ETHICON

Johnson & Johnson SURGICAL TECHNOLOGIES

URGENT: FIELD SAFETY NOTICE

Coated VICRYL™ Plus Antibacterial (polyglactin 910) Suture

Product Code: VCP1226H, Lot: SJBCGZS0

– Voluntary Product Recall (Removal) –

[Insert Date]

Dear Valued Customer,

Ethicon has initiated a voluntary medical device recall (removal) of one (1) lot of Coated VICRYL™ Plus Antibacterial (polyglactin 910) Suture, Product code VCP1226H, Lot SJBCGZS0. Through an internal investigation following a customer complaint, Ethicon determined that five (5) eaches of product were distributed with the foil packaging open on the non-peelable side which would result in a sterility breach.

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	
Coated VICRYL™ Plus Antibacterial (polyglactin 910) Suture	VCP1226H	SJBCGZS0	July 31, 2025	Primary (Individual Unit) Qty = 1 each	(01)10705031149656	2-0, Violet, 6X45cm SUTUPAK™, Non-needled
				Other (Sales Unit Box) Qty = 36 eaches	(01)30705031149650	

Note: This medical device recall (removal) does NOT affect any other product codes or lots of Coated VICRYL™ Plus Antibacterial (polyglactin 910) Suture.

This defect in packaging is visible to the user and, once detected, it is unlikely that the impacted product would be used. In the unlikely event that impacted products are used, a compromised package/seal would impact the sterility of the product and infection may occur. A compromised seal may also result in damage, degradation, and deterioration of the suture. The intended benefit of tissue approximation and/or ligation may not be achieved or sustained, which could lead to potential harms of intraoperative bleeding, treatment failure, prolonged surgery and/ or postoperative wound dehiscence.

The health risk is limited to those products with open foil packaging. Other products in the field with no seal issues are unaffected.

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 determined the root cause of this issue, identified the specific lot impacted, and is implementing corrective actions 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 COATED VICRYL™ PLUS ANTIBACTERIAL (POLYGLACTIN 910) SUTURE.**

The earliest date of distribution for affected product was **September 15, 2022**.

URGENT: FIELD SAFETY NOTICE

Coated VICRYL™ Plus Antibacterial (polyglactin 910) Suture

Product Code: VCP1226H, Lot: SJBCGZS0

– Voluntary Product Recall (Removal) –

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 Coated VICRYL™ Plus Antibacterial (polyglactin 910) 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 [Insert Affiliate Information] 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 Coated VICRYL™ Plus Antibacterial (polyglactin 910) Suture products subject to this recall that are in inventory immediately. To receive credit reimbursement, customers must return product subject to this recall no later than [Insert Date] to [Insert Affiliate Information]. **Any non-affected product and any product returned after the date specified will not receive credit reimbursement.**
7. To return product subject to this recall, [Insert Local Information].

If you require any assistance with returning product, please contact [Insert Affiliate 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 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)

