

## **URGENT: FIELD NOTIFICATION**

### **ETHICON VICRYL RAPIDE™ SUTURE**

(Product Codes: VR493, VR496, VR917,)

### **ENDOLOOP® COATED VICRYL® SUTURE / ENDOLOOP® PDS® II SUTURE**

(Product Codes: EJ10C, EJ10G, EZ10C,)

October XX, 2017

Dear Distributor, Operating Room Supervisors, and Materials Management Personnel:

**PLEASE DISTRIBUTE THIS INFORMATION TO ALL STAFF WITHIN YOUR FACILITY WHO USE ETHICON VICRYL RAPIDE™ SUTURE, ENDOLOOP® Coated VICRYL® SUTURE, and ENDOLOOP® PDS® II 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 medical device correction (notification) of **certain lots** of VICRYL RAPIDE™ suture, ENDOLOOP® Coated VICRYL® suture, and ENDOLOOP® PDS® II suture. It was identified that the shipping label on the outside of the shipper box for some of these codes and lots may have been incorrect. The product labeling for the sales unit and device are correct. Ethicon is requesting that you review your receipts of this product beginning on June 1<sup>st</sup>, 2017 to ensure you received the correct codes and quantity of product you ordered.

**There is no product safety impact and Ethicon has not received any reports of Adverse Events related to this correction.**

**The scope of this correction includes the product codes of ETHICON VICRYL RAPIDE™ Suture, and ENDOLOOP® Coated VICRYL® suture, and ENDOLOOP® PDS® II suture listed below in Table A.**

**URGENT: FIELD NOTIFICATION**  
**ETHICON VICRYL RAPIDE™ SUTURE**  
**ENDOLOOP® Coated VICRYL®/ENDOLOOP® PDS® II SUTURE**  
**(Product Codes in Table A)**

**Table A – Product Subject to this Correction**

<b><u>PRODUCT NAME</u></b>	<b><u>PRODUCT CODES</u></b>	<b><u>PRODUCT LOTS</u></b>
VICRYL RAPIDE™ (Polyglactin 910) SUTURE	VR493	AH9976
VICRYL RAPIDE™ (Polyglactin 910) SUTURE	VR496	AJ1547
VICRYL RAPIDE™ (Polyglactin 910) SUTURE	VR917	AJ1905
ENDOLOOP Ligature made with Coated VICRYL	EJ10G	AJ1086,
ENDOLOOP Ligature made with PDS II	EZ10C	AH9632, AJ0320, AJ0420,
ENDOLOOP Ligature made with PDS II	EZ10G	AH8948, AH9102, AJ0049, AJ0749, AJ0750, AJ1192, AJ2006

**URGENT: FIELD NOTIFICATION**  
**ETHICON VICRYL RAPIDE™ SUTURE**  
**ENDOLOOP® Coated VICRYL®/ENDOLOOP® PDS® II SUTURE**  
**(Product Codes in Table A)**

**IDENTIFICATION OF PRODUCT SUBJECT TO THIS CORRECTION:**

Product subject to this correction in your inventory can be identified by product code and lot number (see Table A).

*The product code can be determined using the Product Identification Tool seen in Attachment 1*

**ACTION REQUIRED FOR CUSTOMERS:**

1. Ethicon is requesting that you review your receipts or examine your inventory of the product listed in Table A beginning on June 1st, 2017 to ensure you received the correct codes and quantity of product you ordered. Refer to Attachment 1 for the Product Identification Tool to identify the products that are subject to this correction by using package labels.
2. If the product you received was correct, please complete the Business Reply Form (Attachment 2) and fax or email it to **[INSERT AFFILIATE EMAIL ADDRESS]** or **[INSERT AFFILIATE FAX NUMBER]** within seven (7) to ten (10) business days. **Please return the BRF even if you do not have impacted product.**
3. If you have received an incorrect quantity or product codes, **please contact [INSERT AFFILIATE NAME] at [INSERT PHONE NUMBER] to correct your orders and receive an RGA (if returning product).** Also, please complete the Business Reply Form (Attachment 2) and fax or email it to **[INSERT AFFILIATE EMAIL ADDRESS]** or **[INSERT AFFILIATE FAX NUMBER]** within seven (7) to ten (10) business days.

