

URGENT MEDICAL DEVICE CORRECTION



July, 2010

4100 Hamline Avenue North
St. Paul, MN 55112-5798
www.bostonscientific.com

Subject: Product Advisory -- Magnetic reed switch performance in CONTAK RENEWAL[®] 3 / 3 RF / 4 / 4 RF and VITALITY[®] HE implantable defibrillators

Dear Doctor,

This letter provides important patient management information regarding certain Boston Scientific CRT-Ds and ICDs manufactured between January 2006 and November 2007. In rare instances, application of a magnet (typically in a clinic/hospital environment) may cause a magnetic reed switch located within the device to become permanently stuck in a closed position and prevent delivery of programmed tachy therapy. No patient deaths or injuries beyond device replacement have been reported as a result of this issue. CRT-Ds and ICDs currently being distributed are not subject to this advisory.

Description

Some Boston Scientific defibrillators include a component referred to as a "magnetic reed switch," designed to sense the presence of a magnet. If Enable Magnet Use is programmed to On (nominally On) and a magnet is applied in emergent situations or during a medical/surgical procedure, the switch is designed to close and temporarily prevent delivery of undesired tachy therapy. When the magnet is removed, the magnetic switch is designed to open and thereby restore ability to deliver programmed tachy therapy.

Magnetic reed switch technology has historically demonstrated a very low but non-zero rate of failing to open upon magnet removal. However, certain Boston Scientific CRT-Ds and ICDs manufactured between January 2006 and November 2007 have exhibited a somewhat higher rate of magnetic reed switch failure. Approximately 34,000 of these devices remain actively implanted; no devices in this population are available for implant. Devices manufactured after November of 2007 have returned to historic performance rates and are not included in this advisory.

The following device mitigations have typically facilitated rapid identification of a stuck reed switch:

- R-wave synchronous tones/beeps are emitted from the device when the switch is closed. [*NOTE: Beeping tones may be initiated for reasons other than a stuck switch.*]
- Upon programmer interrogation, a pop-up message indicates that a magnet is near the device even though a magnet is not in position.
- Daily Measurements are not performed by the device if the reed switch is closed, and "N/R" (not reported) is displayed on the programmer screen and printout. [*NOTE: Daily Measurements may be unavailable for reasons other than a stuck switch.*]

A rate of one failure per 670 devices (0.0015) has been observed to date in the advisory population (average implant time of 38 months). However, with rapid identification and reprogramming, the probability of patient harm (therapy not available when needed due to a stuck magnetic reed switch) is estimated to be less than one in one million for a 60-month device service life.

Clinical Implications

No patient deaths or injuries have been reported as a result of this issue, although some devices have been replaced. Most devices with a magnetic reed switch confirmed to be stuck in a closed position have remained implanted after Enable Magnet Use was programmed to Off (see Recommendations).

The impact of a stuck reed switch depends upon the current status of Enable Magnet Use:

- If the Enable Magnet Use feature is programmed to On, (the nominal setting) and the magnetic reed switch becomes stuck in the closed position, programmed shock and/or anti-tachy pacing therapy will be unavailable. The device will emit R-wave synchronous beeping tones.
- If the Enable Magnet Use feature is programmed to Off and the magnetic switch becomes stuck in the closed position, tachyarrhythmia therapy will be provided as programmed. Beeping tones will not be sounded.

In Boston Scientific defibrillators, bradycardia pacing mode is not altered by magnet application and is therefore unaffected by a stuck switch. Elective replacement indicators, including audible tones (nominally On) remain intact.

Recommendations

Consistent with physician instructions for use and patient manual labeling, physicians should continue routine follow-up sessions and patients should be reminded to contact their clinic or go to the hospital emergency room **immediately** if they hear tones/beeps from their device. In addition, Boston Scientific recommends:

1. In a hospital/clinic/surgery setting, if tones are heard upon magnet application but do not cease upon magnet removal, the device should be interrogated with a programmer and checked per normal standard of care.
2. In the United States, use of the LATITUDE remote patient monitoring system may help identify loss of daily measurements and thereby facilitate timely detection of a stuck reed switch. [NOTE: A pop-up message and/or LATITUDE alert do not appear for missing Daily Measurements.]
3. If a stuck magnetic switch is confirmed, program the Enable Magnet Use feature to Off, which ensures that programmed therapy will be provided to treat tachyarrhythmias. However, if Enable Magnet Use is programmed Off:
 - A magnet will no longer inhibit tachy therapy.
 - The Patient Triggered Monitor feature will no longer be available.

Boston Scientific Technical Services (phone information below) can help physicians re-activate Daily Measurements for devices with a stuck magnetic switch.

4. After consultation with our independent Patient Safety Advisory Board, **Boston Scientific does not recommend prophylactic explant**. We further advise that physicians **do not routinely program Enable Magnet Use to Off in the absence of a confirmed stuck magnetic reed switch** because the benefits of magnet use to disable tachy therapy in emergent situations outweigh the probability of patient harm associated with a stuck reed switch.

