

## Urgent Field Safety Notice – Recall

Address of customer  
& name of contact person

### Sales Division

Lohmann & Rauscher GmbH & Co.KG  
Westerwaldstr. 4 · D-56579 Rengsdorf  
Tel.: XXXX/ Fax: XXXX  
Email: xxxx.xxxx@de.LRmed.com

21.10.2024

## Urgent Field Safety Notice (Product Recall)

Dear customers,

today, we have to inform you about a precautionary product recall:

<b>Product(s) concerned</b>	Opraclean Ribbon Gauze for packing with Iodoform 5m x 1 cm
	REF 13580
<b>Batch(es) affected</b>	Lot 2421211603 Lot 2422111603
<b>L&amp;R reference number</b>	2024-13
<b>Reason for FSN</b>	Increased sinking time of the cotton component due to an ineffective bleaching process
<b>Explanation</b>	Internal investigations revealed that the sinking time of the cotton components used (non-impregnated tamponade) was increased (according to DIN EN 14079). This indicates that the bleaching process was not sufficiently successful. A final toxicological assessment of the residues is not possible.  It has been decided to recall the goods on the market as a precautionary corrective action. There are no more products in L&R stock.
<b>Expectable risk / harm</b>	A possible risk for the patient could be a poorer drainage effect and - as a possible consequence - a wound healing disorder. Up to now we have not any complaints regarding this event.

### The following measures arise for you from this:

- do not use the affected product(s) anymore
- return/destroy the products in stock
- inform all other affected persons (users, customers etc.)
- complete and return the confirmation form

We thank you in advance for your cooperation and apologize for any inconvenience.

With best regards,

Lohmann & Rauscher GmbH & Co KG

i.V. / on behalf of

XXXXYY  
Sales department

i.V. / on behalf of

XXXXYY  
Regional Vigilance Officer

### Annex:

- 1) Confirmation form

**Urgent Field Safety Notice (Product Recall)**

<b>Product(s) concerned:</b>	Opraclean Ribbon Gauze for packing with Iodoform 5m x 1cm REF 13580
<b>Reason for FSN:</b>	Increased sinking time of the cotton component due to an ineffective bleaching process

(please return via Fax to **+49 2634 - 99 xxxx** / via mail to **xxxxxx**, until **XX/XX/202X**)

\* reimbursement is not possible for later responses

**Sender:**

Lohmann & Rauscher GmbH & Co. KG  
Westerwaldstr.4  
56579 Rengsdorf, Germany

**Addressee:**

Address of customer  
+ name of contact person + customer number

& all users who use the mentioned products

**Corrective Actions:**

**Please do not use the affected products anymore.**

We request the following information and confirmation from you (as customer, distributor or retailer of the affected product batch(es)) for verification and for your reimbursement.

I hereby confirm that the affected products are no longer used. Moreover, all persons involved (including third parties, if provided with the affected products) have been informed about this urgent field safety notice.

*Please select one:*

- ☐ The affected products have been used up.
- ☐ The remaining products (including those provided to third parties) will be **returned** to L&R.
- ☐ The remaining products (including those provided to third parties) will be **destroyed**.

Date / Signature: \_\_\_\_\_

Printed Name: \_\_\_\_\_

Position: \_\_\_\_\_

Department / Institution: \_\_\_\_\_

Phone and Email: \_\_\_\_\_

Please enter the returned and destroyed products with quantities in the following table:

REF	Product	Batch(es)	Quantity returned products (Pcs.)	Quantity destroyed products (Pcs.)
13580	Opracleen Ribbon Gauze for packing with Iodoform 5m x 1cm	Lot 2421211603		
13580	Opracleen Ribbon Gauze for packing with Iodoform 5m x 1cm	Lot 2422111603		

Please name a contact person in your company for returns processing\*:

Name	Function
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Telephone number	Email

\*Lohmann & Rauscher will get in touch with the named contact person for the purpose of handling returns!