Steam Sterilizers

Sterilization is the process that destroys all forms of microorganisms, including the most resistant bacterial spores. A critical component of any sound dental practice infection-control program, sterilization not only helps promote a safe work environment for your dental team but most important, ensures patient safety from the risk of disease transmission.

In our evaluation of dental autoclaves, we only discuss the process of sterilization, not that of disinfection. It is important to distinguish the two infection-control measures. According to the Centers for Disease Control and Prevention (CDC), disinfection, like sterilization, destroys pathogenic and other kinds of microorganisms by physical or chemical means. Disinfection is less lethal to microorganisms than sterilization because it kills most recognized pathogenic microorganisms, but not necessarily all microbial forms (e.g., bacterial spores).

How you use patient-care items determines your infection-control practice with them. Items such as dental instruments, devices and equipment are categorized by the CDC as critical, semicritical or noncritical, based on their risk for transmitting disease during patient usage. As defined in Table 1, critical and semicritical instruments that are heat stable should be cleaned and sterilized after each patient use. In addition, these items should be packaged before sterilization to prevent recontamination before usage.

Table 1. Categories of patient-care items.

<table>
<thead>
<tr>
<th>Category</th>
<th>Definition</th>
<th>Examples</th>
<th>Sterilization required if instrument is heat stable?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical</td>
<td>Penetrates soft tissue, contacts bone, enters into or contacts the bloodstream or other normally sterile tissue</td>
<td>Scalers, burs, explorers, band pushers, bone chisels, scalpel blades, surgical instruments</td>
<td>Yes</td>
</tr>
<tr>
<td>Semicritical</td>
<td>Contact mucous membranes or non-intact skin; will not penetrate soft tissue, contact bone or enter into or contact the bloodstream or other normally sterile tissue</td>
<td>Amalgam condensers, mouth mirrors, reusable trays, cheek retractors, orthodontic pliers, dental handpieces†</td>
<td>Yes*</td>
</tr>
<tr>
<td>Noncritical</td>
<td>Contact with intact skin</td>
<td>Curing lights, exam lights, extroral cameras, X-ray heads, facebows, prosthetic and orthodontic appliances, pulse oximeter, blood pressure cuff</td>
<td>No‡</td>
</tr>
</tbody>
</table>

† Although dental handpieces are considered a semicritical item, they should always be heat-sterilized between uses and not treated with a high-level disinfectant.

* In some cases, however, heat sterilization is not feasible. Therefore, high-level disinfection is appropriate. A high-level disinfectant is registered with the U.S. Environmental Protection Agency (EPA) as a “sterilant/high-level disinfectant” and must be labeled as such.

‡ Noncritical instruments, which have a relatively low risk of transmitting infection, may be reprocessed between patients by using an intermediate- or low-level disinfection. An intermediate-level disinfectant is EPA registered as a “hospital disinfectant” and will be labeled for “tuberculocidal” activity (e.g., phenolics, iodophors, and chlorine-containing compounds). A low-level disinfectant is EPA registered as a “hospital disinfectant” but is not labeled for “tuberculocidal” activity (e.g., quaternary ammonium compounds).
Product Review

We evaluated six brands of steam autoclaves in the ADA laboratories. Brands were selected based on 398 responses collected from members of the ADA Clinical Evaluator (ACE) Panel. This panel comprises a volunteer group of ADA dentists who contribute feedback for the clinical input segments of the ADA Professional Product Review program. Product selection does not imply endorsement, approval, or disapproval by the ADA. The FDA has cleared all the products listed in this report.

All sterilizers, which were loaned to us from the manufacturers, were tabletop models with chamber capacities less than two cubic feet or 56 liters. Biological indicator kits or spore suspensions were used to determine the sterilization effectiveness of each unit for wrapped and unwrapped instruments, including lubricated dental handpieces. Moisture retention tests also were performed in accordance with the requirements specified by the Association for the Advancement of Medical Instrumentation (AAMI). For a detailed description of test methods, visit the PPR Web site at “www.ada.org/goto/ppr”.

Table 3. Product features according to the manufacturer.

<table>
<thead>
<tr>
<th></th>
<th>Delta XL Pelton &amp; Crane</th>
<th>EZ10 Tuttnauer Co. Ltd.</th>
<th>Lisa MB 17 Ad-eic Inc.</th>
<th>M11 UltraClave Midmark Corporation</th>
<th>Pvdry2 Barnstead/Harvey</th>
<th>STATIM 5000 SciCan, Inc. (cassette)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Air removal</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Steam-Flush</td>
<td></td>
<td>Steam Flush Cassette</td>
</tr>
<tr>
<td></td>
<td>Gravity displacement</td>
<td>Gravity displacement</td>
<td>Pre- and Post-Vacuum</td>
<td>Steam-Flush Pressure Pulse</td>
<td>Pre- and Post-Vacuum</td>
<td>Steam Flush Pressure Pulse</td>
</tr>
<tr>
<td>Temperature</td>
<td></td>
<td></td>
<td></td>
<td>134°C (273°F)</td>
<td></td>
<td>135°C (275°F)</td>
</tr>
<tr>
<td>Unwrapped Handpiece</td>
<td>Unwrapped</td>
<td>Unwrapped</td>
<td>Unwrapped</td>
<td>134°C (273°F)</td>
<td>Unwrapped</td>
<td>135°C (275°F)</td>
</tr>
<tr>
<td>Wrapped Handpiece</td>
<td>Wrapped</td>
<td></td>
<td></td>
<td>134°C (273°F)</td>
<td></td>
<td>135°C (275°F)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>132°C (270°F)</td>
<td></td>
<td>135°C (275°F)</td>
</tr>
<tr>
<td>Holding Time (minutes)</td>
<td></td>
<td></td>
<td></td>
<td>3</td>
<td></td>
<td>3.5</td>
</tr>
<tr>
<td>Unwrapped</td>
<td></td>
<td></td>
<td></td>
<td>12</td>
<td></td>
<td>6</td>
</tr>
<tr>
<td>Wrapped</td>
<td></td>
<td></td>
<td></td>
<td>4</td>
<td></td>
<td>6</td>
</tr>
<tr>
<td>Drying Time (minutes)</td>
<td></td>
<td></td>
<td></td>
<td>8</td>
<td></td>
<td>6</td>
</tr>
<tr>
<td>Unwrapped</td>
<td></td>
<td></td>
<td></td>
<td>15</td>
<td></td>
<td>40†</td>
</tr>
<tr>
<td>Wrapped</td>
<td></td>
<td></td>
<td></td>
<td>12</td>
<td></td>
<td>12</td>
</tr>
<tr>
<td>Maximum Load (pounds)</td>
<td>Unwrapped</td>
<td></td>
<td></td>
<td>9</td>
<td></td>
<td>12</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Rubber &amp; plastics</td>
<td></td>
<td>3.3</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>unwrapped</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other Cycles</td>
<td>Liquids packs</td>
<td>Liquids dry only</td>
<td>Textile packs</td>
<td>Packs</td>
<td>Towel pack</td>
<td></td>
</tr>
<tr>
<td>Programmable Cycle(s)</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Water Requirement</td>
<td>Distilled</td>
<td>Distilled</td>
<td>Distilled or Demineralized</td>
<td>Distilled or Demineralized</td>
<td>Distilled</td>
<td>Distilled</td>
</tr>
<tr>
<td>Machine Dimensions</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depth X Width X Height (inches)</td>
<td>23 X 19 X 15 (allow 2&quot; clearance)</td>
<td>22 X 20 X 15 (allow 2&quot; clearance)</td>
<td>20 X 18 X 16 (allow 2&quot; clearance in back, 1&quot; on sides)</td>
<td>24 (w/plug) X 18 X 18 (allow 3&quot; clearance in back)</td>
<td>19 X 17 X 6 (allow 2&quot; clearance front, back, sides)</td>
<td></td>
</tr>
<tr>
<td>Features</td>
<td>Programmable cycle preset button</td>
<td>Filtered closed door drying system</td>
<td>Heat to 170°F when activated</td>
<td>Programmed cycle preset buttons</td>
<td>CycleStor USB flash drive (stores cycle information)</td>
<td>LCD display in multiple languages</td>
</tr>
<tr>
<td></td>
<td>Closed door active drying system</td>
<td>Double safety door lock</td>
<td>LCD display in multiple languages</td>
<td>2 large, 2 small instrument trays</td>
<td>Double safety door lock</td>
<td>No door, cassette autoclave</td>
</tr>
<tr>
<td></td>
<td>Automatic preheat mode</td>
<td>4 instrument trays</td>
<td>5 instrument trays</td>
<td>2 large, 2 small instrument trays</td>
<td>Overload warning</td>
<td>Compact &amp; lightweight</td>
</tr>
<tr>
<td>Optional</td>
<td>Printer</td>
<td>Printer Standby heating mode</td>
<td>Printer Lisa log (USB flash drive stores cycle information)</td>
<td>Printer Harvey DH1 for automatic filling of reservoir</td>
<td>Printer</td>
<td>Printer</td>
</tr>
<tr>
<td>Other</td>
<td>Use separate (dedicated) electrical circuit</td>
<td>Electrical supply must be single phase 240 volts, 60 Hz</td>
<td>Use separate (dedicated) electrical circuit</td>
<td>Electrical supply must be 240 volts</td>
<td>Not intended for sterilization of liquids</td>
<td></td>
</tr>
</tbody>
</table>

Table continues...

