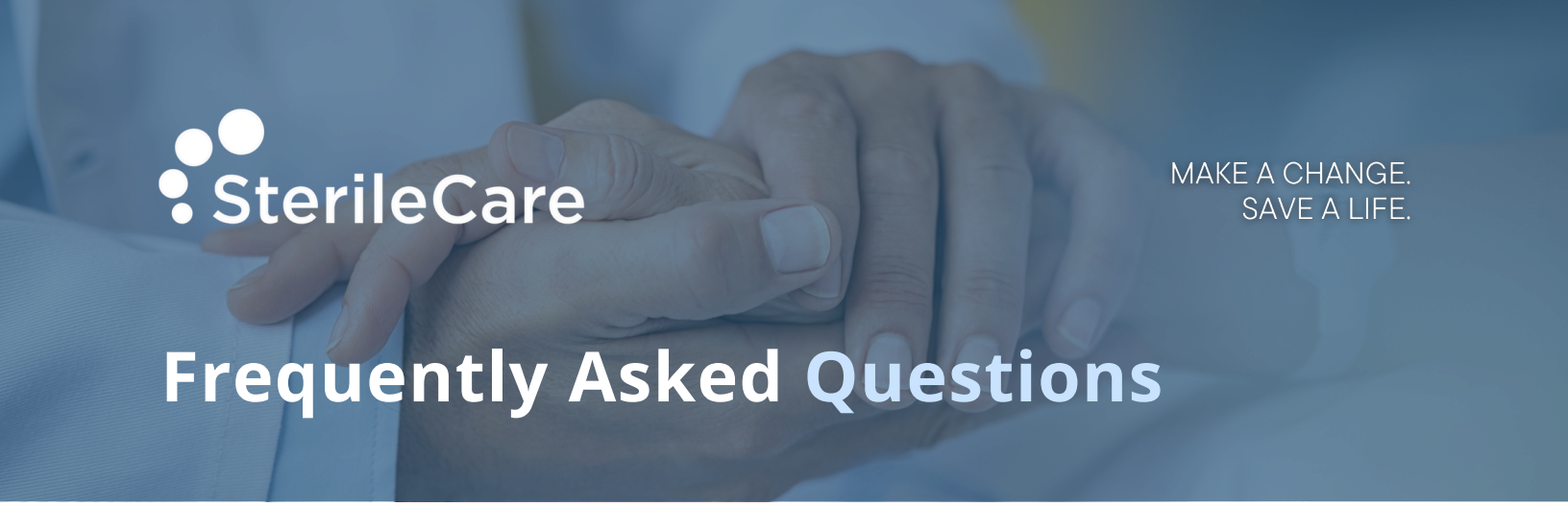

SterileCare

MAKE A CHANGE.
SAVE A LIFE.

Frequently Asked Questions

The following information is intended for Clinicians and Healthcare providers. If you are a patient or caregiver, please contact your healthcare team to discuss this information as it relates to you.

What is the purpose of KiteLock™ 4%?

KiteLock 4% Sterile Catheter Lock Solution (herein referred to as KiteLock 4%) is intended to maintain patency and decrease the risk of bacterial colonisation and biofilm formation within central venous access devices (CVAD).

How does KiteLock™ 4% work?

KiteLock 4% occupies space inside the CVAD lumen, preventing blood from entering. KiteLock 4% contains 4% EDTA that binds to metals, particularly calcium, within the CVAD lumen. Through this action of calcium-binding EDTA, KiteLock 4% prevents and interrupts three interrelated biological processes that are responsible for CVAD dysfunction, morbidity and mortality in patients with CVADs. These three processes include blood clotting, colonization, and biofilm formation, further described as follows:

1. Calcium is essential in the formation of blood clots. EDTA binds to calcium, thereby interrupting clot formation in the CVAD lumen. KiteLock 4% acts as an anticoagulant in the lumen of the CVAD and does not act to prevent clotting inside of the body.
2. Calcium is used by microbes to maintain their cell structure, and to live and grow. Through its calcium-binding action, EDTA disrupts the cell structure of microbes. Through a non-antibiotic mechanism, KiteLock 4% kills organisms that are present within the CVAD lumen.
3. Calcium plays an essential role in the binding of microbes to CVAD lumen walls. If microbes bind to the lumen surface, biofilm formation begins, allowing microbes to grow and proliferate, protected by an extracellular matrix. Through its calcium-binding action, EDTA acts to interrupt the formation of this supportive matrix, thereby interrupting microbial growth and proliferation.
4. Through its calcium-binding action, EDTA acts to disrupt already formed biofilms through interruption of the supportive extracellular matrix. This disruption further contributes to calcium-binding and antimicrobial action for microbes that are protected by biofilm.

How much KiteLock™ 4% should be instilled in the CVAD lumen?

Use sufficient volume of KiteLock 4% to maintain patency of the CVAD. One ampoule should be used per CVAD lumen. For multiple lumen CVADs, multiple vials are needed. Lock each CVAD lumen in accordance with the CVAD manufacturer's recommendations, or as directed by the healthcare provider, per institutional protocol. For institutional protocols where the CVAD lumen fill volume is used to determine the volume of lock solutions, consider that the volume of the lock solution should equal the internal volume of the CVAD and add-on devices plus 20% (10% in infants/neonates), as per established guidelines for CVAD locking[1,2].

How long can KiteLock™ 4% remain in the CVAD lumen?

Refer to institutional policy and procedure for the appropriate interval in which to perform a maintenance flush and/or lock procedure for the applicable type of vascular access device and patient population.

KiteLock 4% has undergone testing in a laboratory setting that demonstrates that the solution is free of precipitates up to 40 degrees C, or 104 degrees F (accounting for extremes in body temperature that may occur). No changes in edetate purity or concentration were observed. The testing was conducted at the clinically relevant period of at least 90 days, therefore supporting the stability of KiteLock 4% in this setting [3].

What patient population is KiteLock™ 4% approved for use in?

The intended population includes patients with central venous access devices [CVADs] (short and long-term CVADS, peripherally inserted central catheters [PICCs], and implanted ports) in settings such as, but not limited to, critical care, hemodialysis, intravenous chemotherapeutic agent and/or antibiotic infusion, parenteral nutrition administration, and apheresis.

Are there contraindications to using KiteLock™ 4%?

KiteLock 4% has no specific contraindications for use regarding patient sex or age. KiteLock 4% has been used safely in adults and children. KiteLock 4% 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.

Is KiteLock™ 4% compatible with intravenous drugs and other intravenous infusions?

To avoid interactions, KiteLock 4% should be cleared from the CVAD by aspirating and discarding the contents then flushing the CVAD lumen with saline prior to administering drugs. After administering drugs/nutrition or withdrawing blood, the CVAD lumen should be flushed again with saline before instilling fresh KiteLock 4% solution. Intraluminal contact of KiteLock 4% with infusates other than physiologic saline is not recommended.

Does KiteLock™ 4% interfere with blood tests?

To avoid laboratory test interferences, KiteLock 4% should be cleared from the CVAD lumen by aspirating and discarding the contents then flushing the CVAD lumen with saline prior to withdrawing blood.

How often should KiteLock™ 4% be used?

KiteLock 4% is indicated to be used following the initial placement of a CVAD, after each injection of a medication/nutrition, after each dialysis session, or after withdrawal of blood for laboratory testing. KiteLock 4% should be replaced each time the CVAD lumen is used. This protocol may vary according to clinician discretion or institutional protocol.

Is KiteLock™ 4% compatible with all central venous access devices?

KiteLock 4% has no specific contraindication for use with common CVAD lumen materials and has been successfully tested with industry-standard silicone and polyurethane CVAD lumen materials.

Do I have to aspirate KiteLock™ 4% before CVAD use?

According to the Instructions for Use, KiteLock 4% should be aspirated and discarded when the CVAD is needed for treatment. To avoid potential drug/nutrition interactions and laboratory test interferences, aspirate and discard KiteLock 4%, and always flush the CVAD with physiological saline before and after use of KiteLock 4%.

