ANTI MICROBIAL 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)-taurodilidone and heparin/urokinase has excellent anticoagulative and anti-microbial properties also against resistant microorganisms like MRSA und VRE.

Therefore TauroLock™ is recommended in different guidelines such as the Hygiene Guidelines completing the German Dialysis Standard, the guidelines from the German Society of Applied Hygiene in Dialysis and the evidence-based recommendations of the German Society for Paediatric Oncology and Hematology (GPOH).

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™-HEP250.000 (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.

TauroLock™ prevents catheter infections:
TauroLock™ is bactericidal and fungicidal within 2 hours:

<table>
<thead>
<tr>
<th>TauroLock</th>
<th>Legend</th>
</tr>
</thead>
<tbody>
<tr>
<td>[Graph showing bacterial log cfu/mL over time in hours]</td>
<td>S. aureus (MRSA)</td>
</tr>
<tr>
<td>[Graph showing fungal log cfu/mL over time in hours]</td>
<td>A. niger</td>
</tr>
<tr>
<td>[Legend showing detection limits]</td>
<td>C. albicans</td>
</tr>
<tr>
<td>*detection limit (10 cfu/ml)</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>46.7% Citrate</th>
<th>30% Citrate</th>
<th>Heparin</th>
</tr>
</thead>
<tbody>
<tr>
<td>[Graph showing bacterial log cfu/mL over time in days]</td>
<td>[Graph showing bacterial log cfu/mL over time in days]</td>
<td>[Graph showing fungal log cfu/mL over time in hours]</td>
</tr>
</tbody>
</table>

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

- **Heparin Lock** — 7 months implanted — S. epidermidis biofilm covers surface completely
- **TauroLock™** — 5 months implanted — No colonization
Instillation of TauroLock™

Follow the manufacturer’s instructions that accompany the particular vascular access product utilized. Specific catheter lock volumes are associated with each device.

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 and children less than two years of age 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.

Product selection for application

<table>
<thead>
<tr>
<th>Product</th>
<th>TauroLock™</th>
<th>TauroLock™</th>
<th>TauroLock™</th>
<th>TauroLock™</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dialysis</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Oncology</td>
<td>● ● ●</td>
<td>● ● ●</td>
<td>● ● ●</td>
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<tr>
<td>Parenteral Nutrition</td>
<td>● ● ●</td>
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</tr>
</tbody>
</table>

TauroLock™ catheter lock solutions are available in different containers:

<table>
<thead>
<tr>
<th>Product</th>
<th>TauroLock</th>
<th>TauroLock HEP</th>
<th>TauroLock HEP</th>
<th>TauroLock HEP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ampoule (10 x 3 mL)</td>
<td>●</td>
<td>●</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ampoule (10 x 5 mL)</td>
<td>●</td>
<td></td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Vial (100 x 10 mL)</td>
<td>●</td>
<td></td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Vial (5 x 5 mL)</td>
<td>●</td>
<td></td>
<td></td>
<td>●</td>
</tr>
</tbody>
</table>

Manufacturer:

TauroPharm GmbH
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Tel.: +49 931 304299-0
Fax: +49 931 304299-29

ISO 13485

85100/08/14
1. GUIDELINES AND RECOMMENDATIONS


1.2. Diagnosis, prevention and treatment of haemodialysis catheter-related bloodstream infections (CRBSI): a position statement of European Renal Best Practice (ERBP)

1.3. Guidelines for the prevention and treatment of dialysis catheter-related bloodstream infections in haemodialysis patients


1.5. Evidence-based Recommendations for the Use of Current CVADs in Paediatrics. A. Simon, Society of Paediatric Haematology and Oncology. EPOI 2013, 3rd Edition

1.6. S3 — Guideline of the German Society for Nutritional Medicine (DiEMG) in cooperation with GesEkes and AXK: Nutritional support in the homecare and outpatient sectors


2. PUBLICATIONS: PROPHYLAXIS OF INFECTION IN DIALYSIS

2.1. A Meta-analysis of hemodialysis Catheter Locking Solutions in the Prevention of Catheter-Related Infection


2.8. The Targeted Use of Taurine Lock in Reduction of Episodes of Line Sepsis in the ‘High Risk’ Haemodialysis Population

M. A. Vermeersch, J. Godard, Poster during European Renal Congress 2006. Harrogate P025 (RA4422)

2.9. Preventing infections of central venous catheters with a taurolidine/citrate solution. O. Kramenkov, Western Galilee Hospital, Nahariya, Israel, Presentation at EDTNA/ERC Congress 2006, Madrid.


3. PUBLICATIONS: PROPHYLAXIS OF INFECTION IN ONCOLOGY

3.1. Central Venous Catheters and Catheter Locks in Children with Cancer: a Prospective Randomized Trial of Taurolidine versus Heparin


3.5. Taurolidine is effective in the treatment of central venous catheter-related bloodstream infections in cancer patients


4. PUBLICATIONS: PROPHYLAXIS OF INFECTION IN PARENTERAL NUTRITION


5. PROVIDE PATENCY TO ACCESS DEVICES BY USING UROKINASE


6. PUBLICATIONS ON ANTIBACTERIAL ACTIVITY OF TAUROLOCK — PREVENTION OF BOFIM


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