IRISH MEDICINES BOARD

Notice Information: - Warning
16 July 2010

Part 1. Product Information

a)	Title:	Counterfeit PROXIMATE® PPH Procedure for Prolapse and Hemorrhoids Set
b)	Product Name/Type:	PROXIMATE® PPH PROCEDURE FOR PROLAPSE AND HEMORRHOIDS SET
c)	Reference:	SN2010(07)
d)	Serial/Batch Number & Expiry Date:	Model Number PPH03 Batch Number F4N12N
e)	Manufacturer/Supplier:	Ethicon Endo-Surgery LLC 475 Calle C 00969 Guaynabo Puerto Rico

Part 2. Target Audience

a)	Target Audience:	General Surgeons Theatre and Nursing Staff Purchasing Managers Nursing Managers Consultant General Surgeons Hospital Managers / CEOs Clinical Directors Risk Managers

Part 3. Problem/Issue

a) Problem/Issue:

The potential supply and use of a counterfeit haemorrhoidal circular stapler product called PROXIMATE® PPH Procedure for Prolapse and Hemorrhoids Set, Product Code PPH03, from the above batch that is 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:	The Irish Medicines Board (IMB) has been alerted that counterfeit haemorrhoidal circular stapler product called PROXIMATE® PPH Procedure for Prolapse and Hemorrhoids Set, Product Code PPH03, has been found in use in a hospital in Italy. The hospital had purchased the PPH03 product from a non European Union-based distributor. The legal product is manufactured by Ethicon Endo-Surgery (EES). To date, there is no evidence that this counterfeit product is on the Irish market but the manufacturer has confirmed that their genuine CE marked device is in general use within Ireland. EES has highlighted the following differences between the counterfeit devices and the genuine devices: 1. The authentic EES product has a bar code on one side of the flap (figure 1 on PDF Document) whereas the counterfeit product does not have a bar code on the flap (figure 2 on PDF Document) Note: Both flaps must be inspected. 2. The 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 (figure 3 on PDF Document) whereas the counterfeit product does not have a batch number on the firing trigger (figure 4 on PDF Document). 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 product. The manufacturer, EES, recommends that all products are purchased from authorised distributors. The counterfeit device may have been supplied through an unauthorised distributor. The only authorised distributor for the Irish market is Johnson & Johnson Medical (Ireland). EES can be contacted through Johnson & Johnson Medical (Ireland), or by calling +1-513-337-8901 if you have medical questions

regarding suspected counterfeit product.

Part 5. Action to be taken

a)	Action to be taken:	The IMB advises that: All product 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, quarantine the product to ensure it will not be used and contact your local EES representative, JOhnson Ireland, who will be able to confirm if the product is authentic. • If you identify that you have product that is counterfeit you should return any such affected product in your possession to Johnson & Johnson Ireland, and inform the IMB.

Part 6. Enquiries

a)	All enquiries should be made to:	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 EES Distributor: Johnson & Johnson Medical (Ireland) Airton Road Tallaght Dublin 24 Ireland Phone: 01-4665 200 Please Click Here to Download a PDF copy of the Safety Notice