

**URGENT: FIELD SAFETY NOTICE**

**VICRYL™ (polyglactin 910) Suture and VICRYL™ Plus Antibacterial (polyglactin 910) Suture  
PDS™ II (polydioxanone) Suture and PDS™ Plus Antibacterial (polydioxanone) Suture  
MONOCRYL™ (poliglecaprone 25) Suture and MONOCRYL™ Plus Antibacterial (poliglecaprone 25) Suture  
– Voluntary Product Recall (Removal) –**

14-May-2024

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 VICRYL™, VICRYL™ PLUS, PDS™, PDS™ PLUS, MONOCRYL™ AND MONOCRYL™ PLUS SUTURES.**

**Purpose of this Letter**

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

VICRYL™ (polyglactin 910) Suture and VICRYL™ Plus Antibacterial (polyglactin 910) Suture

PDS™ II (polydioxanone) Suture and PDS™ Plus Antibacterial (polydioxanone) Suture

MONOCRYL™ (poliglecaprone 25) Suture and MONOCRYL™ Plus Antibacterial (poliglecaprone 25) Suture

**Reason for the Voluntary Removal**

Ethicon identified a manufacturing issue on a specific packaging machine that resulted in a hole in the primary packaging of a small percentage of VICRYL™, VICRYL™ Plus, PDS™, PDS™ Plus, MONOCRYL™ and MONOCRYL™ Plus sutures manufactured between January 27 and March 27, 2024. The occurrence of this defect is rare with an estimated rate of 0.011% of product presenting the condition (99.9% of product is not impacted by this defect). **When present, the hole is always and only on the first package in the horizontal box of quantity 36, and it occurs in the same location on the bottom side foil cavity of the first package towards the peelable flaps.**

**Risk to Health**

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

It is likely that this issue will be detected prior to use in surgery. 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.

A hole in the cavity also exposes the product to the environment which could potentially compromise its physical properties leading to treatment failure which may require additional surgical intervention or prolonged surgery.

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.

**Voluntary Product Recall of specific lots of VICRYL™, VICRYL™ Plus, PDS™, PDS™ Plus, MONOCRYL™, MONOCRYL™ Plus Sutures**

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Ethicon has identified and corrected the manufacturing issue that led to this recall.

### 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 [jjmedical-ch@its.jnj.com](mailto:jjmedical-ch@its.jnj.com) (Johnson&Johnson AG) 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 August 31, 2024 to Johnson&Johnson AG. Any non-affected product and any product returned after the date specified will not receive credit reimbursement.
5. To return product subject to this recall, photocopy the completed BRF, place it in the box with the product, and affix the pre-paid authorized shipping label included with the recall notification letter. Megadyne will pay for the shipping charges only if the authorized label is used. Extra shipping labels may be obtained by calling the Johnson & Johnson AG Customer Services at 0800 830 085. Your account number and mailing address have been pre-populated on the BRF. Please return products to the following address:

Johnson & Johnson AG  
c/o Postlogistik  
Keyword: ETH Suture Recall 2024  
Allmendstrasse 8  
5612 Villmergen

6. Keep this notice visibly posted for awareness until all product subject to this recall has been returned to Johnson&Johnson AG.

If you require any assistance with returning product, please contact Johnson & Johnson AG Customer Services at 0800 830 085.

### 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 this product 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 Johnson & Johnson AG Customer Services at 0800 830 085.

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

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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 NAME	PRODUCT CODE	PRODUCT LOTS
MONOCRYL™ Plus Suture	MCP4423H	UAMHXE
	MCP442H	UAMRKS
	MCP496H	UAMRLE
	MCP497H	UAMHRH
	MCP496H	UAMRLE
		UAMLCU
	Y423H	UBMJED

