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 us. **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 Jaakko Järvenpää, fax 0046 8 626 22 96, e-mail: jjarvenp@its.jnj.com within 3 business days, **even if you do not have the affected product.** If you have products to be returned, keep a copy of this form for your records. 3) To return the affected product, please contact our local customer service (see contact information below). With the return, please include a copy of your Business Reply Form. **Norway** Phone: 667 747 04 Fax: 669 817 77 e-mail: cservno@its.jnj.com **Denmark** Phone: 45 94 82 04 Fax: 45 94 82 12 e-mail: cservdk@its.jnj.com **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	We will process your product return and issue a credit 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 Johan Thorén 0046 8 626 53 84. 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