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# Instrument Processing, Work Flow and Sterility Assurance

A Peer-Reviewed Publication
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## Educational Objectives

The overall goal of this article is to provide the reader with information on instrument processing requirements and the methods for instrument processing. Upon completion of this course, the reader will be able to do the following:

1. List and describe the CDC guidelines for instrument processing in the dental office setting
2. List and describe the flow of instrument processing, as well as the considerations involved
3. List and describe the types of sterilizers available for use in the dental office, the use of cassettes during instrument processing, and the considerations involved in selecting these.
4. List and describe the purpose of sterility assurance and the tests required to monitor and document sterility assurance.


## Abstract

Government agencies regulate and make recommendations on instrument processing and occupational safety. There are a number of requirements and necessary steps involved in instrument processing, including preparation, cleaning and packaging of instruments for sterilization. The use of cassettes reduces the risk of exposure injuries for the operator, while simplifying and streamlining the process. There is a variety of instrument sterilizers for dental office settings including steam sterilizers (autoclaves), chemiclaves and dry heat sterilizers. Each has different features, advantages and disadvantages that must be considered when selecting sterilization equipment for your practice. Monitoring sterilization processes for sterility assurance requires the regular use of mechanical, chemical and biological indicators to assure that these processes and the equipment are providing effective sterilization. Sterility assurance monitoring must be documented to show compliance with regulations governing your practice.


## Instrument Processing Requirements

Instrument processing is a critical aspect of patient safety and one of the few areas of dental patient care in which the patient has no direct involvement and is not normally present to observe. Incomplete or inappropriate instrument processing has the potential to cause harm to both patients and health care workers involved in the process. A systematic approach is useful in work processes where standardization is important to achieve a consistent outcome. A system for instrument processing should include, at a minimum:

1. Following existing standards and recommendations
2. Consideration of physical work flow
3. Occupational safety
4. Selection of equipment
5. Necessary supportive materials
6. Quality assurance
7. Instrument inventory management

These elements should be brought together in a system that is safe, repeatable and learnable using step-by-step procedures. This will discourage those shortcuts that can lead to errors in the sterilization process. Several governmental and regulatory agencies provide regulations, guidelines and recommendations related to infection control in healthcare settings.

## Regulatory and Government Agencies

### Occupational Safety and Health Administration

The Occupational Safety and Health Administration (OSHA) is an agency within the U.S. Department of Labor whose charge is to protect the health and safety of working men and women in the United States. Among the many regulations OSHA administers is the Bloodborne Pathogens Rule. This standard is designed to reduce the risk of occupational exposure to bloodborne pathogens. The regulations define how healthcare workers may handle contaminated instruments and waste, as well as how contaminated waste should be disposed of. Instrument processing is not directly addressed in the rule, although certain aspects of the process will trigger some of the standard's requirements. One example is the use of personal protective equipment (PPE) including protective eyewear, surgical masks, gowns and heavy-duty utility gloves, when handling and cleaning used, contaminated instruments.[1]

### U.S. Food and Drug Administration

The Food and Drug Administration (FDA) Medical Device and Radiological Health branch regulates the claims that manufacturers may make regarding the performance of medical devices and certain products used in health care.[2] Some of the devices used in instrument processing that are regulated by the FDA include sterilizers of all types, instrument washer/thermal disinfectors and high-level disinfectants. In order for a manufacturer to sell these devices in the U.S., it must submit data to the FDA supporting the claims it makes and explaining the instructions for use.[3] For example, manufacturers of autoclaves or dry heat sterilizers must meet specific standards for showing that sterilization will be achieved using the cycles identified in their instructions for use.[2]

### Centers for Disease Control and Prevention

Although a government agency, the Centers for Disease Control and Prevention (CDC) is not a regulatory authority. As part of the U.S. Public Health Service, however, the CDC performs many activities. One of these is the development of evidence-based recommendations for infection control. The recommendations for instrument processing have been well addressed in both the Guidelines for Infection Control in Dental Health-Care Settings—2003[4] and the more recent Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008.[5]

Many state dental licensing boards require licensees to adhere to the infection control recommendations of the CDC. Some states incorporate these recommendations by reference,

while other states have specific language for minimum standards for infection control. In addition, some states require a minimum number of hours in infection control continuing education for relicensure. These boards of licensure vary in the specifics of their regulations, and the individual boards need to be consulted to determine the state requirements.

## Protocol Development

A protocol is necessary for instrument processing to ensure that instruments are consistently processed in an appropriate manner for safe and effective infection control. The protocol should provide step-by-step procedures involved in instrument processing in a manner consistent with agency regulations, guidelines and recommendations.

## Preparation

The first step in developing the protocol for instrument processing is to evaluate the manner in which items are used, their ability to withstand the cleaning and sterilization processes, and the availability of adequate resources. These resources include instruments and devices that need processing after patient use, cleaning devices and sterilizers, and the necessary ancillary items such as cassettes; sterilization wrap; pouches; indicators, chemical integrators and biological indicators; and personnel time to complete the process.

### Critical, Semicritical and Noncritical Instruments

For purposes of selecting the appropriate process, the instruments may be divided into three broad categories: critical, semicritical and noncritical (Table 1).

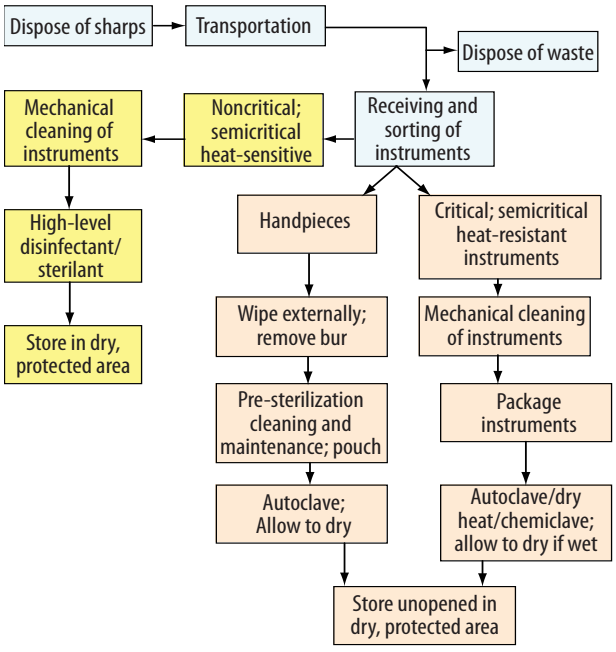
Table 1. Infection-control categories of patient-care instruments

| Category | Definition | Dental Instrument or Item |
|---|---|---|
| Critical | Penetrates soft tissue, contacts bone, enters into or contacts the bloodstream or other normally sterile tissues | Surgical instruments and dental burs, periodontal scalers, scalpel blades |
| Semicritical | Contacts 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 | Dental mouth mirror, amalgam condenser, reusable dental impression trays, dental handpieces* |
| Noncritical | Contacts intact skin | Radiograph head/cone, blood pressure cuff, facebow, pulse oximeter |

*Although dental handpieces are considered semicritical items, they must always be heat-sterilized between uses and not high-level disinfected. If they cannot be heat sterilized, they must be removed from service.
Sources: Guidelines for Infection Control in Dental Health-Care Settings—2003 (CDC); Guideline for disinfection and sterilization in healthcare facilities —2008 (CDC).

In today's dental practice, most items that fall into the critical and semicritical categories either can withstand the heat sterilization process or are available as a single-use disposable (SUD) product. SUD items should never be reprocessed for use on more than one patient.[4,5]

Figure 1. Instrument processing flow




## Use of Cassettes

Instrument cassettes allow procedural sets of instruments to remain intact through all parts of the use, transportation, cleaning, sterilization, and storage processes. Instrument cassettes are a tool for instrument management, providing a means by which to organize, protect and contain instruments (Figure 1). The use of locked instrument cassettes also aids transportation of instruments, reducing the risk of accidental injury to personnel transporting the used instruments as well as reducing the risk of damaging or losing instruments during processing and saving time.[6] The holes in the cassettes permit adequate penetration for cleaning and sterilization. In addition to instrument cassettes, accessory boxes can be used during sterilization. Procedural tubs may be used to organize and store disposables used during dental procedures, including composites, cotton, etc. The use of an instrument cassette does not replace the need for packaging: semicritical and critical instruments should be packaged after cleaning and prior to sterilization.[4]

Figure 2. Cassettes and accessory boxes



## Instrument Processing Area and Work Flow

The instrument processing work flow must follow the CDC guidelines, with the following sequential steps: disposal of sharps; transportation; disposal of single-use disposable instruments and waste; sorting of instruments and handpieces; cleaning; sterilization and storage.[4,5] The instrument processing area should be centrally located and must be designed for this work flow and traffic pattern. The area set aside for cleaning and sterilization of dental instruments should promote a one-directional work flow to avoid the risk of cross-contamination of sterilized items via contact with contaminated items and equipment. It is useful to designate separate areas (spaces) within the sterilization room for receiving, decontamination, cleaning, drying, inspection, packaging, sterilization and storage, to help maintain one-directional flow during instrument processing.

## Transporting

Instruments should be transported from the patient treatment area to the sterilization area after disposable sharps have been placed in an appropriate sharps container. OSHA requires the transport of used sharp instruments in rigid puncture-proof containers with rigid sides and bottom. Handling of contaminated instruments should be minimized during transportation to the instrument processing area. Personnel should wear heavy-duty utility gloves when handling used sharp items during the removal, transport, cleaning and packaging processes, to help prevent accidental puncture injury during these processes.[1,5] Biohazardous waste must be disposed of in an appropriate receptacle in accordance with state and local medical waste regulations.

Figure 3. Use of heavy-duty utility gloves



## Receiving, Sorting and Cleaning

If instruments cannot be cleaned immediately after use, it may be beneficial to use an instrument presoak or enzymatic spray to prevent drying of debris. Handpieces should be wiped externally to remove any debris and the burs removed prior to packaging and sterilization. For all other devices and instruments, cleaning can be carried out using ultrasonic baths and/or instrument washer/disinfectors that hold instrument cassettes or baskets of loose instruments. After cleaning, whether in an ultrasonic bath or instrument washer/disinfector, instruments should be visually inspected for any remaining debris or damage and if necessary cleaned again or, if damage is present, disposed of. If an ultrasonic cleaner was used, the instruments must be rinsed with clean water and must be dry prior to packaging. Hand washing/cleaning of instruments should be avoided and minimized to avoid the risk of exposure to contaminated instruments.

## Preparation and Packaging

Whether the practitioner is using instrument cassettes or sets of loose instruments, items should be packaged in a pouch or wrap made of material intended for the particular type of sterilization process.[5] According to the CDC's Guideline for Disinfection and Sterilization in Healthcare Facilities 2008, wrap or packaging for instruments may consist of "peel-open pouches (e.g., self-sealed or heat-sealed plastic and paper pouches), roll stock or reels (i.e., paper-plastic combinations of tubing designed to allow the user to cut and seal the ends to form a pouch), and sterilization wraps (woven and nonwoven)." The packaging material must allow penetration of the sterilant, prevent contamination during handling, provide an effective barrier to microbial penetration and maintain the sterility of the processed item after sterilization.[7] When loading packages into the sterilizer, correct loading is required for sterilization to occur and packages must remain intact without being pierced or damaged during loading. In accordance with the CDC Guidelines, a chemical indicator should be placed inside each wrapped package. If this indicator cannot be seen from the outside of the package, another indicator (e.g., indicator tape) should be placed on the outside of the package.

## Sterilization

Sterilizing contaminated instruments is an essential component of an effective infection-control program to protect the patient and staff. There is a variety of sterilization methods available for use in reprocessing instruments depending on needs and the type of instruments being processed. In the dental practice setting, the most commonly used and recommended sterilization method is steam (autoclaving). Other options include dry heat sterilizers, and chemiclaves using chemical vapor sterilization.

## Storage

Sterile pouches or wrap will maintain asepsis of instruments for prolonged periods, provided they are not compromised by becoming wet or torn. Studies have indicated that dental instruments remain sterile in packs for prolonged periods, but may show signs of contamination if not handled properly.[8] Therefore, there is no evidence to suggest that packs of dental instruments should be routinely resterilized solely based on the length of time in storage. The event-related shelf-life prac-

tice, as described in the 2008 CDC guideline, recognizes this and the fact that packs will remain sterile unless compromised.

Instruments must only be removed from the sterilizer after completion of the full sterilization cycle and, if wet during sterilization, after the packaging is dry. Storage should be away from sources of moisture and areas subject to excessive dust. Covering packages or storing them in enclosed cabinets or drawers will help maintain their sterility. All of the items in packs that become torn or remaining items in packs that have been opened to remove one or more items in the pack should be reprocessed, beginning with the cleaning step of the process. It is neither necessary nor recommended that sterile packs be routinely resterilized on an arbitrary time schedule.[4,5,8]

## Steam Sterilizers

Pressurization and high temperature are required to produce the saturated steam environment in the sterilizer chamber needed to kill resistant microorganisms. Distilled water is used to generate the steam, thereby preventing mineral buildup in the water reservoir and autoclave chamber. The result is rapid sterilization of packaged (or pouched) items, and rapid and effective penetration of fabrics and sterilization packaging by the sterilant (steam). One disadvantage of autoclaves is the potential over time for corrosion and pitting of metals and damage to materials such as rubbers, plastics and o-rings; this potential can be reduced by closely adhering to the device manufacturer's instructions. Handpieces should be cleaned and prepared for sterilization in accordance with the handpiece manufacturer's instructions and recommendations. To achieve optimal steam sterilization conditions inside the sterilizer chamber, it is necessary to eliminate any air trapped in the chamber and load after the door is closed. Steam sterilizers are classified by the general method used to remove this air.

### Gravity Displacement Autoclaves

Gravity displacement steam sterilizers use the oldest technology and as their name suggests, they rely on the force of gravity to displace the trapped air – steam entering the sterilizer from the top and sides of the chamber displaces the air and forces it out through a drain vent in the base of the chamber. A small amount of trapped air is frequently retained in gravity displacement autoclaves; thus, steam penetration into wrapped loads and lumened devices is not as good as with other types of steam sterilizers, limiting their application. Sterilization cycles for gravity displacement steam sterilizers range from 3 to 30 minutes at 121°C (250°F) to 132°C (270°C).

### Dynamic Air Removal Steam Sterilizers

Dynamic air removal steam sterilizers are the other classification and these sterilizers use either an electronically controlled air valve or a vacuum pump to eliminate the trapped air. The first type of dynamic air removal sterilizer is the Steam Flush Pressure Pulse (SFPP) type which removes the trapped air from the sterilizer chamber and load by opening an electronically controlled valve as required, based on chamber conditions, to create pressure pulses which purge the chamber and load of air. The second type of dynamic air removal sterilizer is the pre/post vacuum type (sometimes referred to as Class B) which uses a vacuum pump to draw the trapped air from the chamber through a series of vacuum and pressure pulses. The vacuum pump is also used to help draw the moisture from the chamber during the drying phase in this type sterilizer. Dynamic air removal steam sterilizers maximize air removal and thus provide better steam penetration into wrapped loads and lumened devices. Thus, these sterilizers are capable of sterilizing a broader range of devices. Sterilization cycles for dynamic air removal steam sterilizers range from 3 to 30 minutes at 121°C (250°F) to 132°C (270°F). One study found a vacuum autoclave offered more reliable sterilization of the internal aspects of dental handpieces than did non-vacuum autoclaves.[9]

The most recent tabletop autoclaves are highly automated and have been designed with a push-button to start the automated cycle as well as offering the option of shorter cycles at a higher temperature or longer cycles at a lower temperature. The total time involved, including heat-up and vent, sterilization and cooling/drying time, ranges from 25 minutes to 75 minutes, depending on the autoclave type and model. Autoclaves with lower height requirements (M3 UltraFast, Midmark) that accept standard instrument cassettes (e.g., Signa-Stat, Hu-Friedy) offer convenience without onerous space requirements. Other autoclaves offer greater capacity and will accept cassettes on racks that can be vertical or horizontal or either, depending on the autoclave and available accessories. The instruments, cassettes, trays and containers that will be used must be considered before purchasing any sterilizer to ensure that the chamber capacity and configuration will meet requirements.

Figure 4. Vertical and horizontal loading of packaged cassettes



## Chemiclaves

Chemiclaves utilize unsaturated chemical vapor for sterilization, typically for 20 minutes at 132°C (270°F). The chemical vapor is produced using a proprietary formaldehyde-and-alcohol formulation that is water-free. Chemiclaves use temperatures similar to autoclaves, with no risk

of instrument corrosion. There is nonetheless still the risk of damage to heat-sensitive plastics, rubbers and o-rings due to exposure to high temperatures. There is also the possibility of exposure to chemicals with use of a chemiclave.

## Dry Heat Sterilizers

Dry heat sterilizers operate at higher temperatures than autoclaves do, and the sterilant (in this case, dry heat) takes longer to penetrate materials, although no drying time is required. Two types are available – forced air and static air. Forced air dry heat sterilizers more effectively transfer heat throughout the chamber to the instruments and therefore have a quicker cycle than static air models do. The most common time-temperature cycles are 170°C (340°F) for 60 minutes, 160°C (320°F) for 120 minutes, and 150°C (300°F) for 150 minutes. Recently, more rapid dry heat sterilizers (COX sterilizers) have become available; these can be operated at 370°F for 6-, 8- or 12-minute cycles, depending upon the instruments and load. While dry heat sterilization is useful for instruments that can be damaged by steam or for materials that are impenetrable and unaffected by steam, the higher temperatures attained are generally considered to be unsuitable for plastic components and mechanical handpieces due to the increased risk of damage to internal components such as o-rings and turbine bearings. In addition, packaging specifically designed for dry heat sterilizers must be used to avoid scorching or melting of the packaging.

Figure 5. Autoclaves




Figure 6. Dry heat sterilizers and chemiclaves



## Work Flow and Space Considerations

The available space within the instrument processing area(s) must be considered when selecting the appropriate equipment. Will the external dimensions and clearance area required for the equipment match the available space? Is plumbing required and can the device be plumbed in? Are there any special electrical requirements? Is the work surface heat- and/or moisture-resistant or resistant to the chemicals used in a chemiclave? Can the work surface support the area and weight of the sterilizer?

Sterilization areas can be segregated, custom-designed or purchased as prefabricated units for a one-directional instrument processing flow. Sterilization casework offers a workflow solution for instrument processing that is prefabricated, efficient and convenient. Depending on the model, the unit may hold one or two tabletop autoclaves of the same size or one standard-size and one tabletop autoclave designed for one cassette load. The surfaces of these units are heat-, chemical- and water-resistant. In addition, some models contain large storage areas for sterilized instruments and separate illuminated areas for contaminated storage (Artizan™ Streamline). Space and configuration of the sterilizer are particularly important if sterilization casework units are used; while within their given space they are optimally designed, there is less flexibility for moving a sterilizer if it is too large for the sterilization area. If selecting a prefabricated instrument processing center, it should also be ascertained that the design is based on current CDC, ADA and OSHA recommendations.

