

July 2010

Subject: Product Advisory Letter

Dear Patient,

Boston Scientific has recently provided doctors with information regarding the CONTAK RENEWAL[®] 3/4, CONTAK RENEWAL 3/4 RF, and VITALITY[®] HE families of implantable defibrillators. We encourage you to contact the doctor who checks your device to discuss this potential performance issue.

Information for patients

Some Boston Scientific defibrillators include a switch designed to sense the presence of a magnet. In emergency situations or during a medical/surgical procedure, a health care provider may apply a magnet to the skin surface just above the implanted device, which will temporarily prevent delivery of undesired shock therapy. When the magnet is removed, shock therapy will once again be available if needed.

In rare instances, application of a magnet (typically in a clinic/hospital environment) may cause this switch to become permanently stuck, preventing delivery of programmed shock therapy even when the magnet is removed. No patients have been harmed by this behavior, but some have required device replacement. Boston Scientific estimates the probability of patient harm to be less than one in one million over a five year device service life.

What should you do?

Please keep all scheduled device follow-up appointments. As always, contact your heart clinic or go to the hospital emergency room **immediately** if you hear tones/beeping from your device.

Questions?

Boston Scientific understands the impact that product advisory messages may have on patients and their families. Nevertheless, 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 heart doctor, who can interpret the information we have provided in light of your current medical situation. You are also welcome to contact Boston Scientific CRM Patient Services at 1.866.484.3268 and press "2".

Sincerely,



Jeff Biggers
Vice President, Quality Assurance
Cardiology, Rhythm & Vascular
Boston Scientific Corporation