Johnson&Johnson MedTech

Ethicon

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) –

[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 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 sutures from **specific 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 as shown in Figure 1.**

All product from lots found in Attachment 1 may be returned, but sutures from these lots that do not have a hole in the primary packaging can remain in your inventory and are safe to use in accordance with the appropriate IFU.

To reduce potential customer inventory issues, Ethicon is providing the following options for your inventory of lots from Attachment 1:

1) Return only the first package of a complete box, **or**
2) Examine the first package of a complete box and return only those packages found to have a hole in the primary packaging.

This option is provided as not every box will contain a suture package with this defect. If the defect exists, it will only be present on the first suture package in a box and will always be visible in the same approximate location per the picture in Figure 1. The remaining 35 suture packages in the box are not impacted by the manufacturing issue and are safe to use in accordance with the appropriate IFU.

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) –

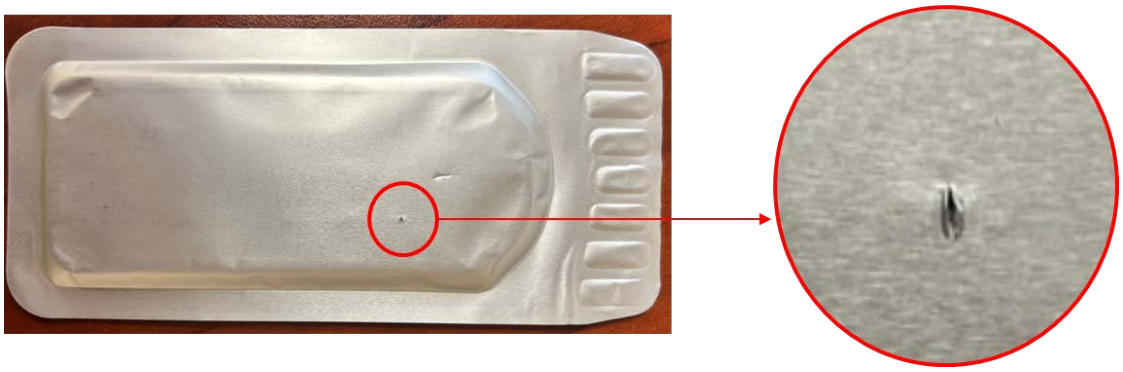


Figure 1: Foil suture package (bottom side) indicating hole location. Top side of suture package contains printed product information as shown in Attachment 2.

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.

Ethicon has identified and corrected the root cause of the manufacturing issue that led to this recall (removal).

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) –

ACTION REQUIRED

1. Determine whether you have inventory of the lots listed in Attachment 1. If so, you may
    - Option 1: Remove the first package of suture from a complete box,
        i. Quarantine and return it for credit. You may use the remaining 35 sutures in accordance with the IFU. (See Figure 2 below for location of first package)

        OR

        ii. Examine the first package of a complete box prior to use. Quarantine and return this unit if a packaging defect is identified. (See Figure 2 below for location of first package). If no defect is found, the product and remaining 35 sutures in the box may be used accordance with the IFU.

    OR

    - Option 2: Quarantine all product in scope and return all inventory for credit.

Figure 2: Location of first package

First package is defined as the package closest to the front of the box with the foil cavity side facing the box. The front of the box contains the labeling for the product.

Figure 2: Sales unit box (QTY:36) indicating location of first package.

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 (removal) has been forwarded to another facility, contact that facility to arrange return. Please consider including a copy of this recall letter when communicating.

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) –

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 (removal)**.
4. Customers are required to return unused sutures with holes in the primary packaging subject to this recall (removal) that are in inventory immediately. To receive credit for items returned, customers must return product no later than August 31, 2024 to [Enter Affiliate Information]. All product listed on Attachment 1 may be returned, but to reduce potential customer inventory issues, Ethicon is providing you with the options to remove the first package or to examine your inventory of lots from Attachment 1 and return only those individual sutures found to have a hole in the primary packaging. Any product not found in Attachment 1 and any product returned after the date specified will not receive credit.
5. Keep this notice visibly posted for awareness until all product subject to this recall has been returned to [Enter Affiliate Information].
6. 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 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 (removal) 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)

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) –

Attachment 1: Impacted Product Information
REFER TO ACTION REQUIRED FOR FURTHER INSTRUCTIONS.

