Objectives
At the end of this program, participants will be able to...

• identify best practices for preparation of soiled instruments after Surgery.
• explain best practices for reprocessing soiled instruments with an emphasis on steam sterilization,
• understand best practices for sterile storage and quality assurance testing.

BEST PRACTICES
In the U.S., instrument reprocessing best practices are detailed in AAMI Standards, AORN Perioperative Standards and RPs, along with other documents, such as SGNA which focuses on HLD of flexible endoscopes.
BEST PRACTICES
Why are they so important?

Best practices should be adhered to in any profession, because they reflect the values of that profession. In healthcare, adherence to sterilization best practices ensures patient safety, as one of our greatest threats is healthcare associated infections (HAIs).

In the U.S., it is estimated that 1/20 patients contact at least one HAI during their hospital stay. That’s nearly 5,000 patients per day with over 300 deaths per day!

Healthcare Associated Infections

While the delivery of non-sterile instruments certainly is not a leading cause of surgical site infections, it has been documented by the CDC and the national media, as one of the causes.

We must do everything possible to reduce HAIs, which means compliance with best practices not some of the time, not most of the time, but all of the time!

Instrument reprocessing has become very complex!

No health care facility wants to find themselves in the local or national news regarding improper instrument reprocessing.

But it has happened...

- VA Medical Center in St. Louis notified 1,800 veterans that they may have been exposed to HIV, hepatitis or other viruses in the facility’s dental clinics. (Dec, 2010)
- Ottawa Public Health issued letters to 6,800 warning they may have been exposed to hepatitis B, hepatitis C or HIV after being treated with dirty endoscopes. (Oct, 2011)
- South Hills Endoscopy Center in Pittsburgh notified patients that an endoscope used during a surgical procedure had not undergone all steps in the disinfection process. (March, 2012)
- PA hospital was found negligent last year for having improperly cleaned and sterilized endoscopes used in 2004 and 2005. (July, 2012)
- Quebec hospital failed to properly reprocess an endoscope for just eight years and sent 1,800 patients to come in for HIV, hepatitis B and C testing. (June, 2013)
It is important to know…

All national survey organizations now audit healthcare facilities for strict compliance with standards, guidelines, and MFG’s instructions for use (IFU).

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:

The Accreditation Association for Ambulatory Healthcare (AAAHC) added an infection control chapter to their standards handbook.

Infection control highlights included:

“Adhering to standards, guidelines, and manufacturer’s instructions for cleaning, disinfection, and sterilization of instruments, equipment, supplies, and implants.”

Reference:
Beginning in 2010, surveyors have spent additional time during surveys evaluating the cleaning, disinfection and sterilization processes.

In 2011, Joint Commission surveyors received in-depth training on sterilization processes. This education was provided in collaboration with AAMI and included a review of all aspects of the AAMI ST79 guideline on steam sterilization. Thereafter, a similar educational module was delivered on HLD of endoscopes.

Considered the bible of sterilization, this comprehensive guide to steam sterilization in healthcare facilities covers all aspects of facility design, personnel and reprocessing procedures.

ORDER CODE: AAMI ST:79
List Price: $275.00 plus shipping
Member Price: $135.00 plus shipping

Sterilization is a patient safety issue and requires a “systems approach”

Surgery
• pre-clean and transport soiled items to CSSD.

CS/SPD
• clean and disinfect 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 STERILE, On Time and Complete.

Infection Prevention
• audit for compliance with best practices.
Point of Use Preparation
(Soiled Items)

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.

Do not allow blood to dry on instruments!

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.
If you do, here is a great idea!

Implement a Case Cart Checklist that OR fills out after Surgery. This form is attached to each Case Cart returned to Decontamination for reprocessing.

Source:
Col. Kimberly A. Smith, RN, MS, CNOR, CSPD
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 _____________________
Transportation
(Soiled Items)

Think confinement.
Select containers that prevent spillage:
• bins with lids
• impermeable bags
• enclosed or covered carts
• closed rigid sterilization containers

Per OSHA - transport carts, bins or bags must be labeled as biohazard

Improper transport
Sterilization Best Practices

**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.

Temperature and humidity control is important for staff comfort and the containment of microbial growth, especially mold. A daily record should be kept.

Commercial fans and reservoir type water humidifiers should not be used.

Facility Design
*(Environmental Control: Temperature)*

- 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 should be controlled between 30-60% in all work areas, except sterile storage where it should not exceed 70%.
Sterilization Best Practices

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

Sterilization Best Practices

Good ☺ Bad 😞

Sterilization Best Practices

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

For complex instruments, specific times may be stated for soaking, ultrasonic cleaning and rinsing.
Some healthcare facilities do not follow MFG’s IFU, as they take too long.

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 have that much time?
• Do you have an ultrasonic?
• Is it being used?
• For how long?

