Safety Communication رسالة سلامة

PACEMAKERS- Potential for Moisture to Enter the Pulse Generator Header

Device/ Product Description:	SUBSET OF ASSURITY™ AND ENDURITY™ PACEMAKERS
Affected product:	MODELS PM1152, PM1160, PM1172, PM1240, PM1272, PM2152, PM2160, PM2172, PM2240, PM2260, PM2272 Devices manufactured on specific manufacturing equipment between 2015 and 2018
Manufacturer:	St. Jude Medical Inc
Problem:	Malfunction caused by intermittent incomplete mixing of epoxy during manufacture, which may allow moisture ingress into the pulse generator header.
Recommendation /Actions:	- Deployed a new Electronics Performance Indicator (EPI) tool to assist in patient management in patients followed with Merlin.net. - 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.

<table>
<tr><td></td><td colspan="2">

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.

For more information, please click here.

If you think you had a problem with your device or a device your patient uses, please report the problem to SFDA through:
NCMDR
Vigilance system
(19999)unified call center
</td></tr>
<tr><td rowspan="4">Authorized Representative Details</td><td>AR name:</td><td>Al-Jeel Medical & Trading Co. LTD</td></tr>
<tr><td>Assigned Contact Person:</td><td>Meshal Aleshaiwy</td></tr>
<tr><td>Mobile/Phone:</td><td>+(966) 508827808</td></tr>
<tr><td>Email:</td><td>aljeel.sfda@aljeel.com</td></tr>
</table>