Objectives

- Understand the Importance of Following Best Practices in ASC settings
- Describe proper practices for decontamination and sterilization
- Review the documentation requirements when reprocessing reusable devices
- Learn what CMS surveyors are looking for during site visits

Challenges

- High volume of procedures
- Small, constricted work area for SPD
- May not have automated equipment
- Less inventory
- Staff may need to wear many hats
- Need to meet the same requirements as the hospital
- In a shorter work day

Doing the Right Thing for the Patient

- When a patient has surgery in an ambulatory surgery center their expectations are that they will get the same care as they would in a traditional hospital setting.
- The instrumentation needs to be processed following the same standards used in a hospital.
- This is confirmed in the ANSI/AAMI ST79 Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health care facilities introduction overview, which states “This recommended practice… includes ambulatory-care and office-based facilities.

Key Trends for ASCs and Outpatient Surgery

THE OVERALL ASC SURGICAL PROCEDURE VOLUME INCREASED 22.9 PERCENT NATIONWIDE, WITH 35.8 MILLION OUTPATIENT PROCEDURES OCCURRING IN HOSPITAL OUT-PATIENT AND STAND-ALONE ASCS

GI PROCEDURES GREW 19.4 PERCENT FROM 2015 TO 2016

EYE PROCEDURES JUMPED 2.8 PERCENT

Ensuring the safety of healthcare for patients

Lapses in infection control in any healthcare setting, including Ambulatory Surgical Centers (ASCs), put patients at risk.

Typical surgical procedures conducted in ASCs include endoscopies, colonoscopies (including removal of identified polyps), orthopedic procedures, plastic/reconstructive surgeries, eye, foot, and ear/nose/throat surgeries.

Of 68 ASCs assessed, two-thirds (67.6%) had at least one lapse in infection control.

What is being done to address these findings?

Documentation

- IFUs
- Standards and Guidelines
- Reporting requirements for quality assurance
- Work instructions should be
  - Reviewed
  - Posted
  - Understood
  - Accessible

DOCUMENTATION REQUIREMENTS WHEN REPROCESSING REUSABLE DEVICES

Reference Documents

- AAMI: ST79 Comprehensive Guide to Steam Sterilization in Health Care Facilities
- AORN Guidelines for Perioperative Practice
- SGNA's Standards and Position Statements
- CDC Guideline for Disinfection and Sterilization in Healthcare Facilities

DOCUMENTATION REQUIREMENTS WHEN REPROCESSING REUSABLE DEVICES

Required Documentation

- Sterilizer Records
- Automated Washer Records
- Biological Records
- Equipment Testing Records
- Tracing to the Patient

CMS Self-Audit Fact Sheet

Centers for Medicare & Medicaid Services Hospital Infection Control Worksheet

What Is a Self-Audit, and Why Does It Matter?

Self-audits generally focus on assessing, correcting, and maintaining controls to promote compliance with applicable laws, rules, and regulations.