Further Information

Quarterly updates for all product advisories are provided in our CRM **Product Performance Report**, found at www.bostonscientific.com/ppr. A search tool is also available to determine if a specific device is affected by this issue.

If you have any questions regarding this communication, please contact your local Boston Scientific representative, United States Technical Services at 1.800.CARDIAC (227.3422), or European Technical Services at +32 2 416 7222.

Sincerely,



Jeff Biggers
Vice President, Quality Assurance
Cardiology, Rhythm & Vascular
Boston Scientific Corporation

PHYSICIAN DEVICE ADVISORY NOTICE

Advisory Date: July 2010

Manufacturer	Boston Scientific Corporation / Guidant	
Product(s)	<i>Trade Name</i>	<i>Model Number</i>
	CONTAK RENEWAL [®] 3 CRT-D	H170, H175, H177, H179
	CONTAK RENEWAL 3 RF CRT-D	H210, H215, H217, H219
	CONTAK RENEWAL 4 CRT-D	H190, H195, H197, H199, M170, M175, M177, M179
	CONTAK RENEWAL 4 RF CRT-D	H230, H235, H239
	VITALITY [®] DR HE ICD	T180
Manufactured (Date)	between January 2006 and November 2007	
Performance Failure	Application of a magnet (typically in a clinic/hospital environment) may cause a switch within the device to become permanently stuck in a closed position and prevent delivery of programmed tachy therapy.	
Root Cause (if known)	In rare instances, a magnetic reed switch in the identified population may fail to open when a magnet is removed from device proximity. If this occurs when Enable Magnet Use is programmed On, tachy therapy would not be available.	
Date Manufacturer Corrected Product Available	November 2007	
Has all affected product been retrieved?	No devices in this population remain available for implant. CRT-Ds and ICDs currently being distributed are not subject to this advisory.	
FDA classification status	pending	

CLINICAL ACUITY	USA	Worldwide
a) Total number of units currently implanted	~26,000	~34,000
b) Estimated number of potentially affected devices of this mode distributed worldwide	~39,000	~52,000
c) Probability of this performance failure over 60-month device service life	0.0029	0.0029
d) Observed rate of performance failure to date	0.0018	0.0015
e) Mean age of product in implanted population	38 months	38 months
f) Patient deaths reported	0	0
g) Patient deaths with probable relationship to device failure	0	0
h) Probability of patient harm (therapy not available when needed due to a stuck magnetic reed switch) over 60-month device service life	less than 1 in 1 million	less than 1 in 1 million
NOTE: 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	
<input type="checkbox"/> Battery Failure	<input type="checkbox"/> CRT (left ventricular pacing)
<input type="checkbox"/> Diagnostic Data Failure	<input type="checkbox"/> Lead Failure
<input type="checkbox"/> Brady Therapies (lower rate pacing)	<input type="checkbox"/> Hermeticity or internal component
<input type="checkbox"/> Brady Therapies (runaway pacing)	<input type="checkbox"/> EMI Susceptibility
<input checked="" type="checkbox"/> Tachy Therapies (ATP)	<input type="checkbox"/> Telemetry Failure
<input checked="" type="checkbox"/> Tachy Therapies (shock)	<input checked="" type="checkbox"/> Other (specify) magnetic reed switch

PATIENT MANAGEMENT RECOMMENDATIONS		
Verify normal device function (at normal follow-up interval)?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Verify normal device function (as soon as possible)?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Specific measures to assess:		
<p>1) Consistent with physician instructions for use and patient manual labeling, physicians should continue routine follow-up sessions, and patients should be reminded to contact their clinic or go to the hospital emergency room immediately if they hear tones/beeps from their device.</p> <p>2) In a hospital/clinic/surgery setting, if tones are heard upon magnet application <u>but do not cease upon magnet removal</u>, the device should be interrogated with a programmer and checked per normal standard of care.</p> <p>3) In the United States, use of the LATITUDE remote patient monitoring system may help identify loss of daily measurements and thereby facilitate timely detection of a stuck reed switch. [NOTE 1: A pop-up message and/or LATITUDE alert do not appear for missing Daily Measurements. NOTE 2: Daily Measurements may be unavailable for reasons other than a stuck switch.]</p> <p>4) Prophylactic explant is NOT recommended.</p>		
Programming changes:	<input checked="" type="checkbox"/> Recommended if a stuck magnetic switch is confirmed	
<p>If a stuck magnetic switch is confirmed, program the Enable Magnet Use feature to Off, which ensures that programmed therapy will be provided to treat tachyarrhythmias. However, if Enable Magnet Use is programmed Off:</p> <ul style="list-style-type: none"> ➤ A magnet will no longer inhibit tachy therapy. ➤ The Patient Triggered Monitor feature will no longer be available. <p>Do not routinely program Enable Magnet Use to Off in the absence of a confirmed stuck magnetic reed switch because the benefits of magnet use to disable tachy therapy in emergent situations outweigh the probability of patient harm associated with a stuck reed switch.</p>		
Accelerated device follow-up?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No

CONTACTS

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