

URGENT: VOLUNTARY MEDICAL DEVICE RECALL (REMOVAL)

PROXIMATE® Hemorrhoidal Circular Stapler
(Specific Lots of Product Codes PPH01 & PPH03)

14 December 2018

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

Ethicon has initiated a voluntary recall (removal) of specific lots of **PROXIMATE® Hemorrhoidal Circular Stapler (PPH01 & PPH03)**, as listed in the following table. Ethicon has confirmed that some devices contained in these lots may have been assembled without a washer. **For that reason, we are issuing this voluntary recall for the following listed product lots.**

Our records indicate that you have ordered or received the PROXIMATE® Hemorrhoidal Circular Stapler. **PLEASE DISTRIBUTE THIS INFORMATION TO ALL STAFF WITHIN YOUR FACILITY WHO USE PROXIMATE® Hemorrhoidal Circular Stapler.**

EFFECTIVE IMMEDIATELY – DO NOT USE OR DISTRIBUTE THE FOLLOWING PRODUCT LOTS BELONGING TO PROXIMATE® Hemorrhoidal Circular Stapler (ONLY SPECIFIC LOTS BELOW). REFER TO ACTION REQUIRED FOR FURTHER INSTRUCTIONS:

Table 1 Impacted PROXIMATE® Hemorrhoidal Circular Stapler Details

PRODUCT NAME	PRODUCT CODE	PRODUCT LOTS		
PROXIMATE® HCS Hemorrhoidal Circular Stapler	PPH01	P9461W	P94K20	
PROXIMATE® PPH Hemorrhoidal Circular Stapler	PPH03	P93K95	P9420Y	P94A4T
		P93L1M	P9420Z	P94D3N
		P93M3G	P9441H	P94F3Z
		P93T35	P9450L	P94G04
		P93T7F	P9463J	P94H5F
		P93W3M	P94765	P94J4W
		P93W3N	P9487Z	P94J80
		P93Y58	P94901	P94K2A
		P94117	P94A20	R9200Z

The medical assessment concluded that this situation may potentially cause bleeding or soft tissue injury during use as the device may not fully cut when fired.



To date, Ethicon has not received any reports of adverse events associated with the issue that led to this recall. Health care practitioners who have treated patients using PROXIMATE® Hemorrhoidal Circular Stapler should follow those patients post-operatively in the usual manner with no additional action required.

We have identified the root cause and we have implemented immediate corrective actions to address the issue.

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

This voluntary medical device recall has been communicated to the Health Sciences Authority (HSA).

This recall does NOT affect any other lots for PROXIMATE® Hemorrhoidal Circular Stapler devices other than the lots shown above.

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 PROXIMATE® Hemorrhoidal Circular Stapler 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.
4. Complete the Business Reply Form (BRF) (Attachment 2) confirming receipt of this notice email it 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.**
5. Keep this notice visibly posted for awareness until all product subject to this recall has been returned to Stericycle. While processing your returns, please maintain a copy of this notice with the product subject to this action and keep a copy for your records.
6. Customers are required to return all PROXIMATE® Hemorrhoidal Circular Stapler products subject to this recall that are in their inventory immediately. To receive replacement product, customers must return product subject to this recall by **April 1, 2019**. Any unused PROXIMATE®

Hemorrhoidal Circular Stapler product lots subject to this recall returned after **April 1, 2019** will not be eligible for replacement.

If you require any assistance with returning product, please contact your Ethicon sales representative

We recognize the recall of the PROXIMATE® Hemorrhoidal Circular Stapler may be disruptive to your facility and we apologize for any inconvenience this may cause.

If you have additional questions regarding this recall or to report any customer complaints, 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 PROXIMATE® Hemorrhoidal Circular Stapler (Specific Lots listed above)

This tool will help customers identify product lots of PROXIMATE® Hemorrhoidal Circular Stapler subject to this recall by using the packaging labels. Please refer to table above for a list of all product lots subject to this recall.

SINGLE UNIT CARTON (CONTAINING (1) SEALED TYVEK TRAY)

FRONT OF SINGLE UNIT CARTON



PRODUCT CODE (SAME LOCATION FOR PPH01 & PPH03)

LABEL ON SINGLE UNIT CARTON



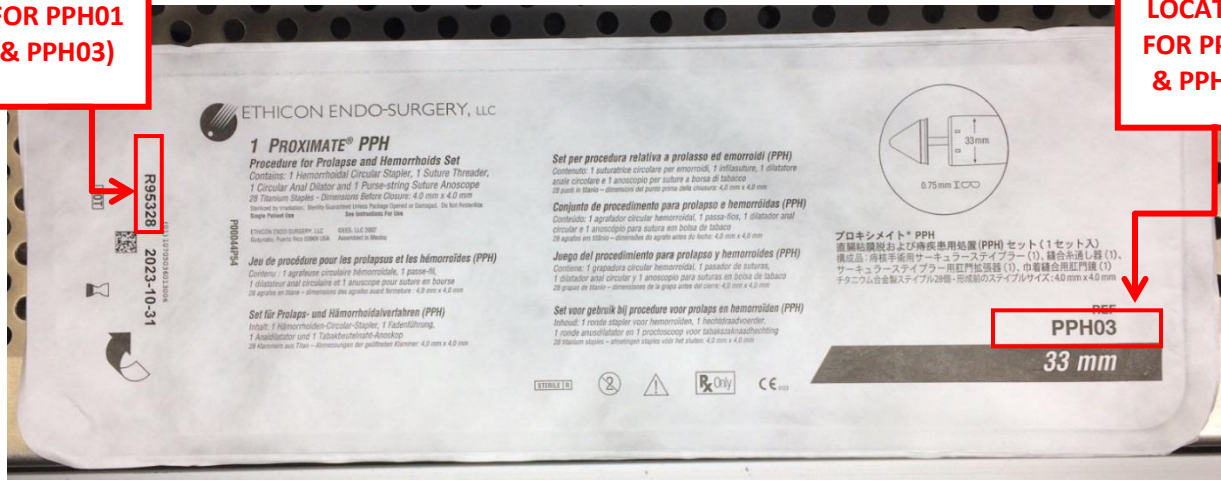
PRODUCT LOT

TYVEK TRAY (CONTAINING (1) PROXIMATE® Hemorrhoidal Circular Stapler)

TOP OF TYVEK TRAY

PRODUCT LOT (SAME LOCATION FOR PPH01 & PPH03)

PRODUCT CODE (SAME LOCATION FOR PPH01 & PPH03)



ATTACHMENT 2: Business Reply Form (BRF)

Your timely response to this customer notification is requested. Please complete and hand this form to your Ethicon sales representative **within 3 business days, even if you do not have the 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 PROXIMATE® Hemorrhoidal Circular Stapler subject to this recall.
- We have PROXIMATE® Hemorrhoidal Circular Stapler lots subject to this action and are returning the following products:

PRODUCT CODE: PPH01		PRODUCT CODE: PPH03	
LOT #	Quantity Returning (Eaches) ¹	LOT #	Quantity Returning (Eaches) ¹

¹Note: Each Sales Unit Box contains (3) eaches / devices.

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