



STERILECARE

INFECTION PREVENTION

WWW.STERILECAREINC.COM

2022



ABOUT US

A Canadian medical device company with a patent protected non-antibiotic antimicrobial

Our product addresses top global medical issues including hospital acquired infections and the war against multi-drug resistant bacteria.

KiteLock 4% Sterile Catheter Lock Solution is a medical device poised to change clinical practice and outcomes.



Karen Mueller

CEO, Founder

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Registered nurse

Canadian Vascular Access Association: past Board of Directors, current Toronto Chapter Executive, member of the Canadian Guidelines for Vascular Access and Infusion Therapy 2019

Canadian Antimicrobial Innovation Coalition (CAIC): member

Speaker at International conferences



THE PROBLEM

Healthcare-acquired infections are preventable

LIFELINES:

Central Venous Access Devices (CVADs), or catheters, are used for life saving treatments such as chemotherapy, dialysis, intensive care, nutrition, etc

Current Clinical Complications

- Currently report CLABSIs in the ICU
 - 70% of CVADs are outside the ICU
- 4-20% death rate related to infections (up to 35% if caused by super bugs)
- up to 40% of CVADs have complications



Cost of Complications

- \$34 – 56,000 USD per infection
- Recorded expenditure to treat CLABSIs is millions per year in each country
- Cost of occlusions = unknown



NEW ERA OF RISK: THE SLOW PANDEMIC

Challenging Modern Medicine

- Refocus on hardwiring prevention efforts of catheter-related infection
- Stop the rise of antibiotic resistance organisms
- Save our antibiotics for when we need them



63% - 300%

A dramatic increase in CLABSIs was found during the COVID-19 pandemic.



4.95 M Deaths

globally, were contributed to antibiotic-resistant organism infections in 2019.



A Global Threat

Medical procedures such as surgery could become extremely difficult, or even impossible, due to antimicrobial resistance.

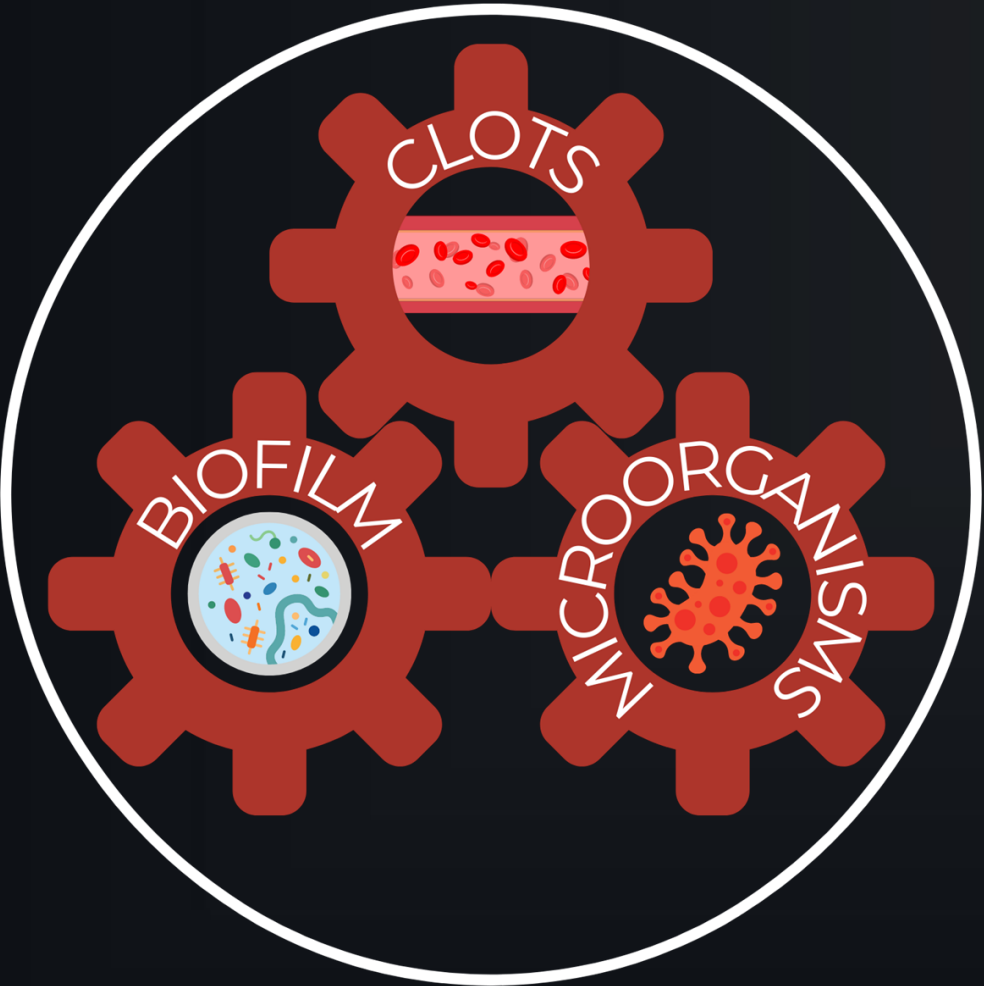


10 Million

By 2050, 10 million people will die a year.

THE TRIPLE THREAT

CVADs Three Interrelated Processes



1 Clot Formation

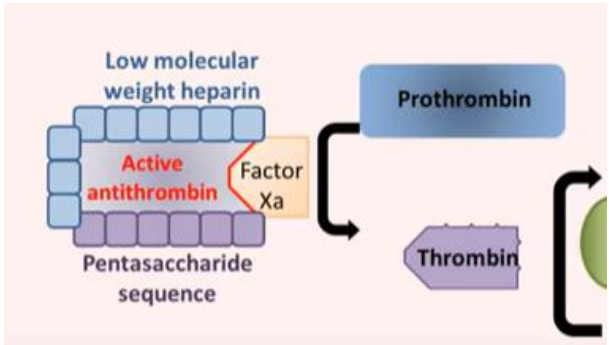
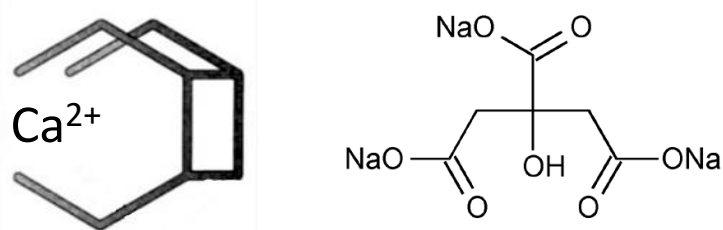
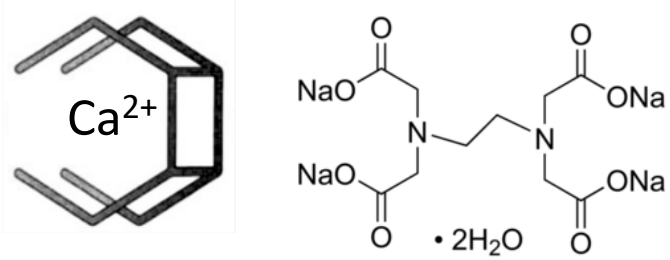
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2 Microorganisms
Bacteria/Fungi/Resistant Strains

