VOLUNTARY MEDICAL DEVICE RECALL
URGENT

FOR A SUBSET OF ASSURITY™ AND ENDURITY™ PACEMAKERS

MODELS PM1160, PM1172, PM1240, PM1272,
PM2160, PM2172, PM2240, PM2260, PM2272

March 15, 2021

Dear Abbott Customer,

Overview:

Abbott is informing customers of an issue which may affect a subset of Assurity™ and Endurity™ pacemakers. Through Abbott's post market surveillance processes, a low observed rate (0.049%) of malfunctions has been detected among devices manufactured on specific manufacturing equipment between 2015 and 2018. These units were from a manufacturing process which is no longer in use. No affected devices remain available for implant.

There have been no reports of serious harm to patients as a result of this issue.

Abbott has identified a subset of approximately 95,000 devices within the referenced timeframe that are potentially susceptible to this issue. Our records indicate you are following one or more patients implanted with one of these devices (see enclosed Device List).

The issue is caused by intermittent incomplete mixing of epoxy during manufacture, which may allow moisture ingress into the pulse generator header. As a result, the potential for affected devices is inconsistently dispersed throughout the above time period. To date, one hundred thirty-five (135) devices have been observed with this issue. The reported clinical impact has included loss of telemetry / communication, reduced battery longevity, loss of pacing, and/or shortened duration between Elective Replacement Indicator (ERI) and End of Service (EOS). Forty-eight (48) devices were returned with an associated report suggesting loss of pacing. Additionally, twenty-one (21) returned devices reached ERI earlier than expected with an average of 17 days from ERI to EOS.

Patient Management Recommendation:

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

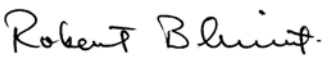
- **Prophylactic generator replacement is not recommended.** This is due to the very low rate of occurrence, and the low potential for patient harm when prompt replacement is performed following an unexpected ERI/EOS alert.
- **Routine follow-up should remain as per standard of care and clinical protocol.**
  - During follow-up, review any impact to device function including measured battery voltage or any unexpected change in battery consumption.
  - Evaluate potential for risk in patients who are pacemaker dependent and unable to be reliably followed using remote monitoring.
- **Prompt replacement for devices that reach ERI or EOS unexpectedly** or experience one of the clinical impacts listed above commensurate with the patient's underlying clinical condition.
- **When possible, monitor patients using Merlin.net** to benefit from alert monitoring between routine device checks. For patients currently enrolled in Merlin.net, remind them of the importance of using remote monitoring. ERI and EOS alerts are currently monitored daily.

Abbott will notify 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