ETHICON
Johnson & Johnson SURGICAL TECHNOLOGIES

URGENT: FIELD SAFETY NOTICE

PDS® Plus Antibacterial (polydioxanone) Suture
Product Code: PDP9625H, Lot: SCMAZH
– Voluntary Product Recall (Removal) –

28/03/2023

Dear Valued Customer,

Ethicon has initiated a voluntary medical device recall (removal) of one (1) lot of PDS® Plus Antibacterial (polydioxanone) Sutures, Product Code PDP9625H, Lot SCMAZH. Ethicon has received complaint reports of suture breakage during intra-operative use for Product Code PDP9625H, Lot SCMAZH, and a portion of returned complaint samples exhibited tensile values below the minimum specification.

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

PRODUCT NAME	PRODUCT CODE	PRODUCT LOT	EXP DATE	UNIQUE DEVICE IDENTIFICATION		DESCRIPTION / SIZE
				PACKAGING LEVEL & QTY	UDI-DI	
PDS® Plus Antibacterial (polydioxanone) Suture	PDP9625H	SCMAZH	February 28, 2024	Primary (Individual Unit) Qty = 1 each	(01)10705031124691	PDS PLUS CLR 27IN(70CM) USP3-0(M2) S/A PC-25 PRIME
				Other (Sales Unit Box) Qty = 36 eaches	(01)30705031124695	

Note: This medical device recall (removal) does NOT affect any other product codes or lots of PDS® Plus Antibacterial (polydioxanone) Suture.

Failure in suture tensile strength could potentially result in poor performance of the impacted product because the intended benefit of tissue approximation and/or ligation may not be achieved. In such an instance the potential harms would include bleeding/hemorrhage, treatment failure/wound dehiscence, surgery prolonged and surgery intervention. However, none of these potential harms have been reported to occur to date as a result of using Product Code PDP9625H, Lot SCMAZH.

To date, Ethicon has not received any reports of adverse events or injuries associated with the issue that led to this recall. Health care practitioners who have treated patients using this product should follow those patients post-operatively in the usual manner with no additional action required.

Ethicon has identified the specific lot impacted and is working to address the issue and prevent reoccurrence.

Records indicate that you have ordered or received product subject to this recall. **PLEASE DISTRIBUTE THIS INFORMATION TO ALL STAFF WITHIN YOUR FACILITY WHO USE PDS® PLUS ANTIBACTERIAL (POLYDIAXANONE) SUTURES.**

The earliest date of distribution for affected product was **August 12, 2022**.

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PDS® Plus Antibacterial (polydioxanone) Suture

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IDENTIFICATION OF PRODUCT SUBJECT TO THIS RECALL:

Product subject to the recall in your inventory can be identified by product code and lot described in above table. All unused PDS® Plus Antibacterial (polydioxanone) Suture products subject to this recall are required to be returned. Please utilize **Attachment 1** for assistance in identifying subject products.

ACTION REQUIRED:

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 2) confirming receipt of this notice and return to MDFieldActionsUKirl@its.jnj.com within three (3) business days. **Please return the BRF even if you do not have product subject to this recall**.
5. Keep this notice visibly posted for awareness until all product subject to this recall has been returned. 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.
6. Customers are required to return unused PDS® Plus Antibacterial (polydioxanone) Suture products subject to this recall that are in inventory immediately.
7. To return product subject to this recall, please complete the declaration below advising of your contact and collection details and our returns team will contact you to arrange collection.

If you require any assistance with returning product, please contact MDFieldActionsUKirl@its.jnj.com

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 this product may be disruptive to your facility and we apologize for any inconvenience this may cause.

