

## Sterilization - Packaging and Storage

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### Wet Packages (9/10) **UPDATED** (2/16)

**Question:** Occasionally packages are still wet when we take them out of the sterilizer. Can we put them on a rack on the counter top to dry so we can begin to sterilize another load of instruments?

**Answer:** No. It is critical to allow packages to dry and cool inside the sterilizer chamber to maintain sterility. Handling a wet package increases the chances of contaminating the contents. Packs should not be touched until they are cool and dry because hot packs act as wicks, absorbing moisture, and hence, bacteria from hands and the environment (e.g., counter tops). Also, wet packs can tear easily. Manufacturers usually address “wet packs” in the troubleshooting section of their instruction manuals. In general, if a vacuum drying cycle is not available, such as with a pre/post vacuum autoclave, other methods for drying packs include using an automatic open-door drying cycle or having the sterilizer pull in fresh air through filters. If these options are not available, it may be necessary to manually open the sterilizer door to allow moisture to escape. Cool down period begins within the sterilizer chamber to minimize condensation. The cool down process can take up to two hours depending on the type of sterilizer, time being sterilized, the temperature and humidity of the ambient environment. If you are having a problem with wet packs and cannot resolve the issue after consulting the sterilizer instruction manual, you should contact the manufacturer for assistance.



### References

- Association for the Advancement of Medical Instrumentation, American National Standards Institute. Comprehensive guide to steam sterilization and sterility assurance in health care facilities. ANSI/AAMI ST79:2010/A12010/A22011/A32012/A42013. Arlington, VA: Association for the Advancement of Medical Instrumentation, Consolidated Text 2014.
- CDC. Guidelines for infection control in dental health-care settings – 2003. MMWR 2003; 52(No. RR-17):1–66.
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- Miller CH, Palenik CJ. Instrument Processing. In: Miller CH, Palenik DJ, eds. *Infection Control and Management of Hazardous Materials for the Dental Team*, 4<sup>th</sup> ed St. Louis: Mosby: 2009:135–169.

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### Packaging Material with a Built-In Internal Indicator (2/10) **UPDATED** (2/16)

**Question:** Many paper peel pouches have a built-in internal chemical indicator (CI). Is it true that we don't have to place an additional internal CI strip inside the package before sterilization.

**Answer:** Traditionally, plastic/paper peel pouches only had built-in external chemical indicators (CIs) and since it is required to use a CI inside every package being sterilized, you had to place an additional CI strip inside the package amongst the instruments. According to national standards paper peel pouches with built-in internal chemicals (CI) do not require an additional CI strip. However, USAF dental clinics will use an additional internal CI strip when using peel pouches with built-in internal CIs. The built-in internal CIs are small and can be easily missed when they have not properly changed. For this reason and to heighten patient safety, Air Force dental clinics will use an additional internal CI (a Class 5/integrator) in all packages, including peel pouches with built-in internal chemical indicators (CIs).



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### Sealing Sterilization Wraps with External Indicator Tape (12/08) **UPDATED** (2/16)

**Question:** When using external chemical indicator (CI) tape ("autoclave" tape) to seal the wrapping on cassettes how much should we use—is there a requirement to wrap the tape all the way around the cassette or is it acceptable to use just enough to seal the wrap shut?

**Answer:** The new Air Force Dental initiative is to have CI tape visible on all sides of a wrapped package. Wrapping the tape around the entire package adds a little more reinforcement to protect the package, but there is no requirement to tape completely around the package. External CIs such as "autoclave tape" are applied to the outside of a package or wrapping material and are primarily used to identify packages that have been processed through a heat sterilizer, thus preventing the accidental use of non-sterile items. Chemical Indicator (CI) tape commonly looks like masking tape and has fine lines throughout the tape that darken when a certain temperature is reached. External CIs do not guarantee that sterilization has been achieved or even that a complete sterilization cycle has occurred. Some external CIs change color long before proper sterilization conditions are even met. The CI must be appropriate for the sterilization process being used (e.g., steam autoclave, dry heat, chemiclave).

