

**December 3, 2009**                      **Advisory Notification/Response**

**Canadian Heart Rhythm Society Device Advisory Committee (CHRS DAC)**

Re: A small proportion of Boston Scientific CRT-D (COGNIS) and ICD (TELIGEN) devices have been reported to develop a weakened bond between the header and the titanium case when **implanted subpectorally**. This does not affect devices implanted subcutaneously. This may present clinically as oversensing, inhibition of pacing, changes in lead impedance, loss of pacing or tachycardia therapies or result in inappropriate shocks.

**Class of Advisory:** Class I

**Urgency of Advisory:** Semi-urgent

**Nature of the Advisory:** There have been 2 cases of patients who have had either an inappropriate shock and/or had noise detected by pocket manipulation or arm movement. This is thought to represent a 0.05% rate of failure. There have been no patient deaths reported or attributed to this mode of failure. Risk factors for failure in this situation are thought to be relationship of the location of the device to the patient's ribs, increased muscle mass, and increased activity level. It is unknown whether the rate of failure will increase with time.

Boston Scientific has found that the bond between the header and the case in the COGNIS and TELIGEN devices can be weakened by the forces applied during a subpectoral implant procedure or when pushed against a rib during contraction of the pectoralis muscle. This can result in changes in lead impedance and result in electrical noise that can either inhibit pacing or cause inappropriate therapy. Additional mechanical stress can result in complete disruption of this bond, which could lead to complete loss of both pacing and tachy therapies.

**Scope of the Problem:** This advisory affects approximately 5% of all COGNIS/TELIGEN devices implanted, approximately 3850 worldwide. The failure rate is currently estimated at 0.05%.

**Response of the Canadian Heart Rhythm Society**

**Recommendations:**

1. The CHRS DAC encourages physicians to promptly notify patients with potentially affected devices of this issue, being careful to emphasize the low rate of failure due to this issue. The CHRS DAC recommends that Physicians and Hospitals/Clinics communicate the nature of the advisory to all affected patients within 10 days, focusing initially on more urgent contact with dependent patients who have a subpectoral implant. A sample notification letter is available at [www.chrsonline.ca](http://www.chrsonline.ca) (coming online December

4, 2009). Some patients may hear about this issue in the lay press and will require reassurance.

2. The CHRS DAC agrees with the manufacturer's independent safety board's recommendation to monitor these devices at 3 monthly intervals. The CHRS DAC encourages each center to increase follow up visits to q 3 monthly, as per the manufacturers discretion, in an attempt to detect early failures.
3. The CHRS DAC recognizes that affected patients that are not pacing dependent and their Physicians may choose to proceed with early IPG replacement because of potential concern of unpredictable failure, influenced by the proportion of pacing, preimplant symptoms and patient preference. Given the recognized risk of device replacement (5% complications), which may be even higher with a subpectoral implant, the CHRS DAC encourages individualized decision-making that would favor deferring replacement until the generator reaches elective replacement indicator (ERI).

Ratika Parkash

CHRS DAC Deputy Chair

[parkashr@cdha.nshealth.ca](mailto:parkashr@cdha.nshealth.ca)