



Summary of Clinical Data KiteLock 4% Sterile Catheter Lock Solution

KiteLock Product Video : [Sterilecare KiteLock 4% - YouTube](#)

Publications :

1. Kite et al: *Ex vivo* microbiological assays; 2004 <https://pubmed.ncbi.nlm.nih.gov/15243062/>
 Title: **Use of In Vivo-Generated Biofilms from Hemodialysis Catheters To Test the Efficacy of a Novel Antimicrobial Catheter Lock for Biofilm Eradication In Vitro**
 Summary: T-EDTA is effective against killing and removing clinically relevant microorganisms from *in vivo* generated biofilms within hemodialysis catheters and *in vitro* using a model.
2. Percival et al: *In vitro* microbiological assays; 2005 <https://pubmed.ncbi.nlm.nih.gov/16018425/>
 Title: **Tetrasodium EDTA As A Novel Central Venous Catheter Lock Solution Against Biofilm**
 Summary: Tetrasodium EDTA can significantly reduce or eradicate CVC-associated biofilms of clinically relevant microorganisms, including candida, MRSA and VRE.
3. Kanaa et al: *Randomized Control Trial in Hemodialysis*; 2015
<https://pubmed.ncbi.nlm.nih.gov/26141306/>
 Title: **Cathasept Line Lock and Microbial Colonization of Tunneled Hemodialysis Catheters: A Multicenter Randomized Controlled Trial**
 Summary: 117 hemodialysis patients from 4 centres across UK
 - Primary end-point: Rate of bacterial colonisation:
 - Reduction of bacterial colonization by 87%
 - Secondary end-point: Rate of infection of bloodstream
 - 5 heparin group; 2 EDTA group
 - Catheter patency: intraluminal occlusions similar in both groups
4. **Summary of Clinical Findings From Multicentre Human Clinical Trial**
 Written by: Dr Chantal Lainesse, Clinical Pharmacologist (*available on request*)
 Summary: A review of the Kanaa et al, 2015 study and relevant outcomes by a third party analyst.
5. Liu et al: *Microbiological assays of current bacterial/fungi strains including antibiotic resistant strains (MRSA, VRE, etc)*; 2018 <https://pubmed.ncbi.nlm.nih.gov/30487154/>
 Title: **Tetrasodium EDTA Is Effective at Eradicating Biofilms Formed by Clinically Relevant Microorganisms from Patients' Central Venous Catheters**
 Summary: The goal in this study were 2-fold: (i) to identify microorganisms isolated by 300 CVAD tips or from human bloodstream infections and test their biofilm-forming ability and (ii) to evaluate the efficacy of tetrasodium EDTA at eliminating biofilms, toward its use as an antimicrobial lock solution. Tetrasodium EDTA was effective at eliminating Gram-positive, Gram-negative, and fungal species and represents a promising alternative to antibiotic treatment with less chance of the organisms developing resistance. The results will be of interest to researchers and clinicians and will lead to improved patient care.
 (Note: The study reviews time to eradicate biofilms of microorganisms found in CVADs.)

