ASSEMBLY OF SPECIALTY DEVICES

Glass Syringes: When glass syringes are being processed, the barrel should be removed and placed side by side with the syringe; the barrel and syringe should be separated with 4x4 nonsterile radiopaque gauze if the syringe will be used in the OR. (If the gauze is not radiopaque, it cannot be detected if inadvertently left in the patient.)

NOTE: Only nonsterile gauze products that have been provided with sterilization instructions should be used.

Procedure Needles: The stylette should be removed. Whether the lumen should be flushed depends on the manufacturer’s instructions (see “Devices with Lumens” below). Procedure needles should be packaged so as to prevent the needle from puncturing the packaging and/or injuring personnel. Most facilities today have discontinued the use of reusable procedure needles because of the risk of puncture injuries to reprocessing personnel.

Devices with Lumens: Unless recommended by the manufacturer, devices with lumens (e.g., needles and catheters) need not be flushed with water before prevacuum steam sterilization. If the manufacturer does recommend flushing of the device (which might be the case if a gravity-displacement cycle is to be used), distilled or deionized water should be used and sterilization should follow immediately after packaging. (Regular tap water, which can contain pyrogens, should not be used.) The distilled or deionized water will become steam as it heats during the sterilization cycle and help sterilize the inside of the lumen. When a bottle of sterile distilled water is used, it should be labeled with the date it was opened. Any unused water should be discarded 24 hours after the bottle is opened. If the sterile water is poured into a bowl, the bowl should be kept covered to prevent contaminants from entering the water.

Lumens should always be checked for cleanliness and blockages. Small lumened devices (e.g., Frazier suction catheters) can be flushed with water to verify that the water flows through. A cotton-tipped applicator or a non-linting pipe cleaner, moistened with sterile distilled water, should be passed through the lumen; care should be taken to rub the walls. The applicator or non-linting pipe cleaner should not show any evidence of soil after it is removed (Figure 8-56). If soil is seen, the instrument should be returned to the decontamination area for recleaning. Some pipe cleaners and cotton-tipped applicators leave residual behind (Figure 8-57). Non-linting pipe cleaners are now commercially available.
Small lumens can now be inspected with devices designed for this purpose. One type consists of a distal tip composed of a light source and camera lens at the end of a 50-centimeter flexible shaft (Figure 8-58). This inspection device is designed for instruments with lumens 3 mm or larger in diameter. Integral software allows viewing and recording on most computers.
**Multi-part Instruments:** Instruments with removable parts must be disassembled before being placed in trays unless the manufacturer’s instructions specify otherwise. If the instrument is to remain disassembled, all of the parts must be present and should be listed on the count sheet (i.e., the instrument name should be given, followed by the number of pieces). If the instructions of the instrument manufacturer indicate that the instrument can be reassembled for sterilization, care should be taken to reassemble it correctly.

**Complex Instruments:** Trays containing more than one complex instrument should be biologically tested to ensure that proper sterilization conditions occur inside the tray. Chapter 10 discusses how to perform product testing to determine the effectiveness of both sterilization and drying.

**Eye Instruments:** As discussed in Chapter 5, residues on eye instruments can cause Toxic Anterior Segment Syndrome (TASS). The American Society of Cataract and Refractive Surgery has recommended the use of sterile deionized or distilled water for the rinsing of eye instruments prior to sterilization. Eye instruments are delicate and must be handled carefully. The tips of the instruments should be inspected. Because they are small and of delicate design, such instruments should be inspected using a microscope. Eye instruments should not be placed on top of each other in the tray, and the tips should not protrude through the basket.

**Dental Instruments:** The CDC and the American Dental Association (ADA) have categorized dental instruments as critical, semicritical, or noncritical devices, depending on their use. Critical dental instruments include any devices that penetrate oral soft tissue or bone (e.g., extraction forceps, scalpel blades, bone chisels, periodontal scalers, and surgical burs). Semicritical dental instruments, such as amalgam condensers and air or water syringes, are not intended to penetrate oral soft tissue or bone.

