

FREQUENTLY ASKED QUESTIONS

KITELOCK™ 4% STERILE CATHETER LOCK SOLUTION

How often do we have to use KiteLock?

SterileCare Inc. recommends that KiteLock be used in the same way as your current solution - every time the catheter is not in use, lock it and allow KiteLock to disinfect the catheter between treatments.

What is biofilm?

Biofilm is a slime produced by bacteria to protect themselves. It provides shelter under which the bacteria proliferate and transfer information, including resistance to antibiotics. A biofilm can be made up of a single species or different species of bacteria and yeast. It lines the inside of the catheter and occasionally releases bacteria, putting the patient at risk of bacterial infection. Biofilm is impenetrable to today's antibiotics.

How safe is KiteLock?

KiteLock is tetrasodium ethylene diamine tetra acetic acid (EDTA). EDTA has been used for many decades for intravenous chelation therapy to treat lead poisoning in people. If the entire vial of KiteLock was completely administered to a patient at one time, the exposure to EDTA would be 30X less than what a patient would be exposed to during chelation therapy. In addition, KiteLock has passed the standard toxicity tests to make sure it is not mutagenic or carcinogenic, and that it is biocompatible.

Can we use it in children?

KiteLock was approved for use in children (not neonates) in Canada in July 2019, and in Europe in January 2020, based on a long-term quality improvement study conducted by Toronto Sick Kids.

What patient population can KiteLock be used in?

KiteLock is indicated for use in Central Venous Access Devices (CVADs) such as CVCs, PICCs and ports. It is compatible with polyurethane, silicone, and most standard catheter materials. Examples of patients with CVADs are hemodialysis patients, cancer patients and total parenteral nutrition (TPN) patients. KiteLock is not recommended for midline catheters or peripheral intravenous (PIV) catheters, since studies have not yet been conducted.

Was there a clinical trial conducted?

Yes. A randomized clinical trial was conducted in hemodialysis patients where KiteLock (aka Cathasept) was compared to the current standard of care, heparin at 5000 U/mL. KiteLock demonstrated a statistically significant decrease in bacterial colonization compared to heparin by 87%. Reference to this article is Kanaa et al, 2015. *AJKD*;66(6):1015-1023.

Will KiteLock contribute to antibiotic resistance?

No, since KiteLock is a non-antibiotic antimicrobial. Its antimicrobial mechanisms of action are related to its chelation properties, which are different from the mechanisms of action of today's antibiotics. KiteLock complies with Global Antimicrobial Stewardship Programs.

How long do I need to lock the catheter in order for KiteLock to be effective?

Due to KiteLock's chelating abilities, it will impact coagulation and micro-organisms as soon as the CVAD is locked. It has been shown to take 3 to 6 hours to eradicate most common mono-species and mixed-species *biofilm*. (Note: it is the only catheter lock solution proven to do this.) Within 24 hours, KiteLock eradicates *Candida* sp and MRSA (methicillin-resistant *Staphylococcus aureus*) bacteria and biofilm. KiteLock is indicated for the maintenance of patency and to decrease the risk of bacterial colonization and biofilm formation within CVADs. Because of this, we recommend KiteLock as a first-line-of-defence catheter lock solution as soon as the CVAD is inserted.

Does KiteLock have a Drug Identification Number (DIN)?

No. KiteLock is not a drug. It is a Class II medical device. Therefore, it does not require a DIN.

Where else is it used in the world?

Canada is the first country to have KiteLock approved. The first patients to benefit from KiteLock are Canadian patients. In June 2019, KiteLock was CE Mark approved for use in other global countries.

How does KiteLock work?

KiteLock is comprised of EDTA and water. EDTA is a known chelator. This means it has an affinity for metals and elements such as calcium. Bacterial cell walls are made of calcium so as they are exposed to EDTA, calcium is removed thereby destroying the wall and killing the bacteria. A similar process happens for biofilm where calcium removed by EDTA destroys the scaffolding of the slime, thereby making holes in the biofilm for EDTA to reach the bacteria.

Do I have to aspirate KiteLock or can I flush it?

According to the Directions for Use, it is recommended that KiteLock be aspirated when the catheter is needed for treatment, and flushed with saline before and after use of KiteLock. The rationale is two-fold: (1) flushing fluid, whether it is saline, heparin, citrate or KiteLock, with biofilm and bacterial debris into the patient is not good clinical practice; and (2) although there is a large margin of safety associated with intravenous administration of much higher concentration EDTA, on-going administration of KiteLock in the bloodstream of patients has not yet been investigated.

Is KiteLock compatible with all CVADs?

Regulatory approval requires that compatibility studies be conducted before approval. In the case of KiteLock™, these were conducted with commonly used catheters (polyurethane and silicone) and accepted by the regulatory authority.