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,

Local /BU Manager

Enclosure: May 2019 Performance Note