![Figure 8-59 — Various dental instruments](image)

Dental instruments should be inspected for cleanliness and functionality by means of a lighted magnifying lamp, then assembled into sets or trays and wrapped, packaged, or placed into a container system for sterilization. Many dental instruments have sharp and very delicate tips, so much care should be taken when processing them. Hinged instruments should be processed in the open and unlocked position.
The complex miniature architecture of dental burs and endodontic files makes pre-cleaning and sterilization very difficult. It is essential to use a lighted magnifier when checking and inspecting these items so that debris left after the decontamination process can be detected. Reusable dental burs and endodontic files, as packaged by the manufacturer, are not sterile and should therefore be cleaned/decontaminated and sterilized before use. (Some burs and files are single-use; check the manufacturer’s IFU before reprocessing them.) Most endodontic instruments as supplied from the manufacturer have been found to have metallic spurs and debris on their surfaces. In some cases, even epithelial cells have been found on new, unused files. Furthermore, the manufacturing process produces milling marks and metal debris, and dentine fragments appear to adhere to deposits of carbon and sulfur resulting from the decomposition and oxidation of the lubricating oil used during machining. (Segall, et al., 1877; Zmener and Spielberg, 1995; Marsicovetere, et al., 1996; Johnson, et al., 1997; Linsuwanont, 2002) The manufacturer’s IFU must be followed to ensure effective cleaning.

Proper cleaning of rotating instruments (e.g., dental handpieces) is essential before sterilization. If debris remains inside of a handpiece, it can cause the instrument to fail; debris will also hamper sterilization. Proper care can result in longer handpiece life, reduced repair cost, less frustration, and the elimination of costly downtime. See Figures 8-60 and 8-61.

Figure 8-60 — Microscopic view of debris on a dental bur after cleaning

Figure 8-61 — Damage to dental handpiece because of improper cleaning

The following figures show various types of dental burs, endodontic files, and dental handpieces.
The dental instrument manufacturer’s instructions for packaging and sterilization should always be followed. Steam sterilization after each use is usually recommended for heat-tolerant instruments. Dental handpieces and other devices that are used in a patient’s mouth and are
attached to air lines and water lines can be contaminated internally with patient tissue and should be thoroughly cleaned and sterilized after each use. Handpieces that cannot be sterilized should not be used. Carbon steel items, such as burs, hand-held instruments, the cutting edges of orthodontic instruments, and the grasping surfaces of forceps, are prone to rusting and dulling, so they should be carefully inspected after each use.

Failure to comply with the handpiece manufacturer’s instructions for lubrication can cause the oil to gum up inside the turbine and other moving parts. Some low-speed attachments disassemble into multiple parts for proper lubrication. (http://www.medidenta.com/handpiece-maintenance-sterilization-ezp-39.html) If available, an automated dental handpiece cleaning/lubrication system, which standardizes cleaning and ensures proper lubrication of the handpiece, should be used (see Chapter 5). The individual handpiece manufacturer’s IFU should be followed.

Sterilization methods that can be used for heat-stable critical and semicritical dental instruments include steam sterilization, chemical (formaldehyde) vapor sterilization, and dry heat sterilization. All three sterilization processes can damage some dental instruments, including handpieces, which is why compliance with the manufacturer’s IFU is so important.

Critical and semicritical instruments to be stored should be wrapped or placed in containment devices (e.g., cassettes or organizing trays) designed to maintain sterility during storage.

Laryngoscope Handles and Blades: After they are cleaned according to the manufacturer’s IFU, there are several options for processing laryngoscope handles and blades. Many laryngoscope blades can be high-level-disinfected. If high-level disinfection is used (check the manufacturer’s IFU for compatible chemicals), the blade must be protected from recontamination after processing. One way of accomplishing this is to place the blade in a zip-lock bag and then apply a “Clean Not Sterile” label to the top of the bag (Figure 8-65). (Make sure that you clean your hands first.) The label will be damaged if anyone opens the bag. At some facilities, laryngoscope blades are sterilized, which is acceptable but not necessary (CDC, 2003).

![Figure 8-65 — Laryngoscope blade in zip-lock bag with “clean not sterile” label](image)

The Joint Commission has advised that laryngoscope blades should be packaged and stored in some way to prevent recontamination (Joint Commission, 2013). Examples of noncompliance include unwrapped blades in an anesthesia drawer, unwrapped blades on top of a code cart, and handles that are not processed after each use.
After cleaning and high-level disinfection, laryngoscope blades should not be placed in a paper–
plastic pouch for storage. Paper–plastic pouches should only be used if the blades will be
sterilized (otherwise, it could be wrongly assumed that the blades are sterile).

