

URGENT: FIELD SAFETY NOTICE
MENTOR® Smooth Round Saline DV Breast Implants
 (Lot Numbers with Expiration Dates from January 01, 2025 to September 30, 2025)
 – Voluntary Product Recall (Removal) –

October 11, 2021

Dear Valued Customer,

**PLEASE DISTRIBUTE THIS INFORMATION TO ALL STAFF WITHIN YOUR FACILITY WHO USE
 MENTOR® Smooth Round Saline DV Breast Implants.**

Mentor has initiated a voluntary Medical Device Recall (removal) regarding specific lots of MENTOR® Smooth Round Saline Diaphragm Valve (DV) Breast Implants which have expiration dates from January 01, 2025 to September 30, 2025. A small number of devices, due to an issue involving specific equipment used during manufacturing, may have a potentially weakened area on the base patch portion of the shell where the Mentor logo and identification numbers are located. This may result in premature deflation for which replacement surgery may be needed. As of October 11, 2021, a total of five (5) complaints have been reported related to leakage related to weakened area on the base patch portion of the shell, occurring intraoperatively or postoperatively.

Our records show that your facility received one or more of the subject product(s). Please carefully review this notice for the steps that you should take to respond to this medical device recall (removal).

Product Identification:

Product subject to the recall (removal) in your inventory can be identified by Expiration Date. All unused MENTOR Smooth Round Saline DV Breast Implants with an expiration date between January 01, 2025 and September 30, 2025 are subject to this recall (removal) and are required to be returned. The expiration date can be determined by using the Impacted Product List in **Attachment 1** and the Product Identification Tool in **Attachment 2**.

Product Description	Product Code	Unique Device Identifier/GTIN	Expiration Date Range
MENTOR Smooth Round Saline DV Breast Implant	See Attachment 1	See Attachment 1	January 01, 2025 - September 30, 2025

Potential Patient Impact:

Patients that have been implanted with product within the scope of this recall may be at increased risk for premature breast implant deflation. However, no prophylactic replacement surgery is recommended for these patients. It is not possible to determine if the implanted product within the scope of this recall is affected. Please continue to follow patients per your standard postoperative protocol, continue to monitor for implant deflation and, if deflation occurs, manage per your normal standard of care.

Any patients having the identified breast implants that subsequently experience deflation should be reported to the Mentor complaints department, and breast implants should be returned for analysis.

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ACTION REQUIRED FOR CUSTOMERS:

1. Examine your inventory immediately to determine if you have product subject to this recall on hand and quarantine such product(s).
2. Remove the product subject to this recall and communicate the issue to relevant operating room or materials management personnel, or anyone else in your facility who needs to be informed.
3. If any product subject to this recall has been forwarded to another facility, contact that facility to arrange return. Please consider including a copy of this recall letter when communicating.
4. Complete the Business Reply Form (BRF) (Attachment 3) confirming receipt of this notice and return to [Insert Affiliate Information] within three (3) business days. Please return the BRF even if you do not have product subject to this recall.
5. Follow instructions in the letter and immediately return any inventory of MENTOR Smooth Round Saline DV Breast Implants with expiration dates ranging from January 01, 2025 to September 30, 2025 subject to this recall to [Insert Affiliate Information].
6. Keep this notice visibly posted for awareness until all product subject to this recall has been returned to [Insert Affiliate Information]. While processing your returns, please maintain a copy of this notice with the product subject to this recall and keep a copy for your records.
7. Customers are required to return unused impacted MENTOR Smooth Round Saline DV Breast Implants with expiration dates ranging from January 01, 2025 to September 30, 2025 subject to this recall that are in their inventory immediately. To receive credit reimbursement, customers must return product subject to this recall. Any non-affected product and any product returned after the date specified will not receive replacement.

If you have additional questions regarding this medical device recall (removal), please contact [INSERT AFFILIATE NAME] at [INSERT PHONE NUMBER].

As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported to your Sales Representative or your National Health Authority. If you have any further questions related to this notice or if you need any additional communications, please contact your local Sales Representative.

Sincerely,

Debra Smith
Quality Head

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Attachments:

Attachment 1: List of Impacted Product Codes

Attachment 2: Product Identification Tool

Attachment 2: Business Reply Form

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ATTACHMENT 1: List of Impacted Product Codes

Product Description	Product Code	Unique Device Identifier / GTIN	Expiration Date Range
MENTOR Smooth Round Saline DV Implant	350-1610	00081317001171	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-1615	00081317001188	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-1620	00081317001195	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-1625	00081317001201	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-1630	00081317001218	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-1635	00081317001225	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-1640	00081317001232	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-1645	00081317001249	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-1650	00081317001256	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-1655	00081317001263	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-1660	00081317001270	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-1670	00081317001287	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-1680	00081317001294	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-1685	00081317001300	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-1690	00081317001317	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-1695	00081317001324	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-1697	00081317001331	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-2175	00081317001348	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-2200	00081317001355	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-2225	00081317001362	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-2250	00081317001379	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-2275	00081317001386	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-2300	00081317001393	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-2325	00081317001409	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-2350	00081317001416	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-2375	00081317001423	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-2400	00081317001430	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-2425	00081317001447	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-2450	00081317001454	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-2475	00081317001461	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-2500	00081317001478	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-2550	00081317001485	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-2600	00081317001492	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-2650	00081317001508	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-2700	00081317001515	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-2750	00081317001522	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-2800	00081317001539	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-3170	00081317001560	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-3190	00081317001577	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-3210	00081317001584	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-3230	00081317001591	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-3250	00081317001607	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-3270	00081317001614	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-3290	00081317001621	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-3310	00081317001638	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-3330	00081317001645	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-3380	00081317001652	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-3420	00081317001669	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-3460	00081317001676	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-3500	00081317001683	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-3560	00081317001690	January 01, 2025 - September 30, 2025
MENTOR Smooth Round Saline DV Implant	350-3630	00081317001706	January 01, 2025 - September 30, 2025

