CUSTOMER
STREET

ZIP CODE CITY
COUNTRY

Field Safety Corrective Action

2023-05-12

PRODUCT RECALL

Immediate compliance required

Trade name of the affected product: SecuroDrain and NeuroVac
Type of activity: field safety corrective action
Item number / batch:

REF	LOT
01.3307	210109, 211088, 211153, 301009
01.3357	210110, 211081, 212029, 301150
01.3457	211138, 211234, 301254
21-0711	210179, 211089, 212085
21-0734	210112
23-0711	211078
23-0734	210108, 210149, 301077

Information on the affected products
Neuromedex GmbH hereby issues a voluntary product recall for the aforementioned products. The products were sold by both Neuromedex GmbH and Dispomedica GmbH.

Description of the problem:
Due to a mix-up, some of the 7 mm flat drainage tubes were provided with the wrong raw material identification in the production area. Specifically, small amounts of two batches of raw material were mixed up and both were incorrectly marked (complete perforation instead of 3/4 perforation and vice versa). The incorrectly marked raw materials were later packed and sterilised. We assume that approximately 15% of the goods listed above were made entirely or partly with a different perforation design.
The wound drainage serves to remove haematoma and seroma from the wound. The different perforations (complete or 3/4 perforations) permit a stronger or weaker drainage performance, however this is generally also influenced considerably by the length adaptation to the wound area undertaken by the user.
In our opinion, this mixing does not endanger the patient or user:

- The user notices the different perforation length (complete perforation or 3/4 perforation) immediately after removal from the sterile packaging.
- The product can also be used reliably if the perforation length differs.

Possible consequences are:

- Delays during surgery
- Where applicable, different control intervals for the connected suction reservoir or drainage bag must be taken into account.

To date, we have not received any reports of patient injuries resulting from the situation described.
According to our records, you have received products to which this recall applies. This product recall applies only to the product and batches specified above.

Kind regards

Neuromedex GmbH
[redacted]

NEUROMEDEX®

Neuromedex GmbH
Vierenkamp 15
22453 Hamburg I Germany

phone +49 (0)40 696 564 100
fax +49 (0)40 696 564 200
web www.neuromedex.com

Hamburger Volksbank eG
IBAN DE04 2019 0003 0019 5623 06
BIC GENODEF1HH2

VAT-ID: DE 118647409
Trade Register
HRB 19038

Management Board
Marco Geyer
Markus Drewes

ADVICE ON IMPLEMENTING CORRECTIVE ACTION

Measures on the part of our end-user customers:

According to our records, your institution has received one or more products of the affected combination of products/batches listed in this safety note. Please forward this notification to anyone within your organization who needs to be informed of this. When doing so, please consider doctors, risk managers but also supply chains, distribution centres etc.

We ask you to take the following measures immediately and with priority:

- Please identify the affected products, block them from use and return the goods.
- Stop using the affected products.
- Please confirm that you have received this information and that you have carried out the measures by filling out the attached confirmation form and immediately returning it to Neuromedex GmbH using the contact details provided.

In case of any returned goods, a replacement will, of course, be arranged or the price will be credited to you.

We apologize for any inconvenience this may cause you. If you have any questions about the recall procedure, you are welcome to call us at any time at +49 (0) 40 696 564 101. We would like to thank you in advance for your understanding and support.

Please confirm to us that you have implemented the aforementioned measure in the field. After implementing the measure, please return the completed acknowledgement form (see page 3) to our sales department.

Measures on the part of our retail customers:

According to our records, you have received one or more products of the affected combination of products/batches listed in this safety note. Please forward this notification to anyone within your organization who needs to be informed of this. Please also forward this notification to all customers who have received the products listed in this safety corrective action.

We ask you to take the following measures immediately and with priority:

- Please identify the affected products, block them from use and return the goods.
- Stop using the affected products.
- Please confirm that you have received this information and that you have carried out the measures by filling out the attached confirmation form and immediately returning it to Neuromedex GmbH using the contact details provided.

In case of any returned goods, a replacement will, of course, be arranged or the price will be credited to you.

We apologize for any inconvenience this may cause you. If you have any questions about the recall procedure, you are welcome to call us at any time at +49 (0) 40 696 564 101. We would like to thank you in advance for your understanding and support.

Please confirm to us that you have implemented the aforementioned measure in the field. After implementing the measure, please return the completed acknowledgement form (see page 3) to our sales department.

Contact partner:

Should you require further information or assistance in this matter, please contact our sales department:

Contact: Stephanie Göger
Phone: +49 (0) 40 696 564 101
Fax: +49 (0) 40 696 564 200
Mail: contact@neuromedex.com

Our quality policy is geared to ensuring the excellent quality of our products as well as a high level of customer satisfaction and thus long-term, stable relations between our company and our customers. Therefore, we wish to express our sincere apologies for any disruptions caused by this product recall.

NEUROMEDEX®

Neuromedex GmbH
Vierenkamp 15
22453 Hamburg I Germany

phone +49 (0)40 696 564 100
fax +49 (0)40 696 564 200
web www.neuromedex.com

Hamburger Volksbank eG
IBAN DE04 2019 0003 0019 5623 06
BIC GENODEF1HH2

VAT-ID: DE 118647409
Trade Register
HRB 19038

Management Board
Marco Geyer
Markus Drewes

SAFETY CORRECTIVE ACTION

Confirmation form / response

Trade name of the affected product: SecuroDrain and NeuroVac
Type of activity: field safety corrective action / product recall
Item number / batch:

REF	LOT
01.3307	210109, 211088, 211153, 301009
01.3357	210110, 211081, 212029, 301150
01.3457	211138, 211234, 301254
21-0711	210179, 211089, 212085
21-0734	210112
23-0711	211078
23-0734	210108, 210149, 301077

Please return the completed form to us at your earliest convenience.
Fax: +49 (0) 40 696 564 200
Email: contact@neuromedex.com

Name of the facility (e.g. dealer, hospital, medical practice):

Facility address:

Measures implemented:

We hereby confirm the receipt of this field safety corrective action. We have taken note of this field safety corrective action, understood it and forwarded it to all persons/facilities affected by it. We have checked our stock with regard to the affected items. We have provided a record of used and blocked (returned) products in the product list below. We further confirm that after returning the products, we will no longer have any other products from these batches in stock.

Product list:

REF	LOT	Quantity delivered:	Quantity blocked:	Quantity used:

Form completed by:

....
Date Signature Printed name

Stamp

NEUROMEDEX®

Neuromedex GmbH
Vierenkamp 15
22453 Hamburg I Germany

phone +49 (0)40 696 564 100
fax +49 (0)40 696 564 200
web www.neuromedex.com

Hamburger Volksbank eG
IBAN DE04 2019 0003 0019 5623 06
BIC GENODEF1HH2

VAT-ID: DE 118647409
Trade Register
HRB 19038

Management Board
Marco Geyer
Markus Drewes