重要安全性訊息更新

針對部分 ASSURITY™ 及 ENDURITY™ 心臟節律器

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

2021 年 10 月 5 日

醫師及專業醫護人員您好：

雅培持續追蹤 2021 年 3 月之客戶安全性通知，內容為部分 Assurity™ 和 Endurity™ 心臟節律器可能因製程中環氧樹脂間歇性的不完全混合而受到影響，此事件可能導致水分進入節律器和導線的接頭處，進而造成器材功能中斷的風險。如 2021 年 3 月通知所述 (請見下方連結)，目前該特定製程已不再使用，且受影響的器材也不再用於植入手術中。

未曾接獲因該事件導致患者嚴重傷害之通報。

2021 年 3 月，雅培通知醫師大約有 95,000 台以特定製造設備生產的醫材可能受此問題影響。通報的臨床影響包括遠距監測/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。

自 2021 年 3 月以來，雅培的上市後監測發現 29 台不在 2021 年 3 月通知範圍內之器材發生水分進入的問題。依據進一步調查通報事件，雅培擴大通知範圍，另外納入大約 240,000 台的器材。擴大群體後得知觀察到的事件比率為 0.01%。

雅培記錄顯示，您的患者植入如附件醫材清單所述之可能受影響的節律器。雖然整體風險特性低，但請參考下方之患者處置建議。

雅培展開了新的**電子性能指示 (EPI) 工具，以協助患者之進一步處置。**EPI 工具利用 Merlin.net 的現有數據，協助 ERI 識別因喪失密封度而導致異常的電力系統。EPI 工具估計靈敏度為 87% (偵測異常電力系統的能力)，估計特異性 > 99.9%。EPI 工具能即早提供指示，平均在器材功能中斷前 6 週便可偵測出來 (例如失去遠距監測/通訊等)。EPI 工具為雅培的監測流程，檢視所有透過 Merlin.net 通訊之受影響器材的資料，如果偵測到 EPI 信號，雅培將透過 Merlin.net 上的電子郵件聯絡資訊通知醫療單位。故請確認 Merlin.net 上保有貴單位之最新的聯絡資訊。

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，雅培提供下列更新準則：

- **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 EPI 通知或 ERI/EOS 警報後再更換節律器，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。**請檢視器材功能，包含量測電池電壓或電池消耗的所有非預期變化。此外，患者若需依賴心臟節律器但無法使用遠端監測確實追蹤，亦請評估其潛在之風險。
- **收到 EPI 通知、達到 ERI/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，其可每日監測 ERI 及 EOS 警報，現在也亦可以使用 EPI 工具監測安全性通知之受影響族群。

收到此通知後，請協助完成通知確認表，並留存本通知與確認表，以確保有效之通知。

關於其他資源，您可於 www.cardiovascular.abbott/pacemaker-lookup 利用器材查找工具，協助確認後續追蹤患者是否受到影響。

此外，最初 2021 年 3 月的通知請參見：https://www.cardiovascular.abbott/int/en/hcp/product-advisories.html。

雅培會將該事件呈報相關權責主管機關。若有需要，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 Update

FOR A SUBSET OF ASSURITY™ AND ENDURITY™ PACEMAKERS

MODELS PM1152, PM1160, PM1172, PM1240, PM1272, PM2152, PM2160, PM2172, PM2240, PM2260, PM2272

October 2021

Dear Physician or Healthcare Professional:

Abbott is following up on our March 2021 customer Safety Notification communication affecting a subset of Assurity™ and Endurity™ pacemakers which may be impacted by intermittent incomplete mixing of epoxy in the manufacturing process. This issue may potentially allow moisture ingress into the pulse generator header, introducing a risk of interrupting device functionality. As described in the March 2021 communication (see hyperlink below), this specific manufacturing process is no longer in use, and no affected devices remain available for implant.

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

In March 2021, Abbott notified physicians that approximately 95,000 devices manufactured on specific manufacturing equipment were potentially susceptible to this issue. 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).

Since March of 2021, Abbott's post-market surveillance process has identified 29 devices exhibiting moisture ingress that were out of the range of the March 2021 communication. Based on further investigation of the reported events, Abbott is expanding the communication to include approximately 240,000 additional devices. This expanded population has demonstrated an observed issue rate of 0.01%.

Abbott records indicate you are following one or more patients implanted with a potentially affected device as noted in the enclosed Device List. The overall risk profile is low, though please reference the patient management recommendations below.

Abbott has deployed a new **Electronics Performance Indicator (EPI) tool to assist 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 estimated sensitivity is 87% (ability to detect abnormal electrical system behavior of this nature) and estimated specificity is > 99.9%. The EPI tool has been designed to provide earlier indication, with detection occurring on average 6 weeks before an interruption of a device function (e.g. loss of telemetry / communication, etc.). The EPI tool is an Abbott surveillance process that reviews data from all devices within the 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.

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 updated 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 replacement is performed following an EPI notification or an ERI/EOS alert.
- **Routine follow-up should remain as per standard of care and clinical protocol.** Review device function including measured battery voltage or any unexpected change in battery consumption. Also, evaluate the potential for risk in patients who are pacemaker dependent and are unable to be reliably followed using remote monitoring.

- **Prompt replacement for devices that receive an EPI notification, reach ERI/EOS,** 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, which provides daily monitoring of ERI and EOS alerts and will now also include monitoring of the safety notification population by the EPI tool.

Please return a completed Acknowledgement Form and maintain a record of this notice along with a copy of the completed Acknowledgement Form to ensure effectiveness of the communication.

As an additional resource, a device lookup tool has been made available at www.cardiovascular.abbott/pacemaker-lookup and can aid you or your practice in confirming impact for those patients you are following.

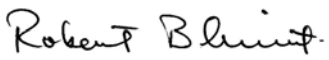
Additionally, the initial March 2021 communication is located at: https://www.cardiovascular.abbott/int/en/hcp/product-advisories.html.

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,



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