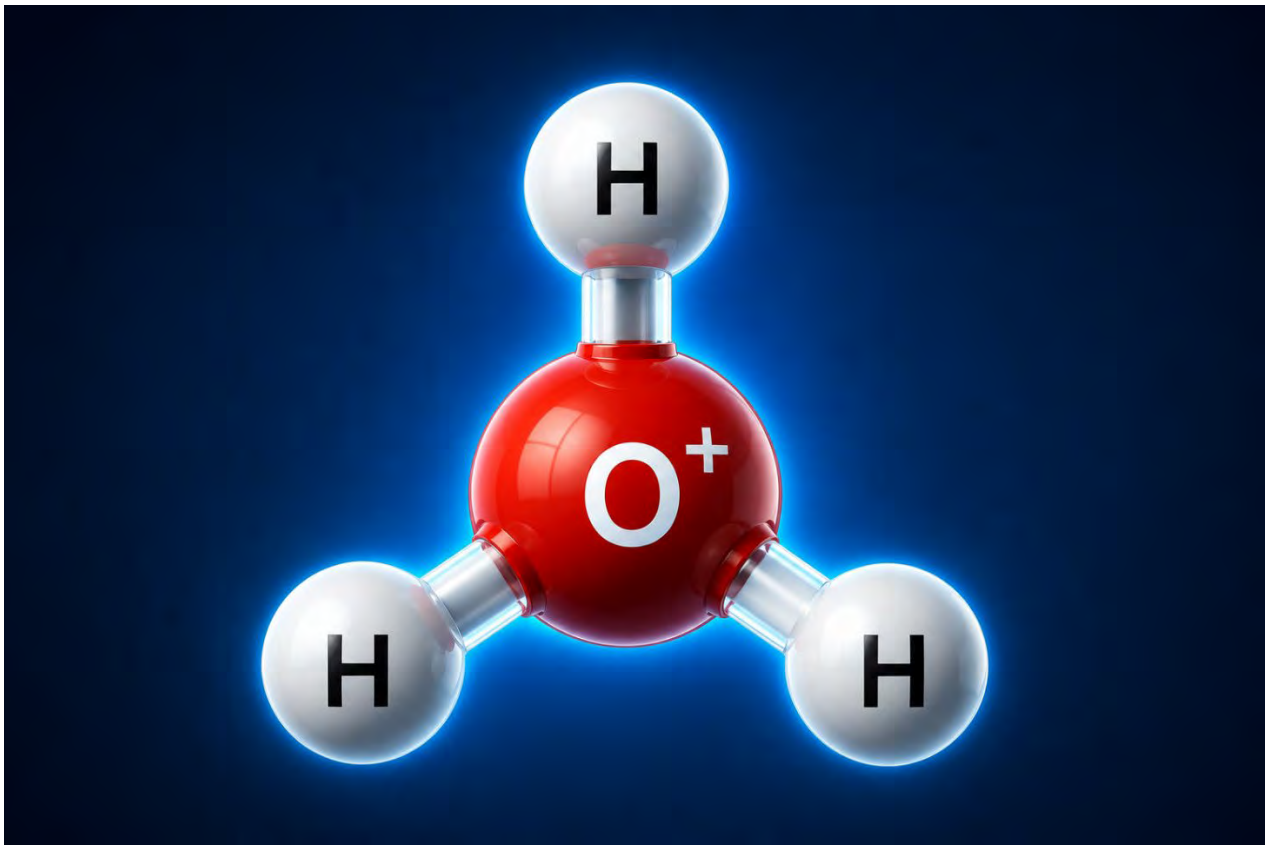
New Century

Medical Device & Endoscope Sterilization Paradigm Shift



Preface

As a physicist and manufacturer who has been working on sterilization technologies for over thirty years, I have had the opportunity to work with hundreds of hospitals, thousands of healthcare professionals, and countless types of medical devices throughout this process. This journey taught me an important fact: while some studies are carried out to meet an existing need, others begin by questioning an idea that has been accepted as truth for years. The book in your hands is the product of this questioning.

In recent years, CRE and Klebsiella outbreaks originating from endoscopes in some of the world's most advanced hospitals have clearly revealed that sterilization is not merely about killing microorganisms. The real challenge lies in reliably reaching complex device geometries where bacteria hide, and managing these processes through verifiable engineering methods. This awareness led me to develop a new approach that brings physics, chemistry, biology, and engineering together on a single platform.

This book is not only the story of the HDROZONE Platform and the hydronium (H3O+) heavy molecule approach, but also an invitation to rethink the future of sterilization science.

If, through this booklet—which I have intentionally kept brief and free from overwhelming technical details—I can spark new questions regarding sterilization, offer a fresh perspective, or contribute to scientific discourse for the benefit of humanity, I will have achieved my purpose.

Hasan Tahsin Özbek
HDROZONE Technology Developer

TABLE OF CONTENTS;

- **Chapter 1:** The Shift in the Sterilization Paradigm and the Emergence of the Endoscope Crisis
- **Chapter 2:** CRE, Klebsiella, FDA, CDC and US Congress findings
- **Chapter 3:** Biofilm and complex device geometry
- **Chapter 4:** Why is the classical approach being questioned?
- **Chapter 5:** H_3O^+ (hydronium) heavy molecule approach and the engineering philosophy of HDROZONE
- **Chapter 6:** Conclusion and outlook

The Sterilization Paradigm Is Changing

Chapter 1

Why Is the Sterilization World Asking the Wrong Question?

