



## **URGENT FIELD SAFETY NOTICE**

Date: October 10, 2019

Object: Additional information on the use of Next Generation Mojave Absorbent Table Cover

Affected products:

Device Commercial Name	Article Code	Packaging
Next Generation Mojave Absorbent Table Cover	NGATC4090N-EU	42 eaches / box

Dear Sir / Madam,

As patient safety is our mutual priority you are receiving this Field Safety Notification from us.

It came to our attention that the Next Generation Mojave Absorbent Table Cover with article code NGATC4090N-EU is being used as a positioning tool to (re)position a patient at the OR table.

We would like to emphasize that this product is designed and intended to be used as an absorbent table cover, hence not as a positioning device.

Absorbent table covers are intended to act as a barrier between the patient and the OR table to absorb bodily fluids and keep the OR table clean.

In addition to this, for *positioning* and/or securing a patient on the OR table, specific local guidelines and hospital protocols will apply.

Please follow the instructions for use provided with our product as a reference for the intended use.

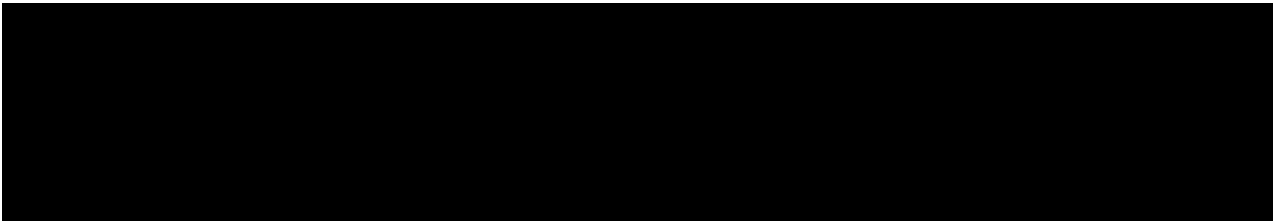
For any question or assistance that you may need, your sales contact remains at your disposal.

We would be grateful if you could acknowledge receipt of the present communication by returning at your earliest convenience - but no later than *November 15, 2019* - the attached reply form duly completed and signed.

Please note that the undersigns confirm that this notice has been reported to the appropriate Regulatory Agency.

Please accept our apologies for the inconvenience this may have caused.

Yours faithfully,



This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

This means, if you are a distributor, that this information has to be forwarded to any customers which was delivered with one of the affected batches.

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



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## Field Safety Notice Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	ECL-FSCA-148
FSN Date*	17 October 2019
Product/ Device name*	Next Gen Mojave Absorbent Table Cover
Product Code(s)	NGATC4090N-EU
Batch/Serial Number (s)	All

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation		
<input checked="" type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Please return this reply form.
Name*		
Signature*		
Date*		

<b>4. Return acknowledgement to sender</b>	
Email	<a href="mailto:Jiska.andriessen@ecolab.com">Jiska.andriessen@ecolab.com</a> Subject: FSN Next Gen Mojave
Deadline for returning the customer reply form*	<i>15 november 2019</i>

Mandatory fields are marked with \*

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.



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