



## **Instrument Sterilization: The Case for High-Velocity Hot Air Sterilization of Dental and Microsurgical Instruments**

*Nelson S. Slavik, PhD discusses a sterilization method that can effectively sterilize dental and microsurgical instruments while increasing instrument life span.*

### **Abstract**

Traditionally steam sterilization has been the primary mechanism by which to sterilize dental and medical surgical instruments. However, advances in sterilization technologies have provided another thermal sterilization technology that uses high-velocity hot air to effectively sterilize instruments in significantly shorter time periods without the use of water, thus eliminating instrument drying and instrument corrosion. With concurrent advances in heat-resistant materials, most dental and microsurgical instruments are compatible with the temperatures employed in this sterilization process. Shorter sterilization processing cycles result in reducing expensive instrument investment and assuring efficient instrument use. Eliminating instrument corrosion provides a longer, useful lifespan of delicate, costly instruments, in turn lowering dental practice operating costs.

### **Introduction**

The use of steam sterilization is the predominant method to sterilize dental and medical surgical instruments having direct patient contact. The effectiveness of steam sterilization is, however, predicated on the adherence to the critical factors that allow steam to have direct contact with the instrument. Inattention to prescribed packing, packaging, or operational conditions can lead to ineffective sterilization and put patient and practitioner at risk. Other factors such as instrument turnaround time and instrument corrosion also make steam sterilization less desirable for the dental office where procedural timing and delicate instrumentation are required for an efficient and successful practice.

Of other chemical and thermal alternatives to steam sterilization, only dry heat sterilization has gained wide acceptance in the dentistry. Each, including traditional dry heat sterilization, has its limitations to scope of usefulness and logistical ease in the clinical setting. For the chemical sterilization alternatives, sterilization time, the toxicity of the chemical, and potential corrosiveness limit, if not exclude, chemical sterilization as a viable alternative. Traditional dry heat methodologies are limited by lengthy sterilization times (one hour at 340<sup>0</sup>F; one to two hours at 320<sup>0</sup>F, dependent on device used), but do not possess the problems of chemical toxicity or corrosion exhibited by chemical sterilization technologies. However, the lack of uniform sterilizing heat distribution and corresponding uneven temperature pattern in traditional dry heat sterilizers has combined to make validation of the sterilization process difficult. The resurgence of dry heat as a legitimate sterilization technology began in 1960 with work conducted by the National Aeronautics

and Space Administration (NASA) for ensuring the sterility of lunar and planetary spacecraft. Conducted at the Army BioLabs at Fort Detrick, Maryland under the direction of Dr. Charles R. Phillips, this work led to the selection of dry heat as the only viable sterilization option for total sterilization of planetary and interplanetary spacecraft. Evaluated and found unacceptable as a means of sterilization were steam sterilization, gaseous and liquid chemical sterilants, and radiation. Dry heat sterilization technology was first used on the Mars Viking I and II Landers in the mid-1970's and continues to be used today as the primary method for sterilizing all planetary and interplanetary spacecraft.

Although the use of dry heat by NASA was limited to static dry heat (non-moving air), data generated in these studies demonstrated that the rate of heated airflow over a bacterial spore populated surface significantly increased spore destruction rate. This observation was noted by Dr. Keith Cox, D.D.S. in the mid 1980's and inspired his development of the patented Cox RapidHeat™ Transfer Sterilizer. Differing from the traditional dry heat sterilizer in which air remains static (air movement only by gravity convection) or in which air is minimally re-circulated by mechanical convection to enhance heat distribution, this novel approach employs directed, uniform high-velocity hot air across the surface of the instruments. The result is a marked reduction in time required for instrument sterilization from hours by traditional dry heat sterilization versus six to twelve minutes at 375<sup>0</sup>F in the Cox RapidHeat™ Transfer sterilizer. The device was granted 510(k) status from the U. S. Food and Drug Administration (FDA) in 1987 and 1988 as a Class II (Performance Standards) device.

