

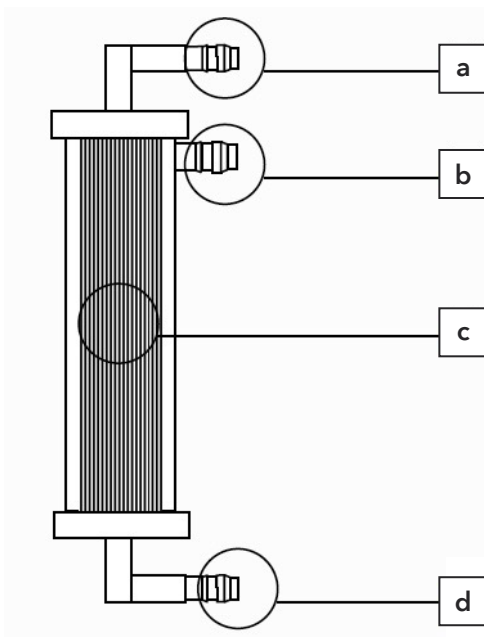
Dialyclean™ ultrafilter

Product description

The Dialyclean™ ultrafilter is used for ultrafiltration of the dialyzing and infusion solutions used in hemodialysis, hemofiltration and hemodiafiltration and may only be used with the Flexya™ dialysis machine. It is supplied sterile. The Dialyclean™ ultrafilter consists of a cylindrical polycarbonate body that contains a bundle of microporous hollow-fibers made of highly permeable polyethersulfone. During dialysis, the dialyzing and infusion solutions generated by the machine must be ultrafiltered to ensure the biological purity needed for treatment. The solution to be treated is drawn into the device through access at its base, purified through an ultrafiltration membrane process and drawn out through the special connector. The porosity and chemical-physical properties of the fiber wall allow the retention of bacteria and endotoxins from the dialysis and infusion fluids.

The device is equipped with a round RFID tag (transponder) on the side wall of the housing, containing the identification code of each single device for automatic recognition by the Flexya™ dialysis machine.

A typical circuit diagram is reported in figure 1.



Legend:

- a. Rinsing outlet connector
- b. Purified dialysis fluid connector
- c. Hollow-fiber bundle
- d. Dialysis fluid inlet connector

Figure 1

Intended use

Ultrafilter for dialysis fluid and infusion fluid.

Codes available

Code	Name	Description	CND	GMDN
IBP4314	Dialyclean™	Dialysis fluid ultrafilter for Flexya equipment	Z12090285	47739

Sterilization method and validity

Sterile and non-pyrogenic.

Sterilizing agent: ethylene oxide.

Shelf life: 3 years.

Do not resterilize.

Technical characteristics

The technical characteristics of the Dialyclean™ ultrafilter are reported below:

Components	Materials
Membrane	Polyethersulfone
Housing	Polycarbonate
Header	Polycarbonate
Potting	Polyurethane
O-ring	Silicone rubber
Transponder	High performance acrylic - Polyester
L joint	Polycarbonate
Straight joint	Polycarbonate

Technical characteristics										
Model	Effective surface area (m ²)	Fiber wall thickness (µm)	Fiber inside diameter (µm)	Effective fiber length (mm)	External fiber compartment volume (mL)	Internal fiber compartment volume (mL)	Maximum flow (mL/min)	Average pressure drop (mmHg) ¹	Maximum TMP ² (mmHg)	Operating life (hours)
Dialyclean™	2.2	30	200	301	192	109	1200	144	600	400

¹ Q_v = 500 mL/min

² TMP = Transmembrane pressure

Packaging

Model	Primary packaging - Pouch	
	Material	Pouch weight (g)
Dialyclean™	OPA/PP shatterless Medical grade paper 60 g/m ²	11

Model	Secondary packaging - Box			
	Box	Internal division	Weight ³ (kg)	Pcs/Box
Dialyclean™	Rippled cardboard box Dimensions: 39 x 18 x 14 cm	Rippled cardboard (soft)	1.7	6

³ Box weight filled with products

Storage and disposal conditions

Storage conditions: store at temperatures between 0 and +30 degrees Celsius.

Disposal: replace the ultrafilter after 400 hours of operation. Disposal must be carried out in accordance with the regulations in force.

Biocompatibility

Biocompatibility tests of the Dialyclean™ ultrafilters have been performed according to ISO 10993-1 and related applicable standard series.

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