Sterilization of Flexible Endoscopes

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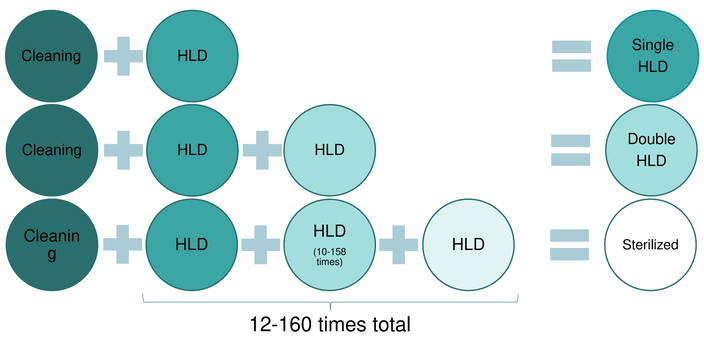
Introduction

Reusable medical devices are cleaned manually and/or in an automated system such as in a washer disinfector according to the device manufacturer's recommendations. Then, they are subjected to the healthcare center's terminal process such as terminal sterilization or high-level disinfection (HLD) depending on the Spaulding classification. Cleaning reduces the bioburden and removes foreign material that interferes with terminal processes.[1] Cleaning should be done promptly after use as foreign matter and soiled organic material may dry onto instrumentation. Sterilization is a validated process used to render a product free of all forms of viable microorganisms.[2] HLD is a process that kills all microbial pathogens but not necessarily high number of bacterial spores.[2]

Reprocessing of reusable medical devices is regarded as a process that renders devices safe with low risk to patients, some exceptions exist, such as flexible endoscopes. Many infection outbreaks have been associated with endoscopes. The fact that most types of endoscopes can remain contaminated after HLD reprocessing indicates that the margin of safety with endoscope reprocessing is minimal or non-existent[3], due largely to endoscope design complexity[4], insufficient cleaning[5], and biofilms inside their channels.[6] Since sterilization provides a higher microbial kill compared to HLD process, it is expected to significantly improve the margin of safety, provided sufficient cleaning. Therefore, unless contraindicated, it is preferred to sterilize semi-critical devices rather than high-level disinfect them[7]; however, this is often impractical. The challenge with sterilization is mainly due to the material compatibility limitations[8] where they are not compatible with most sterilization modalities, including steam and vaporized hydrogen peroxide. Although ethylene oxide is compatible, it is not practical due to slow turnaround times.[9] Hydrogen peroxide sterilization is relatively fast but not compatible with most current endoscopes, mainly due to the use of a lubricant inside the endoscopes that reacts with hydrogen peroxide and corrodes the endoscope from inside out when processed a few times with vaporized hydrogen peroxide sterilizers.[10]

In summary, in order to potentially provide a higher standard of care by reducing infection rates, new endoscope designs need to be made easier to clean with more robust materials that are compatible with fast low temperature sterilization technologies.

What Will It Take to Bring an High Level Disinfectant to a Sterilant[12]?



Margin of Safety

Table 1[8]: Sterilization of Flexible Endoscopes by Modality

	Flexible Endoscope	Steam	Vaporized H_2O_2	EtO
Surgical scopes	Bronchoscope	☹	☺	☺
	Ureteroscope	☹	☺	☺
	Cystoscope	☹	☺	☺
GI scopes	Gastroscope	☹	😐	☺
	Duodenoscope	☹	😐	☺
	Enteroscope	☹	😐	☺
	Colonoscope	☹	😐	☺

☹ = not compatible* ☺ = compatible* 😐 = unknown compatibility*

*Compatibility may vary for specific terminal sterilization technology and flexible endoscope manufacturer and model

Biocides require greater contact times for sterilization compared to HLD.[12] These data indicate that in order to achieve sterilization with a given biocide, a device would need to be reprocessed through HLD between 12 and 160 times which signifies a greater margin of safety for sterilization over the current practice of high level disinfection.[12] In light of this, terminal sterilization modalities were reviewed for suitability (Table 1).[8] Currently, only hydrogen peroxide and ethylene oxide sterilization are indicated for flexible endoscopes.[8] Steam sterilization was found to be incompatible with flexible endoscopes.[8] Gastrointestinal endoscopes are only specifically indicated for ethylene oxide sterilization.[8] However, due to its impracticability, ETO sterilization is not a viable option due to long turn around times and carcinogenicity concerns.[9] Hydrogen peroxide sterilization of GI endoscopes is unknown but surgical flexible endoscopes have been shown to be compatible with the process.[8]

H_2O_2 Sterilization of Flexible GI Endoscopes

Table 2[8]: Comparison of Surgical and GI Flexible Endoscopes

	GI Endoscope	Surgical Endoscope
Visualization system	Video or Fiber	Video or Fiber
Illumination	Fiber optics	Fiber optics
Lumens	Up to 6 channels	Up to 2 lumens
Working length	Up to 2000mm	Up to 670mm
Material	Proprietary	Proprietary but compatible to low temperature sterilization processes

A review of the aspects of flexible GI endoscopes and surgical endoscopes indicate that there may be some material differences as well as longer channels – Table 2.[8] The review indicates that longer channels and material differences may be the barrier to claiming GI endoscope sterilization compatibility with H_2O_2.

H_2O_2 Sterilization Efficacy of Flexible GI Endoscopes

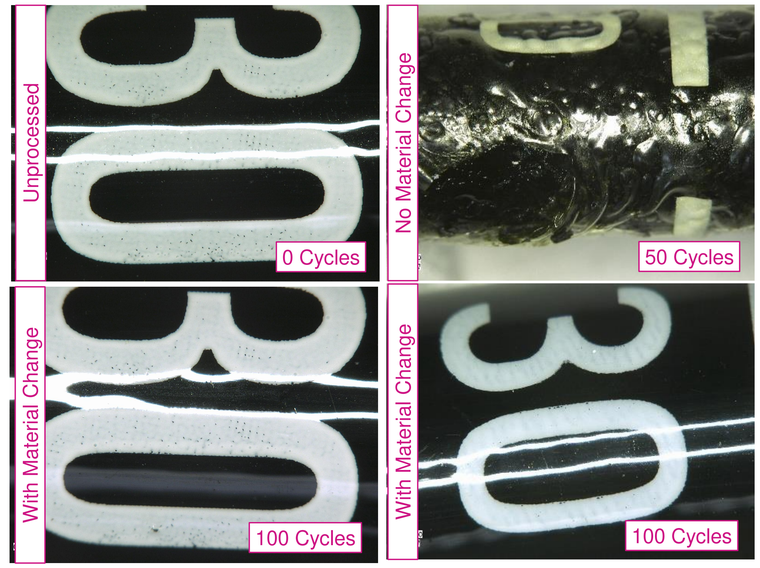
Long narrow lumens limit the use of newer low temperature vaporized H_2O_2 sterilization modalities. However, sterilant penetration into these diffusion restricted spaces can be overcome – Table 3.[13]

Table 3[13]: Sterilization Efficacy of GI Scopes with a Vaporized H_2O_2 Sterilization Process (1/2 Cycle)

Test	Endoscope	Organism	Suction/Biopsy	Air	Water	Water Jet/Aux.
		Microbial Load	≥7.6 $\log_{10}$	≥ 7.2 $\log_{10}$	≥ 7.2 $\log_{10}$	≥ 6.9 $\log_{10}$
1	Colonoscope	*Geobacillus stearothermophilus*	0 CFU	0 CFU	0 CFU	0 CFU
	Colonoscope		0 CFU	0 CFU	0 CFU	0 CFU
2	Colonoscope		0 CFU	0 CFU	0 CFU	0 CFU
	Colonoscope		0 CFU	0 CFU	0 CFU	0 CFU
3	Colonoscope		0 CFU	0 CFU	0 CFU	0 CFU
	Colonoscope		0 CFU	0 CFU	0 CFU	0 CFU

H_2O_2 Sterilization Material Compatibility of Flexible GI Endoscopes

Figure 1[14]: Material Compatibility of GI Endoscope through a Vaporized H_2O_2 Sterilization Process



Material testing with vaporized hydrogen peroxide sterilizer revealed material incompatibility with flexible GI endoscopes – Figure 1.[14] However, introduction of material changes to the endoscope revealed that vaporized hydrogen peroxide sterilization may be feasible. It may be possible with material changes to achieve material compatibility with low temperature sterilization.

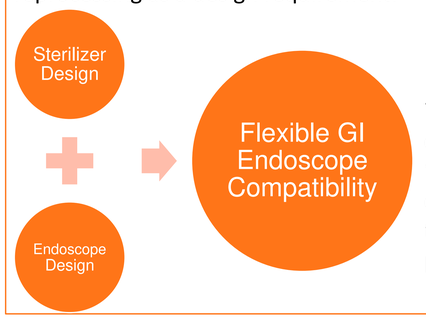
Conclusions

Hydrogen peroxide compatible flexible endoscopes have been limited to surgical endoscopes.[8] Review of endoscope designs indicates some of the reasons behind this may be difficulty in sterilization of longer lumens and material limitations of GI endoscopes.

However, here we show that hydrogen peroxide sterilization of flexible GI endoscopes may be possible. A minimum of 6-log reduction of microbial spores are demonstrated using a vaporized hydrogen peroxide process (half-cycle). Moreover, material limitations may be overcome with adjustments to the device construction.

If device and sterilizer manufacturers work together terminal sterilization may be an option that is readily practicable.

Device manufactures should consider new endoscope designs with reprocessing as a design requirement:



- Easier to clean
- Material compatibility with fast LTS technologies

Thorough and effective cleaning, coupled with sterilization on "easier to clean" endoscope designs should help to mitigate the current associated infection problems.

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2 ANSI/AAMI ST91:2015
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4 CDC Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the Healthcare Infection Control Practices Advisory Committee, Jan 2017
5 CDC guideline for disinfection and sterilization in healthcare facilities, 2008
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11 Roger Vu - Sr. Scientist, Keyvan Nowruzi – Principal Scientist, Shresha Manohar – Sr. Scientist, Todd Morrison – Principal Engineer, Navid Omidbakhsh – Early R&D Lead, employees of Advanced Sterilization Products, Irvine California, US. This research was funded by ASP.
12 FDA-Cleared Sterilants and High Level Disinfectants with General Claims for Reprocessing Reusable Medical and Dental Devices, Mar 2015
13 Internal testing conducted at ASP documented in LNB-4552 pages 73-75 & 88-93
14 Internal testing conducted at ASP documented in LNB-4586 page 120 and LNB-4555 page 121
Internal testing conducted at ASP documented in LNB-4586 page 106 and LNB-4440 page 158

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