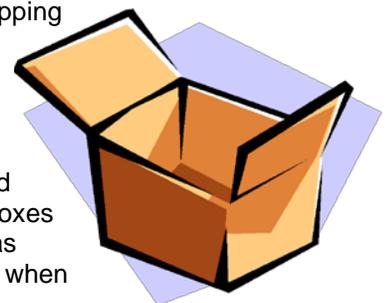


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### Cardboard Shipping Boxes (12/07) **UPDATED** (2/16)

**Question:** We're running out of space on the shelves in supply. We are now stacking the shipping boxes with extra supplies in the back of the room. Is there a policy on having cardboard shipping boxes in the dental clinic?

**Answer:** According to the *USAF Guidelines for Infection Control in Dentistry* shipping cartons cannot be used to dispense sterile or clean patient treatment items in dental operatories, laboratories, instrument processing, or supply areas. External shipping cartons/boxes are considered to be "dirty" because they have been exposed to unknown and potentially high microbial contamination. Also, cardboard shipping boxes serve as generators and reservoirs for dust and can potentially house vectors such as roaches. Interior boxes may be used to store supply items, but need to be discarded when the last item is used and not "reused" to store other items.



**References**

- Air Force Instruction 44-108, Infection Control Program (2014 edition). Available at [www.e-publishing.af.mil/](http://www.e-publishing.af.mil/). Accessed January 2016.
- Association for the Advancement of Medical Instrumentation, American National Standards Institute. Comprehensive guide to steam sterilization and sterility assurance in health care facilities. ANSI/AAMI ST79:2010/A12010/A22011/A32012/A42013. Arlington, VA: Association for the Advancement of Medical Instrumentation, Consolidated Text 2014.
- USAF Guidelines for Infection Control in Dentistry.

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**Storing Sterile Instruments (6/07) UPDATED (2/16)**

**Question:** Can you review the recommendations for storing sterile instruments?

**Answer:** Instrument processing requires numerous steps, so care must be taken to avoid contamination of the instruments during storage. All sterile supplies and instruments need to be stored in a manner that preserves the integrity of the package. All packages must be examined carefully before use to ensure that the barrier wrap has not been compromised during storage.



DO	DON'T
<ul style="list-style-type: none"> <li>+ Allow packages to dry in the sterilizer before handling to avoid contamination.</li> <li>+ Store sterile items and dental supplies in clean, dry, and dust/lint-free areas with limited access—covered or closed cabinets are recommended.</li> <li>+ Follow medical treatment facility (MTF) guidelines when storing clean and sterile materials. (In the absence of MTF guidance store clean and sterile materials at least 8 to 10 inches above the floor, 18 inches below the ceiling, and 2 inches from the outside walls.)</li> <li>+ Keep like items together—sterile with sterile and clean with clean.</li> <li>+ Implement stock rotation practices (e.g., “first in, first out”) with older items being used first.</li> <li>+ Do not stack wrapped kits or peel pouches. Aesulaps can be stacked, but no higher than 18 inches</li> </ul>	<ul style="list-style-type: none"> <li>- Do not store sterile supplies or patient-care items under the sink (or any location where they may become wet), on the floor, windowsills, or any area other than designated shelving or cabinets.</li> <li>- Do not store sterile items with items not intended for clinical use such as office or cleaning supplies).</li> <li>- Do not use shipping box (carton) to dispense sterile or clean patient treatment items in dental operatories, laboratories, instrument processing, and supply areas.</li> <li>- Do not handle sterile packages when hot or when wet. Do not handle unnecessarily to avoid contamination.</li> </ul>

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**Sterilizing Hinged Instruments (5/07)**

**Question:** Should hinged instruments be sterilized in the opened or closed position?

**Answer:** Sterilization can be achieved only if the sterilizing agent (e.g., steam) contacts all instrument surfaces. Therefore, hinged instruments, such as hemostats, scissors, and extraction forceps, should be sterilized in the open position to ensure that the sterilizing agent adequately contacts all surfaces.



## Reference

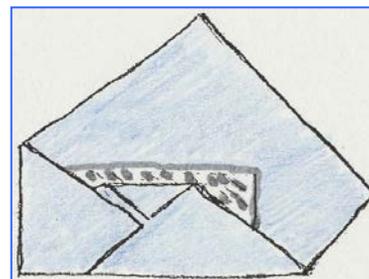
- Association for the Advancement of Medical Instrumentation, American National Standards Institute. Comprehensive guide to steam sterilization and sterility assurance in health care facilities. ANSI/AAMI ST79:2010/A12010/A22011/A32012/A42013. Arlington, VA: Association for the Advancement of Medical Instrumentation, Consolidated Text 2014.