Do you know how many devices require ultrasonic cleaning?
Do not forget loaners!

Knowing this information will tell you if you have the right type and right amount of equipment?
How many of you reprocess Ophthalmic instruments?

Improper cleaning of eye instruments can cause toxic anterior segment syndrome (TASS). TASS is an acute inflammation of the anterior chamber, or segment, of the eye that usually starts within 24 hrs. of cataract surgery.

Patients with TASS complain of blurred vision, mild ocular pain and eye redness. Left untreated, TASS can result in permanent iris damage.

EXAMPLE - MFG’s Cleaning IFU

BAUSCH + LOMB Storz Ophthalmic Instruments

Bausch + Lomb is pleased to announce the availability of new cleaning instructions for our surgical instruments marketed under the Storz Ophthalmic Instrument and Bausch + Lomb Instrument brands.

Manual Cleaning
1. Disassemble the instrument as applicable and inspect the instrument for damage or corrosion.
2. Pre-rinse the instrument by holding it under cold running water for at least 30 seconds, rotating the instrument to expose all surfaces and cavities to flowing water. Additional rinsing may be necessary depending on the size and extent of soiling of the instrument.
3. Place the instrument into a suitable clean basin filled with fresh neutral pH cleaning solution prepared according to the directions of the solution manufacturer. Use only cleaning solutions that are labeled for use with medical devices or surgical instruments.
4. Using a soft cleaning brush gently scrub all surfaces of the instrument while keeping the instrument submerged in the cleaning solution for at least 5 minutes. Clean the instrument until all visible soil has been removed.
5. Rinse the instrument by holding it under cold running water for at least 30 seconds, rotating the instrument to expose all surfaces and cavities to flowing water. Additional rinsing may be necessary depending on the size of the instrument and the amount of soil.

EXAMPLE - MFG’s Cleaning IFU

BAUSCH + LOMB Storz Ophthalmic Instruments

Ensure that the instrument is fully immersed in the cleaning solution. The following conditions were validated using a neutral pH detergent (Steris ProKlenz NpH) and a severe organic soil challenge (Biomedical Instrumentation and Technology 2007;41(4):324-331).

1. Disassemble the instrument as applicable and inspect the instrument for damage or corrosion.
2. Pre-rinse the instrument by holding it under cold running water for at least 30 seconds, rotating the instrument to expose all surfaces and cavities to flowing water. Additional rinsing may be necessary depending on the size and extent of soiling of the instrument.
3. Place the instrument into a suitable clean basin filled with fresh neutral pH cleaning solution prepared according to the directions of the solution manufacturer. Use only cleaning solutions that are labeled for use with medical devices or surgical instruments.
4. Using a soft cleaning brush gently scrub all surfaces of the instrument while keeping the instrument submerged in the cleaning solution for at least 5 minutes. Clean the instrument until all visible soil has been removed.
5. Rinse the instrument by holding it under cold running water for at least 30 seconds, rotating the instrument to expose all surfaces and cavities to flowing water. Additional rinsing may be necessary depending on the size of the instrument and the amount of soil.

© 2013, SPSmedical Supply Corp. 1-800-722-1529
6. Place the instrument in an ultrasonic bath filled with fresh neutral pH cleaning solution and sonicate for 5 minutes. Use only cleaning solutions that are labeled for use with medical devices or surgical instruments. Ensure that the instrument is fully immersed in the cleaning solution. Do not overload the ultrasonic bath or allow instruments to contact one another during cleaning. Do not process dissimilar metals in the same ultrasonic cleaning cycle.

7. **WARNING:** Do not process powered instruments in an ultrasonic cleaner.

8. The cleaning solution should be changed before it becomes visibly soiled. The ultrasonic bath should be drained and cleaned each day it is in use or more frequently if visible soiling is evident.

9. Repeat steps 4-6 as necessary if visible soil remains on the instrument.

10. Rinse the instrument by holding it under warm (27°C – 44°C; 80°F – 100°F) running water for at least 30 seconds, rotating the instrument to expose all surfaces and cavities to flowing water. Additional rinsing may be necessary depending on the size of the instrument.

11. If the instrument has lumens the lumens should be flushed using a syringe filled with 50cc of warm distilled or deionized water using a stopcock as follows:

   a. Place syringe tip into a beaker of warm (30°C – 40°C/85°F – 105°F) distilled or deionized water and fill to the 50cc mark.
   b. Connect the end of the syringe to the center stopcock fitting.
   c. Rotate the stopcock lever to the male Luer fitting (irrigation) or to the female Luer fitting (aspiration) to allow fluid flow to the appropriate Luer fitting.
   d. Connect the stopcock to the appropriate Luer connector on the instrument.
   e. Push on the syringe plunger to force fluid through the lumen into another beaker for proper disposal. Do not draw flushing fluid back through the lumen. Disconnect the syringe. Disconnect the syringe/stopcock from the instrument.
Reprocessing Complex Instruments

How many of you reprocess Rigid Containers?

