Haemodialysis

Dialysers and Filters

Product Range

Fresenius Medical Care

Contents

Cardioprotective Haemodialysis

Despite significant improvements in the quality and efficacy of haemodialysis therapy in recent years, cardiovascular disease (CVD) remains the leading cause of death for dialysis patients. Today, almost every other dialysis patient dies from cardiovascular complications.

Fresenius Medical Care is supporting nephrologists worldwide in reducing their patients' risks for cardiovascular morbidity and mortality.

Innovative membranes like Fresenius Polysulfone® or Helixone®, modern monitoring devices like the Blood Volume Monitor, the Blood Temperature Monitor and Online Clearance Monitoring (OCM®), ultra-pure dialysis fluid prepared with DIASAFE®*plus* and modern ONLINE haemodiafiltration systems support the reduction of CVD risk factors.

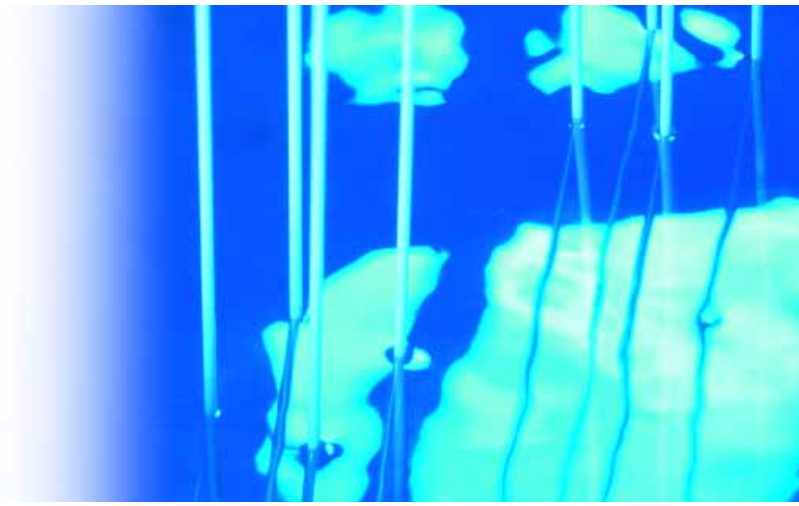
Moreover, one of our major goals in coming years is the development and implementation of innovative new therapies and products that further improve the cardiovascular prognosis of dialysis patients.

Fresenius Polysulfone® and Helixone® Dialysis Membranes

With over thirty years of experience in the development and manufacturing of dialysis membranes, Fresenius Medical Care offers a broad spectrum of dialysers to meet the specific demands of the different therapy modalities and the individual needs of every patient.

Fresenius Polysulfone®

Commonly regarded as the “gold standard” for dialysis membranes, Fresenius Polysulfone® stands for performance and safety in haemodialysis since three decades.

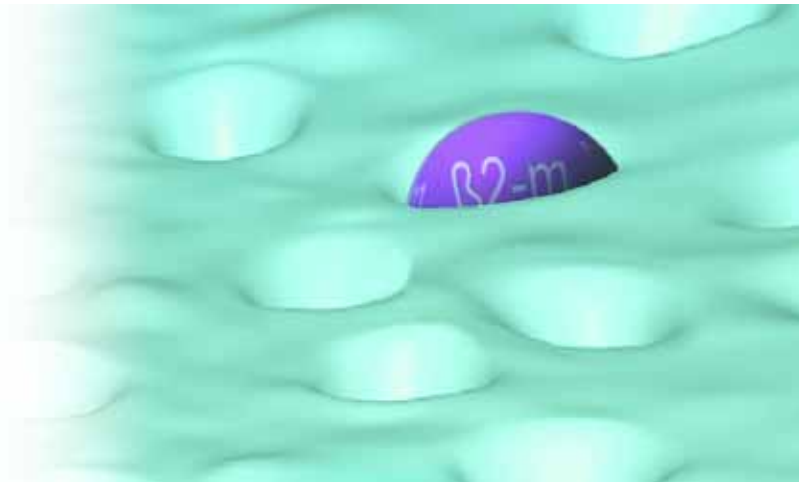


Numerous scientific publications and millions of treatments reflect the good experiences and satisfaction with this synthetic membrane among clinical staff and patients.

The Fresenius Polysulfone® membrane is available in the F-series low-flux and high-flux dialysers and invests these dialysers with a high performance, a good endotoxin retention and an excellent haemocompatibility.

helixone®

Continuing to set the standard for novel dialysis products, Fresenius Medical Care developed an advanced, Fresenius Polysulfone®-based dialysis membrane – the Helixone® membrane.



Manufacturing of the Helixone® membrane employs a new process of membrane making – the Nano Controlled Spinning (NCS™) Technology.

By means of this technology it is possible to create a defined pore structure and pore distribution profile of the inner membrane layer according to the desired application.

Helixone® is the membrane of the FX-class of dialysers.

FX-class Haemo*dia*filters

INLINE Steam sterilised

This series of haemodiafilters has particularly been developed for high-volume HDF treatments with fluid exchange rates above 15 liters per treatment. Together with the modern housing design, the advanced variant of the Helixone® membrane used in these types of haemodiafilters allows for:

- An enhanced removal of low molecular-weight substances, in particular phosphate
- An improved middle-molecule removal
- Higher fluid exchange rates during haemo-diafiltration (> 15 L / treatment)

In vitro performance data/technical data

	FX 600	FX 800	FX 1000
Ultrafiltration coeff. (mL/h x mmHg)	52	63	75
Clearance Q_B = 300 mL/min, Q_D = 500 mL/min, Q_F = 0 mL/min			
Urea	268	276	278
Creatinine	238	250	262
Phosphate	228	238	248
Vitamin B_{12}	165	176	178
Inulin	111	123	126
Clearance Q_B = 300 mL/min, Q_D = 500 mL/min, Q_F = 75 mL/min			
Urea	284	289	290
Creatinine	262	271	280
Phosphate	254	262	269
Vitamin B_{12}	199	209	211
Inulin	150	161	164

In vitro performance: T = 37°C (EN 1283, ISO 8638).
Ultrafiltration coefficients: human blood, Hct 32 %, protein content 6 %.

Effective surface (m^2)	1.5	1.8	2.2
Blood flow range (mL/min)	150 – 400	200 – 500	250 – 600
Wall thickness / lumen (µm)	35/210	35/210	35/210
Priming volume (mL)	97	118	138
Membrane material		Helixone®	
Housing material		Polypropylene	
Potting compound		Polyurethane	
Sterilisation method		INLINE Steam	
Form of treatment		HDF/HF	
Units per box	20	20	20
Art.-No.	**500 813 1**	**500 814 1**	**500 972 1**

FX-class High-Flux Dialysers

INLINE Steam sterilised

A completely new concept of dialysers has led to the improved performance profile of the FX-class of dialysers achieved by various technical improvements to all components of the dialyser including the membrane Helixone®.

- Improved diffusive and convective clearances
- Refined haemodynamics
- Increased patient safety
- Simplified handling and priming
- Reduction of waste

helixone®

In vitro performance data/technical data

	FX 40	FX 50	FX 60	FX 80	FX 100
Ultrafiltration coeff. (mL/h x mmHg)	20	33	46	59	73
Clearance Q_B = 200 mL/min					
Urea	170	189	193	197	– *
Creatinine	144	170	182	189	–
Phosphate	138	165	177	185	–
Vitamin B_{12}	84	115	135	148	–
Inulin	54	76	95	112	–
Clearance Q_B = 300 mL/min					
Urea	– *	250	261	276	278
Creatinine	–	210	230	250	261
Phosphate	–	201	220	239	248
Vitamin B_{12}	–	130	155	175	192
Inulin	–	81	104	125	142

In vitro performance: Q_D = 500 mL/min, Q_F = 0 mL/min, T = 37 °C (EN 1283. ISO 8637).
Ultrafiltration coefficients: human blood, Hct 32 %, protein content 6 %.