URGENT: FIELD SAFETY NOTICE

Coated VICRYL™ Plus Antibacterial (polyglactin 910) Suture

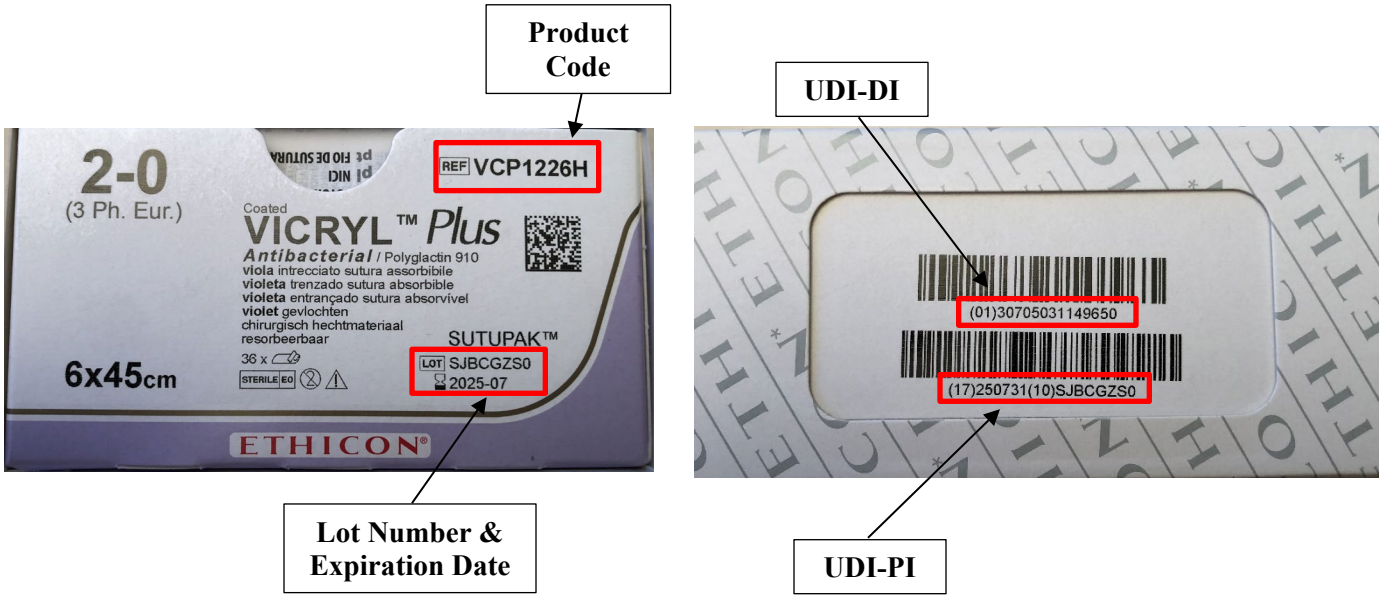
Product Code: VCP1226H, Lot: SJBCGZS0

– Voluntary Product Recall (Removal) –

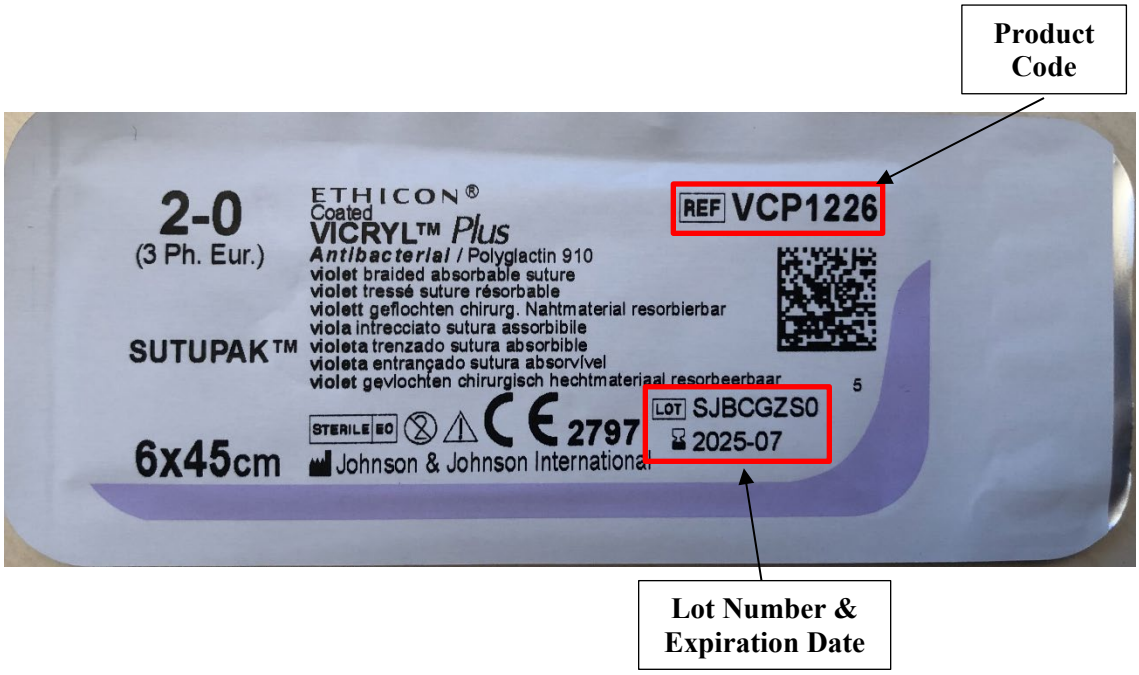
Attachment 1: Product Identification Tool

Please refer to the below to identify the location of the subject product code, lot number, expiration date, and UDI for Coated VICRYL™ Plus Antibacterial (polyglactin 910) Suture, Product Code: VCP1226H, Lot: SJBCGZS0 by using the packaging labels.

Sales Unit Box



Individual Unit – Sealed Foil Pouch



URGENT: FIELD SAFETY NOTICE

Coated VICRYL™ Plus Antibacterial (polyglactin 910) Suture

Product Code: VCP1226H, Lot: SJBCGZS0

– Voluntary Product Recall (Removal) –

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 [INSERT AFFILIATE NAME] at [INSERT FAX NUMBER] or e-mail the form to [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 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]

Your Name/Title:	Date:
Email Address:	Telephone Number:
J&J Account Number:	
Reference PO for Credit, if needed:	
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	
Coated VICRYL™ Plus Antibacterial (polyglactin 910) Suture	VCP1226H	SJBCGZS0	July 31, 2025	Primary (Individual Unit) Qty = 1 each	(01)10705031149656	
				Other (Sales Unit Box) Qty = 36 eaches	(01)30705031149650	