High-velocity hot air sterilization has since been recognized and validated for use in healthcare applications including medical and dental offices, laboratories, ambulatory care clinics, and hospitals by the Centers for Disease Control and Prevention in their publications "Guidelines for Infection Control in Dental Health-Care Settings – 2003" and "Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008." <sup>1,2</sup> Standards for use and process validation have been issued under the auspices of the American National Standards Institute and the Association for the Advancement of Medical Instrumentation in standards ANSI/AAMI ST40:2004(R)2010 and ANSI/AAMI ST50:2004(R)2010. <sup>3,4</sup>

As stipulated by FDA, high-velocity hot air sterilizers operate at 375<sup>0</sup>F under varying time exposures, dependent on whether the instrument is unwrapped (six-minute exposure), wrapped (twelve-minute exposure), or as unwrapped hand pieces and medical drills (eight-minute exposure). Dry heat functions to sterilize by the transfer of heat to the microorganism, causing dehydration and the organism's inability to reproduce due to enzymatic damage (metabolic and genetic). Time-temperature profiles have been established for wrapped instruments, unwrapped instruments, and surgical drills to deliver a Sterility Assurance Level (SAL) representing a microbial inactivation level of twelve Logs of *Bacillus atrophaeus* spores as required by FDA and ANSI/AAMI standards.

### **Instrument and Materials Compatibility**

As with any thermal sterilization device, temperature compatibility with all intrinsic instrument components is imperative. For a high-velocity hot air (HVHA™) sterilizer operating at 375<sup>0</sup>F, most of today's instruments and their components are constructed of materials that would not be subjected to damage at this elevated temperature. Standard hand pieces, pliers, and cutters are typically composed of 440-C stainless steel or other high temperature-resistant metals (including solders). The temperatures used in dry heat sterilization whether static, low-convection, or HVHA™ processes do not contribute to corrosion or the stressors that dull, pit, or crack instruments. Surgical stainless steels that are used in biomedical applications are also used in industrial applications requiring thermal compatibility in excess of 2000<sup>0</sup>F due to their ability to provide good strength and good resistance to corrosion and oxidation at these elevated temperatures.<sup>5</sup>

For those instruments that contain plastic or other non-metal components there may be susceptibility to repeated exposure to 375<sup>0</sup>F, although most non-metal components compatible with a steam sterilization process are also compatible with exposure to 375<sup>0</sup> F. Changes in color, cracking, or other alteration in physical appearance are visible indicators that the elevated temperature is affecting the material and could affect the instrument's performance. In recent years the creation of more heat-tolerant materials (e.g., heat-resistant fluoropolymers and silicones) and their replacement of heat-intolerant materials used in medical devices has reduced significantly the number of instruments that are intolerant to dry heat sterilization conditions.

Significant with any hot air sterilization method are the hot, dry conditions that minimize or eliminate instrument corrosion. With any chemical or steam sterilization method, chemical and/or water (steam) react with metals to corrode. Corrosion impacts on the ability to properly sterilize an instrument (e.g., micro-pitting) and the instrument's efficacy of use (e.g., dulling), resulting in shortening the effective lifetime of an instrument. Instrument exposure to chloride environments (e.g., chlorine containing cleaners/disinfectants) is a primary source for pitting and cracking regardless of a wet- or dry heat sterilization process, however a wet heat (steam) sterilization process amplifies the corrosion process and significantly impacts on an instrument's material integrity. Contrary, dry heat sterilization is a moisture- or water-free process that does not provide the conditions necessary promote corrosion. The temperatures used in dry heat sterilization whether static, low-convection, or high-velocity hot air processes also do not impact on corrosion or any other stainless steel stressor.

### **Instrument Turnaround**

To minimize expensive instrument inventory and to assure efficient instrument use require a quick turnaround of instruments from one patient to the next. Often instrument sterilization is the most time consuming operation in this preparatory process. All thermal sterilization processes are time and temperature dependent and sterilization times cannot be shortened to expedite the process. Comparison of times required of steam sterilization and high velocity hot air sterilizers must accurately reflect the total time required of the sterilization process from the time the instrument is placed into the sterilizer until the time it is removed. Complete steam sterilization processing time includes (1) the time necessary

to achieve the required temperature and pressure; (2) the sterilization cycle time and (3) instrument drying cycle time.

Two types of steam sterilizers are typically found within dental practices: traditional vacuum-assist autoclave and cassette autoclave. These types of steam sterilizers require up to 17 minutes to achieve the required temperature and pressure before the sterilization cycle is initiated. For the vacuum-assist sterilizers programmed for operation at 270<sup>0</sup>F, the sterilization time ranges from four to eight minutes for unwrapped and wrapped instruments, respectively. These sterilization cycle times are roughly equivalent to those of the most commonly used cassette autoclave at 270<sup>0</sup>F with unwrapped and wrapped instruments having a three and half-minute and a six-minute cycle time, respectively. However, the most critical time factor is the time required for instrument drying, thirty minutes for the vacuum-assist autoclave and sixty minutes for the commonly-used cassette unit [as prescribed in the sterilizer's FDA 510(k)]. Total instrument turnaround time therefore is considerable with vacuum-assist units taking from 48 to 52 minutes. For cassette autoclaves the turnaround time ranges from 46 to 70 minutes. See Table I.

