

Fuhrmann GmbH · Bövingen 139 · D-53804 Much

Addressee

**Contact person:**

Name

phone. +49 2245-91 96-33

fax +49 2245-91 96-60

qw@fuhrmann.de

SRN Nummer: DE-MF-000006652

Date

**Urgent safety information – Positioning Aid LaRs (REF 300000 und REF 300300)**

Dear Sir or Madam,

for reasons of patient safety, we have to inform you about the following corrective actions.

**Description of the problem**

The above mentioned products are coated foam rolls. One customer has complained that the coating has partially come off under heavy mechanical stress.

**Potential hazards and possible risks for patients, users (operators) or third persons**

There is no acute patient hazard if the sterile foam rolls are subjected to normal mechanical loading during flexible positioning and repositioning of the respective limb.

Should the coating peel off due to strong mechanical stress, there is a possibility of contamination of the surgical area.

We therefore recommend covering the sterile foam rolls with a protective pad or cloth before using them in case of strong mechanical stress.

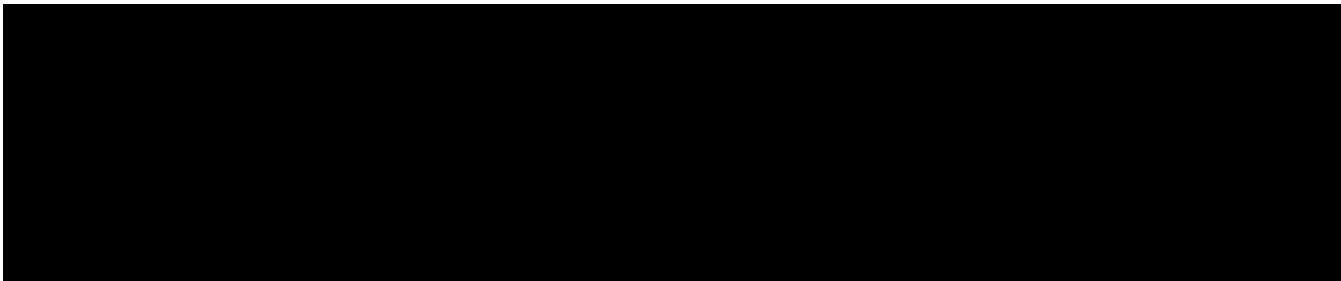
The following products that have been delivered to you are affected:

REF	Name	LOT	UDI	quantity delivered
300000	Positioning Aid, small, sterile, (LaRs) coated foam rolls, 80 x 90mm, à 1 piece	30136796	-	
300300	LaRs large, sterile coated foam rolls, 300 x 150 x 180mm, à 1 piece	30136748 30137046 30137161 30137292 30137362 30137866	-	

**What measures are to be taken by the addressee**

1. Please immediately check your stock and immediately isolate the product listed above.  
If you have continued to distribute the product that is the subject of this safety information, please identify your other customers and inform the affected customer(s) of this safety information immediately. **If it can be ensured** that the customers concerned have received this safety information and that the product is used in accordance with this safety information, it is not mandatory to return the products.  
We would like to ask you to monitor and follow up the measures with your customers!
2. Complete the enclosed reply form in full and send it to the above address by post, e-mail, or fax by **04.02.2022**.

**Please note:** Please return the completed reply form even if you no longer have any remaining stocks of the product concerned. Due to legal requirements, we must ensure and document that you have received this information, and your reply serves as proof of this.



Upon receipt of your reply form, you will be contacted by our customer service team to arrange the return and, if necessary, replacement of the affected goods. We will only take back goods from the affected batch (see table above).

**Pass on this safety information!**

Please ensure that all relevant persons in your organisation are aware of this safety information. After a final assessment, the competent supervisory authority may also be informed about this measure.

We apologise for any inconvenience caused to you in connection with this safety information and thank you in advance for your support to enable this measure to be implemented quickly and effectively.

With best regards

**Contact**

Person Responsible for Regulatory Compliance according to article 15 MDR

**Annex**

**Urgent safety information – Positioning Aid LaRs (REF 300000 und REF 300300)**

Affected REF/batches see cover letter.

**Reply form**

Upon receipt of your reply form, you will be contacted by our customer service team to arrange the return and, if necessary, replacement of the affected goods.

**(Please tick!)**

- We do not have any remaining stocks of the product concerned in stock.
- We have forwarded this safety information to all relevant users and can ensure that the products are used in accordance with this safety notice. A return shipment is not necessary.
- We have the following number of items in stock (please enter in the table below).  
Only goods from the affected batches that are affected by this recall will be taken back or exchanged. Please do not return any goods unsolicited.

REF	LOT	Quantity (please specify number of pieces)

<b>Name of the institution</b>	
<b>Street</b>	
<b>Postcode/ City</b>	
<b>Name of contact person (in block capitals)</b>	
<b>Email</b>	

\_\_\_\_\_

Date

\_\_\_\_\_

Signature

