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

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SUBJECT

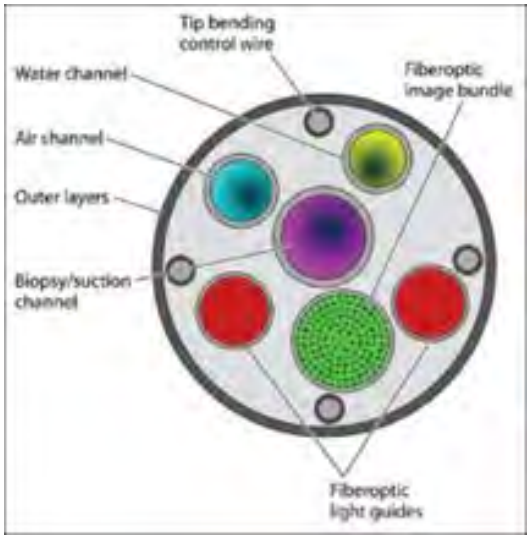
This document evaluates the technical suitability, risk areas, and overall outcomes of VH_2O_2, HPGP, and HDROZONE sterilization approaches for flexible endoscopes, taking into account the material structure of the devices.

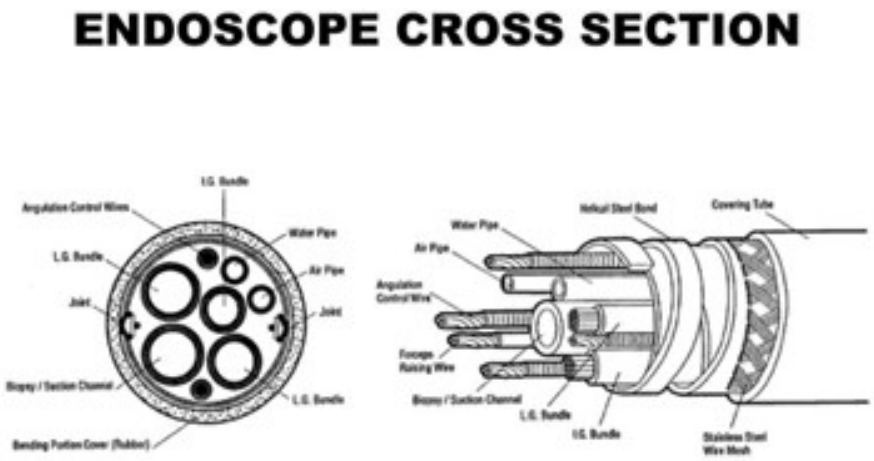
The evaluation is structured around the following key aspects:

- 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?

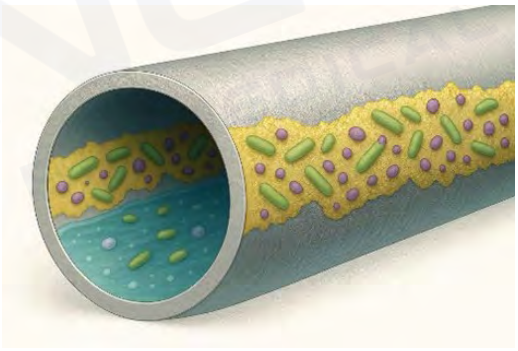




Flexible endoscope sterilization faces a fundamental challenge: the device is not made of a single homogeneous material.

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_2O_2 (VH_2O_2) and HPGP Sterilization Methods to These Problems

