



رقم المحفوظات: ٣٧/٢٥
رقم الصادر: ١٢/١/١٤٩٢
بيروت، في: ١٧ أيار ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس.

الجهاز المعنى بالمتابعة:

- Surgiflo Hemostatic Matrix Kit with Thrombin Plus Flex Tip
Trade Mark: Ethicon Inc
Local Representative:

بناء على التقرير الصادر عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA

والتوصية الصادرة عن الشركة المصنعة والتي تفيد بوجود خلل في عملية تعقيم الصنف الوارد أعلاه، نرجو منكم متابعة هذا الموضوع مع الأطباء الاختصاصيين والعمل بموجب التوصيات الصادرة عن الشركة المصنعة والمتابعة مع الشركة الموردة لاتخاذ الاجراء المناسب.
نرجو تعميم هذه النشرة على المستشفيات المعنية والعمل بموجب التوصيات الصادرة عن الشركة المصنعة.



مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة.

يبلغ:

- دائرة البرامج والمشاريع
- المحفوظات

وثيقة معنيفة للأصل
بيروت في ٢٠ أيار ٢٠١٢
د. وليد عثمان
مدير عام الصحة
عناية غصن



ETHICON™ | Biosurgery

Urgent Product Information

SURGIFLO™ Haemostatic Matrix Kit & SURGIFLO™ Haemostatic Matrix Kit with Thrombin
(List of Product Codes & Lots Enclosed)

**PLEASE DISTRIBUTE THIS INFORMATION TO ALL STAFF WITHIN YOUR DEPARTMENT
WHO USE THE ABOVE LISTED PRODUCTS**

August 21st, 2012

Dear Customer:

As a precautionary measure, ETHICON, Inc. is notifying customers of a potential defect in the packaging of the SURGIFLO™ Haemostatic Matrix Kit and SURGIFLO™ Haemostatic Matrix Kit with Thrombin distributed between the 29th September 2011 and 7th August 2012. The company has identified an issue within the packing process where a cut could potentially breach the double Tyvek® pouch of the packaging which poses an increased risk of infection if the product were to be used. The issue was discovered through the complaint review process where in all of the cases reported to date the defects were detected by the customer prior to use.

We have not received any reports of adverse events related to this issue.

Ethicon, Inc. is requesting that customers inspect their inventory for cuts or slits in the Tyvek® packaging. Please see enclosed list of product codes and lot numbers that could potentially be impacted (*Appendix I*). Please refer to *Appendix II* for additional information and photographs illustrating how to inspect your product inventory to determine whether or not you have any defective product.

If during your inspection you identify any product exhibiting this defect please contact us on fax number 01344 324684; marked for the attention of Jonathan Davies. You will subsequently be contacted to arrange uplift of the product. Additionally customers are requested to report the incident through the standard customer complaint process.

The MHRA has been notified of this action.

If you have any further questions, please call Helen Chamberlain, Marketing Manager on **07778 333500** or contact your Ethicon Biosurgery Territory Manager. Thank you for your cooperation and immediate assistance.

Sincerely,

Nisha Johnson
Business Unit Director
Biosurgery

Lynn Heaver
Regulatory Affairs Cluster Lead
MD&D

Ferrosan Medical Devices A/S is the legal manufacturer of the SURGIFLO™ Haemostatic Matrix Kit and ETHICON, Inc is the distributor of the product.

Enclosures: Appendix I: Product Codes and Lot Numbers
Appendix II: How to Identify Product Defect

APPENDIX I

EU CODES

PRODUCT CODE	LOT/BATCH NUMBER
MS-0010	235490
MS-0010	237120
MS-0010	238600
MS-0011	235488
MS-0011	237119
MS-0011	237498
MS-0011	238635
MS-0011	238783