Medtronic

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Notice of Medical Device Performance Note

Low Voltage Capacitor

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

7th May 2019

Attention: Risk management Director and O.R Materials Management
CC: The Chairman Medical Board and relevant Head of Departments

Dear Healthcare Professional,

Medtronic is issuing a Performance Note regarding 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. This Performance Note, like others previously issued, is provided for transparency to a rare failure mode and can also be accessed from the CRHF Product Performance Report at http://wwwp.medtronic.com/productperformance/performance-notes.html

On 8th May 2019, Medtronic posted the attached Performance Note on our website.

Actions and Information

- 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.
- After review of this information, complete the enclosed Customer Confirmation Form and email/ provide to your local Medtronic representative.

Sincerely,

[redacted]

Diana Teo
QRA Lead Cluster 1

Enclosure: May 2019 Performance Note
Customer Confirmation Form

Medtronic

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/

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ALL CUSTOMERS PLEASE COMPLETE THE FORM IN ITS ENTIRETY

Customer Contact Details	Medtronic Contact Details
	Name:
Physician / HCP/Hospital :	**Contact:**
Address:	**Email:**
Phone no:	
E-mail:	

Indicate in the columns below on all Product code and serial number in your facility. If your list is too long, you may attached a spreadsheet to list the fields as per below table.

For Physicians: In the event you no longer implant and/or manage patients with these types of devices, please provide a detailed explanation in the table below under Remarks so that Medtronic's records can be updated accordingly.

Product Code	Lot #	Remarks

Note: The addressee may continue to receive reminders of this notice until a response is received.

By signing this form, I confirm that I have received and understand attached information:
Notice of Medical Device Performance Note Low Voltage Capacitor, dated on 7th May 2019.

Name: _____ (print) Signature: _____ Stamp: _____ Date:_____