Rigid sterilization container systems must also be cleaned between uses. Per OSHA regulations, cleaning should be performed in an appropriate decontamination area with personnel wearing appropriate PPE.

Each container should be disassembled (i.e. retention plate) and cleaned to the MFG’s validated IFU.

Let’s take a look at a leading rigid container MFG’s IFU for cleaning:

Example – MFG’s Cleaning IFU
Aesculap

Manual Cleaning:
1. Use a soft sponge and a mild detergent (see recommended cleaners section) and clean the STERILCONTAINER and all the components (including PrimeLine lid with reusable filter) under water.
2. Rinse thoroughly under running water to remove all detergent residue, as residues can affect the container system.
3. To remove sterilization adhesive tape remnant of surface abrasions, we recommend the use of Aesculap-Eloxal Cleaner (Catalog number JG601). This is a non-abrasive cleaner. Apply the cream with a soft dry cloth and rub to polish the surface. Thoroughly rinse under running water to remove all residual cleaning cream.
4. Thoroughly dry all components with a soft dry cloth. 

Wear proper protective personal attire when cleaning.
**Example – MFG’s Cleaning IFU**

**Aesculap**

**Mechanical Cleaning:**
1. Place the STERILCONTAINER bottom in the washer with the inside surface facing down to avoid water collection.
2. Fold the handles towards the inside of the PRIMELINE LID. Place the lid with the inside surface facing down to avoid water collection.
3. Retention plates inside the PRIMELINE LID should be placed away from the direct force of pressurized washer jets to avoid damage during the washing cycle. Reusable filters can be cleaned mechanically inside the retention plate.
4. Thoroughly dry (either with a soft, dry cloth or air dry) the STERILCONTAINER and PRIMELINE LID before final assembly. Ensure that the cleaning equipment has been properly maintained and that the cleaning cycle has been adequately validated prior to use.

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**Chemical Disinfection**

Cleaning alone is not adequate for soiled medical devices that present a high risk of disease transmission to workers or patients. Such medical devices should be subjected to a microbicidal process, per their MFG’s IFU.

Microbicidal processes include disinfection and sterilization by thermal or chemical means. AAMI ST79 provides a flow chart illustrating the use of microbicidal processes to help ensure devices are safe for personnel to handle and indicating the processing stages at which PPE is required.

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**Chemical Disinfection**

Chemical disinfection can be performed by manually soaking a device in a basin of liquid chemical germicide solution or by means of an automated equipment such as washer-disinfectors.

After chemical disinfection, medical devices should be thoroughly rinsed of all chemicals and then dried before undergoing sterilization.
Chemical Disinfection

Disinfectants intended for general purpose use, i.e. on environmental surfaces, are regulated by the EPA.

Chemical disinfectants intended for use as the terminal step in processing reusable critical and semi-critical medical devices are regulated by the FDA and require premarket clearance.

Glutaraldehyde has been widely used for a long time in health care facilities as a HLD for reusable medical devices. Most solutions are acidic and must be activated to become sporicidal. There are a variety of brand names available in a variety of concentrations, with and without surfactants.

OPA has demonstrated superior mycobactericidal activity compared to glutaraldehyde and requires no mixing or activation. OPA has been shown to last longer before reaching its MEC and the concentration of the active ingredient does not decrease with age along.
Other solutions FDA-cleared for HLD include hydrogen peroxide, sodium hypochlorite and peracetic acid in a variety of concentrations and combinations. The FDA website has a listing of manufacturers, active ingredients and contact conditions for each cleared solution.

Because most HLDs are reused, they must be tested and recorded prior to each use to assure that they remain above their MRC. If the test strip fails, the HLD solution should not be used, even if it’s within the reuse life.

Chemical HLD is recognized as the standard for the reprocessing of flexible gastrointestinal endoscopes by SGNA, ASGE, ACG, AGA, APIC and AST. Also, the CDC and The Joint Commission recognize HLD as appropriate for gastrointestinal endoscopes.
Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes

You should be following the updated 2012 SGNA Standards
www.sgna.org

SGNA Standards of Infection Control in Reprocessing of Flexible Endoscopes

5. Manual HLD:
1. Completely immerse the endoscope and all removable parts in a basin of HLD.
   a. The basin must be of a size to accommodate the endoscope without undue coiling, and must have a tight-fitting lid to contain the chemical vapors.
   b. To prevent damage, the endoscope should not be soaked with other sharp instruments.

