TauroLock™

SOLUZIONI ANTIMICROBICHE PER IL LOCK DEI CVC, IL MANTENIMENTO DELLA PERVIETA E CONTROLLO DELLE INFEZIONI



TAUROLOCKED LINES SAVE LIVES

20 YEARS

TauroLock™

Profilassi contro le infezioni del flusso ematico catetere correlate (CRBSI)

I cateteri venosi centrali (CVC) fungono da dispositivi di accesso vascolare a breve o lungo termine in emodialisi, oncologia, nutrizione parenterale e terapia intensiva. Tuttavia, comportano anche il rischio di infezioni correlate al catetere (CRI) e malfunzionamenti del CVC.

Queste infezioni possono essere scatenate dalla colonizzazione microbica del catetere, da cui i microrganismi potrebbero ulteriormente diffondersi nel flusso sanguigno. Le CRI possono portare all'attivazione cronica del sistema immunitario e a sintomi settici che richiedono la rimozione immediata del catetere.

DIALISI

Tasso di infezione (per 1.000 giorno di cateteri)	**Soluzione**	**Livello di evidenza*/p-value/letteratura**
2,7	Citrato 4 %	1B / p=0,003 / Winnicki et al. (vedi lett. 3.3)
0,67	TauroLock™-HEP500 (2x) + TauroLock™-U25.000 (1x)	
1,08	Eparina 5.000 IU/ml	2B / p=0,023 / Fontseré et al. (vedi lett. 3.12)
0,04	TauroLock™-HEP500	
1,59	Eparina 5.000 IU/ml	2B / p=0,004 / Murray et al. (vedi lett.3.13)
0,69	TauroLock™-HEP500	
2,4	Eparina 5.000 IU/ml	1B / p=0,1 / Solomon et al. (vedi lett. 3.7)
1,4	TauroLock™	
3,25	Eparina 5.000 IU/ml	2B / p=0,001 / Solomon et al. (vedi lett. 3.8)
1,33	TauroLock™-HEP500	

NUTRIZIONE PARENTERALE

Tasso di infezione (per 1.000 giorno di cateteri)	**Soluzione**	**Livello di evidenza*/p-value/letteratura**
1,0	Eparina 100 IU/ml	1B / p=0,005 / Tribler et al. (vedi lett. 4.8)
0,0	TauroLock™-HEP100	
1,44	Salina 0,9 %	1B / p=0,002 / Wouters et al. (vedi lett. 4.21)
0,33	Taurolidina 2 % (senza citrato)	
6,58	Salina 0,9 %	2B / p<0,001 / Touré et al. (vedi lett.4.13)
1,09	TauroLock™	

ONCOLOGIA PEDIATRICA

Tasso di infezione (per 1.000 giorno di cateteri)	**Soluzione**	**Livello di evidenza*/p-value/letteratura**
1,4	Eparina 100 IU/ml	1B / p=0,001 / Handrup et al. (vedi lett. 4.1)
0,4	TauroLock™-HEP100	
1,3	Eparina 100 IU/ml	1B / p=0,03 / Dümichen et al. (vedi lett. 4.3)
0,3	TauroLock™	
2,3	Eparina 200 IU/ml	2B / p=0,004 / Simon et al. (vedi lett. 4.5)
0,5	TauroLock™	

Eparina · Citrato 4 % · Salina · Come in **NutriLock™** · **TauroLock™** o varianti

*Secondo i criteri del Center for Evidence-Based Medicine

TauroPharm ha sviluppato soluzioni lock per catetere per prevenire le CRI. L'efficacia antimicrobica delle soluzioni **NutriLock™** e **TauroLock™** è fondata sulla taurolidina – un componente attivo con ampia attività contro batteri (MRSA e VRE compresi) e funghi. Le soluzioni **TauroLock™** e **NutriLock™** non contengono antibiotici.

Il CDC e l'ERBP richiedono l'uso di soluzioni lock antimicrobiche come **TauroLock™**. Più specificamente, diverse linee guida nazionali raccomandano anche soluzioni lock a base di taurolidina per dialisi, oncologia e nutrizione parenterale (vedi lett. 1, accesso tramite codice QR).