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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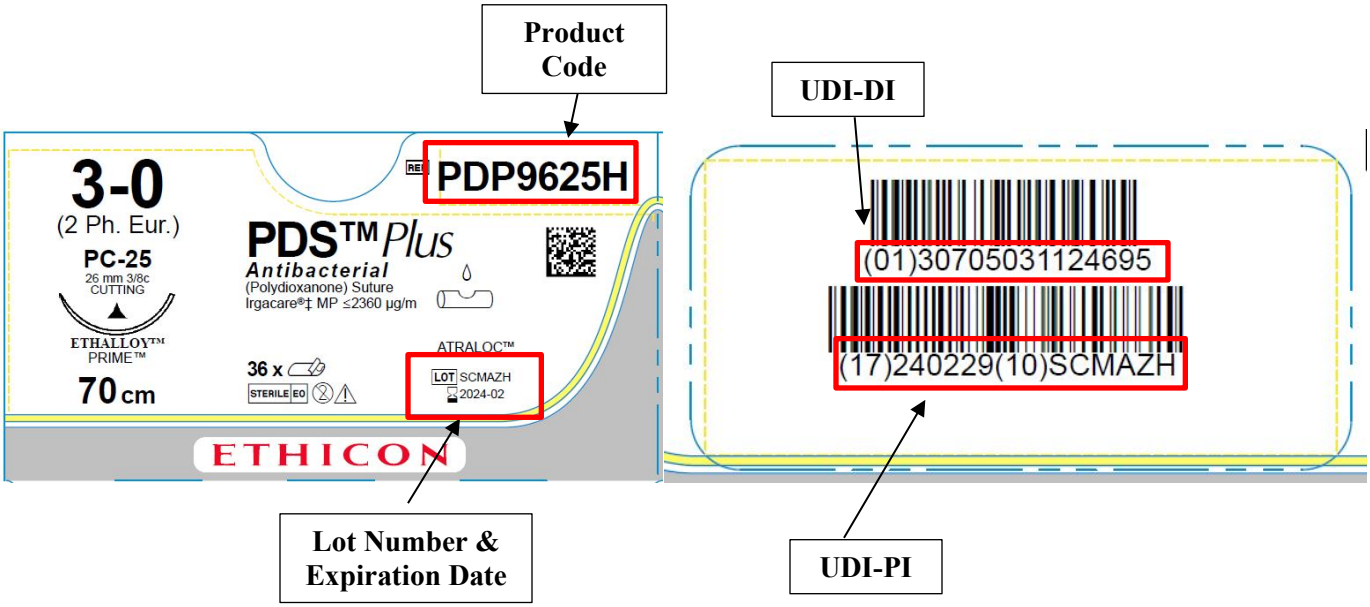
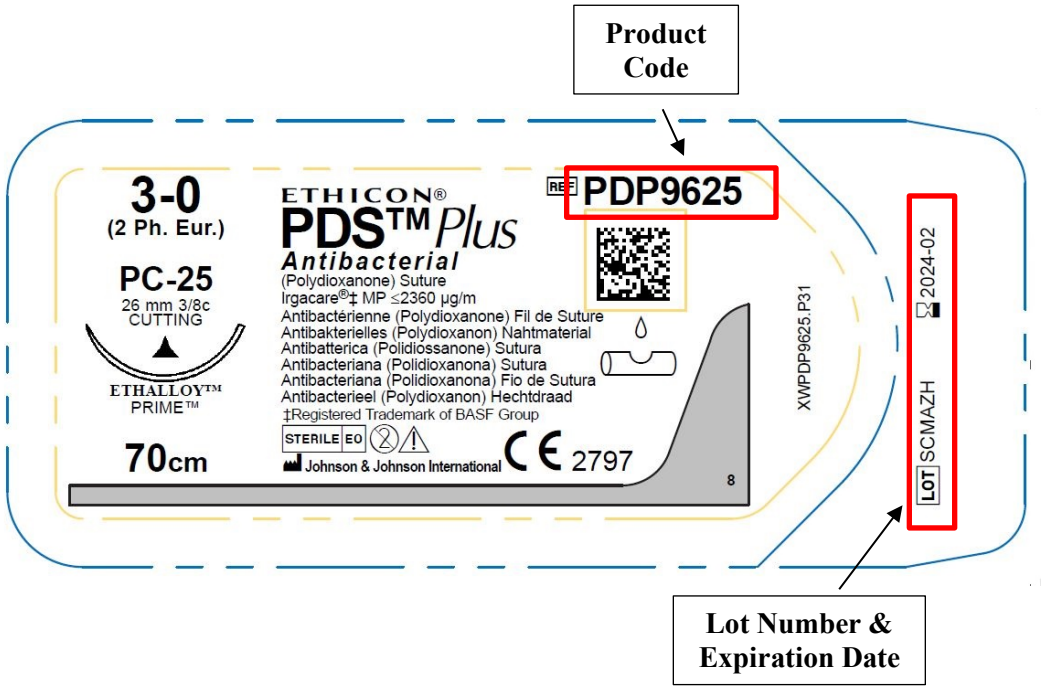
Attachment 1: Product Identification Tool

Please refer to the below to identify the location of the subject product code, lot number, expiration date, and UDI for PDS® Plus Antibacterial (polydioxanone) Suture, Product Code: PDP9625H, Lot SCMAZH by using the packaging labels.

Sales Unit Box



Individual Unit – Sealed Foil Pouch



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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 email it to MDFieldActionsUKirl@its.jnj.com **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.

Your Name/Title:	Date:
Email Address:	Telephone Number:
Hospital Name:	
Collection Address:	
Signature*: **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 NAME	PRODUCT CODE	PRODUCT LOT	EXP DATE	UNIQUE DEVICE IDENTIFICATION		QUANTITY RETURNING (EACHES)
				PACKAGING LEVEL & QTY	UDI-DI	
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