GLOBAL CRISIS IN ENDOSCOPE STERILIZATION

Why Is a New Sterilization Technology Needed in the Era of CRE, Klebsiella, and Biofilm?

A Scientific Perspective on the HDROZON Hybrid Reactive Gas Sterilization Platform

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EXECUTIVE SUMMARY

One of the most significant developments in medical device sterilization over the past decade has been the emergence of a global confidence crisis in the reprocessing of flexible endoscopes.

Reprocessing protocols that were once considered safe are now being re-evaluated by the world's leading healthcare authorities. The reason is not simply the emergence of more resistant bacteria. The primary reason is that the increasingly complex engineering design of modern endoscopes has begun to challenge existing reprocessing methods.

Hospital outbreaks associated with **Carbapenem-Resistant Enterobacterales (CRE) and Klebsiella pneumoniae**, particularly those involving flexible duodenoscopes, have marked the beginning of a new era in endoscope reprocessing. Following outbreaks reported in the United States, the **FDA, CDC, AAMI,** and other healthcare organizations conducted comprehensive investigations into reprocessing practices, questioning not only user procedures but also device design, reprocessing technologies, and validation methods. (Senate Health Committee)

This White Paper examines the technical causes of this global crisis and explains the engineering approach behind the **HDROZON Hybrid Reactive Gas Sterilization Platform**, which has been developed to address these challenges.

KEYS
Endoscope, Sterilization, HDROZON, Biofilm, CRE, Klebsiella, Reprocessing, Lumen, Contamination.

1. THE WORLD'S NEW STERILIZATION CHALLENGE

Sterilization technologies have been evolving for approximately one hundred and fifty years. Steam sterilization, ethylene oxide, hydrogen peroxide, plasma systems, and high-level disinfection methods have enabled the safe reuse of millions of medical devices.

However, endoscopes are an exception to this general picture.

Modern flexible endoscopes feature:

- Working channels extending several meters in length,
- Micro-lumens with diameters of 1–2 mm,
- Movable elevator mechanisms,
- Optical systems,
- Polymer and elastomer components,
- Electronically controlled parts integrated within the same device.

Because of this complex design, the reprocessing of endoscopes represents an engineering challenge that is fundamentally different from that of conventional surgical instruments. Today, the issue is no longer simply the effectiveness of the disinfectant.

The real question is:

Can all internal surfaces of these complex devices truly be reprocessed safely?

2. HOW DID THE CRE AND KLEBSIELLA CRISIS BEGIN?

Beginning in 2012, outbreaks reported in the United States and Europe drew attention to **CRE** and **Klebsiella pneumoniae** infections associated with reprocessed duodenoscopes.

One of the most significant incidents occurred at **UCLA Ronald Reagan Medical Center.** Following **ERCP** procedures performed using duodenoscopes that had been reprocessed according to the manufacturer's instructions, patients developed **CRE infections.** Seven confirmed infections and two deaths were reported.

Similarly, **Virginia Mason Medical Center** experienced a major outbreak involving multidrug-resistant bacteria. (Clinician.com)

These events were not merely a clinical issue; they also marked a turning point that necessitated the re-evaluation of both sterilization technologies and endoscope design.

According to the investigation report published by the U.S. Senate, between 2012 and 2015, at least 25 duodenoscope-related outbreaks were reported across the United States and Europe, affecting approximately 250 patients. (Senate Health Committee)

3. WHY DID THE FDA AND CDC BECOME CONCERNED?

The most striking aspect of these outbreaks was that, in some hospitals, contamination could not be completely eliminated despite strict adherence to the manufacturer's reprocessing instructions.

The technical evaluations conducted by the **FDA** and **CDC** highlighted a common conclusion:

The problem was not limited to user practices alone; it also involved:
- Device design,
- Narrow and elongated lumens,
- Microscopic gaps within the elevator mechanism,
- Biofilm formation,
- Difficulties in validating the reprocessing process. (PMC)

As a result, the FDA requested manufacturers to improve their reprocessing validation studies. Additional safety measures, microbiological culturing, sterilization alternatives, and more easily reprocessable device designs became key areas of focus. (U.S. Food and Drug Administration)

4. THE TRUE SOURCE OF THE PROBLEM: BIOFILM

One of the primary factors complicating endoscope reprocessing is biofilm.

