Advanced Technology Addresses Sterilization Challenges in Medical Instrumentation

OVERVIEW

The need for an alternative method to sterilize medical instruments has been acknowledged by the FDA and CDC for decades, as evidenced by the increase in disease transmission resulting from the failure to remove microbial contaminants in increasingly complex medical instruments and devices. For example, flexible endoscopes and orthopedic implants present sterilization challenges due to their complex construction, the inclusion of electrical and mechanical components, and material sensitivities to thermal or chemical sterilants.

THE CHALLENGE

The challenges are twofold: (1) difficulty in thoroughly cleaning the instrument, and (2) the sterilant's inability to reach and eliminate all microbial life. Ineffective cleaning remains a major issue because modern instrument design often limits access for cleaning agents and brushes, making it hard to remove organic and microbial residues such as biofilms. Design features needed for flexible endoscopes and orthopedic devices—such as complex geometries, narrow lumens, dead-end channels, bends, channel connections, adhesive joints, fibers, meshes, and complex mechanical parts—create barriers. Failing to properly clean these devices of blood, tissue, and bone residues, including biofilms, which act as barriers to thermal and chemical sterilants and increase microbial load, undermines the goal of effective microbial destruction.

LIMITATIONS OF THE EXISTING STERILIZATION METHODS

A complex instrument or implant design creates additional barriers that prevent the sterilant from reaching all internal recesses of the device, jeopardizing sterility after sterilization. The maze of channels, orifices, and cannulas either slows down or blocks the chemical agent's entry, whether as vapor, gas, or steam, by not allowing enough time or concentration for effective microbial kill. These delays are affected by the distance the gas or vapor must travel and the twists in its path. Entrapped air can act as an extra barrier to vapor or gas penetration, or dilute chemical concentrations or temperatures below the levels needed to kill microbes. For gas or vapor sterilization methods (including steam sterilization), removing any toxic residues or condensed water formed during the process is also essential.

To address issues with existing thermal or chemical sterilization methods, any alternative sterilization process must be capable of overcoming barriers created by the logistical and physical complexities of complex medical instruments and devices. The process must also ensure that it does not damage the material composition or shorten the lifespan of the instrument or device.

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THE SOLUTION:
HIGH-VELOCITY HOT AIR WITH TEMPERATURE CONTROL

CPAC Equipment, Inc.'s (CPAC) ongoing research into High-Velocity Hot Air (HVHA) dry heat sterilization technology suggests that a new and potentially disruptive sterilization method for medical instruments has been overlooked for over 60 years. The National Aeronautics and Space Administration (NASA) considers dry heat its primary sterilization method, capable of sterilizing more than 90% of its current spacecraft components. The agency has increased the sterilization temperature range to 392°F as new heat-resistant materials have been developed, further establishing dry heat sterilization as NASA's "Gold Standard" for ensuring spacecraft sterility and as the "only NASA-approved method for reducing microbial contamination in encapsulated bioburden." NASA has demonstrated that spacecraft components with complex electronics, diverse material compositions, and structural intricacies can be effectively sterilized using dry heat technology. It is difficult to imagine that healthcare instruments and devices are any more complex or made of materials that are not—or cannot be—compatible with the varied and uniform temperatures and conditions used in modern dry heat sterilization.

CPAC's Rapidheat HVHA sterilizers provide a range of dry heat sterilization temperatures from 250°F to 375°F, offering a solution to temperature incompatibilities during processing that makes time-temperature parameters practical and feasible. When evaluating any sterilization technology, it is essential to consider all the following factors: (1) any potential negative impact of the sterilization agent on each device component during sterilization; (2) the sterilization agent's ability or inability to reach all internal and external surfaces of the device at the required temperature or concentration for the necessary duration; (3) the capacity to monitor the sterilization agent's effectiveness in achieving the spore inactivation threshold; (4) the logistical feasibility of the process within healthcare or veterinary facilities; (5) cost-effectiveness; and (6) the ability to complete the process within a reasonable time to meet spore kill requirements. For a sterilization process to be effective and acceptable, all these factors must be satisfied. RapidHeat HVHA sterilizers meet or exceed these standards.

KEY BENEFITS

Through its significant advances in dry heat sterilization, CPAC's HVHA technology has emerged as an innovative and disruptive healthcare sterilization method with potential applications in pharmaceuticals, life sciences, and complex medical instruments, including orthopedic devices and possibly flexible endoscopes. Real-time measurement of microbial inactivation using strategically placed thermo-sensors can replace prescriptive cycles. No other sterilization technology offers real-time monitoring of microbial inactivation to manage sterilization cycle duration. Table I below provides an overview of the comparison.

TABLE I

Process Attributes	Chemical	Steam	HVHA
Form of Agent Contact	Gaseous/Vapor	Water Vapor	Conductive Heat
Type of Sterilant	Surface	Surface	Whole Device
Metal Corrosion	Yes	Yes	No
Influenced by Organic/ Inorganic Contaminants*	Yes	No	No
Barriers Presented by Biofilms and Other Organics	Yes	Yes	No
Sterilization Residues Requiring Removal**	Yes	Yes	No
Quantification of 12-Log Spore Kill	No	No	Yes
Prescriptive and Non-Prescriptive Cycles	No	Yes	Yes

*As an organic or inorganic composition

**Including water vapor

SUMMARY

HVHA technology has advanced traditional dry heat sterilization, which NASA has long relied on as its primary and "gold standard" sterilization method.

Heating by conduction penetrates the entire medical instrument or device, ensuring sterilization reaches all internal parts, mated surfaces, channels, and lumens, and penetrates residues that may harbor or shield microbial contaminants.

Temperatures that can be effectively used range from 250°F to 375°F, with total sterilization cycle times decreasing significantly at the higher temperatures.

CPAC's RapidHeat HVHA sterilizers can precisely control and maintain temperatures within ±0.4°F, ensuring uniform temperature distribution throughout the chamber. This enables real-time, quantitative monitoring of microbial spore inactivation throughout the entire sterilization cycle.

HVHA fulfills the industry goal of providing healthcare facilities with new, advanced technology that can validate and fully sterilize complex instruments.

- Lower temperature cycle settings of HVHA ensure thermal compatibility across various instrument types and compositions, making HVHA thermal compatibility equivalent to steam sterilization.
- HVHA sterilization effectively and efficiently penetrates and sterilizes any residual biofilm and shielded bioburden left in complex or lumened instruments after cleaning.
- Unlike other vapor or gas sterilants, HVHA can quickly and easily penetrate both porous and non-porous instruments with complex structures and lengths that create obstacles or barriers.
- HVHA technology allows real-time, precise monitoring of microbial log reduction, which can be measured next to, on, or inside an instrument, providing reliable assurance of sterilization that chemical or biological indicators cannot achieve.
- HVHA's independent wireless thermal control sensors can control cycle times to ensure the sterilization of complex medical devices like orthopedic devices and flexible endoscopes, replacing traditional fixed cycles.

As adoption of the HVHA sterilization technology increases, it is set to redefine industry standards for effective and efficient results, establishing a new benchmark for future innovation.

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