

## [High Priority ] - A32699 : Bard— WaveLinQ 4 Fr EndoAVF Systems: May Exhibit Magnetic Deficiency between Venous and Arterial Catheters, Potentially Resulting in Magnets Failing to Attract Each Other

### Medical Device Ongoing Action

**Published:** Wednesday, May 15, 2019

#### UMDNS Terms:

- Catheters, Vascular, Infusion, Central Venous [10729]

#### Product Identifier:

[Consumable]

Product	Bard Peripheral Vascular, a BD company Product No.	Lot No.
WaveLinQ 4 Fr EndoAVF Systems	W04200	S0053

**Geographic Regions:** (Impact in additional regions has not been identified or ruled out at the time of this posting), U.S.

**Manufacturer(s):** Bard Peripheral Vascular, a BD company PO Box 1740, Tempe, AZ 85280-1740, United States

**Suggested Distribution:** Cardiology/Cardiac Catheterization Laboratory, Critical Care, Dialysis/Nephrology, Emergency/Outpatient Services, Nursing, OR/Surgery, Materials Management

#### Problem:

In an April 26, 2019, Urgent Medical Device Recall Notification letter submitted by an ECRI Institute member hospital, Bard states that the above product may exhibit a magnetic deficiency between the venous and arterial magnetic catheters, potentially resulting in the magnets failing to attract each other. Bard also states that failure or suboptimal attraction of the magnets can be identified by the physician during the procedure, and would allow either aborting the procedure, replacing the catheters and re-attempting during the same procedure, or re-attempting in a different anatomic location as indicated. This problem may cause a procedural prolongation in obtaining or creating a functional fistula and the need for additional contrast required to perform the necessary fluoroscopy, which may also pose an incremental risk of harm to a diabetic patient's kidney function. Bard further states that it is unclear whether any other problems regarding fistula formation may occur because of sub-optimal attraction or alignment of the magnets; therefore, while serious adverse effects related to this problem have not been reported, they may still occur. The manufacturer has not confirmed the information provided in the source material.

#### Action Needed:

Identify, isolate, and discontinue use of any affected product in your inventory. If you have affected product, verify that you have received the April 2019 Urgent Medical Device Recall Notification letter, mailing label, and Recall and Effectiveness Check Form from Bard. Complete the Recall and Effectiveness Check Form, and return it to Bard using the instructions on the form. If you are unable to e-mail or fax the form to Bard, contact the Bard Peripheral Vascular (BPV) customer support center by telephone at (800) 321-4254 (select option 5) to report the required information verbally. To obtain a return authorization (XC) number to facilitate product return, contact the BPV customer support center by telephone or by e-mail at [BPV.CustomerSupportCenter@crbard.com](mailto:BPV.CustomerSupportCenter@crbard.com). Mark the outside package as "RECALLED PRODUCT," and include the XC number. All products should be returned to: Bard Peripheral Vascular, Inc., 1415 W. 3rd St., Tempe, AZ 85281, United States. Upon receipt of affected product, BPV will provide your facility with replacement product. U.S. customers should report serious adverse events or product quality problems relating to the use of affected product to FDA's MedWatch Adverse Event Reporting program by telephone at (800) 332-1088, by fax at (800) 332-0178, by mail (using postage-paid FDA Form 3500, available [here](#)) at Food and Drug Administration, HF-2, 5600 Fishers Lane, Rockville, MD 20852-9787; or online at the [MedWatch website](#). Inform all relevant personnel at your facility of the information in the letter, and forward a copy of the letter to any facility to which you have further distributed affected product.

#### For Further Information:

Bard

Website: [Click here](#)

#### Comments:

- This alert is a living document and may be updated when ECRI Institute receives additional information.

#### Source(s):

- 2019 May 15. Member Hospital. Bard letter submitted by an ECRI Institute member hospital (includes reply form) [Download](#)