IRISH MEDICINES BOARD

# Notice Information: - Advisory
# 18 June 2012

## Part 1. Product Information

| | | |
|---|---|---|
| a) | Title: | Counterfeit Ethicon Endo-Surgery (EES) LIGACLIP® EXTRA LIGATING CLIP CARTRIDGES |
| b) | Product Name/Type: | Counterfeit Ethicon Endo-Surgery (EES) LIGACLIP® EXTRA LIGATING CLIP CARTRIDGES. Product Lot: LT300 |
| c) | Reference: | SN2012(05) |
| d) | Manufacturer/Supplier: | Ethicon Endo- Surgery LLC<br>Guaynabo,<br>Puerto Rico 00969<br>USA |

## Part 2. Target Audience

| | | |
|---|---|---|
| a) | Target Audience: | General Surgeons<br>Theatre and Nursing Staff<br>Purchasing Managers<br>Nursing Managers<br>Consultant General Surgeons<br>Hospital Managers / CEOs<br>Clinical Directors<br>Risk Managers<br>Hospital Personnel<br>Clinical Engineers<br>Patients |

## Part 3. Problem/Issue

| | | |
|---|---|---|
| a) | Problem/Issue: | The supply and use of counterfeit LIGACLIP® EXTRA LIGATING CLIP CARTRIDGES that are not guaranteed to meet the required standards of safety and quality, as required by the medical devices legislation. |

## Part 4. Background Information

| | | |
|---|---|---|
| a) | Background Information: | Ethicon Endo-Surgery (EES) recently became aware of the distribution of counterfeit LIGACLIP® EXTRA LIGATING CLIP CARTRIDGES (Product Code LT300). The exact risks associated with the use of the counterfeit product are unknown. As the counterfeit product was not manufactured by EES they cannot confirm the performance, mechanical properties, biocompatibility or sterility of the counterfeit products.<br><br>The counterfeit product was discovered as a result of an investigation by EES. The product was purchased in the United States from an unauthorised distributor. EES are working closely with the FDA and EU regulators to investigate this matter. As a precautionary measure EES is notifying all customers of the issue.<br><br>Attached is the letter that EES is sending to all of its customers. The letter details the differences that EES has identified between the counterfeit devices and the genuine devices:<br><br>1. The counterfeit product sales unit box is shrink wrapped.<br><br>2. An unusual font on the sales unit box distorts the company name.<br><br>3. Individual clip package misspells “STERILE” as “STEMIKE.”<br><br>Further details and images may be found in attachment A.<br><br>The manufacturer, EES, strongly discourages the purchase of products from unauthorized distributors. It recommends that all products are purchased directly from EES or an authorised distributor. EES can be contacted by calling Eimear Butler, Regulatory Affairs Associate, Johnson & Johnson Medical Ltd Ireland Tel.: 01 4665286. |

## Part 5. Action to be taken

a) Action to be taken:

The IMB advises that:

• All products in your possession should be checked using the details above to

assess whether the product is genuine or counterfeit.

• If from your assessment, you determine or suspect that you have product that

is counterfeit; identify, locate and quarantine all products 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, advise the IMB immediately that you

have identified counterfeit products by emailing vigilance@imb.ie

## Part 6. Enquiries

a) All enquiries should be made to:

ENQUIRIES

All adverse incidents relating to a medical device should be reported to the:

Irish Medicines Board

Kevin O'Malley House

Earlsfort Centre

Earlsfort Terrace

Dublin 2

Telephone: +353-1-6764971

Fax: +353-1-6344033

E-mail: vigilance@imb.ie

Website: www.imb.ie

Enquiries should be addressed to:

Local Johnson & Johnson Medical Ltd Office:

(EES is part of the Johnson & Johnson Group of Companies)

Eimear Butler

Regulatory Affairs Associate.

Johnson & Johnson Medical Ltd.

Airton Road

Tallaght Dublin 24 Tel.: 01 4665286 Fax: 01 4665340 Click here to view

Dublin 24

Tel.: 01 4665286

Fax: 01 4665340

Click here to view PDF Version of this Safety Notice

Click here to view Attachment A

Click here to view Counterfeit Notice