

URGENT: FIELD NOTIFICATION
ETHICON ETHIBOND EXCEL™ SUTURE, Size 2-0
(Product Code: W10B77, Lot Number MBM232)

March 26, 2019

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

PLEASE DISTRIBUTE THIS INFORMATION TO ALL STAFF WITHIN YOUR FACILITY WHO USE ETHICON ETHIBOND EXCEL™ SUTURE, Size 2-0.

We have initiated a medical device correction (notification) regarding **one lot** of ETHIBOND EXCEL™ suture, size 2-0. We identified a small number of boxes within the impacted lot that may contain PROLENE™ sutures inside the sales unit carton. In this scenario, the impacted boxes containing the incorrect suture will have a blue package color on the sales unit carton instead of the typical orange color for ETHIBOND EXCEL™. The product labeling for the individual/primary Tyvek Pouch for PROLENE™ inside the ETHIBOND EXCEL™ packaging is correct. Ethicon is requesting that you review your inventory of this product to determine if you have received impacted product.

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

The scope of this correction includes one lot of ETHICON ETHIBOND EXCEL™ suture, size 2-0 listed in the below table.

Table 1 – Product Subject to this Correction

PRODUCT DESCRIPTION	PRODUCT CODE	PRODUCT LOT
2-0 ETHIBOND EXCEL Green/White 10X30 inch (75cm) Double Armed V-7 Needles with Firm Pledgets 6mmX3mmX1.5mm	W10B77	MBM232

IDENTIFICATION OF PRODUCT SUBJECT TO THIS CORRECTION:

Product subject to this correction in your inventory can be identified by using the Product Identification Tool (Attachment 1).

ACTION REQUIRED FOR CUSTOMERS:

1. Ethicon is requesting that you examine your inventory to determine if you may have impacted product. 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 any product subject to this action has been forwarded to another facility, contact that facility to make the facility aware of the notification.
3. Complete the Business Reply Form (BRF) (Attachment 2) confirming receipt of this notice and hand it to your Ethicon Sales Representative within three (3) business days. **Please return the BRF even if you do not have the product lots subject to this notification.**
4. If you have impacted product in inventory, please contact us and return the product to your Ethicon Sales Representative. In addition, a product complaint should be submitted via your Ethicon Sales Representative.

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

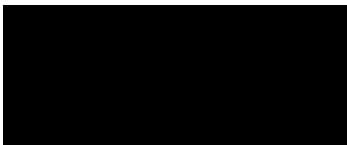
If you have additional questions regarding this medical device correction (notification), please contact your Ethicon Sales Representative.

Attachments:

Attachment 1: Product Identification Tool

Attachment 2: Business Reply Form

Yours sincerely,



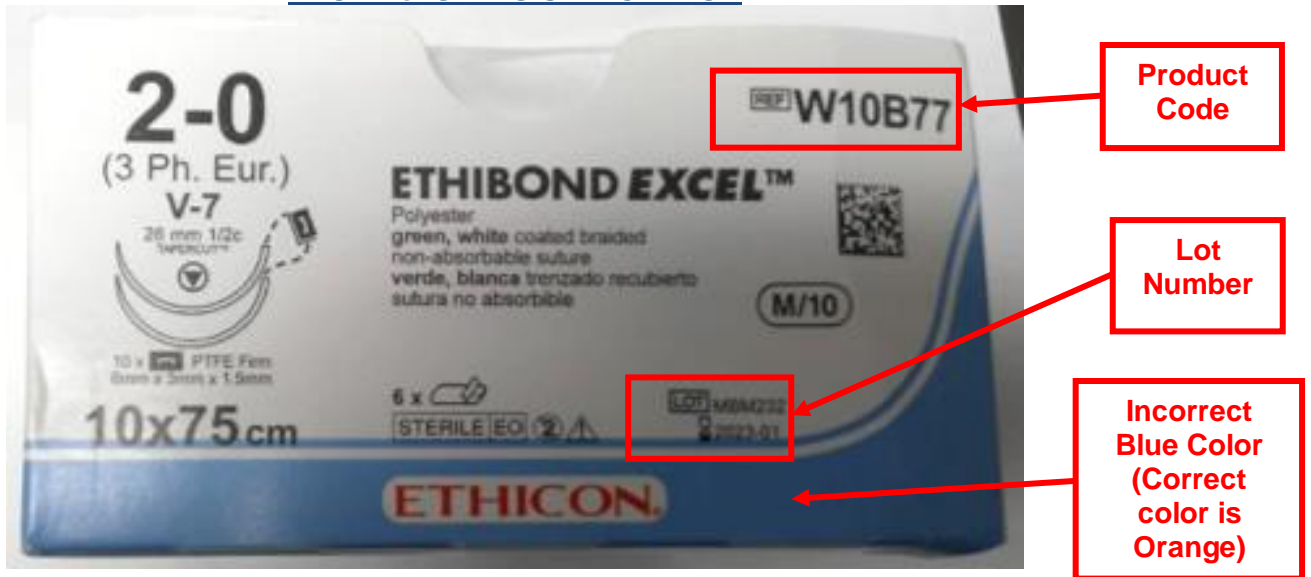
Lee Ching Hwee
Manager, Regulatory Affairs

