



رقم المحفوظات: ٧٩/٢٥
رقم الصادر: ١٢/١/٢٠١٢
بيروت، في: ٧ - تموز ٢٠١٢

جانب نقيب الاطباء في لبنان/بيروت

الموضوع: إشعار بمتابعة جهاز طبي مغروس Basic dressings, absorbents, swabs

الجهاز المعنى بالمتابعة:

- Basic dressings, absorbents, swabs, procedure packs X-ray detectable swab, Multi-X
- Trade Mark: Frontier Multigate

بناء على التقارير الصادرة عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA

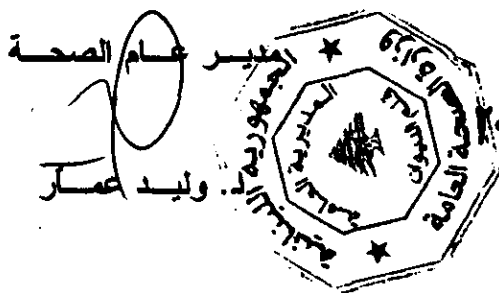
والتوصية الصادرة عن الشركة المصنعة والتي تفيد بوجود خلل في عملية توضيب الصنف المذكور أعلاه، نرجو منكم متابعة هذا الموضوع مع الاطباء الاختصاصيين والعمل بموجب التوصيات الصادرة عن الشركة المصنعة.

مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة.

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات



وثيقة مطابقة للأصل
بيروت، في: ٩ تموز ٢٠١٢
مس قسم الدروس والتأهيل
العلاقات الصحية والسريرية
عبد الحليم





رقم المحفوظات: ٣٩/٢٥
رقم الصادر: ١٢/١٨٤٩٦
بيروت، في: ٧ - تموز/٢٠١٢

جانب نقيب الاطباء في الشمال/طرابلس

الموضوع: إشعار بمتابعة جهاز طبي مغروس Basic dressings, absorbents, swabs

الجهاز المعنى بالمتابعة:

- Basic dressings, absorbents, swabs, procedure packs X-ray detectable swab, Multi-X
- Trade Mark: Frontier Multigate

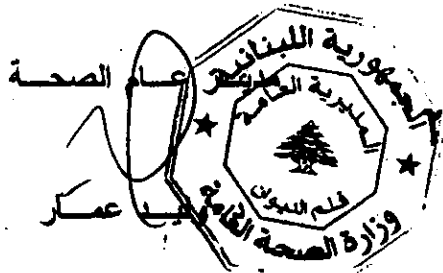
بناء على التقارير الصادرة عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA

والتوصية الصادرة عن الشركة المصنعة والتي تفيد بوجود خلل في عملية توضيب الصنف المذكور اعلاه، نرجو منكم متابعة هذا الموضوع مع الاطباء الاختصاصيين والعمل بموجب التوصيات الصادرة عن الشركة المصنعة.

مرفق ربطا:

- التوصية الصادرة عن الشركة المصنعة.
- يبلغ:
- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات



وثيقة مطابقة للأصل
بيروت في ٩ تموز/٢٠١٢
بمس قسر الدروس والقضايا
العلاقات الصحية والدولية
عبدالله شمس





