URGENT: MEDICAL DEVICE RECALL (REMOVAL)

PDS* Plus Antibacterial (Polydioxanone) Suture
(Specific Product Codes and Lots Below)

April 26, 2019

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

PLEASE DISTRIBUTE THIS INFORMATION TO ALL STAFF WITHIN YOUR FACILITY WHO USE PDS* PLUS ANTIBACTERIAL (POLYDIOXANONE) SUTURE (ONLY SPECIFIC LOTS FOR PRODUCT CODES PDP346H, PDP695H and PDPB346)

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.

EFFECTIVE IMMEDIATELY – DO NOT USE OR DISTRIBUTE THE FOLLOWING PRODUCT LOTS BELONGING TO PDS* PLUS ANTIBACTERIAL (POLYDIOXANONE) SUTURE (SPECIFIC PRODUCT CODES AND LOTS BELOW). REFER TO ACTION REQUIRED BELOW FOR FURTHER INSTRUCTIONS:

PRODUCT NAME	PRODUCT CODE	PRODUCT LOTS	DESCRIPTION / SIZE	PRODUCT EXPIRY DATE ON LABEL	CORRECT PRODUCT EXPIRY DATE
PDS* PLUS ANTIBACTERIAL (POLYDIOXANONE) SUTURE	PDP346H	LL6459	Size 0 PDS Plus Violet 36" Single Armed CT-1 Needle	9/30/2022	9/30/2019
	PDP695H	LL6590	Size 1 PDS PLUS Violet 27" Single Armed OS-4 Needle	9/30/2022	9/30/2019
	PDPB346	LMM273	Size 0 PDS Plus Violet 36" Single Armed CTB-1 Needle	10/31/2022	10/31/2019

Ethicon has initiated a medical device recall (removal) of three (3) lots of **PDS* PLUS ANTIBACTERIAL (POLYDIOXANONE) SUTURE** as listed in the table above. The three (3) lots were distributed with the incorrect expiry date on the label. The lots were labelled with an expiry date of five (5) years from date of manufacture instead of the correct expiry date of two (2) years from date of manufacture. Distribution of the subject product lots started on November 17, 2017.

We have identified the root cause of the labelling error and we have implemented immediate corrective

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actions to address the issue.

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

To date, Ethicon has not received any reports of adverse events associated with the issue that led to this recall (removal).

IDENTIFICATION OF PRODUCT LOTS SUBJECT TO THIS RECALL (REMOVAL):

Product lots subject to the recall (removal) in your inventory can be identified by product code and lot number (see product code and lot listing above). All unused PDS* PLUS ANTIBACTERIAL (POLYDIOXANONE) SUTURE product lots subject to this recall are required to be returned. The product codes and lot numbers can be determined by using the Product Identification Tool within Attachment 1.

ACTION REQUIRED:

1. Examine your inventory immediately to determine if you have product lots subject to this recall (removal) on hand and quarantine such product(s).

2. Remove the product lots subject to this recall (removal) and communicate the issue to relevant operating room or materials management personnel, or anyone else in your facility who needs to be informed. If any product lots subject to this recall (removal) have been forwarded to another facility, contact that facility to arrange return.

3. Complete the Business Reply Form (BRF) (Attachment 2) confirming receipt of this notice and return 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 recall (removal).**

4. Keep this notice visibly posted for awareness until all product lots subject to this recall (removal) have been returned to your Ethicon Sales Representative. While processing your returns, please maintain a copy of this notice with the product lots subject to this recall (removal) and keep a copy for your records.

5. Customers are required to return unused PDS* Plus Antibacterial (Polydioxanone) Suture product. lots subject to this recall (removal) that are in your inventory immediately. Only unused PDS* Plus Antibacterial (Polydioxanone) Suture product lots subject to this recall (removal) returned by April 13, 2018 will be credited to your account. Any unused PDS* Plus Antibacterial (Polydioxanone) Suture product lots subject to this recall (removal) returned after April 13, 2018 will not be eligible for credit.

