HDROZONE™

Ultra-Low Temperature Sterilization (37–42 ˚C):

Polymer Safety, Lumen Performance, and Clinical Outcomes

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ABSTRACT

In modern surgical and endoscopic practice, sterilization is not merely a process of microbial elimination; it is a critical process in terms of preserving device integrity and maintaining clinical safety on a sustainable basis.

Flexible endoscopes, robotic surgical instruments, and polymer-based medical devices present specific requirements during sterilization due to their sensitivity to heat and oxidative stress.

In this study, the HDROZONE™ approach has been evaluated on the basis of ultra-low temperature (37–42 ˚C) operation and controlled reactive chemistry principles, with polymer safety, intraluminal sterilization performance, and impact on clinical outcomes addressed systematically.

KEYS
HDROZONE, Polymer, Lumen, TASS, Residuals, Toxicity, Microstructure, Biofilm, Penetration, Stability

INTRODUCTION

Sterilization technologies are the primary determinant of the safe use of medical devices.

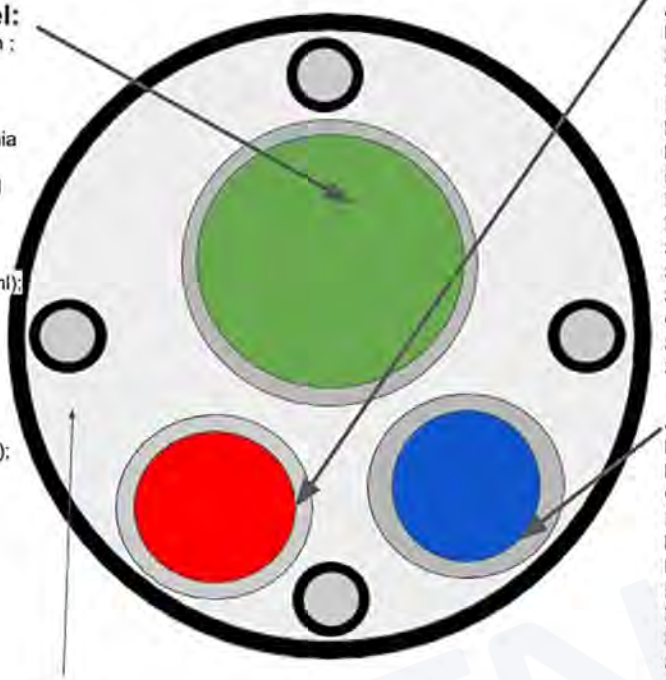
Conventional approaches are based on:

- High temperatures
- Aggressive chemical agents

However, medical devices in current use — flexible endoscopes, robotic surgical instruments, and polymer-based complex systems — are not fully compatible with classical sterilization methods.

This situation creates a critical need to balance sterilization efficacy with material integrity.

DEFINITION OF THE CLINICAL PROBLEM



The Endoscope and Polymer Era

Modern devices are no longer predominantly metal-based. They incorporate:

- PEEK
- PTFE
- Silicone
- Elastomers
- Optical fiber systems

These materials are:

- Sensitive to high temperatures
- Susceptible to microstructural deformation
- Vulnerable to chemical stress

Clinical Risks in the Field

Key problems observed in clinical practice:

- Uncertainty regarding intraluminal sterilization
- Endoscope damage (micro-cracks)
- Degradation of image quality
- Risk of Toxic Anterior Segment Syndrome (TASS)
- Reuse safety concerns

These conditions directly translate into clinical outcomes.

ULTRA-LOW TEMPERATURE (37–42 ˚C): THE CRITICAL THRESHOLD

Temperature Range of Current Systems

Many low-temperature systems operate in the 45–55 ˚C range. This range is close to the critical threshold values for polymers.

Thermal Behavior of Polymers

The key concept for polymers is the Glass Transition Temperature (Tg). As the Tg is approached:

- Chain mobility increases
- Microstructure becomes relaxed
- Deformation begins

Effect of the 37–42 ˚C Range

The HDROZONE™ operating range:

- Remains below the Tg
- Maintains chain stability
- Does not alter surface tension

CONSEQUENTLY:

- Micro-crack formation is prevented
- Optical degradation does not occur
- Internal lumen surfaces remain stable

POLYMER DAMAGE: CLINICAL SIGNIFICANCE

Micro-Damage Mechanism

High temperature and oxidative stress lead to:

- Capillary crack formation
- Surface roughening
- Protein adhesion

Clinical Effects

Such damage results in:

- Biofilm formation
- Sterilization resistance
- Increased infection risk

HDROZONE™ APPROACH

The HDROZONE™ approach operates on the basis of:

- Low temperature
- Controlled oxidation
- Stabilized reactive species

Clinical effects:

- Surface is preserved
- Device service life is extended
- Re-sterilization safety is enhanced

STERILIZATION WITHIN THE LUMEN

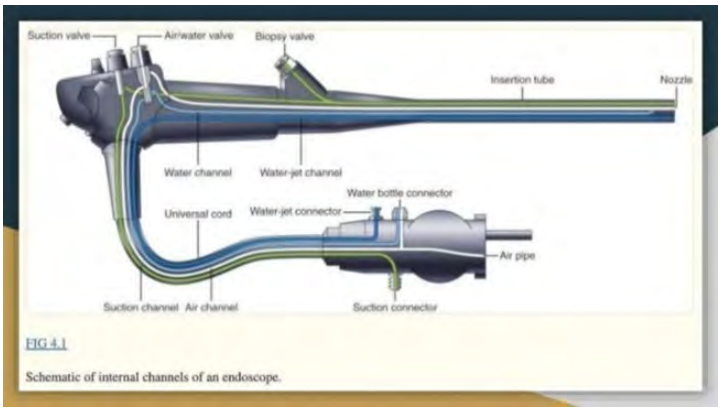
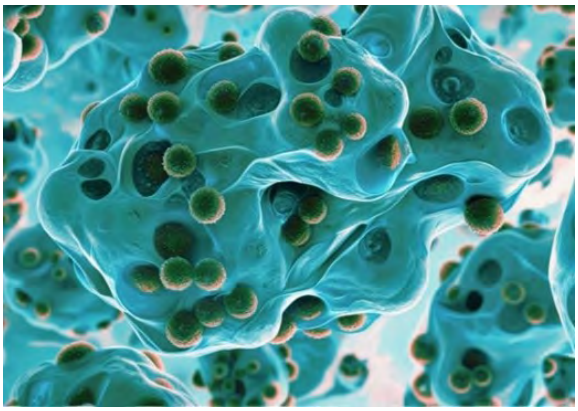


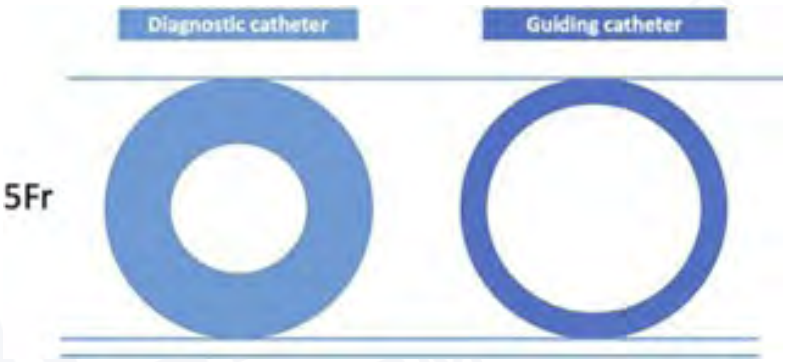
FIG 4.1
Schematic of internal channels of an endoscope.



Critical Clinical Problem

The most vulnerable component of endoscopes is

- The internal lumen surface.



Limitations of Current Systems

- Efficacy diminishes as gas advances through the lumen
- Sterility decreases at the distal end

HDROZONE Approach

The HDROZONE™ approach achieves intraluminal performance through:

- Directed delivery of reactive species
- Central transport within the lumen
- Reduced surface loss

RESULT:

- Deep penetration
- Homogeneous sterilization

Residuals and Toxicity

Post-sterilization residuals can cause:

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

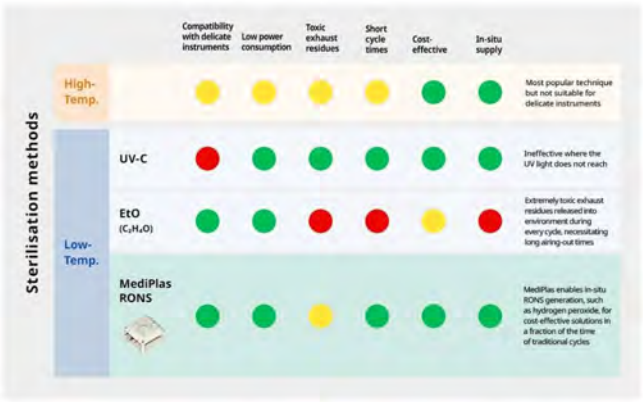
The HDROZONE™ approach addresses this through:

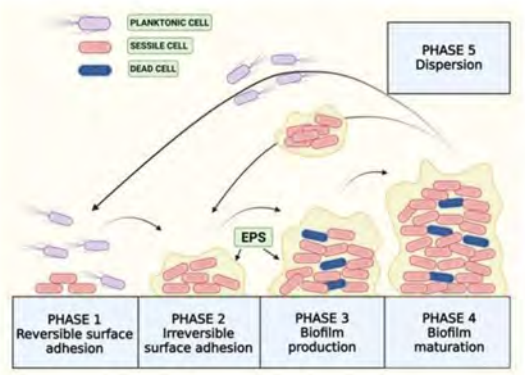
- Decomposition of reactive species at the end of the process
- Reduction of residuals to a minimum level

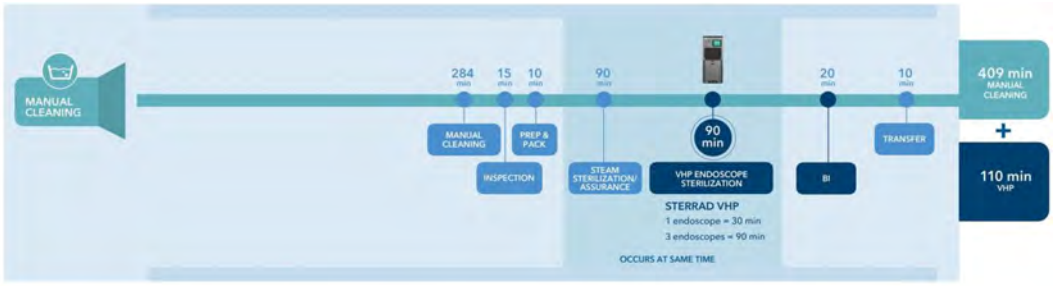
RESULT:

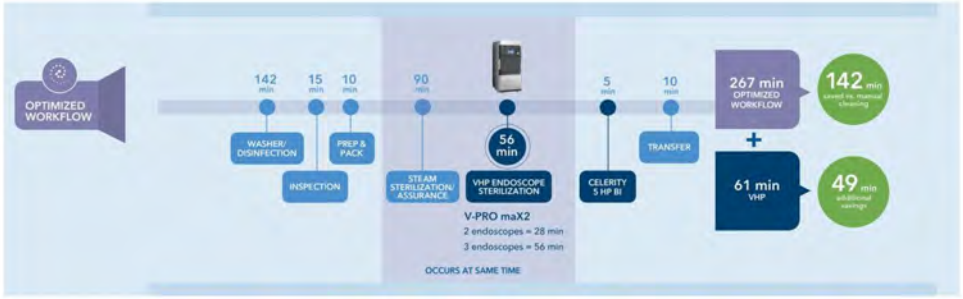
- Patient safety is improved
- Risk of complications is reduced

COMPARATIVE CLINICAL ASSESSMENT









Key market participants in low-temperature sterilization include Advanced Sterilization Products (ASP) and STERIS.

Criterion	Conventional H_2O_2 Systems	HdrOzone
Temperature	45–55 ˚C	37–42 ˚C
Polymer impact	Potentially	Controlled
Lumen performance	Damaging	Enhanced
Residuals	Limited	Minimized
Humidity effect	May be present	Tolerable

CLINICAL USE BENEFITS

Endoscope Use
- Extended device service life
- More stable image quality
- Safe reuse

Surgical Safety
- Reduced infection risk
- Enhanced sterilization reliability

Operational Continuity
- Fewer device failures
- Reduced need for re-sterilization

IMPACT ON CLINICAL OUTCOMES

The HDROZONE™ approach:

- Improves patient safety
- Reduces complications
- Enhances device performance

FUTURE PERSPECTIVE

Sterilization technologies are evolving away from high-temperature-based systems toward controlled-chemistry, low-temperature-based systems.

CONCLUSION

HDROZONE™:

- Operates at ultra-low temperature
- Protects polymers
- Enhances lumen performance
- Minimizes residuals

OFFICIAL CONCLUSION STATEMENT

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

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