March 23, 2009

Subject: Product Advisory – Inappropriate therapy associated with certain right ventricular (RV) lead complications may occur more frequently if the Respiratory Sensor is programmed On.

Dear Doctor,

This letter provides important patient management information regarding Boston Scientific COGNIS® CRT-Ds and TELIGEN® ICDs. Our records indicate that you have implanted or are monitoring patients with one of these devices. The patient management recommendations described below and reviewed by our independent Patient Safety Advisory Board will eliminate incremental risks described in this advisory.

Background
COGNIS CRT-Ds and TELIGEN ICDs include a Respiratory Sensor that can be activated to monitor the patient's respiratory rate. Daily minimum, maximum, and median respiratory rate data are stored in the defibrillator for up to one year, and can be reviewed for patterns or trends on the programmer’s Respiratory Rate Trend screen.

Description
For any implantable defibrillator, delivery of appropriate therapy is dependent upon lead system integrity. Conversely, if any component of the defibrillator system is compromised, appropriate therapy cannot be assured. For example, certain RV lead complications (such as chronic lead fracture and acute lead connection issues) can cause inappropriate shocks or anti-tachycardia pacing, and/or inhibition of pacing. Boston Scientific has recently determined that if the Respiratory Sensor is programmed On, such RV lead complications may cause additional oversensing, thereby increasing the probability of inappropriate therapy. Five to eight successive inappropriate shocks could leave the device unable to treat an actual arrhythmia until the current episode ends. To date, the greatest extent of inappropriate therapy has been observed in a single pacemaker-dependent patient with a fractured lead. No patient deaths have been reported.

Rate of Occurrence
Boston Scientific estimates that the Respiratory Sensor is programmed On in approximately 8,000 COGNIS and TELIGEN devices worldwide. Inappropriate therapy as described above has been reported 15 times (0.2%). However, additional events can be prevented if the recommendations below are followed.

Patient Management Recommendations
Device programming records should be reviewed for each patient with a COGNIS CRT-D or TELIGEN ICD to determine if the Respiratory Sensor is programmed to On or Off.

- **When the Respiratory Sensor is Off, this advisory does not apply and routine follow-up is indicated.**
- **If the Respiratory Sensor is On, Boston Scientific recommends that the Respiratory Sensor be programmed Off** as follows:
  1. Select the SETTINGS tab
  2. Select the SETTINGS SUMMARY tab
  3. In the BRADY section, select the NORMAL SETTINGS details icon
  4. In the SENSORS AND TRENDING section, select the ACCELEROMETER details icon
  5. For RESPIRATORY SENSOR, select Off, and press PROGRAM

However, physicians should review concurrent risks such as pacemaker dependency, historic lead fracture performance, patient age and activity level, etc. when considering the most appropriate management options for each patient.
Boston Scientific continues to explore opportunities to further mitigate implantable systems against system malfunctions such as lead fractures. A change to non-invasively address this issue is under development and will be made available following regulatory submission and approval.

**Devices Affected**
Only COGNIS CRT-Ds and TELIGEN ICDs with the Respiratory Sensor programmed On are potentially susceptible to this behavior.

**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. 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
**PHYSICIAN DEVICE ADVISORY NOTICE**

**Advisory Date:** March 23, 2009

<table>
<thead>
<tr>
<th>Manufacturer(s)</th>
<th>Boston Scientific Corporation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product(s)</strong></td>
<td><strong>Trade Name</strong></td>
</tr>
<tr>
<td></td>
<td>TELIGEN ICD</td>
</tr>
<tr>
<td></td>
<td>COGNIS CRT-D</td>
</tr>
<tr>
<td></td>
<td><strong>Model Number</strong></td>
</tr>
<tr>
<td></td>
<td>E102, E110, F102, F110</td>
</tr>
<tr>
<td></td>
<td>N106, N107, N118, N119, P106, P107</td>
</tr>
<tr>
<td><strong>Performance Failure</strong></td>
<td>Inappropriate therapy associated with certain right ventricular (RV) lead complications may occur more frequently if the Respiratory Sensor is programmed On.</td>
</tr>
<tr>
<td><strong>Root Cause</strong></td>
<td>If the Respiratory Sensor is programmed On, certain RV lead complications (such as chronic lead fracture and acute lead connection issues) may cause additional oversensing, thereby increasing the probability of inappropriate therapy.</td>
</tr>
<tr>
<td><strong>Has all affected product been retrieved?</strong></td>
<td>☐ Yes ☒ No</td>
</tr>
</tbody>
</table>

