

ANZCDACC 5th September 2013, Patient letter

PRODUCT:

**COGNIS Implantable Cardiac
Resynchronization Therapy Defibrillators
(CRT-Ds) and TELIGEN DR & VR Implantable
Cardioverter-Defibrillators (ICDs)**

Manufactured prior to December 2009

Boston Scientific (the manufacturer of the ICD) and the TGA (the body that regulates medical devices in Australia) have recently identified a potential problem with a number of ICDs manufactured prior to December 2009.

The ICD's affected suffer premature battery failure due to a problem with one of the components within the device. This means the ICD uses excess current and the battery runs down prematurely and requires early replacement. It is currently estimated 0.67% or (approximately 1 in 150 ICDs) are potentially effected. Your cardiologist will likely contact you in the next few days if you have been implanted with one of these devices.

The ICD checks its battery status automatically on a regular basis and has a safety feature which will "beep" for approximately 20 seconds every 6 hours when the battery level falls to the level where replacement is required.

If your device **does beep** you should contact your cardiologist or pacemaker clinic immediately and arrange a check of your device within the next 24hrs.

The current recommendation is to continue with normal follow up of your device (every 3-6 months) but you might want to discuss with your cardiologists about reducing this interval if you are particularly concerned.

You may also be suitable for "remote monitoring" (where you are given a monitor to take home which allows your cardiologist to follow your device more closely via the internet). Your cardiologist may discuss this option with you at your next clinic visit.

Importantly the device continues to function normally and will treat potentially life threatening rhythm problems should they occur. To date no patient has suffered any serious problems as a result of this potential problem.

If you have any concerns you should contact your cardiologist or pacemaker clinics to discuss this hazard alert further.