



Fully Comprehensive Premium Range

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POLYPURE® FAMILY OF DIALYZERS

EXCELLENCE IN RENAL CARE

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Allmed Medical GmbH is a vertically integrated developer and manufacturer of end-to-end solutions for Hemodialysis. Allmed has widely proven itself as a leading provider of the latest Hemodialysis products and services at world-class standards.

Allmed's POLYPURE® Dialyzer family is its newest and highest-performing family of Dialyzers. The family is composed of different series; low, medium and high flux and various surface areas, ranging from 1.0 m² to 2.0 m², as well as different sterilization modes, making it suitable for any patient's needs and all therapeutic requirements.

Within each series of the family, POLYPURE® has proven the capability to outperform all its competitors in terms of Clearance and diffusive permeability. The underlying cutting edge technology that allows POLYPURE® to do so, is its fibre structure, as the fibres are micro-undulated in a unique manner, decreasing resistance to dialyzate flow, minimizing dead spaces, and thus allowing for full capillary utilization which leads to unprecedented Clearance per surface area.

POLYPURE® is composed of Polysulfone fibres which have evidently proven to be the gold standard in hemodialysis membranes. The unique Polysulfone membranes used in the POLYPURE® family are exclusively manufactured for Allmed by FIBRON AG in Germany.



POLYPURE

Polysulfone Hemodialyzers

Characteristics

POLYPURE is the first member of the now complete POLYPURE family. Due to its exceptional membrane design and uniform pore distribution, this series remains one of the highest performing low flux dialyzers available on the world market today.



- Sterilization: Gamma
- Housing: Polycarbonate
- Potting: Polyurethane
- Membrane type: Enhanced Micro-Undulated Polysulfone
- Fibre wall thickness: 40 µm
- Internal fibre diameter: 200 µm
- Packing:
 - Individual blister
 - Box 12 units

Low Flux POLYPURE Series

As the earliest of its siblings, this series has helped build the credibility of the POLYPURE name, which now enjoys the trust of customers worldwide.

Micro-Undulated Polysulfone Hollow Fibre Hemodialyzers

Micro-Undulation Technology improves dialyrate distribution within the dialyzer and increases clearance values, due to enhanced blood-dialyrate contact surface area.

POLYPURE - Low Flux Dialyzers

		POLYPURE 10	POLYPURE 13	POLYPURE 14	POLYPURE 16	POLYPURE 18	POLYPURE 20
Clearance in vitro (ml/min) QB = 200 ml/min QD = 500 ml/min QF = 0 ml/min T = 37 °C Maximun TMP = 500 mmHg	Urea	183	191	192	195	196	197
	Creatinine	164	176	178	184	188	189
	Phosphate	140	151	155	161	165	170
	Vitamin B ₁₂	85	98	102	111	118	121
Clearance in vitro (ml/min) QB = 300 ml/min QD = 500 ml/min QF = 0 ml/min T = 37 °C Maximun TMP = 500 mmHg	Urea	234	253	260	266	269	275
	Creatinine	199	221	225	237	246	249
	Phosphate	162	180	189	192	201	212
	Vitamin B ₁₂	92	107	113	125	133	137
Surface Area (m ²)		1.0	1.3	1.4	1.6	1.8	2.0
UF Coefficient (ml/h*mmHg)		8.1	10.5	11.4	12.9	14.6	16.2
Blood Priming Volume (ml)		59	69	75	86	105	109
Internal Fibre Diameter		200 µm					
Fibre Wall Thickness		40 µm					
Membrane Type		Micro-Undulated Polysulfone					
Housing Material		Polycarbonate					
Potting Material		Polyurethane					
Sterilization		Gamma					
<ul style="list-style-type: none"> • Performance data were measured in vitro according to standard EN 1283 • UF measurement: using bovine/human blood (Hct 32%; protein 60g/l) • Typical values obtained with an individual batch of fibres, clinical use may illustrate a difference in results in relation to different Ultrafiltration/measuring techniques and possible variation between batches of fibres. 							

