MENTOR

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To:
Materials Managers

May 26, 2014

URGENT FIELD SAFETY NOTICE
MENTOR® Gel Sizers

Multiple Lots – see Attachment 1
Reference PRE-14-004M

The purpose of this communication is to inform you that Mentor is conducting a voluntary field safety corrective action (i.e., a product recall) of multiple lots of MENTOR® Sizers.

Overview:	A complaint was received for a volume discrepancy between the pad print (500cc) and laser engraved marking and all other product labeling (550cc) on a MENTOR® Gel Sizer manufactured at Mentor Leiden. During the bounding investigation, a second lot was identified as having a style discrepancy between pad print (Moderate Profile, MP) and all other product labeling (Moderate Plus, M+).

Details on Affected Devices, to assist in identification of the specific lots involved:	This letter applies to: • Only the lots listed on Attachment 1 This letter does NOT apply to: • Any other MENTOR® products or lots not listed on Attachment 1 Attachment 2 provides guidance on how to identify impacted products.

Actions requested on your part:	• 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 who 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 products listed below have been

	returned to Mentor. • Maintain a copy of this notice with the affected product. • Monitor patients implanted with these products to your standard protocol.

Description of the problem:	A complaint was received for a volume discrepancy between the pad print (500cc) and laser engraved marking and all other product labeling (550cc) on a MENTOR® Gel Sizer manufactured at Mentor Leiden. During the bounding investigation, a second lot was identified as having a style discrepancy between pad print (Moderate Profile, MP) and all other product labeling (Moderate Plus, M+). Potential Customer/Patient Impact: Misjudging the size or style of an implant can result in asymmetric outcome which may need additional surgery to correct. In keeping with our commitment to provide customers with quality products, Mentor has voluntarily decided to recall the lots of impacted products that are on the field. The lots listed in Attachment 1 are involved in this Field Safety Corrective Action.

Why you are being contacted:	You are receiving this letter because our records indicate that you have received the affected product lot.

Available Assistance:	In addition to your local sales representative, you may contact the local Mentor sales offices to answer any questions you may have.

Additional Information:	The applicable regulatory agencies are being notified. Mentor is voluntarily taking this action. 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.

Respectfully yours,

[redacted]

[redacted], Plant QA Manager
Mentor Medical Systems BV

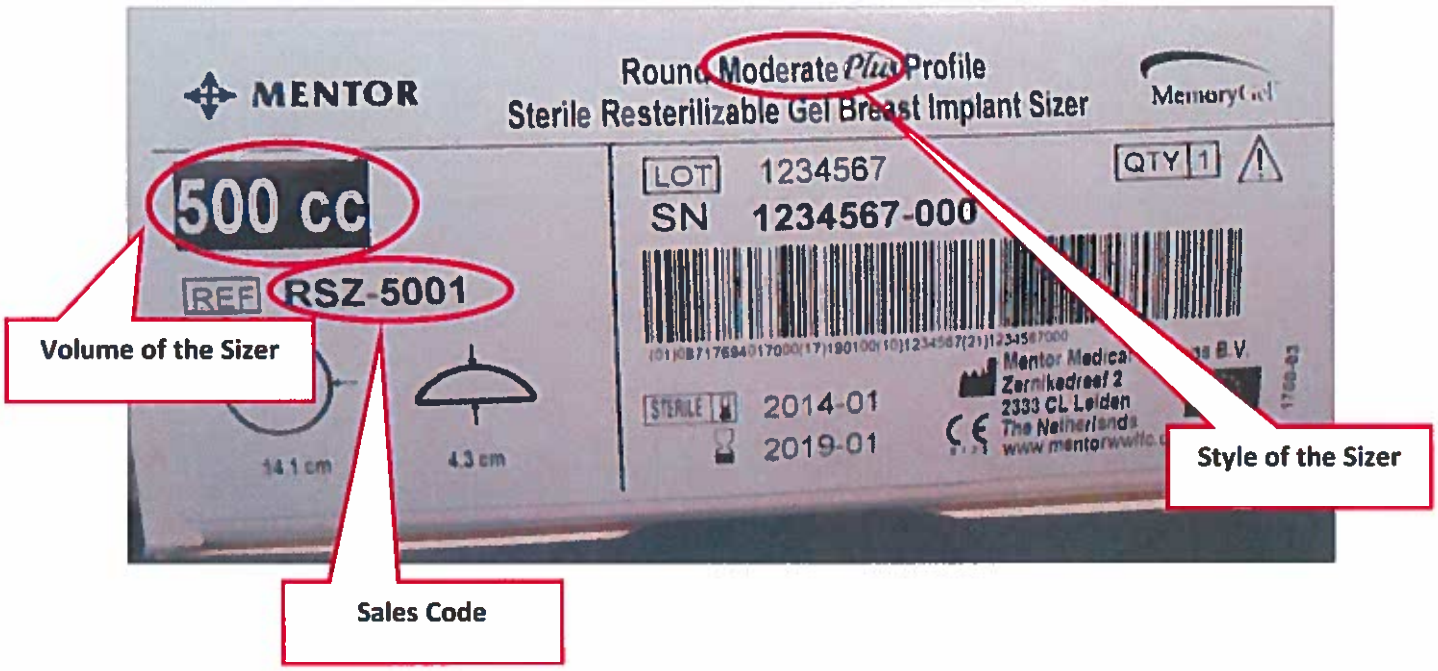
Attachment 1 – List of Impacted Product Codes and Lots

