Urgent Field Safety Notice

Voluntary recall of specific lot numbers of ELISIO™-H and ELISIO™-M dialyzers

NIPRO INDIA CORPORATION (NIC)

- **Product codes**: ELI-21H-GIN and ELI-21M-GIN
- **Lot numbers**: 20E21K2, 20E22K2, 20F23K2, 20F25K2, 20F27K2, 20F28K2, 20F04K2
- **FSCA 2020/10/29**
- **Type of action**: Voluntary recall of specific lot numbers of ELISIO™-H and ELISIO™ -M dialyzers

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Dear Sir or Madam,

The purpose of this communication is to inform you that NIPRO INDIA CORPORATION is voluntarily initiating Field Safety Corrective Action 2020/10/29 on specific lot numbers of the below medical devices:

- ELISIO™-H dialyzer
- ELISIO™-M dialyzer

Details of the affected devices:

All devices with product code ELI-21H-GIN (bearing lot numbers 20E21K2, 20E22K2, 20F23K2, 20F25K2, 20F27K2, 20F28K2) and all devices with product code ELI-21M-GIN (bearing lot number 20F04K2) are involved in the FSCA.

Description of the problem:

At Nipro, we have a continuous commitment to patient safety and routinely monitor the performance of our products to ensure that we meet customer expectations.

Nipro India Corporation (NIC) has identified an issue that, in specific lot numbers of product codes ELI-21H-PO-GIN and ELI-21M-GIN, a fiber leakage can occur during the dialysis session.

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Root cause analysis:

The fiber leakage was investigated at NIC. It has been determined that the leakage was caused by the use of an inappropriate tool during the production process. The tool overcame the wall/baffle on the back side of the coupler and damaged the hollow fiber, causing blood leakage detection or priming leakage immediately after the start of dialysis. This tool was used from 20 May 2020 to 03 July 2020.

Corrective and preventive action:

A new tool was introduced on 03 July 2020 in the production process. This tool has an indentation on its handle, which stops the tweezers at the coupler entrance. Therefore, the tips of new tool cannot get over the wall/baffle.

The first lot numbers after the implementation of the above corrective actions:

- **ELI-21H-GIN**: 20G22K2
- **ELI-21M-GIN**: No ELI -21M-GIN was produced since the implementation of the corrective action

Action to be taken by the user:

The customer is required to check the list of affected lot numbers and to provide the quantity of affected dialyzers at each facility that needs to be recalled using the attached Response letter. The pieces of the above-mentioned lots still in stock will have to be shipped back to Nipro Medical Europe

Transmission of this Field Safety Notice:

This notice should be distributed to the Nurse Manager of each affected facility and to all other concerned persons. Please complete and return Response letter by November 18th, 2020 to Vanessa Windscheid (RAQA Director, Nipro Medical Europe) at quality@nipro-europe.com. Please act immediately so we are assured that you have received and distributed this important communication.

Contact reference person:

The undersigned: Vanessa Windscheid (RAQA Director, Nipro Medical Europe)

Sincerely,

Vanessa Windscheid
Digitally signed by Vanessa Windscheid
Date: 2020.11.04 12:03:53 +01'00'

Vanessa Windscheid PhD
RAQA Director, Nipro Medical Europe

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