

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

XXXXXX

Sales department

i.V. / on behalf of

XXXXXX

Regional Vigilance Officer

Annex:

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

Annex 1: Confirmation form

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 xxxx, 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 relabelled 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
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Telephone number Email

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

Annex 2 – Original FSN by MedNet



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@medneteurope.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