REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH
The Director General

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٣٧١٣
رقم الصادر: ١٢/١/٢٨٧١٦
بيروت، في: ٢ - ايار ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي

Surgical Instruments, Miscellaneous Irrigating Handpiece.
Sonopet Ultrasonic Aspirator Console

الجهاز المعني بالمتابعة:

- Surgical Instruments, Miscellaneous Irrigating Handpiece. Sonopet Ultrasonic Aspirator Console
- Trade Mark: Stryker
- Local Representative: Ets.F.A Kettaneh

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

الجمهورية اللبنانية
المديرية العامة
وزارة الصحة العامة

مدير عام الصحة
د. وليد عمار

Museum Street - Hussein Mansour Bldg. - Beirut, Lebanon - Tel.: 961.1.615724 - 615725 - Fax: 961.1.615730 - Email: directorgeneral@moph.gov.lb

Date

URGENT FIELD SAFETY NOTICE: RA2013-053

Dear Customer

Stryker Product Number	Product Description	Stryker Serial Number	Dates of Distribution
5450-850-000	Sonopet Console 110V (with pedal and pole)	See attached list	13th October 2011 – 19th October 2012
5450-851-000	Sonopet Console 100V	See attached list	
5450-852-000	Sonopet Console 230V	See attached list	

Dear Customer

Please find attached details of a Product Action that has been initiated by Stryker Instruments concerning the above referenced subject devices. This action has been taken to ensure that users are aware of important Information concerning the devices listed above.

Our records indicate that you have received at least one of the subject devices and you are therefore affected by this action. You are required only to read the attached Field Safety Notice and then sign and return the Customer Response Form confirming that you have received the Field Safety Notice and completed the actions requested by the manufacturer. It may be that you no longer have any physical inventory on site. Completing this form will allow us to update our records and will also negate the need for us to send any further unnecessary communications on this matter. Therefore please complete even if you no longer have any of the subject devices in your physical inventory.

We request that you respond to this notice within seven calendar days from the date of receipt. The target date for completion of this action is 28th July 2013 and your timely response will enable us to ensure that we meet this target.

Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.

Name: Position: E-mail:

In line with the recommendations of the Meddev Vigilance Guidance document Ref 2.12-1, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

On behalf of Stryker we thank you sincerely for your help and support in completing this action within date and regret any inconvenience that may be caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remain on the market.

Yours....

Date:

URGENT Field Safety Notice: RA2013-053

For the attention of:

Stryker Product Number	Product Description	Stryker Serial Number	Dates of Distribution
5450-850-000	Sonopet Console 110V (with pedal and pole)	See attached list	13th October 2011 – 19th October 2012
5450-851-000	Sonopet Console 100V	See attached list	
5450-852-000	Sonopet Console 230V	See attached list	

Stryker® Instruments has initiated a Product Field Action for the product referenced above.

Product Description
The Sonopet Console is indicated for use in surgical procedures where fragmentation, emulsification, and aspiration of soft and hard tissue is desirable. This includes neurosurgery, gastrointestinal and affiliated organ surgery, urological surgery, plastic and reconstructive surgery, general surgery, orthopaedic surgery, gynaecological surgery, thoracic surgery, laparoscopic surgery, and thoracoscopic surgery.

Issue
Customer complaints were received indicating that the Irrigation Pump was not functioning, therefore compromising the flow of saline to the tip. Consequently the cooling function could be lost, causing the tip to heat up which potentially could result in tissue burns to the patient.

Root Cause
The RY1 contact of the supply boards had a conduction defect, which caused the irrigation pump failure. The cause of the conduction defect was corrosion inside of the relay. The corrosion would have been a result of improper storage conditions at the supplier.

Potential Hazards
There is a potential for the relay in the power supply board of the console to fail during a procedure resulting in irrigation pump failure and loss of irrigation. The resultant overheating of the tip could in turn lead to thermal injury to critical soft tissue, including nerves, blood vessels and vital organs.

Immediate actions
We request that you read this notice carefully and complete the following actions:

1. Immediately locate subject devices referenced in this notice.
   a. Inspect each device in line with the manufacturer's instructions as per attached protocol

2. Immediately withdraw from service any units that fail inspection and quarantine until they are upgraded in line with the manufacturer's instructions.
3. Device that pass the inspection may remain in service
    a. Ensure that a process is put in place to ensure that each unit is inspected in line with the manufacturer's instructions prior to each use.
4. Circulate this Field Safety Notice internally to all interested/affected parties.
5. Maintain awareness of this notice internally until all required actions have been completed within your facility.
6. Inform Stryker if any of the subject devices have been distributed to other organisations.
    a. Please provide contact details so that Stryker can inform the recipients appropriately.
7. Inform Stryker of any adverse events associated with use of subject devices
    a. Please comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.
8. Customers will be requested to complete and return the completed customer response form.
    a. On receipt of the completed response form a Stryker representative will contact users to arrange for a mutually convenient time to upgrade all units.
    b. Please complete this form even if you do not have any product to return. This will preclude the need for Stryker to send any unnecessary reminder notices.
    c. Please return this notice within five working days. This will preclude the need for us to send any further reminders.

Stryker® maintains its commitment to developing, manufacturing and marketing the highest quality products for surgeons and patients. We apologize for any inconvenience this Field Safety Action may create and appreciate your cooperation with our request.

If you have any further enquiries, please do not hesitate to contact the undersigned.

Yours .....

RA2013-053: Sonopet IFU inspection process

Inspect each device in line with the manufacturer's IFU to verify that the irrigation function is working correctly.

Observe all warnings and cautions:

In particular reference the existing warnings and cautions from page 16:

Use: CAUTION: DO NOT use ultrasonic vibration without irrigation fluid flowing at the tip of the hand-piece.

WARNINGS:

- ALWAYS use irrigation when using the ultrasonic hand-piece.
- DO NOT use excessive or insufficient irrigation flow.
- Failure to comply may result in the inability to view the surgical site or excessive heat and a potential burn injury, respectively.