IRISH MEDICINES BOARD
SAFETY NOTICE

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Counterfeit Ethicon Endo-Surgery (EES) LIGACLIP® EXTRA LIGATING CLIP CARTRIDGES.

IMB Safety Notice: SN2012(05)
Circulation Date: 18 June 2012

PRODUCT NAME: LIGACLIP® EXTRA LIGATING CLIP CARTRIDGES

PRODUCT CODE: LT300

MANUFACTURER:
Ethicon Endo- Surgery LLC
Guaynabo,
Puerto Rico 00969
USA

TARGET GROUPS
General Surgeons
Theatre and Nursing Staff
Purchasing Managers
Nursing Managers
Consultant General Surgeons
Hospital Managers / CEOs
Clinical Directors
Risk Managers
Hospital Personnel
Clinical Engineers
Patients

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.

BACKGROUND
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.

SAFETY NOTICE

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.

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:

1. The counterfeit product sales unit box is shrink wrapped.
2. An unusual font on the sales unit box distorts the company name.
3. Individual clip package misspells "STERILE" as "STEMIKE."

Further details and images may be found in **attachment A.**

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.

ACTIONS OR RECOMMENDATIONS

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

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

SAFETY NOTICE

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