

URGENT: MEDICAL DEVICE RECALL (REMOVAL) **VICRYL RAPIDE™ (Polyglactin 910) SUTURE** **(SPECIFIC CODES AND LOTS LISTED BELOW)**

September XX, 2017

Dear Customer, Operating Room Supervisors, Materials Management Personnel, and Chief of Surgery:

PLEASE DISTRIBUTE THIS INFORMATION TO ALL STAFF WITHIN YOUR FACILITY WHO USE VICRYL RAPIDE™ (Polyglactin 910) SUTURE

At Ethicon, Inc. ("Ethicon"), our first priority is to our customers and their patients, and that includes the safe and effective use of our products.

Ethicon has initiated a medical device recall (removal) of **certain lots** of VICRYL RAPIDE™ (Polyglactin 910) Suture. We have identified that certain lots of sizes 2-0 and 4-0 for VICRYL RAPIDE™ SUTURE (Product Codes and Lot Numbers listed in table below) exhibited suture damage due to a manufacturing equipment issue. The manufacturing equipment issue has been corrected.

The medical assessment concluded that this situation could result in a potential superficial wound dehiscence or contribute to impaired wound healing but only occasionally and/or under unusual circumstances.

Ethicon has not received any reports of Adverse Events associated with the product subject to this recall (removal).

Health care practitioners that have treated patients using VICRYL RAPIDE™ SUTURE from the lots listed in the table below, should continue to follow those patients post-operatively in the usual manner.

This medical device recall (removal) has been communicated to the U.S. Food and Drug Administration (FDA).

EFFECTIVE IMMEDIATELY – DO NOT USE OR DISTRIBUTE THE FOLLOWING PRODUCT CODES/LOTS:

PRODUCT NAME	PRODUCT CODE	PRODUCT LOT	DESCRIPTION/SIZE
VICRYL RAPIDE™ (Polyglactin 910) SUTURE	MPVR4260H	AH6847	Size 4-0 VICRYL RAPIDE Undyed 75cm PS-2 Needle
VICRYL RAPIDE™ (Polyglactin 910) SUTURE	V2140H	AH6862	Size 4-0 VICRYL RAPIDE Undyed 70cm RB-1 Needle
VICRYL RAPIDE™ (Polyglactin 910) SUTURE	V2140H	AH7675	Size 4-0 VICRYL RAPIDE Undyed 70cm RB-1 Needle

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PRODUCT NAME	PRODUCT CODE	PRODUCT LOT	DESCRIPTION/SIZE
VICRYL RAPIDE™ (Polyglactin 910) SUTURE	V2140H	AH9170	Size 4-0 VICRYL RAPIDE Undyed 70cm RB-1 Needle
VICRYL RAPIDE™ (Polyglactin 910) SUTURE	VR2217	AH7884	Size 2-0 VICRYL RAPIDE Undyed 90cm V-34 Needle
VICRYL RAPIDE™ (Polyglactin 910) SUTURE	VR2217	AH9680	Size 2-0 VICRYL RAPIDE Undyed 90cm V-34 Needle
VICRYL RAPIDE™ (Polyglactin 910) SUTURE	VR2253	AH8749	Size 2-0 VICRYL RAPIDE Undyed 75cm FS-1 Needle
VICRYL RAPIDE™ (Polyglactin 910) SUTURE	VR2253	AH9686	Size 2-0 VICRYL RAPIDE Undyed 75cm FS-1 Needle
VICRYL RAPIDE™ (Polyglactin 910) SUTURE	VR2253	AJ0204	Size 2-0 VICRYL RAPIDE Undyed 75cm FS-1 Needle
VICRYL RAPIDE™ (Polyglactin 910) SUTURE	VR2253	AH9968	Size 2-0 VICRYL RAPIDE Undyed 75cm FS-1 Needle
VICRYL RAPIDE™ (Polyglactin 910) SUTURE	VR2253	AJ1166	Size 2-0 VICRYL RAPIDE Undyed 75cm FS-1 Needle
VICRYL RAPIDE™ (Polyglactin 910) SUTURE	VR2279	AH7676	Size 4-0 VICRYL RAPIDE Undyed 75cm V-4 Needle
VICRYL RAPIDE™ (Polyglactin 910) SUTURE	VR2294	AH7679	Size 4-0 VICRYL RAPIDE Undyed 75cm FS-3 Needle
VICRYL RAPIDE™ (Polyglactin 910) SUTURE	VR2294	AH7684	Size 4-0 VICRYL RAPIDE Undyed 75cm FS-3 Needle
VICRYL RAPIDE™ (Polyglactin 910) SUTURE	VR2297	AH7680	Size 4-0 VICRYL RAPIDE Undyed 75cm FS-2 Needle
VICRYL RAPIDE™ (Polyglactin 910) SUTURE	VR2297	AH7711	Size 4-0 VICRYL RAPIDE Undyed 75cm FS-2 Needle
VICRYL RAPIDE™ (Polyglactin 910) SUTURE	VR2297	AH7686	Size 4-0 VICRYL RAPIDE Undyed 75cm FS-2 Needle
VICRYL RAPIDE™ (Polyglactin 910) SUTURE	VR2297	AJ0770	Size 4-0 VICRYL RAPIDE Undyed 75cm FS-2 Needle
VICRYL RAPIDE™ (Polyglactin 910) SUTURE	VR2297	AJ0794	Size 4-0 VICRYL RAPIDE Undyed 75cm FS-2 Needle
VICRYL RAPIDE™ (Polyglactin 910) SUTURE	VR496	AH7694	Size 4-0 VICRYL RAPIDE Undyed 18" PS-2 Needle
VICRYL RAPIDE™ (Polyglactin 910) SUTURE	VR945	AH6611	Size 2-0 VICRYL RAPIDE Undyed 36" CT-1 Needle
VICRYL RAPIDE™ (Polyglactin 910) SUTURE	VRI253H	AH8642	Size 2-0 VICRYL RAPIDE Undyed 75cm FS-1 Needle
VICRYL RAPIDE™ (Polyglactin 910) SUTURE	VRI253H	AH8644	Size 2-0 VICRYL RAPIDE Undyed 75cm FS-1 Needle
VICRYL RAPIDE™ (Polyglactin 910) SUTURE	W9941	AH8379	Size 2-0 VICRYL RAPIDE Undyed 75cm FS Needle
VICRYL RAPIDE™ (Polyglactin 910) SUTURE	W9941	AH9666	Size 2-0 VICRYL RAPIDE Undyed 75cm FS Needle

