Cardioprotective Haemodialysis

Concentrates and Solutions

Extended Product Range

Cardioprotective Haemodialysis SPOT

FRESENIUS MEDICAL CARE

Acid Concentrates

AC-F – Liquid 1+44 acid concentrates in canisters

The mixing ratio for all acid concentrates listed below is 1+44. All of them are designed for use with bi*bag*®, Flexicart or liquid bicarbonate concentrate 8.4%. The labels of acid concentrates are marked red.

Liquid acid concentrates in canisters (1 + 44 AC-F)
Composition of ready-to-use dialysis fluid (after mixing with bicarbonate concentrate 8.4 % and purified water)

Type	Na^+ mmol/L	K^+ mmol/L	Ca^{2+} mmol/L	Mg^{2+} mmol/L	Cl^- mmol/L	HCO_3^- mmol/L	Acetate mmol/L	Glucose g/L	Osmolarity mosm/L	Art. No. 4.7 L	Art. No. 7.8 L
AC-F 119/4	138.00	1.00	1.00	0.5	107.00	32.00	3.00	1.00	288	662 263 1	662 262 1
AC-F 113	138.00	1.00	1.75	0.5	108.50	32.00	3.00	1.00	290	362 163 1	362 162 1
AC-F 207	138.00	2.00	1.25	0.5	108.50	32.00	3.00	–	285	F00002004	F00002005
AC-F 219/3	138.00	2.00	1.00	0.5	108.00	32.00	3.00	1.00	290	462 863 1	462 862 1
AC-F 213	138.00	2.00	1.75	0.5	109.50	32.00	3.00	1.00	292	362 463 1	362 462 1
AC-F 229	138.00	2.00	1.25	0.5	109.50	32.00	3.00	2.00	298	762 163 1	–
AC-F 319	138.00	3.00	1.00	0.5	109.50	32.00	3.00	1.00	292	662 363 1	662 362 1
AC-F 313	138.00	3.00	1.75	0.5	110.50	32.00	3.00	1.00	294	462 663 1	462 662 1
AC-F 419	138.00	4.00	1.25	0.5	110.50	32.00	3.00	1.00	295	262 163 1	262 162 1
AC-F 413/1	138.00	4.00	1.50	0.5	110.00	32.00	3.00	1.00	296	462 763 1	462 762 1
Canisters / pallet										**90**	**60**

Granudial AF – Dry acid concentrates

Granudial AF must be dissolved with purified water with the help of a suitable mixing device according to the instructions given in the package insert in order to obtain liquid acid concentrate. The yielded liquid acid concentrate is for use in a mixing ratio of 1+34. It is designed for use with bi*bag*® or Flexicart or liquid bicarbonate concentrate 8.4 %.

Dry acid concentrates: Granudial AF
Composition of the ready-to-use dialysis fluid (after mixing with bicarbonate concentrate 8.4 % and purified water)

Type	Na^+ mmol/L	K^+ mmol/L	Ca^{2+} mmol/L	Mg^{2+} mmol/L	Cl^- mmol/L	HCO_3^- mmol/L	Acetate mmol/L	Glucose g/L	Weight kg	Litres of conc./box	Art. No.
AF 10	140.00	2.00	1.50	1.0	109.00	32.00	6.00	–	25	100	508 712 C
AF 11	140.00	3.00	1.50	1.0	110.00	32.00	6.00	–	25	100	508 787 C
AF 13	140.00	2.00	1.25	1.0	108.50	32.00	6.00	–	25	100	508 823 C
AF 15	138.00	2.00	1.75	0.5	108.50	32.00	6.00	–	25	100	508 704 C
Boxes / pallet											**24**

FRESENIUS MEDICAL CARE

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Cardioprotective Haemodialysis

Concentrates and Solutions
Product Range

Cardioprotective Haemodialysis SPOT

FRESENIUS MEDICAL CARE

Protect your Patient

Cardioprotective Haemodialysis

The reduction of risk factors for cardiovascular diseases (CVD) is core to the development of dialysis systems and products at Fresenius Medical Care. Outstanding cardioprotection must be reflected in all levels of product development and application.

Wide-ranging cardioprotection

There have been tremendous improvements in the quality and efficacy of haemodialysis (HD) therapy in recent years. Despite this, cardiovascular diseases (CVD) remain the leading cause of death for patients with end-stage renal disease (ESRD).

Services

Over 30 years of experience in dialysis at your service.

- Project Planning and Consulting
- Training and Education
- Technical Services
- Water Quality Service (WQS)
- Medical Information Services

Products

State-of-the-art technologies enable advanced cardioprotective therapies.

- CorDiax product line:
  - 5008 CorDiax and 5008S CorDiax
  - FX CorDiax haemo*dia*filter
  - BCM-Body Composition Monitor
- Classix product line:
  - 4008S classix
  - FX classix dialysers
- Therapy Data Management System (TDMS)
- Online Purification Cascade (OPC)

Moreover, both overall and cardiovascular mortality are markedly greater in ESRD patients than in the general population. This is why we put Cardioprotective Haemodialysis on the SPOT. A comprehensive approach that includes services, products and therapies is needed to achieve the best therapeutic performance – meaning improved clinical outcomes and better quality of life, enhanced control of therapy costs, and simpler, safer handling.

Outcomes

Achieving better outcomes with cardioprotective therapies.

- Reduced mortality risk
- Fewer cardiovascular complications
- Optimised use of resources

Therapies

Cardioprotective therapies designed by the world market leader in haemodialysis.

- High-Flux dialysis
- HighVolume**HDF**®
- Advanced Fluid Management

Acid Concentrates

smart*bag*® – Liquid 1+44 acid concentrates in bags

The smart*bag*® is a flexible canister which combines the advantages of a canister and a bag.

The smart*bag*® 4.7 L – containing liquid acid concentrates (1+44 AC-F)
Compositions of ready to use dialysis fluid (after mixing with bicarbonate concentrate 8.4 % and purified water)

Type	Na^+ mmol/L	K^+ mmol/L	Ca^{2+} mmol/L	Mg^{2+} mmol/L	Cl^- mmol/L	HCO_3^- mmol/L	Acetate mmol/L	Glucose g/L	Osmolarity mosm/L	Art. No. 4.7 L Box of 60	Art. No. 4.7 L Box of 2
smart*bag*® 111.5	138.00	1.00	1.50	0.5	108.00	32.00	3.00	1.00	289.55	F00 000 064	F00 000 64D
smart*bag*® 211.25	138.00	2.00	1.25	0.5	108.50	32.00	3.00	1.00	290.80	F00 000 065	F00 000 65D
smart*bag*® 211.5	138.00	2.00	1.50	0.5	109.00	32.00	3.00	1.00	291.55	F00 000 066	F00 000 66D
smart*bag*® 211.75	138.00	2.00	1.75	0.5	109.50	32.00	3.00	1.00	292.30	F00 000 232	F00 002 32D
smart*bag*® 311.25	138.00	3.00	1.25	0.5	109.50	32.00	3.00	1.00	292.80	F00 000 067	F00 000 67D
smart*bag*® 311.5	138.00	3.00	1.50	0.5	110.00	32.00	3.00	1.00	293.55	F00 000 068	F00 000 68D
smart*bag*® 411.25	138.00	4.00	1.25	0.5	110.50	32.00	3.00	1.00	294.89	F00 000 236	–
Acid concentrate per pallet										**564 L**	**564 L**
Bags / box – boxes / pallet										**60 – 2**	**2 – 60**

The smart*bag*® CA 4.2 L – containing liquid acid concentrates (1+44 AC-F)
Compositions of ready to use dialysis fluid (after mixing with bicarbonate concentrate 8.4 % and purified water)

Type	Na^+ mmol/L	K^+ mmol/L	Ca^{2+} mmol/L	Mg^{2+} mmol/L	Cl^- mmol/L	HCO_3^- mmol/L	Citrate mmol/L	Acetate mmol/L	Glucose g/L	Art. No. 4.2 L Box of 72	Art. No. 4.2 L Box of 2
smart*bag*® CA 211.5	138.00	2.00	1.50	0.50	109.00	32.00	1.00	-	1.00	F00 000 949	F00 006 557
smart*bag*® CA 211.75	138.00	2.00	1.75	0.50	109.50	32.00	1.00	-	1.00	-	F00 006 558
smart*bag*® CA 311.5	138.00	3.00	1.50	0.50	110.00	32.00	1.00	-	1.00	F00 002 007	F00 020 07D
smart*bag*® CA 311.75	138.00	3.00	1.75	0.50	110.50	32.00	1.00	-	1.00	-	F00 006 559
smart*bag*® CA 411.5	138.00	4.00	1.50	0.50	111.00	32.00	1.00	-	1.00	F00 002 008	F00 006 560
Acid concentrate per pallet										**604 L**	**504 L**
Bags / box – boxes / pallet										**72 – 2**	**2 – 60**

Concentrate platforms: for application with 5008 CorDiax - M442061 / for application with 5008S CorDiax - M423591

smart*b*ag® 300 L – Liquid 1+44 acid concentrates

The smart*b*ag® 300 L facilitates central concentrate supply at a minimum of storage space.

The smart*b*ag® 300 L – containing liquid acid concentrates (1+44 AC-F)
Compositions of ready to use dialysis fluid (after mixing with bicarbonate concentrate 8.4 % and purified water)

Type	Na^+ mmol/L	K^+ mmol/L	Ca^{2+} mmol/L	Mg^{2+} mmol/L	Cl^- mmol/L	HCO_3^- mmol/L	Acetate mmol/L	Glucose g/L	Osmolarity mosm/L	Art. No. 300 L
smart*b*ag® 211.25	138.00	2.00	1.25	0.5	108.50	32.00	3.00	1.00	290.80	F00 001 168
smart*b*ag® 211.5	138.00	2.00	1.50	0.5	109.00	32.00	3.00	1.00	291.55	F00 003 068
smart*b*ag® 311.25	138.00	3.00	1.25	0.5	109.50	32.00	3.00	1.00	292.80	F00 003 069
smart*b*ag® 311.5	138.00	3.00	1.50	0.5	110.00	32.00	3.00	1.00	293.55	F00 003 070
smart*b*ag® 411.25	138.00	4.00	1.25	0.5	110.50	32.00	3.00	1.00	294.89	F00 006 659
Acid concentrate per pallet										**600 L**
Boxes / pallet										**2**

Please order your individual retrofit kit (Art. No. 6362981) for CDS 08.

Code message: e. g. **smart*b*ag® 211.5** (**2**xx.x = **K^+** in mmol/L) (x**1**x.x = **Glucose** in g/L) (xx**1.5** = **Ca^{2+}** in mmol/L)

Technical changes reserved.

Acid Concentrates

AC-F – Liquid 1+44 acid concentrates in canisters

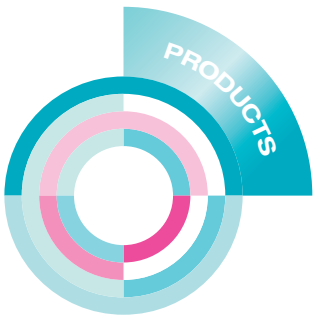
The mixing ratio for all acid concentrates listed below is 1+44. All of them are designed for use with bibag.

Within the haemodialysis machine 1 litre of acid concentrate is mixed with 1.575 litres of liquid bicarbonate concentrate 8.4 % and 42.425 litres of purified water in order to obtain 45 litres of ready-to-use dialysis fluid. The mixing ratio of the haemodialysis machine must be set accordingly (1+44 AC-F).

The labels of acid concentrates are marked red.

Liquid acid concentrates in canisters (1+44 AC-F)
Composition of ready-to-use dialysis fluid (after mixing with bicarbonate concentrate 8.4 % and purified water)

Canister 4.2 L		Canister 7.8 L									
Type	**Art. No.**	**Type**	**Art. No.**	**Na^+ mmol/L**	**K^+ mmol/L**	**Ca^{2+} mmol/L**	**Mg^{2+} mmol/L**	**Cl^- mmol/L**	**HCO_3^- mmol/L**	**Acetate mmol/L**	**Glucose g/L**
AC-F 211.25	F00 006 337	AC-F 219/1	462 462 1	138.00	2.00	1.25	0.50	108.50	32.00	3.00	1.00
AC-F 211.5	F00 006 338	AC-F 213/4	262 862 1	138.00	2.00	1.50	0.50	109.00	32.00	3.00	1.00
AC-F 211.75	F00 006 339	AC-F 213	362 462 1	138.00	2.00	1.75	0.50	109.50	32.00	3.00	1.00
AC-F 311.25	F00 006 340	AC-F 313/2	562 962 1	138.00	3.00	1.25	0.50	109.50	32.00	3.00	1.00
AC-F 311.5	F00 006 341	AC-F 313/1	562 662 1	138.00	3.00	1.50	0.50	110.00	32.00	3.00	1.00
AC-F 311.75	F00 006 343	AC-F 313	462 662 1	138.00	3.00	1.75	0.50	110.50	32.00	3.00	1.00
AC-F 411.25	F00 006 344	AC-F 419	262 162 1	138.00	4.00	1.25	0.50	110.50	32.00	3.00	1.00
AC-F 411.5	F00 006 345	AC-F 413/1	462 762 1	138.00	4.00	1.50	0.50	111.00	32.00	3.00	1.00
Canisters / pallet	**90**		**60**								



Granudial AF – Dry acid concentrates

Granudial AF must be dissolved with purified water with the help of a suitable mixing device according to the instructions given in the package insert in order to obtain liquid acid concentrate. The yielded liquid acid concentrate is for use in a mixing ratio of 1+34.

Dry acid concentrates: Granudial AF
Composition of the ready-to-use dialysis fluid (after mixing with bicarbonate concentrate 8.4 % and purified water)

Type	Na^+ mmol/L	K^+ mmol/L	Ca^{2+} mmol/L	Mg^{2+} mmol/L	Cl^- mmol/L	HCO_3^- mmol/L	Acetate mmol/L	Glucose g/L	Weight kg	Litres of conc./box	Art. No.
AF80	138.00	2.00	1.50	0.5	106.00	32.00	6.00	1.00	29	100	F00 000 405
AF81	138.00	3.00	1.50	0.5	107.00	32.00	6.00	1.00	29	100	F00 000 406
AF82	138.00	2.00	1.75	0.5	106.50	32.00	6.00	1.00	29	100	F00 000 854
AF83	138.00	2.00	1.25	0.5	105.50	32.00	6.00	1.00	29	100	F00 000 855
AF84	138.00	4.00	1.50	0.5	108.00	32.00	6.00	1.00	29	100	F00 003 558
Boxes / pallet											**24**

DIAMIX Semi – Dry acid concentrates

DIAMIX must be dissolved with purified water with the help of a suitable mixing device to obtain liquid acid concentrate for use in a mixing ratio of 1+44.

Semi-dry acid concentrates: DIAMIX
Composition of the ready-to-use dialysis fluid (after mixing with bicarbonate concentrate 8.4 % and purified water)

Type	Na^+ mmol/L	K^+ mmol/L	Ca^{2+} mmol/L	Mg^{2+} mmol/L	Cl^- mmol/L	HCO_3^- mmol/L	Acetate mmol/L	Glucose g/L	Weight kg	Litres of conc./barrel	Art. No. 193 L
DIAMIX AC-F 219/1	138.00	2.00	1.250	0.5	108.50	32.00	3.00	1.00	349	750	800 157 1
DIAMIX AC-F 213/4	138.00	2.00	1.500	0.5	109.00	32.00	3.00	1.00	349	750	800 257 1
DIAMIX AC-F 313/2	138.00	3.00	1.250	0.5	109.50	32.00	3.00	1.00	349	750	800 357 1
DIAMIX AC-F 313/1	138.00	3.00	1.500	0.5	110.00	32.00	3.00	1.00	349	750	800 457 1
DIAMIX AC-F 419	138.00	4.00	1.250	0.5	110.50	32.00	3.00	1.00	349	750	800 557 1
DIAMIX AC-F 413/1	138.00	4.00	1.500	0.5	111.00	32.00	3.00	1.00	349	750	800 657 1

Bicarbonate Concentrates

bibag

The online dry bicarbonate concentrate for Fresenius Medical Care haemodialysis machines.

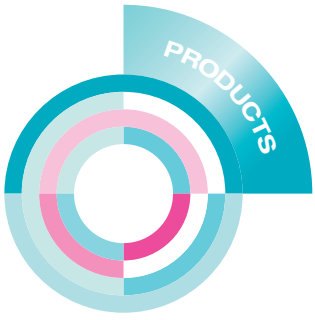
bibag				
Type	**Weight**	**Composition**	**Units / box**	**Art. No.**
bibag	650 g	$NaHCO_3$	16 bags	508 992 1
bibag	900 g	$NaHCO_3$	12 bags	508 991 1
bibag 5008	650 g	$NaHCO_3$	16 bags	506 078 1
bibag 5008	900 g	$NaHCO_3$	12 bags	506 080 1
Boxes / pallet				**56**

bibag 5008 is the standard module for the 5008 CorDiax, 5008S CorDiax and 4008 classix HD machines.

Granudial BI – Dry bicarbonate concentrate

Granudial BI must be dissolved with purified water with the help of a suitable mixing device according to the instructions given in the package insert in order to obtain liquid 8.4 % bicarbonate concentrate.

Dry bicarbonate concentrates: Granudial BI Composition of the concentrate						
Type	**Na^+ mmol/L**	**HCO_3^- mmol/L**	**Quantity**	**Weight / Box kg**	**Litres of conc./box**	**Art. No. for 1 box**
BI 84	1000	1000	4 bags / box	34	400	508 861 C*
BI 840	1000	1000	2 bags / box	17.5	200	508 860 1**
Boxes / pallet						***24 ****48**



Saline 0.9 % in Frekaflex bags

Frekaflex bags are made of PVC and are equipped with 2 Luer-Lock connectors. The solution is specified for rinsing and priming the tubing system and may not be used as infusion solution.

Saline 0.9 % in Frekaflex bags					
Type	**Na^+ mmol/L**	**Cl^- mmol/L**	**Art. No. 30 × 250 mL**	**Art. No. 15 × 500 mL**	**Art. No. 10 × 1000 mL**
Saline 0.9 %	154	154	F00 004 551	F00 004 550	F00 004 549
Bags / pallet			**1680**	**840**	**560**

FRESENIUS
MEDICAL CARE

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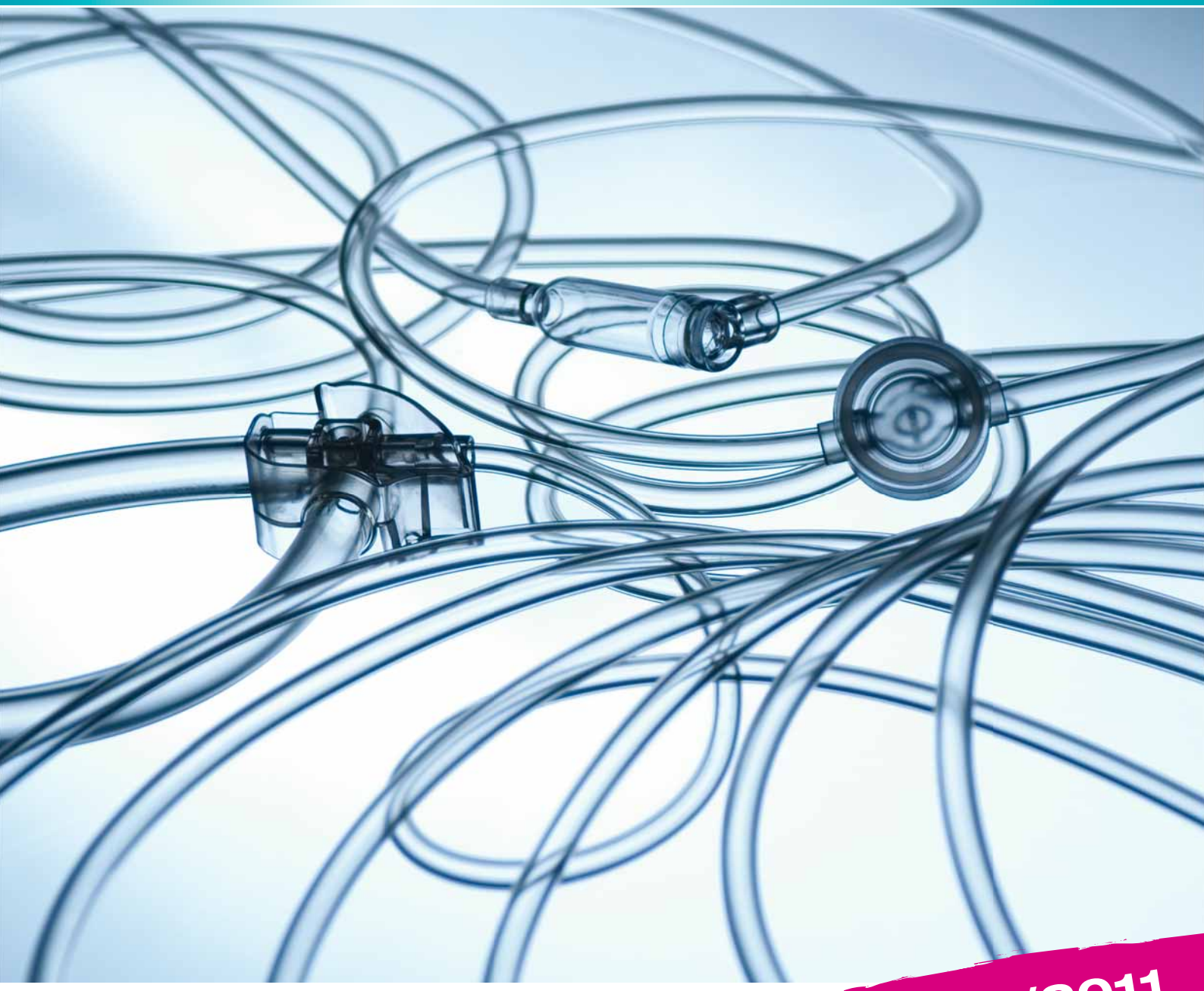
F00006694 MT-EN (1.0 BG-Burg 10.15)

Haemodialysis

Bloodlines, Tubing Systems, Accessories

Product Range



2010/2011

Fresenius Medical Care

5008 Therapy System – the innovation …

Enabling the application of ONLINE Haemodiafiltration in the most practical way.

ONLINE Priming / ONLINE HDF

- Saline free priming of extracorporeal circuit
- ONLINE HDF treatment as standard
- Enabled by the SafeLine included in every bloodline set

Reliable Precision

- Exact measurement of arterial pressure via pressure dome
- Trouble-free air detection directly on system tube

Convenience

- Clear layout and optimised tube lengths
- Machine assisted set-up and disassembling
- Reduced filling volume and less blood-air contact

4008 Sustained dependability

Reliability established over several years and millions of treatments.

Superior quality and safety

- Consistent and validated manufacturing
- Rigorous testing of bloodline performance
- Highly compatible interface between bloodlines and machine

Reliable therapy

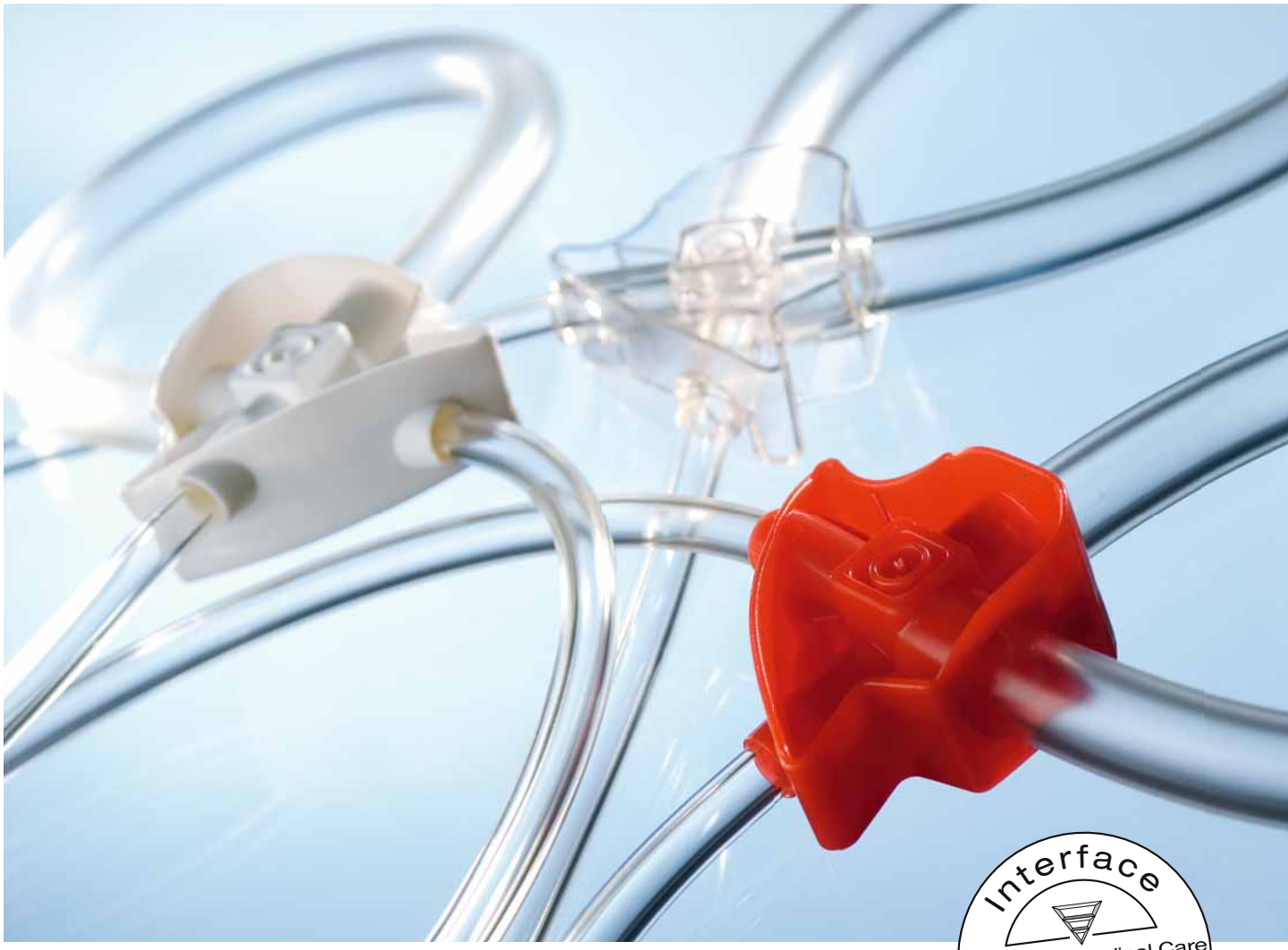
- Matured technology recognised worldwide
- Extensive experience in the production of bloodlines – ensuring consistent product quality

Meeting diverse needs

- Appropriate sterilisation to suit varying demands
- Broad product range to meet all requirements

Ensuring safety with the authentic Fresenius Medical Care Original Bloodlines….

Quality and reliability characterise the Fresenius bloodlines in function and use.



Handling

- Clearly colour-coded components
- Ergonomic components and layout

Safety

- Assurance of highest safety and performance with our 4008 and 5008 machines
- Transducer protector with integrated inspection windows
- Injection port with enlarged finger-protection shield

Quality

- Certified quality systems for development, production and sales
- Perfect compatibility to machine interfaces

Biocompatibility

- Use of plasticisers with high haemocompatibility and low cytotoxic reaction
- Free of DEHP

Product Range 5008

DEHP-free

LifeLine*Beta*

- Phtalate free
- Beta-sterilisation by accelerated electrons (e-beam)
- Fewer material alterations in comparison to gamma-irradiation
- No radioactive source of radiation

Adult Bloodlines

Beta sterilisation – DEHP free

Type	To be used with	Filling volume	Units per box	Art.-No.
AV-Sets				
AV-Set ONLINEplus 5008-R	5008/5008S	132 ml	24	F00000384
AV-Set ONLINEplus BVM 5008-R	5008	136 ml	24	F00000385
AV-Set ONLINE Priming 5008S-R	5008S	132 ml	24	F00000700
SN-Sets				
SN-Set ONLINEplus 5008-R	5008/5008S	166 ml	20	F00000386
SN-Set ONLINEplus BVM 5008-R	5008	169 ml	20	F00000387

Paediatric Bloodlines

Beta sterilisation – DEHP free

Type	To be used with	Inner diameter pump segment	Filling volume	Units per box	Art.-No.
AV-Sets					
AV-Set ONLINEplus BVM Paed 5008-R	5008	8 mm	108 ml	24	F00001068
SN-Sets					
SN-Set ONLINEplus BVM Paed 5008-R	5008	8 mm	142 ml	20	F00001069

BVM: Blood Volume Monitor
-R: Beta Sterilisation (Radiation)

Inner diameter of pump segment: 8 mm
Diameter of venous bubble catcher: 22 mm

Product Range 4008

DEHP-free

LifeLine*Beta*

- Phtalate free
- Sterilisation by accelerated electrons (e-beam)
- Less material alterations in comparison to gamma-irradiation
- No radioactive source of radiation

Adult Bloodlines

Beta sterilisation – DEHP free

Type	To be used with	Filling volume	Units per box	Art.-No.
AV-Sets				
AV-Set B-R	2008/4008	161 ml	24	F00001124
AV-Set SRB-R	2008/4008	161 ml	24	F00000257
AV-Set SRB BVM-R	4008	172 ml	24	F00000258
SN-Sets				
SN-Set B-R	2008/4008	197 ml	20	F00001125
SN-Set SRB L-R	2008/4008	211 ml	20	F00000259
SN-Set SRB L BVM-R	4008	225 ml	20	F00001132

Paediatric Bloodlines

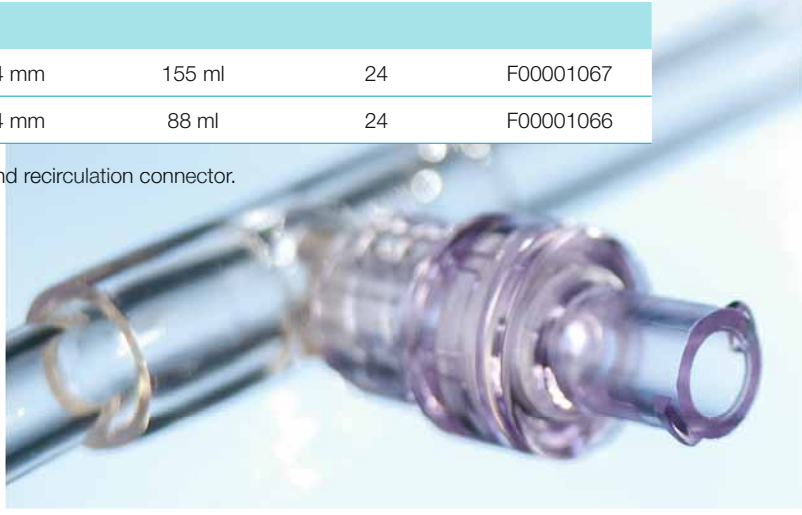
Beta sterilisation – DEHP free

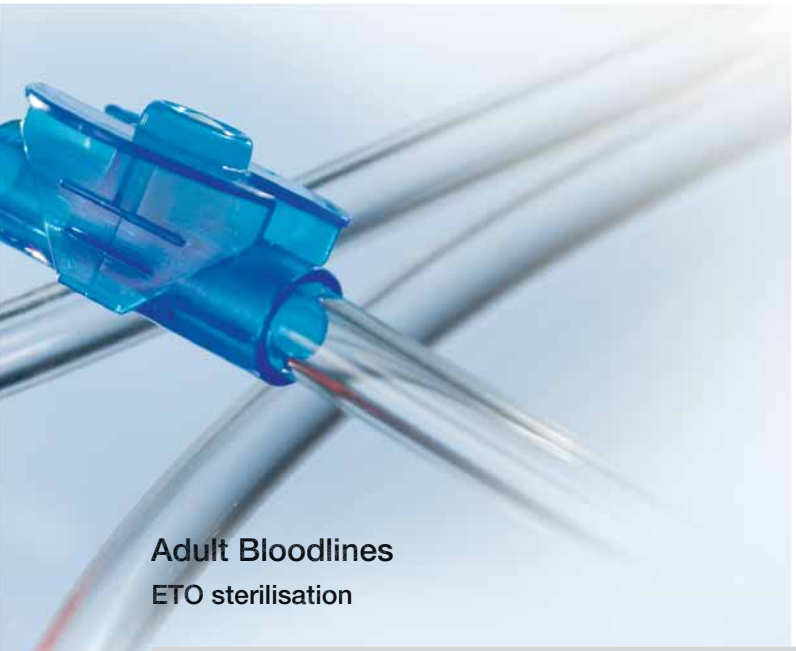
Type	To be used with	Inner diameter pump segment	Filling volume	Units per box	Art.-No.
AV-Sets					
AV-Set-FMC Paed R	2008/4008	6.4 mm	117 ml	24	F00001064
AV-Set-FMC BVM/BTM Paed R	4008	6.4 mm	126 ml	24	F00001065
AV-Set-FMC Paed/Baby R	2008/4008	6.4 mm	56 ml	24	F00001063
SN-Sets					
AV-SN-Set-FMC Paed R	2008/4008	6.4 mm	155 ml	24	F00001067
AV-SN-Set-FMC Paed/Baby R	2008/4008	6.4 mm	88 ml	24	F00001066

All paediatric bloodlines 4008 are equipped with spike, waste bag and recirculation connector.

S: Spike
R: Recirculation connector
B: Waste bag
L: Long tubes to SN expansion chamber (needed for SN-treatment with 4008 S)
BVM: Blood Volume Monitor
-R: Beta Sterilisation (Radiation)

Inner diameter of pump segment: 8 mm
Diameter of venous bubble catcher: 22 mm





BasicLine

- Sterilisation by ethylene oxide
- Special pre-conditioning and degassing process leads to minimised residual ETO content

Adult Bloodlines

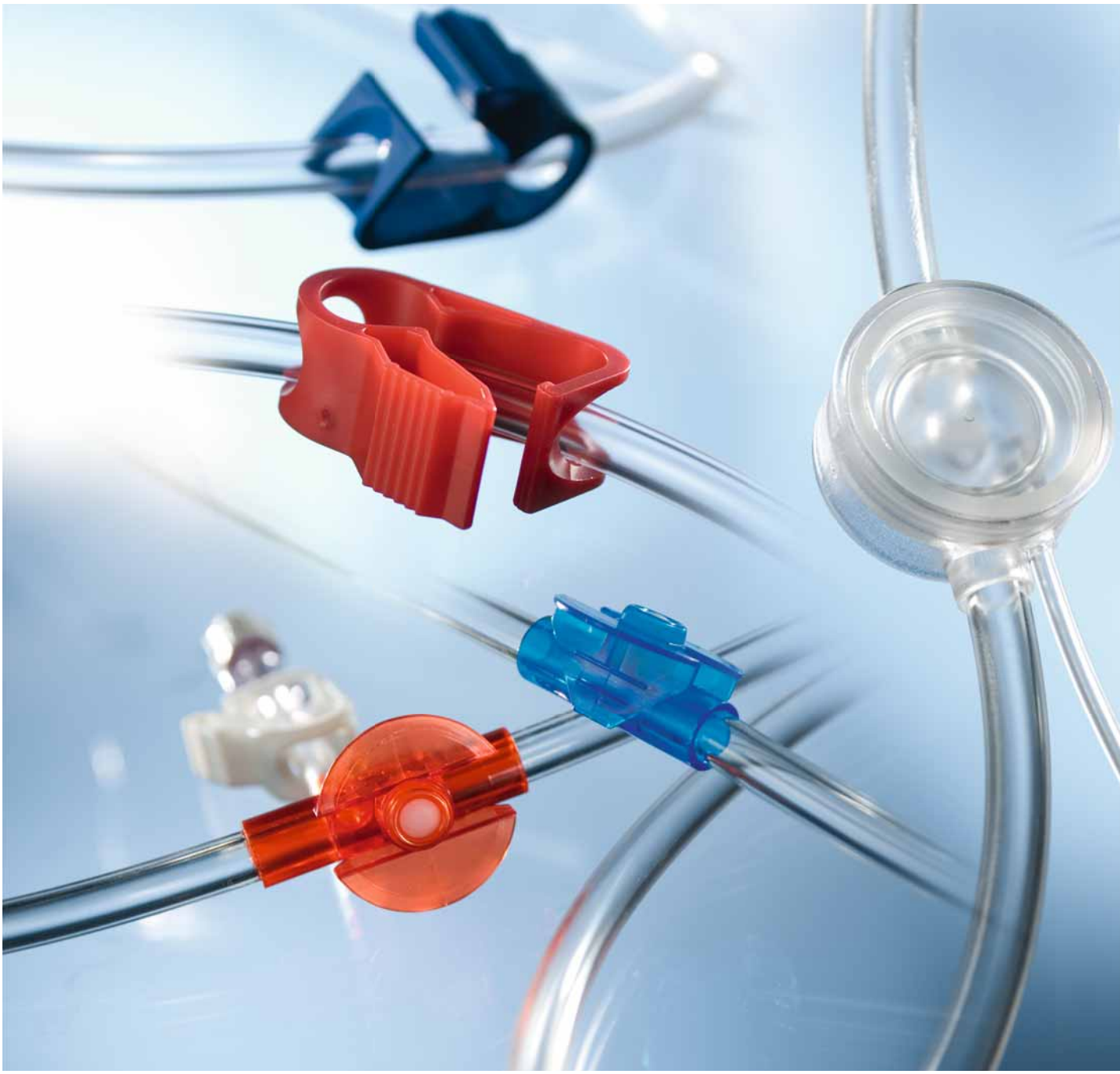
ETO sterilisation

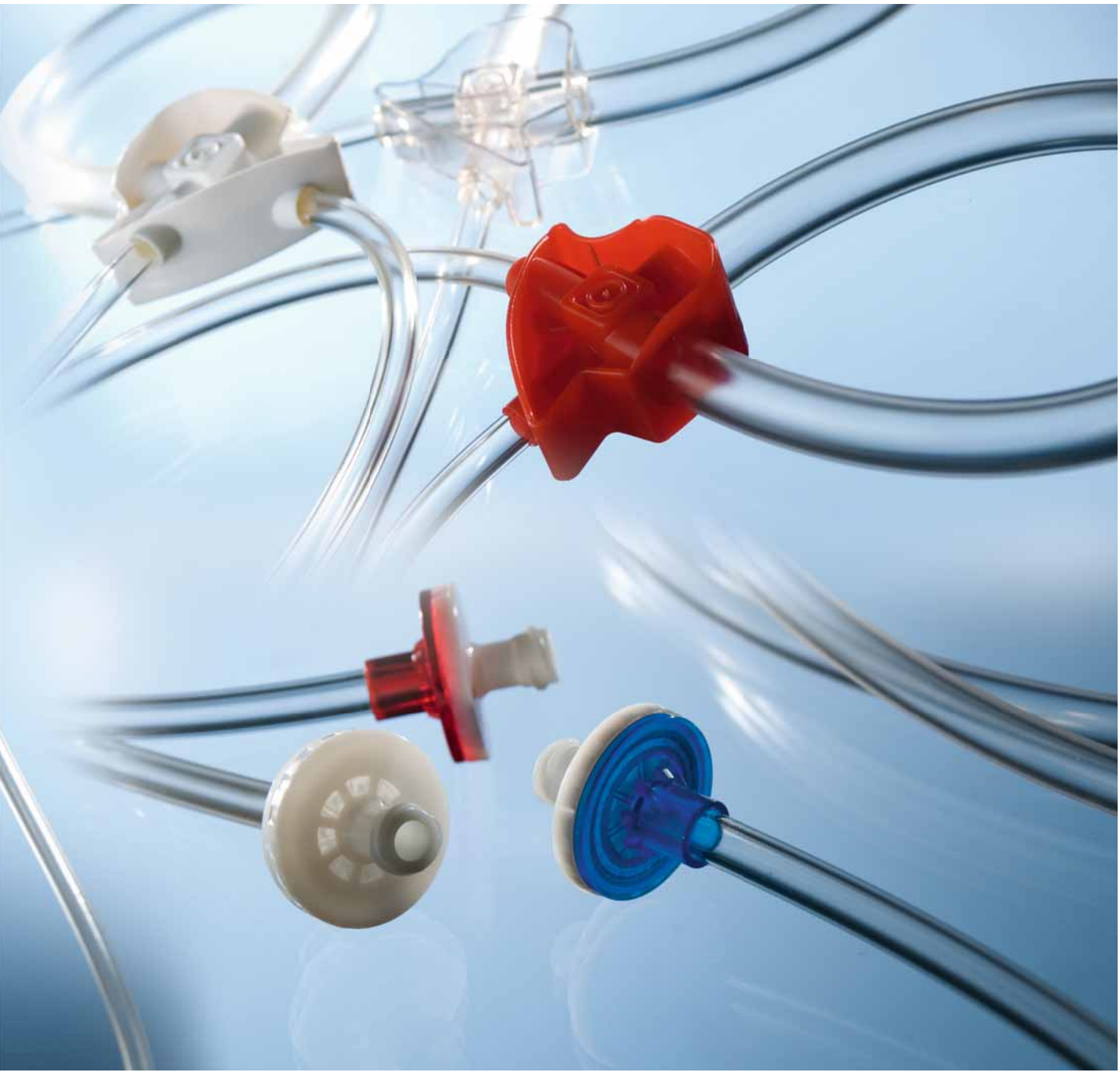
Type	To be used with	Filling volume	Spike	Waste bag	Recircu-lation connector	Units per box	Art.-No.
AV-Sets							
AV-Set-FMC (FA 204 C/FV 204 C)	2008/4008	161 ml	•		•	24	5000541
AV-Set-FMC (FA 204 B/FV 204 B)	2008/4008	161 ml		•		24	5000561
AV-Set-FMC (FA 204 C/FV 204 E)	2008/4008	161 ml	•	•	•	24	5003451
AV-Set-FMC (FA 204 C/FV 204 E) BVM	4008	172 ml	•	•	•	24	5016631
SN-Sets							
AV-SN-Set-FMC (FA 514 SN C/FV 204 E)	2008/4008	211 ml	•	•	•	20	5017411

BVM: Blood Volume Monitor

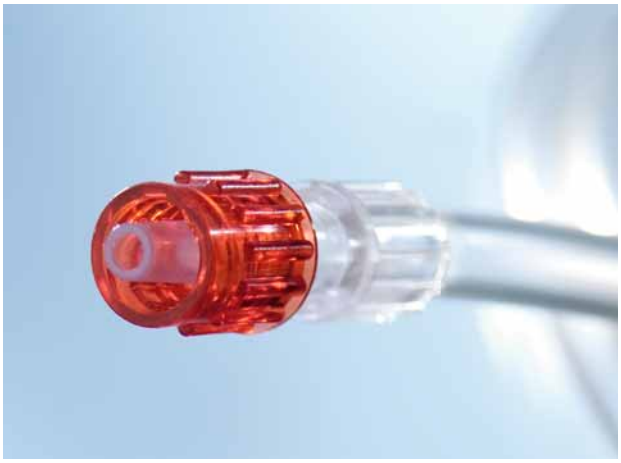
Inner diameter of pump segment: 8 mm
Diameter of venous bubble catcher: 22 mm

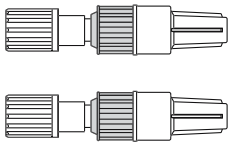
Fresenius Medical Care's bloodline components …





Components

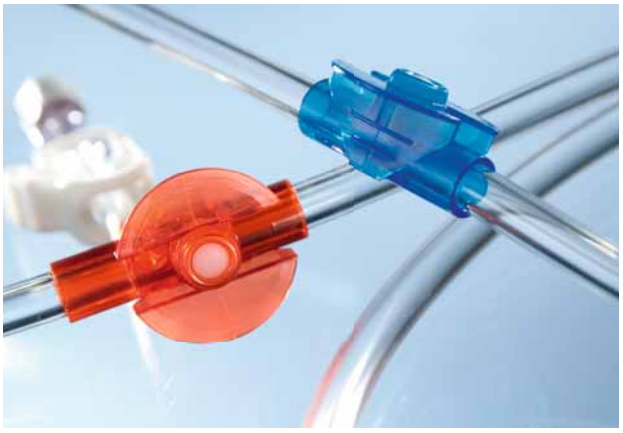


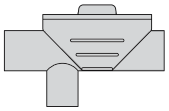


Patient connectors

Optimal handling and safety:

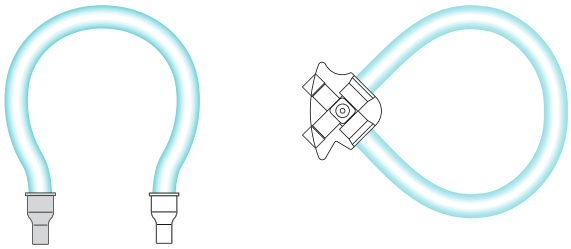
- Ergonomic grip on the rotating part ensures secure connection
- Easy to remove protective caps





Injection ports

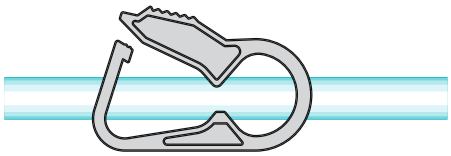
- Latex-free septum
- Colour coding
- Large finger-protection shield



Pump segment 4008 / 5008

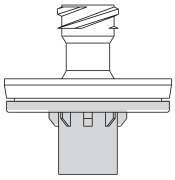
- Perfect fit to the Fresenius Medical Care dialysis machines (geometry, shore hardness, occlusion performance)
  - Qualified for the effective blood flow measurement
  - Allows achievement of prescribed dialysis dose

Components



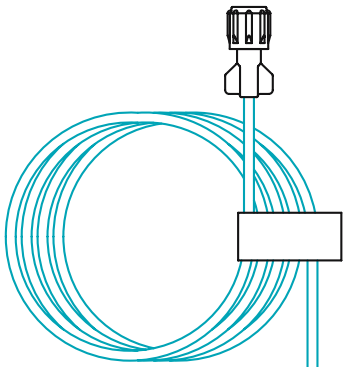
Line clamps

- Colour coding
- Optimal ergonomics for easy and reliable handling
- No additional clamps required



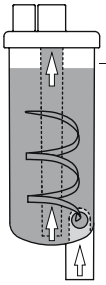
Transducer protectors

- Inspection windows
- Colour coding



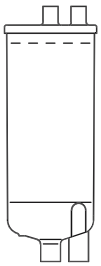
Heparin line

- Luer-Lock female Adapter with protecting cap
- Easy to remove paper tape



Arterial bubble catcher

- Dynamic blood flow due to special geometry
- Safe and effective air separation

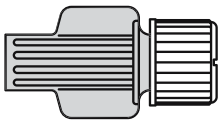


Single Needle chamber

- Dynamic blood flow
- Level mark for easy handling

Venous bubble catcher

- Inlet distributor reduces activation of clotting
  - Directed blood flow
  - No "free fall" of blood
- Allows an easy and correct positioning in the air detector due to the special shape of venous bubble trap (22 mm Ø)

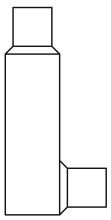


Dialyser connector

- Soft material allows safe connection to dialyser
- Easy to remove protective caps

Pressure dome

- Precise pressure measurement
- Reduced filling volume
- No blood-air contact



BVM cuvette

- Precise BVM measurement
- Easy handling

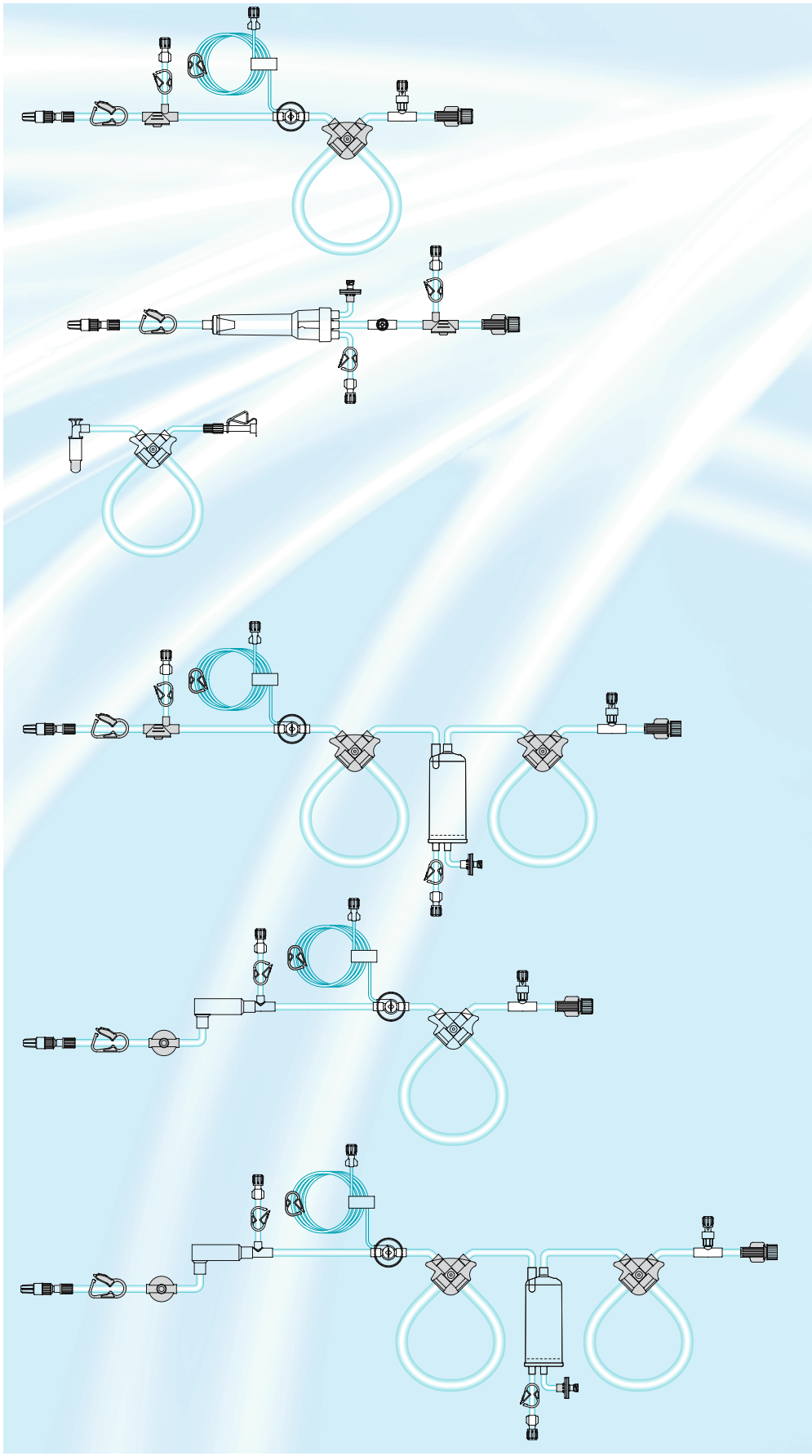
Technical drawings 5008

AV-Set ONLINEplus 5008-R (F00000384)

Arterial line

Venous line

SafeLine



Variants

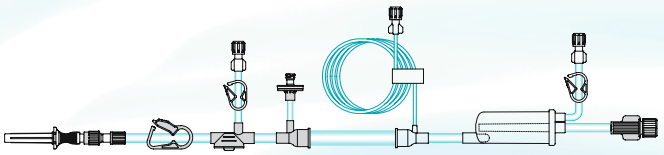
(Venous line and SafeLine unchanged)

SN-Set ONLINEplus 5008-R (F00000386)

AV-Set ONLINEplus BVM 5008-R (F00000385)

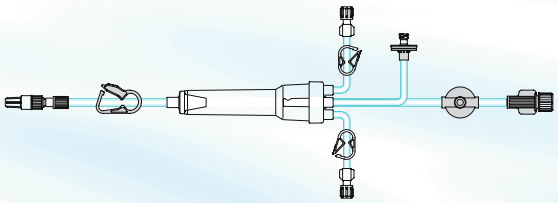
SN-Set ONLINEplus BVM 5008-R (F00000387)

Technical drawings 4008

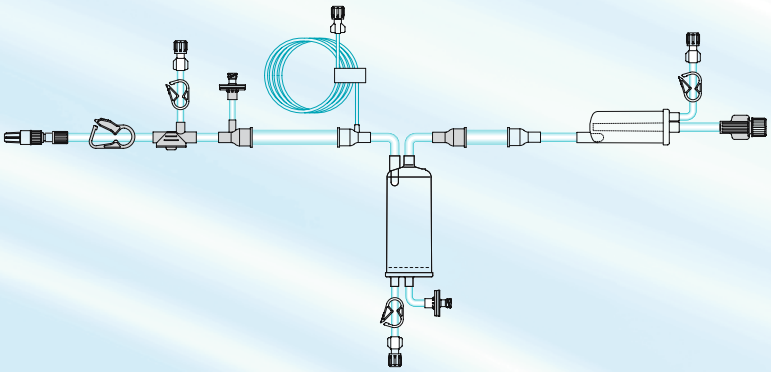


AV-Set SRB-R (F00000257)

Arterial line



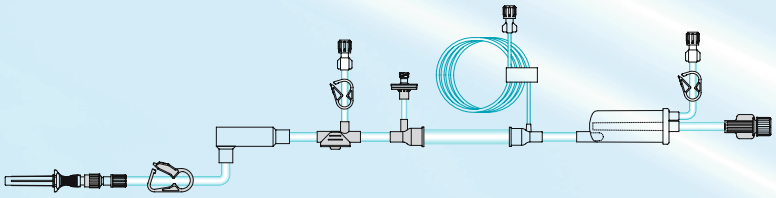
Venous line



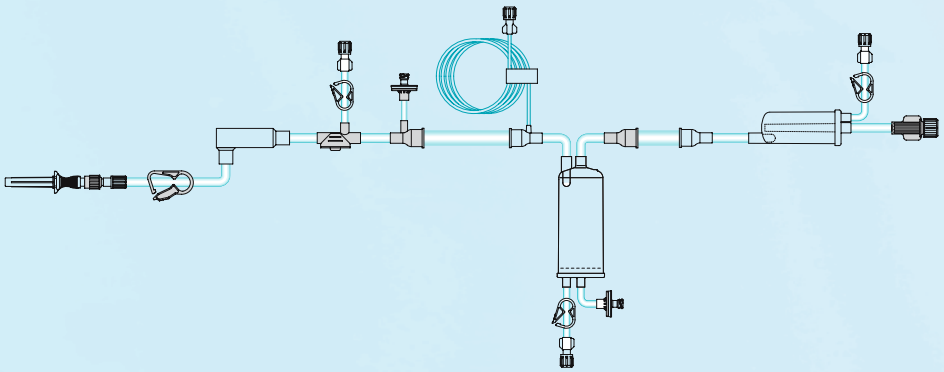
Variants

(Venous lines unchanged)

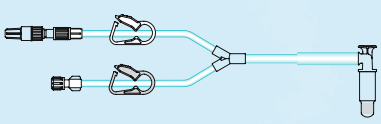
SN-Set B-R
(F00001125)



AV-Set SRB BVM-R
(F00000258)



AV-SN-Set-FMC (FA 514-SN C/ FV 204E) BVM
(5017411)



SafeLine
(F00001195)

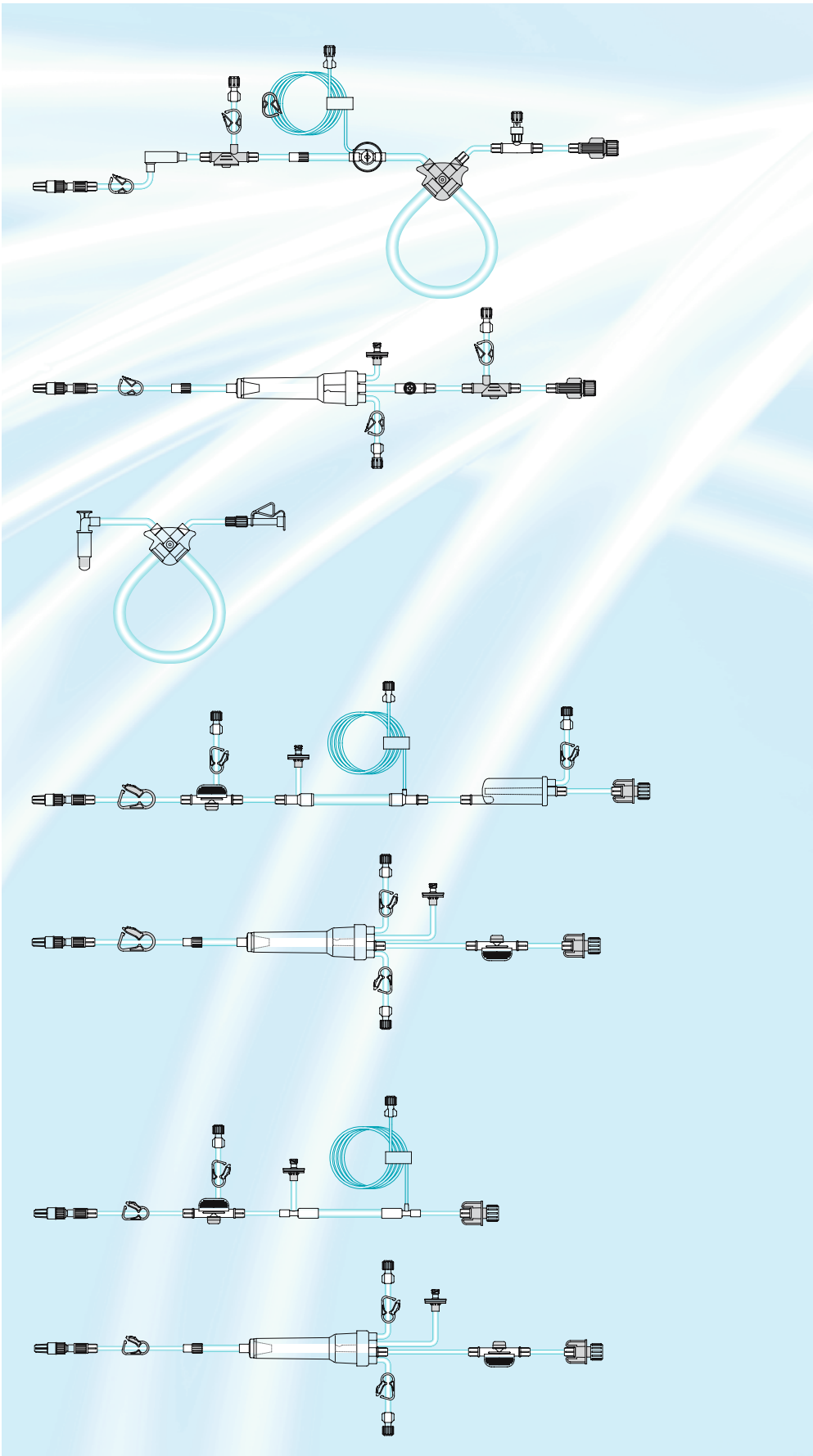
Technical drawings paediatric lines

5008
AV-Set ONLINEplus – BVM Paed 5008-R (F00001068)

Arterial line

Venous line

SafeLine



4008
AV-Set-FMC Paed R (F00001064)

Arterial line

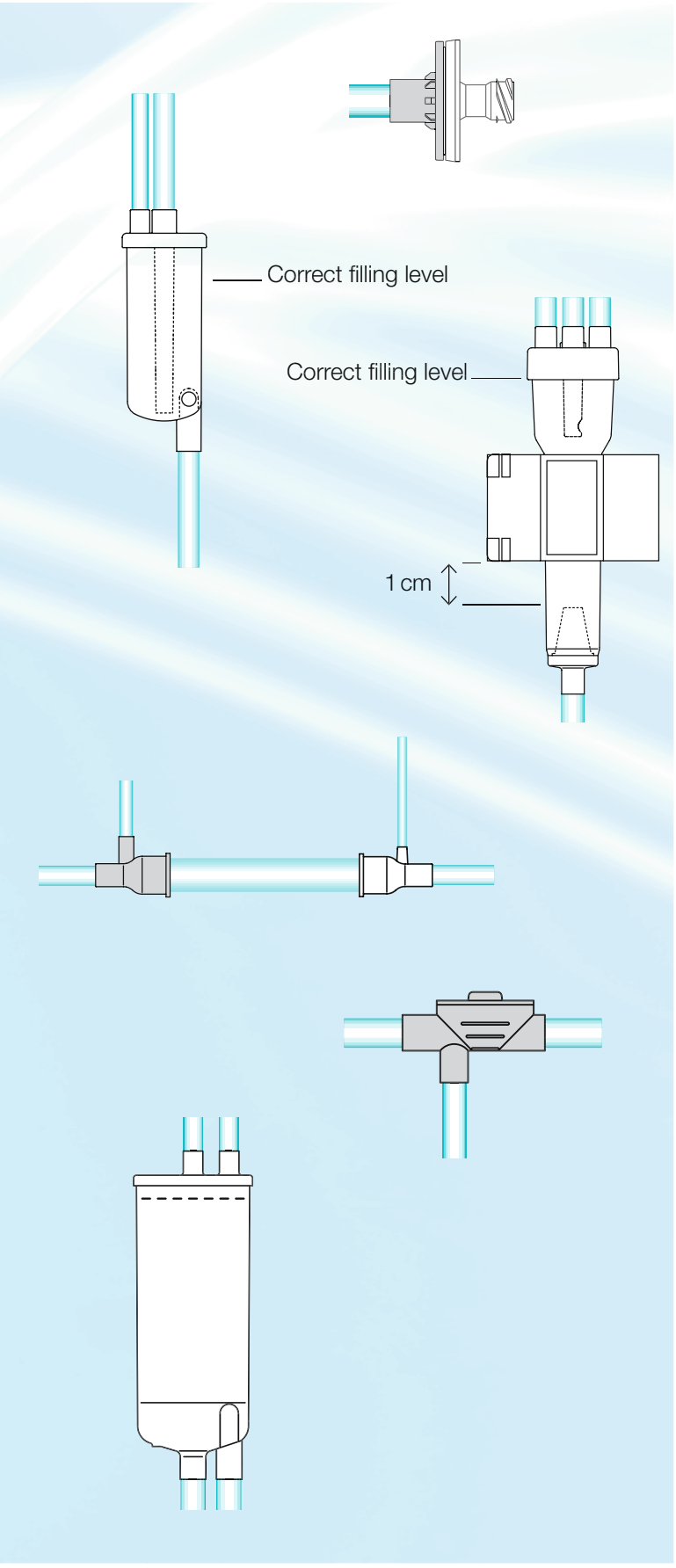
Venous line

AV-Set-FMC Paed/Baby R (F00001063)

Arterial line

Venous line

Important handling aspects …



Pressure line

Connect the pressure transducer protector to the machine ensuring it is straight and secure (do not overtighten!). If the membrane is wet, replace either the bloodline or the pressure line with a new one.

Arterial bubble catcher

For level setting release the cap, raise the level slowly to the filling line. Make sure that the caps are secure and the clamps closed.

Venous bubble catcher (4008)

Rest the shoulder of the chamber on the top of the level detector holder, so the filter of the chamber is 1 cm below the level of the door.
Make sure that the caps are secure and the clamps closed.

Pump segment (4008)

Insert the pump segment with the red colour coding on the left hand side.

SN-pump segment (4008)

Make sure that all air has been removed during the priming of the pump segment.

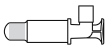
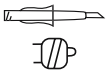
Injection port

Clean the septum by using an alcohol wipe. Hold the injection port by the finger grips underneath the protection shield. Insert the needle directly into the septum (90°).

SN-chamber

Place the chamber into the holder.
Connect the pressure line (see above).
Make sure that the caps are secure and the clamps closed.
Do not invert the chamber.
During priming, the filling level will be set automatically (do not raise the level manually).

Accessories

Type	To be used with	Sterili-sation	Description	Connectors	Units per box	Art.-No.
HF / HDF						
Drainage connector	4008/5008	Beta	ONLINEplus HDF 5008		12	7030031
SafeLine	4008	Beta	ONLINEplus 4008, pump segment 6.4 mm		100	F00001195
Tubing system FS 130	4008	ETO	Standard HDF, Pump segment 4.4 mm		40	5046301
Infusion sets						
Frekaflex infusion set	4008	ETO	Infusion set Luer-Lock male/ Luer-Lock male with roller clamp		150	2889011
Infusion set	4008	ETO	Infusion set with vented spike, Luer-Lock male and drip chamber		150	5016371
Transfer set	4008	ETO	Infusion set Luer-Lock male / Luer-Lock male		150	5016391
Waste bags						
Waste bag 2,000 ml	4008	ETO	Rinsing of extracorporeal circuit		100	5015091
Transducer protectors						
Transducer protector	4008/5008	ETO	Luer-Lock male/female		100	5015911
Pressure line 30 cm	4008/5008	ETO	Complete pressure line 30 cm, Luer-Lock male/female		100	5014631
Pressure line 60 cm	4008/5008	ETO	Complete pressure line 60 cm, Luer-Lock male/female		200	5019151
Various accessories						
Heparin syringe 30 ml	5008	ETO	Luer-Lock male, separate closure cap, latex-free plug		100	5030321
Heparin syringe 20 ml	4008/5008	ETO	Luer-Lock male, separate closure cap, latex-free plug		120	F0000125*
SN-adapter Luer-Lock	4008/5008	ETO	Y-adapter, 2 x Luer-Lock female, 1 x Luer-Lock male		100	5027851

*coming soon

Type	To be used with	Sterili-sation	Description	Connectors	Units per box	Art.-No.
Scissor clamp	4008/5008	---	For clamping tubes		5	2845241
Recirculation connector	4008/5008	Beta	For short-circuit of A/V-set, Luer-Lock female / Luer-Lock female		100	5015971
Adapter Luer-Lock female / Luer-Lock female	4008/5008	ETO	For short circuit of blood tubings (A/V-sets)		100	5014801
Adapter Luer-Lock male / Luer-Lock male	4008/5008	ETO	For short circuit of fistula needles		100	5014771
Spike	4008/5008	Beta	Spike/Luer-Lock female		100	5015921
Prolongation 75 cm	4008/5008	Beta	Luer-Lock male/female		100	7030011
Dialyser exchange set	4008/5008	ETO	Tubing system for exchange of dialyser during treatment, short-circuit AV-set		75	5018001
Mounts						
Universal mount, single	4008	---	Mount for arterial bubble trap for 4008 E/H		1	5000271
Universal mount, double	4008	---	Mount for arterial bubble trap and SN expansion chamber, for 2008 and 4008 B/S		1	5000261
HD Connection-Disconnection Set						
proHD Set S		ETO	Drape, nitrile gloves, non-woven gauzes, adhesive tapes, haemostatic plasters		170	F00000836
proHD Set M		ETO	Drape, nitrile gloves, non-woven gauzes, adhesive tapes, haemostatic plasters		170	F00000837
proHD Set L		ETO	Drape, nitrile gloves, non-woven gauzes, adhesive tapes, haemostatic plasters		170	F00000838

The letters S, M and L in the name of the proHD Sets indicate the glove size. For more detailed information see brochure F00001561

Fresenius Medical Care

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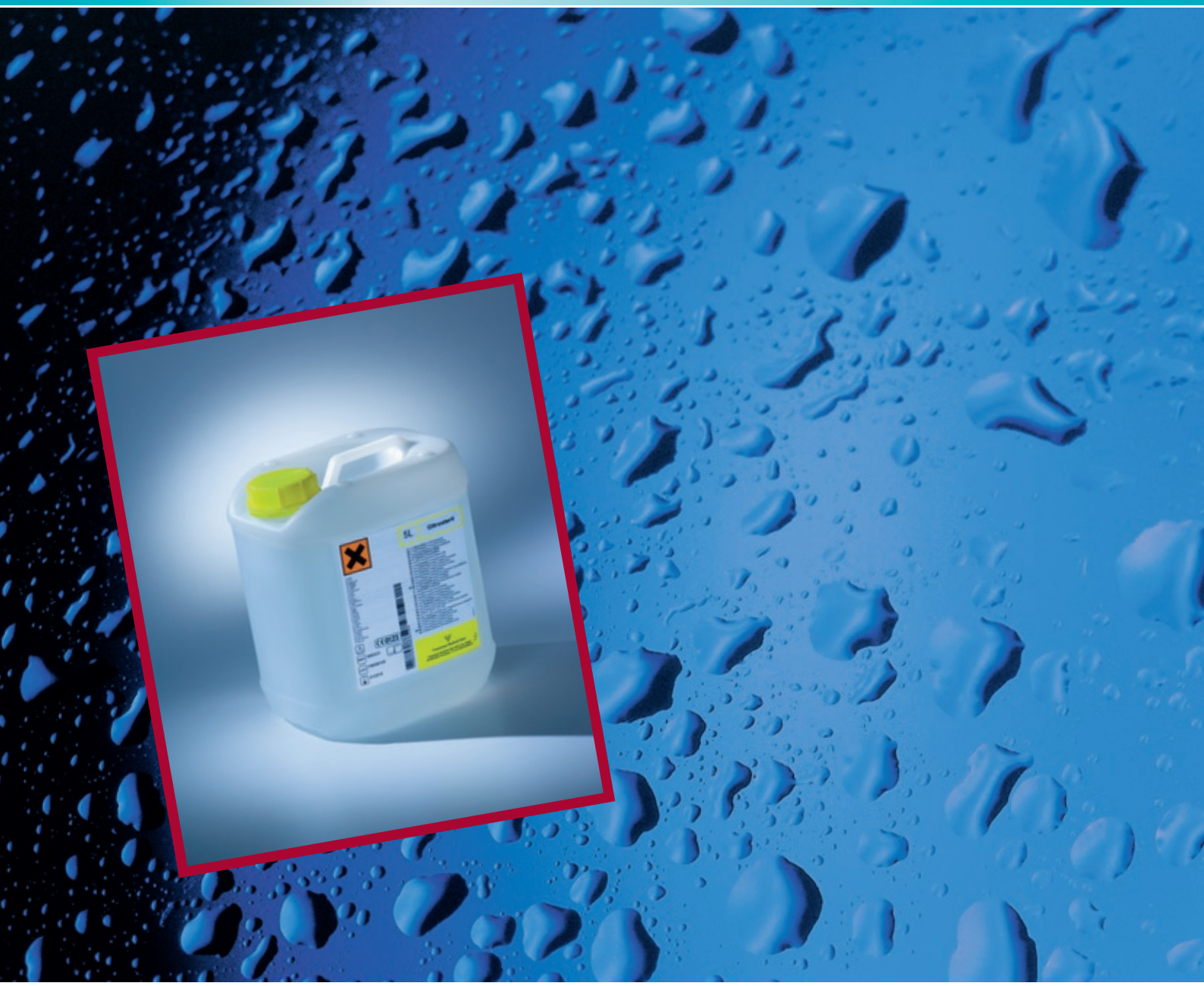
F00001752 GB (1 A&O 09.10)

Haemodialysis

Citrosteril

For Heat Disinfection of Haemodialysis Machines with Recirculation



Fresenius Medical Care

Citrosteril

For Heat Disinfection of Haemodialysis Machines with Recirculation

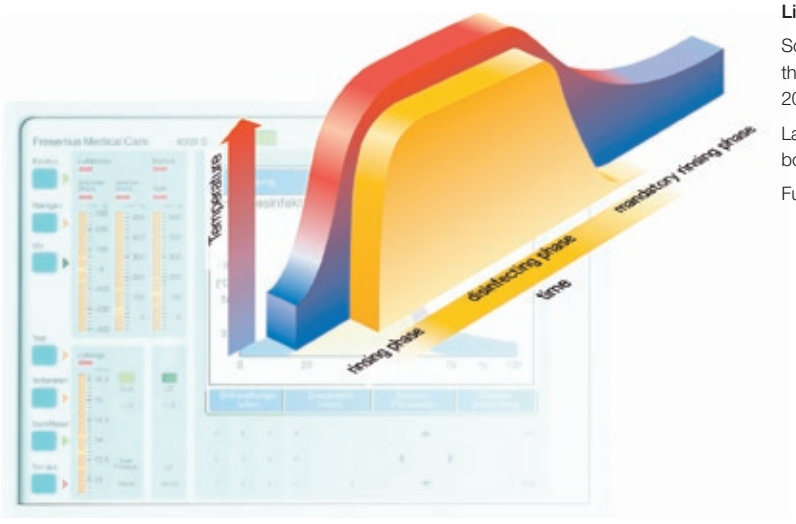
Citrosteril – for thermochemical disinfection in haemodialysis machines, e.g. haemodialysis system 4008 or therapy system 5008.

- pH value 1.7 to 2.0
- dissolution of blood residues
- excellent removal of $CaCO_3$
- disinfection and decalcification in one process
- active ingredients composed of natural substances
- biodegradable
- odourless
- free from colouring additives

Action

The synergistic effect of its components makes Citrosteril a potent disinfectant solution.

Citrosteril at 84°C has a broad spectrum of microbiocidal activity and works bactericidal, virus inactivating (HBV, HCV, HIV) and fungicidal.



Specifications and order information:

100 g Citrosteril contains:

21 g citric acid 1-hydrate; lactic acid, malic acid

Unit	Language combination	Art. No.
1 × 5 L	multilingual	508 533 1
6 × 2 L	multilingual	508 536 1

Literature:

Solbach W, Universität zu Lübeck: Verification of the sporicidal efficacy of the product Citrosteril at 85°C in the Fresenius 5008 dialysis machine, 20.12.2002

Labor Dr. Merk&Kollegen, Ochsenhausen: Antiviral efficacy of Citrosteril against bovine Parvovirus, 9.9.2005

Further information is available on request.

Fresenius Medical Care

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Гемодиализ

Диализаторы и фильтры

Каталог продукции

Fresenius Medical Care

Содержание

Кардиопротективный гемодиализ

Несмотря на существенное повышение качества и эффективности гемодиализа за последние годы, сердечно-сосудистые заболевания (ССЗ) остаются основной причиной смерти диализных пациентов. На сегодняшний день каждый второй пациент погибает от сердечно-сосудистых осложнений.

Fresenius Medical Care поддерживает усилия мирового сообщества нефрологов в деле снижения риска сердечно-сосудистой заболеваемости и смертности среди пациентов.

Такие инновационные мембраны, как Fresenius Polysulfone® или Helixone®, современные устройства мониторинга – Blood Volume Monitor (монитор объема крови), Blood Temperature Monitor (монитор температуры крови) и Online Clearance Monitoring (OCM®) (монитор отслеживания клиренса), ультрачистая диализная жидкость, получаемая при помощи фильтров DIASAFE®*plus*, и современная система гемодиафильтрации ONLINE помогают снизить выраженность факторов риска ССЗ.

Более того, одной из основных наших задач на ближайшие годы является разработка и внедрение новых инновационных продуктов и методов лечения, которые позволят улучшить прогноз сердечно-сосудистой патологии у диализных пациентов.

Диализные мембраны Fresenius Polysulfone® и Helixone®

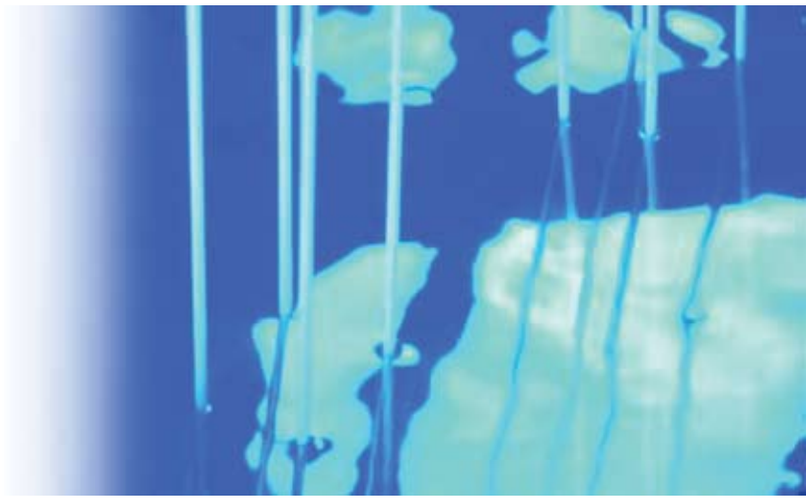
Имея более чем тридцатилетний опыт разработки и производства диализных мембран, Fresenius Medical Care предлагает широкий спектр диализаторов, отвечающих специфике различных видов терапии и индивидуальным потребностям каждого пациента.

Fresenius Polysulfone®

Обычно характеризующийся как “золотой стандарт” для диализных мембран, Fresenius Polysulfone® олицетворяет эффективность и безопасность в гемодиализе в течение трех десятилетий.

Многочисленные научные публикации и миллионы проведенных процедур отражают благоприятный опыт и удовлетворение этой синтетической мембраной среди медицинского персонала и пациентов.

Мембрана Fresenius Polysulfone® представлена в низко- и высокопоточных диализаторах серии F и придает этим диализаторам высокую эффективность, хорошую способность к задержке эндотоксина и исключительную биосовместимость.



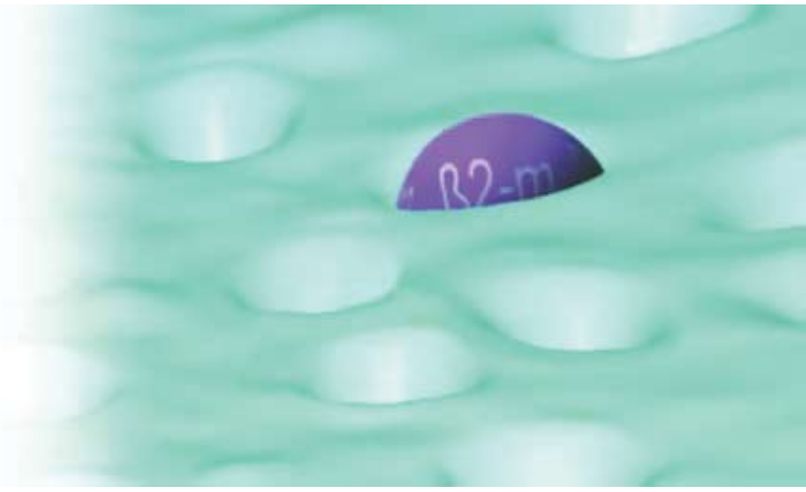
helixone®

Продолжая устанавливать стандарты в области новейших диализных продуктов, Fresenius Medical Care разработала улучшенную, основанную на Fresenius Polysulfone®, диализную мембрану – Helixone® .

При производстве мембраны Helixone® используется новая технология контролируемого на наноуровне вытягивания волокна (Nano Controlled Spinning (NCS™) Technology).

При использовании этой технологии становится возможным создание заданной структуры пор и их распределения по внутреннему слою мембраны в соответствии с областью применения мембраны.

Helixone® – мембрана диализаторов класса FX.



Гемо*диа*фильтры класса FX

INLINE паровая стерилизация

Данная серия гемодиафильтров разрабатывалась прежде всего для высокообъемной гемодиафильтрации (HDF) с объемом замещения более 15 литров за процедуру.

Наряду с современным дизайном корпуса продвинутый вариант мембраны Helixone®, использующейся в этих типах гемодиафильтров, обеспечивает:

- Более эффективное выведение низкомолекулярных веществ, в особенности фосфата
- Улучшенное выведение среднемолекулярных веществ
- Более высокие объемы замещения в ходе гемодиафильтрации (> 15 л за процедуру)

helixone®

Показатели in vitro/технические данные

	FX 600	FX 800	FX 1000
Коэфф. ультрафильтрации (мл/ч x ммHg)	52	63	75
Клиренсы Q_B = 300 мл/мин, Q_D = 500 мл/мин, Q_F = 0 мл/мин			
Мочевина	268	276	278
Креатинин	238	250	262
Фосфат	228	238	248
Витамин B_{12}	165	176	178
Инулин	111	123	126
Клиренсы Q_B = 300 мл/мин, Q_D = 500 мл/мин, Q_F = 75 мл/мин			
Мочевина	284	289	290
Креатинин	262	271	280
Фосфат	254	262	269
Витамин B_{12}	199	209	211
Инулин	150	161	164
Показатели in vitro: T = 37 °C (EN 1283, ISO 8638). Коэффициент ультрафильтрации: человеческая кровь, Hct 32%, содержание белка 6%.			
Эффективная поверхность ($м^2$)	1,5	1,8	2,2
Кровоток (мл/мин)	150–400	200–500	250–600
Толщина стенки / просвет (μм)	35/210	35/210	35/210
Объем заполнения (мл)	97	118	138
Материал мембраны		Helixone®	
Материал корпуса		Полипропилен	
Материал заливки		Полиуретан	
Метод стерилизации		INLINE паровая	
Виды терапии		HDF/HF	
Единиц в коробке	20	20	20
Артикул	**500 813 1**	**500 814 1**	**500 972 1**

Высокопоточные диализаторы класса FX

INLINE паровая стерилизация

Полностью обновленная концепция позволила улучшить характеристики диализаторов класса FX за счет различных технических усовершенствований всех компонентов диализатора, включая саму мембрану Helixone®.

- Улучшенные диффузионные и конвективные клиренсы
- Утонченная гемодинамика
- Повышенная безопасность пациента
- Упрощенная промывка
- Уменьшение количества отходов

helixone®

Показатели in vitro/технические данные

	FX 40	FX 50	FX 60	FX 80	FX 100
Коэфф. ультрафильтрации (мл/ч x ммHg)	20	33	46	59	73
Клиренсы Q_B = 200 мл/мин					
Мочевина	170	189	193	197	–*
Креатинин	144	170	182	189	–
Фосфат	138	165	177	185	–
Витамин B_{12}	84	115	135	148	–
Инулин	54	76	95	112	–
Клиренсы Q_B = 300 мл/мин					
Мочевина	–*	250	261	276	278
Креатинин	–	210	230	250	261
Фосфат	–	201	220	239	248
Витамин B_{12}	–	130	155	175	192
Инулин	–	81	104	125	142
Показатели in vitro: Q_D = 500 мл/мин, Q_F = 0 мл/мин, T = 37 °C (EN 1283. ISO 8637). Коэффициент ультрафильтрации: человеческая кровь, Hct 32%, содержание белка 6%.					
Эффективная поверхность ($м^2$)	0,6	1,0	1,4	1,8	2,2
Кровоток (мл/мин)	50–200	100–300	150–400	200–500	250–600
Толщина стенки / просвет (μм)	35/185	35/185	35/185	35/185	35/185
Объем заполнения (мл)	32	53	74	95	116
Материал мембраны			Helixone®		
Материал корпуса			Полипропилен		
Материал заливки			Полиуретан		
Метод стерилизации			INLINE паровая		
Виды терапии	HD	HD	HD	HD/HDF/HF	HD/HDF/HF
Единиц в коробке	20	20	20	20	20
Артикул	**500 884 1**	**500 885 1**	**500 886 1**	**500 888 1**	**500 890 1**

* соответственно рекомендованному кровотоку

Низкопоточные диализаторы класса FX

INLINE паровая стерилизация

Изменение мембраны Helixone® на уровне наношкалы для обеспечения элиминации низкомолекулярных веществ привело к появлению нового поколения низкопоточных диализаторов с оптимальными диффузионными клиренсами.

Новая низкопоточная мембрана Helixone® обладает следующими преимуществами:

- Увеличенный до 1,8 нм размер пор
- Более равномерное распределение пор
- Повышенная эффективность на единицу площади поверхности

Показатели in vitro/технические данные

	FX 5	FX 8	FX 10
Коэфф. ультрафильтрации (мл/ч x ммHg)	8	12	14
Клиренсы Q_B = 200 мл/мин			
Мочевина	180	191	193
Креатинин	165	178	181
Фосфат	141	160	170
Витамин B_{12}	88	107	121
Клиренсы Q_B = 300 мл/мин			
Мочевина	228	254	261
Креатинин	200	225	231
Фосфат	164	194	210
Витамин B_{12}	94	120	138
Показатели in vitro: Q_D = 500 мл/мин, Q_F = 0 мл/мин, T = 37 °C (EN 1283. ISO 8637). Коэффициент ультрафильтрации: человеческая кровь, Hct 32%, содержание белка 6%.			
Эффективная поверхность ($м^2$)	1,0	1,4	1,8
Кровоток (мл/мин)	100–300	150–400	200–500
Толщина стенки / просвет (μм)	35/185	35/185	35/185
Объем заполнения (мл)	54	74	95
Материал мембраны		Helixone®	
Материал корпуса		Полипропилен	
Материал заливки		Полиуретан	
Метод стерилизации		INLINE паровая	
Виды терапии		HD	
Единиц в коробке	20	20	20
Артикул	**500 483 1**	**500 473 1**	**500 474 1**

Fresenius Polysulfone®
Высокопоточные диализаторы и гемо*диа*фильтры

INLINE паровая стерилизация

В высокопоточных стерилизованных паром диализаторах Fresenius Polysulfone® сочетаются преимущества гемосовместимой мембраны и безопасного метода стерилизации.

- Исключительная гемосовместимость
- Оптимальные характеристики
- Широкий выбор диализаторов (0,7–2,4 м^2)
- Применимость для HD, HF, HDF
- Эффективное выведение β_2-микроглобулина
- Высокая задерживающая способность по отношению к эндотоксину

- Уникальная INLINE паровая стерилизация – отсутствие остаточных количеств стеирлизующего агента или его производных
- Отсутствие потребности в промывке перед процедурой (экономия времени)

Fresenius Polysulfone®

Показатели in vitro/технические данные

	F40S	F50S	F60S	F70S	HF80S	HdF100S
Коэфф. ультрафильтрации (мл/ч x ммHg)	20	30	40	50	55	60
Клиренсы Q_B = 200 мл/мин						
Мочевина	165	178	185	190	192	–*
Креатинин	140	160	172	177	180	–
Фосфат	138	158	170	174	177	–
Витамин B_{12}	80	100	118	127	135	–
Инулин	54	75	88	98	110	–
Клиренсы Q_B = 300 мл/мин						
Мочевина	–*	225	242	245	248	271
Креатинин	–	195	215	220	225	252
Фосфат	–	190	210	216	220	240
Витамин B_{12}	–	112	134	145	155	190
Инулин	–	83	97	109	120	145
Показатели in vitro: Q_D = 500 мл/мин, Q_F = 0 мл/мин, T = 37 °C (EN 1283. ISO 8637). Коэффициент ультрафильтрации: человеческая кровь, Hct 32%, содержание белка 6%. Использовать только на аппаратах с контролем ультрафильтрации!						
Эффективная поверхность (м^2)	0,7	1,0	1,3	1,6	1,8	2,4
Кровоток (мл/мин)	50–200	100–300	150–400	200–500	200–600	250–600
Толщина стенки / просвет (μм)	40/200	40/200	40/200	40/200	40/200	35/185
Объем заполнения (мл)	42	63	82	98	110	138
Материал мембраны	Fresenius Polysulfone®					
Материал корпуса	Поликарбонат					
Материал заливки	Полиуретан					
Метод стерилизации	INLINE паровая					
Виды терапии	HD	HD	HD/HDF	HD/HDF	HDF/HF	HDF/HF
Единиц в коробке	12	12	12	12	12	12
Артикул	**500 714 1**	**500 815 1**	**500 716 1**	**500 717 1**	**500 718 1**	**500 719 1**

* соответственно рекомендованному кровотоку

Fresenius Polysulfone®
Низкопоточные диализаторы (HPS)

INLINE паровая стерилизация

Высокая эффективность для диализаторов низкопоточного ранга в сочетании с преимуществами паровой стерилизации.

- Высокие клиренсы за счет нового дизайна
- Микроундуляция гарантирует эффективный поток диализата
- Исключительная гемосовместимость
- Широкий выбор диализаторов (0,8–2,2 м^2)
- Высокая способность к ретенции эндотоксина
- Уникальная INLINE паровая стерилизация – отсутствие остаточных количеств стерилизующего агента или его производных

Fresenius Polysulfone®

Показатели in vitro/технические данные

	F4HPS	F5HPS	F6HPS	F7HPS	F8HPS	F10HPS
Коэфф. ультрафильтрации (мл/ч x ммHg)	8	10	13	16	18	21
Клиренсы Q_B = 200 мл/мин						
Мочевина	170	179	186	188	190	–*
Креатинин	149	162	173	175	177	–
Фосфат	123	139	148	155	159	–
Витамин B_{12}	75	84	92	102	106	–
Клиренсы Q_B = 300 мл/мин						
Мочевина	–*	227	243	247	252	259
Креатинин	–	196	215	220	224	230
Фосфат	–	162	175	186	193	208
Витамин B_{12}	–	91	100	113	118	131
Показатели in vitro: Q_D = 500 мл/мин, Q_F = 0 мл/мин, T = 37 °C (EN 1283. ISO 8637). Коэффициент ультрафильтрации: человеческая кровь, Hct 32%, содержание белка 6%. Использовать только на аппаратах с контролем ультрафильтрации!						
Эффективная поверхность (м^2)	0,8	1,0	1,3	1,6	1,8	2,2
Кровоток (мл/мин)	50–200	100–300	150–400	200–500	250–600	300–600
Толщина стенки / просвет (μм)	40/200	40/200	40/200	40/200	40/200	40/200
Объем заполнения (мл)	51	63	78	96	113	132
Материал мембраны	Fresenius Polysulfone®					
Материал корпуса	Поликарбонат					
Материал заливки	Полиуретан					
Метод стерилизации	INLINE паровая					
Виды терапии	HD					
Единиц в коробке	12	12	12	12	12	12
Артикул	**500 704 1**	**500 705 1**	**500 706 1**	**500 707 1**	**500 708 1**	**500 720 1**

* соответственно рекомендованному кровотоку

Fresenius Polysulfone®
Низкопоточные диализаторы

Стерилизация окисью этилена (ETO)

Широкий выбор продукции позволяет обеспечить индивидуальные потребности пациента.

- Исключительная гемосовместимость
- Широкий выбор диализаторов (0,4–1,8 м^2)
- Высокая задерживающая способность по отношению к эндотоксину

Fresenius Polysulfone®

Показатели in vitro/технические данные

	F3	F4	F5	F6	F7	F8
Коэфф. ультрафильтрации (мл/ч x ммHg)	1,7	2,8	4,0	5,5	6,4	7,5
Клиренсы Q_B = 200 мл/мин						
Мочевина	125	155	170	180	184	186
Креатинин	95	128	149	164	169	172
Фосфат	50	78	103	123	132	138
Витамин B_{12}	20	32	45	60	68	76
Клиренсы Q_B = 300 мл/мин						
Мочевина		–*	206	222	236	240
Креатинин		–	175	194	210	216
Фосфат		–	115	145	155	165
Витамин B_{12}		–	47	62	72	82
Показатели in vitro: Q_D = 500 мл/мин, Q_F = 0 мл/мин, T = 37 °C (EN 1283. ISO 8637). Коэффициент ультрафильтрации: человеческая кровь, Hct 32%, содержание белка 6%.						
Эффективная поверхность (м^2)	0,4	0,7	1,0	1,3	1,6	1,8
Кровоток (мл/мин)	50–200	50–200	100–300	150–400	200–500	250–600
Толщина стенки / просвет (µм)	40/200	40/200	40/200	40/200	40/200	40/200
Объем заполнения (мл)	28	42	63	82	98	110
Материал мембраны	Fresenius Polysulfone®					
Материал корпуса	Поликарбонат					
Материал заливки	Полиуретан					
Метод стерилизации	ETO					
Виды терапии	HD					
Единиц в коробке	12	12	12	12	12	12
Артикул	**500 165 1**	**500 161 1**	**500 162 1**	**500 145 1**	**500 163 1**	**500 164 1**

* соответственно рекомендованному кровотоку

Педиатрические фильтры FX paed, FX 40

INLINE паровая стерилизация

Относящиеся к классу FX диализаторы FX paed и FX 40 удовлетворяют высоким требованиям, предъявляемым к изделиям для педиатрического диализа.

- Современная технология корпуса и мембраны
- Небольшие площадь поверхности мембраны и объем заполнения
- Исключение перегиба магистралей благодаря латеральному расположению портов крови
- Быстрая и простая подготовка
- Высокопоточная диализная мембрана с высоким уровнем выведения средних молекул

Показатели in vitro/технические данные

	FX paed	FX 40
Коэфф. ультрафильтрации (мл/ч x ммHg)	7	20
Клиренсы Q_B = 100 мл/мин, Q_D = 300 мл/мин		
Мочевина	76	–
Креатинин	64	–
Фосфат	57	–
Витамин B_{12}	34	–
Инулин	20	–
Клиренсы Q_B = 200 мл/мин, Q_D = 500 мл/мин		
Мочевина	–	170
Креатинин	–	144
Фосфат	–	138
Витамин B_{12}	–	84
Инулин	–	54
Показатели in vitro: Q_F = 0 мл/мин, T = 37 °C (EN 1283. ISO 8637). Коэффициент ультрафильтрации: человеческая кровь, Hct 32%, содержание белка 6%.		
Эффективная поверхность ($м^2$)	0,2	0,6
Кровоток (мл/мин)	20–100	50–200
Толщина стенки / просвет (μм)	35/220	35/185
Объем заполнения (мл)	18	32
Материал мембраны	Helixone®	
Материал корпуса	Полипропилен	
Материал заливки	Полиуретан	
Метод стерилизации	INLINE паровая	
Виды терапии	HD	
Единиц в коробке	20	20
Артикул	**500 822 1**	**500 884 1**

Фильтр диализной жидкости DIASAFE®*plus*

Фильтр диализной жидкости DIASAFE®*plus* представляет собой усовершенствованную модель хорошо зарекомендовавшего себя фильтра DIASAFE® Fresenius Medical Care.

- Приготовление сверхчистой диализной жидкости (эндотоксины < 0,03 МЕ/мл, микробная контаминация < 0,1 КОЕ/мл)
- ONLINE приготовление замещающей жидкости для HF и HDF
- Микробиологическая безопасность, обеспеченная двойной фильтрацией замещающей жидкости через фильтры DIASAFE®*plus*
- Проверка функциональности фильтров в автоматических тестах
- Высокая устойчивость к дезинфицирующим агентам, таким, как Puristeril® 340 и Diasteril®, Citrosteril®, Sporotal® 100

Fresenius Polysulfone®

Технические данные

	DIASAFE®*plus*
Материал мембраны	Fresenius Polysulfone®
Эффективная поверхность (м²)	2,2
Материал корпуса	Полипропилен
Материал заливки	Полиуретан
Уплотнители	Силикон
Скорость фильтрации	5 мл/мин ммHg (3,75 л/мин bar; макс. 2 bar)
Время службы	Стандартный HD: макс. 12 недель ONLINE HF/HDF, ONLINE заполнение/промывка: макс. 12 недель или 100 процедур
Дезинфекция	Puristeril® 340 (надуксусная кислота); Diasteril® (гидроксиуксусная кислота) или Citrosteril® (лимонная кислота); Sporotal® 100 (гипохлорит натрия) макс. 11 раз
Единиц в коробке	12
Артикул	500 820 1

Принадлежности	Safe line™	Тест pH на остаточный (Puristeril® 340)	Индикаторный тест (Diasteril®)
Единиц в коробке	100	100	100
Артикул	504 580 1	629 916 1	628 816 1

Fresenius Medical Care

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Haemodialysis

DIASAFE®*plus*

Fresenius Polysulfone® Dialysis Fluid Filter

Fresenius Medical Care

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 world-wide in reducing their patients' risks for cardiovascular morbidity and mortality.

Innovative membranes like Fresenius Polysulfone® and 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.

The Dialysis Fluid Filter DIASAFE®*plus*

The quality and purity of the dialysis fluid are of major concern in modern-day renal replacement therapies, as large volumes of dialysis fluid come into contact with the patient's bloodstream during each treatment.

Bacterial endotoxins present in contaminated dialysis fluid may elicit undesirable acute reactions and influence the long-term outcome of patients on chronic haemodialysis.

Although water used for the production of dialysis fluid is treated by a series of purification steps, it still may not meet the stringent requirements on bacterial contamination levels laid down by various regulatory bodies.

By the application of special filters that are highly efficient in retaining bacterial contaminations, the required purity grades of dialysis fluid can be achieved easily.

The DIASAFE®*plus* filter, located at the end of the water treatment chain, ensures the safe production of ultrapure dialysis fluid. This is attributed to the excellent endotoxin-retention capabilities of its Fresenius Polysulfone® fibres.

Fresenius Polysulfone®

DIASAFE®*plus* is an integral part of contemporary dialysis machines. Only three handling steps are necessary to install or exchange DIASAFE®*plus* (Fig. 1):

- Open the locks of the filter holder
- Slide DIASAFE®*plus* filter into the guide grooves
- Close the locks – DIASAFE®*plus* is ready to use

Fig. 1: DIASAFE®plus can be connected with 3 rapid handling steps only. The DIAFIX™ lock system ensures a safe and hygienic connection.

The use of DIASAFE®*plus* is a key step towards Good Dialysis Practice.

Dialysis Fluid Purity

Dialysis fluids may contain microbial impurities such as endotoxins derived from bacterial fragments. Endotoxins are known to cause acute adverse reactions and promote long-term complications in haemodialysis patients [1, 2].

The toxic properties of endotoxins can be ascribed mainly to their lipid A component, which is not exposed by intact bacteria, but released only during growth or lysis of gram-negative bacteria [3, 4].

Endotoxin fragments may have molecular weights well below 2000 Da. These fragments are small enough to pass across both, low- and high-flux haemodialysis membranes into the patient's blood-stream (Fig. 2).

With respect to endotoxin permeability, significant differences exist between the various types of dialysis membranes, thereby offering variable degrees of safety during haemodialysis [3].

In order to avoid endotoxin-related complications during routine haemodialysis, the European Best Practice Guidelines for Haemodialysis (EBPG) [5] advise the usage of water having a purity level in compliance with the recommendations of the European Pharmacopoeia. However, the usage of ultrapure water for conventional high-flux dialysis is strongly recommended by the EBPG (Table 1).

Ultrapure water or dialysis fluid can easily be achieved through the application of special dialysis fluid filters – such as DIASAFE®*plus*.

	Pure water	Ultrapure water
Microbial contaminations (CFU/mL)	≤ 100	< 0.1
Bacterial endotoxins (IU/mL)	< 0.25	< 0.03

Table 1: The different purity levels of pure and ultrapure water according to the EBPG.

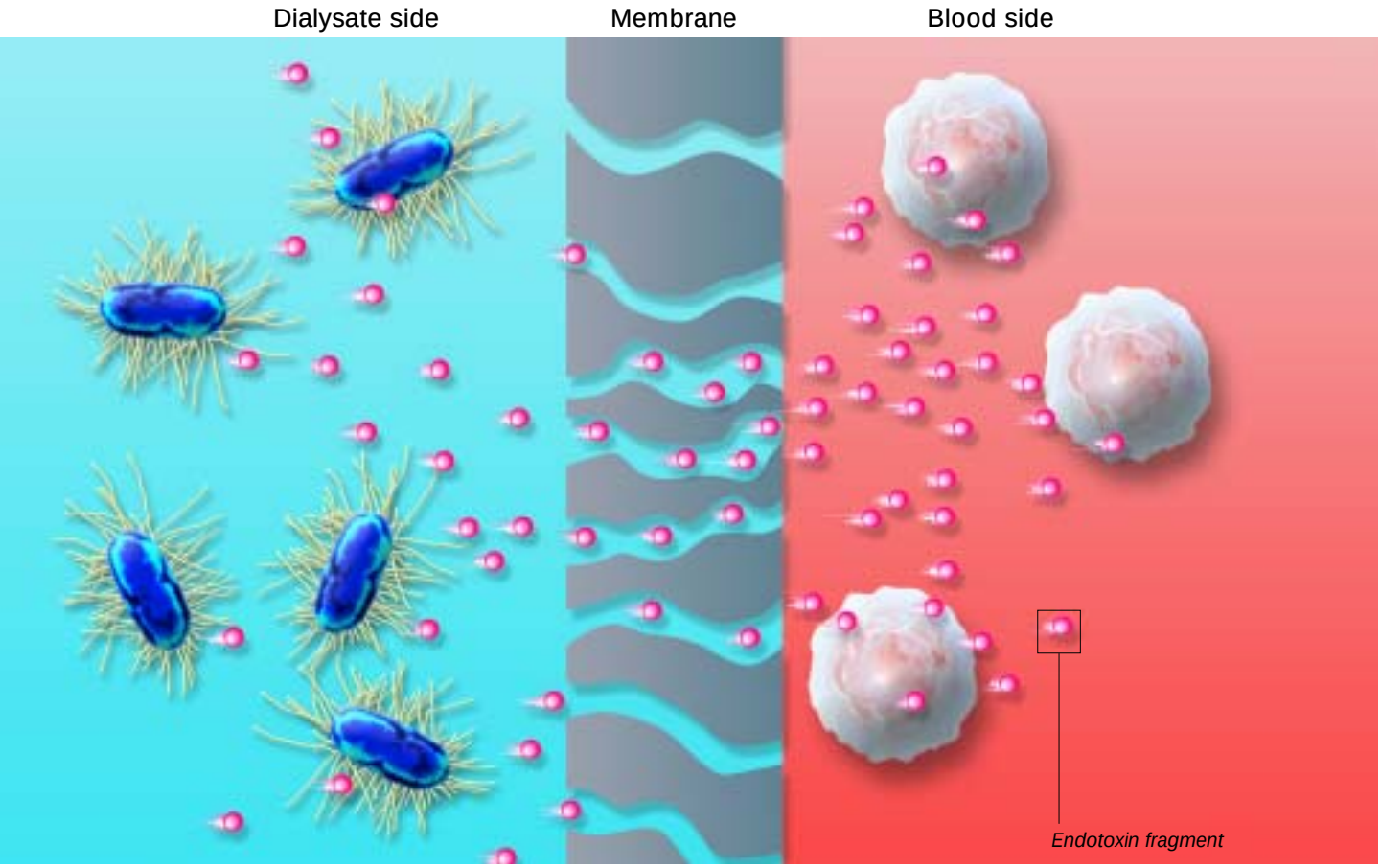

Fig. 2: Fragments of bacterial endotoxins enter the patient's blood-stream and activate leucocytes, thereby leading to acute and chronic complications in haemodialysis patients.

Clinical Advantages of Using Ultrapure Dialysis Fluid

Endotoxins can activate immune-competent cells in a number of ways, thereby contributing to chronic inflammation that is present in all haemodialysis patients [6] (Fig. 3). Recent evidence demonstrates that chronic inflammation is a major risk-factor for progressive atherosclerotic cardiovascular disease (CVD) [7].

Besides the application of haemodialysis membranes with a high biocompatibility, the usage of ultrapure dialysis fluid, in particular, has been shown to reduce markers of chronic inflammation in haemodialysis patients [8]. Therefore, it is suggestive that ultrapure dialysis fluid has a beneficial effect on inflammatory diseases such as atherosclerotic CVD [9].

Moreover, oxidative stress – a situation, in which the normal balance between production of reactive oxygen species (ROS) and antioxidant activity is tilted in favour of ROS – is increased by several treatment-related stimuli, including bacterial endotoxins derived from the dialysis fluid [10, 11].

As oxidative stress is associated with the progression of malnutrition, anaemia and inflammatory diseases such as atherosclerosis, it appears desirable to reduce dialysis-induced oxidative mechanisms, e. g. through the usage of biocompatible membranes and ultrapure dialysis fluid [10, 11].

The importance of ultrapure dialysis fluid in routine haemodialysis treatments is emphasized by the finding that endotoxins act in synergy with advanced glycation end-products (AGE), which enhance inflammation and oxidative stress [12]. Furthermore, the use of ultrapure dialysis fluid has been shown to reduce the plasma levels of the AGE compound pentosidine [13].

Finally, ultrapure dialysis fluid has also been shown to improve iron utilization and the response to erythropoietin; thus, ultrapure dialysis fluid could be beneficial for anaemia treatment allowing for a reduction in erythropoietin dosage, while maintaining optimal haemoglobin levels [14, 15].

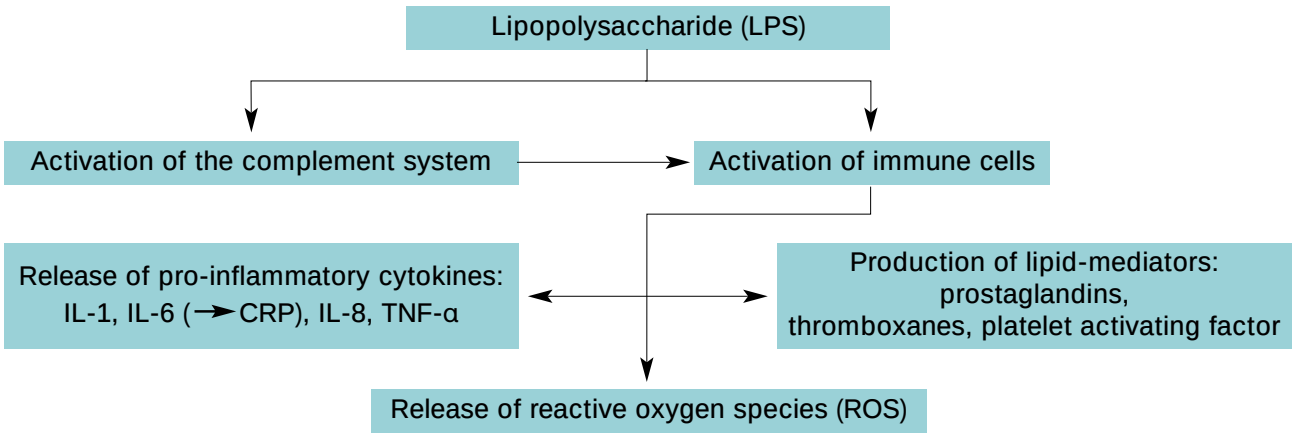

Fig. 3: Endotoxins (LPS) stimulate the release of pro-inflammatory cytokines, reactive oxygen species and lipid-mediators from immune-competent cells.

DIASAFE®*plus* in the ONLINE*plus*™ System

Ultrapure dialysis fluid prepared with the DIASAFE®*plus* dialysis fluid filter, together with haemodialysers containing endotoxin-retaining membranes (Fresenius Polysulfone® or Helixone®) are the main building blocks for a high-quality haemodialysis treatment.

The ONLINE*plus*™ system takes the quality standards of convective treatment modalities as haemodiafiltration/haemofiltration (HDF/HF) one step further: using two DIASAFE®*plus* dialysis fluid filters in series, an extremely high microbiological safety is achieved by double filtration of the substitution fluids used in ONLINE HDF/HF therapies [16].

Besides improving hygiene and safety of convective therapy modalities, the ONLINE*plus*™ option also offers additional treatment features and adds to ease of handling.

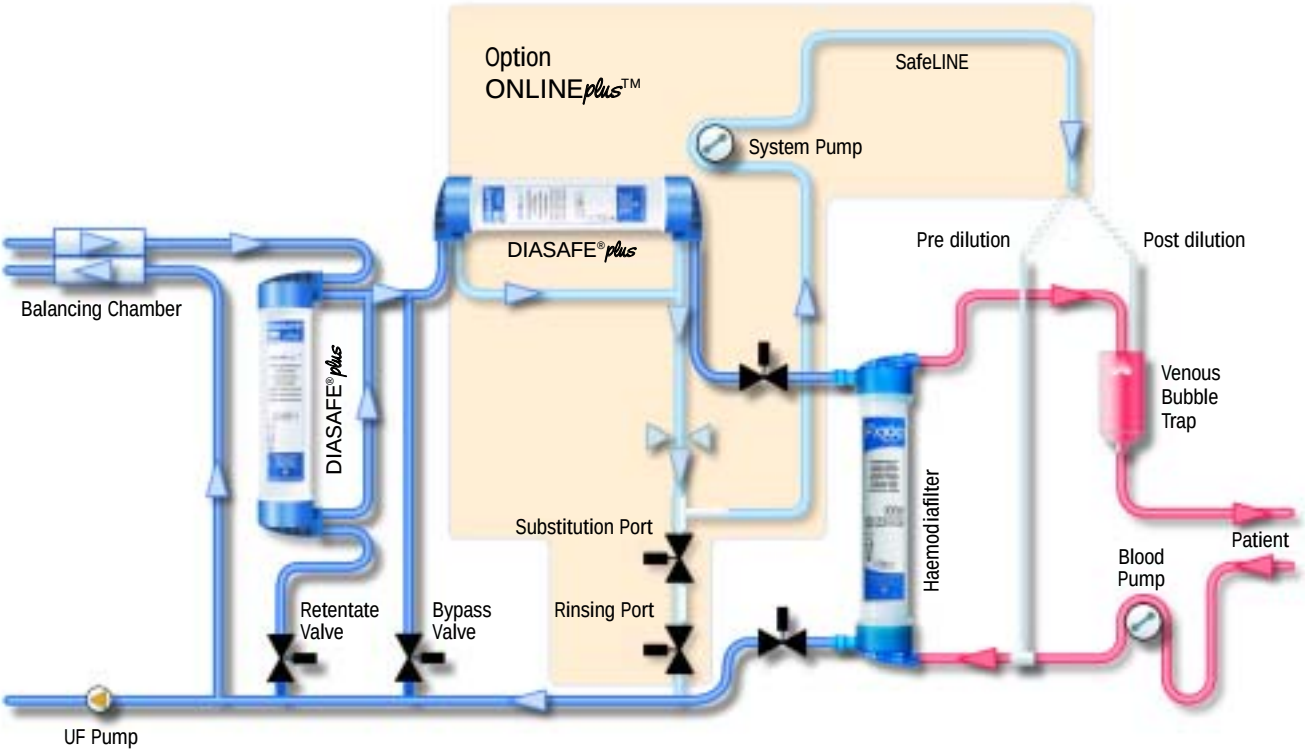

Fig. 4: Schematic flow chart of ONLINE haemodiafiltration with the ONLINEplus™ system

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Technical Data

Membrane material	Fresenius Polysulfone®
Effective Surface (m^2)	2.2
Weight (g)	170
Housing material	Polypropylene
Potting material	Polyurethane
Sealings	Silicone
Connection to machine	DIAFIX™ Lock System
Filtration rate	5 mL/min mm HG (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 or Puristeril® *plus* (peracetic acid) Diasteril® (hydroxyacetic acid) or Citrosteril® (citric acid) Sporotal® 100 (sodium hypochlorite) max. 11 times
Article number	500 820 1

732 167 1/8 GB (2 g/h/b 02.05)

Fresenius Medical Care

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Haemodialysis

Fistula Needles

Product Range

FRESENIUS MEDICAL CARE

Benefits of Fresenius Medical Care Fistula Needles

Fistula needles are the crucial link between the patient and the dialysis machine, requiring quality, safety and comfort – for patient and user.

Biocompatibility

- All Fresenius Medical Care needles are dry-siliconised for easier, smoother puncturing and to reduce blood-material interactions.

Optimised geometry and flow

- Vessel-trauma and pain perception during puncture are minimised due to the optimal ratio of cutting and stretching, the needle's sharp tip and rounded and polished trailing edge.
- Ultra-thin walls of the needles and larger inner lumen diameters permit maximum blood flow rates.
- Lesions or limitations in blood flow are reduced as the special slit-formed back-eye of the arterial and single needle reduces suction of the needle towards the inner wall of the vessel.

Ergonomic wing design

- The convenient rotating wings enable user-friendly handling and adaptation to puncture technique. (Figure 2)
- Textured wings provide a secure grip.

Colour-coded application guidance

- Colour-coded clamps, wings and hubs enable easy differentiation of the needles. (Figures 4 & 5)

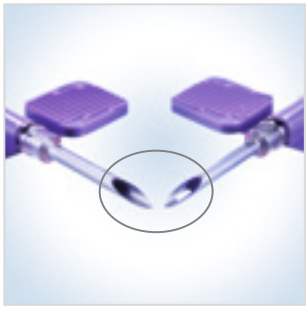

Figure 1: Special slit-formed back-eye of arterial and single needle

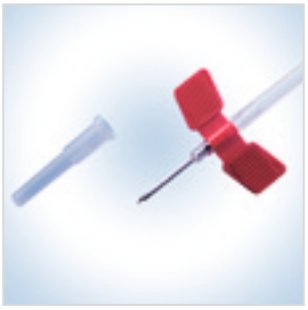

Figure 2: Rotating wing design allows maximum control and easy gripping during cannulation

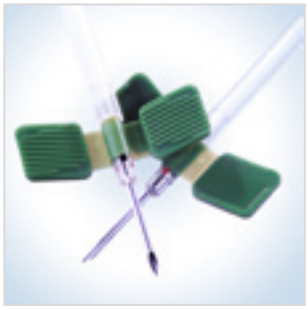

Figure 3: Black and red dots indicate the position of the needle even during the treatment

Figure 4: Colour-coded clamps for arterial and venous needles

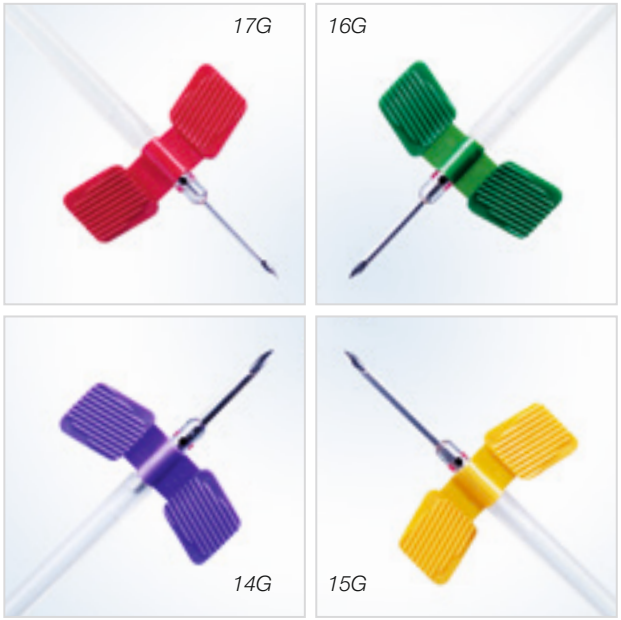

Figure 5: Wing colour indicates needle diameter

Product Range
Gamma-sterilised Fistula Needles

Colour code of wing	Type	Needle (diameter x length)	Tubing length	Art. No.
Standard				
14 G	A401 V401	2.0 x 20 mm	150 mm 150 mm	507 740 1 507 840 1
15 G	A511 V511 A501 V501 A551 V551	1.8 x 15 mm 1.8 x 20 mm 1.8 x 25 mm	150 mm 150 mm 150 mm 150 mm 150 mm 150 mm	507 751 1 507 851 1 507 750 1 507 850 1 507 755 1 507 855 1
16 G	A611 V611 A601 V601 A651 V651	1.6 x 15 mm 1.6 x 20 mm 1.6 x 25 mm	150 mm 150 mm 150 mm 150 mm 150 mm 150 mm	507 761 1 507 861 1 507 760 1 507 860 1 507 765 1 507 865 1
17 G	A711 V711 A701 V701	1.5 x 15 mm 1.5 x 20 mm	150 mm 150 mm 150 mm 150 mm	507 771 1 507 871 1 507 770 1 507 870 1
AV Sets (arterial and venous needle)				
15 G	AV501 AV552	1.8 x 20 mm 1.8 x 25 mm	150 mm 300 mm	507 950 1 507 655 1
16 G	AV601 AV652	1.6 x 20 mm 1.6 x 25 mm	150 mm 300 mm	507 960 1 507 665 1
17 G	AV701 AV752	1.5 x 20 mm 1.5 x 25 mm	150 mm 300 mm	507 970 1 507 676 1
Single needle				
15 G	SN500 SN550	1.8 x 20 mm 1.8 x 25 mm	100 mm 100 mm	508 150 1 508 155 1
16 G	SN600 SN650	1.6 x 20 mm 1.6 x 25 mm	100 mm 100 mm	508 160 1 508 165 1
17 G	SN700	1.5 x 20 mm	100 mm	508 170 1

All needles are dry-siliconised and equipped with a convenient rotating wing.

Product Range
ETO-sterilised Fistula Needles

Colour code of wing	Type	Needle (diameter x length)	Tubing length	Art. No.
Standard				
14 G	A V A V	2.0 x 25 mm	150 mm 150 mm 300 mm 300 mm	508244 1 508257 1 508249 1 508262 1
15 G	A V A V	1.8 x 25 mm	150 mm 150 mm 300 mm 300 mm	508862 1 508863 1 508250 1 508263 1
16 G	A V A V	1.6 x 25 mm	150 mm 150 mm 300 mm 300 mm	508864 1 508865 1 508251 1 508264 1
17 G	A V A V	1.5 x 25 mm	150 mm 150 mm 300 mm 300 mm	508866 1 508867 1 508252 1 508265 1
Single needle				
15 G	SN	1.8 x 20 mm	100 mm	508293 1
16 G	SN	1.6 x 20 mm	100 mm	508294 1

All needles are dry-siliconised and equipped with a convenient rotating wing.

A: arterial needle
V: venous needle
SN: single needle

Importance of optimal needle size

In haemodialysis, solute clearance depends, among other factors, upon the effective blood flow (Q_B) passing through the dialyser. A high extracorporeal Q_B results in high dialysis efficacy Kt/V.

Particularly in HighVolume**HDF**® (postdilution haemodiafiltration) a high blood flow is important to obtain adequate substitution volumes and subsequently a high middle molecule clearance.

Prerequisite for an ideal Q_B is an adequately sized needle. The use of the needle sizes shown opposite is recommended in order to obtain the indicated blood flow rates.

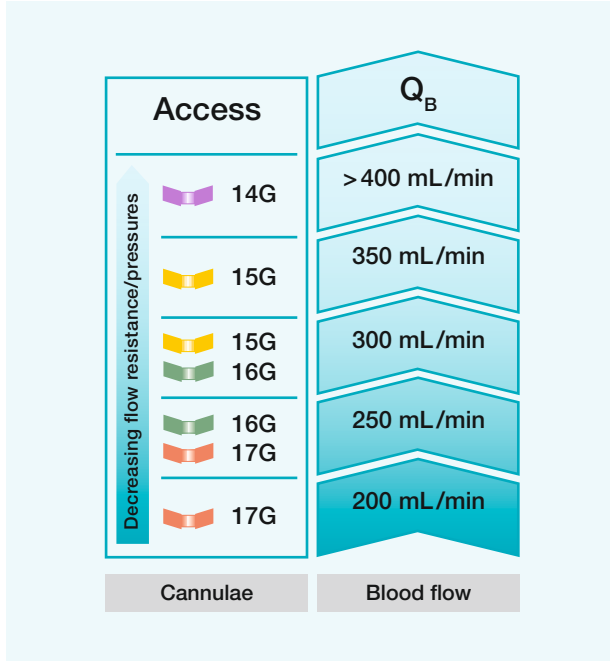

Figure 6: Recommended size of fistula needle in relation to the desired blood flow rate

The larger the inner diameter of the needle, the higher the blood flow is at constant pressure.

For example, with a maximum arterial pressure of –200 mmHg, a bigger needle diameter facilitates a significantly higher Q_B.

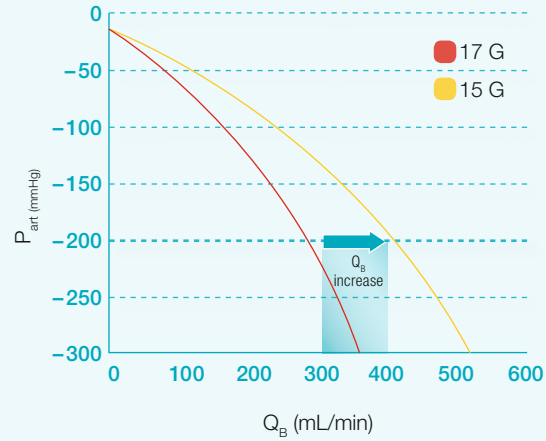

Figure 7: Selection of needle size

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FX CorDiax

Capillary High-Flux Dialysers

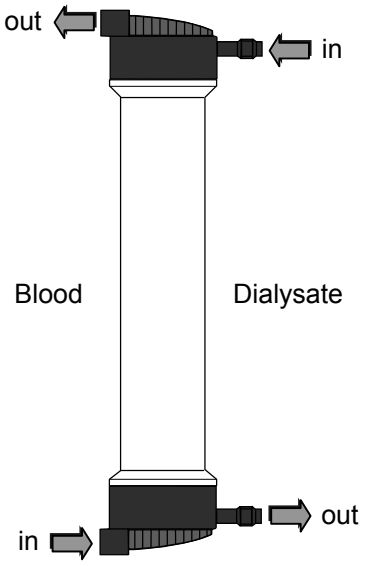
CE 0123

FX CorDiax		40	50		60			80			100			120		
Art.-No.		F00001588	F00001589		F00001590			F00001591			F00001592			F00002384		
	Q_B [mL/min]	200	200	300	200	300	400	200	300	400	300	400	500	300	400	500
Clearances [mL/min]	Cytochrome C	48	71	76	88	96	100	101	111	117	125	133	137	136	145	150
Q_D = 500 mL/min	Inulin	56	81	88	105	116	122	114	127	135	144	154	161	149	160	166
Q_F = 0	Vitamin B_{12}	96	126	144	149	175	191	158	190	209	207	229	244	213	237	252
	Phosphate	142	173	215	184	237	270	189	248	285	258	299	325	262	305	332
	Creatinine	155	180	229	190	252	290	193	261	303	272	321	352	274	325	357
	Urea	175	191	255	196	271	319	198	280	336	283	341	378	284	343	380
K_0A Urea	mL/min	547	886		1164			1429			1545			1584		
UF-coefficient (at Q_B max)	mL/h/mmHg	21	33		47			64			74			87		
S (sieving coefficient)	Albumin	< 0.001														
	Myoglobin	0.5														
	β_2-Microglobulin	0.9														
Max. TMP	mmHg	600														
V (blood priming volume)	mL	32	53		74			95			116			132		
Δ P (pressure drop blood, Q_B = 300 mL/min)	mmHg	202	121		87			67			55			49		
Max. dialysate flow	mL/min	500	800		1000			1000			1000			1000		
Recommended blood flow range	mL/min	50–200*	100–300*		150 – 400*			200 – 500*			250 – 600*			300 – 600*		
A (effective surface area)	m²	0.6	1.0		1.4			1.8			2.2			2.5		
Membrane		Helixone®*plus*														
Sterilisation method		INLINE steam														

In vitro; acc. to EN 1283, ISO 8637; *in vitro* data are likely to differ from *in vivo* data due to the patient's blood composition and clinical settings.

* For additional information see the section under "WARNINGS" in the Instructions for Use.

Haemodialysis



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Cardioprotective Haemodialysis

FX CorDiax

Designed to Dialyse. Built for Cardioprotection

Cardioprotective Haemodialysis SPOT

FRESENIUS MEDICAL CARE

Protect your Patient

Cardioprotective Haemodialysis

The reduction of risk factors for cardiovascular diseases (CVD) is core to the development of dialysis systems and products at Fresenius Medical Care. Outstanding cardioprotection must be reflected in all levels of product development and application.

Wide-ranging cardioprotection

There have been tremendous improvements in the quality and efficacy of haemodialysis (HD) therapy in recent years. Despite this, cardiovascular diseases (CVD) remain the leading cause of death for patients with end-stage renal disease (ESRD).

Cardioprotective

Services

Over 30 years of experience in dialysis at your service.

- Project Planning and Consulting
- Training and Education
- Technical Services
- Water Quality Service (WQS)
- Medical Information Services

Products

State-of-the-art technologies enable advanced cardioprotective therapies.

- CorDiax product line:
  - 5008 CorDiax and 5008S CorDiax
  - FX CorDiax haemo*dia*filter
  - BCM-Body Composition Monitor
- Classix product line:
  - 4008S classix
  - FX classix dialysers
- Therapy Data Management System (TDMS)
- Online Purification Cascade (OPC)

Moreover, both overall and cardiovascular mortality are markedly greater in ESRD patients than in the general population. This is why we put Cardioprotective Haemodialysis on the SPOT. A comprehensive approach that includes services, products and therapies is needed to achieve the best therapeutic performance – meaning improved clinical outcomes and better quality of life, enhanced control of therapy costs, and simpler, safer handling.

Haemodialysis

Outcomes

Achieving better outcomes with cardioprotective therapies.

- Reduced mortality risk
- Fewer cardiovascular complications
- Optimised use of resources

Therapies

Cardioprotective therapies designed by the world market leader in haemodialysis.

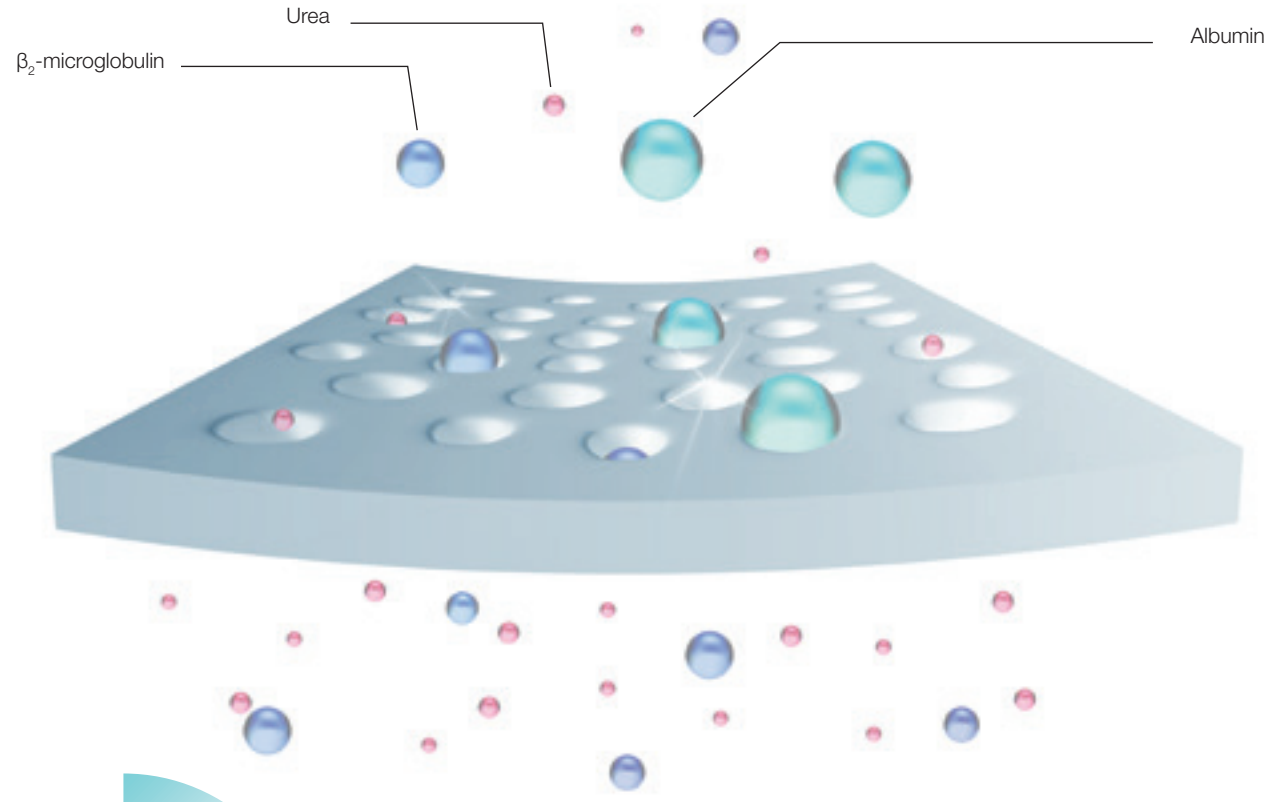
- High-Flux dialysis
- HighVolume**HDF**®
- Advanced Fluid Management

Cardioprotection – at the heart of long-term haemodialysis

The effects of chronic kidney disease (CKD) as well as the effects of dialysis itself can lead to cardiovascular diseases [e.g. atherosclerosis and left ventricular hypertrophy (LVH)], the largest causes of death in haemodialysis patients.[1] Improved middle molecule removal, through enhanced High-Flux membranes for haemodiafiltration, can substantially reduce these risks.[2]

A number of large, multi-centre studies show that the use of High-Flux membranes improves patient survival and quality of life.[3]

Middle molecule removal means the selective filtration of a broad range of uraemic toxins with a molecular weight higher than 500 Dalton (Da). At the same time, the membrane should prevent the loss of substances known to be associated with patient survival, such as serum albumin. This high sieving potential must be accompanied by excellent biocompatibility.
Innovative membranes such as Helixone® provide enhanced filtration, with high sieving of low molecular weight (LMW) and middle molecular weight (MMW) substances as well as volume exchange, while



reducing the induction of inflammatory cascades that are central to many aspects of CVD. State-of-the-art technologies such as Fresenius' Nano Controlled Spinning (NCS™) and INLINE steam sterilisation are the result of continual innovation at Fresenius Medical Care.

Advances in material and production technologies have permitted improvements in the wall structure by opening up the support region of the membrane. The Helixone®*plus* membrane in the new FX CorDiax dialysers improves the clearance of middle molecules while the loss of essential blood components such as albumin is curtailed. The Helixone®*plus* membrane upgrades the FX-class® dialyser into the CorDiax product line, which provides products for superior cardioprotective therapies.

SPOT on:

- CVD are the largest causes of death in dialysis patients.
- High-Flux membranes enhance middle molecule removal and reduce risk factors.
- FX CorDiax for enhanced survival and better outcomes.

The new FX CorDiax

Advances in fibre design allow better removal of uraemic toxins

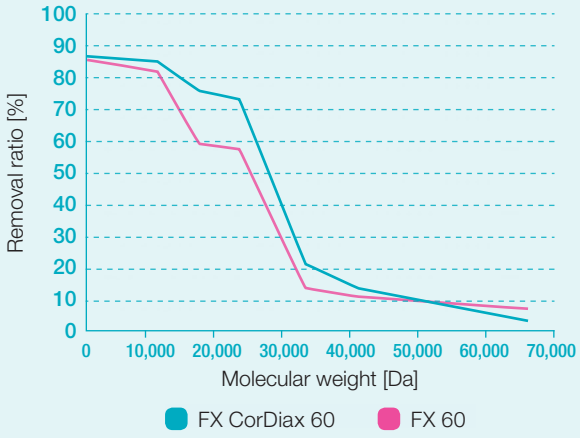
- The fibre support region underneath the inner surface has been “opened up”, optimising porosity and therefore also the convective filtration (“flushing”) of larger uraemic toxins such as β_2-microglobulin (≈ 11,800 Da) or myoglobin (≈ 17,000 Da).
- At the same time the size of the pores of the inner surface area was not increased to avoid flushing of albumin.

FX CorDiax eliminates more middle molecules than FX

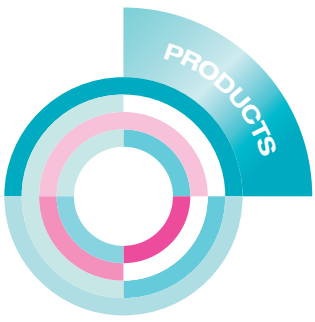
Maduell et al. determined middle molecule removal of FX CorDiax 60 compared to FX 60 in HDF postdilution treatments. Significantly higher removal rates were observed with FX CorDiax for

- Urea (60 Da)
- β_2-microglobulin (11.8 kDa)
- Myoglobin (17.2 kDa)
- Prolactin (22.9 kDa)
- α_1-microglobulin (33 kDa)

The authors concluded that “… treating patients with online haemodiafiltration and FX CorDiax 60 instead of FX 60 dialysers results in significantly increased reduction ratios of middle sized molecules without clinically relevant changes in albumin loss.



Removal ratios of FX 60 and FX CorDiax 60 dialysers in post-dilution HDF[1] (Q_B = 400 mL/min, Q_D = 500 mL/min)

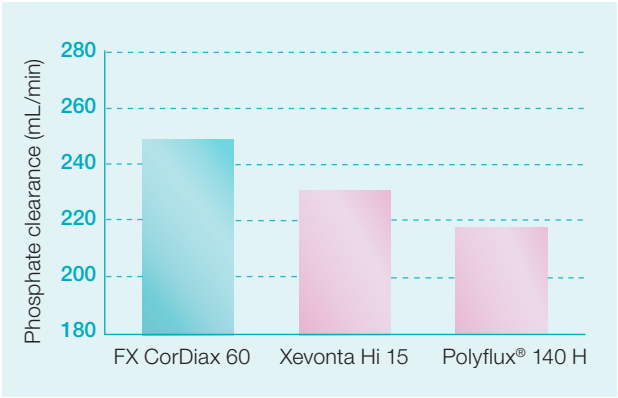


1 Maduell et.al.; ERA-EDTA Congress 2013, May 20, Poster Number MP 390.

- The benefits of the advanced fibre design is not limited to better middle molecule removal. The reduced transmembrane resistance of the FX CorDiax improves the removal of low molecular weight substances, e.g. phosphate.

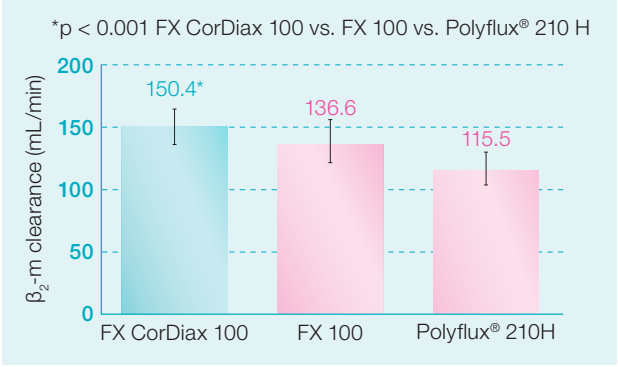
SPOT on:

- High selective permeability for middle molecules
- Improved removal of phosphate



Comparison of aqueous in-vitro clearances of phosphate (Q_B = 300 mL/min, Q_D = 500 mL/min). Investigations carried out by EXcorLab GmbH, an Accredited Calibration and Testing Laboratory.

- In a postdilution HDF treatment the use of FX CorDiax 100 dialysers resulted in a significantly higher clearance of β_2-microglobulin than FX 100 and Polyflux® 210H dialysers. The albumin loss was low and similar for all dialysers.[2]



FX CorDiax offers significantly better β_2-m clearance than FX and Polyflux®[2]

	Albumin loss (g/4h)
FX CorDiax 100	1.74 ± 1.01
FX 100	2.10 ± 1.00
Polyflux® 210H	1. 31 ± 0.12

Comparison of albumin loss in a post-dilution HDF treatment (Q_B = 350 mL/min, Q_D = 800 mL/min, Q_S = 80 mL/min)[2]

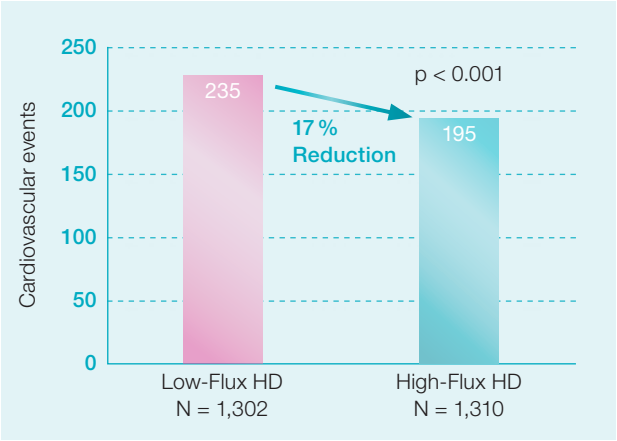
2 Bock A. et al., J Am Soc Nephrol (2013); 24: SA-PO404.

The new FX CorDiax

Clearing middle molecules improves survival rates

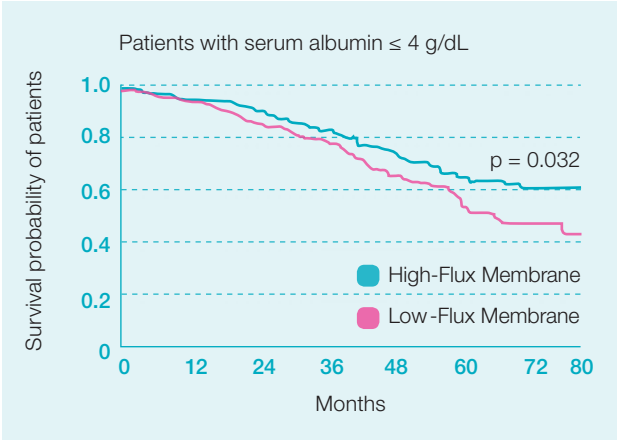
The use of High-Flux membranes instead of Low-Flux membranes improved patient survival rates.

- A meta-analysis of 33 randomised controlled trials and 3,820 patients showed a reduction in cardiovascular mortality of 17 %.[1]
- All-cause mortality in diabetics and patients with albumin ≤ 4 g/dl was significantly improved.[2]



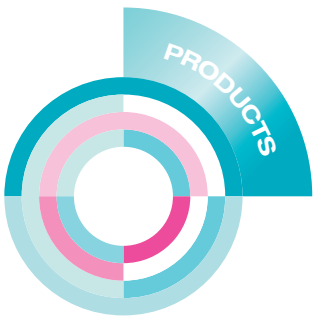
Comparison of cardiovascular mortality when High-Flux instead of Low-Flux dialysers were used[1]

(Graph adapted from original publication)



Comparison of all-cause mortality when High-Flux instead of Low-Flux dialysers were used[2]

(Graph adapted from original publication)



1 Palmer S.C. et al., Cochrane Database of Systematic Reviews (2012); Issue 9.
2 Locatelli F. et al., J Am Soc Nephrol (2009); 20: 645-654.

Cardioprotective Haemodialysis

Innovation at all Levels

FX-class® Design

Cardioprotective Haemodialysis SPOT

FRESENIUS MEDICAL CARE

Protect your Patient

Superior by Design

Several state-of-the-art technologies have been combined to create the distinctive, functional features of FX-class® dialysers, which are refined and optimised for performance, safety and handling:

- Design of dialyser housing and fibre bundle for more uniform dialysate flow.
- Refined blood inlet port for improved haemodynamics.

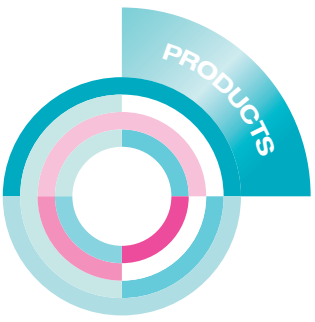
Advances in material and production technologies have permitted improvements in the wall structure of the Helixone®*plus* membrane of the FX CorDiax.

- More porous Helixone®*plus* membrane wall for higher clearance of middle molecules.

Optimised dialysate flow
The 3-dimensional microwave structure of the fibre ensures uniform radial dialysate flow around each fibre within the bundle by preventing fluid channelling, thereby further enhancing clearance values and improving the overall performance of the dialyser.

Better haemodynamics
The lateral blood-inlet port ensures more homogenous blood flow in the dialyser header, preventing stagnation zones. The design essentially eliminates the risk of kinking, contributing to improved safety.

Enhanced convection
The more open structure of the Helixone®*plus* membrane support region serves to reduce diffusion resistance and increases convective filtration. This facilitates clearance of a broad range of uraemic toxins, especially the middle molecules.

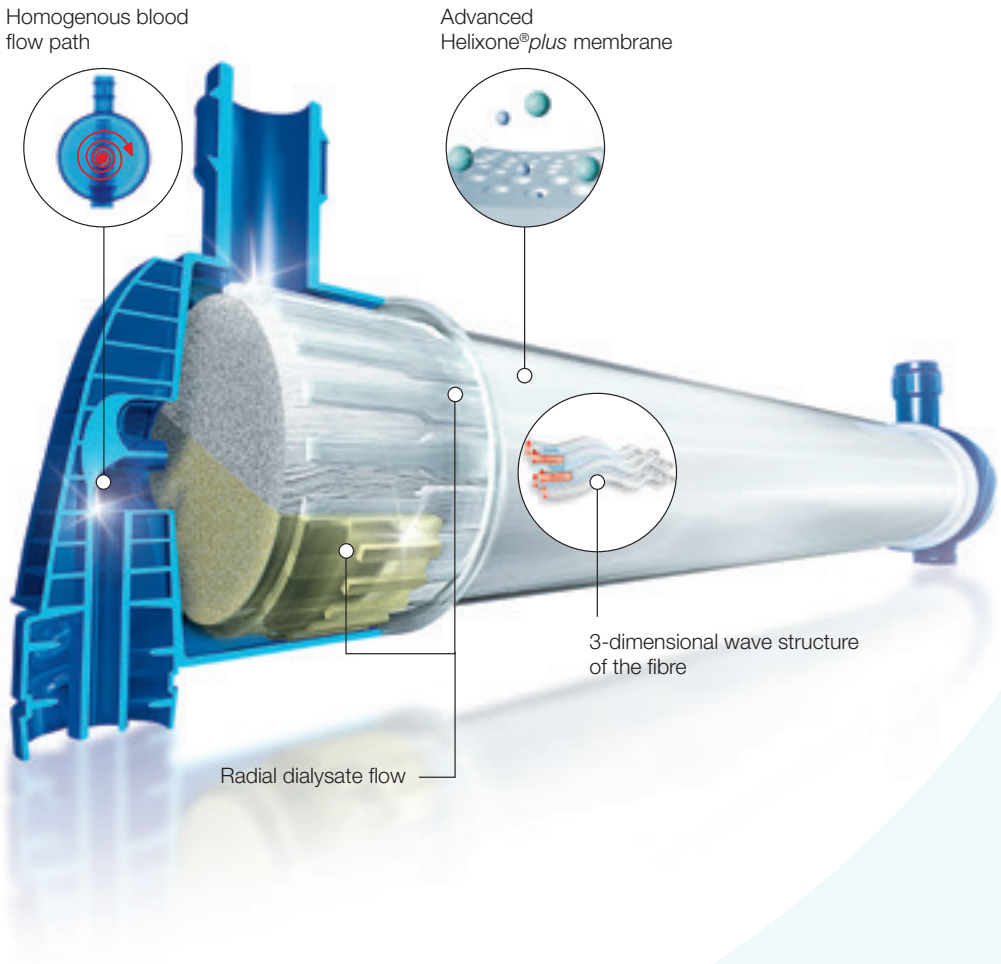


Kind to the environment

Advanced design goes beyond direct functionality, it also has to be easy on the environment. FX-class® dialysers weigh less than half as much as previous dialysers, and at the same time use ecologically friendly plastics. This means a lower carbon-footprint as a result of fewer materials, less packaging, less fuel for transport and cleaner waste management. Due to less priming volume and easy preparation, costs are reduced as well.

SPOT on:

- Optimised performance due to radial dialysate flow.
- Enhanced clearance of middle molecules enabled by a more porous support region of the membrane.



Cardioprotective Haemodialysis

The Pure Difference

INLINE Steam Sterilised Dialysers

INLINE Steam Sterilised Dialysers

Cardioprotective Haemodialysis SPOT

FRESENIUS MEDICAL CARE

Protect your Patient

Clean and safe

FX-class® dialysers are sterilised using the unique INLINE steam sterilisation process specifically developed by Fresenius Medical Care.

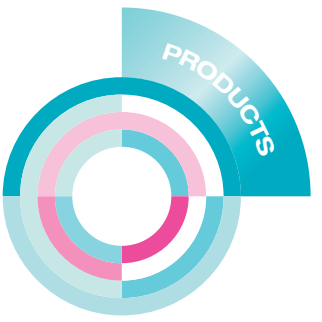
During the INLINE steam sterilisation process, both the blood and the dialysate compartments are rinsed continuously with steam > 121°C. Since no additional chemicals are needed for cleaning or sterilisation, the finished dialysers have extremely low levels of residuals.

Purity ensured – with steam

No chemical residuals with INLINE steam sterilisation
No need for gamma sterilisation – high energy ionising radiation can degrade and alter the material chemistry, producing potential cytotoxic and carcinogenic residuals inside the dialyser.[1]

Low rinsing volumes
Minimal preparation time – since dialysers are clean on arrival, rinsing times prior to use are substantially reduced.

Less rinsing – lower costs
Lower rinsing volumes mean reduced preparation times and costs.



1 Shintani H. et al., Journal of Analytical Toxicology (1989); 13: 354-357.
2 Müller T. F. et al., Nephron (1998); 78: 139-142.

SPOT

SPOT on:

- Reduced risk of blood contact with toxic residuals.[1]
- Activation of the complement system is reduced.[2]

Integrity test: Air pressure is applied to the fibre bundle from one side while the other side contains sterile water. If any leakages were present in the membrane, air would pass the membrane and create bubbles.

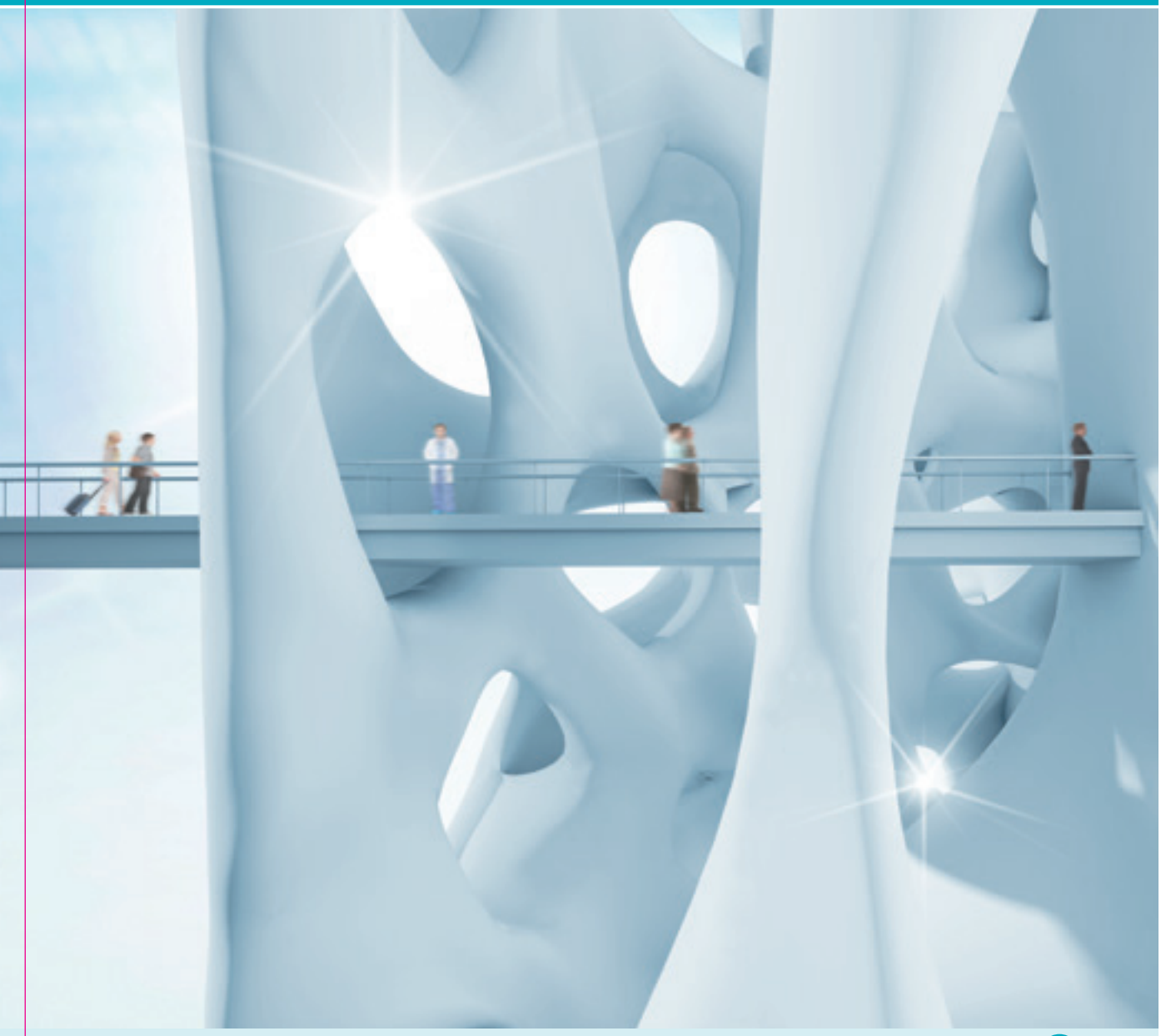
INLINE steam sterilisation process and integrity test

Cardioprotective Haemodialysis

Purity by Design

Superior Endotoxin Retention

Superior Endotoxin Retention



Cardioprotective Haemodialysis SPOT

FRESENIUS MEDICAL CARE

Protect your Patient

What are endotoxins?

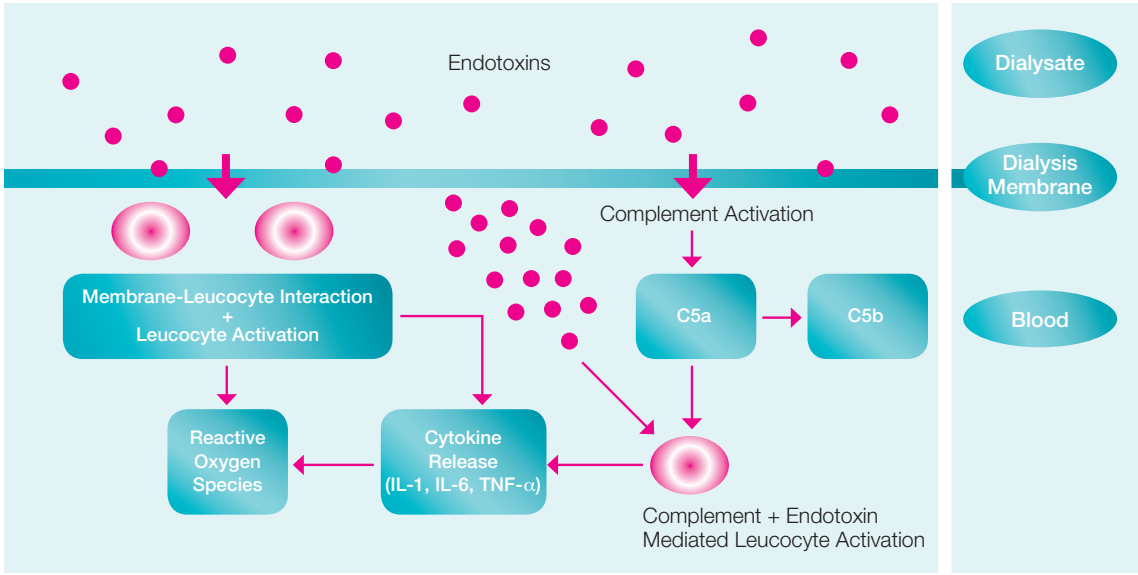
Endotoxins are large molecules from the outer membrane wall of gram-negative bacteria. Chemically, endotoxins are lipopoly-saccharides (LPS), having lipid and poly-saccharide components.

Microbial contamination of water or fluid conduits can therefore lead to the presence of endotoxins in dialysis fluid.

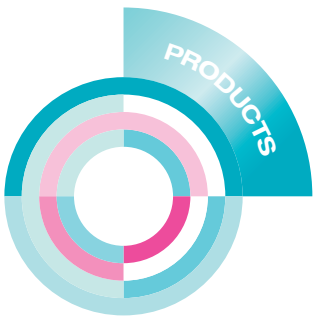
While intact endotoxins are relatively large molecules, their smaller endotoxin fragments may pass across dialysis membranes into the patient's blood via backdiffusion or backfiltration.

Greater protection through active prevention

Once in the patient's blood, endotoxins can induce complement and leucocyte activation, leading to inflammatory responses. Sometimes, these may result in acute reactions such as fever, headaches, convulsions or low blood pressure. In the longer term, they may also contribute to chronic conditions such as amyloidosis, an increased need for EPO, immune disorders or accelerated atherosclerosis. Atherosclerosis and cardiovascular diseases are the most frequent causes of death for dialysis patients.



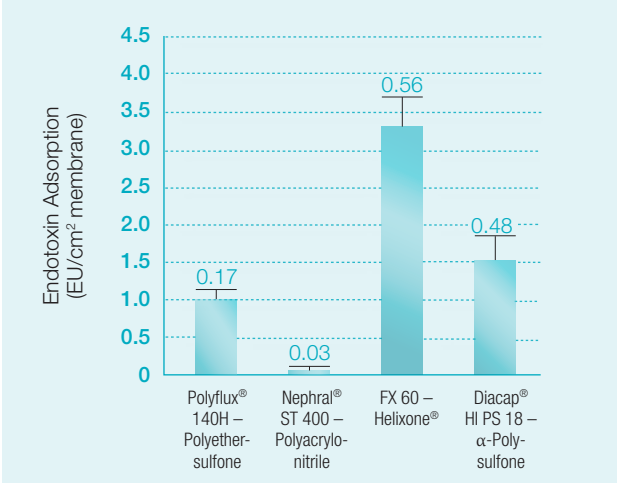
Inflammatory responses simulated by blood-membrane interactions and bacterial dialysate contaminants



Membranes, such as Helixone®, which have a high endotoxin retention capacity, protect the patient from inflammation, particularly when ultrapure dialysate is not available.[1]

SPOT on:

- Absence of endotoxins minimises inflammation.
- Reduced cardiovascular risk factors.



Endotoxin adsorption per cm² membrane surface area after 120 min in-vitro dialysis with contaminated dialysate (endotoxin from bacterial culture filtrates; initial concentration 50 EU/mL).[1]

(Graph adapted from original publication)

How to prevent endotoxins entering dialysis fluids

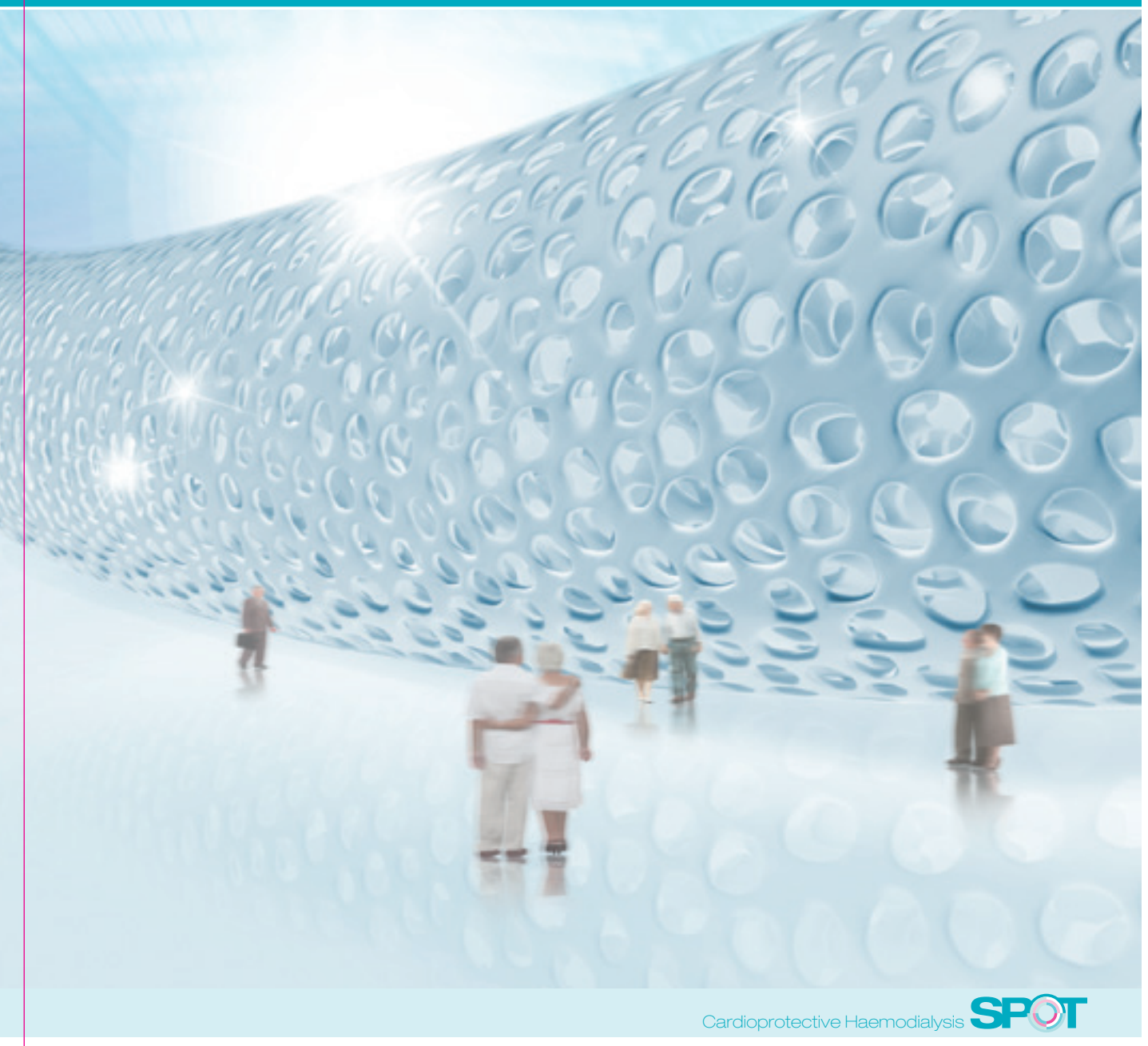
- Improved overall hygiene management.
- Mandatory use of ultrapure dialysis fluid by using dialysis fluid filters such as DIASAFE®*plus* to remove residual endotoxins from dialysis fluid.
- Use of dialysis membranes with high endotoxin retention capacities, particularly when ultrapure dialysate is not available (e.g. Helixone® or Helixone®*plus*).

1 Weber V. et al., Blood Purif (2003); 21: 365.

Cardioprotective Haemodialysis

Open up to Porosity

Enhanced Middle Molecule Removal



Cardioprotective Haemodialysis SPOT

FRESENIUS MEDICAL CARE

Protect your Patient

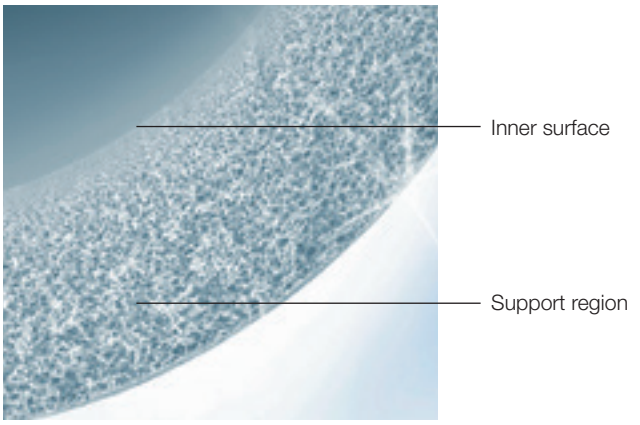
Key to optimal middle molecule removal

Solutes encounter resistance while traversing the membrane wall. Resistance to solute transport is affected, in part, by pore size at the inner surface and the porosity of the membrane wall.

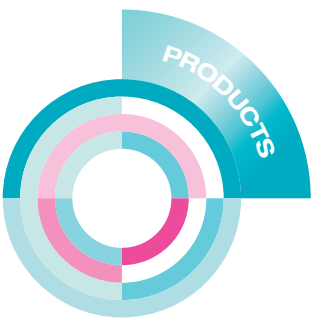
Furthermore, wall structure and thickness as well as inner fibre dimensions and 3-dimensional microwave structure play important roles in transmembrane flux.

The new membrane structure of Helixone®*plus* allows the easy passage of middle molecules across the more porous support region of the membrane.

- The structure of the support region is crucial to overall performance.
- Membrane porosity, together with the pore size, regulates the transport of middle molecules.



Close-up of the inner surface and the support region of the Helixone®*plus* membrane



Refined membrane architecture

New production technology combined with INLINE steam sterilisation allows crucial enhancements of membrane porosity, reducing flow resistance and improving transport across the membrane.

- Significantly improved removal of middle molecules while preventing the loss of useful substances, such as serum albumin.

SPOT

SPOT on:

- Optimised membrane porosity for enhanced removal of middle molecules.

Cardioprotective Haemodialysis

Improved Survival – Better Outcomes

High-Flux Dialysis

FRESENIUS MEDICAL CARE

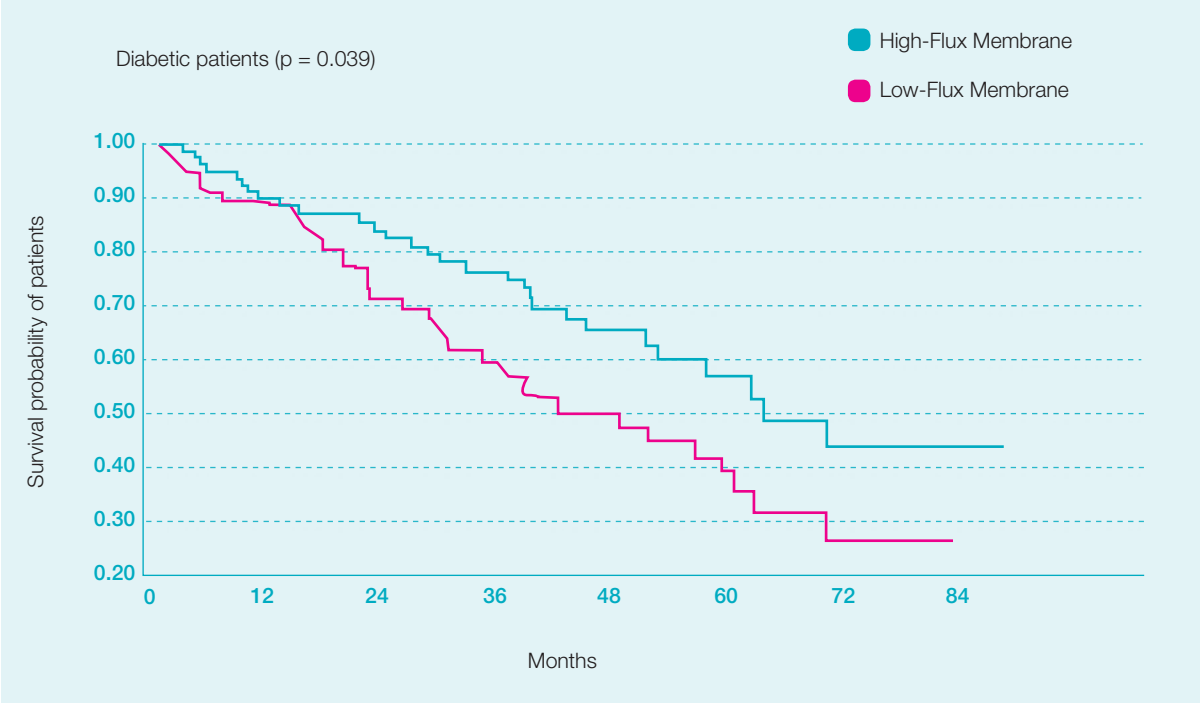
Protect your Patient

Extended survival

Use of High-Flux membranes enhances the removal of uraemic toxins, particularly middle molecules such as β_2-microglobulin.

A growing body of evidence has emerged in recent years demonstrating that use of High-Flux dialysis membranes as well as advanced treatment modalities such as HighVolume**HDF**® may contribute towards reduced risk of death.

The results of the MPO study indicate the beneficial effect of High-Flux membranes in terms of reduced mortality for patients with serum albumin levels ≤ 4.0 g/dL or diabetes.[1]



Kaplan-Meier survival curves for the subpopulation of patients with diabetes (log-rank test p = 0.039)[1]

(Graph adapted from original publication)

Reduced complications

Enhanced middle molecule removal contributes towards reducing the complications of haemodialysis as well as improving long-term patient outcomes by affecting:[2]

- **Inflammation** – lower CRP levels.[3]
- **Anaemia** – haemoglobin levels improve at lower EPO doses.[4]
- **Amyloidosis** – efficient removal of β_2-microglobulin and other middle molecules can reduce the relative risk of developing amyloidosis by up to 50 %.[5, 6]
- **Immune dysfunction** – aberrant suppression of IFN-γ may be corrected.[7]

The clinical benefits of High-Flux HDF are described in more detail in the chapter “Clinical Benefits of the Removal of Middle Molecules”.

SPOT

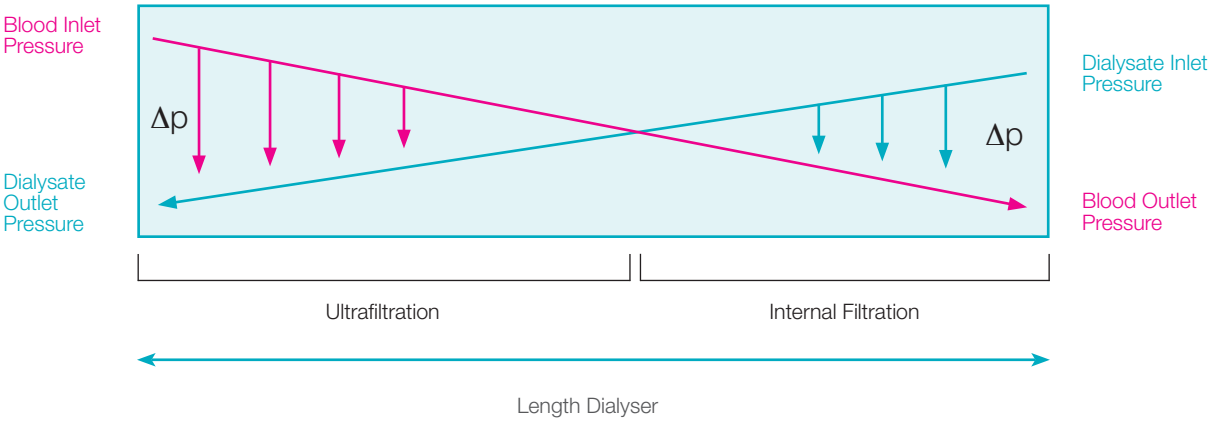
SPOT on :

- High-Flux dialysis can reduce secondary diseases.
- Prolonging patients’ lives.[1]
- Control of anaemia and amyloidosis.

Protect your Patient

Evolution of fibre design

Reducing the inner fibre diameter from 200 µm to 185 µm acts to increase internal filtration, thereby increasing the pressure gradient along the length of the fibre. This results in a greater pressure difference between the blood and dialysate compartments. Together with structural refinements to the support region of the fibre, this enables improvements in both diffusive and convective transport, which is of particular importance when performing High-Flux haemodialysis.



1 Locatelli F. et al., Journal of American Society of Nephrology (2009); 20: 645-654.
2 Tattersall J. et al., Nephrol Dial (2007); 22(Suppl.2); ii5-ii21.
3 Pedrini L. A. et al., Nephrol Dial Transplant (2011); doi: 10.1093/ndt/gfq761.
4 Merello Godino J. I. et al., Int J Artif Organs (2002); 25(11): 1049-1060.

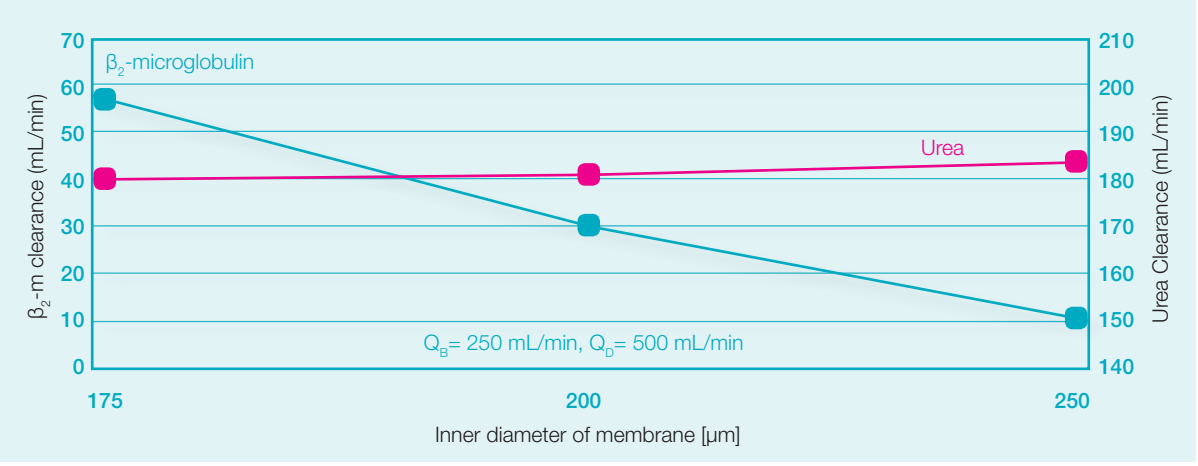
- Modification of the inner diameter increases the pressure gradient between blood and dialysate compartments.

- The result is improved clearance of middle molecules such as vitamin B_{12}, inulin, β_2-microglobulin and myoglobin.[8]

- The increased pressure gradient combined with structural refinements to the membrane (support region) enhances diffusive as well as convective filtration, especially when performing High-Flux haemodialysis with FX CorDiax.

SPOT on:

- Specific fibre design leads to increased removal of middle molecules.



Reduced inner diameter improves middle molecule elimination[8]

(Graph adapted from original publication)

5 Koda Y. et al., Kidney Int (1997); 52: 1096-1101.
6 Locatelli F. et al., Kidney Int (1999); 55: 286-293.
7 Lonnemann G. et al., Blood Purif (2003); 21(3): 225-231.
8 Dellanna F. et al., (1996); NDT 11 (Suppl 2): 83-86.

Protect your Patient

Guidelines recommend High-Flux dialysers

Clinical practice guidelines in Europe recommend the use of High-Flux haemodialysers:

European Renal Best Practice Advisory Board; Guideline 2.1:

"Synthetic High-Flux membranes should be used to delay long-term complications of haemodialysis therapy … even in low-risk patients..."[1]

The Renal Association (UK):

"Suggest that high-flux dialysers should be used instead of low-flux dialysers to provide haemodialysis. Evidence of improved patient survival with the use of high-flux membranes is restricted to incident patients, who have lower serum albumin concentrations (< 4 g/L) or have diabetes mellitus, and prevalent patients who have been on haemodialysis > 3.7 years"[2]

1 Tattersall J., Nephrol Dial Transplant (2010); 25: 1230–1232.

2 Mactier R. et al., Renal Association 2009, Renal Association Clinical Practice Guidelines. Haemodialysis membranes (Guidelines 4.1 to 4.5). http://www.renal.org/clinical/GuidelinesSection/Haemodialysis.aspx. Accessed 2 Dec. 2012.

Cardioprotective Haemodialysis

Advance the Experience
HighVolume**HDF**®

Cardioprotective Haemodialysis SPOT

FRESENIUS MEDICAL CARE

Protect your Patient

Better filtration

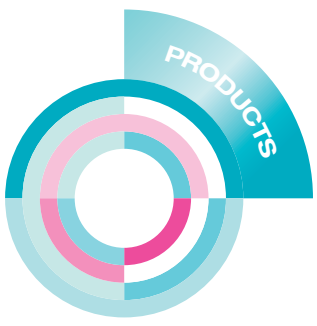
In recent years, there has been increased interest in more efficient haemodialysis treatment modalities. The main emphasis today is on the efficient removal of a wide range of uraemic toxins, particularly larger middle molecules such as β_2-microglobulin, a surrogate of middle molecules. However, excessive loss of useful substances such as albumin needs to be curtailed.

The high removal of larger solutes during HighVolume**HDF**® is achieved through a combination of two principles: diffusion and convection at high substitution volumes. Solute removal by convection occurs along a pressure gradient facilitated by the ultrafiltration of fluid across a highly permeable membrane.

HighVolume**HDF**® improves patient outcomes and exerts beneficial effects on the main cardiovascular risk factors:

- Intradialytic haemodynamic stability[1]
- Anaemia[2]
- Inflammation[3]
- Serum β_2-m and phosphate levels[4,5,6]

HighVolume**HDF**® is currently considered as the most efficient renal replacement therapy.



Improved survival

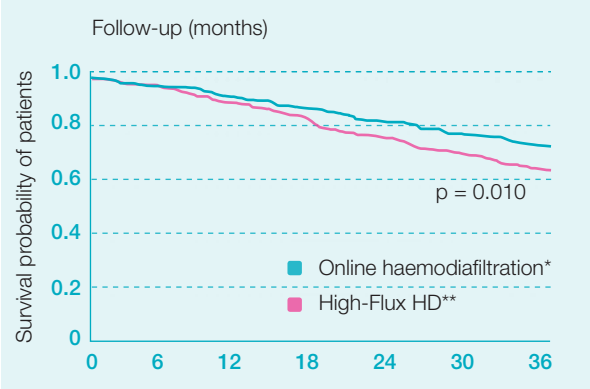
SPOT

SPOT on:

- High convective transport enhances the removal of uraemic toxins, especially in the middle molecular range.

The Catalonian high-volume HDF study,[7] on behalf of the Estudio de Supervivencia de Hemodiafiltración On-Line (ESHOL) study group, is a multi-centre, prospective randomised controlled trial, which showed a wide range of benefits for patients being treated with high-efficiency post-dilution HDF (HighVolume**HDF**®). Achieving a mean delivered total substitution volume of 21 L/session should therefore be the target for every HDF treatment.

The primary outcome all-cause mortality was significantly reduced for the patients being treated with HighVolume**HDF**®.



Results from the Catalonian high-volume HDF study[7]
*median delivered convective volume ranged from 23 to 24 L/session
**92% on High-Flux HD

Improved survival

30% **risk reduction in all-cause mortality (p = 0.01)**

55% risk reduction in mortality from infection (p = 0.03)

61% risk reduction in mortality from stroke (p = 0.03)

Reduced treatment costs

22% risk reduction in all-cause hospitalisation (p = 0.001)

Better patient well-being

28% risk reduction in incidence of hypotensive episodes (p < 0.001)

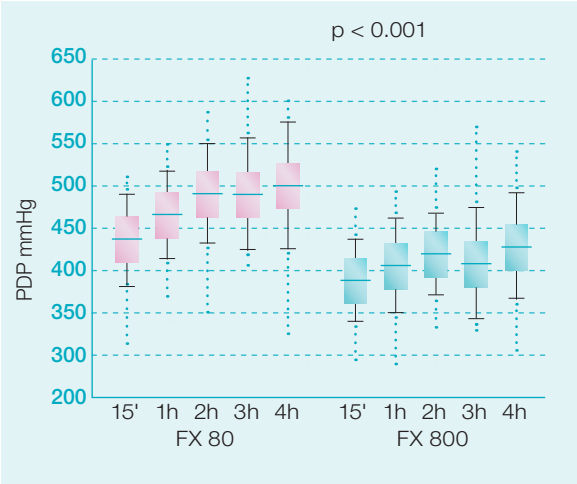
1 Locatelli F. et al., J Am Soc Nephrol (2010); 21: 1798–1807.
2 Bonforte G. et al., Blood Purif (2002); 20: 357–363.
3 Pedrini L. et al., Nephrol Dial Transplant, advanced access published Jan 18, 2011.
4 Canaud B., Contrib Nephrol (2007); 158: 216–224.
5 Penne L. et al., Clin J Am Soc Nephrol (2010); 5: 80–86.
6 Davenport A., Nephrol Dial Transplant (2010); 25: 897–901.
7 Maduell F. et al., J Am Soc Nephrol (2013); 24: 487–497.

Protect your Patient

FX CorDiax haemo*dia*filter – Superior by design

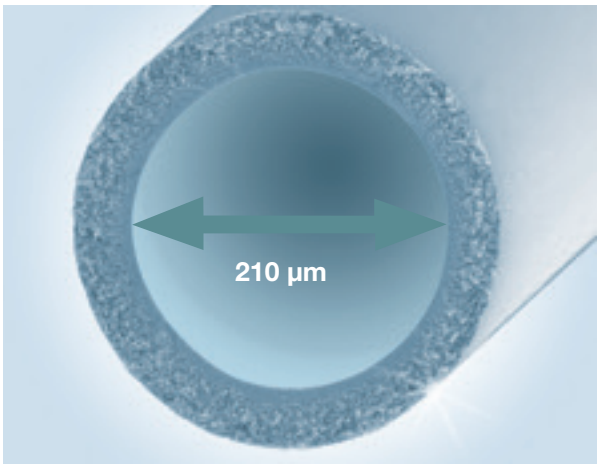
HighVolume**HDF**® therapy requires specially designed filters. Stepping up to this challenge, we developed the FX CorDiax haemo*dia*filter for HighVolume**HDF**® with the most efficient removal of middle molecules while minimising albumin loss.

- **Increased fibre lumen for better flow conditions**
  An increase of its inner diameter results in a substantially reduced pressure drop within a hollow fibre according to the Hagen Poiseuille law. Differences in the capillary diameter of a dialyser can therefore affect its performance and the quality of the treatment provided to a patient. The inner diameter of FX-class® haemo-*dia*filters is 210 µm compared to 185 µm of FX-class® HD filters. The larger inner diameter facilitates improved flow conditions which allowed for a significantly higher convective volume in a HDF treatment.[1]

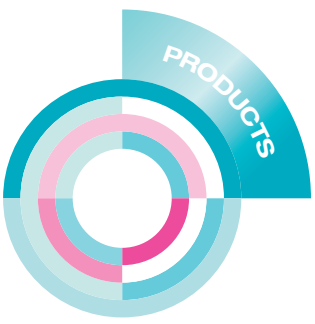


Reduced dialyser inlet pressure of FX 800 (210 µm) vs. FX 80 (185 µm)[1]

(Graph adapted from original publication)



The 210 µm fibre lumen of FX CorDiax haemo*dia*filters optimises blood flow conditions within the dialyser for maximal HighVolume**HDF**® performance.



1 Vega Vega O. et.al.; ERA-EDTA Congress 2012, Poster 457—FP.

Cardioprotective Haemodialysis

When Performance is Priority

Clinical Benefits of the Removal of Middle Molecules

Clinical Benefits of the Removal of Middle Molecules

Cardioprotective Haemodialysis SPOT

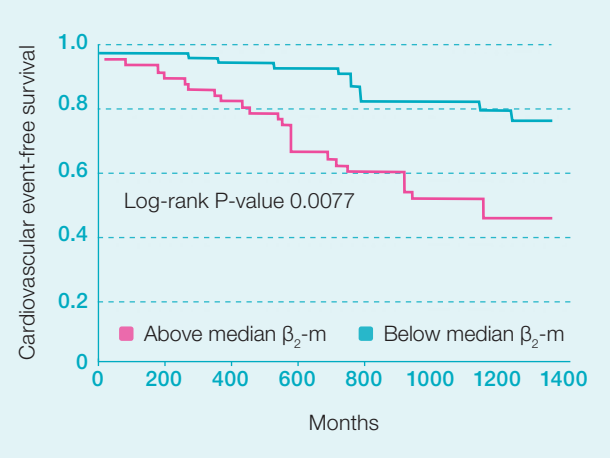
FRESENIUS MEDICAL CARE

Protect your Patient

Improved survival with High-Flux membranes

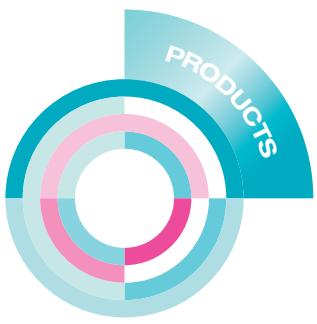
On top of traditional cardiovascular risk factors, increased middle molecule levels such as β_2-microglobulin (β_2-m) pose an additional risk for the development of cardiovascular diseases (CVD) in end stage renal disease (ESRD) patients. The European Uremic Toxin Work Group (EUTox) confimed the power of β_2-m to predict overall and cardiovascular mortality and cardiovascular events in patients at different stages of CKD.[1]

Thus, enhanced middle molecule removal contributes towards improving long-term patient outcomes and reducing dialysis related complications.



Kaplan-Meier estimates of the probability of cardiovascular event-free survival of predialysis patients, as a function of median plasma β_2-m level[1]

(Graph adapted from original publication)

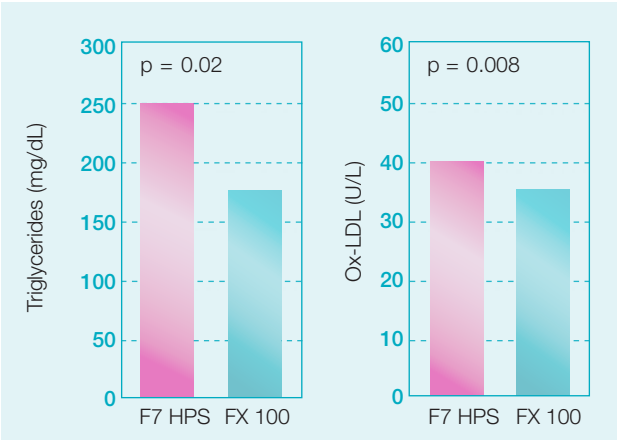


Cardioprotective Haemodialysis

- **Dyslipidaemia** – the use of High-Flux Helixone® membranes improves plasma lipid profiles,[2] reducing levels of LDL (low-density lipoprotein) and VLDL (very low-density lipoprotein) and increasing those of protective HDL (high-density lipoprotein). The levels of triglycerides and oxidised LDL, an indicator of oxidative stress and a specific risk factor for atherosclerosis, are also significantly reduced using Helixone® membranes.[3]

SPOT on:

- Improved patient survival.[1]
- Reduced risk factors of atherosclerosis.[3]



Improving plasma lipid profiles: reduction of ox-LDL and triglycerides with FX 100 dialysers[3]

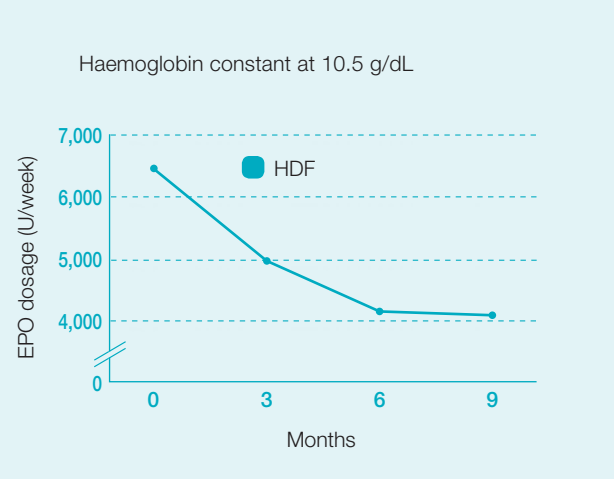
(Graph adapted from original publication)

Protect your Patient

Cardioprotective Haemodialysis

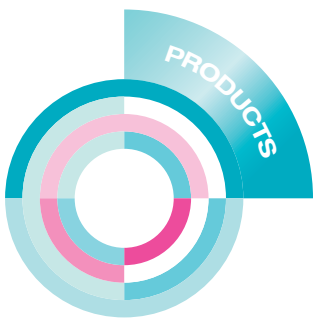
- **Amyloidosis** – a debilitating complication of longterm haemodialysis, amyloidosis involves the build-up of β_2-microglobulin. FX-class® High-Flux dialysers efficiently remove β_2-microglobulin and other middle molecules, reducing the risk of carpal tunnel syndrome.[4,5]

- **Inflammation** – specialised production processes such as INLINE steam sterilisation as well as the high endotoxin retention properties of FX-class® dialysers contribute to reducing the levels of endotoxin exposure during haemodialysis. This results in the reduced induction of inflammatory responses.[2]



With High-Flux membranes, it was possible to progressively reduce the EPO dose while maintaining Hb control[6]

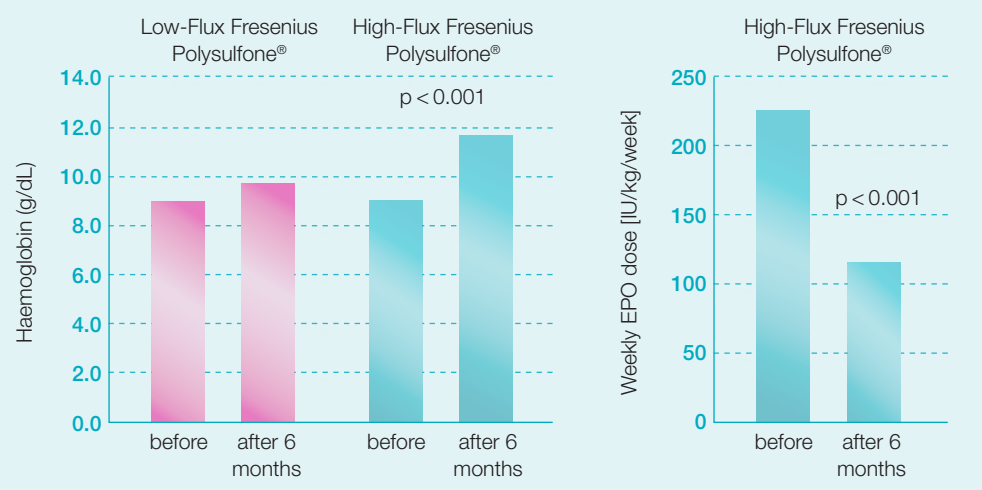
(Graph adapted from original publication)



- **Anaemia management** – it was shown that High-Flux membranes improved control of anaemia in EPO hypo-responsive patients while allowing a progressive reduction in the exogenous EPO dose by 25 to 45 %.[7] Hence, High-Flux membranes offer the potential to reduce EPO costs.

SPOT on:

- Improved anaemia control.[6,7]
- Reduced inflammation.[2]
- Reduced risk of CVD due to minimising the risk factors.



Recovery of haemoglobin (Hb) levels was significantly better after 6 months for patients treated with High-Flux vs Low-Flux membranes. Further, in this patient group the mean EPO dose was significantly lower.[7]

(Graph adapted from original publication)

The FX CorDiax allows the enhanced removal of middle molecules which, together with other factors, contributes towards improved survival.

1 Liabeuf S. et al., Kidney International (2012) 82, 1297.
2 Merello Godino J. I. et al., Int J Artif Organs (2002); 25(11): 1049-1060.
3 Wanner C. et al., JASN (2002); 13 (SU-P0645): 600A.
4 Ahrenholz P. G. et al., Clinical Nephrology (2004); 62: 21-28.
5 Koda Y. et al., Kidney Int (1997); 52: 1096-1101.
6 Bonforte G. et al., Blood Purif (2002); 20: 357-363.
7 Ayli D. et al., J Nephrol (2004); 17: 701-706.

Performance Data

Sieving coefficients of FX CorDiax High-Flux Dialysers and Haemo*dia*filters	Molecular weight (Dalton)	
Albumin	66,500	< 0.001
Myoglobin	17,053	0.5
β_2-microglobulin	11,731	0.9
Inulin	5,200	1

Membrane material		Helixone®*plus*
Sterilisation method		INLINE steam
Housing material		Polypropylene
Potting compound		Polyurethane
Units per box		24

FX CorDiax High-Flux Dialysers		FX CorDiax 40	FX CorDiax 50	FX CorDiax 60	FX CorDiax 80	FX CorDiax 100	FX CorDiax 120
Clearance (Q_B = 300 mL/min)							
Cytochrome c	12,230	48 *	76	96	111	125	136
Inulin	5,200	56 *	88	116	127	144	149
Vitamin B_{12}	1,355	96 *	144	175	190	207	213
Phosphate	132	142 *	215	237	248	258	262
Creatinine	113	155 *	229	252	261	272	274
Urea	60	175 *	255	271	280	283	284
Clearance (Q_B = 400 mL/min)							
Cytochrome c	12,230	–	–	100	117	133	145
Inulin	5,200	–	–	122	135	154	160
Vitamin B_{12}	1,355	–	–	191	209	229	237
Phosphate	132	–	–	270	285	299	305
Creatinine	113	–	–	290	303	321	325
Urea	60	–	–	319	336	341	343
**Clearance (Q_B = 200 mL/min)*							
Ultrafiltration coeff. (mL/h x mmHg)		21	33	47	64	74	87
In vitro performance: Q_D = 500 mL/min, Q_F = 0 mL/min, T = 37 °C (EN 1283). Sieving coefficients: human plasma, $Q_B$max, Q_F = 0.2 x $Q_B$max (EN1283). Ultrafiltration coefficients: human blood (Hct 32 %, protein content 6 %).							
Effective surface (m²)		0.6	1.0	1.4	1.8	2.2	2.5
K_oA Urea		547	886	1,164	1,429	1,545	1,584
Priming volume (mL)		32	53	74	95	116	132
Article number		**F00001588**	**F00001589**	**F00001590**	**F00001591**	**F00001592**	**F00002384**

FX CorDiax Haemo*dia*filters		FX CorDiax 600	FX CorDiax 800	FX CorDiax 1000
Clearance (Q_B = 300 mL/min, Q_F = 75 mL/min)				
Cytochrome c	12,230	131	141	151
Inulin	5,200	144	156	166
Vitamin B_{12}	1,355	204	217	225
Phosphate	132	257	267	271
Creatinine	113	271	277	280
Urea	60	285	291	292
Clearance (Q_B = 400 mL/min, Q_F = 100 mL/min)				
Cytochrome c	12,230	149	160	172
Inulin	5,200	166	178	190
Vitamin B_{12}	1,355	235	251	262
Phosphate	132	307	321	328
Creatinine	113	327	339	343
Urea	60	354	365	367
Ultrafiltration coeff. (mL/h x mmHg)		46	62	76
In vitro performance: Q_D = 500 mL/min, T = 37 °C (EN 1283). Sieving coefficients: human plasma, $Q_B$max, Q_F = 0.2 x $Q_B$max (EN1283). Ultrafiltration coefficients: human blood (Hct 32 %, protein content 6 %).				
Effective surface (m²)		1.6	2.0	2.3
K_oA Urea		1,148	1,365	1,421
Priming volume (mL)		95	115	136
Article number		**F00001593**	**F00001594**	**F00001595**

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Cardioprotective Haemodialysis

FX classix

High-Flux Dialysis for Improved Survival

Cardioprotective Haemodialysis SPOT

FRESENIUS MEDICAL CARE

Protect your Patient

Cardioprotective Haemodialysis

The reduction of risk factors for cardiovascular diseases (CVD) is core to the development of dialysis systems and products at Fresenius Medical Care. Outstanding cardioprotection must be reflected in all levels of product development and application.

Wide-ranging cardioprotection

There have been tremendous improvements in the quality and efficacy of haemodialysis (HD) therapy in recent years. Despite this, cardiovascular diseases (CVD) remain the leading cause of death for patients with end-stage renal disease (ESRD). Moreover,

Services

Over 30 years' experience in dialysis at your service.

- Project planning and consulting
- Training and Education
- Technical Services
- Water Quality Service (WQS)
- Medical Information Services

Products

State-of-the-art technologies enable advanced cardioprotective therapies.

- CorDiax Product line:
  - 5008 CorDiax and 5008S CorDiax
  - FX CorDiax dialysers
  - BCM-Body Composition Monitor
- Classix Product line:
  - 4008S classix
  - FX classix dialysers
- Therapy Data Management System (TDMS)
- Online Purification Cascade® (OPC)

overall and cardiovascular mortality is markedly greater in ESRD patients than in the general population. This is why we put Cardioprotective Haemodialysis on the SPOT. A comprehensive approach that includes services, products and therapies is needed to achieve the best therapeutic performance – meaning improved clinical outcomes and better quality of life, enhanced control of therapy costs, and simpler, safer handling.

Outcomes

Achieving better outcomes with cardioprotective therapies.

- Reduced mortality risk
- Fewer cardiovascular complications
- Optimised use of resources

Therapies

Cardioprotective therapies designed by the world market leader in haemodialysis.

- High-Flux dialysis
- ONLINE HDF
- Advanced Fluid Management

Protect your Patient

Cardioprotection at the heart of long-term haemodialysis

Chronic kidney disease (CKD), as well as the effects of dialysis itself, can lead to cardiovascular diseases (CVD) such as atherosclerosis and left ventricular hypertrophy (LVH), the largest causes of death in haemodialysis patients.[1]

Fresenius Medical Care's mission is to enable nephrologists to provide the best possible therapy for their long-term haemodialysis patients in order to minimise the risk of CVD.

In addition to the efficient removal of uraemic toxins, protecting patients through a high level of membrane biocompatibility and endotoxin retention is crucial in Cardioprotective Haemodialysis.

Therefore, Fresenius Medical Care has developed a new class of dialyser, which opens the door to cardio-protective renal replacement therapy – the FX classix:

FX classix – highest level of biocompatibility

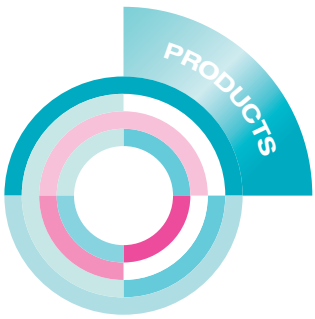
- INLINE steam sterilisation enables the production of sterile and pyrogen-free dialysers and ensures high biocompatibility.[2]

FX classix – maximum endotoxin retention

- The Helixone® membrane has a high endotoxin retention capacity, which minimises the risk of inflammation.[3]

FX classix – cost saving potential

- FX classix dialysers provide an additional cost saving potential thanks to the lower rinsing volumes enabled by INLINE steam sterilisation as well as the lower weight of the dialysers, which could result in lower waste management costs.



References

1. de Jager D. et al., JAMA (2009); 302: 1782–1789.
2. Müller T. F. et al., Nephron (1998); 78: 139–142.
3. Weber V. et al., Blood Purif (2003); 21: 365.

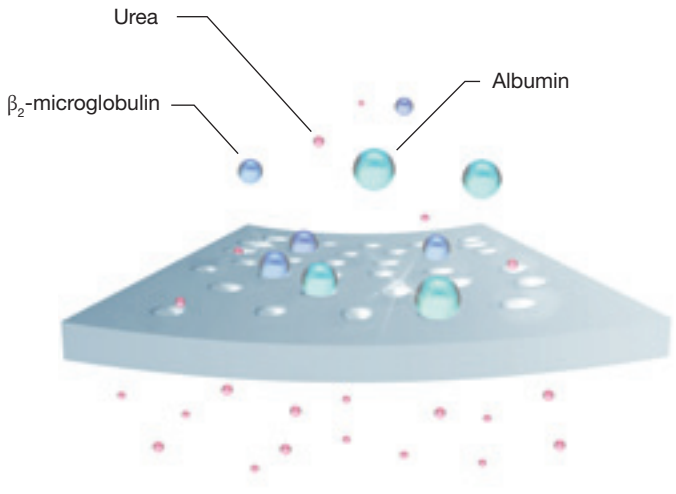
FX classix – high performance

- Performing High-Flux dialysis has advantages over Low-Flux dialysis: thanks to the larger pores on the inner surface of the innovative Helixone® membrane, High-Flux dialysers also remove middle molecules such as β_2-microglobulin while preventing the loss of essential blood components such as albumin. In addition, the permeability to water is much higher than in Low-Flux dialysers.

