



Health innovation that matters

Statement Regarding Affect of Class 2 Device Recall in Lebanon

This statement is to confirm that the 'Class 2 Device Recall' posted on the FDA website (www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=140876) did not affect products or patients in Lebanon.

The field action was implemented to inform physicians that certain Model 106 Pulse Generators demonstrated delays in sensing during use of the 'Verify Heartbeat Detection' feature and exhibit potential for decreased battery longevity. Due to a manufacturing process change, a small percentage (~1.99%) of Model 106 AspireSR® generators would not provide a numerical beats per minute (BPM) value when using the "Verify Heartbeat Detection" feature in the VNS Therapy programming software: "?????" may be displayed. In addition, these generators may experience a minor reduction in battery longevity. No delays in sensing during use of the 'Verify Heartbeat Detection' were experienced in Lebanon and therefore Lebanon was not affected by this Field Safety Notice.

Ongoing trending and investigation of post-market feedback identified earlier this year that the occurrence rate of premature EOS within the potentially affected device population associated with this manufacturing process change is now 1.5% for Model 105 and 3.7% for Model 106. Subsequently LivaNova has decided to extent the Field Safety Notice to all Model 105 and Model 106 serial numbers manufactured during the limited period in which this manufacturing process was used.

Although the device's lifetime may be reduced, its functions are not affected by this issue and the delivery of therapy is unaffected until the device reaches end of service (EOS). Similarly, the device's battery status indicators (i.e., IFI, NEOS, and EOS) are also unaffected and will accurately reflect the device battery status. The manufacturing issue has been corrected and does not affect devices manufactured after September 2015.

None of the possibly affected serial numbers was shipped to Lebanon and therefore Lebanon is not affected by this issue.

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Statement Regarding Affect of Urgent Field Safety Notice Model 105 Aspire HC® and 106 AspireSR® VNS Therapy® Generators

This statement is to confirm that the 'Urgent Field Safety Notice' of 30 June 2017, reference number NM-HOU-2017-001, posted on the HPRA website (http://www.hpra.ie/docs/default-source/field-safety-notices/june-2017/v32376_fsn.pdf?sfvrsn=2), did not affect products or patients in Lebanon.

None of the possibly affected serial numbers was shipped to Lebanon and therefore Lebanon is not affected by this issue.

Ger J. Kamminga

A handwritten signature in black ink, appearing to be 'Ger J. Kamminga', written over a horizontal line.

Director Commercial Quality

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