

Urgent Field Safety Notice – Recall

Address

Sales Division

Lohmann & Rauscher d.o.o.
Oreškovićeva 10a HR-10000 Zagreb
Tel.: 01 6609543 Fax; 01 6609548
Email: info@hr.LRmed.com

Zagreb, 26.09.2019.

Urgent Field Safety Notice **Product Recall due to possible non-sterility**

Dear Sir or Madam,

Today, in terms of patient safety, we would like to inform you about the precautionary product recall of the cardboard kidney shells in our KitPack set systems.

After re-validation of our EO sterilization process, it was found that in single cases a non-sterility may be present.

The affected products and batches were immediately quarantined in the warehouse.

Theoretically, the non-sterility could lead to inflammation or infection.

Please return the products in the attachment with the enclosed form. Of course, the products will be exchanged free of charge or credited upon request.

Please ensure within your organization that all users of the above mentioned products and other relevant persons are aware of this **Urgent Field Safety Notice** and send the enclosed confirmation back to us.

If you have delivered the product to third parties, please forward a copy of that information to them.

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

Yours truly,

Lohmann & Rauscher GmbH & Co KG
i.V. / On behalf of

i.V. / On behalf of

LRHR
Sales department

Tvrtko Blaić Milutinović, dipl.ing.
Regional Vigilance Officer

Attachment:

1) Urgent Field Safety Notice, Product Recall due possible non-sterility

Enclosure 1

Urgent Field Safety Notice!

26.09.2019.

Product Recall due to possible non-sterility

(via Fax to 01 6609 548)

Sender: Lohmann & Rauscher d.o.o.
Oreškovićeve 10a
HR-10000 Zagreb

Addressee:

Description: Recall of cardboard kidney shells in our KitPack set systems due to possible non-sterility

Corrective Actions:

Please do not use set systems with cardboard kidney shells anymore.

Please inform all employees who use the products about this Field Safety Notice and confirm that you are not using the set systems with cardboard kidney shells.

The undersigned confirms (please tick):

- [...] that he does not use the set systems with cardboard kidney shells,
- [...] that he informs all persons involved about this important information about the above mentioned products,
- [...] that he no longer owns the products listed above,

- [...] that he has not given the above mentioned products to third parties,
- [...] that he has informed third parties, if they have received from him the above-mentioned products, about the safety information and non-use of the set systems with cardboard kidney shells.

- [...] that the affected products delivered to him that are still in his or her possession or in the possession of a third party, will be returned to Lohmann & Rauscher GmbH & Co. KG,

To ensure a free return to us, please contact our L&R returns department:

Ms. Petra Gamilec, tel.: 01 6609 625 / Fax:01 6609 548, e-mail: info@hr.LRMed.com

Contact Person for Lohmann & Rauscher within your facility:

Name	Function
Telephone number	Email

Adaption on the customer orders

Please enter the returned products with quantity in the following table:

REF	Product	Lot number (batch)	Quantity returned products
233363	Set za kateterizaciju		

Date / Signature : _____

Printed Name: _____

Position: _____

Department / Institution: _____

Phone and Email: _____