ASP SUMMIT
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Shine on Flexible Endoscope Reprocessing

2025 Webinar 05 | Series

Why do we accept "Imperfection" when "Utopia" is possible?

ASP Advanced Sterilization Products

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Intro

We often discuss the contamination levels within flexible endoscopes. We accept that flexible endoscopes have long narrow lumens and complex channels which trap moisture and organic material to create biofilm. We acknowledge this risk because of the process.

But 'Why Do We Accept Imperfection when Utopia is Possible?'

Are we doing all we can to decontaminate flexible endoscopes to the required levels? Is there an acceptable hierarchy of risk using such endoscopes?

Based upon Spaulding classification, this hierarchy reflects the likelihood of contamination and difficulty of reprocessing, not the importance of decontaminating!
Should we migrate towards the highest standard of decontamination available for all endoscopes to reduce contamination present? What would you expect as a patient?

Systems we use have been in place for many years, why does the quickest cycle within a washer/disinfector become our standard? Surely, we should utilise the best cycle configuration that would include 'drying' and 'sterilization' of the endoscope as part of the reprocessing?

"If we always do what we always did, we always get what we always got?"
HENRY FORD

It's time for change!

Despite decades of continual improvement when decontaminating endoscopes, outbreaks linked to contaminated endoscopes continue.

Are we doing all we can to eradicate the known risks that lurk within Flexible Endoscopes?
It looks at incidents across the world and discusses whether we can remove the obstacles that are preventing change to reprocessing flexible endoscopes.
Can we modify the decontamination life cycle to ensure endoscopes are decontaminated to a more assured level?

Does this include the practicalities of sterilization?
We know that residual fluid remains within the endoscope post processing, and during the webinar we look at various ways of reducing the probability of such moisture creating communities of micro-organisms that are more commonly known as biofilms.

What are the obstacles we need review, where do the problems exist?

Education and culture | **Decontamination systems** | **Device design**

There is a need to discuss how we develop a strategic evolution to meet modern infection control challenges.

Topic • 01

Risks associated with the use of flexible endoscopes

There are several examples of infection transmission from across the world. Should there be a hierarchy of risk for flexible endoscopes and a discussion whether traditional interpretation is still relevant to risks that exist.
Are we doing enough to prevent biofilm and can systems be enhanced to eradicate the possibility of biofilm taking hold?

“Inadequate decontamination procedures and equipment malfunction were two leading causes of post endoscopic infection and contamination. More than 91% of the infections could be prevented if quality control systems were improved”.[1]
Levels of decontamination are based upon Spaulding classification, this hierarchy was developed many years ago and reflects the likelihood of contamination and difficulty or reprocessing, not the importance of decontaminating! Should we migrate towards the highest standard of decontamination available for all endoscopes to reduce contamination present? What would you expect as a patient?[2]

We all discuss updating Spaulding, but is the industry bold enough to do it and what would be the consequences???

Rauwers AW, Kwakman JA, Vos MC, Bruno MJ. Endoscope-associated infections: a brief summary of the current state and views toward the future. Techniques in Gastrointestinal Endoscopy. 2019;21(4):150608. doi:10.1016/j.tgie.2019.04.006 - https://www.science direct.com/science/article/abs/pii/S1096288319300300

Standards used to decontaminate flexible endoscopes have promoted high level disinfection as the 'utopia'. Should we be looking at different levels dependent on the hierarchy of risk? Are risks appropriate and where is the evidence of harm within higher risk endoscopic applications?
Are we accepting 'Imperfect' systems and are we happy to continue and not evolve?

There is a great deal of evidence available to confirm we are harming patients. Thankfully, the ratio is very low, but one Healthcare Associated Infection, is one too many!

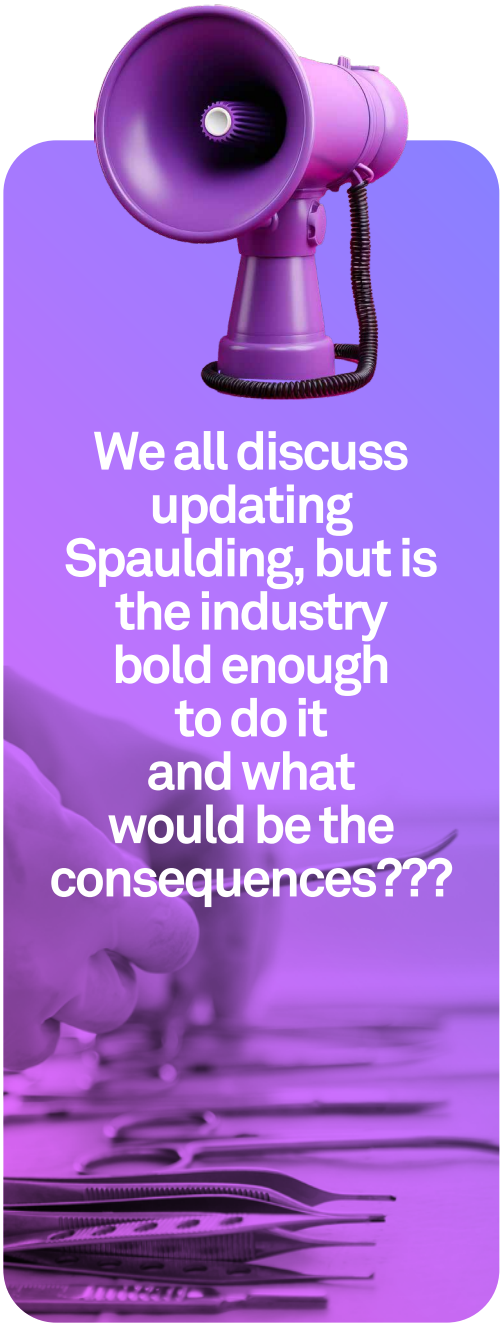
Decontamination systems must evolve, why accept the current life cycle with acknowledged limitations.

Should we evolve into utopia, 'Sterilization of Endoscopes'? Do we underestimate the risk when decontaminating such medical devices?

Show me the Evidence!

Is our assumption of the risks a reality? That is an argument that is often raised from Clinical teams that may have differing priorities (patient related management). Show us the evidence? Ethically, is it incorrect not to use the highest standard of decontamination possible?

This study looks at several historical incidents that have been linked to transmission of micro-organisms between patients using a variety of flexible endoscopes. In these incidents there are proven links to devices as the primary source of this transmission. Such incidents are prevalent across the globe, and we ask, is the evidence presented the tip of the iceberg?



Do we understand the true risk and the correct ratio of infections because of decontamination activities not being completed correctly?

Do we undertake routine surveillance of patients post procedures? Do we monitor internal contamination within scopes?[3]

Topic • 02

Obstacles preventing: Culture/Technical/Resources?

Concerns are identified within the decontamination and healthcare industry for reprocessing of flexible endoscopes. What are the obstacles to prevent evolution towards 'Utopia'?

- **Culture - Not considering decontamination as part of device procurement and limited desire to evolve our systems. First they purchase the endoscope and only then consider Decontamination!**
- **Greater priorities within the organisation**
- **The secret greenhouse that is biofilm within Endoscopes**
- **Difficulties cleaning ancillary Items**
- **Servicing Regimes for the Endoscope in alignment with device manufacturers instructions**
- **Education and competence**

'Manual cleaning is prone to human error and not reproducible - Manual cleaning is a complex process that requires high levels of technical skill and concentration. Reprocessing staff rate manual cleaning as the most challenging part of reprocessing.'[4]

Critical Subtasks of Reprocessing

Human-factors–designed IFUs significantly reduce errors during reprocessing, increasing the likelihood of achieving sterility — and recommends applying these design principles (including perhaps electronic aids) broadly to improve patient safety.[5]

TABLE 1: Five Critical Subtasks of Reprocessing in Jolly et al. (2012)

Task	Reprocessing Error	Potential Consequence	Mean Completed with Error (%)
Observing scope for leak	Incomplete leak detection	Costly damage to scope	83.3
Suctioning detergent	Channels not completely flushed	Remaining bioburden	54.2
Brush instrument channel	Channel not completely brushed	Remaining bioburden	95.8
Attach channel plug/ injection tube	Channels not completely flushed	Remaining bioburden or detergent	95.8
Drying	Channels left moist	Bacterial or viral growth in internal channels	75.0

Biofilm Formation – An unachievable challenge to eradicate?

Jolly JD, Hildebrand EA. Better instructions for use to improve reusable medical equipment (RME) sterility. Human Factors. 2013. V55,N2:397-410

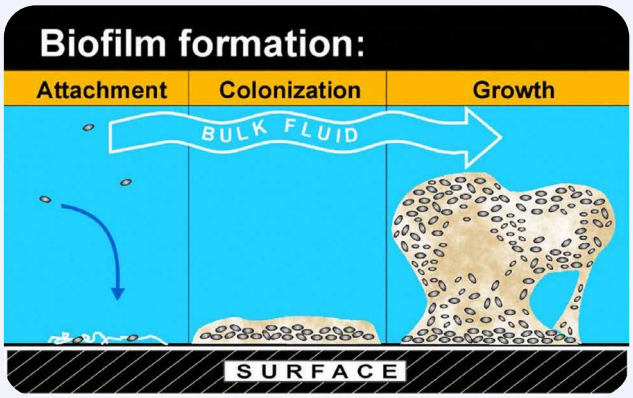
Biofilm – The Secret Greenhouse:

Issues such as biofilm are discussed constantly, are we doing enough to implement change? We have the knowledge and awareness of the problem, but why do we not innovate to prevent? Why can't we achieve 'Utopia'?

The earliest evidence of biofilm dates back 3.5 billion years, they are natural phenomena. Can we open the vault?

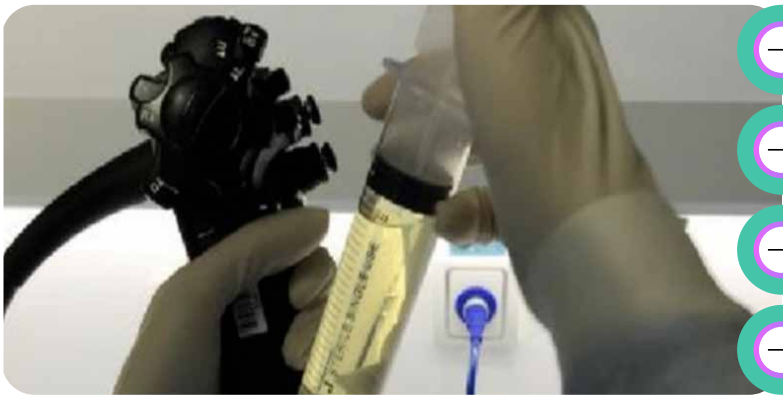
'The application of medical devices has been shown to significantly improve a patient's quality of life. Unfortunately, this process is also associated with the appearance of a number of infections, usually caused by biofilms.'

Is it about controlling, accepting, rather than removal? New technologies to clean scopes, use of different manual cleaning brushes, differing chemistry, drying efficacy and better use of controlled environment storage systems will all form part of an equation to reduce the impact and ultimately infection risks to patients.[6]



Biofilm in a lumen diagram https://www.bayarealyme.org/blog/straight-talk-biofilms-new--answer-treating-lyme-disease/, accessed Nov 2025

Microbiological surveillance systems are an option, to routinely determine biofilm present, the benefits of such surveillance are:



- To check the quality of endoscope reprocessing
- To confirm the reprocessing quality or to
- Identify possible weak points at an early stage
- Provide information about possible risks

Comparative Study of Microbiological Monitoring Results from Three Types of Sampling Methods after Gastrointestinal Endoscope Reprocessing -Ma -2019 -BioMed Research International -Wiley Online Library

There are inconsistencies with such monitoring and how do we identify the correct level of contamination?
According to the French guidelines, Pineau differentiated between different action and alert levels. There are great variations in national guidelines concerning acceptable number of germs, action and alert levels. [7]

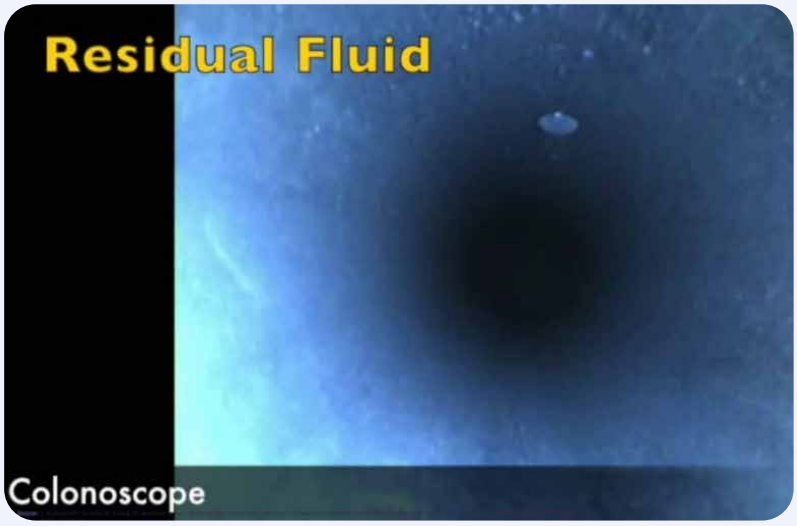
'If we look, we may find what we do not want to find!'

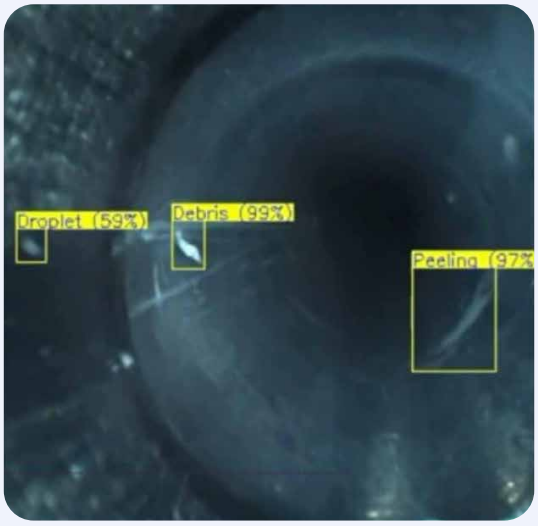
JOHN PRENDERGAST

Other monitoring methods for flexible endoscope use include protein testing and visual inspections. ANSI/AAMI ST91:2021 specifies using a borescope to visually inspect the internal channels of flexible endoscopes for cleanliness, damage, and to identify issues like residual water or debris.[8]

Use of such innovative technology is done to supplement manual visual inspection, which may not be sufficient on its own to ensure effective cleaning.[9]

This returns us to human factors and the ability of trained or untrained technicians to determine if contamination or damage is present within the endoscope??





Courtesy of Monique Barakat, MD PhD, Associate Professor of Pediatrics & Medicine | Divisions of Pediatric and Adult Gastroenterology and Hepatology | Stanford University School of Medicine Stanford, CA USA\

Topic • 03

The Decontamination life cycle optimization

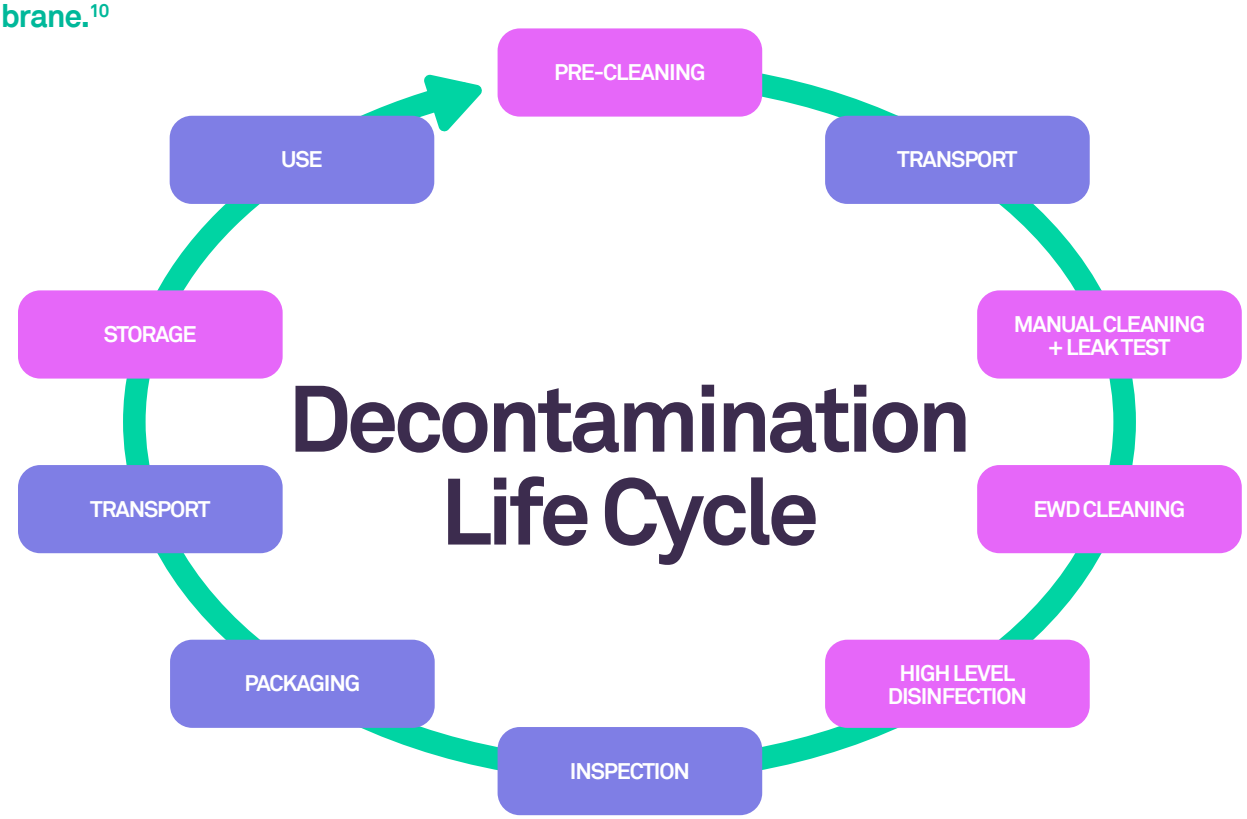
The current life cycle of a flexible endoscope, distinguishes the journey from patient to reprocessing and back to patient. It was not originally designed to account for today's awareness of biofilm and antimicrobial resistance. Can we rethink the life cycle, to include all the multiple factors to ensure a safe flexible endoscope is prepared for the next patient?

We must redevelop our decontamination life cycle to ensure our systems present greater assurance to patients. Enhancement of quality control systems and technician training reduce the potential of error within manual cleaning. Such cleaning remains a critical part of the life cycle, will that change ? As a minimum we must review and advance our pre-cleaning systems.

• Utilization of automated pre-cleaning systems is on the horizon and may reduce manual intervention in the longer term.

• Commercial suppliers claim that the use of high-pressure irrigation, combined with inorganic nanoparticles, combine to create efficient antibiofilm agents to clean flexible endoscopes.

• **Their antimicrobial effect is mainly based on electrostatic binding to the bacterial cell wall and/or release of metal ions. Interaction with the bacterial surface leads to the destruction of the cell membrane.**[10]



HSE, 2019. Health Service Executive Standards and Recommended Practices for Operational Management of Endoscope Decontamination Facilities. https://www.hse.ie/eng/about/who/nqpsd/qps-improvement/hse-s-tandards-and-recommended-practices-for-the-operational-management-of-edu-s-qpsd-d-082-1-v1.pdf
WHO Global Guidelines for the Prevention of Surgical Site Infection (2018), The cycle of decontamination of a reusable surgical instrument, pag. 49
NSW Government – Clinical excellence Commission: Reprocessing of Reusable Medical Devices: https://www.cec.health.nsw.gov.au/keep-patients-safe/infection-prevention-and-control/Reprocessing-of-Reusable-Medical-Devices#:~:text=Reprocessing%20is%20a%20multistep%20process,(if%20applicable)%20and%20storage. accessed on 12/03/2023

Cycle configuration within the Endoscope washer disinfectors should be reviewed, to include better outcomes with enhanced cleaning performance, high level disinfection and an appropriate drying purge at end of cycle.

Much progress has been made on the back of incident and advent of international standards (Ref ISO 15883 part 4), this includes the importance of cleaning efficacy, channel patency and high level disinfection, however does the need for quicker cycles impact on our outcome? Do we ignore the drying process within EWD cycle because of other priorities?[11]

Evidence is available to confirm the removal of residual moisture reduces the potential of biofilm formation within the endoscopes. The more we can remove during the automated process, the likely reduction of biofilm formation within the endoscope![12]

A study demonstrated that EWD alcohol flush and air purge cycles were insufficient for drying endoscopes, while a 10-minute forced air drying cycle effectively dried multiple channels!! Other EWD cycles showed similar results.[13]

Other factors that should be reviewed for drying efficacy:

Courtesy Eng John Prendergast (NWSSP- SES –Environmental Management and Engineering)

- **Air Quality**
  Pharmacopeia standards/Microbiological tests?
- **Time of Purge Stage**
  Purge through each lumen (40 to 60 seconds???)
- **Pressure through each lumen during the purge phase**

Is operational use of controlled environment storage systems for flexible endoscopes appropriate? Are they type tested, commissioned and operated to provide an endoscope that is acceptably dry?