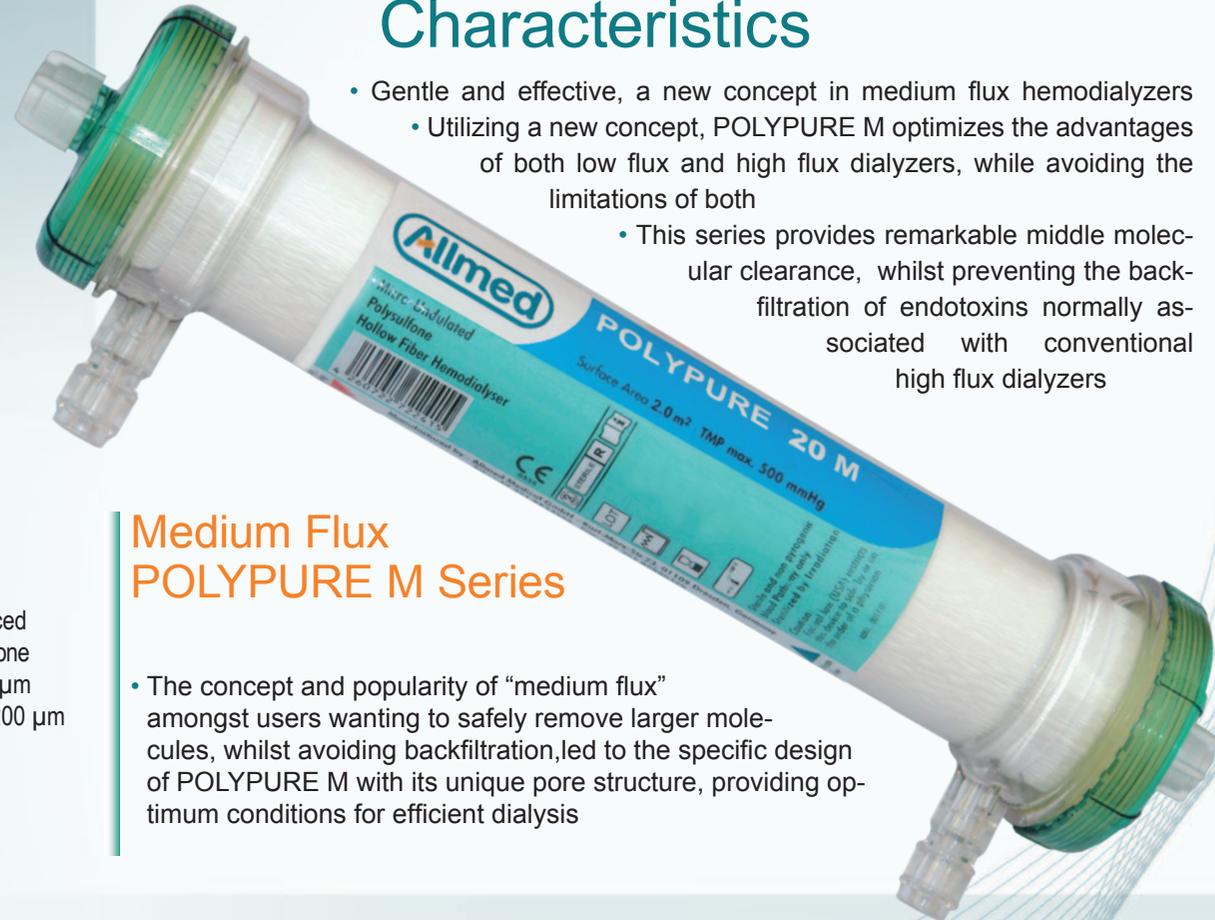


■ POLYPURE M

Polysulfone Hemodialyzers

Characteristics

- Gentle and effective, a new concept in medium flux hemodialyzers
 - Utilizing a new concept, POLYPURE M optimizes the advantages of both low flux and high flux dialyzers, while avoiding the limitations of both
 - This series provides remarkable middle molecular clearance, whilst preventing the backfiltration of endotoxins normally associated with conventional high flux dialyzers



- Sterilization: Gamma
- Housing: Polycarbonate
- Potting: Polyurethane
- Membrane type: Enhanced Micro-Undulated Polysulfone
- Fibre wall thickness: 40 µm
- Internal fibre diameter: 200 µm
- Packing:
 - Individual blister
 - Box 12 units

Medium Flux POLYPURE M Series

- The concept and popularity of “medium flux” amongst users wanting to safely remove larger molecules, whilst avoiding backfiltration, led to the specific design of POLYPURE M with its unique pore structure, providing optimum conditions for efficient dialysis

Micro-Undulated Polysulfone Hollow Fibre Hemodialyzers

Micro-Undulation Technology improves dialyzate distribution within the dialyzer and increases clearance values, due to enhanced blood-dialyzate contact surface area.

