

Optiflux® Dialyzer Port Cap Change

PRODUCT NOTIFICATION

Dear Valued Customer:

Thank you for being a loyal Fresenius Medical Care customer. This is to alert you of a change to the port caps supplied with Optiflux E-Beam dialyzers.

The dialyzer blood port cap is the sterile barrier on the blood ports of the Optiflux E-Beam dialyzers. We have adapted this cap for use on both the blood and dialysate ports of the dialyzers. The user can move the cap from the blood port to the dialysate port just prior to attaching the bloodlines. The caps can seal the dialysate ports during priming and can be reattached post-treatment to prevent leaks during disposal. This dual-purpose cap has allowed us to eliminate the two adaptor caps placed within the dialyzer overwrap. The cap should be pushed not twisted onto the dialysate port of the dialyzer. There will be tactile click the first time the cap is placed on the dialysate port.



Figure 1: Blood Port Cap

This change impacts the following Fresenius Optiflux High Flux dialyzers:

Material	Description
0500316E	OPTIFLUX 160NRe DIALYZER FINISHED ASSY.
0500318E	OPTIFLUX 180NRe DIALYZER FINISHED ASSY.
0500320E	OPTIFLUX 200NRe DIALYZER FINISHED ASSY.
0500325E	OPTIFLUX F250NRe DIALYZER

The Optiflux High Flux Dialyzer Instructions for use (F50010927 Rev 07/2023) have been revised to add the following:

- **Remove the dialyzer cap from the arterial end of the dialyzer and immediately secure it to the dialysate port. Aseptically connect the arterial (red) dialyzer end of the bloodline to the lower dialyzer blood port.**
- **Remove the dialyzer cap from the venous end of the dialyzer and immediately secure it to the dialysate port. Aseptically connect the venous (blue) dialyzer end of the bloodline to the upper dialyzer blood port.**

Please be aware that you may receive product with the existing caps as well as the new dual-purpose caps for a period of time. Please contact Fresenius Medical Care Customer Service at 800-323-5188 for further information. Thank you for your continued support of our Fresenius Medical Care hemodialysis products.

Sincerely,



Stephen Jaquith

Product Director, Concentrates and Dialyzers

Please forward this letter to the Nurse Manager, Chief Technician and Patient Care Staff

Indications for Use

Optiflux F160NRe, F180NRe, F200NRe and F250NRe dialyzers are intended for patients with acute or chronic renal failure when conservative therapy is judged to be inadequate.

CAUTION: Federal (US) law restricts these devices to sale by or on the order of a physician.

NOTE: Read the Instructions for Use for safe and proper use of these devices. For a complete description of hazards, contraindications, side effects, and precautions, see full package labeling at fmcna.com. In rare cases, thrombocytopenia or hypersensitivity reactions including anaphylactic or anaphylactoid reactions to the dialyzer or other elements in the extracorporeal circuit may occur during hemodialysis.

The suitability of a dialyzer for a particular treatment is the responsibility of the physician.

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