Optiflux® Dialyzer Label Change

PRODUCT NOTIFICATION

Dear Valued Customer:

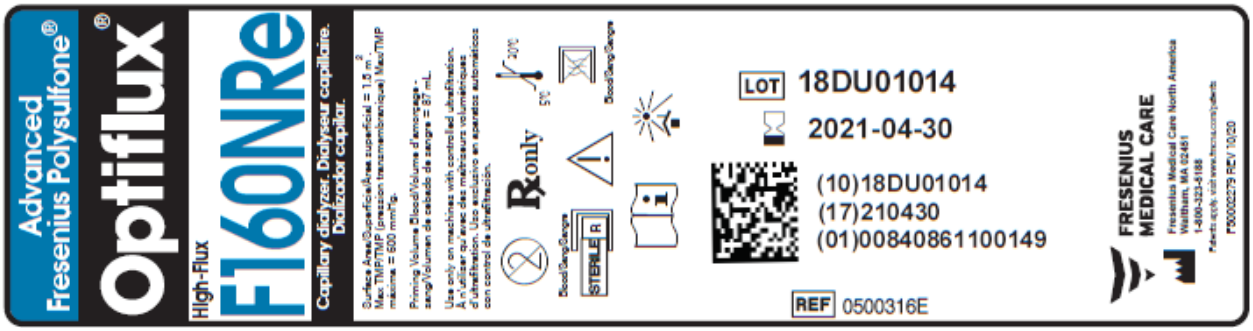
Thank you for being a loyal Fresenius Medical Care Renal Technologies customer.

We have updated the layout and coloring of the product and case labels for our remaining Hemoflow™ and Optiflux® dialyzers. Orientation of the printing on the product label has been changed to make it easier to identify and read key information in the vertical treatment position. Coloring specific to each model will also be added to both the product label and the case label to improve identification of the various models. Key relevant information will now be displayed as symbols on the product label, case label and instructions for use.

Representative comparisons of product label, case label and a table of symbols are included for your reference.

New F160NRe (ebeam) Dialyzer Label:

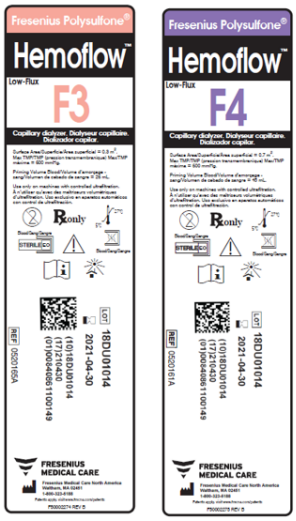
Please note that we have added a small "e" to the end of the model's name to coincide with the product or reference number. For example, the Optiflux F160NR model will be the Optiflux F160NRe.



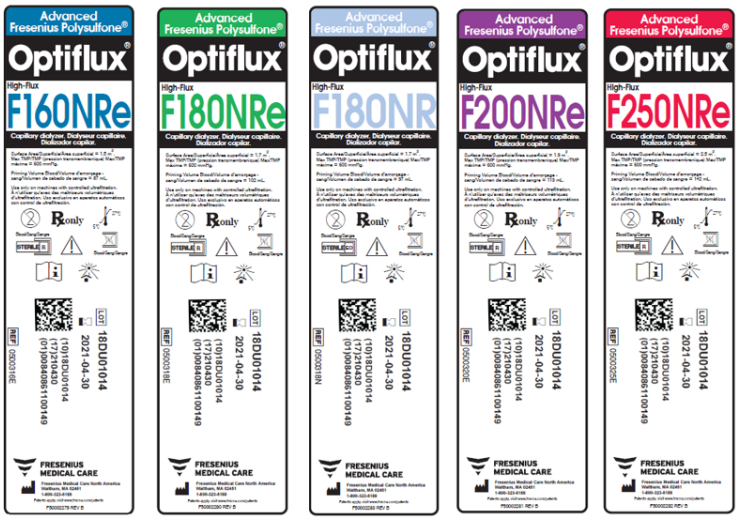
Current F160NR (ebeam) Dialyzer Label:

Example of new dialyzer labels

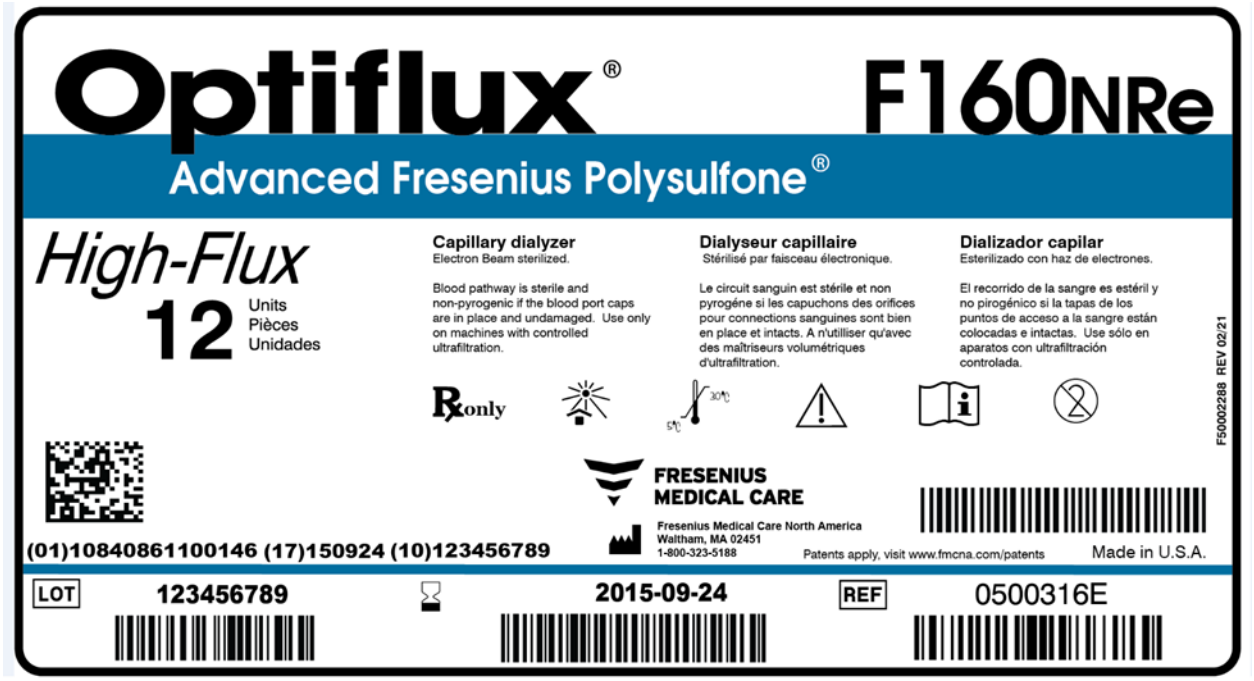
Low Flux



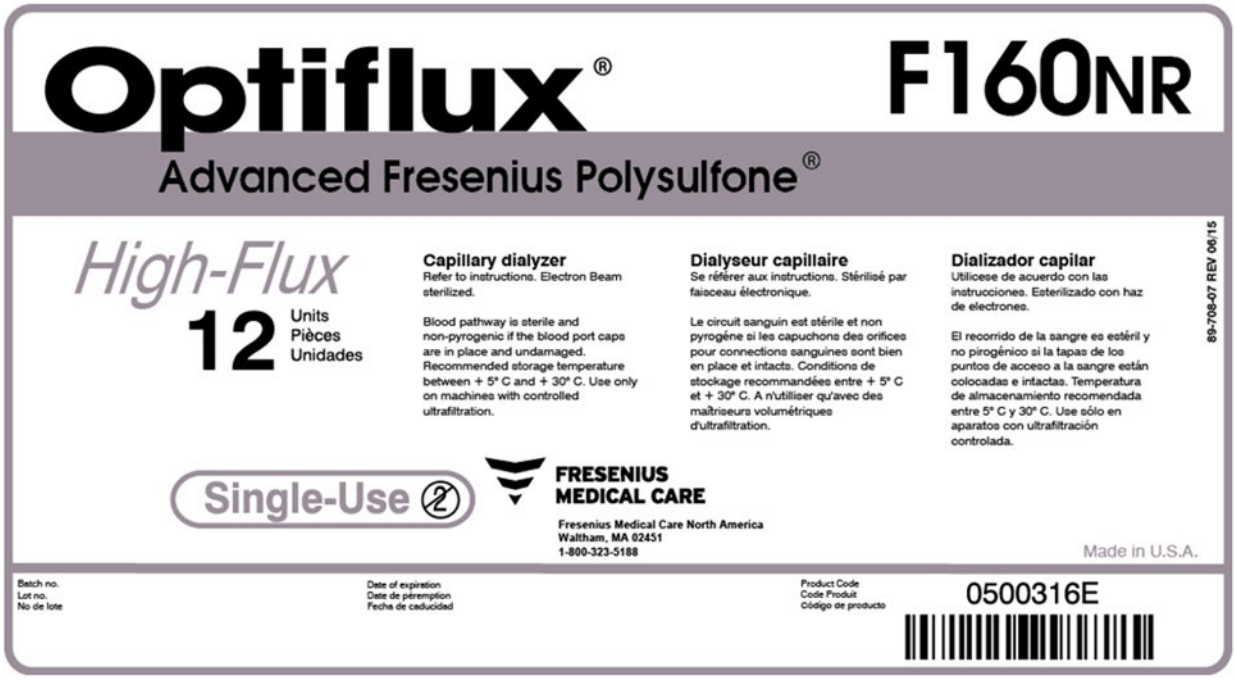
High Flux



New F160NRe (ebeam) Dialyzer Case Label:



Current F160NR (ebeam) Dialyzer Case Label:



The Instructions for Use (IFU) or package insert has a symbols table and glossary for determining symbol meaning as needed. The symbols table is indicated below.

Symbols/Simbolos/Symboles

Symbol	EN	ES	FR	Source-Symbol Number	Definition
	Temperature limit	Límite de temperatura	Limit de température	ISO 15223:2016 5.3.7	Indicates the temperature limits to which the medical device can be safely exposed.
	Use by date	Fecha de caducidad	Date de péremption	ISO 15223:2016 5.1.4	Indicates the date after which the medical device is not to be used.
	Batch code	Código de lote	Code du lot	ISO15223:2016 5.1.5	Indicates the manufacturer's batch code so that the batch or lot can be identified
	Catalogue number	Numero de pedido	Numero de catalogue	ISO15223:2016 5.1.6	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Do not re-use	No reutilizar	Ne pas réutiliser	ISO 15223:2016 5.4.2	Indicates a medical device that is intended for one use or for use on a single patient during a single procedure.
	Sterile fluid path that has been sterilized using irradiation	Camino fluido estéril ha sido esterilizado con irradiación	hemin de fluide stérile qui a été stérilisé par faisceau d'irradiation	ISO 15223:2016 5.2.4 ISO 15223:2016 5.2.9	Indicates a medical device that has been sterilized using irradiation. Indicates the presence of a sterile fluid path with- in the medical device in cases when other parts of the medical device, including the exterior, might not be supplied sterile.
	Fluid path is non-pyrogenic	La ruta del fluido no es pirogénica	Chemin de fluide est non pyrogène	ISO 15223:2016 5.6.2 ISO 15223:2016 5.6.3	Indicates the presence of a fluid path. Indicates a medical device that is non-pyrogenic.
