July 20, 2012

Update on Product Performance

Canadian Heart Rhythm Society
Société canadienne de rythmologie

Canadian Heart Rhythm Society Device Committee

Re: Cognis and Teligen ICDs; prior draft version (June 6) indicating advisory is updated

Dear CHRS Device Committee Members,

Nature of the Update: Cognis and Teligen ICDs (all models) may exhibit an electrical component failure that results in significant loss of device function. This component, the "transformer", is used to multiply the low voltage of the ICD battery to a high voltage shock. The malfunction occurs during a high voltage charge, either during capacitor reform or at the time of delivery of tachy-therapy. The loss of function may occur to any of the following functionalities: telemetry during programming or interrogation, pacing, tachy therapy, or remote monitoring follow-up. Some patients have reported a sudden heating sensation at their implant site, thought to be due to rapid battery depletion.

Scope of the Problem: The malfunction has been reported in 26 of 233 000 devices implanted worldwide (1 out of 8900 devices implanted; 0.011%). One patient death related to a transformer failure has been reported. Analysis of that patient's ICD revealed that transformer malfunction occurred during a capacitor reform. BSCI has indicated to CHRS that the transformer is meeting the expected standard of performance. Further, no specific root cause has been identified and this issue has been labeled as 'random component failure'. Only one reported transformer failure occurred after the initial 2 years of the device service. Based on these data, BSCI does not expect the rate of failure to increase over time.

Response of the Canadian Heart Rhythm Society

Recommendations:

1. The CHRS-DC encourages that patients may be informed of this issue at their next routine clinic visit, but this is left to the discretion of their device specialist.
2. Patients should be advised to contact the clinic if a sudden heating sensation is felt at the implant site, which may be caused by a transformer failure.
3. Follow up visits as per the Canadian guidelines (Gillis et al. CJC 2002) should be continued, either in clinic or through remote monitoring.
4. The CHRS-DC does not recommend routine replacement of these devices unless an abnormality is identified.
5. Missing data between in-clinic visits using the LATITUDE remote monitoring system may indicate a possible transformer malfunction. Any notification of missing data should be followed up.
6. Any Cognis or Teligen devices explanted should be returned to the company for analysis to verify the occurrence of this defect.
7. The CHRS-DC does not feel this is an advisory at this time but continues to evaluate this issue and will update the CHRS members with any changes in recommendations on an urgent basis.

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