Sterilization science has been built on the same basic principle for approximately one hundred and fifty years.

If you can kill a microorganism, sterilization is considered successful.

The correctness of this approach was not questioned for many years.

Because the devices being sterilized largely had simple geometries.

Surgical scissors made of stainless steel…

Forceps…

Retractors…

Metal trays…

Surgical equipment with open surfaces…

In these devices, the main determinant of the sterilization problem was indeed the biological effectiveness of the sterilant used.

Steam reached higher temperatures.

Ethylene oxide provided higher penetration.

Formaldehyde was phased out in favor of newer systems.

Hydrogen peroxide started a new era in low-temperature sterilization.

Gamma and electron beam started a new era in bulk sterilization.

Every new technology was looking for an answer to the same question.

"How can we kill the microorganism more effectively?"

That was the right question for a century.

However, today's question is no longer this.

A Silent Global Shift

The medical world has undergone a major transformation in the last thirty years that went unnoticed.

This transformation did not begin with antibiotics.

It did not begin with sterilization devices either.

The transformation began with the medical devices being used.

Once, the instruments used by surgeons were mostly devices whose external surfaces were visible, made entirely of metal, and geometrically simple.

Today, when we look at the same operating room, we see a completely different world.

Robotic surgery systems…

Flexible endoscopes…

Microsurgical devices…

Laparoscopic systems…

Optical channels…

Electronic sensors…

Polymer-based structures…

Micro-lumens…

In other words;

Medical devices have evolved not biologically, but technologically through engineering.

However, sterilization science did not change at the same pace.

Sterilization was still placing the microorganism at its center.

Whereas the problem was no longer the microorganism itself.

Where Did the Real Change in Sterilization Begin?

One of the greatest turning points in the history of sterilization took place not in laboratories, but in endoscope design rooms.

Flexible endoscopes are one of the greatest achievements of modern medicine.

Today, the lives of millions of people are being saved thanks to these devices.

However, these same devices also pose the greatest challenge to sterilization science.

For the first time, sterilization technologies must confront not only microorganisms,

but also complex engineering geometries,

all while material and sterilization costs have increased considerably.

This is exactly where the paradigm shift begins.

The Problem Is No Longer Bacteria

This sentence seems wrong at first glance.

Because bacteria make patients sick.

Bacteria cause infection.

Bacteria cause death.

However, from the perspective of sterilization, bacteria are no longer the problem itself.

The problem;

Is where the bacteria are located.

Killing a bacterium is easy.

Reaching that bacterium is becoming more difficult every year.

Because bacteria no longer live on stainless steel surfaces.

Modern bacteria;

Within biofilm,

In micro cracks,

On polymer surfaces,

Behind moving mechanical systems,

In meter-long lumens with a diameter of 1–2 mm,

Live in microscopic dead volumes.

Sterilization technologies, on the other hand, developed for many years to sterilize open surfaces.

Therefore, the crisis we face today is not biological.

It is geometric.

The Endoscope Sterilization Crisis Is Actually an Engineering Crisis

The CRE and Klebsiella outbreaks reported in different countries in recent years appear at first glance to be the subject of infectious diseases.

However, when these events are examined carefully, they reveal a different reality.

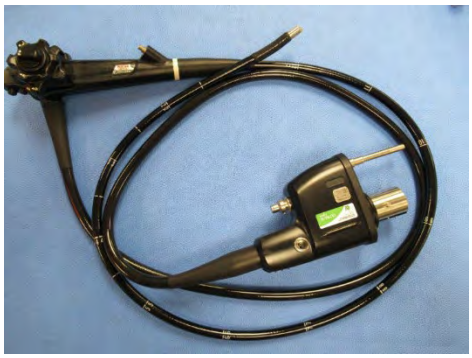
The bacterium causing the infection is the same.

Klebsiella pneumoniae has been known for years.

The CRE has been known for years.

The bacterium has not changed.

The device has changed.



Modern duodenoscopes consist of dozens of components.

Inside them;

- Moving elevator mechanism,
- Narrow lumens,
- Micro channels,
- Connection spaces,
- Polymer junction points,
- Materials with different surface energies,
- Blind volumes are present.

In other words;

Endoscopes are no longer devices belonging to the era in which conventional sterilizers were designed.

They are devices from a new world.

The Biggest Question FDA Asked the World

The most important contribution made by the FDA after the CRE outbreaks was not developing a new sterilization method.

FDA asked a much more important question.

"How do you know that you have really cleaned it?"

This question is perhaps the most important question in the history of sterilization.

Because for the first time, sterilization;

From chemical effectiveness,

Shifted to verifiable engineering performance.

It is no longer enough just to kill.

It is necessary to reach.

It is necessary to demonstrate that it has reached.

It is necessary to obtain the same result in every cycle.

This is where the concept of "validated reprocessing" was born.

New Paradigm in Sterilization

The competition is no longer about producing stronger chemicals.

