

Urgent Field Safety Notice – Recall

Address

Sales Division

Sales Division

Lohmann & Rauscher GmbH & Co.KG

Westerwaldstr. 4 · D-56579 Rengsdorf

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

Email: **xxx.xxxx@de.LRmed.com**

Date

Urgent Field Safety Notice

Product Recall due to breaking and fraying of the x-ray thread in RK gauze compresses (in KitPack procedure packs)

Dear Sir or Madam,

Today we would like to inform you about the precautionary product recall of gauze compresses with RK thread due to a possible breaking or fraying of the RK thread used. The affected gauze compresses with RK thread are integrated in KitPack procedure packs.

Based on feedback from three clinics, it has become known that under tension the RK thread in the affected gauze compresses can break and fray at individual points.

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

Theoretically, small pieces of thread could occur when the RK thread breaks or frays. This could, for example, lead to inflammation and/or granuloma formation when remaining in the body.

Please return the products you have in stock using the enclosed formular. 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 Safety Precaution 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, Product Recall due to breaking and fraying of the x-ray thread in RK gauze compresses (in KitPack procedure packs)

Enclosure 1

Urgent Field Safety Notice!

Date

Product Recall due to breaking and fraying of the x-ray thread in RK gauze compresses (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: Product Recall due to breaking and fraying of the x-ray thread in RK gauze compresses (in KitPack procedure packs)

Table should be adapted to the respective customer

If necessary, name sales contact person

Corrective Actions:

Please do not use KitPack procedure packs with the affected RK gauze compresses 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 the affected RK gauze compresses.

The undersigned confirms (please tick):

[...] that he does not use the set systems with the affected RK gauze compresses,

[...] 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 mentioned products to third parties,

[...] that he has informed third parties, if they have received from him the mentioned products, about the safety information and non-use of the set systems with the affected RK gauze compresses.

[...] 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,

Please name a contact person in your company for returns processing:

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 for the purpose of handling returns!

Adaption on the customer orders

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

REF	Product	Lot number (batch)	Quantity returned products
XXX	KitPack procedure packs		

Customer address data, signiture

Date / Signature : _____

Printed Name: _____

Position: _____

Department / Institution: _____

Phone and Email: _____

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

Email: xxxx.xxxx@de.LRmed.com

Date

Urgent Field Safety Notice

due to breaking and fraying of the x-ray thread in gauze compresses (in KitPack procedure packs)

Dear Sir or Madam,

Today we would like to inform you about the precautionary product recall of gauze compresses with x-ray thread due to a possible breaking or fraying of the x-ray thread used. The affected gauze compresses with x-ray thread are integrated in KitPack procedure packs.

Based on feedback from three clinics, it has become known that under tension the x-ray thread in the affected gauze compresses can break and fray at individual points.

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

Theoretically, small pieces of thread could occur when the x-ray thread breaks or frays. This could, for example, lead to inflammation and/or granuloma formation when remaining in the body.

Since the gauze compresses with x-ray thread 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 gauze compresses with x-ray thread from the Kit-Pack procedure packs and please discard these products before use in the operating theatre. Before using the other components, please check whether they are contaminated by parts of the x-ray thread.

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: Do not use gauze compresses with x-ray thread. Please discard"

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 breaking and fraying of the x-ray thread in gauze compresses (in KitPack procedure packs)

Enclosure 1

Urgent Field Safety Notice!

Date

due to breaking and fraying of the x-ray thread in gauze compresses (in Kit-Pack 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 breaking and fraying of the x-ray thread in gauze compresses (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 gauze compresses with x-ray thread 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 gauze compresses with x-ray thread.

The undersigned confirms (please tick as appropriate)

- that he will not use the affected gauze compresses with RK thread from the Kit-Packs,
- that he has informed all persons involved about this important information,
- that he no longer possesses the mentioned products,
- that he has not sold the mentioned products to third parties,
- that he has informed third parties, if they have received the mentioned products from him, of the Field Safety Notice and non-use of the gauze compresses concerned with x-ray thread 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, signiture

Date / Signature : _____

Printed Name: _____

Position: _____

Department / Institution: _____

Phone and Email: _____

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Urgent Field Safety Notice

Product Recall due to breaking and fraying of the x-ray thread in RK gauze compresses (in SetPack)

Dear Sir or Madam,

Today we would like to inform you about the precautionary product recall of gauze compresses with RK thread due to a possible breaking or fraying of the RK thread used.

Based on feedback from three clinics, it has become known that under tension the RK thread in the affected gauze compresses can break and fray at individual points.

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

Theoretically, small pieces of thread could occur when the RK thread breaks or frays. This could, for example, lead to inflammation and/or granuloma formation when remaining in the body.

Please return the products you have in stock using the enclosed formular. 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 Safety Precaution 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

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Enclosure 1

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Date

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

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

Description: Product Recall due to breaking and fraying of the x-ray thread in RK gauze compresses (in Setpack)

Table should be adapted to the respective customer

If necessary, name sales contact person

Corrective Actions:

Please do not use products with the affected RK gauze compresses anymore.

Please inform all employees who use the products about this Field Safety Notice and confirm that you are not using the products with the affected RK gauze compresses.

The undersigned confirms (please tick):

[...] that he does not use the products with the affected RK gauze compresses,

[...] 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 mentioned products to third parties,

[...] that he has informed third parties, if they have received from him the mentioned products, about the safety information and non-use of the products with the affected RK gauze compresses.

[...] 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,

Please name a contact person in your company for returns processing:

Contact Person for Lohmann & Rauscher within your facility:

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Adaption on the customer orders

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

REF	Product	Lot number (batch)	Quantity returned products
XXX	SetPack procedure packs		

Customer address data, signiture

Date / Signature : _____

Printed Name: _____

Position: _____

Department / Institution: _____

Phone and Email: _____