
Urgent Field Safety Information

Recall for

DracoFoam infektt haft 5x5 cm, Article -No. 13924

DracoFoam Ferse, Article -No. 13936

03.11.2022

From:

Dr. Ausbüttel & Co. GmbH
Ernst-Abbe-Str. 4
D-44149 Dortmund
Germany

To:

Distributors and users of the affected devices

Dear Sir or Madam,

we need to inform you of a product Field Safety Corrective Action (FSCA).

Affected Devices:

Polyhexanid containing foam dressing with adhesive border DracoFoam infektt haft 5x5 cm
Foam dressing for the heel DracoFoam Ferse

Product	Article-No.	Batch (Lot)
DracoFoam infektt haft 5x5 cm	13924	19101169/0
DracoFoam Ferse	13936	20123185/0
DracoFoam Ferse	13936	20123186/0

Description of the problem and cause:

During a check of our Enterprise-Resource-Planning System, it was discovered that an incorrect expiry date was entered into the system when some products were booked. As a result, the wrong expiry date was also printed on the outer packaging. However, the data printed on the sterile barrier system is correct. Since this can lead to confusion about the shelf life of the product, we are recalling the affected products.

Actions to be taken by the distributors and users:

Please quarantine and destroy all products of the described batches. Then, please fill out the attached response form and send it back to us by December 1st, 2022. Please send it back even if you no longer have any remaining stocks of the affected product.

This only affects products with the lot numbers listed above.

There are no safety risks for patients if the device has already been used.

Transfer of information:

Please make sure that all users within your organization or other end-users are notified of this FSCA. In case you gave products to other parties please forward a copy of this notification or inform the contact given below.

Please keep this information as long as the FSCA is ongoing.

Thank you for your cooperation.

The BfArM has received a copy of this FSCA.

Contact:

Dr. Fabian Jansen, PRRC

vigilanz@draco.de

0231 – 28 666 822

Signature

User Response form

Actions to be taken (please verify by checking the boxes)

Product	Article-Nr.	Batch (Lot)	I confirm,
DracoFoam Infekt haft 5x5 cm	13924	19101169/0	<input type="checkbox"/> to not use the aforementioned devices, <input type="checkbox"/> the destruction of these devices, _____ (amount) <input type="checkbox"/> to have forwarded the information to other users, if necessary, <input type="checkbox"/> to not have passed the device to other users, <input type="checkbox"/> to not have any devices affected on stock.
DracoFoam Ferse	13936	20123185/0	<input type="checkbox"/> to not use the aforementioned devices, <input type="checkbox"/> the destruction of these devices, _____ (amount) <input type="checkbox"/> to have forwarded the information to other users, if necessary, <input type="checkbox"/> to not have passed the device to other users, <input type="checkbox"/> to not have any devices affected on stock.
DracoFoam Ferse	13936	20123186/0	<input type="checkbox"/> to not use the aforementioned devices, <input type="checkbox"/> the destruction of these devices, _____ (amount) <input type="checkbox"/> to have forwarded the information to other users, if necessary, <input type="checkbox"/> to not have passed the device to other users, <input type="checkbox"/> to not have any devices affected on stock.

Products obtained from wholesalers: no yes, name: _____

Customer details

Name:	
Company:	
Customer ID:	
Address:	
ZIP / City:	
Signature / Date:	

Please send your reply until 01.12.2022:

E-Mail: recall@draco.de

Fax: 0231 – 286 66 900

Post: Dr. Ausbüttel & Co. GmbH
Ernst-Abbe-Str. 4
44149 Dortmund

Your reply helps to evaluate this FSCA.