



رقم المحفوظات: ٤٥ / ٤١
رقم الصادر: ١٤٥٢٢٦ / ١٤
بيروت، في: ٣٠ تموز ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس

Implants, breast, silicone gel. Siltex Round ultra high profile gel breast implant/ Siltex UHP CI

الجهاز المعنى بالمتابعة:

- Implants, breast, silicone gel. Siltex Round ultra high profile gel breast implant/ Siltex UHP CI
- Trade Mark: Mentor Medical Systems
- Local Representative:

بناء على التقارير الصادرة عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA

والتوصية الصادرة عن الشركة المصنعة والتي تشير الى وجود خلل في تاريخ انتهاء الصلاحية، 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





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To:
Materials Managers

May 10, 2013

**URGENT FIELD SAFETY NOTICE
(Field Alert)
MENTOR™ Breast Implants**

1 Lot – see Attachment 1

The purpose of this communication is to inform you that Mentor is conducting a voluntary field safety notice (Field Alert) of one (1) lot of MENTOR® Breast Implants.

Overview:	The company has identified an issue where one lot of these products was inadvertently shipped out beyond its expiration date because of a scanning error in the company's inventory and distribution system.
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Details on Affected Devices, to assist in identification of the specific lots involved:	<p>This letter applies to:</p> <ul style="list-style-type: none"> • Only the one (1) lot listed on Attachment 1 <p>This letter does NOT apply to:</p> <ul style="list-style-type: none"> • Any other MENTOR products or lots not listed on Attachment 1 • Any PERTHESE™ products <p>Attachment 2 provides guidance on how to identify impacted products.</p>
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Actions requested on your part:	<ul style="list-style-type: none"> • Read the "Description of the problem" section below. • Immediately identify and quarantine all unused product listed below in a manner that ensures the affected product will not be used. • Review, complete, sign and return the enclosed Field Action Reply Form (attachment 3) in accordance with the directions on the form within 5 business days of receipt of this notification. • Return any affected product per the attached instruction, or contact your local sales representative to facilitate return of the affected product within 30 business days. Credit or replacement will be provided based on product availability. • Forward this notice to anyone in your facility that needs to be informed. • If any product listed below has been forwarded to another facility, contact that facility to arrange return. • Maintain awareness of this notice until all product listed below has been returned to Mentor. • Maintain a copy of this notice with the affected product.
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Description of the problem:	<p>The company has identified an issue where one lot of these products was inadvertently shipped out beyond its expiration date because of a scanning error in the company's inventory and distribution system.</p> <p>The lot listed in Attachment 1 may contain a secondary inventory label with an incorrect expiry date (different from the product label).</p> <p>To date, no complaints have been reported that are connected to this issue.</p> <p>In keeping with our commitment to provide customers with quality products, Mentor has voluntarily decided to remove the product. Mentor has already implemented corrective actions to ensure that this issue does not reoccur.</p>
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Why you are being contacted:	You are receiving this letter because our records indicate that you have received the affected lot.
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Available Assistance:	In addition to your local sales representative, you may contact the local Mentor sales offices to answer any questions you may have.
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Additional Information:	<p>The applicable regulatory agencies are being notified. Mentor is voluntarily taking this action.</p> <p>We apologize for any inconvenience this communication may cause. We know that you place high value in our products and we appreciate your cooperation in this matter. Mentor is committed to maintaining your confidence in the safety and quality of the products that Mentor supplies.</p>
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Respectfully yours,

Barbara Heitzmann, Plant QA Manager
Mentor Medical Systems BV

Attachment 1 – List of Impacted Product Codes and Lots

MENTOR Breast Implants

Sales Code	Lot Number	Expiry Date
3545160	5741158	May 2012