URGENT: MEDICAL DEVICE RECALL (REMOVAL)

DERMABOND™ PRINEO™ SKIN CLOSURE SYSTEM (22 CM)
(Product Code CLR222US / Specific Lots Below)

April 16, 2019

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

PLEASE DISTRIBUTE THIS INFORMATION TO ALL STAFF WITHIN YOUR FACILITY WHO USE DERMABONDTM PRINEOTM SKIN CLOSURE SYSTEM (22 CM) (PRODUCT CODE CLR222US)

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 DERMABOND™ PRINEO™ SKIN CLOSURE SYSTEM (22 CM) (PRODUCT CODE CLR222US):

PRODUCT NAME	PRODUCT CODE	DESCRIPTION / SIZE	PRODUCT LOTS		
DERMABOND™ PRINEO™ SKIN CLOSURE SYSTEM (22 CM)	CLR222US	Skin Closure System (2-Octyl Cyanoacrylate) 22cm x 4cm Mesh Patch / 1~3.8ml Adhesive Applicator	LEJ230	LGP814	LHH686
			LEJ246	LGR689	LHH784
			LEJ259	LGR710	LHP498
			LEJ368	LGR756	LHP599
			LGP375	LHH468	LHP602
			LGP605	LHH469	LHP868
			LGP606	LHH560	
			LGP675	LHH608	

Ethicon has initiated a medical device recall (removal) of SPECIFIC LOTS of DERMABOND™ PRINEO™ SKIN CLOSURE SYSTEM (22CM) (PRODUCT CODE CLR222US) ("DERMABOND™ PRINEO™ System") (Lot numbers listed in table above). Through post-market surveillance and investigation efforts, Ethicon discovered that specific lots of DERMABOND™ PRINEO™ System may not dry within the specified time after proper application, and thus may fall off. This issue has been identified in specific lots as listed in the table above. Product replacement will be made available per instructions outlined below.

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

Health care practitioners that have treated patients using DERMABOND™ PRINEO™ System, from the

specific lots listed in the table above, should continue to follow those patients in the usual manner.

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

Product lots subject to the recall in your inventory can be identified by product code and lot number (see product code listing above). All unused DERMABOND™ PRINEO™ System product lots subject to this recall are required to be returned. The product code and lot number 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.

3. If any product lots subject to this recall (removal) has been forwarded to another facility, contact that facility to arrange return.

4. 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).**

5. Keep this notice visibly posted for awareness until all product lots subject to this recall (removal) have been returned to Stericycle. 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.

6. Customers are required to return unused DERMABOND™ PRINEO™ System product lots subject to this recall (removal) that are in their inventory immediately. Only unused DERMABOND™ PRINEO™ product lots subject to this recall (removal) returned by February 28, 2018 will be eligible for replacement. Any product lots subject to this recall (removal) returned after February 28, 2018 will not be eligible for replacement.

7. To return product lots subject to this recall (removal), photocopy the completed BRF, place it in the box with the product, and 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 DERMABONDTM PRINEOTM System may be disruptive to your facility and we apologize for any inconvenience this may cause.

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Tel: +65 6918 8000
Business Reg No. 52836279L Company Reg No. 197402104W

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

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ATTACHMENT 1: Product Identification Tool for DERMABOND™ PRINEO™ System (Code CLR222US / Specific Lots Above)

This tool will help customers identify lots of DERMABOND™ PRINEO™ System subject to this recall (removal) by using the package labels. This document applies to the sales unit box and tyvek trays for Product Code CLR222US and Lot Number LGP606.

SALES UNIT BOX (CONTAINING (2) SEALED TYVEK TRAYS)

TOP OF SALES UNIT BOX

SIDE OF SALES UNIT BOX

Johnson & Johnson Medical Singapore
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2 Science Park Drive, #07-13, Ascent, Singapore Science Park 1, Singapore 118222
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TYVEK TRAYS (CONTAINING (1) ADHESIVE APPLICATOR & (1) MESH PATCH)

TOP OF TYVEK TRAY

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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 DERMABOND™ PRINEO™ lots subject to this recall (removal).

☐ We have DERMABOND™ PRINEO™ lots subject to this recall (removal) and are returning the following products:

PRODUCT NAME	PRODUCT CODE	LOT #	Quantity Returning (Eaches)	LOT #	Quantity Returning (Eaches)	LOT #	Quantity Returning (Eaches)
DERMABOND™ PRINEO™ SKIN CLOSURE SYSTEM (22 CM)	CLR222US	LEJ230		LGP814		LHH686	
		LEJ246		LGR689		LHH784	
		LEJ259		LGR710		LHP498	
		LEJ368		LGR756		LHP599	
		LGP375		LHH468		LHP602	
		LGP605		LHH469		LHP868	
		LGP606		LHH560			
		LGP675		LHH608			

*Each Sales Unit box includes two (2) eaches (One Tyvek Tray = One Each).

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

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