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

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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
CONTAK RENEWAL TR 2	H140, H145
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

PHYSICIAN DEVICE ADVISORY NOTICE

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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