KEBO MED A/S
ATT. JESPER MOLLER
Formervangen 5
GLOSTRUP 2600
DENMARK

FIELD SAFETY NOTICE

According to MEDDEV 2.12/1 rev. 8 ANNEX 5

Commercial name of product:	**Basin Liner**
Type of action:	Advice regarding use of the device
Attention:	Theatre/Operating Room Manager/Quality Manager

Date: 3rd of June 2014

Dear Customer,

Details of affected devices:
The product list is attached to this Field Safety Notice.

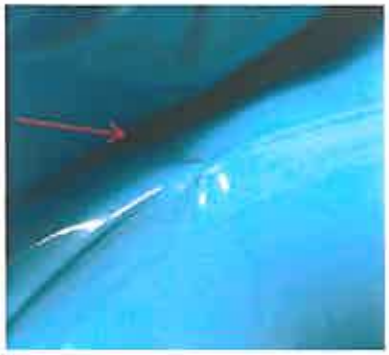
Description of the problem:
During normal performance vigilance of the basin liner, it has been identified that a very low number of basin liners have small holes or cracks. These holes or cracks could, if present potentially compromise the sterile field.

Actions to be taken by the user:
Microtek Medical has assessed the issue carefully and advises that prior to use the customer visually verify that this defect is not present.

Microtek Medical B.V.
a division of Ecolab
P.O. Box 234 7200 AE Zutphen The Netherlands
Hekkehorst 24, 7207 BN Zutphen The Netherlands
Tel. +31 (0)575 599 200 Fax +31 (0)575 599 299
www.ecolab.com
www.microtekmed.com

While unfolding the drape, perform 100% inspection for any possible cracks, cuts or holes prior to use. This decision is being taken considering the low patient risk and low market rate of complaints. Should the defect be present, we advise performing the surgery with a different basin liner.

What to look for:



Please affix a copy of this advisory notice to the product and ensure that the information communicated in this notice is brought to the attention of all relevant personnel, and return the completed acknowledgment to us. If you have provided this product to any other institutions, please forward a copy of this letter to those institutions.

Transmission of this Field Safety Notice: (if appropriate)

This notice has been provided to:

Local Competent Authorities

MEDCERT GmbH - Notified Body CE 0482
Pilatuspool 2
20355 Hamburg
Germany

TÜV NORD CERT GmbH - Notified Body CE 0044
Langemarckstraße 20
45141 Essen
Germany

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Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please contact your local Customer Service or Account Manager if you have any questions or concerns regarding this notification.

Maintaining a high level of safety and quality is our highest priority and we are diligently working to return to the normal use of the product.

Sincerely,

Chad Carter
Director of Surgical & OEM – Europe

Dieter Wirbals
Director Regulatory Affairs - Europe

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Response Form – Basin Drape

Please Fax or Email this Completed Response Form to:

TO:	Dieter Wirbals, Microtek Medical BV
FAX:	+31 575 599299
EMAIL:	Dieter.Wirbals@ecolab.com
RE:	Voluntary Medical Device Notification – Basin Drape

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

NAME:	
POSITION:	
EMAIL ADDRESS:	
SIGNATURE:	
DATE:	
HOSPITAL/INSTITUTE:	
CONTACT TELEPHONE NUMBER:	

PLEASE RESPOND BY JUNE 23, 2014

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MICROTEK MEDICAL PRODUCTS AFFECTED BY THIS NOTIFICATION

Part Number	Description
17700	Single Ring Basin Liner
16700A	Equipment Cover
3109N	Single Ring Basin Liner
3109NT	Single Ring Basin Liner, with tape
3108N	Single Ring Basin Liner
33099	NaCl Bowl Drape
9386001	Ring Basin Liner
3309N	Double Ring Basin Liner, Folded
TP1909A	Single Ring Basin Liner, Green
TP1909B	Single Ring Basin Liner, Green Unfolded

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