



رقم المحفوظات: ٢٥ / ٢٠١٢  
رقم الصادر: ١٣٨ / ٢٠١٢  
بيروت، في: ٥ - آب - ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

**الموضوع:** إشعار بمتابعة جهاز طبي  
Folio dress gown Comfort Basic

الجهاز المعني بالمتابعة:

- Folio dress gown Comfort Basic
- Trade Mark: Paul Hartmann
- Local Representative:

بناء على التوصية الصادرة عن الشركة المصنعة والتي تشير الى وجود خلل في عملية تغليف الصنف المذكور أعلاه مما قد يؤثر على فعالية التعقيم، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ريبطاً:

- التوصية الصادرة عن الشركة المصنعة

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات







HARTMANN  
Middle East  
هارتمان  
الشرق الأوسط

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Date 23 July 2012

### Urgent Field Safety Notice – Product Recall

Dear Dr. Sulaiman

Today we have to inform you about the attached Field Safety Notice (FSN).

We kindly ask you to confirm the receipt of this following FSN and initiate the necessary steps to recall the products as described. For the required confirmations please use the attached response form.

Please be aware that you are responsible to report this issue to the competent authorities in your country. We kindly request you to send us a copy of your report to the authorities latest until July 31, 2012.

For questions or further information, please do not hesitate to contact us.

Kind regards

PAUL HARTMANN Middle East FZE

Alexander Burger  
Managing Director

Dr. Fatima Zaid Abu Zanat  
Regional Regulatory Affairs Coordinator

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HARTMANN helps healing.

formed pursuant  
to law no. 2 of 1996  
with limited liability  
Registration No. DAFZA/0085

ذات مسؤولية محدودة تأسست  
بموجب القانون رقم 2 لسنة 1996  
تسجيل رقم : DAFZA/0085



## Urgent Field Safety Notice (Product Recall)

**Corrective Action: Recall of various sterile surgical gowns and isolation gowns under the brand Foliadress as per attachment 1**

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July 23, 2012

**Sender:** PAUL HARTMANN Middle East FZE  
Dubai Airport Free Zone  
West Wing 3, Office No. 222  
P.O. Box 54525  
Dubai  
United Arab Emirates

**Recipient:** Abdulrehman Algosaihi G.T.C.  
Dr. Mohammed Sulaiman  
King Abdul Aziz Avenue, Old Airport Road  
Al Gosaihi Building  
P.O. Box 215  
Riyadh 11411  
Saudi Arabia

**Affected product:**

Complete list as per attachment 1

**Description of the problem:**

A quality inspection revealed the individual occurrence of micro-holes in a number of blisters (sterile packaging) containing sterile surgical gowns and isolation gowns. The micro-holes are unlikely to be detected through visual inspection. As a result, the sterility of affected products may be compromised.

As we are unable to reliably exclude a risk of individual occurrence of micro-holes in these products, we have decided to take all necessary precautions and recall the potentially affected references. For references and details to Lot number please refer to attachment 1.

**Advise on action:**

Please examine your inventory and do not use the affected products any longer. We kindly ask you to confirm the receipt of this notification and report back volume of affected stock by returning the below attached form (attachment 2).

Upon receipt of your response (attachment 1 & 2) we will contact you to discuss the details to collect the articles from your warehouse.

Your usual HARTMANN sales representative or customer service contact is happy to assist you with any further enquiries in this matter. In addition, you may contact us directly via a dedicated hotline:

Phone: +971 4 2996996

Fax: +971 4 2996998

Email: [fatima.z.abuzanat@hartmann.info](mailto:fatima.z.abuzanat@hartmann.info)

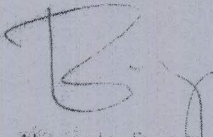


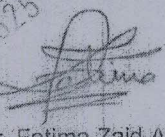
**Transmission of this Field Safety Notice:**

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected products have been transferred to. Therefore please take adequate measures.

We earnestly regret any inconvenience caused by this measure.

Dubai, July 23, 2012  
PAUL HARTMANN Middle East FZE

  
Alexander Burger  
Managing Director

  
Dr. Fatima Zaid Abu Zanat  
Regional Regulatory Affairs Coordinator

PAUL HARTMANN  
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**Attachement**

1. Productlist
2. Response form