ASP™ Advanced Sterilization Products

The Challenge Of Endoscope Decontamination:

Duodenoscopes, a bridge to far?

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The Challenges of Endoscope Decontamination?

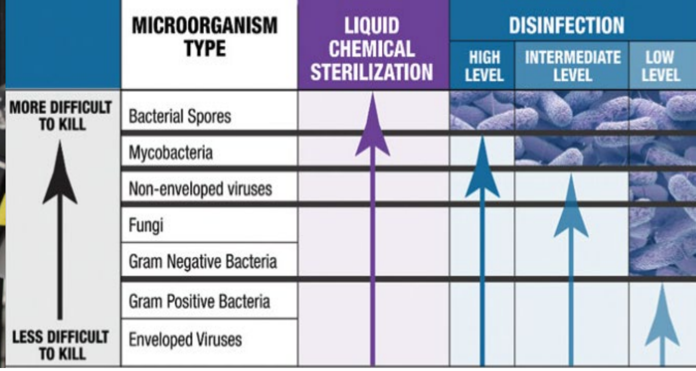
Logistics

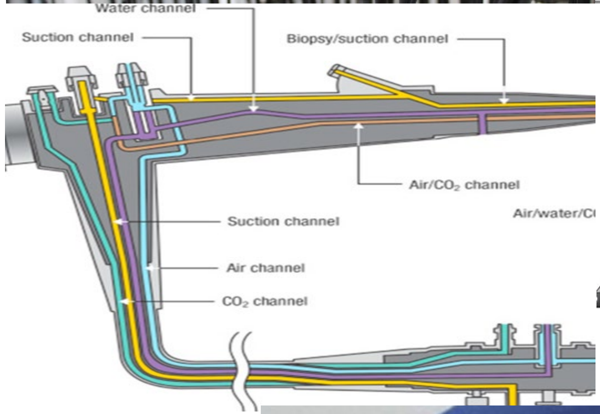
Complex design

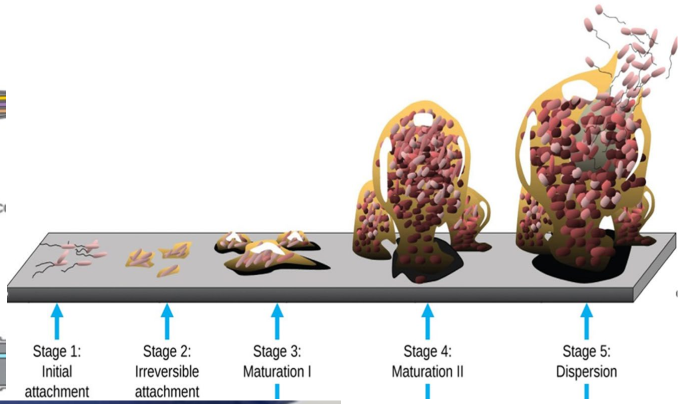
Limitations of HLD

Biofilm formation

What are our options







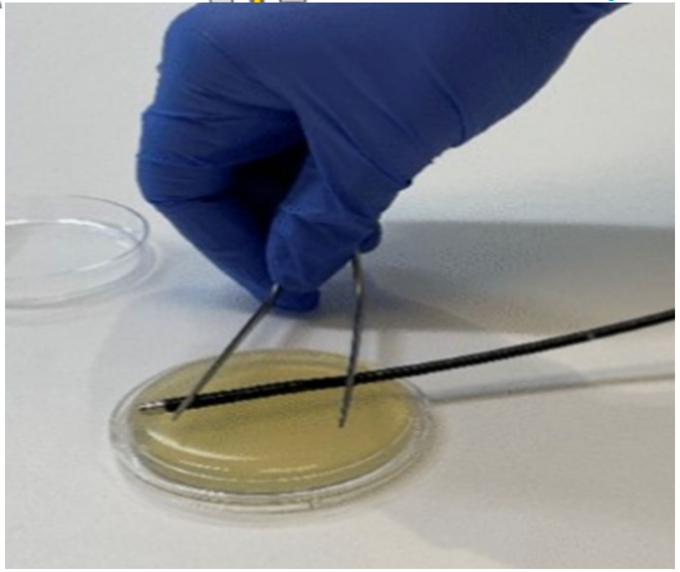


Image 1: https://addler.com/rigid-endoscopes/
Image 2: https://www.steris.com/healthcare/knowledge-center/sterile-processing/liquid-chemical-sterilization
Image 3: https://www.sciencedirect.com/science/article/abs/pii/S0001209216300035
Image 4: https://www.bayarealyme.org/blog/straight-talk-biofilms-new-answer-treating-lyme-disease/
Image 5: https://aricjournal.biomedcentral.com/articles/10.1186/s13756-024-01486-2

