

Urgent Field Safety Notice –

Recall

KBC Sestre milosrdnice
Klinika za traumatologiju
Draškovićeve 19
10000 Zagreb

Lohmann & Rauscher d.o.o.
Jakuševačka 1E
10010 Zagreb
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Urgent Field Safety Notice

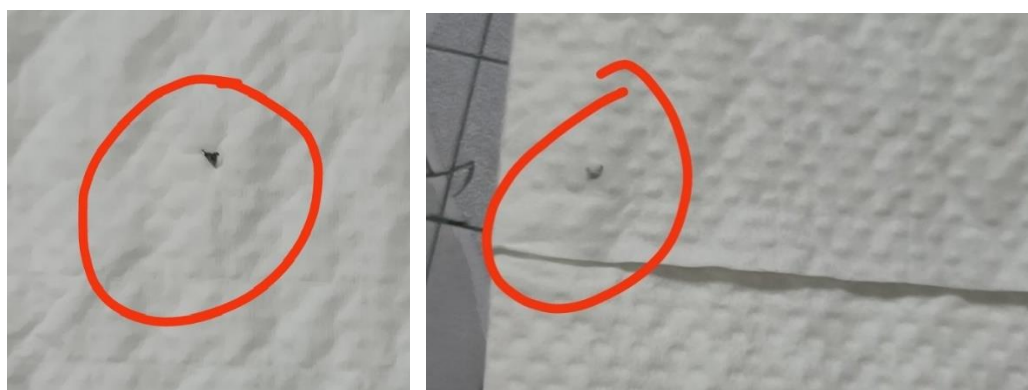
Product recall due to metal pieces in towels (part of Sentinex surgical gowns)

Dear Sir or Madam,

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

REF	Product	Lot
19303	Sentinex PRO Surgical Gown Standard Spunl., wrapped, XL long 170 cm, sterile	21443L031

During internal quality controls metal pieces of 0.5 -1 mm size were found in the enclosed towels that were delivered together with Sentinex surgical gowns. These are incorporated in the material and may protrude slightly in some cases.



The affected products and batches were immediately quarantined in the warehouse.

Theoretically, using the towel to dry off e.g. excess disinfectant could cause damage to surgical gloves and thus damage the sterile barrier or it could lead, in the worst case, to smallest injuries, e.g. to fingers. The use of the towel on the patient (to dry off e.g. excess disinfectant or liquids) could theoretically also result in smallest injuries to the patient.

Please do not use the products anymore and destroy them.

For processing, please complete and return the enclosed confirmation to us. The products will of course be exchanged free of charge or credited on 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.

This procedure is coordinated with the national supervisory authorities.

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

Matija Fresl
Sales department

Goran Grabovac
Regional Vigilance Officer

Attachment:

- 1) Urgent Field Safety Notice, Product Recall due to metal pieces in towels (part of Sentinex surgical gowns)

Attachment 1

Urgent Field Safety Notice!

Product Recall due to metal pieces in towels (part of Sentinex surgical gowns)

(via Fax to +385 1 6609 548)

Sender: Lohmann & Rauscher d.o.o.
Jakuševečka 1E, HR-10010 Zagreb

Addressee: KBC Sestre milosrdnice
Klinika za traumatologiju
Draškovićeva 19,
10000 Zagreb

Description: Urgent Field Safety Notice – product recall due to metal pieces in towels (part of Sentinex surgical gowns)

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Corrective Actions:

We ask you not to use the towels (part of Sentinex surgical gowns) anymore.

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

The undersigned confirms, *(please tick)*:

- that he destroys the affected products with the towels still in his possession or in the possession of third parties.
- that he does not use the towels,
- that he has informed all persons involved of this important information concerning the above-mentioned product,
- that he no longer possesses the above-mentioned products,
- that he has not given the above mentioned products to third parties,
- that he has informed third parties, if they have received the above mentioned products from him, about the safety information and non-use of the towels concerned (part of Sentinex surgical gowns).

Please name a contact person in your company for processing:

Name contact person

Function

Phone

Email

