

URGENT: MEDICAL DEVICE RECALL (REMOVAL)

ETHIBOND EXCEL® Polyester Suture
(Product Code X425H / Lot PBQ426)

May 22, 2019

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

Our records indicate that you have ordered or received the ETHIBOND EXCEL® Polyester Suture.
PLEASE DISTRIBUTE THIS INFORMATION TO ALL STAFF WITHIN YOUR FACILITY WHO USE ETHIBOND EXCEL Suture.

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

PRODUCT NAME	PRODUCT CODE	PRODUCT LOT	DESCRIPTION / SIZE
ETHIBOND EXCEL® Polyester Suture	X425H	PBQ426	ETHIBOND Green 75cm USP1 Single Armed CT-1

Ethicon has initiated a voluntary recall (removal) of one (1) lot of ETHIBOND EXCEL Suture, as listed in the table above. Ethicon has determined that there is a possibility that a suture raw material containing high endotoxin levels was used in the manufacturing of this lot. Based on the medical assessment, if high endotoxin values are present it has the potential to cause severe or life-threatening reaction in patients such as hypotension, septic shock, bleeding and Disseminated Intravascular Coagulation (DIC). While Ethicon's testing has shown no elevated levels of endotoxin, we are taking the precautionary measure of issuing this voluntary recall (removal) for the above listed product lot.

To date, Ethicon has not received any confirmed reports of adverse events associated with the issue that led to this recall (removal). Health care practitioners who have treated patients using affected ETHIBOND EXCEL Suture should closely follow those patients post-operatively.

Ethicon has initiated a corrective action to investigate this issue and implement actions to prevent the re-occurrence of the issue.

Refer to Attachment 1 for assistance in identifying the product lot subject to this recall (removal).

This voluntary medical device recall (removal) has been communicated to the U.S. Food and Drug Administration (FDA).

IDENTIFICATION OF PRODUCT SUBJECT TO THIS ACTION:

Product subject to the recall (removal) in your inventory can be identified by product code and lot number (see product code listing above). All unused ETHIBOND EXCEL® Polyester Suture product subject to this recall (removal) are required to be returned. The product code and lot number 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 voluntary recall and communicate the issue to relevant operating room or materials management personnel, or anyone else in your facility who needs to be informed.
3. If any product subject to this action has been forwarded to another facility, contact that facility to arrange return. Please consider including a copy of this recall (removal) letter when communicating.
4. 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 product subject to this recall (removal).**
5. Keep this notice visibly posted for awareness until all product subject to this recall has been returned to **your Ethicon sales representative**. While processing your returns, please maintain a copy of this notice with the product subject to this recall (removal) and keep a copy for your records.
6. Customers are required to return unused impacted ETHIBOND EXCEL Suture products that are in their inventory immediately. To receive replacement product, customers must return product subject to this recall by July 31, 2019. **Any non-affected product and any product returned after the date specified will not be replaced.**
7. To return product subject to this action, please contact your Ethicon sales representative.

If you require any assistance with returning product, please contact **your Ethicon sales representative**.

We recognize the recall of the ETHIBOND EXCEL Suture may be disruptive to your facility and we apologize for any inconvenience this may cause.

If you have additional questions regarding this action or to report any customer complaints, please contact your Ethicon sales representative.



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Attachments:

Attachment 1: Product Identification Tool

Attachment 2: Business Reply Form

Yours sincerely,



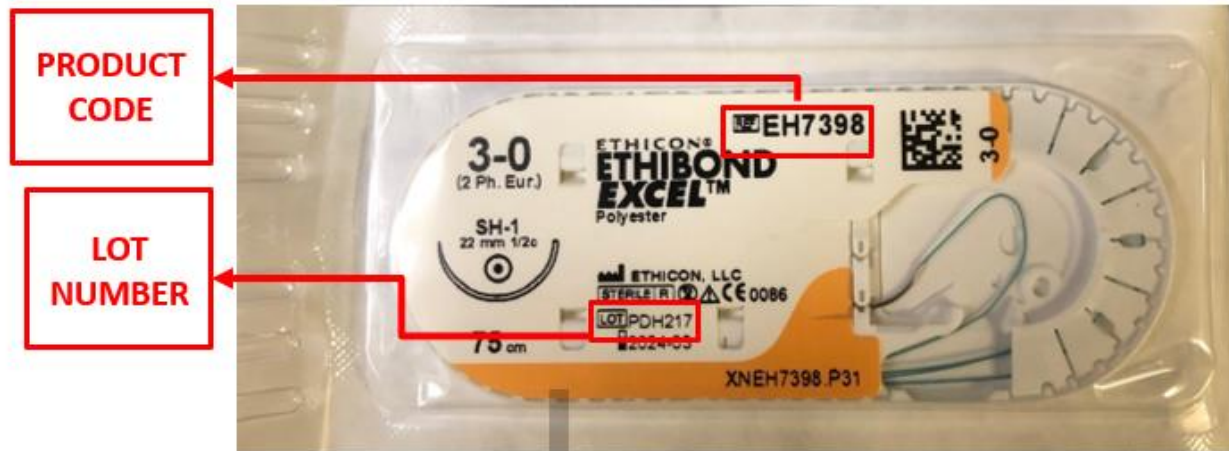
Lee Ching Hwee
Manager, Regulatory Affairs

cc: Chairman Medical Board
Relevant Head of Departments

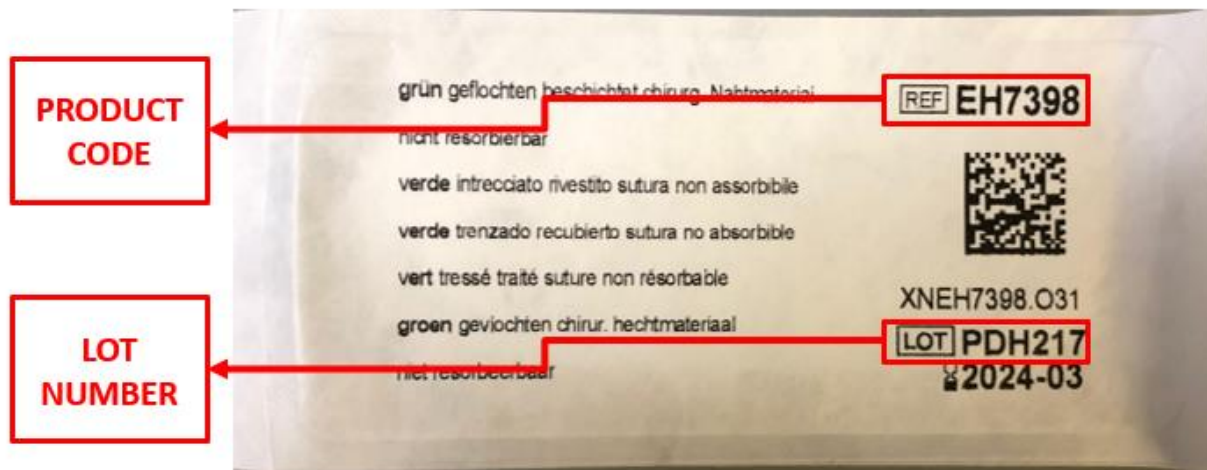
ATTACHMENT 1: Product Identification Tool for ETHIBOND EXCEL® Polyester Suture (Product Code X425H / Lot PBQ426)

This tool will help customers identify the lot of product subject to this action by using representative package labels. This document applies to the Tyvek® package and sales unit carton for Product Code X425H / Lot PBQ426.

Tyvek® Package (containing 1 DEVICE tray) FRONT of Tyvek Package



BACK of Tyvek Package



Sales Unit Carton (containing 36 DEVICE trays)
FRONT of Sales Unit Carton



BACK of Sales Unit Carton



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.**

If you have product lots subject to this recall (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 ETHIBOND EXCEL® Polyester Suture subject to this action.
☐ We have ETHIBOND EXCEL® Polyester Suture subject to this action and are returning the following products:

Device Name	Product Code	Lot Number	Quantity Returning (in “Eaches”)
ETHIBOND EXCEL® Polyester Suture	X425H	PBQ426	

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