RÉPUBLIQUE LIBANAISE
MINISTÈRE DE LA SANTÉ PUBLIQUE
Le Directeur Général

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٣٨١٢٥
رقم الصادر: ١٣/١/١٤٦٠٧
بيروت، في: ٢٧ نيسان ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي

Infusion and transfusion, heart lung circuits; cardio-pulmonary reservoirs. Cardiotomy reservoir/ autotransfusion reservoir

الجهاز المعني بالمتابعة:

- Infusion and transfusion, heart lung circuits; cardio-pulmonary reservoirs. Cardiotomy reservoir/ autotransfusion reservoir
- Trade Mark: Maquet Inc
- 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 عملية توضيب الصنف المذكور اعلاه مما قد يؤثر على فعالية التعقيم، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
د. وليد عمار

Rue de la Musée - Imm. Hussein Mansour - Beyrouth, Liban - Tel.: 961.1.615724 - 615725 - Fax: 961.1.615730 - Email: dirctorgeneral@moph.gov.lb

MAQUET
GETINGE GROUP

URGENT – FIELD SAFETY NOTICE
2013-03-18

PLEASE FORWARD THIS INFORMATION TO ALL USERS AND BIOMEDICAL STAFF CONCERNED.

Subject: Insufficient heat sealing of sterile bags of Cardiotomy/Autotransfusion Reservoirs (need part number or identifying number)

Products affected: **See List of Affected Products and Lot Numbers attached**

Dear Customer,

It has come to the attention of MAQUET that specific lots of Cardiotomy Reservoirs and Autotransfusion Reservoirs manufactured between July 25, 2012 and November 8, 2012 may potentially have an incomplete seal on the final package. Based on our investigation, it has been determined that in some cases the incomplete seal could compromise the integrity of the sterile package. Our shipping records indicate that products from the specific lots affected were distributed to your facility.

Patient Risk:
No product complaints or patient injuries have been reported to date. The instructions for use state "Do not use the device if it or the sterile packaging is damaged". As a result, incomplete sealing would be detected during package inspection prior to use.

MAQUET'S Corrective Action
Please take the following corrective actions immediately:

- Review your current stock and identify if you have any devices from the affected lots of reservoirs remaining in your inventory.
- Should you have any of this product in your stock, please do not use it and instead, remove the product from clinical use.
- Complete and return the enclosed Letter of Acknowledgment and the list of affected products and lot numbers to your local MAQUET representative to acknowledge receipt and understanding of this notification and to document the current status of devices shipped to your facility; i.e., the number of devices remaining in your inventory.

Your MAQUET sales representative will contact you regarding return and replacement of product remaining in your inventory.

MAQUET

We apologize for any inconvenience this may cause. If you have questions or require additional information, please contact your local MAQUET representative or MAQUET Customer Service.

Yours sincerely
Maquet Cardiopulmonary AG

Dr. Wolfgang Rencken
President/CEO

Arne Briest
Director Quality Assurance

Attachment:
Letter of Acknowledgement Customer
List of affected products

Catalogue number	Model number	Lot	Device Mfr Date	Country
701004265	HC 2811#Kardiotomiereservoir	70082812	27.07.2012	GB
701004265	HC 2811#Kardiotomiereservoir	70082812	27.07.2012	GB
701004266	HC 2821#Kardiotomiereservoir	70083244	29.08.2012	GB
701004266	HC 2821#Kardiotomiereservoir	70083985	05.10.2012	GB