Boston Scientific

Date: April, 2012

Subject: Transformer Component Malfunction Observed in COGNIS® and TELIGEN® Implantable Defibrillators

Boston Scientific's ***Product Performance Report (PPR)*** provides up-to-date performance information for our implantable pacing and defibrillation products. The ***PPR*** is published quarterly on our website at ***www.bostonscientific.com/ppr***. Current performance data can provide important context for patient management decisions. Among currently active investigations reported in our ***PPR*** Q1 2012 edition is Pattern 101 "Transformer."

Pattern Description and Clinical Implications

The COGNIS and TELIGEN defibrillator family is performing within reliability expectations. However, an electrical component referred to as a "transformer" has exhibited an identifiable pattern of malfunction that has occurred at a low rate (currently 26 out of 233,000 or 1 out of every 8,900 devices implanted). A transformer is used in all implantable defibrillators to multiply the low voltage of the battery (~3 volts) to the high voltage of a shock (~800 volts). Transformer malfunction has occurred during a high voltage charging cycle (a capacitor reform or a therapeutic shock) and has resulted in:

- loss of telemetry (programming/interrogation)
- loss of brady therapy
- loss of tachy therapy (shock and ATP)
- loss of remote follow-up (note: for patients monitored remotely via the LATITUDE® Patient Management System, a notification is provided when data from a patient's device is more than fourteen days late)
- four patient reports (out of 26 confirmed occurrences) of a sudden heating sensation at the implant site, likely due to rapid battery depletion

One patient death has been reported. Laboratory analysis of this patient's device determined that a transformer malfunction had occurred during an automatic capacitor reform.

Rate of Occurrence

As stated in the "Malfunction Details" section of the Q1 2012 ***PPR***, there have been a total of 26 confirmed transformer malfunctions out of approximately 233,000 COGNIS and TELIGEN defibrillators implanted worldwide. Engineering analysis indicates that the probability of malfunction decreases as implant time increases.

Recommendations

There are no additional clinical recommendations beyond current standard of patient care and current device labeling. Use of the LATITUDE remote monitoring system will provide notification of missing data between office visits, which may significantly reduce the time to detect a transformer malfunction, should it occur.

COGNIS and TELIGEN Models

All COGNIS and TELIGEN defibrillators use this transformer component.

COGNIS CRT-D	N118/N119/N120/P106/P107/P108
TELIGEN DR ICD	E110/E111/F110/F111
TELIGEN VR ICD	E102/E103/F102/F103

Additional Information

An independent panel of physicians and safety advocates regularly reviews our field performance data, including this malfunction pattern. Boston Scientific will further analyze the failure mechanism and continuously monitor field performance of COGNIS and TELIGEN devices. We will include detailed, up-to-date product performance information within our ***PPR***, published quarterly at ***www.bostonscientific.com/ppr***.

Please report all adverse clinical events to Boston Scientific and appropriate regulatory authorities, and return explanted products to the manufacturer. If you have questions regarding this communication, please contact your Boston Scientific representative or Technical Services.

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