Class 1 Device Recall Diamondback 360 Peripheral Orbital Atherectomy System.

Class 1 Recall
Diamondback 360 Peripheral Orbital Atherectomy System.

See Related Information[22]

Date Posted	August 14, 2014
Recall Status[1]	Open
Recall Number	Z-2155-2014
Recall Event ID	68806[23]
Premarket Notification 510(K) Number	K133399[24]
Product Classification	Catheter, Peripheral, Atherectomy[25] - **Product Code** MCW[26]
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 artificial 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, 100680.
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 [2]	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 Report[27]