Ethicon Endo-Surgery

URGENT FIELD SAFETY NOTICE

ATTENTION	**Operating Room Director and Materials Management**
TYPE OF ACTION	**URGENT DEVICE RECALL**
REF / DATE	PSX-2012-10 / 17-October-2012
PRODUCT	Ethicon Endo-Surgery has initiated a global voluntary recall for **all** PSX Proximate® Skin Staple Extractor.
DEVICE DETAILS	The recall involves the following product code **PSX** — Proximate® Skin Staple Extractor Expiration date September 2012 – August 2017 See Attachment A for images to help identify affected products
REASON	Ethicon Endo-Surgery initiated a voluntary global recall for all PSX Proximate® Skin Staple Extractor because the possibility exists that damage to the packaging may have compromised the sterility of the device. Ethicon Endo-Surgery has received no customer complaints related to this issue and no reports of adverse events associated with the recalled product. The issue was detected internally during the packaging process.
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 EES PSX Proximate® Skin Staple Extractors PRODUCT CODE, PSX.** 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**.
TRANSMISSION	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 Card. 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.
CONFIRMATION	The Field Safety Action is being conducted with the full knowledge of the U.S. Food and Drug Administration (FDA) and EU National Competent Authorities