

Urgent Field Safety Notice: Recall

Issued by:

Dr. J. Hänsler GmbH, Nordring 8, D-76473 Iffezheim,
Managing Director: Robert Viebahn

Recipients:

Physicians and Medical Users

Identification of Product

OZONOSAN Germ Stop – Transfer Filter Set
Batches M109921, M110921 M101922, M101928, M101935, M101940 and
M103003

Description of problem including the identified cause:

Dear Doctor, Dear Madam, Dear Sir,

As we have found, you have received the product "OZONOSAN Germ Stop" from one of the above mentioned batches. We are requesting you to return these batches by means of a voluntary recall, as this product does not meet our quality expectations due to inadequate documentation and there could be a potential risk of insufficient sterilization.

According to our risk analysis in accordance with EN ISO 14971, the risk of contamination and a resultant serious adverse event is unlikely to occur, especially since the germicidal system does not come into contact with the patient or blood. No incident has ever occurred up to now, but as a precautionary measure we are recalling the product.

What measures should be taken by the recipient?

- Please check your inventory to see if the recalled product is still in your stock with the above batches.
- Please complete the attached confirmation form to confirm receipt of this field safety notice and to indicate whether you still have products with the above batch number in stock. Please return the form even if none of the products with this batch number are still in stock.
- If you are a retailer, please notify all the facilities/practices to which you have distributed the product in question. Please also complete the confirmation form of this field safety notice and send it to us.
- Please send us the affected products with the above mentioned batch numbers and a copy of the confirmation form of the field safety notice. You will receive a replacement immediately.

Passing on the information we have here circulated

Please ensure in your organization that all users of the above-mentioned products and other persons to be informed are aware of this Urgent Field Safety Notice. If you have passed on the product to a third party, please forward a copy of this information or inform the contact person at Dr. Hänsler listed below.

Please retain this information at least until such time as this action has been complied with / terminated.

This field safety notice has been forwarded to the Federal Institute for Drugs and Medical Devices (*Bundesinstitut für Arzneimittel und Medizinprodukte*).

Persons to contact:

Robert Viebahn, Managing Director,
Dr Renate Viebahn-Hänsler, SO (Safety Officer),
Manfred Pfetzer, QMR (Quality Management Representative):
e-mail: manfred.pfetzer@ozonosan.de
phone: 07229-30 46 0
fax: 07229-30 46 30

We are sorry to have to burden you with this inconvenience. However, we have already solved the problem so that we are able to send you replacement products immediately.

With best regards,

Dr. J. Hänsler GmbH
Robert Viebahn

Please send your reply to:

Dr. J. Hänsler GmbH
Nordring 8,
D-76473 Iffezheim,

CUSTOMER CONFIRMATION FORM

I / We have duly received the Safety Circular from Dr. J. Hänsler GmbH dated 31 March 2020.

Identification of the product:

OZONOSAN Germ Stop - Transfer Filter Set

Batches M109921, M110921, M101922, M101928, M101935, M101940, M103003

I / We have checked through the batches of OZONOSAN germicide listed above and have found:

_____ items (number) in our practice / in stock and **will send them back to Dr. J.Hänsler GmbH by 30 April 2020 at the latest**

no more in our practice / in stock.

If you are a supplier: Please mark with a cross or tick in this box that you have **forwarded this Customer Confirmation Form to all** your customers who have received the above product(s).

This form has been filled out by::

Company: _____

Name of authorized representative: _____

Date: _____

Telephone: _____

E-Mail: _____

Fax: _____

Stamp / Signature