

OUS Customer Letter

Notice of Counterfeit Product labeled PROXIMATE® PPH Procedure for Prolapse and Hemorrhoids, product code PPH03

July 7th, 2010

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

Dear Healthcare Professional:

Ethicon Endo-Surgery (EES) recently became aware of the existence of a Counterfeit Product labeled PROXIMATE® PPH Procedure for Prolapse and Hemorrhoids Set, **product code PPH03**, bearing lot number **F4N12N**. This is a Hemorrhoidal Circular Stapler product available in a 33 mm diameter size only.

The PROXIMATE® PPH Hemorrhoidal Circular Stapler has been designed for the procedure for prolapse and hemorrhoids.





Physicians, nurses and all other healthcare professionals should carefully examine all PROXIMATE® PPH Hemorrhoidal Circular Stapler products before use.

The counterfeit product was discovered as a result of an investigation by EES in response to a customer complaint. At this time, EES is aware of the distribution of counterfeit product in Italy only, and we are working closely with the Italian Ministry of Health on the investigation. Our Legal team is also working closely with the Italian authorities to investigate this matter and help prevent further distribution of counterfeit product.

As a precautionary measure, we are also notifying the appropriate legal and health authorities in Europe and other worldwide health authorities.

Because EES did not manufacture this product, we cannot confirm the performance, mechanical properties, biocompatibility or sterility of this device. We are informing healthcare professionals of this situation so you can take the appropriate preventative action to help ensure patient safety.

The following detail should assist in determining if the product you have is counterfeit:

Features of the Authentic EES Product PROXIMATE® PPH Procedure for Prolapse and Hemorrhoids set	Features of the Counterfeit Product
<p>A. Authentic EES Product has a bar code on one side of the flaps. Note: Both flaps must be inspected. (See Picture 1)</p>	<p>A. Counterfeit Product does not have a bar code on the flap.</p>
 <p>Picture 1</p>	
<p>Authentic EES Product: One side of the flaps has a bar code</p>	<p>Counterfeit Product: No bar code on both flaps</p>
<p>B. Authentic EES Product has a batch number on the firing trigger. The batch number should be visible in an unopened blister by removing the blister from the carton. (see picture 2)</p>	<p>B. Counterfeit Product does not have a batch number on the firing trigger.</p>
 <p>Picture 2</p>	
<p>Authentic EES Product: Batch number on firing trigger</p>	<p>Counterfeit Product: No batch number on firing trigger</p>

Please convey this information to your staff and any others who use the PROXIMATE PPH Hemorrhoidal Circular Stapler 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 notify your local authorities immediately.

For further instructions, or if the product is coming from channels known to have distributed counterfeit product, please contact your local authority.

EES takes measures to help ensure the integrity of the products it provides through its supply chain by either selling directly or through authorized distributors. EES does not recommend the purchase of products from unauthorized distributors that do not purchase directly from EES. If you have purchased EES products from another source, you should verify the origin of that product by contacting the distributor directly. [Affiliate to add list of authorized distributors]

EES will not warrant or assume liability for any counterfeit product and cannot provide credit or exchange products purchased from unauthorized distributors.

If you have medical questions regarding suspected counterfeit product, please contact your local EES office (local contact to be added by affiliate) or +1-513-337-8901 (outside the U.S.). In the U.S., call the EES Customer Service Centre at 1-800-USE-ENDO (873-3636) or contact your sales representative.

EES will continue to work with the Ministry of Health in Italy and worldwide health authorities to investigate this matter and help prevent further distribution of counterfeit products.

Sincerely,

Sender's Name
Sender's Title
Sender's Telephone
Sender's Email

Enclosure