URGENT MEDICAL DEVICE CORRECTION

FOR A SUBSET OF AVEIR™ VR LEADLESS PACEMAKERS
MANUFACTURED PRIOR TO FEBRUARY 1, 2024
MODEL LSP112V

April 2024

Dear Physician or Healthcare Professional:

Summary:
Abbott is informing customers of the potential for electromagnetic interference (EMI) to cause an inadvertent mode change in a subset of Aveir™ VR LSP112V devices manufactured with firmware version 19.05.00 prior to February 2024. This issue is corrected through a firmware upgrade.

There have been zero (0) reports of permanent harm to patients due to this issue with two devices replaced due to early detection of Recommended Replacement Time (RRT) (see Risk to Health below). If present, the mode change is detected during a Merlin programmer interrogation session as the Aveir VR device may potentially present in Emergency VVI (EVVI) or MRI (VOO) mode. As communication with the Aveir VR pacemaker requires a Merlin programmer (remote monitoring is not currently available), the issue will be detected at a scheduled in-clinic follow-up unless patient symptoms prompt an earlier evaluation.

The issue may cause an Aveir VR device to enter either EVVI or MRI mode. The parameters for EVVI mode are VVI pacing at 6 V @ 0.6 ms and 70 bpm, and MRI mode is VOO mode at 5 V @ 1 ms and 85 bpm. Compared to nominal settings[1], the increased pacing output and rate of each mode may reduce longevity.

Risk To Health:
Among approximately 12,000 Aveir VR devices subject to this notification, two patient effects have been reported. Four patients (0.034%) reported the sensation of an elevated heart rate consistent with the mode change. Two devices (0.017%) exhibited early detection of RRT and were subsequently replaced. Early RRT is consistent with the increased pacing outputs. Each month of operation if in MRI mode or EVVI mode is estimated to consume 8% of the device longevity (Beginning of Service (BOS) to RRT) as measured at beginning of life. The service life for a device if operating entirely in EVVI or MRI mode from BOS to RRT will be approximately 13 months. Inadvertent mode change without patient symptoms has been reported at follow-up in 13 other devices (0.112%). Those Aveir VR devices were successfully reprogrammed to their original settings and remain in-service.

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

1. **Prophylactic device replacement is NOT recommended.**
    - All currently manufactured LSP112V devices utilize the upgraded firmware.
    - Following the firmware upgrade, the implanted device will be equivalent to newly manufactured LSP112V devices.

2. As part of follow-up, suggested within 3 months, upgrade the LSP112V firmware.
    - For most devices, the upgrade will execute automatically when interrogated. If required, contact Technical Services to assist with the upgrade.
    - If the device presents in MRI or EVVI mode, reprogram the device to the desired mode and settings.

Action Abbott Has Taken:
Upgraded Merlin™ PCS 3650 programmer software facilitates the download of Aveir device firmware version 19.12.00 through an automatic prompt to the user during an in-clinic interrogation. All device settings and therapies remain active during the firmware download. Zero (0) devices with firmware 19.12.00 have experienced the reported mode change issue.

This programmer software and upgraded device firmware are available to clinics starting April 2024.

[1] Aveir VR Instructions for Use: ARTEN600175956; pgs. 62-63

Additional Information:
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.

Abbott has notified applicable regulatory agencies about this matter.

Adverse reactions or quality problems experienced with the use of this product should be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

The Instructions for Use has content available regarding potential EMI sources.

During the upgrade if any issues are encountered, or if further support is required, contact Technical Services at 1-800-722-3774 (U.S.).

A list of Abbott advisories is available at https://www.cardiovascular.abbott/us/en/hcp/product-advisories.html. We sincerely apologize for any difficulties or inconvenience that this may cause you and your patients. 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