

# URGENT MEDICAL DEVICE CORRECTION



## Cardiac Rhythm Management

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**Subject:** Product Advisory – Mechanical stress associated with subpectoral implantation may weaken the bond between the header and the titanium case in COGNIS® cardiac resynchronization therapy defibrillators (CRT-Ds) and TELIGEN® implantable cardioverter defibrillators (ICDs).

Dear Doctor,

This letter provides important patient management information regarding Boston Scientific COGNIS CRT-Ds and TELIGEN ICDs. Engineering simulations and field reports indicate that in some cases, implanted devices may encounter sufficient mechanical stress to weaken the bond between the header and case when positioned subpectorally. While implant orientation is not reported to Boston Scientific, our records indicate that your health care facility may implant or is currently monitoring devices that may be at risk if implanted in a subpectoral location.

### Description of Behavior

Boston Scientific has determined that the bond between the header and case could be weakened by significant forces associated with a subpectoral implant procedure or when a device in a subpectoral position is pushed against a rib during contraction of the pectoralis muscle. A weakened header bond may alter lead impedance and introduce noise that may inhibit pacing therapy or initiate inappropriate tachy therapy. Additional mechanical stress applied to a weakened bond may eventually cause header connection wires to fracture, resulting in loss of therapy.

This advisory is limited to devices identified in Table 1 that were implanted subpectorally. Devices implanted *subcutaneously* are not included in this advisory.

### Clinical Implications

A weakened header bond can result in one or more of the following device behaviors:

- Significant changes in measured lead impedance
- Noise on real-time or stored electrograms
- Intermittent inhibition of pacing
- Inappropriate anti-tachy pacing or shock therapy
- Loss of pacing therapy
- Loss of anti-tachy pacing and shock therapy

No patient deaths related to this behavior have been reported. Patients have required early device replacement due to inappropriate shocks and/or noise induced by pocket manipulation or arm movement. Regulatory authorities have been notified of these observations.

### Rate of Occurrence

The implant orientation of devices is not reported to Boston Scientific, making it difficult to provide rate of occurrence and prediction information. We have received two (2) reports worldwide of subpectoral implants with weakened header bonds. We estimate that 5% of approximately 77,000 COGNIS and TELIGEN devices worldwide have been implanted in a subpectoral location.

The following factors may also impact the risk of failure if implanted in a subpectoral location:

- Exact location of the patient's ribs relative to the device
- Body size and/or muscle mass of the patient (risk may increase for larger/muscular patients)
- Activity level and/or occupation of the patient (risk may increase for more active patients)

## Recommendations

### **For future implants:**

- Boston Scientific recommends that subpectoral implantation of affected COGNIS CRT-Ds or TELIGEN ICDs (Table 1) be avoided until improvements to header bond strength are available for devices in your geography.

### **For affected devices (Table 1) implanted in a subpectoral location:**

- Follow patient at least once every three months as recommended in device instructions for use.
- Consider advising patients to contact their physician or clinic if they receive shocks, in order to ensure timely review of associated electrograms and other device data via in-clinic or remote interrogation.

Where available, consider using the LATITUDE® Patient Management System to facilitate remote device checks between in-clinic follow-ups.

If a patient's device was implanted **subcutaneously**, it is excluded from this advisory and no change to current patient management is recommended.

## Devices Affected

Model numbers listed in Table 1 are affected by this advisory if they have been implanted subpectorally.

**Table 1.** Device models affected if implanted subpectorally.

Family	Model Numbers
TELIGEN ICD	E102, E110, E111 F102, F110, F111
COGNIS CRT-D	N106, N107, N108, N118, N119 P106, P107, P108

*NOTE: TELIGEN VR Models E103 and F103 are **not** affected*

A device model and serial number search tool is available at [www.bostonscientific.com](http://www.bostonscientific.com) in the Product Performance Resource Center.

Boston Scientific has identified manufacturing process changes to strengthen the bond between the header and case. Bond strength improvements will be implemented by geography as regulatory approval is received.

## Warranty Program

The warranty offered with each device applies to all advisory devices experiencing this behavior. Assistance for patient unreimbursed medical expenses may be available in certain geographies.

## Further Information

Boston Scientific recognizes the impact of this communication on you and your patients and wants to reassure you that patient safety remains our primary concern. Quarterly updates will be provided in our Product Performance Report, found at [bostonscientific.com](http://bostonscientific.com). If you have any questions regarding this communication, please contact your local Boston Scientific CRM representative, United States Technical Services at 1.800.CARDIAC (227.3422), or European Technical Services at +32 2 416 7222.

Sincerely,



William E. Young  
Vice President, Reliability and Quality Assurance  
Boston Scientific Cardiac Rhythm Management