Boston Scientific Recalls INGENIO Family of Pacemakers and CRT-Ps Due to Risk of Incorrect Transition to Safety Mode

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

- Product Names: INGENIO Family of Pacemakers and CRT-Ps (includes models ADVANTIO DR EL, INGENIO DR EL and VITALIO DR EL)
- Product Codes: LWP
- Model Numbers: J174, J177, K174, K184, and K187
- Manufacturing Dates: September 2011 to December 2018
- Distribution Dates: November 1, 2011 to August 1, 2020
- Devices Recalled in the U.S.: 48,000
- Date Initiated by Firm: June 3, 2021

Device Use

Boston Scientific INGENIO family pacemakers or cardiac resynchronization therapy pacemakers (CRT-Ps) are devices used with patients who have low heart rates, and patients with moderate to severe heart failure, a condition in which the heart cannot pump enough blood to meet the body's needs.

Reason for Recall

Boston Scientific is recalling INGENIO family of pacemakers and CRT-Ps due to the risk of incorrect transition to safety mode. Safety mode is intended to provide backup if the device is faulty. However, in safety mode, there is a risk of inappropriate loss of pacing due to sensing of muscle contractions. If the device incorrectly goes into safety mode, the device cannot be reprogrammed and must be replaced.

The use of affected product may cause serious adverse health consequences, including early device replacement, loss of pacing or ability to regulate heart rate with serious or life threatening injury (for example, need of temporary pacing where a healthcare provider delivers controlled electric pulses to pace a heart), worsening of heart failure and death.

There have been 65 reported incidents, including three injuries which required patients to receive temporary external pacing. There have been no reports of death.

Who May be Affected

- Health care providers using affected Boston Scientific Recall of INGENIO family of pacemakers and CRT-Ps
- Patients implanted with affected devices

What to Do

On June 3, 2021, Boston Scientific sent all affected customers an Important Medical Device Advisory. The letter requested customers to:

- When assessing potential risk for a patient if their device incorrectly transitions to safety mode, consider patient-specific factors (which may vary over time), including underlying health issues, pacemaker dependence, or problems with pacing.
- If a device incorrectly enters safety mode, schedule replacement. Boston Scientific does not recommend preventive replacement for affected devices. However, for individual patients, factors such as those listed above in the previous bullet and shared decision-making may support consideration of early device replacement to prevent unintended outcomes. In these cases, the following guidance should be considered:
    - For EL pacemakers, if early replacement is planned, schedule replacement when the service life of the device is four years (or less, if the device currently indicates fewer than four years remaining).
    - For CRT-Ps, if early replacement is planned, schedule replacement when the service life of the device remaining is three years (or less, if the device currently indicates fewer than three years remaining).
- Perform a system follow-up remotely or in person at least every 12 months. For patients who may not require early device replacement, continue with existing follow-up

procedures until there is one year of service life expected and then follow-up every three months until replacement (as indicated in the device's instructions for use).

- For each patient with an affected device, add the Boston Scientific INGENIO EL Pacemakers and CRT-Ps Physician Letter sent on June 3, 2021 to their medical record to maintain awareness of this topic for the remaining service life of the device.
- Report adverse events experienced with the INGENIO family of pacemakers or CRT-Ps to Boston Scientific or the FDA's MedWatch Adverse Event Reporting program.
- Return explanted devices to Boston Scientific. A no-cost Return Product Kit is available from your local Boston Scientific representative. This kit is also available at no charge through Boston Scientific's Customer Service department at 1-800-CARDIAC (227-3422) or 651-582-2698.

Contact Information

Customers in the U.S. with questions about this recall should contact Boston Scientific at 1-800-227-3422.

Full List of Affected Devices

A complete list of affected devices is available in the Medical Device Recalls database (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=187900).

Additional Resources:

1. Medical Device Recall Database Entry (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=187900)
2. Boston Scientific INGENIO EL Pacemakers and CRT-Ps Physician Letter

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.