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6. Hill et al: *Clinical and financial efficacy of KiteLock 4% in adults; 2020*
<https://pubmed.ncbi.nlm.nih.gov/32815457/>
 Title: **Efficacy of 4% tetrasodium ethylenediaminetetraacetic acid (T-EDTA) catheter lock solution in home parenteral nutrition patients: A quality improvement evaluation**
 Summary: In total, 20 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.
7. Quirt et al: *Clinical and safety efficacy of KiteLock 4% in children; 2020*
<https://pubmed.ncbi.nlm.nih.gov/32770561/>
 Title: **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**
 Webinar: <https://www.youtube.com/watch?v=jfZMelfdH0>
 Summary: Twenty patients were included. The rate of CLABSI before 4% tetrasodium EDTA was 2.7+4 per 1000 catheter days. Patients received 4% tetrasodium EDTA for a median of 365 (278–365) days, with 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) ($P = .018$).
8. Mercer, David F: *“This therapy holds the promise to reduce CVC-related complications to perhaps as low as biologically possible in this population.” 2021* <https://pubmed.ncbi.nlm.nih.gov/34151434/>
 Title: **Preventing Central Venous Catheter Complications in Children Using 4% Tetrasodium EDTA Locks: A Small Study With a Big Impact**
 Summary: The results of the Quirt et al, 2020 publication are truly impressive—infections and catheter thrombosis–related complications were reduced to nearly zero in the cohort: only three children even developed a line infection, no line exchanges were required, and need for thrombolytic therapy reduced by roughly 90%. The locks could be safely flushed through the lines and were almost universally well tolerated.
9. Dr George Ouellet, Nephrologist, Montreal, Quebec: *Poster Presentation WCN 2021*
[\(PDF\) POS-602 TETRASODIUM EDTA REDUCES ALTEPLASE USE IN PATIENTS WITH DYSFUNCTIONAL HEMODIALYSIS CATHETERS \(researchgate.net\)](#)
 Title: **Tetrasodium EDTA Reduces Alteplase Use in Patients with Dysfunctional Hemodialysis Catheters.**

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Current Clinical Projects:

1. **"Cost-utility of KiteLock in preventing central line-associated blood stream infections in children with intestinal failure: a Markov model from the Ontario healthcare payer perspective."** Results: KiteLock was found to dominate compared to heparin lock in Markov model, since it was more effective and less expensive. [Heparin lock and KiteLock comparison \(ivteam.com\)](https://www.ivteam.com/2021/05/12/heparin-lock-and-kitelock-comparison/) Pending publication.

2. **Compassionate Use Clinical Trial in Pediatrics, Boston Children's Hospital, USA**

<https://clinicaltrials.gov/ct2/show/NCT04559334>

Study Description Summary: In this research study we want to learn more about a study drug, tetrasodium sodium EDTA (KiteLock™) for maintaining the patency (blood flow) through a central venous catheter. Catheter occlusions such as blood clots have been shown to increase the risk of central line-associated bloodstream infection (CLABSI). This treatment consists of instilling a daily a dose of a solution, similar to heparin or saline lock flushes, into the catheter when it is not in use. The aim is to prevent CLABSI without increasing complications such as catheter breakage.

3. **Control of Line Complications with KiteLock (CLiCK) RCT trial in ICU Patients:** Royal Columbian Hospital, BC, Canada (Six Canadian ICU sites participating)

<https://clinicaltrials.gov/ct2/show/NCT04548713?cond=KiteLock&draw=2&rank=1>

Study Description Summary : To our knowledge, the efficacy of an EDTA catheter locking solution has not yet been investigated in the intensive care patient population. The study team proposes to fill this knowledge gap by performing a multi-centre, cluster-randomized, crossover study evaluating the impact of KiteLock Sterile Locking Solution on a primary composite outcome of CLABSI, intraluminal occlusion, and alteplase use in the ICU of five ICU's compared to the standard of care saline lock.

4. Hamilton Health Sciences Centre (Juravinski Cancer Center) evaluated KiteLock as the standard of care lock solution in the oncology patient population from November 2021 to April 2022. The project data will be analyzed and published. See: www.hamiltonhealthsciences.ca

"Our primary focus is to provide the highest level of care to our patients," says Ted Scott, VP Research and Chief Innovation Officer at HHS. "We engaged the CAN Health Network and launched this project with SterileCare with the intention of improving outcomes for our oncology patients undergoing treatment."

5. **The CLOCK (Catheter Lock) trial: Improving outcomes in pediatric oncology patients in Australia.**

The University of Queensland has been awarded a \$2 million grant from the Queensland Cancer Council to conduct a top-level, multi-site clinical trial of catheter lock solutions. The goal of the study is to evaluate the effectiveness of the CVAD lock solution compared to usual care to reduce infections, thromboses and blockages for children being treated for cancer.

<https://medicine.uq.edu.au/article/2021/11/2-million-boost-improve-treatment-children-cancer-0>

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