A New Physical Boundary in Sterilization Technology

Analysis of the Physico-Chemical Model

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Hydronium Ionization and Long-Lumen Sterilization Technical Report

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ABSTRACT

The widespread adoption of minimally invasive surgery and flexible endoscopy systems has revealed the geometric limit problem in sterilization processes. Particularly:

- Ø1–2 mm diameter
- 1–15+ meter length
- Complex internal surface structures

These factors define the physical boundaries of diffusion-based low-temperature sterilization methods. This study comprehensively defines, based on H_2O_2–O_3–DBD plasma combination leading to hydronium (H_3O^+) and peroxizone (H_2O_4) formation:

- Reactive species generation kinetics
- Plasma environment parameters
- Intra-lumen transport mechanisms
- Biological validation
- Material interaction
- Residue and toxicology

Core Approach:

Sterilization is not a passive diffusion problem but an **electric field-assisted reactive transport and phase-controlled chemical generation** problem.

KEYLER
Peroxysone, DBD Plasma, Reactive Transport, Diffusion, Kinetics, Ionization, Validation, Toxicology

1. INTRODUCTION AND PROBLEM STATEMENT

Flexible endoscopes and robotic surgical instruments, due to their:

- Multi-layered structure
- Heterogeneous surface energy
- Long and narrow lumen geometry

represent boundary conditions for classical sterilization models.

Diffusion-based gas penetration:

- Decreases exponentially with distance
- Loses energy through surface interactions
- Is interrupted by phase changes

This situation particularly limits sterility assurance in long lumens.

2. PHYSICAL LIMITS OF EXISTING TECHNOLOGIES

2.1 Diffusion Limitation

Concentration along the lumen:

$$C(x) = C_0 e^{-kx}$$

(where k = surface interaction coefficient, x = lumen length)

Result:

As x increases, C(x) decreases rapidly and becomes ineffective beyond a certain length.

2.2 Condensation

Gas-phase H_2O_2:

- Loses energy through wall collisions
- Transitions to liquid phase under local temperature/partial pressure conditions

Result:

- Film formation
- Flow blockage
- Cessation of further penetratio

2.3 Gas Depletion

- Reactives are consumed along the lumen
- Active species concentration drops at distal ends

2.4 Plasma System Limitations

- Radicals have very short lifetimes
- Localized production → localized effect
- Not sustainable along the lumen

2.5 Ozone System Limitations

- High oxidative aggression
- Difficult to control
- Material damage risk

General Conclusion:

No system currently exists that simultaneously provides:

- Long-distance penetration
- Low temperature
- Low material damage
- Low residue

3. HYBRID REACTIVE SYSTEM DEFINITION

3.1 System Components

- H_2O_2: Precursor
- O_3: Oxidative driver
- DBD Plasma: Energy source and control mechanism

3.2 Reactive Species

- H_3O^+: Ionic carrier
- H_2O_4: Stable oxidant
- $OH\cdot$: Highly reactive radical

3.3 Fundamental Transport Mechanism

Classical: $J = -D\nabla C$

Hybrid: $J = -D\nabla C + \mu CE$

(D = diffusion coefficient, μCE = electric field-driven drift)

4. PLASMA PHYSICS

4.1 Operating Range

- Pressure: 0.1 – 0.4 Pa
- Voltage: ~6 kV
- Current: ~20 mA
- Frequency: 50–100 Hz

4.2 Plasma Parameters

- Electron density: $n_e \approx 10^{13} – 10^{15}\, m^{-3}$
- Electron temperature: $T_e \approx 1–3 eV$

4.3 Debye Length

$$\lambda_D = \sqrt{\frac{\varepsilon_0 k T_e}{n_e e^2}}$$

$\approx 10^{-4} - 10^{-3}$ m

Result:

- λD < lumen diameter
- Plasma remains volumetrically stable
- Ions remain in the volume rather than collapsing onto the wall

