www.arcroyal.ie
Virginia Road, Kells,
Co Meath, Ireland
Tel: +353 (0)46 928 0100
Fax: +353 (0)46 928 0110
Email: info@arcroyal.ie

Field Safety Notice

Date: 21July2014

Commercial Name: ArcRoyal. Custom procedural trays (CPTs)

FSN Identifier: FSN14F001 Microtek Basin Liners

Type of action: Field safety corrective action – Device Return and Replaced

Attention:
This letter is to inform you of a urgent field safety notice initiated by Microtek Please refer to appendix I for the field safety notice issued by Microtek. The contents of this Field safety notice supersedes a prior advisory notice sent on the 17th of June 2014.

Details on affected items

Below is a list of all Products which have been supplied to you from ArcRoyal that is affected by this Advisory notice

Lot Number	Pack Ref	Qty of Cases	Qty of Components	Qty of Trays	SO number

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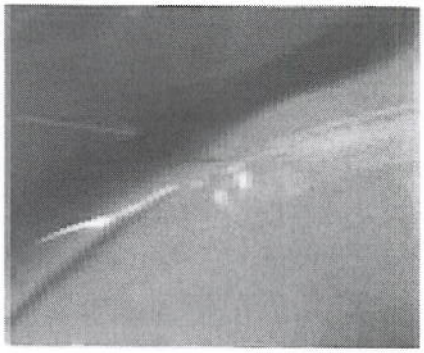
Description of the Problem
There may be possible cracks, cuts or holes in the Basin Liner as in the photographs below



Advice on Action to be taken by the user:
The above listed ArcRoyal custom procedure Trays, which may be in your inventory or supplied to you shortly, contain recalled Microtek Basin Liners. Sterile replacement Basin Liners will be made available to you by ArcRoyal as soon as possible. To minimize disruption and ensure continuous patient care, ArcRoyal is recommending the following:

1. Check your inventory to identify affected ArcRoyal custom procedure trays
2. Please complete and return the attached FSCA response form (Annex II) to ArcRoyal via fax or email. This should be done even if you have no effected product
3. Do not use any affected ArcRoyal customer procedure Trays until the replacement product is received at your facility and available for use
4. Upon opening an affected ArcRoyal custom procedure Tray, Health care professional should remove the Microtek Basin Liner and use the replacement product shipped to you
5. Retain and quarantine the recalled Microtek basin liner for return to ArcRoyal.

Transmission of this Field safety notice:
Please immediately forward this information to all departments within your organisation who may be using or ordering ArcRoyal Custom procedure trays. Additionally, please ensure that a copy of this information is provided to any other organisations to which the affected devices have been transferred.

We appreciate your immediate attention and cooperation and sincerely regret any inconvenience that this may cause you. Should you have any questions or concerns about the matter, please don't hesitate to contact me.

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The undersign confirms that this notice has been notified to the appropriate Regulatory agency

Yours Sincerely,

Irene Armstrong
Compliance Engineer
ArcRoyal.

Appendix I

FSN From Microtek

ECOLAB®

ARCROYAL LTD.
Attn Martin Elliot
Virginia Road
Kells Co. Meath
IRELAND

URGENT FIELD SAFETY NOTICE

According to MEDDEV 2.12/1 rev. 8 ANNEX 5

Commercial name of product:	**Basin Liner**
Type of action:	Field Safety Corrective Action Follow up to Field Safety Notice dated 3 June 2014
Attention:	Theatre/Operating Room Manager/Quality Manager

Date: 14-July-2014

Dear Customer,

This field safety notice is to inform you of a voluntary recall involving Ecolab-Microtek Medical Basin Liners listed on the attached sheet. The content of this field safety notice supersedes a prior field safety notice sent on 3 June 2014.

Details of affected devices:
The product list is attached to this Field Safety Notice. All lot numbers are included in the scope of 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.

MICROTEK™
MEDICAL EUROPE

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

Actions to be taken by the user:
Please immediately examine your stock and promptly quarantine the product codes in the attached list. The scope of this recall includes all lot numbers.

In addition, if you have further distributed the products subject to this recall, please identify your customers and notify them at once of this product recall. Please monitor and reconcile the recall of product from your customers.

Please complete and return the enclosed response form by either fax or email as soon as possible, but no later than August 1, 2014.

Upon receipt of the completed response forms, we will issue a return material authorization (RMA) and ask that you return any unused product to Microtek Medical at the address listed in the attached form. We will issue a credit for the unused product upon receipt.

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

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the Field Safety Corrective Action.

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a division of Ecolab
P.O. Box 234 7200 AE Zutphen The Netherlands
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Tel. +31 (0)575 599 200 Fax +31 (0)575 599 299
www.ecolab.com
www.microtekmed.com

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

Sincerely,

Welmoed Clous
Vice President Regulatory Affairs EMEA

Ronald Groen
Director Supply Chain Operations EMEA
HEALTHCARE

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a division of Ecolab
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Response Form – Basin Liner

Please Fax or Email this Completed Response Form to:

TO:	Customer Service, Microtek Medical BV
FAX:	+31 575 599299
EMAIL:	custservnl@ecolab.com
RE:	Voluntary Medical Device Recall – Basin Liner

CUSTOMER NAME:	
CONTACT PERSON:	
CONTACT PERSON PHONE:	

Please check ALL appropriate boxes

☐ I have read and understand the recall instructions provided in the 11 July 2014 letter.

☐ I have checked my stock and have returned inventory consisting of _____ cases.

Any adverse events associated with recalled product?: ☐ Yes ☐ No

If yes, please explain:

_____

Please check the appropriate box(es) to describe your business:

☐ wholesaler/distributor ☐ retailer

☐ re-packer ☐ manufacturer

☐ hospital/medical facility ☐ medical laboratory

Please confirm the quantity of recalled product remaining available for use at your facility:

Product SKU	Lot Number(s)	Quantity Originally Shipped to Customer	Quantity of Product Available for Return and Credit
17700			
16700A			
3109N			
3109NT			
3108N			
33099			
9386001			
3309N			
TP1909A			
TP1909B			

PLEASE RESPOND BY AUGUST 1, 2014

ECOLAB®

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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Appendix II
Response Form

ArcRoyal

Field Safety Corrective Action Response Form

Please read the attached Field Safety Notice. After reading please acknowledge that you have received, read and understood the actions to be taken by completing the information below.

The completed response form should be immediately returned via fax or email to

Fax: 00353469280110 Email:iarmstrong@arcroyal.ie

I have checked our inventory and found the following number of affected ArcRoyal Custom procedure Trays

CPT pack Ref	CPT Lot Number	Quantity (if none please indicate 0)

Tick Box √ for yes response

1. This facility agrees to utilize the supplied sterile replacement product and will remove the recalled Microtek Basin Liner upon opening the ArcRoyal CPT ☐

2. This facility agrees to retain and quarantine the recalled Microtek Basin Liner for return to ArcRoyal ☐

Facility Name	
Facility Address	
Your Printed name and Title	
Signature and Title	
Phone Number/Fax Number	