

Date

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)

Dear Valued Customers,

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 240 cc (P/N 354-5240). Refer to Appendix I of this notification for images and details.

As a result of the labeling 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: <u>7464368</u> Volume & Dimension: 350cc	2) Part Number: 354-5240 Lot number: <u>7464364</u> Volume & Dimension: 240cc
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- To return the affected product, complete BOTH the customer acknowledgement and product return sections of the attached Business Reply Form (BRF). Use the enclosed prepaid shipping label, attach the BRF with your product return, and return the affected products along with the BRF to [\[enter the Affiliate local facility address or location\]](#). Contact your local 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.
- Upon receipt of the completed BRF and your product return, [\[enter Affiliate Name\]](#) will provide credit/replacement product for noted quantity of the affected and returned products on the BRF. Incomplete BRFs cannot be processed.



- 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.

Why You Are Being Contacted

You are receiving this letter because our records indicate you have received MENTOR® Siltex Round Ultra High Profile gel breast implant Cohesive I 350cc (P/N 354-5350) and 240cc (P/N 354-5240) or may have used it.

If you have additional questions about this action, please contact your Sales Representative or call [\[enter Affiliate Name and local contact details\]](#).

We apologize for any inconvenience this will cause you, but rest assured it is our utmost intent to make this process as easy for you as possible.

Sincerely,

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Appendix I

Labeling samples

Lot Number Information



Part Number and Dimension Information