

TauroLock™

TRIPLICE EFFICACIA

Anti-infezione

Anti-occlusione

**Soluzioni
TauroLock™**

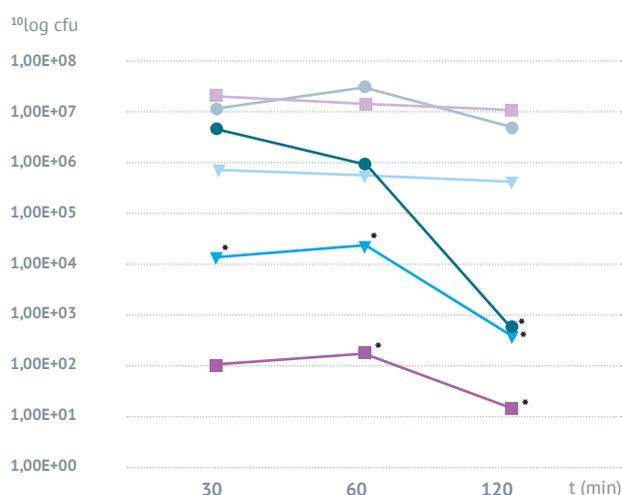
Anti-biofilm

**TAUROLOCKED
LINES SAVE
LIVES**

20 YEARS

Soluzioni antimicrobiche per il lock del catetere con **triplice efficacia** contro la minaccia di biofilm, infezioni e malfunzionamento.

1 Prevenzione ed eradicazione di Biofilm – in vitro ed in vivo



Rimozione del biofilm (vedi lett. 7.6)

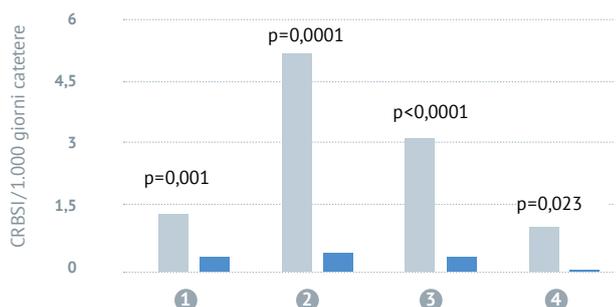
Tutti i nostri prodotti contengono taurolidina, un agente antimicrobico che è stato studiato per decenni in numerose pubblicazioni. La taurolidina si è dimostrata efficace contro oltre 500 germi: batteri gram-positivi e gram-negativi, compresi ceppi resistenti agli antibiotici, e anche funghi (vedi lett. 7.1, accesso tramite codice QR). È stato scoperto che sradica il biofilm di vari germi (vedi lett. 7.2; 7.5 e 7.6). In un altro studio, **TauroLock™** ha inattivato vari ceppi di *S. aureus* (compreso MRSA) anche nel biofilm datato (vedi lett. 7.4). Questo **effetto antibiofilm** non è stato rilevato solo in studi in vitro, ma anche nei pazienti: la taurolidina si è dimostrata **“completamente sicura ed efficace”** nella rimozione di batteri e funghi come *Stafilococchi*, *Escherichia coli*, *Enterobacter*, *Pseudomonas aeruginosa*, *Clostridium perfringens* (vedi lett. 4.3 e 5.2).

*p<0.05

S. aureus	P. aeruginosa	C. albicans
● controllo	■ controllo	▼ controllo
● TauroLock™	■ TauroLock™	▼ TauroLock™

2 Prevenzione delle infezioni

Numerosi studi clinici documentano la protezione dei CVC contro le infezioni con soluzioni lock a base di taurolidina.

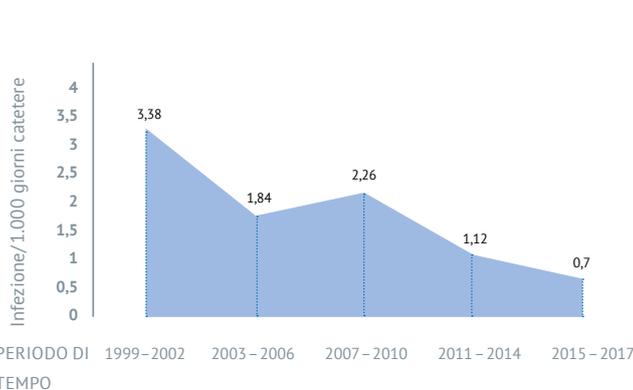


Prevenzione delle CRBSI con le soluzioni **TauroLock™** in oncologia (1, 2), nutrizione parenterale (3), dialisi (4)

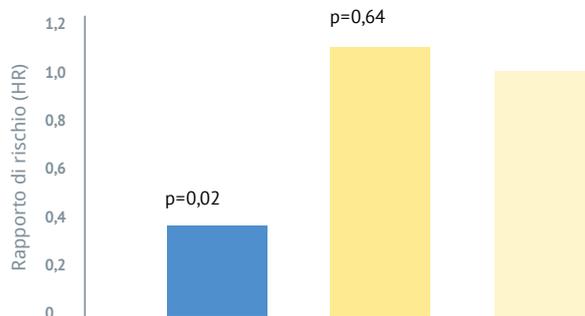


■ Comparatore ■ Prodotto **TauroLock™**

- 1 **TauroLock™-HEP100** (vedi lett. 4.1)
- 3 **TauroLock™-HEP500** (vedi lett. 6.4)
- 2 **TauroLock™** (vedi lett. 4.2)
- 4 **TauroLock™-HEP500** (vedi lett. 3.6)



Indagine di 19 anni: l'incidenza di infezioni si è ridotta da 2,36 per 1.000 giorni catetere a 0,3 per 1.000 giorni catetere (rate ratio 7,87; $p < 0,001$). L'uso di **TauroLock™-HEP** a partire dal 2002 nei pz. con > 3 inf./anno è associato alla riduzione di CRBSI (vedi lett. 6.2).



Sostituzione del CVC per infezione

Studio multicentrico osservazionale in emodialisi (vedi lett. 3.3)

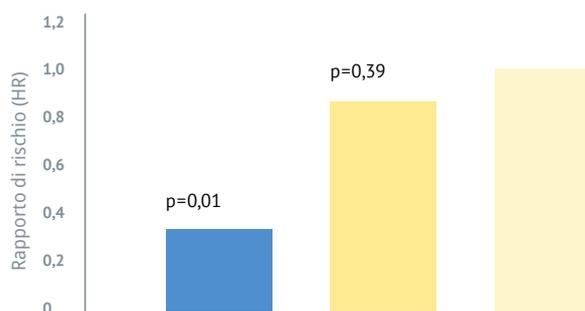
- **TauroLock™-HEP500**
- Citrato ad alta concentrazione (46,7 % citrate)
- Citrato a bassa concentrazione (4 % and 30 % citrate), come riferimento

3 Prevenzione di trombosi ed occlusioni

Tutti i prodotti **TauroLock™** contengono il citrato (4 %) come anti-coagulante, raccomandato da FDA, ERBP ed altri come sicuro nel prevenire la coagulazione del sangue. In emodialisi, numerosi pazienti richiedono un maggiore effetto anticoagulante. Ecco perchè è stato sviluppato **TauroLock™-HEP500**: che mantiene ancora meglio la pervietà (vedi lett. 3.3; 3.4 e 3.7)

La combinazione di un agente antimicrobico con un anticoagulante è risultato essere più efficace (vedi lett. 2.4). Gli esperti definiscono associazione di componenti: "... i risultati più promettenti si ottengono quando i componenti antibatterici vengono integrati a lock con con citrate o eparina" (vedi lett. 2.3).

L'efficacia maggiore si ottiene con l'aggiunta di urochinasi trombolitica, come in **TauroLock™-U25.000**, un approccio **moderno e unico** (vedi lett. 3.1 e 3.2).



Sostituzione del CVC per malfunzionamento

Studio multicentrico osservazionale in emodialisi (vedi lett. 3.3)

- **TauroLock™-HEP500**
- Citrato ad alta concentrazione (46,7 % citrate)
- Citrato a bassa concentrazione (4 % and 30 % citrate), come riferimento

La formazione del biofilm e la coagulazione del sangue dovrebbero essere prevenute fin dall'inizio a causa del rischio di: infiammazione silente, trombosi, infezione del flusso ematico, insuccesso del trattamento antibiotico o persino resistenza agli antibiotici e sostituzioni del catetere a causa di infezione o malfunzionamento.

Prevenire è meglio che curare!

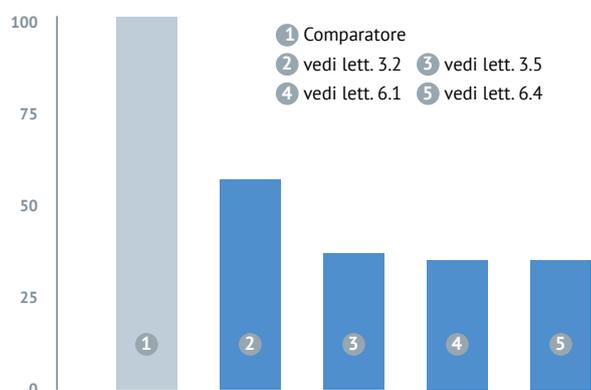
4. Sicurezza

TauroLock™, TauroLock™-HEP100, TauroLock™-HEP500 e NutriLock™ sono approvate per l'uso dalla nascita in avanti, neonati inclusi (per i dati clinici vedere lett. 4.1; 5.1; 5.2 e 6.3). Per maggiori dettagli riferirsi alle IFU.

I prodotti TauroLock™ hanno dimostrato di migliorare anche il quadro infiammatorio dei pazienti (vedere lett. 3.6; 3.7 e 3.8).

5. Risparmio sui costi

I prodotti TauroLock™ non proteggono i pazienti solo dalle complicanze. Riducono anche i costi associati al catetere rispetto alle alter soluzioni lock.



Costi associati al catetere inclusa la soluzione lock
Il comparatore dei lock è impostato al 100 %



Bibliografia



LINEE GUIDA

- **Position statement of European Renal Best Practice (ERBP) 2010**
 “B.3.1 The preventive use of antimicrobial locks is advocated to reduce the rate of CRBSI...
 The 46.7 and 30% [citrate] concentration ranges have been considered unsafe. For that reason, the low 4% concentration might be preferred, as also proposed by the American Society of Diagnostic and Interventional Nephrology (ASDIN).”
- **Guideline of the German Society of Nephrology 2019**
 “...Blocking with antibacterial lock solutions may be part of measures against overly high bloodstream infections in catheter patients (Cat. IB)...taurolidine and gentamicin exert only antimicrobial effectiveness...
 ...An additional option is the intermittent (once weekly) use of urokinase in the lock solution (Cat IB)...”
- **Australian guidelines for haemodialysis catheters 2015**
 “Taurolidine has been found to:

 - have a very broad-spectrum antimicrobial activity.
 - decrease development of biofilms.
 - be associated with a reduced CRBSI rate compared to heparin.”
- **GAVeCeLT consensus 2016**
 “...the drugs most likely to be used as antibacterial lock are taurolidine and citrate, which have optimal characteristics in terms of safety, efficacy and cost effectiveness.”
- **INS 2024**
 “61.B.8.d.i. Taurolidine was effective in prevention of catheter-related bloodstream infections (CR-BSIs) for patients on HPN... (I)”
- **ESPEN guideline on home parenteral nutrition 2020**
 “Recommendation 34: As an additional strategy to prevent CRBSIs, taurolidine locking should be used because of its favorable safety and cost profile. Grade of Recommendation B - Strong consensus (100% agreement)”

Fabbricante



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Publications on safety and efficacy

1. GUIDELINES AND RECOMMENDATIONS

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1.5. FDA issues warning on tricitrasol dialysis catheter anticoagulant
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1.7. ESPEN guideline on home parenteral nutrition
Pironi et al. *Clin Nutr* 2020. DOI: 10.1016/j.clnu.2020.03.005

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

1.9. 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.

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

2.3. Any use for alternative lock solutions in the prevention of catheter-related blood stream infections?
Labriola et al. *J Vasc Access* 2017 Mar 6;18(Suppl. 1):34-38. DOI: 10.5301/jva.5000681.

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Zhao et al. *Am J Kidney Dis* 2014. DOI: 10.1053/j.ajkd.2013.08.016

3. CLINICAL STUDIES: DIALYSIS

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Al Ali et al. *Nephrol Dial Transplant* 2018. DOI: 10.1093/ndt/gfx187

3.2. 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

3.3. The best solution down the line: an observational study on taurolidine- versus citrate-based lock solutions for central venous catheters in hemodialysis patients
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3.4. 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
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