URGENT: MEDICAL DEVICE RECALL (REMOVAL)

VICRYL™ Plus Absorbable Surgical Suture (Code VCP311H, Lot KK6394)
ETHIBOND Excel Polyester Suture (Code X424H, Lot LPJ539)

April 29, 2019

Dear Customer:

At Ethicon, LLC. (hereinafter referred to as Ethicon) our first priority is to our customers and patients. We are committed to ensuring the safe and effective use of our products.

Ethicon is initiating a voluntary recall (removal) regarding the VICRYL™ Plus Absorbable Surgical Suture and ETHIBOND Excel Polyester Suture with the product code and lot number as listed in the following table. The event is isolated to one (1) lot of the VICRYL™ Plus Absorbable Surgical Suture and one (1) lot of ETHIBOND Excel Polyester Suture where the test results of suture diameter failed in the sampling test conducted by National Medical Products Administration

The product code and lot number subject to this recall (removal) are shown in the following table:

Product Name	Product Code	Lot Number
VICRYL™ Plus Absorbable Surgical Suture	VCP311H	KK6394
ETHIBOND Excel Polyester Suture	X424H	LPJ539

This medical device recall (removal) does NOT involve any other lots of VICRYL™ Plus Absorbable Surgical Suture or ETHIBOND Excel Polyester Suture or any other Ethicon sutures with the exception of the lots listed above.

While the suture diameter test results failed to meet the product registration standard, Ethicon has confirmed that the product subject to this recall (removal) does meet the Ethicon specification including suture diameter, therefore, no product performance or patient safety risk is expected to patients should the product be used according to Instruction For Use (IFU) indications. However, as a precaution, Ethicon has decided to voluntarily recall the VICRYL™ Plus Absorbable Surgical Suture and ETHIBOND Excel Polyester Suture with the code and lot number listed in the table above.

The product identification tool is shown in Attachment 1. This tool can be used to determine the product code and lot number on the product label, so as to help identify the product subject to this recall (removal).

Johnson & Johnson Medical Singapore
a division of Johnson & Johnson Pte Ltd.
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Business Reg No. 52836279L Company Reg No. 197402104W

We sincerely apologize for any inconvenience caused to you by this product recall (removal). We understand that you have high expectation for our products; so, we will devote every effort to maintaining your confidence in the quality of our products. In addition, we thank you for your cooperation and supports for this recall (removal) activity.

ACTION REQUIRED:

1. Please send this urgent medical device recall (removal) notification to everyone concerned in your organization.

2. Please examine and isolate the inventory as soon as possible and return to your Ethicon Sales Representative.

3. Please complete Attachment 2: Business Reply Form, according to the information provided therein, and return to your Ethicon Sales Representative, even if you have do not have product subject to this recall (removal) to return.

4. For the issue of returns and exchanges, please contact your Ethicon Sales Representative.

If you need clinical or product support, please contact your Ethicon sales representative.

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

Yours sincerely,

[redacted]

Lee Ching Hwee
Manager, Regulatory Affairs

cc: Chairman Medical Board
Relevant Head of Departments

ATTACHMENT 1: Product Identification Tool of VICRYL™ Plus Absorbable Surgical Suture and ETHIBOND Excel Polyester Non-absorbable Surgical Suture

This tool will help identify the products subject to this recall (removal) according to the packaging labels.

The sales unit carton and foil pouch of VICRYL™ Plus Absorbable Surgical Suture (Product Code: VCP311H, Lot: KK6394):

FRONT OF SALES UNIT CARTON

TOP OF FOIL POUCH

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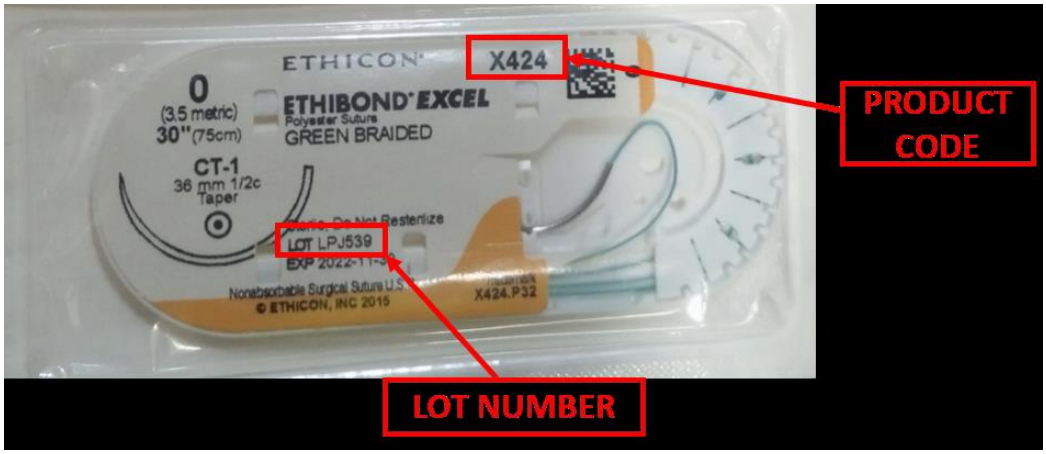
The sales unit carton and foil pouch of ETHIBOND Excel Polyester Non-absorbable Surgical Suture (Product Code: X424H, Lot: LPJ539).

FRONT OF SALES UNIT CARTON

TOP OF FOIL POUCH



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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 Surgical Suture subject to this recall (removal).

☐ We have the Surgical Suture subject to this recall (removal), and will return the following product to our supplier:

Product Code	Lot number	Quantity Returning (Eaches)
VCP311H	KK6394	
X424H	LPJ539	

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

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