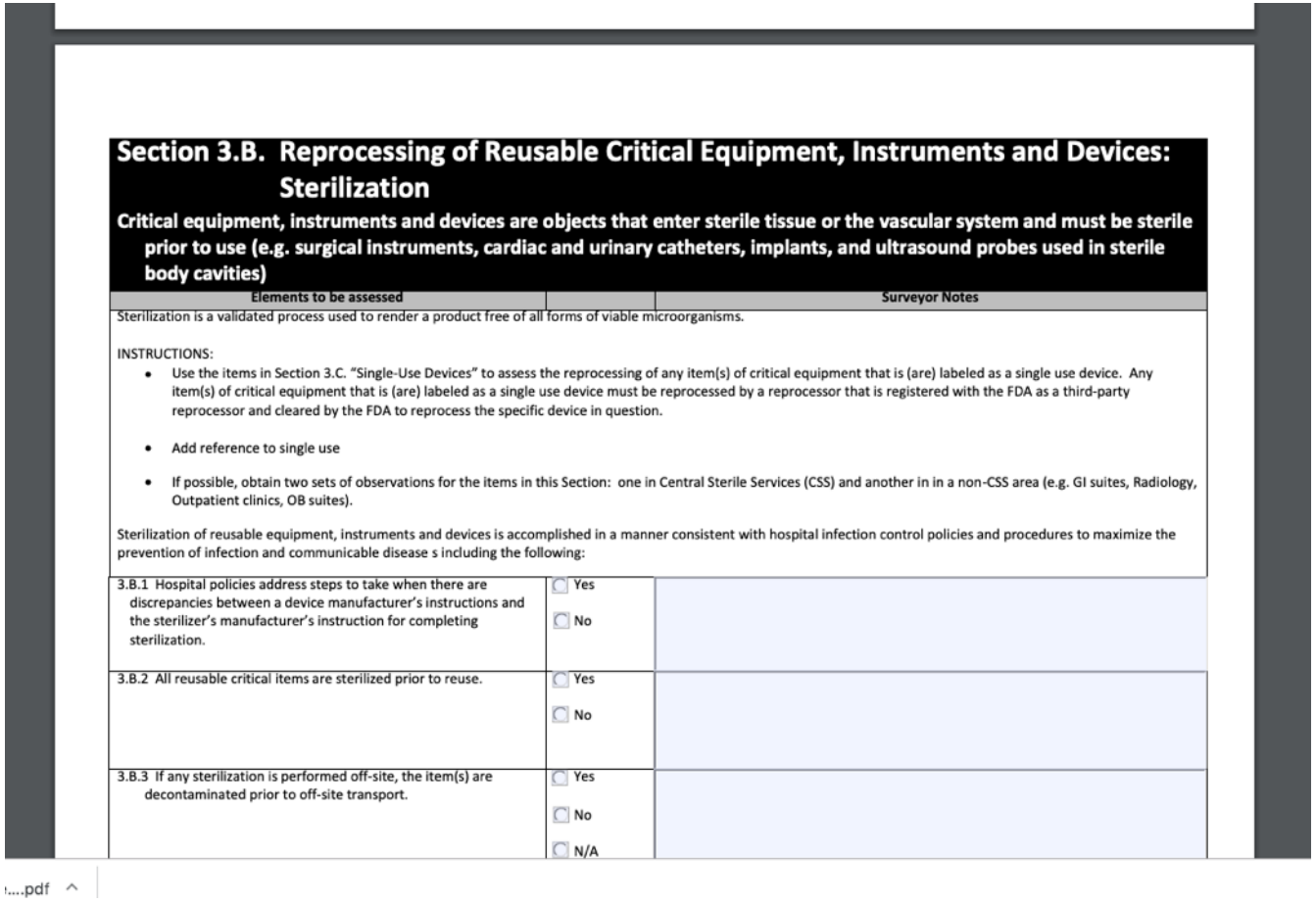
Step One–Identify the Risks

Which compliance issues and risks are of greatest concern?

Where are we most vulnerable to these risks?

Step Two–Audit the Risks: Review Standards and Procedures

The second step is to examine and assess the effectiveness and use of standards and procedures that define appropriate behavior



Section 3.B. Reprocessing of Reusable Critical Equipment, Instruments and Devices: Sterilization

Critical equipment, instruments and devices are objects that enter sterile tissue or the vascular system and must be sterile prior to use (e.g. surgical instruments, cardiac and urinary catheters, implants, and ultrasound probes used in sterile body cavities)

Elements to be assessed		Surveyor Notes
Sterilization is a validated process used to render a product free of all forms of viable microorganisms. INSTRUCTIONS: • Use the items in Section 3.C. "Single-Use Devices" to assess the reprocessing of any item(s) of critical equipment that is (are) labeled as a single use device. Any item(s) of critical equipment that is (are) labeled as a single use device must be reprocessed by a reprocessor that is registered with the FDA as a third-party reprocessor and cleared by the FDA to reprocess the specific device in question. • Add reference to single use • If possible, obtain two sets of observations for the items in this Section: one in Central Sterile Services (CSS) and another in in a non-CSS area (e.g. GI suites, Radiology, Outpatient clinics, OB suites). Sterilization of reusable equipment, instruments and devices is accomplished in a manner consistent with hospital infection control policies and procedures to maximize the prevention of infection and communicable disease s including the following:		
3.B.1 Hospital policies address steps to take when there are discrepancies between a device manufacturer's instructions and the sterilizer's manufacturer's instruction for completing sterilization.	☐ Yes ☐ No	
3.B.2 All reusable critical items are sterilized prior to reuse.	☐ Yes ☐ No	
3.B.3 If any sterilization is performed off-site, the item(s) are decontaminated prior to off-site transport.	☐ Yes ☐ No ☐ N/A	

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ASC Infection Control Survey
“Single Use Devices, Sterilization, and High-Level Disinfection”

- Pre-cleaning must always be performed prior to sterilization and high-level disinfection
- Sterilization must be performed for critical equipment (i.e., instruments and equipment that enter normally sterile tissue or the vascular system, such as surgical instruments)
- High-level disinfection must be performed for semi-critical equipment (i.e., items that come into contact with non-intact skin or mucous membranes such as reusable flexible endoscopes, laryngoscope blades)
- Observations are to be made of staff performing equipment reprocessing (e.g., surgical techs), unless these activities are performed under contract or arrangement off-site from the ASC.

