

URGENT: MEDICAL DEVICE RECALL (REMOVAL)

VICRYL™ Plus Absorbable Surgical Suture
(Product Code VCP311H, Lot KK6377)

April 26, 2019

Dear Customer:

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.

Ethicon is initiating a voluntary recall (removal) regarding the VICRYL™ Plus Absorbable Surgical Suture with the product code and lot number as listed in Table 1. The event is isolated to one (1) lot of the VICRYL™ Plus Absorbable Surgical Suture where the test results of suture diameter failed in the sampling test conducted by Shanghai Xuhui Food And Drug Administration. The suture diameter test results failed to meet the company product registration standard 4.2.1 of YZB/USA 4743-2011 Absorbable Suture: VICRYL Plus.

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

Table 1: Absorbable surgical suture subject to this recall	
Product Code	Lot Number
VCP311H	KK6377

This medical device recall (removal) does NOT involve any other lots of VICRYL™ Plus Absorbable Surgical Suture with the exception of the lot listed above.

Ethicon has confirmed that the product subject to this recall (removal) meets 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 with the code and lot number listed in Table 1 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).

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.



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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.

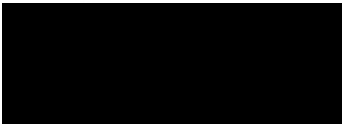
If you need clinical or product support, please contact your Ethicon sales representative.

Attachments:

Attachment 1: Product Identification Tool

Attachment 2: Business Reply Form

Yours sincerely,



Lee Ching Hwee
Manager, Regulatory Affairs

cc: Chairman Medical Board
Relevant Head of Departments

ATTACHMENT 1: Product Identification Tool for VICRYL™ Plus Absorbable Surgical Suture

This tool will help identify the products subject to this recall (removal) according to the packaging labels. This document applies to the sales unit carton and foil pouch of VICRYL™ Plus Absorbable Surgical Suture (Product Code: VCP311H, Lot: KK6377).

FRONT OF SALES UNIT CARTON



TOP OF FOIL POUCH



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** VICRYL™ Plus Absorbable Surgical Suture (Product Code VCP311H, Lot KK6377) subject to this recall (removal)
- ☐ We **have** the VICRYL™ Plus Absorbable Surgical Suture (Product Code VCP311H, Lot KK6377) subject to this recall (removal), and will return the following product to our supplier:

Product Code	Lot number	Quantity Returning (Eaches)
VCP311H	KK6377	

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