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## Single vs. Double Wrapping Cassettes (2/07 **UPDATED** (2/16)

**Question:** We use instrument cassettes in our dental clinic and wondered if the cassettes should be wrapped with one or two wraps before sterilization?

**Answer:** All dental surgery sets should be double wrapped (either double wrapped using 1-ply wrapping material or single wrapped using 2-ply wrapping material) to provide aseptic presentation according to nationally recognized guidelines. The best way to determine how to wrap your other kits is to review the wrapping material manufacturer instructions for use (IFU). Some manufacturers make a 1-ply wrapping material and may require sequential or simultaneous wrapping using two sheets, other manufacturers make 2-ply wrapping material and may have different IFU (e.g. wrapping with a single sheet of 2-ply wrapping material). Therefore it is essential to check the IFU of the product you are using.



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## Labeling Paper/Plastic Peel Pouches (12/06)

**Question:** How should paper/plastic peel type pouches be labeled? If I handwrite the information on the label, do I need to use a special marking pen?

**Answer:** Automated labeling devices are available that can print the information on self-adhesive labels that can be placed on the package. This provides an efficient, legible, and standard way of labeling and is preferable to handwriting information on the package. If it is necessary to handwrite information on the label, marking pens should be indelible, nonbleeding, and nontoxic. Felt-tip ink pens or a very soft lead pencil may be used. Paper/plastic peel packages should be labeled on the plastic portion or on the self-sealing tab. Writing on the paper side of the pouch may cause damage to the package and thus compromise the barrier protection and is not recommended.



Example of an automated labeling device

## Reference

- Association for the Advancement of Medical Instrumentation, American National Standards Institute. Comprehensive guide to steam sterilization and sterility assurance in health care facilities. ANSI/AAMI ST79:2010/A12010/A22011/A32012/A42013. Arlington, VA: Association for the Advancement of Medical Instrumentation, Consolidated Text 2014.

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## Correct Procedures for Opening Sterile Packages (8/06) **UPDATED** (11/10)

**Question:** Would you review the correct procedures for opening sterile packages both for nonsurgical and surgical dental procedures? One of the things we want to know is whether or not we should wear gloves when opening the package?

**Answer:** The following sequence of procedures may vary based upon the dental procedure, products used, and local policies, but in general to maintain the sterility of the dental instruments, it is recommended that you carefully open the sterile package(s) of instruments after seating the patient.



Alternatively, if you know the patient has arrived in the dental clinic you can open the package(s), as described below, and immediately cover the instruments with a sterile drape before seating the patient.

**If the instruments are to be used for a nonsurgical procedure:**

- a. Check to ensure the packaging material is not torn or punctured.
- b. Don protective clothing, mask, and protective eyewear.
- c. Open sterile package(s) of instruments with clean, ungloved hands and without directly touching the contents. (If you open the packages with gloved hands, the gloves will become contaminated from microorganisms on the outside of the package.) If opening a wrapped cassette, be careful not to touch the inside of the wrapping material because it can serve as a sterile field for the instruments.
- d. Wash and dry your hands and don gloves.
- e. Proceed with opening the cassette and/or arranging the instruments for the procedure.

**The general principles are the same for surgical procedures. If the instruments are to be used for a surgical procedure:**

- a. Check to ensure the packaging material is not torn or punctured.
- b. Don protective clothing, mask, and protective eyewear.
- c. Surgical instruments are double wrapped which enhances sterility maintenance. The outer wrapping can be removed with clean, ungloved hands and discarded be careful not to touch the inner wrapped package. This removes any contamination on the package from storage or transport to the operatory.
- d. Perform surgical hand antisepsis and don sterile gloves.
- e. The inner packaging material can be touched with sterile gloves and can serve as a sterile field for the instruments.
- f. Proceed with opening the cassette and/or arranging the instruments for treatment.



**Selected References:**

- Miller CH, Palenik CJ. Instrument Processing. In: Miller CH, Palenik DJ, eds. *Infection Control and Management of Hazardous Materials for the Dental Team*, 4<sup>th</sup> ed St. Louis: Mosby:2009:159–160.
- Miller CH, Palenik CJ. A Clinical Asepsis Protocol. In: Miller CH, Palenik DJ, eds. *Infection Control and Management of Hazardous Materials for the Dental Team*, 4<sup>th</sup> ed St. Louis: Mosby:2009:226.

