Johnson&Johnson MedTech

Ethicon

URGENT: FIELD SAFETY NOTICE

ETHILON™ Nylon Suture, PERMA-HAND™ Silk Suture,
PROLENE™ Polypropylene Suture, ETHIBOND EXCEL™ Polyester Suture
– Voluntary Product Recall (Removal) –

[Date]

Dear Operating Room Supervisors, Materials Management Personnel, and Chief of Surgery,

Records indicate that you have ordered or received product subject to this recall. Product subject to the recall in your inventory can be identified by product code and lot described in **Attachment 1**.

PLEASE DISTRIBUTE THIS INFORMATION TO ALL STAFF WITHIN YOUR FACILITY WHO USE ETHILON™, PERMA-HAND™, PROLENE™ AND ETHIBOND EXCEL™ SUTURES.

Purpose of this Letter

Ethicon has initiated a voluntary medical device recall (removal) of specific suture lots across the below product families:

ETHILON™ Nylon Suture

PERMA-HAND™ Silk Suture

PROLENE™ Polypropylene Suture

ETHIBOND EXCEL™ Polyester Suture

Reason for the Voluntary Removal

Ethicon identified a manufacturing issue on a specific machine that resulted in an open seal on the primary packaging of a small percentage of ETHILON™, PERMA-HAND™, PROLENE™ AND ETHIBOND EXCEL™ sutures manufactured between September 20, 2024 and October 14, 2024.

Risk to Health

Ethicon has not received any complaints or reports of injuries related to this issue.

The issue may be detectable to the user. If the defect is not detected, the breach in sterility could introduce pathogens to the patient and cause infection. This may necessitate medical interventions such as use of antibiotics and/or surgical intervention. The chance of systemic infection is very unlikely because of the small inoculum of bacteria that would likely be present and the use of prophylactic antibiotics prior to or after surgery. Therefore, the probability of harm to the patient is extremely rare.

The health risk is limited to those products with compromised packaging. Other products in the field with no seal issues are unaffected. Health care practitioners who have treated patients using these product lots should follow those patients post-operatively in the usual manner with no additional action required.

Ethicon has identified the root cause of the manufacturing issue that led to this recall and implemented controls to prevent recurrence.

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ACTION REQUIRED

1. Examine your inventory immediately to determine if you have product subject to this recall on hand and quarantine such product(s). If you have product subject to this recall, please maintain a copy of this notice with the quarantined product and keep a copy for your records.
2. Communicate the issue to relevant operating room or materials management personnel, or anyone else in your facility who needs to be informed. 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.
3. Complete the Business Reply Form (BRF) (Attachment 3) confirming receipt of this notice and fax or email to [Enter Affiliate Information] within three (3) business days. **Please return the BRF even if you do not have product subject to this recall**.
4. Customers are required to return unused sutures subject to this recall that are in inventory immediately. To receive credit reimbursement, customers must return product subject to this recall no later than **March 31, 2025** to [Enter Affiliate Information]. Any non-affected product and any product returned after the date specified will not receive credit reimbursement.
5. Keep this notice visibly posted for awareness until all product subject to this recall has been returned to [Enter Affiliate Information].

If you require any assistance with returning product, please contact [Enter Affiliate Information] at [Enter Affiliate Information].

Other Information

At Ethicon, our first priority is to our customers and their patients, and that includes the safe and effective use of our products. We recognize the recall of these products may be disruptive to your facility and we appreciate your assistance in this matter.

If you have additional questions regarding this voluntary product recall or require any assistance with returning product, please contact [Enter Affiliate Information].

As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported to your Sales Representative, directly to Ethicon, 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.

ATTACHMENTS:

Attachment 1: Impacted Product Information
Attachment 2: Product Identification Tool
Attachment 3: Business Reply Form (BRF)

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Attachment 1: Impacted Product Information

EFFECTIVE IMMEDIATELY – DO NOT USE OR DISTRIBUTE THE FOLLOWING PRODUCT LOTS. REFER TO ACTION REQUIRED FOR FURTHER INSTRUCTIONS.

PRODUCT CODE	PRODUCT LOT	PRODUCT CODE	PRODUCT LOT
1669H	103GR2	EH7491H	103D42
1669H	103J14	EH7585H	103DQR
623H	10386S	EH7797BH	103J2H
628H	1033PK	EH7808BH	103E7A
644H	103EXA	EH7827BH	103EX9
661H	103GR7	F2416H	103E7C
661H	103H5A	F3223BH	103EJH
6664H	103G1B	K833H	103K99
699G	102TMJ	K872H	103DBT
8706H	103E22	W723H	103G13
8706H	103EMJ	W8003T	103GT2
8833H	103HC4	X425H	103H4B
8935H	103HBP	X872H	103ELK
8963H	103E8Z		

