Dialysis Fluid Filter DIASAFE®*plus*

Atitikimas 14 pirkimo daliai

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

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

Fresenius Polysulfone®

Technical data

	DIASAFE®*plus*
Membrane material	Fresenius Polysulfone®
Effective surface (m²)	2.2
Housing material	Polypropylene
Potting compound	Polyurethane
Sealings	Silicone
Filtration rate	5 mL/min mmHg (3.75 L/min bar; max. 2 bar)
Operating time	Standard HD: max. 12 weeks ONLINE HF/HDF, ONLINE priming/rinsing: max. 12 weeks or 100 treatments
Disinfection	Puristeril® 340 (peracetic acid); Diasteril® (hydroxyacetic acid) or Citrosteril® (citric acid); Sporotal® 100 (sodium hypochlorite) max. 11 times
Units per box	12
Art.-No.	**500 820 1**

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

Hygiene

Citrosteril

Heat Disinfectant for Haemodialysis Machines with Recirculation

FRESENIUS MEDICAL CARE

Citrosteril

Heat Disinfectant for Haemodialysis Machines with Recirculation

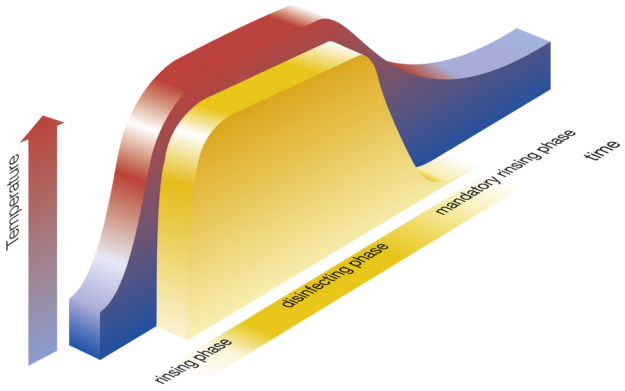
Disinfectant for chemo-thermal disinfection of haemodialysis machines[1].

- 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 micro-biocidal activity and works bactericidal and virucidal[2] including HBV/HCV/HIV.



Specification

100 g 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 × 5 L (carton)	multilingual	F00005158
6 × 2 L (carton)	multilingual	508 536 1

Literature:

1. 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
2. Labor Dr. Merk & Kollegen, Ochsenhausen: Antiviral efficacy of Citrosteril against bovine Parvovirus, 9.9.2005

Further information is available on request.

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Atitikimas 19 pirkimo daliai

Puristeril®*plus*

The Superior Solution for Cold Disinfection

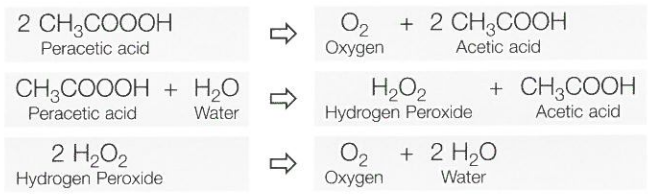
Fresenius Medical Care

Puristeril®*plus*

The disinfectant Puristeril®*plus* combines the outstanding advantages of peracetic acid with substantially increased convenience in transportation and handling.

Superior efficacy and environmental friendliness

- Puristeril®*plus* shows the superior efficacy of a peracetic acid based disinfectant[1,2]. Peracetic acid is widely used for disinfection due to its exceptionally broad spectrum of microbicidal activity in low concentrations and short exposure times[3,4,5].
- Puristeril®*plus* decomposes in a non-toxic way. The following degradation processes take place:



- After use Puristeril®*plus* is easily removable by rinsing with purified water[6].
- The use concentration of Puristeril®*plus* has a pH of approximately 2.8, thus the necessary decalcification of haemodialysis machines is easily achieved.
- Puristeril®*plus* is designed for cold disinfection. In principle it can be used for all haemodialysis systems like haemodialysis machines, water treatment devices and ring mains.

Convenience in transportation and handling

Due to the altered concentration of the active substances, Puristeril®*plus* offers substantially increased convenience in transportation and handling.

