ASP SUMMIT
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Shine on Flexible Endoscope Reprocessing

2025 Webinar 03 | Series

# Flexible Endoscope Decontamination: The challenge of biofilms!

ASP Advanced Sterilization Products


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**Manchester, United Kingdom**


# Intro

**Endoscope reprocessing is a challenge for healthcare professionals and institutions. In recent years, several outbreaks have been linked to limitations in endoscope decontamination. In this webinar we will discuss the current gaps in flexible endoscope decontamination, the inadequacy of sampling and test methods for biofilm, the risk of biofilm, the potential of biofilm accumulation in flexible endoscopes and what can or should we do to combat this. We start with an overview of the 3 areas (biofilms, the decontamination process and testing) we then look to what can we do to improve these processes to give greater assurance to our patients. The main takeaway is that current decontamination practices are inadequate and sterilization should be adopted.**

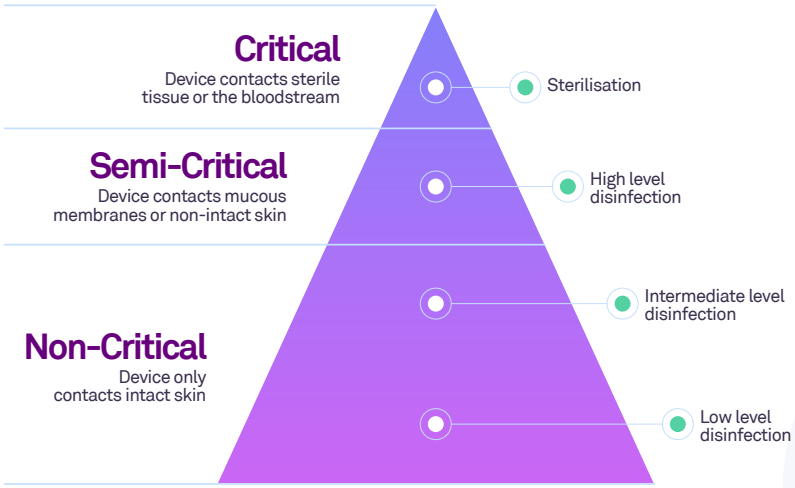
*We will examine real-world studies to show why Vaporized Hydrogen Peroxide (VHP) with plasma is the practical solution to these challenges.*

Topic • 01

# Endoscope Decontamination overview

**Endoscope decontamination has advanced significantly over the last decade and a half, but it's still in its infancy compared to the processes for stainless steel surgical instruments. This highlights the need for greater emphasis on terminal processes for flexible endoscopes.**

This overview begins with the **Spaulding Classification**, a system for matching the disinfection and sterilization of reusable medical devices with appropriate processes based on the risk of the tissue they come into contact with. This system, originally proposed in 1939 and published in 1957, is widely used and explains where endoscopes fit into this classification.[1]



The Spaulding Classification

*"Despite significant advances in endoscope technology, endoscopes still remain on the original 1957 classification, treating them as semi-critical devices."*

Then the **Endoscope Reprocessing Cycle** is outlined, which includes several steps:

1. **Leak tests**
2. **Manual cleaning**
3. **Automated cleaning** (in some countries)
4. **High-level disinfection or liquid chemical sterilization**
5. **Transport and/or storage and drying**
6. **Clinical application/use.**[2]

The overview also highlights the progression of endoscope decontamination, since 2008, noting the rapid advancement in technologies and the increased application of flexible endoscopes. It also questions whether these advances should change the classification of endoscopes.[3]

Topic • 02

# Endoscope Decontamination assurance tests

Emphasizing the importance of validating various aspects of the decontamination process, including machines, water, environment, and endoscopes. It highlights the need for daily checks, weekly tests, quarterly validations, and annual re-validations. This topic also mentions the use of process challenge devices and cleaning efficacy tests. [4]

The main focus is on water, noting that Total Viability Count (TVC) is not comprehensive and may not detect all organisms, such as Legionella. The timing of sample collection is crucial, as many organisms can die off in a sample before it reaches the lab. This topic also discusses the challenges in isolating certain pathogens, such as E. coli, and Klebsiella pneumniae, which are commonly associated with duodenoscope associated infections.

Research findings are presented, including an eight-year study on duodenoscope contamination in Holland, which found that 15% of patient-ready duodenoscopes were still contaminated with gastrointestinal microorganisms despite efforts to reduce contamination rates. The study concludes that duodenoscope contamination remains a significant problem, particularly in reprocessing biopsy and suction channels. [5]

***"...few assurance tests are conducted, as a matter of practice, during endoscope reprocessing."***

Another study discusses an endoscope-associated outbreak of OXA-181-carbapenemase-producing Klebsiella pneumoniae in Germany. The outbreak strain was detected in 19 patients and was also isolated from reprocessed endoscopes. The study highlights the persistence of bacterial communities in channels despite cleaning and standard decontamination methods may fail since biofilms showed tolerance to the disinfectant.[6]

**There is much focus on the process and machines with regard to testing but very little for the finished product, more detailed standardized tests are required to give assurance of the safety of the patient ready device.**

Topic • 03

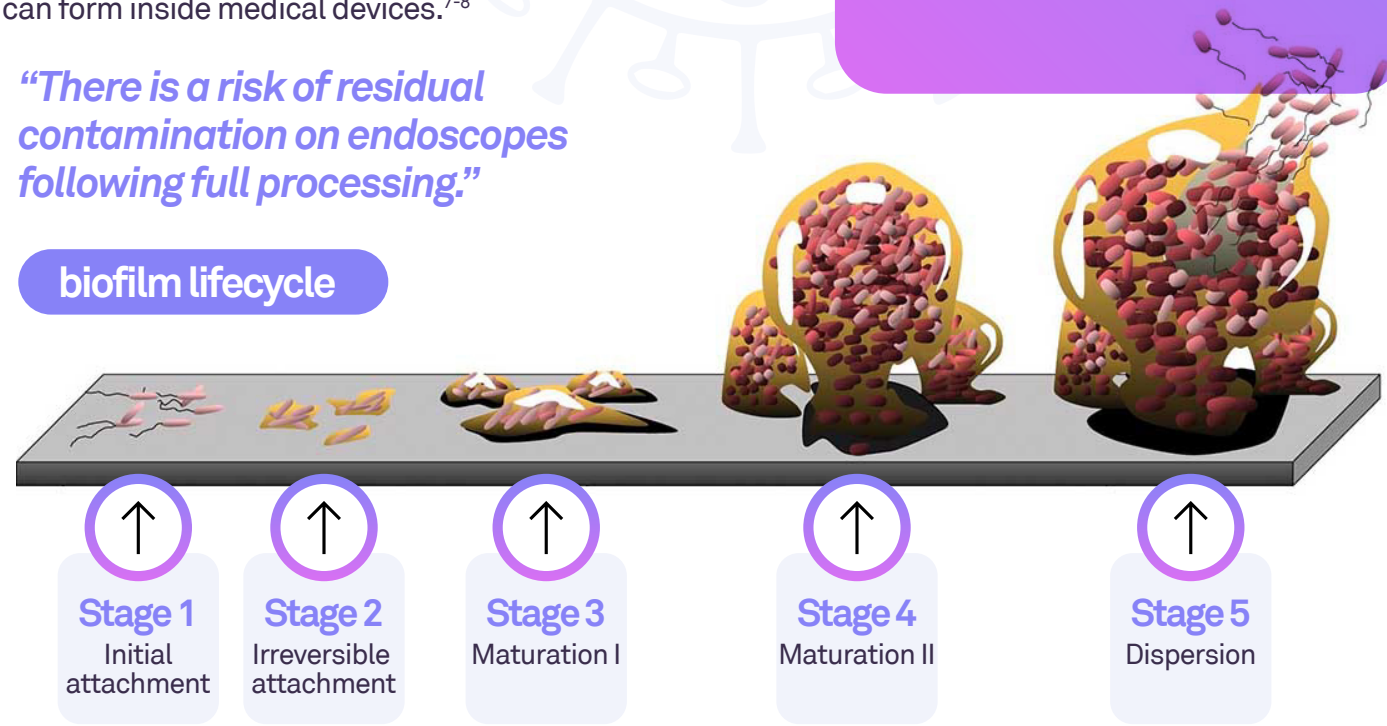
# Biofilms – the challenge for endoscopes reprocessing