POLYPURE M - Medium Flux Dialyzers

		POLYPURE 10M	POLYPURE 13M	POLYPURE 16M	POLYPURE 18M	POLYPURE 20M
Clearance in vitro (ml/min) QB = 200 ml/min QD = 500 ml/min QF = 0 ml/min T = 37 °C Maximun TMP = 500 mmHg	Urea	183	192	195	196	198
	Creatinine	166	177	185	188	189
	Phosphate	148	163	172	177	181
	Vitamin B ₁₂	92	110	121	132	138
	Inulin					
Clearance in vitro (ml/min) QB = 300 ml/min QD = 500 ml/min QF = 0 ml/min T = 37 °C Maximun TMP = 500 mmHg	Urea	235	256	268	271	276
	Creatinine	203	224	240	248	252
	Phosphate	178	203	219	226	235
	Vitamin B ₁₂	101	122	141	149	160
	Inulin					
Surface Area (m ²)		1.0	1.3	1.6	1.8	2.0
UF Coefficient (ml/h*mmHg)		15.2	19.8	24.7	27.6	31.2
Blood Priming Volume (ml)		59	69	86	105	109
Internal Fibre Diameter		200 µm				
Fibre Wall Thickness		40 µm				
Membrane Type		Micro-Undulated Polysulfone				
Housing Material		Polycarbonate				
Potting Material		Polyurethane				
Sterilization		Gamma				
<ul style="list-style-type: none"> • Performance data were measured in vitro according to standard EN 1283 • UF measurement: using bovine/human blood (Hct 32%; protein 60g/l) • Typical values obtained with an individual batch of fibres, clinical use may illustrate a difference in results in relation to different Ultrafiltration/measuring techniques and possible variation between batches of fibres 						



POLYPURE S

Polysulfone Hemodialyzers

Characteristics

POLYPURE S is the lower flux version of its senior sibling POLYPURE S+. This series enjoys the same groundbreaking steam technology which is utilised in the POLYPURE S+ version,



High Performance POLYPURE S Series

and all its featured benefits, but it is designed for patients who require lower flux treatments.

- Sterilization: Steam
- Housing: Polycarbonate
- Potting: Polyurethane
- Membrane type: Enhanced Micro-Undulated Polysulfone
- Fibre wall thickness: 40 µm
- Internal fibre diameter: 200 µm
- Packing:
 - Individual blister
 - Box 12 units

Micro-Undulated Polysulfone Hollow Fibre Hemodialyzers

Micro-Undulation Technology improves dialyrate distribution within the dialyzer and increases clearance values, due to enhanced blood-dialyrate contact surface area.

POLYPURE S Hemodialyzers

		POLYPURE 10S	POLYPURE 13S	POLYPURE 16S	POLYPURE 18S	POLYPURE 20S
Clearance in vitro (ml/min) QB = 200 ml/min QD = 500 ml/min QF = 0 ml/min T = 37 °C Maximun TMP = 500 mmHg	Urea	183	189	191	192	193
	Creatinine	161	173	176	180	182
	Phosphate	140	151	156	162	173
	Vitamin B ₁₂	81	93	109	113	119
	Inulin					
Clearance in vitro (ml/min) QB = 300 ml/min QD = 500 ml/min QF = 0 ml/min T = 37 °C Maximun TMP = 500 mmHg	Urea	234	248	257	261	264
	Creatinine	195	215	229	234	242
	Phosphate	162	181	191	206	214
	Vitamin B ₁₂	89	105	122	128	135
	Inulin					
Surface Area (m ²)		1,0	1,3	1,6	1,8	2,0
UF Coefficient (ml/h*mmHg)		12.1	14.7	17.1	19.2	21.6
Blood Priming Volume (ml)		59	69	86	105	109
Internal Fibre Diameter		200 µm				
Fibre Wall Thickness		40 µm				
Membrane Type		Micro-Undulated Polysulfone				
Housing Material		Polycarbonate				
Potting Material		Polyurethane				
Sterilization		Steam				
<ul style="list-style-type: none"> • Performance data were measured in vitro according to standard EN 1283 • UF measurement: using bovine/human blood (Hct 32%; protein 60g/l) • Typical values obtained with an individual batch of fibres, clinical use may illustrate a difference in results in relation to different Ultrafiltration/measuring techniques and possible variation between batches of fibres. 						



