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Medline International Germany GmbH - Wilhelm-Sinsteden-Str. 5-7 - D-47533 Kleve

Kleve, July 25th, 2014

URGENT FIELD SAFETY NOTICE

Our Reference: **FSCA 14-03** (replaces FSN 14-03, June 2014)
Concerning: **Microtek Basin Liners** (References 3109N and 3309N) included in Medline custom sterile packs
Attention: **Theatre/Operating Room Manager**
+ All departments concerned using the 16700A

Dear Customer,

The purpose of this letter is to inform you of a voluntary recall/removal of basin liners initiated by our supplier Microtek. The content of this field safety notice **replaces** the prior field safety notice FSN 14-03 sent in June 2014.

Due to 2 components (ref: **3109N** and **3309N**) included in some custom sterile packs, Medline is impacted by this urgent field safety notice. Nevertheless, we took the decision, not to recall the whole custom sterile packs **but only to have the basin liners included in the packs discarded.**

Details of affected devices:

The product codes concerned are listed in the attachment. ALL lots are concerned.

Description of the problem:

During normal performance vigilance of the basin liner, it has been identified by Microtek Medical B.V. that a very low number of basin liners have a small holes or cracks. These holes or cracks could, if present potentially compromise the sterile field.



Actions to be taken by the user

Several steps must be followed by your healthcare facility:

Step 1) Could you please urgently check your stock and promptly put on quarantine the concerned custom sterile packs. The scope of this recall includes all lot numbers.

Step 2) We have decided to apply a “warning sticker” on each custom sterile pack to inform the concerned users that the basin liner included has to be removed. Other components can be used safely. With this letter, you receive this warning sticker in sufficient quantity to be applied visibly on the concerned sets, if applicable.

Please put the stickers with WARNING on every set concerned still in your stock.

If the quantity is not sufficient please contact RA-Kleve and we will send you the remaining stickers immediately.

Step 3) Please complete and send back the enclosed attachment by either fax or email as soon as possible, but not later than August 8th 2014.



Picture of the 3109N basin liner

Picture of the 3309N basin liner

Either the 3109N OR the 3309N is included in the sets you receive, listed on the attachment form

Step 4) The custom sterile packs can be released and used once Step 3 is completed.

Step 5) Discard all basin liners taken out of the used custom sterile packs

All stock of your sets currently in our warehouses, will be labelled with the warning sticker. New production of these sets will be manufactured without the basin liner. This will be mentioned on the new labels (“does not contain basin liner from Microtek”). This will be applied until a suitable alternative has been found.

The RA department remains at your disposal for all your information requested related to this Field Safety Notice and Microtek’s FSCA.

Yours Sincerely,

i. A. Andrea de Meijer
RA specialist

- Enclosures:
- Field safety notice Response Form –
 - Acknowledgement + Stock information



**Immediate Attention Requested:
Field safety notice Response Form – Stock level information**

Response form
to be sent to:
Fax +49 2821 7510 7804 or
email gmb-eu-ra-kleve@medline.com before August 8th, 2014

Reference: FSCA 14-03 (replaces FSN 14-03)

- I, _____, acknowledge the receipt of the notification relative to the basin liners included in the list of custom sterile packs below. I have read and understood the notification.
- I have no affected products in stock
- I have affected products in stock and have relabeled the sets (put the sticker on)
- I will inform all departments concerned and all users are aware

Pack References	Quantity in stock <i>(to be filled by the customer)</i>

Name: _____

Position: _____

Facility: _____

Address: _____

Customer number: _____

Telephone: _____

Fax: _____

Date: _____

Signature: _____

Kenneth SMITH – Quality & Regulatory Affairs manager