cc: Chairman Medical Board
Relevant Head of Departments

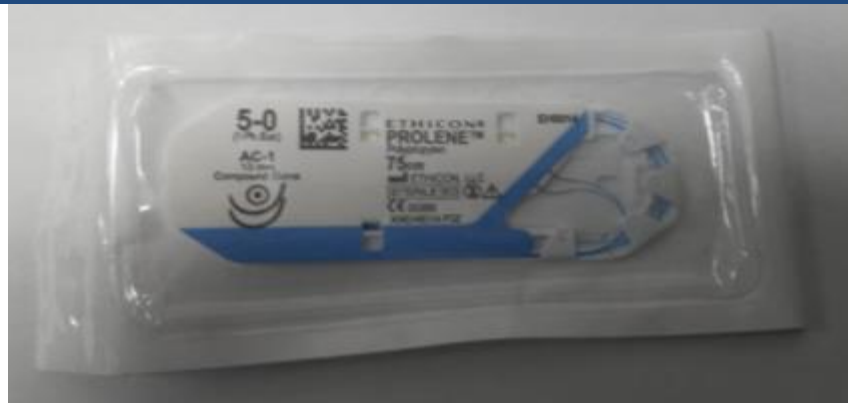
ATTACHMENT 1: Product Identification Tool for ETHICON ETHIBOND EXCEL™ SUTURE, Size 2-0

This tool will help customers identify the product subject to this correction by using the packaging labels. This document applies to the Sales Unit Carton and Tyvek Pouch graphics for the ETHIBOND EXCEL (Product Code W10B77, Lot MBM232) involved in this notification letter.

ETHIBOND EXCEL™ SUTURE SALES UNIT CARTON (INCORRECT LABEL COLOR) FRONT of SALES UNIT CARTON



INDIVIDUAL/PRIMARY TYVEK POUCH for PROLENE™ SUTURE, Size 5-0 INSIDE THE IMPACTED ETHIBOND EXCEL™ SALES UNIT (INCORRECT PRODUCT INSIDE BOX)



ATTACHMENT 2: Business Reply Form (BRF)

Your timely response to this customer notification is requested. Please complete this form and hand it to your Ethicon Sales Representative **within 3 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 ETHIBOND EXCEL™ suture (Product Code W10B77, Lot MBM232). 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 have NO impacted ETHIBOND EXCEL™ suture (Product Code W10B77, Lot MBM232) subject to this correction (notification), however we will maintain a copy of this notice within our facility.
- We have impacted ETHIBOND EXCEL™ suture (Product Code W10B77, Lot MBM232) subject to this correction (notification) and below are the quantities noted. We will return the product as noted above and submit a product complaint.

PRODUCT NAME	PRODUCT CODE	PRODUCT LOT	Quantity Returning (Boxes)
ETHIBOND EXCEL™ Polyester Suture, Size 2-0	W10B77	MBM232	

Print Name of Person Completing Business Reply Form:	Sign & Date:
Customer Account Details (Name and Address)	