* refer to recommended blood flow range

Effective surface (m^2)	0.6	1.0	1.4	1.8	2.2
Blood flow range (mL/min)	50 – 200	100 – 300	150 – 400	200 – 500	250 – 600
Wall thickness / lumen (µm)	35/185	35/185	35/185	35/185	35/185
Priming volume (mL)	32	53	74	95	116
Membrane material			Helixone®		
Housing material			Polypropylene		
Potting compound			Polyurethane		
Sterilisation method			INLINE Steam		
Form of treatment	HD	HD	HD	HD/HDF/HF	HD/HDF/HF
Units per box	20	20	20	20	20
Art.-No.	**500 884 1**	**500 885 1**	**500 886 1**	**500 888 1**	**500 890 1**

FX-class Low-Flux Dialysers

INLINE Steam sterilised

A modulation of the Helixone® membrane at the nanoscale level targeting the elimination of low molecular weight solutes led to a new generation of low-flux dialysers with an optimal diffusive clearance.

The new low-flux Helixone® membrane offers the following advantages:

- An increased pore size of 1.8 nm
- More even distribution of the pores
- Increased performance per unit surface area

In vitro performance data/technical data

	FX 5	FX 8	FX 10
Ultrafiltration coeff. (mL/h x mmHg)	8	12	14
Clearance Q_B = 200 mL/min			
Urea	180	191	193
Creatinine	165	178	181
Phosphate	141	160	170
Vitamin B_{12}	88	107	121
Clearance Q_B = 300 mL/min			
Urea	228	254	261
Creatinine	200	225	231
Phosphate	164	194	210
Vitamin B_{12}	94	120	138

In vitro performance: Q_D = 500 mL/min, Q_F = 0 mL/min, T = 37 °C (EN 1283, ISO 8637).
Ultrafiltration coefficients: human blood, Hct 32 %, protein content 6 %.

Effective surface (m^2)	1.0	1.4	1.8
Blood flow range (mL/min)	100 – 300	150 – 400	200 – 500
Wall thickness / lumen (µm)	35/185	35/185	35/185
Priming volume (mL)	54	74	95
Membrane material		Helixone®	
Housing material		Polypropylene	
Potting compound		Polyurethane	
Sterilisation method		INLINE Steam	
Form of treatment		HD	
Units per box	20	20	20
Art.-No.	**500 483 1**	**500 473 1**	**500 474 1**

Fresenius Polysulfone®
High-Flux Dialysers and Haemo*dia*filters

INLINE Steam sterilised

The Fresenius Polysulfone® High-Flux Steam dialyser range combines the advantages of a blood compatible membrane with a safe sterilisation procedure.

- Excellent blood compatibility
- Optimal performance
- Wide product range (0,7 – 2,4 m²)
- Suitable for HD, HF, HDF treatments
- Effective β_2-microglobulin removal
- High endotoxin retention capacity
- Unique INLINE Steam Sterilisation – no sterilisation by-products or residues – dry
- No pretreatment rinsing procedures required (time saving)

Fresenius Polysulfone®

In vitro performance data/technical data

	F40S	F50S	F60S	F70S	HF80S	HdF100S
Ultrafiltration coeff. (mL/h x mmHg)	20	30	40	50	55	60
Clearance Q_B = 200 mL/min						
Urea	165	178	185	190	192	– *
Creatinine	140	160	172	177	180	–
Phosphate	138	158	170	174	177	–
Vitamin B_{12}	80	100	118	127	135	–
Inulin	54	75	88	98	110	–
Clearance Q_B = 300 mL/min						
Urea	– *	225	242	245	248	271
Creatinine	–	195	215	220	225	252
Phosphate	–	190	210	216	220	240
Vitamin B_{12}	–	112	134	145	155	190
Inulin	–	83	97	109	120	145

In vitro performance: Q_D = 500 mL/min, Q_F = 0 mL/min, T = 37 °C (EN 1283, ISO 8637).
Ultrafiltration coefficients: human blood, Hct 32 %, protein content 6 %. Use only on machines with controlled ultrafiltration!