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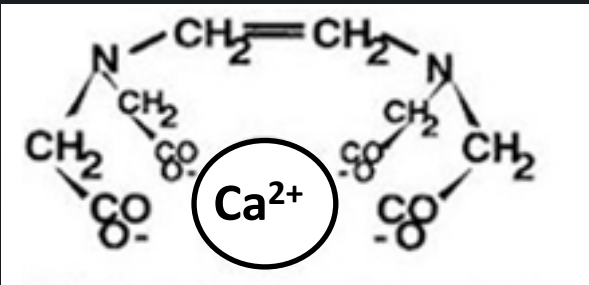
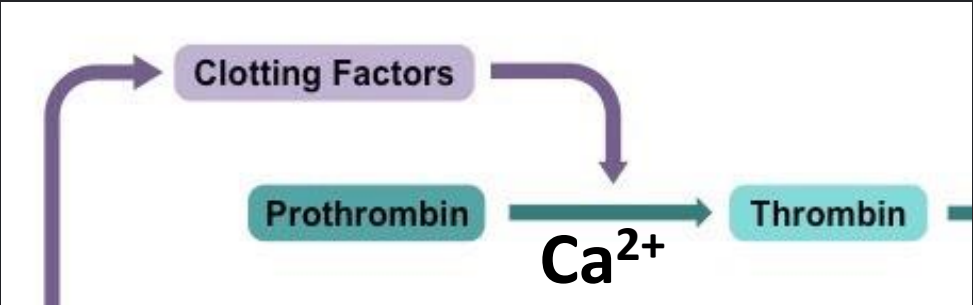
3 Biofilm
Bacteria/Fungi/Resistant Strains

ANTICOAGULANT LOCK SOLUTIONS

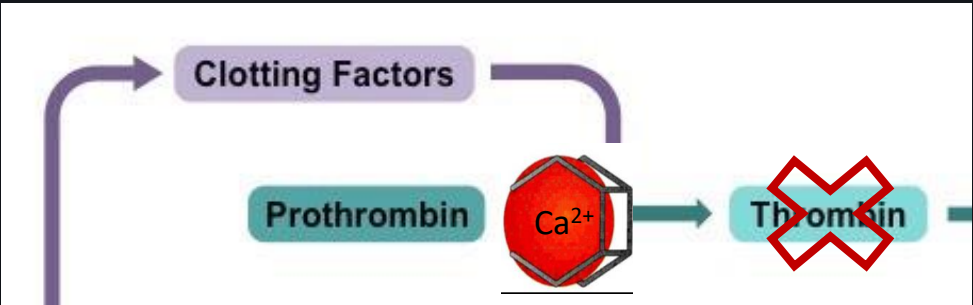
Heparin	Citrate	T-EDTA
Intraluminal and systemic	Intraluminal only	Intraluminal only
		
• Binding affinity to antithrombin • Heparin Induced Thrombocytopenia (HIT) • Stimulates biofilm formation • Global push for change in practice related to risks	• Calcium removal stops coagulation cascade • low binding affinity for calcium	• Calcium removal stops coagulation cascade • strong binding affinity for calcium • 10x stronger than citrate



Disodium EDTA



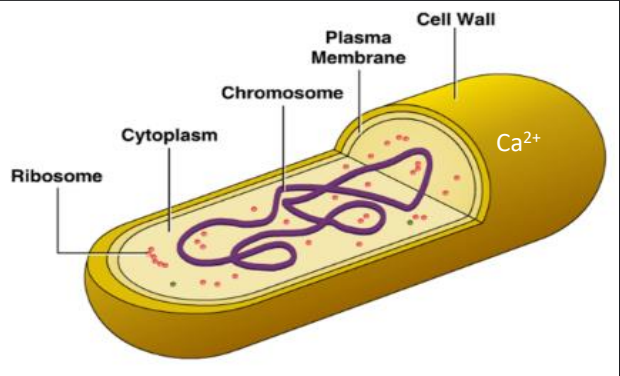
Saline does not provide protection against clot formation



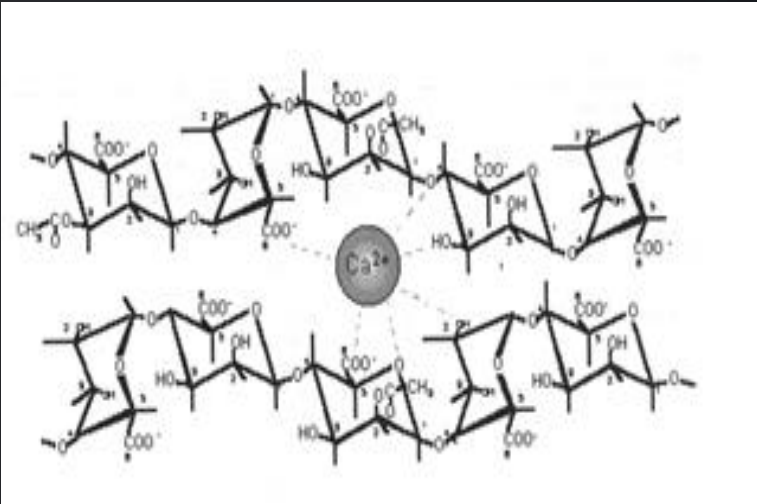
*Proescher 1951. Anti-coagulant properties of Ethylene Bis-imodiacetic acid (synonym to EDTA). Proceedings of the Society for Experimental Biology and Medicine. 76(4):
Hendrickx 2001 A comparative prospective study on the use of low concentrate citrate lock versus heparin lock in permanent dialysis catheter. Int J Artif Organs; 24(4)
Quirt 2020 Reduction of CLABSI and Line Occlusions in Pediatric Intestinal Failure Patients receiving long-term PN using alternative Locking solutions, 4% EDTA

