الموضوع: إشعار بمعالجة جهاز طبي مغروس

Implantable, Catheter, Guiding, Vascular BARD Biopsy Systems and support catheters (Microsheath and Usher)

الجهاز المعني بالمنطقة:
- Implantable, Catheter, Guiding, Vascular BARD Biopsy Systems and support catheters (Microsheath and Usher)
- Trade Mark: Bard Peripheral Vascular (BPV)
- Local Representative:

FDA

بناء على التقرير الصادر عن وكالة ال

التوجيه الصادرة عن الشركة المصنعة والتي تشير إلى وجود خلل في عملية تعميم الصفوف المذكور أعلاه، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنوية.

مرفق ريبط:
- التقرير الصادر عن وكالة ال

FDA

- د.أ. محمد الباي

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New Search

Class 2 Recall
USHERR® Support Catheter-Angled Tip WL 130cm

Date Posted
June 10, 2013

Recall Number
Z-1529-2013

Product
The USHERR® Peripheral is a single lumen support catheter, with a standard luer fitting at the proximal end. The USHERR® Peripheral is available in a length 130 cm with an angled tip shape.

Code Information
PC USH07AT; Lot: PCWC10009

Recalling Firm/Manufacturer
Bard Peripheral Vascular Inc
1625 W 3rd St Ste 109
Tempe, Arizona 85281-2438

Consumer Instructions
Contact the recalling firm for information.

For Additional Information Contact
Chad Modra
480-305-2602

Reason for Recall
Bard Peripheral Vascular (BPV) is initiating this recall because a combination of Bard, UltraClip, Dual Trigger Tissue Markers and support catheters (Microsheath and Usher) were inadvertently distributed to customers without completing the sterilization process (non-sterile).

Action
The firm, BARD Peripheral Vascular, sent an "URGENT MEDICAL DEVICE RECALL NOTIFICATION" letter on January 23, 2013, to its customers. Bard EXPANDED its recall to include (Microsheath and Usher support Catheters) and sent another "URGENT MEDICAL DEVICE RECALL NOTIFICATION" letter dated March 5, 2013 describing the additional products, to its customers. The letter described the product, problem and actions to be taken. The customers were instructed as follows: Do not use or further distribute any affected product, check all inventory locations within your institution; remove any identified product from your shelves and return to Bard Peripheral Vascular, Inc. 1415 W. 3rd Street, Tempe, AZ 85281. If you have further distributed any of the product, immediately contact that location and advise them of the recall and have them return to BPV. If you have used the affected product, consider notifying, educating and monitoring those affected; and complete and return the Recall and Effectiveness Check form via fax to: ATTN: Recall Coordinator in Customer Service at 1-800-694-6712, even if you no longer have possession of the product; if unable to FAX call BPV at 1-800-321-4254 Option #2 Ext 2727 and report verbally. Please call our Recall Coordinator at 1-800-321-4254 Option #2 Ext 2727 (M-F 7am to 4pm MST) or email at hf㎍via.carlin@cr Bard.com with any questions.

Quantity in Commerce
223

Distribution
Nationwide distribution including AL, AR, AZ, CA, CO, CT, DC, FL, GA, HI, IA, IL, IN, KY, KS, LA, MA, MD, MI, MN, MO, MS, NC, NJ, NY, OH, OK, PA, TX, VA, WA, WV and WI.

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7/1/2013