Boston Scientific Corporation Recalls EMBLEM S-ICD (Subcutaneous Implantable Cardioverter Defibrillator) System Due to Risk of Short-Circuit

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 (Include the following information)

- EMBLEM S-ICD (Subcutaneous Implantable Cardioverter Defibrillator)
- Lots: See below
- Model: S-ICD A209 and MRI S-ICD A219
- Distribution Dates: June 1, 2015 – September 30, 2019
- Devices Recalled in the U.S.: 2825
- Date Initiated by Firm: December 2, 2020

Device Use

The EMBLEM S-ICD (Subcutaneous Implantable Cardioverter Defibrillator) is part of the Boston Scientific S-ICD System. The Boston Scientific S-ICD is an implantable cardioverter defibrillator (https://www.nhlbi.nih.gov/health-topics/defibrillators) that is intended to provide electrical shock to stop dangerously fast heart rhythms and pacing for a short time after shocks if needed. These cardiac devices are placed under the skin in the upper chest area.

Reason for Recall

Boston Scientific is recalling the EMBLEM S-ICD because a manufacturing process may allow moisture to get inside the defibrillator and cause a short-circuit when it tries to deliver high voltage shocks. If this happens during use, patients may experience less shock than intended or may not receive a shock at all. The device may also beep, not respond to a device check in, and issue battery alerts.

A defibrillator with the manufacturing error may delay or prevent the device from delivering a lifesaving electrical shock to a person in cardiac arrest (tachycardia) and lead to serious injury or death. Additional surgeries may also be needed to replace failed devices.

The manufacturer has received six complaints about this device issue. There have been no reports of injuries or deaths.

Who May be Affected

- Health care providers using the affected Boston Scientific device
- Patients who have procedures with the affected Boston Scientific device

What to Do

In December 2020, Boston Scientific sent an Urgent Medical Device Advisory to all affected customers. The notice instructed customers to:

- Follow-up in the next 6 weeks and discuss this advisory with patients to ensure awareness, to review their individual clinical status and perspective, and to determine their individual risk status.
    - Perform a system follow-up every 3 months per labeling thereafter via remote or in-office interrogation.
- Enroll and monitor patients through LATITUDE remote monitoring to detect any alerts or artifacts on the devices in between office device checks.
    - Ask patients to inform their clinic if they are unsuccessful in interrogating their device.
- Investigate any suspected indication of inability to interrogate, premature battery depletion, or prolonged charge time alerts.
    - Contact Boston Scientific Technical Services for assistance as needed.
- Demonstrate the device beeper to the patient during the next office visit.
    - For patients not monitored by LATITUDE, repeat the beeper demonstration following any MRI scan, as strong magnetic fields may cause permanent loss of beeper volume; and
    - Remind patients to promptly contact their physician if beeping tones are heard from their device, if a shock is delivered, or if any LATITUDE communicator transmissions are unsuccessful.
    - Reinforce that your patient should promptly report any new or unexpected symptoms suspicious for a ventricular tachyarrhythmia by contacting their clinic and, if applicable, perform a remote interrogation via LATITUDE.
- Evaluate the risk for life-threatening harm due to device malfunction. This is greatest for patients who:

- Have a history of life-threatening ventricular arrhythmias such as secondary prevention
- Are unable to be reliably followed remotely or in person every three months
- Are not monitored via LATITUDE and are unable to hear beeping tones

- Replace any device suspected of exhibiting electrical overstress.
  - Routine replacement of a device is not recommended
    - Consider prophylactic device replacement after taking individual patient preferences and circumstances into account through a process of shared decision-making.
  - Return explanted devices to Boston Scientific. A no cost Return Product kit is available from your local Boston Scientific representative.
- Update medical Records with this letter for each patient with an affected EMBLEM S-ICD
  - Append their medical record with a copy of this letter to maintain awareness of this topic for the remaining service life of the device.
  - Any adverse events or quality problems experienced with use of this product should be reported in accordance with all applicable local regulations and to Boston Scientific.

Contact Information

Customers who have questions about the notification should contact their local sales representative or the Boston Scientific Technical Services team's 24-hour call center at (800)-CARDIAC (227-3422) or by emailing tech.services@bsci.com (mailto:tech.services@bsci.com).

Full List of Affected Devices:

Model GTIN A209: 00802526575181; 00802526575143; 00802526544101; 00802526575129; 00802526548406; 00802526575211; 00802526575136; 00802526575105; 00802526575204; 00802526575112; 00802526575167; 00802526575228; 00802526599002; 00802526575174; 00802526577147

Model GTIN A219: 00802526581519; 00802526584404; 00802526584411; 00802526590436; 00802526590429; 00802526590405

Additional Resources:

- EMBLEM MRI S-ICD Model A219 Recall Database Entry (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=184795)

- EMBLEM S-ICD Model A209 Recall Database Entry (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=184794)
- Urgent Medical Device Advisory (https://www.bostonscientific.com/content/dam/bostonscientific/quality/dlt/reg-code-228/2020Dec_EMBLEM Electrical Overstress_PhysLtr_US_Final.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.