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

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

بناءً على التقرير الصادر عن وكالة الـ FDA الذي يشير إلى خلل في فعالية جهاز المذكور

أعلان مما قد يؤثر على فعالية التَّققيم، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ريطاً:
- التوصية المصدرة عن الشركة المصنعة

زيادة البرامج والمشاريع المستفيضات الحكومية
- المحفوظات

د. وليد عمراً
مدير عام الصحة

Rue de la Musée • Imm. Hussein Mansour • Beyrouth, Liban • Tel.: 961.1.615724 - 615725 • Fax. 961.1.615730 • Email: directorgeneral@moph.gov.lb
Medical & Radiation Emitting Device Recalls

<table>
<thead>
<tr>
<th>Date Posted</th>
<th>February 12, 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recall Number</td>
<td>Z-0803-2013</td>
</tr>
<tr>
<td>Product</td>
<td>BREG Cold Therapy Combination Units containing Sterile Polar Pads. 02366 Rev M, PAD M/U XL STER, Mfg.Date: 112012, Model #: 10903, 10703, 09101, 09111, 09131, 09731, 09611, 09621, and 09631. Local anesthetic effect.</td>
</tr>
<tr>
<td>Code Information</td>
<td>Affected product will be identified by date of manufacture from January 2010 through October 2012.</td>
</tr>
<tr>
<td>Recalling Firm/Manufacturer</td>
<td>Breg Inc 2865 Loker Ave E City Beav, California 92010-6626</td>
</tr>
<tr>
<td>Consumer Instructions</td>
<td>Contact the recalling firm for information</td>
</tr>
<tr>
<td>For Additional Information Contact</td>
<td>Carol Emerson 800-321-0607</td>
</tr>
<tr>
<td>Reason for Recall</td>
<td>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.</td>
</tr>
<tr>
<td>Action</td>
<td>The firm, BREG, sent an &quot;URGENT: MEDICAL DEVICE RECALL&quot; 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.</td>
</tr>
<tr>
<td>Quantity in Commerce</td>
<td>44,883 units</td>
</tr>
<tr>
<td>Distribution</td>
<td>Worldwide Distribution-USA (nationwide) and the countries of Australia, Singapore, Chile, Latvia.</td>
</tr>
</tbody>
</table>

Links on this page:

4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. ../../cFPMN/pmM.cfm
8. ../../../cFRL/I.cfm
9. ../../../cFMAUE/TextSearch.cfm
10. ../../../cFRES/res.cfm
11. ../../../cFPMa/pma.cfm
12. ../../../cFCOD/classification.cfm
13. ../../../cFSt/Standards/search.cfm
14. ../../../cFCFR/CFR5earch.cfm
15. ../../../cFCORD/RH/classification.cfm
16. ../../../cFCAsm/Assembler.cfm
17. ../../../cMedusa/searchReportText.cfm
18. ../../../cFClia/ScSearch.cfm
19. ../../../cFTPLC/TPLC.cfm

BREG Sterile Polar Pads

Date Posted: February 12, 2013
Recall Number: Z-0804-2013
Model #: 02510, 02901, 02330, 02350, 02490, 02356, 02498, 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 Response Form by mail, fax or mail, and contact Breg for a Return Authorization to 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

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9. ./cfMAUDE/TextSearch.cfm
10. ./cfRES/res.cfm
11. ./cfPMAD/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/searchReport2Text.cfm
18. ./cfClinSearch.cfm
19. ./cfTPLC/tplc.cfm