

URGENT: FIELD SAFETY NOTICE **ETHICON VICRYL™ (Polyglactin 910) Violet Absorbable Suture** **(Product Codes JV1036 and JV1038, Specific lots)**

July XX, 2017

Dear Theatre Staff, Materials Management Personnel, and Chief of Surgery:

PLEASE DISTRIBUTE THIS INFORMATION TO ALL STAFF WITHIN YOUR FACILITY WHO USE ETHICON VICRYL™ (POLYGLACTIN 910) ABSORBABLE 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.

We have initiated a voluntary field safety notice (removal) for **specific lots** of two (2) codes of ETHICON VICRYL™ (Polyglactin 910) Violet Absorbable Suture (Product Codes JV1036 and JV1038, Specific lots listed in **Table A** below).

As part of an established over-labeling process at our distribution center, specific over-labels are placed on products before final shipments to the intended countries. It was identified that in specific lots, distributed only in Italy, the Italian over-labels prepared for the VICRYL™ Violet Absorbable Suture incorrectly identified the product as a “VICRYL *black Non-Absorbable*” product. While our evaluation of a potential safety risk indicates that the probability of adverse consequences is extremely rare in patients in whom these sutures were used, we believe it is prudent to remove the potentially affected products.

At this time, Ethicon has received no reports of Adverse Events for this issue.

Health care practitioners that have treated patients using product from lots distributed in Italy (indicated in Table A below) of ETHICON VICRYL™ (Polyglactin 910) Violet Absorbable Suture should continue to follow those patients in the usual manner.

This field safety notice has been communicated to the Medicines and Healthcare Products Regulatory Agency (MHRA).

The scope of this action (removal) is limited to specific lots distributed in Italy (listed in Table A below) of two (2) codes of ETHICON VICRYL™ (Polyglactin 910) Violet Absorbable Suture (Product Codes JV1036 and JV1038)

EFFECTIVE IMMEDIATELY – DO NOT USE OR DISTRIBUTE THE FOLLOWING PRODUCT CODES/LOTS (DISTRIBUTED ONLY IN ITALY) – TABLE A:

PRODUCT NAME	DESCRIPTION/SIZE	PRODUCT CODE	PRODUCT LOTS
ETHICON VICRYL™ (Polyglactin 910) Violet Absorbable Suture	2-0 VICRYL Violet Suture, Length 75cm, Single Armed, TE PLUS Needle	JV1036	EL8HHGM0
			HE8DRZM0
			JH8CMZM0
			GB8JDKM0
			HH8GZBM0
			JM8GBGP0
GE8GHCM0			
JA8BMMM0			
KB8GRCP0			
GG8GQCM0			
JB8HBZM0			
KG8CJXP0			
GP8GGSM0			

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PRODUCT NAME	DESCRIPTION/SIZE	PRODUCT CODE	PRODUCT LOTS
ETHICON VICRYL™ (Polyglactin 910) Violet Absorbable Suture	Size 1 VICRYL Violet Suture, Length 75cm, Single Armed, TE PLUS Needle	JV1038	EP8GMGM0 HB8HKKM0 JH8HLZM0 GA8BWLM0 HG8DGZM0 JL8HGTM0 GJ8BTLM0 HH8BTGM0 KA8GKHP0 GK8JQSM0 JA8DCXM0 KH8BHXP0 GP8GSBM0 JB8BHMM0 KL8BRHP0

IDENTIFICATION OF PRODUCT SUBJECT TO THIS ACTION (REMOVAL):

Product subject to this action (removal) in your inventory can be identified by product code and lot. Unused ETHICON VICRYL™ (Polyglactin 910) Violet Absorbable Suture product from specific lots listed in TABLE A above are subject to this action (removal) and is required to be returned. The product code(s) and lot(s) can be determined by using the examples in the provided Product Identification Tool in Attachment 1.

