

FIELD SAFETY NOTICE

Commercial name of the product: Basin Liner within Mölnlycke ProcedurePak®
Type of action: Advice regarding use of the device
Attention: Theatre/Operating Room Manager

Details of affected devices:

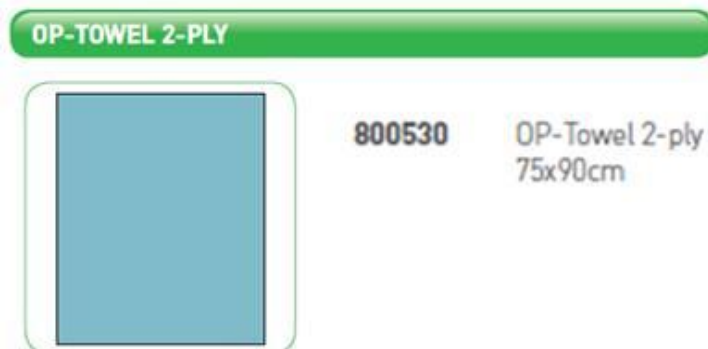
The product list is attached to this FSN.

Description of the problem:

During standard rigorous quality checking of components for use within Mölnlycke Health Care ProcedurePak®, it has been found that some units of the basin liners provided in the pack, have small holes in them which could be undetectable in normal use. Although the instructions for use of the basin liner itself clearly state that it should not be used to hold fluids or material for invasive use, these holes could, if present potentially compromise the sterile field.

Mölnlycke Health Care has assessed the issue thoroughly and advises that an extra sterile layer should be placed between the sterile basin liner and the non sterile basin/bowl into which it is normally placed. We suggest a medium sized impermeable non-adhesive drape, such as OP-towel 800530 (shown below) should be used. Mölnlycke Health Care will supply this free of charge on request.

In order to minimise disruption of surgical procedures, you may continue to receive this product for a short time. All product provided during this time will be appropriately marked with a copy of the advisory notice. We ask that you take the recommended actions as specified above.



Actions to be taken by the user:

1. Please identify and isolate all affected unused product at your facility.
2. **Please affix a copy of this advisory notice to each tray and make sure that its contents are brought to the attention of all relevant personnel**
3. Please complete the attached Confirmation form and email/fax back per its instructions. This step is required to confirm receipt of communications with all customers.
4. Return the attached response form (even if no recalled product is in inventory).



Ref: 50042553

Date: 03/10/13

5. If you have forwarded any affected product to any other healthcare institutions, please forward a copy of this letter and fax back containing affected serial numbers to those institutions.

Please contact your local Mölnlycke Health Care Customer Service or Account Manager if you have any questions or concerns regarding this notification. You may also contact:

Vigilance: Caroline Price (vigilance@molnlycke.com) or +44 (0)161 777 2646

Mölnlycke Health Care also confirms that this notice has been notified to the appropriate Regulatory Agency. Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately.

Sincerely,

A handwritten signature in black ink, appearing to read "Caroline".

Caroline Price
Vigilance Manager

A handwritten signature in blue ink, appearing to read "Steven Dowdley".

Steven Dowdley
Global Director of Regulatory Affairs

PLEASE COMPLETE AND RETURN THIS FORM TO:

Caroline Price, Vigilance Manager
Mölnlycke Health Care
2 Omega Drive
Irlam
Manchester
M44 5BJ

Telephone +44 (0)161 777 2679
Fax **+44 (0)161 621 2045**
E-mail: vigilance@molnlycke.com

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I have read this Field Safety Notice and I understand the actions required.

NAME : _____

POSITION : _____

EMAIL ADDRESS : _____

SIGNATURE : _____

DATE : _____

HOSPITAL/INSTITUTE AND CONTACT TELEPHONE NUMBER : _____