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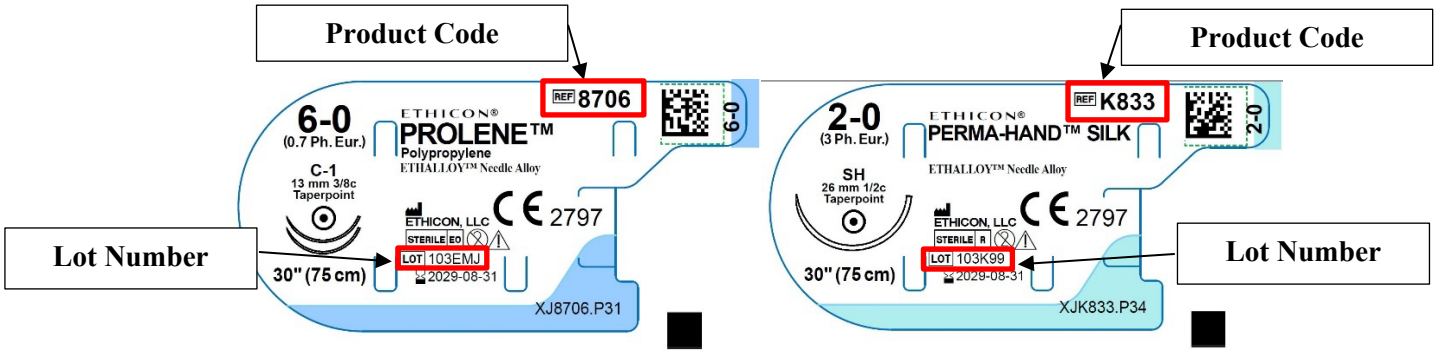
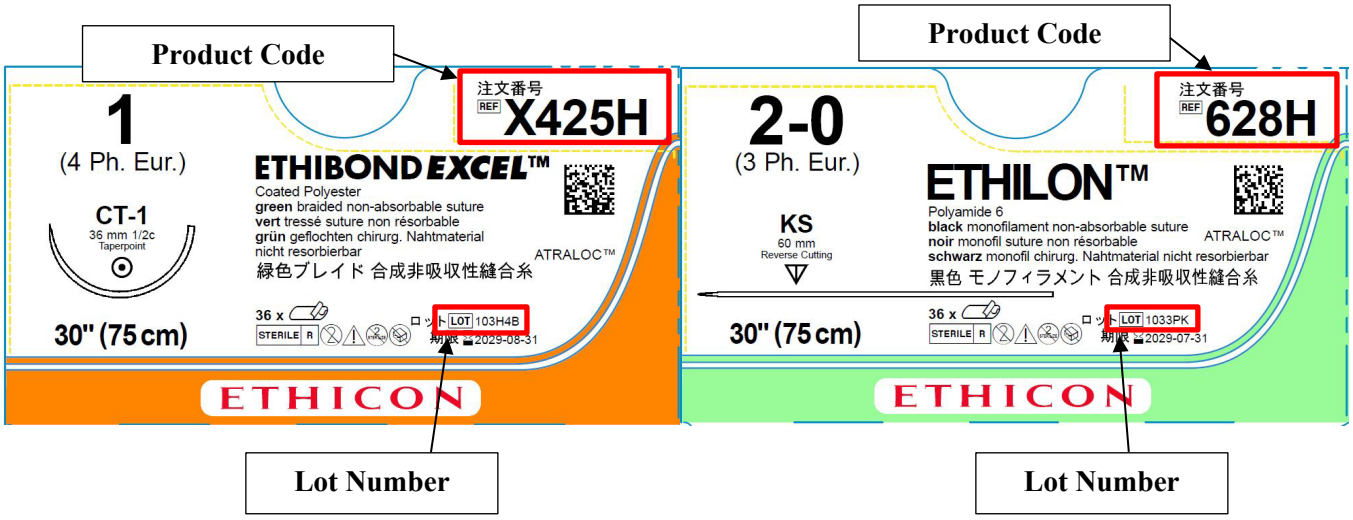
Attachment 2: Product Identification Tool

Please refer to the representative sample pictures below to identify the location of the subject product code and lots for impacted products by using the packaging labels.

Individual Unit



Box



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Attachment 3: Business Reply Form

Business Reply Form (BRF)

Your timely response to this recall notification is requested. Please complete this form and fax or email it to [Enter Affiliate Information] or e-mail the form to [Enter Affiliate Information] **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 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:
Email Address:	
Reference PO for credit, if needed.	
Signed*: **Your signature provides confirmation that you have received and understood this notification*	
Your comments are welcome.	

Product Inventory – *please check one*

☐ We have NO inventory of product subject to this recall (removal).
☐ We have product subject to this recall (removal) and are returning the following products:

PRODUCT CODE		PRODUCT LOTS		QUANTITY RETURNING (EACHES)