Class 1 Recall
Diamondback 360 Peripheral Orbital Atherectomy System.

Date Posted: August 14, 2014
Recall Status: Open
Recall Number: Z-2155-2014
Recall Event ID: E8808623
Premarket Notification 510(K) Number: K13339024
Product Classification: Catheter, Periphera, Atherectomy - Product Code MCW025

Product: CSI Cardiovascular Systems, Inc., Diamondback 360 Peripheral Orbital Atherectomy System, Model Number DBP-125MICRO145, Part Number 7-10003. The Diamondback 360 Peripheral Orbital Atherectomy System is a percutaneous orbital atherectomy system indicated for use as therapy in patients with occlusive atherosclerotic disease in peripheral arteries and who are acceptable candidates for percutaneous transluminal atherectomy. The OAS supports removal of stenotic material from artifical arteriovenous dialysis fistulae (AV shunt). The system is a percutaneous orbital atherectomy system indicated as a therapy in patients with occluded hemodialysis grafts who are acceptable candidates for percutaneous transluminal angioplasty.

Code Information: 100573, 100575, 100674, 100676, 100678, 1008010.

Recalling Firm/Manufacturer: Cardiovascular Systems, Inc., 651 Campus Dr, Saint Paul, Minnesota 55112-3495

For Additional Information Contact: Customer Service, 877-274-0901

Manufacturer Reason for Recall: CSI has initiated a recall on the Diamondback 360 Peripheral Orbital Atherectomy Device because it may contain a saline sheath that may experience cracking, fracture, and release particulate during use.

FDA Determined Cause: PRODUCTION CONTROLS: Process Control

Action: Cardiovascular System, Inc. sent consignees an Urgent Medical Device Recall letter dated May 23, 2014. The letter described the Affected Product, Recall Description, Instructions which included to remove the affected product and return it to CSI and to complete and return the Customer Acknowledgement Form. For further Information they customers were instructed to contact Customer Service, Cardiovascular System, Inc., 877-274-0901. For questions regarding this recall call 877-274-0901.

Quantity in Commerce: 48

Distribution: Nationwide Distribution including AZ, AR, CA, CT, FL, IL, IA, MD, MI, NY, NC, PA, TN, and TX.

Total Product Life Cycle: TPLC Device Report27