

# Technical Evaluation of **HPGP & HDROZONE** (Hydronium Heavy Molecule) Sterilization Methods in Flexible Endoscopes

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## SUBJECT

This document evaluates the technical suitability, risk areas, and overall outcomes of  $VH_2O_2$ , HPGP, and HDROZONE sterilization approaches for flexible endoscopes, taking into account the material structure of the devices.

The evaluation is structured around the following key aspects:

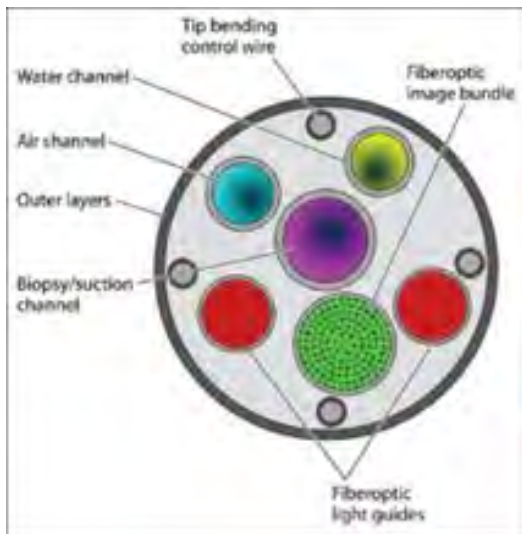
- Endoscope material structure
- Critical surfaces in sterilization
- Intra-lumen sterilization requirements
- Behavior of polymer, elastomer, metal, and optical components
- Suitability and risk assessment for HDROZONE



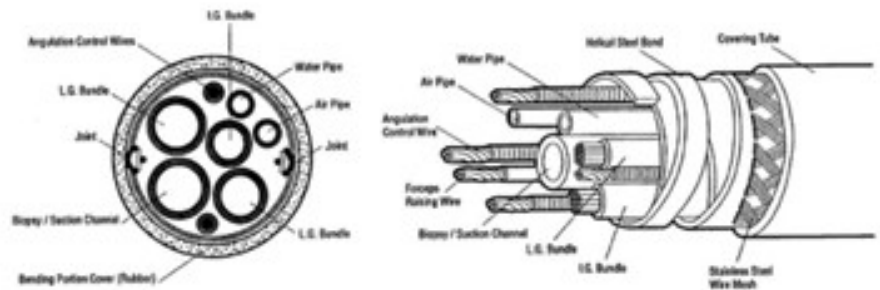
## KEYS

HPGP,  $VH_2O_2$ , Hydronium, Infiltration, Diffusion, Condensation, Hybrid, Distal

# 1. WHAT IS THE PROBLEM IN ENDOSCOPE STERILIZATION?



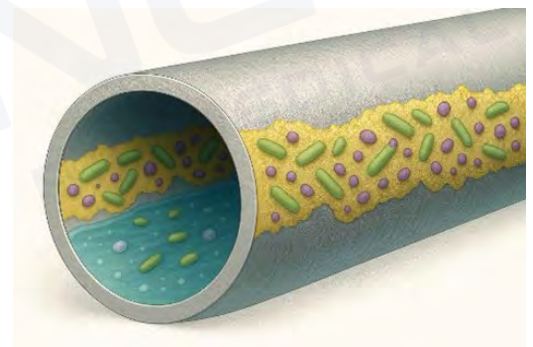
## ENDOSCOPE CROSS SECTION



Flexible endoscope sterilization faces a fundamental challenge: the device is not made of a single homogeneous material.

A flexible endoscope is a complex multi-layered hybrid medical device that includes:

- Outer sheath
- Inner spiral / braid structure
- Deflectable distal tip
- Working channel / lumens
- Optical system
- Control cables
- Adhesives and connectors



Because of this structure, sterilization is not merely an external surface issue.

### 1.1 Approach of H<sub>2</sub>O<sub>2</sub> (VH<sub>2</sub>O<sub>2</sub>) and HPGP Sterilization Methods to These Problems

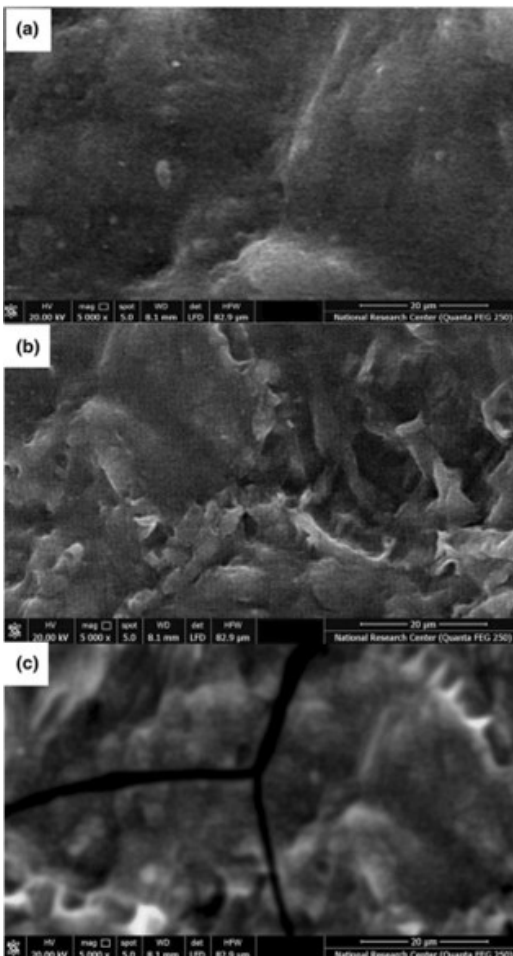
- Vapor-phase hydrogen peroxide creates strong oxidative effect on surfaces.
- It relies on penetration, diffusion, and condensation mechanisms.
- Reactive loss can occur inside lumens.
- Efficacy against biofilm depends on surface access.

#### CONCLUSION:

H<sub>2</sub>O<sub>2</sub> systems are strong in surface sterilization but show limited effectiveness in long and narrow lumens.

## 2. MATERIAL-BASED PROBLEM DEFINITION IN ENDOSCOPES

### 2.1 Outer Sheath



Materials used:

- TPU
- Silicone elastomer
- Pebax

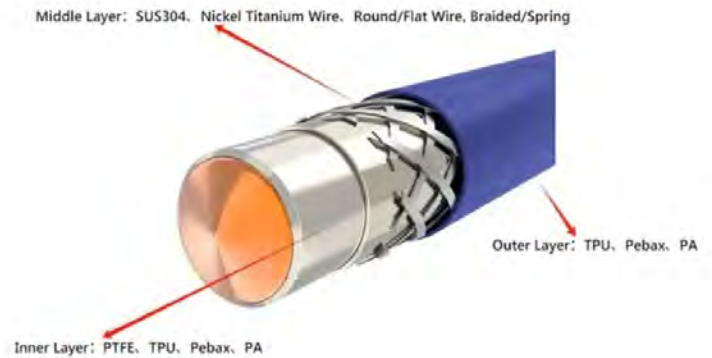
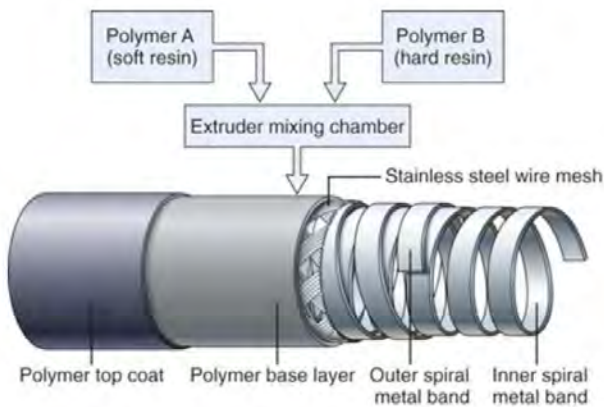
**Conclusion:**

The outer sheath is the primary critical area for sterilization-related damage.

**H<sub>2</sub>O<sub>2</sub> vs Hdrozone**

- H<sub>2</sub>O<sub>2</sub>:
  - High oxidative density, increased risk of surface damage
- Hdrozone:
  - Controlled oxidant distribution, low-temperature advantage

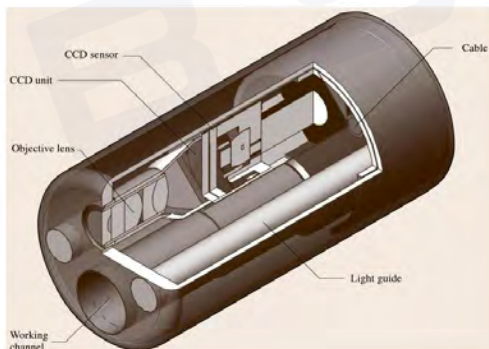
## 2.2 Inner Spiral / Braid Structure



### CONCLUSION:

The metal carrier structure is a low-risk area for both HDROZONE and H<sub>2</sub>O<sub>2</sub>.

## 2.3 Distal Deflectable Tip



### CONCLUSION:

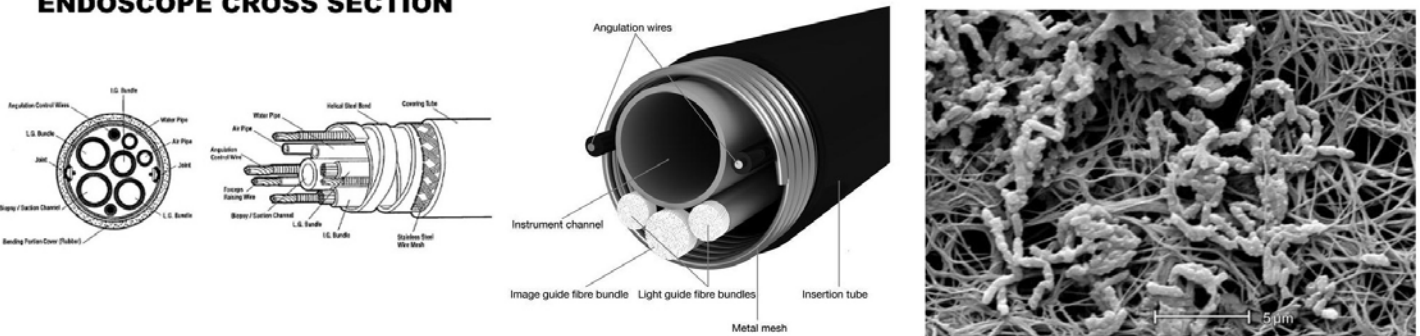
The distal tip is a high-risk area where chemical and mechanical stresses converge.

### H<sub>2</sub>O<sub>2</sub> vs Hdrozone

- H<sub>2</sub>O<sub>2</sub>: Possible condensation and localized concentration increase
- Hdrozone: More homogeneous gas-phase distribution

## 2.4 Working Channel / Lumen

### ENDOSCOPE CROSS SECTION



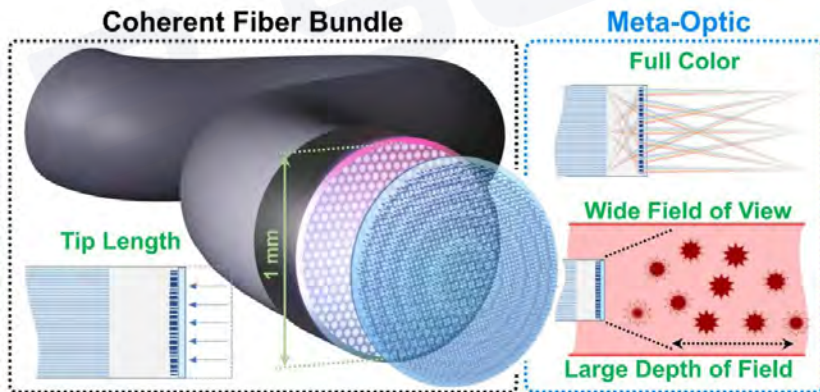
### CONCLUSION:

**The effectiveness of lumen inner surface sterilization is the main indicator of overall success.**

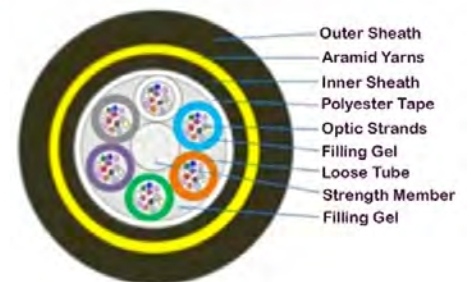
### H<sub>2</sub>O<sub>2</sub> vs Hdrozone

- H<sub>2</sub>O<sub>2</sub>: Diffusion and vaporization are limited
- Hdrozone: Gas-phase + reactive species generation advantage

## 2.5 Optical System



### Cross Section Of Fiber Optic Cable



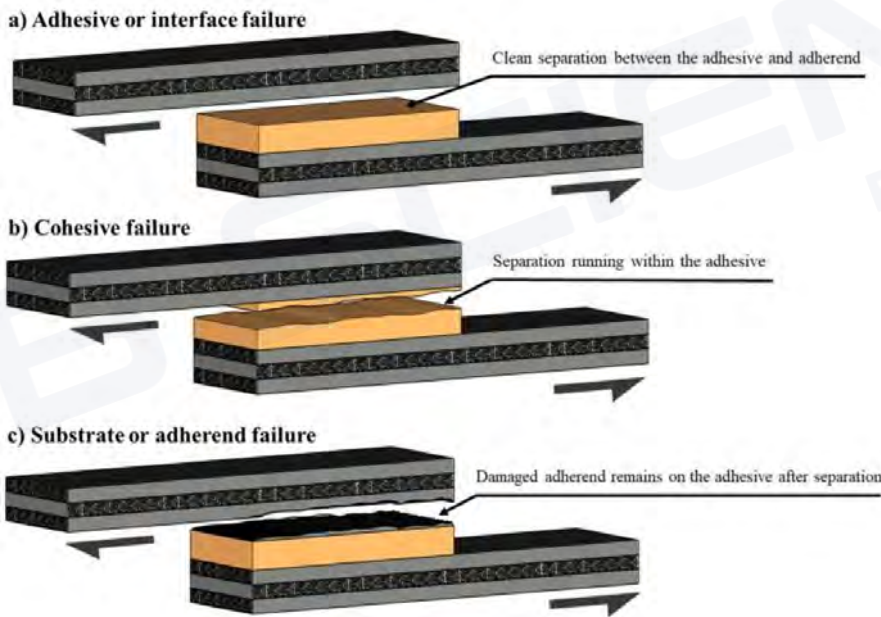
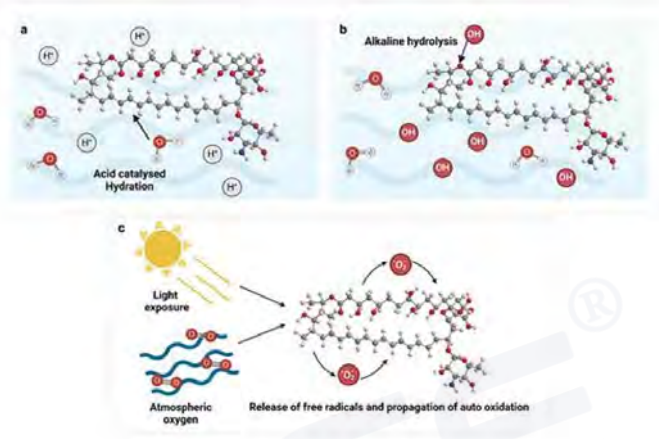
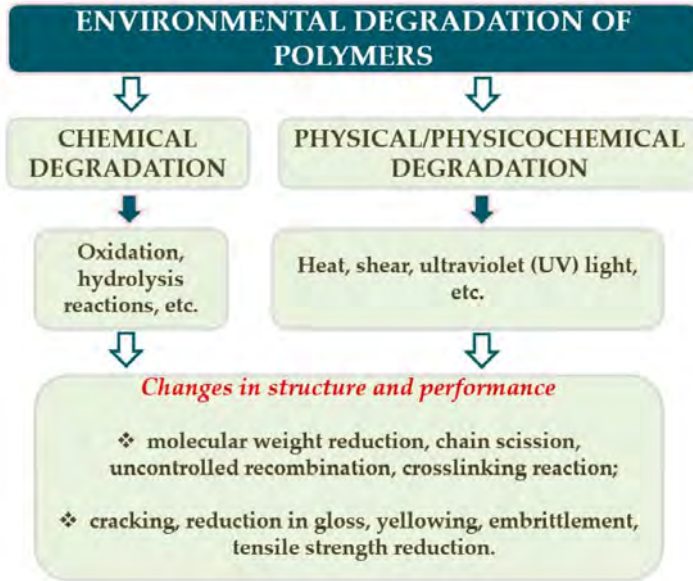
### CONCLUSION:

**Optical glass is low-risk, while epoxy connections are high-risk.**

### H<sub>2</sub>O<sub>2</sub> vs Hdrozone

- H<sub>2</sub>O<sub>2</sub>: Oxidative stress on epoxy
- Hdrozone: Low-temperature advantage

## 2.6 Adhesives and Bonding Agents



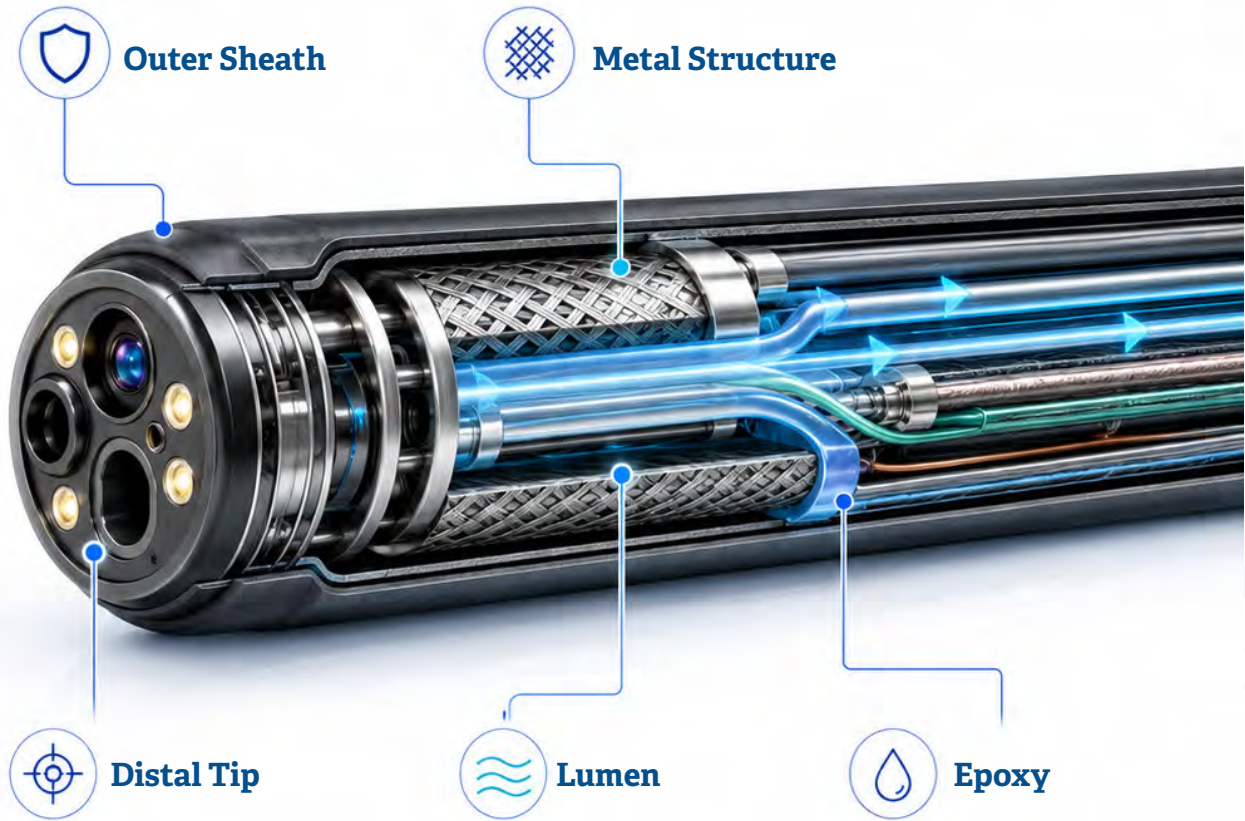
### CONCLUSION:

**Epoxy and adhesives are among the most critical weak points in endoscopes.**

### H<sub>2</sub>O<sub>2</sub> vs Hdrozone

- H<sub>2</sub>O<sub>2</sub>: Intense oxidative effect
- Hdrozone: Controlled chemical effect

## TECHNICAL SUITABILITY ASSESSMENT OF H<sub>2</sub>O<sub>2</sub> VS. HDROZONE IN ENDOSCOPE STERILIZATION



REGION	H <sub>2</sub> O <sub>2</sub>	HDROZONE
Outer Sheath	Medium-High Risk	Medium Risk
Metal Structure	Low Risk	Low Risk
Distal Tip	High Risk	Medium-High Risk
Lumen	Limited	Higher Potential
Epoxy	High Risk	Medium Risk

Key Determining Factors for HDROZONE:

- Lumen inner surfaces
- Distal tip
- Biofilm regions

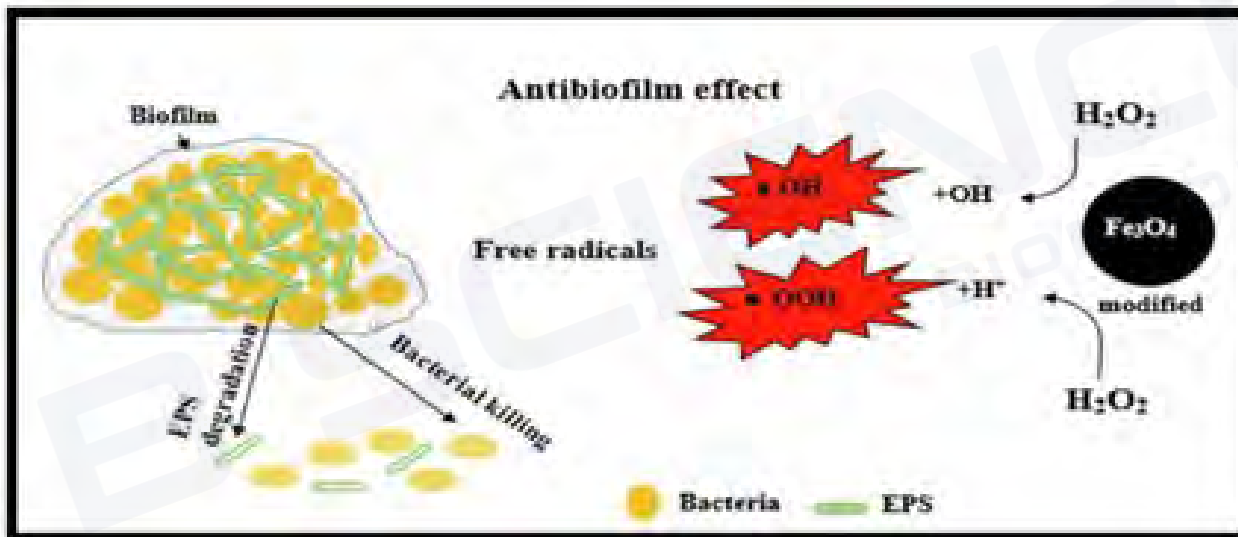
### Comparative Result

- H<sub>2</sub>O<sub>2</sub>: Surface-dominant sterilization
- Hdrozone: Lumen-focused sterilization approach

## MATERIAL DAMAGE COMPARISON (H<sub>2</sub>O<sub>2</sub> VS. HDROZONE)

- H<sub>2</sub>O<sub>2</sub>: High oxidative density
- Hdrozone: More balanced oxidant distribution

## EFFICACY COMPARISON OF H<sub>2</sub>O<sub>2</sub> VS. HDROZONE IN ENDOSCOPE STERILIZATION



- H<sub>2</sub>O<sub>2</sub>: Strong surface effect, low penetration potential
- Hdrozone: Strong surface effect, high penetration potential

## ULTRA-LOW TEMPERATURE EFFECT IN STERILIZATION

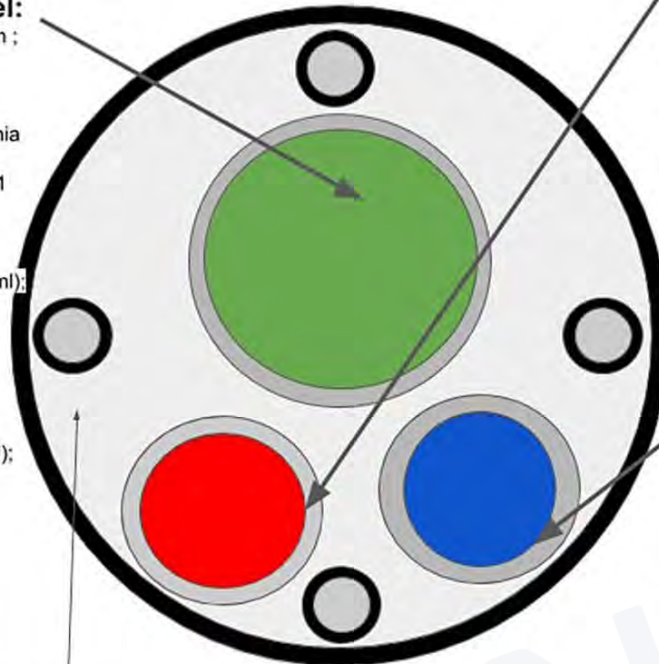
- H<sub>2</sub>O<sub>2</sub>: Generally 45–55°C (low temperature), but local heating may occur
- Hdrozone: Controlled ultra-low temperature (37–42°C)

