STERILIZATION
Best Practices

Presented by SPSmedical
• Largest sterilizer testing Lab in North America and now a part of CROSSTEX, a Cantel Medical Company
• MFG. sterility assurance products that offer advanced technologies
• Provide full day sterilization Seminars and on-site Facility sterilization audits
• Corporate member of AAMI, serving on many sterilization working groups

Objectives
At the end of this program, participants will be able to…
• identify best practices for preparation and transport of surgical instruments at point of use (POU),
• describe best practices for reprocessing surgical instruments,
• explain best practices for storage and distribution of sterile surgical instruments.

Sterilization Best Practices
In the U.S., sterilization best practices are detailed in AAMI Standards & AORN Standards and Recommended Practices. These documents are commonly referenced by health care facilities and Survey organizations.

The Centers for Medicare & Medicaid Services (CMS) has recently revised their Survey and Certification document to include more stringent audits in the areas of infection control and sterilization. Areas of emphasis include:
• Compliance with nationally recognized standards/documents.
• Formal training in areas of infection control and sterilization.
• Compliant cleaning, sterilization and monitoring procedures.
• Established criteria for flash sterilization.

Reference:

In 2011, Joint Commission surveyors received in-depth training on sterilization processes in collaboration with AAMI and included a review of all aspects of the AAMI ST79.

Let’s take a journey together and discuss the American national standards for Sterilization Best Practices!
Sterilization is a patient safety issue and requires a “systems approach”

**Surgery**
- Prepare and transport items to Decontamination.

**CS/SPD**
- clean and disinfect soiled items in Decontam area,
- inspect and assemble items in Prep & Pack area,
- package and sterilize items in Sterilization area,
- maintain sterility of items in Sterile Storage area,
- distribute items Sterile, On Time and Complete.

**Infection Prevention**
- audit Surgery/CS compliance with best practices.

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**Point of Use Preparation**

(Soiled Items)

**Surgery**
should pre-clean instruments to remove gross soil immediately after use. Arrange instruments in an orderly fashion with hinges open and keep sets or multi-part items together.

Moisten trays with a wet towel or an enzymatic solution to prevent blood from drying.

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**Sterilization Best Practices**

Good ☺

Bad 😞

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**AORN RP: Care of Instruments**

Instruments should be wiped as needed with sterile surgical sponges moistened with sterile water during the procedure to remove gross soil.

Instruments with lumens should be irrigated with sterile water as needed throughout the surgical procedure.
Dried blood is very difficult to clean!

Point of Use Preparation
(Soiled Items)

AORN RP: Care of Instruments
Blood and body fluids, as well as saline, are highly corrosive. Corrosion, rusting, and pitting occur when saline, blood, and debris are allowed to dry in or on surgical instruments.

Dried blood and debris can be difficult, if not impossible to remove from all surfaces during the decontamination process; therefore, subsequent disinfection or sterilization may not be achieved.

Here is a great idea!

If your facility needs help, try implementing a Case Cart Check List that the OR fills out after Surgery and attaches to each Case Cart prior to transport to the Decontamination area.

Source: Col. Kimberly A. Smith, RN, MS, CNOR, CSPD
former Chief, Perioperative Nursing
Madigan Army Medical Center
Tacoma, WA

CASE CART CHECKLIST

- Linen has been removed
- All sharps have been removed
- Lumens have been flushed
- Instruments have been sprayed

Date __________________ Room ___________________
Surgical Technician Nurse

Yes    No

Transportation
All instruments opened during a surgical procedure should be considered contaminated and reprocessed.

Instruments must be contained during transport and should be transported in a timely manner to a location designed for decontamination.

Decontamination
Staff should wear appropriate PPE when handling contaminated items. Examples of PPE include:

- hair cover,
- face mask,
- face shield or eye goggles,
- utility gloves,
- fluid resistant covering with sleeves,
- shoe covers.

Sterilization Best Practices

Temperature and humidity control is important for staff comfort and the containment of microbial growth, especially mold.

