ETHICON

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

# URGENT: FIELD SAFETY NOTICE

## PROXIMATE® Hemorrhoidal Circular Stapler
## (Specific Lots of Product Codes PPH01 & PPH03) – Voluntary Product Recall

DATE

Dear Customers:

**PLEASE DISTRIBUTE THIS INFORMATION TO ALL STAFF WITHIN YOUR FACILITY WHO USE PROXIMATE® Hemorrhoidal Circular Stapler**

At Ethicon Endo-Surgery, LLC ("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 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 |

# URGENT: FIELD SAFETY NOTICE

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## **(Specific Lots of PPH01 & PPH03)** – Voluntary Product Recall

Ethicon has initiated a voluntary recall (removal) of specific lots of **PROXIMATE® Hemorrhoidal Circular Stapler (PPH01 & PPH03)**, as listed in the table above. 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 above listed product lots.**

The medical assessment concluded that this situation may potentially cause bleeding or soft tissue injury 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 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 and fax or email it to [Insert Affiliate Information] 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 [Insert Affiliate Information]. 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 affected lots of PROXIMATE® Hemorrhoidal Circular Stapler products that are in their inventory immediately. To receive replacement product, customers must return product subject to this recall by **April 1, 2019** and place a replacement order. Any unused PROXIMATE® Hemorrhoidal Circular Stapler product lots subject to this recall returned after **April 1, 2019** will not be eligible for replacement.

7. To return unused PROXIMATE® Hemorrhoidal Circular Stapler product lots subject to this action, photocopy the completed BRF, place it in the box with the product, and affix the pre-paid authorized shipping label included with the recall notification letter. Ethicon will pay for the shipping charges only if the authorized label is used. Extra shipping labels may be obtained by calling [Insert Affiliate Information]**.** Your account number and mailing address have been pre-populated on the BRF.

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 action or to report any customer complaints, please contact [Insert Affiliate Information].

As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported to your Sales Representative, directly to Ethicon, or your National Health Authority. If you have any further questions related to this notice or if you need any additional communications, please contact your local Sales Representative.

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

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PROXIMATE® Hemorrhoidal Circular Stapler

**(Specific Lots of PPH01 & PPH03)** – Voluntary Product Recall

## 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

**LABEL ON SINGLE UNIT CARTON**


PRODUCT LOT

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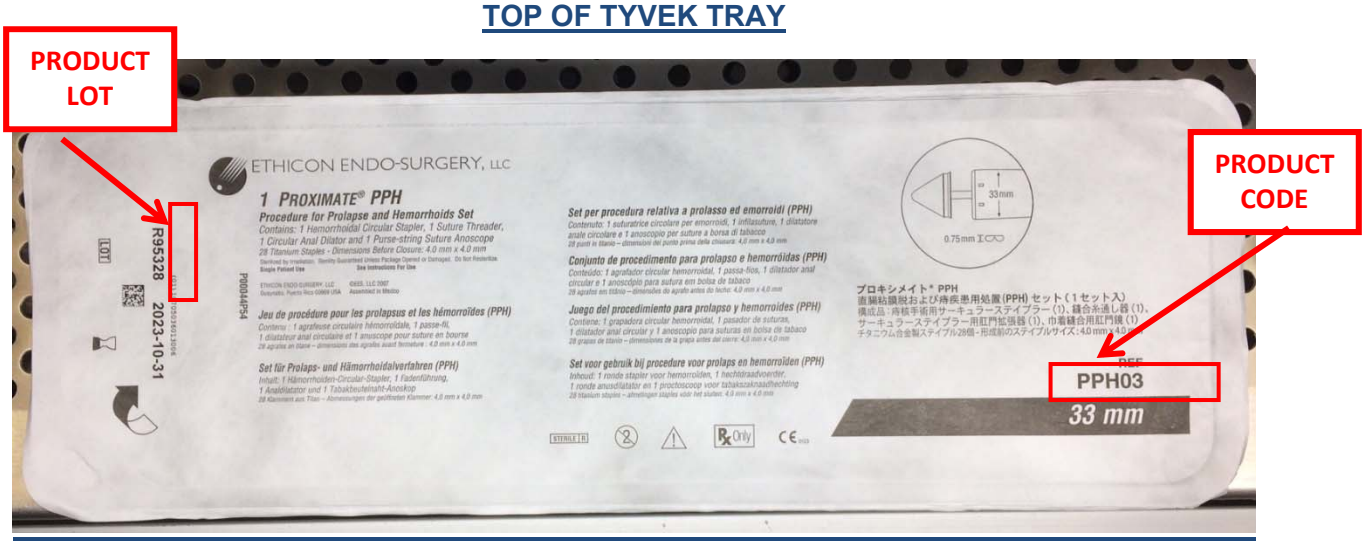
## TYVEK TRAY (CONTAINING (1) PROXIMATE® Hemorrhoidal Circular Stapler)

### 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 and fax this form to [Insert Affiliate Information], [INSERT FAX NUMBER] or e-mail the form to [INSERT AFFILIATE EMAIL ADDRESS] **within 3 business days, even if you do not have 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 NAME | PRODUCT CODE | LOT # | Quantity Returning (Eaches) [1] |
|---|---|---|---|
| PROXIMATE® Hemorrhoidal Circular Stapler | PPH01 | | |
| | PPH03 | | |

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

[Account Name]
[Account Address]

| | |
|---|---|
| Print Name of Person Completing Business Reply Form: | Telephone Number: |
| Account Number:<br>(number used to order J&J product) | Date: |
| Replacement Product Shipping Address (If different from above): | |
| Signed*:<br><br>*Your signature provides confirmation that you have received and understood this notification | |
| *Your comments are welcome.* | |