

## Urgent Field Safety Notice

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

#### NIPRO INDIA CORPORATION (NIC)

- **Product codes:** ELI-17H-GIN, ELI-19H-GIN, and ELI-19M-GIN
- **Lot numbers:** See table below
- **FSCA number:** FSCA 2020/11/12
- **Type of action:** Release and recall of specific lot numbers of ELISIO™-H and ELISIO™-M dialyzers

Dear Sir or Madam,

This communication follows the previous Field Safety Notice communicated to you by Nipro India Corporation, with reference FSCA 2020/11/12, impacting the following products:

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

#### Details of the affected devices:

Product Code	Lot Number
ELI-19M-GIN	20E23K2
ELI-19H-GIN	20E25K2
ELI-19H-GIN	20E27K2
ELI-19H-GIN	20E29K2
ELI-19H-GIN	20F01K2
ELI-19H-GIN	20F05K2
ELI-19H-GIN	20F09K2
ELI-17H-GIN	20F13K2
ELI-17H-GIN	20F14K2
ELI-17H-GIN	20F16K2
ELI-17H-GIN	20F20K2
ELI-17H-GIN	20F21K2
ELI-17H-GIN	20F22K2
ELI-17H-GIN	20F29K2
ELI-17H-GIN	20G16K2



**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 received an increasing number of complaints from different countries regarding blood leakage that occurred during dialysis treatment.

**Root cause analysis:**

The fiber leakage was investigated by Nipro India Corporation.

Two root causes were identified:

- It has been determined that the leakage was caused by the use of an inappropriate tool during the production process, which caused damage to the hollow fiber. The purpose of this tool was to remove residual urethane.
- In some cases, "inspection/rework" was performed after the wetting leak test process. Instead, it should be done before the wetting leak test, as per standard procedure.

**Corrective and preventive action:**

The following two corrective actions have been implemented:

- The wetting leak test is conducted after rework for 100% of products, where applicable.
- The urethane removal tool has been improved so that it cannot reach the fibers.

A new tool was introduced on 03 July 2020 in the production process whose tip cannot reach the hollow fibre.

The following preventive actions have been implemented:

- The working method has been adopted in the K2 assembly line.
- All operators and staff responsible for the K2 assembly line have been re-educated and re-trained accordingly.

To prevent reoccurrence, we shall establish a process that eliminates urethane adhesion itself and without rework.

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

- **ELI-17H-GIN:** 20J20K2
- **ELI-19H-GIN:** 20J24K2
- **ELI-19M-GIN:** reference not yet available

Based on the analysis of the complaint samples received, of retained samples, and of manufacturing records:

**LOT TO BE RELEASED:**

Product Code	Lot Number
ELI-19M-GIN	20E23K2
ELI-19H-GIN	20E25K2
ELI-19H-GIN	20F09K2
ELI-17H-GIN	20F13K2
ELI-17H-GIN	20F14K2
ELI-17H-GIN	20F16K2
ELI-17H-GIN	20F20K2
ELI-17H-GIN	20F21K2
ELI-17H-GIN	20F29K2

All pieces in stock with lot numbers matching the above-mentioned "TO BE RELEASED" list may be used.

**LOT TO BE RECALLED:**

Product Code	Lot Number
ELI-19H-GIN	20E27K2
ELI-19H-GIN	20E29K2
ELI-19H-GIN	20F01K2
ELI-19H-GIN	20F05K2
ELI-17H-GIN	20F22K2
ELI-17H-GIN	20G16K2

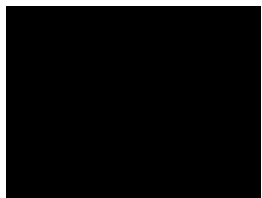
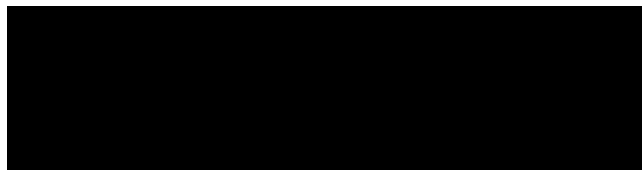
All pieces in stock with lot numbers matching the above-mentioned "TO BE RECALLED" list must be shipped back to Nipro Medical Europe. Please contact your local Nipro representative for further information about this action.

**Transmission of this Field Safety Notice:**

This notice should be distributed to the Nurse Manager of each affected facility and to all other persons concerned.

Please act immediately so we are assured that you have received and distributed this important communication. If you have questions regarding this communication, please contact Nipro Medical Europe's Quality department at [quality@nipro-europe.com](mailto:quality@nipro-europe.com).

Sincerely,



Confidential

## Field Safety Notice Response Form

### NIPRO INDIA CORPORATION

- **FSCA number:** FSCA 2020/11/12
- **Product codes:** ELI-17H-GIN, ELI-19H-GIN, and ELI-19M-GIN
- **Lot numbers:**
- **Type of action:** Release and recall of specific lot numbers of ELISIO™-H and ELISIO™-M dialyzers

Dear Sir or Madam,

Please complete and sign this response form by 29 January 2021.

**Hospital name:** Click or tap here to enter text.

**Product code and Lot number of products affected:** Click or tap here to enter text.

**Contact person name, surname:** Click or tap here to enter text.

**Contact person job title:** Click or tap here to enter text.

**Contact person email/telephone details:** Click or tap here to enter text.

Response **required:**

- ☐ We hereby acknowledge the receipt, distribution, and implementation of this important information. The preventive action has been/will be implemented by our institution.

Please check **one** of the two:

- ☐ We have no unit of the products affected by this notice.

- ☐ We are affected by this notice of the above lot number(s).



Product code	Lot number	Quantity (units)

Please send this response form by 29 January 2021.

**Scan and email this signed form:**

To: [quality@nipro-europe.com](mailto:quality@nipro-europe.com)

CC: [vanessa.windscheid@nipro-group.com](mailto:vanessa.windscheid@nipro-group.com); [damiano.cani@nipro-group.com](mailto:damiano.cani@nipro-group.com)

Date & Location

Signature or stamp of medical center

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