Medtronic News

HeartWare International Issues Voluntary Device Correction For HeartWare® Batteries

FRAMINGHAM, Mass., May 1, 2014 /PRNewswire/ -- HeartWare International, Inc. (Nasdaq: HTWR), today issued a voluntary Urgent Medical Device Correction related to all HeartWare® Ventricular Assist System batteries, product codes 1650 and 1650-DE. In letters to clinicians and patients, the company reports an observed increase in complaints related to earlier-than-expected battery depletion and routine battery handling.

HeartWare is providing information to assist patients and clinicians in monitoring battery performance, recognizing abnormal behaviors and reinforcing proper power management. Premature or unrecognized deterioration of battery capacity or lapses in recommended power management pose a risk to the patient and, although rare, may result in serious injury or death. If a battery shows abnormal behavior, patients are instructed to stop using that battery and contact their VAD Coordinator for a replacement.

Similar to the battery in a mobile cell phone,HeartWare® batteries will begin to lose charge over time. If a fully-charged battery lasts less than two hours or if the controller switches back-and-forth between batteries, patients are asked to take the affected battery out of service and replace it with a new one.

No deaths have been reported to HeartWare that were directly related to a faulty battery. However, between January 1, 2011 and March 31, 2014, three deaths were reported that were potentially related to power source management. Of those, two patient deaths occurred after both sources of power were simultaneously disconnected; the third patient had batteries that far exceeded their expected useful life. A fourth death was originally reported as possibly related to power management, but was later determined to be more likely related to an accidental disconnection of the driveline.

Clinicians and patients are encouraged to review the correction letters and the Patient Manual to ensure proper power management.

Patients with questions about this announcement should contact their physician or VAD Coordinator at their hospital center. Clinicians with questions related to the correction should contact their HeartWare representative or HeartWare's 24-hour Clinical Support line at (888) 494-6365 or via email at FSCA@heartware.com.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

About HeartWare International

HeartWare International develops and manufactures miniaturized implantable heart pumps, or ventricular assist devices, to treat patients suffering from advanced heart failure. For additional information, please visit the Company's website at www.heartware.com.

Investor and media contact:
Christopher Taylor
HeartWare International, Inc.
Email: ctaylor@heartwareinc.com
Phone: +1 508 739 0864

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