PRODUCT NAME	PRODUCT CODE	PRODUCT LOT
MONOCRYL™ Plus Antibacterial (poliglecaprone 25) Suture	MCP3200H	UAMPTL
	MCP3212H	UBMPSZ
	MCP3212H	UCMCXJ
	MCP3213H	UAMRDT
	MCP3213H	UAMJZL
	MCP3213H	UAMJUR
	MCP3213H	UAMRDK
	MCP3213H	UAMLCP
	MCP4423H	UAMHXE
	MCP4424H	UBMMXK
	MCP442H	UAMRKS
	MCP496H	UAMRLE
	MCP496H	UAMLCU
	MCP497H	UAMHRH
MONOCRYL™ (poliglecaprone 25)	C458	UBMHPC
	C490	UAMEUD
	C589	UBMEML
	Y293H	UBMEJR
	Y398H	UAMPJB
	Y398H	UAMMXQ
	Y423H	UBMJED
	Y426H	UAMKHE
	Y935H	UBMCAA
	Y935H	UBMDKC
	Y936H	UBMJQM
PDS™ II (polydioxanone) Suture	PEE2993H	UBMQHD
	W9073H	UBMBZJ
	W9077H	UBMHPH
	W9101H	UAMHJS
	W9101H	UAMLPS
	W9116H	UBMAJQ
	W9125H	UAMRRP
	Z14H	UAMQDZ
	Z1721H	UAMMQH
	Z9210H	UBMEUS
	Z925H	UBMKBQ

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) –

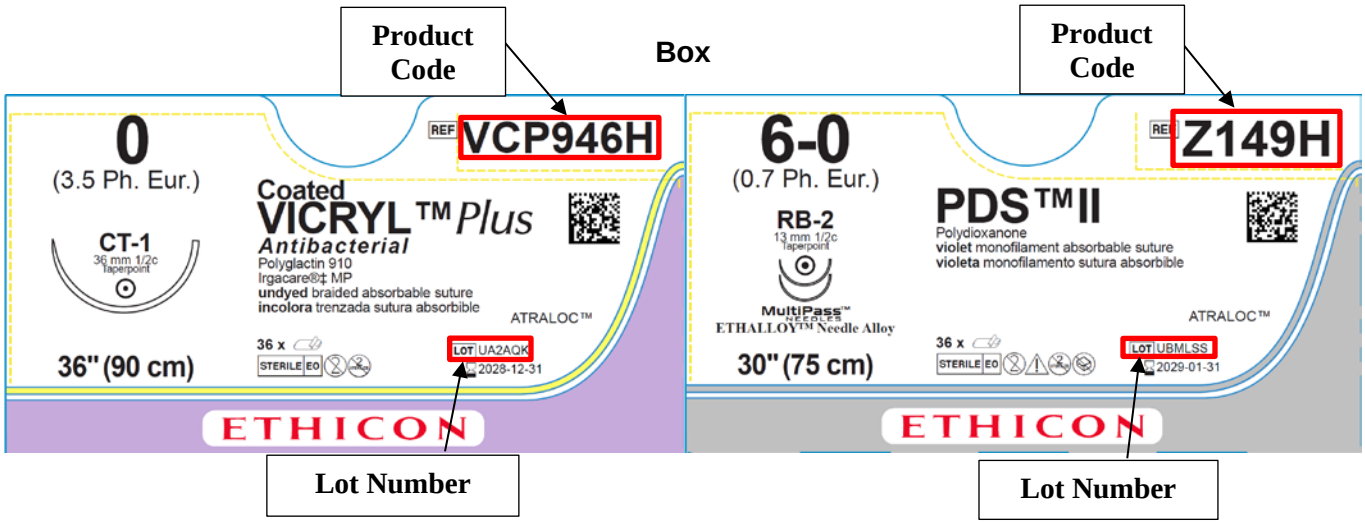
PRODUCT NAME	PRODUCT CODE	PRODUCT LOT
PDS™ Plus Antibacterial (polydioxanone) Suture	PDP9109H	UBMJDU
	PDP9333H	UBMJAM
	PDP9333H	UBMEZX
VICRYL™ Plus Antibacterial (polyglactin 910) Suture	VCP9582H	UBMERQ
VICRYL™ (polyglactin 910) Suture	J2575H	UBMHZK
	J310H	UAMPML
	J327H	UAMPEP
	J458H	UAMQRT
	J493H	UAMMKE
	J699H	UAMQME
	J9527H	UBMCST
	J9571H	UAMMLJ
	JE2672H	UBMEZC
	MPV489H	UAMPZR

