

## 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

21.10.2025

## Urgent Field Safety Notice (Product Recall)

Dear customers,

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

|                                 |                                                                                                                                                                                                           |
|---------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Product(s) concerned</b>     | Setpack/ Toptex Laparotomy Swabs<br><i>See enclosure in annex 1</i>                                                                                                                                       |
| <b>Batch(es) affected</b>       | <i>See enclosure in annex 1</i>                                                                                                                                                                           |
| <b>L&amp;R reference number</b> | 2025-16                                                                                                                                                                                                   |
| <b>Reason for FSN</b>           | Compromised sterile packaging                                                                                                                                                                             |
| <b>Explanation</b>              | During routine testing at L&R, the integrity of the sterile packaging's seam of above mentioned products was found to be compromised. The sterility of the product can therefore no longer be guaranteed. |
| <b>Expectable risk / harm</b>   | Potential infection due to insterility of product                                                                                                                                                         |

### 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

### Annexes:

- 1) REF and batch list
- 2) Confirmation form

Annex 1: REF and batch list

| REF   | Product                                                                        | Batch(es) |
|-------|--------------------------------------------------------------------------------|-----------|
| 15015 | Setpack Toptex lite Laparotomy Swab X-ray, 40x40cm, blue, 4ply, 5 pcs, sterile | 252358015 |
| 22332 | Setpack Laparotomy Swabs 40x70, 5 pcs, sterile, X unwashed                     | 252448332 |
| 79096 | Setpack Toptex lite without loop<br>40 x 40 cm, white, 6-ply, 5 pcs            | 251528096 |
|       |                                                                                | 252158096 |

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

|                              |                                               |
|------------------------------|-----------------------------------------------|
| <b>Product(s) concerned:</b> | Laparotomy Swabs<br><i>REF: See enclosure</i> |
| <b>Reason for FSN:</b>       | Compromised sterile packaging                 |

(please return via Fax to **+49 2634 - 99 xxxx** / via mail to **xxxxx**, until **30/11/2025**)

\* 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<br><i>returned</i><br>products<br>(Pcs.) | Quantity<br><i>destroyed</i><br>products<br>(Pcs.) |
|-----|---------|-----------|---------------------------------------------------|----------------------------------------------------|
| xxx | xxx     | xxx       |                                                   |                                                    |

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

| Name | Function |
|------|----------|
|------|----------|

|                  |       |
|------------------|-------|
| Telephone number | Email |
|------------------|-------|

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