Ambulatory Surgical Center (ASC) Infection Control Surveyor Worksheet (ICSW)

Does the ASC have an explicit infection control program?

Does the ASC's infection control program follow nationally recognized infection control guidelines?

Is there documentation that the ASC considered and selected nationally recognized infection control guidelines for its program?

Does the ASC have a licensed health care professional qualified through training in infection control and designated to direct the ASC's infection control program?

Does the ASC have a system to actively identify infections that may have been related to procedures performed at the ASC?

Infection Control Worksheet: Infection Prevention

All patient care areas have readily accessible, in appropriate locations: a. Soap and water b. Alcohol-based hand rubs

Staff perform hand hygiene: a. After removing gloves b. Before direct patient contact c. After direct patient contact d. Before performing invasive procedures (e.g. placing an IV)

Wash hands after contact with blood, body fluids, or contaminated surfaces (even if gloves are worn)

Infection Control Worksheet: Sterilization

Critical equipment is sterilized

Are sterilization procedures performed on-site?

Items are pre-cleaned according to manufacturer’s instructions or, if the manufacturer does not provide instructions, evidence-based guidelines prior to sterilization includes results from each load

A sterilized item intended for immediate use is not stored for later use nor stored from one case to another

Infection Control Worksheet: Sterilization Containment

Items are appropriately contained and handled during the sterilization process to assure that sterility is not compromised prior to use

After sterilization, medical devices and instruments are stored in a designated clean area so that sterility is not compromised

Sterile packages are inspected for integrity and compromised packages are reprocessed

Infection Control Worksheet: IUSS Sterilization

Is immediate-use steam sterilization (IUSS) performed on-site?

Work practices ensure proper cleaning and decontamination, inspection, and arrangement of the instruments into the recommended sterilizing trays

The item is placed within a container intended for immediate use. The sterilizer cycle and parameters used are selected according to the manufacturers' instructions for use

The sterilizer function is monitored with monitors (e.g., mechanical, chemical and biologic)

The processed item must be transferred immediately, using aseptic technique

Restrictions on IUSS

- Immediate-use steam sterilization is NOT performed on the following devices:
  - Implants
  - Post-procedure decontamination of instruments used on patients who may have Creutzfeldt-Jakob disease or similar disorders
  - Devices that have not been validated with the specific cycle employed
  - Single-use devices that are sold sterile

Infection Control Worksheet: HLD

Medical devices and instruments are visually inspected for residual soil and re-cleaned as needed before high-level disinfection

Chemicals used for high-level disinfection are prepared according to manufacturer instructions

Tested for appropriate concentration according to manufacturer's instructions

Replaced according to manufacturer's instructions

Documented to have been prepared and replaced according to manufacturer's instructions

Infection Control Worksheet: Environmental Infection Control

Operating rooms are cleaned and disinfected after each surgical or invasive procedure with an EPA-registered disinfectant

Operating rooms are terminally cleaned daily

Environmental surfaces in patient care areas are cleaned and disinfected, using an EPA-registered disinfectant on a regular basis (e.g., daily), when spills occur and when surfaces are visibly contaminated

The ASC has a procedure in place to decontaminate gross spills of blood

Processing environment

Processing environment

THE PROCESSING ENVIRONMENT IS AN IMPORTANT PART OF INFECTION PREVENTION.

THE PROCESSING ENVIRONMENT NEEDS TO BE CLEAN TO PREVENT CONTAMINATION OF THE INSTRUMENTATION, PROVIDE EMPLOYEE SAFETY AND MAINTAIN STERILITY.

IT MUST ALSO PREVENT CONFUSION AS TO WHETHER OR NOT AN ITEM HAS BEEN CLEANED.

ACCORDING TO AAMI ST79, THE STERILE PROCESSING AREA SHOULD HAVE A ONE-WAY DIRECTIONAL FLOW TO PREVENT CROSS-CONTAMINATION.

