The Cardiac Society
of Australia and
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ANZCDACC Advisory Notice 25th November 2015

Device: Medtronic InSync III Cardiac Resynchronization Therapy Pacemakers (CRT-P) Models 8042, 8042B, 8042U

Advisory Grade TGA: Hazard Alert (All stock implanted, no stock to recall)
ANZDACC Advisory Grade: Semi-urgent

Number at risk in Australia and New Zealand: 1378 Devices

Risk: There is the potential for unexpected high battery impedance, which can result in premature battery depletion, erratic battery behavior and loss of ventricular capture. Modeling by Medtronic predicts an estimated failure rate between 0.16% and 0.6% for the remaining active devices. There is no provocative testing that can predict which specific devices may fail, and there is no programming that can mitigate this issue.

Description: Unexpected high battery impedance due to development of a resistive film on the Cathode of the pacemaker battery secondary to an unintended interaction between the fluoride in the Cathode and Titanium in the current collector.

Presentation: Patients who are pacing dependent can present with syncope or presyncope. In addition, loss of left ventricular pacing can cause heart failure symptoms or worsening heart failure.

Advice: Prophylactic device replacement in non-pacemaker-dependent patients is not currently recommended. For pacemaker-dependent patients, physicians should carefully weigh the risks and benefits of device replacement on an individual patient basis. Medtronic estimates the patient mortality risk of the advisory is 0.007% to 0.02% and, as such, is comparable to the estimated patient mortality risk of complications associated with an early device replacement (0.005%).

Home monitoring is not possible for these devices and so increased in-office follow-up (three- to six-monthly) is recommended. In addition, the patient should maintain an awareness of new symptoms or symptom progression.