Figure 7. Sterilization casework



## Sterility Assurance

Sterility assurance provides operators with the knowledge that sterilization procedures are effective or that corrective action is required. It should be noted that most failures in sterilization are due to operator error and not to any inherent defect in the sterilization device.[10] In addition to errors associated with cleaning and packaging of items to be sterilized, improper loading of the sterilizer and overloading can result in an increase in heat-up time and can delay complete penetration of the sterilant into the load. The use of instrument cassettes reduces the risk of inadvertently overloading sterilizers. Similarly, lack of separation between packages/cassettes can preclude or delay the sterilant from reaching all areas of all items in the sterilizer. Other operator errors related to the sterilization process include use of incorrect time and temperature for the sterilization cycle, resulting in the continued presence of organisms, incorrect maintenance of the sterilizer, and handling packaging and items that are not yet dry (if using an autoclave or chemiclave).[5] To ensure sterility, mechanical, chemical and biological indicators are required to evaluate the effectiveness of sterilization.[5]

## Mechanical/Digital Monitoring

Mechanical (analog) monitoring involves the use of time, temperature and pressure gauges that can be viewed to verify these parameters. Gauges/displays on sterilizers must be monitored for cycle times, temperature and pressure during sterilization. If any readings are incorrect, this is an indication that the sterilization device may be malfunctioning or that an operator error has occurred. Conversely, correct readings are not conclusive for effective sterilization and are only indicative of occurrences in the sterilizer where the mechanical probe is located. Many current sterilizers have digital readings, which are more reliable than mechanical controls. Many autoclaves now also provide printouts of temperature, the time at the temperature, and pressure measurements during the sterilization cycle; the printout can then be placed in the documentation for sterilization as part of the permanent records.

Figure 8. Digital displays




## Chemical Indicators

Both external and internal chemical indicators are available, in accordance with the Association for the Advancement of Medical Instrumentation (AAMI) guidelines. Chemical indicators consist of heat- or chemical-sensitive ink impregnated on to an indicator strip or tape. In the case of some sterilization pouches, the ink may be embedded on the surface of the pouch itself. External indicators must be used along with internal indicators unless the internal indicator is visible from outside the package. The internal indicator should be placed inside the packaging among the instruments and the external indicator should be placed on the external surface of the packaging. External indicators (Class I and II) and internal indicators (Class III, IV, V) are available.

### *Classes of Chemical Indicators*

**Class I:** (external chemical indicators). These are process indicators. They are intended for use with individual units (such as packs or containers) and indicate that the unit has been exposed to the sterilization process. These indicators distinguish between processed and unprocessed units.

**Class II** These are indicators used for specific tests. The Bowie-Dick or air-removal test is a Class II indicator test used only for testing of dynamic air removal steam sterilizers. This test must be performed daily, within a test pack, in an empty autoclave prior to that day's use of the autoclave, in accordance with AAMI standards.[11] This test is also performed for sterilizer qualification.

**Class III:** Single-variable indicators. These are designed to react to one of the critical variables; intended to indicate exposure to a sterilization process at a stated value of the chosen variable.

**Class IV:** Multi-variable indicators. These are designed to react to two or more of the critical variables in the sterilization process; intended to indicate exposure to a sterilization process at stated values of the chosen variables.

**Class V** (integrating indicator): Internal use indicator that measures all variables for sterilization cycles. Class V indicators are considered adequate for all instruments except implantable devices (including dental implants).

Source: ANSI/AAMI.2006;ST79,A1,A2.

A sixth type of indicator, the Class VI emulating indicator, is an internal cycle verification indicator. This type of indicator is designed to react to all critical variables of the sterilization cycle for the specific sterilization process. External indicators do not indicate if the temperature was achieved for the appropriate length of time nor if the sterilant penetrated the packages. Readings from chemical indicators cannot determine that all microorganisms were killed, only that the sterilant reached that area and that there was no obvious malfunction in the operation of the sterilizer. Failed chemical indicator tests mean that the items that had been processed during that cycle should not be used and must be reprocessed.[11,12]

## Biological Monitoring

Biological monitoring must be conducted at least weekly as well as every time an implant is sterilized, per the CDC guidelines. Many states mandate weekly testing, and the reader should check with the regulations for the state in which he or she practices to obtain up-to-date information on mandated testing and regulations. Biological indicators (BI) test the ability of the sterilization cycle to kill resistant microorganisms in a given sterilizer at a given time, and these offer greater sterility assurance than chemical indicators do. The resistance of microorganisms to sterilization ranges from low (lipids and medium-sized viruses such as hepatitis B and HIV) to high. Other than prions, the most resistant microorganisms are bacterial spores and these are used to test the ability of the sterilization process to kill microorganisms.[13] Since spores are used as BIs, this is also known as the "spore test." The specific spore used depends on the class of sterilizer. For steam autoclaves and chemiclaves, *Geobacillus stearothermophilus* (formerly *Bacillus stearothermophilus*) is used; for dry heat sterilizers, *Bacillus subtilis* is used.

Both a test and a control BI must be used. The control BI is not exposed to the sterilization procedure, with the objective of verifying that the spores were viable and that growth of spores occurred in the absence of exposure to the sterilant (if not, a negative test BI result following sterilization is meaningless). It

is important to follow the manufacturer's instructions on use and temperature settings for the specific spore test being used.

