



California Medical Device Recall Information



Recall Name

HeartWare Recalls HeartWare® Ventricular Assist System Due to Hardware Failure

Recall Date	Product Description	Recalling Firm	Recall Reason
12/06/13	HeartWare® Ventricular Assist System	HeartWare International, Inc. Miami Lakes, FL	<p><i>The driveline connector locking mechanism may fail to engage as a result of a faulty manufacturing assembly process.</i></p> <p><i>This failure could result in unexpected pump stoppage and potentially lead to serious adverse health consequences including death.</i></p>
Recall Class	Product Identification	Distribution	Affected Dates
I	Catalog Numbers: 1100 1103 1101 1104 1102 1205 Serial Numbers: <ul style="list-style-type: none"> • HW001 - HW 11270; • HW20001 - HW 20296 	CA, nationwide	Manufactured: March 6, 2006 through October 17, 2013. Distributed: March 17, 2006 through November 29, 2013.

FOR ADDITIONAL INFORMATION, PLEASE VISIT:

<http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm395252.htm>