ACTION REQUIRED:

1. Examine your inventory immediately to determine if you have product subject to this action (removal) on hand and quarantine such product(s).
2. Remove the product subject to this action (removal) and communicate the issue to relevant Theatre staff or materials management personnel, or anyone else in your facility that needs to be informed.
3. If any product subject to this action (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 NAME]** at **[INSERT FAX NUMBER]** or **[INSERT EMAIL ADDRESS]** within three (3) business days. Please return the BRF **even if you do not have product subject to this action (removal)**.
5. Keep this notice visibly posted for awareness until all product subject to this action (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 action (removal) and keep a copy for your records.
6. Customers are required to return all unused ETHICON VICRYL™ (Polyglactin 910) Violet Absorbable Suture products, from specific lots listed in **TABLE A** that are in their inventory immediately. Only product subject to this action (removal) returned by **[AFFILIATE TO INSERT DATE]** will be eligible for credit.
7. To return product subject to this action (removal), photocopy the completed BRF, place it in the box with the product, and affix the pre-paid authorized shipping label included with the field safety notice. **[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.

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

We recognize the removal of the ETHICON VICRYL™ (Polyglactin 910) Violet Absorbable Suture may be disruptive to your facility and we apologize for any inconvenience this may cause.

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

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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ATTACHMENT 1: Product Identification Tool for ETHICON VICRYL™ (Polyglactin 910) Violet Absorbable Suture (Product Codes JV1036 and JV1038, Specific lots listed in TABLE A)

This tool will help customers identify the codes and lots of product subject to this action (removal) by using the package labels. This document applies to the Sales Unit Carton and Individual Foil Pouch for the product codes indicated in Table A of this letter.

SALES UNIT CARTON
(Containing Thirty-Six (36) VICRYL Sutures)

FRONT OF SALES UNIT CARTON



**Lot
Number**

**Product
Code**

FRONT OF SALES UNIT CARTON (WITH OVER-LABEL)



**Incorrect
Over-Label
(Italian)**

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COUNTRY SPECIFIC OVER-LABELS PLACED ON
FRONT SALES UNIT CARTON

(INCORRECT OVER-LABEL)

Sutura chirurgica non assorbibile
nera monofilamento
Distribuito da:
JOHNSON & JOHNSON MEDICAL S.p.A.
via del Mare, 56
00040 Pomezia - Roma - Italia

Sutura quirúrgica no absorbible
negro monofilamento
Distribuido por: JOHNSON & JOHNSON P.P.,S.A.
Paseo de las Doce Estrellas, 5-7
Campo de las Naciones
28042 Madrid

MBE01

(CORRECT OVER-LABEL)

Sutura chirurgica assorbibile
viola intrecciato
Distribuito da:
JOHNSON & JOHNSON MEDICAL S.p.A.
via del Mare, 56
00040 Pomezia - Roma - Italia

Sutura quirúrgica absorbible
violeta trenzado recubierto
Distribuido por: JOHNSON & JOHNSON P.P.,S.A.
Paseo de las Doce Estrellas, 5-7
Campo de las Naciones
28042 Madrid

MAA01

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FOIL POUCH
(Containing One (1) VICRYL Suture)