SGNA Standards of Infection Control in Reprocessing of Flexible Endoscopes

5. Manual HLD
2. Flush disinfectant into all channels of the endoscope until it can be seen exiting the opposite end of each channel. Take care that all channels are filled with the chemical, and that no air pockets remain within the channels.
SGNA Standards of Infection Control in Reprocessing of Flexible Endoscopes

5A. Manual HLD:

a. Complete microbial destruction cannot occur unless all surfaces are in complete contact with the chemical.

b. Since internal contact cannot be visually confirmed because of scope design, purging until a steady flow of solution observed is necessary.

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SGNA Standards of Infection Control in Reprocessing of Flexible Endoscopes

5A. Manual HLD:

3. Cover the soaking basin with a tight-fitting lid to minimize chemical vapor exposure.

Note that:

a. Exposure to chemical vapors may present a health hazard.

b. The reprocessing area should have engineering controls to ensure good air quality.

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SGNA Standards of Infection Control in Reprocessing of Flexible Endoscopes

5A. Manual HLD:

4. Soak the endoscope in the HLD solution for the time/temperature required to achieve HLD. Use a timer to verify soaking time.

5. Purge all channels completely with air before removing the endoscope from the HLD solution. Note that purging the channels preserves the concentration and volume of the chemical, and prevents exposure from dripping and spilling.
### SGNA Standards of Infection Control in Reprocessing of Flexible Endoscopes

#### 5A. Manual HLD:

6. RINSE (same as after Manual Cleaning)
   a. Thoroughly rinse the endoscope and all removable parts with clean water to remove residual debris and detergent.
   b. Purge water from all channels using forced air. Dry the exterior of the endoscope with a soft, lint-free cloth to prevent dilution of the liquid chemical germicide used in subsequent steps.

#### 6. Drying:

a. Purge all channels with air until dry.

Note that:

1) Bacteria such as *Pseudomonas aeruginosa* have been identified in both tap and filtered water, and may multiply in a moist environment.

2) Avoid the use of excessively high air pressure which can damage the internal channels of flexible endoscopes.

b. Flush all channels, including accessory channels, with alcohol until the alcohol can be seen exiting the opposite end of each channel.

1) 70% isopropyl alcohol is used to assist in drying the interior channel surfaces.

2) It must be properly stored in a closed container between uses, because when exposed to air, it rapidly evaporates, and if less than recommended % level, cannot be relied upon to assist in the drying process.

3) Alcohol flushes should be used even when sterile water is used for rinsing.
SGNA Standards of Infection Control in Reprocessing of Flexible Endoscopes

6. Drying:
c. Purge all channels with air. Note that alcohol mixes with the remaining water on the channel surfaces and acts to encourage evaporation of the residual water as air flows through the channel.
d. Remove all channel adapters.

e. Dry the exterior of the endoscope with a soft, clean lint-free towel.
f. Thoroughly rinse and dry all removable parts. Do not attach removable parts (e.g. valves, etc.) to the endoscope during storage as this can trap liquid inside.

SGNA Standards of Infection Control in Reprocessing of Flexible Endoscopes

7. Storage:
Hang the endoscope in a vertical position to facilitate drying (with caps, valves, and other detachable components removed, per MFG’s IFU).
a. The storage area should be clean, well ventilated and dust free.
b. Correct storage will prevent damage.
c. The interval of storage before use has limited investigations and warrants further data.
SGNA Standards of Infection Control in Reprocessing of Flexible Endoscopes

5B. Automated HLD:

Automated Endoscope Reprocessors (AERs) standardize the disinfection process and decrease personnel exposure to HLDs.

NOTE:
It is necessary to follow all steps for the manual cleaning prior to using an AER.

SGNA Standards of Infection Control in Reprocessing of Flexible Endoscopes

5B. Automated HLD:

An AER should have the following features:

a. Circulate fluids through all endoscope channels at an equal pressure without trapping air. Channel flow sensors provide an added measure of compliance.

b. Detergent and disinfectant cycles should be followed by thorough rinse cycles and forced air to remove all used solutions.

c. Disinfectant should not be diluted with any fluids.

d. Machine should be self-disinfecting.

e. No residual water should remain in hoses and reservoirs.

f. Cycles for alcohol flushing and forced air drying are desirable.

g. Should also feature a self-contained or external water filtration system.

In addition, a method to automatically store or print data verification of cycle completion, is desirable.
SGNA Standards of Infection Control in Reprocessing of Flexible Endoscopes

To use an AER:
1. Follow steps for manual cleaning of endoscope.
2. Prepare the AER according to the MFG’s guidelines.
3. Place the endoscope in the AER and attach all channel adapters according to the MFG’s IFU.
   a. The elevator channel of a duodenoscope has a very small lumen. Since most AERs cannot generate pressure required to force fluid through the lumen, a 2-5 ml syringe must be used to manually reprocess (all steps) the elevator channel unless the AER is validated to perfuse this channel.

To use an AER:
4. Place valves and other removable parts into the soaking basin of the AER. Unless the AER has a dedicated space for accessories, reprocess these items separately.
5. If the AER has a cycle that uses enzymatic detergent, it should be a product that is compatible with the AER and the endoscope.
6. Set the AER for the appropriate time and temperature depending on the chemical used.
7. Start the AER and allow it to complete all cycles or phases. Note that if cycles or phases are interrupted, HLD cannot be ensured and the full cycle must be repeated.

To use an AER:
8. If AER does not include a final alcohol rinse, this step should be done manually followed by purging all the channels with air until dry. The ERCP elevator and elevator channel must be manually perfused and dried per MFG’s instructions.
9. Drying and storage procedures are the same as described in the manual disinfection section.

To get a free copy of the complete SGNA document, go to: www.sgna.org
Chemical HLD Safety

Healthcare facilities are responsible for providing a safe work and patient care environment. Patients, visitors, and health care workers should be protected from injuries or illnesses caused by hazardous chemicals.

When handling HLDs, personnel should wear protective apparel that may include, but is not limited to:

- 100% nitrile rubber or 100% butyl rubber gloves when handling glutaraldehyde. PVC gloves should not be worn because they absorb glutaraldehyde.
- Protective eye wear, face mask, and impervious gown.

Chemical HLD Safety

**Glutaraldehyde** should only be used in well ventilated areas or in freestanding or vented chemical fume hoods. Vapor generated from glutaraldehyde can may aggravate preexisting respiratory conditions.

AAMI describes adequate ventilation as:

1. Room large enough to ensure adequate dilution of vapors.
2. 10 air exchanges per hour.
3. Exhaust located at the source of the discharge of vapors.
4. Fresh air return at ceiling level across room from exhaust vents.
5. Routine maintenance and surveillance of system.
6. Elimination of cross draft effects.
7. Air must not be recirculated.

Chemical HLD Safety

**Glutaraldehyde** can be absorbed by inhalation, ingestion and through the skin. It has a detectable odor at 0.04 parts per million volume (ppmv) and is irritating to skin and mucous membranes at 0.3 ppmv.

Vapors are released whenever solutions are disturbed and the surface tension is broken, such as mixing, adding and removing equipment, or disposing of a glutaraldehyde solution can cause a break in the surface tension. Whenever the glutaraldehyde solution is not being accessed, it should be covered with a tight-fitting lid.
Chemical HLD Safety

Glutaraldehyde vapor monitoring is important per The American Conference of Governmental Industrial Hygienists (ACGIH) which recommends a ceiling limit of 0.05 ppm for occupational exposure.

OSHA has not established exposure limits; however, OSHA can regulate exposure and has recommended following the ACGIH limit.

Chemical HLD

To avoid these glutaraldehyde issues, many health care facilities have switched to using an OPA for HLD. The Rapicide® OPA/28 features the fastest disinfection time, twice the reuse period of other OPA brands and guaranteed materials compatibility.

Chemical HLD Safety

Exposure monitoring is not required; however, OPA is still a potential irritant of eyes, skin, nose and other tissues resulting in symptoms such as stinging, excessive tearing, coughing, and sneezing. Like glutaraldehyde, OPA fixes proteins, allows for biofilm formation and exposure causes staining on linen, skin, instruments and AERs.
Reprocessing Complex Instruments

Training and Education
Personnel should receive initial training and competency validation on procedures, chemicals used, and PPE and should receive additional training when new equipment, instruments, supplies, or procedures are introduced.

Employers must provide a written hazard communication program, hazard evaluation, hazardous materials inventory, Safety Data Sheets, labels on all containers of hazardous chemicals, and employee training.

Quality Control Program
A quality control program should be established in all areas where HLD is used. Quality control programs should be documented and should include, but not be limited to:
- Orientation programs
- Competency assurance
- Continuing education
- Quality control checks
- Investigation of adverse events
- Monitoring of solution replacement intervals

Quality Control Program
Surfaces of complex instruments require meticulous cleaning in order to minimize infection control risks to patients and staff. Inadequate cleaning can potentially leave residual protein on a surface.

Quality control checks, such as ATP systems and VERIFIND™ Protein Detection Kit, provide rapid and easy to read cleaning verification.
Decontamination

Mechanical cleaners are available as:
• Ultrasonic
• Washer-sanitizers
• Utensil washers
• Cart washers
• Pasteurizers
• Washer disinfectors
• Washer decontaminators

Improper loading – need to separate trays

Improper loading of cart washer – need to remove retention plates
Reprocessing Complex Instruments

Cleaning Verification

AAMI standards now recommend that mechanical cleaners be tested at least weekly, preferably daily for cleaning effectiveness.

Sterilization Best Practices

Prep & Pack

Staff should inspect all instruments for cleanliness and function. Any that is observed to not be clean, should be returned to Decontamination for cleaning.