**PLEASE RETURN THE BRF IF YOU HAVE OR DO NOT HAVE IMPACTED PRODUCT.**

**There is no product safety impact and Ethicon has not received any reports of Adverse Events related to this correction.**

If you have additional questions regarding this medical device correction (notification) 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 the FDA's MedWatch Adverse Event Reporting program online, by regular mail or by fax:

• Online: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)

• Regular Mail:

Use postage-paid FDA form 3500 available at: [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm)  
Mail to: MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787

• Fax: 1-800-FDA-01<sup>[HS1]</sup>

**URGENT: FIELD NOTIFICATION**  
**ETHICON VICRYL RAPIDE™ SUTURE**  
**ENDOLOOP® Coated VICRYL®/ENDOLOOP® PDS® II SUTURE**  
**(Product Codes in Table A)**

**ATTACHMENTS:**

Attachment 1: Product Identification Tool

Attachment 2: Business Reply Form (BRF)

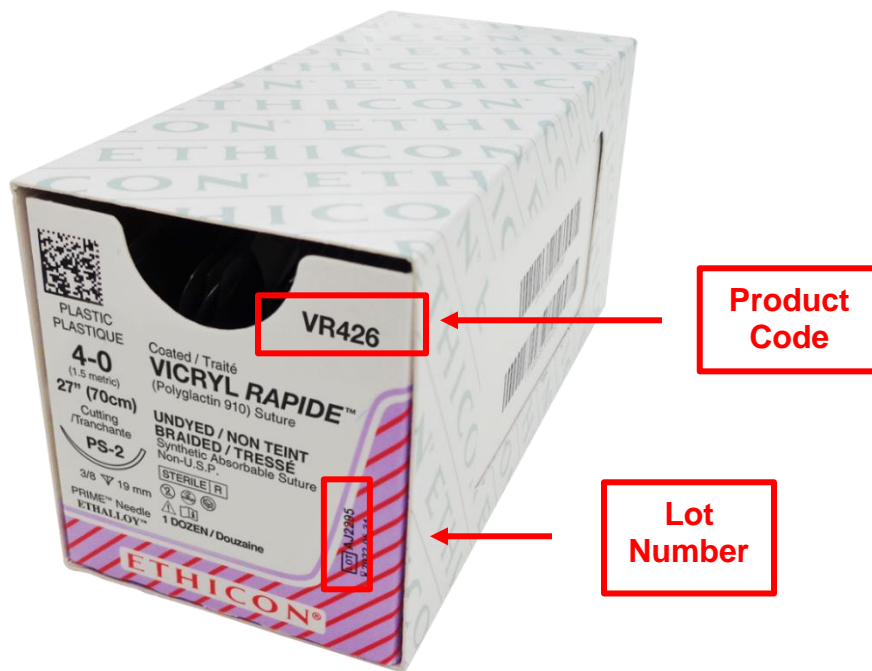
**URGENT: FIELD NOTIFICATION**  
**ETHICON VICRYL RAPIDE™ SUTURE**  
**ENDOLOOP® Coated VICRYL®/ENDOLOOP® PDS® II SUTURE**  
(Product Codes in Table A)

**ATTACHMENT 1: Product Identification Tool for ETHICON  
VICRYL RAPIDE™ SUTURE, ENDOLOOP® Coated VICRYL® SUTURE, and ENDOLOOP®  
PDS® II SUTURE**

This tool will help customers identify the products subject to this correction by using the packaging labels. This document applies to the Foil Pouch/Tyvek and Sales Unit Graphics for the product code identified in **Table A** of this correction letter.

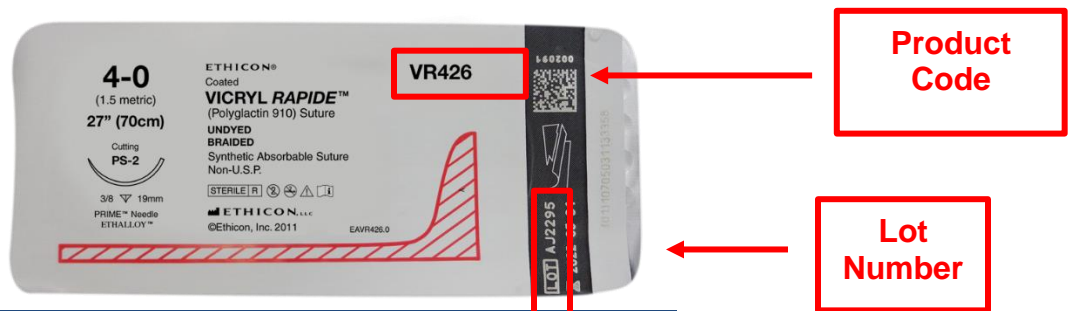
**VICRYL RAPIDE™ SUTURE SALES UNIT CARTON**

**FRONT of SALES UNIT CARTON**



**VICRYL RAPIDE™ SUTURE FOIL POUCH**

**FRONT of FOIL POUCH**



Medical Device Correction (Notification) of **ETHICON VICRYL RAPIDE™ Suture, ENDOLOOP® Coated VICRYL® SUTURE, and ENDOLOOP® PDS® II SUTURE**

**URGENT: FIELD NOTIFICATION**  
**ETHICON VICRYL RAPIDE™ SUTURE**  
**ENDOLOOP® Coated VICRYL®/ENDOLOOP® PDS® II SUTURE**  
(Product Codes in Table A)

