ANZCDACC Advisory Notice 5th September 2013

Device: **Boston Scientific: COGNIS Implantable Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) and TELIGEN DR & VR Implantable Cardioveter-Defibrillators (ICDs)** Manufactured prior to December 2009

Advisory Grade TGA: Class I Hazard Alert (All Devices Implanted)
ANZDACC Advisory Grade: Semi Urgent

Number in Australia: Approximately 300 at risk

Risk: Approximately 0.67% or 1 in 150.

Description: Boston Scientific has identified a low voltage (LV) capacitor component that, in some devices, may experience diminished performance after two or more years of implant time. This can increase battery use and eventually trigger one or more Safety Architecture alerts, accompanied by patient-audible beeping. All devices that experience diminished LV capacitor performance require replacement. If not replaced, increased current drain could deplete the battery and compromise therapy or telemetry.

Presentation: Advisory presents with “beeping” of device or safety alerts or battery at ERI (prematurely).

Advice: All devices with this problem should be replaced. Otherwise surveillance is satisfactory. Usual in office follow-up (3-6 monthly) is sufficient and it is strongly advised to place patients with these devices on home monitoring.