DIASAFE®*plus*

... offering the **plus** in value

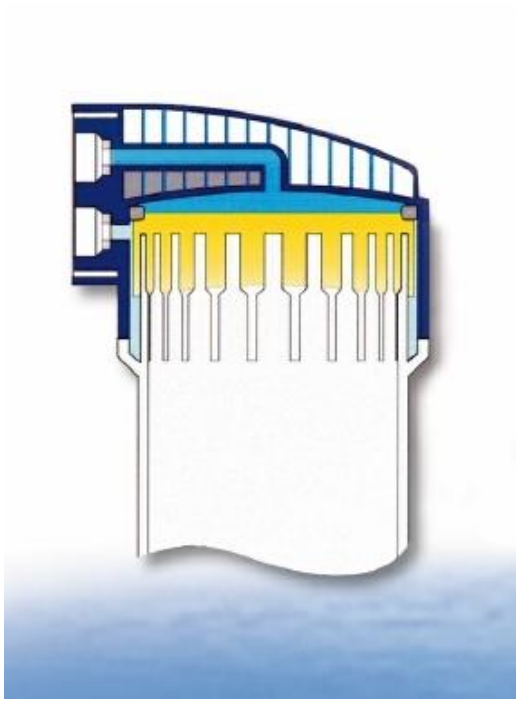
Ultrapure Dialysis Fluid - Good Dialysis Practice

Fresenius Medical Care

DIASAFE®*plus* Fluid Filter

DIASAFE®*plus* Fluid Filter

- New filter design concept
  - improved flow distribution/header design
  - hygienic connectors: DIAFIX® Lock System, exclusive to DIASAFE®*plus*
- fast and easy installation/exchange
- Increased surface area - 2.2 m²
  - increased safety
  - increased retention capacity
- Filter life-time*:
  - 100 treatments or 12 weeks
  - Improved chemical resistance



*** integrity test passed**

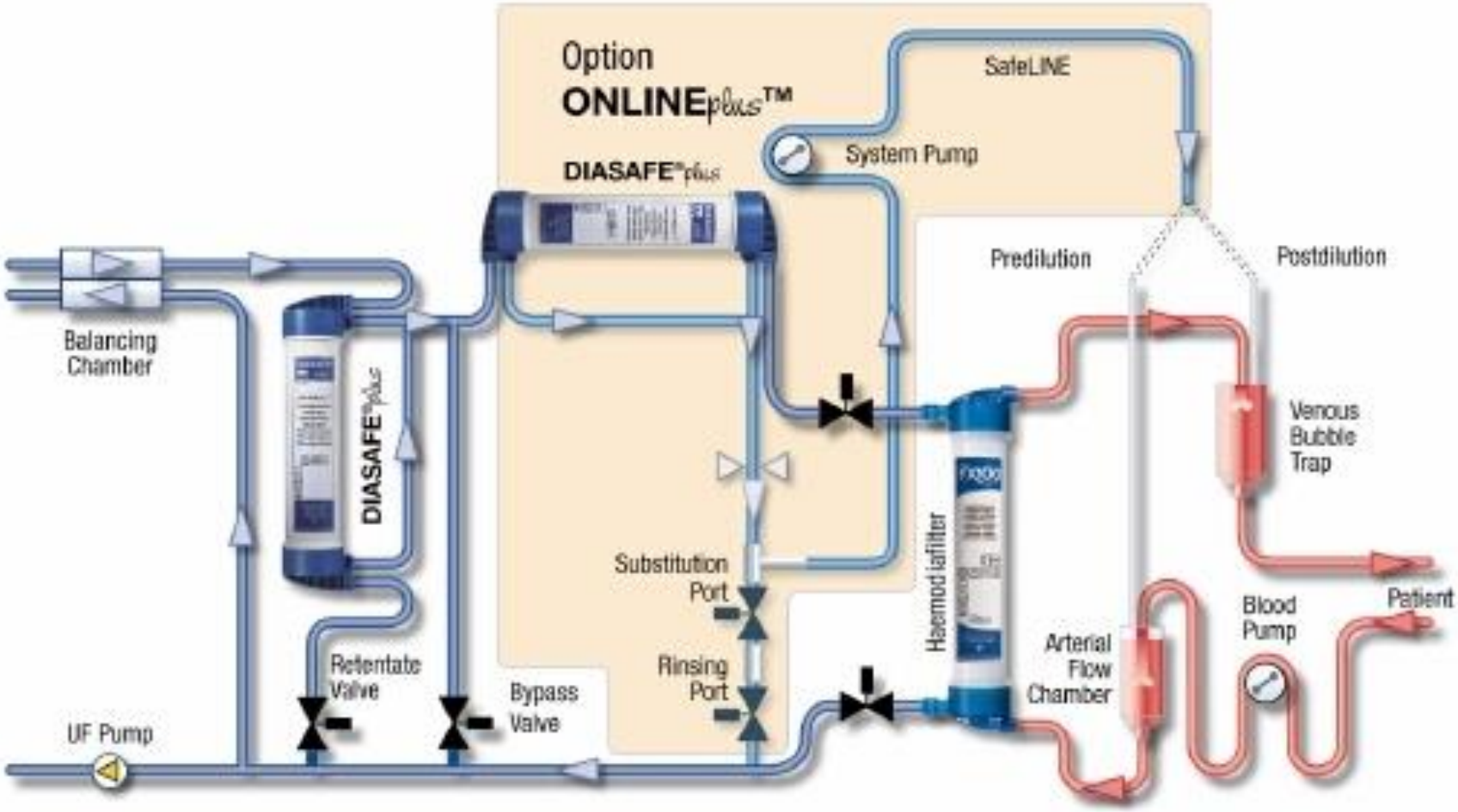
Special Filter Holder: Handling

The DIAFIX™ Lock System facilitates the simple, rapid and safe connection of the filters to the machine:

1. Open locking
2. Insert DIASAFE *plus*
3. Close locking

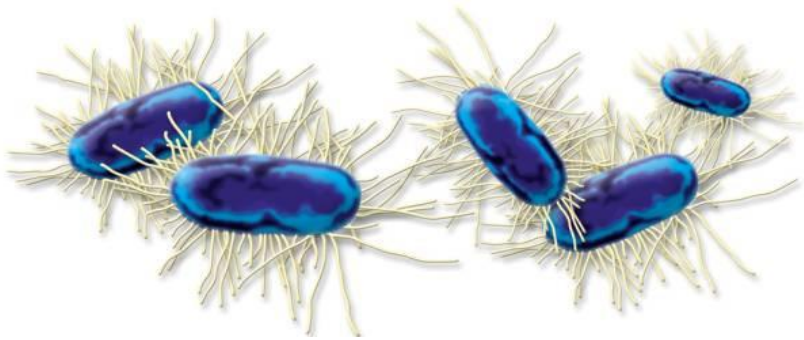
3 rapid handling steps only

DIASAFE® *plus*



Dialysis fluid quality

- Amount of dialysis fluid contacting the patients blood: 360 L / week
  (HD, QD = 500 ml/min, 3 x 4h)



- HDF: Higher QD
  Substitution fluid (directly injected into extracorporeal blood circuit)

- Removal of inorganic contaminations → water treatment system

  Microbiological quality → Ultrafilters

Backtransport in dialysers

Backdiffusion + Backfiltration = Backtransport

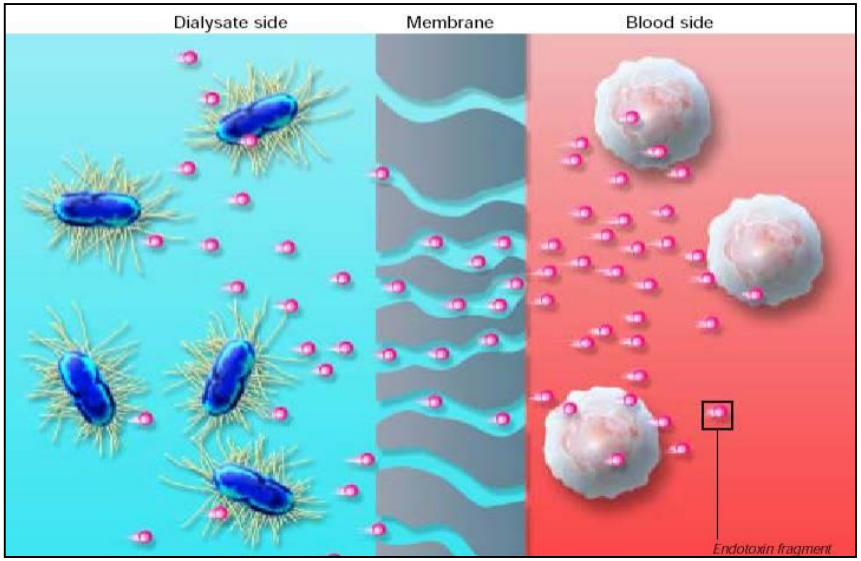
LPS

Lipid A fragments	2000 – 4000 Da
other LPS fragments	< 8000 Da

Peptidoglycan

Muramin peptides	400 – 1000 Da

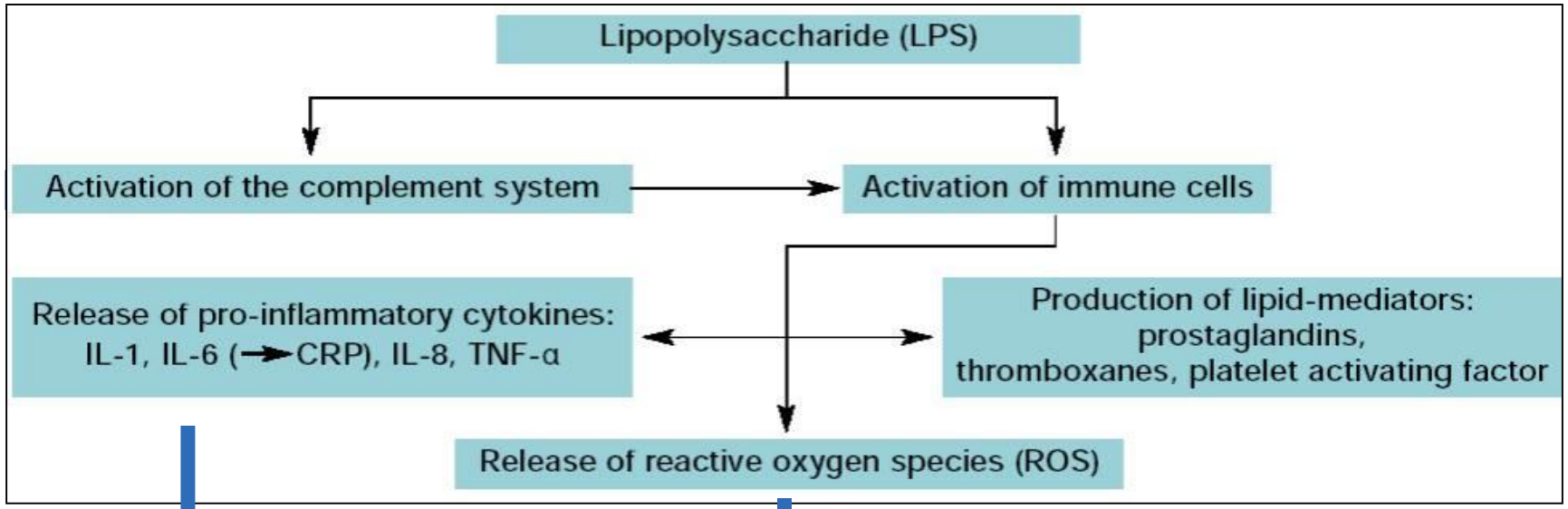
$ß_2$- M	11 800 D



Membranes function by size exclusion principles only.

→ ***The dialysis membrane is no "one-way street"***

Backtransport in dialysers

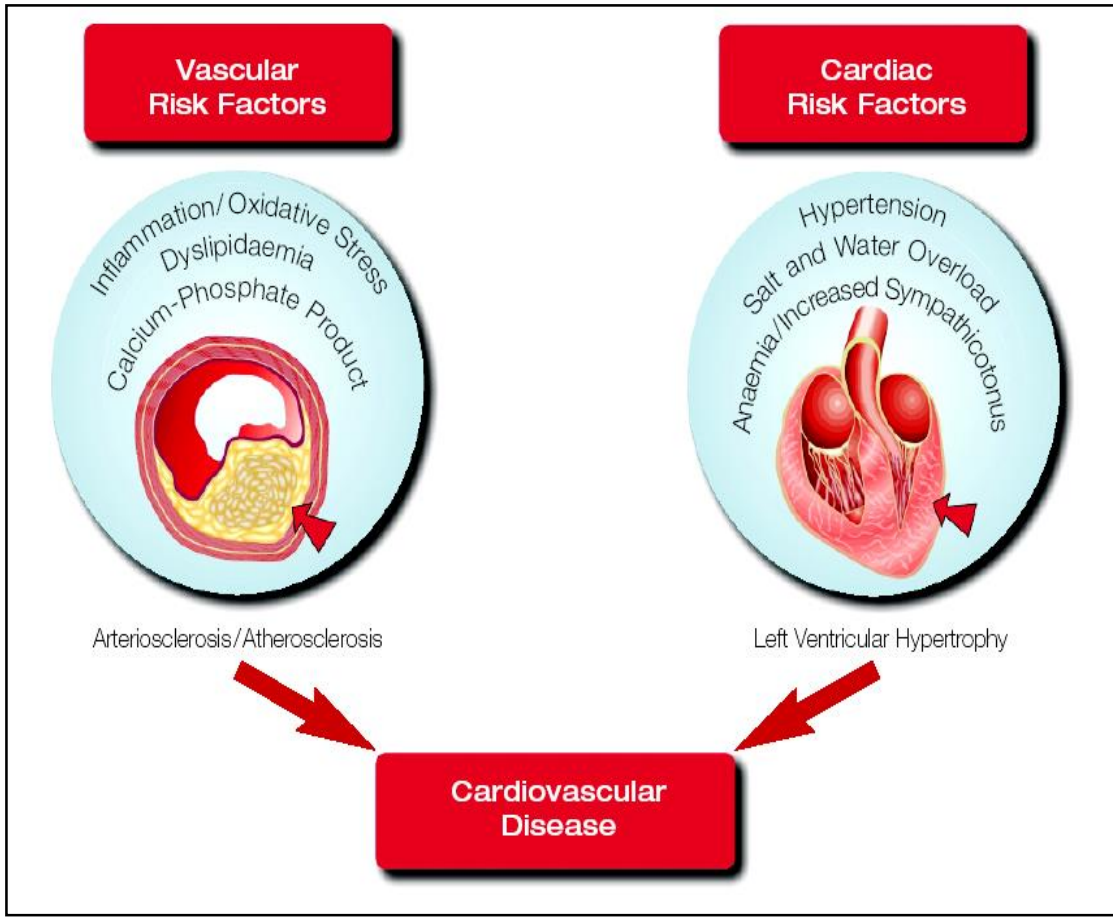


Inflammation

Oxidative stress

Clinical advantages of using ultrapure dialysis fluid

- Reduction of
  chronic micro-inflammation
  oxidative stress
- Lower inflammatory response
- (cytokine expression, c-reactive protein synthesis)
- Less hypoalbuminemia, as a consequence of lower inflammatory response
- Improved iron utilization and better response to EPO
  → better control of anaemia
- Reduction of plasma pentosidine levels (AGE compound)
- Higher quality treatment short- and long-term
- Lower incidence of dialysis-related Amyloidosis



Dialysis Fluid

- Components (water, concentrates) according to chemical and microbiological standards.
- Microbiological quality defined for dialysis fluid before filtration to increase safety:

	Water* European Pharmacopoeia 2005	Concentrate EN 13867 (2002) Ph. Eur. 2005	Dialysis Fluid	ONLINE substitution fluid (ISO Standard (draft))**
Microbial counts (CFU/mL)	<100	<100	<100	$<10^{-6}$
Endotoxin levels (IU/mL)	<0.25	<0.5	<0.25	<0.01 (below detection limit)

* Ph. Eur. 5.0: haemodialysis solutions, cencentrated, water for diluting (reverse osmosis)

** ISO Standard for dialysis fluid for haemodialysis and related therapies (draft)

- Maintenance and disinfection of all systems dialysis fluid comes into contact with is necessary!

Ultrapure Fluid

Incoming dialysis fluid filtered by two DIASAFE®*plus*- filters
→ resulting in ultrapure dialysis fluid:

Effective retention of microorganisms and endotoxins by DIASAFE*plus*® *(Weber et al. 2000)*

		Bacteria count [CFU/mL]	Endotoxins [IU/mL]
Effective retention by 1st DIASAFE*plus*®	Dialysis fluid	< 0.01	< 0.01
Effective retention by 2nd DIASAFE*plus*®	Dialysis fluid	0	< 0.01

→ Filtration across DIASAFE®*plus* effectively removes bacteria and endotoxins

DIASAFE® *plus*

Features

- high retention capacity for bacterial products
- cross-flow filtration
- hygienic connector technique
- new filter design
- filter life-time
- chemical resistance

Benefits

- ultrapure dialysis fluid
- no accumulation of contaminants
- no source of contamination
- high filtration rates at low pressure
- 100 treatments or 12 weeks
- disinfection and cleaning agents validated for HD machine

DIASAFE® *plus*

for **filtration of dialysis fluids**
and for
preparation of substituate solution
for ONLINE-HDF and HF treatments

Specifications DIASAFE®*plus*

Filtration rate	5 mL/min mmHg (3.75 L/min bar)
max. filtration pressure	2 bar
Membrane material	Fresenius Polysulfone®
Membrane surface	2.2 m^2
Housing material	Polypropylene
Potting material	Polyurethane
Sterilisation	INLINE Steam
Article No.	500 8201

