decision is made to replace an affected device based on individual patient circumstances, St. Jude Medical has announced they will provide a replacement device at no cost.
- Enroll patients in Merlin@Home, St. Jude Medical's home monitoring system for these devices, especially those who have difficulty recognizing their device's ERI alerts. For patients already enrolled in Merlin@Home, explain the importance of ongoing home monitoring. Utilize the "Direct Alerts" feature to provide you with an alert notification when a patient's device has reached ERI. Please see additional information about the **Merlin@Home Monitoring System** below. If a home monitor is ordered for a patient with an affected device, St. Jude Medical will cover the cost of the home monitor.
- Ensure that the ERI battery alert is ON for all patients. Review the most recent "Programmed Parameters" printout.
  - Review the "Trigger Alerts When" section, and ensure that the "Device at ERI" parameter is **"On"** for both the "Show on FastPath" and "Notify Patient" selections.
  - If the "Device at ERI" alert is **"Off"**, the patient should be seen promptly to program this parameter to **"On"**.
- Advise affected patients that an ERI alert triggers a vibratory notification, and perform the following procedures at each scheduled office visit:
  - Interrogate the patient's device to determine if an ERI alert has been triggered. Premature battery depletion can be identified by health care providers through home monitoring showing ERI or more advanced battery depletion.
  - Perform a patient notifier test to confirm that the patient feels and recognizes the vibratory alert.
  - Patients who cannot feel the vibratory alert may experience loss of battery and/or loss of device function without their awareness.
  - Advise the patient to contact your office promptly should they feel a vibratory alert. An in-office evaluation should be performed to determine the reason for the alert as other non-critical events can also trigger a vibratory alert.

Recommendations for Patients and Caregivers:

- **Contact your physician if you feel a vibratory alert.** St. Jude Medical ICD and CRT-D devices are designed to deliver a vibratory alert to you when the battery is nearing its end of life. Immediately contact your physician if you feel the device's vibratory battery alert. Devices affected by this advisory may reach end of battery life anywhere from within one day to several weeks after the vibratory alert has

been delivered. If the device does deliver a vibratory alert due to low battery, it will need to be replaced.

- **Register for home monitoring.** St. Jude Medical devices are capable of home monitoring, which can alert your physician to a notification that the battery is approaching end of life. If you do not already use home monitoring for your device, and especially if you have difficulty recognizing your device's end of battery alerts, you and your physician should consider whether home monitoring is appropriate for you. Please see additional information about the **Merlin@Home Monitoring System** below.
- **Seek immediate medical attention** if you have symptoms of lightheadedness, dizziness, loss of consciousness, chest pain, or severe shortness of breath. These may be signs of a depleted battery.

Management of your implanted device and your medical condition must be individualized. You should consult with your health care provider to determine the best course of action.

Merlin@Home Monitoring System:

At this time, the FDA recommends that patients, patient caregivers, and health care providers enroll in and utilize the St. Jude Medical Merlin@Home monitoring system to help detect battery depletion. The FDA is investigating cybersecurity concerns associated with these devices, including the Merlin@Home.

The FDA (in partnership with the Department of Homeland Security ICS-CERT) continues to investigate recent allegations of cybersecurity vulnerabilities associated with St. Jude Medical cardiac devices, including the Merlin@Home monitoring system. Despite the allegations, at this time, the FDA strongly recommends that the Merlin@Home device be used to monitor the battery for these affected devices. The ICD and CRT-D devices identified in this safety communication provide life-saving therapy, and the FDA believes that the benefits of monitoring outweigh any potential cybersecurity vulnerabilities.

FDA Actions:

The FDA will continue to monitor affected St. Jude Medical ICD and CRT-D devices for any adverse events related to premature battery depletion or cybersecurity vulnerabilities, and the agency will keep the public informed as new information becomes available.

Reporting Problems to the FDA:

Prompt reporting of adverse events can help the FDA identify and better understand the risks related to the use of medical devices. If you suspect or experience a problem with these devices, we encourage you to file a voluntary report through MedWatch, the FDA Safety Information and Adverse Event Reporting program. Health care personnel employed by facilities that are subject to FDA's user facility reporting requirements should follow the reporting procedures established by their facilities.

Additional Resources:

- **St. Jude Medical – Premature Battery Depletion Information (https://www.sjm.com/en/professionals/resources-and-reimbursement/technical-resources/product-advisories-archive)** **(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**

Contact Information:

If you have questions about this communication, please contact the **Division of Industry and Consumer Education (DICE) (/MedicalDevices/DeviceRegulationandGuidance/ContactDivisionofIndustryandConsumerEducation/ucm20041265.htm)**

at **DICE@FDA.HHS.GOV (mailto:DICE@FDA.HHS.GOV)**, 800-638-2041 or 301-796-7100.

More in Safety Communications (/MedicalDevices/Safety/AlertsandNotices/default.htm)

Information About Heparin (/MedicalDevices/Safety/AlertsandNotices/ucm135345.htm)

Reducing Risks Associated with Medical Device Misconnections (/MedicalDevices/Safety/AlertsandNotices/TubingandLuerMisconnections/default.htm)