Definition and Technical Assessment of the Non-Damaging Sterilization Boundary and Validation Protocol for Flexible Endoscopes Using Hdrozone

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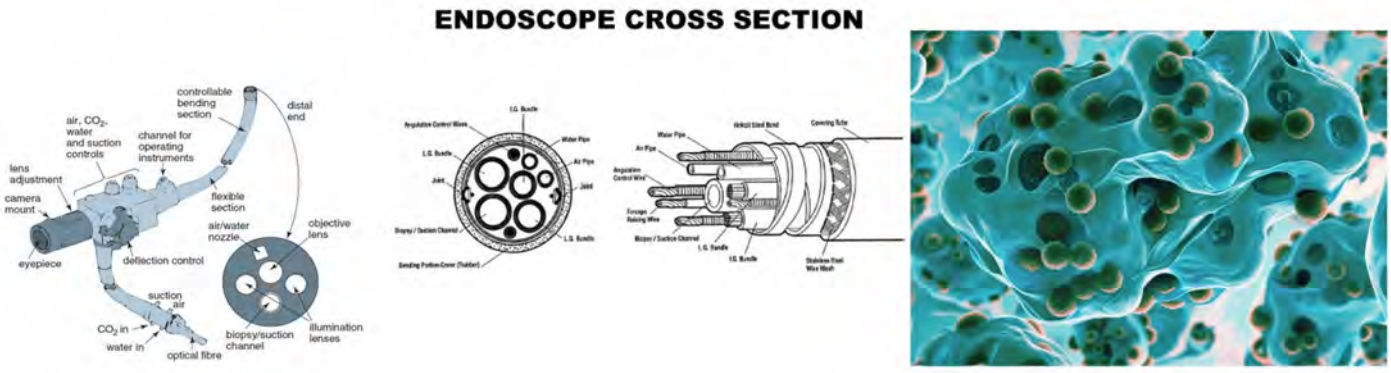
EXECUTIVE SUMMARY

Flexible endoscopes are multi-layered hybrid medical devices consisting of elastomers, fluoropolymers, metals, and optical components. This composite structure simultaneously necessitates both microbiological efficacy and the preservation of material integrity throughout the sterilization process.

This study evaluates the applicability of the Hdrozone sterilization approach for flexible endoscopes in terms of material compatibility, lumen penetration, functional integrity, and residual safety. It also establishes the validation framework for defining the non-damaging sterilization window.

KEYS
Sterilization, Hdrozone, Lumen, Penetration, Compatibility, Residuals, Oxidation, Endoscope

PROBLEM STATEMENT



The fundamental challenge in flexible endoscope sterilization is that the device is not a homogeneous structure.

A flexible endoscope is a multi-layered system comprising:

- Outer sheath polymers
- Inner spiral metal structure
- Flexible distal tip
- Internal lumen channels
- Optical system
- Adhesive and epoxy joints

Due to this structure, the sterilization challenge involves:

- Not merely surface sterilization
- Required access to internal lumen surfaces
- Presence of biofilm and organic residues
- Varying chemical resistance of different materials

Therefore, the sterilization process simultaneously demands:

- Achieving microbiological efficacy
- Preventing material damage
- Avoiding functional degradation
- Maintaining optical quality
- Ensuring residual safety

DEFINITION AND TECHNICAL FRAMEWORK

The Hdrozone sterilization approach is a method targeting low-temperature sterilization through the controlled use of gas-phase oxidant systems.

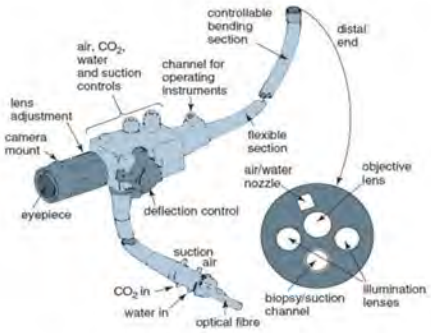
The technical objectives of this approach are:

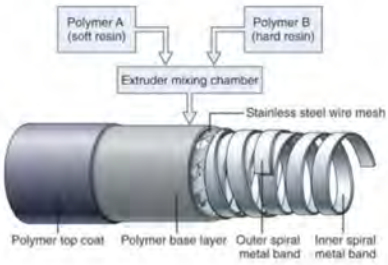
- Achieving target microbiological efficacy
- Preserving material, functional, and optical integrity
- Remaining within safe residual limits

The objective within this framework is to define the non-damaging sterilization process window for flexible endoscopes.

This approach is consistent with reprocessing validation requirements for reusable medical devices.

ENDOSCOPE STRUCTURE AND MATERIAL ANALYSIS





A flexible endoscope consists of the following key components:

- TPU / silicone / Pebax outer sheath
- PTFE / FEP / ETFE lumen channels
- Stainless steel spiral structure
- Nitinol support elements
- Optical fiber or lens system
- Epoxy and medical-grade adhesives

Within this structure:

- PTFE and metal components are chemically more resistant
- TPU, silicone, and epoxy regions are chemically more sensitive

Hypothesis

When the Hdrozone cycle is operated in a regime characterized by:

- High oxidant predominance
- Controlled radical activity
- Low temperature
- Controlled humidity

It can establish a non-damaging sterilization window within acceptable material change limits for flexible endoscopes.

This statement constitutes a hypothesis requiring experimental validation.

VALIDATION APPROACH AND SAMPLE PLAN

The validation approach consists of three levels:

- Coupon tests
- Sub-system tests
- Full device tests

Coupon Tests

- TPU
- Silicone
- Pebax
- PTFE / FEP / ETFE
- Epoxy
- Lens adhesive
- Seal elastomers

Sub-System Tests

- Insertion tube
- Bending section
- Distal tip
- Working channel

Full Device Tests

- Baseline reference
- Nominal cycle
- Worst-case cycle
- Aged cycle

a minimum of n=10 controls and multiple dose groups shall be applied.

