

stay•safe® CAPD/DPCA
Training Manual



# The ultimate system for your safety



### stay•safe® is environmentally friendly

The new Fresenius Medical Care CAPD generation stay•safe® is manufactured from Biofine®. Biofine® is a material from the group of Polyolefines developed by Fresenius Medical Care research.

The Biofine® material for the stay•safe® components is environmentally friendly – from production to use and later disposal. When incinerating, only carbon dioxide and water are produced, which means no hydrochloric acid, dioxins or furans are formed.

### stay • safe® is safe and easy to handle

The heart of the new <code>stay•safe®</code> is the revolutionary DISC. This central control switch regulates all treatment steps such as

- 1. Outflow
- 2. "Flush"
- 3. Inflow and inflow rate
- 4. Automated closing of the system with the PIN

The sequence of the individual steps is controlled by simply turning. Operating errors are essentially excluded. Clamps and breaking cones are not necessary.

# Your instructions for the stay • safe® system

These instructions will provide you with information on how to use the <code>stay•safe®</code> system. It is part of your CAPD-training provided by your dialysis center.

stay•safe® is a CAPD double bag system for single use. It allows you to make a safe disconnection with the catheter adaptor already closed. The proven PIN technology ensures the contamination-safe inline sealing of the system.

#### The DISC

① Outflow



2 Flush



3 Inflow and inflow speed



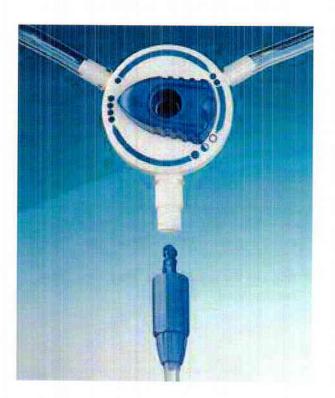
Automatic sealing of the system with the PIN



### The Organizer

The Organizer can be used on the infusion pole with an appropriate Holder, but also on a table without a support. Four suction cups ensure the secure attachment to the table.

- a Inserted DISC
- (b) Catheter extension with disinfection cap
- © DISC protection cap
- d New disinfection cap





#### 3. Washing hands

- Wash your hands thoroughly with a liquid soap (e. g. Freka®-SOFT) paying attention to the areas between the fingers
- Dry thoroughly using disposable towels



#### 4. Checking the solution bag

- Press lightly on the solution bag
- Take the solution bag out of the open outer wrapper and check whether the solution is clear
- Hang the solution bag onto a hook on the infusion pole. Separate the drainage bag from the solution bag
- Never use the solution if the bag is damaged or the fluid looks cloudy!



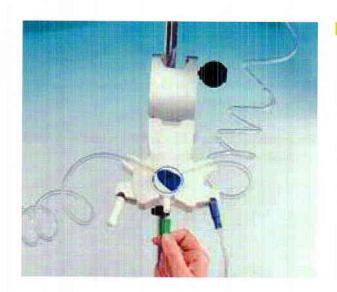
#### 5. Inserting the DISC into the Organizer

- Unroll the line between the solution bag and the DISC
- Press the DISC into the Organizer
- Press the lines into the line guides of the Organizer
- Unroll the line between the DISC and the drainage bag and hang the drainage bag onto the lower hook of the infusion pole



# Removing the protection cap of the DISC

Unscrew the protection cap of the DISC and discard it



### 10. Connecting to the system

 Unscrew the catheter extension from the disinfection cap and screw onto the DISC

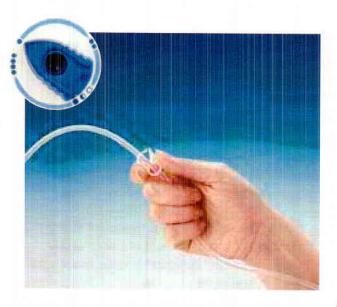
The used disinfection cap (with the used PIN) remains in the Organizer



#### 11. Outflow

Open the clamp on the catheter extension

The DISC is automatically in the outflow ("•") position. The outflow procedure starts



