

August 2019

Dear Patient,

We would like to let you know about a possible issue with some EMBLEM™ subcutaneous implantable cardioverter defibrillators (S-ICDs). Your S-ICD is part of a limited group of these devices (about 400 out of over 56,000 distributed worldwide) that may not last as long as expected. In some of these S-ICDs, an electrical part within the device may cause the battery to wear out faster than normal.

Your physician can follow battery wear in your S-ICD through LATITUDE™ remote monitoring and/or regular scheduled in-office device follow up. You can also listen for device beeping, which means your device must be checked as soon as possible. Our company has already let your physician know about this issue as we hope to prevent a situation where battery wear is not detected, and the device is not able to work as intended. Devices that have shown this battery wear have been successfully replaced, and no other injuries have occurred.

To confirm that your S-ICD is part of the affected group, visit this website: www.BostonScientific.com/lookup. You will need to enter your language, as well as the model and serial number of your S-ICD from your patient ID card. The letter we sent to your physician is also available at this location.

What should you do?

- Keep all your medical appointments and S-ICD device checks.
- Talk to your physician about the best steps for managing your device.
- Have your physician or device nurse/technician turn on your device's beeper in the clinic, so you know what it sounds like.
- If you don't have a Boston Scientific LATITUDE™ home monitor, ask your physician if it is an option for you.
- Call your physician if you hear beeping sounds from your S-ICD.

Patient safety is our highest priority. We encourage you to discuss this letter with your physician to determine how this new information may affect you.

Sincerely,



Renold J. Russie
Vice President, Quality Assurance



Kenneth Stein, MD, FACC, FHRS
Senior Vice President and Chief Medical Officer, CRM