



رقم المحفوظات: ٣١/٢٥  
رقم الصادر: ١٣/١/١٤٤٥٦  
بيروت، في: ٢٦ نيسان ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

**الموضوع:** إشعار بمتابعة جهاز طبي

Pads, Circulating-Fluid, Sterile Polar Pads Contained in Cold  
Therapy Combination Units

**الجهاز المعنى 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:**

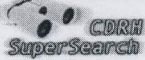
- التوصية الصادرة عن الشركة المصنعة
- **يبلغ:**
- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة  
د. وليد عمّار



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**Medical & Radiation Emitting Device Recalls**

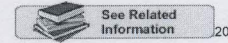


510(k)<sup>7</sup> | [Registration & Listing](#)<sup>8</sup> | [Adverse Events](#)<sup>9</sup> | [Recalls](#)<sup>10</sup> | [PMA](#)<sup>11</sup> | [Classification](#)<sup>12</sup> | [Standards](#)<sup>13</sup> | [CFR Title 21](#)<sup>14</sup> | [Radiation-Emitting Products](#)<sup>15</sup> | [X-Ray Assembler](#)<sup>16</sup> | [Medsun Reports](#)<sup>17</sup> | [CLIA](#)<sup>18</sup> | [TPLC](#)<sup>19</sup>

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**Class 2 Recall  
BREG Cold Therapy Combination  
Units**



<b>Date Posted</b>	February 12, 2013
<b>Recall Number</b>	Z-0803-2013
<b>Product</b>	BREG Cold Therapy Combination Units containing Sterile Polar Pads. 02356 Rev M, PAD M/U XL STER, Mfg.Date: 112012. Model #: 10903, 10703, 09101, 09111, 09131, 09731, 09611, 09621, and 09631. Local anesthetic effect.
<b>Code Information</b>	Affected product will be identified by date of manufacture from January 2010 through October 2012.
<b>Recalling Firm/ Manufacturer</b>	Breg Inc 2885 Loker Ave E Carlsbad, California 92010-6626
<b>Consumer Instructions</b>	Contact the recalling firm for information
<b>For Additional Information Contact</b>	Carol Emerson 800-321-0607
<b>Reason for Recall</b>	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.
<b>Action</b>	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.
<b>Quantity in Commerce</b>	44,883 units
<b>Distribution</b>	Worldwide Distribution-USA (nationwide) and the countries of Australia, Singapore, Chile, Latvia.

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6. </scripts/cdrh/devicesatfda/index.cfm>
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**Medical & Radiation Emitting Device Recalls**

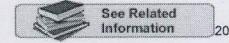


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[CFR Title 21](#)<sup>14</sup> [Radiation-Emitting Products](#)<sup>15</sup> [X-Ray Assembler](#)<sup>16</sup> [Medsun Reports](#)<sup>17</sup> [CLIA](#)<sup>18</sup> [TPLC](#)<sup>19</sup>

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**Class 2 Recall  
BREG Sterile Polar Pads**



<b>Date Posted</b>	February 12, 2013
<b>Recall Number</b>	Z-0804-2013
<b>Product</b>	BREG Sterile Polar Pads; 02356 Rev M, PAD M/U XL STER, Mfg.Date: 112012. Model #: 02510, 09901, 02330, 02350, 02490, 02356, 02496, 02410. Local anesthetic effect.
<b>Code Information</b>	Affected product will be identified by date of manufacture from January 2010 through October 2012
<b>Recalling Firm/ Manufacturer</b>	Breg Inc 2885 Loker Ave E Carlsbad, California 92010-6626
<b>Consumer Instructions</b>	Contact the recalling firm for information
<b>For Additional Information Contact</b>	Carol Emerson 800-321-0607
<b>Reason for Recall</b>	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.
<b>Action</b>	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.
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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%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%20)