

Urgent Field Safety Notice (Product Recall)

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

July 23, 2012

Sender: "Affiliate name" / "distributor name"

Recipient: „customer address“

Affected product:

Complete list as per attachement 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 attachement 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 (attachement 2).

Upon receipt of your response (**attachement 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 „phonehotline“

Fax „faxhotline“

Email „dedicated email adress“

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.

Place, date

Affiliate / Distributor name

Signatories

Attachement:

1. Productlist
2. Response form

Attachement 2:

„customer address“

Return by fax until to: „contact person“

„Affiliate / Distributor name“
contact person + details

Recall of various sterile surgical gowns and isolation gowns as per attached list

We hereby confirm receipt of the field safety notice issued by „Affiliate / Distributor name“ dated July 23, 2012 and transmission on all those who need to be aware within our organisation or to any organisation where the potentially affected products have been transferred and that all our stocks of the affected lots are blocked and will be returned to HARTMANN.

The result of an examination of our stocks is as follows:
Please indicate:

- After thorough examination no stocks of the affected articles was discovered
- Stocks existing:

Please use the prepared column in attachement 1 for your answer!

Trade name	REF / Article number	Article description	Stock quantity to be returned
„productname“ (customer individuell)	„Number“	„Details“	„Number of packs“
...

No more stocks of affected articles exist.

Date: _____

Stamp + Signature

Anlage 1 / attachment 1: Artikelliste / product list

DK

Handelsname / trade name	REF (Artikelnr.) / REF (article no.) x = 0 - 9 (nicht auf Sterilverpackung / not on sterile packaging)	Artikelbezeichnung / article description	betroffene Lot-Nr. / affected lot no. alle LOT mit der Ziffernfolge / all LOT with digit sequence (x: betriebsinterne Ziffer und hier ohne Belang) (x: internal digit without relevance)
Foliodress gown Comfort Basic	992172x	FoliodressGown Comf Basic L st krepp P28	xxxx0100x
Foliodress gown Comfort Basic	992173x	FoliodressGown ComfBasic XL st krepp P28	xxxx0100x
Foliodress gown Comfort Perfect	992182x	Foliodress Gown Comf Perfect L st P28	xxxx0100x
Foliodress gown Comfort Perfect	992183x	Foliodress gown Comf Perf C&T XL P28	xxxx0100x
Foliodress gown Comfort Perfect	992184x	Foliodress Gown Comf Perfect XXL CT P28	xxxx0100x
Foliodress gown Comfort Special	992192x	Foliodress Gown Comf. special L C&T P28	xxxx0100x
Foliodress gown Comfort Special	992193x	Foliodress Gown Comf Special XL C&T P28	xxxx0100x
Foliodress gown Comfort Special	992194x	Foliodr. Gown Comf. special XXL C&T P28	xxxx0100x
Foliodress gown Comfort Special Classic	992164x	Foliodr. Comf. special L classic C&T P28	xxxx0100x
Foliodress gown Comfort Special Classic	992165x	Foliod. Comf. special XL classic C&T P28	xxxx0100x
Foliodress gown Comfort Special Classic	992166x	Foliod.Comf. special XXL classic C&T P28	xxxx0100x
Foliodress gown Comfort Urology	992180x	Foliodress Urology st Gown L P28	xxxx0100x
Foliodress gown Comfort Urology	992181x	Foliodress Urology st Gown XL P28	xxxx0100x
Foliodress gown Protect A Reinforced	992201x	Foliodress Gown Prot. A reinf. L st P28	xxxx0100x
Foliodress gown Protect A Reinforced	992202x	Foliodress Gown Prot. A reinf. XL st P24	xxxx0100x
Foliodress gown Protect A Reinforced	992203x	Foliodress Gown Prot. A reinf.XXL st P24	xxxx0100x
Foliodress gown Protect A Standard	992189x	Foliodress Gown Prot. A stand L st P28	xxxx0100x
Foliodress gown Protect A Standard	992190x	Foliodress Gown Prot. A stand XL st P28	xxxx0100x
Foliodress gown Protect A Standard	992191x	Foliodress Gown Prot. A stand XXL st P28	xxxx0100x
Foliodress gown Protect Open Back	992178x	Foliodress Protect Open Back L st P36	xxxx0100x
Foliodress gown Protect Open Back	992179x	Foliodress Protect Open Back XL st P36	xxxx0100x
Foliodress gown Protect Reinforced	992147x	Foliodress Protect standard XXL st P28	xxxx0100x
Foliodress gown Protect Reinforced	992154x	Foliodress Protect verstaerkt M st P36	xxxx0100x
Foliodress gown Protect Reinforced	992155x	Foliodress Protect verstaerkt L st P28	xxxx0100x
Foliodress gown Protect Reinforced	992156x	Foliodress Protect verstaerkt XL st P28	xxxx0100x
Foliodress gown Protect Reinforced	992157x	Foliodress Protect verstaerkt XXL st P28	xxxx0100x
Foliodress gown Protect Standard	992144x	Foliodress Protect standard M st P36	xxxx0100x
Foliodress gown Protect Standard	992145x	Foliodress Protect standard L st P28	xxxx0100x
Foliodress gown Protect Standard	992146x	Foliodress Protect standard XL st P28	xxxx0100x