URGENT: FIELD SAFETY NOTICE

Product Mix of Siltex Round Ultra High Profile Gel Breast Implant Cohesive I 350cc (P/N 354-5350) and 240cc (P/N 354-5240)

April 16, 2019

Dear Valued Customer:

Mentor has identified a labelling error on two (2) lots of MENTOR® Siltex Round Ultra High Profile gel breast implant Cohesive I, 350cc (P/N 354-5350) and 240cc (P/N 354-5240), manufactured at our Mentor Medical Systems B.V., Leiden facility in The Netherlands.

The labelling (product part number, lot number, volume & dimensions) on product packaging does not match the label that is laser-engraved directly on the device. The labelling on the device (laser marked patch) accurately describes the device. The issue was discovered through customer complaints, and confirmed through inspection of product on hold at one of the Johnson & Johnson distribution centers. The products impacted in this notification are Siltex, round, Cohesive I 350 cc (P/N 354-5350) and 240cc (P/N 354-5240). Refer to Appendix I of this notification for images and details.

As a result of the labelling discrepancy, there is a risk for prolonged surgical time or potentially, the need to reschedule procedures while the desired size implant is retrieved. In the unlikely case the breast implant is used in a patient, there is a risk for cosmetic outcome dissatisfaction and an increased potential for revision surgery.

This action has been notified to the appropriate Regulatory Agencies.

Product Description

MENTOR® Gel Breast Implants are silicone elastomer mammary devices. Mentor offers two types of shell surfaces: SILTEX™ and smooth surfaced. The SILTEX™ shell is textured to provide a disruptive surface for collagen interface. Gel Breast Implants have a variety of cohesivity levels of the filling material. The devices are available in a round shape with different projections and in several contour shapes with different heights and projections. The volume indicated on the product label is the fill volume of the gel.

What Actions are required

- Evaluate your current inventory of Siltex Round Ultra High Profile gel breast implant Cohesive I 350cc (P/N 354-5350) and 240cc (P/N 354-5240). If you have inventory lots listed below, ***DO NOT USE***. **Remove** and **Return** all affected products immediately.

1) Part Number: 354-5350
   Lot Number: ***7464368***
   Volume and Dimension: 350cc

2) Part Number: 354-5240
   Lot Number: ***7464364***
   Volume and Dimension: 240cc

Johnson & Johnson Medical Singapore
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Business Reg No. 52836279L Company Reg No. 197402104W

- To return the affected product, complete BOTH the customer acknowledgment and product return sections of the attached Business Reply Form (BRF). Attach the BRF with your product return, and return the affected products along with the BRF to your Mentor Sales Representative. Contact your Mentor Sales Representative if further assistance is needed to complete the BRF or if you have questions on product return.

- Complete the BRF within 3 business days even if you no longer have inventory of the above affected products.

- If you have already successfully implanted the device, update patient records to reflect the correct product part number and lot number for traceability. We have verified that the affected products listed in this notification were manufactured and sterilized according to all design specifications. Therefore, there is no additional risk to patient safety other than what is mentioned above.

- Ensure that anyone in your facility who needs to be aware of this notification reads this letter carefully.

- Maintain a copy of this communication where the inventory and usage of the Siltex Round Ultra High Profile gel breast implant Cohesive I 350cc (P/N 354-5350) and 240cc (P/N 354-5240) products are located and until all affected products are returned.

Attachments:
Attachment 1: Product Identification Tool
Attachment 2: Business Reply Form

