

**Urgent Field Safety Notice –
Address**

Sales Division

Sales Division

Lohmann & Rauscher GmbH & Co.KG

Westerwaldstr. 4 · D-56579 Rengsdorf

Kurz. Tel.: 99-XXXX/ Fax: 99-XXXX

Email: xxxx.xxxx@de.LRmed.com

Date

Urgent Field Safety Notice

due to defect MICRO FEATHER DISPOSABLE OPHTHALMIC SCALPEL (in Kitpack procedure packs)

Dear Sir or Madam,

Today we would like to inform you about a precautionary product recall of defect MICRO FEATHER DISPOSABLE OPHTHALMIC SCALPEL (in Kitpack procedure packs). (see enclosed FSN of manufacturer)

The products and batches affected by this defect were immediately quarantined in our warehouse.

The manufacturer found out that the plastic handle of the product changes over time for some reason, resulting in weakening of the fixing strength which can cause the blade to fall out of the handle.

This may cause an injury or harm to the patient or user. It may also lead to the interruption or delay of surgical procedures (see enclosed FSN of manufacturer).

Since the products are part of the Kitpack procedure packs delivered to you, the following measures must be taken in the interest of patient safety:

Please do not use the affected products from the Kitpack procedure packs and please discard these products before use in the operating theatre.

In order not to endanger the operation and to maintain direct patient care, we will label the Kitpack procedure packs still in stock with the following additional information:

"Attention: Please discard the ophthalmic scalpels inside"

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

The products will, of course, be exchanged free of charge or credited on request.

Please ensure in your organisation that all users of the products listed below and other persons to be informed are aware of this Urgent Field Safety Notice and return the enclosed confirmation to us completed.

If you have passed on the products to third parties, please forward a copy of this information to them.

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

Attachment:

- 1) Urgent Field Safety Notice due to defect MICRO FEATHER DISPOSABLE OPTHALMIC SCALPEL (in Kitpack procedure packs)

Enclosure 1

Urgent Field Safety Notice!

Date

due to defect MICRO FEATHER DISPOSABLE OPHTHALMIC SCALPEL (in Kitpack procedure packs)

(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: Field Safety Notice due to defect MICRO FEATHER DISPOSABLE OPHTHALMIC SCALPEL (in Kitpack procedure packs)

Table should be adapted to the respective customer

If necessary, name sales contact person

Corrective Actions:

Please do not use the affected products in the Kitpack procedure packs anymore.

Please inform all employees, who use the products, about this Field Safety Notice and confirm that you are not using the affected products

The undersigned confirms (please tick as appropriate)

- that they will not use the affected products from the Kitpacks,
- that they has informed all persons involved about this important information,
- that they no longer possesses the mentioned products,
- that they has not sold the mentioned products to third parties,
- that they has informed third parties, if they have received the mentioned products from them, of the Field Safety Notice and non-use of the affected products from the Kitpack procedure packs.

Please name a contact person in your company:

Contact Person for Lohmann & Rauscher within your facility:

Name	Function
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Telephone number	Email
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*Lohmann & Rauscher will get in touch with the named contact person

Adaption on the customer orders

Please enter the products with quantity in the following table:

REF	Product	Lot number (batch)	Quantity
XXX	Kitpack procedure packs		

Customer address data,

Date / Signature : _____

Printed Name: _____

Position: _____

Department / Institution: _____

Phone and Email: _____