Cleaning, Packaging & Sterilization of Instruments
Continuing Education Program

Following established protocols for instrument processing is an important aspect of modern health care as it helps to minimize the patient’s risk for infection of the surgical site.

This program is intended to provide an “overview” of current recommended practices and is approved for continuing education credit.
6 Steps of Instrument Reprocessing

1. Transport
2. Cleaning & Inspection
3. Packaging
4. Sterilization
5. Storage & Delivery
6. Quality Assurance
TRANSPORT

Contaminated instruments should be handled carefully to prevent exposure using appropriate PPE (personal protection equipment).

At point of use, they should be placed in a sealed, leak proof container (displaying a biohazard symbol) to prevent any injuries or cross contamination during transport to the processing area.
TRANSPORT from Treatment Area

- Organization
- Efficiency
- Safety
- Puncture resistant, leak-proof container with lid
CLEANING

Manually or mechanically clean soiled instruments as soon as possible in a designated area, wearing appropriate PPE.

Quick cleaning removes blood much easier, and can minimize instrument staining, corrosion and/or pitting.
CLEANING

Be sure to use *approved* cleaning solutions and cleaning brushes as commercial products not intended for use with surgical instruments can cause damage and/or limit cleaning effectiveness.
Mechanical cleaning is a safer practice for staff and a more effective process over manual cleaning.

Therefore, whenever possible, mechanically clean instruments, using warm water and a neutral pH detergent.
Ultrasonic Cleaner

- Remove gross soil before using
- Use an enzymatic cleaning solution
- Use treated water when needed
- Change solution AT LEAST daily
- Must use lid
- Don’t overload
- Periodically perform ‘foil test’
Instrument Washer

- Increase productivity
- Improve cleaning effectiveness
- Decrease personnel sharps risk
- Accommodate more instruments than ultrasonic units
- Use automated washing cycles
- Eliminate need for manual presoaking, hand scrubbing, rinsing, and drying
- Some have high temp cycle = thermal disinfection
RINSING

After cleaning, thoroughly rinse instruments with tap water and ensure all debris and detergent residue is removed.

If the tap water is of poor quality, consider using treated water as a final rinse to avoid instrument staining.
INSPECTION

Each instrument should be critically inspected after each cleaning for residual debris or damage.

Replace instruments as needed and never sterilize a “dirty” instrument.
In addition, check each instrument for proper function and lubricate as required by the instrument manufacturer.

Hinged instruments with stiff joints may be a sign of inadequate cleaning.
Instrument packaging should be done in a clean and low contamination area, using FDA approved products:

- Sterilization pouch
- Sterilization wrap
- Sterilization container
PACKAGING

Sterilization pouches are for packaging loose instruments and small, light weight items.

Paper/plastic pouches allow you to see the contents and come with a build in adhesive strip for seal sealing. It is important to remove all excess air, prior to sealing the sterilization pouch.
For quality assurance, be sure to include a chemical indicator inside each pouch.

Per CDC guidelines, this will verify sterilization parameters were met inside, as well as outside the pouch (time, temperature and sterilant contact).
Special Note:
Some new technology pouches come printed with an external and internal chemical indicator.

If the internal indicator is a multi-parameter chemical indicator, there is no need to add a separate indicator strip inside.
PACKAGING

To assist sterilization and aid drying, place pouches facing each other and on edge using a divider.

Note: Pouch dividers are commercially available to accommodate different size sterilizers.
PACKAGING

Sterilization wrap is ideal for packaging surgical kits. For sterility maintenance, be sure to use two layers of wrap per industry standards and the wrap MFR’s FDA clearance.
PACKAGING

For quality assurance, include a chemical indicator inside to verify the sterilant reached the inside of the package.

Wrap in a way that allows sterile presentation and aseptic and delivery of the surgical pack or kit.
Sterilization indicator tape should be used to secure the wrapper.

Special Note:
Most steam indicator tapes contain latex in the adhesive and lead in the color change ink. Latex and lead-free indicator tape is commercially available.
STERILIZATION

Heavier wraps should be placed on the lower shelf of the sterilizer and pouches (being lighter) on the top, on edge.

