

# URGENT FIELD SAFETY NOTICE

<b>ATTENTION</b>	Operating Room Director and Materials Management																																												
<b>TYPE OF ACTION</b>	URGENT DEVICE RECALL																																												
<b>REF / DATE</b>	PRR35/PXR35-2014-08 / 26-Aug-2014																																												
<b>PRODUCT</b>	Ethicon Endo-Surgery, LLC (Ethicon) is initiating a global voluntary recall for:  <b>PROXIMATE® RH Rotating Head Skin Stapler, PRR35</b> <b>PROXIMATE® Fixed Head Skin Stapler, PXR35</b>																																												
<b>DEVICE DETAILS</b>	<p>The recall involves following products:</p> <p>Product Code: <b>PRR35</b>                  Full Device Name:  <b>PROXIMATE® RH Rotating Head Skin Stapler (35 Regular)</b>                  Contains 35 Stainless Steel Staples - Approximate Closed Dimensions: 5.7 mm x 3.9 mm</p> <p>Product Code: <b>PXR35</b>                  Full Device Name:  <b>PROXIMATE® Fixed Head Skin Stapler (35 Regular)</b>                  Contains 35 Stainless Steel Staples - Approximate Closed Dimensions: 5.7 mm x 3.9 mm</p>																																												
<b>REASON</b>	The global voluntary recall will be initiated because the device may have a non-conforming component that may cause the device to fire an unformed staple.																																												
<b>ACTION</b>	<p>We need your help in ensuring that <b>all affected products</b> are located, accounted for, and returned to [Affiliate Name].</p> <p><b>EFFECTIVE IMMEDIATELY – DO NOT USE PRODUCT CODES PRR35 and PXR35 WITH PRODUCT LOTS NOTED BELOW:</b></p> <table border="1"> <thead> <tr> <th>Device Name</th> <th>Product Code</th> <th>Product Lot</th> <th>Affected Expiration Date</th> </tr> </thead> <tbody> <tr> <td rowspan="6">PROXIMATE® RH Rotating Head Skin Stapler</td> <td rowspan="6">PRR35</td> <td>L4EG3F</td> <td>3/31/2019</td> </tr> <tr> <td>L4EK3Y</td> <td>3/31/2019</td> </tr> <tr> <td>L4EP22</td> <td>4/30/2019</td> </tr> <tr> <td>L4ER1D</td> <td>5/31/2019</td> </tr> <tr> <td>L4ER9X</td> <td>5/31/2019</td> </tr> <tr> <td>L4EU87</td> <td>5/31/2019</td> </tr> <tr> <td rowspan="10">PROXIMATE® Fixed Head Skin Stapler</td> <td rowspan="10">PXR35</td> <td>L4EG2T</td> <td>3/31/2019</td> </tr> <tr> <td>L4EH20</td> <td>3/31/2019</td> </tr> <tr> <td>L4EH85</td> <td>3/31/2019</td> </tr> <tr> <td>L4EK50</td> <td>3/31/2019</td> </tr> <tr> <td>L4EN94</td> <td>4/30/2019</td> </tr> <tr> <td>L4EP2F</td> <td>4/30/2019</td> </tr> <tr> <td>L4EP6G</td> <td>5/31/2019</td> </tr> <tr> <td>L4ER1L</td> <td>5/31/2019</td> </tr> <tr> <td>L4EU0J</td> <td>5/31/2019</td> </tr> <tr> <td>L4EN58</td> <td>4/30/2019</td> </tr> <tr> <td>L4EV07</td> <td>5/31/2019</td> </tr> </tbody> </table> <p><u>Please note: This recall involves only the specified lots listed above of PROXIMATE® RH Rotating Head Skin Stapler and PROXIMATE® Fixed Head Skin Stapler. No other product lots are affected.</u></p>			Device Name	Product Code	Product Lot	Affected Expiration Date	PROXIMATE® RH Rotating Head Skin Stapler	PRR35	L4EG3F	3/31/2019	L4EK3Y	3/31/2019	L4EP22	4/30/2019	L4ER1D	5/31/2019	L4ER9X	5/31/2019	L4EU87	5/31/2019	PROXIMATE® Fixed Head Skin Stapler	PXR35	L4EG2T	3/31/2019	L4EH20	3/31/2019	L4EH85	3/31/2019	L4EK50	3/31/2019	L4EN94	4/30/2019	L4EP2F	4/30/2019	L4EP6G	5/31/2019	L4ER1L	5/31/2019	L4EU0J	5/31/2019	L4EN58	4/30/2019	L4EV07	5/31/2019
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	<p>1) Examine your inventory immediately to determine if you have affected product on hand and <b>remove</b> the affected product.</p> <p>2) Fill out the Business Reply Form and return it back to <b>[Affiliate Name]</b> within 3 business days, <b>even if you do not have affected product</b>. If you have product to be returned, keep a copy of this form for your records.</p> <p>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:</p> <p style="padding-left: 40px;"><b>[Affiliate Name / Affiliate Address]</b></p> <p><b>Your Sales Representative is available to provide assistance in the completion of this voluntary recall if you should request help.</b></p>
<p><b>TRANS-MISSION</b></p>	<p>Please share this information with all of the appropriate staff at your facility and any other organization where the product has been transferred.</p>
<p><b>CONTACT</b></p>	<p><b>[Affiliate Name]</b> will process your product return and issue a credit/replacement upon return of the product and the Business Reply Form.</p> <p>If you have additional questions about this action, please contact your Sales Representative or call <b>[Affiliate Name]</b>.</p> <p>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.</p>
<p><b>CONFIRM-ATION</b></p>	<p>The Field Safety Action is being conducted with the full knowledge of the U.S. Food and Drug Administration (FDA) and appropriate EMEA Regulatory Authorities.</p>

<b>ETHICON</b> <small>Member of Johnson &amp; Johnson Family of Companies</small>	<b>Business Reply Form</b>	<b>REF: PRR35/PXR35-2014-08</b>
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Your timely response to this recall notification is requested. Please fill out and mail or fax this form to [Local Affiliate Address and Fax number] within 3 business days **even if you do not have product to return**. If you have affected product 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 affected PROXIMATE® Skin Staplers
- We have affected PROXIMATE® Skin Staplers and are returning the following devices:

Device Name	Product Code	Product Lot	Quantity Returning (Number in "batches")
PROXIMATE® RH Rotating Head Skin Stapler	PRR35	L4EG3F	
		L4EK3Y	
		L4EP22	
		L4ER1D	
		L4ER9X	
		L4EU87	
PROXIMATE® Fixed Head Skin Stapler	PXR35	L4EG2T	
		L4EH20	
		L4EH85	
		L4EK50	
		L4EN94	
		L4EP2F	
		L4EP6G	
		L4ER1L	
		L4EU0J	
		L4EN58	
L4EV07			

\_\_\_\_\_  
Name/Signature/Date

\_\_\_\_\_  
Facility Name

\_\_\_\_\_  
Customer Number