Abbott (Formerly St. Jude Medical Inc.), Recalls Ellipse Implantable Cardioverter Defibrillators Due to Exposed Aluminum Wires That May Prevent Defibrillation Therapy

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

- Certain Ellipse Implantable Cardioverter Defibrillators
- Lot Numbers: All lots manufactured between April 5, 2019 - May 29, 2019
- Model Numbers: CD1377-36C, CD1377-36QC, CD1411-36Q, CD2377-36QC, CD2411-36C, CD2411-36Q
- Manufacturing Dates: April 5, 2019 to May 29, 2019
- Distribution Dates: May 6, 2019 to June 14, 2019
- Devices Recalled in the U.S.: 108
- Date Initiated by Firm: June 20, 2019

Device Use

Abbott implantable cardioverter defibrillators provide pacing for slow heart rhythms and electrical shock or pacing to stop dangerously fast heart rhythms. These cardiac devices are implanted under the skin in the upper chest area with connecting insulated wires called "leads" that go into the heart. A patient may need an implantable cardiac device if their heartbeat is too slow (bradycardia), too fast (tachycardia), or needs coordination to treat heart failure.

Reason for Recall

Abbott is recalling the Ellipse Implantable Cardioverter Defibrillators (ICDs) because electrical failures have been identified and determined to be due to a faulty manufacturing process causing some aluminum wires to be partially exposed. ICDs which contain aluminum wires that are not fully insulated are prone to electrical shorting of the capacitor. The potential patient impact could be the inability to deliver high voltage therapy. There is currently no available method or procedure to determine which of these devices have this issue prior to failure.

Abbott is aware of zero (0) related reports of this failure occurring in any affected implanted devices. Of the devices recalled in the US, 31 devices have been implanted. The complaints and MDRs available have either reported that the affected devices have been replaced or are scheduled to be replaced with another ICD generator. None of the complaints or MDRs indicate that any patient harm or adverse events have occurred, and no deaths have been reported.

Who May be Affected

- Patients who have the affected implanted Ellipse Implantable Cardioverter Defibrillators
- Healthcare professionals who use the Ellipse Implantable Cardioverter Defibrillators

What to Do

On June 21, 2019, Abbott hand-delivered an Urgent Medical Device Recall letter to customers. The letter directed customers to take the following actions:

- Review the device model and serial numbers to identify the impacted patients and return the acknowledgement form to the sales representative.
- **Device explant and replacement are recommended.** Abbott will work with you to provide an Abbott replacement device.

Contact Information

Customers with questions about patient management or this recall, please contact Abbott Support at 1-800-727-7846 (select option #3), 8:30 AM – 5:30 PM (Central Time), Monday through Friday.

Additional Resources

- Abbott Urgent Medical Device Recall Notice (June 21, 2019) (Abbott Urgent Medical Device Recall Notice (June 21, 2019))

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems they experience using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) either online, by regular mail or by FAX to 1-800-FDA-0178. Health care professionals employed by facilities that are subject to FDA's user facility reporting requirements (/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities) should follow the reporting procedures established by their facilities.

More Information

- Class 1 Device Recall Abbott Ellipse VR, CD 1377-36C Implantable Cardioverter Defibrillators (ICDs) (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=174305)
- Class 1 Device Recall Abbott Ellipse VR, CD 1377-36QC Implantable Cardioverter Defibrillators (ICDs) (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=174306)
- Class 1 Device Recall Abbott Ellipse VR, Tiered-therapy Cardioverter/Defibrillator CD 1411-36Q (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=174307)
- Class 1 Device Recall Abbott Ellipse DR, CD 2377-36QC Implantable Cardioverter Defibrillators (ICDs) (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=174308)
- Class 1 Device Recall Abbott Ellipse DR, Tiered-therapy Cardioverter/Defibrillator CD 2411-36C (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=174309)
- Class 1 Device Recall Abbott Ellipse DR, Tiered-therapy Cardioverter/Defibrillator CD 2411-36Q (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=174310)