

January 4, 2008

Subject: **Update** to May 12, 2006 **Product Advisory** regarding certain defibrillators that were implanted in an uncommon orientation.

Dear Patient,

On May 12, 2006, Boston Scientific CRM issued a **Product Advisory** concerning reports of device malfunction associated with implantation of certain defibrillators in an uncommon orientation (beneath the pectoral muscle with the serial number facing the ribs). We have recently updated physicians regarding performance of these devices, and have identified additional device models that may also be subject to this failure mechanism. While implant orientation of your specific device was not reported to us, our records indicate that you have a device that may be at risk if implanted in this unusual orientation.

What Is the Issue?

Most defibrillators are implanted just under the skin in the upper chest area. Occasionally, a doctor may choose to implant a device under the chest muscle. The doctor also has an option to face the device away from or toward the ribs.

The information in **this letter applies only to those devices that are implanted beneath the pectoral muscle and facing the ribs, which is an uncommon implant orientation**. In some cases, devices implanted in this way may be subject to mechanical damage that could impact ability to deliver appropriate therapy. Should this occur, your device may beep (16 tones every 6 hours) and/or your doctor may see a warning on the programmer screen when he or she checks your device. Keep in mind that the large majority of patients are not at risk for this problem.

There have been no reported patient deaths associated with this issue, but devices have been replaced earlier than expected.

What You Should Do

Please keep all scheduled appointments and discuss this information with your doctor. Contact your clinic if you hear beeping from your device.

Questions?

Our product surveillance is continuous to ensure that devices perform properly and provide the health benefits that you and your doctor expect. If there is a change in the safety status of your device, we will update your doctor. If you have further questions, please contact your doctor or Boston Scientific CRM Patient Support Services at 1.866.484.3268 and press "2."

Sincerely,



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