REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH
The Director General

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٣٨١/٢٥
رقم الصادر: ١٢/٧/٥٢١٩
بيروت، في: ٣٠ تموز ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس
Implantable, Catheter, Guiding, Vascular BARD Biopsy Systems and support catheters (Microsheath and Usher)

الجهاز المعني بالمتابعة:

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

بناء على التقرير الصادر عن وكالة ال FDA

والتوصية الصادرة عن الشركة المصنعة والتي تشير الى وجود خلل في عملية تعقيم الصنف المذكور أعلاه، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التقرير الصادر عن وكالة ال FDA

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
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Class 2 Recall USHER® Support Catheter- Angled Tip WL130cm

See Related Information[20]

Date Posted	June 10, 2013
Recall Number	Z-1529-2013
Product	USHER® Support Catheter- Angled Tip WL130cm, RI 7F; REF USH07AT; PK1022-01A; Rx only, Non-Pyrogenic, Sterile; Bard Peripheral Vascular; Manuf: FlowCardia, inc., a Subsidiary of C. R. Bard, Inc., 745 North Pastoria Ave, Sunnyvale CA 95085. The Usher® Peripheral is a single lumen support catheter, with a standard luer fitting at the proximal end. The Usher® Peripheral is available in a length 130 cm with an angled tip shape.
Code Information	PC USH07AT; Lot# FCWC10009
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 480-303-2602
Reason for Recall	Bard Peripheral Vascular (BPV) is initiating this recall because a combination of Bard¿ UltraClip¿ Dual Trigger Tissue Marker's 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 1-800-994-6772, even if you no longer have possession of the product; if unable to FAX call BPV at 1-800-321-4254 Option #2 Ex 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 H!Usilvia.carrilio@crbard.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 WY.

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