



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.:

Date:

LT300-2012-06

13 July 2012

Direct Line:

+49 2590 9167-0

Direct Fax:

+49 2590 9167-11

Email:

eescomplaintemea@its.jnj.com

Regional Office
Europe, Middle East, Africa

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

Notice of **Counterfeit** LIGACLIP® EXTRA LIGATING CLIP CARTRIDGES

Dear Healthcare Professional:

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

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.

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

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.

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

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.

Geschäftsführerin:
Karen Puck

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. EES strongly discourages the purchase of products from unauthorized distributors and will not warrant or assume liability for any products purchased from unauthorized distributors.



**Ethicon
Endo-Surgery**

PART OF THE JOHNSON-JOHNSON FAMILY OF COMPANIES

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

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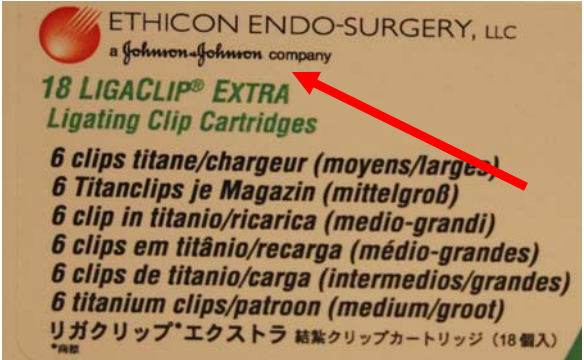

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ATTACHMENT A – Identifying Counterfeit Product

All healthcare professionals should carefully examine all LIGACLIP® Products before use. The following detail can help you determine if the product you have is counterfeit:

Features of the <u>Counterfeit</u> Product	Features of <u>Authentic</u> LIGACLIP® Clips
<p>1. Sales unit box is shrinkwrapped.</p> <p>2. An unusual font on the sales unit box distorts our company name. (See below.)</p>  <p>3. Individual clip package misspells “STERILE” as “STEMIKE.” (See below.)</p> 	<p>1. EES sales unit box is <u>not</u> shrinkwrapped.</p> <p>2. EES product clearly indicates our company name on the sales unit box. (See below.)</p>  <p>3. EES individual clip package is correctly labeled. (See below.)</p> 

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.