

March 23, 2009

Subject: Product Advisory Letter -- Respiratory Sensor Oversensing

Dear Patient:

Boston Scientific would like you to know that we have recently provided information to your heart doctor regarding the possible need for a change in the settings of your defibrillator. **Please note that at this time, there is no indication that your system has a problem.**

Background

Your defibrillator system consists of two parts – a wire or *lead* positioned within your heart and the defibrillator itself, which monitors your heart and provides therapy by way of an electrical pulse and/or shock when needed. For any implantable defibrillator, delivery of appropriate therapy is dependent upon lead system integrity. If the lead becomes damaged or is not securely connected to the defibrillator, appropriate therapy cannot be assured. Boston Scientific has recently determined that if a feature called the Respiratory Sensor is programmed **On**, such lead complications may cause the defibrillator to be overly sensitive to heart signals, referred to as *oversensing*, thereby increasing the probability of inappropriate pacing or shocks.

Why are we communicating?

Although lead complications are rare, turning the Respiratory Sensor **Off** will lessen the potential for inappropriate therapy should you experience a lead problem. If reprogramming of your defibrillator to turn the Respiratory Sensor **Off** is necessary, it can be done easily in your doctor's office and will not impact the normal function of your device.

What You Should Do

Please keep all scheduled appointments and thoroughly discuss this advisory information with your heart doctor. Because every patient's heart condition is unique, appropriate treatment decisions relative to this advisory can only be made by you and your doctor, who is fully aware of your medical history.

Questions?

All of us at Boston Scientific understand the impact that product advisory messages have on patients and their families, but we believe it is important to bring this information to both you and your doctor. If you have further questions, you are welcome to contact our Patient Support Services at 1.866.484.3268 (option 2).

Sincerely,



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