

URGENT: FIELD SAFETY NOTICE

ETHIBOND EXCEL® Polyester Suture

(Product Code EH7674H, XNPE7055H, and XNPE868H / Lot PBQ686, PBQ875, PBQ876)

– Voluntary Product Recall (Removal) –

[Insert Date]

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 | EH7674H | PBQ686 | ETHIBOND EXCEL GREEN/ 30IN USP 1 (M4) |
| ETHIBOND EXCEL® Polyester Suture | XNPE7055H | PBQ875 | ETHIBOND EXCEL GREEN/ 75CM USP 1 (M4) |
| ETHIBOND EXCEL® Polyester Suture | XNPE868H | PBQ876 | ETHIBOND EXCEL GREEN/ 75CM USP 1 (M4) |

Ethicon has initiated a voluntary recall of three (3) lots of ETHIBOND EXCEL Suture as listed in the table above distributed in Austria, France, Germany, Italy, Latvia and Switzerland. Ethicon has determined that there is a possibility that a suture raw material containing high endotoxin levels was used in the manufacturing of these lots. Based on the medical assessment, if high endotoxin values are present it has the potential to cause a toxic effect in the patient, such as hypotension, septic shock, bleeding and Disseminated Intravascular Coagulation (DIC).

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

The root cause of the raw material endotoxin results has been investigated and additional controls have been implemented to prevent recurrence of the issue.

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

This voluntary medical device recall has been communicated to all impacted Health Authorities in EEA and Switzerland.

URGENT: MEDICAL DEVICE RECALL (REMOVAL)

ETHIBOND EXCEL® Polyester Suture – Voluntary Product Recall (Removal)

IDENTIFICATION OF PRODUCT SUBJECT TO THIS ACTION:

Product subject to the recall 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 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 letter when communicating.
4. Complete the Business Reply Form (BRF) (Attachment 2) confirming receipt of this notice and fax or email it to [Insert Affiliate Information] within three (3) business days. Please return the BRF even if you do not have product subject to this recall.
5. Follow instructions in the letter and immediately return any inventory of ETHIBOND EXCEL Suture products subject to this recall no later than May 31, 2020 to [Insert Affiliate Information].
6. Keep this notice visibly posted for awareness until all product subject to this recall has been returned. While processing your returns, please maintain a copy of this notice with the product subject to this recall and keep a copy for your records.
7. Customers are required to return unused **impacted ETHIBOND EXCEL Suture** products subject to this recall that are in their inventory immediately. To receive credit reimbursement, customers must return product subject to this recall no later than May 31, 2020. **Any non-affected product and any product returned after the date specified will not receive replacement.**

If you require any assistance with returning product, please contact [Insert Affiliate Information].

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

At Ethicon, our first priority is to our customers and their patients, and that includes the safe and effective use of our products. We recognize the recall of this product may be disruptive to your facility and we apologize for any inconvenience this may cause.

If you have additional questions regarding this recall, please contact [Insert Affiliate Information].

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

URGENT: MEDICAL DEVICE RECALL (REMOVAL)

ETHIBOND EXCEL[®] Polyester Suture – Voluntary Product Recall (Removal)

further questions related to this notice or if you need any additional communications, please contact your local Sales

Attachments:

Attachment 1: Product Identification Tool

Attachment 2: Business Reply Form

URGENT: MEDICAL DEVICE RECALL (REMOVAL)

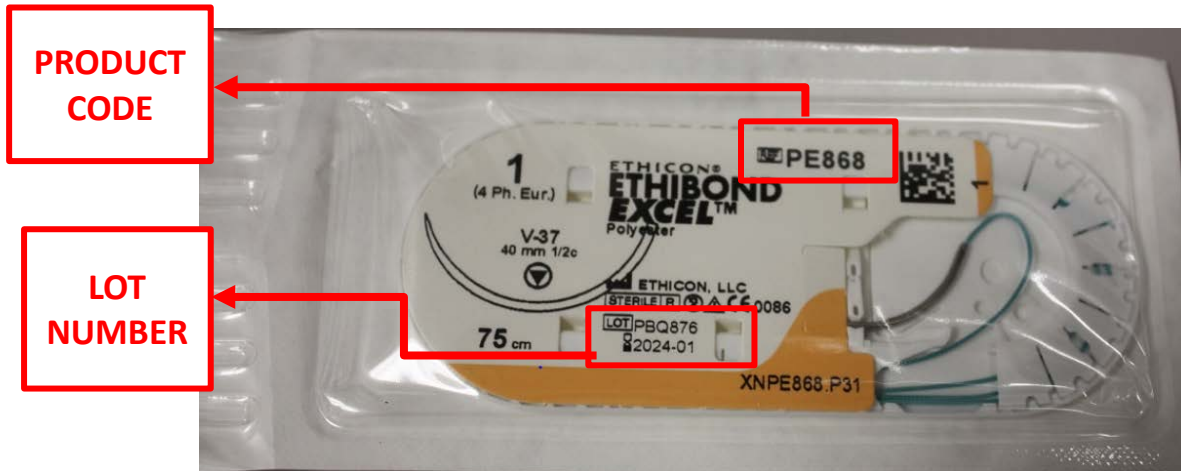
ETHIBOND EXCEL® Polyester Suture – Voluntary Product Recall (Removal)

