URGENT MEDICAL DEVICE INFORMATION

Boston Scientific

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

April 5, 2007

Subject: Product Advisory – Potential for reduced ERI to EOL time due to low-voltage capacitor degradation in a subset of ICDs and CRT-Ds

Dear Doctor,

This letter provides important patient management information regarding a subset of Guidant CRM ICDs and CRT-Ds. Our records indicate that you have implanted or are monitoring patients with one of these devices.

Description of Issue
Boston Scientific has recently identified low-voltage capacitors from a former supplier that may be subject to degradation at a low rate of occurrence. These capacitors may cause accelerated battery depletion and may reduce the time between elective replacement indicator (ERI) and end of life (EOL) to less than three months. Device replacement indicators continue to function normally. Devices in this subset have been removed from distribution and are being retrieved from hospital inventory. There have been no patient deaths or serious injuries associated with this behavior.

Rate of Occurrence
There have been no confirmed reports of shortened ERI to EOL time. However, 19 of approximately 73,000 devices in this population worldwide have been confirmed to have accelerated battery depletion, which could have resulted in shortened ERI to EOL time. While it is projected that less than 2% of this device population may exhibit a shortened ERI to EOL time, follow-up recommendations provided below will eliminate patient risk.

Recommendations
If a patient has a device with a degraded capacitor, the time from implant to 2.65 volts (Middle of Life 2 / MOL2) will be reduced. To determine whether a patient may be at risk for a reduced ERI to EOL time, it is important to note when 2.65 volts (MOL2) was observed. For each patient:

1. Review patient records to assess battery voltage.
2. If battery voltage is ***above*** 2.65 volts (MOL2), continue to follow patient every three months per device labeling.
3. If battery voltage is ***at or below*** 2.65 volts (MOL2), determine the time between device implant and this observation.
4. If the time from implant to 2.65 volts (MOL2) is greater than 27 months (Note: For VITALITY® EL / 2 EL / HE devices, this value is 32 months), the patient is not at risk for a shortened ERI to EOL time, **and this advisory no longer applies.**
5. If the time from implant to 2.65 volts (MOL2) is 27 months or less (Note: for VITALITY EL / 2 EL / HE devices, this value is 32 months), **the patient should be followed monthly until ERI**. For devices that require monthly follow-up, replace the device within 30 days after ERI is displayed as ERI to EOL time may be shortened.

Note: In geographies where available, the LATITUDE® Patient Management System can facilitate patient monitoring and also provide automatic notification when the device reaches a battery status of ERI.

Devices Affected
The potential for shortened ERI to EOL time due to low-voltage capacitor degradation is confined to a subset of devices within the CONTAK RENEWAL® 3 & 4, VITALITY and VITALITY 2 families. Enclosed is a list of patients at your clinic who were implanted with a device from this population. In addition, a model/serial search tool is available to determine if a specific device is subject to this product advisory (go to the Product Performance Resource Center located at www.guidant.com/ppr/).

Warranty Program
With certain terms and conditions, warranty and unreimbursed medical expense programs are available for this population.

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 9357.

Sincerely,

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

PHYSICIAN DEVICE ADVISORY NOTICE

Advisory Date: April 5, 2007

Manufacturer(s)	Boston Scientific Corporation		
Product(s)	*Trade Name* VITALITY® DS DR/VR VITALITY EL VITALITY AVT VITALITY 2 DR/VR VITALITY 2 EL DR/VR VITALITY DR HE CONTAK RENEWAL® 3/HE CONTAK RENEWAL 4/HE CONTAK RENEWAL 3 RF/HE CONTAK RENEWAL 4 RF/HE CONTAK RENEWAL 4 AVT/HE	*Model Number* T125/T135 T127 A155 T165/T175 T167/T177 T180 H170/H175/H177/H179 H190/H195/H197/H199 H210/H215/H217/H219 H230/H235/H239 M170/M175/M177/M179	
Manufactured on or before (Date)	October 2006		
Performance Failure	Potential for reduced ERI to EOL time.		
Root Cause (if known)	Low-voltage capacitor degradation		
Date Manufacturer Corrected Product Available (if known)	October 2006		
Has all affected product been retrieved?	☐ Yes	☒ No	retrieval underway

FDA CLASSIFICATION STATUS

Advisory classification	Class:	☒ Decision Pending
CLINICAL ACUITY	*(USA)*	*(Worldwide)*
a) Total number of units currently implanted	50,850	67,542
b) Estimated number of potentially affected devices of this mode worldwide	55,637	72,467
c) Estimated incidences of this performance failure over the projected life of the device	1.7% (zero incidences of compromised therapy if monitored per guidelines below)	1.7% (zero incidences of compromised therapy if monitored per guidelines below)
d) Total number with observed performance failure	0 – reduced ERI to EOL time (15 - accelerated battery depletion)	0 – reduced ERI to EOL time (19 - accelerated battery depletion)
% of performance failures d/b x 100 =	0%	0%
e) Mean age of product in implanted population	15 months	15 months
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
- ☐ Hermeticity or internal component
- ☐ EMI Susceptibility
- ☐ Telemetry Failure
- ☒ Low-voltage capacitor degradation leading to a decline in battery voltage and reduced time from ERI to EOL

PATIENT MANAGEMENT RECOMMENDATIONS

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

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- If the time from implant to 2.65 volts (MOL2) is greater than 27 months (Note: For VITALITY® EL / 2 EL / HE devices, this value is 32 months), the patient is not at risk for a shortened ERI to EOL time, **and this advisory no longer applies.**
- If the time from implant to 2.65 volts (MOL2) is 27 months or less (Note: for VITALITY EL / 2 EL / HE devices, this value is 32 months), **the patient should be followed monthly until ERI**. For devices that require monthly follow-up, replace the device within 30 days after ERI is displayed as ERI to EOL time may be shortened.

Programming changes	☐ Required	☐ Recommended
If programming changes are required, specify changes: **none required**		
Accelerated device follow-up	☒ Yes (In some cases) If the time from implant to 2.65 volts (MOL2) is 27 months or less (32 months for VITALITY EL / 2 EL / HE devices), the patient should be followed **monthly** until ERI.	☐ No
Timeline - months:		

CONTACT

Boston Scientific Cardiac Rhythm Management
4100 Hamline Avenue North
St. Paul, MN 55112-5798
Tel: 651.582.4000
Fax: 651.582.4166
crmevent@guidant.com
www.guidant.com

Boston Scientific Europe S.A.
Park Lane
Culliganlaan 2B
1831 Diegem
Belgium
Tel: 32.2.714.14.11
Fax: 32.2.714.14.12
eurtechservice@guidant.com