Biofilm is a three-dimensional microbial structure composed of polysaccharides, proteins, lipids, and extracellular DNA, formed when bacteria adhere to a surface.

This structure may contribute to:

- Stronger microbial adhesion to surfaces,
- Reduced penetration of disinfectants into the biofilm,
- Increased resistance to environmental stresses.

Particularly in flexible endoscopes that are used over extended periods, the control of organic residues and biofilm formation is one of the key factors directly affecting the quality of the reprocessing procedure.

Therefore, the challenge is not simply to kill the bacteria.

The real challenge is to reach the microscopic environment where the bacteria hide.

5. WHY IS ENDOSCOPE STERİLİZATİON AN ENGİNEERİNG CHALLENGE?

Many people consider sterilization to be merely a chemical process.

In reality, however, endoscope sterilization requires the integration of multiple disciplines, including:

- Fluid mechanics,
- Gas diffusion,
- Vacuum technology,
- Plasma physics,
- Reactive oxygen chemistry,
- Materials science,
- Biofilm biology.

The transport of the sterilant through long and narrow lumens depends not only on the type of gas used, but also on the pressure profile, diffusion mechanism, vacuum cycles, and process control.

For this reason, the performance of modern sterilization systems cannot be explained solely by the chemical potency of the sterilant.

6. WHY ARE EXİSTİNG TECHNOLOGİES BEİNG RE-EVALUATED?

Steam sterilization, ethylene oxide, hydrogen peroxide-based systems, and high-level disinfection methods currently play a significant role in healthcare.

However, when it comes to complex flexible endoscopes, factors such as:

- Narrow lumens,
- Movable mechanisms,
- Biofilm formation,
- Material sensitivity,
- Low-temperature requirements,

make the reprocessing process considerably more complex.

For this reason, the global discussion in recent years has not focused on abandoning existing technologies altogether, but rather on developing new process architectures capable of addressing these complex challenges.

7. HDROZON APPROACH

The HDROZON Platform is a hybrid low-temperature sterilization technology developed to address the multidisciplinary challenges encountered in endoscope reprocessing.

The platform integrates the following complementary processes within a single sterilization cycle:

- Hydrogen Peroxide (H_2O_2),
- Ozone (O_3),
- Heavy Molecule Technology,
- Controlled Deep Vacuum,
- Low-Temperature Plasma Activation.

The objectives of this hybrid architecture are to:

- Facilitate gas transport through complex lumens,
- Enable the controlled generation of reactive oxygen species (ROS),
- Create a hydronium- and oxidative reaction environment that may contribute to reducing the biofilm burden,
- Develop a low-temperature sterilization process compatible with sensitive endoscope components.

The HDROZON approach considers sterilization not merely as the application of a chemical agent, but as an integrated system in which physics, chemistry, and process engineering are optimized together.

8. CONCLUSION

Endoscope-related CRE and Klebsiella pneumoniae infections have become one of the most significant turning points in sterilization science in recent years.

This crisis has compelled not only hospitals to re-evaluate their reprocessing practices, but also device manufacturers, regulatory authorities, and sterilization technologies.

Today, the fundamental question is no longer:

“Which disinfectant is more effective?”

The real question is:
How can reliable, reproducible, and material-compatible sterilization be achieved throughout the entire length of the complex lumens found in modern endoscopes?

The HDROZON Heavy Molecule Sterilization Platform addresses this challenge through an engineering-based approach by integrating hydrogen peroxide, ozone, controlled deep vacuum, and plasma technology into a single hybrid sterilization process.

As antimicrobial resistance continues to increase, the future of endoscope sterilization will be shaped not only by more powerful sterilants, but by hybrid process technologies that seamlessly integrate physics, chemistry, and engineering.

- 30-References The Literature Sources We Used in Our hdrOzone Studies