CVAD MICROORGANISMS

		Lock Solutions Effectiveness	
	Microorganism Strain	Planktonic State (free floating)	Sessile State (biofilm)
Gram-positive organisms: 40 - 80% CRBSIs	➤coagulase-negative staphylococci, 34.1% ➤enterococci, 16% ➤Staphylococcus aureus, 9.9%	Most Antimicrobial Lock Solutions are effective against free floating microorganisms	tEDTA 4%
Gram negative organisms: 20-30% CRBSIs	➤Klebsiella, 5.8% ➤Enterobacter, 3.9% ➤Pseudomonas, 3.1% ➤E.coli, 2.7% ➤Acinetobacter, 2.2% ➤Others, 10.5%		
Yeast / Fungi	➤Candida albicans ➤Candida glabrata		
Antibiotic Resistant	➤MRSA ➤VRE		



Bacteria; Yeast
Planktonic State
(Free Floating)



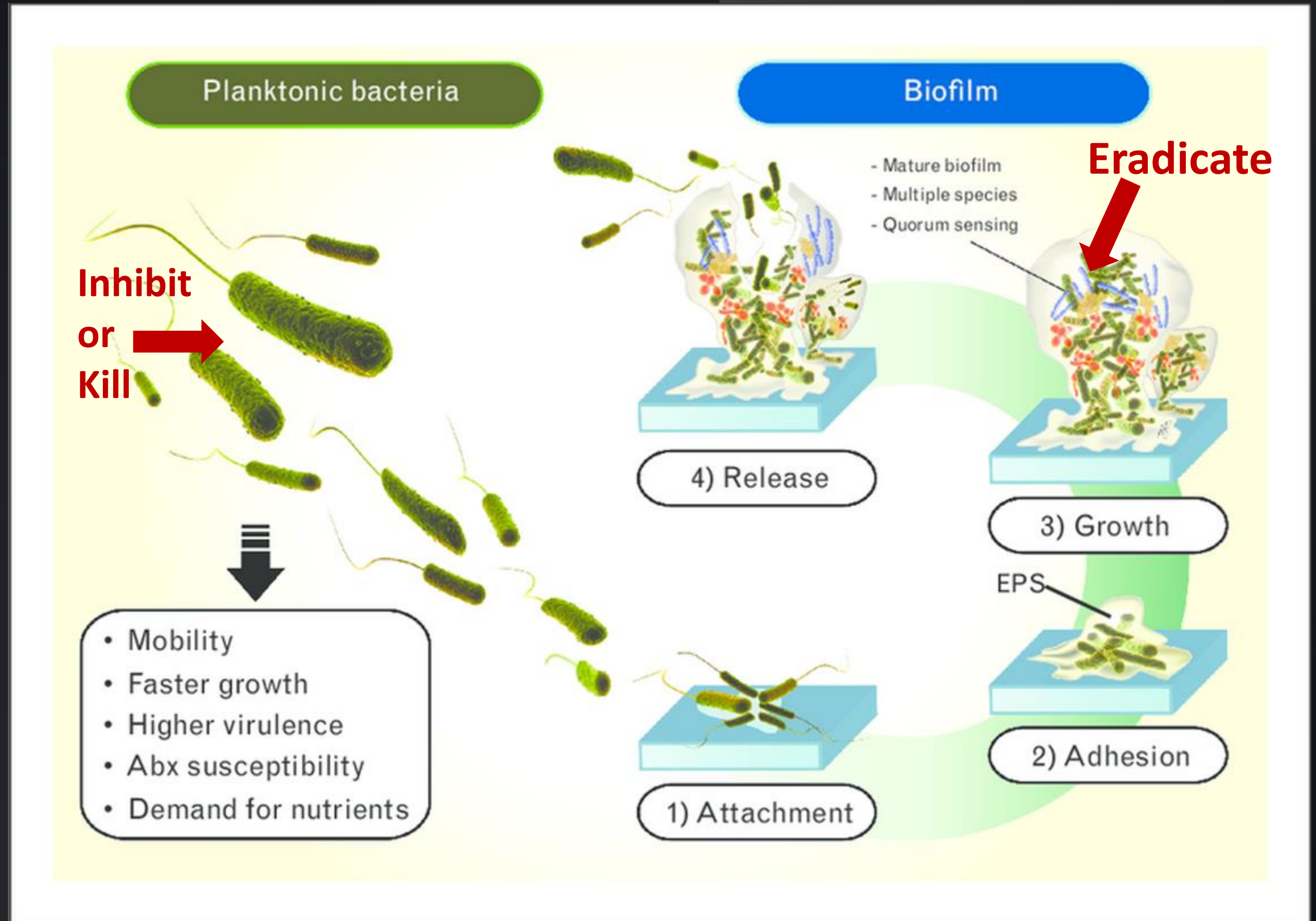
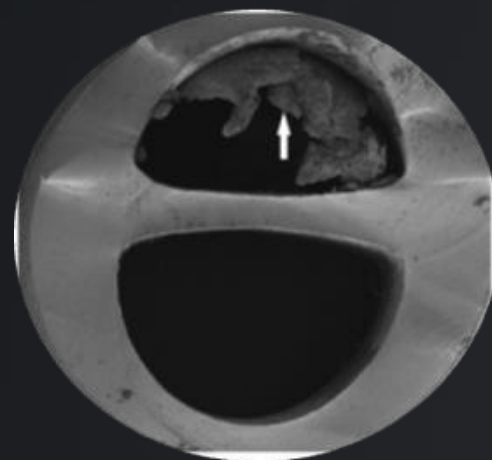
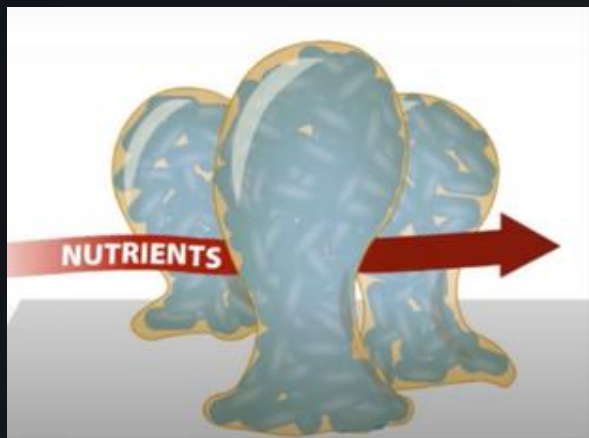
Biofilm
Complex Matrix
Sessile State

