Ultraflux® AV 400S / 600S / 1000S

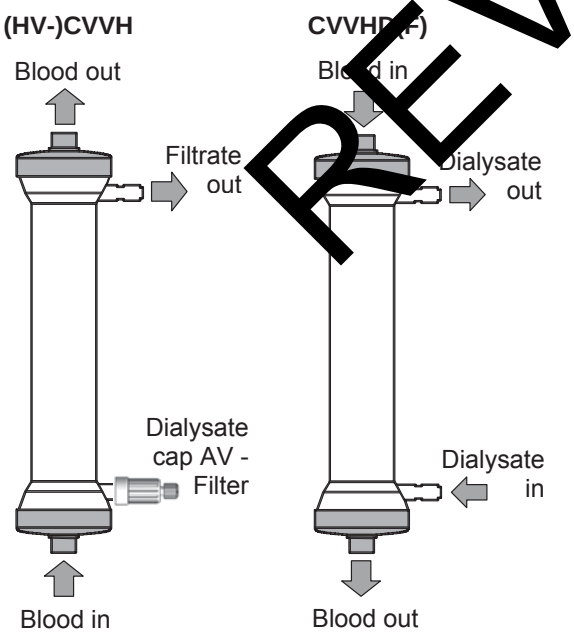
Capillary Haemofilters for Continuous Renal Replacement Therapies
CAVH(D), CVVH(D), CVVHDF, High-Volume CVVH (HV-CVVH)

CE 0123

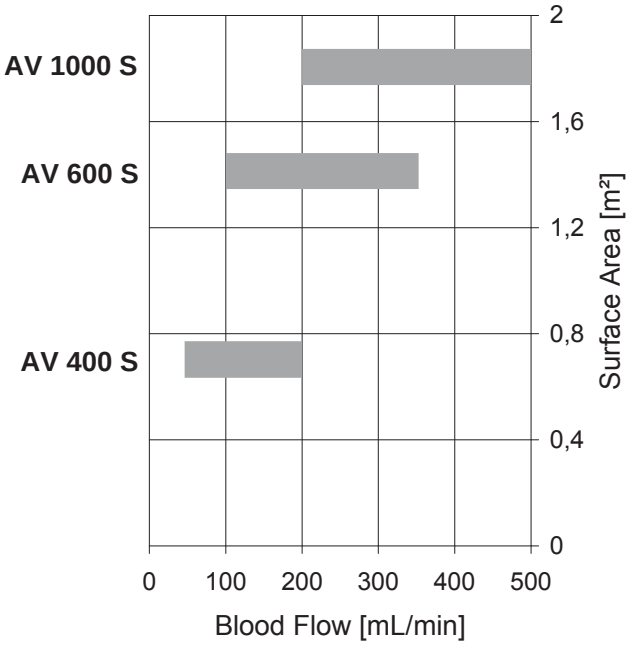
Technical Data		AV 400S	AV 600S	AV 1000S
	Art. No.	5007341	5007361	5008981
S (sieving coefficient)	Vit. B_{12}	1		
	Inulin	1		
	β_2-M	0.65		
	Albumin	0.001		
Membrane material		Fresenius Polysulfone®		
Inner lumen		220 µm		
Wall thickness		35 µm		
Sterilisation method		INLINE steam		
Blood connectors Filtrate- / dialysate connectors		acc. to EN 1283, ISO 8637		
Max. filtrate flow		20% of effective blood flow		
TMP max.		600 mm Hg		
Recommended blood flow range		50 - 200 mL/min	100 – 350 mL/min	200 – 500 mL/min
V (priming volume) blood / filtrate Δ P (pressure drop) blood, Hct. 45%		52 mL / 135 mL 50 mmHg (Q_B=100 mL/min)	105 mL / 210 mL 45 mmHg (Q_B=200 mL/min)	130 mL / 300 mL 52 mmHg (Q_B=300 mL/min)
A (effective surface area)		0.7 m²	1.4 m²	1.8 m²
Recommended period of use		max. 72 hours		

In vitro data are likely to differ from *in vivo* data due to the patient's blood composition and clinical settings.

Preferable Flow Directions



Recommended Blood Flow Range



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GB **Instructions for Use**

Ultraflux® AV 400 S / AV 600 S / AV 1000 S

Capillary Haemofilter for Continuous Renal Replacement Therapies

GENERAL NOTES

Refer to product or carton label for:

	Single use only	STERILE	Blood pathway sterile. Steam sterilised
	Expiry date		Refer to instructions for use
LOT	Batch	REF	Order number
	Date of manufacture	+5°C / +30°C	Storage temperature range
	Units	UF Control	Use only on machines with exact UF-control

Indication: Ultraflux® AV-filters are designed for single use in acute dialysis with machine-assisted continuous veno-venous haemofiltration, haemodialysis and haemodiafiltration (CVVH, CVVHD, CVVHDF). AV 1000 S is specifically recommended for High-Volume CVVH / CVVHDF.

Ultraflux® AV-filters 400S and 600S are also suitable for a non-machine assisted continuous arterio-venous haemofiltration or haemodialysis (CAVH, CAVHD).

Contra-indications: Contra-indications are unknown. Generally, contra-indications for acute dialysis are applicable.

