

2015-16 PRODUCT CATALOG



IMPROVING PATIENT SAFETY THROUGH INNOVATIVE
PRODUCT ENGINEERING AND DESIGN

A DIVISION OF INTEGRATED MEDICAL TECHNOLOGIES, INC.



OVER 25 YEARS OF
PROFESSIONAL USE

A U.S. engineering and manufacturing firm dedicated to providing quality sterile processing and related products that enhance patient safety to the dental and healthcare industries while reducing patient treatment costs. Located in Western New York in the village of Leicester, CPAC Environmental Solutions manufactures high-velocity hot air sterilizers, static dry heat sterilizers, dental evacuators, sterilization containers, sterilization indicators, and their world recognized CPAC Silver Recovery Systems – the legacy business on which the company was founded.

MISSION

Our mission is to provide customers with the highest quality of US manufactured products that offer the greatest value, quality and service and to do so with integrity and a commitment to continuous improvement. We accept this challenge with a commitment to excellence knowing that achievement will contribute to the growth and success of our customers, employees, company and the communities which we serve.

VISION

In focusing on patient safety improvements with meaningful product solutions and alternatives, CPAC Environmental Solutions will continually sustain a company infrastructure that pushes innovation, research, product development, manufacturing systems, cost control and marketing of the Company and its products with the vision and drive to achieve maximum growth.

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STERILIZATION OF DENTAL AND MICROSURGICAL INSTRUMENTS”



2364 Leicester Road • PO Box 175
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STERISURE.COM





THE LEADER
IN HIGH-VELOCITY HOT AIR
TECHNOLOGY FOR INSTRUMENT
STERILIZATION.



THE COX RAPIDHEAT ADVANTAGE

- Completes Sterilization Cycles in 6, 8 and 12 minutes
- Does not corrode, pit, or dull instruments
- Uses 84% LESS Energy than Steam
- No water, steam, or chemicals
- USA Made – FDA Approved

BENEFITS OF DRY HEAT STERILIZATION

- Promotes longer instrument life - Does not corrode, pit, or crack
- Faster instrument turnaround – Reduces instrument investment
- Eliminates need for water, rust inhibitors or chemicals
- Lower maintenance cost – No toxic residue or effluent

FAST, EASY TO USE AND CONVENIENT!
PREFERRED METHOD OF STERILIZATION BY PROFESSIONALS WORLDWIDE

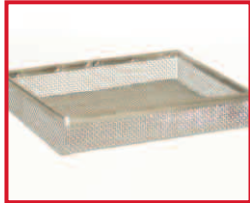


SPECIFICATIONS

| | |
|---------------------------|--|
| Unit Size (OD) | 17" W x 17" D x 15" H, 432 mm x 432 mm x 381 mm |
| Chamber Size (ID) | 8.25" W x 7.5" D x 3" H |
| Weight | 50 lbs (23 Kg) |
| Dimensional Shipping | 61 lbs, 24" x 22" x 19" |
| Instrument Basket | 8.25" W x 7.5" D x 1.5" H |
| Dimensions | 216 mm x 229 mm x 38 mm |
| Electrical | 110-120V, 60Hz, 1100 Watts warm up, 300 Watts operating 220-240V, 50Hz, 1100 Watts warm up, 300 Watts operating |
| Sterilization Temperature | 375° Fahrenheit (190° Celsius) |
| Warranty | One year (parts and labor) |
| Model | 6000 |
| Approvals | ETL FDA 510(k) K881371 Health Can Lic #93771 UL 61010-1 CAN/CSA C22.2 No.61010-1, CSA C22.2 No. 61010-2-040-07 |



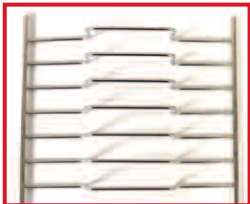
INCLUDED WITH STERILIZER



INSTRUMENT BASKET



BASKET REMOVAL TOOL



**INSTRUMENT RACK
(FOR PACKAGED INSTRUMENTS)**



COOLING RACK

STERILIZATION TIMES

- Cycle 1: 6 minutes for unwrapped instruments
- Cycle 2: 8 minutes for hand pieces and medical drills
- Cycle 3: 12 minutes for packaged instruments