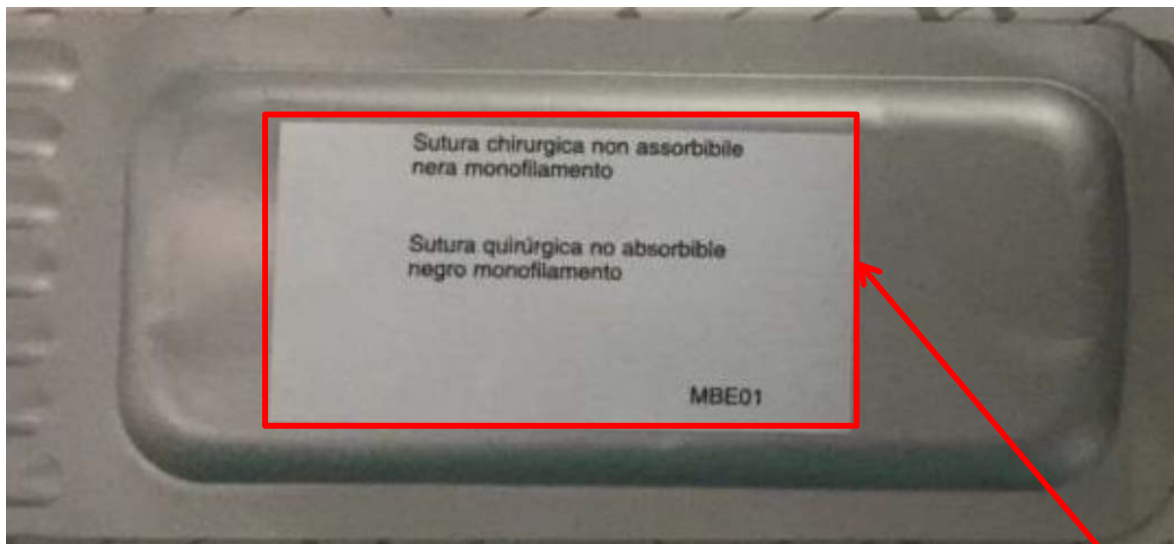
FRONT OF FOIL POUCH



**Lot
Number**

**Product
Code**

BACK OF FOIL POUCH (WITH OVER-LABEL)

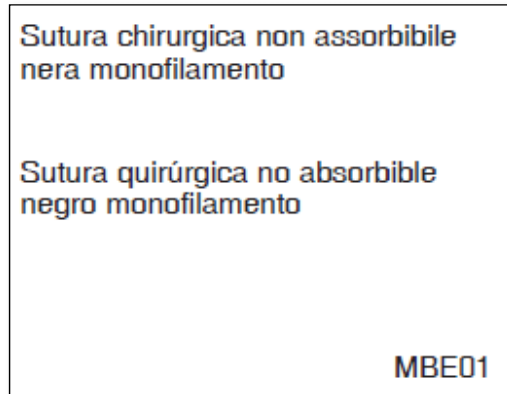


**Incorrect
Over-Label
(Italian)**

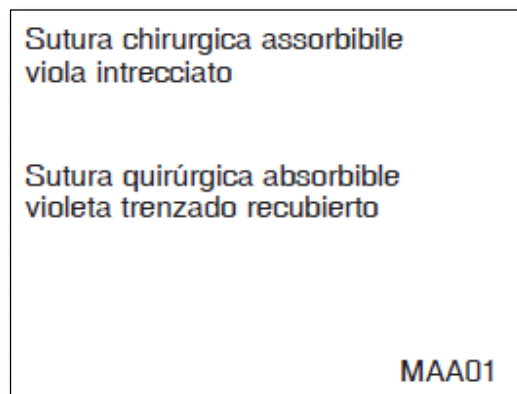
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COUNTRY SPECIFIC OVER-LABELS PLACED ON
BACK OF INDIVIDUAL FOIL POUCH

(INCORRECT OVERLABEL - FOIL POUCH)



(CORRECT OVERLABEL - FOIL POUCH)



ATTACHMENT 2: Business Reply Form (BRF)

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Your timely response to this action (removal) is requested. Please complete and fax this form to **[INSERT AFFILIATE NAME]** at **[INSERT FAX NUMBER]** or e-mail the form to **[INSERT EMAIL ADDRESS]** within **3 business days, even if you do not have product subject to this action (removal) to return.**

If you have product subject to this action (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** ETHICON VICRYL™ (Polyglactin 910) Violet Absorbable Suture product subject to this action (removal).
- We have ETHICON VICRYL™ (Polyglactin 910) Violet Absorbable Suture product subject to this action (removal) and are returning the following devices:

Device Name	Product Code	Product Lot	Quantity Returning (in “Eaches”)
ETHICON VICRYL™ (Polyglactin 910) Violet Absorbable Suture	JV1036	Refer to Table A above	
ETHICON VICRYL™ (Polyglactin 910) Violet Absorbable Suture	JV1038	Refer to Table A above	

[Account Name]
[Account Address]

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