## LUMEN PERFORMANCE COMPARISON IN ENDOSCOPES

### Biopsy / Suction Channel:

Aspergillus Spp; Bacillus megaterium ;  
Bacillus simplex (1 CFU/20ml) ;  
Brevibacterium casei ;  
Candida albicans (69 CFU/15ml) ;  
Carbapenemase Klebsiella pneumonia  
(KPC) ;  
Coagulase-negative Staphylococci (1  
Cfu);  
Enterobacter aerogenes(5 CFU) ;  
Klebsiella oxytoca (7 CFU/ml) ;  
Klebsiella pneumonia (300CFU/100ml);  
Lactococcus Lactis Ssp. Lactis ;  
Micrococcus luteus (2 CFU/20ml ) ;  
Multidrug-resistant Pseudomonas  
aeruginosa ;  
Neisseria Spp. ;  
Ochrobactrum anthropi ;  
Pseudomonas aeruginosa (100 CFU);  
Pseudomonas putida;  
Rhizobium radiobacter ;  
Sphingomonas Sp;  
Staphylococcus aureus;  
Staphylococcus capitis ;  
Staphylococcus haemolyticus;  
Staphylococcus warneri;  
Stenotrophomonas maltophilia  
(100CFU);  
Streptococcus mitis ;  
Streptococcus oralis

Tip Bending  
Control Wire



### Instrument Channel:

Acinetobacter calcoaceticus-baumannii ;  
Bacillus subtilis;  
Enterobacter cloacae (>1000 CFU/ml) ;  
Enterococcus faecium ;  
Escherichia coli (>1000 CFU/ml);  
Klebsiella pneumonia (300CFU/100ml) ;  
Kocuria kristinae;  
Neisseria flavescens ;  
Pseudomonas aeruginosa (49CFU - >100 CFU) ;  
Pseudomonas putida;  
Sphingomonas paucimobilis (>100 CFU / 100 ml) ;  
Staphylococcus epidermidis (40 CFU) ;  
Stenotrophomonas maltophilia (>100  
CFU/endoscope) ;  
Staphylococcus pasteurii ;  
Staphylococcus warneri

### Air/Water Channel

Bacillus Spp (2,070CUF/ml);  
Bacillus subtilis;  
Coagulase Negative Staph (16CFU/100ml) ;  
Escherichia coli (>1000 CFU/ml);  
Micrococcus luteus (2 CFU/20ml ) ;  
Moraxella spp (1CFU) ;  
Neisseria subflava ;  
Pseudomonas aeruginosa (49CFU - >100 CFU) ;  
Rothia dentocariosa ;  
Sphingomonas Sp ;  
Staphylococcus epidermidis (40 CFU) ;  
Staphylococcus warneri ;  
Streptococcus salivarius (3 CFU)

## Lumen Sterilization Comparison

- H<sub>2</sub>O<sub>2</sub>: Limited in long lumens (effective up to ~1.5 m)
- Hdrozone: Gas-phase advantage (effective up to 15 m)

## OVERALL COMPARATIVE EVALUATION OF H<sub>2</sub>O<sub>2</sub> VS. HDROZONE IN ENDOSCOPE STERILIZATION

### Strengths of Both Methods

#### H<sub>2</sub>O<sub>2</sub>:

- Strong surface sterilization
- Widespread use and acceptance

#### Hdrozone:

- Ultra-low temperature
- Superior gas-phase penetration
- Significant lumen advantage

## Critical Risks of Both Methods

### **H<sub>2</sub>O<sub>2</sub>:**

- Epoxy damage
- Excessive surface oxidation

### **Hdrozone:**

- Requires careful process control

## FINAL CONCLUSION

- H<sub>2</sub>O<sub>2</sub>: Surface-oriented sterilization with limited lumen efficacy due to condensation issues.
- Hdrozone: Lumen-oriented hybrid hydronium sterilization method thanks to its hybrid nature.

### Overall Assessment:

In flexible endoscope sterilization, H<sub>2</sub>O<sub>2</sub> systems are strong in surface sterilization, whereas **HDROZONE systems offer significant technical advantages** in both surface sterilization and long-lumen penetration.

**HDROZONE is a hybrid heavy-molecule sterilization method that provides clear superiority over H<sub>2</sub>O<sub>2</sub> systems — particularly in lumen penetration and low-temperature compatibility — for flexible endoscopes. It serves as an effective problem-solving technology for complex, long-lumen medical devices.**

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