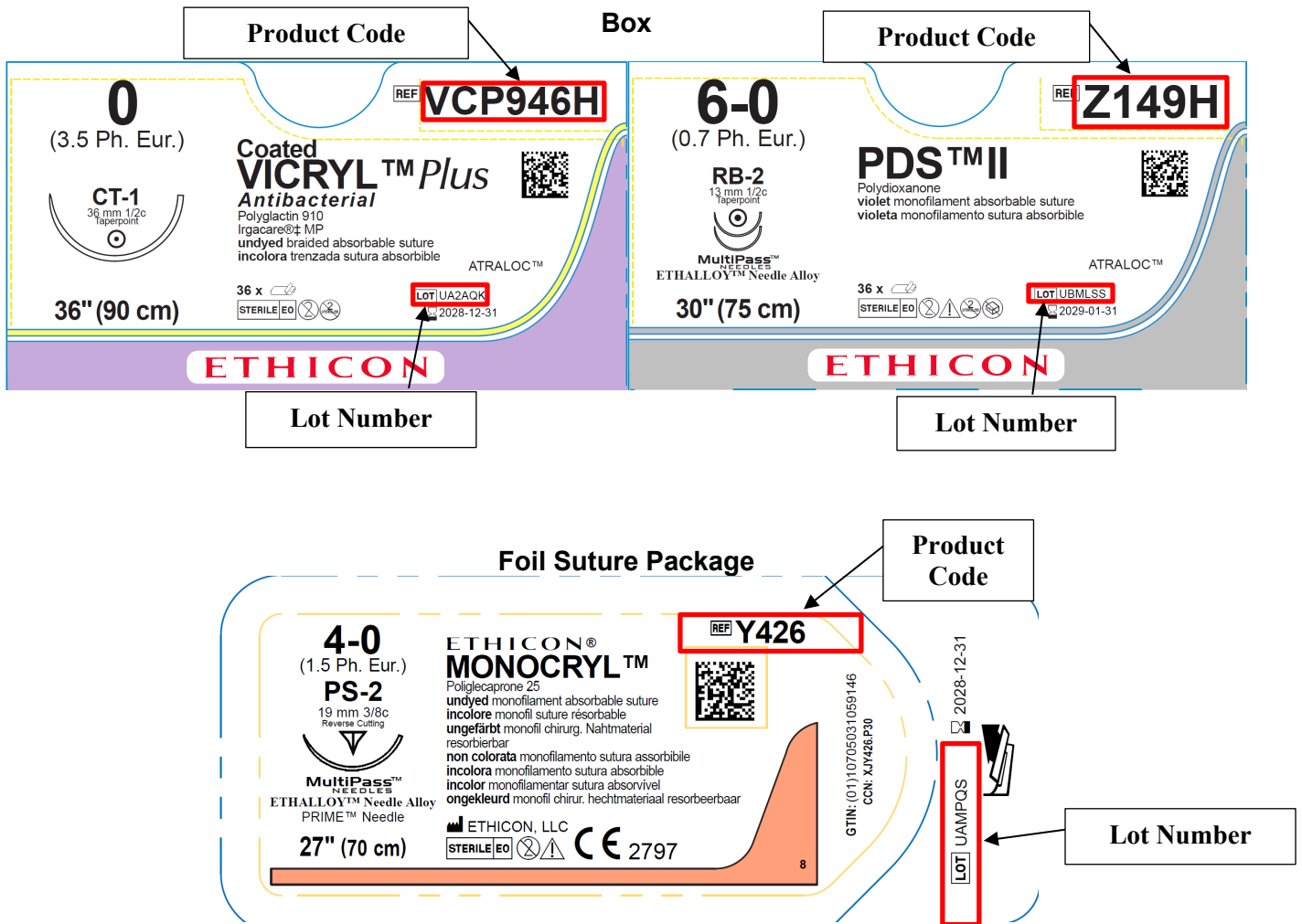
PRODUCT NAME	PRODUCT CODE	PRODUCT LOTS
PDS™ II (polydioxanone) Suture	Z14H	UAMQDZ
	Z1721H	UAMMQH
VICRYL™ Suture	J2575H	UBMHZK
	MPV489H	UAMPZR

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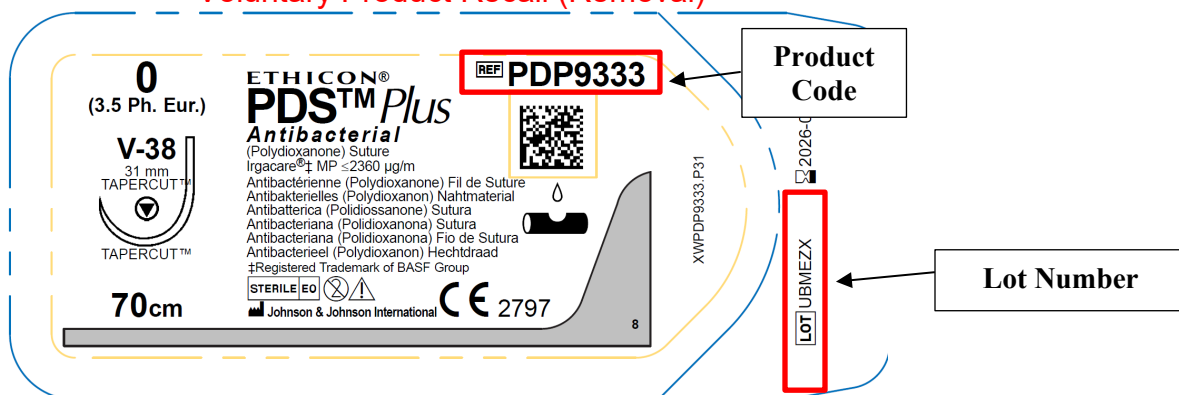
**Attachment 2: Product Identification Tool**

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.



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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 email it to [jnmedical-ch@its.jnj.com](mailto:jnmedical-ch@its.jnj.com) (Johnson&Johnson AG) **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.

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.	