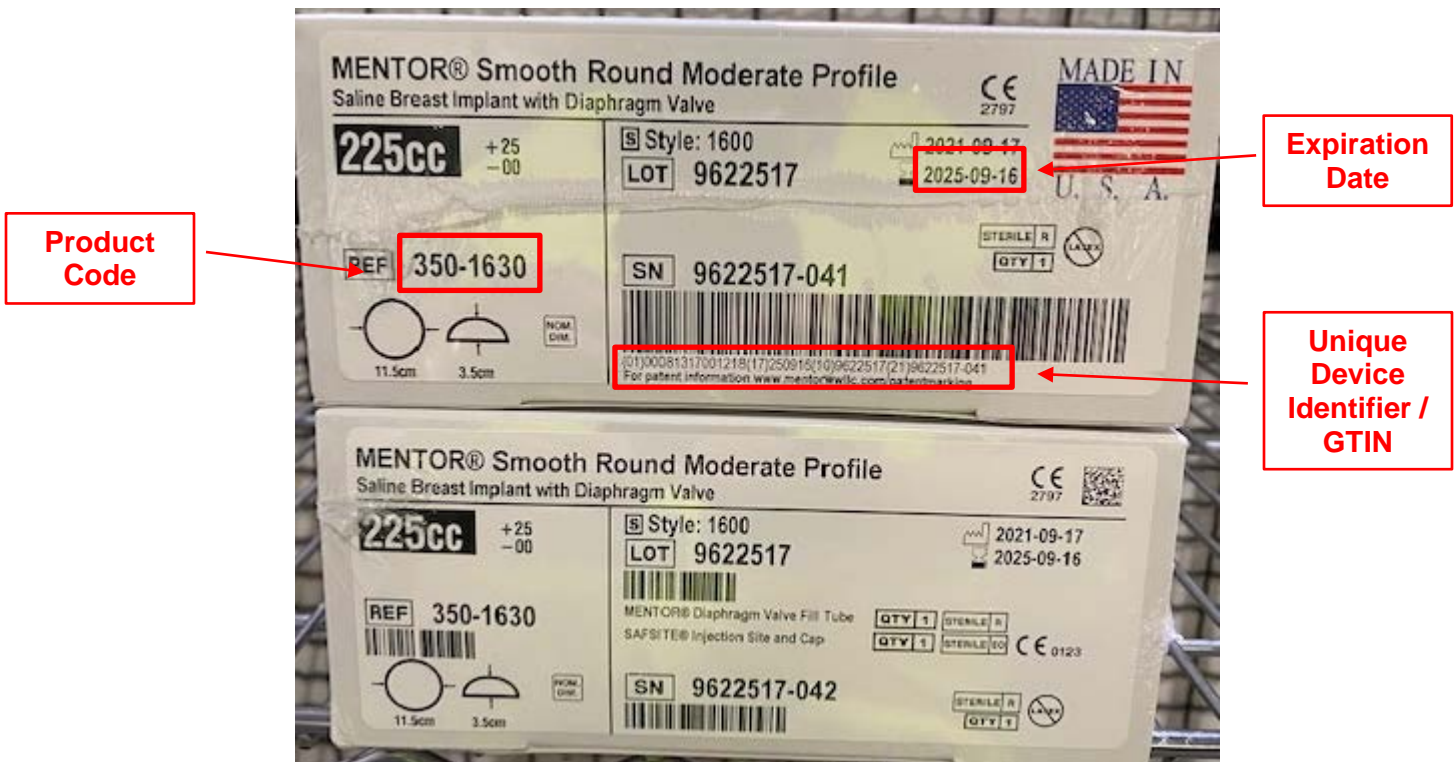
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ATTACHMENT 2: Product Identification Tool

This tool will help customers identify the product subject to this recall (removal). This document applies to the sales unit carton and foil packaging for MENTOR Smooth Round Saline DV Breast Implants with expiration dates ranging from January 01, 2025 to September 30, 2025.



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ATTACHMENT 3: Business Reply Form (BRF)

Your timely response to this customer notification is requested. Please complete this form and fax or email it to **[INSERT AFFILIATE NAME]** at **[INSERT FAX NUMBER]** or **[INSERT AFFILIATE EMAIL ADDRESS]** within **3 business days, even if you do not have product subject to this recall to return.**

If you have product subject to this recall (removal) to return, please make a photocopy of your completed Business Reply Form and enclose with your return. Thank you for your cooperation.

[Account Name]
[Account Address]

Print Name of Person Completing Business Reply Form:	Telephone Number:
Account Number: (number used to order J&J product)	Date:
Replacement Product Shipping Address (If different from above) or reference PO for replacement shipment:	
Signed*:	
<small>*Your signature provides confirmation that you have received and understood this notification</small>	
Your comments are welcome.	

Product Inventory – please check one

- We have **NO** MENTOR Smooth Round Saline DV Breast Implants subject to this recall (removal).
- We have MENTOR Smooth Round Saline DV Breast Implants subject to this recall (removal) and are returning the following products:

PRODUCT NAME	PRODUCT CODE	PRODUCT LOT	GTIN / UDI Number	Quantity Returning (Units)