■ POLYPURE H

Polysulfone Hemodialyzers

Characteristics

POLYPURE H features a highly intelligent membrane design, which is able to perfect the delicate balance between substantial middle molecular removal and loss of Albumin. This series provides a Myoglobin sieving coefficient of 0.45 while maintaining an Albumin sieving coefficient of only 0.001, thus providing the patient a treatment which is both safe and effective.



- Sterilization: Gamma
- Housing: Polycarbonate
- Potting: Polyurethane
- Membrane type: Enhanced Micro-Undulated Polysulfone
- Fibre wall thickness: 40 µm
- Internal fibre diameter: 200 µm
- Packing:
 - Individual blister
 - Box 12 units

High Flux POLYPURE H Series

POLYPURE H comes in a new smart environmentally friendly package, which reduces waste, handling time and box weight remarkably compared to other dialyzers. The series also benefits from a new smart dual use plug, eliminating the need for separate dialyzer port plugs. Allmed has recently introduced a new surface area to this series; POLYPURE 14H..

Micro-Undulated Polysulfone Hollow Fibre Hemodialyzers

Micro-Undulation Technology improves dialyzer distribution within the dialyzer and increases clearance values, due to enhanced blood-dialyzer contact surface area.

POLYPURE H - High Flux Dialyzers

		POLYPURE 10H	POLYPURE 13H	POLYPURE 14H	POLYPURE 16H	POLYPURE 18H	POLYPURE 20H
Clearance in vitro (ml/min) QB = 200 ml/min QD = 500 ml/min QF = 0 ml/min T = 37 °C Maximun TMP = 500 mmHg	Urea	184	192	193	195	196	198
	Creatinine	173	184	185	191	193	195
	Phosphate	160	174	177	183	187	190
	Vitamin B ₁₂	111	129	135	142	149	156
	Inulin	80	95	99	108	116	123
Clearance in vitro (ml/min) QB = 300 ml/min QD = 500 ml/min QF = 0 ml/min T = 37 °C Maximun TMP = 500 mmHg	Urea	238	256	261	270	275	279
	Creatinine	215	237	239	252	260	266
	Phosphate	193	216	223	233	242	251
	Vitamin B ₁₂	125	147	156	165	176	186
	Inulin	86	104	109	120	131	139
Surface Area (m ²)	1.0	1.3	1.4	1.6	1.8	2.0	
UF Coefficient (ml/h*mmHg)	33	44	47	55	59	68	
Blood Priming Volume (ml)	59	69	75	86	105	109	
Internal Fibre Diameter	200 µm						
Fibre Wall Thickness	40 µm						
Membrane Type	Micro-Undulated Polysulfone						
Housing Material	Polycarbonate						
Potting Material	Polyurethane						
Sterilization	Gamma						
<ul style="list-style-type: none"> • Performance data were measured in vitro according to standard EN 1283 • UF measurement: using bovine/human blood (Hct 32%; protein 60g/l) • Typical values obtained with an individual batch of fibres, clinical use may illustrate a difference in results in relation to different Ultrafiltration/measuring techniques and possible variation between batches of fibres 							



■ POLYPURE S+

Polysulfone Hemodialyzers

Characteristics

POLYPURE S+ is the first and only autoclaved high flux Polysulfone dialyzer. A highly innovative steam technology allows for a truly steam sterilized Polysulfone dialyzer. This series features the same smart design concept enjoyed by its siblings in the POLYPURE family, but enjoys the benefits of steam sterilization;



- Sterilization: Steam
- Housing: Polycarbonate
- Potting: Polyurethane
- Membrane type: Enhanced Micro-Undulated Polysulfone
- Fibre wall thickness: 40 µm
- Internal fibre diameter: 200 µm
- Packing:
 - Individual blister
 - Box 12 units

High Flux POLYPURE S+ Series

- such benefits include
- environmental friendliness
- lower priming requirements
- optimized rheology during clinical use

Allmed has recently introduced a new surface area to this series; POLYPURE 14S+.

Micro-Undulated Polysulfone Hollow Fibre Hemodialyzers

Micro-Undulation Technology improves dialyrate distribution within the dialyzer and increases clearance values, due to enhanced blood-dialyrate contact surface area.

POLYPURE S+ - High Flux Dialyzers

		POLYPURE 10S+	POLYPURE 13S+	POLYPURE 14S+	POLYPURE 16S+	POLYPURE 18S+	POLYPURE 20S+
Clearance in vitro (ml/min) QB = 200 ml/min QD = 500 ml/min QF = 0 ml/min T = 37 °C Maximun TMP = 500 mmHg	Urea	185	191	192	193	194	196
	Creatinine	170	178	180	183	187	189
	Phosphate	158	172	176	178	183	186
	Vitamin B ₁₂	108	126	133	136	145	148
	Inulin	74	89	93	97	109	115
Clearance in vitro (ml/min) QB = 300 ml/min QD = 500 ml/min QF = 0 ml/min T = 37 °C Maximun TMP = 500 mmHg	Urea	241	258	261	264	270	275
	Creatinine	207	225	231	234	245	250
	Phosphate	191	211	219	225	236	241
	Vitamin B ₁₂	121	144	152	157	170	175
	Inulin	80	98	103	110	121	129
Surface Area (m ²)	1.0	1.3	1.4	1.6	1.8	2.0	
UF Coefficient (ml/h*mmHg)	32	43	47	53	58	66	
Blood Priming Volume (ml)	59	69	75	86	105	109	
Internal Fibre Diameter	200 µm						
Fibre Wall Thickness	40 µm						
Membrane Type	Micro-Undulated Polysulfone						
Housing Material	Polycarbonate						
Potting Material	Polyurethane						
Sterilization	Steam						
<ul style="list-style-type: none"> • Performance data were measured in vitro according to standard EN 1283 • UF measurement: using bovine/human blood (Hct 32%; protein 60g/l) • Typical values obtained with an individual batch of fibres, clinical use may illustrate a difference in results in relation to different Ultrafiltration/measuring techniques and possible variation between batches of fbres 							



*refer to product direction for use

POLYPURE® is a trademark of Allmed Medical GmbH.

■ BIOCARB-G

Sodium Bicarbonate Powder

- Hermetically sealed package ready for the on-line preparation of liquid bicarbonate solution.
- Made of an environmentally-friendly material (Polypropylene)
- 2 filters (0.2 μm), one on the inlet and another on the outlet
- End ports open - no sealed layer to perforate, therefore reducing the risk of damage to the machine
- Available in 650–750 g Sodium Bicarbonate powder (Eur. pharma) suitable for 5–6 hours of treatment
- Unique universal cartridge design
- 60% stock reduction in comparison with canisters of liquid bicarbonate solution
- External caps available - top and bottom - which provide protection and allow for hygienic post-usage disposal
- Packed as 10 cartridges per box

