

Field Safety Notice/Recall
Address

Sales Switzerland
Lohmann & Rauscher AG
Oberstrasse 222. CH-9014 St. Gallen
Tel.: +41 71 274 25 70 / Fax: +41 71 274 25 71
E-Mail: info@ch.LRmed.com

29.06.2021 / **3rd Extension Recall**

Urgent Field Safety Notice

Recall due to breaking and fraying of the X-ray detectable thread in gauze swabs (RK thread)
contained in Kitpack® OR Custom Procedure Trays

Dear Sir or Madam,

Today we wish to inform you, for the safety of your patients, of the extension of the on-going product recall of gauze swabs with X-ray detectable thread due to the possible breaking or fraying of the RK thread used. The affected gauze swabs with RK thread are included in Kitpack OR Custom Procedure Trays.

Feedback from three hospitals had brought to our attention that under tension the RK thread in the affected gauze swabs can break and fray in a few places.

After a further complaint, – and after consultation with the responsible regulatory authority – please take the actions below for the affected products.

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

In theory, breaking or fraying of the RK thread might result in small, loose pieces of thread, potentially causing inflammation and/or granuloma formation if, for example, they remain in the body.

As the gauze swabs with RK thread are included in the Kitpack OR Custom Procedure Trays supplied to you, the following actions must be taken for the safety of your patients:

Do not use the affected gauze swabs with RK thread in the Kitpack OR Custom Procedure Trays; discard them prior to use of the trays in OR.

Check the other components for contamination with pieces of RK thread prior to use.

To ensure surgeries continue to run smoothly and patient care is not affected, we will further label the Kitpacks still in our warehouse as follows:

**"Warning: Do not use the gauze swabs with RK thread contained in the packs.
Please discard."**

The other components of the Kitpack OR Custom Procedure Trays are not affected and can be used as usual.

Please ensure in your organisation that all users of the products listed in Annex 2 and other persons to be informed are aware of this

urgent field safety notice

and please complete and return the attached confirmation

by no later than 25.06.2021.

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

Thank you in advance for your understanding and cooperation.

Please don't hesitate to contact us if you have any questions.

Yours sincerely,

Lohmann & Rauscher AG



Mirto Meyer
Executive Director



David Styger
Regional Safety Officer

Annexes:

Annex 1

Field Safety Notice/Confirmation

(please complete and return by 25.06.2021)

Annex 2

affected Kitpack with REF/LOT

(please complete and return by 25.06.2021)

Annex 1

Urgent Field Safety Notice

Recall due to breaking and fraying of the X-ray detectable thread in gauze swabs (RK thread)

in Kitpack® OR Custom Procedure Trays

Please sign and return by no later than 25.06.2021 to:

By email: info@ch.LRmed.com

By fax **+41 71 274 25 71**

Sender: Lohmann & Rauscher AG
Oberstrasse 222
CH-9014 St. Gallen

Recipients: **Address**
and all users who use the products listed below.

Description: **Urgent Field Safety Notice**
Recall due to breaking and fraying of the X-ray detectable thread in
gauze swabs (RK thread)
in Kitpack® OR Custom Procedure Trays

Please refer to Annex 2 for the items affected

Actions:

Do not use the affected gauze swabs with RK thread in the Kitpack OR Custom Procedure Trays.

Please inform all employees who use the products about this field safety notice and confirm that you are not using these products.

The undersigned confirms (please tick)

- ☐ that they do not use the affected gauze swabs with RK thread in the Kitpack OR Custom Procedure Trays
- ☐ that they have informed all persons involved about this important notice regarding the above mentioned product
- ☐ that they no longer own the products listed above
- ☐ that they have not passed on the products listed above to third parties
- ☐ that they have informed third parties to whom they have passed on the products listed above about the field safety notice and non-use of the affected gauze swabs with RK thread in the Kitpack OR Custom Procedure Trays.

Annex 2

REF	Product	Batch	Quantity
253767	KP CH Brust/Lipo/Abdomino	203958767	
240468	KP CH Lochtuch	203528468	
255599	KP CH Arthroskopie	203768599	
255292	KP CH Universal	203528292	
254951	KP CH Kopf	203848951	
264248	KP CH Universal	203918248	
264366	KP CH procto	203828366	
264366	KP CH procto	203958366	

Customer confirmation

Address

Date/signature:

Name in capital letters:

Position:

Department/Institution:

Telephone and email address: