ETHICON

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

# URGENT: FIELD SAFETY NOTICE
# ETHICON VICRYL™ Suture Product Codes JV7549 & V549G

April 14, 2015

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

ETHICON has initiated a voluntary recall for select lots of **ETHICON VICRYL™ Suture Product Codes JV7549 and V549G** (size 9-0 (M0.3)). The sutures provided in these product codes are labeled to contain braided sutures however they may contain braided or monofilament sutures. This voluntary product recall is being executed because the use of a monofilament suture labeled as a braided suture could impact the tissue handling expectations, knot tying capabilities and tissue closure tension which may present a clinical risk.

## EFFECTIVE IMMEDIATELY – DO NOT USE PRODUCT CODES JV7549 and V549G WITH PRODUCT LOTS NOTED BELOW:

| Device Name | Product Code | Product Lot | Affected Expiry Date |
|---|---|---|---|
| ETHICON VICRYL™ Suture size 9-0 (M0.3) | JV7549 | HG5JBMN | June 2019 |
| | | HG5JBMN5 | June 2019 |
| | | HM5CGMN | December 2019 |
| | | | |
| ETHICON VICRYL ™ Suture size 9-0 (M0.3) | V549G | HM5BJLN | December 2019 |

Please see **Attachment A** for a Product Identification Tool to assist in identifying the impacted lots of product using package labels.

PLEASE NOTE: This recall involves only the specified lots listed above of ETHICON VICRYL™ Suture Product Codes JV7549 & V549G. No other product lots are affected.

The voluntary recall has been communicated to the European Competent Authorities in the countries affected by this product recall.

ETHICON has received no reports of adverse events associated with the recalled product.

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**Action Needed:**

1. Examine your inventory immediately to determine if you have recalled product on hand. **Remove and quarantine** the recalled product and communicate the issue to relevant operating room or materials management personnel or anyone else in your facility who needs to be informed.

2. If any product included in this recall has been forwarded to another facility, contact that facility to arrange return.

3. Complete the Business Reply Form (BRF) (**Attachment B**) confirming receipt of this notice within three (3) business days. The BRF may be sent to [enter local Affiliate or Sales Representatives Email Address, Fax number]. Please return the BRF **even if you do not have affected product.**

4. Keep this notice visibly posted for awareness with or near all product listed above until all such product has been returned to ETHICON. While processing your returns, please maintain a copy of this notice with the affected product and keep a copy for your records

5. Credit is available for customers who return affected product.

    - All affected product must be returned immediately. Any product returned after July 31, 2015 will not be eligible for credit.

    - To return affected product, photocopy the completed BRF, place it in the box with the product, and return the product to your Sales Representative.

6. For help to identify an alternative product code, please speak directly with your Sales Representative**.**

If you need clinical or product support, please contact your local Sales Representative or ETHICON.

As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported your Sales Representative, directly to ETHICON, or your National Health Authority.

If you have any further question related to this notice or if you need an additional communications letter, please contact your Sales Representative.

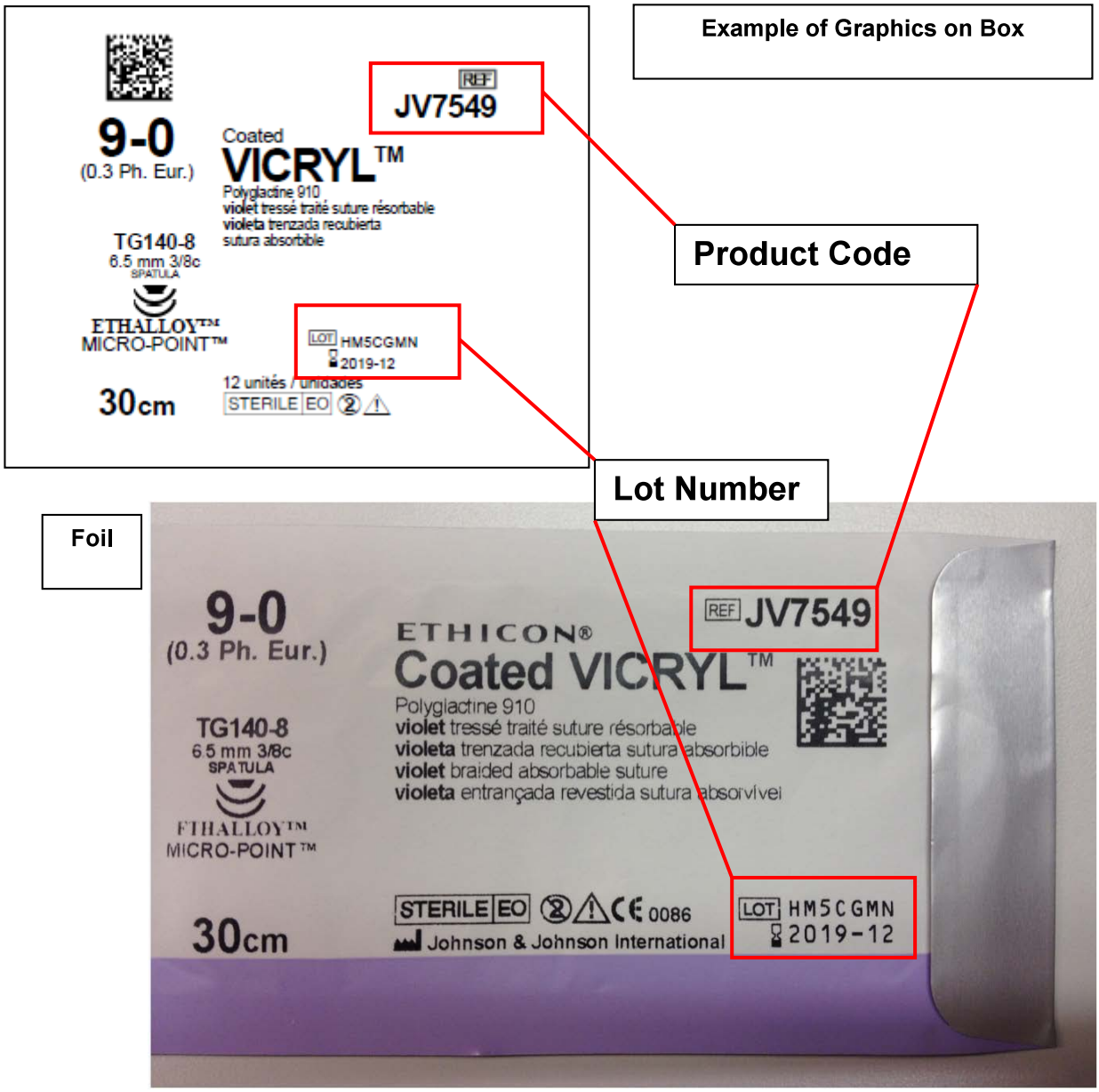
**Attachments:**
Attachment A: Product Identification Tool
Attachment B: Business Reply Form

# ATTACHMENT A: Product Identification Tool

## ETHICON VICRYL™ Suture Product Codes JV7549 & V549G

This tool will help customers identify the impacted lots of product using package labels. This document applies to the box labels and foil of the packaging for product codes JV7549 and V549G.

Product Code JV7549 is used as the example.



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# ETHICON VICRYL™ Suture Product Codes JV7549 & V549G

## ATTACHMENT B: Business Reply Form

Please confirm that you have received the FIELD SAFETY NOTICE regarding the product recall of **ETHICON VICRYL™ Suture Product Codes JV7549 and V549G** (size 9-0 (M0.3)). Your timely response to this notification is requested. Please complete and fax/e-mail this form to [Local Affiliate, Email Address, Fax number ] **within 3 business days, even if you do not have product to return.**

If you have ETHICON VICRYL™ Suture devices 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 affected ETHICON VICRYL™ Suture devices for return.**

☐ **We have affected ETHICON VICRYL™ Suture devices and are returning the following devices:**

| Device Name | Product Code | Product Lot | Quantity Returning |
|---|---|---|---|
| ETHICON VICRYL™ Suture size 9-0 (M0.3) | JV7549 | HG5JBMN | |
| | | HG5JBMN5 | |
| | | HM5CGMN | |
| | | | |
| ETHICON VICRYL™ Suture size 9-0 (M0.3) | V549G | HM5BJLN | |

| Facility Name: | Street Address: | City, Country, Postal Code: |
|---|---|---|
| | | |

| Print Name of Person Completing Business Reply Form: | Telephone Number: |
|---|---|
| Customer Number: | Date: |
| Signed*:<br>**Your signature provides confirmation that you have received and understood this notification* | |
| *Your comments are welcome.* | |