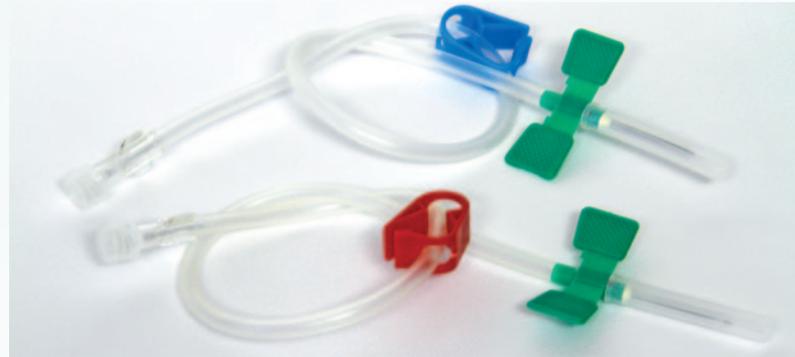


Sodium Bicarbonate Powder

■ Fistula Needles

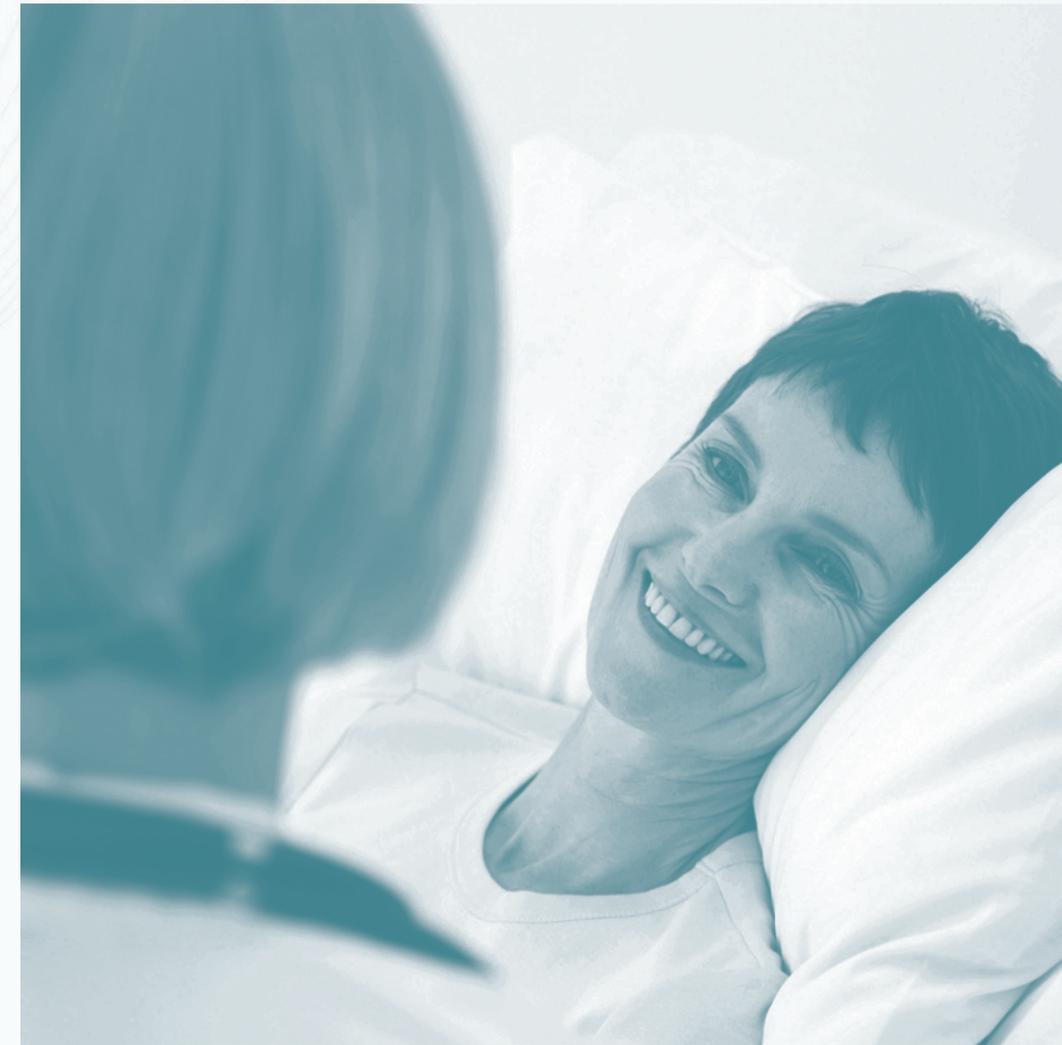
Vascular Access of Hemodialysis

Allmed-Arteriovenous fistula (AVF) represents the optimal permanent solution for vascular access in hemodialysis, both from the blood flow standpoint and the possible complications standpoint