PHYSICAL SEPARATION MAY NOT BE POSSIBLE. IN THAT CASE, SPATIAL SEPARATION COULD BE ACCEPTABLE WITH A ONE-WAY DIRECTIONAL WORKFLOW PATTERN AND GOOD WORK PRACTICES.

Point of use

- Processing instrumentation is a team effort.
- It begins at the point of use to prevent the formation of biofilm. It is at the point of use that debris can begin to dry.
- Techniques used to keep debris moist are to place a towel moistened with water over the instrument, placing the instrument inside a package designed to maintain humid conditions, or using a pretreatment instrument spray.
- After the instrumentation has been treated, they need to be safely transported to the decontamination room.

Transport

Before being transported, the contaminated instrumentation needs to be contained and marked as being biohazardous.

The method of transport is determined by the contamination.

According to the OSHA Bloodborne Pathogens Standard, contaminated instrumentation that is sharp must be transported completely covered in a closed container, or in a puncture-resistant, leak-proof container labeled as biohazardous.

The acceptable labeling methods required by OSHA are the biohazard label or a red bag.

Decontamination

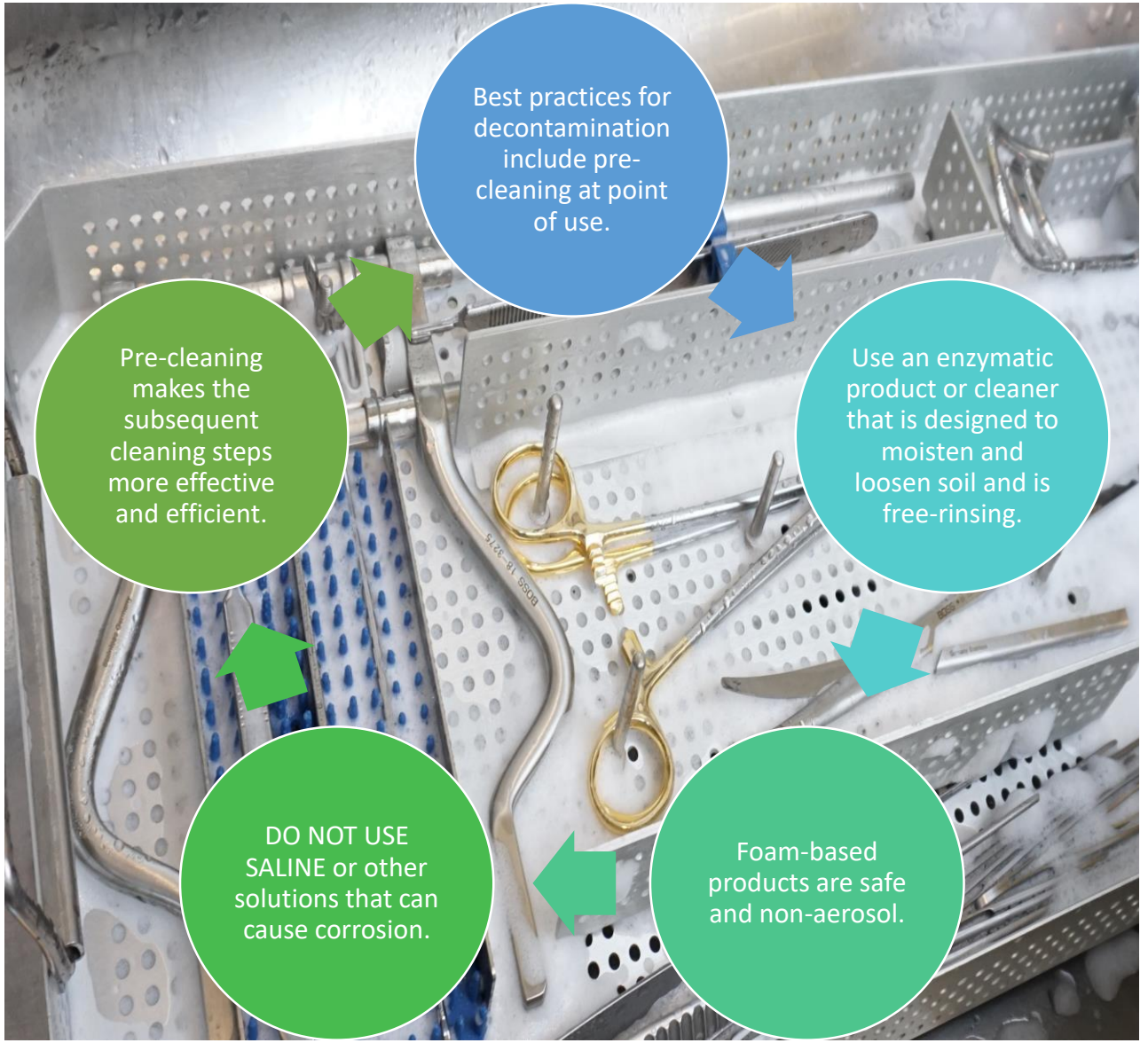
Instrumentation should only be cleaned in the decontamination room, including loaner instrumentation.

