Innovation Brief - Sterile Catheter Lock Solution 4% tetrasodium EDTA (KiteLock™)

Summary

Disruptive innovation

This briefing introduces a disruptive / transformative innovation newly available via NHS Supply Chain: Sterile Catheter Lock Solution 4% tetrasodium EDTA (KiteLock™).

Reviewed by clinical specialists and supported by key stakeholders, this device is a novel catheter lock solution that addresses the three major causes of catheter-related complications. It is intended to maintain patency and decrease the risk of colonization and biofilm formation within Central Venous Access Devices (CVAD).

Introduction

This document is intended to inform clinical stakeholders and procurement teams about innovative products that have undergone a clinical review and are now accessible through NHS Supply Chain.

Disruptive innovations

- A disruptive innovation is novel to the NHS but is proven in clinical practice.
- It should offer improvements compared to the existing provision of care.
- The proposed format should not exist elsewhere (either within or beyond the health and care sector).

Please note: while robust evidence or validated savings may not yet be available, early data and clinical insights support the potential for patient and system-level improvements.

Departments / stakeholders for engagement

- NHS procurement teams
- Acute NHS hospitals
- Paediatrics
- Intensive Care Units (ICUs)
- Oncology / haematology
- Emergency departments

Opportunity

Sterile Catheter Lock Solution 4% tetrasodium EDTA (KiteLock™) is an optimal catheter lock solution proven to keep the catheter lumen patent, reduce the incidents of catheter related infection, produce minimal or no side effects, cost effective and easy to use.

Clinical impact to patient safety includes:

- KiteLock 4% is the only globally approved lock solution safe enough for children.
- Infections are prevented and therefore the use of antibiotics is avoided.
- Better patient outcomes

Product overview

KiteLock™ 4% Sterile Catheter Lock Solution is a non-antibiotic antimicrobial agent capable of eradicating bacteria and yeast by penetrating their associated established biofilms as demonstrated in several microbiological studies and a multicentre randomized clinical trial in haemodialysis patients.

KiteLock™ 4% does not contribute to antibiotic resistance and helps spare the use of our current antibiotic arsenal, thus is in line with Antibiotic Stewardship Programs of hospitals worldwide.

Composition

Background information

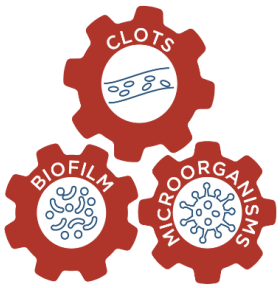
Central Venous Access Devices (CVADs) have become essential in the management of not only critical-care patients in the Intensive Care Unit (ICU) but also outside of the ICU, such as cancer and haemodialysis patients as well as patients needing total parenteral nutrition (TPN). Yet the inside of a catheter is a major source of infection. At least 70% of all nosocomial bloodstream infections occur in patients with CVADs.

Most catheters are colonised with microorganisms embedded in a biofilm which are difficult to treat. KiteLock™ 4% Sterile Catheter Lock Solution is the only solution available to knock out all three of these interrelated processes to reduce CVAD complications.

Clinical relevance and patient benefits

KiteLock™ as an effective in vitro anticoagulant agent. EDTA (ethylenediaminetetraacetic acid) has been used for decades as a powerful anticoagulant preventing clot formation in vitro which unlike heparin has no in vivo anticoagulant activity as it binds to calcium within the blood and is immediately excreted by the kidneys. KiteLock™ as an effective non-antibiotic antimicrobial and anti-biofilm agent.

Several microbiological assays have been conducted against clinically relevant microbial strains (bacteria and fungi) from in vivo and ex vivo generated biofilms demonstrating KiteLock™'s ability to reduce by 4-6-fold the number of relevant catheter-dwelling G+ and G- bacteria, yeast (Candida sp.) and their associated biofilm including Methicillin Resistant Staphylococcus Aureus (MRSA) and Vancomycin Resistant Enterococci (VRE) within 24 hours.



The multifocal mechanisms of action of tetrasodium EDTA in killing microbes and inhibiting and eradicating biofilm formation primarily involve its metal-chelating activity.

Pathway change

Based on recent NHS-focused evidence and clinical publications, this delivers measurable impact across the following pathways:

- Non chemotherapy infusion pathways (for example antibiotics, iron, biologics).
- Antibiotics stewardships.
- Acute and emergency care - enhances safety where Intravenous (IV) solutions are frequently utilised.
- Critical care and paediatric intensive care units (ICUs) where CVAD are frequently used.
- Vascular access and medication safety pathways - reduces CVAD-related complications, unnecessary clinical procedures, treatment delays, and unnecessary use of antibiotics treatments.

Supply details

National Product Code (NPC) FMT85010
Manufacturer's Product Code (MPC) SC001

Supplier - Scott Medical Distribution UK LTD
Class IIa Medical Device
Brand - Kitelock 4%
Unit of Issue: Box of 60 ampules

Supporting evidence and notes

1. Resources | SterileCare
   https://sterilecareinc.com/resources/

2. A comparison of catheter lock solutions and associated complications in paediatric intestinal failure patients - ScienceDirect
   https://www.sciencedirect.com/science/article/pii/S2950456224000356

3. Use of 4% tetrasodium ethylenediaminetetraacetic acid - EDTA (KiteLock™) to prevent central venous catheter-related bloodstream infections in paediatric haemodialysis patients
   https://link.springer.com/article/10.1007/s00467-024-06601-4

4. Implementing a 4% EDTA Central Catheter Locking Solution as a Quality Improvement Project in a Large Canadian Hospital - PubMed
   https://pubmed.ncbi.nlm.nih.gov/38968588/

5. KiteLock™ 4% the next generation of CVAD locking solutions - PubMed
   https://pubmed.ncbi.nlm.nih.gov/38271043/

6. Cost-utility analysis of 4% tetrasodium ethylenediaminetetraacetic acid, taurolidine, and heparin lock to prevent central line-associated bloodstream infections in children with intestinal failure - PubMed
   https://pubmed.ncbi.nlm.nih.gov/37465871/

7. Efficacy of 4% tetrasodium ethylenediaminetetraacetic acid (T-EDTA) catheter lock solution in home parenteral nutrition patients: A quality improvement evaluation - PubMed
   https://pubmed.ncbi.nlm.nih.gov/32815457/

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