This enables moisture to drain out without wetting other items in the load.
STERILIZATION

Sterilizers are Class 2 medical devices requiring FDA clearance.

They are available in a variety of sizes with the following processes most common to medical:

- Steam
- Chemical vapor
- Dry heat / Rapid heat transfer
STERILIZATION

Saturated steam under pressure is one of the oldest methods used to sterilize surgical instruments.

The CDC recommends steam sterilization as the *process of choice*, because it is efficient, fast, and inexpensive.

*Figure 1-5. Chamberland’s Autoclave. The first pressure steam sterilizer (autoclave) was built in 1880 by Charles Chamberland, a pupil and collaborator of Louis Pasteur. It was patterned after Pasteur’s steam “digester” and resembled a modern pressure cooker. Chamberland also invented the porcelain bacterial filter.*

Chamberland autoclave built in 1880
STERILIZATION

By heating distilled water under pressure, moist heat is created and rapidly kills microorganisms. Some common steam sterilizer cycle parameters are:

- 250°F/121°C for 30 min (Gravity)
- 270°F/132°C for 10 min (Gravity)
- 270°F/132°C for 4 min (DAR)

Dry times are additional and can be from 15 to 30 minutes, depending on load.

Gravity = Gravity Displacement; DAR = Dynamic Air Removal
There are three (3) different types of steam sterilizers:

1. Gravity Displacement
2. Prevacuum
3. Steam Flush Pressure Pulse (SFPP)

Gravity displacement sterilizers heat the water which converts it to steam and pushes the air out the drain gradually. This is called “passive air removal”.

STERILIZATION
STERILIZATION

Prevacuum (also called Class B) sterilizers heat water and convert it to steam; however, they use a vacuum pump to quickly remove the air which allows for faster cycles. This is called “dynamic air removal”.

Because prevacuum steam sterilizers rely on a pump to remove air, an air removal test called *Bowie-Dick test* should be performed daily.
AIR REMOVAL TEST

**Test Procedure:**
Place a Bowie-Dick test pack on the lowest shelf, over the drain in an empty chamber at 273°F for 3.5 or 4 minutes exposure time.

After processing, the color change indicator inside the test pack should show a uniform color to pass.

Retain the indicator as part of your Infection Control records.
Steam-flush-pressure-pulse (SFPP) sterilizers are also considered dynamic air removal, but use steam flushes and pressure pulses to remove the trapped air from the chamber and load. As with prevacuum sterilizers, air removal is more efficient than gravity displacement sterilizers and permits shorter cycle times.

Because SFPP air removal occurs through atmospheric pressure pulses rather than the vacuum pulses used in prevacuum sterilizers, a daily air removal test is not necessary.
Sterile items should be stored in a manner that reduces the potential for contamination.

The shelf-life of sterile items is event related and depends on the quality of the packaging material, storage conditions and amount of handling.
Storage & Delivery

Sterile packages should always be handled with care. Avoid dragging, crushing, bending, compressing or puncturing, as this can compromise sterility.

Be sure to inspect sterile packages before distributing. Do not use any package that is damaged, wet or opened.
Quality Assurance

Sterility assurance of processed instruments should be routinely verified using three (3) types of indicators:

1) Physical

2) Chemical

3) Biological
Quality Assurance

1) Physical indicators are the time, temperature and pressure gauges built into sterilizers. These readings should be recorded for every cycle and verified prior to unloading the sterilizer. Hospital sterilizers are required to have a chart or printout, whereas this is optional for sterilizers located in private offices or clinics.
2) Chemical indicators should be on the outside and inside of all packages to verify they have been processed.

The outside can be a single parameter indicator, i.e. change with heat alone; however, the internal should be multi-parameter requiring more than just heat to make it pass.
Quality Assurance

We mentioned that some newer pouches now offer external and internal indicators printed with every pouch.

Be sure the supplier has validated the internal indicator as a multi-parameter indicator, per CDC guidelines.
3) Biological indicators provide users the highest level of sterility assurance and contain bacterial spores available in plastic vial or paper strip format.

