

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