REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH
The Director General

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٣٨١/٢٥
رقم الصادر: ١٢/١/٢٥٢٤٨
بيروت، في: ٣٠ تموز ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي

Surgical instruments, miscellaneous, evacuator. Neptune waste management system

الجهاز المعني بالمتابعة:

- Surgical instruments, miscellaneous, evacuator. Neptune waste management system
- Trade Mark: Stryker Instruments
- Local Representative:

بناء على التقارير الصادرة عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA

والتوصية الصادرة عن الشركة المصنعة والتي تشير الى وجود خلل في عمل الصنف الوارد أعلاه مما قد يؤثر على سلامة المريض، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

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UK

URGENT Field Safety Notice: RA 2012-035B

15th May 2013

Description: Neptune Waste Management System.

Catalog No: 0702-001-000, 0702-002-000, 0702-004-000, 0700-001-000, 0700-002-000, 0700-003-000, 0700-007-000

Serial No: All devices/serial numbers

Dear Customer,

On 22nd May 2012 you were notified of a Product Field Action that had been initiated by Stryker Instruments Kalamazoo concerning the above referenced devices.

The reason for the FSCA was that Stryker had received a customer report informing them of a patient fatality which had been caused because of the Neptune Rover, a high suction device, being connected to a passive chest drainage tube post-operatively.

The IFU that was valid at this time for these devices did not specifically warn users against connecting the Neptune Rover, which is a high vacuum/high flow device, to passive drainage tubes. At the time the manufacturer updated the IFU to include a specific warning against this type of usage:

> *WARNING: DO NOT apply High Flow suction or allow extended exposure of suction to tissue associated with procedures that require either no suction, low vacuum or low flow suction, for example, passive chest drainage. ALWAYS consider the type of tissue associated with the surgical procedure BEFORE using this system. Failure to comply may result in severe injury or death.*

Passive drainage is defined as using "gravity or capillary action to draw fluid from the wound or cavity".

As an additional corrective action the manufacturer is requesting that labels containing this warning are now placed on all subject devices.

Please find enclosed copies of these labels in local language and also the current IFU in local language.

NOTE: the warning labels and the current version of the IFU have been sent to the Theatre Manager at your facility.

Immediate Actions Required

We request that you:

1. Immediately check your internal inventory and locate all subject devices.
    - Ensure that labels are applied to each unit
        i. Please refer to the attached protocol which illustrates how to apply labels.
2. Dispose of any obsolete versions of the device IFU and replace with the attached IFU (reference: 0702-002-700 Rev H).
    - We suggest that the revised IFU is made available to users of the device at point of use.
3. Circulate this Field Safety Notice internally to all interested/affected parties.
    - Include any personnel responsible for the allocation/maintenance of equipment.
4. Maintain awareness of this notice internally until all required actions have been completed within your facility.
5. Inform Stryker if any of the subject devices have been distributed to other organisations. *(Please provide contact details so that Stryker can inform the recipients appropriately).*
6. Please inform Stryker of any adverse events associated with the use of the subject devices.
    - Comply with any local regulations concerning the reporting of adverse events to local Competent Authorities.
7. Complete the attached customer response form and return to Daniel Rana by fax (01635 262 464) or by e-mail (daniel.rana@stryker.com).
   (Please complete this form even if you do not have any product to return. This will preclude the need to Stryker to send any reminder notice).

We would like to reassure you that Stryker® maintains its commitment to developing, manufacturing and marketing the highest quality products for surgeons and patients.

We thank you sincerely for your help and support in completing this action on time and apologize for any inconvenience this Field Safety Corrective Action may create.

Should you have any further enquiries or requirements concerning this action please contact the undersigned in the first instance.

Yours faithfully,

Rana

Daniel Rana
Quality Assurance and Regulatory Affairs