Boston Scientific: COGNIS Implantable Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) and TELIGEN DR & VR Implantable Cardioveter-Defibrillators (ICDs) (10 October 2014 Addendum)

Link to ANZCDACC Advisory Notice from 5 September 2013

In addition to the original advisory below

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

Boston scientific has included

Device: **Boston Scientific: COGNIS Implantable Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) and TELIGEN DR & VR Implantable Cardioveter-Defibrillators (ICDs)** Manufactured prior to March 2010

This is an additional 27,300 active devices that may exhibit diminished LV capacitor performance at a rate that is similar to the August 2013 advisory population (approximately 0.67% or 1 in 150).

Boston Scientific has projected cumulative rate of occurrence for LV capacitor malfunction within the total advisory population is approximately 2.9% at 60 months and the potential for life-threatening harm from loss of therapy is estimated to be less than 1 in 125,000 (0.0008%) at 60 months.

Boston scientific also provides a software upgrade to enable detection of the advisory. All patients in this device cohort should have this upgrade at next follow-up but within 3 months of their notification in September 2014.

Our advice remains unchanged from the previous advisory notice. See below.

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.

Letter from Boston Scientific available here.