

Field Safety Notice – Recall

Lohmann & Rauscher d.o.o.
Oreškovićevo 10a, HR-10000 Zagreb
Tel.:01/6609543 Fax: 01/6609548
Email: info@hr.LRmed.com

Zagreb, 29.08.2017.

Urgent Field Safety Notice Product Recall due to possible unsterility

| REF | Product | Lot |
|-------|-----------------------------|------------|
| 23094 | Metalline Tracheo 8x9 50ste | 1728112208 |

Dear Sir or Madam,

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

Event

In the course of a control of the production process by our Quality Assurance Department (QA), in single cases leakages (cannulas) were discovered in the sealing of the sterile packaging of the final products (14 products with leakages (cannulas) in 82.200 products tested). The affected batch was partly delivered in the market (in the market: 36.950 pieces).

Further procedure

The probably affected products were immediately separated and the affected batch was blocked in the warehouse.

Until today we have not received any complaints from the market. Theoretically, the unsterility could cause inflammation or infection on the tracheostoma.

Please send the affected batches of the products (see list in enclosure) with the enclosed form back to us (small amounts can be destroyed locally). You will receive a credit note for the returned/destroyed products in short term.

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.

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

Sales department

Regional Vigilance Officer

LRHR
Sales department

Ines Vlahović, dipl.oec / Tvrtko Blaić Milutinović, dipl.ing.
Regional Vigilance Officer

Attachment:

Urgent Field Safety Notice, Product Recall due to possible unsterility

List of affected articles and batches

Urgent Field Safety Notice!

29.08.2017.

Product Recall due to possible unsterility

(via Fax to 01 6609 548)

Sender: Lohmann & Rauscher d.o.o.
Oreškovićeva 10a
HR-10000 Zagreb

Addressee: Ortopedski centar „Patrik“
Ante Starčevića 9
20350 Metković
& all users who use the below mentioned products.

Description: Recall of the following products due to possible unsterility

| REF | Product | Lot |
|-------|-----------------------------|------------|
| 23094 | Metalline Tracheo 8x9 50ste | 1728112208 |

Corrective Actions:

We ask you not to use the above mentioned product anymore and to send them back to us!

To ensure a free return to us, please contact our L&R returns department:

Ms. Zvonkica Jurić tel. 01/6609543 / fax. 01/6609 548, email: info@hr.LR.med.com

Contact Person for Lohmann & Rauscher within your facility:

| | |
|------|----------|
| Name | Function |
| | |

| | |
|------------------|-------|
| Telephone number | Email |
| | |

Please inform your employees who use the product of this Field Safety Notice and confirm to us that the product is not used anymore and the product has been returned to us or have been destroyed locally.

The undersigned confirms (please tick):

- that he does not possess the above mentioned product anymore,
- that he has not given the above mentioned product to third parties,
- that if he has given the above mentioned product to employees or third parties, he has informed the employees and third parties about the recall,
- that he will return the above mentioned product, which have been delivered to him and are still in his possession or in the possession of third parties, to Lohmann & Rauscher
- that he destroyed a small amount locally (maximum: 2 packages = 100 pieces).

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

| REF | Product | Lot | Quantity of returned products | Destroyed |
|-------|-----------------------------|------------|-------------------------------|-----------|
| 23094 | Metalline Tracheo 8x9 50ste | 1728112208 | | |

Date / Signature : _____

Printed Name: _____

Position: _____

Department / Institution: _____

Phone and Email: _____