

Ethicon Endo-Surgery (Europe) GmbH, Weseler Str. 42, 48249 Dülmen, Germany

[Addressee's Name] [Business Name] [Street Address] [City, State Zip Code] [Country]

Your Ref.:

Our Ref.: LT300-2012-06 Date: 13 June 2012

Direct Line: +49 2590 9167-0 Direct Fax: +49 2590 9167-11 Email: eescomplaintemea@its.jnj.com

Notice of Counterfeit LIGACLIP® EXTRA LIGATING CLIP CARTRIDGES

Dear Healthcare Professional:

Ethicon Endo-Surgery (EES) recently became aware of the distribution of **counterfeit LIGACLIP® EXTRA LIGATING CLIP CARTRIDGES (Product Code LT300)**. Because EES did not manufacture these products, we cannot confirm the performance, mechanical properties, biocompatibility or sterility of these clips. We are informing you so you can take preventive action to help ensure patient safety.

All healthcare professionals should carefully examine all LIGACLIP® products before use. Information in Attachment A can help you determine if the product you have is counterfeit.

Please convey this information to your staff and any others who use **LIGACLIP®** products in the operating room so they will be able to identify the characteristics of a suspected counterfeit product.

If you receive any product that you suspect is counterfeit, do not use it. Quarantine the product to ensure it will not be used. Contact your local EES representative, as EES may be able to determine if the product is authentic. If it is determined to be counterfeit, please contact your national competent authority.

The counterfeit product was discovered as a result of an investigation by EES. It was purchased in the United States from an unauthorized distributor. We are working closely with the FDA to investigate this matter and to help prevent further distribution of counterfeit product. As a precaution, we are also notifying appropriate legal and health authorities worldwide.

EES takes measures to help ensure the integrity of the products we provide through our supply chain by selling directly to customers or through authorized distributors. <u>EES</u> <u>strongly discourages the purchase of products from unauthorized distributors</u> and will not warrant or assume liability for any products purchased from unauthorized distributors.

Regional Office Europe, Middle East, Africa

Ethicon Endo-Surgery (Europe) GmbH Hummelsbütteler Steindamm 71

22851 Norderstedt Germany

Telefon: +49 (0)40 5297-3200 Telefax: +49 (0)40 5297-3119

Bank: Deutsche Bank AG Konto 096 335 6 100 BLZ 200 700 00

Sitz der Gesellschaft: Norderstedt Eingetragen beim Amtsgericht Kiel Handelsregister HRB 3098 NO VAT No. DE 118 643 874

Geschäftsführerin: Karen Puck



To identify authorized distributors contact your local JnJ Customer Support Center. If you have purchased EES products from another source, you should verify the origin of that product by contacting the distributor directly.

Yours sincerely,

Peter Schroeer EES Authorized Representative Director EMEA Quality Systems & Regulatory Affairs Tel.: +49 2590 9167-0 Fax.: +49 2590 9167-11 Mobile: +49 172 53 222 88 E-mail: pschroee@its.jnj.com

Attachment A

Regional Office

Europe, Middle East, Africa

Ethicon Endo-Surgery (Europe) GmbH Hummelsbütteler Steindamm 71 22851 Norderstedt Germany

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