Yours sincerely,

Lee Ching Hwee
Manager, Regulatory Affairs

cc: Chairman Medical Board
Relevant Head of Departments

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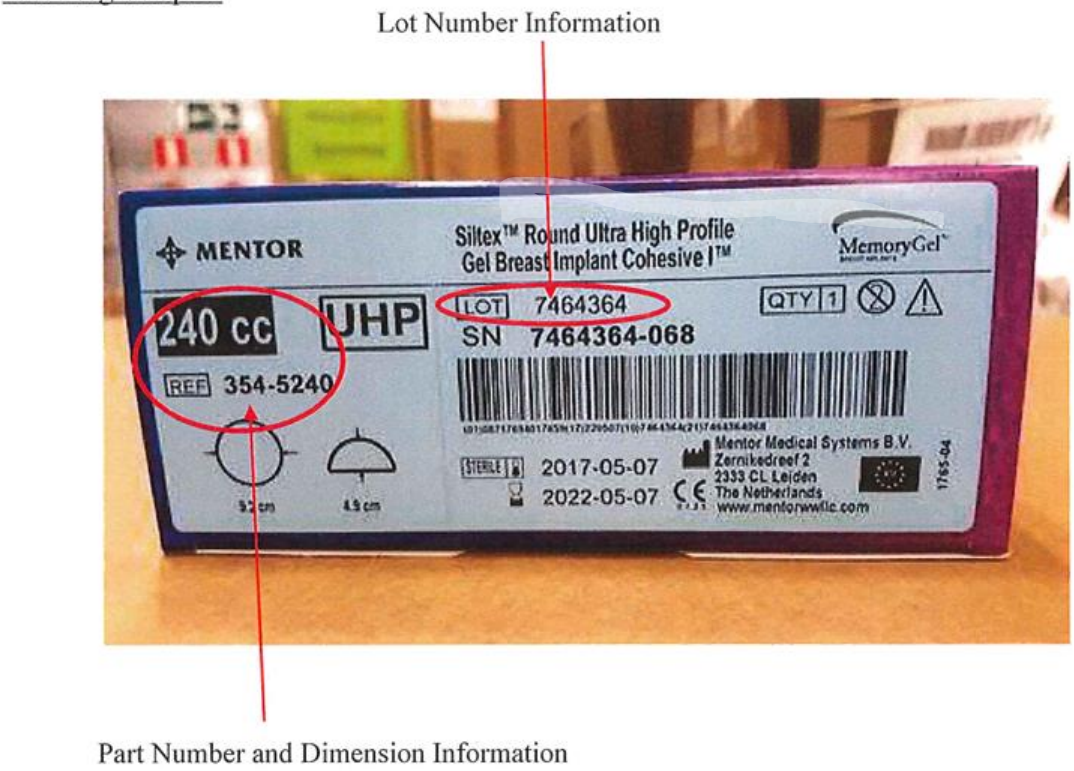
ATTACHMENT 1: Product Identification Tool for Siltex Round Ultra High Profile Gel Breast Implant Cohesive I

Appendix I

Labeling samples



ATTACHMENT 2: Business Reply Form (BRF)

Your timely response to this customer notification is requested. Please complete this form and hand it to your Mentor Sales Representative **within 3 business days, even if you do not have product subject to this correction.**

Please complete the following information:

We hereby acknowledge receipt of this medical device correction letter from Ethicon regarding Siltex Round Ultra High Profile Gel Breast Implant Cohesive I 350cc (P/N 354-5350) and 240cc (P/N 354-5240). We have distributed this information to all staff within our facility that use the affected products and will maintain a copy of this notice with the identified product(s).

Product Receipts – please check one:

☐ We have NO impacted Siltex Round Ultra High Profile Gel Breast Implant Cohesive I 350cc (P/N 354-5350) and 240cc (P/N 354-5240) subject to this correction (notification), however we will maintain a copy of this notice within our facility.

☐ We have impacted Siltex Round Ultra High Profile Gel Breast Implant Cohesive I 350cc (P/N 354-5350) and 240cc (P/N 354-5240) subject to this correction (notification) and below are the quantities noted. We will return the product as noted above and submit a product complaint.

PRODUCT NAME	PRODUCT CODE	PRODUCT LOT	Quantity Returning (Boxes)
Siltex® Round Ultra High Profile Gel Breast Implant Cohesive I™	**354-5350**	**7464368**	
Siltex® Round Ultra High Profile Gel Breast Implant Cohesive I™	**354-5240**	**7464364**	

Print Name of Person Completing Business Reply Form:	Sign & Date:
Customer Account Details (Name and Address)	

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