HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Medtronic Implantable Pacemaker & CRT-P Devices

Affected Models: Azure™, Astra™, Percepta™, Serena™, Solara™

Priority 2 – Warning

HPRA Safety Notice: SN2019(21) **Issue Date: 7th June 2019**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Medtronic Inc.	V39970

ISSUE
Medtronic issued a field safety notice (FSN) and a Performance Note to advise of a rare but potentially serious failure mode identified in a population of Azure™ and Astra™ pacemakers, and Percepta™, Serena™ and Solara™ Cardiac Resynchronization Therapy Pacemakers (CRT-P). Medtronic has advised that under rare conditions, internal cracking within the capacitor used in these devices may result in the development of a leakage pathway. This pathway may cause high current drain and lead to rapid battery depletion. The Performance Note also highlighted that the reports received included a no output / no telemetry scenario. As the battery may

deplete rapidly, the elective replacement indicator (ERI) for pacemaker-dependent patients should be followed up immediately.

Medtronic is advising physicians/healthcare practitioners to continue normal patient follow-up in accordance with standard practice, and **where possible**, continue to utilize the low battery voltage wireless CareAlert™, together with remote monitoring via CareLink™ home monitor or the MyCareLink Heart™ mobile app.

Healthcare providers should pay immediate attention to any unexpected changes in longevity of the device as well as to the inability to interrogate the device and/or transmit data. Please see accompanying Medtronic FSN and Performance Note for further details regarding this issue and required patient follow up.

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

1. Review the accompanying FSN and Performance Note and follow the instructions provided by the manufacturer.
2. Acknowledge receipt of the FSN to the manufacturer.
3. Forward a copy of this Safety Notice, the FSN and the Performance Note to all relevant personnel within your organisation, or any person/s or organisation to whom/which this device has been transferred.
4. Report any adverse events associated with these devices to the manufacturer and the HPRA.

TARGET GROUPS

Cardiologists	Electrophysiologists
Cardiac surgeons	Primary care physicians
Cardiac pacemaker/ICD technicians	Medical Directors
Clinical Engineers / Biomedical Engineers	Nursing Staff
HSE Hospital Staff	Private Hospital Staff
Hospital Managers	Purchasing / Procurement / Material Managers
Supplies Managers	Theatres
Risk Managers	

BACKGROUND

Azure™ and Astra™ cardiac pacemakers are cardiac devices that monitor and regulate a patient's heart rate by providing single or dual chamber rate-responsive bradycardia pacing. Percepta™, Serena™, and Solara™ Cardiac Resynchronization Therapy Pacemakers (CRT-P) additionally provide sequential biventricular pacing therapies.

Medtronic has advised that as of 26th April 2019 they have received 3 complaints of this issue from approximately 266,700 devices worldwide. Medtronic has indicated that one of these events is thought to have contributed to a patient death. Medtronic has informed the HPRA that 659 devices within the scope of this FSN have been supplied to the Irish market.

The performance note for this issue indicates that the three confirmed failures occurred within 9 months post implant, and that the most susceptible period for a leakage pathway to develop in the capacitor is within the first 12 months following implant.

Healthcare practitioners are also advised to follow the Instructions For Use (IFU) and verify the status of the implanted system and the clinical effectiveness of the device at each follow-up. In addition, Medtronic advise to pay attention to any unexpected changes in remaining longevity estimates or the inability to interrogate the device and/or transmit data and to contact Medtronic Technical Services if there are concerns with a specific patient. Please see the accompanying FSN and Performance Note.

The HPRA is issuing this Safety Notice to raise awareness of this issue.

MANUFACTURER CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

Medtronic Inc.
710 Medtronic Parkway,
Minneapolis,
MN 55432
USA

Telephone: 01-5111400
E-mail: vigilance.eu@medtronic.com
Website: www.medtronic.ie

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie