

URGENT: FIELD SAFETY NOTICE **VICRYL Suture and VICRYL Plus Suture Products** **(Multiple Product Codes/Lot Numbers)**

March XX, 2019

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

Ethicon has initiated a voluntary recall (removal) of specific product codes and lots of **VICRYL Suture and VICRYL Plus Suture**, as listed in the table below. The lots and codes below may contain product that does not match the sales unit carton and foil label. The mixed suture may be a different size or type than indicated on the label. The physical product inside the suture tray matches the product noted on the lid of the tray inside the foil pouch.

EFFECTIVE IMMEDIATELY – DO NOT USE OR DISTRIBUTE THE FOLLOWING PRODUCT LOTS BELONGING TO VICRYL Suture and VICRYL Plus Suture (ONLY SPECIFIC LOT BELOW). REFER TO ACTION REQUIRED FOR FURTHER INSTRUCTIONS:

PRODUCT NAME	PRODUCT CODE	PRODUCT LOT	DESCRIPTION/SIZE
Vicryl	8PB2643YD	MGZ072	VICRYL UND 8X45CM M1.5 USP4/0 SGLE ARM RB-1 PLUS C/R
	V703D	MMK012	VICRYL VIO 6X45CM M3 USP2/0 SGLE ARMED V-5 C/R
	V797D	MGZ085	VICRYL VIO 8X45CM M1 USP5/0 SGLE ARMED TF PLUS C/R
Vicryl Plus	VCP773D	MM6814	VICRYL PLUS VIO 8X45CM M1.5 USP4/0 SGLE ARMED SH C/R

This voluntary recall (removal) does NOT affect any other product codes or lots for VICRYL Suture, and VICRYL Plus Suture.

Our records indicate that you may have ordered or received product subject to this recall (removal). The product families include Coated VICRYL® (polyglactin 910) Suture and Coated VICRYL® Plus Antibacterial (polyglactin 910) Suture. **PLEASE DISTRIBUTE THIS INFORMATION TO ALL STAFF WITHIN YOUR FACILITY WHO USE VICRYL Suture and VICRYL Plus Suture.**

If the mix results in the incorrect suture being used, the tensile strength or absorption profile may be inadequate for the procedure. Suture breakage could occur during surgery or post operation. Intra operative suture breakage requires an alternative device to be used to complete the procedure. If suture breakage occurs post operation prior to complete wound healing, wound dehiscence and impaired healing may happen, requiring additional surgical and/or medical intervention to prevent further injury or permanent impairment of body structure/function.

Medical Device Recall of **VICRYL Suture and VICRYL Plus Suture**

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To date, Ethicon has not received any reports of adverse events associated with the issue that led to this recall (removal). Health care practitioners who have treated patients using VICRYL Suture and VICRYL Plus Suture Products should follow those patients post-operatively in the usual manner with no additional action required.

We have identified the root cause and we have implemented immediate corrective actions to address the issue.

Refer to Attachment 1 for assistance in identifying the product lot subject to this recall (removal).

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 listing above). All unused VICRYL Suture and VICRYL Plus Suture product 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 attached at 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 voluntary 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. Do not open foil pouches to confirm contents.
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 Information]** within three (3) business days. **Please return the BRF even if you do not have the product lots subject to this recall.**
5. Customers are required to return unused impacted **VICRYL Suture and VICRYL Plus Suture** subject to this recall (removal) that are in their inventory immediately. To receive replacement product/credit, customers must return product subject to this recall (removal) by July 31, 2019 and place a replacement/credit note order. **Any non-affected product and any product returned after the date specified will not be replaced.**
6. To return product subject to this recall (removal), photocopy the completed BRF, place it in the box with the subject products, and affix the pre-paid authorized shipping label included with this 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 contacting **[INSERT AFFILIATE NAME]** or **[INSERT PHONE NUMBER]**.

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If you require any assistance with returning product lots subject to this recall, please contact **[INSERT AFFILIATE NAME]** or **[INSERT PHONE NUMBER]**.

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

If you have additional questions regarding this recall or to report any customer complaints, please contact **[INSERT 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: Product Identification Tool
Attachment 2: Business Reply Form