BIs are available as self-contained vials, sealed ampoules and strips impregnated with the resistant spores. Mail-in tests using professional labs provide third-party verification for sterility assurance. In addition, because they microscopically view any positive spore tests these tests can confirm that the problem was a sterilization failure and not contamination of the test during handling. Other ways to provide a higher level of quality assurance, such as the use of a Class V indicator challenge pack with each load, provide immediate verification (as a BI equivalent), which removes the drawback of waiting for up to a week for results (associated with the mailing, laboratory test and report on results with mail-in spore tests). In-house BI tests using self-contained vials remove mailing and turnaround time, and offer results within 24 hours. In-house tests therefore offer the ability to take corrective action quickly, should this be required but do not provide third-party verification. Several in-house rapid result spore tests are available (3M™ Attest™; Ethox; Pro-Test; SporeCheck™, Hu-Friedy).

Figure 9. Biological indicator kit




A spore test kit provides self-contained ampoules, a crusher that removes the vial's inner barrier between the spores and the culture medium, and a compact tabletop incubator offers convenience (SporeCheck™, Hu-Friedy). Prior to placing the test vial in the chamber, the sterilizer number, load number and processing date must be written on the vial label. After the test vial is placed in an instrument tray, peel pouch or AAMI challenge pack, it should be placed in the sterilizer together with the instruments to be sterilized, in the spot where sterilization would be hardest to achieve (typically near the door on the bottom shelf or over the drain area). The outside of the vial also has an external chemical indicator strip that turns brown if mechanical parameters were met.

Figure 10. Placing the BI in the sterilizer



Assuming this strip is brown, after 10 minutes' cooling time has elapsed, both the test and the control vials are crushed and placed in the incubator for 24 hours. The operator can then view the color of the liquid in the test and the control vials – if the culture medium is still purple while the control test's culture medium is yellow, the test is negative, indicating sterilization occurred. If the color is yellow, the test is a fail (growth of spores has occurred during incubation).

Table 2. Test results

| Test BI | Control BI | Pass/Fail |
|---|---|---|
|  |  | Pass |
|  |  | Fail |
|  |  | Fail (inconclusive) |

The steps using these tests are simple, and the results must be noted in the record book for documentation. A negative biologic indicator test gives a high level of assurance that the instruments were properly sterilized.

Any failed test BIs and all control test BIs must be autoclaved at 250°F/121°C for at least 30 minutes prior to disposal. If a BI (spore) test is positive while the mechanical and chemical indicators suggested that the sterilizer was working properly, the test should be repeated using the same cycle before the sterilizer is used again, and any implantable devices must be pulled and (re)sterilized as well as other instruments, which should be repackaged for sterilization. If the repeat test produces a negative test result, the sterilizer can be used again. If it is still positive, the sterilizer must be seen by a sterilizer maintenance specialist. Chemical and biological indicator tests must then be run in three consecutive empty autoclave cycles and produce negative results before the sterilizer is used again. In addition, if using a dynamic air removal steam sterilizer, the Bowie-Dick test (Class II chemical indicator) must also be run in the three consecutive cycles.[14]

## Documentation

Documentation must be maintained for all sterilizers and sterilization procedures and should be initialed by the operator. Maintenance records for the sterilizer should include the sterilizer's serial and model numbers, dates and details for

maintenance/servicing, and sterilization cycles immediately following maintenance/servicing. All sterilization cycles must be fully recorded, and the time, date and sterilizer used must be noted on external packaging prior to sterilization and storage of the package. Against each sterilization cycle in the record, the operator should record charts, note gauges and attach printouts demonstrating mechanical monitoring of appropriate time, temperature and pressure. All spore test results must be thoroughly documented for the specific sterilizer, with date, time and results noted.

## Inventory Management

Many factors should be taken into account when determining the right inventory mix to serve the needs of an individual practice. Considerations include the nature and number of procedures, the number and type of practitioners, the hours and days of operation, and the time required to process used items. Inadequate inventory may inhibit the ability to provide care in a timely manner and may add pressure on staff responsible for the processing of instruments.

Management of inventory can be streamlined by maintaining sets of instruments in pouches or cassettes assembled by procedure. This makes it easier for personnel to quickly assess the availability of instruments needed, based on appointment types scheduled. It is also recommended to store enough sterilized instrument sets for an entire day, so that procedures can still be performed and patient flow is unaffected if equipment associated with instrument processing is unavailable due to malfunction or repair.

## Summary

Instrument processing requires adherence to established principles and guidelines in order to achieve a consistent outcome. Office protocols, appropriate equipment, adequate inventory and training of personnel involved in the process are important to ensure proper instrument asepsis. Instrument sterilization is mandatory for all critical instruments, handpieces, and heat-resistant semicritical instruments. In order to provide assurance that sterilizers are achieving their objectives and killing microorganisms, a sterility assurance program must be conducted and documented at specified intervals, and instruments must be reprocessed if indicated by the test results.

