HDROZONE™

Ultra-Low Temperature Sterilization in Flexible Endoscopes:

Polymer Stability, Lumen Physics, and Clinical Risk Management

Hasan Tahsin ÖZBEK • Bülent DEVECİ • Yüksel ERGÜN

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THE REAL PROBLEM

Flexible endoscopes are:

- Long
- Narrow
- Polymer-based
- Structurally complex with intricate mechanical design

For these reasons, they represent the most challenging class of medical devices from a sterilization standpoint.

This is not merely theoretical:

- Some studies have identified contamination in up to 32% of processed endoscopes
- A single channel can harbour millions of bacteria

The core question: "We cleaned it — but is it truly sterile?"

KEYS

Lumen, Polymer, Stability, TASS, Residual, Biofilm, Diffusion, Penetration, Reactive Transport

1. WHY IS ENDOSCOPE STERILIZATION SO DIFFICULT?

Reference manufacturers in this space include Olympus Corporation and Pentax Medical.

Structure

- Lumen (channel)
- Polymer outer structure
- Optical system

Critical reality:

- Narrow lumens → difficult to clean
- Complex internal architecture → microorganisms find refuge

Therefore: Sterilization failure = not a system error, but a physical limitation.

2. WHERE CURRENT SYSTEMS FALL SHORT

2.1 Diffusion Problem

H_2O_2 based systems:

- Rely on gas diffusion
- Lose efficacy within the lumen

Scientific reality: In long and narrow lumens, penetration is limited due to H_2O_2 condensation.

2.2 Humidity Problem in H_2O_2 Sterilization

- Humidity alters gas behaviour
- Cycle cancellations occur

2.3 Polymer Damage

Repeated sterilization causes wear and tear in endoscopes, accelerating material degradation over time.

3. THE CORE CRITICAL ISSUE: POLYMER PHYSICS

What is rarely stated openly, but is the reality:

Endoscopes age because of sterilization.

3.1 Mechanism

High temperature + oxidation leads to:

- Increased chain mobility
- Micro-cracking (crazing)
- Surface roughening

3.2 Clinical Chain

- Surface deteriorates
- Proteins adhere
- Biofilm forms
- Sterilization becomes increasingly difficult

This cycle is self-perpetuating.

4. ULTRA-LOW TEMPERATURE (37–42 °C) IN STERILIZATION: THE GAME-CHANGING FACTOR

Current systems:

- 45–55 °C

HDROZONE:

- 37–42 °C

Why Is This Difference Critical?

From a polymer standpoint:

- Does not approach the Glass Transition Temperature (Tg)
- Chain structure is preserved
- Microstructure remains stable

Clinical implications:

✓ Optical quality is maintained
✓ Surface integrity is preserved
✓ Biofilm formation is reduced

This is not simply "lower temperature" — it is a fundamentally different material regime.

5. THE LUMEN PROBLEM IN STERILIZATION

Clinical reality: The majority of infections originate from the lumen.

The Problem
- Efficacy diminishes as gas advances
- Lost at the surface
- Cannot reach the distal end

Consequence:
- Sterility is unreliable
- Biofilm persists

6. THE HDROZONE™ DIFFERENCE

HDROZONE™:
- Does not rely on passive diffusion
- Uses directed reactive species transport

What Does This Mean?
- Reactive species remain centrally within the lumen
- Do not deposit on the surface
- Are carried forward to the distal end

Clınıcal outcome:
✓ Efficacy at the distal end
✓ Homogeneous distribution
✓ More reliable sterilization

7. THE REALITY OF RESIDUALS AND TASS

Post-sterilization risks include:

- Toxic residuals
- Toxic Anterior Segment Syndrome (TASS)
- Tissue irritation

Clinical reality: Sterilization is not only about killing — it must leave the device clean.

HDROZONE Approach:

- Reactive species decompose at the end of the process
- Residuals are minimized

8. REAL-WORLD MARKET PLAYERS

Key competitors in low-temperature sterilization: Advanced Sterilization Products and STERIS.

Problem	Current Systems	HdrOzone
Lumen penetration	Limited	Enhanced
Polymer damage	Present	Minimized
Temperature	High (45–55 ˚C)	Low (37–42 ˚C)
Residuals	Risk present	Low
Humidity	Problematic	Tolerable

Concise Assessment

Current systems:

✓ They work

! But operate within constrained physics

HDROZONE™ operates on different physics.

9. THE CLINICAL OUTCOMES THAT MATTER

The impact of HDROZONE™:

1. Infection risk ↓
• Biofilm is reduced

2. Device service life ↓
• Polymer is protected

3. Operational safety →
• Sterilization is more predictable

10. THE DIRECTION THE INDUSTRY IS HEADING IN STERILIZATION TECHNOLOGIES

Today:
• Diffusion-based systems

Tomorrow:
Directed reactive species systems.

11. CONCLUSION

HDROZONE:
✓ Operates at ultra-low temperature
✓ Protects polymers
✓ Resolves the lumen problem
✓ Minimizes residuals

Currently, the endoscopy sterilization sector is relying on "good enough" technologies.

But the real need is: non-damaging + deep + reliable sterilization.

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