

## **Urgent Field Safety Notice – Recall**

**Address**

**Sales Division**

**Sales Division**

Lohmann & Rauscher GmbH & Co.KG

Westerwaldstr. 4 · D-56579 Rengsdorf

**Kurzz.** Tel.: 99-XXXX/ Fax: 99-XXXX

Email: xxxx.xxxx@de.LRmed.com

**Date**

### **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

XXXXXX

**Sales department**

XXXXXX

**Regional Vigilance Officer**

Attachment:

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

Enclosure 1

**Urgent Field Safety Notice!**

**Date**

**Product Recall due to possible non-sterility**

**(via Fax to 02634 - 99 xxxx)**

**Sender:** Lohmann & Rauscher GmbH & Co. KG  
Westerwaldstr.4  
D-56579 Rengsdorf

**Addressee:** Adresse  
Xxx  
xxx  
& all users who use the below mentioned products.

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

**Table should be adapted to the respective customer**

**If necessary, name sales contact person**

**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. / Mr. XXX/YYY Tel. 02634 / 99-XXXX / Fax., email XXX**

**Contact Person for Lohmann & Rauscher within your facility:**

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Name	Function
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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 pro- ducts
XXX	KitPack set system		

**Customer address data, signiture**

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

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

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

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

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