Cycle Plan

- 1x
- 10x
- 25x
- 50x
- 100x

Test Groups

- Control
- Low oxidative load
- Nominal process
- High oxidative load
- Humidity effect
- Time effect
- Cycle repetition effect
- Plasma-free control

Measurement Methods

Mechanical	Chemical	Functional	Residual	Microbiological
• Hardness	• FTIR spectroscopy	• Channel flow rate	• H_2O_2 / O_3 residuals	• BI / CI
• Tensile strength	• Contact angle measurement	• Optical quality	• Off-gassing	• Internal lumen testing
• Bending	• Mass change	• Image performance		• Distal tip testing
• Torsion	• Surface analysis			
• Leak test				

Acceptance Criteria

- Leak test shall pass
- No visible damage
- Optical quality shall be maintained
- Channel flow rate shall remain unchanged
- Adhesive integrity shall be preserved
- Residuals shall be below defined limits
- Microbiological efficacy shall be achieved

Non-Damage Decision System

- Pass
- Conditional pass
- Fail

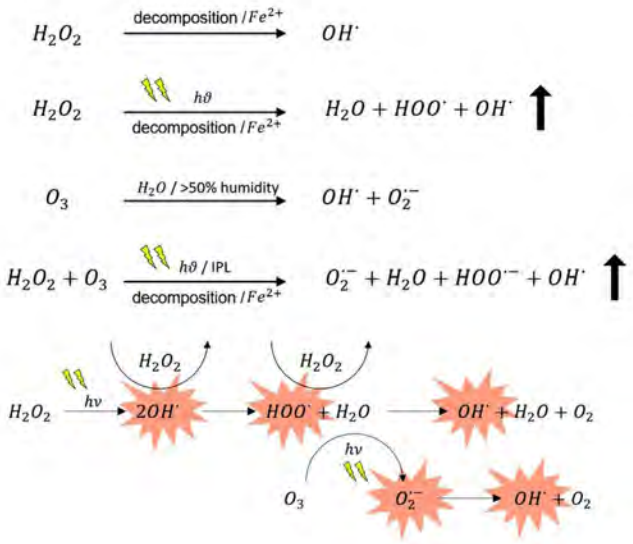
Damage Index (DI)

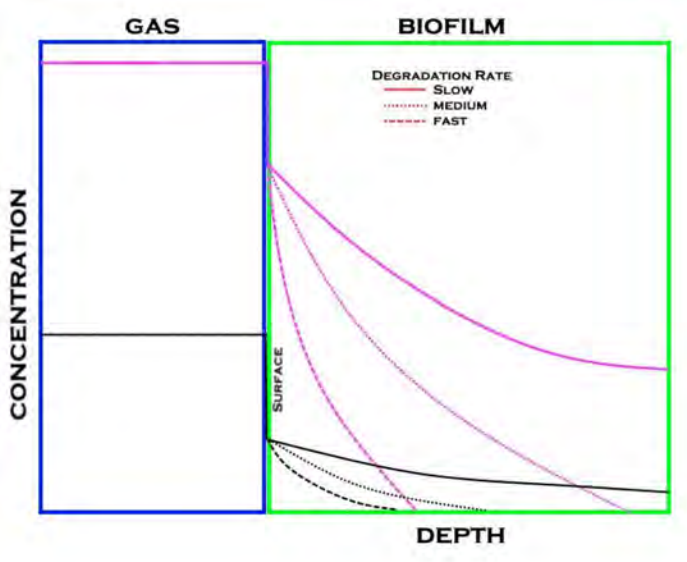
DI = 0.25 × Mechanical + 0.20 × Optical + 0.20 × Chemical + 0.20 × Functional + 0.15 × Residual

Worst-Case Definition

- Longest lumen
- Narrowest channel
- Most sensitive polymer
- Highest humidity
- Maximum cycle count

H_2O_2 & HDROZONE COMPARISON





▸ **H_2O_2 Sterilization:**

- Strong oxidative effect at the surface
- Condensation-based mechanism
- Lumen penetration may be limited

▸ **Hdrozone Sterilization:**

- Gas-phase distribution
- Reactive species generation approach
- Efficacy potential on internal lumen surfaces

▸ **Material Perspective:**

- H_2O_2: Higher stress on epoxy and elastomers
- Hdrozone: Controlled chemical impact

TECHNICAL OUTCOME ASSESSMENT

- PTFE, FEP, ETFE: Compatible
- Metal structure: Compatible
- Optical glass: Compatible
- TPU: Critical
- Silicone: Critical
- Epoxy: Critical
- Distal tip: Critical

Sterilization success is determined by the performance on internal lumen surfaces.

CONCLUSION

Flexible endoscope sterilization represents one of the most challenging sterilization problems due to material diversity and lumen geometry.

▸ **The Hdrozone approach is technically a viable sterilization method owing to:**

- Low-temperature operation
- Gas-phase delivery
- Lumen penetration potential

▸ **Compared to H_2O_2 systems, it offers:**

- Similar surface efficacy
- Higher potential within lumens

▸ **Final suitability is determined through:**

- Material compatibility testing
- Cyclic aging
- Lumen penetration validation
- Microbiological efficacy testing

OFFICIAL CONCLUSION STATEMENT

This study was prepared with the objective of assessing whether the Hdrozone sterilization cycle can achieve microbiological efficacy in flexible endoscopes while remaining within acceptable limits with respect to material integrity, functional performance, optical quality, and residual safety, and to establish the technical framework for defining the non-damaging sterilization process window.

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