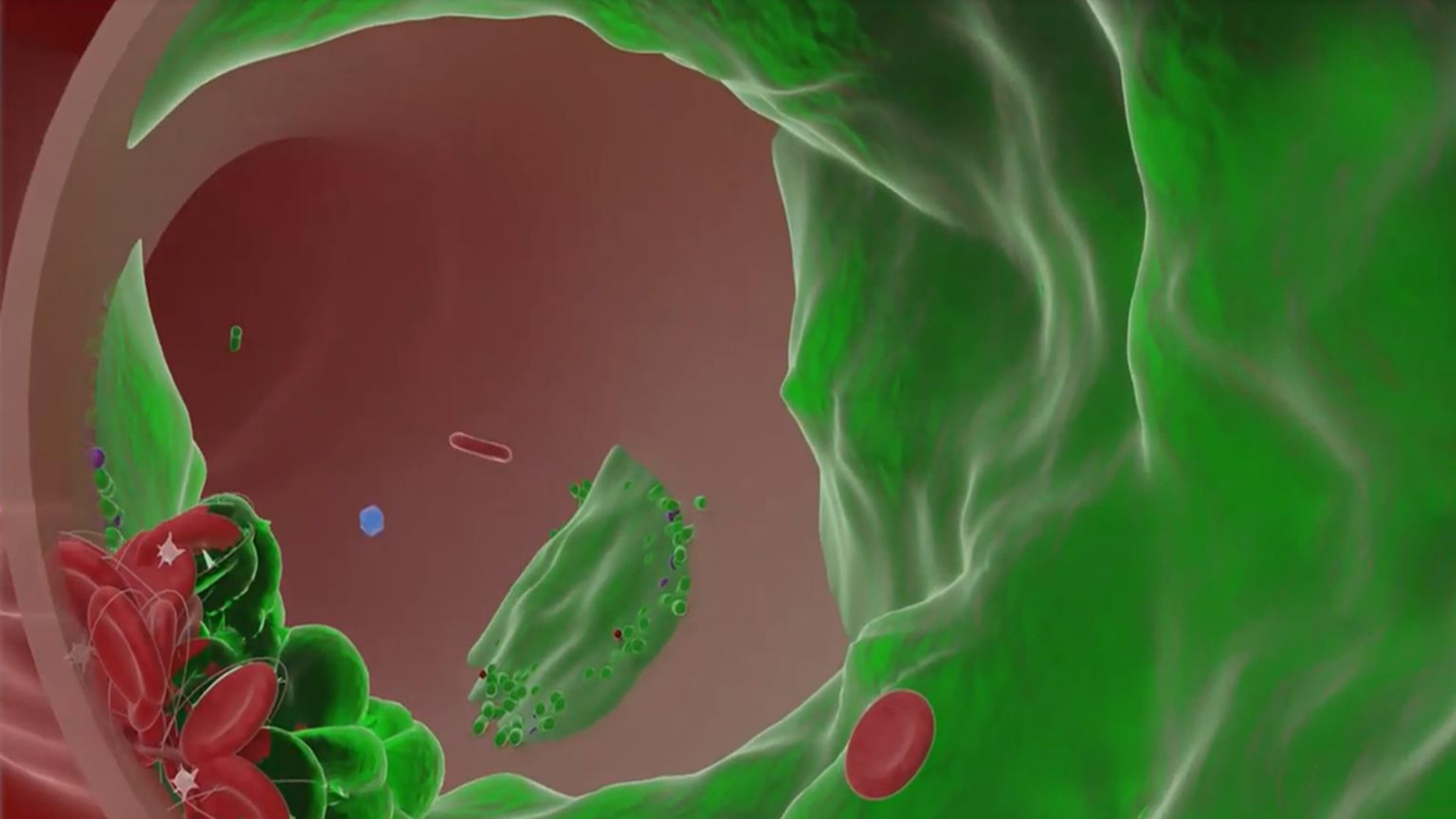
Haddadin Y, Annamaraju P, Regunath H. Central Line Associated Blood Stream Infections. [Updated 2022 Apr 6]. In: StatPearls. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. <https://www.ncbi.nlm.nih.gov/books/NBK430891>
Liu F, Hansra S, Crockford G, Köster W, Allan BJ, Blondeau JM, Lainesse C, White AP. 2018. Tetrasodium EDTA is effective at eradicating biofilms formed by clinically relevant microorganisms from patients' central venous catheters. mSphere 3:e00525-18. <https://doi.org/10.1128/mSphere.00525-18>

PROBLEM: COLONIZATION & BIOFILM FORMATION

Planktonic bacteria: unprotected independent cells

Sessile bacteria: protected biofilm community
(100-1000 times less susceptible)

