REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH
The Director General

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٢٨/٤٥
رقم الصادر: ١٢/٧/٢٦٠٥
بيروت، في: ٥ - آب ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي
Rigid Suction Wands

الجهاز المعني بالمتابعة:

- Rigid Suction Wands
- Trade Mark: Edwards Lifesciences
- Local Representative: Benta Trading

بناء على التقرير الصادر عن الوكالة الأوسترالية TGA والذي يشير الى وجود خلل في عملية توضيب الصنف الوارد أعلاه مما قد يؤثر على سلامة المريض، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التقرير الصادر عن الوكالة الأوسترالية TGA

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
د. وليد عمار

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

Edwards

URGENT FIELD SAFETY NOTICE
PRODUCT RECALL – ACTION REQUIRED

Edwards Lifesciences Suction Wand Model S099
Ref: # FCA-29

[date]

To: «Ship_to_Name»
Attn: Risk Management and Department of Cardiac Surgery

Dear Valued Customer:

Details of Affected Device:
Edwards Lifesciences Rigid Suction Wand Model S099

Description of Issue
During inspection of some distributed rigid suction wands (models S099), Edwards discovered plastic particulate inside the sterile pouch and within the internal diameter of the rigid suction wands. The particulate ranged from 0.26 to 0.41 inches (6.6 to 10.4mm) in size. Particulate not detected during the preparation of the device may pose a risk as it may enter into the pericardium and could cause abrasions to the surface of the heart. We believe that risk of injury to patients from this issue is unlikely; however, as patient safety is our highest priority, we are voluntarily recalling all unused Edwards' rigid suction wands.

Actions to be Taken by User
Our records show that you have purchased one or more lots of the affected products. Please review your entire inventory for any rigid suction wands (models S099) in your inventory. Please quarantine the affected product from your inventory and return all devices with remaining shelf life to Edwards. Expired product, if identified, should be disposed of per your inventory management procedures.

Please acknowledge that you have reviewed this Recall Notice and confirm that you have taken appropriate action by completing, signing and dating the enclosed Recall Response Form and returning the form to Edwards.

Please fax the form to Edwards Customer Service at XXX within three days of receipt of this Recall Notice. The return of this form allows us to confirm that you have reviewed this notice and have taken appropriate action. Please contact Customer Service at XXX to obtain a Returned Goods Authorization number to return your current product and to receive replacement product.

Edwards

Please return all affected product to the following address:

XXX

Transmission of this Field Safety Notice
Please provide this Recall Notice to others within your organization who should be aware of this action or to any others outside of your organization where potentially affected devices may have been transferred. If you have further distributed this product, you should notify your customers to the retail level and retrieve unused product. All product with a valid shelf life is affected by this recall.

Edwards has communicated this Field Safety Notice to all appropriate regulatory authorities.

We sincerely regret the inconvenience caused by this action and greatly appreciate your immediate attention to this matter. Our Customer Service organization or your Edwards Sales Representative can answer questions about alternative suction wand product availability. If you have questions that have not been answered by this letter, please call Edwards Customer Service at XXX from the hours of XXX.

Sincerely,

[redacted]
Sr. Director of Quality, CSS
Edwards Lifesciences, LLC
Phone: 801-565-[redacted]
E-mail: [redacted]@edwards.com

Attachments:
Recall response form