High velocity hot air sterilization is a dry heat process and as such, does not require a drying cycle. Complete processing time includes the time required to attain 375<sup>0</sup>F, usually three to four minutes with the sterilization cycle time of six minutes or twelve minutes for unwrapped and wrapped instruments, respectively, resulting in a total processing time of ten to sixteen minutes. A comparison of total treatment times between steam sterilization technologies and the Cox RapidHeat<sup>™</sup> Transfer sterilizer is shown in Table I.

### **Operational Requirements and Logistics**

High velocity hot air sterilizers were developed primarily for use within dental clinical practices and as such, the sterilizers are small, designed for tabletop use (Figure 1) or to be portable by placement on a moveable cart. High velocity hot air sterilizers typically operate on 110-120V or 220V and are energy efficient (e.g., 1100 watts for the initial warm up stage at the beginning of the day and 300 watts during the sterilization cycle). High velocity hot air sterilizers require no water or steam for operation, making their placement contingent only on the availability of conventional or field generated electricity.

Standard controls minimize error and make the operation of the unit easy for dental or medical staff. Controls are limited to an On/Off switch and for pre-programmed cycle time designations (e.g., wrapped, unwrapped, or hand pieces). Operationally, the sterilizer is turned on at the beginning of the day and turned off at the completion of the day's practice. The sterilizer typically requires approximately fifteen minutes to initially heat to operational temperature. Once the unit is at temperature it will automatically maintain that temperature throughout the day. As such when instruments are ready to be sterilized, only three to four minutes are required to heat the chamber and the instrument load to temperature. Once the chamber is at operational temperature, the sterilization cycle is automatically initiated. The operator is notified at the completion of the cycle and the instruments are removed from the unit and allowed to cool before use.

TABLE I

**Comparison of Total Treatment Times Between Steam Sterilization and High Velocity Hot Air™ Sterilization**

Sterilizer Type	Pre-Cycle Heating Time (Min)	Sterilizing Cycle Time (Min)		Drying Cycle Time (Min)	Total Elapsed Processing Time (Min)
		UW <sup>1</sup>	W <sup>2</sup>		
Vacuum-Assist Autoclave <sup>3</sup> @ 270°F	15-17	3	5	30	48-52
Cassette-Type Autoclave <sup>4</sup> @ 270°F	3-4	3.5	6	60	67-70
Cassette-Type Autoclave <sup>5</sup> @ 270°F	3-4	3.5	5.5	40	46-50
HVHA Sterilizer <sup>6</sup> @ 375°F	3-4	6	12	0	10-16

<sup>1</sup> Unwrapped Instruments

<sup>2</sup> Pouched Instruments

<sup>3</sup> Midmark M11; M11 website brochure

<sup>4</sup> SciCan 5000; FDA 510(k)

<sup>5</sup> Midmark M3; FDA 510(k)

<sup>6</sup> CPAC Equipment Cox RapidHeat™ Transfer Sterilizer

FIGURE 1

**Example of a Countertop High Velocity Hot Air Sterilizer**



Cox RapidHeat™ Transfer Sterilizer  
Courtesy CPAC Equipment, Inc., Leicester, NY

### **Wrapped Versus Unwrapped Instruments**

CDC recommends sterilization of unwrapped instruments only be conducted under “immediate use” (previously termed “flash sterilization”) or emergency situations that require a rapid turnaround of the critical instrument.<sup>1</sup> Situations in which unwrapped instrument sterilization is permitted, critical and semi-critical instruments must be protected from environmental contaminants during their transport to point of use to maintain sterility. Unwrapped instruments are to be used immediately after undergoing the sterilization process. For steam sterilization if there is an interrupted or inadequate drying cycle, instruments removed from the sterilizer will be wet, making aseptic transfer to the point of use more difficult.<sup>1</sup> Dry heat sterilizers do not require a drying cycle. CDC recommends that all semi-critical and critical instruments should be packaged before sterilization if they are not to be used immediately.<sup>1,7</sup>

Wrapping or pouching instruments with the appropriate packaging avoids potential environmental contamination during the instrument’s transfer to point of use and also allows for the temporary or long-term storage of the instrument before patient use. Increasingly, state regulations are mandating that instruments be wrapped or pouches during sterilization. Adhering to CDC recommendations, even in the absence of state regulations, will minimize any potential liability.