Laryngoscope handles are considered contaminated after use and must be processed before
use on the next patient. Many manufacturers suggest using a high-level disinfection or
sterilization process to decontaminate handles, but recommendations vary according to the
handle manufacturer. As for all medical devices, the manufacturer's IFU must be followed. It
should be noted that state regulations might require additional processing. Once cleaned and
disinfecting or sterilized, the handles should be packaged (e.g., in a zip lock bag). The package
should be labeled “Clean Not Sterile” or with similar wording to advise the end user that the
handle has been reprocessed.

SEPARATION OF INSTRUMENTS INSIDE SETS

Items that need to be separated in sets should be placed in absorbent, non-packaging material
such as lint-free surgical towels or autoclavable bags or 100% medical-grade paper envelopes
or bags (not paper–plastic pouches). Other products on the market today, such as pouch rolls,
can also be used to keep instruments separated within sets (pouch rolls are not paper–plastic
pouches). Some manufacturers offer small containment devices that can be used inside
wrapped sets or rigid containers (Figure 8-66). It is important to obtain the manufacturer's
instructions and to verify that the product has been validated for use inside a wrapped set or
rigid container and for the sterilization technology to be used. Follow the manufacturer’s IFU for
sterilization cycles and placement inside the set (e.g., rolled up or flat). Regardless of the type of
material used to separate instruments inside a wrapped set or container, a chemical indicator
should be placed inside the package.

Figure 8-66 — Small containment device (2.75 x 2.75 x 1.18 inches)

Paper–plastic (peel) pouches should not be placed inside an instrument tray/set, whether the
tray/set is wrapped or in a rigid container. To ensure adequate contact with the sterilant, they
must always stand on edge, paper to plastic, which cannot be accomplished in a tray or set. In
addition, one type of packaging material should never be placed inside another type of
packaging material (e.g., forceps should not be separated by wrapping them in paper wrap and
then placing them inside a rigid container or wrapped set). This process exceeds the capability
of the packaging material, as determined by product testing. In addition, the manufacturer of the
outside packaging will not have validated the packaging material to be used with another
packaging material inside. See Figure 8-67 for an example of the improper use of packaging
materials inside a rigid container.
CHEMICAL INDICATORS

A Type 4 or higher CI should be placed inside every package to be sterilized. For packages that permit visualization of internal chemical indicators (e.g., paper–plastic pouches), an external chemical indicator (e.g., tape) is not required; however, many facilities do affix a piece of tape to the package to label it. For wrapped sets (including organizing trays), the CI should be placed in the center of the set or pack, where sterilant penetration is the most difficult to achieve. (ANSI/AAMI ST77 defines an organizing tray as “a metal or plastic containment device that organizes and protects instruments and components in specified locations within the device and that is usually wrapped with an approved wrapping material.”) “This location might or might not be the center of the package, tray, or containment device” (ANSI/AAMI ST79). For a rigid sterilization container system, the container manufacturer should be consulted for the recommended locations for chemical indicators. If the container manufacturer does not provide recommendations, the following instructions should be adhered to: Two CIs should be placed in opposite corners of the inside basket. For multi-level sets, a CI should be placed on each level. Whenever instruments are separated inside a set (e.g., placed in an organizing basket, autoclaveable bag, or surgical towel), a CI should be placed inside the immediate container. See Figures 8-68 and 8-69.
A CI should be placed in each paper–plastic pouch (unless the pouch has an embedded indicator as part of the packaging). It should be positioned in such a way that the post-sterilization result of the chemical indicator can be seen (e.g., it should be facing up). For larger packs, a CI should be selected that is long enough (some have an extender piece on them) that the end user can easily locate the CI inside the packs.

See Chapter 10 for additional information on chemical indicators.

TEXTILE PACKS

Most healthcare facilities have changed from constructing reusable textile packs in-house to purchasing commercially available disposable packs. However, some facilities are returning to the use of reusable surgical textiles (linens) as a “green” project (to save the environment). If textile packs are being prepared in the preparation area, there should be a separate enclosed space (separate from the remainder of the preparation and packaging area). The air flow should be of a down-draft type, and the number of air exchanges per hour should be sufficient to minimize lint particles in the air (ANSI/AAMI ST79). There should be sufficient space for clean textile storage (both before and after assembly into packs), an illuminated inspection table, and patching equipment. For additional information, see AAMI’s recommended practice, Reprocessing of Reusable Textiles in Health Care Facilities (ANSI/AAMI ST65).