Several key facts that must be considered when using such systems:

Courtesy John Prendergast archive

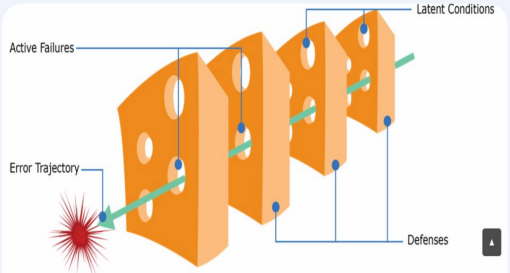
- If configured, a drying function is intended to supplement, if necessary, any drying provided as part of the automated processing cycle.
- Endoscopes inserted, must be positioned within cabinet for validated drying phase of process.
- Equipment is type tested as part of manufacture, we periodically test using standard surrogates, do they replicate operational endoscopes?[14]

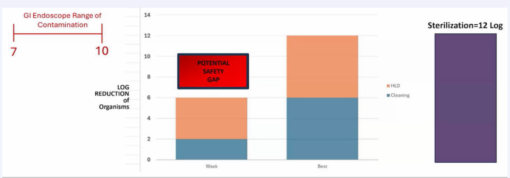
Topic • 04

Sterilization of Flexible Endoscopes

The Margin of Safety:

Rutala and Weber1 estimated the safety margin associated with each stage of the endoscope reprocessing cycle. They observed an initial contamination level of 108 to 1010 microorganisms per endoscope. After reprocessing they estimated that these numbers would be reduced to between 1 and 10^{-2} microorganisms per endoscope clearly indicating a very limited safety margin associated with the reprocessing stages.[15]





Method	Microbial Reduction	Eliminates Spores?
Cleaning + HLD	6 $\log_{10}$	✗ No
Sterilization	12 $\log_{10}$	✓ Yes

https://www.safechoicesafety.com/how-a-piece-of-cheese-can-save-a-life/
https://www.asp.com/en-gb/products/terminal-sterilization/ultra-gi

Progression to Utopia:

The benefits of moving towards sterilization of endoscopes, the systems available and positives and negatives that exist.

Sterilization of endoscopes is necessary for scopes for use on higher risk patients and where we penetrate sterile fields.

Are there other contributory transmission factors that contradict the suggestion that sterilization is necessary? Or are we accepting imperfection?

Sterilization is possible, and as part of a combined process, presents best assurance of a safe endoscope. Without sterilization are we gambling?

"Reprocessing of Endoscopes need to be treated like an operating theatre procedure" - meaning the same meticulous attention for detail is needed each and every time'.[16]

M Alfa (Principal Investigator, St Boniface Research Centre, Winnipeg, Canada)

Device compatibility is an imperative factor when considering a move towards a terminal sterilization process. Additional needs include:

- Verification that the sterilant can penetrate the length of each lumen within the endoscope
- No harmful residues should remain on conclusion of reprocessing.
- Safety of staff in relation to exposure to hazardous sterilization solutions

Source: Courtesy of Advanced Sterilization Products – R&D

Conclusion

We need to determine the risk and react appropriately with procedure and bioburden present when using flexible endoscopes.

Advancement in reprocessing techniques must be considered and changes accepted in accordance with equipment available and developments – evolution towards Sterilization must be a primary consideration.[17]

Use of single use endoscopes scopes solve many of the issues discussed in certain areas of healthcare, single use device has many advantages over re-usable.

Advancement in endoscope technology must include better designs (robust) and ensure decontamination is considered as part of design innovation.

"The road to utopia winds through valleys of challenge and peaks of possibility'

Take home messages

1. *Risks are well known, why are we accepting imperfection*
2. *We cannot eradicate biofilm, but we can control and minimize*
3. *Life Cycle reconfiguration is necessary for reprocessing Flexible Endoscopes*
4. *Utopia is possible, we just need to evolve, resource and adapt to new methods and systems.*

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