Mederen Neotech Ltd.
Address: Harakevet St. 58, Tel Aviv-Jaffa, Israel, postal Code: 6777016
Corporation number: 515505329
www.mederen.com • info@mederen.com

01/01

14.02.2025

Medical Device Safety Notification

Affected device:

Gastric catheter, with radiopaque line, Ch/Fr 22, 1100 mm, catalog number 0313-M100-22, production date 16.01.2023, lot number 2256107, registration certificate No. RZN 2018/7433 dated 02.08.2018, risk class 2a, type code 169460, manufactured by Mederen Neotech Ltd., Harakevet St.58, Tel Aviv-Jaffa, 6777016, Israel (place of manufacture Ningbo Greatcare Trading Co., Ltd., Address: Unit 93, Building 12, No.818, Qiming Road, Yinzhou, 315105 Ningbo, Zhejiang, China).

Reason for field safety corrective action:

The company received a report of an adverse event involving a medical device: a physician was checking the location of a catheter after its placement by aspirating gastric contents. The sound produced by the introduction of air was not loud enough. The physician removed the catheter. Visual inspection of the device revealed that the lateral openings at the distal end of the catheter were blocked. A similar catheter was used to perform the procedure. A sample of the medical device was not received by the manufacturer for analysis. There have been no other reports of similar incidents.

Follow-up actions by Mederen Neotech Ltd:

20,385 product packages were imported into the Russian Federation.

A comprehensive investigation of the issue is currently underway, including at the site of production of the medical device. Until the investigation is completed, shipment of potentially affected medical devices has been suspended.

Required action for users:

Distributor: Check the availability of medical device stocks Gastric catheter, with X-ray contrast line, Ch/Fr 22, 1100 mm, catalog number 0313-M100-22, produced on 16.01.2023, lot number 2256107 in your warehouses. If such products are available, immediately stop distributing these medical devices.

User: Check the availability of the medical product Gastric catheter, with radiopaque line, Ch/Fr 22, 1100 mm, catalog number 0313-M100-22, manufactured on 16.01.2023, lot number 2256107 in your warehouses. If such products are available, we ask you to:

1) Immediately stop using these medical products;

2) Contact the distributors who supplied you with the medical products to agree on further actions.

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Corrective & Preventive Action Plan:

No	Corrective action steps	Deadline	Status
1	Contact the medical organization where the adverse event was registered to determine the details of the incident	15.01.2025	Completed
2	Send a message about the problem to the production site to initiate an investigation at the production	17.01.2025	Completed
3	Block the specifiedx medical devices in the company's warehouse	17.01.2025	Completed
4	Informing partners and subjects of circulation of medical devices about the suspension of shipments and use of medical devices until the investigation	01.03.2025	In progress
5	Investigation at the place of production of medical devices	01.06.2025	In progress
6	Further actions aimed at resolving the situation	31.12.2025	Not started

We sincerely apologize for any inconvenience caused and hope for your understanding. Patient safety is our company's top priority.

If you have any questions, complaints, or suggestions, please contact our authorized representative in the Russian Federation, Alfamedex LLC, 113 Lakhtinsky Ave., LETTER A, office 2, 197229, Saint Petersburg, Russia; Tel/Fax: +7 (812)- 627-21-41; E-mail: info@alfamedex.ru

CEO Natalia Goldberg
Mederen Neotech Ltd.

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