- **Transportation: Classification as NO DANGEROUS GOODS**
  A major improvement is achieved by the fact, that Puristeril®*plus* is classified according to international transportation regulations (ADR, IMDG, IATA) as "no dangerous goods". No restrictions concerning transportation exist.
- **Handling: Less and smaller risks**
  Within the category "Dangerous Substances" Puristeril®*plus* is classified as showing lower risks in handling, thus also less safety precautions are necessary.
- **Odour: Weak smell of acetic acid**
  With Puristeril®*plus* the problem with the pungent odour of peracetic acid is solved. Puristeril®*plus* has an odour similar to that of weak acetic acid.

When using Puristeril®*plus* together with high-flux membrane treatments it is recommended to carry out a regular alkaline cleaning (for example using Sporotal®100), in accordance with the instructions provided by the manufacturer of the machine.

Specification		
	Art. No.	Language combination
Puristeril®*plus*	508 570 1	D/NL/F/GB/S/DK
Puristeril®*plus*	508 571 1	E/P/I/H/HR/GR
Puristeril®*plus*	508 572 1	RUS/SK/RO/PL/SLO/GB

Quantity/canister: 5 kg
Canisters/pallet: 90
Shelf life: 2 years
Storage conditions: +5°C to +30°C

Disinfection programmes: Puristeril®*plus* can be used in all FMC 4008 and 2008 haemodialysis machines specifically in the programmes I (F-D-M) or III (F-D-M-HR)

Testing for freedom of residues: For safety reasons, a test for freedom from disinfectant residues must be performed after the completion of the disinfection procedure. The presence of Puristeril®*plus* residues in a concentration above the haemolytic limiting concentration is detectable by either potassium iodide starch paper or colour test strips for peracetic acid (Merck 1.10084).

LITERATURE

1. Solbach W, Ohgke H: Verification of the sporicidal efficacy of the product Puristeril®*plus* at 37°C in 4008 H(E) - 4008 B(S) Dialysis Systems (Fresenius Medical Care); Institute for Hygiene and Med. Microbiology, Medical University Lübeck, 7.3.2000
2. Solbach W, Ohgke H: Hygienic Evaluation of the Disinfectability of the Port of the Dialysis System 4008 (E)/(H) – 4008 B (S) using the disinfectant Puristeril®*plus* (Fresenius Medical Care); Institute for Hygiene and Med. Microbiology, Medical University Lübeck, 31.3.2000
3. Jentsch G: Peracetic Acid – a Disinfectant Agent; Hyg. Med. 3 (1978) 230–233
4. Wallhäußer KH: Praxis der Sterilisation – Desinfektion – Konservierung; Georg Thieme Verlag Stuttgart – New York 1995:511
5. Werner HP (Institute for Hygiene, Johannes-Gutenberg-University, Mainz, Germany): Disinfectants in Dialysis: Dangers, Drawbacks and Disinformation, Nephron 49; (1988), 2
6. Solbach W, Ohgke H, Senkpiel K: Test for disinfectant residues after rinsing with reverse osmosis water in 4008 E (H) – 4008 B (S) dialysis systems (Fresenius Medical Care); Institute for Hygiene and Med. Microbiology, Medical University Lübeck, 13.3.2000

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Fresenius Medical Care

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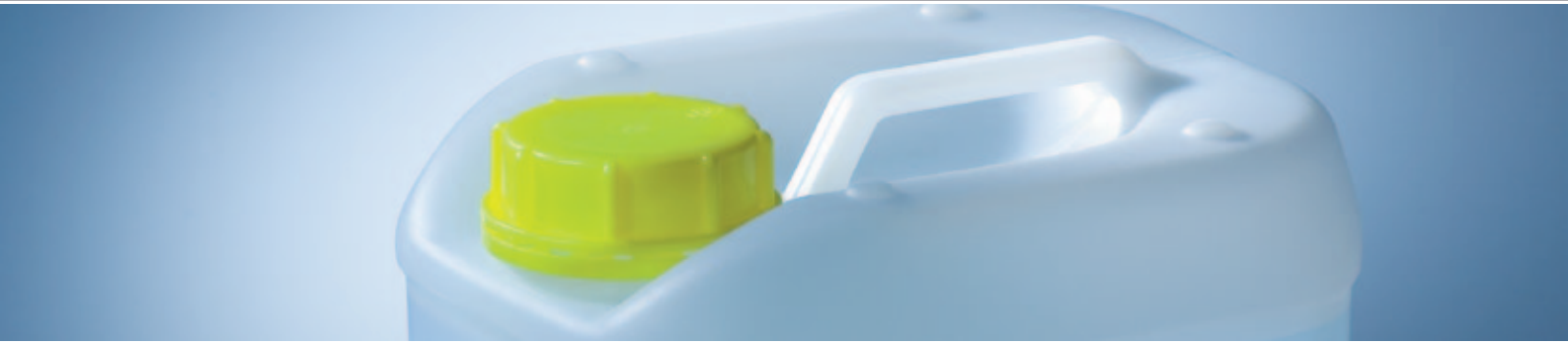
Cleaning and disinfecting the system hydraulics