* refer to recommended blood flow range

Effective surface (m²)	0.7	1.0	1.3	1.6	1.8	2.4
Blood flow range (mL/min)	50 – 200	100 – 300	150 – 400	200 – 500	200 – 600	250 – 600
Wall thickness / lumen (µm)	40/200	40/200	40/200	40/200	40/200	35/185
Priming volume (mL)	42	63	82	98	110	138
Membrane material	Fresenius Polysulfone®					
Housing material	Polycarbonate					
Potting compound	Polyurethane					
Sterilisation method	INLINE Steam					
Form of treatment	HD	HD	HD/HDF	HD/HDF	HDF/HF	HDF/HF
Units per box	12	12	12	12	12	12
Art.-No.	**500 714 1**	**500 815 1**	**500 716 1**	**500 717 1**	**500 718 1**	**500 719 1**

Fresenius Polysulfone® Low-Flux Dialysers (HPS)

IINLINE Steam sterilised

High performance dialysers in the Low-Flux range combined with the advantages of steam sterilisation.

- Higher clearances by a **new design**
- Microundulation ensures efficient dialysate flow
- Excellent blood compatibility
- Wide product range (0.8 – 2.2 m²)
- High endotoxin retention capacity
- Unique INLINE Steam Sterilisation, no sterilisation residues or by-products – dry

Fresenius Polysulfone®

In vitro performance data/technical data

	F4HPS	F5HPS	F6HPS	F7HPS	F8HPS	F10HPS
Ultrafiltration coeff. (mL/h x mmHg)	8	10	13	16	18	21
Clearance Q_B = 200 mL/min						
Urea	170	179	186	188	190	– *
Creatinine	149	162	173	175	177	–
Phosphate	123	139	148	155	159	–
Vitamin B_{12}	75	84	92	102	106	–
Clearance Q_B = 300 mL/min						
Urea	– *	227	243	247	252	259
Creatinine	–	196	215	220	224	230
Phosphate	–	162	175	186	193	208
Vitamin B_{12}	–	91	100	113	118	131

In vitro performance: Q_D = 500 mL/min, Q_F = 0 mL/min, T = 37 °C (EN 1283, ISO 8637).
Ultrafiltration coefficients: human blood, Hct 32 %, protein content 6 %. Use only on machines with controlled ultrafiltration!

* refer to recommended blood flow range

Effective surface (m²)	0.8	1.0	1.3	1.6	1.8	2.2
Blood flow range (mL/min)	50 – 200	100 – 300	150 – 400	200 – 500	250 – 600	300 – 600
Wall thickness / lumen (µm)	40/200	40/200	40/200	40/200	40/200	40/200
Priming volume (mL)	51	63	78	96	113	132
Membrane material	Fresenius Polysulfone®					
Housing material	Polycarbonate					
Potting compound	Polyurethane					
Sterilisation method	INLINE Steam					
Form of treatment	HD					
Units per box	12	12	12	12	12	12
Art.-No.	**500 704 1**	**500 705 1**	**500 706 1**	**500 707 1**	**500 708 1**	**500 720 1**

Fresenius Polysulfone® Low-Flux Dialysers

ETO sterilised

The wide product range is tailored to meet the requirements of the individual patient.

- Excellent blood compatibility
- Wide product range (0.4 – 1.8 m²)
- High endotoxin retention capacity

Fresenius Polysulfone®

In vitro performance data/technical data

	F3	F4	F5	F6	F7	F8
Ultrafiltration coeff. (mL/h x mmHg)	1.7	2.8	4.0	5.5	6.4	7.5
Clearance Q_B = 200 mL/min						
Urea	125	155	170	180	184	186
Creatinine	95	128	149	164	169	172
Phosphate	50	78	103	123	132	138
Vitamin B_{12}	20	32	45	60	68	76
Clearance Q_B = 300 mL/min						
Urea		– *	206	222	236	240
Creatinine		–	175	194	210	216
Phosphate		–	115	145	155	165
Vitamin B_{12}		–	47	62	72	82

In vitro performance: Q_D = 500 ml/min, Q_F = 0 ml/min, T = 37 °C (EN 1283. ISO 8637).
Ultrafiltration coefficients: human blood, Hct 32 %, protein content 6 %.