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VICRYL RAPIDE™ (Polyglactin 910) SUTURE (SPECIFIC CODES AND LOTS)

IDENTIFICATION OF PRODUCT SUBJECT TO THIS RECALL (REMOVAL):

Product subject to the recall (removal) in your inventory can be identified by product code and lot number (see product code and lot listing above). All unused VICRYL RAPIDE™ SUTURE products subject to this recall (removal) are required to be returned. The product code and lot number can be determined by using the Product Identification Tool within Attachment 1.

ACTION REQUIRED:

1. Examine your inventory immediately to determine if you have product subject to this recall (removal) on hand and quarantine such product(s).
2. Remove the product subject to this recall (removal) 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 (removal) has been forwarded to another facility, contact that facility to arrange return.
4. Complete the Business Reply Form (BRF) (Attachment 2) confirming receipt of this notice and fax or email it to **[INSERT AFFILIATE EMAIL ADDRESS]** or **[INSERT AFFILIATE FAX NUMBER]** within three (3) business days. **Please return the BRF even if you do not have product subject to this recall (removal).**
5. Keep this notice visibly posted for awareness until all product subject to this recall (removal) has been returned to **[INSERT AFFILIATE NAME]**. While processing your returns, please maintain a copy of this notice with the product subject to this recall (removal) and keep a copy for your records.
6. Customers are required to return all unused VICRYL RAPIDE™ SUTURE products that are in their inventory immediately. Only unused VICRYL RAPIDE™ SUTURE product subject to this recall (removal) returned by December 15, 2017 will be eligible for replacement. Any product subject to this recall (removal) returned after December 15, 2017 will not be eligible for replacement.
7. To return product subject to this recall (removal), 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. **[INSERT AFFILIATE NAME]** will pay for the shipping charges only if the authorized label is used. Extra shipping labels may be obtained by calling **[INSERT AFFILIATE NAME]** at **[INSERT PHONE NUMBER]**. Your account number and mailing address have been pre-populated on the BRF.

If you require any assistance with returning product, please contact **[INSERT AFFILIATE NAME]** at **[INSERT PHONE NUMBER]**.

We recognize the recall (removal) of the VICRYL RAPIDE™ SUTURE may be disruptive to your facility and we apologize for any inconvenience this may cause.

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If you have additional questions regarding this recall (removal) or to report any customer complaints, please contact **[INSERT AFFILIATE NAME]** at **[INSERT PHONE NUMBER]**.

Attachments:

Attachment 1: Product Identification Tool
Attachment 2: Business Reply Form

URGENT: MEDICAL DEVICE RECALL
VICRYL RAPIDE™ (Polyglactin 910) SUTURE
(SPECIFIC CODES AND LOTS)

ATTACHMENT 1: Product Identification Tool for VICRYL RAPIDE™ SUTURE (SPECIFIC CODES AND LOTS LISTED IN TABLE ABOVE)

This tool will help customers identify the product subject to this recall (removal) by using the package labels. This document applies to the VICRYL RAPIDE™ SUTURE, sales unit carton, and foil pouch for Product Code VR2297.

Please note: *The labels listed below are used for illustration purposes only. Refer to the table listed above for a list of product codes and lot numbers subject to this recall (removal).*

VICRYL RAPIDE™ SUTURE SALES UNIT CARTON (CONTAINING 36 EACHES)

FRONT of SALES UNIT CARTON (PRODUCT CODE VR2297)



VICRYL RAPIDE™ SUTURE FOIL POUCH (CONTAINING 1 EACH)

FRONT of FOIL POUCH (PRODUCT CODE VR2297)



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ATTACHMENT 2: Business Reply Form (BRF)

Your timely response to this customer notification is requested. Please complete and fax this form 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 (removal) to return.

If you have product subject to this recall (removal) to return, please indicate the product code, lot number and quantity of eaches being returned in the table below and make a photocopy of your completed Business Reply Form and enclose with your return - Please refer to the above listed table of product subject to this recall (removal). Thank you for your cooperation.

Product Inventory: – please check one

- We have no VICRYL RAPIDE™ SUTURE subject to this recall (removal).
- We have VICRYL RAPIDE™ SUTURE subject to this recall (removal) and are returning the following products:

Device Name	Product Code	Lot Number	Quantity Returning (in “Eaches”)
VICRYL RAPIDE™ (Polyglactin 910) SUTURE			

[Account Name]
[Account Address]

Print Name of Person Completing Business Reply Form:	Telephone Number:
Account Number: <small>(number used to order J&J product)</small>	Date:
Signed*: <small>*Your signature provides confirmation that you have received and understood this notification</small>	
Your comments are welcome.	