



TauroLock™

ANTIMICROBIAL CATHETER LOCK SYSTEM
TO PROVIDE PATENCY AND INFECTION CONTROL

Prophylaxis against catheter related bloodstream infections:

Central venous catheters (CVC) are used as short or long term vascular access devices in hemodialysis, oncology, ICU and total parenteral nutrition. High risks for CVC malfunction are catheter related infections (CRI). These infections may be triggered by microbial colonization of the catheter and the microorganisms can spread from here to the bloodstream. CRI may develop septic symptoms which require the immediate removal of the catheter.

TauroLock™ catheter lock solutions **do not contain antibiotics** and were developed for prophylactic use. They reduce catheter related infections significantly (~ 90%).

The combination of citrate (4%) with (cyclo)-taurolidine and heparin/urokinase has excellent anticoagulative and antimicrobial properties also against resistant microorganisms like MRSA und VRE.

Therefore TauroLock™ is recommended in different guidelines (see ref. A.) such as the Hygiene Guidelines completing the German Dialysis Standard, the evidence-based recommendations of the German Society for Paediatric Oncology and Hematology (GPOH) and the hygiene guidelines of the University of Bonn (Germany).

Prophylaxis against biological occlusion in the catheter:

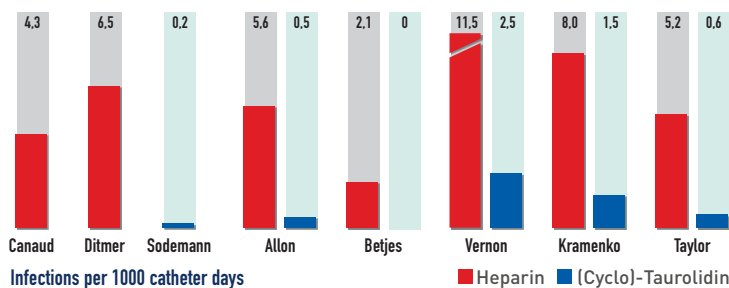
The TauroLock™ Catheter Lock System contains a threefold prophylaxis against occlusion in the catheter: All locking solutions contain 4% citrate as anticoagulant. This concentration removes calcium safely and effectively from the clotting cascade.

The optional use of low concentrated heparin supports an additional anticoagulative effect via binding to antithrombin. The prophylactic use of TauroLock™-U25.000 (which contains 25.000 IU of urokinase) achieves the best prophylaxis against occlusion by prevention of biological clotting.

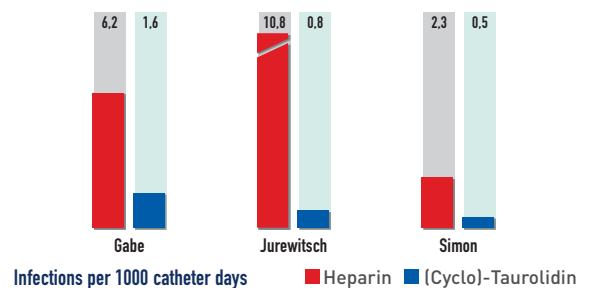
The decision which locking solution is most adequate depends on the individual patient situation. The alternative use of different locking solutions in the same catheter (e.g. TauroLock™-HEP500, TauroLock™-U25.000) is possible.

(Cyclo)-Taurolidin prevents catheter infections:

DIALYSIS



ONCOLOGY/PARENTERAL NUTRITION



TauroLock™ is safe:

The concentration of 4% citrate in TauroLock™ is according to the recommendation of the FDA, dated from April 2000, safe and efficient (ref.: FDA Warning Letter, April 2000).

No hypocalcemic effects due to high concentrated citrate solutions (30% resp. 46,7%), e.g. arrhythmia, cardiac arrest*, emboli**, tingling in the fingers and metallic taste observed***.

TauroLock™ is biocompatible and non toxic.

* Punt, C.D., Boer, W.E. Cardiac arrest following injection of concentrated trisodium citrate, Clinical Nephrology, 2008, 69: 117-118.