The CDC says sterilizers should be tested at least weekly, and every load that contains an implant. An *unprocessed* Control test, from the same lot must be included.
Quality Assurance

In-office biological monitors are processed along with a normal load. After processing, the plastic vial is activated by crushing the side and then incubated.

Sterilizer failure is noted if the test vial changes color from purple to yellow. An unprocessed vial should be incubated each time to verify test results.
Quality Assurance

A BI inside a Test Pack should be used to monitor large sterilizers when processing packaged instruments.

Steam - place on the bottom shelf, directly above the drain with a load.

The SPSmedical Steam BI test pack includes a BI, along with a Class 5 integrator for immediate release of load, and is FDA cleared for use with standard or extended sterilization cycles.
Quality Assurance

Paper strip biological indicators can be sent to an outside lab for 3rd party verification.

After processing a spore strip along with a normal load, the strip(s) are sent to a lab for incubation. Test results are returned via mail or fax, with some services offering internet record keeping via password.

If a failure is recorded, the Laboratory calls the user with recommendations and instructions to retest.
Quality Assurance

What’s New?
The FDA has approved the SPS STEAMPlus integrator as equal in performance to the spore test.

This does not mean it replaces the weekly spore test; however, we do recommend it be used with each steam cycle to protect against the release of non-sterile items.
Quality Assurance

While sterilizers can and do mechanically fail, operator error is the leading cause of sterilizer failure, e.g.

- Cold start
- Wrong cycle
- Overloading
- Improper packaging

Per CDC guidelines, sterilizers that fail the weekly spore test, should not be used until a passed test is recorded.
Now, let’s test your knowledge on Instrument Reprocessing

1. Transport
2. Cleaning & Inspection
3. Packaging
4. Sterilization
5. Storage & Delivery
6. Quality Assurance

Order These Products Now

Or visit www.henryschein.com/assure
Test Questions

1. You should wear PPE when handling soiled instruments.  __ True  __ False
2. Manual cleaning is preferred over mechanical cleaning.  __ True  __ False
3. All instruments should be inspected after cleaning.  __ True  __ False
4. Peel pouches are ideal for packaging loose instruments.  __ True  __ False
5. The CDC says steam sterilization is the process of choice.  __ True  __ False
6. All sterilizers have the same setting for time and temperature.  __ True  __ False
7. Packages should be dry when removing from the sterilizer.  __ True  __ False
8. The shelf-life of sterilized packages is event-related.  __ True  __ False
9. Each package should have an external and internal indicator.  __ True  __ False
10. Steam sterilizers should be spore tested at least weekly.  __ True  __ False

After successfully answering these test questions, you may print the “Certificate of Completion” posted on the next slide
Certificate of Completion

Presented by:
Crosstex/SPSmedical and Henry Schein
EDUCATION DEPARTMENT

Attended the Continuing Education Program:

“Cleaning, Packaging and Sterilization of Instruments”

1.5 Contact Hours / CEU - IAHCSMM (Code 00070511A)
1.5 Contact Hours / CEU - CBSPD (Code: 21741WCOR09)
1 Contact Hour / CEU - DANB (Code: 32336-001-05-05)

Charles Hughes
Chuck Hughes, VP Infection Prevention Consulting Services
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Your Sterility Assurance Experts

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References & Resources

Association for the Advancement of Medical Instrumentation
4301 North Fairfax Dr, Suite 301, Arlington, VA 22203-1633
703-525-4890  Fax: 703-276-0793  www.aami.org

Association of periOperative Registered Nurses
2170 South Parker Road, Suite 400  Denver, CO  80231-5711
800-755-2676   www.aorn.org

Centers for Disease Control and Prevention
1600 Clifton Road  Atlanta, GA 30333
800-232-4636   www.cdc.gov

Certification Board for Sterile Processing & Distribution (CBSPD)
148 Main St, Suite C-1  Lebanon, NJ 08833
908-236-0530   www.sterileprocessing.org

International Assoc. of Healthcare Central Service Materiel Management
55 West Wacker Dr., Suite 501  Chicago, IL 60601
312-440-0078  Fax: 312-440-9474  www.iahcsmm.org
Continuing Education

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- Selection & Use of Packaging Systems
- Steam Sterilization: Process of Choice
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