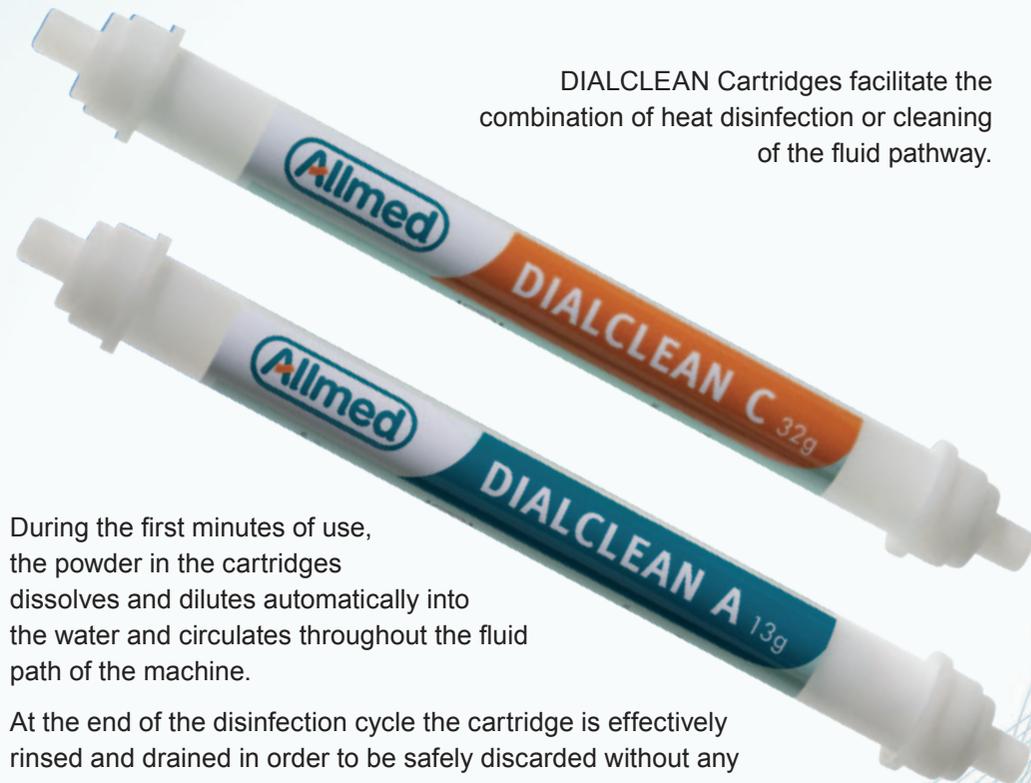
Available sizes: From 14 gauge to 17 gauge
Ultra thin wall and ideal bevel shaped cannula
Smooth silicone layer
Tubing length of 15 cm or 30 cm
Rough wings allow for a secure grip and control along with comfortable handling during needle insertion
Fixed or without back-eye
Venous/arterial colour coded (blue & red)
2 sterilization possibilities: Gamma - ETO

Vascular Access of Hemodialysis



■ DIALCLEAN Cartridges

Disinfection of Dialysis Machines



DIALCLEAN Cartridges facilitate the combination of heat disinfection or cleaning of the fluid pathway.

During the first minutes of use, the powder in the cartridges dissolves and dilutes automatically into the water and circulates throughout the fluid path of the machine.

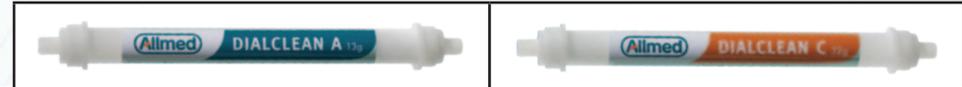
At the end of the disinfection cycle the cartridge is effectively rinsed and drained in order to be safely discarded without any chemical residue.

Disinfectant for Dialysis Machines

The use DIALCLEAN is to make sure that the dialysis machines are free from precipitated salts of calcium magnesium & organic deposits all through the fluid pathway.