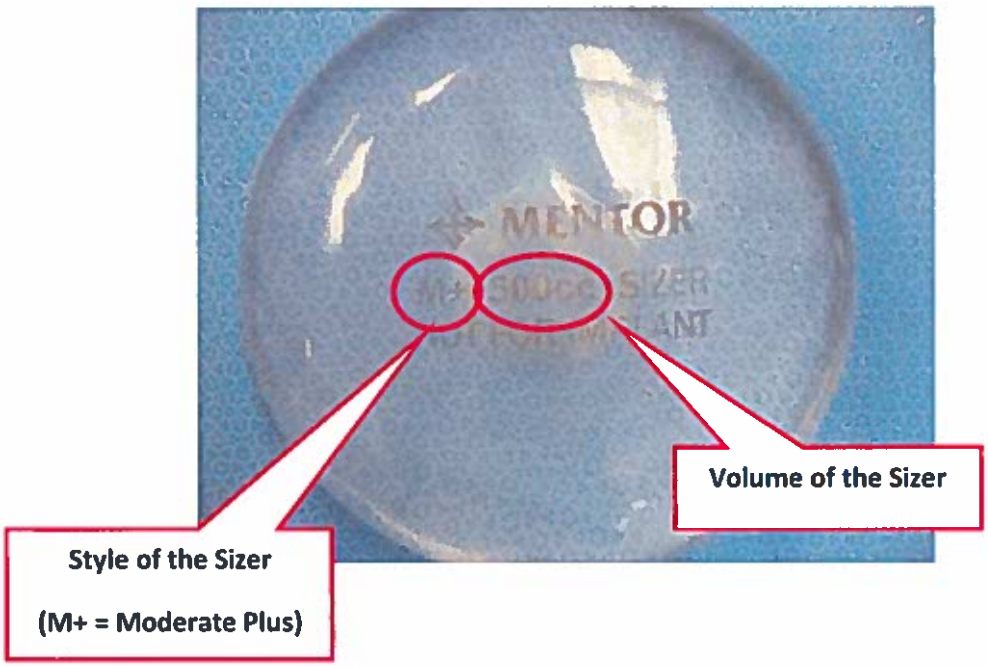
Mentor Sizers

Lot Number	Item / Product code	Manufacturing date	Expiry date
6680501	RSZ-5501	Feb/2013	Feb/2018
6749298	RSZ-2751	Aug/2013	Aug/2018

Attachment 2 – How to identify impacted products

SAMPLE ONLY





Attachment 3: Field Action Reply Form

To whom it may concern:

Your account has been identified as having received products that may potentially be affected by the recall detailed in the attached documents. PLEASE FORWARD THIS TO ALL RELEVANT DEPARTMENTS WITHIN YOUR HOSPITAL.

Please fill out the form below and return it signed by email to <Affiliate Contact> ...@its.jnj.com.

We appreciate your collaboration in returning to us this form within 3 days of receipt.

Our team will contact you to arrange collection of the unused products-please quarantine the concerned products in preparation for this. Please place a copy of the below form in the return box with the implants.

Thank you for your help in this urgent matter.

○ We have NO affected products for return
□ Implanted □ normal return

○ We have affected products for return, see details below:

Contact Name: _____

Hospital Name/department: _____

Phone number: _____

Email: _____

Fax: _____

Implant Collection Place: _____

Date/Signature: _____

Product Code	Lot Number	Product Description	Full Box Qty to Return	Eaches Qty to Return

Please send the completed form tor: <Affiliate Contact> ...@its.jnj.com