



رقم المحفوظات: ٣٧١٢٥
رقم الصادر: ١٣/١/٢٠١٢
بيروت، في: ١٥ شباط ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس

Implants, Multiple - Breast Implants, Infusion Sets

الجهاز المعنى بالمتابعة:

- Implants, Multiple - Breast Implants, Infusion Sets
- Trade Mark: Mentor
- 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 عدم ذكر تاريخ انتهاء الصلاحية على

الصنف المذكور أعلاه، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

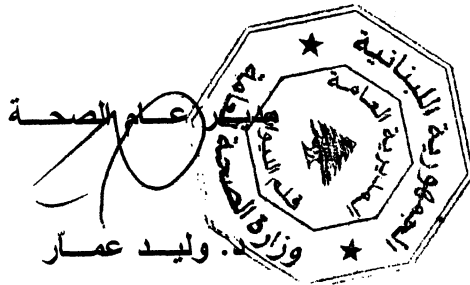
- التوصية الصادرة عن الشركة المصنعة

يبلغ:

دائرة البرامج والمشاريع

- المستشفيات الحكومية

- المحفوظات





To:
Materials Managers

28 December 2012

**URGENT FIELD SAFETY NOTICE
(Removal)
MENTOR® Breast Implants, Winged Infusion Sets, and PSI-TEC Tubing**

Multiple Lots – see Attachment 1

The purpose of this communication is to inform you that Mentor is conducting a voluntary field safety notice (removal) of specific lots of MENTOR® Breast Implants, Winged Infusion Sets (used with MENTOR Smooth Tissue Expanders) and PSI-TEC Tubing (used with MENTOR Body Contouring devices).

Overview:	The company has identified an issue where some lots of these products were inadvertently shipped out beyond their expiration date because of a scanning error in the company's inventory and distribution system.
Details on Affected Devices, to assist in identification of the specific lots involved:	This letter applies to: <ul style="list-style-type: none">• Only the 23 lots listed on Attachment 1 This letter does NOT apply to: <ul style="list-style-type: none">• Any other MENTOR products or lots not listed on Attachment 1• Any PERTHESE™ products Attachment 2 provides guidance on how to identify impacted products.
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 Affiliate Survey Form 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.

	<ul style="list-style-type: none"> • 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 some lots of these products were inadvertently shipped out beyond their expiration date because of a scanning error in the company's inventory and distribution system.</p> <p>Some of the lots listed on 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 one or more of the affected lots.
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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,

Miguel Ávila, Worldwide Director of Quality and Regulatory Compliance
Mentor Worldwide LLC

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Attachment 1 – List of Impacted Product Codes and Lots

MENTOR Breast Implants

Sales Code	Lot Number	Expiry Date
3144380	5767786	Oct-2011
3144480	5768522	Sep-2011
3244225	5704200	Oct-2011
3245600	5733031	Mar-2012
3341509	5706625	Dec-2011
3505350BC	5778603	Nov-2012
3541259	5730919-011	Mar-2011
3541259	5730919	Mar-2011
3541515	5775474	Oct-2011
3542251	5739762	Apr-2012
3542509	5736734	Apr-2012
3543257	5710243	Nov-2011
3543507	5734394	Apr-2012
3544001	5664930-007	Mar-2011
3545135	5741173	May-2012
3545160	5741158	May-2012
3545160	5750107	May-2012
3545185	5741159	May-2012
3546211	5806217	Feb-2011
3546313	5866608	Nov-2012

Winged Infusion Sets, 21-Gauge

Sales Code	Lot Number	Expiry Date
200593001	4152421	May-2011
7B3050	61121388	May-2011

PSI-TEC Tubing, 12'

Sales Code	Lot Number	Expiry Date
PT5558	PT0610	Mar-2012

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Attachment 2 – How to Identify Impacted products

SAMPLE ONLY