Side effects: In rare cases hypersensitivity reactions may occur during acute dialysis treatment. In severe cases dialysis must be discontinued and the appropriate medication initiated.

The filter is steam-sterilised and thus contains no sterilisation residues.

Anticoagulation: It is recommended to introduce an anticoagulant to the extracorporeal blood circuit during priming and treatment. Nature, amount and method of application of an anticoagulant must be prescribed by the responsible physician in consideration to the patient's condition (e.g. initial heparin bolus of 30-50 IU/kg BW followed by a continuous dose of 5-20 IU/h/kg BW). For a body weight of 70 kg this corresponds to an initial dose of 2000-3500 IU followed by a continuous dose of 350-1400 IU/h.

Coagulation should be monitored at regular intervals (e.g. hourly measurement of the activated clotting time ACT or partial thromboplastin time PTT). Particularly for patients with a tendency to bleed we recommend regular control by means of the ACT and/or PTT.

Materials: Membrane: Fresenius Polysulfone®,
Housing: Polycarbonate, potting material: Polyurethane, O-ring: silicone

Further information may be obtained on request.

WARNINGS

Continuous renal replacement therapies require careful monitoring of the patient. Therefore a dialysis system equipped with the appropriate safety devices such as a blood leak detector, pressure monitors, an air detector etc.. should be used.

An exact recording of the ultrafiltration volume and the balancing of the substitution and filtrate volume must be guaranteed by a suitable system.

To ensure correct handling of the Ultraflux® AV-filters during priming, performing and termination of the treatment the instructions provided with the dialysis machine (e.g. multiFiltrate, ADM 08 / ABM) should be followed.

Use only if unit package is intact, sealing caps are in place and the Ultraflux® AV-filter is undamaged.

Ultraflux® AV-filters must not be used after the expiry date (see label).

Each Ultraflux® AV-filter is checked for integrity prior to leaving the factory. If a blood leak should arise, the filter must be exchanged.

The Ultraflux® AV-filter is intended for single-use only. Re-use may be hazardous to both the patient and operator. Cleansing solutions and disinfectants may damage materials employed for the housing, potting and membrane. Safety of use can no longer be guaranteed and the manufacturer assumes no liability.

PERFORMANCE OF TREATMENT

Priming

For priming the Ultraflux® AV-filter must be filled with isotonic saline solution and has to be de-aerated. Once this is achieved no further rinsing is required.

The detailed priming procedure depends on the equipment used and the instructions provided with the acute dialysis machine have to be followed. In general the following recommendations are valid:

CVVH: The arterial blood inlet should preferably be located at the lower end and the venous blood outlet at the upper end of the filter. The filtrate should be withdrawn at the upper filtrate port whereas the lower filtrate port remains closed with the closure cap (see drawing).

CVVHD(F): For enhanced effectiveness blood and dialysate should be in counter-current flow with blood inlet at the upper end and blood outlet at the lower end of the dialyser whereas the dialysate inlet is at the lower end and the dialysate outlet at the upper end of the dialyser (see drawing).

Patient connection

The detailed procedure depends on the dialysis system utilised and the instructions provided with the machine have to be followed. In general the following notes are valid:

Connect the arterial blood tubing system to the patient's blood circulation. Avoid entry of air. Allow the blood to flow into blood tubing system and filter until nearly all the saline solution is expelled (recommended pump setting approx. 100 mL/min).

At the beginning of the treatment it is recommended to circulate the blood for approximately 1 min without filtration. Subsequently adjust treatment parameters to desired settings.

Inspect again all connections and components for leaks and proper fitting.

Substitution of the filtrate volume

Depending on the desired fluid removal the filtrate volume can be substituted either completely or partly with haemofiltration solution. The substitution solution can be administered into extracorporeal circuit either upstream of the filter (predilution) or downstream of the filter (postdilution). Ensure an exact fluid balancing of the filtrate and substituate volume.

Recommendation for postdilution CVVH and postdilution CVVHDF

If the blood water content is reduced too much, the risk of clotting in the extracorporeal circuit increases. Therefore it is advisable to keep the blood water content within a certain uncritical range. We recommend to set the maximal total filtrate flow (= exchange rate filtrate/substituate + water removal rate) to 20% of the blood flow.

If higher substitution volumes are required, the substitution solution should be administered in the predilution mode.

Exchange of Ultraflux® AV-filter

If the filter is clotted (irregular colouring of the capillaries, persistent TMP alarm) or if the filter shows a blood leak (red colouring of the filtrate) the filter must be exchanged. Whether it is possible to reinfuse the blood with saline solution (for example 250 mL bag) must be decided by the attending physician.

In general during longer lasting treatments it is recommended to exchange the Ultraflux® AV-filter together with the blood lines after a maximal use of 72 hours.

Termination of treatment

For the termination of the treatment refer to the instructions for use of the dialysis machine used.

The blood should be completely reinfused to the patient using saline solution (e.g. 250 mL bag, pump setting approx. 100 mL/min).

WARRANTY

Products with proven manufacturing defects will be replaced if the defect is reported stating the lot number.

The manufacturer will not be liable for any misuse, improper handling, non-compliance with instructions for use and cautionary notes and for any damage incurred subsequent to the manufacturer's delivery of the filter.