Newbridge Road Industrial Estate
Blackwood
South Wales
NP12 2YN

Product Recall

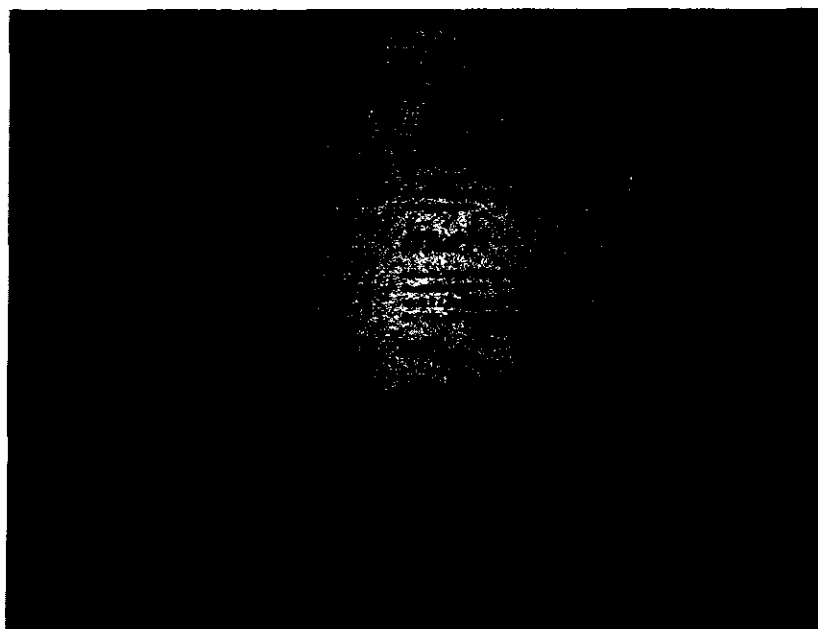
Multi-X 10 cm x 7.5 cm 32 ply X-ray detectable gauze swabs
X-ray detectable thread fault

23th October 2012

To all users of Multi-X 10 cm x 7.5 cm 32 ply X-ray detectable gauze swabs.

Details of the relevant device:

10 cm x 7.5 cm 32 ply
X-ray detectable gauze
swabs: Lot - 12401406



Example of the products packaging

Description of the issue:

The lot 12401406 of this product had been reworked for packaging reasons and had then been re-sterilised. The maximum cumulative irradiation dose had been exceeded. The effect was to reduce the binding to the polymeric carrier of the contrast agent to such an extent that the contrast agent and carrier presented as a powder on the surface of the gauze.

The x-ray detectable filament is made from barium sulphate and polypropylene. Barium sulphate is commonly used clinically as a contrast medium for detectable devices and ingestible solutions. Barium Sulphate is selected as a contrast medium as it has extremely low solubility in aqueous solutions and hence is not readily absorbed by the body but passes through normal excretory channels.

Polypropylene also is insoluble in aqueous solutions and is not absorbed by the body. The x-ray filament has been tested for biological safety in accordance with ISO10993 applicable for the device application. The product passed all tests.

The weight of the filament per 10cm gauze is 0.004g and therefore the available barium sulphate per 10cm gauze is 0.00024g or 2.4mg. The LD₅₀ for barium sulphate in rats is 15,000mg/kg (oral). No data is available for absorption through the skin.

Given the low availability and the high toxicity rating the clinical risk to the patient from absorption of barium sulphate is considered negligible.

The physical deterioration of the x-ray detectable filament means the item will probably not meet the BP monograph requirements. This batch is therefore unsuitable for surgical use due to the uncertainty of detection in the case of accidental surgical gauze retention.

Action to be taken by the user:

Immediately stop using this lot of product and return it to the supplier. The product is exclusively distributed by:
United Drug Medical : Units B1-B2 Bond Close, Kingsland Business Park, Basingstoke, Hampshire, RG24 8PZ, U.K.
Tel : 01256 365490

Transmission of this Product Recall Notice:

This should be passed on to all those who need to be aware within your organisation. Please disseminate this notice within your organisation and other organisations to which you have transferred this effected lot of product.

Contact reference person:

In case of query in respect of this notice, please contact:

Helen Ford
Customer Services
Frontier Multigate Limited

at the address overleaf or by telephoning **01495 233050** or via email to hford@frontiermedical.eu

I confirm that this notice has been notified to the appropriate regulatory body.

Please acknowledge receipt of this notice by return email to hford@frontiermedical.eu including in the subject or title; *Acknowledgment of receipt of the Multigate PRN.*

Thank you.

Yours sincerely,



Derek Lloyd
Group Quality Assurance Manager