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## Author Profile


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Eve Cuny is the Director of Environmental Health and Safety and Assistant Professor in the Department of Pathology and Medicine at the University of the Pacific School of Dentistry. She has consulted with the Centers for Disease Control and Prevention, American Dental Association, California OSHA, California Dental Board and other agencies on issues related to safety and infection control in dentistry. She has presented over 100 continuing education programs throughout the world and published numerous articles and textbooks. Ms. Cuny is also founder and managing partner of Eve Cuny Consultants, LLC, a consulting group specializing in product evaluation, professional writing and other services to the dental profession and industry.

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Dr. Fiona M. Collins has authored and presented CE courses to dental professionals and students in the US and internationally, and has worked in the United States, Middle East, The Netherlands and United Kingdom. She is a past member of the Academy of General Dentistry Foundation Strategy Board, and has been a member of the British Dental Association, Dutch Dental Association, and the International Association for Dental Research. Dr. Collins has been an active consultant in the dental industry for several years, and is a member of the American Dental Association and the Organization for Asepsis and Safety Procedures.


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## Questions

1. A systematic approach is useful in work processes where standardization is important to achieve a consistent outcome.
   a. True
   b. False

2. The charge of the Occupational Safety and Health Administration (OSHA) is to protect the health and safety of _____.
   a. patients
   b. working men and women in the United States
   c. working men and women globally
   d. all of the above

3. The Bloodborne Pathogens Rule is designed to reduce the risk of _____.
   a. occupational exposure to bloodborne pathogens
   b. occupational exposure to airborne pathogens
   c. a and b
   d. none of the above

4. The FDA Medical Device and Radiological Health branch regulates the claims that manufacturers may make regarding the performance of medical devices and certain products used in health care.
   a. True
   b. False

5. Many state dental licensing boards require licensees to adhere to the infection control recommendations of the CDC.
   a. True
   b. False

6. A protocol is necessary for instrument processing to ensure that instruments are consistently processed in an appropriate manner for safe and effective infection control.
   a. True
   b. False

7. Critical instruments _____.
   a. only contact intact skin
   b. only contact mucous membranes or skin
   c. penetrate soft tissue, contact bone, enter into or contact the bloodstream or other normally sterile tissues
   d. none of the above

8. Handpieces are _____ devices, and must be _____.
   a. critical; cold sterilized
   b. semicritical; cold sterilized
   c. semicritical; heat sterilized
   d. critical; heat sterilized

9. Instrument cassettes allow procedural sets of instruments to remain intact through all parts of the use, transportation, cleaning, sterilization, and storage processes.
   a. True
   b. False

10. The use of locked instrument cassettes _____.
    a. aids transportation of instruments
    b. reduces the risk of accidental injury to personnel transporting used instruments
    c. reduces the risk of damaging or losing instruments during processing and saves time
    d. all of the above

11. The use of an instrument cassette replaces the need for packaging.
    a. True
    b. False

12. The instrument processing work flow must follow the CDC guidelines and it is useful to designate separate areas for each step.
    a. True
    b. False

13. OSHA requires the transport of used sharp instruments in rigid puncture-proof containers with rigid sides and bottom.
    a. True
    b. False

14. Personnel should wear _____ when handling used sharp items.
    a. sterile surgical gloves
    b. nonsterile latex gloves
    c. heavy-duty utility gloves
    d. none of the above

15. For all instruments and devices other than handpieces, cleaning can be carried out using _____.
    a. ultrasonic baths
    b. instrument washer/disinfectors
    c. dishwashers
    d. a or b

16. Items for sterilization should be packaged in a pouch or wrap made of material intended for the particular type of sterilization process.
    a. True
    b. False

17. Biological monitoring must be conducted at least weekly as well as every time an implant is sterilized.
    a. True
    b. False

18. Sterile pouches or wrap will maintain asepsis of instruments for prolonged periods, provided they are not compromised by becoming wet or torn, and they should be stored in a dry, protected area.
    a. True
    b. False

19. Sterilization areas can be segregated, custom-designed or purchased as prefabricated sterilization casework for a one-directional instrument processing flow.
    a. True
    b. False

20. Gravity displacement steam sterilizers _____.
    a. rely on the force of gravity to displace the trapped air
    b. result in less steam penetration in lumened devices than other types of steam sterilizers
    c. operate at cycles ranging from 3 to 30 minutes at 121°C (250°F) to 132°C (270°C)
    d. all of the above

21. Dynamic air removal steam sterilizers use _____ to eliminate trapped air.
    a. a vacuum pump
    b. a mechanically controlled air valve
    c. an electronically controlled air valve
    d. a or c

22. Steam Flush Pressure Pulse sterilizers remove the trapped air from sterilizer chambers and loads by _____.
    a. opening an electronically controlled valve as required
    b. creating pressure pulses which purge the chamber and load of air
    c. opening a mechanically controlled valve as required
    d. a and b

23. Documentation must be maintained for all sterilizers and sterilization procedures and should be initialed by the operator.
    a. True
    b. False

24. Chemiclaves utilize unsaturated chemical vapor for sterilization, typically for 20 minutes at 132°C (270°F) and dry heat sterilizers utilize dry, heated air.
    a. True
    b. False

