



Urgent Field Safety Notice
FOR A SUBSET OF ZENEX™, ASSURITY™, AND ENDURITY™ PACEMAKERS
MODELS PM2152, PM2162, PM2172, PM2272, PM2282

July 2022

Dear Physician or Healthcare Professional:

Abbott is informing clinicians of the potential for device malfunction which may affect a specific subset of serial numbers of Zenex™, Assurity™, and Endurity™ pacemakers. Through June 2022, Abbott's product performance surveillance processes have identified an observed rate of 0.15% of distributed product detected with interrupted device functionality such as loss of pacing, reduced battery longevity, devices reverting to back-up mode, and/or loss of telemetry / communication. These devices were distributed and implanted in geographies outside the United States.

There have been no reports of permanent harm to patients resulting from this issue.

Issue Overview:

A manufacturing laser surface preparation subprocess, unique to a single assembly line subject to process variation, may not have properly prepared the device's metal housing potentially leading to abnormal device-to-header adhesion. This in turn may allow moisture ingress into the pulse generator header. This specific manufacturing process is no longer in use.

To date, one hundred twenty-eight (128) complaints have been identified from approximately 83,000 specific serial numbers potentially susceptible to this issue. Functionality interruption was noticed on average after 749 days (~2.1 years) of implant duration. The reported clinical impact has included loss of pacing, reduced battery longevity, devices reverting to back-up mode, and/or loss of telemetry / communication. Based on data reviews, the functionality interruption may occur as soon as within a week from the last transmission date in Merlin.net.

Our records indicate you have received or are following one or more patients implanted with one of these devices (see enclosed Device List). Patient management recommendations for this population are noted below.

For any unused devices, your Abbott Representative will assist you to quarantine, return to Abbott, and replace affected serial number devices. To this end, either through your Abbott representative or through email delivery, a letter was provided approximately one (1) week ago with a list of serial numbers of potentially non-implanted devices. Please identify and quarantine any unused product, and return these devices to Abbott.

Patient Management Recommendations:

Recognizing that each patient requires individual consideration by their physician, in consultation with Abbott CRM's Medical Advisory Board (MAB), Abbott provides the following guidelines:

- **Prophylactic generator replacement is NOT generally recommended.**
- **When possible, monitor patients using Merlin.net** to benefit from compliance and alert monitoring, including Electronics Performance Indicator (EPI – see description below), between routine device checks. For patients currently enrolled in Merlin.net, remind them of the importance of using remote monitoring, which provides daily monitoring of ERI alerts and will now also include monitoring of the safety notification population by the EPI tool.

- **Consider individualized therapy up to and including generator replacement for patients who are at high risk if interruption of pacemaker function were to occur**, potentially considering
 - Adequacy of intrinsic / underlying rhythm
 - Individual patient characteristics and circumstance
 - Ability to adequately monitor patients based on risk
- **Prompt replacement for devices that receive an EPI notification, reach ERI**, or experience one of the clinical impacts listed above, unless particular patient circumstances preclude this.

Abbott will continue to follow its product performance surveillance processes relating to this population of potentially impacted devices, and provide further guidance if appropriate.

EPI (Electronics Performance Indicator) Description:

The EPI tool assists in patient management in patients followed with Merlin.net. The EPI tool supplements ERI using data available on Merlin.net to identify abnormal electrical system behavior resulting from loss of hermeticity. The EPI tool is an Abbott surveillance process that reviews data from all devices within this affected population communicating with Merlin.net. If an EPI signal is detected, Abbott will notify the clinic using the email contact information in Merlin.net. Please ensure your clinic contact information in Merlin.net is current.

Additional Information:

As an additional resource, a device lookup tool has been 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.

Abbott has notified all applicable regulatory agencies about this matter. Please share this notification with others in your organization, 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 us with this process.

Sincerely,



Robert Blunt
Divisional Vice President, Quality
Abbott Cardiac Rhythm Management