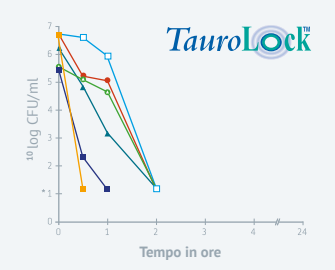
TauroLock™, TauroLock™-HEP100/500, TauroLock™-U25.000 e **NutriLock™** sono stati utilizzati con successo in regimi terapeutici per ridurre le CRI.

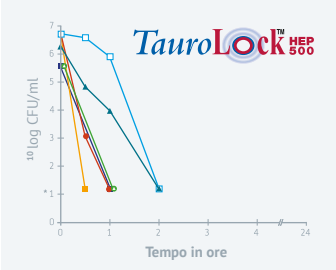
La formula base di **TauroLock™** (taurolidina e citrato al 4 %) ha dimostrato di ridurre significativamente le infezioni del torrente ematico catetere correlate (vedi lett. 2.2 e 2.3) e le infezioni da CRBSI in oncologia pediatrica (vedi lett. 4.1 e 4.3). .

Maggiori informazioni su **taurolock.com**

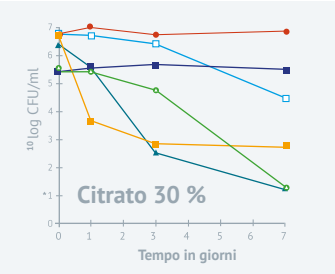
TauroLock™

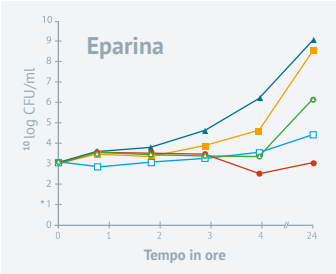
TauroLock™ è battercida e fungicida entro 2 ore**





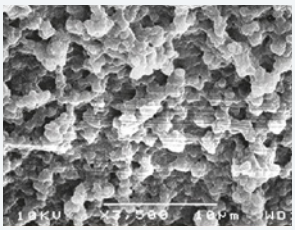
Per comparazione: attività di citrato** 30 % ed eparina***



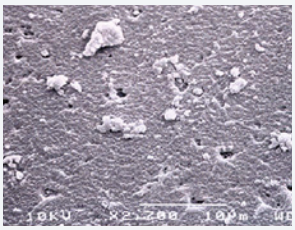


*Limite di rilevabilità (10 cfu/ml) **Dati Propri ***Vedi lett. 5.4

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



Lock con eparina
Biofilm di S. epidermidis* (vedi lett. 3.14)



Lock con taurolidina-citrato
Nessuna colonizzazione (vedi lett. 3.14)

Profilassi contro l'occlusione biologica

Le soluzioni **TauroLock™** garantiscono una triplice profilassi contro l'occlusione all'interno del catetere.

Tutte le varianti del prodotto contengono il 4 % di citrato come anti-coagulante. Questa concentrazione rimuove il calcio in modo sicuro ed efficace dalla cascata coagulativa.

Per i pazienti dializzati, raccomandiamo **TauroLock™-HEP500** come soluzione lock standard. La sua efficacia rispetto al tasso di pervietà è comparabile a 5.000 IU/ml di eparina (vedi lett. 3.1.8). L'uso di **eparina** a bassa concentrazione favorisce un effetto anticoagulante, poiché l'eparina si lega all'antitrombina.

L'associazione di **TauroLock™-HEP500** e **TauroLock™-U25.000** (che contiene 5.000 UI/ml di urochinasi) può ridurre significativamente il tasso di complicanze di pervietà. Quattro studi clinici hanno dimostrato che il protocollo 2+1 ha prodotto risultati migliori rispetto al citrato al 4 % o al solo **TauroLock™-HEP500** (vedi lett. 3.3 and 3.4).

I prodotti TauroLock™ e NutriLock™ sono clinicamente sicuri

Le soluzioni **TauroLock™** e **NutriLock™** hanno dimostrato una buona biocompatibilità.

La concentrazione di citrato al 4 % in tutte le varianti di **TauroLock™** è sicura ed efficace, secondo le raccomandazioni contenute nella Warning Letter dell' FDA (Aprile 2000), nell'ERBP e in diverse linee guida nazionali (vedi lett. 1.5 and 1.6).

Instillazione di TauroLock™

Per altri prodotti, visita **taurolock.com**

1. Lavare il dispositivo con 10 ml di soluzione salina.
2. Aspirare **TauroLock™** dal contenitore utilizzando una siringa adatta.
3. Instillare **TauroLock™** lentamente (non più di 1 ml al secondo, per neonati e bambini di età inferiore ai due anni non più di 1 ml ogni 5 secondi) nel dispositivo di accesso in una quantità sufficiente a riempire completamente il lume. Consultare le istruzioni del produttore per il volume di riempimento specifico o specificarlo durante l'impianto. Il volume deve essere rigorosamente rispettato.
   TauroLock™ rimarrà all'interno del dispositivo di accesso fino al trattamento successivo (fino a un massimo di 30 giorni).
4. Prima del trattamento successivo, **TauroLock™** deve essere aspirato e smaltito in conformità con le norme dell'istituto per lo smaltimento dei rifiuti infettivi.
5. Lavare il dispositivo con 10 ml di soluzione salina.

Seguire le istruzioni del produttore per il dispositivodi accesso vascolare venoso in uso. Ogni dispositivo richiede un volume specifico di lock del catetere.

Questo protocollo non sostituisce le istruzioni per l'uso del produttore.



Letteratura

Istruzioni d'uso

Maggiori informazioni su **taurolock.com**

TauroLock™



Confezioni delle soluzioni TauroLock™ e NutriLock™

TauroLock™	10x3 ml · 10x5 ml · 100x10 ml
TauroLock™ HEP 100	10x3 ml
TauroLock™ HEP 500	10x5 ml · 100x10 ml
TauroLock™ U 25000	5x5 ml
NutriLock™	10x3 ml

Il giusto prodotto per ogni paziente

	DIALISI	NUTRIZIONE PARENTERALE	ONCOLOGIA
TauroLock™	✓	✓ ✓ ✓	✓ ✓ ✓
TauroLock™ HEP 100		✓ ✓ ✓	✓ ✓ ✓
TauroLock™ HEP 500	✓ ✓ ✓		
TauroLock™ U 25000	✓ ✓ ✓	✓ ✓	✓ ✓
NutriLock™		✓ ✓ ✓	

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Distributore

Maggiori informazioni su **taurolock.com**

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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.

1.4. Prevention of infections that originate in blood vessel catheters; Part 1 – Nontunneled 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.

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.

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

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.

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.

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.

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
Simon et al. *Am J Infect Control* 2008. DOI: 10.1016/j.ajic.2007.02.007

2.5. A multi-national survey of experience and attitudes towards managing catheter related blood stream infections for home parenteral nutrition
Joly et al. *Clin Nutr* 2023. DOI: 10.1016/j.clnesp.2023.06.032

3. CLINICAL STUDIES: DIALYSIS

3.1. Effect of taurolidine citrate and unfractionated heparin on inflammatory state and dialysis adequacy in hemodialysis patients
Ezzat et al. *J Vasc Access* 2023. DOI: 10.1177/11297298211023295

3.2. Prevention of tunneled cuffed catheter dysfunction with prophylactic use of a taurolidine urokinase lock: A randomized double-blind trial
Bonkain et al. *PLoS One* 2021. DOI: 10.1371/journal.pone.0251793

3.3. Taurolidine-based catheter lock regimen significantly reduces overall costs, infection, and dysfunction rates of tunneled hemodialysis catheters
Winnicki et al. *Kidney Int* 2018. DOI: 10.1016/j.kint.2017.06.026

3.4. Safety and efficacy of taurolidine/urokinase versus taurolidine/heparin as a tunneled catheter lock solution in hemodialysis patients: a prospective, randomized, controlled study
Al-Ali et al. *Nephrol Dial Transplant* 2018. DOI: 10.1093/ndt/gfx187

3.5. Prevention of dialysis catheter-related sepsis with a citrate-taurolidine-containing lock solution
Betjes et al. *Nephrol Dial Transplant* 2004. DOI: 10.1093/ndt/gfh014

3.6. Approaches to prolong the use of uncuffed hemodialysis catheters: results of a randomized trial
Filiopoulos et al. *Am J Nephrol* 2011. DOI: 10.1159/000324685

3.7. A randomized double-blind controlled trial of taurolidine-citrate catheter locks for the prevention of bacteremia in patients treated with hemodialysis
Solomon et al. *Am J Kidney Dis* 2010. DOI: 10.1053/j.ajkd.2009.11.025

3.8. Observational study of need for thrombolytic therapy and incidence of bacteremia using taurolidine-citrate-heparin, taurolidine-citrate and heparin catheter locks in patients treated with hemodialysis
Solomon et al. *Semin Dial* 2012. DOI: 10.1111/j.1525-139X.2011.00951.x

3.9. Efficacy of systematic catheter locks solution of taurolidine/heparin versus taurolidine/urokinase in end-stage renal insufficiency stage 5D
Fontseré et al. *Nefrologia* (Engl Ed) 2021. DOI: 10.1016/j.nefro.2021.02.004

3.10. The best solution down the line: an observational study on taurolidine- versus citrate-based lock solutions for central venous catheters in hemodialysis patients
Van Roeden et al. *BMC Nephrology* 2021. DOI: 10.1186/s12882-021-02519-3

3.11. A new haemodialysis catheter-locking agent reduces infections in haemodialysis patients
Taylor et al. *J Ren Care* 2008. DOI: 10.1111/j.1755-6686.2008.00027.x

3.12. Tunneled catheters with taurolidine-citrate-heparin lock solution significantly improve the inflammatory profile of hemodialysis patients
Fontseré et al. *Antimicrob Agents Chemother* 2014. DOI: 10.1128/AAC.02421-14

3.13. Taurolidine-citrate-heparin catheter lock solution reduces staphylococcal bacteraemia rates in haemodialysis patients
Murray et al. *QJM* 2014. DOI: 10.1093/qjmed/hcu128

3.14. Prevention of Hemodialysis Catheter-Related Bloodstream Infection Using an Antimicrobial Lock
Quarello et al. *Blood Purif.* 2002. *DOI:10.1159/000046990*

4. CLINICAL STUDIES:
ONCOLOGY AND PARENTERAL NUTRITION

4.1. Central venous catheters and catheter locks in children with cancer: a prospective randomized trial of taurolidine versus heparin
Handrup et al. *Pediatr Blood Cancer* 2013. DOI: 10.1002/pbc.24482

4.2. Taurolidine/Citrate Lock Therapy for Primary Prevention of Catheter-Related Infections in Cancer Patients: Results of a Prospective, Randomized, Phase IV Trial (ATAPAC)
Longo et al. *Oncology* 2017. DOI: 10.1159/000470911

4.3. Randomized controlled trial of taurolidine citrate versus heparin as catheter lock solution in paediatric patients with haematological malignancies
Dümichen et al. *J Hosp Infect* 2012. DOI: 10.1016/j.jhin.2012.01.003

4.4. Taurolidine-citrate lock solution for the prevention of central lineassociated bloodstream infection in paediatric haematology-oncology and gastrointestinal failure patients with high baseline central-line associated bloodstream infection rates
Chong et al. *J Paediatr Child Health* 2020. DOI: 10.1111/jpc.14506

4.5. Taurolidine-citrate lock solution (TauroLock) significantly reduces CVAD-associated grampositive infections in pediatric cancer patients
Simon et al. *BMC Infect Dis* 2008. DOI: 10.1186/1471-2334-8-102

4.6. Taurolidine-Citrate Line Locks Prevent Recurrent Central Line-Associated Bloodstream Infection in Pediatric Patients
Clark et al. *Pediatr Infect Dis J* 2019. DOI: 10.1097/INF.0000000000002191

4.7. Taurolidine lock in the treatment of colonization and infection of totally implanted venous access devices in cancer patients
Brescia et al. *J Vasc Access* 2023. DOI: 10.1177/11297298211026453

4.8. Taurolidine-citrate-heparin lock reduces catheter-related bloodstream infections in intestinal failure patients dependent on home parenteral support: a randomized, placebo-controlled trial
Tribler et al. *Am J Clin Nutr* 2017. DOI: 10.3945/ajcn.117.158964

4.9. Effects of prophylactic use of taurolidine-citrate lock on the number of catheter-related infections in children under 2 years of age undergoing surgery
Łyszkowska et al. *J Hosp Infect* 2019. DOI: 10.1016/j.jhin.2019.04.022

4.10. Pediatric Home Parenteral Nutrition in France: A six years national survey
Goulet et al. *Clin Nutr* 2021. DOI: 10.1016/j.clnu.2021.08.002

4.11. Cost-effectiveness of taurolidine locks to prevent recurrent catheter-related blood stream infections in adult patients receiving home parenteral nutrition: a 2-year mirror-image study
Lannoy et al. *Clin Nutr* 2021. DOI: 10.1016/j.clnu.2021.01.017

4.12. The incidence and management of complications of venous access in home parenteral nutrition (HPN): A 19 year longitudinal cohort series
Leiberman et al. *Clin Nutr ESPEN* 2020. DOI: 10.1016/j.clnesp.2020.03.025

4.13. Taurolidine lock solution in the secondary prevention of central venous catheter-associated bloodstream infection in home parenteral nutrition patients
Touré et al. *Clin Nutr* 2012. DOI: 10.1016/j.clnu.2012.01.001

4.14. Taurolidine-Citrate Lock: Risk Factors Associated with a Failure of Catheter-Related Bloodstream Infection Prevention in Home Parenteral Nutrition in Adults
Lauverjat et al. *Clin Nutr* 2017. DOI: 10.1016/S0261-5614(17)30669-6

4.15. Taurolidine locks significantly reduce the incidence of catheter-related blood stream infections in high-risk patients on home parenteral nutrition
Saunders et al. *Eur J Clin Nutr* 2015. DOI: 10.1038/ejcn.2014.32

4.16. Significant reduction in central venous catheter-related bloodstream infections in children on HPN after starting treatment with taurolidine line lock
Chu et al. *J Pediatr Gastroenterol Nutr* 2012. DOI: 10.1097/MPG.0b013e31825bb0ae

4.17. Efficacy of taurolidine on the prevention of catheter-related bloodstream infections in patients on home parenteral nutrition
Al-Amin et al. *J Vasc Access* 2013. DOI: 10.5301/jva.5000168

4.18. Taurolidine lock - experience from the West of Scotland
Cullis et al. *Clin Nutr* 2011. DOI: 10.1016/j.clnu.2010.12.008

4.19. Effectiveness of Taurolock™ in preventing recurrent catheter-related bloodstream infections in patients on home parenteral nutrition
Taniguchi et al. *Proc Nutr Soc* 2009. DOI: 10.1017/S0029665109001992

4.20. Taurolidine lock is highly effective in preventing catheter-related bloodstream infections in patients on home parenteral nutrition: a heparin-controlled prospective trial
Bisseling et al. *Clin Nutr* 2010. DOI: 10.1016/j.clnu.2009.12.005

4.21. Randomised clinical trial: 2% taurolidine versus 0.9% saline locking in patients on home parenteral nutrition
Wouters et al. *Clin Nutr* 2018. DOI: 10.1111/apt.14904

4.22. Taurolidine lock is superior to heparin lock in the prevention of catheter related bloodstream infections and occlusions
Olthof et al. *PLoS One* 2014. DOI: 10.1371/journal.pone.0111216

4.23. Prophylactic urokinase in the management of long-term venous access devices in children: a Children's Oncology Group study
Dillon et al. *J Clin Oncol* 2004. DOI: 10.1200/JCO.2004.07.019

5. STUDIES: IN-VITRO AND BIOFILM

5.1. In Vitro Approach for Identification of the Most Effective Agents for Antimicrobial Lock Therapy in the Treatment of Intravascular Catheter-Related Infections Caused by Staphylococcus aureus
Hogan et al. *Antimicrob Agents Chemother* 2016. DOI: 10.1128/AAC.02885-15

5.2. Antimicrobial activity of a novel catheter lock solution
Shah et al. *Antimicrob Agents Chemother* 2002. DOI: 10.1128/AAC.46.6.1674-1679.2002

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Torres-Viera et al. *Antimicrob Agents Chemother* 2000. DOI: 10.1128/AAC.44.6.1720-1724.2000

5.4. Superior antimicrobial activity of trisodium citrate over heparin for catheter locking
Weijmer et al. *Nephrol Dial Transplant* 2002. DOI: 10.1093/ndt/17.12.21891

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