

KiteLock™ 4%

SterileCare

KiteLock4%™ Sterile Catheter Lock Solution

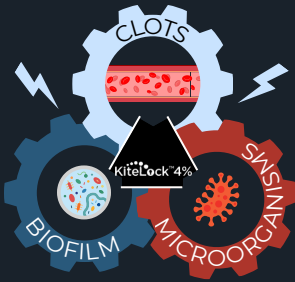
Evidence Summary



KiteLock 4% Evidence Summary

KiteLock 4%™ Sterile Catheter Lock Solution

KiteLock 4% is a novel catheter lock solution that addresses the three major causes of catheter-related complications. KiteLock 4% is:



- **A non-antibiotic antimicrobial** that inhibits the growth of bacteria inside of a central venous catheter in order to decrease the risk of catheter-related infections.
- **An anticoagulant** that Interferes with blood clotting inside of the catheter, which decreases risk of occlusions of central venous catheters that contribute to the inability to administer medications and infusions.
- **Antibiofilm** - Able to remove biofilm, an important step in treating and killing bacteria inside of the catheter.

This reference guide provides a list of studies using KiteLock 4%, along with a brief synopsis. For additional information regarding ongoing clinical studies, please visit sterilecare.com or contact info@sterilecareinc.com.

KiteLock Product Video: Sterilecare KiteLock 4% - YouTube

A Comparison of Catheter Lock Solutions and Associated Complications in Pediatric Intestinal Failure Patients

Ahisar Y et al. 2024. <https://www.sciencedirect.com/science/article/pii/S2950456224000356>

Summary: A multicenter, retrospective review of children with intestinal failure on parenteral nutrition and receiving care from an Intestinal Rehabilitation team (2017–2022) was performed. Children using Taurolidine (T) or T-EDTA locks were included. Rates of central line associated bloodstream infections (CLABSI), occlusions, and breakages were compared and reported as mean events per 1000 catheter days (CDs) with standard errors (SE). Forty-eight children (4 months–16 years) were included for a total of 112 catheters, mostly single lumen, peripherally inserted central catheters (76 %) or tunneled CVCs (21 %). T and T-EDTA locks accounted for 22,530 CDs and 7913 CDs respectively. Rates of CLABSI did not differ between groups (T 1.5/1000 CDs, SE=0.79, and T-EDTA 0.4/1000 CDs, SE=0.41, $p=0.17$). CVC occlusions requiring catheter replacement were similar (2.3 vs. 1.3 per 1000 CDs, $p=1.00$) as were fractures requiring replacement (4.0 vs. 2.1 per 1000 CDs, $p=0.73$). The incidences of CLABSI, occlusions requiring catheter replacement and fractures requiring catheter replacement were similar; however, patients receiving T-EDTA lock had 73% less CLABSI, 43% less CVC occlusions requiring replacement, and 47.5% less fractures requiring replacement than those receiving taurolidine.

Use of 4% Tetrasodium EDTA (KiteLock 4%) to Prevent Central Venous Catheter-Related Bloodstream Infections in Pediatric Hemodialysis Patients

Robinson C et al. 2024: <https://link.springer.com/article/10.1007/s00467-024-06601-4>

Summary: A single-center before-and-after quality improvement study was conducted to compare the safety and efficacy of 4% tetrasodium EDTA and heparin (1000u/ml). Twenty-two pediatric chronic hemodialysis patients were included. CRBSI incidence was 0.89 infections per 1000 catheter-days (25,769 total catheter-days) before and 0.18 per 1000 catheter-days (5426 total catheter-days) after 4% tetrasodium EDTA (IRR 0.21, 95%CI 0.03–1.52). The single episode of CRBSI that occurred after the implementation of KiteLock was related to a *Staphylococcus aureus* exit site and tunnel infection. CVC replacement procedure incidence was 1.99 procedures per 1000 catheter-days (4027 total catheter-days) before and 1.29 per 1000 catheter-days (5426 total catheter-days) after 4% tetrasodium EDTA (IRR 0.65, 95%CI 0.24–1.79). There were no significant differences in hemodialysis treatment parameters, alteplase use or access complications. CVC locking with 4% tetrasodium EDTA was associated with sustained reductions in CRBSI and CVC replacement procedure incidence. Incorporation of 4% tetrasodium EDTA locking into standardized CVC care bundles may prolong vascular access survival.