The competition is:

Developing engineering platforms that can understand complex device geometries,

Managing gas transport,

Using vacuum physics,

Taking biofilm behavior into account,

Creating reactive species in a controlled manner,

And validating all of these according to international standards.

The future of sterilization will be no longer written in chemistry,

It will be written where chemistry and physics come together.

And perhaps the most important question from now on is:

Are sterilization systems really killing bacteria, or are they only killing the bacteria they can reach?

The answer to this question will determine the future not only of endoscopes, but of all reusable complex medical devices.

Chapter 1 Summary

“Briefly Summarizing,”

What Is the Paradigm in Endoscope Sterilization?

Endoscope-associated infections have led to the reconsideration of the basic assumptions accepted in sterilization science for many years. The problem is no longer only to develop a stronger sterilant; the real problem is to create a reliable, verifiable and reproducible sterilization environment that can reach biofilm structures formed within complex endoscope geometries and the farthest points of microscopic lumens.

The CRE and Klebsiella pneumoniae outbreaks in recent years have shown that existing reprocessing approaches face technical limitations, particularly in flexible endoscopes with complex structures.

Therefore, the new paradigm of sterilization is moving not only toward increasing chemical effectiveness; but toward hybrid sterilization technologies that understand device geometry, manage gas transport, target the biofilm barrier and combine physics, chemistry and process engineering on the same platform.

The real solution to the endoscope crisis is not so much developing stronger disinfectants, but being able to develop next-generation engineering approaches that can reach the physical world where bacteria are hidden.

The endoscope crisis shows us that bacteria have not changed, but the rules of the game have changed.

Sterilization science has focuset on the microorganism for many years.

However, today the determining factor is not the microorganism itself, but the complex device geometry in which it is hidden.

Therefore, future sterilization systems will be evaluated not only by biological killing effectiveness; but also by geometric access, reactive species transport, overcoming the biofilm barrier and verifiable process engineering.

Chapter 2

The Crisis That Changed the World

CRE, Klebsiella and the Collapse of Endoscope Sterilization

"No one thought the field of sterilization would ever change. That was until deadly bacterial infections were traced back to endoscopes in top-tier hospitals, even after being fully reprocessed per manufacturer guidelines."

This was not merely the problem of a few hospitals.

This event was a turning point in the history of sterilization.

Looking back today, the world of sterilization is divided into two periods.

Before the CRE outbreaks.

After the CRE outbreaks.

CRE, Klebsiella Were Not Just Hospital-Specific Problems

At first, everyone thought this was a local infection problem.

Perhaps a hospital staff member had incorrectly performed the procedure.

Perhaps it had not been cleaned sufficiently.

Perhaps there had been user error.

Perhaps there was a lack of training.

However, as months passed, the same picture began to emerge again in different cities.

Los Angeles.

Seattle.

Chicago.

Pennsylvania.

Centers in Europe.

The same bacterium.

The same type of device.

The same question.

How could this happen?

The World's Best Hospitals Failed at Endoscope Sterilization

The most striking aspect of these events was not the infection.

The most striking aspect was,

The best hospitals failing.

Because these hospitals;

Employed the most experienced teams.

Had the most advanced reprocessing systems.

Followed manufacturer procedures.

Had complete quality records.

Despite this, CRE transmission occurred.

This is where the entire paradigm collapsed.

Because for the first time, the following possibility began to be discussed.

"Could the problem actually not have been the user?"

Reports Reaching the FDA

The incident reports coming to FDA began to increase.

At first glance, they appeared to be independent of one another.

However, when the events were put together, an interesting picture emerged.

They all had common characteristics.

Complex endoscopes.

Narrow lumens.

Elevator mechanisms.

Biofilm.

CRE.

Klebsiella.

High mortality.

Recurring events.

FDA stopped evaluating at the events individually for the first time and began looking at the entire system.

The Question Changed

Until that day, the question asked by the FDA was this.

"Is the sterilization device killing microorganisms?"

The new question was now this.

"Can the sterilization system reach every part of the endoscopes?"

These two questions are not the same.

The first is microbiology.

The second is engineering.

For the first time in the history of sterilization, engineering began to move ahead of microbiology.

Invisible Enemy in Sterilization

In reality, the bacteria were visible.

They could be cultured in the laboratory.

Their resistance profiles could be determined.

An antibiogram could be prepared.

What remained unseen was not the microorganism itself,

But;

Rather the microenvironment in which it resided.

A one-millimeter lumen.

A three-micrometer crack.

Behind the elevator mechanism.

A dried protein layer.

Biofilm matrix.

This was the real enemy.

Sterilization systems could see the bacterium.

But they could not see the geometry where the bacterium was hiding.

Why Was CRE So Important?

CRE is not merely a resistant bacterium.

CRE is the stress test of modern sterilization.

Because this bacterium asks the following.

"Can you really reach me?"

This is actually the whole event.

CRE is not the first organism to challenge sterilization systems.

But it is one of the first organisms to reveal the missing part of sterilization science.

Therefore, CRE is not merely a microbiological issue.

It is an engineering indicator.

The Painful Lesson Given by Klebsiella

Klebsiella pneumoniae has been known for years.

It is not a newly emerging bacterium.

However, its role in the endoscope crisis has surprised the whole world.