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Dental handpieces and sterilization considerations

The CDC recommends that dental handpieces be heat sterilized after patient use. Although there is no epidemiologic evidence to implicate handpieces in disease transmission, patient cross-contamination can occur when saliva is retracted into the turbine chamber.

Low-speed handpiece components that are used intraorally, high-speed handpieces, and reusable prophylaxis angles, should all be sterilized. Because these devices contain lumens and other areas that are difficult to penetrate by sterilization processes, the dental handpieces pose the most difficult challenge to sterilant penetration.

Modern high-speed and low-speed handpieces are heat tolerant. Many older models that are heat-sensitive can be retrofitted with heat stable components. Turbine design and lumen permeability among these products will differ, likely affecting sterilization outcomes. Proper cleaning these instruments before sterilization helps reduce the bioburden of microorganisms and improve sterilization efficacy.

As always, follow the manufacturers’ instructions on cleaning, lubrication and sterilization.
Noncritical patient care items generally do not require sterilization. As with critical and semicritical patient-care items, how you use noncritical items will determine their level of disinfection per CDC guidelines. Again, keep in mind that disinfection does not ensure the degree of safety associated with proper sterilization processes.

You should use medical devices approved by the Food and Drug Administration (FDA) to sterilize patient-care items. There are four primary types of sterilizers: steam autoclave, unsaturated chemical vapor sterilizer, forced air convection sterilizer and dry heat oven.

Unsaturated chemical-vapor sterilizers use a low-humidity process that eliminates the drying stage, thereby reducing the risk of rusting or dulling of stainless and carbon steel materials. Because of the use of chemical agents, these sterilizers typically cost more than steam autoclaves and dry heat ovens.

Dry heat ovens use a process of hot air conduction to reach surfaces that cannot be disassembled while reducing the risk of rusting or dulling of metals. Although less expensive than steam autoclaves and unsaturated chemical-vapor sterilizers, dry heat ovens require longer treatment cycle times and their use of high temperatures render them unsuitable for heat-sensitive items.

The forced air convection sterilizer, like the conduction type, uses dry heated air. Used primarily by orthodontic practices, forced air convection sterilizers offer brief sterilization cycles and typically are more expensive than simple dry heat ovens.

The steam autoclave uses steam under pressure as its sterilant. This type of autoclave is economical, reliable and efficient. It has been shown to produce a lower rate of sterilization failure than unsaturated chemical vapor sterilizers and dry heat ovens.

Whatever type of sterilizer you decide to use, your infection control program not only should include cleaning and sterilizing of patient care items, but also monitoring to ensure effective sterilization. Because factors (Table 2) such as overloading or sterilizer malfunctioning can lead to sterilization failure, your monitoring method should comprise a combination of mechanical, chemical, and biological techniques. For more about monitoring methods, see sidebar, page 3.
An in-office testing kit should include a small, disposable sampling device with a nutrient medium coated membrane filter (to support colony growth). Some kits also include a pipette that allows you to dispense a standard amount of water from the dental unit onto the device. Other kits are designed to have the sampling device dipped into a water sample until the membrane filter is wetted.

### Product Review

For this review, we evaluated four waterline testing kits marketed in the United States: Aquasafe Water Test Kit (Pall Corp.), HPC Total Count Sampler (Millipore), Total Aerobic Bacteria/Total Coliform Paddle Tester (Hach Co.), Waterclave Dental Waterline Test Kit (Waterclave) (Table 1). Product inclusion does not imply endorsement, approval, or disapproval by the ADA.

In the ADA laboratory, we measured total viable counts with each device using water samples that contained known levels of bacteria. We also received 52 survey responses from dentists about these products.

#### Table 1. Water Quality Testing Kit Features According to the Manufacturer.

<table>
<thead>
<tr>
<th>Product (Manufacturer)</th>
<th>Sampling Description</th>
<th>Grid Surface</th>
<th>Color Indicator</th>
<th>Incubation Temperature and Time</th>
<th>Storage Temperature</th>
<th>Kit Contents</th>
<th>Cost/test†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aquasafe Water Test Kit (Pall Corp.)</td>
<td>Pipette sample to dish</td>
<td>Yes</td>
<td>Yes</td>
<td>Room temperature 48-72 hours*</td>
<td>Room temperature</td>
<td>4 monitoring devices, 4 pipettes Instructions</td>
<td>$5.60</td>
</tr>
<tr>
<td>HPC Total Count Sampler (Millipore)</td>
<td>Dip paddle</td>
<td>Yes</td>
<td>No</td>
<td>25-35°C at least 48 hours</td>
<td>Room temperature</td>
<td>25 monitoring devices Instructions</td>
<td>$4.16</td>
</tr>
<tr>
<td>Total Aerobic Bacteria/Total Coliform Paddle Tester (Hach)</td>
<td>Dip paddle</td>
<td>Yes</td>
<td>Yes</td>
<td>25-30°C 24-48 hours</td>
<td>Refrigeration</td>
<td>10 monitoring devices Instructions</td>
<td>$3.16</td>
</tr>
<tr>
<td>Waterclave Dental Waterline Test Kit (Waterclave)</td>
<td>Pipette sample to dish</td>
<td>Yes</td>
<td>Yes</td>
<td>Room temperature 7-10 days</td>
<td>Refrigeration</td>
<td>100 monitoring devices, Reusable pipette, Glass test tubes and rack, Sterilization pouches for reusable equipment, Storage container, Marker for labeling monitoring devices Instructions</td>
<td>$4.75 with the initial kit purchase $1.65 for refill</td>
</tr>
</tbody>
</table>

* If no growth after 72 h, incubate a second 72 h.
† Based on kit MSRP. Actual retail price may vary.

### Lab Notes: Total Viable Counts

**Clinical Significance:** Testing was conducted to confirm the reliability of the test kits to represent microbial content in water samples when compared with the colony counting guide provided by the manufacturer (see Figures 1 and 2), and to test the devices’ ability to discriminate between clean and unclean water samples (see Table 2).

**Basic Methods:** After following their respective directions for use, we inoculated each device with water samples containing various levels of Pseudomonas aeruginosa and Klebsiella pneumoniae: 1 CFU/ml, 10 CFU/ml, 100 CFU/ml, and 1000 CFU/ml. Samples containing 100 CFU/ml and fewer were intended to simulate acceptable water samples (below 500 CFU/ml); a count of 1000 CFU/ml simulated an unacceptable water sample.

We incubated the devices at room temperature and humidity (20°C; 70% humidity) for seven days to simulate dental office conditions.

Measurement of microbiologic contamination is performed after test samples have been incubated per the manufacturers’ instructions. You can count the visible colonies that have formed or you can compare your sampling device with sample images provided by the manufacturer. Some kits use color indicators, which make bacterial colonies easier to visualize.

For a detailed description of test methods, visit the PPR Web site at "www.ada.org/goto/ppr".

**Results:** The reliability of manufacturer-provided guides to represent in a sample contaminated with 1000 CFU/ml is shown in Figures 1 and 2. Whether or not each kit was able to discriminate between an acceptable and unacceptable water sample is shown in Table 2.

**Comments:** Distinguishing features between these devices include the type of growth medium coating the membrane filter, the surface area on which the sample is plated; presence of gridlines and use of color indicator to aid in counting and visualizing colonies; and the ability to accurately measure the amount of water being sampled.

Table 2. Potential causes of ineffective sterilization.

<table>
<thead>
<tr>
<th>Factor</th>
<th>Cause/Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improperly cleaned instruments</td>
<td>Any visible debris, organic or inorganic, will interfere with microbial inactivation and can compromise the disinfection or sterilization process. Cleaning should remove organic and inorganic debris.</td>
</tr>
<tr>
<td>Improper packaging material</td>
<td>Prevents sterilant from penetrating into instruments. Packaging materials should be compatible with sterilizing process.</td>
</tr>
<tr>
<td>Overloading of packaging material and/or instruments</td>
<td>Can result in cool air pockets and items not being sterilized. Follow manufacturer’s recommendations for loading capacity.</td>
</tr>
<tr>
<td>Inadequate time and temperature</td>
<td>May lead to sterilization failure. Follow manufacturer’s recommendations for appropriate cycle time and temperature.</td>
</tr>
</tbody>
</table>

Modified from Miller CH and Palenik CJ (2005).

Dental handpieces, both high- and low-speed types, are categorized as semicritical devices; however, the CDC recommends that they always be heat sterilized between uses and not processed with a high-level disinfectant. For more information about dental handpieces, see sidebar, page 4.

**Steam Sterilizer Operation**

The steam sterilizer is a popular method of sterilization for patient-care items that are heat stable and moisture tolerant. Steam sterilization destroys microorganisms using steam heat generated at a required temperature and pressure for a specified time. The sterilizers we reviewed required different cycle times between 66 minutes and 17 minutes, depending on the type of load processed and device-specific parameters (Table 3), at a temperature of 270-275°F.

There are three main types of steam sterilizers: prevacuum, steam-flush pressure pulse and gravity displacement. In prevacuum steam sterilizers, the dynamic-air-removal cycle uses one or more pressure and vacuum excursions at the beginning of the cycle to remove air. A poststerilization vacuum cycle accelerates drying of fabric loads by expelling excess steam, which should reduce moisture levels with packages. Also, it shortens the drying cycle, an important consideration in a busy practice that requires quick turnaround time on sterilized patient items. Prevacuum sterilizers generally cost more than the other types of sterilizers. We evaluated the Lisa MB 17 (A-dec Inc.) and PVdry2 (Barnstead/Harvey) sterilizers in this report.

