December 1, 2009

Subject: Product Advisory Letter

Dear Patient,

Boston Scientific has recently provided doctors with important information regarding the COGNIS® and TELIGEN® families of implantable defibrillators. We encourage you to contact the doctor who checks your device to discuss this potential performance issue.

Information for patients
Most defibrillators are implanted just under the skin in the upper chest area. Occasionally, a doctor may choose to implant a device deeper, under the chest muscles. Boston Scientific has learned that some devices implanted in this deeper location may be subject to mechanical stress during pectoral muscle contractions that could impact the ability to deliver appropriate therapy. A small number of patients have received inappropriate shocks and required early device replacement.

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 it was implanted in this less-common, deeper location.

What should you do?
Please keep all scheduled follow-up appointments. Discuss this letter with your heart doctor, who can interpret the information we have provided in light of the position of your defibrillator and your current medical situation. Contact your doctor or clinic if you receive shocks from your device.

Questions?
Boston Scientific understands the impact that product advisory messages have on patients and their families, and we believe it is important to bring this information to both you and your doctor. If you have not already done so, we encourage you to talk to your doctor about your device and the information in this letter. You are also welcome to contact Boston Scientific CRM Patient Services at 1.866.484.3268 and press "2".

Sincerely,

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