For reusable textiles, there are strict pack construction criteria to ensure that sterilization can take place. Textile packs should be no larger than 12 inches x 12 inches x 20 inches (30.5 cm x 30.5 cm x 51 cm), weigh no more than 12 pounds (5.5 kg), and have a maximum density of 7.2 pounds (3.3 kg) per cubic foot. Before being assembled into a pack, textiles should be inspected on a lighted work table for holes and tears. Any holes found must be patched on both sides of the textile with heat-sealed patches. Patches do not permit penetration of the sterilant, so they should not be placed close together in the same area.

The overall quality of the textile should be evaluated each time it is processed. Most textiles today have a grid on the material to document the number of times the textile has been processed. It is important to mark this grid each time and to verify that the specified number of processings has not been exceeded (Figure 8-70). It should be noted that a textile might not withstand the total number of expected processings. The number and location of patches, among other factors, should be evaluated.
All textiles must be delinted. Lint from any source is problematic for the operating room. Lint in the environment is a source of potential infection. Once airborne, lint can settle on contaminated surfaces and then become airborne again, settling on the sterile field and in the surgical incision and contaminating the tissue on which it settles. Lint can also clog OR ventilation filters, reducing their effectiveness. (Manz, et al., 2006) The use of terry cloth towels in SPD should be discontinued. Delinting should be performed in a separate, controlled area with proper ventilation (10 air exchanges per hour under positive pressure [ANSI/AAMI ST79]).

Packs should be assembled so that the first item to be used is on top. The contents and their order in the textile pack should be defined by the using department. All textiles should be fan-folded to facilitate air removal, sterilization, and aseptic presentation. A Type 4 or higher CI should be placed in the middle of the pack; the tab of the CI should be visible so that the end user can easily remove it for inspection before using the textiles in the pack.

As previously stated, manufacturers’ IFUs for sterilization of all woven textiles should be obtained and followed.
BASIN SETS

Basin sets are prepared with non-linting absorbent material between basins and all other contents (e.g., emesis basins, paint cups) to help steam pass between the items (Figure 8-72); this is referred to as “wicking.” (Steam cannot penetrate adequately if metal basins are nested directly in other metal basins.) All basins in a set should face the same direction (upward) and be positioned on the sterilizer rack so that the water can run out. A CI should be placed in the middle of the basin set. For a double basin set (two large basins with components), an additional CI should be placed in the bottom basin to help verify that steam reached this surface during the sterilization process. The diameters of the two basins should differ by at least 1 inch (2.5 cm) to create a space for air to be removed and steam to enter. If the two basins have the same diameter, several clean, non-linting, folded surgical towels should be placed inside the bottom basin to elevate the top basin. Wrapped basin sets should not weigh more than 7 pounds (3.2 kg). Small items such as medicine glasses should not be placed inside basin sets unless they can be oriented to ensure drainage of condensate. Metal light handles should be positioned with the handles (long end) positioned into the basin set to facilitate condensate drainage.

Figure 8-72 — Absorbent material between basins

QUALITY ASSURANCE

There should be a quality assurance process for preparation of trays and devices. Any complaints from the user departments should be followed up and feedback given in writing. To facilitate the tracking of quality issues, all similar trays should be numbered (e.g., Major Tray #1, #2, #3, and so on) so that problems can be tracked to the specific tray or device. All baskets should have ID tags; any that are missing should be replaced. Some facilities have a Quality Assurance report form that end users (e.g., OR personnel) can complete to report quality issues. Such a process can identify SPD education and training issues (e.g., soiled instruments in sets, incorrect instruments in sets, broken and/or damaged instruments).

SUMMARY

It is important that SPD personnel understand that strict adherence to the physical environmental conditions in the preparation and packaging area must be maintained and that any deviations must be reported immediately. After items have been cleaned and inspected, they must be packaged in such a way that they can be sterilized effectively and remain sterile until used. In this chapter, the packaging materials that are available for use for the various types of sterilization have been discussed. Wrapping methods and other preparation techniques
have also been reviewed. It is also important that SPD technicians understand the proper organization of instrument sets and the preparation of basin sets and textile packs.

REFERENCES AND SUGGESTED READING


Please click on the link below to go to the quiz.

[https://www.spdceus.com/modules/sixth/ttech/module_17_20_quiz.htm](https://www.spdceus.com/modules/sixth/ttech/module_17_20_quiz.htm)