



رقم المحفوظات: ٤٧/٢٥
رقم الصادر: ١٩٨/١٥٤٤٤
بيروت، في: ٢٤ أيار ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس.

الجهاز المعنى بالمتابعة:

- Wound management, non-adhesive wound contact layer, INADINE
Povidone iodine non-adherent dressing
Trade Mark: Systagenix Wound Managenet
Local Representative:

بناء على التقارير الصادرة عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA

والتوصية الصادرة عن الشركة المصنعة والتي تفيد بوجود مشكلة في عملية تعقيم الصنف
الوارد أعلاه، نرجو منكم تعميم هذه النشرة على المستشفيات المعنية.

مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة.
- يبلغ:
- دائرة البرامج والمشاريع
- الموقع الإلكتروني لوزارة الصحة
- المحفوظات

مدير عام الصحة

د. وليد عمار



وثيقة متابعة الإصدار
بيروت في
رئيس قسم امانة السر
عنايتة فاضل





Urgent Field Safety Notice

INADINE® PVP-I Non Adherent Dressing

Date: 30th August 2012

Ref: 2012-027

Details of affected devices:

Product Codes: P01491 (9.5cm x 9.5cm)
Lot Numbers: 1227 / 1228 / 1229

Description of the problem:

Systagenix has become aware that the sterility of the product (Product Code P01491; manufacturing Lot Nos. 1227 / 1228 / 1229) may be compromised in a proportion of these batches.

If the sterility was compromised, subsequent use of the wound dressing product may pose an increase in the risk of localised infection.

Recognising that in routine wound management any wound has the potential to develop infection, and monitoring for infection is a fundamental element of standard wound care practice, Systagenix has elected to initiate a voluntary field action of the product code and lot numbers listed above as a precautionary measure.

Advice on action to be taken by the user:

- Please immediately discontinue distribution and use of product with the product code and lot numbers listed above and set aside for return to Systagenix.
- Clinician's should monitor any patients who have used any of the affected product for any signs of localised infection i.e. heat, pain, redness or swelling around the wound or increased wound drainage.
- If symptoms are presented then the medical professional should treat appropriately.

Transmission of this Field Safety Notice: (if appropriate)

Systagenix has prepared a communication to all those who have received potentially affected product and this is provided as an attachment.

Contact reference person:

Dr. W Pigg
Vice President Product Development and Quality
Systagenix Wound Management
Gargrave
North Yorkshire
BD23 3RX

The undersign confirms that this notice has been notified to the appropriate Regulatory Agency

We regret any inconvenience that this action may cause, and we appreciate your cooperation.

A handwritten signature in black ink, appearing to read "Dr. W. Pigg".

Dr. W. Pigg
Vice President Product Development and Quality
Systagenix Wound Management