	Consult instructions for use	Consulte las instrucciones de uso	Consulter les instructions d'utilisation	ISO 15223:2016 5.4.3	Indicates the need for the user to consult the instructions for use.
	Caution	Precaución	Attention	ISO 15223:2016 5.4.4	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Caution: Federal law restricts this device to sale by or on the order of a physician	Precaución: La Ley Federal restringe este dispositivo a la venta por o bajo la orden de un médico	Attention: La loi fédérale limite cet appareil vendu par ou sur ordre d'un médecin.	21CFR809.109(b)(1)	Caution: Federal law restricts this device to sale by or on the order of a physician
	Keep away from sunlight	mantener alejado de la luz solar directa	tenir à l'écart de la lumière directe du soleil	ISO 15223:2016 5.3.2	Indicates a medical device that needs protection from light sources
	Manufacturer	Fabricante	Fabricant	ISO15223:2016 5.1.1	Indicates the medical device manufacturer,defined in EU Directives 90/385/ EEC, 93/42/EEC and 98/79/EC.

Please be aware that you may receive product with the existing labels for a period of time. Please contact customer service at 800-323-5188 for further information.

Thank you for your continued support of our Fresenius Renal Technologies 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, F180NR, F200NRe, and F250NRe dialyzers are intended for patients with acute or chronic renal failure when conservative therapy is judged to be inadequate. Hemoflow F3 and F4 dialyzers are designed for single use in acute and chronic hemodialysis. The suitability of a dialyzer for a particular treatment is the responsibility of the physician.

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.