Bard Peripheral Vascular Inc. Recalls Halo One Thin-Walled Guiding Sheath Due to Sheath Separation, Kinking, or Tip Damage

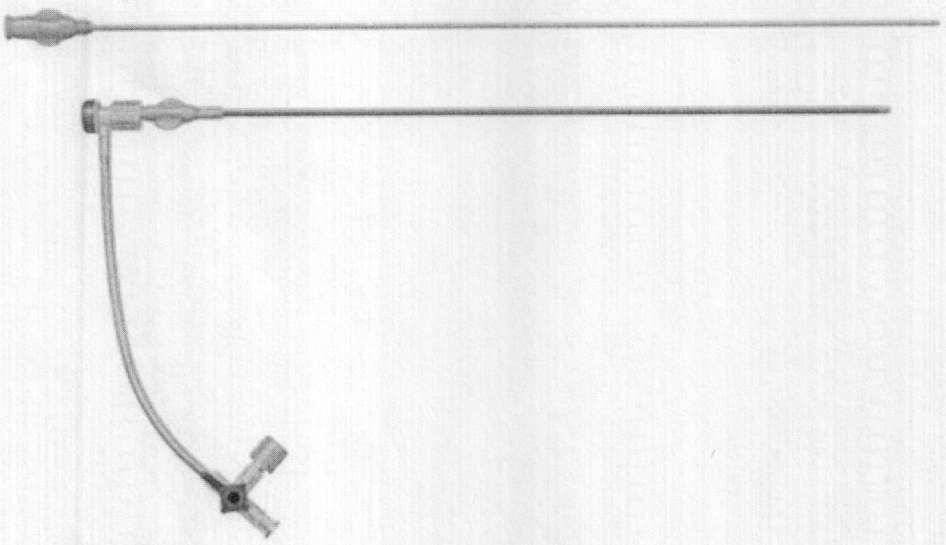
The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Product

- Halo One Thin-Walled Guiding Sheath
- Product Codes: HAL545, HAL590 HAL510F
- Lot Numbers: 50137556, 50137557, 50137598 50137682 50137723, 50137735, 50137875, 50137965, 50138274, 50138119, 50138118, 50138122, 50138273, 50138435, 50138437, 50138701, 50138439, 50137570, 50137770, 50137979, 50138696, 50137866, 50137924, 50138170, 50138765
- Manufacturing Dates: April 12, 2016 to July 7, 2016
- Distribution Dates: June 24, 2016 to July 12, 2016
- Devices Recalled in the U.S.: 101 units distributed in Arizona, Florida, Kansas, Louisiana, Maine, Michigan, Missouri, Nevada, New Hampshire, New York, Ohio, Texas, Utah, Washington

Device Use

The Halo One Thin-Walled Guiding Sheath is used to introduce and/or guide the placement of interventional and diagnostic devices into veins and arteries through an incision made on a patient's leg.



Halo One Thin-Walled Guiding Sheath

Reason for Recall

Bard Peripheral Vascular Inc. is recalling the Halo One Thin-Walled Guiding Sheath because the sheath body may separate from the sheath hub while removing the device from the patient's leg. The company also reports that the sheath may kink, and that its tip may become damaged during the procedure.

The use of affected sheaths may result in prolonged procedure times and on additional surgical intervention to remove detached components from the patient. The affected product may cause other serious adverse health consequences such as internal tears and perforation to arteries or veins, excessive bleeding, and death.

Who May be Affected

- Health care professionals using the Halo One Thin-Walled Guiding Sheath
- All patients undergoing procedures involving these guiding sheaths

What to Do

On January 10, 2017, Bard Peripheral Vascular sent a Medical Device Recall Notification, which instructed consignees to:

- Stop using, or further distributing, any affected products
- Check all inventory locations for affected product codes and lot numbers
- Remove any affected products from the shelves
- If an affected product has been used, complete and return the "Recall and Effectiveness Check Form," which was attached to the notification, and which indicates no product will be returned
- Contact the firm's Recall Coordinator at 1-800-321-4254 Option #2 Ext. 2501 (Monday - Friday 6am to 3pm Mountain Standard Time) or by email at **raye.seisinger@crbard.com (mailto:raye.seisinger@crbard.com)**
- Report adverse events or quality problems experienced with use of the product to the FDA through:

- **MedWatch Online (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home)**
- Phone: 800-FDA-1088
- Fax: 800-FDA-0178

Date Recall Initiated

December 2, 2016

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to **MedWatch: The FDA Safety Information and Adverse Event Reporting Program (https://www.accessdata.fda.gov/scripts/medwatch/)** either online, by regular mail or by FAX

More in Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/default.htm)

2017 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm535289.htm)

2016 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm480134.htm)