重要安全性通知

針對部分 ASSURITY™ 及 ENDURITY™ 心律調節器

型號 PM1152、PM1160、PM1172、PM1240、 PM1272、PM2152、PM2160、PM2172、PM2240、PM2260、PM2272

2021 年 3 月 15 日

雅培客戶您好：

概述：

雅培目前通知客戶與部分 Assurity™ 及 Endurity™ 心臟節律器相關之事件。透過雅培的上市後監控程序，發現 2015 年至 2018 年間由特定製造設備所生產的醫材，具有低觀察率 (0.049%) 的故障情況。目前舊有設備已停用，受影響的器材已不再用於植入手術。

未曾接獲該事件導致患者嚴重傷害之通報。

雅培在調查時間內，列出約 95,000 台可能受此問題影響之醫材。根據記錄顯示，您的患者植入有其中一款節律器 (請參見附件的醫材清單)。

此事件主要是製程中環氧樹脂間歇性的不完全混合，其可能讓水分進入節律器和導線的接頭處，造成受影響節律器在上述期間電位輸出不穩定。截至目前為止，已發現有 135 台節律器有此問題。通報的臨床影響包括遙測/與程控儀通訊功能異常、電池壽命降低、節律異常，及/或縮短擇期更換指示 (ERI) 至使用終期 (EOS) 之間的時間。48 台退回的節律器，其隨附報告顯示為節律異常。此外，21 台退回的節律器比預期更早達到 ERI，從 ERI 至 EOS 平均為 17 天。

患者處置建議：

諮詢雅培 CRM 醫療諮詢委員會 (Abbott CRM's Medical Advisory Board; MAB)後，針對醫師個別診療每位患者時，雅培提供下列準則：

- **不建議預防性更換節律器**。由於該事件發生率極低，且於收到非預期 ERI/EOS 警報後立即更換節律器，患者受到傷害的可能性很低。
- **應依標準治療及臨床規則進行常規追蹤。**
  - 追蹤期間，請檢視對器材功能造成的所有影響，包含測量電池電壓或電池消耗的所有非預期變化。
  - 患者若依賴心臟節律器但無法以遠端監測確實追蹤，則請評估其可能之風險性。
- **器材達到非預期 ERI 或 EOS**，或患者潛在的臨床情況類似上述其中一項臨床影響，**請立即更換器材**。
- **儘可能使用 Merlin.net 監測患者**，其有益節律器常規檢查之間的警報監測。請提醒目前加入 Merlin.net 的患者，使用遠端監測的重要性。目前正於每日進行 ERI 及 EOS 警報監測。

雅培會將呈報該事情至相關權責主管機關。若有必要，亦請將本通知轉知相關人員。

若有不良反應或任何品質問題請通報雅培。若對本通知有任何疑問，請接洽雅培當地代表。此外，如果有相關之節律器移除，亦請聯絡雅培代表寄回該醫材，以協助進行產品評估及分析。

對此造成您的困擾或不便，我們深表歉意。雅培致力提供最高品質的產品及服務，感謝您為此事件提供協助。

順頌　時祺

Robert Blunt
區域品質部門副總裁
雅培心律管理

Urgent Field Safety Notice

FOR A SUBSET OF ASSURITY™ AND ENDURITY™ PACEMAKERS

MODELS PM1152, PM1160, PM1172, PM1240, PM1272, PM2152, 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:

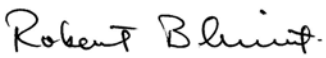
- **Prophylactic generator replacement is not recommended.** This is due to the very low rate of occurrence, and the low potential for patient harm when prompt replacement is performed following an unexpected ERI/EOS alert.
- **Routine follow-up should remain as per standard of care and clinical protocol.**
  - 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