

Urgent Field Safety Notice – Recall

Poliklinika Korak
Papandopulova 8b
21000 Split

Lohmann & Rauscher d.o.o.
Jakuševička 1E
10010 Zagreb
Tel.: 091/223-1601 Fax: 01/6609-548
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20.04.2022

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 the market, it has become known that the x-ray thread in the affected gauze compresses can break under tension and fray at individual points.

Due to two additional reports from two different clinics in Switzerland it was decided to extend the scope of a former recall.

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 Kitpack 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

Martina Liverić
Sales department

Goran Grabovac
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!

20.04.2022.

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

(via Fax to +385 1 6609 548)

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

Addressee: Poliklinika Korak
Papandopulova 8b
21000 Split

Description: Field Safety Notice due to breaking and fraying of the x-ray thread in gauze compresses (in Kitpack procedure packs)

REF	LOT	Naziv proizvoda
234159	202158159	KP Split/HR Komplet za artro kolj234159A
29677	194528677	KP Pula/HR za artrosk.koljena P 5778B
29677	201358677	KP Pula/HR za artrosk.koljena P 5778B
29677	203018677	KP Pula/HR za artrosk.koljena P 5778B
29677	204868677	KP Pula/HR za artrosk.koljena P 5778B

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 x-ray thread from the Kitpacks,
- 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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