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

August 24, 2006

Subject: **Update to the June 23, 2006 Product Advisory Letter**

Dear Doctor:

This message is an update to a product advisory letter issued by Guidant (now Boston Scientific) on June 23, 2006 regarding the potential for loss of therapy associated with the failure of a low-voltage capacitor in a *subset* of INSIGNIA®/ NEXUS® pacemakers, CONTAK RENEWAL® TR and TR2 cardiac resynchronization therapy pacemakers (CRT-Ps), and VENTAK PRIZM® 2, VITALITY® and VITALITY 2 implantable cardioverter defibrillators (ICDs).

Summary of the June 23, 2006 Product Advisory Letter

At the time of the initial communication, five reports of device malfunction had been confirmed within a population limited to approximately 49,800 devices manufactured with a capacitor potentially susceptible to degradation. Physicians were asked to perform an in-clinic follow-up exam as soon as possible for all patients implanted with a device in this susceptible population as patients may experience intermittent or permanent loss of output or telemetry, or premature battery depletion. No inventory from this subset remains available for implant.

Update to Rate of Occurrence Information

- **Observed Events:** Since June 23, 2006, five additional clinical failures worldwide have been confirmed. A total of 10 failures to date represents 0.032% of the implanted population, now estimated to be 31,000 devices. Seven of 10 failures were identified while implanted and three were identified prior to the implant procedure. There have been no reports of patient death associated with this issue. To date, there have been three reports of patients experiencing syncope associated with loss of pacing.
- **Returned Product Testing:** As of August 18, 2006, 13,857 devices were tested from non-implanted inventory containing a capacitor potentially susceptible to degradation. Analysis identified five capacitor failures, which represents 0.036% of devices tested.
- **Projected Rate of Occurrence:** While a statistically significant projection of expected failures for implanted devices is not possible at this time, testing to date suggests that the frequency of new failures will continue to decrease in the future.

Current Recommendations

Physicians should consider the low and declining device failure rate and the unique needs of individual patients when making medical decisions regarding patient management. Boston Scientific believes that for most patients, normal monitoring according to device labeling is a reasonable course of action. As always, advise patients to seek attention immediately if they experience syncope or lightheadedness. Should the device exhibit the behaviors described in Table 1 below, please contact your local Boston Scientific sales representative or Technical Services for assistance with further device evaluation.

Indicators of Capacitor Malfunction

Table 1 lists device behaviors that may be indicative of a capacitor malfunction, and may present individually or in combination:

Table 1. Indicators of Capacitor Malfunction

	Pacemakers INSIGNIA/NEXUS	*CRT-Ps* RENEWAL TR/TR2	*ICDs* VENTAK PRIZM 2, VITALITY and VITALITY 2
Device Behavior	▪ intermittent or permanent loss of pacing output ▪ inability to interrogate ▪ erased values in Daily Measurements ▪ ERT or EOL indicator message displayed earlier than expected ▪ a gas gauge less than BOL within six months of implant	▪ ERI or EOL indicator message displayed earlier than expected ▪ Fault Code 11 message (high current indicator) ▪ a gas gauge less than BOL within six months of implant	▪ ERI or EOL indicator message displayed earlier than expected ▪ a battery voltage less than 3.10V within six months of implant

Devices Affected

The subset of devices affected remains unchanged. Your local Boston Scientific sales representative can provide a list of devices specific to your clinic. You may also use the Device Look-up/Search tool available at www.guidant.com.

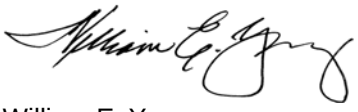
Warranty Supplement Program

Boston Scientific'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. The program is available through December 31, 2006.

Further Information

Patient safety remains Boston Scientific's primary concern, and we are committed to providing you and patients with timely and relevant product information. Future updates will be published quarterly in our Product Performance Report available at www.guidant.com/ppr. If you have any questions, 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 9357.

Sincerely,



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