Do not allow cleaning brushes on clean side. Why? No PPE and brushing contaminates the assembly area.

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

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

* Many lumen devices will state in their IFU (Instructions for Use) that flushing just prior to steam sterilization is necessary.

Sterilization Best Practices

Prep & Pack

Staff should only use approved packaging materials, such as: disposable pouches, disposable or reusable wrappers, and rigid sterilization containers.

Sterilization Packaging

Always obtain and keep on file, the mfg.’s test data and instructions for use, care and handling.

Be sure your packaging IFU matches what you are doing, i.e. double pouching, for use inside trays or containers, extended cycles, stacking in sterile storage?
Never place adhesive tape on the inside or outside of surgical trays or rigid containers.

Special Note:

Paper/plastic pouches are not recommended inside wrapped trays or rigid containers, as sterility can be compromised.

All paper bags, wire baskets and any other “validated” containment device may be used.

Improper load label placement may end up in the sterilizer drain.
Reprocessing Complex Instruments

Sterilization Best Practices

Sterile Processing
should use saturated steam sterilization as the process of choice whenever possible. Steam sterilization is fast, reliable and economical.

There are two (2) common types of steam sterilizers: Gravity displacement and Dynamic air removal. Flash sterilization (now referred to as IUSS) can be done with either of these types of steam sterilizers.

Loading

Linen packs, basins and solid bottom trays should be placed on their sides.
Instrument sets with wire or mesh bottom trays should be placed flat on the bottom of the cart, so condensation does not drip down and wet other items in the load.

MFG’s IFU (Instructions For Use)

If your facility reprocesses complex devices, then you are probably dealing with “extended cycles”. As with cleaning, it is important to know which and how many of your devices require extended settings (exposure time and/or dry time).
Reprocessing Complex Instruments

MFG’s with at least one extended cycle...

- Abbott Spine
- Acclarent
- Acumed
- Biomet
- Blackstone
- Boss
- Boston Scientific
- CR Bard
- CarboMedics
- Cochlear
- D.O.R.C.
- DePuy Mitek
- DePuy Orthopedics
- DePuy Spine
- Drager
- Elekta
- Ellman
- Elmed
- EMS
- Encision
- Encore
- Estech
- Ethicon
- FCI
- FH Orthopedics
- FlashPak
- Genesis Biologics
- Globus

Extended Cycle (examples)

- Gore
- Greenwald
- Hand Innovations
- Heine
- Hitachi Medical Systems
- Hu-Friedy
- Hydrocision
- Innovasis
- Insight
- Integra
- Invuity
- Jardon
- K2M
- Kapp
- Lanx
- LDR Spine USA
- Medacta
- Medartis
- Mednext
- Metronic
- Micoline
- MissOnix
- Navasive
- On-X
- Ortho Development
- Orthofix
- Osteomed
- Pega Medical
Reprocessing Complex Instruments

Extended Cycle (examples)

- Respironics
- Rhein Medical
- Richard Wolf
- Ruggles
- SeaSpine
- Small Bone Innovations
- Spinal Elements
- Spine Weave
- Stryker
- Suprasson
- Surgipro
- Synthes
- The Electrode Store
- Thompson Surgical
- Thorame
- TriMed
- Unisensor
- US Spine
- Vacumetrics
- Varian
- Viasys
- Vites
- Wallach
- Welch-Allyn
- Wells-Johnson
- Wexler
- Zimmer

Once again, it is critical that healthcare facilities receive and follow the MFG’s IFU for all reusable medical devices in use.

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

Securing MFG’s IFUs?

Healthcare facilities will find that securing validated instructions for cleaning, packaging, and sterilization is less of a task by contacting the device MFG’s corporate office and asking to speak directly to Quality Control or Regulatory Affairs.

These departments routinely work with these issues and should provide this critical information to you with no problem and of course, at no charge.
Securing MFG’s IFUs?

Another option is to hire a Company to do the search for you and to keep the MFG’s IFU updated. In the U.S., there are companies that provide an internet based library with electronic copies that can be printed out.

“Flash” Sterilization changes to “Immediate-Use”

AAMI, AORN and other organizations have agreed that “flash” is an antiquated term that does not fully describe the various steam sterilization cycles now used to on items not intended to be stored for later use.

“Immediate-Use” is broadly defined as the shortest possible time between a sterilized item’s removal from the sterilizer and its aseptic transfer to the sterile field.

Immediate-Use Steam Sterilization (Minimum cycle parameters)

Gravity-displacement
270°F/132°C, 3 min exposure for nonporous items
270°F/132°C, 10 min exposure for porous items

Dynamic air removal (pre-vacuum or SFPP)
270°F/132°C, 3 or 4 min exposure for porous or nonporous items

Note: As discussed earlier, some devices require much longer times and some are not recommended for use in gravity cycles at all. Be sure you know what type of cycles your sterilizers are capable of running.
Immediate-Use Steam Sterilization

The same critical reprocessing steps must be followed as a safe process does not include short-cuts. A sterilized item intended for immediate use is not stored for future use, nor held from one case to another.

