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الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٣٧/٥٥
رقم الصادر : ١٢/١١/٥٥١
بيروت، في : ٢ أيار ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس.

الجهاز المعني بالمتابعة:

- Sterilization, chemical indicators; Bowie & Dick Type Test
  Trade Mark: Valisafe International
  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 عمل الصنف الوارد أعلاه، نرجو منكم تعميم هذه النشرة على المستشفيات المعنية.

مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة.

يبلغ:

- دائرة البرامج والمشاريع
- الموقع الالكتروني لوزارة الصحة
- المحفوظات

مدير عام الصحة
د. وليد عمار

الجمهورية اللبنانية
المديرية العامة
قلم الديوان
وزارة الصحة العامة

وثيقة مطابقة للأصل
بيروت في ٢١ أيار ٢٠١٢
رئيس قلم أمانة السر
عناية فحص

الجمهورية اللبنانية
وزارة الصحة العامة

Urgent Field Advisory Notice

Medisafe International
Twyford Road, Bishop's Stortford,
Hertfordshire CM23 3LJ, U.K.
T: +44 (0)1279 461641
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www.medisafeinternational.com
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Valisafe Bowie & Dick Type Test
FAN identifier: 27072012
Type of action: Field Safety Corrective Action

Date: 27th July 2012

Attention: All distributors and users of Valisafe Bowie & Dick Type Test Product Code V3501020

Details on affected devices: *All batches of the above product*

Description of the reported problem:

The Bowie-Dick alternative test is widely used and recognized as a valuable means of monitoring the air removal performance of vacuum-assisted steam sterilizers within the (once a day) Bowie and Dick test cycle.

Bowie and Dick alternative test packs should be used in sterilizers operated and tested in accordance with HTM 2010 / CFPP0101 Part C/EN285 - the routine testing of the sterilizers includes weekly automatic control tests, air leakage tests and air detector function tests. The routine performance tests results must be documented accordingly.

In the event that the Valisafe Bowie & Dick alternative test pack (V3501020) is used in sterilisers utilising either trans- or super-atmospheric cycle profiles then there is a slight risk that the test pack may not detect a failure within the daily B&D test cycle,

However, in a sterilizer operated and tested in accordance with HTM 2010/ CFPP0101 Part C/EN285 which includes weekly automatic control tests, air leakage tests and air detector function tests the risk to the patient is low, if a) the product is insufficiently sensitive in pre-vacuum (ie sub-atmospheric pulsing) sterilizers or b) the product is inappropriately used in trans- or super-atmospheric sterilizers

Advise on action to be taken by the user:

In case that the aforementioned product is utilised in a trans- or super-atmospheric sterilizer, ensure that weekly automatic control tests, air leakage tests and air detector function tests have been carried out and that satisfactory results are documented. If this is not the case users should contact their AED (Authorised Engineer in Decontamination) immediately for further investigation to be carried out.

Preventive actions by the Manufacturer:

The labelling and the instructions for use will be amended to reflect the intended use of the product.

Transmission of this Field Safety Notice:

Identify locations where product has been supplied
Communicate the contents of this FSN to all customers supplied.

Contact reference person:

Elizabeth Livermore
Medisafe UK Ltd.- Quality Manager
The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency

Signature

World Leaders
In Advanced Surgical
Instrument Reprocessing
Technology

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Please sign and return this form to acknowledge receipt of Field Service Notice.			
Name of Hospital/ Organisation		Address	
Contact Name			
Contact Title			
Contact Signature			
Contact Phone No		Date	

PLEASE COMPLETE AND FAX THIS FORM TO 01279 461 643

OR EMAIL TO elivermore@medisafeinternational.com

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