

URGENT: FIELD SAFETY NOTICE

Specific Lots of the following ETHICON suture products:
PDS™ II (polydioxanone) Suture, PDS™ Plus Antibacterial (polydioxanone) 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 **Figure 1**.

**PLEASE DISTRIBUTE THIS INFORMATION TO ALL STAFF WITHIN YOUR FACILITY WHO USE
PDS™ II, PDS™ PLUS, PROLENE™ AND ETHIBOND EXCEL™ SUTURES.**

Purpose of This Letter

Ethicon has initiated a voluntary medical device recall (removal) of the below suture codes and lots.

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

Figure 1

PRODUCT NAME	PRODUCT CODE	PRODUCT LOT		UDI
PDS™ II (polydioxanone) Suture	Z127H	104BQC		10705031060227
PDS™ Plus Antibacterial (polydioxanone) Suture	PDP127H	104M7E		10705031047907
PROLENE™ Polypropylene Suture	8706H	104E88	104E89	10705031019430
		1047TZ	104BQ0	
		104DA2	104JAR	
		104JPJ	104SES	
	8711H	104KHD	104SER	10705031019560
ETHIBOND EXCEL™ Polyester Suture	X843H	10489X		10705031058088

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Reason for the Voluntary Removal

Ethicon identified an issue with a raw material used to coat some surgical needles that may result in diminished performance and/or removal of some silicone needle coating during use. This issue impacts needles on specific lots of PDS II™, PDS Plus™, PROLENE™ AND ETHIBOND EXCEL™ sutures. (Refer to **Figure 1**)

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

Risk to Health

Ethicon has not received any complaints or reports of injuries related to this issue from the impacted product lots.

When the impacted product is used, the user may notice needles sticking to the needle holder, may or may not observe silicone residue adhering to the tissue surface, or feel an increase in needle penetration force. The possible silicone residue from the needle coating could trigger a local inflammatory response or delay the surgical procedure. For impacted sutures used in cardiovascular procedures, silicone residue from the needle coating could theoretically enter the blood stream and present an embolic risk. This is very unlikely due to the relatively small amount of needle coating and the fact that the needle is usually passed from the outside of a vessel to the inside, thereby preventing most of the residual silicone from being introduced into the blood stream.

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.

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 2) 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 **June 30, 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]**.

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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: Product Identification Tool

Attachment 2: Business Reply Form (BRF)

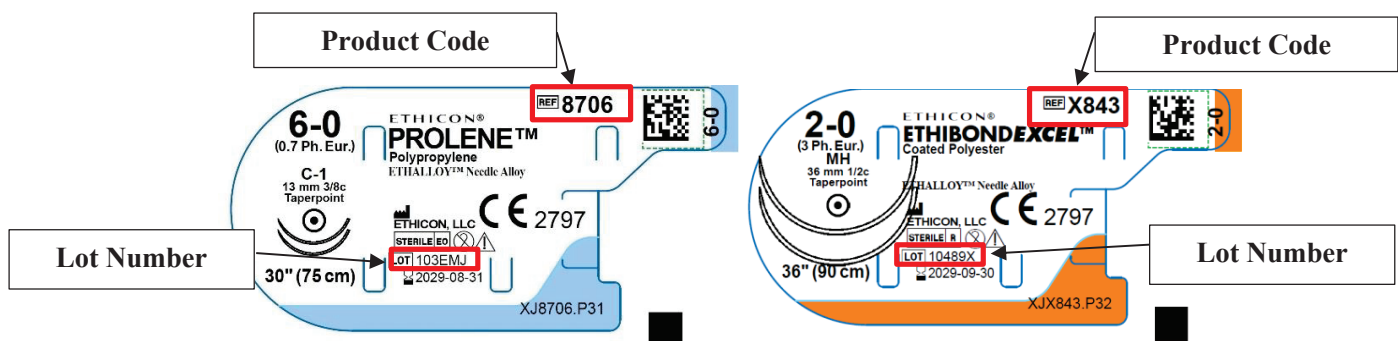
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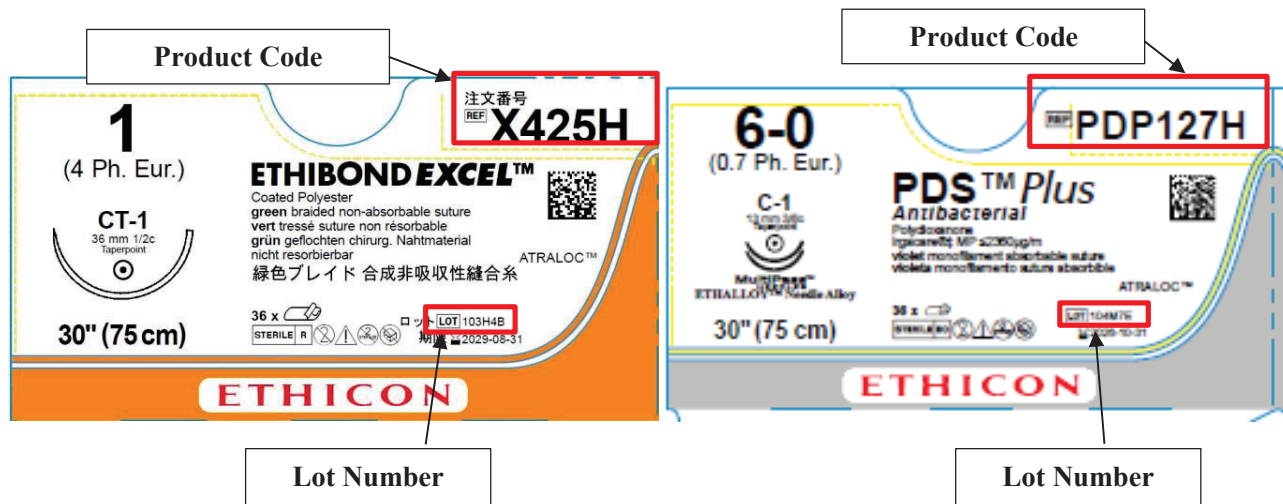
Attachment 1: Product Identification Tool

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 2: 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*:	
<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 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)		