6. To return unused PDS* Plus Antibacterial (Polydioxanone) Suture product lots subject to this recall (removal), photocopy the completed BRF, place it in the box with the subject product, and contact your Ethicon Sales Representative.

If you require any assistance with returning product lots subject to this recall (removal), please contact your Ethicon Sales Representative.

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We recognize the recall of the PDS* Plus Antibacterial (Polydioxanone) Suture may be disruptive to your facility and we apologize for any inconvenience this may cause.

If you have any questions regarding other alternative product(s) or if you need any product support, you can 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

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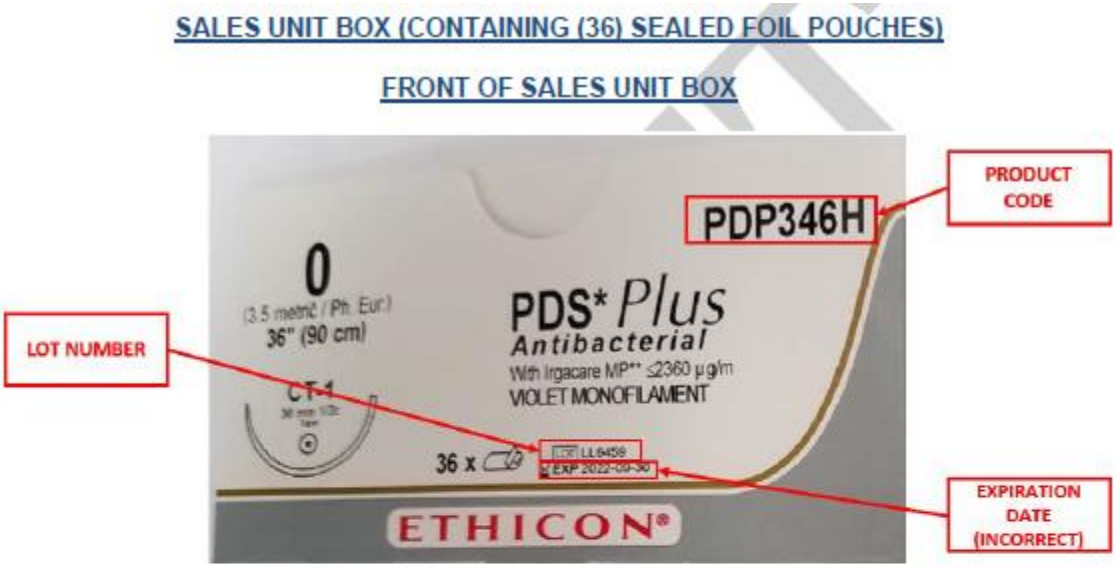
ATTACHMENT 1: Product Identification Tool for PDS* PLUS SUTURE (Specific Product Code(s) and Lot(s) Above)

This tool will help customers identify lots of PDS* Plus Antibacterial (Polydioxanone) Suture subject to this recall (removal) by using the package labels. This document applies to the sales unit box and foil pouch for product code PDP346H and lot number LL6459. Please refer to table above for a list of all product lots subject to this recall (removal).

SALES UNIT BOX (CONTAINING (36) SEALED FOIL POUCHES)

FRONT OF SALES UNIT BOX



FOIL POUCH (CONTAINING (1) PDS* PLUS SUTURE)

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 PDS* Plus Suture lots subject to this recall (removal).

☐ We have PDS* Plus Suture lots subject to this recall (removal) and are returning the following products:

PRODUCT NAME	PRODUCT CODE	LOT #	Quantity Returning (Eaches)
PDS* PLUS ANTIBACTERIAL (POLYDIOXANONE) SUTURE	PDP346H	LL6459	
	PDP695H	LL6590	
	PDPB346	LMM273	

* Each Sales Unit Box contains (36) eaches / foil pouches.

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

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