Logistics- Inventory

Expensive Devices = limited Inventory

Leads to fast paced service

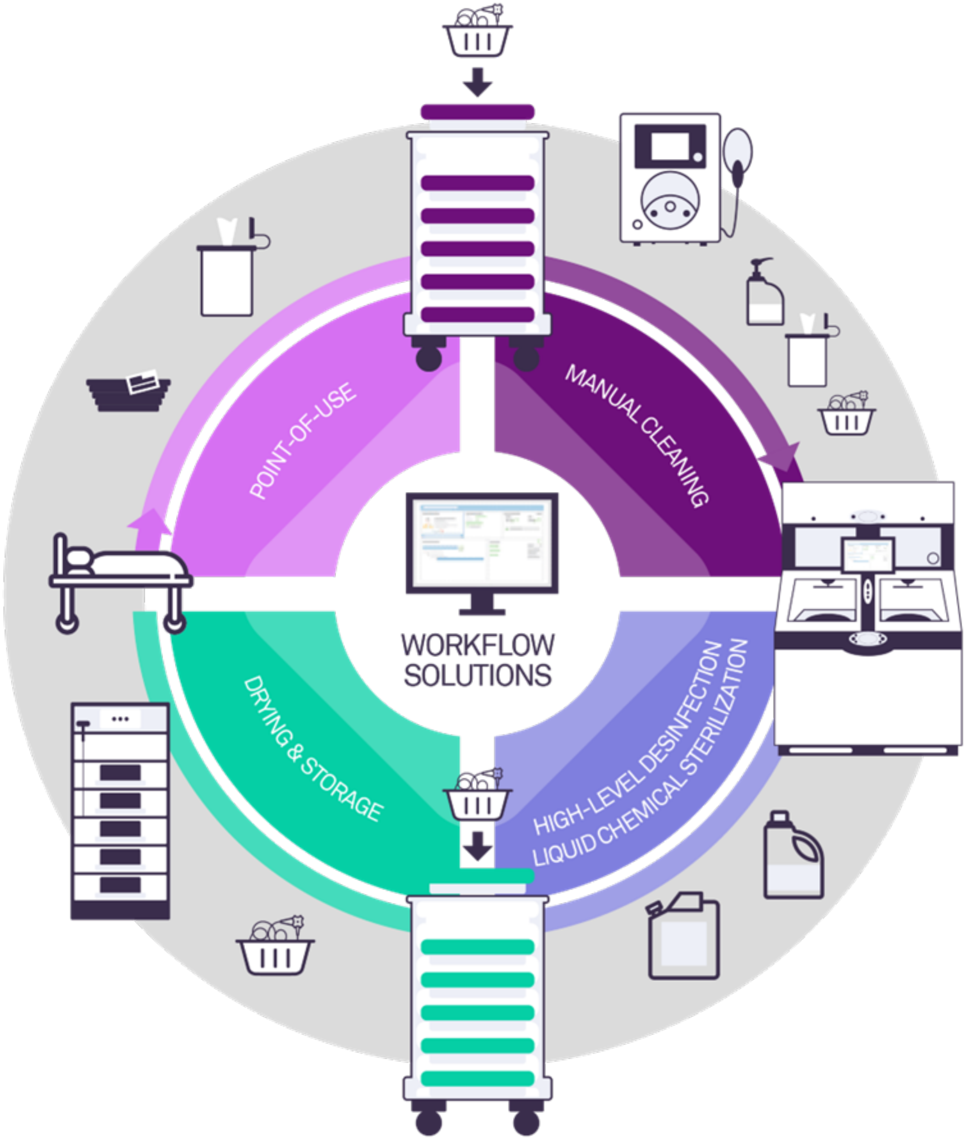


Image 1: https://addler.com/rigid-endoscopes/
Image 2: ASP Endoscope Decontamination Cycle

Logistics- Transport

Not all Endoscope users are next to the EDU

Not sealed

Risk of damage to distal tip

(particularly finer scopes)

Green sheet is not a sterile barrier

Limited protection from atmosphere

Bacterial growth will continue

Image 1:https://www.cantelmedical.eu/product/cleanascope-transport-storage-system/

Logistics- Storage

Large units

Limited capcity

Suitable locations with adequate ventilation

Robust cleaning regime

Validated storage time

Conflict between IPC & OEM

Image 1:https://www.harloff.com/product/suredry-endoscope-cabinet-with-hepa-filter-stainless-e-lock-scss8036dredp/

Logistics- Storage

Large units

Limited capcity

Suitable locations with adequate ventilation

Robust cleaning regime

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Conflict between IPC & OEM

Image 1:https://www.capsahealthcare.com/blog/endoscopy/endoscope-drying-cabinets-6-reasons/

Complex Design

- Heat liable
- Material Compatibility
- Extremely narrow lumens
- Inaccessible channels

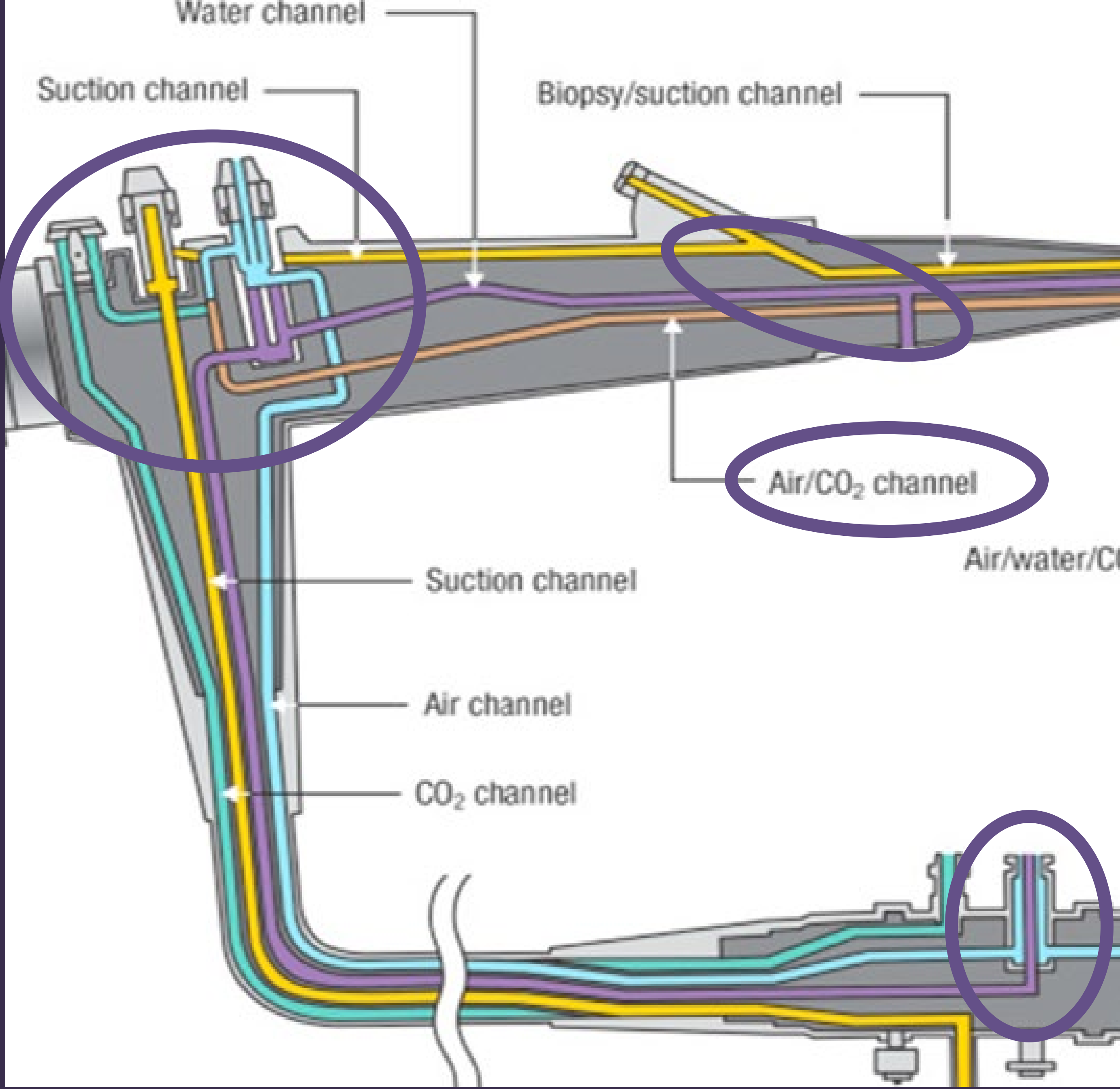


Image 1:Lisa Spruce, Back to Basics: Flexible Endoscope Processing, AORN Journal, Volume 103, Issue 5, 2016, Pages 489-499, ISSN 0001-2092

Complex Design

Duodenoscopes!

Protective hood

Extremely complex distal tip

Hinges and moving parts

Obscured channel and crevices

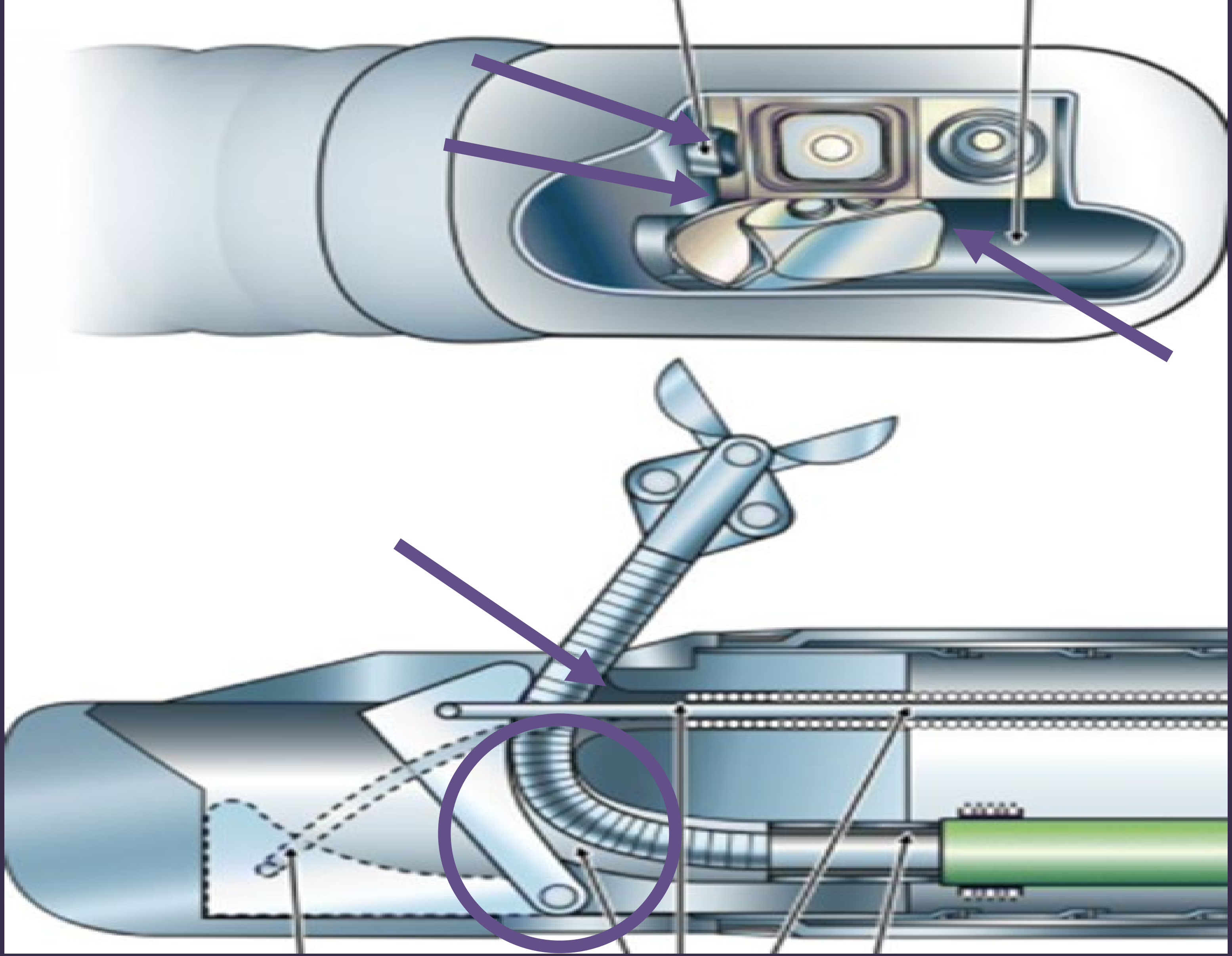


Image 1: https://www.fujifilm.com/sg/en/healthcare/endoscopy/endoscopy-scopes/duodenoscopes
Image 2: https://www.fujifilm.com/ph/en/healthcare/endoscopy/endoscopy-scopes/duodenoscopes
Image 3: https://www.duomed.com/en-BE/duodenoscopes/ed-580xt
Image 4: https://link.springer.com/article/10.1007/s10096-019-03671-3

Complex Design

Research

8 years of duodenoscope contamination, Holland 2024, Pub.Med

Contaminated duodenoscopes caused several hospital outbreaks. Despite efforts to reduce contamination rates, 15% of patient-ready duodenoscopes are still contaminated with gastrointestinal microorganisms.

***Conclusion**:*

Duodenoscope contamination remains a significant problem, with high contamination rates despite several interventions. Reprocessing the biopsy and suction channels is especially challenging

Duodenoscope-associated infection prevention: A call for evidence-based decision making, USA 2020, PMC.Pub.Med

Recent outbreaks of duodenoscope-associated multidrug-resistant organisms (MDROs) have brought attention to the infection risk from procedures performed with duodenoscopes.

***Conclusion**:*

Many clinicians and researchers believed the risk of post-ERCP infection was extremely low. There is now substantial evidence that duodenoscope reprocessing does not reliably eliminate soil or bioburden, allowing potential pathogens to remain on endoscopes causing harm to patients.

Expected to occur in as few as 1 in 1,765 or as many as 10% of ERCP procedures.

Source 1:Van der Ploeg K, Haanappel CP, Voor In 't Holt AF, de Groot W, Bulkmans AJC, Erler NS, Mason-Slingerland BCGC, Severin JA, Vos MC, Bruno MJ. Unveiling 8 years of duodenoscope contamination: insights from a retrospective analysis in a large tertiary care hospital. Gut. 2024 Mar 7;73(4):613-621.

Source 2: Ofstead, C.L., Buro, B.L., Hopkins, K.M., Eiland, J.E., Wetzler, H.P. and Lichtenstein, D.R., 2020. Duodenoscope-associated infection prevention: a call for evidence-based decision making. Endoscopy international open, 8(12), pp.E1769-E1781.

Limitations of HLD

Challenges with duodenoscopes reprocessing partially due to device complexity.

Lack of margin of safety with High Level Disinfection (HLD).

The same limitations with HLD are prevalent for Liquid Chemical Sterilisation (LCS).

If its not wrapped its not sterile!

Correct rinse agent, potable water will recontamination the device, not rinsed sterile, its not sterile!

Research shows evidence of clinical infection and biofilm accumulation.

Image: https://www.iqendoscopes.com/what-is-the-alternative-to-endoscope-disinfection

Limitations of HLD

Chemical requires complete saturation.

Chemical requires contact time.

Dilution increases the risk so the correct concentration must be closely observed.

Many Hospital Acquired Infections (Bacterial strains) can become resistant to Chemicals.

Manual processes are subjective, repeatability is challenging.

Image: https://www.iqendoscopes.com/what-is-the-alternative-to-endoscope-disinfection

Limitations of HLD

Research

Rate and impact of duodenoscope contamination: A systematic *review and meta-analysis, Denmark 2020, eClinical Medicine, The Lancet.*

Multiple infection outbreaks have been linked to contaminated duodenoscopes worldwide.

***Conclusion**:*

Analysis demonstrates that there is a 15.25% contamination rate of reprocessed patient-ready duodenoscopes.

Flexible gastrointestinal endoscope processing challenges, current issues and future perspectives. USA, 2021, Journal of Hospital infection

Post-processing monitoring studies consistently show high levels of positive cultures remaining on endoscopes.

***Conclusion**:*

The processing deficiency is attributed to the complex design of endoscopes, incomplete cleaning, formation of biofilms and lack of margin of safety with HLD.

Vaporized hydrogen peroxide can sterilize flexible endoscopes with a sterility assurance level of 10−6.

Source 1:Larsen, S., Russell, R.V., Ockert, L.K. et al. (2020) 'Rate and impact of duodenoscope contamination: a systematic review and meta-analysis', Eclinical Medicine, 25, article 100451

Source 2: Omidbakhsh, N., Manohar, S., Vu, R. and Nowruzi, K., 2021. Flexible gastrointestinal endoscope processing challenges, current issues and future perspectives. Journal of Hospital Infection, 110, pp.133-138.

Biofilm formation

What is a biofilm?

A thin but robust layer of mucilage adhering to a solid surface and containing a community of bacteria and other microorganisms.

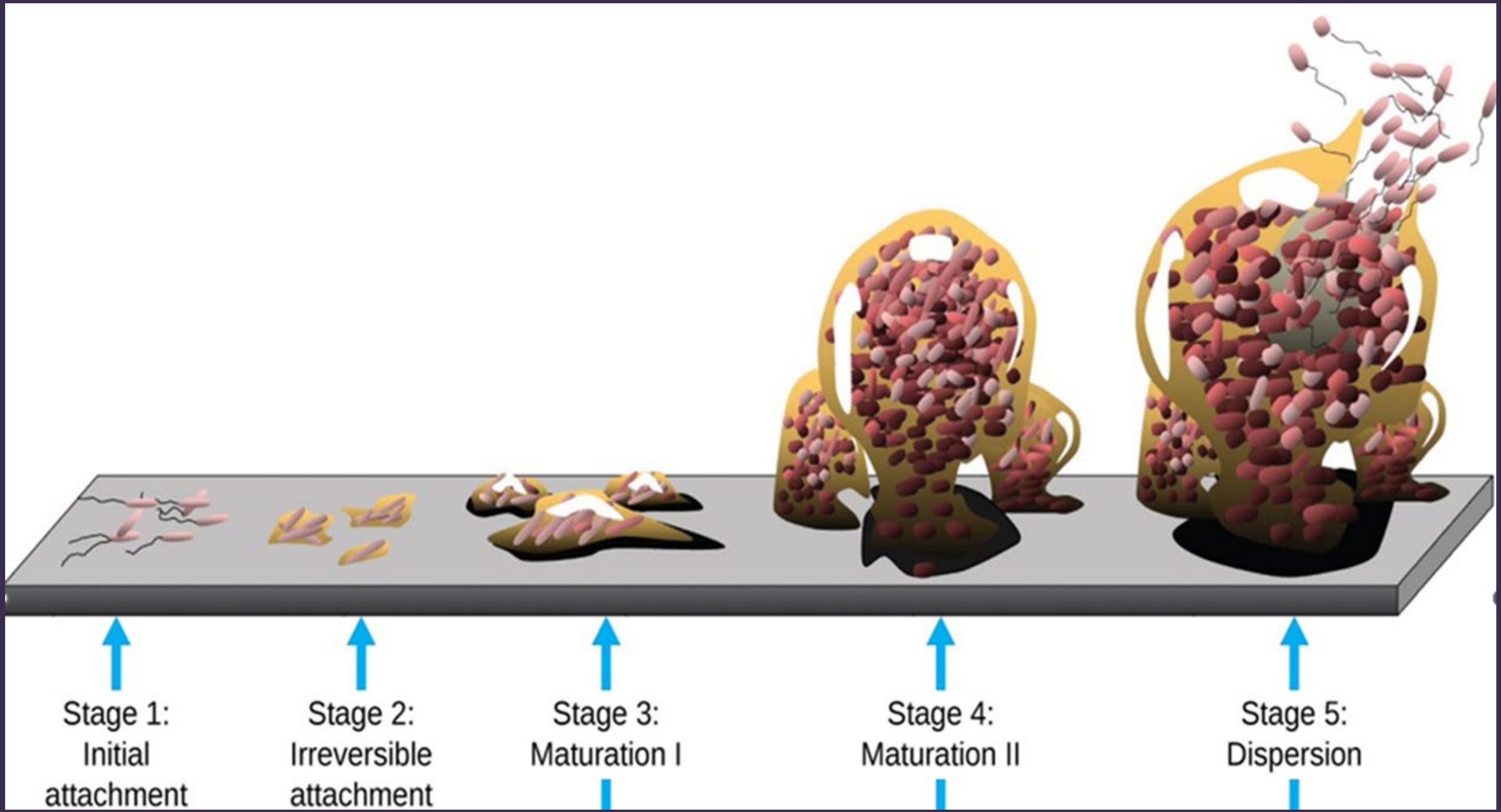


Image: https://www.bayarealyme.org/blog/straight-talk-biofilms-new-answer-treating-lyme-disease

Biofilm formation

What is the risk of biofilm?

Biofilm can have TVC counts >10^8 cfu's, 100,000,000 / One Hundred Million.

Resistant to HLD, Chemical can flow over. (increased Chlorine results in thicker layer).

Brushing may not be effective; research suggests presence post manual clean.

Presence in Endoscopes will likely be Pathogenic.

Biofilm testing, Not Simple, Not routine, Accuracy is not confirmed.

Limitations of HLD

Research

Pineau et al (2024) Endoscope sampling and culturing methods. Pineau et al, UK, 2024

Background Contamination rates in studies vary from 0.4% to 49%, sampling and culturing methods or definition of indicator micro-organisms vary widely.

Bioburden extraction efficacy varied from 1%-39% using different culturing methods.

***Conclusion**:*

Recommended a harmonized and standardized sampling and culturing method for flexible endoscopes.

Biofilm accumulation in new flexible gastroscope channels in clinical use. Primo et al, UK, 2022.

Assess the accumulation of protein and biofilm on the inner surfaces of new flexible gastroscope channels after 30 and 60 days of patient use and full reprocessing.

***Conclusion**:*

Bacteria were recovered from 8 of 21 channels, most air or water channels. 39%

Extensive biofilm was detected in air, water, and air–water junction channels (n = 18 of 28). Nearly 70%

(20 of 28). Residual protein was detected in the air and water channels. 72%

(28 of 28) showed residual matter. 100%

Source 1: Primo, M.G.B., Tipple, A.F.V., de Melo Costa, D., Guadagnin, S.V.T., Azevedo, A.S., de Oliveira Leão, L.S.N., Alfa, M. and Vickery, K., 2022. Biofilm accumulation in new flexible gastroscope channels in clinical use. Infection Control & Hospital Epidemiology, 43(2), pp.174-180

Source 2: Pineau, L., Alfa, M. and Radix, C., 2024. Endoscope sampling and culturing methods. Journal of Hospital Infection, 149, pp.36-45.

What are our options?

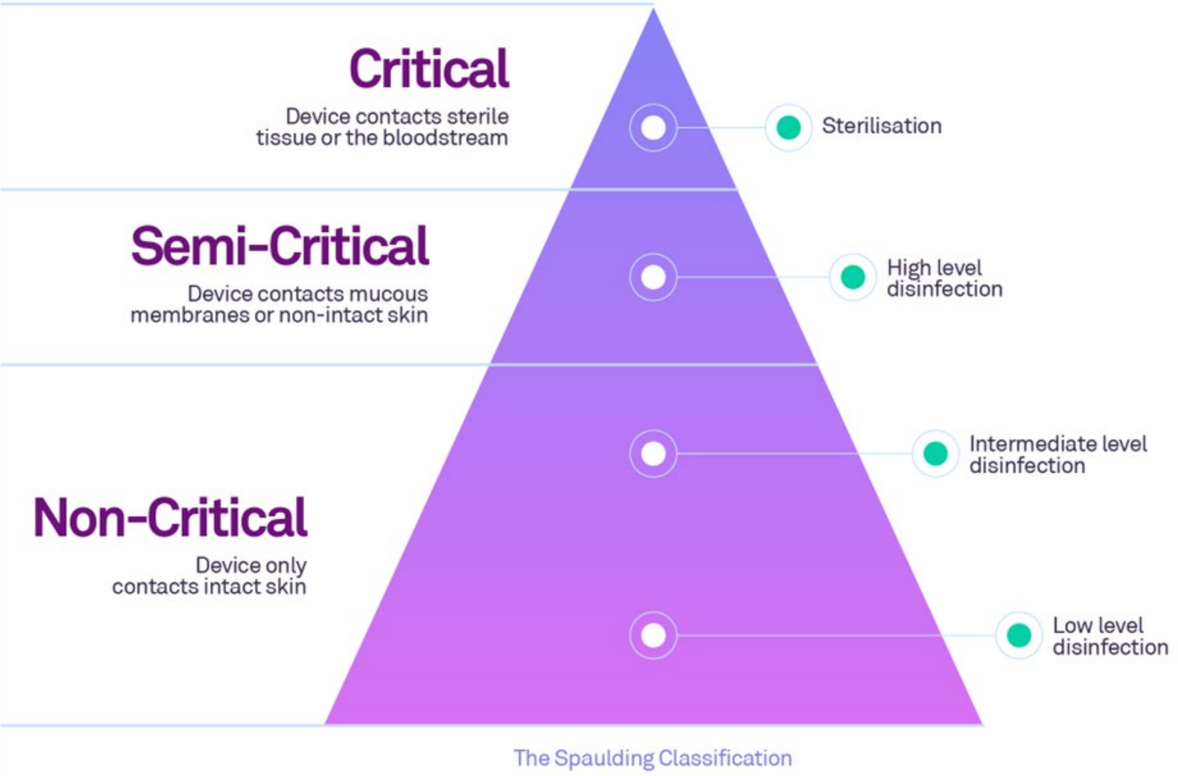
Spaulding

Contact with Mucosa = HLD/LCS?

- *Critical Scopes, Sterilise?*
- *But isn't it possible this is all scopes?*

Endoscopic instruments?

- *Always sterile?*



Research shows HPGP is the most effective sterilant after moist heat

Image: https://medical.olympusamerica.com/products/endojaw-disposable-biopsy-forceps

STERRAD™ 100NX Sterilizer with ALLClear™ Technology

ASP's Flagship Product in Terminal Sterilization using low temperature H_2O_2 gas plasma technology

Key Features:

- 5 cycles (STANDARD, FLEX, DUO, EXPRESS, ULTRA GI) designed to sterilize a variety of medical instruments
- Upgradeable platform
- ALLClear™ Technology within the system increases sterilization productivity
- Leverages plasma technology to break down residual H2O2 into oxygen and water vapor, safely sterilizing instruments without leaving toxic resides

STERRAD™ Systems Global Footprint

22,000+ Systems | 11,000+ Hospitals | 50+ Countries | 15 Million+ Cycles Annually[1]

1: https://www.asp.com/en-us/products/terminal-sterilization/sterrad-100nx

Why aren't GI scopes commonly sterilized today?

