Ethicon Endo-Surgery

# URGENT FIELD SAFETY NOTICE

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| **ATTENTION** | **Customer - Operating Room Director and Materials Management** |
| **TYPE OF ACTION** | URGENT DEVICE RECALL |
| **REF / DATE** | PPH-2012-08 / 02-August-2012 |
| **PRODUCT** | Ethicon Endo-Surgery has initiated a voluntary global recall for specific production lots of<br>• PROXIMATE® PPH Procedure for Prolapse and Hemorrhoids Set Product Code: PPH03<br>• PROXIMATE® HCS Procedure for Prolapse and Hemorrhoids (PPH) Set Product Code: PPH01 |
| **DEVICE DETAILS** | The recall involves the following product codes and lot numbers identified in Attachment A<br>**PPH03** — PROXIMATE® PPH Procedure for Prolapse and Hemorrhoids Set<br>**PPH01** — PROXIMATE® HCS Procedure for Prolapse and Hemorrhoids (PPH) Set<br>See Attachment A for detailed descriptions of the affected lot numbers. See Attachment B for images to help identify affected products. |
| **REASON** | Ethicon Endo-Surgery has initiated a voluntary global recall for specific production lots of<br>• PROXIMATE® PPH Procedure for Prolapse and Hemorrhoids Set Product Code: PPH03<br>• PROXIMATE® HCS Procedure for Prolapse and Hemorrhoids (PPH) Set Product Code: PPH01<br>due to difficulty firing the device which may result in incomplete firing stroke that may result in an incomplete staple formation. We are working to implement actions to resume production. |
| **ACTION** | We need your help in ensuring that **all affected products** are located, accounted for, and returned to [Affiliate Name].<br>**EFFECTIVE IMMEDIATELY – DO NOT USE THIS PRODUCT**<br>1) Examine your inventory immediately to determine if you have affected product on hand and **remove** the affected product.<br>2) Fill out the Business Reply Form and return it back to [Affiliate Name] within 3 business days, **even if you do not have affected product.** If you have product to be returned, keep a copy of this form for your records.<br>3) To return affected product, enclose a copy of the Business Reply Form with the product, and use the pre-paid shipping label to return to:<br>[Affiliate Name / Affiliate Address]<br>**Your Sales Representative is available to provide assistance in the completion of this voluntary recall if you should request help**. |
| **TRANSMISSION** | Please share this information with all of the appropriate staff at your facility and any other organization where the product has been transferred. |

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| **CONTACT** | Ethicon Endo-Surgery is dedicated to ensuring we implement this voluntary global recall as quickly and effectively as possible.<br><br>[Affiliate Name] will process your product return and issue a credit/replacement upon return of the product and the Business Reply Form.<br><br>If you have additional questions about this action, please contact your Sales Representative or call [Affiliate Name].<br><br>We apologize for any inconvenience this will cause you, but rest assured it is our utmost intent to make this process as easy for you as possible. |
| **CONFIRMATION** | This action has been notified to the appropriate Regulatory Agencies. |