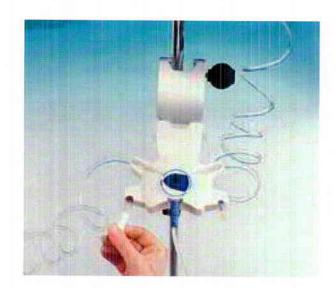
### 15. Closing the clamp

Close the white clamp on the catheter extension



### 16. Removing the protection cap

- Unscrew the protection cap from the new disinfection cap
- Screw the protection cap onto the used disinfection cap



### 17. Disconnecting

Unscrew the catheter extension of the DISC

The PIN remains firmly in the catheter extension



#### 21. Prepare the new bag

- Take a new bag
- Check the glucose concentration, expiry date and the volume of the solution as well as the bag and the outer wrapper for possible damage
- Turn the bag around with the drainage bag on top
- Place the bag in the outer wrapper on the heating plate
- Turn on the PD-THERMOSAFE®plus



# Cardioprotective Haemodialysis

# **Concentrates and Solutions**

Extended Product Range





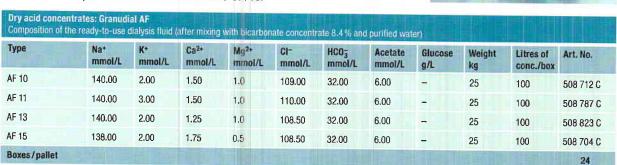
### AC-F - Liquid 1+44 acid concentrates in canisters

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

Туре	Na+ mmol/L	K+ mmol/L	Ca <sup>2+</sup> mmol/L	Mg <sup>2+</sup> mmol/L	CI- mmol/L	HCO <sub>3</sub> mmol/L	Acetate mmol/L	Glucose g/L	Osmolarity mosm/L	Art. No. 4.7 L	Art. No. 7.8
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					KIN		F. L.			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 bibag® or Flexicart or liquid bicarbonate concentrate 8.4 %.





# Cardioprotective Haemodialysis

# **Concentrates and Solutions**

Product Range

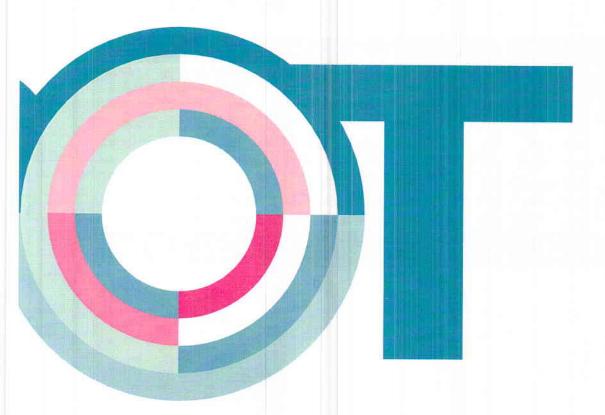






Moreover, both overall and cardiovascular mortality are markedly greater in ESRD patients than in the general population. This is why we put Cardioprotective Haemodialysis on the SPOT. A comprehensive approach that includes services, products and therapies is needed to

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
- HighVolumeHDF®
- Advanced Fluid Management

# smartbag® 300 L - Liquid 1+44 acid concentrates

The smartbag® 300 L facilitates central concentrate supply at a minimum of storage space.



Туре	Na* mmol/L	K+ mmol/L	Ca <sup>2+</sup> mmol/L	Mg <sup>2+</sup> mmol/L	CI- mmol/L	HCO <sub>3</sub>	Acetate mmol/L	Glucose g/L	Osmolarity mosm/L	Art. No. 300 L
smart <i>b</i> ag® 211.25	138.00	2.00	1.25	0.5	108.50	32.00	3.00	1.00	290.80	F00 001 168
smartbag® 211.5	138.00	2.00	1.50	0.5	109.00	32.00	3.00	1.00	291.55	F00 003 068
smartbag® 311.25	138.00	3.00	1.25	0.5	109.50	32.00	3.00	1.00	292.80	F00 003 069
smart <i>b</i> 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 <i>b</i> 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 pall	et									600 L
Boxes/pallet										2

