RÉPUBLIQUE LIBANAISE
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الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٢٨/ ٢٠٥
رقم الصادر: ١٣/١/ ٢٠١٥
بيروت، في: ١٢ شباط ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي
Endotherapy device, NAVIX Access Device

الجهاز المعني بالمتابعة:

- Endotherapy device, NAVIX Access Device
- Trade Mark: Xlumena, Inc.
- Local Representative:

بناء على التوصية الصادرة عن الشركة المصنعة التي تشير الى وجود خلل في عمل الصنف المذكور 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

مدير عام الصحة
د. وليد عمار

الجمهورية اللبنانية
المديرية العامة
وزارة الصحة العامة

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

Xlumena

Urgent Field Safety Notice

NAVIX™ Access Devices (Model/Catalog NVX-10-03)

15 April 2013

MEDICAL DEVICE RECALL

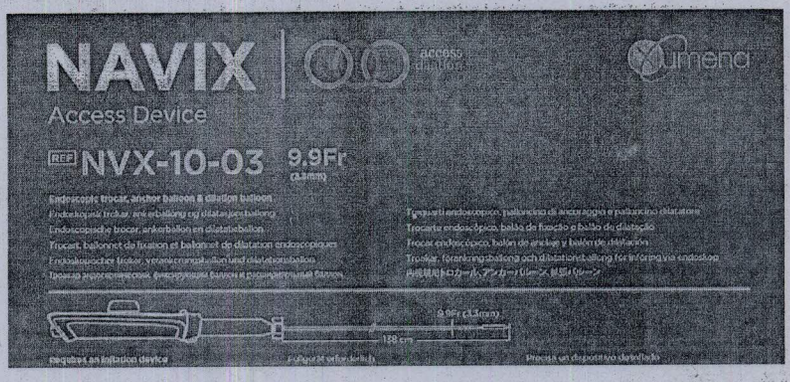
Date: 15 April 2013

Attention: [Customer]

Details on affected devices:

Xlumena, Inc. is initiating a voluntary Medical Device Recall of all NAVIX™ Access Devices (Model/Catalog NVX-10-03). Please immediately discontinue use and segregate the product:

All lot numbers for NAVIX™ Access Devices (Model/Catalog NVX-10-03)



Description of the problem:

A product investigation of the NAVIX™ Access Devices (Model/Catalog NVX-10-03 found that product fractures can occur at the distal end of the catheter under load. No other Xlumena product is affected by this action.

Advise on action to be taken by the user:

1. Immediately remove all units of NAVIX™ Access Device from your inventory (including inventory in Central Services, Shipping and Receiving or Endosuites).
2. Segregate this product in a secure location for return to Xlumena.
3. Record product lot numbers and quantities in the form below. FAX the form to: +3113 547 9301
4. Package the product in an appropriate shipping box.
5. Label the shipping box with this return authorization number: (RMA 0198)
6. Seal the box and return to:

Healthlink Europe BV / XLumena
Daltonstraat 4
Zwijndrecht 3335 LR
The Netherlands
Phone: +3113 547 9300

Attention: Customer Service

Xlumena

Urgent Field Safety Notice

NAVIX™ Access Devices (Model/Catalog NVX-10-03)

15 April 2013

MEDICAL DEVICE RECALL

Product Verification Form:

☐ We do not have any **NAVIX Access devices (Model/Catalog NVX-10-03)** in inventory.

☐ We have verified the following items for return to Xlumena:

Lot Number	Quantity being returned

Name: _____ Hospital / Department: _____

Phone or email: _____

Transmission of this Field Safety Notice:
This notice needs to be passed on to those within your organization or to any organisation where the affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact: Central Services, Shipping and Receiving or Endosuites.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:
Please feel free to contact dhasker@xlumena.com at Xlumena, with any questions, or the Xlumena Authorized Representative in Europe:

Customer Service
Healthlink Europe BV
De Tweeling 20-22
's-Hertogenbosch 5215 MC
The Netherlands
Phone: +3113 547 9300

We regret any inconvenience to you and appreciate your action to correct this issue.
The undersign confirms that this notice has been notified to the appropriate Regulatory Agency.

Greg R. Patterson
President & CEO
Xlumena, Inc.