The decontamination room should have all the necessary decontamination equipment, cleaning implements and cleaning chemistries to thoroughly clean instrumentation.

Personnel must wear the required personnel protective equipment (PPE) to be protected from biohazardous material.

The standard PPE are Hair covering, Fluid-resistant face mask, Fluid-resistant gown with sleeves, Eye protection, Utility gloves, Liquid-resistant shoe covers

Pre-Cleaning



Why Pre-Clean?

To prevent build up of bioburden

To avoid development of biofilms

To prevent drying of secretions

Should take place at point of use immediately following the procedure

To keep instrument moist and to facilitate the subsequent cleaning process

Handling Contaminated Items

Remove contaminated items from their transport containers.

Sort items segregating general instruments from delicate items.

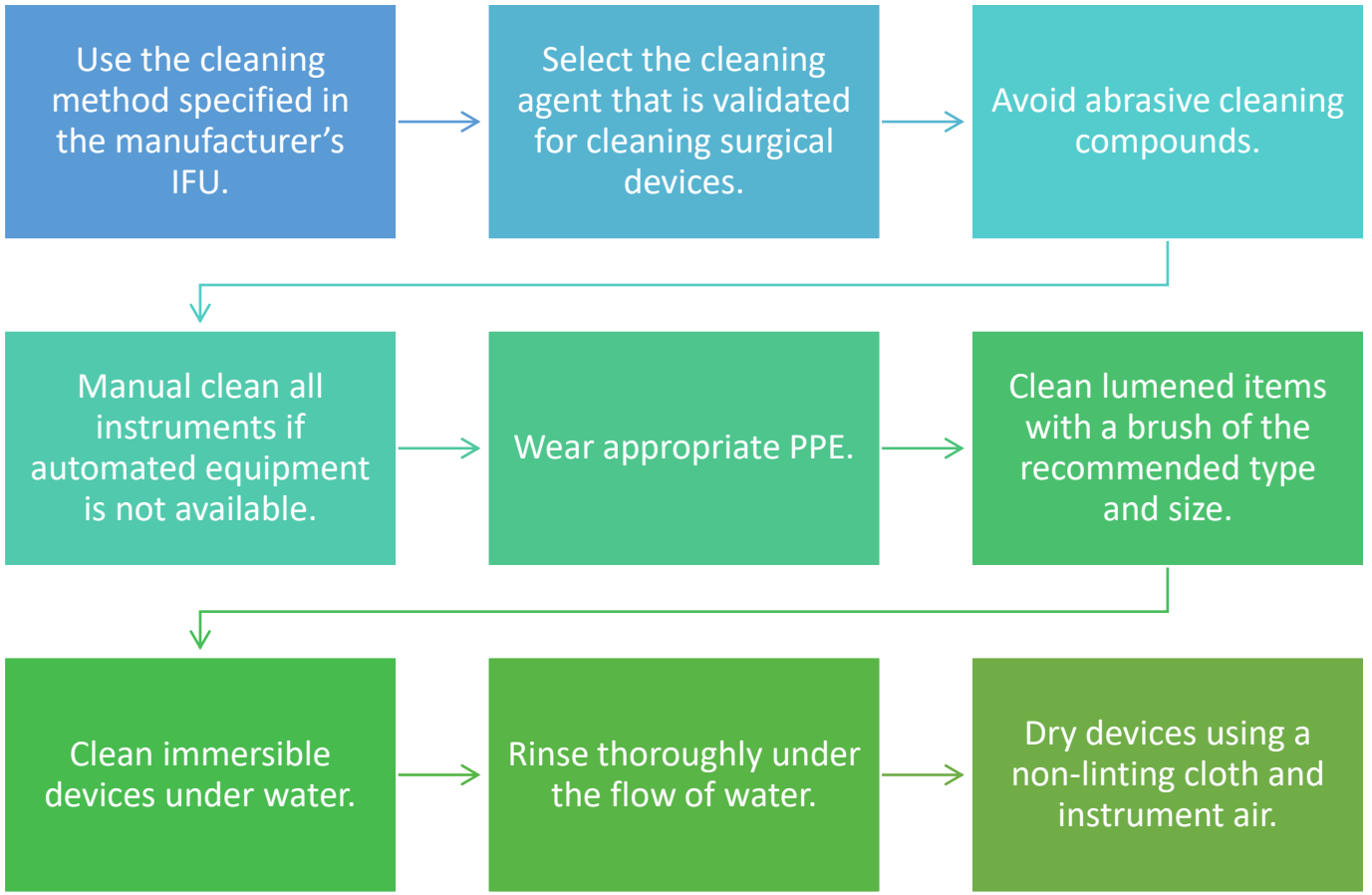
Use repair tags to identify instruments needing repair. These tags remain throughout the cleaning process.

