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

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 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.: 251,346 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

St. Jude Medical is recalling certain models of the Fortify, Unify, and Assura ICDs and CRT-Ds due to reports of rapid battery failure caused by deposits of lithium (known as "lithium clusters"), forming within the battery, and causing a short circuit.

If the battery unexpectedly runs out before the patient is aware of the rapid battery drain and able to have it replaced, the ICD or CRT-D will be unable to deliver life-saving pacing or shocks, which could lead to patient death.

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 October 10, 2016, St. Jude Medical sent notification letters to customers and health care providers informing them of the possibility of premature battery depletion in affected ICD and CRT-D devices.

Additionally, on October 11, 2016, the FDA issued a **safety communication (/MedicalDevices/Safety/AlertsandNotices/ucm524666.htm)** regarding this recall, and provided recommendations for health care providers, patients, and caregivers.

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, CD1357-40Q
- 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, CD-2241-40Q, CD2263-40, CD2263-40Q
- Fortify Assura DR: Model No(s). CD2257-40, CD2257-40Q, CD2357-40C, CD2357-40Q
- Fortify Assura ST DR: Model No(s). 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, CD3257-40Q, 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 may contact St. Jude Medical Customer Service at: 1-866-915-5065.

Date Recall Initiated

October 10, 2016

Additional Resources:

- **St. Jude Medical – Premature Battery Depletion Information (https://www.sjm.com/en/professionals/resources-and-reimbursement/technical-resources/product-advisories-archive)**
- **St. Jude Medical – Battery Advisory (https://www.sjm.com/en/patients/arrhythmias/resources-support/battery-advisory)**
- **Premature Battery Depletion of St. Jude Medical ICD and CRT-D Devices: FDA Safety Communication (/MedicalDevices/Safety/AlertsandNotices/ucm524666.htm)**

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.

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)