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.

FRESENIUS MEDICAL CARE

Cleaning and disinfecting the system hydraulics

Disinfection and decalcification of single-station 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 Puristeril*plus* must be used for disinfecting single station reverse osmosis units.

Mechanism of antimicrobial action[1]

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 (HOCl) is formed which has an oxidizing effect through the release of oxygen.

Atitikimas 18, 19, 20 pirkimo dalims

Properties of the products approved for Fresenius Medical Care dialysis systems

	Citrosteril	Diasteril	Puristeril*plus*	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, potassium 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 compatibility (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*plus*/ 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

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

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Atitikimas 36, 37, 38 pirkimo dalims

TauroLock™

ANTIMICROBIAL CATHETER LOCK SOLUTIONS
PATENCY MAINTENANCE AND INFECTION CONTROL

Prophylaxis against catheter-related bloodstream infections (CRBSI)

Central-venous catheters (CVC) serve as short- or long-term vascular access devices in haemodialysis, oncology, parenteral nutrition, and intensive care. But they also carry the risk of catheter-related infections (CRI) and CVC malfunctions. Those infections can be triggered by microbial colonisation of the catheter, from which the microorganisms might further spread into the bloodstream. CRI can lead to chronic activation of the immune system and to septic symptoms that require an immediate removal of the catheter.

DIALYSIS

Infection rate (per 1,000 catheter days)	**Product**	**Evidence level*/p-value / literature**
2.7	Citrate 4 %	1B / p=0.003 / Winnicki et al. (Lit. 3.1.3)
0.67	TauroLock™-HEP500 (2x) / TauroLock™-U25.000 (1x)	
1.08	Heparin 5000 IU/mL	2B / p=0.023 / Fontseré et al. (Lit.3.1.12)
0.04	TauroLock™-HEP500	
1.59	Heparin 5000 IU/mL	2B / p=0.004 / Murray et al. (Lit. 3.1.13)
0.69	TauroLock™-HEP500	
2.4	Heparin 5000 IU/mL	1B / p=0.1 / Solomon et al (2010, Lit. 3.1.7)
1.4	TauroLock™	
3.25	Heparin 5000 IU/mL	2B / p=0.001 / Solomon et al (2012, Lit. 3.1.8)
1.33	TauroLock™-HEP500	

PARENTERAL NUTRITION

Infection rate (per 1,000 catheter days)	**Product**	**Evidence level*/p-value / literature**
1.0	Heparin 100 IU/mL	1B / p=0.005 / Tribler et al (Lit. 3.2.8)
0.0	TauroLock™-HEP100	
1.44	Saline 0.9 %	1B / p=0.002 / Wouters et al (Lit. 3.2.21)
0.33	2 % Taurolidine (Citrate-free)	
6.58	Saline 0.9 %	2B / p<0.001 / Touré et al (Lit. 3.2.13)
1.09	TauroLock™	

PAEDIATRIC ONCOLOGY

Infection rate (per 1,000 catheter days)	**Product**	**Evidence level*/p-value / literature**
1.4	Heparin 100 IU/mL	1B / p=0.001 / Handrup et al (Lit. 3.2.1)
0.4	TauroLock™-HEP100	
1.3	Heparin 100 IU/mL	1B / p=0.03 / Dümichen et al (Lit. 3.2.3)
0.3	TauroLock™	
2.3	Heparin 200 IU/mL	2B / p=0.004 / Simon et al (Lit. 3.2.5)
0.5	TauroLock™	

Heparin · 4 % Citrate · Saline · as in **NutriLock™** · **TauroLock™** or variant