Material compatibility challenges with H_2O_2

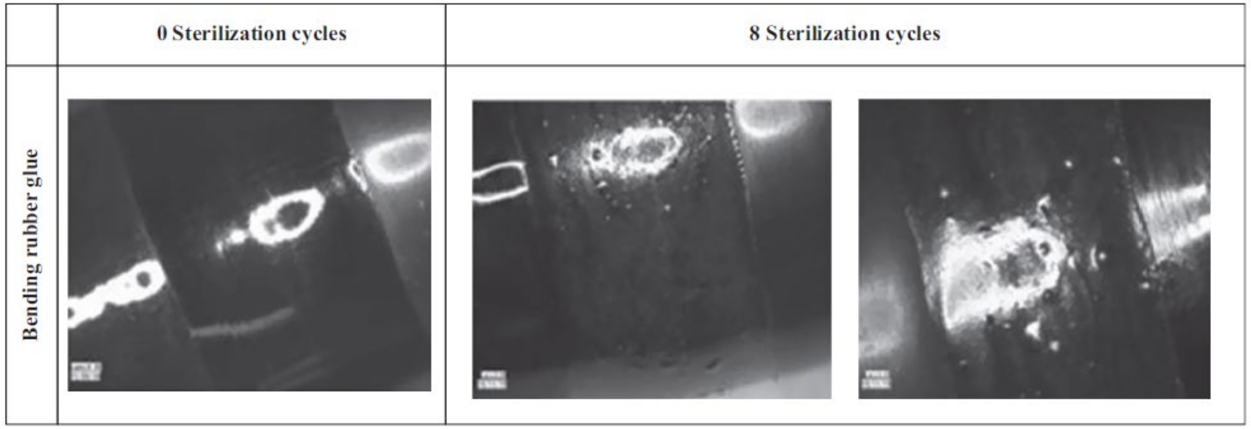


Figure 2. Olympus CF-HQ190L colonoscope glue bead at the beginning and end of test. Blistering of the glue was observed after 8 cycles.

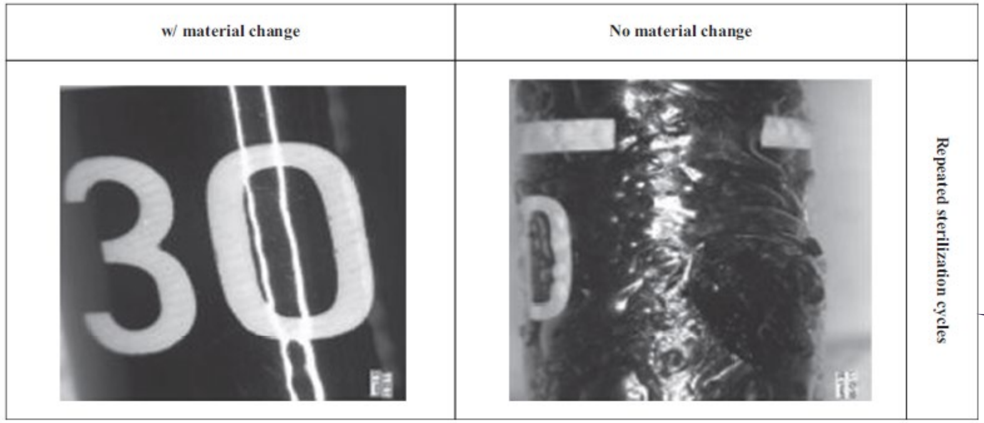


Figure 3. Comparison of the insertion tube of the same endoscope model using the same sterilization cycle when two different lubricants are used.

Replacing certain resins and/or lubricants can make GI endoscopes compatible with vaporized hydrogen peroxide gas plasma sterilizers

Source: Flexible gastrointestinal endoscope processing challenges, current issues and future perspectives N. Omidbakhsh*, S. Manohar, R. Vu, K. Nowruzi Research & Development Department, Advanced Sterilization Products, Irvine, CA, USA. Research funded by ASP.

Technology Overview: ULTRA GI Cycle

ULTRA GI Cycle is a new sterilization cycle for the STERRAD™ 100NX Sterilizer with ALLClear Technology. It adds **breakthrough indications to the STERRAD Systems portfolio to terminally sterilize hydrogen peroxide compatible duodenoscopes using ASP's patented technology.**

ULTRA GI Cycle is designed for the sterilization of **H_2O_2 compatible multi-channel flexible duodenoscopes** with up to 4 channels.

- Initial multi-channel dimensions in claims (duodenoscopes): ≥1mm x ≤1500mm and ≥2mm x ≤1630mm
- **Throughput:** One flexible endoscope per tray/shelf and up to 2 flexible endoscopes per cycle, 3 cycles/cassette. Cycle time = 68 minutes

Only duodenoscopes that have been cleared as compatible with vaporized hydrogen peroxide are acceptable. Check STERRAD User Guide "STERRAD Sterilizer Cycle Selection table" for ULTRA GI Cycle compatible duodenoscopes.

ASP™ Advanced Sterilization Products

Final Thought

Event related Sterility Assurance?

Thank you, any questions?

Image: https://www.sgs.com/en-gb/service-groups/microbiology-and-validation