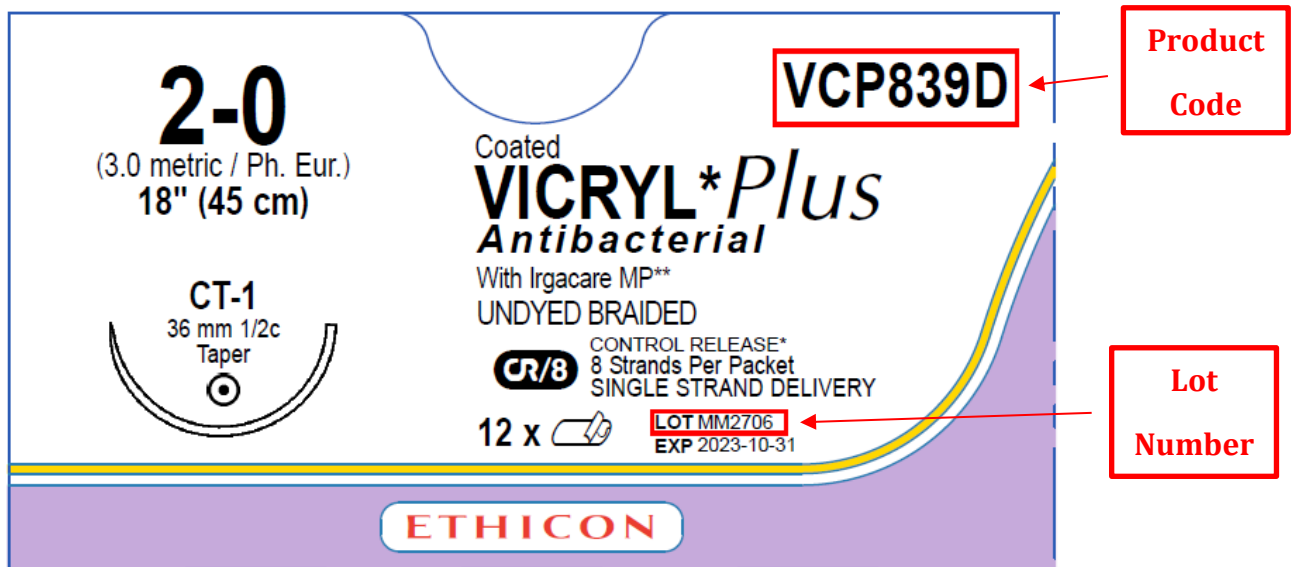
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VICRYL Suture and VICRYL Plus Suture
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ATTACHMENT 1: Product Identification Tool for VICRYL Suture and VICRYL Plus Suture Products

This tool will help customers identify the impacted product subject to this recall (removal). This document applies to the sales unit carton and foil packaging for specific product codes and lots for VICRYL Suture and VICRYL Plus Suture Products. While the labeling below is an example and is representative of an impacted product code/lot, sutures within each product family have very similar labeling and the product codes and lot numbers can be identified using the same images below.

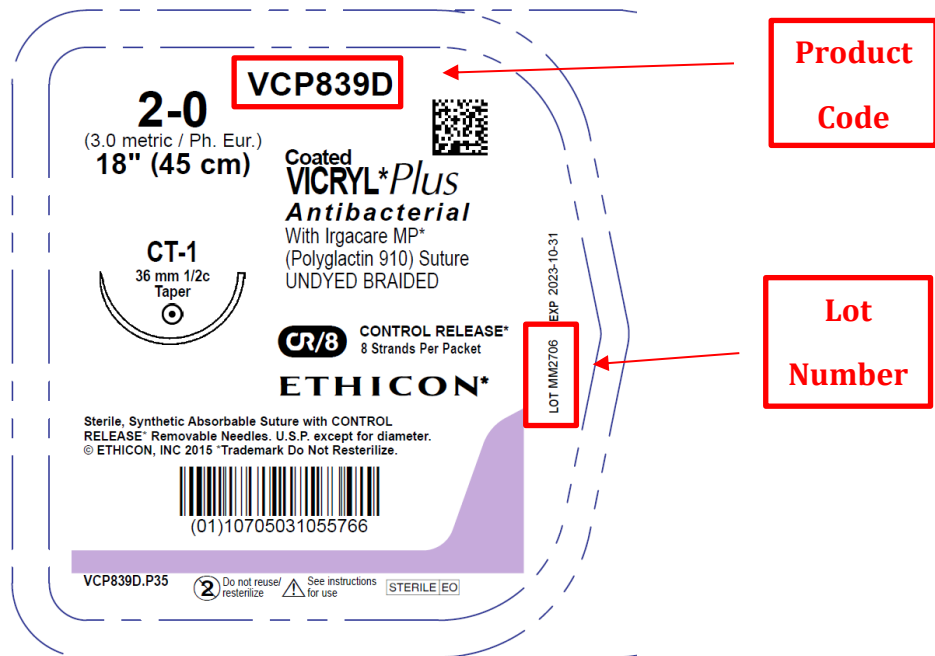
FRONT OF SALES UNIT CARTON (Representative Sample)



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VICRYL Suture and VICRYL Plus Suture Products (Multiple Product Codes/Lot Numbers)

FOIL PACKAGE (Representative Sample)



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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 the product subject to this recall to return.

If you have product subject to this recall (removal) to return, please make a photocopy of your completed Business Reply Form and enclose with your return. Thank you for your cooperation.

Product Inventory – please check one

- We have **NO** VICRYL Suture and/or VICRYL Plus Suture Products subject to this recall (removal).
- We have VICRYL Suture and/or VICRYL Plus Suture Products subject to this recall (removal) and are returning the following products:

PRODUCT NAME	PRODUCT CODE	PRODUCT LOT	Quantity Returning (Eaches)
Vicryl	8PB2643YD	MGZ072	
	V703D	MMK012	
	V797D	MGZ085	
Vicryl Plus	VCP773D	MM6814	

[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.	