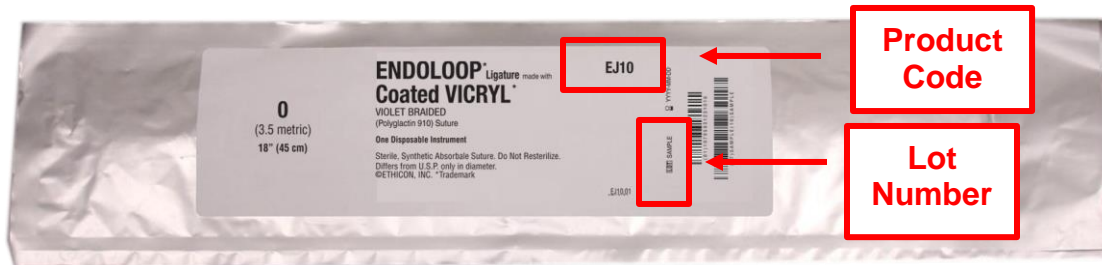
**ENDOLOOP® Coated VICRYL® SUTURE SALES UNIT CARTON**

**FRONT of SALES UNIT CARTON**



**ENDOLOOP® Coated VICRYL® SUTURE FOIL POUCH**

**FRONT of FOIL POUCH**



**URGENT: FIELD NOTIFICATION**  
**ETHICON VICRYL RAPIDE™ SUTURE**  
**ENDOLOOP® Coated VICRYL®/ENDOLOOP® PDS® II SUTURE**  
(Product Codes in Table A)

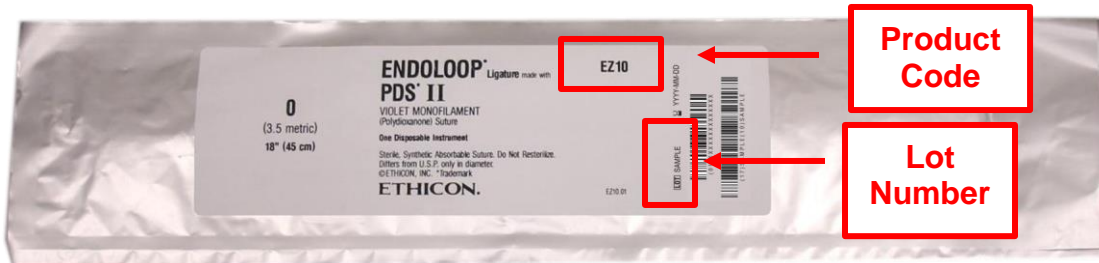
**ENDOLOOP® PDS® II SUTURE SALES UNIT CARTON**

**FRONT of SALES UNIT CARTON**



**ENDOLOOP® PDS® II SUTURE FOIL POUCH**

**FRONT of FOIL POUCH**



**URGENT: FIELD NOTIFICATION**  
**ETHICON VICRYL RAPIDE™ SUTURE**  
**ENDOLOOP® Coated VICRYL®/ENDOLOOP® PDS® II SUTURE**  
**(Product Codes in Table A)**

**ATTACHMENT 2: Business Reply Form (BRF)**

Your timely response to this customer notification is requested. Please complete this form and fax or email it to [INSERT AFFILIATE NAME] at [INSERT FAX NUMBER] or e-mail the form to [INSERT AFFILIATE EMAIL ADDRESS] **within 7-10 business days, even if you do not have product subject to this correction.**

**Please complete the following information:**

We hereby acknowledge receipt of this medical device correction letter from Ethicon regarding incorrect shipping label for VICRYL RAPIDE™ suture, ENDOLOOP® Coated VICRYL® suture, and ENDOLOOP® PDS® II suture (Product Codes listed in **Table A**). We have distributed this information to all staff within our facility that use the affected products and will maintain a copy of this notice with the identified product(s).

**Product Receipts – please check one:**

- We do not have any inventory of VICRYL RAPIDE™ suture, ENDOLOOP® Coated VICRYL® suture, and ENDOLOOP® PDS® II suture products (codes and lots listed in **Table A**) subject to this correction (notification), however we will maintain a copy of this notice within our facility.
- We have NO discrepancies in receipts for VICRYL RAPIDE™ suture, ENDOLOOP® Coated VICRYL® suture, and ENDOLOOP® PDS® II suture products (codes listed in **Table A**) subject to this correction (notification), however we will maintain a copy of this notice within our facility.
- We have discrepancies in receipts of VICRYL RAPIDE™ suture, ENDOLOOP® Coated VICRYL® suture, and ENDOLOOP® PDS® II suture products (codes listed in **Table A**) subject to this correction (notification). **We will contact [INSERT AFFILIATE NAME] at [INSERT PHONE NUMBER] to correct our orders and receive an RGA (if returning product).**

- **If you are returning product please record the RGA number:** \_\_\_\_\_

[Account Name]  
 [Account Address]

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