Because Klebsiella has shown us that bacteria no longer live on open surfaces.

They choose

Protected areas.

Narrow volumes.

Form biofilm.

In other words;

Bacteria learned device engineering before we did.

Why Did the US Congress Get Involved?

An infection event is normally a problem for hospitals.

But there was a different situation here.

The problem was recurring.

in different states,

in different hospitals,

with different teams,

in similar devices.

The issue was no longer only health.

It had become a public safety issue.

Therefore, the US Congress became involved.

The investigations did not focus solely on the bacteria themselves.

They investigated:

- What did manufacturers know?
- When did the FDA learn?
- Was the device design adequately evaluated?
- Were reprocessing validations sufficient?
- Did the user instructions truly represent real-world operating conditions?

These questions are still valid today.

A Reality Unnoticed By the World!

CRE outbreaks are not actually the success of bacteria.

They are the failure of the sterilization paradigm.

Because the entire system was built on this assumption.

"The sterilant reaches everywhere."

However, it did not.

This is where the crisis began.

A New Concept Was Born in the History of Sterilization

After these events, new expressions began to be used more frequently in the literature.

Cleanability

Validated Reprocessing

Design for Reprocessing

Human Factors

Worst-Case Validation

None of these are coincidental.

Because for the first time, sterilization ceased to be only microbiology.

It became an engineering science.

Chapter 2 Summary

CRE outbreaks, Klebsiella infections, and FDA investigations have taught us one fundamental lesson:

the problem is not the bacteria themselves.

The true challenge lies in increasingly complex device geometries—niches where bacteria can hide and which current reprocessing procedures struggle to reach.

The future of sterilization science relies less on formulating stronger chemicals and more on developing engineering solutions capable of understanding and verifiably managing these intricate geometries.

Chapter 3

Bacteria Have Learned to Hide

Biofilm, Micro-Geometry, and Sterilization's Hidden Enemy

Why Does Sterilization Fail?

When sterilization fails, the sterilant itself is typically the first point of blame.

The chemical lacked sufficient strength.

The duration was too short.

The temperature fell low.

The operator committed an error.

The system malfunctioned.

Yet, recent endoscope crises have shown that none of these causes fully account for the problem.

True failure rarely stems from a lack of chemical potency; rather, it occurs at the physical limits of where the sterilant can penetrate.

Sterilization is not simply about generating active reactants—it is about delivering them to the target.

If you cannot reach the target, even the most potent chemical remains theoretically powerful yet practically ineffective.

Bacteria Are Not Passive Living Organisms

For many years, bacteria were considered single-celled, simple organisms.

Today we know that this approach is incomplete.

Bacteria sense their environment,

choose surfaces,

communicate with each other through chemical signals,

develop collective behavior and create protective structures.

Under suitable conditions, they change the environment in which they live.

Biofilm is the result of this.

Biofilm is not merely a layer formed by bacteria.

Biofilm is an engineering structure in which bacteria build their own living environment.

Biofilm Is Not a Gel Layer

Most people think of biofilm as a thin layer of dirt.

In reality, biofilm is much more complex than this.

Microchannels filled with water,

Polysaccharide networks,

Protein scaffolds,

Extracellular DNA,

Lipid structures,

Ion gradients,

Microcolonies,

Oxygen concentration differences,

pH changes.

Completely different chemical environments may exist within the same biofilm.

In other words:

Biofilm is not a single structure.

It is a living organism that creates its own micro ecosystem.

Endoscopes are Ideal Environments for Biofilm

Now let us think about the inside of an endoscope.

A narrow channel.

Low flow rates.

Organic residues.

Moisture.

Polymer surfaces.

Repeated use.

Repeated drying.

Repeated wetting.

It is difficult to design a more suitable living environment for bacteria than this.

The endoscope actually provides a perfect architecture not for bacteria,

But for the biofilm they form.

Therefore, the problem is not the endoscope.

The problem is:

“Endoscope geometry can allow biofilm formation.”

Micro Geometry: The Invisible Dimension of Sterilization

For many years, the sterilization literature focused on the microorganism.

However, in recent years, attention has shifted to device geometry.

Because the bacterium does not simply remain on the metal surface.

Surface roughness matters.

Micro scratches matter.

The energy of polymer surfaces matters.

Connection areas matter.

Seal transitions matter.

Adhesive boundaries matter.

Even an irregularity at the micrometer level can be a suitable point for biofilm initiation.

Sterilization technologies must now understand not only biology,

But also device architecture at the micro scale.

The Real Barrier is Physical, Not Chemical

For a sterilant to kill the bacterium, it must first reach the bacterium.

This seemingly simple sentence is actually the fundamental physical problem of sterilization.

Gas has movement.

Liquid has movement.

There is diffusion.

There are pressure changes.

There are capillary effects.

There is surface tension.

There is molecular transport.

There are lifetimes of reactive species.

This is where the invisible part of sterilization lies.

Chemistry is effective only if it reaches its target;

Otherwise, its potency remains purely theoretical.

Why Are Long Lumens So Critical?

An endoscope lumen is not merely a thin tube.

As lumen length increases, gas transport changes.

As the diameter decreases, flow behavior changes.

The pressure profile changes.

The distribution of reactive species changes.

Wall interactions increase.