DIALCLEAN A

DIALCLEAN C



Cartridge content	13 grams Anhydrous Sodium Carbonate	32 grams Anhydrous Citric Acid
Action (in combination with the heat disinfection program)	Disinfection and cleaning of the fluid path from organic deposits, fats and proteins	Disinfection and decalcification of the fluid path
Total cartridge weight	Approx. 36 grams	Approx. 55 grams
PH (prepared solution)	Approx. 11	Approx. 2
Cartridge materials	Polypropylene (PP)	Polypropylene (PP)
Residual test needed	No	No
Recommended usage	Refer to operator's manual for respective dialysis machine	Refer to operator's manual for respective dialysis machine
Biodegradable	Yes	Yes
Storage conditions	Store below +30 °C	Store below +30 °C
Shelf life	24 months from date of manufacture	24 months from date of manufacture
Packaging	box of 50 cartridges	box of 50 cartridges

■ MICROPURE-S

Online HDF Set

Due to its proven benefits, on-line hemodiafiltration is growingly becoming a preferred modality for treatment for patients suffering from CKD. Online HDF treatment has demonstrated the capability to remove middle molecular toxins from patients significantly, improving quality of life, decreasing comorbidities, as well as mortality. However, for Online HDF to be safe and effective, substantial amounts of sterile fluid is



required for reinfusion into the patient, either pre dialyzer or post. This fluid would have to be at such a high level of purification, to be considered ultimately safe for direct infusion into the blood stream.

Allmed applied its blood filtration expertise to advance a system of fluid purification. MICROPURE-S is Allmed's latest development in online purification techniques. It incorporates a specialist filter, composed of Allmed's renowned micro-undulated Poly-sulfone membrane, which acts as an effective barrier for pyrogens, bacteria, viruses, particles and endotoxins. This leads to a supply of non-pyrogenic substitution fluid, which can be safely infused directly into the patient's bloodstream.

Online Bacterial and Endotoxin Retention Filter

MICROPURE-S is most flexible in its design, allowing it to function effectively on a wide range of various dialysis machines available on the world market today.

Performance:

- On-line preparation of sterile substitution fluid, when fed with ultrapure dialysis fluid
- Pyrogens, bacteria, viruses, particles and endotoxins retention capabilities, both by size exclusion and the highest retention capacity of the Polysulfone membrane

Ultrafilter:

- Effective Surface (m²): 0.2
- Total volume in use (ml): 83
- Membrane UF coefficient (ml/hr/mmHg/m²): 280
- Housing and Caps: ABS (Acrylonitrile Butadiene Styrene)
- Potting: Polyurethane
- Membrane type: Micro-Undulated Polysulfone
- Fiber wall thickness (µm): 40
- Internal fibre diameter (µm): 200
- Maximum TMP (mmHg): 600

Retention values for bacteria and endotoxins:

- | | |
|--------------------|-------------------------------------|
| Type of challenge: | LRV (Logarithmic reduction value) |
| • Bacterial: | <i>Pseudomonas diminuta</i> : ≥ 7.0 |
| • Endotoxin: | <i>E. Coli</i> : ≥ 3.9 |

Tubing set:

- Tubing material: Medical grade Polyvinyl chloride (PVC)
- Protection caps: Polyethylene
- Injection site: Large finger guard, latex free Injection site
- Clamps: Small and large Clamps with ideal ergonomic features

Sterilization possibilities:

- Gamma - ETO

■ Bloodlines

Standard and Customized

Different configurations are possible, adapted to customers' needs. The bloodline tubing is made of medical grade PVC material available in different grades of rigidity and grades of transparency dependent on customers' requirements.



- Injection site: Large finger guard, latex free injection sites
- Clamps: Small and large clamps with ideal ergonomic features
- Dialyzer connector: Wing shaped grip connector ensures a secure lock to the dialyzer ports. The caps can be used as safety caps on the dialyzer.

- Patient connector: Improved grip on the rotating part for smooth and secure connections to patient's vascular access
- Drip chamber: All sizes and models available, rigid or soft, single or multiple in/outlets, conical or straight, all corresponding to customers' requirements
- Recirculator connector: Can connect venous to arterial line for re-circulation
 - Can be used as attachment hook
 - Can be used as flow resistance in-line during priming (closed cap vented)
 - Is a safety barrier against contamination at the patient connector before connection
- No coloured parts in direct contact with blood
- 2 sterilization possibilities: Gamma - ETO
- Accessories such as infusion line, priming bag, etc. pre-connected or not, as required



Standard and Customized

Blood tubing is specially designed at Allmed to fit each individual machine (Standard and Customized).

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