* Acc. to criteria from the Center of evidence-based medicine

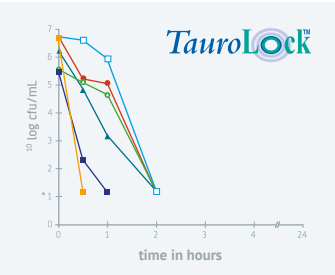
TauroPharm has developed catheter lock solutions to prevent CRI. The antimicrobial efficacy of **NutriLock™** and **TauroLock™** products is based on **taurolidine** – an active ingredient with a broad activity against bacteria and fungi (including MRSA and VRE). **TauroLock™** and **NutriLock™** solutions do not contain antibiotics.

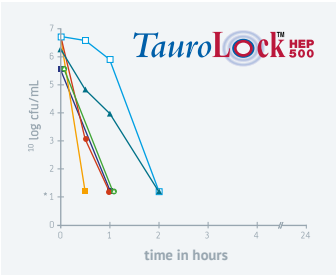
CDC and ERBP demand the use of antimicrobial lock solutions such as **TauroLock™**. More specifically, various national guidelines also recommend taurolidine-based lock solutions for dialysis, oncology, and parenteral nutrition (see literature 1).

TauroLock™, TauroLock™-HEP100/500, TauroLock™-U25.000, and NutriLock™ have been used successfully in regimens to reduce CRI.

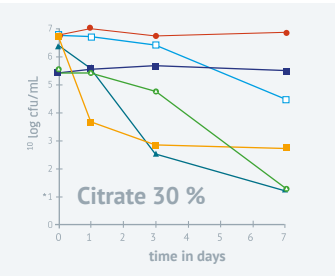
The basic formulation of TauroLock™ (consisting of 1.35 % taurolidine and 4 % citrate) was proven to significantly reduce catheter-associated bloodstream infections (see literature 2.2 and 2.3) and significantly reduce CRBSIs in paediatric oncology (see literature 3.2.1 and 3.2.3).

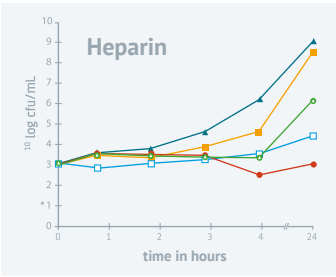
TauroLock™ is bactericidal and fungicidal within 2 hours**:





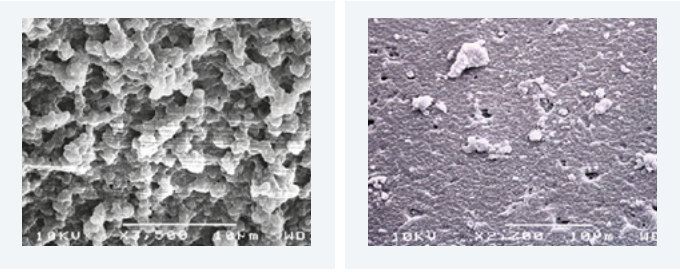
For comparison: activity of citrate** 30 % and heparin***





* Detection limit (10 cfu/ml) ** Own data *** See literature 4.4.

S. epidermidis S. aureus E. coli P. aeruginosa A. niger C. albicans



Heparin Lock
S. epidermidis biofilm *

Taurolidine-Citrate Lock
No colonisation*
* See literature 3.1.14

Prophylaxis against biological occlusion

TauroLock™ solutions ensure a threefold prophylaxis against occlusion within the catheter.

All variants contain **4 % citrate** as an anticoagulant. This concentration removes calcium safely and effectively from the clotting cascade.

For dialysis patients, we recommend **TauroLock™-HEP500** as the standard lock solution. Its efficacy regarding the patency rate is comparable to 5,000 IU/ml of heparin (see literature 3.1.8). This optional use of low concentrated **heparin** fosters an anticoagulative effect, as heparin binds to antithrombin.

Combining **TauroLock™-HEP500** and **TauroLock™-U25.000** (which contains 5,000 IU/ml of **urokinase**) can significantly reduce the rate of patency problems. Four clinical studies found that the **TauroLock™** 2+1 protocol yielded better outcomes than 4 % citrate or **TauroLock™-HEP500** alone (see literature 3.1.3 and 3.1.4).

