



Date: 25 Aug 2014

## FIELD SAFETY NOTICE

**Commercial name of the product:** ProcedurePak®  
**Type of action:** Return of the Device including advice  
**Attention:** Theatre Manager, Distributor

### Details on affected devices:

**See List provided.**

### Description of the problem:

Following the attached notification from Ecolab-Microtek Medical (Urgent Field Safety Notice – Ref date: 14 July 2014, Mölnlycke Healthcare is conducting a voluntary recall involving Ecolab-Microtek Medical Basin Liners that Ecolab-Microtek Medical supply to Mölnlycke Health Care and which are contained within Procedure Pak® products. As such, we stand by Ecolab-Microtek Medical Urgent Field Safety Notice of a voluntary recall of products with the affected batch numbers of this device within ProcedurePak® as identified in provided list, as a precautionary measure.

The Microtek Medical Field Safety Notice is included with this communication.

### Actions to be taken by the user:

1. Please identify and isolate all affected, unused Procedure Pak® products at your facility. Please note: there may be batch/lot numbers on the attached list which have exceeded their expiration date. These can be included in your response.
2. Please complete the attached Confirmation form/fax back per its instructions. This step is required to confirm receipt of communications with **all** customers.
3. Return the attached response form even if no recalled product is in inventory.
4. 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.
5. Mölnlycke Health Care will arrange for collection of the product from your facility.

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: Thomas Pettersson ([vigilance@molnlycke.com](mailto:vigilance@molnlycke.com)) or +46 (0)31 722 33 89

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,

Thomas Pettersson  
Global Vigilance Manager

Steven Dowdley  
Global Director of Regulatory Affairs

**PLEASE COMPLETE AND RETURN THIS FORM TO:**

Thomas Pettersson, Global Vigilance Manager  
Mölnlycke Health Care,  
Unity House,  
Medlock Street,  
Oldham,  
OL1 3HS

Tel: +44 (0)161 621 3967  
Fax: +44 (0)161 621 3966  
E-mail: vigilance@molnlycke.com

**Ref – 50046734**

Product code	Batch/LOT	Quantity Quarantined (pieces/trays)

NAME/POSITION : \_\_\_\_\_

EMAIL ADDRESS : \_\_\_\_\_

CITY/COUNTRY : \_\_\_\_\_

HOSPITAL/INSTITUTE : \_\_\_\_\_

HOSPITAL CONTACT TELEPHONE NUMBER : \_\_\_\_\_

SIGNATURE : \_\_\_\_\_

DATE : \_\_\_\_\_