THE STERISURE STATIC DRY HEAT ADVANTAGE

- SteriSURE Dry Heat Sterilizers kill bacteria and spores without moisture.
 - Does not dull, pit, or rust sharp instruments.
 - Dry heat sterilization does not require a dry cycle that adds to the sterilization cycle time.
- Economical, minimal maintenance, low operating cost, no water or chemicals.
 - SteriSURE Dry Heat Sterilizers require no routine cleaning. The high quality stainless steel construction maintains a great looking unit for years.

STERISURE DRY HEAT STERILIZERS

MICROPROCESSOR CONTROLLED UNITS FOR ALL
METAL AND STEAM SENSITIVE INSTRUMENTS.

SPECIFICATIONS

| | |
|---|---|
| Sterilization Time: | 60 minutes |
| Unit Size (OD): | |
| Model 2100 | 15.25" W x 11" D x11.75" H 387 mm x 279 mm x 298 mm |
| Model 3100 | 17.75" W x 13" D x 12.75" H 450 mm x 330 mm x 324 mm |
| Chamber Size (ID): | |
| Model 2100 | 11.25" W x 7" D x 4.25" H • 286 x 178 x 108 mm |
| Model 3100 | 13.75" W x 8" D x 6.25" H • 349 x 203 x 159 mm |
| Weight: | |
| Model 2100 | 17 lbs (8 Kg) |
| Model 3100 | 27 lbs (13 Kg) |
| Dimensional Shipping Weight/Dimensions: | |
| Model 2100 | 20 lbs, 20" x 16" x 14" |
| Model 3100 | 39 lbs, 22" x 18" x 16" |
| Tray Size: | |
| Model 2100 (2 trays) | 10"W x 6.25"D, 254 mm x 159 mm |
| Model 3100 (3 trays) | 11.75"W x 7.25"D, 298 mm x 184 mm |
| Electrical: | 110V-120V, 60Hz, Model 2100, 500 watts 220V-240V, 50Hz, Model 3100, 750 watts |
| Sterilization Temperature: | 320° Fahrenheit (160° Celsius) |
| Warranty: | One year (parts and labor) |
| Models: | 2100, 3100 |
| Approvals: | ETL FDA 510(k) K094026 IEC Safety Standard 61010-2-040 Validated to AAMI Standards ST-40 and ST-50 UL 61010-1, CAN/CSA C22.2 No. 61010-1 |

PRODUCT FEATURES

- Audible and visual indication of warm-up and completion of sterilization cycle
- Paperless data storage
- Error message will display if cycle is interrupted
- Temperature can be displayed in Celsius or Fahrenheit
- Automatic shutoff (adjustable from 2-4 hours after cycle is complete)
- Maintains temperature between cycles
- Solid State control of heaters

SteriDENT

DRY HEAT STERILIZERS

AFFORDABLE MANUALLY-CONTROLLED STERILIZATION
FOR ALL METAL AND STEAM SENSITIVE INSTRUMENTS.



HIGH-QUALITY, RUGGED PERFORMANCE AND TOTAL DEPENDABILITY

- Stainless steel construction means no rust – ever!
- Utility trays can be sterilized with lids on and stored without contamination.
- Unlike wet heat methods, SteriDent Dry Heat Sterilizers require no routine cleaning.
- Low purchase cost and low operating cost – no distilled water to buy!

THE BEST METHOD FOR SHARP INSTRUMENTS

STERIDENT DRY HEAT STERILIZERS KILL BACTERIA WITHOUT MOISTURE AND WILL NOT DULL SHARP INSTRUMENTS.



SPECIFICATIONS

| | |
|-----------------------------|--|
| Sterilization Time: | 60 minutes |
| Unit Size (OD) | |
| Model 200 | 15.5" W x 9.5" D x 10.5" H 394 mm x 241 mm x 267 mm |
| Model 300 | 19" H x 11" D x 14.5" H 483 mm x 279mm x 368mm |
| Chamber Size (ID) | |
| Model 200 | 11.25" W x 7.5" D x 4.75" H • 286 x 190 x 121 mm |
| Model 300 | 13.5" W x 8" D x 6.75" H • 343 x 203 x 171 mm |
| Weight: | |
| Model 200 | 13 lbs, (6 Kg) |
| Model 300 | 20 lbs, (9 Kg) |
| Shipping Weight/Dimensions: | |
| Model 200 | 16 lbs, 20" x 16" x 14" |
| Model 300 | 45 lbs, 22" x 18" x 18" |
| Tray Size: | |
| Model 200 (2 trays) | 10" W x 6.25" D, 254 x 159 mm |
| Model 300 (3 trays) | 11.75" W x 7.25" D, 298 x 184 mm |
| Electrical: | 110-120V, Model 200, 500 watts 220-240V, Model 300, 750 watts |
| Sterilization Temperature: | 320° Fahrenheit (160° Celsius) |
| Warranty: | One year (parts and labor) |
| Models: | 200, 300 |
| Approvals: | |



FDA 510(k) K771070
UL 61010-1, IEC Safety Standard 61010-2-040
CAN/CSA C22.2 No. 61010-1

PRODUCT FEATURES

- Dry heat sterilization works without pressure, steam, or chemicals, which increases safety.
- SteriDent products feature a rapid-start heating element for fast operation.
- Thermal cutout protection prevents overheating.



DESIGNED FOR **AFFORDABILITY, RELIABILITY, AND EASY INSTALLATION.** ITS WATERLESS OPERATION IS HIGHLY ECONOMICAL.

ULTRA-QUIET

Steri-Vac’s acoustical housing means quiet operation. This model includes a collection canister to separate solids, permitting recovery of lost crowns and inlays.

SIMPLE, STRAIGHT-FORWARD INSTALLATION

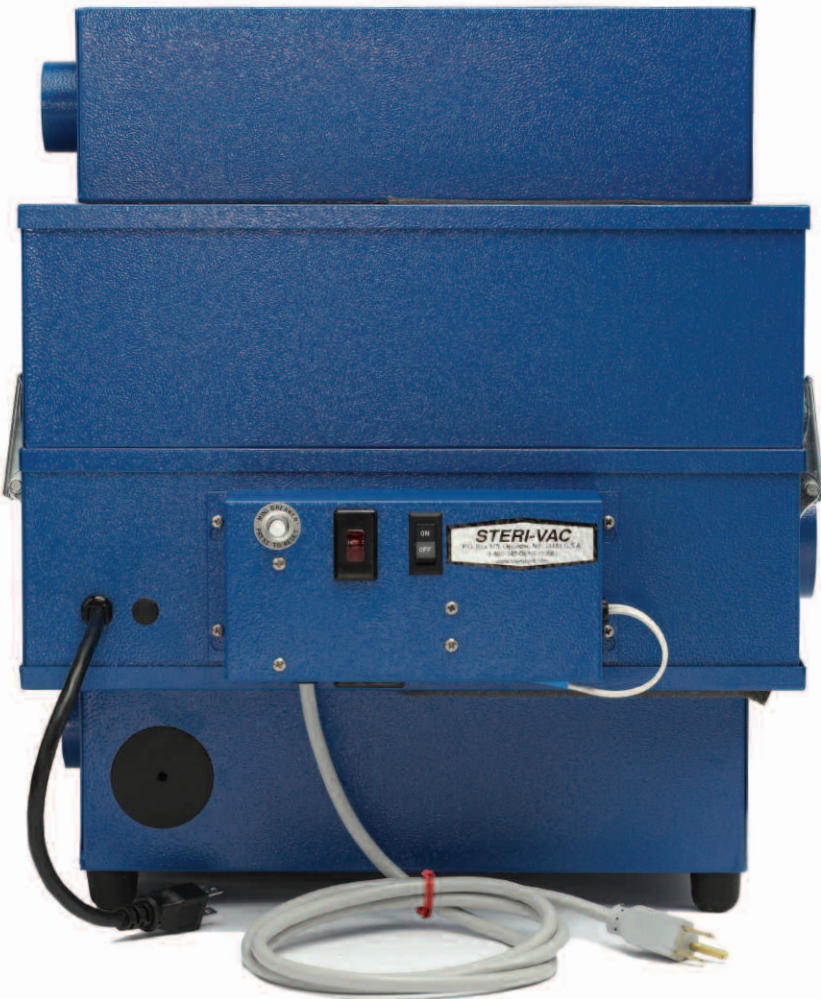
Since running water is not used in this system, installation is simple – no water pump to install. Systems are available for 115V or 230V to simplify electrical requirements.

NO DOWN TIME

A motor can be changed without tools in minutes – no need to call a service technician. Units are supplied with a spare motor.

HIGH-VOLUME EVACUATION

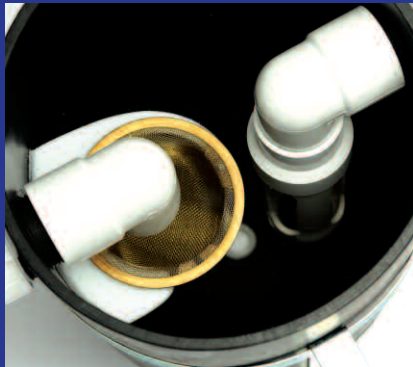
This system effectively serves multiple operatories. Update your present system or use SteriVac as a replacement power source for your current central power unit.



Brushless motor lasts up to five times longer • Minimal cost of ownership
Ideal for up to five operatories • Practically maintenance free
Superior suction • Easily connects to existing plumbing

USES NO WATER

ENVIRONMENTALLY FRIENDLY, WHEREAS COMPARABLE INJECTION PUMP SYSTEMS MAY WASTE AS MANY AS 600 GALLONS PER DAY.



SPECIFICATIONS

| | Central VAC w/ Brushless Motor #400616-115V #400617-230V | Central VAC #400016 (SV-2)-115V #400016-230V | Central VAC w/ Canister and Brushless Motor #400613-115V #400614-230V | Central VAC w/ Canister #400018 (SV-4)-115V #400018-230V |
|--|--|--|---|--|
| Note: All units available in 220-240 VAC, 50/60 HZ | | | | |
| Electrical | 1-1/2 HP 2-stage brushless motor 115 VAC, 50/60 Hz, 14 Amps 230 VAC, 50/60 Hz, 7.2 Amps | 7/8 HP 115 VAC, 50/60 Hz, 8 Amps 230 VAC, 50/60 Hz, 4.0 Amps | 1-1/2 HP 2-stage brushless motor 115 VAC, 50/60 Hz, 14 Amps 230 VAC, 50/60 Hz 7.2 Amps | 7/8 HP 115 VAC, 50/60 Hz, 8 Amps 230 VAC, 50/60 Hz, 4.0 Amps |
| Motor Control | Remote Motor Start | Remote Motor Start | Remote Motor Start | Remote Motor Start |
| Sound Level db | 70 dB | 68 dB | 70 dB | 68 dB |
| Construction | Sheet Metal Powder Coated | Sheet Metal Powder Coated | Sheet Metal Powder Coated | Sheet Metal Powder Coated |
| Chair Capacity | 2-5 | 1-2 | 2-5 | 1-2 |
| Vacuum Suction | 120" of water (9" of Hg) | 80" of water (6" of Hg) | 120" of water (9" of Hg) | 80" of water (6" of Hg) |
| Vacuum Airflow | 125 cfm | 75 cfm | 125 cfm | 75 cfm |
| Canister | None | None | Molded plastic - 5L | Molded plastic - 5L |
| Weight (unit+canister) | 52 lbs | 46 lbs | 60 (52 + 8) lbs | 54 (46 + 8) lbs |
| Shipping Wt./Dim. | 13 lbs, 10" x 11" x 12" 70 lbs, 2 pkgs, 24" x 21" x 23" | 13 lbs, 10" x 11" x 12" 70 lbs, 2 pkgs, 24" x 21" x 23" | 44 lbs, 30" x 15" x 16" 70 lbs, 2 pkgs, 24" x 21" x 23" | 44 lbs, 30" x 15" x 16" 70 lbs, 2 pkgs, 24" x 21" x 23" |
| Ships via | UPS/FEDX | UPS/FEDX | UPS/FEDX | UPS/FEDX |
| Dimensions (unit) | 17" W x 19" D x 19" H | 17" W x 19" D x 19" H | 17" W x 19" D x 19" H | 17" W x 19" D x 19" H |
| Dimensions (canister) | N/A | N/A | 10" Dia. x 16" H | 10" Dia. x 16" H |
| Options | Amalgam separator | Amalgam separator | Amalgam separator | Amalgam separator |
| Warranty: | One year (parts and labor) | | | |