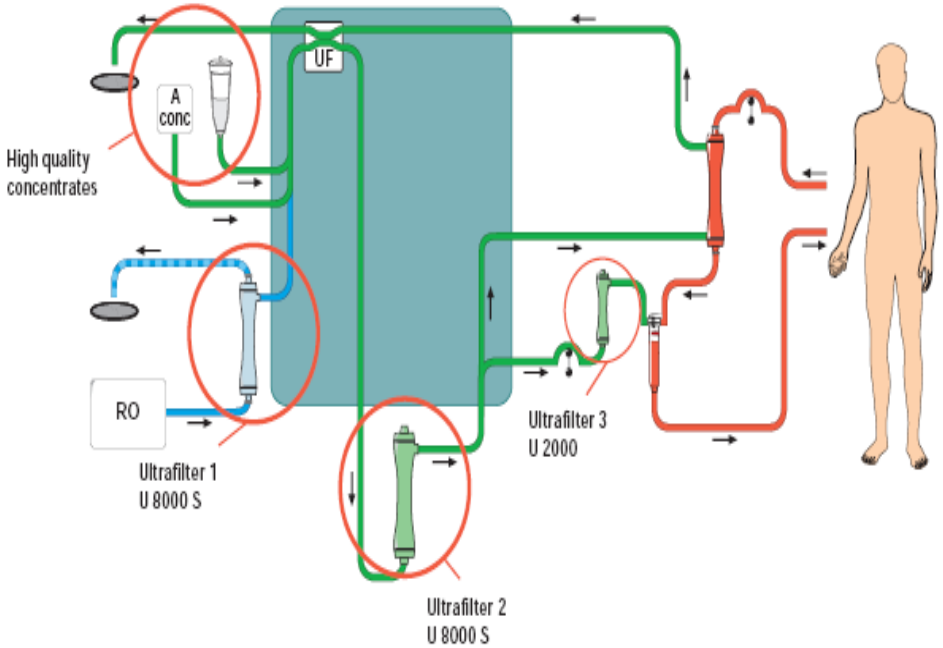
Fresenius Polysulfone®

Specification Diasafe®*plus*

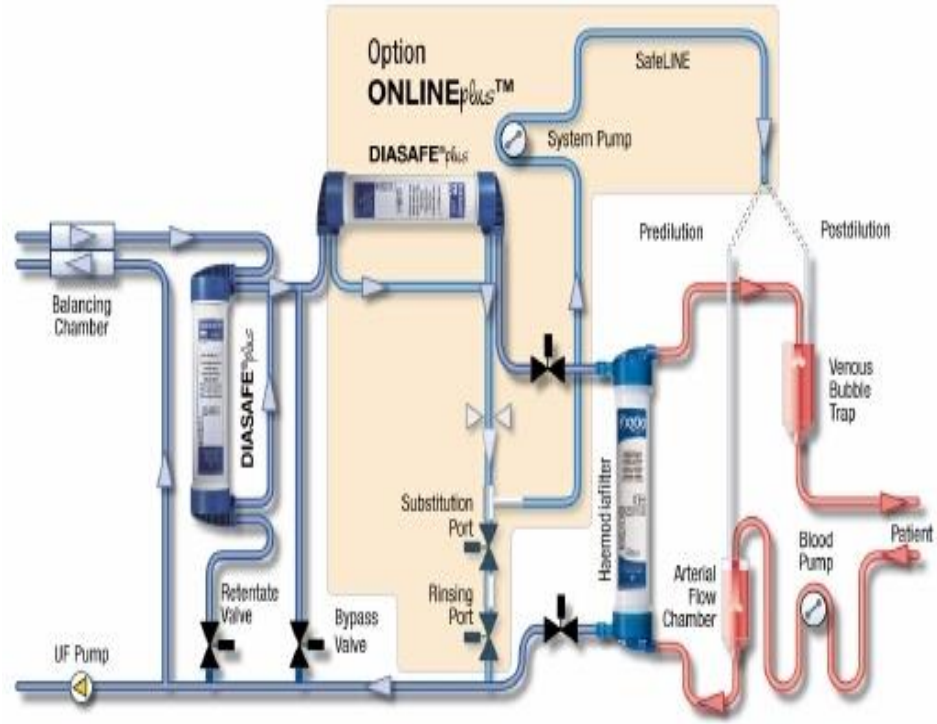
Installation/ Filter exchange	**max. 100 Treatments, resp. 12 Weeks**
Disinfection / Cleaning	**Citrosteril, 84 °C**
	Puristeril
	Diasteril
	Sporotal, 11x

Treatment and cleaning cycles with Sporotal are automatically counted.

Competitor Comparison: Dialysate Fluid Filter System



The ULTRA system by Gambro, with its set-up of ultrafilters, provides ultrapure dialysis fluid and non-pyrogenic substitution fluid for HDF or HF.