In gravity displacement sterilizers, incoming steam fills the chamber and pushes any unsaturated, or heavier, air through a port or drain that is usually located toward the bottom of the chamber. Most steam sterilizers operate as traditional chamber-type autoclaves that can be loaded with trays. Instruments that have been cleaned for sterilization are wrapped or unwrapped within a steel cassette for sterilization. This process is also performed with some steam sterilizers.

As always, you should follow the manufacturers’ directions for loading and testing parameters for packaging types (wrapped and unwrapped), sterilization cycle times and temperatures, sterilization monitoring procedures. Also, ensure that the paper/plastic autoclave pouches are correctly placed (up or down) inside the sterilizer. This product-specific requirement is vital to successful sterilization.

**Using indicators to monitor sterilization effectiveness**

The CDC recommends that you monitor sterilizers at least weekly with biological indicators. Sterilization is best monitored using a combination of mechanical, chemical and biological indicators.

The use of biologic indicators, also called spore tests, is the most effective method for determining sterilization of instrument loads. Biologic indicators consist of highly resistant bacterial spores of *Geobacillus stearothermophilus* (used for monitoring steam and unsaturated chemical vapor sterilizers) or *B. atrophaeus* (formerly *Bacillus subtilis*) (used for monitoring the dry heat sterilizer). Sterilizers should be monitored at least weekly with biological indicators. Because some states have specific requirements on frequency of testing, you should check with your state dental board to determine how often you should monitor your sterilizer.

Chemical indicators in the form of tape, strips, tabs and special markings on packaging material change color to indicate that the instrument load was exposed to sterilization parameters such as heat, time, temperature and steam presence, during the sterilization process.

Chemical indicators are placed either inside or outside the sterilization packages. The CDC recommends placing the chemical indicator on the inside of each package. If you can’t view the internal indicator from the outside, you should also place an exterior chemical indicator on the package. Single parameter chemical indicators measure only one parameter of the sterilization process when used with steam, dry heat and unsaturated chemical vapor sterilizers. One advantage that steam sterilizers have over the other types is that you can use multiparameter chemical indicators to measure different parameters of the sterilization process (such as steam and heat). Multiparameter indicators provide a more reliable indication that sterilization conditions have been met.

Overall, remember that chemical indicators do not guarantee sterilization. They simply indicate that at least some sterilizing conditions have been met. If the indicator fails to change color, the load should be resterilized. Also, keep in mind that because chemical indicators are sterilizer-specific, they cannot be used interchangeably between steam sterilizers and chemical vapor sterilizers. Most important, chemical indicators should not replace biological indicators because only the latter can measure the microbial killing power of the sterilization process.

Mechanical indicators, like chemical indicators, demonstrate that at least some of the sterilizing conditions have been met. With mechanical indicators, cycle time and temperature can be monitored daily. The CDC also recommends that you should monitor each load using mechanical and chemical monitors.
Lab Notes

Sterilization Test for Wrapped Instruments
Clinical Significance: This test evaluated the ability of the sterilizers to process a load containing instruments within a sterilization pouch (total weight 3/4 lbs). We performed tests for each sterilizer using a biological indicator (BI), or a sterile strip inside the pouch, according to the standards set by the American National Standards Institute and AAMI. We followed manufacturer’s directions for each sterilizer regarding the placement and location of the BI. A control BI from the same lot as the test indicator and not processed through the sterilizer was incubated with the test BI.
Results: All six steam sterilizers successfully sterilized the wrapped load. Live spores were recovered from all the nonsterilized positive controls and no contamination was detected from culturing the negative controls (Table 4).

Sterilization Test for Unwrapped Instruments
Clinical Significance: This test evaluated the ability of the sterilizers to process an unwrapped load within a cassette.
Results: All six steam sterilizers successfully sterilized the unwrapped load (Table 4).

Sterilization Test for Dental Handpieces
To test the handpiece sterilization effectiveness of our six sterilizers, we processed three different brands of handpieces in each sterilizer using the standard set by ANSI/AAMI. All handpiece turbines were lubricated before sterilization.
Results: All six steam sterilizers successfully sterilized each handpiece. Live spores were recovered from all the nonsterilized positive controls, and no contaminations were detected from culturing the negative controls (Table 4).

Moisture Retention Test
To calculate the percentage of moisture gain in each handpiece, moisture retention tests were performed by weighing wrapped instruments before and after the steam sterilization.
Clinical Significance: If wet packages are handled before they are dry, they can easily become contaminated by bacteria from hands, air, dust, or contaminated surfaces that contact the wet instrument pack. If instruments are wet at the end of a sterilization cycle, carbon steel items may be affected by corrosion. According to the moisture retention acceptance criteria established by ANSI/AAMI, no visible moisture or droplets are allowed on the outside of loads or instruments after steam sterilization and moisture content should be less than two percent by weight.
Results: All six steam sterilizers passed the moisture test, demonstrating no moisture gain.
Comments: SciCan dry accelerant was used with the STAT IM 5000 per that manufacturer’s recommendation.

What is flash sterilization?
According to the AAMI, flash sterilization is a method for sterilizing items for immediate patient use. This process, which the CDC recommends should be used only in exceptional circumstances, sterilizes an item that has been contaminated during patient use or when critical time constraints prevent using a longer, wrapped sterilization cycle. In other words, the instruments are exposed and because the drying phase may be either shortened or eliminated altogether, the items may be hot and wet when removed from the sterilizer chamber.
The problem with sterilizing unwrapped instruments is maintaining sterility when the instruments are removed from the sterilizer. Unwrapped critical instruments should be used immediately and semicritical instruments should be used immediately or within a short period of time—neither should be stored unwrapped. As always, you should use aseptic measures when transporting items to the point of use.
If you must use flash sterilization, the CDC recommends that you follow these conditions when using unwrapped sterilization cycles: 1) thoroughly clean and dry the instruments before the sterilization cycle; 2) check mechanical monitors and use chemical indicators for each cycle; 3) take care to avoid thermal injury to the dental practitioner or patient; and 4) transport items aseptically to the point of use to maintain sterility. Further, the CDC recommends that you should not sterilize implantable items using the unwrapped or flash cycle because after sterilization, you must quarantine them to obtain biological monitoring results. This additional step negates the time-saving element of the flash sterilization cycle, in addition to introducing risks of contamination through prolonged air-exposure.

Practitioner Input
In our Web-based survey, a total of 398 dentists rated our products on a scale from “Excellent” to “Unacceptable” in each of the following categories: clarity of the product instructions; ease of use; maintenance and programming; control panel; reliability; efficiency; learning curve; and the manufacturer’s provision of repair and customer services.
The pie charts show the overall rating for each sterilizer. The letter “n” indicates the total number of survey respondents. Because there was an insufficient number of survey responses for PVdry2, clinical data are not presented for this product.
For specific information about product ratings and categories, visit the PPR Web site at “www.ada.org/goto/ppr.”
General Discussion
Survey respondents said the most important features when considering a steam autoclave for purchase were product reliability, capacity, automated operation, manual cycle option, cost, and cost-efficiency.

A reliable and efficient sterilization process should be a key feature of your sterilizer. Of course, there are other features you should weigh, too. For example, if office productivity matters to you, consider a fully automatic unit that frees you to perform other activities while sterilization occurs. Or, if you prefer more control over the different processing cycles, consider a programmable autoclave. Consider how much counter space your sterilizing room has, too, because tabletop autoclaves come in varying sizes. In all cases, make sure that your steam sterilizer has easily accessible ports. This will eliminate the nuisance of having to move the unit each time you fill or drain it, a handy consideration for busy practices.

Lastly, you should consider the total production capacity, or throughput, of your autoclave in relation to your practice demands. For example, the STAT/MF5000 cassette autoclave features a removable stainless steel cassette that also functions as the sterilization chamber. When the cassette is inserted into the unit’s insulated steel receptacle, sockets at the rear of the cassette connect to a steam line and exhaust valve inside. This autoclave has a load capacity of 3.3 pounds, the smallest capacity of all the sterilizers in this report. The cassette is also self-enclosed, as opposed to trays and cassettes that can be loaded without spatial restrictions.

A Buyer’s Summary for Steam Sterilizers is presented in Table 4.

Table 4. Buyer’s Summary for Steam Sterilizers.

