

May 15, 2008

Dear ICD patient,

Details Regarding your ICD Battery

Dear Patient:

The manufacturer of your ICD (Boston Scientific formerly Guidant) has contacted us regarding a potential problem with the battery of your ICD. We do not wish to worry you too much as it is very unlikely to cause you any problems. Indeed, there have been no adverse events reported anywhere in the world related to this issue. However, we thought it was important to keep you informed.

Summary of the Issue: At the mid battery life of most ICDs, there is an increase in charge time that can occur because of normal impedance increases in the battery that does not reflect battery depletion. The affected devices have a greater increase in charge time/impedance than normal, which triggers elective replacement indicators (ERI) or end of life (EOL) alerts, and these patients should be evaluated. This affects specific models of the Vitality and Contak family of Boston Scientific devices. This affects from 1-10% of models implanted before July 2006, and less than 1% in those implanted thereafter. There are an estimated 567 such devices that have been implanted in Canada. There are no reports of adverse outcomes to patients to date in Canada or elsewhere.

Health Canada's Therapeutic Products Directorate (TPD) has recently classified the issue a product recall under the current Canadian Medical Device Regulations. To date, the TPD also has not required any further action be taken by Boston Scientific or its customers. The following recommendations have been developed in conjunction with the manufacturer and the Canadian Heart Rhythm Society.

Recommendations

1. You have a built-in alarm system in your device. If this alarm detects that the battery is nearing the ERI or EOL it will emit a beeping noise (16 short beeps over 10-20 seconds). This will be emitted every six hours. If you hear this alarm, please contact the ICD clinic at ???-???-???? on the next working day and we will arrange to see you. It is likely that we will assess your device and recommend a battery change. Please be reassured that your battery will not suddenly give out. Even after the alarm sounds, there are several weeks or months of spare capacity left in the battery.
2. If you have any questions or concerns, or you wish to speak to anyone please contact the clinic at ???-???-???? and someone will speak with you over the phone or arrange a clinic visit.
3. Please do not worry about this issue and continue to live your life normally. If you do not have questions at this time, we look forward to seeing you at your next ICD clinic visit.

Sincerely,

ICD Clinic Staff