重要安全性通知

對於部分 ASSURITY™ 及 ENDURITY™ 心臟節律器

型號 PM2152、PM2162、PM2172、PM2272

2022 年 7 月

醫師及專業醫護人員您好：

雅培特此通知臨床醫師潛在性的產品異常，其可能影響部分序號的 Assurity™ 及 Endurity™ 心臟節律器。截至 2022 年 6 月為止，於雅培之產品性能監視程序中，察覺到 0.15% 的分銷產品出現醫材功能干擾，例如節律漏失、電池壽命降低、醫材返回至備用模式及/或失去遙測/通訊功能之情形。這些醫材曾經分銷及植入於美國以外的地區。

未曾接獲該事件導致患者永久傷害之相關通報。

事件概述：

雷射表面處理之製程中，獨特單一之組裝產線受到程序變動之影響，可能無法妥善製作器材之金屬外殼，造成醫材與頂蓋黏合異常，可能導致水分進入節律器頂蓋處。該特殊製程已不再使用。

目前大約 83000 個可能與該事件相關的特定序號中，有一百二十八 (128) 件有關的客訴。平均植入 749 天 (約 2.1 年) 後，發現功能有受到干擾的情形。已通報的臨床影響包含節律漏失、電池壽命降低、醫材返回至備用模式及/或失去遙測/通訊功能。依據檢視的數據，最快可能在 Merlin.net 最後傳輸日的一週內有功能受到干擾的情形發生。

根據記錄顯示，您的其一或多個患者植入有受影響之節律器 (請參見附錄的醫材清單)。針對該病患之處置建議如下。

對於任何未使用的醫材，雅培業務代表會協助您將其隔離、退回雅培並置換受影響序號之醫材。為此，雅培代表或透過電子郵件約在一 (1) 週前已提供列有可能未植入醫材之序號列表的信件，請識別並隔離任何未使用的受影響產品，並將其退回雅培。

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，對於醫師個別診療每位患者，雅培提供下列準則：

- **通常不建議預防性更換節律器。**
- **儘可能使用 Merlin.net 監測患者，**包含使用電子性能指示(Electronics Performance Indicator, EPI-參看說明如下)，其有益於節律器常規檢查之間的醫囑遵循及警報監測。請提醒目前使用 Merlin.net 追蹤的患者，使用遠端監測的重要性，其可提供每日監測 ERI 警報，現在亦可使用 EPI 工具監測安全警訊之相關族群。

- **如果心臟節律器功能受到干擾，則須考慮對處於高風險的患者進行個別化治療，包括更換節律器。**可能須考慮
  - 是否有足夠的自主心律/基礎心律
  - 個別患者的特性及情形
  - 是否能依風險等級充分監測患者
- **收到 EPI 通知、達到 ERI**，或類似上述其中一項臨床影響，**請立即更換醫材**，除非患者之情況特殊。

雅培會繼續執行這些潛在性受影響醫材之產品性能監測程序，並適時提供進一步指引。

EPI (電子性能指示) 說明：

EPI 工具協助使用 Merlin.net 追蹤的患者進行後續管理。EPI 工具利用 Merlin.net 中的資料，協助 ERI 識別因喪失密封度而導致的電力系統異常。EPI 工具是雅培的監控程序，其檢視所有受影響族群之節律器其與 Merlin.net 連結之資料。如果偵測到 EPI 訊號，雅培將透過 Merlin.net 上的電子郵件聯絡資訊通知院方。故請確認 Merlin.net 中的院方連絡資料為最新資訊。

其他資訊：

關於其他資源，可於 https://www.cardiovascular.abbott/int/en/hcp/product-advisories/laser-adhesion-safety-lookup.html取得受影響醫材的查詢工具(device lookup tool)，其協助您確認患者是否受到影響。

雅培已將此事件呈報所有相關權責主管機關。亦請視需要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。對於本通知若有任何疑問，請洽詢雅培當地業務代表。此外，若有相關之節律器移除，請聯絡雅培業務代表退回該醫材，以進行產品評估及分析。

此事件若造成任何困難或不便，我們謹此致歉。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的協助。

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 PM2152, PM2162, PM2172, PM2272

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 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

Robert Blunt
Divisional Vice President, Quality
Abbott Cardiac Rhythm Management