**ANZCDACC Advisory Notice 6th December 2020**

**Device:**
**Medtronic Cobalt™ and Crome™ ICD and CRT-D**

**Advisory grade TGA:** Urgent Product Defect Correction

**ANZDACC Advisory Grade:** Routine

**Description:**
The of Ventricular fibrillation anti-tachycardia pacing (VF- ATP) parameter in these devices may not be automatically enabled and may require manual programming and as such may inadvertently be set to off.

**Number of devices affected in Australia and New Zealand:**
Australia: and New Zealand: TBA

**Presentation:**
Patient may present with high voltage therapies which were previously treated with ATP

**Rate of occurrence:**
1 incidence out of 3,237 devices implanted worldwide related to this advisory issue. No serious adverse events have been reported. These devices will deliver all programmed high-voltage therapies as programmed, regardless of the VF ATP parameter setting being off. The issue is risk for a high-voltage therapy to be applied for a Fast VT arrhythmia in the VF detection zone, which could have been treated with ATP during Charging.

**Recommendation:**

Confirm the appropriate selection has been programmed for the VF ATP parameter at implant.

At routine follow-up, confirm that the VF ATP parameter is programmed to the desired setting for each patient.

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**The ANZCDACC encourage you to report any adverse event or near (potential) adverse event associated with the use of a medical device including any abnormal CIED or lead function. We encourage reporting to ANZCDACC directly via the Committee chair Dr Paul Gould drpgould@gmail.com and to the following regulators.**

**In Australia, report to the TGA;**

Online https://www.tga.gov.au/reporting-problems

**In New Zealand, report to Medsafe;**

Post Compliance Management Branch, Medsafe, PO Box 5013, Wellington 6145.
Email devices@moh.govt.nz
Fax 04 819 6806