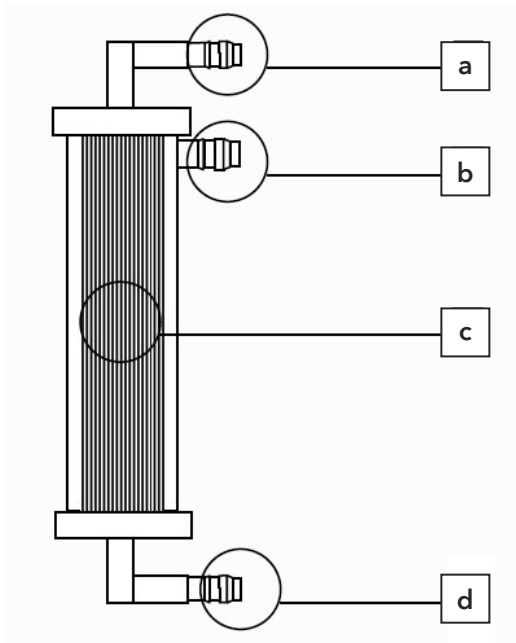


## H<sub>2</sub>Oclean™ ultrafilter

### Product description

The H<sub>2</sub>Oclean™ is a sterile ultrafilter used for ultrafiltration of incoming water that may only be used with the Flexya™ machine. The H<sub>2</sub>Oclean™ ultrafilter consists of a cylindrical polycarbonate body that contains a bundle of microporous hollow-fibers made from highly permeable polyethersulfone. During dialysis, water that comes into the machine must be ultrafiltered to ensure the purity needed for proper execution of the preset treatment. Water is drawn into the device through access at its base, purified through a membrane ultrafiltration process and then drawn out through the special connector. The porosity and composition of the fiber wall ensures removal of endotoxins that may be present in the inlet water. A typical circuit diagram is reported in figure 1.



### Legend:

- a. Rinsing outlet connector
- b. Water outlet connector
- c. Hollow-fiber bundle
- d. Water inlet connector

Figure 1

## Intended use

Ultrafilter for incoming water.

## Codes available

Code	Name	Description	CND	GMDN
IBP4313	H <sub>2</sub> Oclean™	Incoming water ultrafilter for Flexya™ machine	Z12090285	58088

## 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 H<sub>2</sub>Oclean™ ultrafilter are reported below:

Components	Materials
Membrane	Polyethersulfone
Housing	Polycarbonate
Header	Polycarbonate
Potting	Polyurethane
O-ring	Silicone rubber
L joint	Polycarbonate
Straight joint	Polycarbonate

Technical characteristics										
Model	Effective surface area (m <sup>2</sup> )	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 <sup>1</sup> (mmHg)	Maximum TMP <sup>2</sup> (mmHg)	Operating life (hours)
H <sub>2</sub> Oclean™	2.2	30	200	301	192	109	1200	144	600	400

<sup>1</sup> Q<sub>d</sub> = 500 mL/min

<sup>2</sup> TMP = Transmembrane Pressure

## Packaging

Model	Primary packaging - Pouch	
	Material	Pouch weight (g)
H <sub>2</sub> Oclean™	OPA/PP shatterless Medical grade paper 60 g/m <sup>2</sup>	11

Model	Secondary packaging - Box			
	Box	Internal division	Weight <sup>3</sup> (kg)	Pcs/Box
H <sub>2</sub> Oclean™	Rippled cardboard box Dimensions: 39 x 18 x 14 cm	Rippled cardboard (soft)	1.7	6

<sup>3</sup> 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 H<sub>2</sub>Oclean™ ultrafilters have been performed according to ISO 10993-1 and related applicable standard series.

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