Temperature and humidity for each area should be recorded. Commercial fans and reservoir type water humidifiers should not be used.
Facility Design
(Environmental Control)

Decontamination (60-65°F/16-18°C)
General work area (68-73°F/20-23°C)
Sterilization equipment access room (75-85°F/24-29°C)
Sterile storage (up to 75°F/24°C)

Humidity (30-60%, up to 70% in Sterile storage)

Facility Design
(Ventilation)

<table>
<thead>
<tr>
<th>Functional Area</th>
<th>Air Flow</th>
<th>Minimum Air Exchanges</th>
<th>Air Exhausted to Outdoors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decontamination</td>
<td>Negative (in)</td>
<td>10</td>
<td>Yes</td>
</tr>
<tr>
<td>Sterilizer equip. access</td>
<td>Negative (in)</td>
<td>10</td>
<td>Yes</td>
</tr>
<tr>
<td>Sterilizer loading/unloading</td>
<td>Positive (out)</td>
<td>10</td>
<td>Yes</td>
</tr>
<tr>
<td>Restrooms/Housekeeping</td>
<td>Negative (in)</td>
<td>10</td>
<td>Yes</td>
</tr>
<tr>
<td>Prep &amp; Packaging</td>
<td>Positive (out)</td>
<td>10, down draft type</td>
<td>No</td>
</tr>
<tr>
<td>Textile Pack room</td>
<td>Positive (out)</td>
<td>10, down draft type</td>
<td>No</td>
</tr>
<tr>
<td>Clean/Sterile storage</td>
<td>Positive (out)</td>
<td>4, down draft type</td>
<td>No</td>
</tr>
</tbody>
</table>

Sterilization Best Practices

Decontamination
Staff should wash below the water surface to avoid creating aerosols, when manually cleaning items.

Decontamination
Staff should use approved medical cleaning solutions. Commercial products not intended for use with instrument can cause damage and/or limit cleaning effectiveness.

i.e., Comet should not be used
Decontamination

It is important to obtain and follow instrument MFG’s instructions for use (IFU) with regards to water temperature, cleaning solution, brush type, and cleaning procedures.

For complex devices, specific times may be recommended for soaking, ultrasonic cleaning and rinsing.

EXAMPLE - MFG’s Cleaning IFU

SYMMETRY Orthopedic Instruments

1. Submerge in enzymatic detergent.
2. Flush port with 50 ml enzymatic detergent.
4. Scrub with soft bristled brush (agitate instrument while scrubbing).
5. Rinse with warm tap water (38-49°C)
6. Flush port with 50 ml warm tap water.
7. Place in bath of warm water (agitate by hand for at least 1 min). Repeat this process 2 additional times.
8. Ultrasonic for 10 min with neutral pH detergent (flush port with 50 ml prepared detergent before sonication).
9. Flush port with clean tap water (3 times).
10. Rinse for at least 1 min with tap water.
11. Dry with clean, lint free cloth.
12. Inspect.
13. Lubricate tip mechanism and finger slot (do not lubricate flush port).

EXAMPLE MFG’s Cleaning IFU

Zimmer Orthopedic Surgical Instruments

1. Completely submerge instruments in enzyme solution and allow to soak for 20 min.
2. Rinse in tap water for minimum of 3 min.
3. Ultrasonic clean for 10 min.
4. Rinse in purified water for at least 3 min.
5. Repeat sonication and rinse steps.
6. Remove excess moisture from the instrument with a clean, absorbent and non-shedding wipe.
Do you know how many IFUs require ultrasonic cleaning? Do not forget loaners!

Knowing this information, will tell you if you have the right type and right amount of cleaning equipment?

Is your facility compliant…

Or, do you need more resources?

Health care facilities must provide CS/SPD with the necessary space, environmental controls, instruments, reprocessing equipment, water quality, skilled personnel and turnaround time to comply with MFG’s IFUs.

Sterilization Best Practices

Prep & Pack

staff should inspect all instruments for cleanliness and function. Remove any damaged instruments and return any that are dirty to Decontamination.

