RÉPUBLIQUE LIBANAISE
MINISTÈRE DE LA SANTÉ PUBLIQUE
Le Directeur Général

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٢٨/٢٥٠
رقم الصادر: ١٣/١/١٤٤٥٦
بيروت، في: ٢٦ نيسان ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي
Pads, Circulating-Fluid, Sterile Polar Pads Contained in Cold Therapy Combination Units

الجهاز المعني بالمتابعة:

- Pads, Circulating-Fluid, Sterile Polar Pads Contained in Cold Therapy Combination Units
- Trade Mark: Breg Inc, An Orthofix Company
- Local Representative:

بناء على التقرير الصادر عن وكالة ال FDA الذي يشير الى خلل في طريقة حفظ الجهاز المذكور اعلاه مما قد يؤثر على فعالية التعقيم ، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:
- التوصية الصادرة عن الشركة المصنعة

يبلغ:
- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
د. وليد عمار

الجمهورية اللبنانية
وزارة الصحة العامة
قلم الصدور

Rue de la Musée - Imm. Hussein Mansour - Beyrouth, Liban - Tel.: 961.1.615724 - 615725 - Fax: 961.1.615730 - Email: dirctorgeneral@moph.gov.lb

Class 2 Recall BREG Cold Therapy Combination Units

See Related Information[20]

Date Posted	February 12, 2013
Recall Number	Z-0803-2013
Product	BREG Cold Therapy Combination Units containing Sterile Polar Pads. 02356 Rev M, PAD M/U XL STER, Mfg.Date: 112012. Model #s: 10903, 10703, 09101, 09111, 09131, 09731, 09611, 09621, and 09631. Local anesthetic effect.
Code Information	Affected product will be identified by date of manufacture from January 2010 through October 2012.
Recalling Firm/ Manufacturer	Breg Inc 2885 Loker Ave E Carlsbad, California 92010-6626
Consumer Instructions	Contact the recalling firm for information
For Additional Information Contact	Carol Emerson 800-321-0607
Reason for Recall	The recall was initiated because Breg has determined that some Sterile Polar Pads products manufactured from January 2010 to October 2012 may have sustained damage to the product packaging which may compromise product sterility assurance.
Action	The firm, BREG, sent an "URGENT: MEDICAL DEVICE RECALL" letter dated January 14, 2013 to its customers. The letter described the product, problem and actions to be taken. The customers were instructed to immediately examine your inventory and quarantine the product; complete the Return Response Form by email, Fax or mail; and contact Breg for a Return Authorization for the affected product and request replacement by contacting Breg Customer Care at 800-321-0607. Note: response is required even if you have no affected inventory. Should you have any questions regarding this communication or need to report an adverse event, please contact Breg Customer Care at 800-321-0607.
Quantity in Commerce	44,883 units
Distribution	Worldwide Distribution-USA (nationwide) and the countries of Australia, Singapore, Chile, Latvia.

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
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5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. ../cfPMN/pmn.cfm
8. ../cfRL/rl.cfm
9. ../cfMAUDE/TextSearch.cfm
10. ../cfRES/res.cfm
11. ../cfPMA/pma.cfm
12. ../cfPCD/classification.cfm
13. ../cfStandards/search.cfm
14. ../cfCFR/CFRSearch.cfm
15. ../cfPCD_RH/classification.cfm
16. ../cfAssem/assembler.cfm
17. ../Medsun/searchReportText.cfm
18. ../cfClia/Search.cfm
19. ../cfTPLC/tplc.cfm
20. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/relateditems.cfm?page_title=medical%20device%20recalls&item1_text=%3Ch3%3Erelated%20recalls%20for%20BREG%20Cold%20Therapy%20Combination%20Units%3C%2Fh3%3E&item1_url=www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?

See Related Information[20]

Class 2 Recall
BREG Sterile Polar Pads

Date Posted	February 12, 2013
Recall Number	Z-0804-2013
Product	BREG Sterile Polar Pads; 02356 Rev M, PAD M/U XL STER, Mfg.Date: 112012. Model #s: 02510, 09901, 02330, 02350, 02490, 02356, 02496, 02410. Local anesthetic effect.
Code Information	Affected product will be identified by date of manufacture from January 2010 through October 2012
Recalling Firm/ Manufacturer	Breg Inc 2885 Loker Ave E Carlsbad, California 92010-6626
Consumer Instructions	Contact the recalling firm for information
For Additional Information Contact	Carol Emerson 800-321-0607
Reason for Recall	The recall was initiated because Breg has determined that some Sterile Polar Pads products manufactured from January 2010 to October 2012 may have sustained damage to the product packaging which may compromise product sterility assurance.
Action	The firm, BREG, sent an "URGENT: MEDICAL DEVICE RECALL" letter dated January 14, 2013 to its customers. The letter described the product, problem and actions to be taken. The customers were instructed to immediately examine your inventory and quarantine the product; complete the Return Response Form by email, Fax or mail; and contact Breg for a Return Authorization for the affected product and request replacement by contacting Breg Customer Care at 800-321-0607. Note: response is required even if you have no affected inventory. Should you have any questions regarding this communication or need to report an adverse event, please contact Breg Customer Care at 800-321-0607.
Quantity in Commerce	44,883 units
Distribution	Worldwide Distribution-USA (nationwide) and the countries of Australia, Singapore, Chile, Latvia.

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5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. ../cfPMN/pmn.cfm
8. ../cfRL/rl.cfm
9. ../cfMAUDE/TextSearch.cfm
10. ../cfRES/res.cfm
11. ../cfPMA/pma.cfm
12. ../cfPCD/classification.cfm
13. ../cfStandards/search.cfm
14. ../cfCFR/CFRSearch.cfm
15. ../cfPCD_RH/classification.cfm
16. ../cfAssem/assembler.cfm
17. ../Medsun/searchReportText.cfm
18. ../cfClia/Search.cfm
19. ../cfTPLC/tplc.cfm
20. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/relateditems.cfm?page_title=medical%20device%20recalls&item1_text=%3Ch3%3Erelated%20recalls%20for%20BREG%20Sterile%20Polar%20Pads%3C%2Fh3%3E&item1_url=www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?start_search=1&event_id=64177&item2_text=medical%20device%20recalls%