ETHICON
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

URGENT FIELD SAFETY NOTICE

ATTENTION	**Operating Room Director and Materials Management**
TYPE OF ACTION	**URGENT DEVICE RECALL**
REF / DATE	PRR35/PXR35-2014-08 / 26-Aug-2014
PRODUCT	Ethicon Endo-Surgery, LLC (Ethicon) is initiating a global voluntary recall for: **PROXIMATE® RH Rotating Head Skin Stapler, PRR35** **PROXIMATE® Fixed Head Skin Stapler, PXR35**
DEVICE DETAILS	The recall involves following products: Product Code: **PRR35** Full Device Name: **PROXIMATE® RH Rotating Head Skin Stapler (35 Regular)** Contains 35 Stainless Steel Staples - Approximate Closed Dimensions: 5.7 mm x 3.9 mm Product Code: **PXR35** Full Device Name: **PROXIMATE® Fixed Head Skin Stapler (35 Regular)** Contains 35 Stainless Steel Staples - Approximate Closed Dimensions: 5.7 mm x 3.9 mm
REASON	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.
ACTION	We need your help in ensuring that **all affected products** are located, accounted for, and returned to [Affiliate Name]. **EFFECTIVE IMMEDIATELY – DO NOT USE PRODUCT CODES PRR35 and PXR35 WITH PRODUCT LOTS NOTED BELOW:**

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

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.

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	1) Examine your inventory immediately to determine if you have affected product on hand and **remove** the affected product. 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. 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: [Affiliate Name / Affiliate Address] **Your Sales Representative is available to provide assistance in the completion of this voluntary recall if you should request help**.
TRANS-MISSION	Please share this information with all of the appropriate staff at your facility and any other organization where the product has been transferred.
CONTACT	[Affiliate Name] will process your product return and issue a credit/replacement upon return of the product and the Business Reply Form. If you have additional questions about this action, please contact your Sales Representative or call [Affiliate Name]. 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.
CONFIRM-ATION	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.