Patient Safety Alert

Veterans Health Administration Warning System
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AL06-14 June 28, 2006

Item: Boston Scientific Corporation is recalling a specific subset of devices that includes INSIGNIA and NEXUS pacemakers, CONTAK RENEWAL TR/TR2 cardiac resynchronization therapy (CRT) pacemakers, and VENTAK PRIZM 2, VITALITY, and VITALITY 2 implantable cardioverter defibrillators (ICDs). These products are manufactured by the Company's Cardiac Rhythm Management (CRM) Group, formerly Guidant's CRM business. Boston Scientific acquired Guidant on April 21, 2006.

Specific Incident: Boston Scientific/Guidant has recently confirmed five (5) reports of device malfunction associated with the failure of a low voltage capacitor. This may lead to a device malfunction, including intermittent or permanent loss of therapy, or premature battery depletion.

The following models are affected:

Device family	Model Numbers
INSIGNIA	0482, 0484, 0485, 0882, 0982, 0985, 0986, 1190, 1192, 1194, 1195, 1198, 1290, 1291, 1292, 1294, 1295, 1296, 1297, 1298
NEXUS	1325, 1326, 1328, 1390, 1392, 1394, 1395, 1398, 1426, 1428, 1432, 1466, 1467, 1468, 1490, 1491, 1492, 1494, 1495
CONTAK RENEWAL TR	H120, H125
CONTAK RENEWAL TR 2	H140, H145
VENTAK PRIZM 2	1860, 1861
VITALITY	1870, 1871, T125, T127, T135
VITALITY 2	T195, T167, T175, T177

Action: 1. By COB, July 14, 2006, electrophysiology/cardiology staff or other appropriate caregivers must identify all affected patients by implementing each of the following steps a through d. It is important that ALL INFORMATION sources be reviewed to insure that patients will not be missed, as they may be found on one list and not on another.

a) Review the manufacturers letters, attached.

b) Review the patient list posted on the VA National ICD Surveillance Center intranet web site https://icd.sanfrancisco.med.va.gov

c) Review the patient list posted on the VA National Pacemaker web site https://pacemaker.sanfrancisco.med.va.gov.

d) Review your patient records for all patients with implanted Boston Scientific/Guidant devices affected by this recall.

2. By COB, July 21, 2006 contact affected patients to schedule an exam. During the exam pay close attention to the following device behaviors that may be indicative of capacitor malfunction:

- premature battery depletion
- intermittent or permanent loss of therapy or telemetry
- fault codes
- pacing or sensing abnormalities
- loss of daily measurements

3. Return all non-implanted inventory identified in this Alert to Boston Scientific/Guidant.

Addl Information: As the manufacturer continues to investigate this issue additional communications may be forthcoming; VA will provide further Alert notifications as warranted.

Source: Manufacturer and FDA

Contact: Boston Scientific/Guidant at (800)-227-3422

Dr. Edmund Keung at VA National ICD Surveillance Center at (415)-221-4810 Ext 3182

Ron Jones at the VA National Registry, Washington VAMC at (202)-754-8504

GUIDANT

URGENT MEDICAL DEVICE SAFETY INFORMATION & CORRECTIVE ACTION

June 23, 2006

***Subject**: Potential for malfunction in a subset of implantable pacemakers, cardiac resynchronization therapy pacemakers (CRT-Ps), and implantable cardioverter defibrillators (ICDs) manufactured by Guidant Cardiac Rhythm Management (CRM), a Boston Scientific Company*

Dear Doctor,

This letter is intended to inform you of important safety information regarding the potential for malfunction in a subset of INSIGNIA® and NEXUS® pacemakers, CONTAK RENEWAL® TR/TR 2 CRT-Ps, and VENTAK PRIZM® 2, VITALITY® and VITALITY 2 ICDs. Our records indicate that you have implanted or are monitoring patients with one of these devices. The United States Food and Drug Administration may classify this communication as a recall.

Guidant has initiated action to retrieve from hospital and sales force inventory all non-implanted devices within this well-defined subset. Consistent with Heart Rhythm Society and Independent Panel (Robert J. Myerburg, MD, chair) recommendations for timely, transparent and responsible actions, Guidant is taking this product retrieval action before our investigation is complete and prior to finalizing patient care recommendations.