Condensation behavior may change.

Every physical change occurring along the channel may also affect sterilization effectiveness.

Therefore, long-lumen sterilization is not only a microbiological,

but also a fluid mechanics problem.

Biofilm and Geometry Work Together

The greatest rival of modern sterilization is not the bacterium.

It is the cooperation between the bacterium and geometry.

A biofilm can form on a flat metal surface.

However, biofilm formed inside a narrow lumen may behave very differently.

Because geometry protects it.

Flow protects it.

Moisture protects it.

Organic residue protects it.

Therefore, the sterilization system must overcome not only the bacterium,

but also the physical environment protecting it.

How Can This Crisis Be Solved?

Many technologies developed to date have increased sterilization success.

However, the endoscope crisis shows us that a new approach is required.

The goal is no longer only to create stronger oxidation.

The goal is,

to enable the reactive environment to reach the micro volume where the bacterium is hiding.

At this point, sterilization chemistry and the principles of physics become inseparable for the first time.

Deep vacuum is not used only to reduce pressure.

Gas is not used only to transport chemicals.

Plasma is not used only to produce ions.

Reactive oxygen species are not used only to perform oxidation.

All of these gain their true meaning when they form a single engineering system capable of reaching the micro geometry where the bacterium is hiding.

The Point where the HDROZONE Idea was Born

This is exactly where HDROZONE originated.

HDROZONE did not begin with the question of

"Which sterilant is stronger?"

HDROZONE began with the question: How long of a lumen can we sterilize?

"How can we reach the micro geometry where the bacterium is hiding?"

This question changed the entire system.

Chemistry was redesigned.

Vacuum was redesigned.

The gas phase was redesigned.

Plasma was redesigned.

And in this process, the hydronium (H_3O^+) heavy molecule concept forming the patent approach of HDROZONE technology was developed as one of the important components of a controlled reactive gas environment created with a new sterilization method, hydrogen peroxide, ozone and plasma. The aim was not only to define a new oxidant; but to create a new process architecture capable of optimizing the transport of reactive species and their interaction with biofilm in complex long-lumen geometries.

The fundamental approach of HDROZONE was never simply to produce more aggressive chemistry.

The fundamental approach was:

If chemistry cannot reach the target, physics must be solved first.

And when physics is solved, chemistry can work much more effectively.

Chapter 3 Conclusion

Biofilm is the invisible enemy of modern sterilization.

However, biofilm alone is not sufficient.

What makes it powerful is its relationship with complex device geometries.

The endoscope crisis shows us that bacteria have not changed; the environments in which bacteria live have changed.

Therefore, future sterilization systems will focus not only on producing stronger sterilants; but on integrated process engineering capable of delivering reactive species, the gas phase, deep vacuum and controlled reactive environments such as the hydronium (H_3O^+) heavy molecule approach to the micro volumes where bacteria are hiding.

"Why, then, have the sterilization technologies developed to date failed to completely solve this problem?"

Chapter 4

Is Sterilization Chemistry Sufficient?

Or Does the Future of Sterilization Lie in Combining Physics, Chemistry, and Engineering?

A Fundamental Misconception

When we think of sterilization, the first thing that comes to mind is chemistry.

A stronger oxidizer.

A higher concentration.

A longer exposure time.

A higher temperature.

For decades, sterilization technologies evolved under this very assumption: the greater the biological efficacy of the sterilant, the greater the success.

This approach delivered results for many years—primarily because the vast majority of medical devices were suited for it.

However, the medical devices we utilize today are no longer the same. Consequently, relying on the same traditional mindset is no longer sufficient to solve today's challenges.

Chemistry Never Works Alone

Chemistry does not occur by itself.

For every chemical reaction to occur, physical conditions must first be established.

A reaction cannot begin before two molecules encounter each other.

An oxidizer cannot perform oxidation before reaching the target.

Biological effect cannot begin before a reactive species is formed.

In other words;

The prerequisite of chemistry is physics.

For years, chemical effectiveness was measured in sterilization technologies.

However, a much more fundamental question often remained secondary.

Can the chemical really reach the target?

The Journey of a Molecule

A sterilant does not complete its task the moment it is produced.

The real journey begins after this.

The sterilant;

Moves within the chamber.

Responds to pressure changes.

Reaches the lumen entrance.

Enters the narrow channel.

Interacts with the walls.

Loses energy.

Reacts with other molecules.

Its concentration changes.

Some reactive species are formed.

Some disappear.

In other words, sterilization is actually an invisible journey made by millions of molecules.

Unless this journey is completed successfully, chemical effectiveness remains theoretical.

There Is a Different World Inside the Endoscope

The environment in the sterilization chamber and the inside of the endoscope lumen are not the same.

The gas distribution that appears homogeneous inside the chamber may behave completely differently when it enters a narrow lumen.

The diameter decreases.

The surface area increases.

The wall effect increases.

Gas molecules collide with more surfaces.

The lifetime of reactive species may change.

The concentration distribution may change.

Molecular transport may differ.

Therefore, understanding the sterilization chamber is not sufficient.

The physics inside the lumen must be understood.

Why Is Vacuum So Important in Sterilization?

Vacuum is not only used to remove air.