5. REACTION KINETICS

5.1 Key Reactions

$$O_3 + e^- \rightarrow O_2 + O\cdot$$

$$H_2O_2 + e^- \rightarrow 2OH\cdot$$

$$OH\cdot + H_2O \rightarrow H_3O^+$$

$$HO_2\cdot + HO_2\cdot \rightarrow H_2O_4$$

5.2 Differential Kinetic Model

$$\frac{d[OH]}{dt} = k_1[H_2O_2] + k_2[O_3] - k_3[OH]^2$$

$$\frac{d[H_3O^+]}{dt} = k_4[OH][H_2O] - k_5[recombination]$$

5.3 Phase Management

- Plasma ON: Radical production
- Plasma OFF: Stable species formation

This structure enables:

- Controlled reactive production
- Radical suppression
- Stable oxidant generation

6. INTRA-LUMEN TRANSPORT

6.1 Coulomb Repulsion

- Similarly charged ions repel each other
- Concentration builds toward the center

6.2 Flow Characteristics

- Reduced wall interaction
- Decreased energy loss
- Jet-like flow formation

6.3 Conclusion

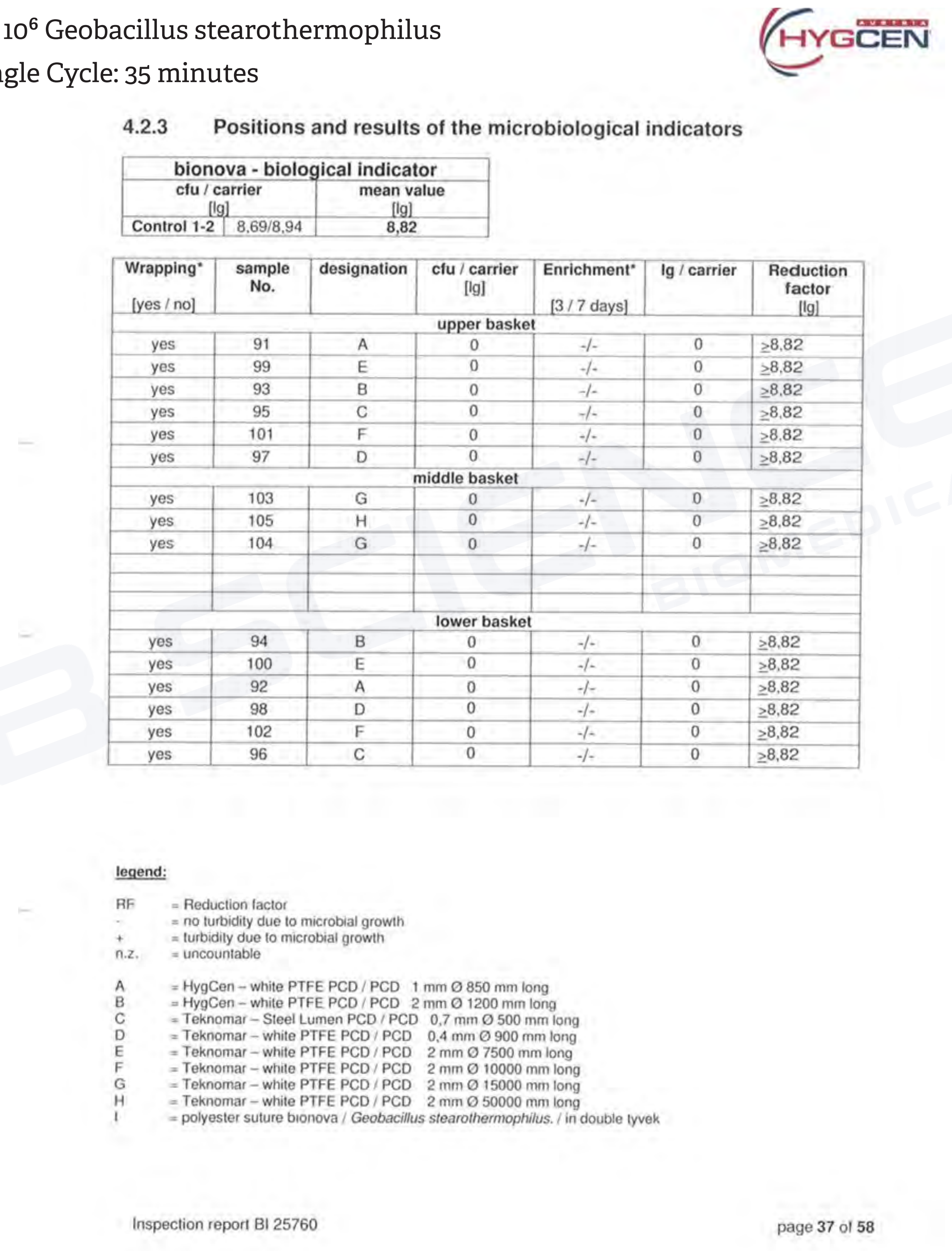
- Concentration loss is minimized

- Long-distance transport becomes possible

7. VALIDATION

7.1 Test Configuration

- Lumen: 2 mm / 15 m
- Load: Full load
- BI: 10^6 Geobacillus stearothermophilus
- Single Cycle: 35 minutes



HYGCEN AUSTRIA

4.2.3 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	91	A	0	-/-	0	≥8,82
yes	99	E	0	-/-	0	≥8,82
yes	93	B	0	-/-	0	≥8,82
yes	95	C	0	-/-	0	≥8,82
yes	101	F	0	-/-	0	≥8,82
yes	97	D	0	-/-	0	≥8,82
			middle basket			
yes	103	G	0	-/-	0	≥8,82
yes	105	H	0	-/-	0	≥8,82
yes	104	G	0	-/-	0	≥8,82
			lower basket			
yes	94	B	0	-/-	0	≥8,82
yes	100	E	0	-/-	0	≥8,82
yes	92	A	0	-/-	0	≥8,82
yes	98	D	0	-/-	0	≥8,82
yes	102	F	0	-/-	0	≥8,82
yes	96	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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7.2 Results

- 100% inactivation
- SAL = 10^{-6}

7.3 Statistics

- Number of repetitions ≥ 3
- Half-cycle validation available

8. MATERIAL COMPATIBILITY

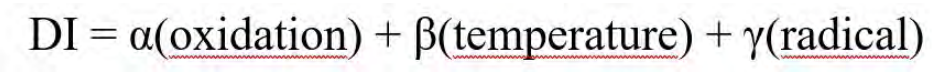
Tested materials:

- 316L,
- PEEK,
- Silicone

8.1 Observations

- No micro-pitting
- Passivation preserved
- No crack formation

8.2 Damage Index



$$DI = \alpha(\text{oxidation}) + \beta(\text{temperature}) + \gamma(\text{radical})$$

Low DI

9. SURFACE ANALYSIS (SEM)

- Surface topography unchanged
- Microstructure stable

10. CHEMICAL RESIDUE (FTIR)

- LOD: 0.01 mg/m^2
- Measured: < LOD

10.1 Conversion Mechanism

- H_2O_2: H_2O
- O_3: O_2

11. CONTROL ALGORITHM

Input Parameters:

- Pressure,
- Humidity,
- Gas ratio,
- Plasma duty cycle

Target:

- Maximize: H_3O^+ and H_2O_4
- Minimize: Radicals and residue

Cycle Structure:

1. H_2O_2 loading
2. O_3 injection
3. Plasma ON
4. Plasma OFF
5. Feedback loop

12. COMPETITIVE ANALYSIS

Parameter	Diffusion Systems	Hybrid System
Transport	Diffusion only	Drift + Diffusion
Lumen Capability	~1 m	15 m
Humidity	Problem	Advantage (reactive)
Control	Limited	Active

13. ECONOMIC IMPACT

- Increased device lifespan
- Reduced consumable costs
- Decreased maintenance requirements

14. REGULATORY COMPLIANCE

- MDR 2017/745
- ISO 14937
- ISO 11138
- ISO 10993

15. TOXICOLOGY AND EMISSIONS

- Residue: Not detectable
- Emissions: O_2 + H_2O
- Toxicity: Non-toxic

16. CONCLUSION

This study demonstrates that:

- Sterilization is not limited to the diffusion model
- Electric field-assisted reactive transport is critical
- Long-lumen sterilization is physically achievable

The H_3O^+ and H_2O_4-based hybrid approach simultaneously delivers:

- Controlled chemistry generation
- Low material damage
- Low residue
- Superior long-distance penetration

KAYNAKÇA

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