Description of Issue
Guidant has recently confirmed five (5) reports of device malfunction associated with the failure of a low-voltage capacitor from a single component supplier. Some capacitors from specific lots may perform in a manner that leads to device malfunction, including intermittent or permanent loss of therapy, or premature battery depletion. One device malfunction was discovered at the time of implant, while four devices were implanted and subsequently required replacement. To date, approximately 49,800 devices have been distributed and approximately 27,200 devices have been implanted worldwide.

Clinical Implications
Patients with affected pacemakers or CRT-Ps may experience intermittent or permanent loss of output or telemetry, or premature battery depletion. Patients with affected ICDs may experience inappropriate sensing or premature battery depletion. There have been no reported patient deaths associated with this issue. There have been two reports of pacemaker patients experiencing syncope associated with loss of pacing output.

Projected Rate of Occurrence
We are very early in our investigation and do not have sufficient information to provide a projected rate of occurrence. We are continuing to diligently gather and analyze data to provide physicians with additional information regarding projected rate of occurrence for implanted devices. This information will be provided in a subsequent communication as soon as it is available.

Recommendations

- Physicians are asked to perform an in-clinic follow-up exam as soon as possible for all patients with implanted devices from this subset. A list of patients with susceptible devices specific to your clinic is included with this communication. At this follow-up visit, please look for the following device behaviors, which may be indicative of capacitor malfunction: premature battery depletion, intermittent or

permanent loss of therapy or telemetry, fault codes, pacing or sensing abnormalities, or loss of daily measurements. Your local representative can provide additional technical guidance to assist in the evaluation of devices in this subset. Please document and report any observations of abnormal behavior through your local representative or Guidant Technical Services.

- Guidant requests that all non-implanted inventory in this subset be returned to Guidant. Your local representative can provide a complete list of device model and serial numbers and is available to coordinate the retrieval process.

Warranty Supplement Program
Guidant's Warranty Supplement Program, subject to certain conditions, provides a no cost replacement device and up to $2500 in unreimbursed medical expenses for devices included in this communication.

Devices Affected
The following models are affected by this communication:

Device Family	Model Numbers*
INSIGNIA	0482, 0484, 0485, 0882, 0982, 0985, 0986, 1190, 1192, 1194, 1195, 1198, 1290, 1291, 1292, 1294, 1295, 1296, 1297, 1298
NEXUS	1325, 1326, 1328, 1390, 1392, 1394, 1395, 1398, 1426, 1428, 1432, 1466, 1467, 1468, 1490, 1491, 1492, 1494, 1495
CONTAK RENEWAL TR	H120, H125
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VENTAK PRIZM 2	1860, 1861
VITALITY	1870, 1871, T125, T127, T135
VITALITY 2	T165, T167, T175, T177

**Not all models are available in all geographies*

Further Information
The Heart Rhythm Society's recommended "Advisory Notice" for this communication is attached.

Guidant recognizes the impact of this communication on you and your patients and wants to reassure you that patient safety remains our primary concern. As always, if you have any questions regarding this communication, please contact your local Guidant representative, Guidant Technical Services at 1.800.CARDIAC (227-3422) or European Technical Services at +32 2 416 9357.

Sincerely,

Renold J. Russie
Director, Product Performance Reporting
Guidant Cardiac Rhythm Management
A Boston Scientific Company

[redacted]

