

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

02.12.2025

Urgent Field Safety Notice (Product Recall)

Dear customers,

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

| | |
|---------------------------------|---|
| Product(s) concerned | Procedure packs (Kitpacks) containing syringes by MedNet Several (see separate table below) |
| Batch(es) affected | Several (see separate table below) |
| L&R reference number | 2025-21 |
| Reason for FSN | Potential contamination of syringes with particles |
| Explanation | The manufacturer MedNet is recalling color-coded syringes (blue and red) due to potential contamination with particles. These syringes were included in L&R procedure packs (Kitpacks). |
| Expectable risk / harm | Particles may not be detectable before use due to the potential for the particle to adhere to the syringe seal; therefore, in the worst-case scenario, their use on patients could lead to an embolism. |

The following measures arise for you from this:

- do not use the syringes in the affected procedure pack(s) anymore
- discard the syringes from the affected procedure packs
- inform all other affected persons (users, customers etc.)
- complete and return the confirmation form

In order to ensure that surgical interventions can continue and direct patient care can be maintained, the remaining procedure packs (Kitpacks) will be relabeled at your site and at L&R with the following additional information:

"Attention: Please do not use the included color-coded 10ml syringes (red or blue). Please discard."

The other components of the respective procedure packs (Kitpacks) are not affected by this recall and can be used as usual.

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

i.V. / on behalf of

XXXXYY
Sales department

XXXXYY
Regional Vigilance Officer

Annex:

- 1) Confirmation form
- 2) Original FSN by MedNet

Urgent Field Safety Notice (Product Recall)

| | |
|------------------------------|--|
| Product(s) concerned: | Procedure packs (Kitpacks) containing syringes by MedNet |
| Reason for FSN: | Potential contamination of syringes with particles |

(please return via Fax to **+49 2634 - 99 xxxx** / via mail to **xxxxx**, until **15 Dec 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 procedure packs have been used up.
- ☐ The remaining procedure packs (including those provided to third parties) will be re-labelled by L&R and the affected syringes therein discarded.

Date / Signature: _____

Printed Name: _____

Position: _____

Department / Institution: _____

Phone and Email: _____

Please enter the quantities of products to be relabeled in the following table:

| REF | Product | Batch(es) | Product quantity in stock (PK) <i>(for relabelling)</i> |
|-----|------------------------|-----------|---|
| xxx | Kitpack procedure pack | xxx | |

(to be adapted to the respective customer order)

Please name a contact person in your company/ institution for the relabeling process*:

Name

Function

Telephone number

Email

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



URGENT FIELD SAFETY NOTICE

Colour Coded Syringes

07.11.2025

By: MedNet GmbH, Borkstrasse 10, 48163 Münster, Germany

For attention of: Manufacturers of medical devices and CPT providers

Affected products and lot number range:

| Part number | Product description | Lot |
|-------------|---|----------|
| 10301200 | Colour Coded Syringe, 10ml, LL, Polycarbonate, blue | P2342004 |
| 10301400 | Colour Coded Syringe, 10ml, LL, Polycarbonate, red | P2416002 |

Description of product problem:

MedNet GmbH is issuing this urgent field safety notice after contamination with particles was identified in some syringes.

Particles may not be detectable before use due to the potential for the particle to adhere to the syringe seal; therefore, in the worst-case scenario, their use on patients could lead to an embolism.

Investigations in the production environment have revealed that 90% of the specified batches are not affected. For the remaining 10%, contamination cannot be definitively ruled out. Therefore, the aforementioned batches are being recalled in their entirety.

Actions to be taken:

To support this recall and ensure that the affected products are removed from the market, please take the following steps:

- Check if any of the affected products listed are in your warehouse.
- Enter your inventory on the following list and immediately stop all further shipments of the affected product.
- Please send the completed confirmation form and the completed list to nicole.boehnisch@mednet-europe.com as soon as possible, but no later than five (5) days after receiving this letter, even if you no longer have any stock.
- Upon receipt of the completed confirmation form, your account manager will contact you to arrange disposal/collection.
- Forward this safety information to all customers who have received the affected product.



Please send us your confirmation that this recall has been communicated to all economic operators who have received products from you as listed below.

We also ask that you ensure the remaining stocks from the economic operators are returned to you so that we can then coordinate the next steps with you.

We rely on your cooperation to process this. We apologize for any inconvenience and thank you for your cooperation.

The relevant competent authority in your respective country has been informed about this urgent field safety notice.

With best regards,

Heiko Laudor
General Manager

Nicole Böhnisch
Quality Management/Regulatory Affairs

Annexes:
Annex 1 – Confirmation

| REF | batch |
|--------|------------|
| 284326 | 2433480167 |
| 284326 | 2436380003 |
| 297410 | 2443180024 |
| 297410 | 2446380062 |
| 297410 | 2503480068 |
| 298622 | 2437480035 |
| 300562 | 2437480108 |
| 300562 | 2505580042 |
| 302251 | 2436580039 |
| 302251 | 2450480050 |
| 282530 | 2507280092 |
| 296368 | 2507380082 |
| 296368 | 2519180056 |
| 296374 | 2507580026 |
| 296374 | 2517480030 |
| 297410 | 2503480068 |
| 297410 | 2513180058 |
| 297410 | 2520380023 |
| 297996 | 2513480103 |
| 302059 | 2514180063 |
| 307546 | 2520680021 |
| 308806 | 2523180153 |