REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH
The Director General

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٢٨/ ٥٠
رقم الصادر : ١٢/١/٥٧٩٢
بيروت، في : ٢ - آب ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس
Peripheral vascular infusion/ aspiration catheter, Maquet HLS Cannula wizh Bioline coating

الجهاز المعني بالمتابعة:

- Peripheral vascular infusion/ aspiration catheter, Maquet HLS Cannula with Bioline coating
- Trade Mark: Maquet Cardiopulmonary AG
- Local Representative:

نرجو الاطلاع على التوصية الصادرة عن الشركة المصنعة والتي تشير الى طريقة الاستعمال حفاظاً على سلامة المريض، ومتابعة هذا الموضوع مع جميع المستشفيات المعنية.

مرفق ربطاً:
- التوصية الصادرة عن الشركة المصنعة

يبلغ:
- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
د. وليد عمار

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FIELD SAFETY NOTICE
2013-06-07

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

Product: HLS arterial cannula with Bioline coating
Model Numbers: BE-PAL 1923 and BE-PAL 2123
Affected Lot Numbers: 92091602, 92094296 and 92094297

Dear Customer,

This letter is to inform you that Maquet Cardiopulmonary has initiated a product recall involving the HLS arterial cannula with Bioline coating Model Number BE-PAL 1923 Lot 92091602 and 92094296 and the HLS arterial cannula with Bioline coating Model Number BE-PAL 2123 Lot 92094297.

Intended Use of Device:

The HLS arterial cannulas are used to introduce blood and sterile solutions into the systemic circulation during extracorporeal circulation procedures.

Maquet CardioPulmonary AG is recalling the devices due to a possibility that the indication on the label may not be correct as it pertains to the size of the cannula. This may create a higher risk of vessel-damaging or the need of replacement of the cannula during surgical intervention.

Corrective Actions:

Please take the following corrective actions immediately:

- Review your current stock and identify if you have any devices from the affected lots 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.

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

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

Arne Briest
Safety Officer Medical Devices

Attachment:
- Letter of Acknowledgement Customer
- List of affected products