25. Chemical indicators consist of heat- or chemical-sensitive ink impregnated on to an indicator strip or tape.
    a. True
    b. False

26. Operator errors during instrument processing include _____.
    a. improper loading and overloading of the sterilizer
    b. lack of separation between packages/cassettes
    c. use of incorrect time and temperature for the sterilization cycle
    d. all of the above

27. External indicators must be used along with internal indicators unless the internal indicator is visible from outside the package.
    a. True
    b. False

28. Class II indicator tests (Bowie-Dick or air-removal tests) _____.
    a. are only used for dynamic air removal steam sterilizers
    b. must be performed at the beginning of each day in an empty sterilizer
    c. are used for sterilization qualification
    d. all of the above

29. Class V integrating indicators measure all parameters for sterilization cycles and are considered adequate for all instruments except implantable devices.
    a. True
    b. False

30. Biological indicator tests _____.
    a. are also known as spore tests
    b. give a high level of assurance that the instruments were properly sterilized if the test is negative.
    c. are required with all sterilizers
    d. all of the above

ANSWER SHEET

# Instrument Processing, Work Flow and Sterility Assurance

Name: Title: Specialty:

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Requirements for successful completion of the course and to obtain dental continuing education credits: 1) Read the entire course. 2) Complete all information above. 3) Complete answer sheets in either pen or pencil. 4) Mark only one answer for each question. 5) A score of 70% on this test will earn you 4 CE credits. 6) Complete the Course Evaluation below. 7) Make check payable to PennWell Corp. **For Questions Call 216.398.7822**

## Educational Objectives

1. List and describe the CDC guidelines for instrument processing in the dental office setting
2. List and describe the flow of instrument processing, as well as the considerations involved
3. List and describe the types of sterilizers available for use in the dental office, the use of cassettes during instrument processing, and the considerations involved in selecting these.
4. List and describe the purpose of sterility assurance and the tests required to monitor and document sterility assurance.

## Course Evaluation

Please evaluate this course by responding to the following statements, using a scale of Excellent = 5 to Poor = 0.

1. Were the individual course objectives met? Objective #1: Yes No Objective #3: Yes No
   Objective #2: Yes No Objective #4: Yes No
2. To what extent were the course objectives accomplished overall? 5 4 3 2 1 0
3. Please rate your personal mastery of the course objectives. 5 4 3 2 1 0
4. How would you rate the objectives and educational methods? 5 4 3 2 1 0
5. How do you rate the author's grasp of the topic? 5 4 3 2 1 0
6. Please rate the instructor's effectiveness. 5 4 3 2 1 0
7. Was the overall administration of the course effective? 5 4 3 2 1 0
8. Do you feel that the references were adequate? Yes No
9. Would you participate in a similar program on a different topic? Yes No
10. If any of the continuing education questions were unclear or ambiguous, please list them.

    _____

11. Was there any subject matter you found confusing? Please describe.

    _____

    _____

12. What additional continuing dental education topics would you like to see?

    _____

    _____

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| 13. | Ⓐ | Ⓑ | Ⓒ | Ⓓ | 28. | Ⓐ | Ⓑ | Ⓒ | Ⓓ |
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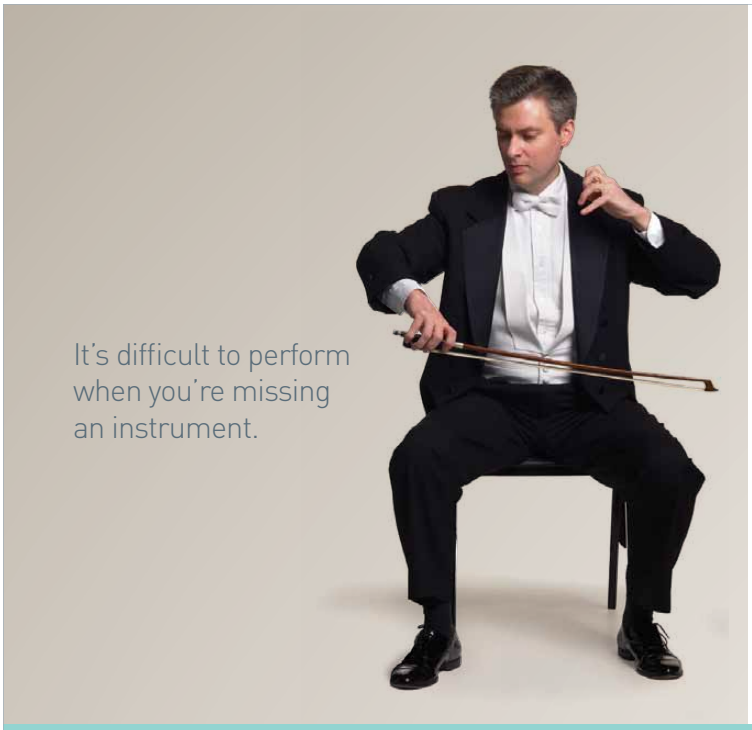




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