Vacuum;

Changes gas transport,

Creates a pressure difference,

Removes air from enclosed volumes,

Facilitates the entry of a new gas phase,

Affects the movement of reactive species.

Therefore, in modern sterilization systems, vacuum is not merely auxiliary equipment.

It is one of the fundamental engineering components of the process.

The purpose of using deep vacuum is not only to reach low pressure.

The purpose is to enable controlled movement of the gas phase within complex geometries.

Why Is the Gas Phase Different?

Liquids and gases do not behave in the same manner.

While liquids exhibit surface tension,

diffusion is the dominant transport mechanism in gases.

Liquid-phase systems are susceptible to air pocket entrapment,

Gas-phase systems demonstrate distinct penetration characteristics.

Consequently, gas-phase sterilization systems can offer unique engineering advantages, particularly when dealing with complex geometries.

However, using the gas phase alone is not sufficient.

at what pressure the gas is,

at what temperature,

at what concentration,

in what reaction environment,

are determining factors.

Why Are Reactive Species Important?

Primary agent used in sterilization is often the starting point.

Actual biological effect is often determined by the reactive species formed during the process.

Hydroxyl radicals.

Superoxide structures.

Singlet oxygen.

Peroxide intermediates.

Other reactive oxygen species.

Equally important as the concentration of these species is where and when they are formed,

Their lifetimes,

Their ability to reach the target are also important.

The invisible engineering of sterilization begins exactly here.

Starting Point of the HDROZONE Sterilization Platform

The fundamental assumption when HDROZONE was developed was this:

The problem is not only to produce a powerful oxidizer.

The problem is;

Managing the reactive environment created,

Within complex device geometries.

Therefore, the process in the HDROZONE platform is not based only on the use of hydrogen peroxide,

Nor on the use of ozone alone,

Nor on plasma alone.

The fundamental approach of the platform;

Hydrogen peroxide,

Ozone,

Controlled deep vacuum,

Plasma activation,

Reactive oxygen species,

And controlled formation of the hydronium (H_3O^+) heavy molecule environment forming the patent approach

Within the same process architecture.

The purpose here is not to define a new chemical.

The purpose is to redesign the reaction environment.

Why a Hybrid Process?

Modern sterilization can no longer be explained by a single parameter.

A successful process must manage

chemistry,

Physics,

Gas transport,

Vacuum cycles,

Plasma energy,

Reaction kinetics,

Material compatibility,

and validation **within the same system.**

The HDROZONE approach is defined as a **“hybrid”** system for this exact reason.

Because here, success does not arise from a single component,

But from the synchronization of complementary engineering processes.

A New Language of Sterilization

Perhaps a new terminology will be used in the future of sterilization technologies.

The concepts we discuss today;

Sterilant

Disinfectant

Chemical agent

Will be tomorrow replaced by the following concepts:

Reactive environment,

Gas engineering,

Geometry management,

Molecular transport,

Validation architecture,

Controlled reaction area.

Hydronium (H_3O^+) heavy molecule-based hybrid process.

This transition is not merely emergence of new medical devices;

it marks a paradigm shift in the core philosophy of sterilization science.

Chapter 4 Summary

The most important lesson taught by the endoscope crisis is this:

Sterilization is not only chemistry.

Sterilization;

Chemistry + physics + geometry + process engineering + biology + validation

Is a multilayered system in which disciplines work simultaneously.

As important as how strong a sterilant is,

It is also decisive under which physical conditions that sterilant reaches the micro volume where the bacterium is hiding.

Therefore, the HDROZONE approach is positioned not merely as proposing a new sterilant, but as a next-generation process engineering approach that combines hydrogen peroxide, ozone, plasma, deep vacuum and the hydronium (H_3O^+) heavy molecule approach within a single controlled reaction architecture.

Chapter 5

HDROZONE's Approach Philosophy to Sterilization

Rethinking Sterilization

Sometimes a technology is born to develop a new product.

Sometimes to improve existing technologies somewhat further.

HDROZONE was born from neither of these two approaches.

The starting point of HDROZONE was a single engineering question.

"Can sterilization in medical devices with complex geometries and very long lumens really reach every point of the device and lumen?"

At first glance, this question seems quite simple.

However, it is actually one of the most difficult questions in modern sterilization science.

Because this question no longer addresses chemical efficacy,

but rather the transport of the reactive enviroment.

Redefining Sterilization

Until today, sterilization has largely been defined through the sterilant used.
Steam sterilization… (new generation polymer materials undergo physical deformation and melting under high temperatures.)
Ethylene oxide sterilization… (Effective but carries long cycle times and toxic residue risks requiring extensive aeration.)
Hydrogen peroxide sterilization… (when liquid hydrogen becomes vapor, it is highly effective on the external surfaces of materials to be sterilized. However, due to condensation, it cannot go more than 1 m into the lumens. For longer lumen sterilization, the dose and exposure time need to be increased. This creates residue risk, corrosion and deformation. The race for shorter duration with hydrogen peroxide is a complete risk factor in sterilization. If plasma is not performed, the residue risk is also very high.)
Ozone sterilization… (considering the half-life of ozone, a long time is needed for sterilization. Since ozone is a very high oxidant, when it penetrates all materials for a long time, high corrosion problem ocurs. In other words, the material oxidizes, deteriorates and deforms, and endoscopes become unusable. Metal materials become yellow and rust.)
This naming appears natural.
However, it also demonstrates an important pattern of thought.
The focus is the chemical used.
HDROZONE starts from a different point.
The question here is not "Which sterilant is being used?"
but
"How is the sterilization environment created?"

