Mederen Neotech Ltd.
Address: Harakevet St. 58, Tel Aviv-Jaffa, Israel, postal Code: 6777016
Corporation number: 515505329
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05/02 16.04.2024

Medical Device Safety Notification

Affected device: I.V. Catheter MEDEREN

Mederen Neotech Ltd. conducted an investigation into the causes of adverse events during the use of the medical device " I.V. Catheter MEDEREN", registration certificate No. RZN 2020/12770 dated 04.12.2020, in accordance with the letters of Roszdravnadzor No. 10-16835/23 dated 27.03.2023, No. 10-27180/23 dated 12.05.2023 and No. 10-25002/24 dated 15.04.2024.

According to these notifications, when the catheter is removed, it is destroyed and part of the medical device remains inside the patient's vein.

Additional studies of the technical characteristics of the medical device were conducted, which did not reveal any defects that could lead to the occurrence of an adverse event.

Most likely, adverse events occur as a result of an attempt by medical personnel to reinsert the needle into the catheter after its insertion into the vein. Reinsertion of the needle leads to damage to the catheter tube, which in turn leads to its rupture. This process is schematically depicted in Figure 1.

Please read the following warnings:

- Do not reinsert a partially or completely removed needle into the catheter. This may lead to damage to the catheter and its migration.

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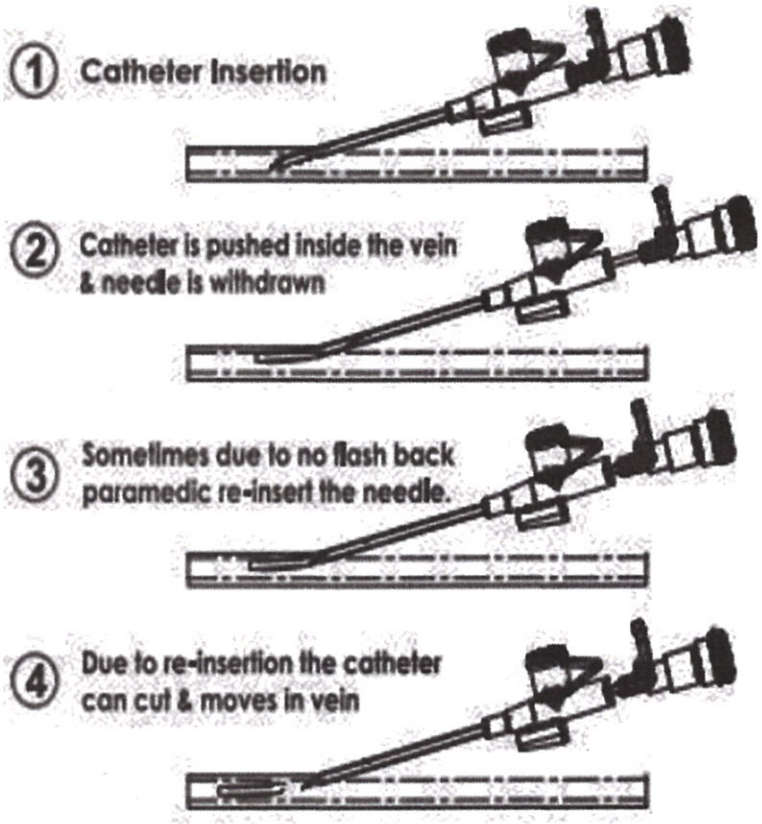
- Do not use sharp instruments when inserting and removing the catheter.



CEO Natalia Goldberg
Mederen Neotech Ltd.

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