Gambro: 3 Ultrafilters for preparation of substitution fluid for HDF or HF

↔ FMC: only 2 DIASAFE*plus* filters necessary

Competitor Comparison: Dialysate Fluid Filter System

Machine	Dialysate Fluid Filter	Membrane	Disinfectants	Duration of Use
FMC 4008 / 5008	2 DIASAFE *plus*	Fresenius Polysulfon	Puristeril Citrosteril Diasteril	100 treatments resp. 3 months
Gambro	2 U8000S + 1 U2000S for ONLINE-HDF	Polyethersulfon	Peracetic acid Citric acid	4 weeks

Summary

DIASAFE®*plus…*

…ensures the safe production of ultrapure dialysis and substitution fluid.

…has excellent endotoxin-retention capabilities of its Fresenius Polysulfone® fibres.

And in additon:

- DIASAFE®*plus* can be used for a maximum of 12 weeks.
- The DIAFIX™ Lock System facilitates simple, rapid and safe connection of the filters to the machine.

New Brochure

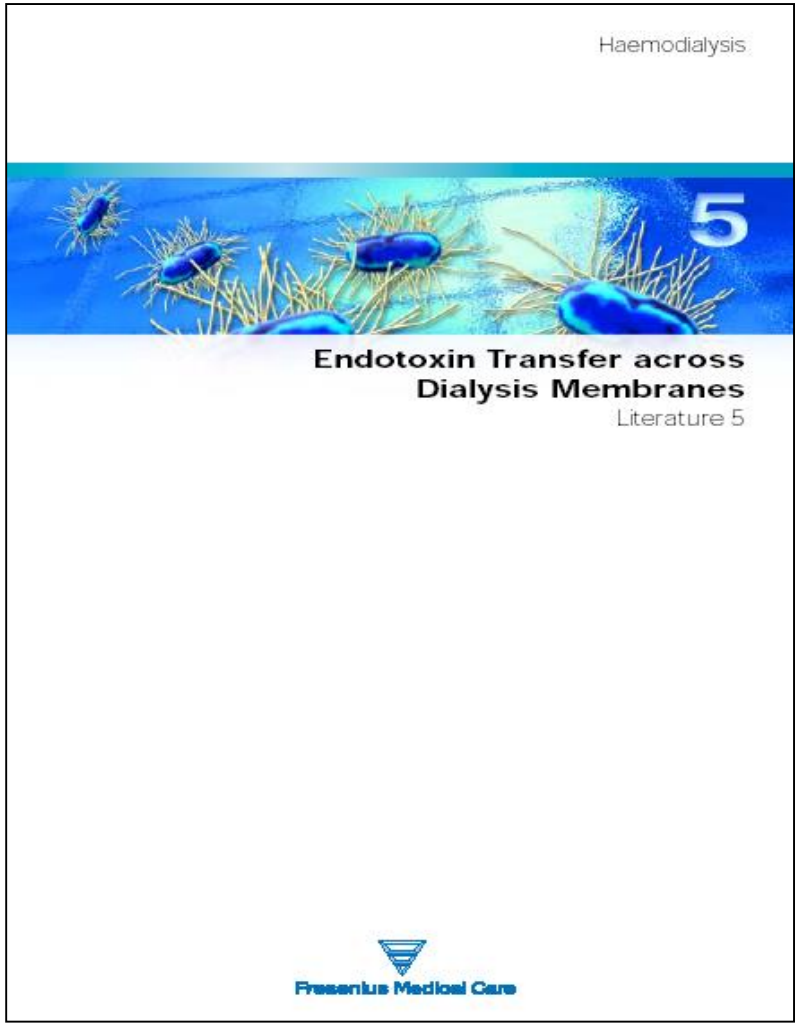
- Clinical advantages of using ultrapure dialysis fluid

- Cardioprotective Haemodialysis
  → ultrapure dialysis fluid supports reduction of chronic inflammation

- Ultrapure dialysis fluid is a mandatory prerequisite for ONLINE HDF
  →major selling point of the 5008

New Literature Compendium

Art no. 733 971 1



Thank you for your attention !