<table>
<thead>
<tr>
<th>Product (No. of clinical survey respondents)</th>
<th>Laboratory Performance Sterilization Tests</th>
<th>Clinical Impressions*</th>
<th>Warranty</th>
<th>Price*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delta XL Pelton &amp; Crane (31) Pass</td>
<td>Excellent % 25 Very Good % 42 Good % 27 Fair % 4 Poor % 1</td>
<td>3 years parts</td>
<td>$5020</td>
<td></td>
</tr>
<tr>
<td>EZ10 Tuttnauer Co. Ltd (20) Pass</td>
<td>Excellent % 25 Very Good % 32 Good % 27 Fair % 8 Poor % 5</td>
<td>2 years parts and labor</td>
<td>$5520</td>
<td></td>
</tr>
<tr>
<td>Lisa 1B17 A-dec Inc. (10) Pass</td>
<td>Excellent % 26 Good % 42 Fair % 27</td>
<td>1 year, or 1,000 cycles, parts and labor</td>
<td>$7635</td>
<td></td>
</tr>
<tr>
<td>M11 UltraClave Midmark Corporation (138) Pass</td>
<td>Excellent % 35 Good % 42 Fair % 18</td>
<td>1 year parts and labor</td>
<td>$5920</td>
<td></td>
</tr>
<tr>
<td>PVdry2 Barnstead/ Harvey (2) Pass</td>
<td>Insufficient number of survey responses</td>
<td>Insufficient number of survey responses</td>
<td>$7522</td>
<td></td>
</tr>
<tr>
<td>STAT/MF5000 SciCan, Inc. (197) Pass</td>
<td>Excellent % 33 Good % 38 Fair % 20</td>
<td>1 year parts and labor</td>
<td>$6925</td>
<td></td>
</tr>
</tbody>
</table>

*Via a Web-based survey of ACE members. Indicates percentage of time a rating was selected for a product.
**Indicates percentage of time “unacceptable” was selected for a product.
* MSRP as of October 2006.

WATER QUALITY MONITORING KITS

The Centers for Disease Control and Prevention recommend that practitioners should periodically monitor the quality of their dental unit water to ensure that waterline treatments are effective.1 The manufacturer of either your dental unit or its water delivery system can suggest such a schedule for you. Alternatively, some manufacturers of waterline cleaners may include a treatment and maintenance protocol with their product’s instruction guide. For example, the maker of the product VistaTab directs you to shock waterlines every 1 to 4 weeks, depending on the results of your water monitoring services of a laboratory. Mail-in and onsite services are available.

There are two simple and inexpensive methods to estimate the number of free-floating heterotrophic bacteria in dental unit water. One method involves using a well-designed water quality indicator that should be self-contained and easy to use in the dental office; should accurately detect a wide concentration range and type of aerobic mesophilic heterotrophic waterborne bacteria within a reasonable incubation time at room temperature; and should be relatively inexpensive to use. These in-office screening kits offer a quick, affordable and easy method of estimating the microbial content in a water sample. If you want a more precise colony count and are willing to pay more for it, you can use the monitoring services of a laboratory. Mail-in and onsite services are available.

Aquasafe Water Test Kit
Pall Corp. (800) 645-6578 www.pall.com

HPC Total Count Sampler
Millipore (800) 645-5476 www.millipore.com

Total Aerobic Bacteria/Total Coliform Paddle Tester
Hach Co. (800) 227-4224 www.hach.com

Waterclave Dental Waterline Test Kit
Waterclave (913) 312-5860 www.waterclave.com

5. ANSI/AAMI ST55:2003. 5.7 Moisture retention acceptance criteria.
Table 2. Did the testing device discriminate between acceptable and unacceptable undiluted water samples?*

<table>
<thead>
<tr>
<th>Product (Manufacturer)</th>
<th>Inoculum Level (CFU/ml)</th>
<th>1</th>
<th>10</th>
<th>100</th>
<th>1000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aquasafe Water Test Kit (Pall Corp.)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No, fewer colonies grew on the test plate than would be expected from the inoculum.*</td>
</tr>
<tr>
<td>HPC Total Count Sampler (Millipore)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Not applicable*</td>
</tr>
<tr>
<td>Total Aerobic Bacteria/Total Coliform Paddle Tester (Hach)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Waterclave Dental Waterline Test Kit (Waterclave)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

* Acceptable samples inoculated with < 500 CFU/ml; Unacceptable samples inoculated with > 500 CFU/ml.
† While these devices correctly indicated that the water sample was < 500 CFU/ml, therefore acceptable, they did underreport growth based on the actual concentration of the inoculum. This tendency to underreport could misrepresent an unacceptable water sample as acceptable at higher concentrations.
§ The device reported that this unacceptable water sample was acceptable.
‡ Instructions for use state that water samples with over 300 CFU/ml should be diluted with the provided dilution kit to obtain an accurate reading.

Visible Colony Count: Actual Test Results Compared With Manufacturer Counting Guides (when provided)

After the samples have been incubated, any microbial colonies will appear as spots on the sample. You can then manually count the number of colonies to estimate your water quality. Alternatively, if your water testing kit includes a colony counting guide, you can visually compare your results with the example counts depicted in the guide. In our report, three manufacturers supplied colony counting guides with their kits.

In Figures 1 through 3, we provide images of our samples versus the counting guides (when available). As you will note, the quality is not as good as what you would actually see with use in the office.

As shown in Figure 1, the colony count on the Aquasafe sample plate (1000 CFU/ml) was lower than that of the guide image representing 500 CFU/ml. This would indicate that the quality of the water sample was acceptable (below 500 CFU/ml) when actually it was unacceptable (above 500 CFU/ml). Likewise, the colony count for the Aquasafe sample plate for 100 CFU/ml did not match the guide image count of 100 CFU/ml. However, sample plates for 1 and 10 CFU/ml compared well with the guide images. The advantages of the Aquasafe kit include a color indicator and grid lines that aid in visualizing and counting colonies. The pipette (provided with the kit) offers control in the amount of water being sampled (1 ml).

As shown in Figure 2, the Total Aerobic Bacteria/Total Coliform sample paddle of 1000 CFU/ml compared well with the provided guide image representing the same amount; the number of colonies appeared similar between the two images. A color indicator makes the colonies easy to see. We had difficulty getting an exact colony count because some of the colonies appeared to be growing into each other. The presence of healthy strains of *Pseudomonas aeruginosa* and *Klebsiella pneumoniae* on ADA lab testing samples may explain the differences in colony appearances between the sample paddle and guide image. These healthy microorganisms can appear different than bacteria typically found in waterline samples.

As shown in Figure 3, the Waterclave sample plate of 1000 CFU/ml accurately depicted the microbial content of the water sample. The grid lines, color indicator and size of the surface area allowed easy visualization of the colonies. Also, the pipette (included with kit) allows the user to control the amount of water sampled (1 ml). One possible disadvantage is that this product does not include an image for comparing colony count levels.
HPC Total Count Sampler: The colony counts of our laboratory generated sample plates approximated the manufacturer guide images for both 1 and 10 CFU/ml counts. Although the sample plate of 100 CFU/ml indicated an acceptable water quality (below 500 CFU/ml), there appeared far fewer colonies on the sample plate than on the guide image. This reporting of fewer colonies may misrepresent an unacceptable water sample as acceptable at higher bacteria concentrations.

Additionally, we had difficulty comparing our sample with the guide image because the guide image depicted distinct, round colonies; whereas in our sample, we observed large spreader colonies. The presence of healthy strains of *Pseudomonas aeruginosa* and *Klebsiella pneumoniae* on ADA lab testing samples may explain these differences in colony appearances. These healthy microorganisms may differ in appearance from bacteria typically found in waterline samples, as depicted in the guide images. Another reason may be the method for collecting the water sample as described in the product’s usage directions. After the sampler has been dipped into the test water, the user is instructed to remove excess water from the paddle by shaking it. This motion pushes bacteria down and out to the edges of the growth area and may contribute to spreader colony formation.

This kit does not offer a color indicator, which makes visualizing colonies difficult. Another potential disadvantage of using the HPC sampler is that water samples with bacterial levels exceeding 300 CFU/ml require dilution per usage instructions. You can achieve dilutions of 1:10 and 1:100 using the standard kit, but to achieve dilutions of 1:1000 and 1:10,000 requires the purchase of a Millipore’s Dilution Kit.

Figure 4 depicts an unused sampler. In this kit, grid lines are provided to aid with the counting of colonies.

**Practitioner Input**

We administered a Web-based survey to members of the ADA Clinical Evaluator (ACE) Panel. This panel comprises a volunteer group of ADA dentists who contribute feedback for the clinical input segments of the ADA Professional Product Review program.

A total of 52 respondents reported their experience with using the waterline test kits evaluated in this review. Respondents considered the following features when rating waterline kits: was the product easy to use?; was the user able to keep a record of test results?; and did the product meet the needs of the dental practice? The pie charts depict what percentage of respondents rated the test kits as Excellent, Very Good, Good, Fair, Poor, or Unacceptable. The letter “n” indicates the total number of survey respondents. For a precise breakdown of how respondents rated each feature, visit “www.ada.org/goto/ppr”.

The following ratings are based on the opinions of fewer respondents and may be less reliable than those reported for Aquasafe Water Test Kit.

**Aquasafe Water Test Kit (Pall Corp.) n=28**

- Excellent: 40%
- Very Good: 31%
- Good: 14%
- Fair: 6%
- Poor: 2%
- Unacceptable: 1%

**HPC Total Count Sampler (Millipore) n=14**

- Excellent: 36%
- Very Good: 29%
- Good: 14%
- Fair: 14%
- Poor: 2%
- Unacceptable: 2%

**Waterclave Dental Waterline Test Kit (Waterclave) n=7**

- Excellent: 34%
- Very Good: 25%
- Good: 14%
- Fair: 29%
- Poor: 24%
- Unacceptable: 13%

The number of survey responses was insufficient to report results for the Total Aerobic Bacteria/Total Coliform Paddle Tester (Hach).

Fifteen percent of the dentists who responded to our Web survey on waterline testing kits claimed to use a water quality test kit. A total of 82% of respondents either were unaware that these products were available or believed that the kits were unnecessary. Most respondents cited their use of distilled and/or filtered water for non-implementation of a water monitoring regimen. It is important to note that biofilm can develop in lines that are regularly cleaned. Also, the use of filtered or distilled water does not prevent biofilm growth in waterlines.
Dental Unit Waterline Cleaning Products

Drinking water must meet standards for concentrations of contaminants and chemicals. The maximum concentration of heterotrophic bacteria for potable tap water is 500 colony-forming units per milliliter (CFU/ml), as established by the Environmental Protection Agency (EPA), the American Public Health Association (APHA) and the American Water Works Association (AWWA). The Centers for Disease Control and Prevention (CDC) also recommends this limit for unfiltered output of dental unit water used in nonsurgical procedures, as well as only using sterile water during oral surgical procedures. It is well established that dental unit waterlines (DUWLs) provide an ideal environment for biofilms to colonize and replicate. The small diameter of dental waterline tubing, combined with their design and flow rate, enable a wide variety of microorganisms like bacteria, fungi, and protozoans to form along their interior surfaces. As the water flows through the waterlines, the microorganisms slough off and contaminate the water. Although there is no evidence to suggest that dental unit water is harmful to patients, the practice of exposing patients or office staff to water of uncertain microbiological quality is inconsistent with generally accepted infection control principles. Evidence has shown that microbial counts can run as high as 200,000 CFU/ml within five days of the installation of new dental unit waterlines. In fact, bacterial levels as high as 10^7 CFU/ml have been found in dental unit waterlines that have not been regularly maintained to deliver water of an optimal microbiologic quality. Therefore, waterline maintenance should be a regular practice of your infection control program, along with sterilization and disinfection procedures, barrier techniques and appropriate waste disposal processes.

The most important factor in successfully maintaining good water quality is strict adherence to maintenance protocols and periodic water testing. Devices and procedures that improve the quality of dental water delivered to patients by maintaining bacterial counts at or below 500 CFU/ml include:

- Independent water reservoirs
- Chemical treatment regimens
- Source water treatment systems
- Daily draining and air purging regimens
- In-line microfilters

For more information about these strategies, see the Sidebar “Strategies to Improve Dental Unit Water Quality.”

As always, you should consult with the manufacturer of your dental units before you initiate any waterline treatment protocol.

In this report, we tested the efficacy of eight chemical cleaners to either initially clean or to maintain bacterial levels within established limits. Chemicals may be introduced into water systems either intermittently (to initially clean or to maintain clean lines) or continuously (to maintain clean lines).

Intermittent cleaning, which reduces or eliminates existing waterline contamination, requires periodic introduction of an aggressive chemical into the dental unit water. Such treatment may be used either as a periodic maintenance treatment or for initial cleaning of contaminated lines (shock treatment). Shock treatment is an aggressive treatment, used in waterlines that have never been cleaned or in waterlines that are being routinely cleaned, but where water quality monitoring has shown an increase in microbial contamination (i.e., above 500 CFU/ml). Cleaners used intermittently are not intended for patient contact and require that the waterlines be flushed after each chemical treatment. One benefit of using intermittent cleaners to maintain water quality is that the active agent is removed from the system before patient treatment, which eliminates any potential adverse effects the chemical may have on the bond strength of dental adhesive materials. However, one possible drawback is that intermittent cleaning may allow for reformation of the biofilm between uses.

In contrast, cleaners intended for continuous use have less chemical concentrate and do not require flushing of waterlines. In addition, these products have been shown to be safe for intraoral nonsurgical use in patients. Intended to maintain bacterial levels at or below established limits, these cleaners are introduced after an initial shock treatment has acted upon biofilm in the waterlines, or they are used with new waterlines in which biofilm has not yet formed.

The main benefit of continuous chemical use is that it reduces the potential for recolonization of waterlines between treatments (although the potential still exists and water quality should be monitored to ensure that it is of acceptable quality). You also will save time because you will not have to flush the waterlines after each chemical treatment. However, studies have found that some chemical cleaners may adversely affect the enamel and dentin bond strength of dental adhesive materials. If you require more information about this issue as it applies to your product, contact that product’s manufacturer.

In sum, consider which process would work best in your office after you have performed an initial cleaning step: periodically administering chemical treatments followed by flushing the waterlines after each treatment, or maintaining a continuous concentration of the chemical in the dental unit water. Remember that with either approach, monitoring water quality is necessary.


BioClenz
Frontier Pharmaceutical Inc.
(800) 767-3486
www.frontierpharm.com

Clorox Regular Bleach
Clorox Co.
www.clorox.com

Lines
Micrylium Inc.
(800) 489-8868
www.micrylium.com

Sterilox
PuriCore
(800) 604-1879
www.puricore.com

Citrisol
Steris Inc.
(877) 755-PURE (7873)
www.steris.com

ICX
A-dec Inc.
(800) 547-1883
www.a-dec.com

VistaTab
Vista Research Group
(866) 559-2837
www.vistaresearchgroup.com

Sterilex Ultra Liquid
Sterilex Corp.
(800) 511-1659
www.sterilex.com

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Table 1. Product features according to the manufacturer.

<table>
<thead>
<tr>
<th>Product (Manufacturer)</th>
<th>Active Ingredient(s)</th>
<th>Contact Time</th>
<th>Can be used during patient treatment</th>
<th>Other accessories required</th>
<th>Tinted solution for visibility</th>
<th>Instructions for non-use periods according to the manufacturer</th>
<th>Additional comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICX A-dec Inc.</td>
<td>Sodium percarbonate</td>
<td>Continuous</td>
<td>Yes</td>
<td>Use a product approved for removing biofilm before starting this product</td>
<td>Colorless</td>
<td>Effective when left in lines for up to 2 weeks of non-use</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Silver nitrate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cationic surfactants</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sterilex Ultra Liquid</td>
<td>Alkaline peroxide</td>
<td>Overnight</td>
<td>No</td>
<td>Pink</td>
<td>None</td>
<td>Biofilm removal claim</td>
<td></td>
</tr>
<tr>
<td>Sterilex Corp.</td>
<td>compound with phase transfer catalyst</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BioClenz Frontier</td>
<td>Active Chlorine</td>
<td>5 minutes</td>
<td>Yes</td>
<td>Colorless</td>
<td>None</td>
<td>Keep out of light</td>
<td></td>
</tr>
<tr>
<td>Pharmaceutical, Inc.</td>
<td>dioxide</td>
<td>(Flush solution)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lines Microlym Inc.</td>
<td>Ethanol</td>
<td>Continuous</td>
<td>Yes</td>
<td>Colorless</td>
<td>None</td>
<td>Mint fragrance</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Chlorhexidine gluconate</td>
<td>Over the weekend or overnight</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VistaTab Vista Research</td>
<td>Sodium chlorite</td>
<td>5 minutes</td>
<td>No</td>
<td>Colorless</td>
<td>None</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group</td>
<td>Sodium dichloroisocyanurate dilydride</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Citrisil</td>
<td>Silver salts</td>
<td>Overnight</td>
<td>Yes</td>
<td>Requires generator and test strips (included)</td>
<td>Colorless</td>
<td>Effective when left in lines for up to 2 weeks of non-use</td>
<td>Citrisil Blue also is available in tablet form. This product produces a blue-colored solution to assist with visual compliance.</td>
</tr>
<tr>
<td>Sterilox PuriCore</td>
<td>85-98% Hypochlorous acid</td>
<td>4 hours (disinfectant solution)</td>
<td>Continuous (main-tenance solution)</td>
<td>Yes</td>
<td>Colorless</td>
<td>None</td>
<td>Solution can also be used as surface disinfectant. Refrigerate unused solution and discard after 96 hours. Biofilm removal claim</td>
</tr>
<tr>
<td>Clorox Regular Bleach</td>
<td>5.25% Sodium</td>
<td>10 minutes</td>
<td>No</td>
<td>Colorless</td>
<td>None</td>
<td>Dilute solution must be made fresh daily</td>
<td></td>
</tr>
<tr>
<td>Clorox Co.</td>
<td>hypochlorite</td>
<td>(1:10 dilution)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

What the CDC Says About Strategies to Improve Dental Unit Water Quality

In 1993, CDC recommended that dental waterlines be flushed at the beginning of the clinic day to reduce the microbial load. However, studies have demonstrated this practice does not affect biofilm in the waterlines or reliably improve the quality of water used during dental treatment. Because the recommended value of <500 CFU/ml cannot be achieved by using this method, other strategies should be employed.

Dental unit water that remains untreated or unfiltered is unlikely to meet drinking water standards. Commercial devices and procedures designed to improve the quality of water used in dental treatment are available; methods demonstrated to be effective include self-contained water systems combined with chemical treatment, in-line microfilters, and combinations of these treatments. Simply using source water containing <500 CFU/ml of bacteria (e.g., tap, distilled, or sterile water) in a self-contained water system will not eliminate bacterial contamination in treatment water if biofilms in the water system are not controlled. Removal or inactivation of dental waterline biofilms requires use of chemical germicides.

When Should Shock Treatments Be Applied?