ATTACHMENT 1: Product Identification Tool for ETHIBOND EXCEL® Polyester Suture

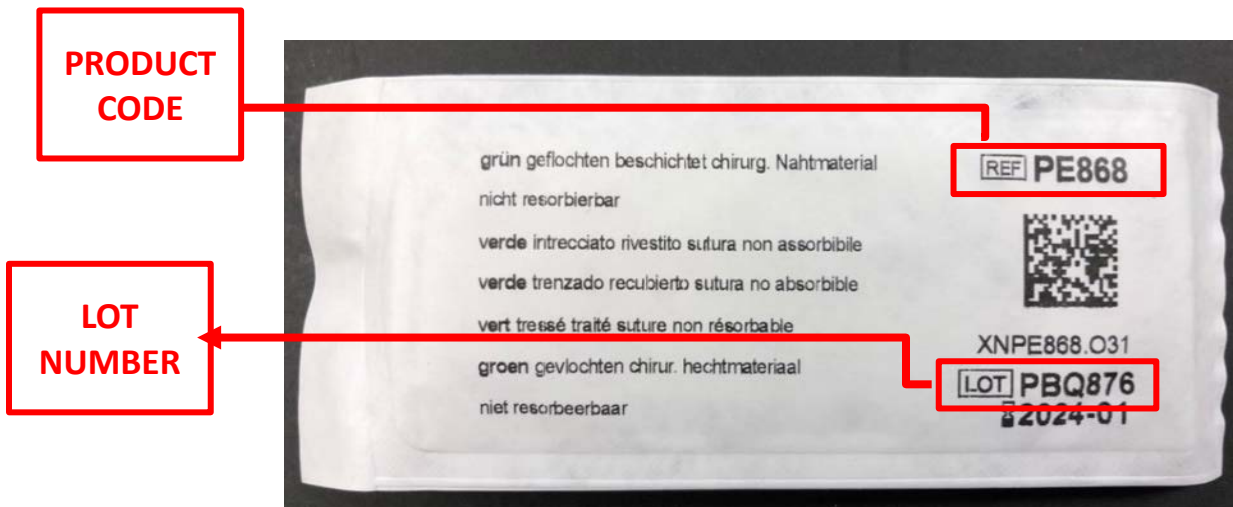
This tool will help customers identify the product code and lot of product subject to this action by using representative package labels.

Tyvek® Package (containing 1 DEVICE tray)

FRONT of Tyvek Package



BACK of Tyvek Package



URGENT: MEDICAL DEVICE RECALL (REMOVAL)

ETHIBOND EXCEL® Polyester Suture – Voluntary Product Recall (Removal)

Sales Unit Carton (containing 36 DEVICE trays)

FRONT of Sales Unit Carton



URGENT: MEDICAL DEVICE RECALL (REMOVAL)

ETHIBOND EXCEL® Polyester Suture – Voluntary Product Recall (Removal)

ATTACHMENT 2: Business Reply Form (BRF)

Your timely response to this customer notification is requested. Please complete and fax this form to [Insert Affiliate Information], within 3 business days, even if you do not have product subject to this recall to return.

If you have product subject to this 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 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 | EH7674H | PBQ686 | |
| ETHIBOND EXCEL® Polyester Suture | XNPE7055H | PBQ875 | |
| ETHIBOND EXCEL® Polyester Suture | XNPE868H | PBQ876 | |

[Account Name]

[Account Address]

| | |
|--|-------------------|
| Print Name of Person Completing Business Reply Form: | Telephone Number: |
| Account Number: (number used to order J&J product) | Date: |
| Replacement Product Shipping Address (If different from above): | |
| Signed*: | |
| <i>*Your signature provides confirmation that you have received and understood this notification</i> | |
| <i>Your comments are welcome.</i> | |