



California Medical Device Recall Information



Recall Name

HeartWare Recalls HeartWare Ventricular Assist System Due to Multiple Reasons

Recall Date	Product Description	Recalling Firm	Recall Reason
Five (5) Recalls Beginning: 04/29/15	HeartWare Ventricular Assist Device (HVAD) Product Codes: 1101 1103	HeartWare International, Inc. Miami Lakes, FL	<i>Worn alignment guides, internal battery failure, power management software upgrades, driveline outer sheath discoloration and cracking, and driveline pulling and snagging.</i>
Recall Class	Product Identification	Distribution	Affected Dates
I	ALL HeartWare systems currently in use.	CA , nationwide	Manufacturing and Distribution Dates: January 2008 to March 2015

FOR ADDITIONAL INFORMATION, PLEASE VISIT:

<http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm451447.htm>