Practitioners must monitor their units to determine when shocking is necessary. Even when using a product continuously, the potential for biofilm to regenerate over time exists. Product instructions do not specifically identify at what point a re-shock may be necessary. The time between re-shock will differ depending upon how quickly a biofilm can re-establish itself. It is important that you routinely monitor your waterlines to determine an appropriate re-shocking schedule. For example, the instructions for use for the product VistaTab direct you to shock waterlines every one to four weeks depending on the results of your water quality monitoring. We determined that a weekly re-shock was necessary to keep bacterial concentrations acceptably low within our system.

Product Review

The chemical cleaners we evaluated were generally inexpensive and easy to use (Table 2) and required use of independent reservoir water bottles. Most dental unit manufacturers offer the reservoir system either as standard or optional equipment. Older dental units can be retrofitted with reservoir water bottles, which also can be used to deliver a special irrigating solution, tap and bottled water. We did not test the compatibility of waterline cleaners with dental restorative materials or dental units or any potential adverse effects associated with their use.
Chemical line cleaner brands, treatment type and product form.

<table>
<thead>
<tr>
<th>Product Manufacturer</th>
<th>Type of Treatment(s)</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>BioClenz Frontier Pharmaceutical, Inc.</td>
<td>Weekly treatment with concentrated solution, then post-treatment waterline flush; Daily continuous use with diluted solution.</td>
<td>Liquid concentrate, 2 parts</td>
</tr>
<tr>
<td>Clorox Regular Bleach Clorox Co.</td>
<td>Weekly treatment with 10% bleach solution, then post-treatment waterline flush.</td>
<td>Liquid concentrate</td>
</tr>
<tr>
<td>Citrisil Sterisol Inc.</td>
<td>Before using this product, existing biologic contamination should be removed using an EPA-registered product.</td>
<td>Enhanced cleaner tablet (orange tablet)</td>
</tr>
<tr>
<td>ICX A-dec Inc.</td>
<td>Before using this product, existing biologic contamination should be removed using an EPA-registered product.</td>
<td>Maintenance tablet (beige tablet)</td>
</tr>
<tr>
<td>Lines Micrylium Inc.</td>
<td>Initial treatment: Full strength solution left in waterlines over the weekend. Flush waterline. Follow with daily use for 3 weeks to precondition the lines. At the end of the 3rd week can be used once per week over the weekend.</td>
<td>Ready-to-use liquid</td>
</tr>
<tr>
<td>Sterillex Puricore</td>
<td>Initial treatment: Leave full strength solution in waterlines for 4 hours. Flush.</td>
<td>Liquid concentrate and generator</td>
</tr>
<tr>
<td>VistaTab Vista Research Group</td>
<td>Initial treatment: Dissolve 2 tablets in water and let sit in waterline for 5 minutes. Post-treatment flush and repeat. Every 1 to 4 weeks*: treatment: Dissolve 1 tablet in water and let sit in waterline for 5 minutes, then post-treatment flush.</td>
<td>2 tablets</td>
</tr>
</tbody>
</table>

Note: *Effluent water should be monitored to determine time interval for retreatment.

### Lab Notes

**We evaluated eight brands of waterline chemical cleaners in the ADA laboratory. Brands were selected based on Web-survey responses collected from members of the ADA Clinical Evaluator (ACE) Panel. This panel comprises a volunteer group of ADA dentists who contribute feedback for the clinical input segments of the ADA Professional Product Review program. Product selection does not imply endorsement, approval, or disapproval by the ADA.**

**For a detailed description of test methods, visit the PPR Web site at “www.ada.org/goto/ppr”**.

#### Shock Treatment (Efficacy of Products used to Eliminate or Reduce Bacterial Counts At or Below Standard Limits in Waterlines with Established Biofilm)

We evaluated the efficacy of chemical line cleaners to reduce microbial numbers in effluent water when introduced to waterlines with established biofilm, per product-specific manufacturers’ instructions. This was accomplished using a stronger concentration of that product for a longer period of time, such as over consecutive nights (see Table 2). The products Citrisil and ICX, because they are only intended for use in pre-treated or new waterlines, were not tested.

**Results:** All products passed (Table 3).

#### Intermittent or Continuous Maintenance Treatment (Efficacy of Products used to Maintain Bacterial Counts in Effluent Water At or Below Standard Limits in Waterlines that have Undergone an Initial Biofilm Treatment)

We evaluated the efficacy of chemical line cleaners to reduce microbial numbers at or below 500 CFU/ml in effluent water for a period of four weeks, per product-specific manufacturers’ instructions, either through presence in the lines continuously or application at regular intervals. The product Sterilex Ultra was not tested due to insufficient dental unit waterline simulators.

**Results:** All tested products passed except Lines (Table 3).

**Comments:** Lines, when used according to the manufacturer’s instructions, failed to reduce bacterial counts in the effluent water after just one week of normal use. Per the manufacturer’s instructions, it was used overnight for the first three weeks of the study, followed by weekend flushes after each use. During this period of preconditioning, bacterial counts were well controlled. But when Lines was used intermittently in the final week of our study, bacterial counts in the effluent water quickly approached levels seen with the control. This suggests that a regimen of continuous overnight flushes using Lines may control bacterial levels more effectively than the weekly use as directed by the manufacturer. However, because this product was not used beyond the first week of “normal use” after the first three weeks of preconditioning, no observations can be made on efficacy based on prolonged use of this product. According to the product’s manufacturer, you can use Lines during hygiene procedures. Although we did not test the product for this purpose, the continual presence of the product perhaps might improve product efficacy. Also, note that using Lines continuously or as a nightly shock treatment will increase the costs associated with its use.

**Practitioner Input**

In our Web-based survey, a total of 323 dentists rated our products on a scale from “Excellent” to “Unacceptable” in each of the following categories: corrosiveness; lack of irritation to the skin and mucous membranes; contact time; cost; packaging and delivery method; directions for use; ease of use; and lack of odor.

The pie charts depict the overall rating for each waterline cleaner. The letter “n” indicates the total number of survey respondents for each product.

For specific information about product ratings and categories, visit the PPR Web site at “www.ada.org/goto/ppr”.

Not surprisingly, survey respondents rated bleach as the most corrosive and irritating to skin and mucous membranes. Bleach also rated poorly with respect to odor, but was rated the most cost effective. ICX had the most “excellent” ratings for all surveyed categories, except cost where it rated second to bleach. Survey responses for Citrisil, BioClenz and VistaTab are not reported here because there were fewer than 30 surveys completed for these products.
Respondents also were surveyed about the best and worst characteristics of these products. Of 370 respondents, 142 said the most important feature when considering a dental unit waterline cleaner for purchase was effectiveness (51%), while 86 said that ease of use was the most important feature (29%). The continuous use tablet ICX was rated highest for ease of use with 70 dentists out of 110 giving it an “excellent” rating (64%). However, some dentists wondered about the potential for the continuous use products to affect bond strength. Contact the manufacturer for more information. For example, A-dec has reported that their product ICX does not affect bond strength.

Four of twenty seven respondents commented that the liquid product Lines leaves a residue on instruments and equipment as well as a taste in the dental unit water. Lines can be used weekly or as a continuous use product. It is unclear as to how the respondents were using the product.

The products ICX and Citrisil are intended for maintenance of clean waterlines. Before you use these products, remember to administer a shock treatment first followed by a post-treatment flush.

Overall, 226 out of 573 (39 percent) survey respondents reported that they did not use a dental unit waterline cleaner. Some well-intentioned respondents mistakenly believed that their use of distilled or filtered water in their dental units obviated the need for any dental unit waterline cleaning regimen. Remember that a filtered or distilled water source for your dental unit only slows, not prevents, biofilm growth in your waterlines.

Table 3. Buyer’s Summary for Chemical Waterline Cleaners.

<table>
<thead>
<tr>
<th>Product Manufacturer (No. of clinical survey respondents)</th>
<th>Did using the product result in acceptable dental unit water quality?*</th>
<th>Clinical Impressions†</th>
<th>Use</th>
<th>Estimated price for each shock treatment</th>
<th>Estimated price for one year of use per dental unit‡</th>
</tr>
</thead>
<tbody>
<tr>
<td>BioClenz Frontier Pharmaceutical Inc. (5)</td>
<td>Initial Shock≠ Maintenance≠</td>
<td>Excellent 23%</td>
<td>Very Good 16%</td>
<td>Good 25%</td>
<td>Fair 22%</td>
</tr>
<tr>
<td>Citrisil Sterisil Inc. (6)</td>
<td>Not Applicable≠ Not Applicable≠</td>
<td>Insufficient number of survey responses.</td>
<td>Insufficient number of survey responses.</td>
<td>Continuous</td>
<td>Use another product for shock</td>
</tr>
<tr>
<td>Clorox Regular Bleach Clorox Co. (54)</td>
<td>Yes Yes≠ Not Applicable≠</td>
<td>60%</td>
<td>25%</td>
<td>12%</td>
<td>3%</td>
</tr>
<tr>
<td>ICX A-dec Inc. (110)</td>
<td>Not Applicable≠</td>
<td>39%</td>
<td>31%</td>
<td>25%</td>
<td>5%</td>
</tr>
<tr>
<td>Lines Micrylium Inc. (27)</td>
<td>Yes No Not Tested</td>
<td>Intermittent or Continuous</td>
<td>$4</td>
<td>$65</td>
<td></td>
</tr>
<tr>
<td>Sterilox Ultra Liquid Sterilex Corp. (40)</td>
<td>Yes Not Tested Not Applicable≠</td>
<td>20%</td>
<td>33%</td>
<td>33%</td>
<td>11%</td>
</tr>
<tr>
<td>Sterilox PuriCore (18)</td>
<td>Yes Not Applicable≠</td>
<td>Continuous</td>
<td>$0 (first 2 years)</td>
<td>$4</td>
<td></td>
</tr>
<tr>
<td>VistaTab Vista Research Group (4)</td>
<td>Yes Yes≠ Not Applicable≠</td>
<td>Insufficient number of survey responses.</td>
<td>Intermittent</td>
<td>$4</td>
<td></td>
</tr>
</tbody>
</table>

