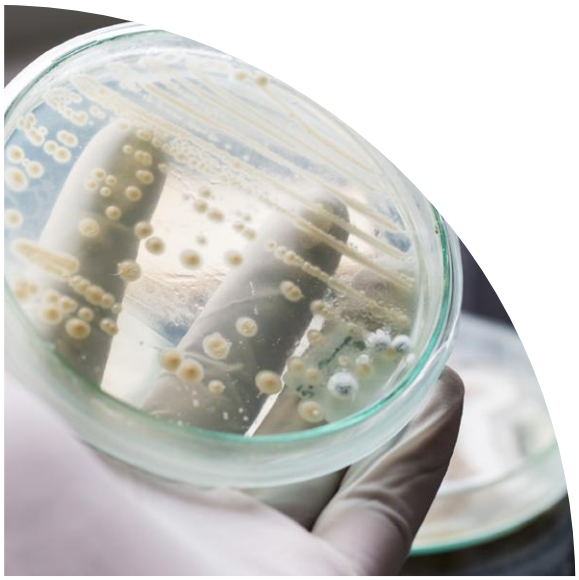



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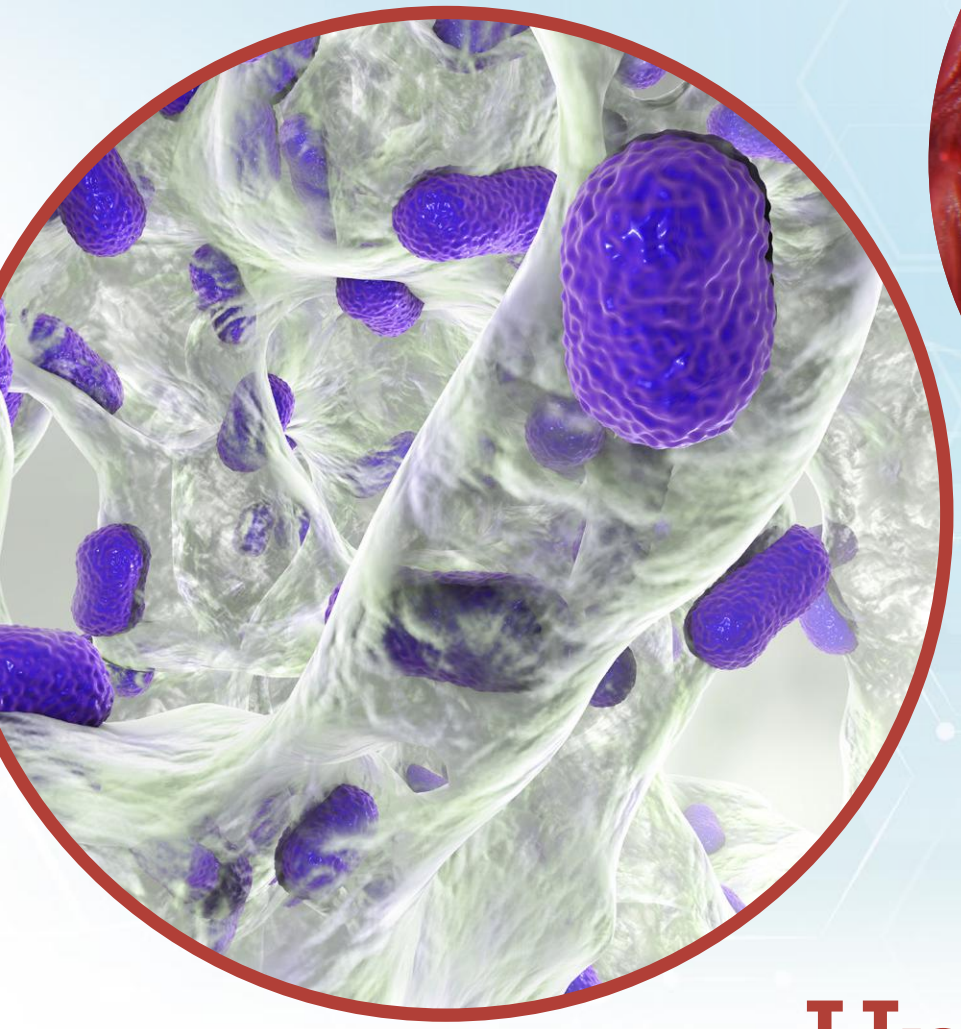