Implementing KiteLock 4% EDTA Central Line Locking Solution as a Quality Improvement Project in a Large Canadian Hospital During a Pandemic

Tremain L et al. 2024: <https://pubmed.ncbi.nlm.nih.gov/38968588/>

Summary: CLABSI data was available for hematology and oncology units only. Two-sample Poisson rate hypothesis tests showed a statistically significant decrease of 59% in CLABSIs per 1000 line days ($P = 0.046$). According to findings from this QI study, 4% EDTA reduces the number of CLABSI cases by 15 per year, which equates to 150 to 255 bed days saved per year, or 0.4 to 0.7 bed equivalents. In terms of dollars saved, there was CAD \$190,830 (US \$140,743) in yearly savings with labor and CAD \$43,260 (US \$31,905.6) without labor. There was no statistically significant difference in thrombolytic use in participating inpatient units ($P = 0.657$). The challenges of the COVID-19 pandemic and nursing shortages likely affected the results.

KiteLock 4%: The Next Generation of CVAD Locking Solutions

Barton A 2024: <https://pubmed.ncbi.nlm.nih.gov/38271043/>

Summary: The triple action of KiteLock 4% locking solution makes this system superior to other locking solutions on the market. The action against biofilm and its ability to eradicate fungus, MRSA and other pathogens is well evidenced and the anticoagulation actions means that using other locking solutions to unblock catheters such as urokinase and alteplase will be reduced, saving time and money. Changing the care and maintenance process to include catheter locking with KiteLock 4% is key to ensuring we get the maximum benefit from the device for our patients.

Comparison of Tetrasodium EDTA 4% with Sodium Citrate 4% as Line-Locking Solutions at 2 Tertiary Hemodialysis Centres

Gage B et al. 2024: doi:10.4212/cjhp.3447

Summary: There was no difference in mean HD pump speed between SC 4% and EDTA 4% (307.7 vs 305.1 mL/min, $p = 0.48$). The number of catheter-use-days on which alteplase was required declined significantly, from 313 days with Sodium Citrate 4% to 94 days with EDTA 4% ($p < 0.001$), with an overall cost reduction of 34% (\$13 183.21).

Administration of 4% Tetrasodium EDTA Lock Solution and Central Venous Catheter Complications in High-Risk Pediatric Patients with Intestinal Failure: A Retrospective Cohort Study

Hirsh T et al. 2024: <https://pubmed.ncbi.nlm.nih.gov/38837803/>

Summary: In a compassionate use protocol for high-risk pediatric patients with intestinal failure, use of 4% T-EDTA reduced composite catheter complications including those leading to emergency department visits, hospital admissions, additional procedures, and mortality. Use of 4% T-EDTA resulted in a 50% reduction in CVC complications compared to baseline rates on heparin/ELT (incidence rate ratio [IRR] 0.50, 95% CI 0.25-1.004 P=0.051).

Cost-Utility Analysis of 4% Tetrasodium Ethylenediaminetetraacetic Acid, Taurolidine and Heparin Lock to Prevent Central Line-Associated Bloodstream Infections in Children With Intestinal Failure

Gattini et al. 2023: <https://pubmed.ncbi.nlm.nih.gov/37465871/>

Summary: 4% Tetrasodium EDTA was dominant (more effective and less expensive) compared to taurolidine and heparin with savings of CAD \$88,277 compared to heparin, and CAD \$52,120 compared to taurolidine lock from the healthcare payer perspective. From the societal perspective, 4% of Tetrasodium EDTA resulted in savings of CAD \$90,696 compared to heparin, and savings of CAD \$36,973 compared to taurolidine lock.

Tetrasodium EDTA Reduces Alteplase Use in Patients With Dysfunctional Hemodialysis Catheters

Ouellet G 2021: Poster Presentation World Congress of Nephrology 2021 (PDF) POS-602
<https://www.sciencedirect.com/science/article/pii/S2468024921007774>

Summary: In a group of twenty-two chronic in-center hemodialysis patients with a dysfunctional catheter, the conversion from a citrate sodium 4% to a tetrasodium EDTA 4% lock solution led to a significant reduction in the use of alteplase.

Efficacy of 4% Tetrasodium Ethylenediaminetetraacetic Acid (T-EDTA) Catheter Lock Solution in Home Parenteral Nutrition Patients: A Quality Improvement Evaluation

Hill et al. 2020: <https://pubmed.ncbi.nlm.nih.gov/32815457/>

Summary: Twenty home parenteral nutrition patients experienced significant reduction in the central line-associated bloodstream infection rate (pre = 1.918/1000 catheter days; post = 0.563/1000 catheter days; P = 0.04). There were no occlusion events reported post intervention. Cost savings was CAD \$324,641.08 over the course of 2 years. This represents a 63% reduction in cost when 4% T-EDTA is used for 24 months compared to using 0.9% sodium chloride, heparin, or taurolidine.

