Update to Field Safety Notice

FOR A SUBSET OF ZENEX™, ASSURITY™, AND ENDURITY™ PACEMAKERS

MODELS PM2152, PM2162, PM2172, PM2272, PM2282

November 2022

Dear Physician or Healthcare Professional:

Abbott is following up on our July 2022 Field Safety Notice affecting a specific subset of Zenex™, Assurity™, and Endurity™ pacemakers. The issue stemmed from an intermittent manufacturing laser surface preparation subprocess at the device header joint potentially leading to moisture ingress.

This specific manufacturing process is no longer in use. No potentially affected devices remain available for implant.

The July 2022 Field Safety Notice indicated that if device functionality interruption were to occur, it presented on average at 749 days (approximately 2.1 years).

Abbott is providing the following supplemental information for consideration by clinicians in determining the appropriate course of action for patients:

- The observed average time to functionality interruption at present is 2.2 years post implant
- There is a high degree of statistical confidence (95%) that, if a malfunction were to occur, **99% of devices will present functionality interruption at or after 1.44 years (526 days)**

This supplemental information on risk timing does not alter the patient management recommendations communicated in the July 2022 Field Safety Notification. Physicians and other healthcare professionals should always monitor patients and use their own medical judgement to make medical decisions, considering each patient's individual clinical situation.

Additional Information:

As an additional resource, a device lookup tool was made available at https://www.cardiovascular.abbott/int/en/hcp/product-advisories/laser-adhesion-safety-lookup.html and can aid you or your practice in confirming impact for those patients you are following.

Additionally, the July 2022 communication is located at: https://www.cardiovascular.abbott/int/en/hcp/product-advisories.html.

Abbott has notified all applicable regulatory agencies about this matter. Please share this notification with others in your organization and follow-up centers, as appropriate.

Adverse reactions or quality problems experienced may be reported directly to Abbott. Should you have any questions about this notice, please contact your local Abbott Representative. In addition, please work with your Abbott Representative to return any explanted devices to Abbott for product evaluation and analysis.

We sincerely apologize for any difficulties or inconvenience that this may cause. Please know that Abbott is committed to providing the highest quality products and support, and we thank you for assisting with this process.

Sincerely,

Robert Blunt

Robert Blunt
Divisional Vice President, Quality
Abbott Cardiac Rhythm Management