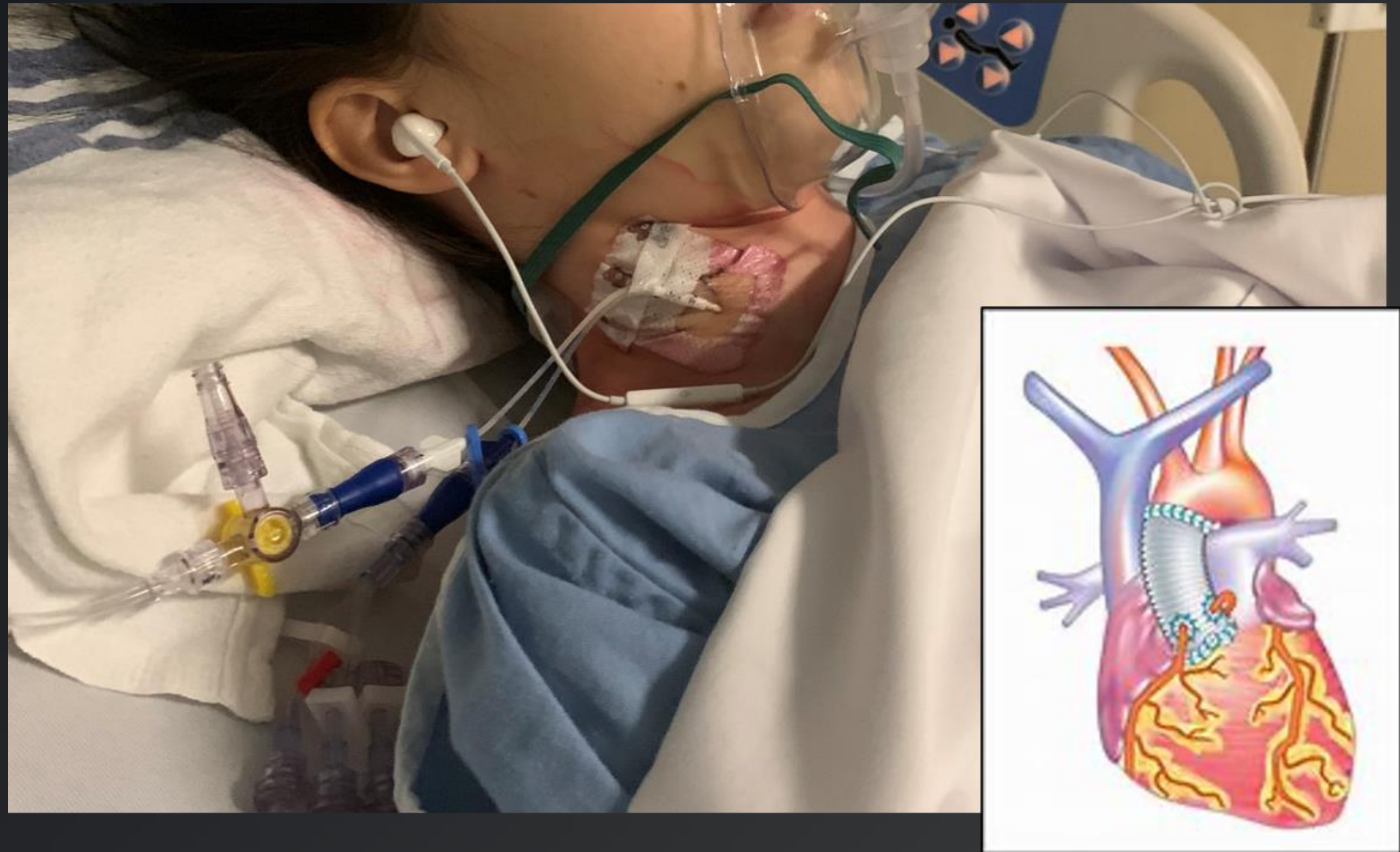




BIOFILM: METASTATIC INFECTIONS

Dissemination of biofilm bacteria, particularly in the clump formation, are the deadly metastasizing infections including

- endocarditis
- osteomyelitis
- encephalitis
- abscess

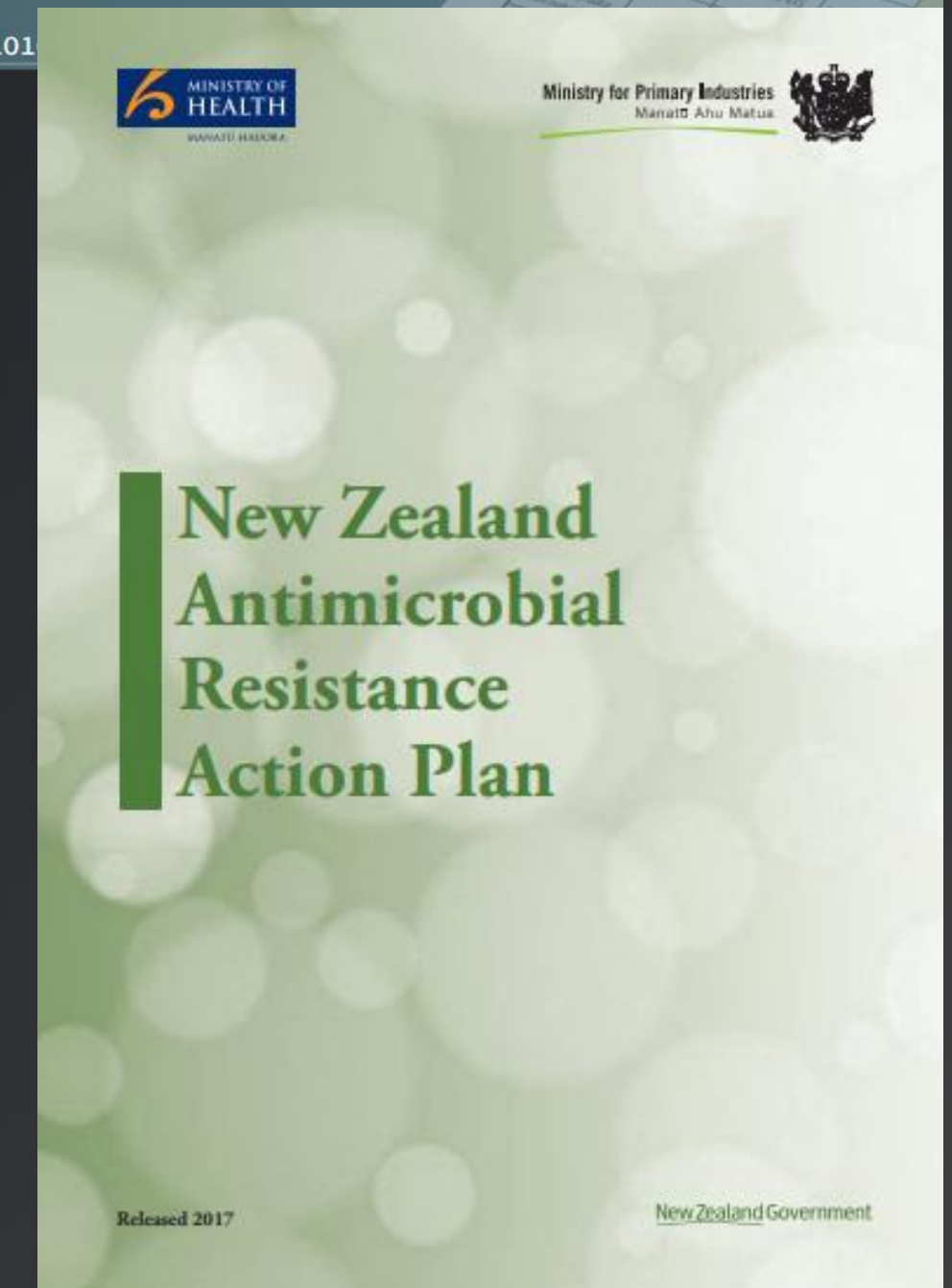
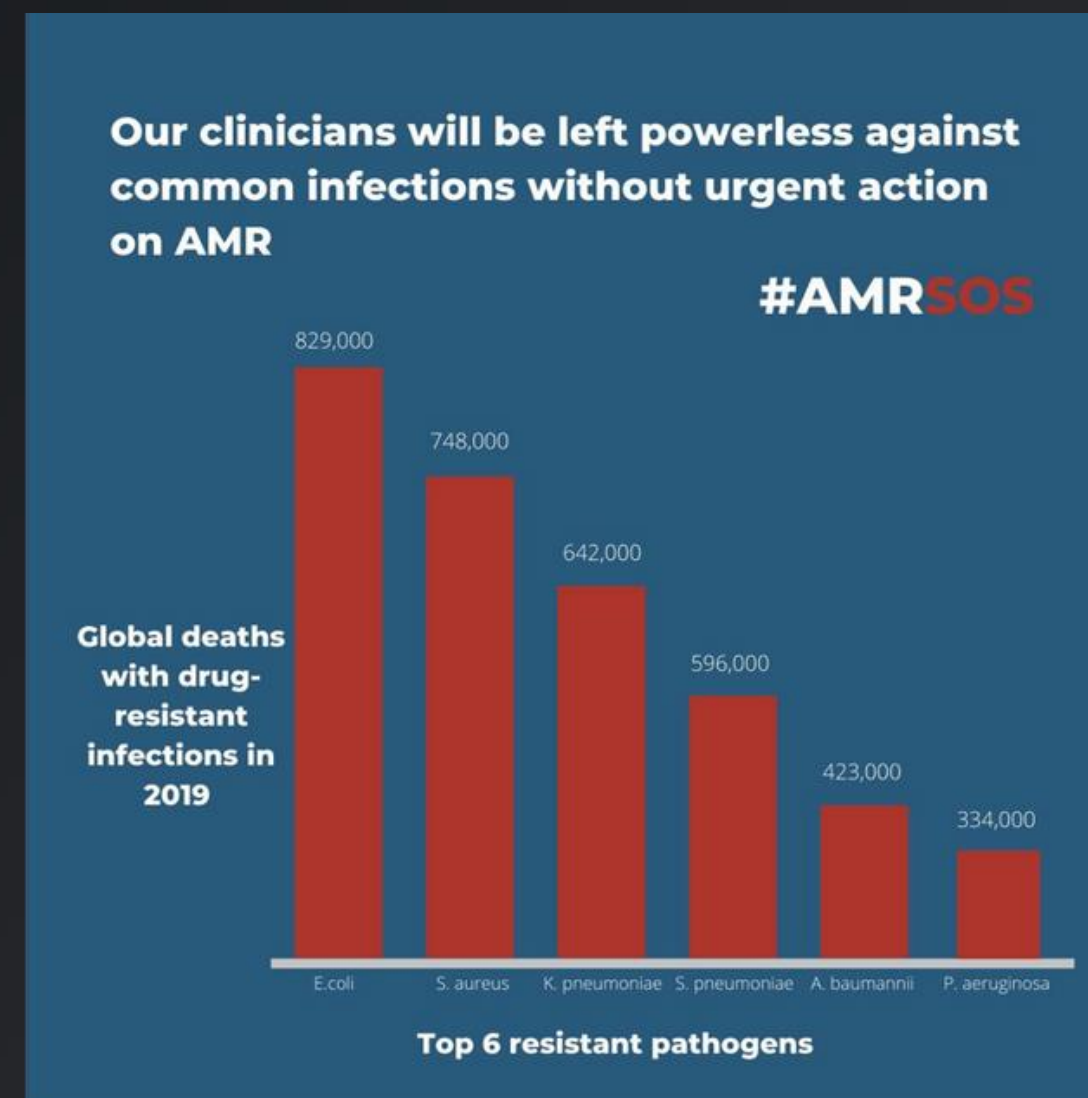


CVCs colonized with *S aureus* biofilm were implicated as the source of metastatic infections in 31% of patients.

Ryder M. Catheter-Related Infections: It's All About Biofilm. *Top Adv Pract Nurs EJournal*. 2005;5(3).

BIOFILM: Antimicrobial Resistance

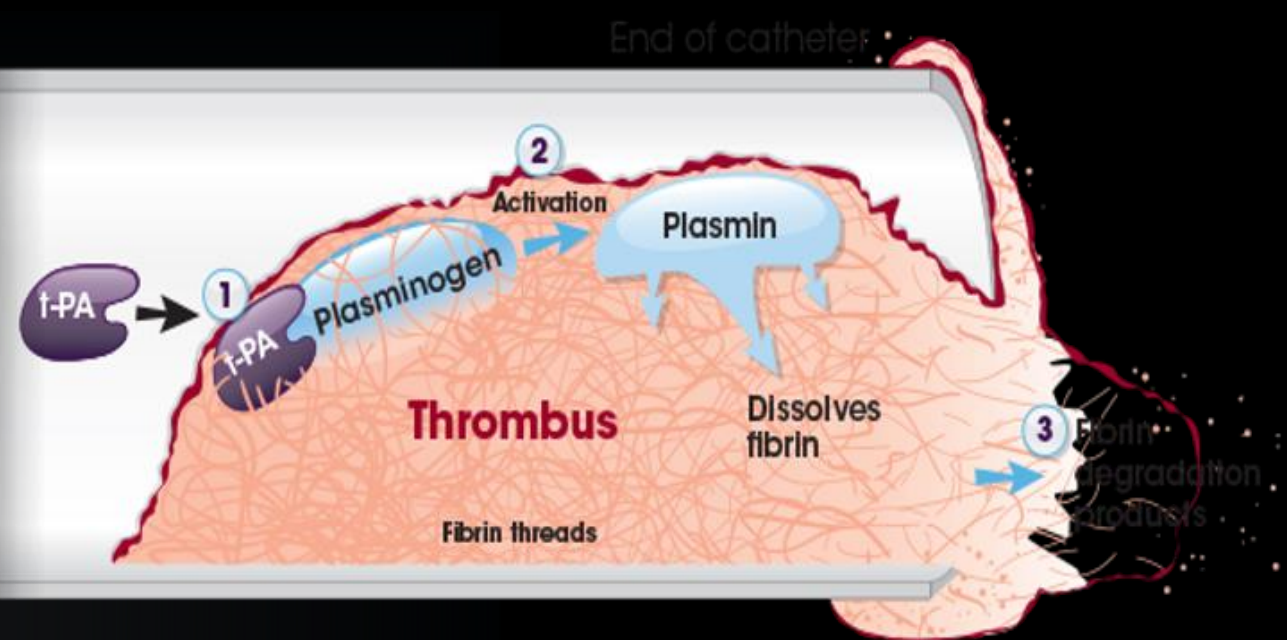
- 1 in 6 CLABSI are from antibiotic resistant organisms (ARO), 2017 CDC
- NZARA 2017 Top Objectives
 1. Awareness and Understanding
 2. Surveillance and Research
 3. Infection Prevention and Control
- If we don't take action, we will be left powerless against common infections



THROMBOLYTICS: (ALTEPLASE) CLOT-BUSTING DRUGS

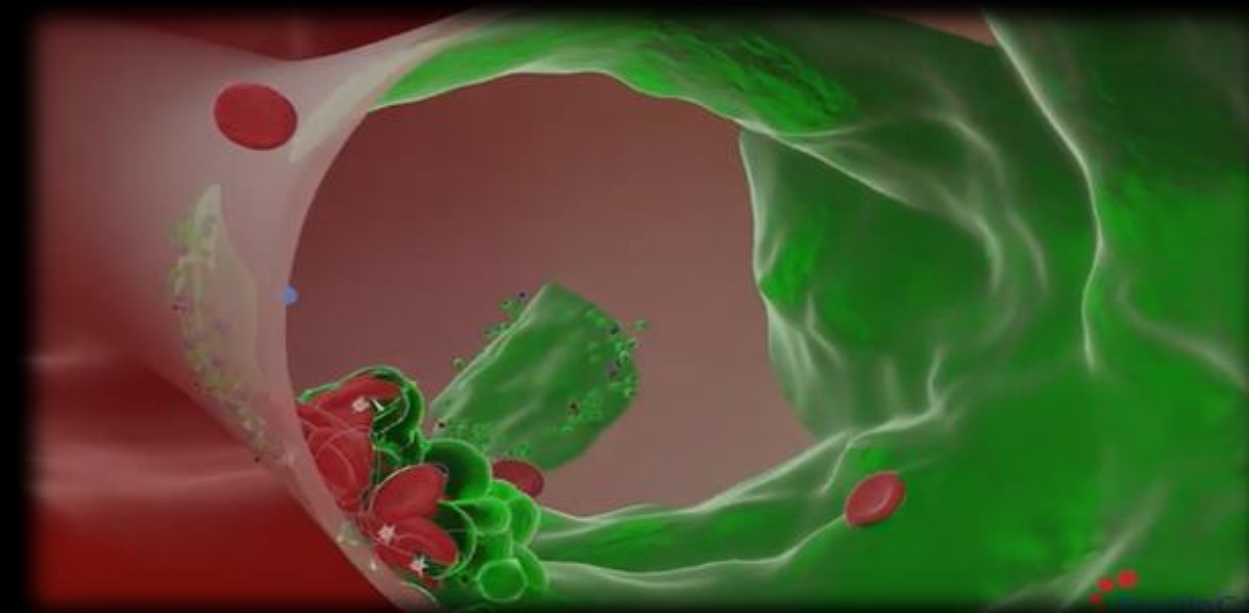
Thrombus / Clot

- Breaks down fibrin threads
- Clearance rate of 86% after two doses
- Costly



Biofilm

- Ineffective against bacteria and/ or biofilm
- Ineffective if biofilm is covering the clot



- CLABSI 3.59 times greater in those patients that received tPA compared with those who did not (Thakrar, 2014)
- The risk of catheter-related sepsis was 2.62 fold higher when thrombosis occurred (Timsit et al, 1998)

Product	Anticoagulant	Antimicrobial	Antibiofilm (prevent)	Antibiofilm (eradicate)	Comments	References
Saline	X	X	X	X	Lock/flush	
Heparin	✓	X	X	X	Stimulates biofilm; HIT	Shanks et al, 2005. Heparin stimulates Staphylococcus aureus biofilm formation. Infection and Immunity, 73(8):4596-4606.
Citrate 4%	✓	✓	✓	X	Need for thrombolytic treatment	Hemmelgarn et al, 2011. Prevention of dialysis catheter malfunction with recombinant tissue plasminogen activator. The New England Journal of Medicine., 364(4):303-312.
Citrate 4% +/- 30% Ethanol	✓	✓	✓	X	Protein precipitation; need for thrombolytic treatment	Schilcher et al, 2013. Ethanol protein precipitation – New safety issues for catheter locking techniques. PLOS ONE, 8(12):1-8.
Antibiotic cocktail	X	✓	✓	X	Antibiotic resistance risk; not efficient against biofilm	Pittiruti et al, 2016. Evidence-based criteria for the choice and the clinical use of the most appropriate lock solutions for central venous catheters (excluding dialysis catheters): a GAVeCeLT consensus.
Taurolidine	✓	✓	✓	X	G+ limitations; need for thrombolytic treatment	Solomon et al, 2010. A randomized double-blind controlled trial of taurolidine-citrate catheter locks for the prevention of bacteremia in patients treated with hemodialysis. American Journal of Kidney Diseases, 55(6):1060-1068.; Arlt et al, 2012. Int. J. Cancer: 131, E804–E812
Alteplase / rtPA	X	X	X	X	Most likely to be associated with undesired effects or hemorrhagic complications; costly	Pittiruti et al, 2016. Evidence-based criteria for the choice and the clinical use of the most appropriate lock solutions for central venous catheters (excluding dialysis catheters): a GAVeCeLT consensus.
4% T-EDTA	✓	✓	✓	✓	MBEC ≤ 4% for G+, G- , yeast including MDR microorganisms	Liu et al, 2018. Tetrasodium EDTA is effective at eradicating biofilms formed by clinically relevant microorganisms from patients’ central venous catheters. mSphere 3(6):1-16

THE SOLUTION

KiteLock™ 4%
Sterile Catheter Lock Solution

ANTI-
COAGULANT

Trusted anticoagulant



Prevents formation of clots to maintain CVAD patency.

ANTI-
MICROBIAL

Effective broad-spectrum antimicrobial



Kills all relevant bacteria that can lead to an infection.

PREVENT &
ERADICATE

The only lock solution with the ability to eradicate biofilm



Biofilm is the source of 80% of CVAD infections.

RESISTANCE

Does not contribute to antibiotic resistance



Effective against multi-drug resistant bacteria.

CHILDREN

Approved for use



The only catheter lock solution regulatory approved for use in children.

Supporting Clinical and Financial Data



Clinical Efficacy of EDTA 4% In Adults

- **71% reduction** in CLABSI ($p = 0.04$)
- **100% reduction** in occlusions
- **63% reduction** in healthcare cost

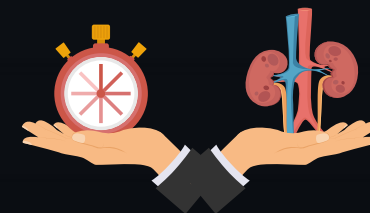
Vaccine Infectious Disease Organization

- Microbiological Analysis of 300 CVAD tips
- Lui et al 2018, tEDTA's effectiveness against biofilms



Reduction of Central Line Complications in Pediatrics

- **100% reduction** in infections ($p = 0.002$)
- **50% reduction** in occlusions ($p = 0.018$)
- Markov Model proves financial efficacy of KiteLock compared to standard of care, heparin



Canadian Dialysis Units

- Up to **70% reduction** in occlusions and alteplase use (costly clot busting drug)
- Data presented at the World Congress of Nephrology April 2021

