HDROZONE™

HYDRONIUM-BASED HYBRID STERILIZATION

Scientific Definition of Damage-Free Sterilization Limits in Flexible Endoscopes

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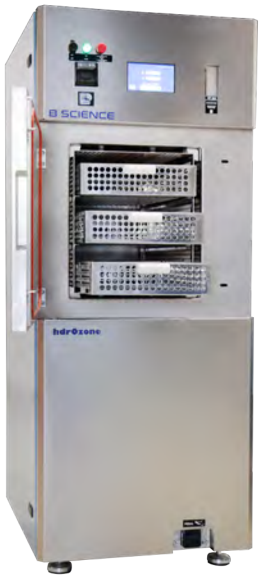
PURPOSE

This document has been prepared to scientifically define the boundary between microbial efficacy and material integrity in the low-temperature sterilization of flexible endoscopes and to demonstrate the position of the HDROZONE™ (H_3O^+-based hybrid sterilization) approach within this boundary.



KEYS
Endoscope, Sterilization, Hydronium, H2O2, Contamination, Biofilm, Risk, Validation

1. PROBLEM STATEMENT

The fundamental problem in flexible endoscope sterilization is as follows:

The high chemical/reactive load applied to achieve sterility in challenging lumens causes irreversible damage to the polymer, elastomer, and adhesive components of the device

This problem creates three critical contradictions:

Penetration vs. Damage

- Aggressive chemistry is required for intra-lumen sterilization.
- The same chemistry damages the outer body.

Radical Effect vs. Material Stability

- High reactive species (especially radicals) are effective in microbial killing.
- However, they break polymer chains.

Low Temperature vs. Chemical Load

- Low temperature is advantageous for the material.
- However, as the chemical load increases, this advantage disappears.

CONCLUSION:

Most current sterilization approaches either guarantee sterility but reduce device lifespan or protect the device but create risks in lumen sterility.

2. ENGINEERING FRAMEWORK FOR THE DEFINITION OF “DAMAGE-FREE” IN ENDOSCOPE STERILIZATION

For an endoscope, damage-free status must be preserved simultaneously across the following four axes:

Mechanical Integrity

- No cracks, hardening, tackiness, or micro-tears in the outer sheath.

Functional Integrity

- No change in bending, torque transmission, channel patency, or leak test results.

Optical / Electrical Integrity

- No degradation in image and light transmission, distal tip transparency, or insulation.

Chemical Safety

- Must not leave unacceptable residues or degradation products.

This approach is compatible with:

- FDA sterilization guidelines
- AAMI TIR17 material compatibility approach

3. RISK DISTRIBUTION IN ENDOSCOPE STRUCTURE

▸ Critical Sensitive Areas

- TPU / silicone / Pebax outer sheath
- Epoxy and adhesive regions
- Distal tip seal areas
- Elastomeric strain-relief zones

▸ Relatively Durable Areas

- Stainless steel spiral structure
- PTFE / FEP / ETFE channels
- Optical glass surfaces

CONCLUSION:

Sterilization must be optimized not for a single “device” but for a multi-material system.

4. ENDOSCOPE DAMAGE MODEL FOR HDROZONE™

HDROZONE generates a hybrid chemical environment. Damage arises from the following total load:

TOTAL DAMAGE LOAD ≈

Oxidative Load + Ionic Load + Moisture Effect + Temperature Effect + Time/Cycle Effect

This model is reduced to 5 control axes:

1. VH_2O_2 equivalent dose
2. O_3 equivalent dose
3. Plasma / radical fraction
4. Relative humidity / water activity
5. Number of cycles (cumulative aging)

Critical Point:

Sterilization is not a single-cycle issue but a cumulative aging problem.

5. DAMAGE-FREE OPERATION WINDOW

REGION A — SAFE WINDOW

- Heavy oxidant dominant
- Low radicals
- Low temperature
- Controlled humidity
- Low residue

RESULT:

- Microbial killing is achieved
- Polymer damage is minima

HDROZONE target regime

REGION B — EFFECTİVE BUT STRESSFUL

- More aggressive chemistry

RISK:

- Hardening
- Color Change
- Seal Fatigue
- Adhesive Damage

Only acceptable with validation

REGION C — DAMAGE ZONE

- High radical density
- Long exposure
- High humidity

RESULT:

- Polymer Swelling
- Oxidation
- Deformation

Must be strictly avoided

6. SCIENTIFIC DESIGN RULES

▸ Rule 1 — Heavy Oxidant Dominance, Not Radicals

- High radicals → chain scission

SOLUTION:

- Keep OH· low
- Plasma should be an auxiliary phase

▸ Rule 2 — Optimal Humidity

- Low humidity - poor transport
- High humidity - aggressive chemistry

TARGET:

- “Humidity present but no wet surface”

▸ Rule 3 — Stable Temperature

- Low temperature is an advantage
- However, local temperature peaks are risky

▸ Rule 4 — The Outer Surface Must Not Be Sacrificed for the Lumen

This is critical:

Sterilization optimization is not only about SAL.