* When tested in the ADA laboratory according to the manufacturers instructions.
† Cleans biofilm contaminated lines. The dental unit water contained less than 500 CFU/ml following this initial treatment.
≠ Over 4 weeks of use dental unit water quality remains < 500 CFU/ml.
† Via a Web-based survey of ACE members. Indicates percentage of time a rating was selected for a product.
‡ Indicates percentage of time “not acceptable” was selected for a product.
** Biofilm contaminated waterlines must be cleaned before using this product.
‡‡ MSRP as of January 2007. Assume each dental unit uses 750 ml to 1 liter of water per day and is operated 5 days per week for 48 weeks per year.
†† Weekly use resulted in water of acceptable quality at the beginning of the week immediately after treatment; however, testing did not include daily water quality analysis over the course of the week.
**DENTISTS, EDUCATORS DISCUSS WATERLINE CLEANERS AND MONITORING KITS**

**Moderator:**
Shannon E. Mills, DDS  
Associate Professor  
Department of Dental Medicine  
University of Nevada School of Medicine  
Las Vegas, NV

**Participants:**
Chris H. Miller, PhD  
Professor of Microbiology  
Executive Associate Dean  
Indiana University School of Dentistry  
Indianapolis, IN  

Nuala Porteous, BDS, MPH  
Associate Professor of Community Dentistry  
University of Texas Health Science Center  
San Antonio, TX

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Mills: Have we established that there is a need for dental unit water line treatment products, and looking at the state of the products currently available, do these products meet the needs of the profession?

Miller: There are numerous studies that have documented the presence of large numbers of microorganisms in untreated dental unit water. I think you can find this to be true if you test water from any dental unit that has never been treated.

Porteous: We cannot say categorically that we've established the need for chemicals, but some chemicals have definitely demonstrated efficacy. And to the second part to the question: We're still lacking a lot of scientific information particularly due to the lack of standardized methods used to conduct studies in clinical settings. We need a whole lot more of those studies, and also data on the number of practitioners who actually treat their water lines. What's happening in those offices where the water is not being treated and those that are being treated with chemicals? In addition, there are numerous chemicals on the market which may be somewhat confusing to practitioners.

Mills: We've established the presence of these microorganisms, that's indisputable. But the health consequences associated with it are still unclear. I believe that there are consequences, but I don't think we've been able to effectively define what they are. We've got Martin's case studies, which is the only documented disease transmission that we can attribute to this problem, and that was published in 1987.

Porteous: Infection control is about prevention. The objective is to break that chain of infection. Even though we don't have the studies to show any epidemiologic evidence of transmission from the dental unit water line, treating waterlines should be a routine part of general infection control practices.

Miller: The overall goal of infection control, the way I've always looked at it is to reduce unnecessary contamination.

Mills: What's new and exciting in the field of dental unit water line cleaners?

Porteous: I think the most exciting development in this area is a biofilm-resistant tubing.

Miller: However, the data in that report showed that they did not reach the recommended limit using biofilm resistant tubing. Nevertheless, I agree with you, that's one of the new exciting areas, but, in the past, we've seen a lot of hoopla about this approach, but the results haven't been that exciting.

Mills: The problems are multiple. The biggest problem is that the surface coating either elutes or becomes inactive. They can be inactivated by contact with the organic material, after being covered by surface coatings, or by mineral deposits that then prevent them from being effective. One of the major problems is that you almost need ultra pure water. You also need a non-eluting material for the tubing. You can get good short term effects from these products, but their long term effects are not known. Maybe dentists will be expected to change the tubing in their units every year.

Miller: What is needed is a device or chemical that will regenerate that surface.

Mills: There are companies looking at that approach.

Porteous: Sterisil manufactures a tubing with a silver coating on the inside.

Mills: Yes, it's ionic silver. Their silver is eluting. There is another product that's not commercially available in dentistry at the moment that's a non-eluting silver material. But the thing is, it's still a technology that hasn't completely come to fruition, but it's certainly a step in the right direction. If you look at the difference between the approaches taken in Europe and the U.S. to solve this problem, it's an interesting dichotomy. In the U.S., the majority of effort is being conducted by second parties (secondary to the manufacturer of the equipment), but with the exception of Pelton & Crane and A-dec, everybody is buying something from another party to use in their equipment; whereas, the Europeans are developing integrated systems. If you look at Sirona, KaVo and Castellini, they're all building water line treatment into their units. As we go forward in the international standards development, they're trying to push that on us—setting a performance standard for dental equipment that most U.S. manufacturers won't be able to meet, presently.

Porteous: I think the second exciting development is the super-oxidized water generating system. It looks very promising. One of the products, Sterilox, was tested in a clinical situation, both as a DUWL cleaner and as a disinfectant for endoscopes. The studies were very well done.

Mills: The key is to have them integrated into the unit, and automated. I think the biggest problem that we have, and the European companies are trying to address this, is that most of our systems require too much user intervention. There are too many opportunities for things to fail, due to lack of compliance. So, if you can develop a MIOX® type system, a mixed oxidant generator, and you can build it into the unit at an affordable price, then I think you really have something.

Porteous: The units that were tested in a clinical situation actually had the super-oxidized water generators in the unit and then the bottle was just filled; it seemed to be very effective. But, there are a limited number of studies. The other thing I think is exciting, from a user viewpoint, is the introduction of cleaners in tablet form.

Mills: We used one of those systems here, and it is easy to use, and I think our compliance is pretty good, but there is still a compliance variable. The other problem that develops over time, and it may be due to occasional breaches, is that biofilm reforms in the system, and the lines have to be reshocked.

Porteous: One other point on the super oxidized system, it has demonstrated effectiveness against pseudomonas and legionella, the most worrisome organisms.

Mills: Right, and it has an advantage over sodium hypochlorite, for example, in that it is significantly less corrosive for the metal parts, whereas, Nuala, I think you demonstrated that chlorine dioxide, in this application doesn't work very well. None of the studies done using chlorine dioxide have demonstrated it to be a very good approach.

Porteous: Particularly stabilized chlorine dioxide, and the process of freshly-generating chlorine dioxide isn't very user-friendly.

Miller: I'd like to reemphasize what both of you said about the labor involved in using these products. That has to be the integral part of any kind of system. If you can't easily use it, it's not going to be accepted.

Mills: What about the independent reservoir system? Is it an aid or an impediment to treatment? And, what's going to supersede it?
Miller: Right now, the independent water reservoir is needed by many of the products that are available. So it does serve a purpose. If you can have something set up - automatic and inline - where you don't have to worry about an independent water bottle that you have to change periodically, it will be extremely valuable to the user.

Porteous: The independent water reservoir system definitely has shown to be useful and manufacturers have been working hard to improve their dental units. Most units, currently available, have self-contained water. However, we have established the need to add an agent to those water bottles. Many times, water bottles are not emptied at the end of the day, resulting in water stagnation and, consequently, the potential for bacterial growth. Independent systems are not the complete answer, but they certainly have a place.

Miller: It's clear that people don't pay enough attention to the cleanliness of those bottles. They not only need to be changed, they need to be cleaned every time. People don't realize that even though you put distilled water in these bottles, that there are still microorganisms there and you will form biofilm in those bottles. They have to be cleaned.

Mills: Even using distilled water has problems. First of all it can, depending upon where you get it from, be contaminated with microorganisms. Secondly, it's acidic. We've seen damage in studies we did using A-dec units that was caused only by distilled water, not by anything else that we added to the system - damaging tubing and causing corrosion on some of the nickel plated brass. Distilled water has a pH around 5.5 due to the dissolved carbon dioxide. People think it's neutral and doesn't have any chemical properties, but it's actually acidic. I don't think it's a huge problem, but I think people underestimate the ability of distilled water to cause some damage to equipment.

Miller: We experienced the same thing several years ago, when we were using a sodium hypochlorite solution with distilled water. And that alone caused excessive problems. When we made the solution with tap water we noticed an improvement. So, that's a very good point.

Porteous: Getting back to the point of the independent reservoir system, I don't believe that municipal systems are impeding dentists from addressing water quality. There are a number of products available for use in dental units without self contained water systems. It's not necessary for practitioners to just move to the independent reservoir systems.

Mills: All that's required is the will to do something, and that's what's lacking, because it's not that difficult to do. However, the cost in general of using the systems that are intended to run on municipal water (like VistaClear, PureTube, Citrisil, and DentaPure) are much higher than those for use with independent reservoir systems. In the case of PureTube and VistaClear, they both also require that the water be carefully conditioned for their products to work. That's a difference between them and DentaPure, which doesn't require conditioning. So, even though all those products are probably effective, interestingly, there are no published studies that I can find on any of those products. Lots of stuff on the chemicals, but nobody seems to be publishing anything on those water management systems.