Reduction of Central Line-Associated Bloodstream Infections and Line Occlusions in Pediatric Intestinal Failure Patients Receiving Long-Term Parenteral Nutrition Using

an Alternative Locking Solution, 4% Tetrasodium Ethylenediaminetetraacetic Acid

Quirt et al. 2020: <https://pubmed.ncbi.nlm.nih.gov/32770561/>

Summary: In this retrospective study of twenty patients with intestinal failure, the rate of CLABSI before the implementation of 4% tetrasodium EDTA was 2.7+4 per 1000 catheter days. Patients who received 4% tetrasodium EDTA demonstrated no infections in the 12 months post-therapy ($P = .002$). Median rates of occlusive episodes for the entire cohort before 4% tetrasodium EDTA were 0 (0–5.0) and 0 (0–2.0) after starting therapy ($P = .018$). In patients with previous occlusions ($n = 9$), the median episodes of alteplase use previously was 5.5 (2.7–19.2) compared with 2.7 (0–2.7) ($P = .018$). These findings suggest that 4% tetrasodium EDTA solution is effective in reducing CLABSI and catheter occlusions in pediatric patients with long-term central access.

Tetrasodium EDTA Is Effective at Eradicating Biofilms Formed by Clinically Relevant Microorganisms from Patients' Central Venous Catheters

Liu et al. 2018: <https://pubmed.ncbi.nlm.nih.gov/30487154/>

Summary: Tetrasodium EDTA was effective at eliminating biofilms formed by gram-positive, gram-negative, and fungal species.

Cathasept Line Lock and Microbial Colonization of Tunneled Hemodialysis Catheters: A Multicenter Randomized Controlled Trial

Kanaa et al. 2015: <https://pubmed.ncbi.nlm.nih.gov/26141306/>

Summary: Incidence rates of catheter colonization were 0.14/1,000 catheter-days in the Cathasept group and 1.08/1,000 catheter-days in the heparin group ($P = 0.02$). CRBSI rates were 0.28/1,000 catheter-days in the Cathasept group and 0.68/1,000 catheter days in the heparin group. The primary endpoint was met. Cathasept significantly reduced tunneled hemodialysis catheter colonization.

Tetrasodium EDTA As A Novel Central Venous Catheter Lock Solution Against Biofilm

Percival et al. 2005: In vitro microbiological assays <https://pubmed.ncbi.nlm.nih.gov/16018425/>

Summary: Tetrasodium EDTA can significantly reduce or eradicate CVC-associated biofilms of clinically relevant microorganisms, including candida, MRSA and VRE. Comparisons of biofilms before and after exposure to tetrasodium EDTA for 21 hours showed that the biofilm viable cell counts of all organisms tested were significantly reduced ($P < .05$).

Use of In Vivo-Generated Biofilms from Hemodialysis Catheters To Test the Efficacy of a Novel Antimicrobial Catheter Lock for Biofilm Eradication In Vitro

Kite et al. 2004: Ex vivo microbiological assays <https://pubmed.ncbi.nlm.nih.gov/15243062/>

Summary: Tetrasodium EDTA was found to have broad-spectrum activity against gram-positive and gram-negative organisms in in-vivo generated biofilms. In all cases, the action of tetrasodium EDTA significantly ($P 0.05$) reduced the viable cell count.

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Product Information

Please refer to the product Instructions for Use for full prescribing and safety information. Product inquiries may be directed to info@sterilecareinc.com or by dialing +1.844.860.5900. Inquiries may also be submitted online at <https://sterilecareinc.com/contact-2/>.

Indications for Use

KiteLock 4% Sterile Catheter Lock Solution is intended to maintain patency and decrease the risk of bacterial colonization and biofilm formation within Central Venous Access Devices (CVAD).

Adverse Reactions, Contraindications, Warnings and Precautions:

There are no known serious product-related adverse reactions when KiteLock 4% Sterile Catheter Lock Solution is used as intended. Parasthesia and/or dysgeusia may occur if the product unintentionally passes into the vein. KiteLock 4% Sterile Catheter Lock Solution should not be used in patients with documented hypersensitivity to edetate. Do not use in pregnant and nursing mothers as safety has not yet been investigated. Do not use in peripheral intravenous catheters. To avoid potential drug interactions and laboratory test interferences, aspirate and discard KiteLock 4% Sterile Catheter Lock Solution and always flush the CVAD with physiological saline before and after use of KiteLock 4% Sterile Catheter Lock Solution.



The evidence cited herein has been compiled in good faith to provide fair and balanced information; however, SterileCare Inc. does not guarantee that the evidence provided herein represents an exhaustive literature search. Additionally, SterileCare Inc. acknowledges that new evidence may emerge at any time, and therefore may not be reflected in this reference guide.

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