New Metric:

- Lumen sterility / outer surface damage ratio

7. VALIDATION THRESHOLD ARCHITECTURE

Primary Criteria

- Stable leak test
- No change in bending
- Unchanged channel flow
- Preserved optical quality
- No surface damage

Secondary Criteria

- Limited hardness change
- Preserved flexibility
- Preserved adhesive strength
- Limited oxidation index
- Low ΔE color change
- Residue below limit

Red Criteria (Reject)

- Distal haze / fogging
- Stickiness
- Micro-cracks
- Bending deviation
- Whitening / crazing
- Increased lumen friction

8. TESTİNG AND VERİFİCATİON PLAN ON ENDOSCOPES

▸ Phase 1 — Base Materials Used in Endoscopes:

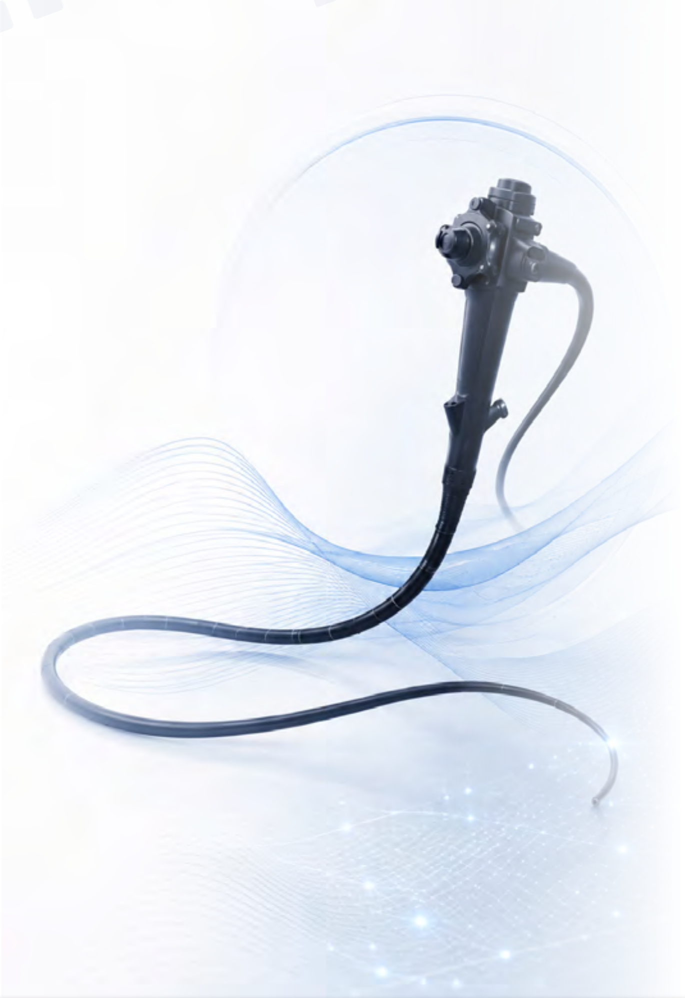
- TPU, silicone, Pebax
- PTFE / FEP
- Epoxy
- Lens
- Elastomers

TEST:

- 1x – 100x cycles
- Oxidative load variation
- Humidity variation
- Plasma on/off

MEASUREMENTS:

- FTIR
- SEM
- Contact angle
- Hardness
- Tensile
- Mass change
- Color



▸ Phase 2 — Sub-systems

- Insertion tube
- Bending section
- Channel
- Distal tip

▸ Phase 3 — Complete Device

- Leak test
- Articulation
- Imaging
- Flow test
- Residue
- BI/CI

9. SCIENTIFIC CONCLUSION

1. Damage-free boundary ≠ maximum microbial inactivation
2. Damage-free boundary = lumen sterility + material preservation
3. HDROZONE Advantage:

   It offers higher material compatibility potential compared to classical plasma systems in a heavy oxidant-dominant – low radical regime.

The future of flexible endoscope sterilization:

It is not more aggressive chemistry, but controlled chemical engineering.

The HDROZONE approach constitutes the engineering foundation of this transition.

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