Never attempt to clean a dirty instrument on the clean side as you are not wearing PPE and you will most likely contaminate yourself, as well as the work area.

Never clean on clean side!

Same goes for rigid sterilization containers — clean them in Decontam, not Assembly area.

Inspection guides and magnification lens should be available and used.
Assembly

- Instruments should be assembled in a manner that will not create damage during sterilization and storage.
- Hinged instruments should be in the open position.

Keep tray weight under 25 lbs.

Should you moisten lumens?

Instruments with lumens* may need to be flushed with treated water before packaging, and any stylets or plugs removed. Sterilization should follow immediately.

* Note: Many lumen devices will state in their IFU that flushing is required with gravity-displacement steam sterilization.

Sterilization Best Practices

Prep & Pack

Staff should only use approved packaging materials, such as: sterilization pouches or tubing, sterilization wraps, and/or rigid sterilization containers.

Should grocery store bags be used? No!

Sterilization Best Practices

Sterilization

Staff should load sterilizers with light items on top and heavier items on the bottom. Peel pouches and solid bottom items, e.g. basins or trays, should be placed on edge to facilitate sterilization and allow for drying.

Note:

It is important to not overload the sterilizer as this can cause sterilization failure and/or wet packs.
Sterilization Best Practices

Steam sterilization should be used whenever possible, selecting a cycle that has been validated by the device MFG, i.e.

- gravity displacement (250°F/121°C for 30 min exposure, or 270°F/132°C for 15 min exposure, plus drying)
- prevacuum (270°F/132°C for 4 min exposure, or 275°F/135°C for 3 min exposure, plus drying)

If you reprocess complex devices, then you are probably faced with “extended cycles”. As with ultrasonic cleaning, it is important know “which and how many” instruments require this special attention.

MFG’s IFU (Instructions For Use)

If you reprocess complex devices, then you are probably faced with “extended cycles”. As with ultrasonic cleaning, it is important know “which and how many” instruments require this special attention.

Sterilization Best Practices

Once again, it is extremely important to obtain and to follow the MFG’s IFU. Any conflicts, should be resolved at time of purchase, loan or trial.

Devices that do not have validated IFU should not be processed. To do so, puts both patients and the health care facility at risk.

Sterilization Best Practices

Once processed, items should be located in low traffic area, until cooled.

While cooling, keep carts away from air vents and do not touch until they have reached room temperature.

*Per USP, room temperature is under 85°F/29°C
All processed items should be visibly inspected and any that are wet, torn or dropped should not be used. Wet packs can be caused by improper: drying time, tray assembly, sterilizer loading, sterilizer performance, steam quality, sterilizer unloading, etc…

Sterile Storage

Sterile items should be stored in a separate, enclosed limited access area, the only function is to store sterile and clean supplies.

It is critical that sterile items be maintained in a clean and dry condition. This is not possible when sterile items are stored in a high traffic area.

Quality Assurance

Sterilizers should be monitored with physical, chemical and biological indicators.

Physical Indicators – chart/print out of each cycle.
Chemical Indicators – outside/inside of each package.
Biological Indicators – at least weekly, preferable daily for steam sterilizers and every load with an implant.

Quality Assurance Tip!
(Keep chart or print out with each cycle)

Quality Assurance Tip!
(Use Chemical Indicators correctly)
Quality Assurance Tip!
(Use Biological Indicators correctly)

Document early release of implants...

For emergency use only.
1) Be sure a BI and a Class 5 chemical indicator is used to monitor each implant load.
2) Complete an early release form to document information along with what could have been done to avoid release until the BI results were known.

How long should you keep sterilization records?

Standards do not say, as this varies from State to State in the U.S.

Your risk management dept. should be able to tell you and be sure to keep all records for that length of time.

CONCLUSION

While non-sterile instruments are not considered the leading cause of health care acquired infections (HAIs), it has been documented by the CDC as one of the many causes. Therefore, we must do everything possible to reduce HAIs, which requires strict compliance with Sterilization Best Practices.

We hope the information shared today, helps you in this important goal!

Thank You!

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REFERENCES:


