U.S. Department of Health & Human Services

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Class 1 Recall HeartWare See Related Information

Date Posted	May 14, 2015
Recall Status[1]	Open
Recall Number	Z-1604-2015
Recall Event ID	71099
Product	HeartWare Ventricular Assist System (HVAD) Pump Driveline Splice Kit Product Usage: Is intended to repair the driveline cable once an electrical break has been identified. These repairs are limited to the portion of the driveline that is outside the patient boundary (exit side).
Code Information	Catalog #: ASY00116: HVAD Pump Driveline Splice Kit Lot #'s 532770, 567949, 480786, 483769, 490692, 539664, and 598189 and Catalog #: ASY00281: HVAD Pump Driveline Splicekit; Large OD Sheath Lot #'s 654090, 672401, 678800, 690423, 833963, 873159, and 880816
Recalling Firm/ Manufacturer	HeartWare Inc 14400 Nw 60th Ave Miami Lakes, Florida 33014-2807
For Additional Information Contact	Clinical Support 305-364-1575
Manufacturer Reason for Recall	Failures of the splice repair kit if exposed to excessive force.
Action	HeartWare, Inc. sent an Urgent Medical Device Correction letter to all affected consignees on May 11, 2015. The letter identified the affected product, problem, and actions to be taken by the consignees. The firm requested that consignees: 1) review the notice and the Patient Communication contents, 2) forward the notice to individuals within their organization who need to be aware of the notice, 3) identify patients that are currently on support and have undergone a driveline splice repair, 4) distribute the Patient Communication to the affected patients in person, 5) continue to reinforce the messages described in the notice with patients who have experienced a splice repair during their regularly scheduled appointments, 6) complete, sign, and return the "Acknowledge and Completion Form to HeartWare within 30 days of receipt of the letter. Should any questions or concerns arise, please contact there local HeartWare representative. Their 24-hour Clinical Support personnel are also available at 1 (888) 494-6365.
Quantity in Commerce	35

Distribution	Worldwide Distribution - US Nationwide in the states of FL, KY, MO, NY, TN,TX, and the countries of: Canada, Germany, Italy, Netherlands, Turkey and United Kingdom.

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55

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