

FIELD SAFETY NOTICE

Commercial name of the product: Mölnlycke Health Care ProcedurePak®
Type of action: Return of the Device
Attention: Theatre Manager, Distributor

Details on affected devices: See list provided.

Product Code	Description
2313276-00	Cysto I/A set Single OD 20Ch ID 14Ch 200cm Drip chamber Sil. Tube + LL
2312879-00	Irrigation set double spike OD 21Ch 200cm Soft drip chber 2 clamps Sil.
2310022-00	Uro I/A double set 240cm Drip chamber Sil. tube
2315156-00	Irrigation set dbl.spike OD 21CH 250cm Soft drip chamber Clamps Sil. tube 10cm.
2312531-00	Lap. suction/irrigation set single spike Removable cannula OD 5mm 44cm
2306221-00	Insufflation Filter Set with 3.1m tubing
2307861-00	Irrigation set double spike OD 30Ch 255cm 3 clamps Sil. tube 15cm

Description of the problem:

Mölnlycke Health Care has identified that the sterile tubing supplied in certain ProcedurePak® trays, may not have received an adequate sterilization dosage. This may lead to a compromise in sterility of one of the component in these trays, according to the list above. As a precautionary measure, we are issuing a Field Safety Notice for the product mentioned above.

Actions to be taken by the user:

1. Please identify and isolate all affected unused product at your facility.
2. 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.
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 and replacement 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: Naila Khalid (vigilance@molnlycke.com) or +44 (0)161 621 3965

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 Petterson
Global Vigilance Manager



Steven Dowdley
Global Director of Regulatory Affairs