Advisory Date: June 23, 2006

Manufacturer(s)	Guidant CRM, a Boston Scientific Company		
Product(s)	*Trade Name* INSIGNIA, NEXUS, CONTAK RENEWAL TR, CONTAK RENEWAL TR2, VENTAK PRIZM 2, VITALITY, VITALITY 2	*Model Number* 482, 484, 485, 882, 982, 985, 986, 1190, 1192, 1194, 1195, 1198, 1290, 1291, 1292, 1294, 1295, 1296, 1297, 1298, 1325, 1326, 1328, 1390, 1392, 1394, 1395, 1398, 1426, 1428, 1432, 1466, 1467, 1468, 1490, 1491, 1492, 1494, 1495, H120, H125, H140, H145, 1860, 1861, 1870, 1871, T125, T127, T135, T165, T167, T175, T177	
Manufactured on or before (Date)	Not Applicable		
Performance Failure	Patients with affected pacemakers or CRT-Ps may experience intermittent or permanent loss of output or telemetry, or premature battery depletion. Patients with affected ICDs may experience inappropriate sensing or premature battery depletion.		
Root Cause (if known)	Failure of low-voltage capacitor		
Date Manufacturer Corrected Product Available (if known)	Non-affected product is available		
Has all affected product been retrieved?	☐ Yes	☒ No	When? Retrieval of non-implanted product in process

FDA CLASSIFICATION STATUS

Advisory classification — Class: — ☒ Decision Pending

CLINICAL ACUITY

	(USA)	*(Worldwide)*
a) Total number of units currently implanted	Approximately 13,800	Approximately 27,200
b) Estimated number of potentially affected devices of this mode worldwide	Approximately 25,400 distributed	Approximately 49,800 distributed
c) Estimated incidences of this performance failure over the projected life of the device	Too early to predict	Too early to predict
d) Total number with observed Performance Failure	2 reports to date	5 reports to date
% of Performance Failures d/b x 100 =	0.008% reported	0.010% reported
e) Mean age of product in implanted population	Not Applicable	Not Applicable
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 FUNCTION AT RISK OF PERFORMANCE FAILURE

- ☒ Battery Failure (premature depletion)
- ☒ Diagnostic Data Failure (daily measurements)
- ☒ 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 (low-voltage capacitor)
- ☐ EMI Susceptibility
- ☒ Telemetry Failure
- ☐ Other (specify)

PATIENT MANAGEMENT RECOMMENDATIONS		
Verify normal device function (at normal follow-up interval)	☒ Yes	☐ No
Verify normal device function (as soon as possible)	☒ Yes	☐ No
Specific measures to assess: Premature battery depletion, intermittent or permanent loss of therapy or telemetry, fault codes, pacing or sensing abnormalities, or loss of daily diagnostic measurements		
Programming changes	☐ Required	☐ Recommended
If programming changes are required, specify changes:		
Accelerated device follow-up	☐ Yes	☒ No
Timeline - months:	Not Applicable	

CONTACT

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GUIDANT

June 23, 2006

Dear Patient,

This letter is intended to make you aware of important safety information for a limited number of INSIGNIA® and NEXUS® pacemakers; CONTAK RENEWAL® TR/TR 2 cardiac resynchronization therapy pacemakers (CRT-Ps); and VENTAK PRIZM® 2, VITALITY®, and VITALITY 2 implantable cardioverter defibrillators (ICDs) manufactured by Guidant Cardiac Rhythm Management (CRM), a Boston Scientific Company.

What Is the Problem?
Some of these devices have been found to contain a component that may prevent the device from delivering therapy or may lead the device battery to run out before it should. These components are from select lots from a single supplier. Not all devices with this component are affected.

What We Would Like You to Do
We recommend that you schedule a follow-up appointment with your doctor to check your device as soon as possible. We also encourage you to talk to your doctor if you have questions about your device or this issue.

What Guidant Will Do
Guidant is providing doctors with additional detail about this issue. We have recommended to doctors that they schedule an in-clinic follow-up for patients who have these devices to perform a diagnostic check on the device as soon as possible.

Questions?
We encourage you to talk to your doctor if you have questions about your device or this letter. You are also welcome to contact Guidant Patient Services at 1.866.GUIDANT (1.866.484.3268) or write to us at:

Guidant Corporation
4100 Hamline Ave. North
St. Paul, MN 55112
www.guidant.com/contact

It matters to us that our devices perform properly and provide you the health benefits you and your doctor expect. Our surveillance is continuous. If there is a change in the safety status of any device, we will update doctors and patients. Please let us know if we can be of further assistance.

Sincerely,

Renold J. Russie
Director, Product Performance Reporting
Guidant Cardiac Rhythm Management
A Boston Scientific Company

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