



رقم المحفوظات: ٢٠١٣ / ١ / ٥
رقم الصادر: ١٢ / ١ / ٥٠
بيروت، في:

٢٠١٣ - آب - ٥

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي

Surgical Instruments, Miscellaneous Irrigating Handpiece.
Sonopet Ultrasonic Aspirator Console

الجهاز المعنى بالمتابعة:

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

بناء على التقارير الصادرة عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA

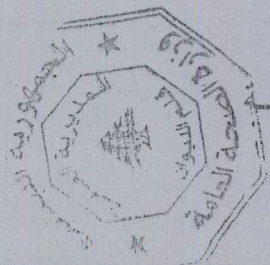
والتوصية الصادرة عن الشركة المصنعة والتي تشير الى وجود خلل في عمل الصنف السوارد اعلاه مما قد يؤثر على سلامة المريض، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة

يلتص:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات



مدير عام الصحة
د. وليد عمار

URGENT Field Safety Notice: RA 2013-053

4th July 2013

Dear Customer,

Stryker Product Number	Product Description	Stryker Serial Number	Dates of Distribution
5450-852-000	Sonopet Console 230v	See attached list	13 th October 2011 to 19 th October 2012

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

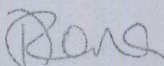
We request that you read this notice carefully and complete the following actions:

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. Devices 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. Please complete and return the attached customer response form to Daniel Rana by fax (01635 262 464) or by e-mail (daniel.rana@stryker.com).
 - 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 apologise for any inconvenience this Field Safety Corrective 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 faithfully,



Daniel Rana
Quality Assurance and Regulatory Affairs