Although this approach may seem small, it changes the entire sterilization engineering.

The Reactive Environment Concept

A sterilization cycle is not merely the introduction of a chemical into the chamber.

A large number of physical and chemical events occur simultaneously inside the chamber.

Pressure is continuously changing.

Gas density is changing.

Reactive species are forming.

Some disappear within milliseconds.

Some form new molecules.

Plasma active regions are forming.

Vacuum changes gas movement.

In other words, the sterilization device creates a controlled reaction ecosystem.

The fundamental approach of HDROZONE is to manage this reaction ecosystem.

Why the Hybrid Method?

Powerful systems in nature do not operate with a single mechanism.

The human body does not use a single defense system.

The immune system manages dozens of mechanisms simultaneously.

The atmosphere does not consist of a single gas.

Cells do not live through a single reaction.

Similarly, sterilization also has limitations in relying on only a single mechanism of action.

HDROZONE therefore adopts a hybrid approach.

Here hydrogen peroxide is not alone.

Ozone is not alone.

Plasma is not alone.

Vacuum is not alone.

The ion system is not alone.

Each works within a controlled process architecture that supports the effectiveness of the others.

Hydronium (H_3O^+) Heavy Molecule Approach

One of the distinguishing features of HDROZONE technology is the hydronium (H_3O^+) heavy molecule concept.

The starting point of this approach is different from the classical sterilization concept.

The aim is not only to produce strong oxidizers.

The aim is to manage the reactive chemistry created by hydrogen peroxide and ozone in a controlled reaction environment more effectively, with plasma activation and deep vacuum support.

In HDROZONE technology, the hydronium heavy molecule approach is not a chemical agent evaluated on its own. Rather;

- Reactive oxygen species,
- Controlled proton transfer,
- Gas phase chemistry,
- Plasma activation,
- Hybrid oxidation mechanisms

Are integrated components of a unified reaction environment.

Therefore, the fundamental strength of HDROZONE lies not only in the components it uses,

But in the controlled reactive atmosphere created by these components together.

Why Is Deep Vacuum at the Center?

One of the most important design decisions made during the development of HDROZONE was not to regard deep vacuum merely as a preparation stage.

Vacuum;

Does not only remove air,

Directs gas transport,

Creates a pressure difference,

Facilitates filling complex lumens with gas,

Affects the movement of reactive species.

Therefore, in HDROZONE, vacuum is not auxiliary equipment.

It is an active component of the sterilization process.

Chemistry and Physics Meet in the Same System

Sterilization was evaluated through chemical effectiveness for many years.

However, in the HDROZONE approach, chemistry is not evaluated alone.

Chemistry;

Works together with vacuum.

Works together with gas transport.

Works together with plasma and ion energy.

Works together with the formation of reactive species.

Works together with the hydronium (H_3O^+) heavy molecule approach.

Therefore, HDROZONE is not merely hybrid chemistry.

It is hybrid process engineering.

The Design Philosophy of HDROZONE

When HDROZONE was developed, the fundamental objective was never to "produce the strongest sterilant".

The fundamental objective;

Was to create an architecture capable of managing all physical and chemical processes of sterilization within a single platform.

Therefore, the following questions were taken as the basis when designing the platform:

Where and how are reactive species formed?

How long can they survive?

What path does the gas follow?

How does the concentration change along the lumen?

At which stage does vacuum provide the greatest contribution?

At which point should plasma be activated?

How does the hydronium (H_3O^+) heavy molecule approach affect the reaction environment?

Without answering all of these questions simultaneously, it is not possible to achieve sustainable success in the sterilization of complex devices.

HDROZONE is Not a Device

Defining HdrOzone only as a sterilization device would be incomplete.

HDROZONE;

Is a hydronium-based sterilization platform.

It is a process approach.

It is an engineering platform.

It is a reaction management system.

It is a validation approach.

It is a sterilization philosophy.

Therefore, the value of HDROZONE emerges not only from which chemicals it uses,

But from how it manages these chemicals.

Looking to the Future

The future of sterilization technologies is not in higher concentrations.

It is not in higher temperatures either.

The future;

Will be in platforms that can understand complex device geometries,

Manage gas transport,

Make vacuum physics part of the process,

Create reactive species in a controlled manner,

Use next-generation reaction architectures such as the hydronium (H_3O^+) heavy molecule approach,

And validate all of these in accordance with international standards.

Chapter 5 Summary

The purpose of developing HDROZONE is not to produce a new sterilant.

The purpose of developing HDROZONE is to redefine the sterilization problem.

This technology;

Combines hydrogen peroxide, ozone, plasma, deep vacuum and the hydronium (H_3O^+) heavy molecule approach within a single hybrid process architecture, taking sterilization beyond being merely a chemical event and treating it as a verifiable system in which physics, chemistry and engineering work together.

Chapter 6

The Future of Sterilization

It is no longer a competition of chemicals, but a race between engineering platforms.