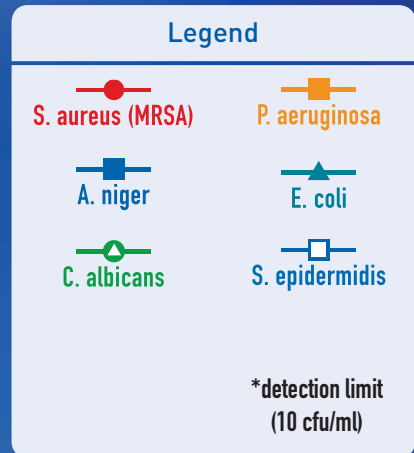
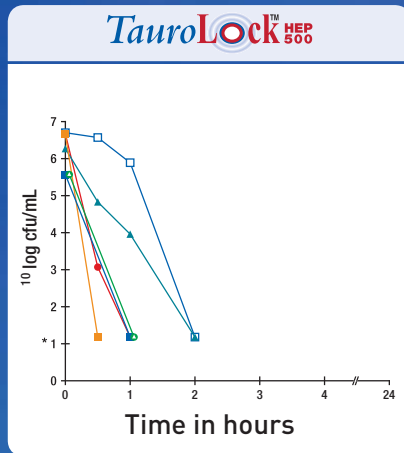
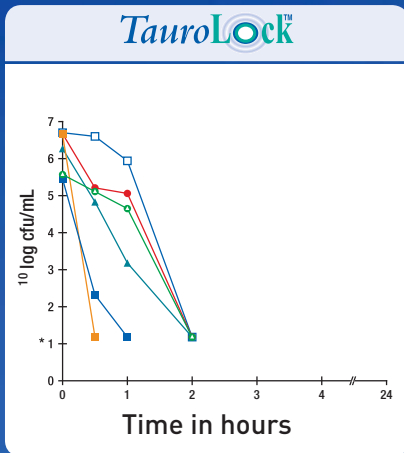
** Willicombe, M.K., Vernon, K., Davenport, A. Embolic Complications From Central Venous Hemodialysis Catheters Used With Hypertonic Citrate Locking Solutions, American Journal of Kidney Diseases, 2009, e-pub.

*** Polaschegg, H.-D., Sodemann, K. Risks related to catheter locking solutions containing concentrated citrate, Nephrol. Dial. Transplant. 2003, 18: 2688-2690.

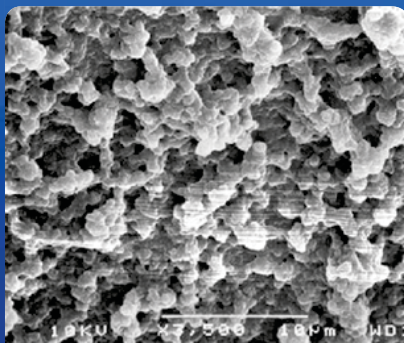
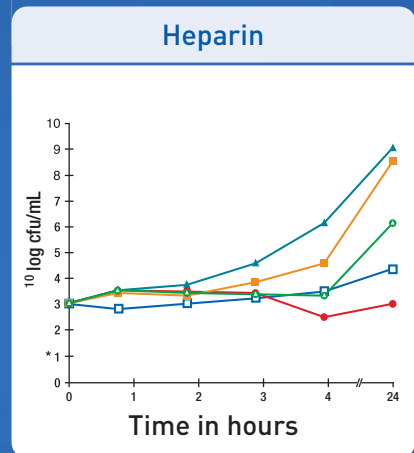
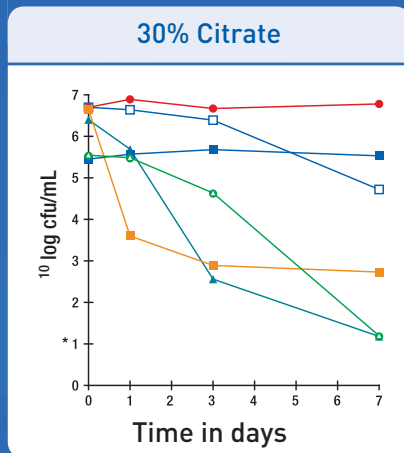
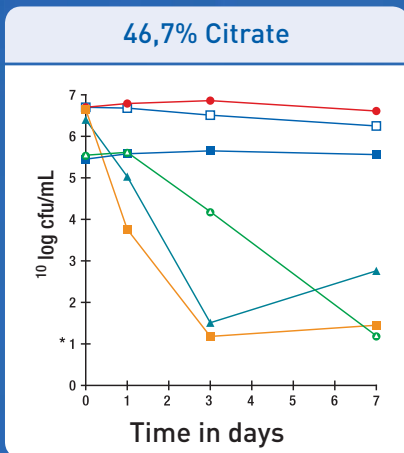


TauroLock™

TauroLock™ is bactericidal and fungicidal within 2 hours:

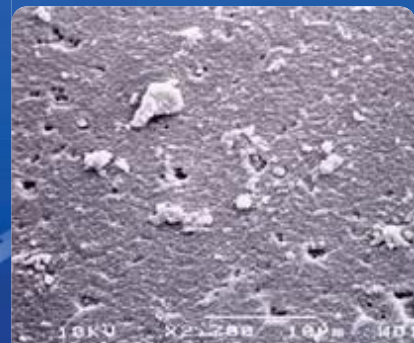


Clearly superior in comparison to the activity of Citrate and Heparin:



Heparin Lock – 7 months implanted – *S. epidermidis* biofilm covers surface completely

If used prophylactically, TauroLock™ prevents the development of a biofilm on the surface of the catheter lumen:



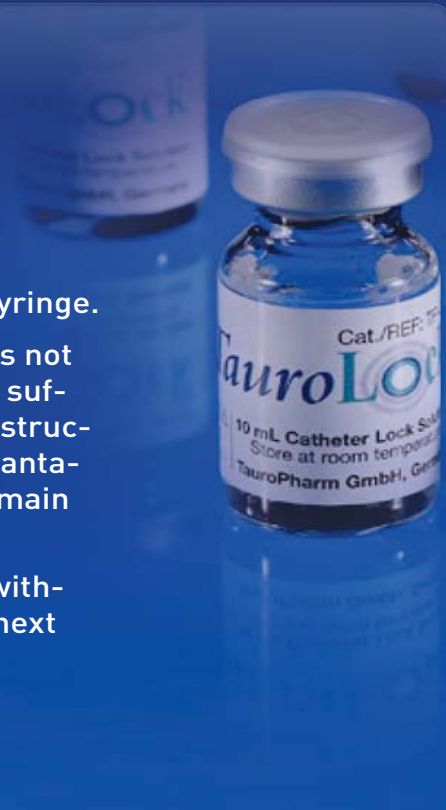
TauroLock™ 5 months implanted – No colonization

TauroLock™ catheter lock solutions are available in different containers:

Produkt	TauroLock™	TauroLock™ HEP	TauroLock™ HEP 560	TauroLock™ U 25000
Ampoule (10 x 5 mL)	●	●	●	
Ampoule (5 x 3 mL)	●			
Vial (100 x 10 mL)	●		●	
Vial (5 x 5 mL)				●

Instillation of TauroLock™

1. Flush the device with 10 mL of saline.
2. Withdraw TauroLock™ from the container using an appropriate syringe.
3. Instill TauroLock™ slowly (not more than 1 mL per second, infants not more than 1 mL per 5 second) 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.
4. If aspiration of TauroLock™ is needed and possible, it should be withdrawn from the port/catheter and discarded prior to initiation of next treatment.
5. Flush the device with 10 mL of saline.



Ordering information: TauroLock™ catheter lock solutions are delivered in boxes containing 5 ampoules (3 mL), 10 ampoules (5 mL) or in boxes containing 100 vials (10 mL).



Prevention of Catheter Related Blood Stream Infections (CRBSI)

Central venous catheters (CVC) are used as short or long term vascular access devices in hemodialysis, oncology, ICU and total parenteral nutrition. They are commonly applied as tunnelled subcutaneous access devices. These mono- or dual-lumen catheters are also compatible with titanium port systems.

Infection and thrombosis are the leading causes of catheter loss with intraluminal infections being more problematic than exit site infections. Therefore minimizing infection incidents is the most important challenge for reducing individual consequences for the patients (risk of endocarditis) and health care expenses.

Catheter related infections may develop septic symptoms which require the immediate removal of the catheter. A systemic antibiotic treatment to salvage the catheter is mostly not successful due to the lack of considerable inhibiting concentrations of the antibiotic substance inside the catheter and the adherence properties of micro organisms. Catheter related bacteraemia is a common complication of all central venous catheters with an incidence of 3 – 9 episodes per 1000 catheter days.

The Antibiotic Lock Technique (ALT) reduces the infection rates in HD catheters and port systems dramatically. It was first described by B. Messing in 1988:

The instillation of an antibiotic solution into the catheter during the interdialytic period can reduce the bacterial colonisation of the lumen and therefore prevent the development of a biofilm. Due to the leakage of the lock solution into the bloodstream, however, the prophylactic use of antibiotics is not recommended because of the resistance development of micro organisms and the corresponding side-effects (ototoxicity of gentamicin).

These aspects taken into account, the antimicrobial ingredient (cyclo)-taurolidine is an active ingredient for the prevention of catheter related blood stream infections. (Cyclo)-taurolidine acts via transferring methylol C-1 building blocks to the nucleophilic centres of microbial structure molecules. As a consequence cell walls of bacteria and fungi are destroyed. (Cyclo)-taurolidine is also active against highly resistant germs like MRSA, VRE and *Mycobacterium chelonae*.

(Cyclo)-taurolidine combined with citrate and heparin resp. urokinase provides the patency of the access device. The active antimicrobial ingredient is systemically non-toxic and is quickly degraded to the physiological amino acid taurine if inadvertently instilled into the blood stream.

The prophylactic use of TauroLock™ therefore solves the problem of catheter- and port-infections safely and effectively.

For these reasons TauroLock™ is recommended e.g. in the Hygiene Guidelines completing the German Dialysis Standard as well as in the evidence –based recommendations of the German Society for Paediatric Oncology and Hematology. (GPOH). It is also supported by the hygiene guidelines of the University of Bonn (Germany).

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