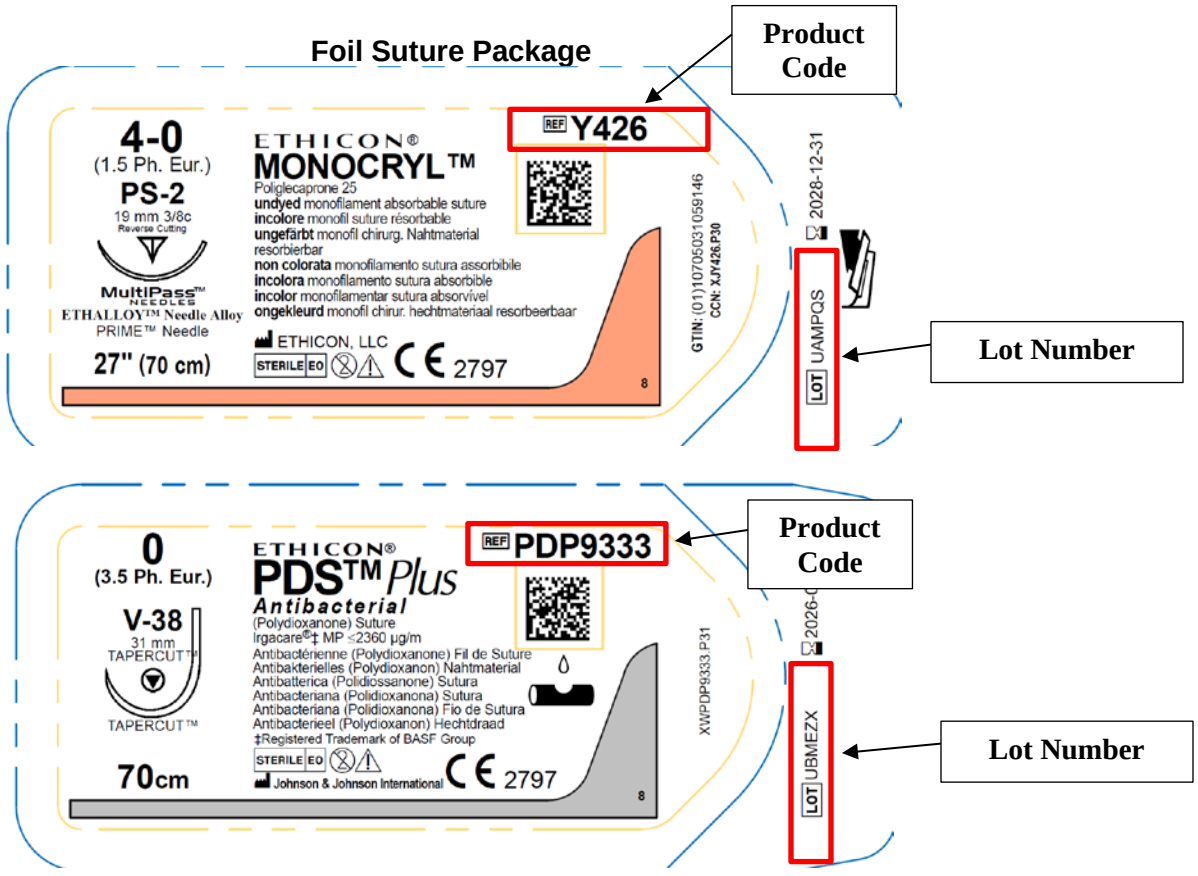
URGENT: FIELD SAFETY NOTICE

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) –

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.





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) –

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 (removal) 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 those that apply:*

☐ We have NO inventory of product subject to this recall (removal).
☐ We have product subject to this recall (removal) and followed Option 1 (i)- Remove the first package of each complete box and return for credit (no inspection):
☐ We have product subject to this recall (removal) and followed Option 1 (ii)- Examine the first package of each complete box prior to use. Quarantine and return if packaging defect is identified.
☐ We have product subject to this recall (removal) and followed Option 2- Quarantine all impacted lots and return for credit.

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) –

PRODUCT CODE	PRODUCT LOT	QUANTITY RETURNING (EACHES)