The End of an Era

Sterilization science has sought to answer the same basic question for approximately one hundred and fifty years.

How are microorganisms killed?

This question was not wrong.

It is not wrong today either.

However, it is now incomplete.

Because modern medical devices are not the devices of the period in which sterilization technologies developed.

Robotic surgery systems…

Flexible endoscopes…

Artificial intelligence-supported imaging systems…

Microelectronic sensors…

Catheters…

Implants…

Complex devices with micro-lumens…

Today's medical devices are not merely products that need to be sterilized.

They are also;

The common product of gas transport,

Materials science,

Polymer chemistry,

Microfluidics,

Reactive oxygen chemistry,

Vacuum engineering,

And plasma physics.

Therefore, it is inevitable that sterilization technologies will also evolve at the same pace.

What will the next-generation sterilization method entail?

In the coming years, sterilization systems will not be defined only by the sterilant they use.

Next-generation systems will be evaluated with the following questions.

Can it reach complex geometry?

Can effectiveness be verified along the lumen?

Is biofilm behavior taken into account?

Can gas transport be modeled?

Can the formation of reactive species be controlled?

Can material aging be managed?

Can residue safety be ensured at the end of the cycle?

Can the data be digitally verified?

Can the process be optimized with artificial intelligence?

From now on, it will not be the sterilization device,

It will be the sterilization platform that is discussed.

Chemistry Alone will be No Longer Enough

The fundamental success criterion of twentieth-century sterilization was the effectiveness of the chemical used.

In the twenty-first century, the success criterion is changing.

Success of,

Chemistry,

Physics,

Software,

Sensor technology,

Vacuum engineering,

Plasma physics,

Microbiology,

And data analysis

All will be the management of all within the same platform.

Sterilization is no longer single-disciplinary.

It is a multidisciplinary engineering field.

The Era of Digital Validation

The issues FDA has focused on in recent years are not only biological indicators.

Data integrity.

Traceability.

Risk management.

Worst-case scenarios.

Cleanability.

Validation.

Reproducibility.

All of these show us that a new era has begun.

Future sterilization systems will not only complete the cycle.

Every cycle will

Measure,

Analyze,

Compare,

Learn,

And continuously improve.

Sterilization will no longer be a static process.

It will transform into self-improving dynamic systems.

From Biology to Physical Ecology

In the future, sterilization will no longer be defined only as the inactivation of microorganisms.

The actual goal will be the elimination of the physical ecosystem in which microorganisms can live.

This means:

The fight will no longer be against individual bacteria,

But against the habitats they create such as:

Biofilm.

Micro cracks.

Enclosed volumes.

Narrow lumens.

Organic residues.

Moisture.

Micro surface energies.

Sterilization technologies will be successful to the extent that they can understand this ecosystem.

HDROZONE's Position in This Evolution!

Where Does HDROZONE Stand Within This Transformation?

The purpose of HDROZONE's emergence is not to compete with existing systems.

The purpose of HDROZONE is to propose a different model of thought.

In this model,

Sterilization is not regarded as the effectiveness of a single sterilant.

Sterilization is the problem of creating a controlled reaction atmosphere.

Conposed of

Hydrogen peroxide,

Ozone,

Deep vacuum,

Plasma,

Reactive oxygen species,

And the hydronium (H_3O^+) heavy molecule environment forming the basis of HDROZONE technology

The purpose is not only oxidation.

The purpose is to create a controlled reactive ecosystem that can be managed within complex device geometries.

HDROZONE -More Than a Device

In the history of sterilization, some technologies have produced new devices.

Others have changed the way of thinking.

Steam sterilization was not merely a new machine.

Ethylene oxide, formaldehyde and other gases were not merely a new gas.

Low-temperature sterilization was not merely a new process.

Each changed how sterilization should be thought about.

This is also the goal of HDROZONE.

Rather than producing a new device,

It is to contribute to redefining the sterilization problem.

The Next Twenty Years

In the coming years, medical devices will become more complex.

Robotic systems will increase.

Microelectronic components will become widespread.

Disposable products and reusable devices will be used together.

Systems with complex lumens will increase.

These developments will also make it necessary for sterilization technologies to change.

The systems of the future;

Will not only sterilize,

Will measure,

Analyze,

Verify,

Learn,

And improve themselves.

Sterilization science will enter a new era where process engineering and artificial intelligence merge.

Final Word

The CRE outbreaks did not merely hidhlight an infection control problem.

They taught us something much more important.

Sterilization is not merely the art of killing microorganisms.

Sterilization,

Is the engineering of being able to understand the complex physical world in which microorganisms are hidden.

At the point we have reached today, the real question is now:

Are sterilization systems really killing bacteria?

Or,

Are they only killing the bacteria they can reach?

The answer to this question will determine the future not only of endoscope sterilization;

but of all reusable medical devices.

The HDROZONE Sterilization Platform aims to contribute to this new era with an engineering philosophy that brings together the hybrid reactive gas approach, controlled deep vacuum, plasma activation and the hydronium (H_3O^+) heavy molecule concept.

However, what is more important than HDROZONE is this:

The world of sterilization now needs to start thinking differently.

Because the winner of the future will not be those who develop stronger chemicals; but those who understand the world in which microorganisms are hidden.