



## Class 1 Device Recall HeartWare

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### Class 1 Recall HeartWare


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<b>Date Posted</b>	May 14, 2015
<b>Recall Status<sup>1</sup></b>	Open
<b>Recall Number</b>	Z-1604-2015
<b>Recall Event ID</b>	<a href="#">Z1099</a>
<b>Product</b>	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).
<b>Code Information</b>	Catalog #: ASY00116: HVAD Pump Driveline Splice Kit Lot #'s 532770, 567949, 480786, 483769, 490692, 539664, and 598189 and Catalog #: ASY00281: HVAD Pump Driveline Splice Kit; Large OD Sheath Lot #'s 654090, 672401, 678800, 690423, 833963, 873159, and 880816
<b>Recalling Firm/Manufacturer</b>	HeartWare Inc 14400 Nw 60th Ave Miami Lakes, Florida 33014-2807
<b>For Additional Information Contact</b>	Clinical Support 305-364-1575
<b>Manufacturer Reason for Recall</b>	Failures of the splice repair kit if exposed to excessive force.
<b>Action</b>	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 their local HeartWare representative. Their 24-hour Clinical Support personnel are also available at 1 (888) 494-6365.
<b>Quantity in Commerce</b>	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.

<sup>1</sup> For details about termination of a recall see [Code of Federal Regulations \(CFR\) Title 21 §7.55](#)

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