Cleaning, decontamination and rinsing are critical and users must follow and complete all required processing steps regardless of the sterilizer exposure parameters being used. The device MFG’s written instructions for use (IFU) must be followed.

Immediate-Use Steam Sterilization (aka Flashing)

IUSS has unique challenges; and therefore, is not recommended by AAMI, AORN, CSA, CMS or The Joint Commission for routine use or implants.

IUSS instruments in the wrong sterilizer mode or at improper exposure times, will certainly get them hot, but they will not be sterile.

Immediate-Use Steam Sterilization

Sterility Assurance
If IUSS an implant is unavoidable, a Class 5 chemical integrator and a biological indicator (BI) should be used to monitor the cycle. Since BI results are not immediate, healthcare facilities rely heavily on the Class 5 integrator for load release.

Remember: Standards say you should be able to track IUSS items back to the individual patient.
Reprocessing Complex Instruments

Sterilization Best Practices

Processed items removed from the sterilizer should be located in low traffic area until cooled.

Do not place carts near air vents or fans as air currents can cause condensation to form.

A minimum of 30 min should be allowed for items to cool to room temperature before handling.

Handling & Inspection

All personnel should be trained to minimize the handling of sterile items. Sterilized items should not be touched while cooling.

All packaged items should be visually inspected for tears or wetness. Wet, torn or dropped items should be returned to the decontamination area for reprocessing.

Sterilization Best Practices

Sterile Storage
Should be in a separate, enclosed area where shelving, counters or containers that can be maintained in a clean and dry condition.

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Sterilization Best Practices

Sterile Storage
For ergonomic reasons, heavy trays should be stored waist high for ease of lifting.

Did you know?
AAMI standards and wrap MFG’s now state do not stack wrapped trays during storage.

Is this okay?

Excellent sterile storage
Improper storage cart

Sterilization Best Practices

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 week, preferable daily with steam sterilizers and every implant load.

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Quality Control

AAMI Standards now define six (6) classes of chemical indicators with recommendations for use for Classes 1 – 6.

- **Class 1** – Process Indicators
- **Class 2** – Specific Test Indicators
- **Class 3** – Single-variable Indicators
- **Class 4** – Multi-variable Indicators
- **Class 5** – Integrating Indicators
- **Class 6** – Emulating Indicators

Class 5 chemical indicators are recommended for complex devices, such as implants and all IUSS cycles.
Validation Testing

Device manufacturer’s know the most difficult to reach locations, as this information was provided by the testing laboratory who validated their device, using:

- Class 5 integrator
- Biological Indicator
- Temperature probe

Quality Control

The results of Class 5 or Class 6 indicators may serve as the basis for the release of routine items.

For monitoring wrapped loads, these chemical indicators must be used within an appropriate process challenge device.

Good PCD placement
Quality Control

Biological Indicators offer the highest level of quality control and consist of bacterial spores of a known population and stated resistance to the sterilization process.

Sterilization Best Practices

Biological Indicators are more than just a pretty vial and should be selected based on three (3) criteria:

1) Accuracy for sterilization cycle being tested,
2) Reduced incubation time (RIT), and
3) Cost (BI, incubator and supplies).

Do not confuse the order of these criteria as faster or less expensive BIs that provide inaccurate test results, are not only invalid, but also a danger to patient safety!

Quality Control

Biological Indicators should be used:

• at least weekly in Steam, preferably every day the sterilizer is used and every load that contains an implant.

Spore growth is indicated by a color change in the media during incubation.
"Terminal" Sterilization

**PCD**
(Process Challenge Device)
BI inside a Test Pack should be used to monitor sterilizers processing wrapped loads. Each mode used should be tested in the shortest cycle.

**Steam** - place the PCD flat on the bottom shelf, directly above the drain with a load.
Immediate-Use Steam Sterilization
BI testing

IUSS should be tested at least weekly, preferably daily and every load with an implant. If both gravity and prevacuum modes are used, the shortest cycle on each mode should be tested.

AORN now recommends that only a sealed container be used to IUSS, and therefore, the BI should be inside an empty container, instead of in an open tray.

Special Note: Implants

AAMI and AORN standards recommend monitoring implant loads with a BI challenge test pack that includes a Class 5 integrator.

Implants may be released off the Class 5 when there is not time to wait for the BI result and the early release is documented.

Critical Assessments

BI challenge test packs should be used during initial installation testing of steam sterilizers after relocation, after sterilizer malfunction, after sterilization failures, after any major repairs of the sterilizer, and for periodic QA testing of representative samples of actual products being sterilized.