Mills: How much is contaminated water contributing to the disease burden among patients and also among those dental personnel who are chronically exposed?

Miller: We've already mentioned that there are no data, that's the problem for us as far as assessing the risk for patients. Most dental patients are usually pretty healthy and not particularly susceptible to the non-pathogenic or opportunistic microorganisms present in water, but on the other hand, there are compromised patients and many we're not aware of because you can't always detect it through a patient history, for example. These patients may be more susceptible to these microorganisms, but there's not any epidemiological evidence documenting this - it's just a natural thing that one thinks of when you think of compromised patients and environmental microbes.

Porteous: I agree, I think we've already touched on that topic. It may be worthwhile doing a national survey on dental professionals' attitudes towards this subject. There was a study done in Europe, and the conclusion was that the temporal onset of asthma may be associated with exposure to contaminated DUWLs. But the two groups that they compared were from rural, Northern Ireland and London, and we didn't get information on the confounding variables. Certainly the air quality in London in comparison to rural Northern Ireland would be much different.

Mills: The article, also noted that smoking was a variable that was associated with the onset of asthma, but it wasn't clear to me from reading the article whether those variables were isolated, in terms of whether people who smoked and have high colony counts in their water were different from people who didn't smoke and have high colony counts.

Miller: To get back to the question, one thing that Dr. Mills has pointed out many times is that it doesn't make much sense for the dental office to spend considerable time and money on maintaining infection control programs with instrument sterilization, disinfection, barrier techniques, waste management, and then use highly contaminated water during intra oral care. I think that's an important consideration.

Mills: Before we move on with this I just want to drop one last comment. I happen to believe, at this point in time, that the greatest risk posed by contamination is to those who are chronically exposed. I think what we're going to see, if we're able to see anything, is that the number of post-operative significant clinical infections associated with contaminated water in patients is low. However, chronic effects among health care workers (for example, exacerbation of asthma) probably mediated by bacteria and toxins may be fairly common. And that's a hunch as much as anything else.

Mills: Is there anything else that would be relevant about integrating water line procedures into practice?

Porteous: Again, I recommend that it should be as simple as possible and make waterline treatment a routine part of practice management.

Mills: And, if possible, make it as automated or as passive as possible. In my mind, the responsibility falls squarely on the shoulders of the manufacturers of dental equipment. The dentists shouldn't even have to think about this. The dentist should buy a piece of equipment and it should produce safe, clean water without them having to do anything after purchase. That's the ideal. It's probably not realistic now, but that's the ideal.

Porteous: I do believe that data derived from studies conducted in clinical settings is lacking. The manufacturers continue to produce great products that they claim work against all relevant organisms. However, the studies that have been done in clinical settings sometimes prove otherwise.

Mills: I think you're approach is very pragmatic. I was proposing an ideal world. In an ideal world, you wouldn't do anything. The example I've always used as a metaphor of control in automobiles: there's a certain number things you can do, but predominately it's the responsibility of the manufacturer to produce automobiles that don't emit nitric oxide and so forth, and the same thing's true here. Manufacturers have the majority of the obligation, over time, to give us units that don't develop contaminated systems, but that's not the real world today.

Porteous: Maybe it's the manufacturers' initial responsibility, but practitioners do have a certain amount of responsibility to monitor and ensure that the quality of their water is up to standard.

Miller: In my opinion, the best way to approach improving dental unit water quality is to understand the biofilm process. Rather than trying to clean up the water, you have to address the original source of the problem — that's the buildup of biofilm.

For the full discussion visit the PPR Web site at “www.ada.org/goto/ppr.”

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The Editor’s Bottom Line

Steam Sterilizers: All steam sterilizers passed all sterilization tests and the moisture retention test. The prices ranged from $5,020 to $7,655. The highly rated M11 UltraClave, priced at $5,920, has programmable cycles and holds nine pounds; however, it has the largest footprint. The Delta XL, the least expensive sterilizer, has a nine-pound capacity and programmable cycles. The Delta MB17, the most expensive unit at $7,655, has a capacity of 10 pounds in a slightly smaller footprint than the other brands. The STAT JM5000, priced at $6,925, occupies 30 percent less space than its competitors; however, its cassette system has a maximum capacity of only 33 pounds.

Dental Unit Waterline Cleaners: All products except Lines reduced bacterial contamination in dental unit waterlines below the recommended limit of 500 CFU/ml. The product ICX earned the highest rating for both overall clinical impression and ease of use. The continuous-use product ICX incurs the highest yearly cost of $140 (along with the product CitriSil), but cannot be used for shock treatment. The product Lines earned the second-highest rating for clinical impression; however, this product failed to maintain bacterial levels below the recommended limit. Clorox Regular Bleach, the most cost-effective cleaner at $4 a year, earned the lowest overall rating among dentists, who also expressed concerns about equipment corrosion associated with product use. Thirty-nine percent of survey respondents said they did not use a waterline cleaner; many respondents cited their use of filtered or distilled water as a mitigating reason. Remember, the use of distilled or filtered water neither prevents biofilm formation and growth nor maintains bacterial levels below 500 CFU/ml.

Dental Unit Water Quality Monitoring Devices: All products except Aquasafe Water Test Kit identified as unacceptable water samples harboring more than 500 CFU/ml. Aquasafe Water Test Kit failed to report a water sample with 1000 CFU/ml as unacceptable (above the limit of 500 CFU/ml for potable water). It also was the most expensive system at $560 per test. Waterclave Dental Waterline Test Kit, which costs $4.75 per test (based on kit purchase), takes up to 10 days for results; however, it was the most accurate system for measuring bacterial concentrations. Total Aerobic Bacterial/Total Coliform Paddle Tester cost the least at $3.16 per test, and provided the quickest results within 24 to 48 hours. Both Waterclave Dental Waterline Test Kit and Total Aerobic Bacterial/Total Coliform Paddle Tester require refrigeration. HPC Total Count Sampler, which costs $4.46 per test, tended to report lower bacterial growth levels. Also, use of this product with water samples containing more than 300 CFU/ml requires dilution of the water sample.

Your Views

A Note from the ADA President: I had the honor and pleasure of serving as the ADA Board of Trustees liaison to the Council on Scientific Affairs (CSA) in 2002-2003. This was an enormously exciting year for the CSA because we spent much of the year laying the groundwork and building the business plan for a new product to launch that would have a significant impact on our practicing dental community.

The ADA Professional Product Review (PPR) is now the publication of scientifically reviewed products and materials used by dental practices throughout the country. The data for PPR come from research in the ADA laboratories and practical reviews of products by a national team of ADA member volunteers known as the ADA Clinical Evaluators (ACE) Panel. I am so proud of the diligent work of our CSA to ensure that the program was created to be an unbiased, scientifically solid review of materials and products that are critically important to the every day practices our members.

As I have traveled throughout the country this year meeting with our membership, I have heard extremely complimentary reviews of the PPR. There is also significant interest by non-member U.S. dentists and the international dental community looking to access the PPR information. I am truly honored to compliment the work of the ADA and the staff who spend enormous amounts of time and energy working to make this publication a bright star in the Association’s list of significant achievements.

Kathy Roth, DDS
President, American Dental Association

Editor’s comment: We thank Dr. Roth for her comments and especially her ongoing support of our editorial mission. During the Council on Scientific Affairs’ business planning for the Professional Product Review, Dr. Roth was an active member of our Action Teams and provided valuable input on the development of the PPR.

Electric Handpiece Burns: I was interested to see your article on handpiece burns from electric handpieces. In 2002, I was doing a crown prep [sic] on a woman with a very small mouth. She had been anesthetized and was wearing a rubber dam. As we were working, she complained of feeling some pain. We gave her more anesthetic, and she seemed comfortable for the rest of the appointment. When we removed the rubber dam, we were shocked to see that there was a large burned area in the commissure of her mouth. We took pictures each week, and the healing process was horrific.

I had never been warned of the possibility of handpiece burns but did notice after this happened that if I lightly pressed on the back of the handpiece while it was running that it would generate heat.

We returned the handpieces [to the manufacturer], and the patient left my practice (though didn’t sue me). It was more than six weeks before she was healed, and for much of the time, she could only open her mouth a few millimeters before it would split again. It was very painful for her.

Again, I had never heard of the possibility of these handpieces causing burning. Thank you for investigating this.

Patricia Rothwell, DDS –Seattle

Editor’s comment: The Food and Drug Administration reports several complaints on this issue. To minimize the risk of electric handpiece burns, practitioners should strictly adhere to their product’s directions for use, maintenance, servicing, and lubrication. To report an adverse experience with an electric handpiece or other dental equipment or material, contact the FDA’s MedWatch program by phone at 1-800-332-1088 or visit the program’s Web site at “www.fda.gov/medwatch/how”.

Neither the ADA nor any of its subsidiaries has any financial interest in the products evaluated in this publication. In some cases, the ADA may accept the loan of high-cost items for evaluation. Any loaned item is returned to the manufacturer/supplier upon completion of the product evaluation. Featured products are selected from among those marketed in the United States, the primary market for PPR; products marketed solely outside the United States are currently not evaluated. The ADA requires all contributors and consultants to this publication to abide by its policy on conflicts of interest. This publication’s Web site at “www.fda.gov/medwatch/how”.

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