TECHNICAL DATA SHEET

Clearum™ HS series high flux dialyzers

PRODUCT DESCRIPTION

The Clearum™ high flux steam sterilized (HS) family of high flux hollow-fiber dialyzers are single use devices for extracorporeal dialysis treatments. The dialyzers' surface areas range from 1.3 to 2.2 m^2.

Blood flows from the inlet to the outlet of the blood compartment into the fiber bundle where the particulate exchange with the dialysis fluid takes place. Solutes are cleared from the blood using diffusion across a semi-permeable membrane, driven by a concentration gradient, from the blood to the dialysate across the membrane. A typical circuit diagram is shown in figure 1.

During dialysis treatment, the blood that is removed from the uremic patient flows through the extracorporeal circuit and enters the hollow-fiber bundle to remove the highly concentrated toxic substances. This exchange re-establishes the electrolyte balance and removes some of the excess plasma water.

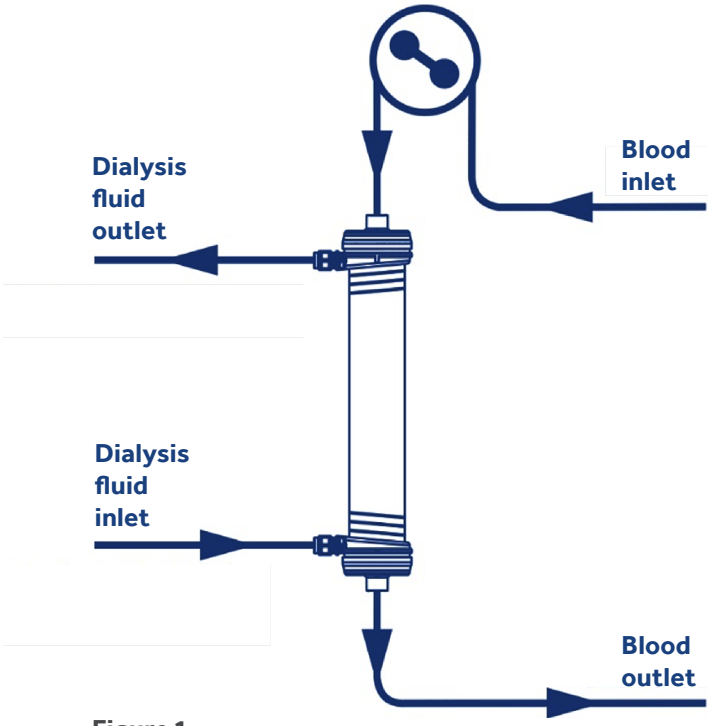

Figure 1

CLEARED INDICATIONS FOR USE IN THE US

The Clearum™ HS dialyzer family is intended for use in acute or chronic renal failure patients requiring hemodialysis.

PRODUCT CODES AVAILABLE

Product Code	Name	Description	GMDN
IBP4370	CLEARUM™ HS 13	1.3 m^2 high – flux dialyzer sterilized by moist heat	44601, 47072
IBP4371	CLEARUM™ HS 15	1.5 m^2 high – flux dialyzer sterilized by moist heat	44601, 47072
IBP4372	CLEARUM™ HS 17	1.7 m^2 high – flux dialyzer sterilized by moist heat	44601, 47072
IBP4373	CLEARUM™ HS 20	2.0 m^2 high – flux dialyzer sterilized by moist heat	44601, 47072
IBP4374	CLEARUM™ HS 22	2.2 m^2 high – flux dialyzer sterilized by moist heat	44601, 47072

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STERILIZATION METHOD AND VALIDITY

Sterile and non-pyrogenic
Sterilizing agent: moist heat with saturated steam
Shelf life: 3 years
Do not resterilize

TECHNICAL CHARACTERISTICS

The technical characteristics of the Clearum™ HS series high flux dialyzers are reported below.

Components	Materials
Membrane	Polyethersulfone (PES) / Polyvinylpyrrolidone (PVP)
Housing	Polypropylene
Header	Polypropylene
Protective caps	Polypropylene
Potting	Polyurethane
O-ring	Silicone

Technical characteristic										
Product Code	Model	Surface area (m^2)	Fiber wall thickness (µm)	Fiber internal diameter (µm)	Blood compartment priming volume (mL)	Blood compartment pressure drop† (mmHg)	Dialysis fluid compartment pressure drop‡ (mmHg)	Total length§ (mm)	External diameter§ (mm)	Weightᴼ (g)
IBP4370	HS 13	1.3	40	200	84	< 90	< 20	306	55	194
IBP4371	HS 15	1.5	40	200	95	< 75	< 20	306	55	205
IBP4372	HS 17	1.7	40	200	105	< 75	< 20	306	55	225
IBP4373	HS 20	2.0	40	200	120	< 90	< 25	366	55	253
IBP4374	HS 22	2.2	40	200	126	< 80	< 25	366	55	265

† Bovine blood: Hct = 32±3%, protein = 60±5 g/L, Q_B = 300 mL/min
‡ Dialysis fluid: NaCl = 0.9%, Q_D = 500 mL/min
§ Outer body characteristics
ᴼ Approximate finished product weight

PERFORMANCE[1]

The performance data provided refers to in-vitro tests performed in accordance with ISO 8637-1. The values indicated are to be considered approximate and may vary due to measurement methods, inherent variations of the membrane, manufacturing and storage conditions. During the treatment, performance on the individual patient may vary due to variable clinical parameters of the patient.

Model	In vitro clearance††				UF coefficient‡‡
	Urea (mL/min)	Creatinine (mL/min)	Phosphates (mL/min)	Vitamin B12 (mL/min)	k_{uf} (mL/h*mmHg)
HS 13	246	220	205	141	42
HS 15	264	240	226	160	48
HS 17	266	243	231	167	55
HS 20	271	253	243	184	64
HS 22	275	258	248	194	70

†† In vitro clearance : Q_B = 300 mL/min, Q_F = 10 mL/min, Q_D = 500 mL/min
‡‡ Ultrafiltration coefficient : Q_B = 300 mL/min, bovine blood Hct = 32±3%, protein = 60±5 g/L

ULTRAFILTRATION RATE[1§§]

§§ Ultrafiltration rate : Q_B = 300 mL/min, bovine blood Hct = 32±3%, protein = 60±5 g/L

Sieving coefficient	
Inulin[ΩΩ]	~1
Myoglobin[ΩΩ]	> 0.5
Albumin[††]	0.004

[ΩΩ] Sieving coefficient as per IFU
[††] Experimental mean value within the limit of ≤ 0.01 as reported in the IFU

STORAGE AND DISPOSAL CONDITIONS

Storage temperature limits: 0 to 86 degrees Fahrenheit.

Disposal: after use, the device and all the connected components must be disposed of in accordance with the guidelines or procedures in force in the hospital/clinic for dangerous hospital medical waste.

BIOCOMPATIBILITY

The Clearum™ HS series high flux dialyzers met the biocompatibility test requirements of ISO 10993-1 and related standards.

PRODUCT USE

See the Clearum™ HS series high flux dialyzers Instructions for Use for details on usage of the product.

1. Based on internal test report VVS.006-02. 2020.

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