Wrapped or pouches instruments require additional sterilization cycle times for both steam and the HVHA™ technologies. For steam sterilizers (vacuum-assist or cassette) sterilization cycle times increase two-fold (from 3 to 6 minutes) and for the Cox RapidHeat™ Transfer sterilizer from 6 to 12 minutes (Table I) for wrapped instruments. However for steam sterilizers, drying cycle times range from 30 to 60 minutes. A drying cycle is not required for the HVHA™ Cox technology. The additional drying cycles required for steam sterilizers dramatically increase the time for instrument processing to a total elapsed processing time between 46 to 70 minutes. To shorten these excessive processing times, the operator has the ability to terminate the drying cycle prematurely. If there is improper drying, cooling will cause any moisture to condense and packaged instruments to remain wet, increasing the potential for instrument corrosion. Furthermore moisture degrades the ability of the packaging to maintain sterility. The practice violates CDC’s recommendations that state “instrument packs should be allowed to dry inside the sterilizer chamber before removing and handling. Packs should not be touched until they are cool and dry because hot packs act as wicks, absorbing moisture, and hence, bacteria from hands.”<sup>1</sup> Elimination or minimization of the sterilizer’s drying cycle is acceptable for “immediate use” or emergency situations only.

Due to the increased temperature employed by dry heat sterilization technologies, nylon pouches are used to package instruments. Standards for instrument placement and wrapping are contained within ANSI/AAMI ST40:2004(R)2010.<sup>6</sup> Nylon can withstand temperatures approaching 420°F. However if uniform heat distribution cannot be maintained within a dry heat sterilizer, hot spots in the chamber may result that exceed nylon’s melting temperature. Only the Cox RapidHeat™ Transfer high-velocity hot air sterilizer has the ability to maintain uniform heat and air velocity distribution to preclude nylon pouch from melting. The inability of any dry heat technology to process pouches instruments limits that technology for “immediate use” or emergency situations only.

### A Comparison Between Steam and HVHA Sterilization

No one sterilization technology can be used under every circumstance. Each has its own limitations with material compatibility, water/steam sensitivity, pressure sensitivity, temperature sensitivity, sterilant penetration, or time requirements for required treatment efficacy. However, for the sterilization of dental and medical surgical instruments there are only two choices to consider: Steam or HVHA™ Sterilization. Provided below in Table II is a feature comparison between Steam and HVHA™ Sterilizers to assist dental or clinical practice in making the appropriate choice.

**TABLE II**

**Feature Comparison – Steam and HVHA™ Sterilizers**

<b>Feature</b>	<b>High Velocity, Hot Air™ Sterilizer (Cox)</b>	<b>Steam Sterilizers (Counter-Top)</b>
Total Sterilization Cycle (Includes Pre-heat and Drying Cycles)	10-16 Minutes	46-70 Minutes
Sterilizer Operation and Mechanical Complexity	Simple	Complex
Electrical Requirements	110V	110-220V
Water/Steam Requirements	No	Yes
Instrument Thermal Compatibility	> 95%	>95%
FDA 510(k) Pre-Market Approved	Yes	Yes
Treatment Cycles Documented and Stored	Yes	Yes
Instrument Drying Cycle Required	No	Yes
Potential for Instrument Corrosion from Process	Low	High
Toxicity of Sterilization Process (Toxic Residues)	None	Low (With No Water Additives)
Sustainability Factors	Energy Consumption; 20% of Energy Required for Steam Sterilization	Highly Energy Dependent; Purified Water Required

## Summary

High velocity hot air sterilization technology is an excellent instrument sterilization option for the dental practice. A moisture-free and water-free environment eliminates instrument corrosion issues that dull and limit the useful lifespan of the delicate instruments used in dentistry. The short sterilization cycles and the elimination of the need for instrument drying provide a rapid turnaround of instruments, resulting in timely availability for the next patient and minimizing instrument inventories. Pre-set time-temperature parameters and automatic controllers ensure sterilization for each sterilization cycle. These sterilization parameters are recorded and stored within internal memory for retrieval via a USB port for external storage or hardcopy printouts, providing the data necessary to document sterilization conditions for each treatment cycle.

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## About the Author

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