HDROZONE™

Hydronium-Based Hybrid Sterilization Platform

The Clinical and Operational Reality of Next-Generation Low-Temperature Sterilization

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EXECUTIVE SUMMARY

Minimally invasive surgery and flexible endoscopy have fundamentally transformed sterilization technology. Today's sterilization challenge is no longer simply "killing microorganisms."

The real problem encompasses:

- Long and narrow lumens
- Complex internal surfaces
- Heat-sensitive materials
- High patient safety expectations

Current low-temperature sterilization systems cannot fully address this new reality.

HDROZONE™ technology transitions sterilization from a passive gas diffusion approach to an active, directed, and controlled reactive transport model.

This white paper presents, clearly and directly:

- The clinical need
- The limitations of current systems
- The differentiating features of the HDROZONE™ approach

KEYS
Hydronium, Sterilization, Lumen, Reactive Transport, Contamination, Material Safety

1. THE REAL PROBLEM IN MODERN STERILIZATION

1.1 Impact of Endoscopy and Robotic Surgery

Systems in current use include:

• Flexible endoscopes

• Robotic surgical instruments (e.g., the da Vinci Surgical System)

• Long-lumen devices

These devices are challenging for conventional sterilization due to their:

• Small diameter

• Extended length

• Multi-surface geometry

1.2 Real Risks Faced by Hospitals

Problems encountered in the field today:

• Uncertainty regarding intraluminal sterilization

• Cycle cancellations

• Humidity-related failures

• Chemical residual risk

• Instrument damage

These issues directly lead to:

• Patient safety risks

• Surgical delays

• Increased costs

• Reduced device service life

2. LIMITATIONS OF CURRENT TECHNOLOGIES

Market leaders in this space include Advanced Sterilization Products and STERIS.

2.1 Vaporized Hydrogen Peroxide (VHP)

Core problem:

- Efficacy diminishes as gas advances through the lumen
- Activity weakens within the lumen

Result:

Unreliable in long lumens.

2.2 Gas Plasma Systems

- Localized effect
- Limited penetration
- Short reactive species lifetime

2.3 Ozone Systems

- High oxidation potential
- Material compatibility risk
- Difficult to control

2.4 Critical Conclusion

No existing system can simultaneously deliver:

- Deep penetration into long lumens
- Low operating temperature
- Material safety
- Low residuals

3. THE HDROZONE™ APPROACH

HDROZONE™ technology moves sterilization to a fundamentally different physical model.

Core Approach

- Directed transport rather than gas diffusion
- Active control rather than passive process
- Stabilized reactive species rather than short-lived radicals

3.1 Hybrid Chemical Mechanism

HDROZONE™ operates through a combination of:

- Hydrogen peroxide (H_2O_2)
- Ozone (O_3)
- Controlled energy activation

This process generates and directs:

- Hydronium ions (H_3O^+)
- Potent oxidant species

3.2 The Critical Difference

In conventional systems: gas disperses passively.
In HDROZONE™: reactive species are actively directed.

This difference fundamentally changes intraluminal behaviour.

4. SOLVING THE LUMEN PROBLEM

The most difficult problem in sterilization: **long and narrow lumens.**

The HDROZONE™ approach:

- Maintains reactive species centrally within the lumen
- Reduces surface losses
- Ensures forward transport to the distal end

Result:

- Deep penetration
- Homogeneous efficacy

5. CLINICAL PERFORMANCE AND VALIDATION

Independent laboratory studies conducted under:

- Challenging load conditions
- Long-lumen scenarios
- Biological indicator (BI) verification

Results:

- High sterilization assurance
- Efficacy at distal endpoints
- Consistent performance

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4.3.3 Positions and results of the microbiological indicators

bionova - biological indicator	cfu / carrier [lg]	mean value [lg]
Control 1-2	8,69/8,94	8,82

Wrapping* [yes / no]	sample No.	designation	cfu / carrier [lg]	Enrichment* [3 / 7 days]	lg / carrier	Reduction factor [lg]
			upper basket			
yes	106	A	0	-/-	0	≥8,82
yes	114	E	0	-/-	0	≥8,82
yes	108	B	0	-/-	0	≥8,82
yes	110	C	0	-/-	0	≥8,82
yes	116	F	0	-/-	0	≥8,82
yes	112	D	0	-/-	0	≥8,82
			middle basket			
yes	118	G	0	-/-	0	≥8,82
yes	120	H	0	-/-	0	≥8,82
yes	119	G	0	-/-	0	≥8,82
			lower basket			
yes	109	B	100	+/+	2,00	6,82
yes	115	E	0	-/-	0	≥8,82
yes	107	A	0	-/-	0	≥8,82
yes	113	D	0	-/-	0	≥8,82
yes	117	F	0	-/-	0	≥8,82
yes	111	C	0	-/-	0	≥8,82

legend:

RF = Reduction factor
- = no turbidity due to microbial growth
+ = turbidity due to microbial growth
n.z. = uncountable

A = HygCen – white PTFE PCD / PCD 1 mm Ø 850 mm long
B = HygCen – white PTFE PCD / PCD 2 mm Ø 1200 mm long
C = Teknomar – Steel Lumen PCD / PCD 0,7 mm Ø 500 mm long
D = Teknomar – white PTFE PCD / PCD 0,4 mm Ø 900 mm long
E = Teknomar – white PTFE PCD / PCD 2 mm Ø 7500 mm long
F = Teknomar – white PTFE PCD / PCD 2 mm Ø 10000 mm long
G = Teknomar – white PTFE PCD / PCD 2 mm Ø 15000 mm long
H = Teknomar – white PTFE PCD / PCD 2 mm Ø 50000 mm long
I = polyester suture bionova / *Geobacillus stearothermophilus.* / in double tyvek

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6. MATERIAL COMPATIBILITY

Sterilization is not only about killing — it is equally about protecting the material.

The HDROZONE™ system features:

• Low-temperature operating regime

• Controlled oxidation

• Stabilized reactive species

Observed Outcomes

• Metal surface stability

• Preservation of polymer integrity

• Absence of micro-damage

7. RESIDUALS AND SAFETY

The most critical post-sterilization risk: Chemical residuals.

The HDROZONE™ approach:

• Reactive species decompose at process completion

• Residual formation is minimized

Result:

• Operator safety

• Patient safety

• Reduction of toxic risks

8. IMPACT ON HOSPITAL OPERATIONS

8.1 Workflow

- Fewer cycle cancellations
- More stable process
- More predictable outcomes

8.2 Economic Impact

- Extended service life of sterilized devices
- Reduced consumable costs
- “Lower maintenance requirements

8.3 Clinical Impact

- Reduced infection risk
- Enhanced patient safety
- Maintained surgical continuity

9. COMPETITIVE PERSPECTIVE

Current systems:

- Manage the problem
- Operate within constraints

HDROZONE™ redefines the problem.
Key Differentiators:

Topic	Conventional System	HdrOzone
Lumen approach	Limited	Extended
Humidity	Problematic	Part of the process
Transport mechanism	Passive	Directed
Process stability	Sensitive	Stable

10. ENVIRONMENTAL AND SAFETY ADVANTAGES

- Lower chemical burden
- Reduced waste generation
- Minimal operator exposure

11. REGULATORY AND STANDARDS COMPLIANCE

The HDROZONE™ platform:

• Is designed in accordance with international sterilization standards

• Provides traceability and documentation infrastructure

12. FUTURE PERSPECTIVE

Sterilization technology is evolving. The new reality:

- Longer lumens
- More sensitive devices
- Stricter regulatory requirements

Under these conditions, diffusion-based systems will no longer be sufficient.

13. CONCLUSION

HDROZONE is not an alternative to existing systems — it represents a new approach.

This next-generation sterilization technology:

✓ Solves the long-lumen problem

✓ Preserves material safety

✓ Minimizes residuals

✓ Delivers operational efficiency

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