

November 27, 2007

Subject: Mid-Life Display of Replacement Indicators

Dear Patient:

Your defibrillator is included in a group of implantable devices in which a small number may signal that replacement is necessary earlier than expected. This issue was communicated to physicians on March 10, 2007. The United States Food and Drug Administration (FDA) has recently provided additional information on their website regarding this topic. We encourage you to contact your physician to discuss how this issue relates to your individual situation.

What Is the Issue?

All implantable defibrillators require replacement when the battery wears down. Boston Scientific defibrillators provide two methods of signaling that replacement time is nearing. First, the device will beep (if your doctor has turned this feature ON) and second, a message will be displayed on the programmer screen during a normal follow-up visit. Certain implantable defibrillators similar to yours have signaled that replacement is necessary earlier than expected. These devices need to be replaced, even though the battery still has considerable energy remaining and the defibrillator is capable of providing therapy. No patients have been harmed due to this issue, but some devices have been replaced earlier than expected.

What You Should Do

Please keep all scheduled appointments and discuss this information with your doctor. When the device signals replacement is necessary, the procedure should be scheduled in a normal manner. As always, if you hear beeping tones from your device, please contact your doctor.

Questions?

If you have further questions, please contact Patient Support Services at 1.866.484.3268 and press "2."

Sincerely,



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