ETHICON

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

URGENT: MEDICAL DEVICE RECALL

ETHICON PERMA-HAND® Silk Suture

(also referred to as MERSILK™ Silk Suture)

(Product Code W584, Lot JCQ247)

January 23rd, 2017

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

PLEASE DISTRIBUTE THIS INFORMATION TO ALL STAFF WITHIN YOUR FACILITY WHO USE ETHICON PERMA-HAND® SILK SUTURE (MERSILK™).

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 medical device recall of one (1) lot of ETHICON PERMA-HAND® Silk Suture (also referred to as MERSILK™ Silk Suture) (Product Code W584, Lot JCQ247). Product from this lot was found to have an open sterile packaging seal which could compromise device sterility. While our Health Hazard Evaluation indicates that there is an extremely rare probability of adverse consequences 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 this lot of ETHICON PERMA-HAND® Silk Suture (MERSILK™) should continue to follow those patients in the usual manner.

This medical device recall has been communicated to the Medicines and Healthcare Products Regulatory Agency (MHRA).

The scope of this action includes one (1) lot of ETHICON PERMA-HAND® Silk Suture (MERSILK™) (Product Code W584, Lot JCQ247).

EFFECTIVE IMMEDIATELY – DO NOT USE OR DISTRIBUTE THE FOLLOWING PRODUCT CODE/LOT:

PRODUCT NAME	DESCRIPTION/SIZE	PRODUCT CODE	PRODUCT LOT
ETHICON PERMA-HAND® Silk Suture (also referred to as MERSILK™ Silk Suture)	Black Braided Silk Non-Absorbable Suture (2-0, CT, 40mm 1/2C, 75cm)	W584	JCQ247

URGENT: MEDICAL DEVICE REMOVAL

ETHICON PERMA-HAND® Silk Suture

(also referred to as MERSILK™ Silk Suture)
(Product Code W584, Lot JCQ247)

IDENTIFICATION OF PRODUCT SUBJECT TO THIS ACTION:

Product subject to the medical device recall in your inventory can be identified by product code and lot. Unused ETHICON PERMA-HAND® Silk Suture (MERSILK™) product from lot JCQ247 is subject to this action and is required to be returned. The product code and lot 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 action on hand and quarantine such product(s).

2. Remove the product subject to this medical device recall 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 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**.

5. Keep this notice visibly posted for awareness until all product subject to this recall 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 and keep a copy for your records.

6. Customers are required to return all unused ETHICON PERMA-HAND® Silk Suture (MERSILK™) products from lot JCQ247 that are in their inventory immediately. Only product subject to this recall returned by March 31, 2017 will be replaced.

7. To return product subject to this action, photocopy the completed BRF, place it in the box with the product, and affix the pre-paid authorized shipping label included with the medical device 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 of the ETHICON PERMA-HAND® Silk Suture (MERSILK™) may be disruptive to your facility and we apologize for any inconvenience this may cause.

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(Product Code W584, Lot JCQ247)

If you have additional questions regarding this action 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 directly to Ethicon following the standard complaint reporting process.

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

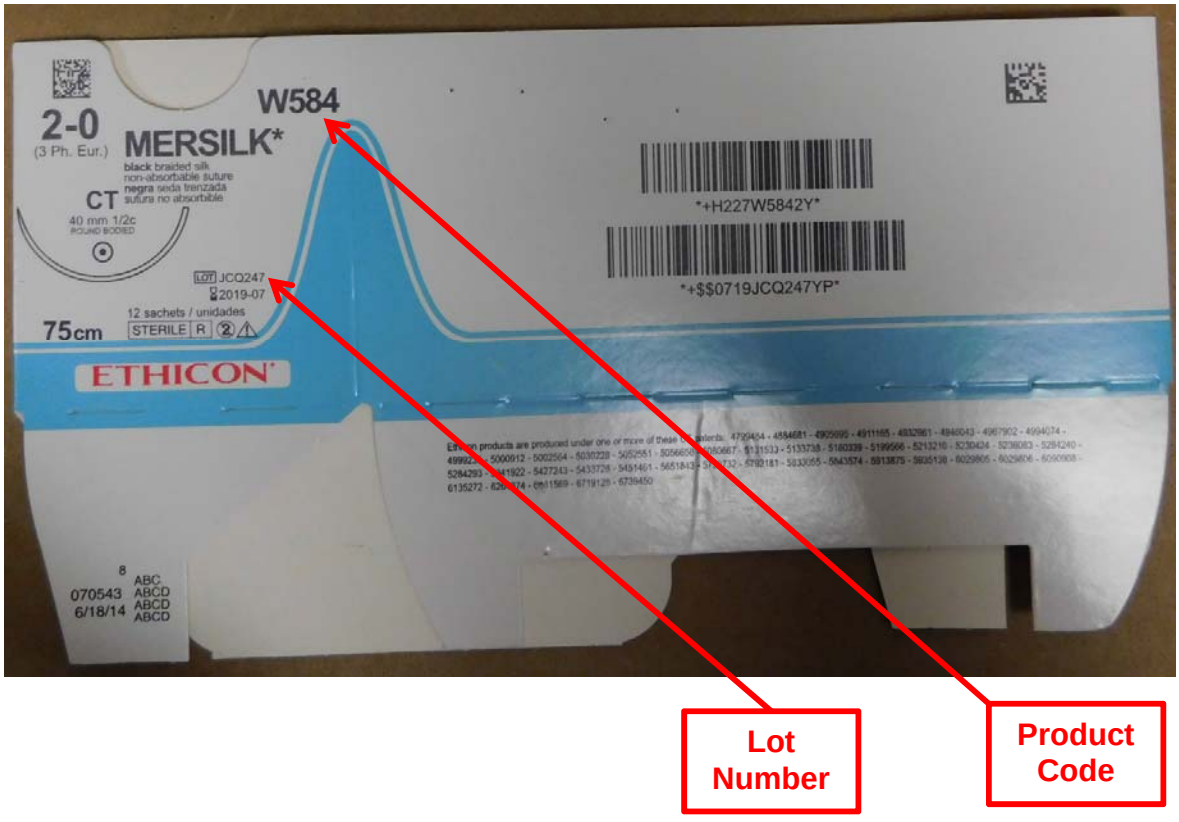
URGENT: MEDICAL DEVICE REMOVAL
ETHICON PERMA-HAND® Silk Suture
(also referred to as MERSILK™ Silk Suture)
(Product Code W584, Lot JCQ247)

ATTACHMENT 1: Product Identification Tool for ETHICON PERMA-HAND® Silk Suture (also referred to as MERSILK™) (Product Code W584, Lot JCQ247)

This tool will help customers identify the lots of product subject to this action by using the package labels. This document applies to the Sales Unit Carton and Tyvek Pouch for the product code identified on page 1 of this letter.

SALES UNIT CARTON
(Containing 12 MERSILK™ Silk Sutures)

Front and Side of Sales Unit Carton



URGENT: MEDICAL DEVICE REMOVAL

ETHICON PERMA-HAND® Silk Suture

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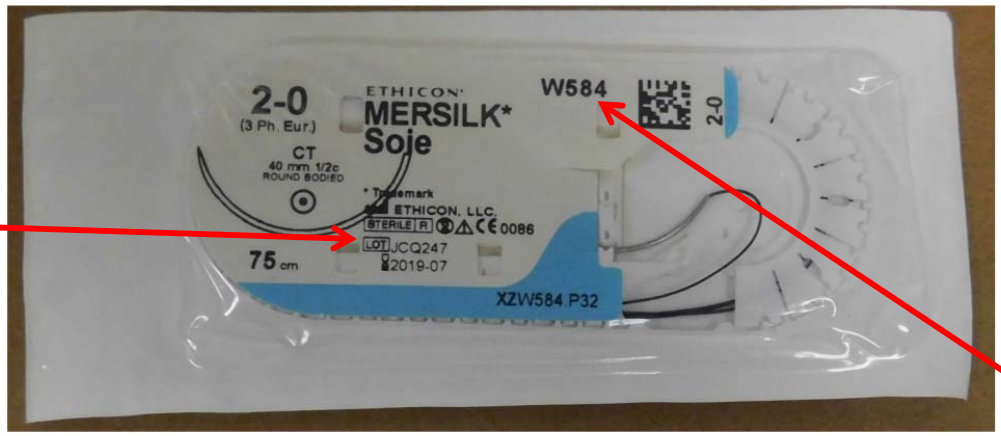
(Product Code W584, Lot JCQ247)

TYVEK POUCH (containing 1 Silk Suture)

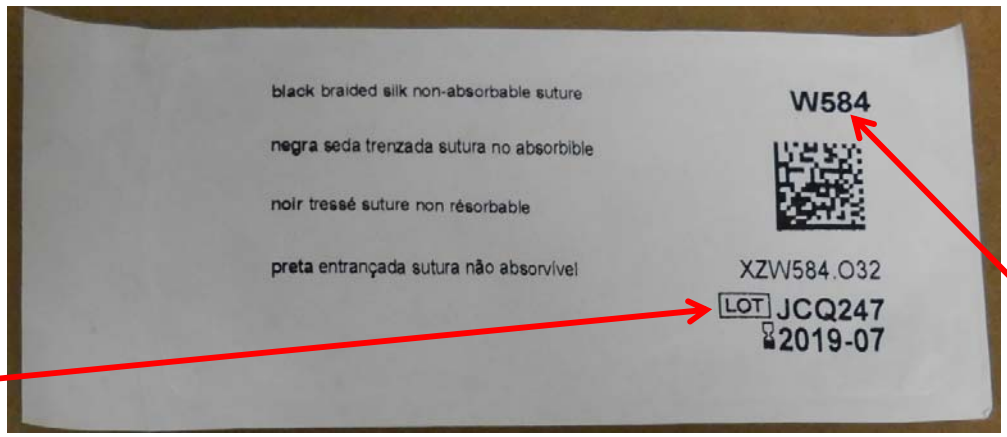
Front of Tyvek Pouch



Lot Number

Product Code

Back of Tyvek Pouch



Lot Number

Product Code

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(Product Code W584, Lot JCQ247)

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 EMAIL ADDRESS] **within 3 business days, even if you do not have product subject to this medical device recall to return.**

If you have product subject to this medical device recall 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 PERMA-HAND® Silk Suture (MERSILK™) product subject to this action.**

☐ **We have ETHICON PERMA-HAND® Silk Suture (MERSILK™) product subject to this action and are returning the following devices:**

Device Name	Product Code	Product Lot	Quantity Returning (in "Eaches")
ETHICON PERMA-HAND® Silk Suture (also referred to as MERSILK™ Silk Suture)	W584	JCQ247	

[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*: **Your signature provides confirmation that you have received and understood this notification*	
Your comments are welcome.	