Remove all disposable products.

Disassemble in preparation for cleaning.

Ensure that box locks and tips are open

Manual Cleaning



Ideal Cleaning Agents

Ideal Cleaning Agents

Be	Be compatible with the medical device.
Be	Be efficacious on all types of clinical soil.
Be	Be non-abrasive.
Be	Be low foaming.
Be	Be free rinsing.
Be	Be biodegradable.
Rapid	Rapidly dissolve/disperse soil.
Be	Be non-toxic.
Have	Have a shelf life consistent with anticipated use.


Rinse under the flow of water
SINK

Ultrasonic Cleaning Equipment

- Designed to remove soil from joints, crevices, lumens and other areas that are difficult to clean.
- Uses a cavitation process to effectively remove soil and bioburden from devices.
- Always use fresh cleaning solution.
- Change after each use to avoid cross-contamination.
- Follow by a thorough clean water rinse.
- Maybe all that’s needed.
- Alternative, follow with mechanical cleaning in washer disinfector.

Loading Mechanical Washers

- Preventive maintenance is crucial.
  - Remove gross debris.
  - Check that spinning arms are unobstructed.
  - Ensure that the drain is clear.
- Separate multi-level sets so that all surfaces are exposed.
- Connect lumened instruments to irrigation ports, if available.
- Open all hinged instruments.
- Ensure that water can drain freely.
- Daily monitor washer using a representative indicator.

Automated Cleaning

Mechanical cleaning is documented, reproducible and automated.

Can increase productivity and can be easily monitored for quality performance.

Selection of the cleaning equipment should be based on the requirements for the device.

Currently available equipment include ultrasonic cleaners, washer disinfectors, cart washers.

Packaging Best Practices

- After instrumentation has been cleaned it is ready for inspection and assembly.
- Preparation and packaging are performed in a clean environment.
- Instrument sets should be assembled so that the sterilant can reach all surfaces.
- Instrumentation is packaged using packaging that has been validated for the method of sterilization to be used.
- Instrumentation is inspected for functionality and cleanliness.
- Instrumentation must be dry before it is placed into the package.
- Sterile packages are inspected for integrity and compromised packages are reprocessed prior to use.

Using Rigid Containers

- Ensure that the container system is suitable for the proposed sterilization use and is compatible with the devices and sterilizers.
- Rigid sterilization containers vary in their mechanics and performance characteristics.
- Most use single use filters that are secured by a retention plate.
- All require tamper evident seals.
- External chemical indicators must be used in addition to internal CIs or integrators.
- Containers, as well as all packaged items, must be dry for future use. Wet items must be reprocessed.
- Only exception is for IUSS (flash) sterilization, which must be documented.

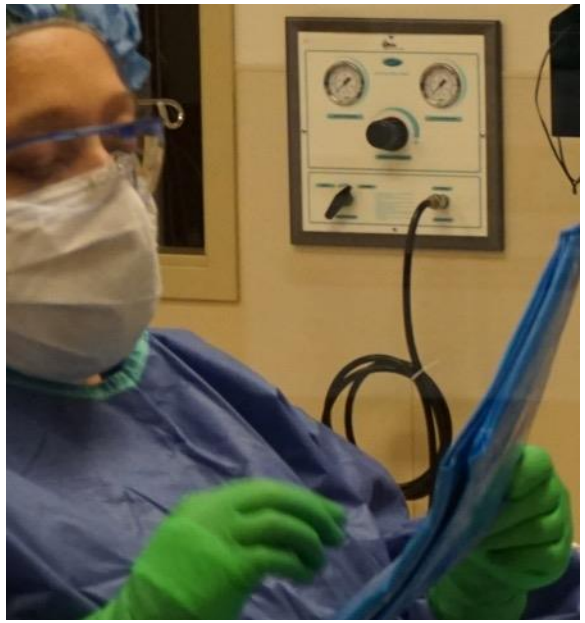
Inspecting Containers

- Check that container corners and edges are free of dents
- Inspect that gaskets are properly affixed
- Rivets and pins are secure
- Check that container surface is free of corrosion
- Ensure that latches close properly
- Ensure that container is cleaned after each use

Using Wrapped Trays

- Require time and attention to detail
- Double or sequential wrap to avoid tears
- Absorbent liners and corner protectors add expense
- Place internal indicator in center of package
- Close with indicator tape
- Wrapped trays cannot be stacked for transport, storage or sterilization

Inspecting Wrapped Trays



1. Check that package is wrapped following AAMI protocols
2. Ensure that tape is affixed to wrap surface
3. Inspect carefully for holes, abrasions or punctures
4. Never write on wrap surface as it can cause punctures
5. Ensure that contents are dry
6. Wrapped trays must be inspected in the OR

Sterilization Best Practices

The sterilization method selected is based on the instrument IFU.

Some items may require a specific type of cycle such as a dynamic air removal or an extended sterilization cycle.

The sterilizer is loaded so that adequate space is left between items to allow for air removal, penetration of steam into each package, and steam evacuation.

Plastic-peel pouches should be placed on their sides.

At the end of the cycle the physical parameters are reviewed to assure that all sterilization parameters have been met.

Allow the load to cool before being handled.

Check the external chemical indicators to assure that the color of the CI has changed.

Types of Sterilizers

Most steam sterilizers today are dynamic air removal units (pre-vacuum steam).

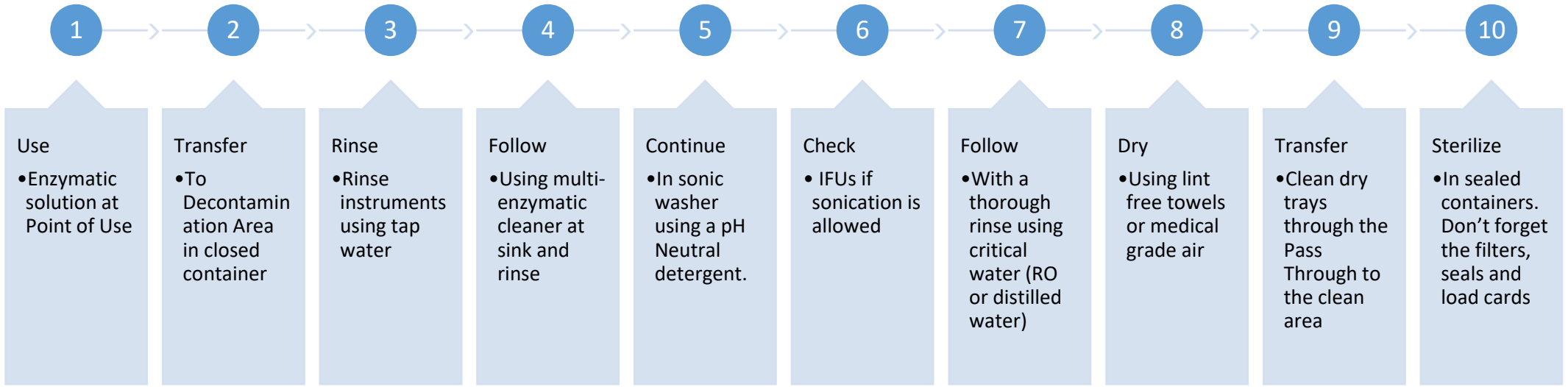
Tabletop sterilizers can be defined as units whose compact chambers offer 2 cubic feet or less of capacity.

While small in size, this type of sterilizer is an ideal solution for small surgery centers and office-based practices.