PERFECT WHERE **CENTRAL INSTALLATION IS IMPRACTICAL** AND FOR PRACTITIONERS WITH AN EXTRA OFFICE TO FURNISH.

COMPACT

Measures only 13” W x 16” D x 26” H. Not an obstacle at chair side and stores inconspicuously.

VALUE PRICED

Easily the least expensive of oral evacuation units. Excellent for limited budgets.

EASY MAINTENANCE

Non-corrosive collection canister cleans easily and is equipped with an automatic overflow shut-off. Motor comes with a one-year guarantee and can be replaced in minutes with a screwdriver.

MOVES EASILY

Rolls quietly on large polyethylene carpet-casters.

EFFICIENT

Adjustable motor speed can evacuate indefinitely at the rate of 75 cfm, or can be adjusted to the user’s preference. Airflow adjustment valves on hoses.

SPECIAL USES

Needed especially by the dentist in a temporary location or when it is not feasible to install a central system. Perfect for such specialists as periodontists, orthodontists, endodontists hygienists and other professions.



IDEAL FOR BACK-UP

A LIFESAVER WHEN THE CENTRAL SYSTEM BREAKS DOWN. THE USER JUST ROLLS IT OUT, PLUGS IT IN, AND KEEPS OPERATING.



SPECIFICATIONS

| | |
|-----------------------|--------------------------------------|
| Electrical | 7/8 HP |
| | 101008 (PV-5) 115 VAC, 50/60 Hz |
| | 101009 230 VAC, 50/60 Hz |
| | 4.0 Amps |
| Sound Level db | 70 db at 100% vacuum |
| Motor Control | Variable Speed Control |
| Construction | Molded polyethylene-Impact Resistant |
| Chair Capacity | Comes with 2 hoses |
| Vacuum Suction | 80" of water (6" of Hg) |
| Vacuum Airflow | 75 cfm |
| Canister | Stainless Steel - 2 Liter |
| Net Weight | 35 lbs |
| Shipping Wt./Dim. | 60 lbs, 20" x 16" x 31" |
| Ships via | UPS/FEDX |
| Dimensions (unit) | 13" W x 16" D x 26" H |
| Dimensions (canister) | 7" Dia. x 8" H |
| Warranty | One year (parts and labor) |

PRODUCT FEATURES

- Equipped with Muffler System for quiet operation
- Valves on each suction hose
- Hanger provided for hose
- High volume suction

STERILIZATION SUPPLIES & ACCESSORIES

CPAC TABLE-TOP IMPULSE SEALERS

- Available with or without built-in pouch cutter
- Seals up to 8” wide pouch/tubing
- Sealing Width – .0625”
- Cutter Model cuts .25” above seal

#400670
Impulse Sealer
Ship Wt – 11 lbs

#400669
Impulse Sealer w/cutter
Ship Wt – 9 lbs



CPAC INSTRUMENT ORGANIZER

- Requires no top cover
- Organizes and secures instruments for sterilization
- Designed for easy insertion into sterilization pouch
- Up to 7 Organizers per COX Instrument Rack (21 instruments/cycle)
- Solid stainless steel construction

CX0403 7” L x 2.5” W x .675” H



CPAC NYLON ROLL STOCK TUBING

- Make Pouches To Any Length
- Convenient, Economical

| | | | | | | | |
|---------|------------------------|---------|------------------------|---------|------------------------|---------|------------------------|
| #400665 | 2” width 100ft Roll | #400666 | 3” width 100ft Roll | #400667 | 4” width 100ft Roll | #400668 | 6” width 100ft Roll |
|---------|------------------------|---------|------------------------|---------|------------------------|---------|------------------------|



CPAC DRY HEAT SELF-SEALING BAGS

- Medical grade paper construction
- Azure strip turns brown when exposed to high temperature.

400597B 2.5”x 1.5”x 10.5” • 250/Box



CPAC DRY HEAT INDICATOR STRIPS

- Exclusively for static and rapid dry heat sterilization
- Strip changes color when exposed to high temperature
- Used inside or outside of bag/pouch

400635
Dry Heat
Indicator Strips
100 4” strips/Box



CPAC SPORE TEST KITS

- Biological Indicator insures sterilization efficacy
- Compliant with CDC Guidelines for weekly testing

400633
Sterilizer Monitoring
Mail-In Service
12 Tests/Box
400634
Sterilizer Monitoring
Mail-In Service
52 Tests/Box



CPAC NYLON STERILIZATION POUCHES

- Self-Sealing and notched for easy opening
- Exclusively for static and rapid dry heat sterilization
- Includes external chemical indicator

400636 2”x 10” • 100/Box
400651 3”x 10” • 100/Box
400637 4”x 10” • 100/Box
400638 7”x 10.5” • 100/Box
400639 9.5”x 13” • 100/Box



CPAC IN-OFFICE BIOLOGICAL INDICATOR MONITORING SYSTEM




- Clear, easy to interpret, system measures sterilizer effectiveness
- CDC Compliant for 7-day incubation

400640
20 BI Strips, 20 Media Tubes,
37°C Incubator, record,
transfer rack
400644
Culture set refill kit • 20/Box
400545
Culture set refill kit • 100/Box



PRODUCT COMPARISONS

CPAC EQUIPMENT STERILIZERS COMPARATIVE ANALYSIS

| FEATURES | |  SteriDENT DRY HEAT STERILIZERS |  SteriSURE PRECISION-CONTROLLED DRY HEAT STERILIZERS |  CoxRAPIDHEAT HIGH-VELOCITY HOT AIR STERILIZERS |
|---|--|---|---|---|
| Dry Heat: 320°F; 60 minute cycle | | ✓ | ✓ | |
| High-Velocity Hot Air: 375°F; 6, 8 & 12 minute cycles | | | | ✓ |
| Automated Controls, Digital Display | | | ✓ | ✓ |
| Sterilization Cycle Data Storage – USB Data Port | | | ✓ | ✓ |
| Cycle Interrupt Monitor | | | ✓ | ✓ |
| Recommended Application | Health & Beauty | ✓ | ✓ | |
| | Dental, Orthodontic | | ✓ | ✓ |
| | Ophthalmology, Health Care Clinics and Hospitals | | | ✓ |
| Electrical Requirements: 110V-120V 220V-240V | | ✓ | ✓ | ✓ |
| FDA (510(k)) | | ✓ | ✓ | ✓ |
| UL-, CSA-, ETL- approved | | ✓ | ✓ | ✓ |

FEATURE COMPARISON HVHA™ AND STEAM STERILIZERS

| FEATURES | High Velocity, Hot Air™ | Steam Sterilizers |
|---|--|--|
| 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 | 20% of Energy Required for Steam Sterilization | Highly Energy Dependent; Purified Water Required |

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

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

“Shorter sterilization processing cycles result in reducing expensive instrument investment and assuring efficient instrument use.”

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°F; one to two hours at 320°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.

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°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.”^{1,2} 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.^{3,4}

As stipulated by FDA, high-velocity hot air sterilizers operate at 375°F under varying time exposures, dependent on whether the instrument is unwrapped (six-minute exposure), wrapped

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°F in the Cox RapidHeat™ sterilizer.

(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°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°F due to their ability to provide good strength and good resistance to corrosion and oxidation at these elevated temperatures.⁵

For those instruments that contain plastic or other non-metal components there may be susceptibility to repeated exposure to 375°F, although most non-metal components compatible with a steam sterilization process are also compatible with exposure to 375°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°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°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

COMPARISON OF TOTAL TREATMENT TIMES BETWEEN STEAM STERILIZATION AND HIGH VELOCITY HOT AIR™ STERILIZATION

TABLE 1

| Sterilizer Type | Pre-Cycle Heating Time (Min) | Pre-Cycle Heating Time (Min) | | Drying Cycle Time (Min) | Total Elapsed Processing Time (Min) |
|--|------------------------------|------------------------------|-----|-------------------------|-------------------------------------|
| | | UW1 | W2 | | |
| Vacuum-Assist Autoclave ³ @ 270°F | 15-17 | 3 | 5 | 30 | 48-52 |
| Cassette-Type Autoclave ⁴ @ 270°F | 3-4 | 3.5 | 6 | 60 | 67-70 |
| Cassette-Type Autoclave ⁵ @ 270°F | 3-4 | 3.5 | 5.5 | 40 | 46-50 |
| HVHA Sterilizer ⁶ @ 375°F | 3-4 | 6 | 12 | 0 | 10-16 |

¹ Unwrapped Instruments ² Pouched Instruments ³ Midmark M11; M11 website brochure ⁴ SciCan 5000; FDA 510(k)
⁵ Midmark M3; FDA 510(k) ⁶ CPAC Equipment Cox RapidHeat™ Transfer Sterilizer

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 on page 17.

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°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 stream sterilization technologies and the Cox RapidHeat™ 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 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.

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.¹ 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.¹ 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.^{1,7}

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

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.

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."¹ 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)2010.⁶ 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 on page 14 is a feature comparison between Steam and HVHA™ Sterilizers to assist dental or clinical practice in making the appropriate choice.

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.

Complete processing time includes the time required to attain 375°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.

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DEMONSTRATED SUSTAINABILITY

The New York State Pollution Prevention Institute at Rochester Institute of Technology conducted a study (June, 2015) to provide an independent, third party energy and water use comparison of the Cox RapidHeat™ Transfer Sterilizer (CRH) to two competitive table-top steam sterilizers. The comparative analysis was based on average measured energy and water use per operational cycle and unit mass of instruments sterilized as well as cycle characteristics. The conclusions drawn from this evaluation were as follows:

As a dry-heat sterilizer, the Cox Rapid Heat Sterilizer uses no water, and is therefore more efficient, relative to water use, than steam sterilizers

Once at operating temperature, and when run under standard* operating conditions, the CRH sterilizer exhibited the following performance results as compared to the steam sterilizers evaluated:

- Cycle times 3X to 6X faster
- Averaged 84% less energy per sterilization cycle
- Averaged 9.5 % (vs. Unit 1) and 10.7% (vs. Unit 2) more energy efficient per unit mass of unwrapped instruments sterilized**
- Averaged 27.2% more energy efficient (vs. Unit 2) and 3.5% less efficient (vs. Unit 1) per unit mass of wrapped instruments sterilized**, ***

Factors such as the mass of instruments, possibility of corrosion, and specific application requirements should also be considered when comparing the CRH sterilizer to steam sterilizers.

* When loaded immediately after previous cycle; does not include standby mode, which uses an average 0.008 kWh/min

** Based on the range of measured data over five tests for each unit

*** Unit 1 had a larger instrument capacity (6 fold) than the CRH sterilizer resulting in a marginally higher energy efficiency per unit mass



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