* refer to recommended blood flow range

Effective surface (m²)	0.4	0.7	1.0	1.3	1.6	1.8
Blood flow range (mL/min)	50 – 200	50 – 200	100 – 300	150 – 400	200 – 500	250 – 600
Wall thickness / lumen (µm)	40/200	40/200	40/200	40/200	40/200	40/200
Priming volume (mL)	28	42	63	82	98	110
Membrane material	Fresenius Polysulfone®					
Housing material	Polycarbonate					
Potting compound	Polyurethane					
Sterilisation method	ETO					
Form of treatment	HD					
Units per box	12	12	12	12	12	12
Art.-No.	**500 165 1**	**500 161 1**	**500 162 1**	**500 145 1**	**500 163 1**	**500 164 1**

Paediatric Filters FX paed, FX 40

helixone®

INLINE Steam sterilisation

As members of the FX-class of dialysers, both the FX paed and the FX 40 dialyser deliver the high expectations on dialysers for application in paediatric dialysis.

- State-of-the-art housing and membrane technology
- Low effective surface areas and low blood filling volumes
- No kinking of blood lines through lateral blood inlet ports
- Fast and easy preparation
- High-flux dialysis membrane with high middle-molecule removal rate

In vitro performance data/technical data

	FX paed	FX 40
Ultrafiltration coeff. (mL/h x mmHg)	7	20
Clearance Q_B = 100 mL/min, Q_D = 300 mL/min		
Urea	76	–
Creatinine	64	–
Phosphate	57	–
Vitamin B_{12}	34	–
Inulin	20	–
Clearance Q_B = 200 mL/min Q_D = 500 mL/min		
Urea	–	170
Creatinine	–	144
Phosphate	–	138
Vitamin B_{12}	–	84
Inulin	–	54

In vitro performance: Q_F = 0 mL/min, T = 37 °C (EN 1283, ISO 8637).
Ultrafiltration coefficients: human blood, Hct 32 %, protein content 6 %.

Effective surface (m^2)	0.2	0.6
Blood flow range (mL/min)	30 – 100	50 – 200
Wall thickness / lumen (µm)	35/220	35/185
Priming volume (mL)	18	32
Membrane material	Helixone®	
Housing material	Polypropylene	
Potting compound	Polyurethane	
Sterilisation method	INLINE Steam	
Form of treatment	HD	
Units per box	20	20
Art.-No.	**500 822 1**	**500 884 1**

Dialysis Fluid Filter DIASAFE®*plus*

The dialysis fluid filter DIASAFE®*plus* is a further development of the successful DIASAFE® filter by Fresenius Medical Care.

- Preparation of ultra pure dialysis fluid (endotoxins < 0.03 IU/mL, microbial contaminations < 0.1 CFU/mL)
- ONLINE preparation of substitution fluid for HF and HDF treatments
- Microbiological safety through redundant double filtration of the substitution fluid using two DIASAFE®*plus* filters in series
- Checking of filter function in automatic integrity tests
- High resistance to disinfection agents, such as Puristeril® 340 and Diasteril®, Citrosteril®, Sporotal® 100

Fresenius Polysulfone®

Technical data

	DIASAFE®*plus*
Membrane material	Fresenius Polysulfone®
Effective surface (m^2)	2.2
Housing material	Polypropylene
Potting compound	Polyurethane
Sealings	Silicone
Filtration rate	5 mL/min mmHg (3.75 L/min bar; max. 2 bar)
Operating time	Standard HD: max. 12 weeks ONLINE HF/HDF, ONLINE priming/rinsing: max. 12 weeks or 100 treatments
Disinfection	Puristeril® 340 (peracetic acid); Diasteril® (hydroxyacetic acid) or Citrosteril® (citric acid); Sporotal® 100 (sodium hypochlorite) max. 11 times
Units per box	12
Art.-No.	**500 820 1**

Accessories	**Safe line™**	**Residual test (Puristeril® 340)**	**pH Indicator test (Diasteril®)**
Units per box	100	100	100
Art.-No.	**504 580 1**	**629 916 1**	**628 816 1**

Fresenius Medical Care

Fresenius Medical Care Deutschland GmbH · 61346 Bad Homburg v. d. H. · Germany · Phone: +49 (0) 6172-609-0 · Fax: +49 (0) 6172-609-2191
Head office: Else-Kröner-Straße 1 · 61352 Bad Homburg v. d. H.
www.fmc-ag.com

732 432 1/7 GB (2 GUT 07.07)