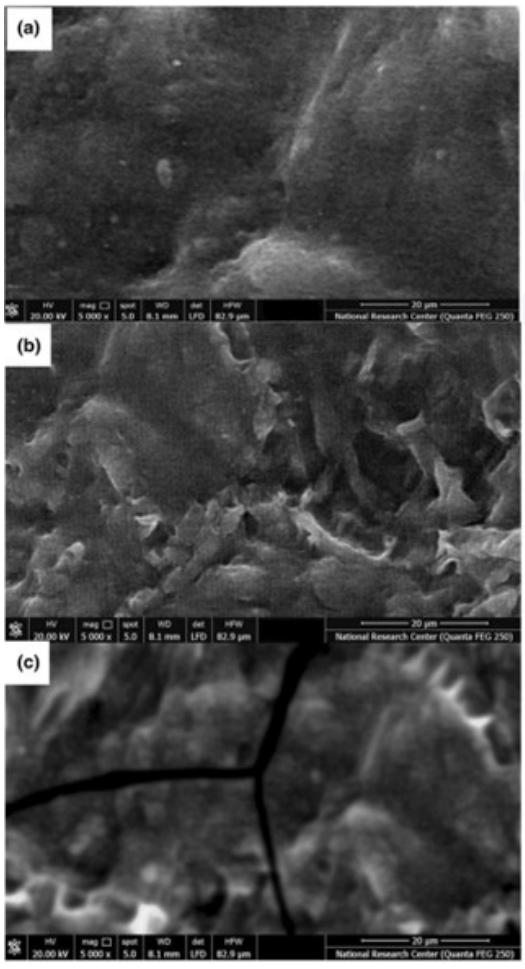
- Vapor-phase hydrogen peroxide creates strong oxidative effect on surfaces.
- It relies on penetration, diffusion, and condensation mechanisms.
- Reactive loss can occur inside lumens.
- Efficacy against biofilm depends on surface access.

CONCLUSION:

H_2O_2 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:

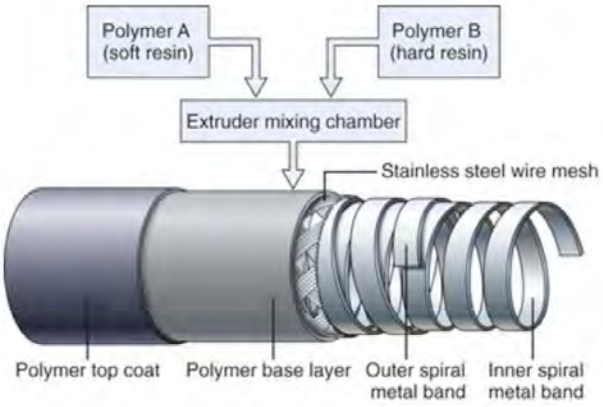
The outer sheath is the primary critical area for sterilization-related damage.

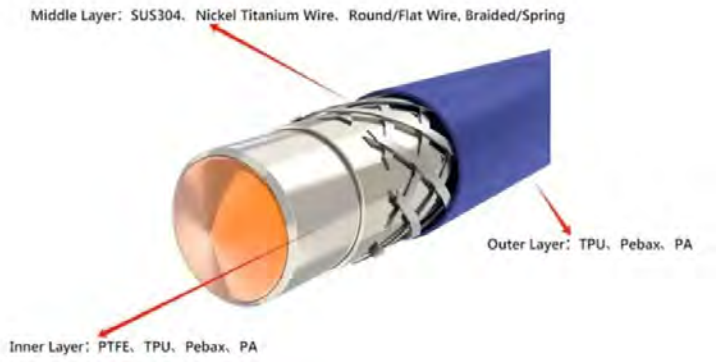
H_2O_2 vs Hdrozone

- H_2O_2:
  - High oxidative density, increased risk of surface damage

- Hdrozone:
  - Controlled oxidant distribution, low-temperature advantage

2.2 Inner Spiral / Braid Structure

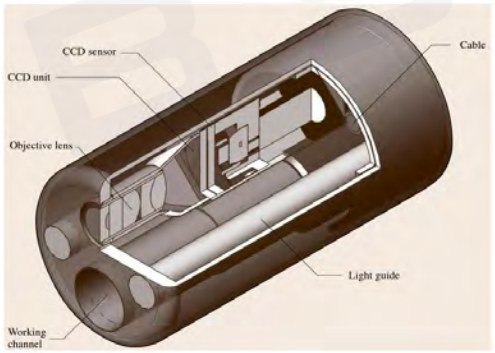




CONCLUSION:

The metal carrier structure is a low-risk area for both HDROZONE and H_2O_2.

2.3 Distal Deflectable Tip



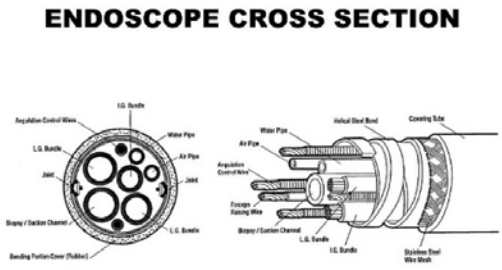
CONCLUSION:

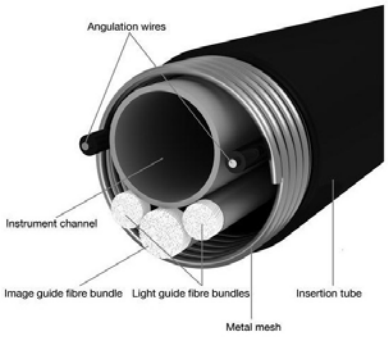
The distal tip is a high-risk area where chemical and mechanical stresses converge.

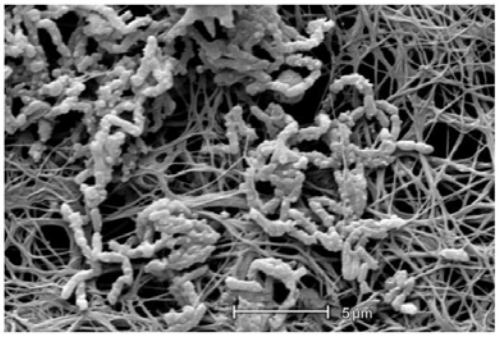
H_2O_2 vs Hdrozone

- H_2O_2: Possible condensation and localized concentration increase
- Hdrozone: More homogeneous gas-phase distribution

2.4 Working Channel / Lumen







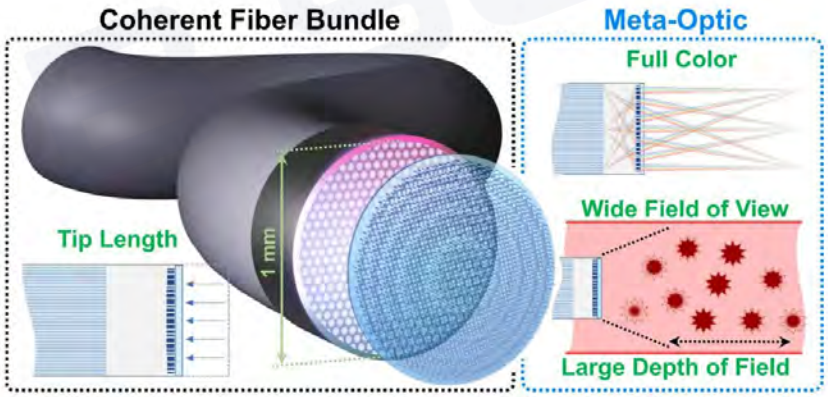
CONCLUSION:

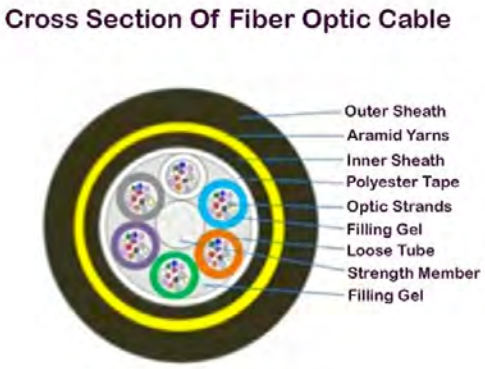
The effectiveness of lumen inner surface sterilization is the main indicator of overall success.

H_2O_2 vs Hdrozone

- H_2O_2: Diffusion and vaporization are limited
- Hdrozone: Gas-phase + reactive species generation advantage

2.5 Optical System





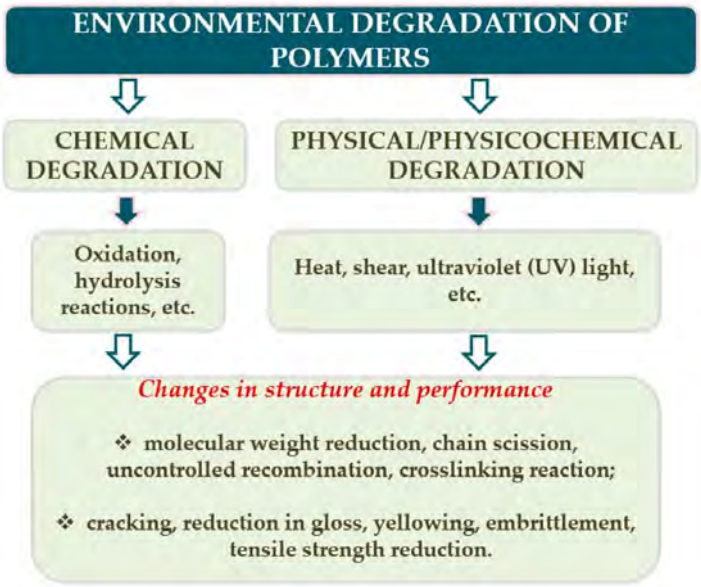
CONCLUSION:

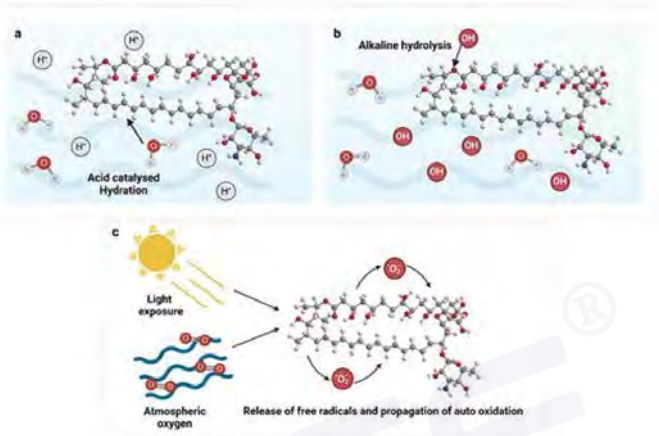
Optical glass is low-risk, while epoxy connections are high-risk.

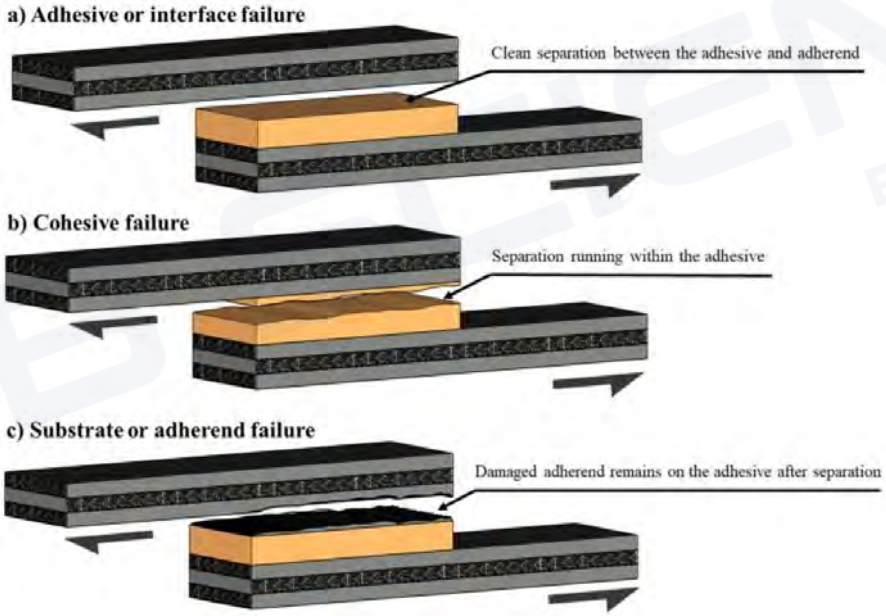
H_2O_2 vs Hdrozone