What clinical considerations are there for situations where KiteLock™ 4% cannot be aspirated and discarded?

In the case where KiteLock 4% is unable to be aspirated from the CVAD lumen, flushing of the lumen may be considered according to institutional policy and procedure. Systemic anticoagulation does not occur when KiteLock 4% is used as directed. In the bloodstream, EDTA binds to circulating calcium at physiological pH and is excreted largely unmetabolized by the kidneys. Coagulation abnormalities were not reported in sheep or in hemodialysis patients when exposed to EDTA for 35 days and 8 months, respectively [3].

Compared to doses of EDTA used in the setting of chelation therapy, the amount of EDTA present in KiteLock 4% is very low and is not expected to have a clinically relevant chelation effect on the body when exposed to the volumes used in the setting of CVAD locking. There is negligible risk that KiteLock 4% may cause clinically relevant hypocalcemia. This has been confirmed by safety and toxicity studies conducted with KiteLock 4%[3].

Additionally, KiteLock 4% has been tested according to industry standards considering the equivalent of exposure from flushing the contents of a triple lumen CVAD (triple lumen X 3 ml = 9 ml/day). Based on toxicological review, KiteLock 4% poses no meaningful risk for chronic toxicity, carcinogenicity, genotoxicity, or reproductive toxicity[3].

When obtaining blood cultures from a CVAD that is locked with KiteLock™ 4%, should the first sample aspirated be used for culture?

Refer to your institutional policy and procedure for blood cultures drawn from the CVAD. Consider current clinical practice guidelines and published evidence in the development of institutional protocols for drawing blood cultures. Recommendations from practice guidelines such as Infusion Therapy Standards of Practice[2] have led to the general practice of using the initial draw from the CVAD for cultures since blood obtained from the first draw would be most indicative of the microorganism burden within the lumen of the CVAD, as opposed to a sample drawn after a waste.

How safe is KiteLock™ 4%?

KiteLock 4% has successfully been tested for safety in accordance with industry standards. The safety of KiteLock 4% has also been supported through clinical studies in adult and pediatric patients.

Are side effects with KiteLock™ 4% expected?

There is a low risk of side effects of KiteLock 4% when used according to the manufacturer's instructions for use. Side effects related to the use of KiteLock 4% are unlikely. Paresthesia (numbness and/or tingling) and dysgeusia (metallic taste) may occur if the product unintentionally passes into the vein. These effects have been observed to be temporary with no permanent effects. Like any solution that has a chelating effect, slow instillation of KiteLock 4% may help to minimize these infrequent side effects, in addition to discomfort on infusion. NOTE: KiteLock 4% is not intended to come into contact with subcutaneous tissue, as transient discomfort related to the pH may occur.

Have Clinical Trials Been Conducted with KiteLock™ 4%?

Yes, several studies have been published, and ongoing studies are being conducted. Visit sterilecareinc.com or contact your sales representative to learn more.

References

KiteLock 4% Instructions for Use GI SC001
KiteLock 4% Directions for Use – WI-4-ENG Dec 2024
1. Polaschegg HD, Shah C. ASAIO J. 2003 Nov-Dec;49(6):713-5. doi: 10.1097/01.mat.0000094040.54794.2d. PMID: 14655740.
2. Nickel B, Gorski L, et al. J Infus Nurs. 2024 Jan-Feb 01;47(1S Suppl 1): S1-S285. doi: 10.1097/NAN.0000000000000532. PMID:38211609.
3. Data on File

Disclosure

This material is provided for your information only and does not imply any product claims or expanded indications outside of the applicable device labeling (IFU). Clinical experiences at one institution or in a specific patient group may not reflect the experiences in other settings or patient populations. This information is provided as a reference only to assist in development of protocols that meet the needs of your institution and patient population. This document is intended for general KiteLock 4% product information only and is not a substitute for medical advice or institutional policy and procedure.

Refer to the KiteLock™ 4% Instructions for Use for Full Prescribing and Safety Information.