Abbott (formally known as “St. Jude Medical”) Recalls Assurity™ and Endurity™ Pacemakers for Potential Moisture Ingress Causing Electrical Short and Reduced Battery Life

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

- Scalable Bradycardia Platform (SBP) Pacemakers: Assurity™ and Endurity™
- Distribution Dates: April 29, 2015 to February 20, 2019
- Devices Recalled in the U.S.: 61,973
- Date Initiated by Firm: March 15, 2021

Device Use

Assurity™ and Endurity™ are implantable pacemakers that detect when the heart is beating too slowly (bradycardia) and then send signals to the heart to make it beat at the correct pace. These pacemakers can be used to provide pacing for one chamber of the heart or both chambers, based on the patient’s condition.

Reason for Recall

Abbott (formally known as “St. Jude Medical”) is recalling a subset of Assurity and Endurity pacemakers built using specific manufacturing equipment, that were then distributed from April 2015 to February 2019. A small number of devices from that time frame have experienced problems when moisture is able to get inside the device. The moisture can cause an electrical short, that may lead to:

- A loss of device pacing
- Telemetry failure or errors in information
- Early and fast battery drain
- Less time between the first battery depletion warning (elective replacement indicator or ERI) and the device’s end of service (EOS)

If the device is unable to deliver pacing, patients may experience slow or irregular heartbeat, fainting, shortness of breath, tiredness, dizziness, or discomfort. Additionally, shorter battery life and device life may lead to an additional pacemaker replacement procedure sooner than expected. Finally, if the system does not relay accurate information via telemetry, medical providers may not know to provide treatment.

There have been 135 complaints, 135 injuries, and no deaths reported for this issue.

Who May be Affected

- Health care providers using the affected devices
- Patients who had procedures using the affected devices

What to Do

On March 15, 2021, Abbott sent customers a letter informing them of the issue and providing patient management guidelines, including:

- **No recommendation for replacing the device if there is no evidence of the issue**, due to a low rate of occurrence and low potential for patient harm as long as a replacement is completed if the device issues an unexpected ERI/EOS alert.
- **Routine follow-up per standard of care and clinical protocol, to include:**
    - A review of any device function impacts such as battery voltage or any unexpected change in battery consumption.
    - Evaluating the potential risk for patients who are pacemaker dependent and unable to be reliably followed using remote monitoring.
- **Prompt replacement for devices that reach ERI or EOS unexpectedly or experience a clinical impact.**
- **If possible, use Abbott’s Merlin.net patience management system for patient monitoring to receive alerts between routine device checks.** Remind patients of the importance of using remote monitoring.

Contact Information

Customers with questions should contact Abbott Technical Support at 1-800-722-3774.

Additional Resources:

- Medical Device Recall Database Entry (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?id=186270)

- Abbott Safety Notification (https://www.cardiovascular.abbott/content/dam/bss/divisionalsites/cv/pdf/reports/assurity-endurity-032021-DDL-US.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program using an online form, regular mail, or FAX.