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Le Directeur Général



الجمهورية اللبنانية وزارة الصحة العامة

المدير العام

رقم المحفوظات: ٥> مه المحلور ... ما ما المحلور ... ما ما المحلور ... ما ما المحلور ... ما ما المحلوب المحلوب

جانب نقيب الاطباء في لبنان/بيروت

الموضوع: إشعار بمتابعة جهاز طبي مغروس Thera Pearl 3-in-1 Breast Therapy

الجهاز المعني بالمتابعة:

- Thera Pearl 3-in-1 Breast Therapy
- Trade Mark: Lansinoh Laboratories
- Local Representative:

بناء على التقرير الصادر عن وكالة ال FDA

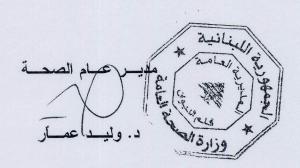
الذي يحذر فيه من استعمال الصنف المذكور أعلاه نظراً لوجود خلل في طريقة عمله ، نرجو منكم متابعة هذا الموضوع مع الاطباء الاختصاصيين والعمل بموجب التوصية الصادرة.

مرفق ربطاً:

- التقرير الصادر عن وكالة ال FDA

يبلغ:

- دائرة البرامج والمشاريع
 - المستشفيات الحكومية
 - المحفوظات



U.S. Food & Drug Administration

Medida & Radiation Emitting Device Recalls

. 1

FDA Home³ Medical Devices⁴ Databases⁵



 $510(k)^7 | Registration \& Listing^8 | Adverse \ Events^6 | Recalls^{10} | PMA^{11} | Classification^{12} | Standards^{13} \\ CFR \ Title \ 21^{14} | Radiation-Emitting \ Products^{15} | X-Ray \ Assembler^{16} | Medsun \ Reports^{17} | CLIA^{18} | TPLC^{19} | Registration^{19} | Cline | Reports^{19} | Registration^{19} | Reg$

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Class 2 Recall THERA PEARL 3-in-1 BREAST THERAPY

See Related Information 20

Date Posted

February 04, 2013

Recall Number

Z-0784-2013

Product

THERA PEARL 3-in-1 BREAST THERAPY, 2 hot and cold packs in plastic box. The Thera Pearl 3-in-1 Breast Therapy is a reusable therapeutic hot and cold pack for use with pain, swelling, engorgement, plugged ducts or mastitis associated with breast feeding or to help encourage let-down while using a breast pump.

Code Information

Lot Numbers 100/12/01, 116/12/01, 108/12/01, 109/12/01, 149/12/01

Recalling Firm/ Manufacturer

Lansinoh Laboratories Inc 333 N Fairfax St Ste 400 Alexandria, Virginia 22314-2632

For Additional Information Contact

Richard Thome 703-299-6477

Reason for Recall

The Spanish translation on the Instructions for Use (IFU) insert and product package for hot and cold packs has incorrect heating instructions which would cause product to over heat.

Action

Lansinoh Laboratories, Inc. sent an Urgent Product Recall letter dated August 14, 2012, to all affected customer. The letter identified the product, the problem, and the action to be taken by the customer. Customers were instructed to stop distributing and quarantine the affected product. Customers were informed that a credit would be issued for the affected product and they were asked to mail the postage paid Business Reply Card even if they do not have the affected product. If necessary call 1-877-366-1182 to arrange pickup. For questions customers were instructed to call the Customer Service Center at 1-800-292-4794. For questions regarding this recall call 703-

299-6477

Quantity in Commerce

51,472 units

Distribution

Nationwide Distribution, including the states of TX, CA, NJ, NY, SD, RI, WV, IL PA, NC and MN.

Links on this page:

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