

TECHNICAL DATA SHEET

Selecta™ and Suprasorb™ Adsorbent Cartridges



PRODUCT DESCRIPTION

Selecta™ and Suprasorb™ adsorbent cartridges, are single use devices indicated for extracorporeal dialysis treatments performed with HFR, Supra and Supra H dual-chamber dialysers. These cartridges are manufactured using the same materials, methods and overall design. Selecta™ has resin volume of 43 mL and Suprasorb™ has volume of 80 mL. Selecta™ and Suprasorb™ cartridges contain only synthetic resin with a microporous structure in the form of small, white insoluble beads. The internal volume not occupied by the resin is saturated with a saline solution (NaCl 0.9%). There are two internal filters, in inlet and outlet, that have different porosity and ensure the removal of particles from the filtered fluid. The ultrafiltrate obtained from the convective section of the dual-chamber dialyzer flows through the adsorbent cartridge from the inlet, (the header with blue ferrule), to the outlet, (the header with white ferrule), as shown in the photos. Then the purified ultrafiltrate passes through the diffusive section of the dual-chamber dialyzer. A typical circuit diagram is reported in figure 1.

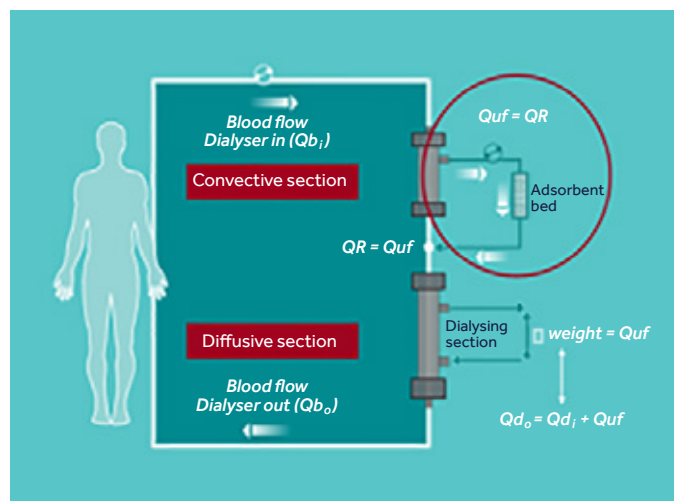


Figure 1

INTENDED USE

The disposable Selecta™ and Suprasorb™ cartridges for Formula™ 2000, Formula™ 2000 plus, Formula™ Therapy, for Flexya™ are exclusively intended for use in HDF hemofiltration treatments with endogenous reinfusion in conditions of chronic renal failure.

CODES AVAILABLE

Code	Name	Description	CND	GMDN
IBP1503	Selecta™	Cartridge for ultrafiltrate regeneration	F010702	34422
IBP1560	Suprasorb™	Cartridge for ultrafiltrate regeneration	F010702	34422

STERILIZATION METHOD AND VALIDITY

Sterile and pyrogen free.
Sterilizing agent: wet heat with saturated steam
Shelf life moist/wet heat sterilization: 2 years.
Do not resterilize.

TECHNICAL CHARACTERISTICS

The technical characteristics of the adsorbent cartridges are reported below.

Components	Materials
Adsorbent materials	Styrene resin
Internal disk filters	Polypropylene
Filling solution	Saline solution
Housing	Polycarbonate
Header	Polycarbonate
Protective caps	Santoprene/thermoplastic elastomer
O-ring	Silicone rubber
Supporting ring	Polycarbonate
Spacer	Polycarbonate
Ferrule	High density polyethylene

Technical characteristics								
Model	Inlet filter porosity (µm)	Outlet filter porosity (µm)	Surface area ¹ (m ² /g)	Particle size ² (µm)	Volume (mL)	Total length ³ (mm)	External diameter ³ (mm)	Weight (g)
Selecta™	25	1.5	600	50-100	43	155	55	255
Suprasorb™	25	1.5	600	50-100	80	155	55	255

¹ Minimum surface area

² 90% in range

³ Outer body characteristics

PACKAGING

Model	Primary packaging – Pouch	
	Material	Pouch weight (g)
Selecta™	PA/PP film	10.1
Suprasorb™	PA/PP film	10.1

Model	Secondary packaging – Box			
	Box	Individual bubble wrap	Weight ¹ (kg)	Pcs/Box
Selecta™	Cardboard box 10 mm Dimensions: 35.5 x 29.0 x 21.5 cm	Bubble bag - 70 g/m ² polythene 15 x 25 cm	5.2	20
Suprasorb™	Cardboard box 10 mm Dimensions: 35.5 x 29.0 x 21.5 cm	Bubble bag - 70 g/m ² polythene 15 x 25 cm	5.1	20

¹ Box weight filled with products

STORAGE AND DISPOSAL CONDITIONS

Storage conditions: store at temperatures between +1 and +30 degrees Celsius.

Disposal: remove from the place of dialysis immediately after use. Disposal must be carried out in accordance with the regulations in force.

BIOCOMPATIBILITY

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