Medtronic News

HeartWare Issues Reminder To December 2013 Driveline Connector Device Correction

FRAMINGHAM, Mass., April 24, 2014 /PRNewswire/ -- HeartWare International, Inc. (Nasdaq: HTWR) today announced issuance of a clinician and patient reminder concerning the Urgent Medical Device Correction distributed to all of its clinical sites by the company in December 2013. The device correction discussed eight complaints that the locking mechanism of the driveline connector of the HeartWare® Ventricular Assist System had failed to engage and instructed clinicians to inspect patient driveline connectors. To ensure full awareness, the company is in the process of redistributing this information to clinicians and patients.

Impacted HeartWare Systems carry catalog numbers: 1100, 1101, 1102, 1103, 1104, and 1205 with serial numbers ranging from: HW001 to HW11270 and HW20001 to HW20296. All devices manufactured since November 2013 incorporate changes in manufacturing procedures which address this issue.

A disconnected driveline would result in a temporary pump stop which could cause serious injury or death, depending on the function of a patient's native heart. HeartWare issued the December 2013 correction following eight reported events in which the locking mechanism failed to engage. Four of these eight cases resulted in a temporary pump stop; however, none resulted in patient injury.

Patients are requested to discuss the correction notice with their physician or VAD Coordinator. Clinicians are asked to inspect the patient's driveline connector for proper locking at implant and at each routine clinic visit to ensure that the connector assembly remains secure. Should the locking mechanism fail to engage or the driveline disconnects from the controller, the driveline connector should be pushed back into the controller immediately. Clinicians should promptly call their HeartWare representative to arrange a permanent repair.

Patients with questions about this announcement should contact their physician or VAD Coordinator at their hospital center. Clinicians with questions related to this announcement or who wish to schedule a driveline connector repair should contact HeartWare Clinical Support 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.

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