TauroLock™ products and NutriLock™ are clinically safe

TauroLock™ products and **NutriLock™** have demonstrated good biocompatibility.

The concentration of 4 % citrate in all **TauroLock™** variants is safe and efficient, see recommendations in FDA Warning Letter, April 2000, ERBP, and various national guidelines (see literature 1.5 and 1.6).

Instillation of TauroLock™

For other products visit **taurolock.com**

1. Flush the device with 10 ml of saline.
2. Withdraw **TauroLock™** from the container, using a suitable syringe.
3. Instill **TauroLock™** slowly (not more than 1 ml per second, infants and children less than two years of age not more than 1 ml per 5 seconds) into the access device in a quantity sufficient to fill the lumen completely. Consult the manufacturer's instructions for the specific fill volume or specify fill volume during implantation. The volume has to be strictly respected. **TauroLock™** will remain inside the access device until the next treatment (up to a maximum of 30 days).
4. Prior to the next treatment **TauroLock™** must be aspirated and discarded in accordance with the institution's policy for infectious waste disposal.
5. Flush the device with 10 ml of saline.

Please follow the manufacturer's instructions for the venous vascular access device at hand. Each device requires a specific catheter lock volume.

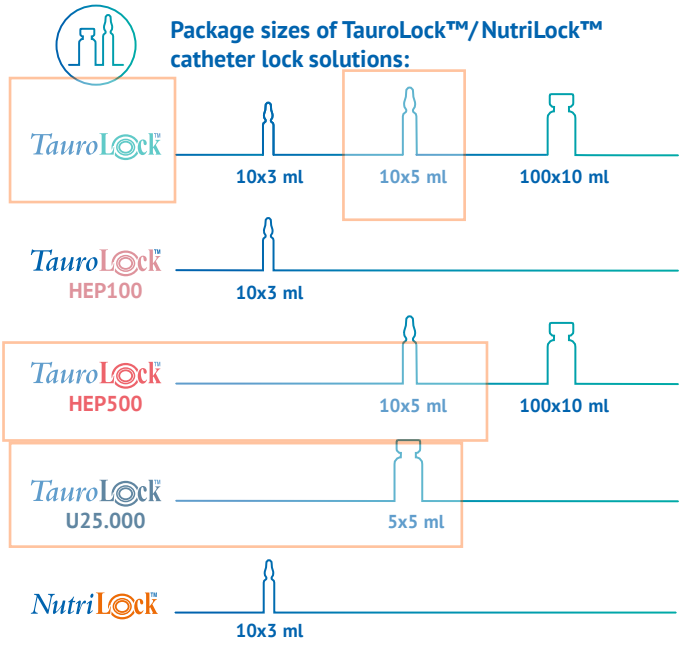
This protocol does not replace the manufacturer's instruction for use.

Instructions for use

TauroLock™

The right product for each patient	DIALYSIS	PARENTERAL NUTRITION	ONCOLOGY
TauroLock™	✓	✓ ✓ ✓	✓ ✓ ✓
TauroLock™ HEP100		✓ ✓ ✓	✓ ✓ ✓
TauroLock™ HEP500	✓ ✓ ✓		
TauroLock™ U25.000	✓ ✓ ✓	✓ ✓	✓ ✓
NutriLock™		✓ ✓ ✓	

Package sizes of TauroLock™/NutriLock™ catheter lock solutions:



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More information on **taurolock.com**

85100EN/49/23

Publications on safety and efficacy

1. GUIDELINES AND RECOMMENDATIONS

1.1. Guidelines for the Prevention of Intravascular Catheter-related Infections
O'Grady et al. and the Healthcare Infection Control Practices Advisory Committee *(HICPAC). Clin Infect Dis* 2011. DOI: 10.1093/cid/cir138

1.2. Infusion Standards of Practice (INS)
Gorski et al. *Journal of Infusion Nursing / Infusion Nurses Society* 2021. DOI: 10.1097/NAN.0000000000000396

1.3. Prevention of infections associated with implantable catheter/port systems for venous access (SF2H)
Hygienes */ French Society for Hospital Hygiene (SF2H)* 2012. Print.

