URGENT MEDICAL DEVICE INFORMATION

Update to May, 2006 ***Product Advisory***

January 4, 2008

Cardiac Rhythm Management
4100 Hamline Avenue North
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Summary

Issue:	Repetitive mechanical stress applied to the titanium case can induce component damage and device malfunction in certain ICD and CRT-D devices implanted subpectorally with the serial number facing the ribs (susceptible orientation shown in Figure 2). Devices implanted subcutaneously or in a subpectoral position with the serial number facing away from the ribs are not included in this advisory. This update identifies additional VITALITY® ICD models (Table 1) that are also subject to this failure mechanism if implanted in a susceptible orientation.
Frequency:	A total of 13 failures have been confirmed from an estimated 950 devices implanted in a susceptible orientation. The failure rate prediction is estimated to be 3% to 4% at 60 months.
Consequence:	Loss of shock therapy, loss of pacing therapy (intermittent or permanent), or loss of telemetry communications.
Actions:	Review patient records to determine if device was implanted subpectorally. Use an AP radiograph to determine specific device orientation. If a subpectoral implant is in a susceptible orientation, consider repositioning or replacement for physically active patients or for patients who regularly need device therapy. Follow patients with susceptible devices at 3-month intervals in accordance with device labeling.

Dear Doctor,

On May 12, 2006, Boston Scientific CRM issued a ***Product Advisory*** describing the potential for device malfunction in certain ICDs and CRT-Ds when implanted subpectorally with the serial number facing the ribs. Further clinical experience and testing indicate that additional VITALITY device models are also subject to this failure mechanism (Table 1).

Description of Issue

Accelerated life testing has shown that repetitive mechanical stress applied to the serial number side of the titanium case can induce component damage and device malfunction. This has occurred *only* when the device was implanted subpectorally with the serial number facing the ribs (Figure 2).

Figure 1. Optimal orientation for subpectoral implants. Leads exit in a counter clockwise direction. Serial number is facing *away* from the ribs.

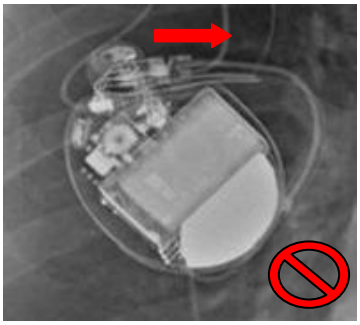

Figure 2. Photo and X-ray. Avoid this orientation for subpectoral implants. Leads exit in a clockwise direction. Serial number is facing the ribs.

Devices Affected

Table 1. Model numbers potentially affected if implanted subpectorally with serial number facing the ribs.

May 12, 2006 Population*	
CONTAK RENEWAL® 3 & 3 HE	H170/H173/H175/H177/H179
CONTAK RENEWAL 3 AVT & 3 AVT HE	M150/M155/M157/M159
CONTAK RENEWAL 4 & 4 HE	H190/H195/H197/H199
CONTAK RENEWAL 4 AVT & 4 AVT HE	M170/M175/M177/M179
VITALITY DR HE	T180
January 4, 2008 Population*	
VITALITY 2 EL DR/VR	T167/T177
VITALITY EL	T127
VITALITY DR+	1872

Notes:

*Not all devices are approved in all geographies.

Standard life VITALITY devices are not included in this advisory (one observation of this type in over 125,000 devices implanted to date).

A device model and serial number search tool is available at www.bostonscientific.com.

Clinical Implications
While there is no way to predict if or when a device in the susceptible orientation will fail, one or more of the following device behaviors indicate that a failure has occurred: loss of shock therapy, loss of pacing therapy (intermittent or permanent), loss of telemetry communications, beeping (16 tones every six hours), and display of a warning screen upon programmer interrogation.

Rate of Occurrence
Six additional failures (total of eight) have been confirmed from the May 12, 2006 population of 70,200 devices. Five failures have been confirmed from 24,700 devices in the January 4, 2008 population. There have been no reported patient deaths associated with this issue.

Because the implant orientation of devices is not reported to Boston Scientific, rate of occurrence or failure rate projections specific to a subpectoral implant with the serial number facing the ribs can only be estimated. ***If it is assumed that 1% of the total population is implanted in a susceptible orientation***:

- A total of 13 failures to date represents 1.4% of approximately 950 devices implanted in a susceptible orientation.
- The projected failure rate for devices implanted in the susceptible orientation is estimated to be 3% to 4% (28 to 38 devices) at 60 months for both the May 12, 2006 population and the January 4, 2008 population.

