



رقم المحفوظات: ٧١٢٥  
رقم الصادر: ١٣/١/٢٠١٣  
بيروت، في: ١٥ شباط ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي

Catheters, Colon, Anal Catheters, The Qufora Irrigation System

الجهاز المعني بالمتابعة:

- Catheters, Colon, Anal Catheters, The Qufora Irrigation System
- Trade Mark: MBH International A/S
- Local Representative:

بناء على التوصية الصادرة عن الشركة المصنعة

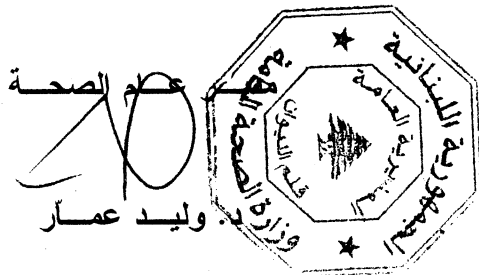
التي تشير الى مضاعفات اثناء استعمال الصنف المذكور أعلاه وقد تؤثر على سلامة المريض، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطا:

- التوصية الصادرة عن الشركة المصنعة

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات



Allerød, February 23rd 2012

To whom it may concern

FIELD SAFETY NOTICE ref FSN-001

RECALL

MBH-International A/S recalls the Ø30 anal catheter for the Qufora irrigation bed systems.

**Catalogue REF's:** 51101, 52501, 53101.

**Lot numbers:** 090401, 090505, 090511, 090801, 091102, 100311, 100816, 101016, 110108, 110331, 110627, 110627, 111025

#### **Background information and scope of the recall**

The Ø30 anal catheter is used with the Qufora irrigation bed systems. The catheter consists of two parts, the catheter itself and a rod. The rod is placed inside the catheter to ensure a smooth insertion into the rectum. After the catheter is placed in the right position the rod is removed.

MBH-International A/S has been informed by a doctor that there is a risk that the rod with force can be pushed beyond the intended stopper. Should it do so the front edge of the catheter is unprotected and could harm the intestinal wall or the anus during insertion.

Investigations by the R&D and the QA departments in MBH-International show that it is possible to push the rod too far although no reported incidents has occurred since the introduction of the product in 2007.

This recall concern all products sold since the initial launch.

#### **Safety concern**

Should the rod be pushed too far there is a risk that the catheter can harm the intestinal wall or the anus.

#### **Advice on action to be taken by the user:**

The customers affected by this recall are kindly advised to return any products and samples of the item in question to MBH-International A/S, Hejrevang 21A, 3450 Allerød, Denmark. All expenses for shipment will be refunded and new products will be supplied by MBH-International A/S.

#### **Transmission of this Field Safety Notice**

**Head Office:**  
MBH-International A/S  
Hejrevang 21 A  
DK-3450 Allerød  
Denmark  
Office (+45) 8830 0592  
Fax (+45) 8830 0593  
[www.mbh-international.com](http://www.mbh-international.com)

**Hong Kong Office:**  
MBH-International Ltd.  
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2A Hart Avenue  
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Hong Kong  
Office (+852) 2369 1778  
Fax (+852) 2366 9781

**Barcelona Office:**  
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**Frankfurt Office:**  
MBH-International A/S  
Hügelstrasse 25 B  
D-65510 Hünstetten  
Germany  
Office (+49) 6126 95 95 627  
Fax (+49) 6126 95 95 628



**MBH  
INTERNATIONAL**

Please forward this information to relevant persons in your organization. Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the recall. In addition if you have further distributed this product, please notify the consignees at once of this notification. Your notification to your customers may be enhanced by including a copy of this letter. This notification should be carried out to the user level. Your assistance is appreciated and necessary.

Yours sincerely,



Quality & Technical Manager, Ph.D.

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