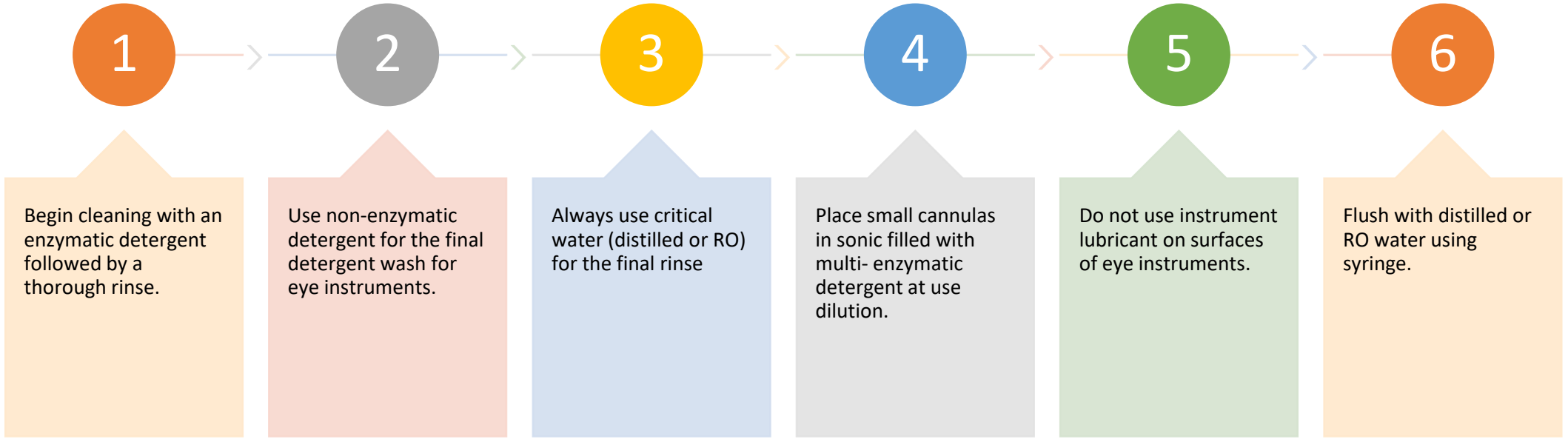
Wrapped trays, peel pouches and even one type of rigid reusable container may be used in tabletop units.

Larger-volume facilities use steam sterilizers, as well as low temperature sterilizers.

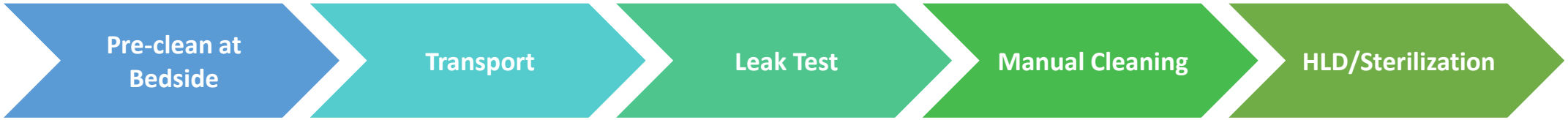
Processing Steps for Ambulatory Surgery Center



Reprocessing Steps Eye Instruments



Reprocessing Steps Endoscopes



- Wipe
- Sunction
- Flush

- Contain
- Label
- Transfer

- Detect Damage
- Test PRIOR to immersion
- Document

- Soak
- Clean Surface
- Brush
- Flush
- Rinse

- Move to separate room
- Inspect
- Rinse after HLD
- Sterilize, if possible

Training and Competency

Continuing education needs to build on the competency of staff.

Certification is a minimum competency.

Review topics directly related to sterile processing, such as those covered today.

- Decontamination
- Detergent selection
- Sterilization
- Packaging

Remember!

1. Sterilization is the absence of all forms of microbial life, including bacterial spores.
2. It is not an absolute.
3. If an item is considered sterile, it has less than 1 chance in 1 million that a viable organism has survived the sterilization process (SAL) is 10-6.
4. Sterilization follows the cleaning and rinsing steps and cannot be achieved unless items are safe to handle and safe to sterilize.

Conclusion

- As John Perkins once said: “Speed is a militant force against effective sterilization.”
- Don’t skip steps.
- Review your IFUs.
- Follow best practices.
- Continue to learn and apply what you’ve learned in your department each and every day.

Thank you from Case Medical

Photos provided by Essex Surgical Specialties

- Q&A