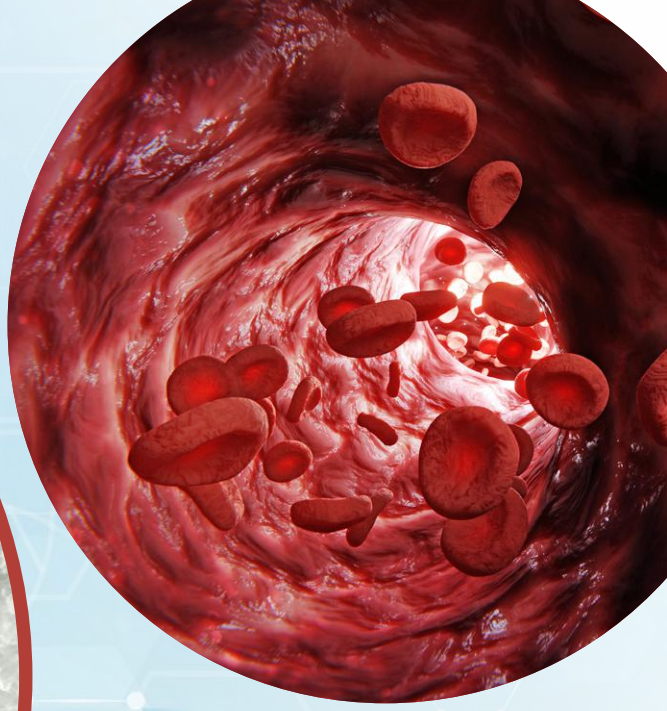

Unlocking THE SECRET TO Beating Superbugs

SterileCare

Written by Pauline Müller

Catheter lock solutions are medically tested and approved liquids used to promote the anti-coagulation of blood and to provide antimicrobial protection inside catheter tubing while it is not in use. But not all lock solutions are equal. Canadian SterileCare Inc.'s patented KiteLock 4%, a non-antibiotic antimicrobial catheter solution, is destroying superbugs on home soil and beyond.

Beating these superbugs has become a medical emergency as antibiotics are proving futile against certain microorganisms and lives hang in the balance. Many superbugs create extracellular matrixes to structure and protect the colony. These organisms typically attach themselves to calcium carbonate-based surfaces that scientists call scaffolds to form what is known as biofilms.

Most biofilms found on medical devices in hospitals have, until recently, been untreatable even with most antibiotics. However, this has been taken to another level due to antimicrobial resistance as the organisms become immune to the medicines meant to eradicate them.

Enter German-manufactured KiteLock 4%, a central venous catheter (CVC) lock solution. A CVC, placed into a large vein above the heart, is essential for life-saving medical treatment but is also at significant risk of leading to bloodstream infections.

Central venous access devices rely on a purpose-specific plastic tubing, known as a catheter, typically fed from a bag to deposit medication or deliver treatments into the bloodstreams of cancer patients, dialysis patients, COVID-19 patients, and other seriously ill people. As necessary as CVCs are in medical recovery, the possibility of complications is always high.

"What people don't realize is that, if [a catheter] gets infected, one in four people will die from the infectious biofilm inside that catheter, not from their disease, so we must take care of that catheter, and that's what we do with the KiteLock 4%," says Karen Mueller, Chief Executive Officer. She explains that, while the new product makes such infections preventable, they are almost impossible to stop without it.

"Catheter infections are considered one of the top hospital-acquired infections. They are acquired in the healthcare system because catheters get contaminated by the healthcare worker and this is almost impossible to stop because bacteria live everywhere. They are deadly, they are costly, and they are preventable."

Fortunately, since the Markham, Ontario-based company, SterileCare Inc., has brought the game-changing solution to market, the situation is changing. In the process, the company, founded 2011, is having an impact on human life. With distribution ranging across Canada, Europe, the Middle East, and Australia, it has become a manufacturer of note.

The Coordinated Accessible National (CAN) Health Network has done much to ensure that this leading manufacturer remains in Canada. To this end, CAN Health footed the bill for a six-month project that would see the full development of the product to prepare it for going to market. This was done in collaboration with Juravinski Hospital and Cancer Centre of Hamilton Health Sciences, an Ontario-based hospital, to test the KiteLock 4%. CAN Health has also made it possible for the company to work with Fraser Health's intensive care unit in British Columbia where the product is applied to minimize vascular catheter complications.

"Coming out of COVID-19, we realized how important infection prevention is. We have a non-antibiotic antimicrobial that kills all kinds of bad bugs, including superbugs, which is our next slower moving pandemic," says Mueller.

With a success rate of 70 to 100 percent, KiteLock 4% is bringing results to the North American health system, and the product has already made a positive impact around the world. That includes reducing blocked CVC catheters due to blood coagulation (occlusion) by well over 60 percent and CVC catheter replacement by more than 10 percent.

KiteLock 4% relies on tetrasodium ethylenediaminetetraacetic acid (EDTA). Known as disodium EDTA, the solution is typically used by cosmetic manufacturers to preserve skin care preparations and help such products perform better. Moreover, it is in a host of hair care products, soap, and even prepared store-bought food items like infant meals.

The use of EDTAs in the medical industry ranges from their use as anticoagulants in test tubes for research samples or blood testing. "When you change disodium EDTA to tetrasodium EDTA, it becomes this really effective antimicrobial that we have a patent on. Nobody knew that something so simple would be so powerful," Mueller says.

Part of what makes biofilms so dangerous is that once the film has formed its matrix, antibiotics cannot penetrate it. That means these bacterial colonies form such a tough barrier that without obliterating the bacteria's protective layer, infections remain inside CVCs.