Incremental risks described in this advisory can be eliminated if recommendations below are followed.

**FDA classification status**

pending

### CLINICAL ACUITY

<table>
<thead>
<tr>
<th></th>
<th>USA</th>
<th>Worldwide</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Estimated number of units implanted</td>
<td>~25,500</td>
<td>~34,000</td>
</tr>
<tr>
<td>b) Estimated number of devices with Respiratory Sensor programmed On</td>
<td>~2,000</td>
<td>~8,000</td>
</tr>
<tr>
<td>c) Estimated incidences of this performance failure over the projected life of the device</td>
<td>Additional events can be prevented if the recommendations below are followed.</td>
<td>Additional events can be prevented if the recommendations below are followed.</td>
</tr>
<tr>
<td>d) Total number with observed performance failure</td>
<td>4</td>
<td>15</td>
</tr>
<tr>
<td>% of performance failures =</td>
<td>0.2%</td>
<td>0.2%</td>
</tr>
<tr>
<td>e) Mean age of product in implanted population</td>
<td>3.4 Months</td>
<td>3.5 months</td>
</tr>
</tbody>
</table>

| f) Patient deaths reported | ☐ Yes ☒ No |
| Number of deaths = | 0 |
| g) Patient deaths with probable relationship to device failure | ☐ Yes ☒ No |
| Number of deaths = | 0 |

* The data analysis provided in this report was generated by the manufacturer and may be subject to change.
DEVICE COMPONENTS AT RISK OF PERFORMANCE FAILURE

- Battery Failure
- CRT (left ventricular pacing)
- Diagnostic Data Failure
- Lead Failure
- Brady Therapies (lower rate pacing)
- Hermeticity or internal component
- Brady Therapies (runaway pacing)
- EMI Susceptibility
- Tachy Therapies (ATP)
- Telemetry Failure
- Tachy Therapies (shock)

PATIENT MANAGEMENT RECOMMENDATIONS

Device programming records should be reviewed for each patient with a COGNIS CRT-D or TELIGEN ICD to determine if the Respiratory Sensor is programmed to On or Off.

- **When the Respiratory Sensor is Off, this advisory does not apply and routine follow-up is indicated.**
- **If the Respiratory Sensor is On, Boston Scientific recommends that the Respiratory Sensor be programmed Off** as follows:
  1. Select the **SETTINGS** tab
  2. Select the **SETTINGS SUMMARY** tab
  3. In the **BRADY** section, select the **NORMAL SETTINGS** details icon
  4. In the **SENSORS AND TRENDING** section, select the **ACCELEROMETER** details icon
  5. For **RESPIRATORY SENSOR**, select **Off**, and press **PROGRAM**

<table>
<thead>
<tr>
<th>Recommended Programming changes</th>
<th>Program Respiratory Sensor to Off</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device follow-up</td>
<td>Physicians should review concurrent risks such as pacemaker dependency, historic lead fracture performance, patient age and activity level, etc. when considering the most appropriate patient management options for each patient.</td>
</tr>
</tbody>
</table>

CONTACT

Boston Scientific Cardiac Rhythm Management
4100 Hamline Avenue North
St. Paul, MN  55112-5798
Tel:  1.800.CARDIAC (227.3422)
Tech.Services@bsci.com

Boston Scientific Europe S.A.
Green Square
Lambroekstraat 5D
1831 Diegem
Belgium
Tel:  +32 2 416 7222
eurtechservice@bsci.com