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**Event-Related Shelf Life (2/06) UPDATED (2/16)**

**Question:** Were considering changing from using expiration dates on our sterilized packages to an event-related shelf life, is this acceptable? What type of information should we include in our operating instructions?

**Answer:** The issue of shelf life has been addressed by several organizations including the Centers for Disease Control and Prevention (CDC), the Association of Operating Room Nurses (AORN), the Association for the Advancement of Medical Instrumentation (AAMI), and The Joint Commission (TJC).

These organizations no longer make specific recommendations regarding expiration policies of sterilized items. Instead of placing an expiration date (time or date-related) on each package, the concept of event-related shelf life for sterilized items is widely accepted. This approach recognizes that the product should remain sterile indefinitely, unless an event causes it to become contaminated (e.g., torn or wet packaging). Also, several studies have shown that the shelf life of packaged sterile items is event related, not time related.

Each dental facility should have a written policy addressing the shelf life of all stored sterile items based on their internal practices. See below for an example of an event-related shelf-life policy. The shelf life of a packaged



sterile item depends on

- the quality of the wrapping material,
- storage conditions,
- conditions during transport, and
- the amount of handling.

It is important to carefully inspect each package (e.g., pouch, pack, cassette) before use to verify barrier integrity and dryness. If the packaging material is compromised, the instruments should be recleaned, packaged in new wrap, and sterilized again. All packages must be labeled with information to facilitate the retrieval of processed items in the event of a sterilization failure (Table 1). There are two differences when labeling event-related and date-related packages labels. The date of sterilization is placed on the event-related label vs. an expiration date. Also, event-related packaging must include an indefinite shelf-life label (e.g., one labeled with indefinite shelf life unless integrity of the package is compromised).

**Table 1: Package Labels**

Information to Place on the Label	Event Related	Date Related
Sterilizer identification number	✓	✓
Load number	✓	✓
Operator's initials	✓	✓
Expiration date		✓
Date sterilized*	✓	

\* Also include a statement indicating indefinite shelf life

**Event-Related Shelf Life Policy Sample\***

- All sterile items will no longer have an expiration date; loss of sterility is event related. These items may be used as long as the integrity of the package is not compromised (e.g., wet, torn, damaged, suspected of being contaminated).

- Place an indefinite shelf-life label on each sterilized item.
- Document each label with at least the sterilizer identification number, load number, operator's initials, and sterilization date.
- Properly wrap and heat sterilize each item to provide an effective barrier to microbes.
- Do not use instrument packs if mechanical or chemical indicators (CIs) indicate inadequate processing.
- Examine wrapped packages of sterilized instruments before opening them to ensure the barrier wrap has not been compromised during storage. Reclean, repack, and resterilize any instrument package that has been compromised (e.g., dropped, torn, or wet).
- Ensure proper storage of items to reduce package contamination and compromise.
- Do not stack wrapped kits. Aesculaps can be stacked, but no higher than 18 inches.
- Maintain stock rotation according to the principle "first in, first out" so that older items are used first.

\* *Dental clinics must coordinate their operating instructions with the Medical Treatment Facility (MTF) Infection Control Committee.*

**Selected References**

- Association for the Advancement of Medical Instrumentation, American National Standards Institute. Comprehensive guide to steam sterilization and sterility assurance in health care facilities. ANSI/AAMI ST79:2010/A12010/A22011/A32012/A42013. Arlington, VA: Association for the Advancement of Medical Instrumentation, Consolidated Text 2014.
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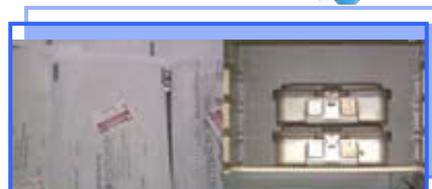
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## Event-Related and Date-Related Shelf Life (2/06)

**Question:** Can we use both event-related and date-related storage practices in the dental clinic?

**Answer:** Generally, clinics should choose one type of package documentation (i.e., event- or date-related). Event-related packaging is used to maintain quality while saving time and

money. Since the sterilization date is placed on all event-related packages, in contrast to an expiration date (date-related), it could become confusing if facilities combine these practices. Also, it may not be cost-effective to use a combination of practices. Whichever practice is adopted, you should be able to justify your choice.



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