Recommendations
Patient management recommendations for both populations remain unchanged from May 12, 2006:

1. For patients implanted with a model listed in Table 1, review records to determine if the device was implanted subpectorally. Devices implanted subcutaneously are not subject to this advisory.
2. For subpectoral implants, use an AP radiograph to determine specific device orientation.
   - If the leads exit the pulse generator in a counter clockwise direction (Figure 1), this advisory does not apply and no change to your current patient management is necessary.
   - If the device is in a susceptible orientation (Figure 2),
     - Advise patient of the potential for device failure.
     - Follow patient at 3 month intervals in accordance with device labeling.
     - Consider device repositioning or replacement for physically active patients or for patients who regularly need device therapy.

     Where available, the LATITUDE® Patient Management System can enable remote follow-ups and facilitate patient monitoring between follow-ups.
3. For future implants, when considering subpectoral implantation of a device from any product family listed in Table 1, orient the device with the serial number facing away from the ribs (Figure 1).

Warranty Supplement Program
Boston Scientific's warranty supplement program, subject to certain conditions, provides full credit for the purchase of a Boston Scientific replacement device and an offer of up to $2500 patient assistance for unreimbursed medical expenses.

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: May 12, 2006 and January 4, 2008

Manufacturer	Boston Scientific Corporation		
Product(s)	*Trade Name* May 12, 2006 Advisory CONTAK RENEWAL® 3/ 3 HE CONTAK RENEWAL 3 AVT/ 3 AVT HE CONTAK RENEWAL 4/ 4 HE CONTAK RENEWAL 4 AVT/ 4 AVT HE VITALITY® DR HE January 4, 2008 Advisory Update VITALITY DR+ VITALITY EL VITALITY 2 EL DR/VR	*Model Number* H170/H173/H175/H177/H179 M150/M155/M157/M159 H190/H195/H197/H199 M170/M175/M177/M179 T180 1872 T127 T167/T177	
Manufactured on or before (Date)			
Performance Failure	Loss of shock therapy, loss of pacing therapy (intermittent or permanent), or loss of telemetry communications		
Root Cause	Repetitive mechanical stress applied to the titanium case can induce component damage and device malfunction in devices implanted subpectorally with the serial number facing the ribs.		
Date Manufacturer Corrected Product Available	For future implants, when considering subpectoral implantation of a device from a product family listed above, orient the device with the serial number facing away from the ribs		
Has all affected product been retrieved?	☐ Yes	☒ No	See patient management recommendations

FDA CLASSIFICATION STATUS

Advisory classification	– Class II for May 12, 2006 population – Decision pending for January 4, 2008 population	
CLINICAL ACUITY	*(USA)*	*(Worldwide)*
a) Total number of units currently implanted	64,600	87,700
b) Estimated number of potentially affected devices of this mode	~700 in susceptible orientation (~1% of implanted population)	~950 in susceptible orientation (~1% of implanted population)
c) Estimated incidences of this performance failure over the projected life of the device	21 to 28 (3% to 4% of devices implanted in a susceptible orientation)	28 to 38 (3% to 4% of devices implanted in a susceptible orientation)
d) Total number with observed performance failure	6	13
% of performance failures d/b x 100 =	0.85%	1.4%
e) Mean age of product in implanted population	~32 months for May 12, 2006 population ~20 months for January 4, 2008 population	
f) Patient deaths reported	☐ Yes	☒ No
Number of deaths =	0 related to this issue	
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
- ☐ Diagnostic Data Failure
- ☒ Brady Therapies (lower rate pacing)
- ☐ Brady Therapies (runaway pacing)
- ☒ Tachy Therapies (ATP)
- ☒ Tachy Therapies (shock)
- ☒ CRT (left ventricular pacing)
- ☐ Lead Failure
- ☒ Internal component
- ☐ EMI Susceptibility
- ☒ Telemetry Failure
- ☐ Other

PATIENT MANAGEMENT RECOMMENDATIONS

Verify normal device function (at normal follow-up interval)	☒ Yes	☐ No
Verify normal device function (as soon as possible)	☐ Yes	☒ No

Patient management recommendations for both populations remain unchanged from May 12, 2006:

1. For patients implanted with advisory product, review records to determine if the device was implanted subpectorally. Devices implanted subcutaneously are not subject to this advisory.
2. For subpectoral implants, use an AP radiograph to determine specific device orientation.
   - ➢ If the leads exit the pulse generator in a counter clockwise direction (serial number facing ***away*** from the ribs), this advisory does not apply and no change to current patient management is necessary.
   - ➢ If the device is in a susceptible orientation (serial number facing the ribs),
     - Advise patient of the potential for device failure.
     - Follow patient at 3 month intervals in accordance with device labeling.
     - Consider device repositioning or replacement for physically active patients or for patients who regularly need device therapy.

     Where available, the LATITUDE® Patient Management System can enable remote follow-ups and facilitate patient monitoring between follow-ups.
3. For future implants, when considering subpectoral implantation, orient the device with the serial number facing away from the ribs.

Programming changes	☐ Required	☐ Recommended
If programming changes are required, specify changes: none required		
Accelerated device follow-up	☐	☒ No
Timeline - months:	3-month intervals per device labeling	

CONTACT

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