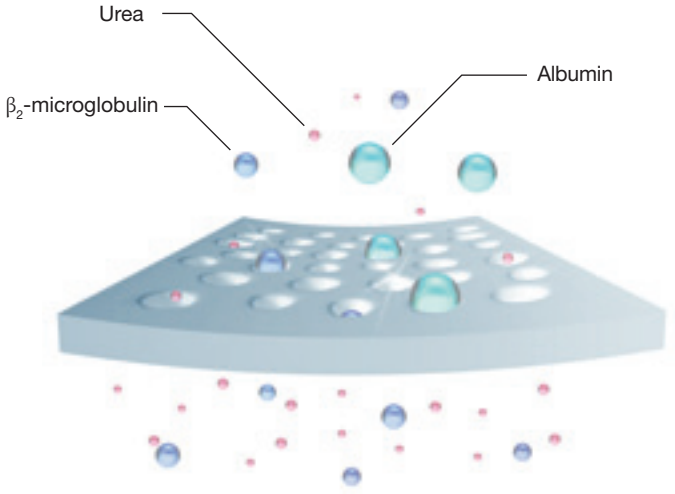
These benefits reduce the risk of CVD and help to improve the long-term outcomes of your patients.

SPOT on:

- Highest biocompatibility due to INLINE steam sterilisation.[2]
- High endotoxin retention of Helixone® membrane.
- Cost saving potential due to lower rinsing volumes.



Low-Flux membrane



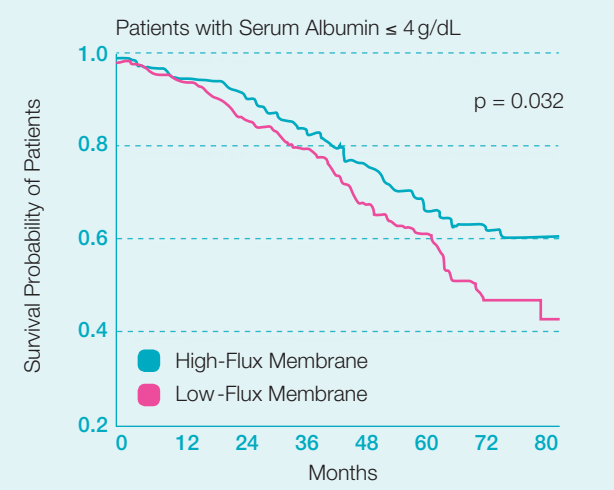
High-Flux membrane

Protect your Patient

Clinical benefits of High-Flux dialysers

Improved survival

The Membrane Permeability Outcome Study (MPO) revealed superior survival rates in high-risk patients when treated with High-Flux membranes compared to Low-Flux membranes. For patients with hypoalbuminaemia (≤ 4 g/dL of serum albumin) or diabetes mellitus, a reduction in the relative risk of death of up to 37 % was observed.[1]



Kaplan-Meier survival curves for the population of patients with serum albumin levels ≤ 4.0 g/dL (log-rank test p = 0.032).[1]

(Graph adapted from original publication)

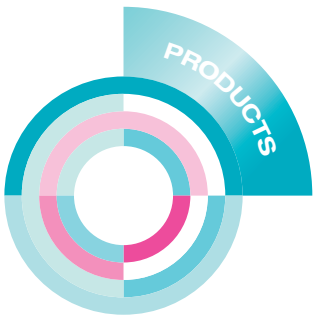
Up to 86 % of dialysis patients worldwide have a serum albumin level ≤ 4 g/dL, underlining the relevance of these risk factors in dialysis.[2]

During the first 4 years of the MPO study, one in eleven events of death was prevented when hypoalbuminaemic patients were treated with High-Flux dialysers instead of Low-Flux dialysers.

Guidelines recommend High-Flux dialysers

As a consequence of the results of the MPO study, High-Flux membranes **are now recommended by the European Renal Best Practice Advisory Board for all haemodialysis patients:**

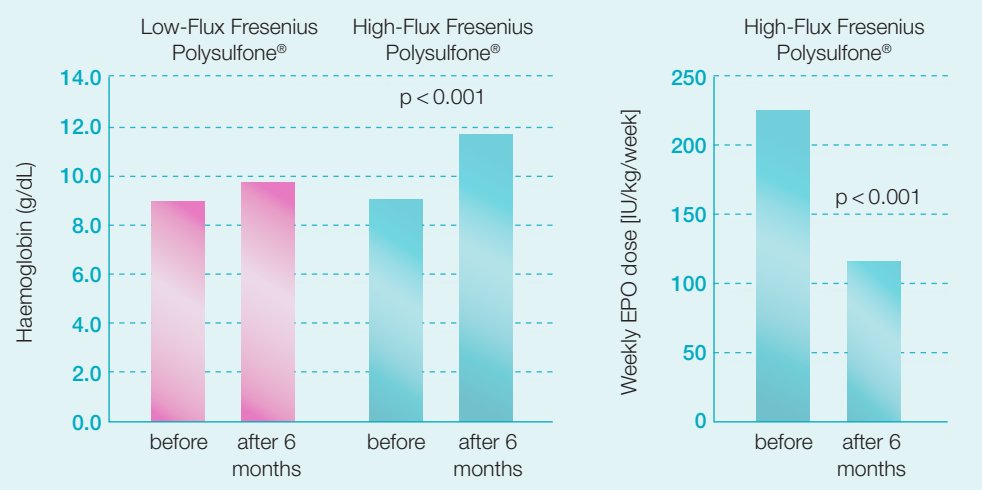
> **"Guideline 2.1: Synthetic High-Flux membranes should be used to delay long-term complications of haemodialysis therapy ... even in low-risk patients..."[3]**



Improved anaemia management

In patients with ESRD, it is often necessary to administer EPO to treat anaemia. In addition to this, inflammation often contributes to EPO hypo-responsiveness.[4] It was shown that High-Flux membranes improved control of anaemia while allowing a progressive reduction in the exogenous EPO dose by 25 to 45 %.[5]

Hence, High-Flux membranes offer the potential to reduce EPO costs.



Recovery of haemoglobin (Hb) levels was significantly better after 6 months for patients treated with High-Flux vs Low-Flux membranes. Further, in this patient group the mean EPO dose was significantly lower.[5]

(Graph adapted from original publication)

SPOT on:

- Improved patient survival with High-Flux dialysis.[1]
- Relative risk reduction of 37 % for hypoalbuminaemic patients with High-Flux dialysis.[1]
- Improved anaemia control through High-Flux dialysis.[5]

References

1. Locatelli F. et al., Journal of American Society of Nephrology (2009); 20: 645–654.
2. The DOPPS report 2004; http://www.dopps.org/pdf/dopps_report_2004.pdf.
3. Tattersall J., Nephrol Dial Transplant (2010); 25: 1230–1232.
4. Gunnell J. et al., Am J Kidney Dis (1999); 33(1): 63–72.
5. Ayli D. et al., J Nephrol (2004); 17: 701–706.

Protect your Patient

Proven benefits of the FX-class® design

Fresenius Polysulfone® has long been the »gold standard« in dialysis membranes. For over 30 years, Fresenius Polysulfone® has stood for outstanding safety and performance. Derived from established Fresenius Polysulfone® technology, the Helixone® membrane is at the core of FX-class® dialysers.

The new FX classix dialysers are part of the FX-class® series. More than 177 million treatments have been performed with FX-class® dialysers proving the record of success of the Helixone® membrane.

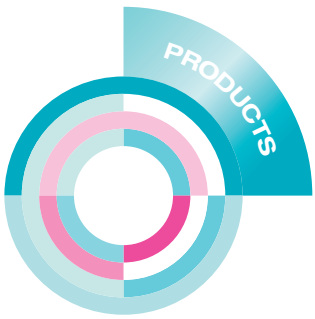
The unique design of the FX-class® dialyser is based on refined and optimised performance and handling. Several state-of-the-art technologies have been combined to offer distinctive benefits:

Helixone® membrane – optimised performance

- Optimised membrane permeability enables efficient removal of low molecular weight substances and middle molecules
- Minimal loss of essential blood components
- Produced with Nano Controlled Spinning (NCS™) technology

Optimised haemodynamics

- Homogenous blood flow in the dialyser header through lateral blood-inlet port
- Fewer stagnation zones in the header region
- Risk of bloodline kinking is diminished



Optimised dialysate flow for higher clearances

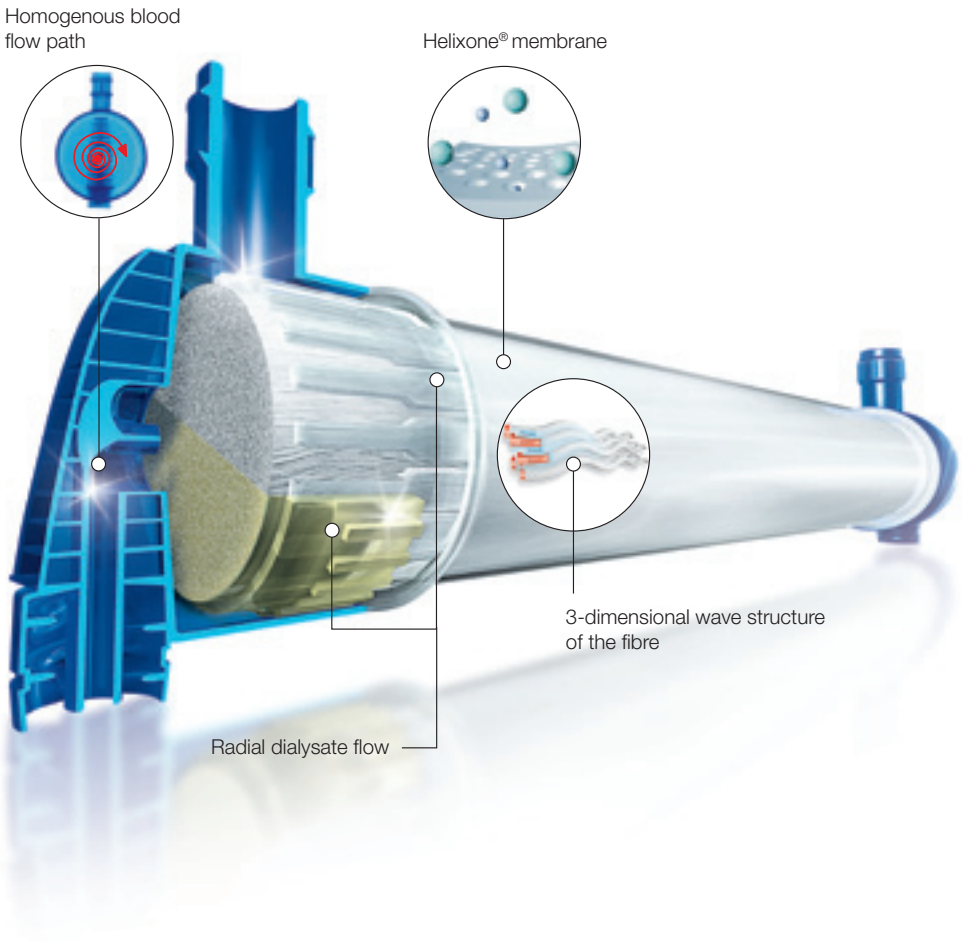
- 3-dimensional microwave structure of the fibres, together with a higher packing density, ensures a homogenous distribution of dialysate over the entire cross-section of the dialyser
- Radial flow of the dialysate around each fibre within the bundle

Kind to the environment

- Usage of ecologically-friendly plastics
- Lower carbon-footprint as a result of fewer materials, less packaging and less fuel for transport

SPOT on:

- Proven and trusted Helixone® membrane.
- Optimised haemodynamics.
- Optimised dialysate flow.
- Environmental-friendliness.



Protect your Patient

Purity ensured – with steam

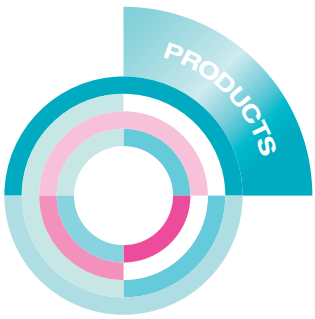
INLINE steam sterilisation

Product safety means patient safety. In the manufacturing process of our dialysers, we comply strictly with highest quality standards. Thus, all the FX classix dialysers pass through the unique INLINE steam sterilisation process specifically developed by Fresenius Medical Care.

The blood and dialysate compartments of the dialysers are rinsed with hot steam > 121°C for 15 minutes. Following this, all dialysers undergo a fibre leakage test to ensure the integrity of every single fibre.

No chemical residuals

INLINE steam sterilisation reduces potential hazards from residuals. The basic principle of this method is extensive rinsing with hot steam – without the need for chemicals or gamma sterilisation processes. Gamma irradiation may induce the degradation and alteration of the material chemistry and generate cytotoxic substances.[1] INLINE steam sterilisation therefore leads to highly purified dialysers free from chemical, cytotoxic and carcinogenic residuals and with excellent haemocompatibility.

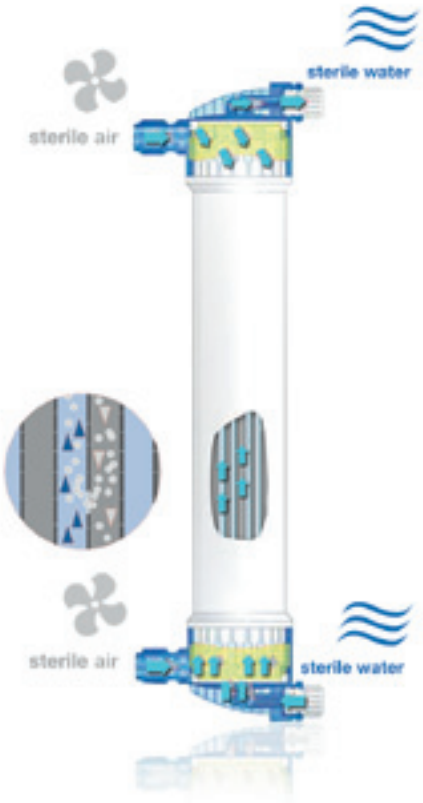


INLINE steam sterilisation process and integrity test

SPOT on:

- Rinsing with hot steam leads to highly purified dialysers.

INLINE steam sterilisation process.



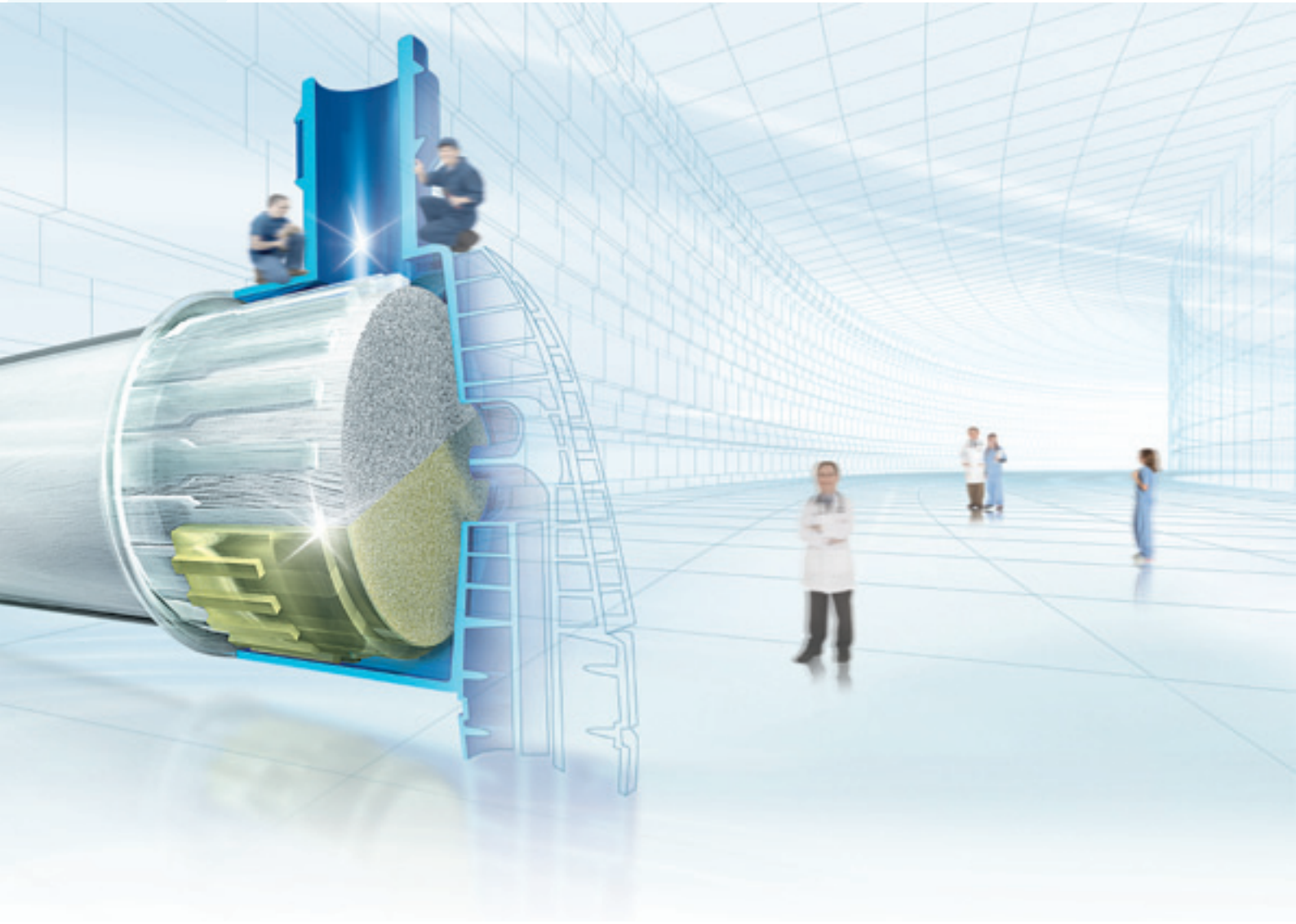
Integrity test: air pressure is applied to the fibre bundle from one side while the other side contains sterile water. If any leakages were present in the membrane, air would pass through the membrane and create bubbles.

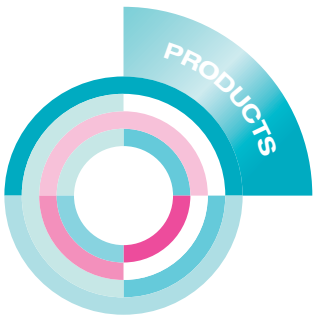
References

1. Shintani H. et al., Journal of Analytical Toxicology (1989); 13: 354–357.

Protect your Patient

Greater protection through active prevention





Superior endotoxin retention

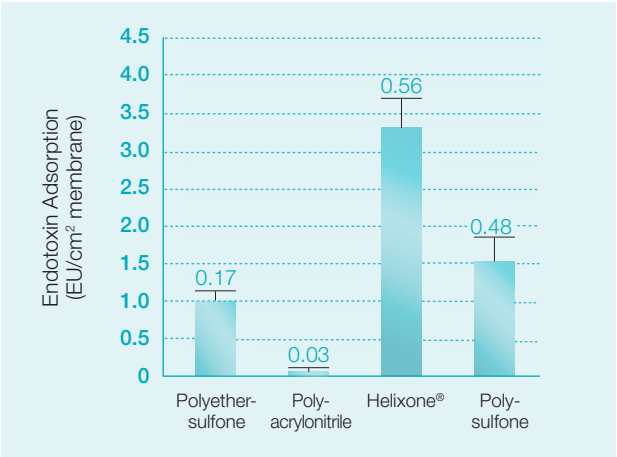
Endotoxins are large molecules from the outer membrane wall of gram-negative bacteria. They are able to enter dialysis fluid, and thus the bloodstream, via the microbial contamination of water or fluid conduits. Once in the patient's blood, endotoxins can induce inflammatory responses and – in the longer term – complications such as amyloidosis or accelerated atherosclerosis.

Membranes, such as Helixone®, which have a high endotoxin retention capacity, protect the patient from inflammation, particularly when ultrapure dialysate is not available.[1] Therefore, it is crucial to prevent endotoxins entering the bloodstream by adopting the following hygiene regime:

- Use of dialysis membranes with high endotoxin retention capacities, such as Helixone®, to protect the patient from inflammation.
- Use of dialysis fluid filters to create ultrapure dialysis fluid free from residual endotoxins.
- Overall hygiene of water supply system.

SPOT on:

- High endotoxin retention of Helixone® membrane.
- Improved patient protection through ultrapure dialysis fluid.



Endotoxin adsorption per cm^2 membrane surface area after 120 min in-vitro dialysis with contaminated dialysate (endotoxin from bacterial culture filtrates; initial concentration 50 EU/mL).[1]

(Graph adapted from original publication)

References

1. Weber V. et al., Blood Purif (2003); 21: 365.

The new FX classix

Optimised use of resources

Lower weight – reduced costs

The reduced weight of the FX classix dialysers – due to less packaging and decreased use of processed materials – allows cleaner, more cost-effective waste management and thus conserves valuable resources.

Less rinsing – reduced costs

Since FX classix dialysers are INLINE steam sterilised, rinsing volumes of only 500 mL are needed per treatment. Consequently, it is possible to apply the dialysers quickly with decreased preparation time.

Moreover, the reduced rinsing volume represents an average cost saving of 50 % for the priming fluid.

The new FX classix

Performance data

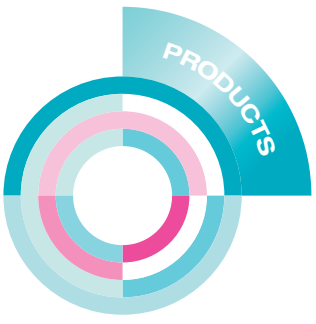
FX classix High-Flux dialysers	Molecular weight (Dalton)	FX 50 classix	FX 60 classix	FX 80 classix	FX 100 classix
Clearance (Q_B = 300 mL/min)					
Cytochrome c	12,230	55	74	89	100
Inulin	5,200	72	95	113	122
Vitamin B_{12}	1,355	137	162	185	201
Phosphate	132	204	225	244	253
Creatinine	113	224	243	259	264
Urea	60	253	266	279	280
Clearance (Q_B = 400 mL/min)					
Cytochrome c	12,230	-	76	92	105
Inulin	5,200	-	99	119	129
Vitamin B_{12}	1,355	-	175	202	222
Phosphate	132	-	252	279	291
Creatinine	113	-	277	300	309
Urea	60	-	312	334	336
Ultrafiltration coeff. (mL/h x mmHg)		27	38	53	68

Sieving coefficients		
Albumin	66,500	< 0.001
Myoglobin	17,053	0.1
β_2-microglobulin	11,731	0.7
Inulin	5,200	1

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 %.

Membrane material	Helixone®
Sterilisation method	INLINE steam
Housing material	Polypropylene
Potting compound	Polyurethane
Units per box	24

Effective surface (m²)		1.0	1.4	1.8	2.2
K_OA Urea		866	1,068	1,394	1,429
Priming volume (mL)		53	74	95	116
Article number		**F00002385**	**F00002386**	**F00002387**	**F00002388**



Protect your Patient

High-Flux dialysis – improved survival. Better outcomes

Almost one in two patients with ESRD dies as a result of cardiovascular disease. That is why Cardioprotective Haemodialysis is a core principle at Fresenius Medical Care, as we work and learn to solve the challenges of modern dialysis. Each step we take is focused on minimising cardiovascular risks and extending patients' lives. In recent years, several studies have demonstrated that patients show improved long-term survival when treated with High-Flux dialysers. Hence, the new FX classix dialysers are a fundamental component of our SPOT programme and help you to protect your patient – day by day.

State-of-the-art technologies enable advanced cardioprotective therapies.

- Efficient removal of uraemic toxins
- Higher clearances by design
- Optimised haemodynamics
- INLINE steam sterilisation
- Optimised use of resources

SPOT on:

- High-Flux dialysis and design benefits.

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F00004643 GB (2.0 BG-E&B 09.12)

- ✓ **EN 973, Type B**
- ✓ **High-quality rock salt**

esco Rock Salt Tablets

High-quality rock salt for regeneration purposes

Field of application

Water softening via ion exchange is the best way to obtain soft water. esco rock salt tablets provide the ideal application properties for use in water softening systems.

- High purity
- even dissolving
- constant quality control

esco Rock Salt Tablets

High-quality rock salt for regeneration purposes

Product range

Packaging size:	25 kg bag (40 x 25 kg per pallet)
Type of packaging:	PE bag
GTIN:	25 kg: 4003885170543

We would be happy to provide you with a sample.

For more information on this and other products, please do not hesitate to contact us.

Product quality

The deposits for esco industrial rock salt are located in the north of Germany. They naturally feature a high ratio of pure white salt crystals.
esco rock salt tablets complies with the requirements of EN 973, Type B for regeneration salts in ion exchangers.

Product properties

esco rock salt tablets is a mined product that was formed around 200 million years ago in the Zechstein sea. The high sodium chloride content of 99 % and the pure white color make esco rock salt tablets a first-class quality product.
The special shape of esco rock salt tablets ensures maximum solubility and dissolving speed.

Certification

esco production facilities hold valid certification to EN ISO 9001.

Service

We offer our customers first class service, guaranteed consistently high product quality and a reliable international delivery.

Company

esco – european salt company is the leading salt producer in Europe and exports significant quantities overseas. Water softening products are constantly being developed and exceed legal requirements. This is made possible by the company's extensive experience in the water softening products market.

esco
european salt company

esco – european salt company GmbH & Co. KG

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A K+S Group company
Version 0.0

Haemodialysis

Puristeril® 340

Cold Disinfectant for Haemodialysis Machines

Fresenius Medical Care

Puristeril® 340

Disinfecting Agent for Haemodialysis Machines Based on Peracetic Acid

Superior efficacy

- Puristeril® 340 shows the superior efficacy of a peracetic acid-based disinfectant.
- Peracetic acid is widely used for disinfection due to its exceptionally broad spectrum of microbiocidal activity at low concentrations and short exposure times.
- Puristeril® 340 decomposes in a non-toxic way. The following degradation reactions take place:

$2\ CH_3COOOH$ Peracetic acid	⇨	O_2 Oxygen $+ 2\ CH_3COOH$ Acetic acid
CH_3COOOH Peracetic acid $+H_2O$ Water	⇨	H_2O_2 Hydrogen Peroxide $+ CH_3COOH$ Peroxide + Acetic acid
$2\ H_2O_2$ Hydrogen Peroxide	⇨	O_2 Oxygen $+ 2\ H_2O$ Water

- After use Puristeril® 340 is easily removable by rinsing with water.
- Due to the low pH value, the necessary decalcification of haemodialysis machines is easily achieved.
- Puristeril® 340 is designed for cold disinfection. In principle it can be used for all haemodialysis systems like haemodialysis machines, water treatment devices and circuit pipes.

Specification

Puristeril® 340 contains peracetic acid and hydrogen peroxide.

Disinfection

Puristeril® 340 is bactericidal, fungicidal, sporicidal, virucidal (incl. HBV/HCV/HIV).
Use Puristeril® 340 in accordance with the instructions provided by the manufacturer of the machine. Puristeril® 340 can be used in all Fresenius Medical Care 2008, 4008 and 5008 haemodialysis machines as well as the GENIUS® system.
For disinfection of water treatment systems, proceed according to the manufacturer's instruction.

Testing for residual disinfectant

For safety reasons, a test to show the absence of residual disinfectant residues must be performed after the completion of the disinfection procedure. The absence of Puristeril® 340 is detectable by potassium iodide starch paper (art.no. 508 521 3).

Stability and storage

Properly stored, the disinfectant remains fully effective for 18 months after production. Keep container sealed at all times and store in an upright position. If possible, store in well-aired rooms at 5 to 25°C. Do not expose to direct sunlight.

Order information

Article	Quantity	Art. No.
Puristeril® 340	1 × 5 kg	508 562 1 (multilingual)
Puristeril® 340	1 × 10 kg	508 563 1 (multilingual)
Puristeril® 340 GENIUS®	1 × 3 kg	508 567 1 (multilingual)

Evaluations are available on request.

Fresenius Medical Care

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