- H_2O_2: Oxidative stress on epoxy
- Hdrozone: Low-temperature advantage

2.6 Adhesives and Bonding Agents







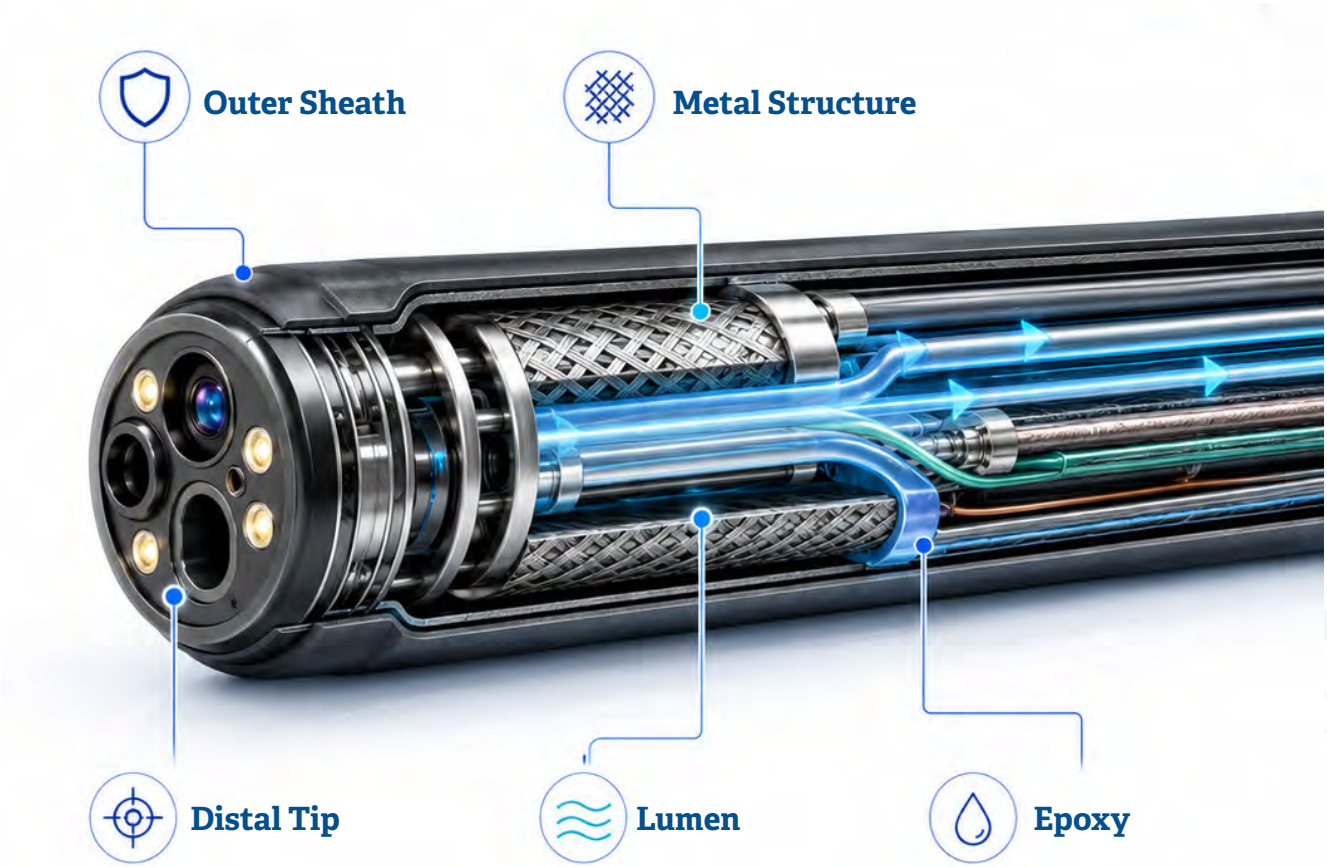
CONCLUSION:

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

H_2O_2 vs Hdrozone

- H_2O_2: Intense oxidative effect
- Hdrozone: Controlled chemical effect

TECHNICAL SUITABILITY ASSESSMENT OF H_2O_2 VS. HDROZONE IN ENDOSCOPE STERILIZATION



REGION	H_2O_2	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

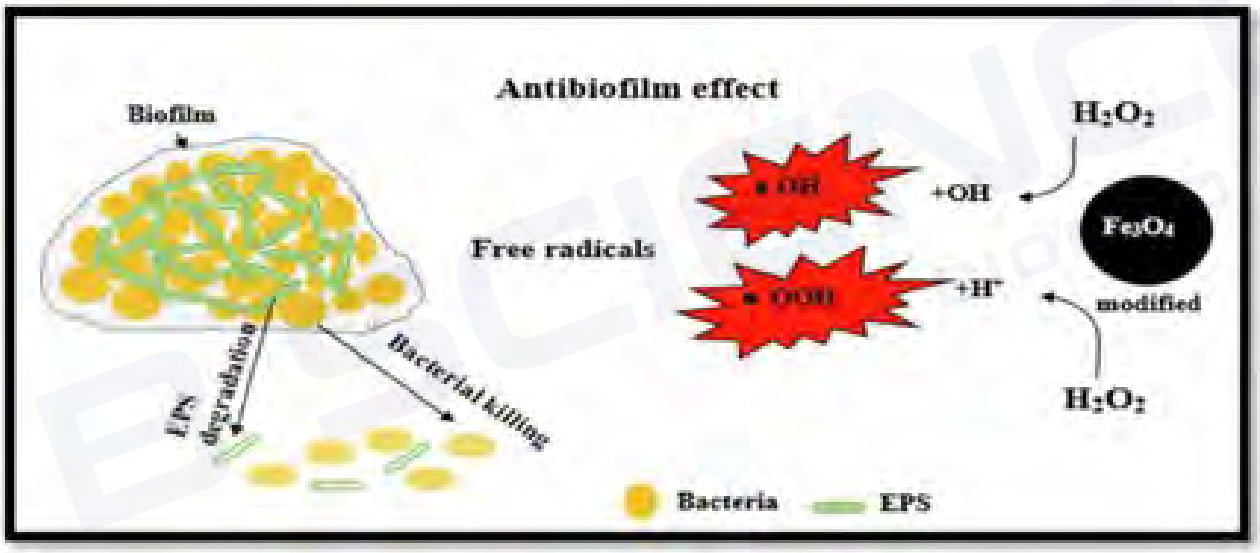
Comparative Result

- H_2O_2: Surface-dominant sterilization
- Hdrozone: Lumen-focused sterilization approach

MATERIAL DAMAGE COMPARISON (H_2O_2 VS. HDROZONE)

- H_2O_2: High oxidative density
- Hdrozone: More balanced oxidant distribution

EFFICACY COMPARISON OF H_2O_2 VS. HDROZONE IN ENDOSCOPE STERILIZATION

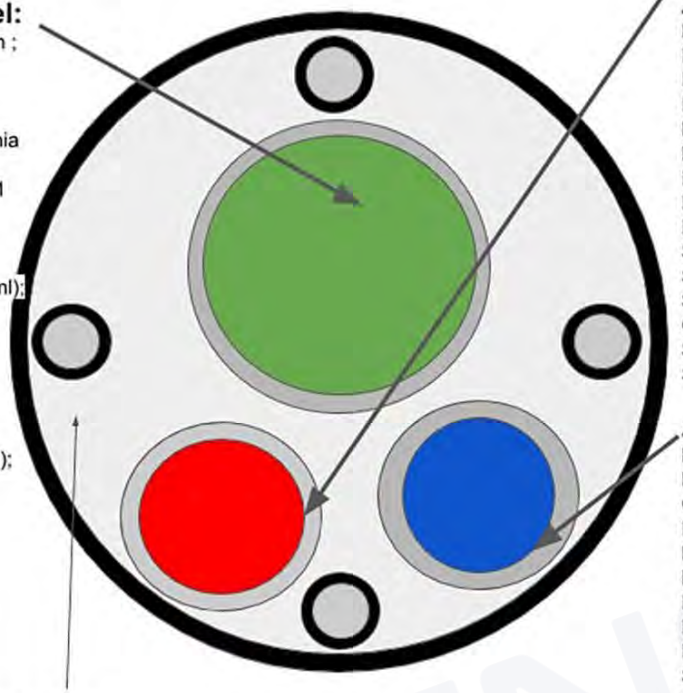


- H_2O_2: Strong surface effect, low penetration potential
- Hdrozone: Strong surface effect, high penetration potential

ULTRA-LOW TEMPERATURE EFFECT IN STERILIZATION

- H_2O_2: 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 pasteuri ;
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_2O_2: Limited in long lumens (effective up to ~1.5 m)
- Hdrozone: Gas-phase advantage (effective up to 15 m)

OVERALL COMPARATIVE EVALUATION OF H_2O_2 VS. HDROZONE IN ENDOSCOPE STERILIZATION

Strengths of Both Methods

H_2O_2:

- Strong surface sterilization
- Widespread use and acceptance

Hdrozone:

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

Critical Risks of Both Methods

H_2O_2:

• Epoxy damage

• Excessive surface oxidation

Hdrozone:

• Requires careful process control

FINAL CONCLUSION

• H_2O_2: 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_2O_2 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_2O_2 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.

- 30- Reference The literature sources we used in our hdrOzone studies