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

Code message: e.g.  $smartbag^{@}$  211.5 (2xx.x = K+ in mmol/L) (x1x.x = Glucose in g/L) (xx1.5 = Ca<sup>2+</sup> in mmol/L)

# 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.



Туре	Na* mmol/L	K+ mmol/L	Ca <sup>2+</sup> mmol/L	Mg <sup>2+</sup> mmol/L	CI- mmol/L	HCO3 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

### 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.



Туре	Na+ mmol/L	K+ mmol/L	Ca <sup>2+</sup> mmol/L	Mg <sup>2+</sup> mmol/L	CI- mmol/L	HCO3 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

# Rinsing Solutions

### 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.

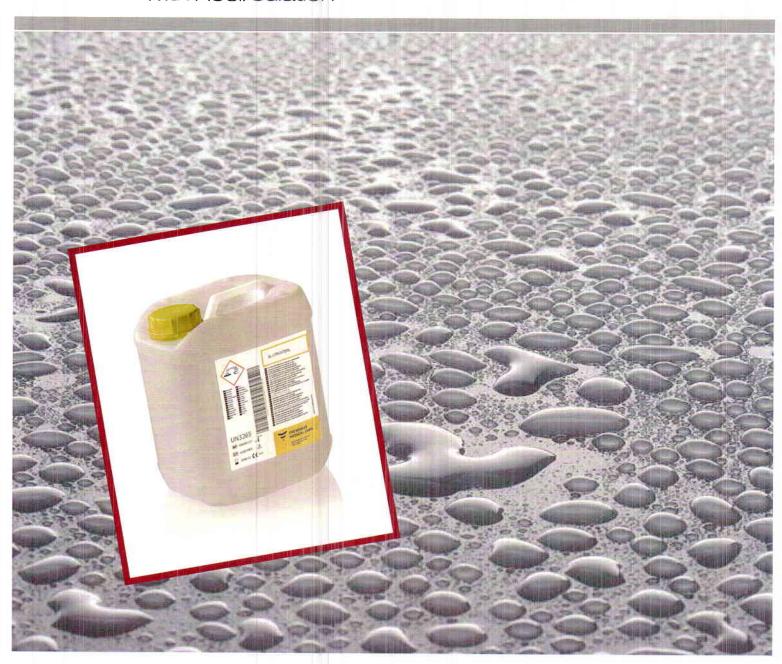


Saline 0.9% in Frekaflex bags							
Туре	Na+ mmol/L	CI- mmol/L	Art. No. 30 × 250 mL	Art. No. 15 × 500 mL	Art. No. 10 × 1000 mL		
Saline 0.9 %	154	154	F00 004 551	F00 004 550	F00 004 549		
Bags/pallet			1680	840	560		

Hygiene

# Citrosteril

Heat Disinfectant for Haemodialysis Machines with Recirculation





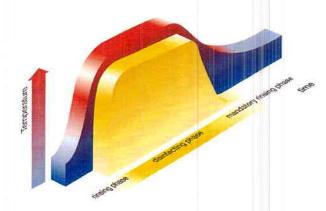
# Disinfectant for chemo-thermal disinfection of haemodialysis machines<sup>1</sup>.

- pH value 1.7 to 2.0
- excellent removal of limescale
- 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 and virucidal<sup>2</sup> including HBV/HCV/HIV.





#### Specification

#### 100g Citrosteril contains:

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

#### Ordering information

Unit	Language combination	Art. No.
1 × 5 L (single canister)	multilingual	F00005157
2 × 5L (carton)	multilingual	F00005158
6 × 2L (carton)	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.



# **Diasteril**

Heat Disinfectant for Haemodialysis Machine





### Diasteril

# Heat Disinfectant for Haemodialysis Machines

This alternative heat disinfectant is based on hydroxyacetic acid.

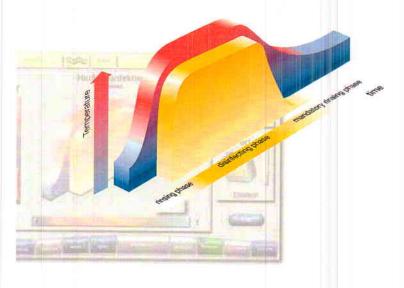
In nature, this physiological acid is present in grapes, sugar cane and in the fat of sheep's wool.

- Decalcification and cleaning effect.
- Broad spectrum of action: bactericidal, virucidal (incl. HBV/HCV/HIV)<sup>1-4</sup>
- Odourless and non-volatile
- Biologically degradable
- No crystallizing



#### Testing for residues

For safety reasons, a test for disinfectant residues must be performed after the completion of the disinfection procedure. The presence of Diasteril is detectable by using pH indicator strips pH-Fix 3.6-6.1 (art. no. 628 816 1).



#### Specifications

opeomodatons	
Composition	
100 g Diasteril contains 21.3 g of hydroxyacetic acid	
Storage	
Storage conditions	+5 to +30°C
Shelf life of original container	4 years

#### Ordering information

Article Volume		Language	Art. No.
Diasteril	6 litres	GB/I/E/P/F/GR	508 565 1
Diasteril	6 litres	D/NL/F/I/SK/CZ	508 564 1
Diasteril	6 litres	RU/SK/RO/PL/CZ/SLO	508 566 1

#### Literature

- Solbach W, Ohgke H: Verification of the sporicidal efficacy of the product Diasteril at 85 °C in the Fresenius 5008 dialysis machine; Institute for Hygiene and Med. Microbiology, University Lübeck, 20.12.2002
- Solbach W, Ohgke H: Test for disinfectant residues after rinsing with osmosis water in Fresenius 5008 dialysis machine; Institute for Hygiene and Med. Microbiology, University Lübeck, 19.12.2002
- Solbach W, Ohgke H: Test of Sporocidal Activity of Diasteril at 85°C in the 5008 S Dialysis machine with ONLINE plus; Institute for Hygiene and Med. Microbiology, University Lübeck, 12.07.2006
- Solbach W, Keller R: Examination of the residual content of disinfectant Diasteril in the ESS dialysis machine with ONLINEplus hydraulics including 1x acid CDS; Institute for Hygiene and Med. Microbiology, University Lübeck, 14.11.2006

Further evaluations available upon request.



Certificate DE13/81841407

The management system of

# esco - european salt company GmbH & Co. KG

Landschaftstr. 1 Hannover, 30159, Germany

has been assessed and certified as meeting the requirements of

ISO 9001:2015

For the following activities

Development, mining, manufacturing, treatment, storage, sales and distribution of products from brine, sea salt, rock salt and vaccum salt, pharmaceutical salt and byproducts, producing and operating of caverns, liquid gas storage

This certificate is valid from 21/07/2017 until 25/07/2019 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 29/04/2019

Issue 5. Certified since 03/09/2013

This is a multi-site certification.

Additional site details are listed on the subsequent page.

Authorised by



SGS United Kingdom Ltd Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

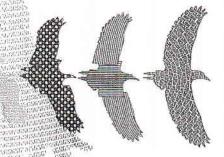
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Certificate DE13/81841407, continued



# esco - european salt company GmbH & Co. KG

ISO 9001:2015



Issue 5

Additional facilities

esco – european sait company GmbH & Co. KG
Werk Bernburg
Kustrenaer Weg 7, Bernburg 06406, Germany

esco – european salt company GmbH & Co. KG Werk Borth Karlstraße 80, Rheinberg, 47495, Germany

esco – european salt company GmbH & Co. KG Werk Braunschweig-Lüneburg Bahnhofstraße 15, Grasieben, 38368, Germany

> Ickenroth GmbH Auf der Heide 4, Staudt, 56424, Germany

Deutscher Straßen-Dienst GmbH Landschaftstraße 1, Hannover, 30159, Germany

Frisia Zout B.V. Lange Lijnbaan 15, NW Harlingen, 8861, Netherlands





Certificate DE13/81841407, continued



# esco - european salt company GmbH & Co. KG

ISO 9001:2015



Issue 5

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Park Lane, Culliganiaan 2G bus 1, Diegem, 1831, Belgium

esco france s.a.s. 49, ave. Georges Pompidou, Levallois-Perret Cedex, 92593, France

> Saline Cérébos s.a.s 1, rue de la Saline, Dombasie-sur-Meurthe, 54110, France

esco france s.a.s
ZA Solvay Porte Est, route des Digues, Dombasie-sur-Meurthe, 54110, France

Vatel, Companhia de Produtos Alimentaris, S.A. Quinta da Figueira - Sobralinho, Alverca, 2616-959, Portugal

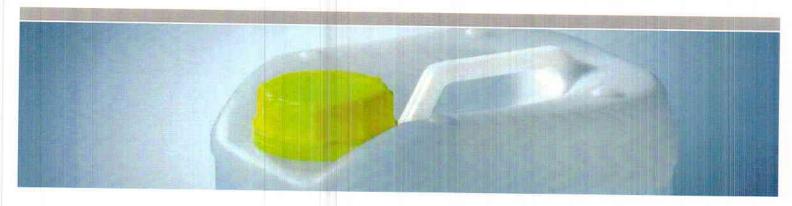
Vatel, Companhia de Produtos Alimentares, S.A. Avenida dos Operários Conserveiros, Olhao, 8700-909, Portugal

esco Spain, S.L. World Trade Center, Muelle de Barcelona, Edlf. Sur, 2ª planta, Barcelona, 08039, Spain





# Cleaning and disinfecting the system hydraulics



#### System processing

Any use of non-approved preparations may cause damage to the system and destroy the structure of applied DIASAFE®plus filters, resulting in a deterioration of the retention rate. Thus, only those disinfectants and cleaning agents mentioned in the instructions for use of the HD system should be used.

#### Disinfection

After each treatment, the system hydraulics must be disinfected with a decalcifying disinfectant to remove calcifications and microorganisms. Otherwise, malfunctions may occur depending on the concentrates used and the bicarbonate concentration. We recommend to disinfect dialysis machines again after a downtime of 72 hours.

The GENIUS® therapy system is disinfected using the peracetic acid vapour of Puristeril 340 GENIUS® and ultraviolet light. In this combination, peracetic acid has a high antimicrobial effect.

#### Cleaning

To remove potential organic deposits resulting from high-flux dialysis treatments, we recommend a weekly cleaning procedure with the alkaline Sporotal 100. During their operating life, DIASAFE®plus filters can be treated eleven times with Sporotal 100. Since alkaline preparations do not have any decalcifying effect, it is not possible to omit the decalcifying disinfection with acid disinfectants after the dialysis treatment.



# Cleaning and disinfecting the system hydraulics

### Disinfection and decalcification of singlestation reverse osmosis units (AquaUNO)

Fresenius Medical Care offers easy-to-use small containers for this application. Single station reverse osmosis units are decalcified with Citrosteril. However, Citrosteril cannot develop any disinfecting action if used at room temperature. Therefore small containers with Puristerilplus must be used for disinfecting single station reverse osmosis units.

#### Mechanism of antimicrobial action<sup>1</sup>

#### Peracetic acid, hydrogen peroxide

Damage of the cell wall through oxidation of membrane proteins, resulting in oxidation of liberated fatty acids, proteins, DNA, etc. Damage of the envelope of enveloped viruses as well as oxidation of the coat proteins.

#### Organic acids (citric acid, glycolic acid)

Destruction of the phospholipid layers in the cell membrane; disturbance of the intracellular pH balance; formation of Ca/Mg salts or salt complexes in the case of citric acid; activity strongly increased by an increase in temperature.

#### Sodium hypochlorite

Reaction of the released chlorine with organic substances, e.g. with the cell wall and cell proteins. In aqueous solutions hypochlorous acid (HOCI) is formed which has an oxidizing effect through the release of oxygen.

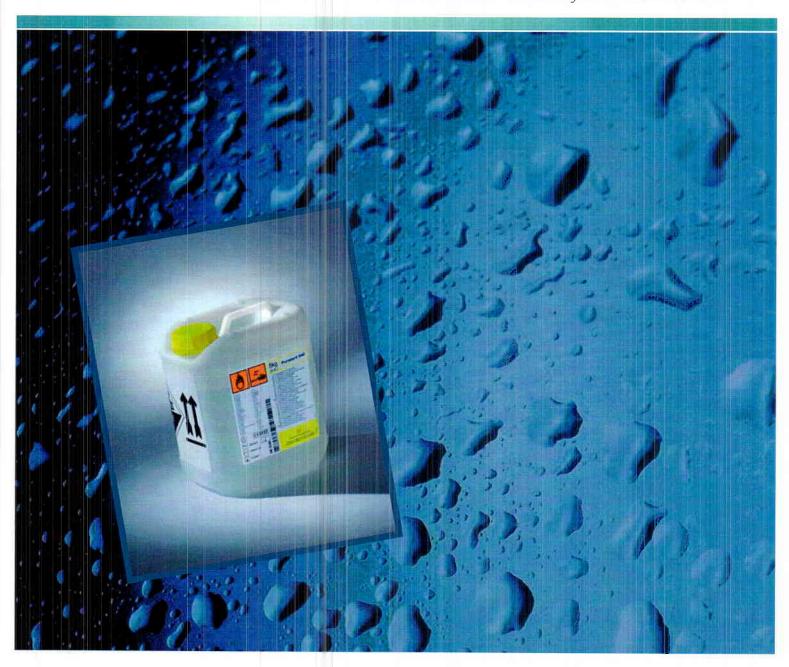
### Properties of the products approved for Fresenius Medical Care dialysis systems

	Citrosteril	Diasteril	Puristeril <i>plus</i>	Puristeril 340	Sporotal 100
Active ingredients	Citric acid, malic acid, lactic acid	Hydroxyacetic acid (glycolic acid)	Peracetic acid, hydrogen peroxide	Peracetic acid, hydrogen peroxide	Sodium hypochlorite, potas- sium hydroxide solution
Antimicrobial action	Heat disinfectant (dialysis machine 84 °C)	Heat disinfectant (dialysis machine 84°C)	Cold disinfectant (dialysis machine 37 °C)	Cold disinfectant (dialysis machine 37 °C)	Cold disinfectant (dialysis machine 37 °C)
Decalcifying	Yes	Yes	Yes	Yes	No
Cleaning	Limited effect	Limited effect	Limited effect	Limited effect	Excellent effect
Material compat- ibility (4008, 5008, DIASAFE® plus)	No restriction	No restriction	No restriction	No restriction	Eleven treatments with DIASAFE® plus during filter life
Storability after manufacture	2 years at 5-25°C	4 years at 5-30°C	2 years at 5-30 °C	18 months at 5-25 °C	12 months at 5-25 °C
Odour	Almost odourless	Almost odourless	Faint odour of acetic acid	Acrid	Faint odour of hypochlorite
Testing of residual disinfectant	Not required	With pH-Fix 3.6+6.1 (part no. 6288161)	with potassium-iodide starch paper (part no. 5085211)	with potassium-iodide starch paper (part no. 5085211), not required for GENIUS® Therapy System	with potassium-iodide starch paper (part no. 5085211)
Used dilution	1 + 24	1 + 24	1 + 24	1 + 24	1 + 34
Consumption 4008 without/with DIASAFE®plus	Approx. 50/66 mL	Approx. 50/66 mL	Approx. 50/66 mL	Approx. 50/66 mL	Approx. 37/49 mL
Consumption 4008 ONLINE <i>plus</i> / 5008/5008S	Approx. 82/96/90 mL	Approx. 82/96/90 mL	Approx. 82/96/90 mL	Approx. 82/96/90 mL	Approx. 61/72/65 mL

<sup>1</sup> Wallhäußers Praxis der Sterilisation. Edited by: Kramer A, Assadian O. Stuttgart, Germany: Georg Thieme Verlag; 2008



Puristeril® 340 Cold Disinfectant for Haemodialysis Machines



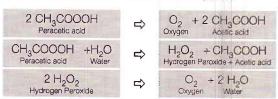


### Puristeril® 340

### 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:



- After use Puristeril<sup>®</sup> 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)