- Tetrasodium EDTA binds to the calcium that provides strength to the matrix of biofilms in a process called chelation, entirely destabilizing the integrity of the bacteria's superstructure and breaking down the film. That, in turn, allows penetration into the now unprotected core of the bacterial colony.

"The way that [tetrasodium EDTA] works is that it grabs onto calcium and pulls it out of the surrounding area. Calcium is vital for blood to clot… Calcium is vital for microorganisms to survive. If you take it away, they die. Calcium is crucial in the formation of the slime called biofilm. If you take the calcium out, it cannot build up," says Mueller. "It works because tetrasodium EDTA has a mechanism of action that applies to all of it, whereas an antibiotic's mechanism of action is specific to one microorganism. That's all that it can do."

While tetrasodium EDTA has been used commercially for many years, Mueller tells me that it was Dr. Peter Kite, a well-known microbiologist from the United Kingdom, who founded KiteLock 4% for CVC protection. Part of Kite's research involved using an endoluminal fibrin analysis system (FAS) brush, with which catheter tubes are unclogged in hospitals, to extract biofilm deposits for studies.

Kite had studied the use of tetrasodium EDTA to solve the challenges presented by film-forming organisms since the early 2000s, proving that 24-hour exposure of a diverse selection of bacterial species by the chemical resulted in a significant enough drop to render any residual presence entirely insignificant. The anticoagulation properties of tetrasodium EDTA also mean that blood cannot become overly viscous or dry inside catheters, ruling out the need for premature cleaning or replacement.

"All these superbugs, including but not limited to Methicillin-resistant Staphylococcus Aureus (MRSA) and Vancomycin Resistant Enterococcus (VRE)—all of those big deadly bugs, we kill them," says Mueller.

Working in medical manufacturing can be challenging but working on the SterileCare Inc. team is all about flexibility. For Mueller, having happy people onboard is imperative to achieving success. "The company has always been virtual so that everybody can do what they need to do at home and work and not be stressed about anything. I am the woman who tries to make people feel good about what they do," she says, explaining that in this way, the team's productivity soars.



"I want people to be their best selves. Here, we have fun. Everybody's motivated. We do good things." The result is a collaborative group of professionals dedicated to delivering what their clients need most: peace of mind and a groundbreaking way of saving lives.

"When you're diagnosed with cancer and you have to get chemotherapy, you are given this catheter that is going to deliver what you think is going to save your life. You have no idea that catheter can also take your life away due to possible infections," Mueller says.

She notes that helping customers adopt this new product has been a long and arduous process. "They say, on average, it takes sixteen years from the idea to commercialization for people to understand the idea, and they are not wrong," she says.

"We have a non-antibiotic antimicrobial that kills all kinds of bad bugs, including superbugs."



Mueller travels the globe to educate and inform those in the medical industry about the phenomenal contribution KiteLock 4% can bring to the field. She recently represented the company at the Infusion Nurses Society conference in Boston on April 2, where she introduced the product to medical field attendees. She also presented at the World Congress for Vascular Access in Toronto, Canada at the end of April.

The daring CEO has also won several awards, including Discovery Parks' 2012 CEO-in-residence program entrepreneur award and Southlake Regional Health Centre's 2017 innovation award. In addition, she was nominated for the RBC Women of Influence in 2020 and in again earlier this year. Mueller also received the Trailblazer of the Year award in 2022 from CAN Health Network as a member who has made an outstanding contribution to the medical field.

As a young trained nurse, her first introduction to losing a life was when, while treating vascular access dialysis patients as part of her everyday routine, a patient died from a catheter bio-film-related infection. The perfectly preventable death became something she bore throughout her career as a reminder of her purpose in life. After exchanging nursing for sales, she happened upon the chance to bring the KiteLock 4% to market and leaped at the opportunity to become a change maker.

Her journey would become even more personal when her daughter received open-heart surgery. "I started this company as a nurse to pay it forward, to make a difference. As much as we won't admit it, our healthcare system is driven by finance, not by outcomes," she says, relating how she went back to school to learn the financial aspects of manufacturing and marketing.

Today, her determination and hard work have brought her to her goal of preventing catheter-related infections and deaths. "I get to say that every day, I get to save babies—people's lives. I am in it because of my passion for what I do—paying it forward. I think when you do that, the rest will follow," she adds with a smile.

Soon, the product promises to be easily accessible in the United States. "In the USA, the Food and Drug Administration has never approved a product like ours in history… So we have been awarded with a breakthrough device designation for approval which means we are fast-tracked, so we have a high probability to be approved but it will take about two years," she says.

At its core, SterileCare Inc. is focused on eliminating the life-threatening health risks and high financial costs caused by infections contracted in medical facilities. Demand for the product has the potential to be huge, according to Mueller, and the company's growth potential is noteworthy. Over the next five years, it aims to distribute KiteLock 4% around the world. With such a powerful contribution to make to the world of human health and medical manufacturing, this nimble and collaborative company will no doubt succeed. ■

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