Medtronic

Urgent Field Safety Notice

Azure™ and Astra™ pacemakers, and Percepta™, Serena™ and Solara™ cardiac resynchronization therapy pacemakers (CRT-P)

Performance Note Low Voltage Capacitor

May 2019

Medtronic reference: FA871

Dear Physician or Healthcare Professional,

Medtronic is issuing a performance note regarding a rare failure mode in a population of Azure™ and Astra™ pacemakers, and Percepta™, Serena™ and Solara™ cardiac resynchronization therapy pacemakers (CRT-P), manufactured with a specific multilayer ceramic capacitor. These devices continue to meet all manufacturing specifications and perform within reliability projections and any unused devices may be implanted.

On May 7th, 2019, Medtronic posted the attached performance note on our website.

In consultation with Medtronic's Independent Physician Quality Panel (IPQP) normal patient follow-up in accordance with standard practice is recommended. Medtronic strongly recommends against prophylactic device replacement as the projected rate for this issue is extremely low and the devices continue to perform within reliability projections. The estimated per patient mortality risk (catastrophic harm) for this issue is estimated to be 0.000008%, as compared to the estimated per patient mortality risk of complications associated with an incremental, early device replacement of 0.027%.

Customer Actions

Please complete the following actions:

- Review the attached performance note regarding a rare failure mode.
- Please share this information with healthcare professionals in your facility that use any of the above listed devices. Also share this information with any other organization where these devices may have been transferred.

Please maintain a copy of this notice in your records.

Medtronic has notified the Competent Authority of your country of this action.

We are committed to patient safety and welcome any questions you may have regarding this communication.

Sincerely,

Enclosure: May 2019 Performance Note

May 2019

PERFORMANCE NOTE

Potential for no output/no telemetry condition in subset of IPG and CRT-P products due to ceramic capacitor leakage pathway.

Medtronic has identified a rare but potentially serious failure mode in a population of Azure™ and Astra™ pacemakers, and Percepta™, Serena™ and Solara™ cardiac resynchronization therapy pacemakers (CRT-P), manufactured with a specific multilayer ceramic capacitor. These devices continue to perform within reliability projections.

While inherently very reliable, a known failure mode of these capacitors is the potential for internal cracking that can be caused by thermal-mechanical stress during manufacturing. Under rare conditions, internal cracking within a capacitor may result in the development of a leakage pathway, causing high current drain and leading to rapid battery depletion. While the issue presents as rapid battery depletion, this is not a battery performance issue.

As of April 26, 2019, three complaints out of ~266,700 devices distributed worldwide since February 2017, have been received that included a no output /no telemetry scenario resulting from rapid battery depletion. Battery depletion due to this issue can range from several days to several weeks. One of these reported events contributed to a patient death. The three confirmed failures occurred within 9 months post implant. The projected rate for this issue is 0.0028%, with the most susceptible period for a leakage pathway to develop in the capacitor being the first 12 months post implant.

Based on the low predicted rate of failure and the recent implementation of process and component enhancements, Medtronic expects few, if any, additional events to occur. Medtronic, in consultation with our Independent Physician Quality Panel, does not recommend device replacement. Physicians should continue normal patient follow-up in accordance with standard practice, and where possible, continue to utilize the low battery voltage wireless CareAlert™ (shipped ON), together with remote monitoring via CareLink™ home monitor or the MyCareLink Heart™ mobile app. Per the instructions for use, at each follow-up, verify the status of the implanted system as well as the clinical effectiveness of the device. Pay attention to any unexpected changes in remaining longevity estimates or the inability to interrogate the device and/or transmit data.

Contact Medtronic Technical Services if you have concerns on a specific patient.

Confirmed premature battery depletions, regardless of cause, are reported in our semi-annual Product Performance report under the confirmed “Malfunctions” section for each device model. Product Performance information can be accessed directly at: http://wwwp.medtronic.com/productperformance/