NOTE: A major repair is a repair outside the scope of normal maintenance, e.g., weld repairs of the pressure vessel, replacement of the chamber door or a major piping assembly, or rebuilds or upgrades of controls.
10 Common BI Mistakes

1. BI not validated for cycle being tested,
2. Not testing shortest cycle on sterilizer when multiple exposure times are used,
3. BI testing a table top steam sterilizer in an empty chamber or from a cold start,
4. BI testing immediate-use (IUSS) sterilizers in an open tray instead of inside an approved rigid container,
5. Improper placement of BI or PCD inside the sterilizer,
6. Not activating STERRAD BI within 5 min of cycle completion,
7. Relying on early readout only and not growing out BI for full incubation time to confirm spore growth results,
8. BI incubator not calibrated to correct temperature,
9. BI incubator unplugged or not heating to correct temperature,
10. Not sending positive BI to Laboratory to confirm spore growth.

STERRAD BI Testing

PCD (Process Challenge Device)

Place the self-contained BI inside a Tyvek peel pouch and placed at the back of the sterilizer, on the bottom shelf with the Tyvek side facing up.

The pouch may be placed on top of a wrapped tray. It is important to note: incubation of the CycleSure™ self-contained BI, must be performed within 5 min of cycle completion.

Sterilization Best Practices

Make sure all of your sterilizer records are kept together and are...

COMPLETE,
ACCURATE,
PRESENTABLE!

Keeping them together is the easiest way for a Surveyor to observe you are in compliance!
How long should you keep your 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 the delivery of non-sterile instruments may not be a leading cause of surgical site infections, it has been documented by the CDC as one of the problems. You and I must do everything possible to reduce HAIs, which means compliance with best practices not some of the time, not most of the time, but all of the time.

I hope the information I have shared today, helps you in this important goal!
THANK YOU!

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References & Resources
Accreditation Association for Ambulatory Health Care (AAAHC). 5250 Old Orchard Road, Suite 200 · Skokie, IL 60077. www.aaahc.org


Extra material to share if there is TIME?

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AAMI/FDA Medical Device Reprocessing Summit

Nearly 250 healthcare professionals attended a 10/2011 Summit held at FDA headquarters in Silver Spring, MD. The focus was on cleaning reusable medical devices and SPSmedical was asked to speak on how to “define clean” and the importance of “complying with MFG’s IFUs”.

10 Things Your Organization Can Do Now to Improve Reprocessing

1) The basics:
   Cleaning and disinfection/sterilization of reusable devices are separate, equally important processes and must be performed before each patient use according to the device manufacturer’s written instructions for use (IFU).

2) The right tools:
   Have the IFU as well as all cleaning implements and equipment required by the IFU readily available in all the reprocessing areas.
10 Things Your Organization Can Do Now to Improve Reprocessing

3) Create a multidisciplinary committee to review the priority issues and set a plan for solving them throughout the organization.

The following areas should be represented:
OR, infection prevention and control, health care technology management (biomed), endoscopy, risk management, quality, safety, education, and materials management.

4) Share lessons learned:
Remind senior management and safety officers that it costs a lot less to “do it right the first time.”
Share lessons learned from other health care organizations that have had to inform patients of patients of exposure to inadequately reprocessed reusable devices.

5) Written procedures:
Establish a formal program for reprocessing, including written standardized policies and procedures that include a chain of accountability. Expert guidance can be obtained from industry experts in order to resolve conflicts between the IFU and facility policies. Written procedures should also be developed and implemented for central sterile processing reporting of inadequate instructions, equipment problems, and in-service issues to the manufacturer and, when applicable, to the FDA’s MedWatch program.
10 Things Your Organization Can Do Now to Improve Reprocessing

6) Standards matter:
   Know the current standards, recommended practices, and IFUs.

7) Purchasing:
   Central sterile processing should be included in purchasing decisions for medical devices, to provide input on whether the device can be reprocessed appropriately and with the facility’s existing resources.

Loaners too!

8) Separate and standardize functions and locations:
   Separate central service (warehouse, stocking, etc.) from reprocessing; create standardized job descriptions and functions.
10 Things Your Organization Can Do Now to Improve Reprocessing

9) Training:
Train and retrain. Ideas include: assess staff competencies; negotiate for training budget with cost/benefit analysis to prove value; partner with vendors for education; create a list of available continuing education units (CEUs) for easy access by staff; work with human resources to create career ladders for certification and promotion; promote the importance of certification. Note: In-service for loaner or new instruments should include reprocessing in-service areas that are separate from (or in) central sterile processing.

10) Assessment:
Conduct an audit of compliance with standards and regulations, using any number of available tools and resources.

For more information regarding the Summit, go to:
www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofReusableMedicalDevices/ucm252941.htm.