1.4. Prevention of infections that originate in blood vessel catheters; Part 1 – Non-tunneled central-venous catheters (KRINKO)
Recommendation of the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at Robert Koch Institute. *Bundesgesundheitsblatt* 2017. DOI: 10.1007/s00103-016-2487-4

1.5. FDA issues warning on tricitrasol dialysis catheter anticoagulant.
Food and Drug Administration / U.S. Department of Health and Human Services. FDA Talk Paper 2000

1.6. Diagnosis, prevention and treatment of haemodialysis catheter-related bloodstream infections (CRBSI): a position statement of European Renal Best Practice (ERBP)
Vanholder et al. *NDT Plus* 2010. DOI: 10.1093/ndtplus/sfq041

1.7. Clinical Practice Guidelines for Vascular Access (NKF/KDOQI)
Guideline 6, Table III-2: Protocols for Urokinase Administration. *Kidney Disease Outcomes Quality Initiative (KDOQI), National Kidney Foundation (NKF)* 2000. DOI: 10.1016/s0272-6386(01)70007-8

1.8. Dialysis standard of the German Society of Nephrology 2022
German Society of Nephrology (Deutsche Gesellschaft für Nephrologie, DGfN) 2022. Print.

1.9. Guideline for infection prevention and hygiene 2019 in addition to the German dialysis standard
German Society of Nephrology (Deutsche Gesellschaft für Nephrologie, DGfN) 2019. Print.

1.10. Clinical Practice Guideline – Vascular Access for Haemodialysis.
Kumwenda et al. *UK Renal Association* 2015. Print

1.11. Evidence-based criteria for the choice and the clinical use of the most appropriate lock solutions for central venous catheters (excluding dialysis catheters): a GAVeCeLT consensus
Pittiruti et al. *J Vasc Access* 2016. DOI: 10.5301/jva.5000576

1.12. ESPEN guideline on home parenteral nutrition
Pironi et al. *Clin Nutr* 2020. DOI: 10.1016/j.clnu.2020.03.005

1.13. ESPGHAN/ESPEN/ESPR/CSPEN guidelines on pediatric parenteral nutrition: Venous access
Kolacek et al. / ESPGHAN/ESPEN/ESPR/CSPEN working group on pediatric parenteral nutrition. *Clin Nutr* 2018. DOI: 10.1016/j.clnu.2018.06.952

1.14. Guidelines of the Italian Association of Pediatric Hematology and Oncology for the management of the central venous access devices in pediatric patients with oncohematological disease (AIEOP)
Cellini et al. *J Vasc Access* 2022. DOI: 10.1177/1129729820969309

1.15. Prevention of infections related to central-venous catheters – for patients, adults and children, receiving short- or long-term parenteral nutrition (SFNCM)
Schneider et al. *French Society for Clinical Nutrition and Metabolism (SFNCM)* 2019. Print.

1.16. Evidence-based recommendations for the use of permanent CVADs in paediatric oncology (GPOH)
Simon et al. *On behalf of the Society for Paediatric Oncology and Haematology (GPOH)* 2018.Print.xsw

1.17. S3-Guideline of the German Society for Nutritional Medicine (DGEM) in Cooperation with the AKE, the GESKES and the DGVS
Lamprecht et al. with the DGEM Steering Committee. *Clinical Nutrition in the Gastroenterology (Part 3) – Chronic Intestinal Failure. German Society for Nutritional Medicine (DGEM)* 2014. Print.

2. META-ANALYSES, REVIEW, SURVEY

2.1. Meta-analysis of the efficacy of taurolidine in reducing catheter-related bloodstream infections for patients receiving parenteral nutrition
Vernon-Roberts et al. *J Parenter Enteral Nutr* 2022. DOI: 10.1002/jpen.2363

2.2. Taurolidine lock solution for catheter-related bloodstream infections in pediatric patients: A meta-analysis
Sun et al. *PLoS ONE* 2020. DOI: 10.1371/journal.pone.0231110

2.3. Taurolidine lock solutions for the prevention of catheter-related bloodstream infections: a systematic review and meta-analysis of randomized controlled trials
Liu et al. *PLoS One* 2013. DOI: 10.1371/journal.pone.0079417

2.4. Review and update of the use of urokinase in the prevention and management of CVAD-related complications in pediatric oncology patients
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