

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 impurity

- **Raucodrape Surgical Incise Drape, 55 x 80 cm, sterile**
Lot 444212206 (REF no. 25447) (single product)
- and
- **Set systems KitPack concerned (with integratd Incise Drape)**

Dear Sir or Madam,

Today, in terms of patient safety, we would like to inform you about a precautionary product recall of the above mentioned products.

After control of Raucodrape Surgical Incise Drape 55 x 80, Lot 444212206 (REF no. 25447) an impurity on 4 products which could be blood was observed. The product was not used on human beings. The 4 products were separated and our Quality Assurance blocked the goods in our warehouse immediatly.

The assumption is that during the packaging process of RD Surgical Incise Drape a worker has injured a finger of his/her hand unnoticeable. The blood contaminated a part of the products of the lot during the packaging process.

Therefore we perform a precautionary recall of the products in terms of patient safety.

Please send the products of the above mentioned batches with the enclosed form back to us. You will receive a credit note for the returned products in short term.

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

XXXXYY
Sales department

XXXXYY
Regional Vigilance Officer

Attachment:
Urgent Field Safety Notice, Product Recall due to impurity

Urgent Field Safety Notice!

Date

Product Recall due to impurity
(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 the following products due to impurity

- **Raucodrape Surgical Incise Drape, 55 x 80 cm, sterile Lot 444212206 (REF no. 25447) (single product)**

and

- **Set systems KitPack concerned (with integratd Incise Drape)**

Corrective Actions:

We ask you not to use the above mentioned products anymore and to send them back to us!

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

Name	Function
Telephone number	Email

Please inform your employees who use the products of this Field Safety Notice and confirm to us that the product is not used anymore and the products have been returned to us.

The undersigned confirms (please tick):

- that he does not possess the above mentioned products anymore,
- that he has not given the above mentioned products to third parties,
- that if he has given the above mentioned products to employees or third parties, he has informed the employees and third parties about the recall,
- that he will return the above mentioned products, which have been delivered to him and are still in his possession or in the possession of third parties, to Lohmann & Rauscher

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

Product (REF)	Batch (LOT)	Quantity of returned products
Raucodrape Surgical Incise Drape (REF 25447)	444212206	
KitPack NN (REF NN)	NN	

Date / Signature : _____

Printed Name: _____

Position: _____

Department / Institution: _____

Phone and Email: _____