St. Jude Medical Recalls Implantable Cardioverter Defibrillators (ICD) and Cardiac Resynchronization Therapy Defibrillators (CRT-D) Due to Premature Battery Depletion - Update

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Product(s):

- Fortify, Unify, and Assura (including Quadra) Implantable Cardioverter Defibrillators (ICD) and Cardiac Resynchronization Therapy Defibrillators (CRT-D)
- Model/Item Numbers: See "Full List of Affected Devices"
- Manufacturing Dates: January 2010 to May 2015
- Distribution Dates: February 2010 to October 2016
- Devices Recalled in the U.S.: 175,624 Nationwide

Device Use

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.

Images of a Fortify Assura VR ICD, and a Quadra Assura CRT-D

Reason for Recall

This recall notice updates FDA's October 2016 recall notice to include information about the Battery Performance Alert (BPA), a new battery performance management tool that St. Jude Medical notified customers about on August 28, 2017.

Who May be Affected

- Patients with a St. Jude Medical ICD or CRT-D device
- Caregivers of patients with a St. Jude Medical ICD or CRT-D device

- Health care providers treating patients with heart failure or heart rhythm problems using St. Jude Medical ICD or CRT-D devices

What to Do

On August 28, 2017, St. Jude Medical **notified physicians (https://www.sjm.com/~/media/galaxy/hcp/resources-reimbursement/technical-resources/product-adviseries-archive/battery-advisory-aug2017/battery-performance-alert-doctor-letter-aug2017-us.pdf?la=en)** **(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)** of the availability of Battery Performance Alert (BPA), a new battery performance management tool that detects and notifies physicians of abnormal battery performance that may lead to premature battery depletion in Implantable Cardioverter Defibrillators.

If a BPA is triggered for a patient's device, the patient's physician will be notified through the device programmer and/or the Merlin@home monitoring system. St. Jude Medical recommends immediate device explant and replacement.

If a BPA is not triggered, St. Jude Medical recommends that physicians follow patient management recommendations included in their **2016 Premature Battery Depletion Advisory (https://www.sjm.com/en/patients/arrhythmias/resources-support/battery-advisory)** **(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**.

Full List of Affected Devices

- Fortify VR: Model No(s). CD1231-40, CD1231-40Q
- Fortify ST VR: Model No(s). CD1241-40, CD1241-40Q
- Fortify Assura VR: Model No(s). CD1257-40, CD1257-40Q, CD1357-40C
- Fortify Assura ST VR: Model No(s). CD1263-40, CD1263-40Q, CD1363-40C, CD1363-40Q
- Fortify DR: Model No(s). CD2231-40, CD2231-40Q
- Fortify ST DR: Model No(s). CD2241-40, CD2241-40Q
- Fortify Assura DR: Model No(s). CD2257-40, CD2257-40Q, CD2357-40C, CD2357-40Q
- Fortify Assura ST DR: Model No(s). CD2263-40, CD2363-40C, CD2363-40Q
- Unify: Model No(s). CD3231-40, CD3231-40Q
- Unify Quadra: Model No(s). CD3249-40, CD3249-40Q
- Unify Assura: Model No(s). CD3257-40, CD3357-40C, CD3357-40Q
- Quadra Assura: Model No(s). CD3265-40, CD3265-40Q, CD3365-40C, CD3365-40Q
- Quadra Assura MP: Model No(s). CD3269-40, CD3269-40Q, CD3369-40C

Contact Information

Customers with questions regarding patient management, including observed changes in battery longevity, should contact your local Sales Representative or Abbot Technical Services at 1-(800)-722-3774, which is available 24 hours a day, 7 days a week.

Date Recall Initiated

August 28, 2017

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to **MedWatch: The FDA Safety Information and Adverse Event Reporting Program (/Safety/MedWatch/HowToReport/ucm2007306.htm)**. Health care professionals employed by facilities that are subject to **FDA's user facility reporting** requirements (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm) 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) (/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)
- St. Jude Medical – Battery Advisory (https://www.sjm.com/en/patients/arrhythmias/resources-support/battery-advisory) (/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)
- FDA 2016 Safety Communication - Premature Battery Depletion of St. Jude Medical ICD and CRT-D Devices (/MedicalDevices/Safety/AlertsandNotices/ucm524666.htm)
- FDA 2016 Recall Notice - St. Jude Medical Recalls Implantable Cardioverter Defibrillators (ICD) and Cardiac Resynchronization Therapy Defibrillators (CRT-D) Due to Premature Battery Depletion (/MedicalDevices/Safety/ListofRecalls/ucm526317.htm)

More in Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/default.htm)

2017 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm535289.htm)

2016 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm480134.htm)