Current Clinical Projects

Hamilton Health Sciences (Cancer Center)

- Hospital wide conversion to KiteLock from Oct '21 to April '22
 - Data being analyzed for reduction in CVAD complications and Financial Impact

CLiCK Study

- Pre-Observation Study: 20% of CVADs are locked
- CLiCK Trial (Control of Line Complications with KiteLock)
- Multi-Centre, cluster randomized, double blinded; crossover study
- 5 Canadian Sites; 3600 patients
- Decrease in CVAD complications: CLABSI, occlusions (alteplase use)

UHN Dialysis

- Quality Improvement Project to determine:
 - Decrease in occlusions (alteplase use)
 - Decrease in infections
 - Financial Impact
- Led by Dr Charmaine Lok



CLINICAL VALIDATION

As

Standard of Care

CLOCK Trial



\$2 million boost to improve treatment for children with cancer - Faculty of Medicine - University of Queensland

The Accelerating Collaborative Cancer Research (ACCR) grant provides funding of \$2,000,000 over four years, comprising \$350,000 per annum from Cancer Council Queensland and a contribution of \$150,000 per annum from UQ.

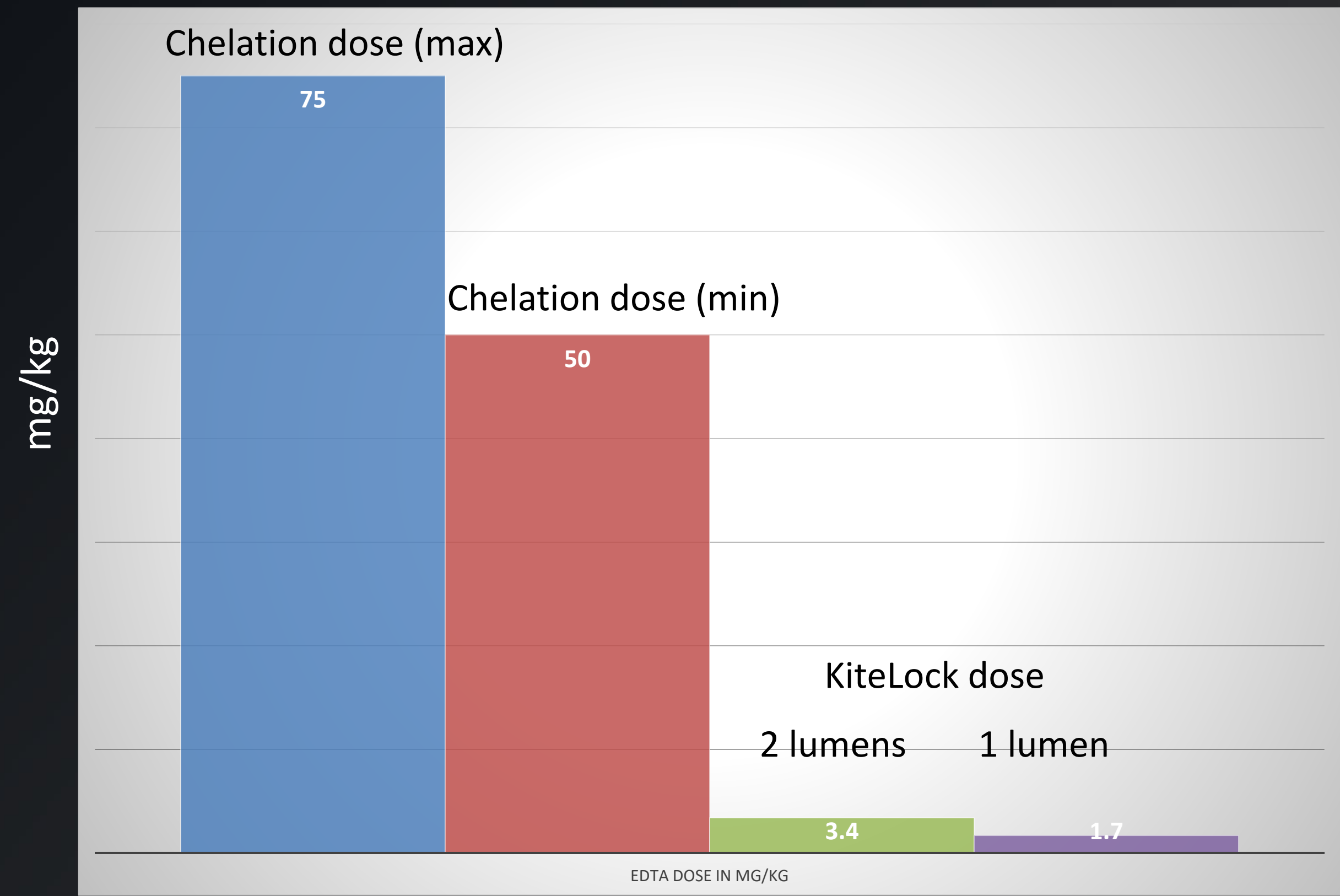
medicine.uq.edu.au

Preventing adverse events during paediatric cancer treatment:

- a multi-site hybrid RCT of catheter lock solutions
- 756 patients
- Australia (Queensland, Victoria, New South Wales and New Zealand)
- Type-1 Hybrid effectiveness-implementation three-arm, superiority, effectiveness RCT (funding by Cancer Council Queensland)

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.

KiteLock 4% Safety Profile



How to Use

- Follow current flush/lock procedures
- Follow Lock guidelines: fill volume of catheter plus 20%
- Regulatory guidelines are to aspirate lock solutions
- If you are not able to aspirate, KiteLock is safe to flush
- Draw up KiteLock from the vial as per your local protocol



Frequently Asked Questions

- KiteLock is a medical device, not a drug
- KiteLock is approved for use in children
- It is compatible with polyurethane, silicone, and most standard catheter materials
- It has a large margin of safety if unable to aspirate

Contraindications / Adverse Effects

➤ Contraindications:

- Documented hypersensitivity to edetate.
- Do not use in pregnant and nursing mothers as safety has not yet been investigated.

➤ Adverse Effects/Reported Complaints:

- Paraesthesia (tingling) and/or dysgeusia (metallic taste)
- Pain on infusion (5 cases internationally)

“

This therapy holds the promise to reduce CVC-related complications to perhaps as low as biologically possible.

”



Preventing Central Venous Catheter Complications in Children Using 4% Tetrasodium EDTA Locks: A Small Study With a Big Impact, Mercer et al, 2021

KiteLock™ 4%
Sterile Catheter Lock Solution

SterileCare

THANK YOU