**It's clear there is a real risk of biofilm accumulation in flexible endoscopes, we also see a direct link with the potential spread of hospital acquired infections.**

Biofilm is a thin but robust layer of mucilage that adheres to a solid surface and contains a community of bacteria and other microorganisms. The biofilm lifecycle is illustrated, showing the different stages of biofilm development. A diagram of biofilm in a lumen highlights how biofilms can form inside medical devices.[7-8]

*"There is a risk of residual contamination on endoscopes following full processing."*

**biofilm lifecycle**



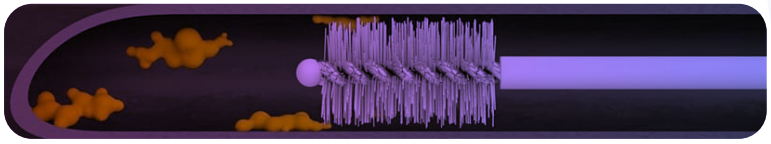

The presentation explains why biofilm is a risk, mentioning that biofilms can have high Total Viability Count (TVC) counts, are resistant to high-level disinfection (HLD), and can persist even after manual cleaning.[9-10] Research by Alfa & Singh (2020) is discussed, emphasizing that residual moisture stimulates bacterial replication and biofilm formation.[9] Another study by Omidbakhsh et al. (2021) highlights the challenges of flexible gastrointestinal endoscope processing, including incomplete cleaning, biofilm formation, and the lack of a margin of safety with HLD.[11]

Further research by McCafferty et al. (2018) discusses gastrointestinal endoscopy-associated infections and their contributing factors, emphasizing the importance of improving endoscope reprocessing and screening for contamination.[10] Primo et al. (2022) found extensive biofilm and residual matter in new flexible gastroscope channels after 30 and 60 days of patient use and full reprocessing.[12] Finally, Pineau et al. (2024) recommend a harmonized and standardized sampling and culturing method for flexible endoscopes.[13]

