

Urgent Field Safety Notice – Recall

Lohmann & Rauscher d.o.o.
Jakuševička 1E
10010 Zagreb
Tel.: 091/223-1601 Fax: 01/6609-548
Email: goran.grabovac@hr.LRmed.com

16.11.2022

Urgent Field Safety Notice

Product Recall due to leaking seal seam of primary packaging (insterility), Vliwaktiv® Absorbent activated charcoal dressing, REF 20254 & 20255

Dear Sir or Madam,

Today, we have to inform you about the precautionary product recall of Vliwaktiv® Absorbent activated charcoal dressing due to a possible insterility caused by a leaking seal seam of the primary packaging.

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

During internal quality checks, the potential leakage of the seal seam was discovered. The product could be unsterile due to the potential leakage of the seal seam of the primary packaging. This could lead to inflammations and/or infections, e.g. when the product is used in wounds. So far, we have not received any evidence/complaints from the market about inflammations or infections.

Please return the products you have in stock using the enclosed form. 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

Siniša Mak
Sales department

i.V. / On behalf of

Goran Grabovac
Regional Vigilance Officer

Attachment:

- 1) Urgent Field Safety Notice / Product Recall due to leaking seal seam of primary packaging (insterility), Vliwaktiv® Absorbent activated charcoal dressing, REF 20254 & 20255**

Urgent Field Safety Notice!

15.11.2022.

**Product Recall due to leaking seal seam of primary packaging (insterility),
Vliwaktiv® Absorbent activated charcoal dressing, REF 20254 & 20255**

(via Fax to 01/6609-548)

Sender: Lohmann & Rauscher d.o.o.
Jakuševička 1E
10010 Zagreb

Description: Product Recall due to leaking seal seam of primary packaging (insterility),
Vliwaktiv® Absorbent activated charcoal dressing, REF 20254 & 20255

Corrective Actions:

Please do not use the affected products of Vliwaktiv® Absorbent activated charcoal dressing anymore.

Please inform all employees who use the products about this Field Safety Notice and confirm that you are not using the affected products of Vliwaktiv® Absorbent activated charcoal dressing.

The undersigned confirms (*please tick*):

- [...] that they do not use the affected products of Vliwaktiv® Absorbent activated charcoal dressing,
- [...] that they inform all persons involved about this important information about the above mentioned products,
- [...] that they no longer own the products listed above,
- [...] that they have not given the mentioned products to third parties,
- [...] that they have informed third parties, if they have received from them the mentioned products, about the safety information and non-use of the products.
- [...] the affected products delivered to them that are still in their 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

Telephone number

Email

*Lohmann & Rauscher will get in touch with the named contact person for the purpose of handling returns!

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

REF	Product	Lot number (batch)	Quantity returned products

Date / Signature : _____

Printed Name: _____

Position: _____

Department / Institution: _____

Phone and Email: _____