Topic • 04

# The future of endoscope reprocessing

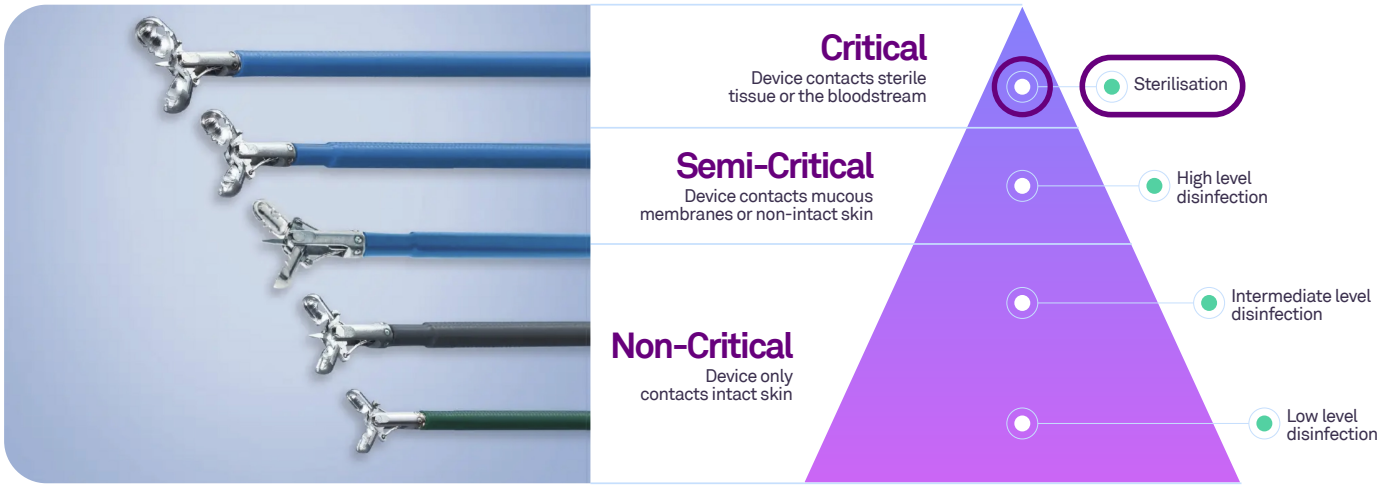
Emphasizing the importance of immediate actions post-disinfection, such as using, drying, or storage scopes in a cabinet. It also reviews manual cleaning processes, questioning the compatibility and effectiveness of brushes used for cleaning endoscope lumens.
The presentation then raises the question of whether automated pre-clean devices could be the future. It mentions the potential use of nanoparticles, nano metals, high-pressure air, and water for biofilm removal.



*"...consider a risk-assessed approach: sterile scopes should be required for immunocompromised patients"*

**Endoscopes should be reclassified as critical devices and research suggests the best current solution is Vaporized Hydrogen Peroxide with Plasma for the terminal process to give greater assurance of safety to our patients.**

The topic continues by exploring the possibility of changing the classification of various endoscopic instruments, such as bronchoscopes, cystoscopes, ureteroscopes, and duodenoscopes. It questions whether these instruments should always be sterile.[14]
The presentation also poses a question about the sterilization of endoscopes in a low-temperature sterilizer, asking if it is done for specific types of scopes or all scopes.[15]
It asserts that sterilization of flexible endoscopes is required, highlighting the effectiveness of gas plasma (HPGP) sterilization. This method is noted for its broad-spectrum efficacy against pathogens, lack of toxic residues, and better penetration compared to standard vaporized hydrogen peroxide (VHP).[16]




The Spaulding Classification

# Conclusion

There is ever increasing research demonstrating the current decontamination process for flexible endoscopes is not sufficiently robust. Knowledge and test methods for defence against biofilms is not widely understood. There is a need for standardised testing for biofilm-enhanced decontamination processes and a reclassification of the devices with terminal sterilisation to ensure safety. Although new technologies are emerging, Hydrogen Peroxide Gas with Plasma is currently being presented as the most promising option for the future of endoscope decontamination.

# Take home messages

1. *New Guidelines on Flexible Endoscopes Reprocessing are required*
2. *More in-depth monitoring and sampling for biofilm is needed.*
3. *Its clear there is a risk of biofilm accumulation, and this presents additional risk due to the level of resistance to standard processes.*
4. *Chemical saturation alone is not enough to remove Biofilms; we need to look towards more robust processes.*
5. *Automation would enhance the assurance of pre-clean processes*
6. *Scopes are critical medical devices and therefore should be Sterilized.*

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Topic • 02

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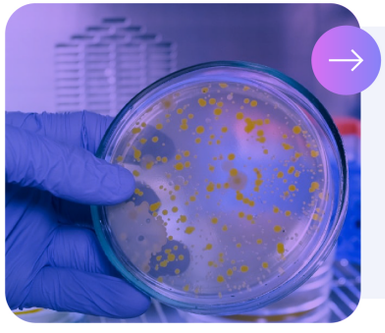

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*"... small amount of assurance tests by comparison that are conducted on the actual devices."*

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