EDUCATION

STERIS UNIVERSITY

Best Practice in Surgical Instrument Reprocessing in an ASC or Clinic Setting

One Integrated Approach to Healthcare.

STERIS

Continuing Education Contact Hours

- Participants must complete the entire presentation/seminar to achieve successful completion and receive contact hour credit. Partial credit will not be given.
- STERIS Corporation is an approved provider of continuing education by the BASC (provider number 1417), CBRN (provider number CEP 11681) for 1 contact hour along with CBSPD and IAHCSMM.
- In accordance with CBRN guidelines, registered nurses must provide their state license number.
- All of the presenters are employees of STERIS Corporation and receive no direct compensation other than their normal salaries for participation in this activity.
- STERIS Corporation is providing the speakers and contact hours for this activity. However, products referred to or seen during this presentation do not constitute a commercial support by the speakers.

Learning Objectives

Upon completion of this presentation, you will be able to:

- Review CDC minimum expectations for nonhospital-based clinics, physician offices, ambulatory surgical centers, and other specialized settings; and
- Discuss best practices in instrument reprocessing as established by CDC and AAMI.

Why Now?

- More than 23 million procedures performed at ASCs annually
- Additional requirements for accreditation
- ASC settings have poor infection prevention infrastructure
- HAI data lacking in ambulatory setting

CDC Minimum Requirements

- Infection Prevention must be priority
- Resources must be available
  - Personnel
  - Equipment and supplies
- At least one employee or available resource trained in Infection Prevention
- Staff orientation, training and annual competency assessment

Why Follow Best Practice?

According to the CDC:

"Disinfection and sterilization are essential for ensuring that medical and surgical instruments do not transmit infectious pathogens to patients. Because sterilization of all patient-care items is not necessary, health-care policies must identify, primarily on the basis of the items' intended use, whether cleaning, disinfection, or sterilization is indicated."

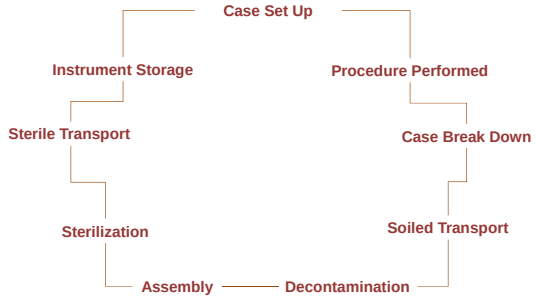
CDC

SAFER·HEALTHIER·PEOPLE™

Common Clinic Issues

- Space deficiencies for instrument reprocessing
- Outdated Supplies
- Reuse of single-use devices
  - Use of instruments that are not “Surgical Grade”
- Sterilization and disinfection knowledge deficiencies

Understanding Instrument Flow



Instrument Cleaning Begins at Point of Use

- Pre-clean at point-of-use per manufacturers IFU
- Properly dispose of waste, linens and sharps
- Return to the reprocessing area as soon as possible
- Keep instruments moist
  - Spray with an approved transport spray or use moist towel
- Prepare for transport
  - Must be in puncture-proof closed container
  - Must be labeled “biohazard”

Instrument/Device Transport

Decontamination Delay

- Transport instruments to decontamination as soon as possible
  - Closed puncture-proof container
  - Labeled “Biohazard”
- Problems caused by delays in transport or cleaning
  - Dried debris is more difficult to clean
  - Biofilms can develop
  - Damage to the passivation layer of surgical instruments

Cleaning vs. Decontamination vs. Disinfection

Cleaning

- Removal of all visible and non-visible soil, and any other foreign material from medical devices being processed.

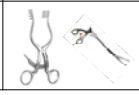
Decontamination

- To make safe by removing or reducing contamination by infectious organisms or other harmful substances; the reduction of contamination to an acceptable level.

Disinfection

- Destruction of nearly all pathogenic microorganisms on an inanimate (non-living) surface.

Spaulding Classification

Patient Contact	Examples	Device Classification	Minimum Inactivation Level
Intact skin		Non-Critical	Cleaning and/or Low/Intermediate Level Disinfection
Mucous membranes or non-intact skin		Semi-Critical	Cleaning and Sterilization (or High Level Disinfection)
Sterile areas of the body, including blood contact		Critical	Cleaning and Sterilization

ASC Decontamination Challenges

- Handwashing sink used for cleaning instruments and scopes
- Inadequate PPE
- Inappropriate or expired cleaning chemistries
- Incorrect dilution or temperature of cleaning chemistries
- Inadequate space for decontamination
- Decontamination and sterilization in the same room

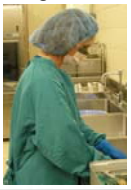
Neat, Clean and Organized

Personal Protective Equipment (PPE)

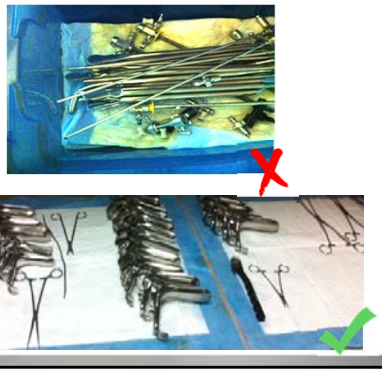
- OSHA requires PPE to protect HCP from exposure to infectious agents
  - Gloves for decontamination
  - Impervious gowns
  - Face masks
  - Face shields
  - Hair protection
  - Shoe covers
- Do not reuse PPE
- Hand hygiene to follow PPE removal

Manual Cleaning

- Three step process – soaking, washing, rinsing
- Used for heat/moisture sensitive devices
- Must have the proper tools for cleaning
- Prepares instruments for further processing
  - Mechanical cleaning/thermal disinfection
  - Chemical disinfection
  - Sterilization



Correct and Not Correct



Automated Cleaning

- Ultrasonic Cleaners
  - Can aid in reaching hard to clean areas such as lumens or box locks
  - Cleans by cavitation
- Automated Washer/Disinfectors
  - All instruments must be open
  - Must be routinely monitored
  - Cleans by impingement

Improper Loading

High Level Disinfection - Soaking

- Monitor solution temperature
- Document soak time
- No perpetual soaking until device is needed
- Monitor solution for minimum effective concentration
- QA monitoring of chemical indicator strips

High Level Disinfection – Soaking, continued

- Should not be used as a substitute for sterilization
- Should take place in the decontamination area
- Follow IFU for the proper preparation of solution
- Pay attention to expiration dates and label containers with preparation date and expiration date
- Follow IFU for proper rinsing
- Keep accurate records of all HLD processes

High Level Disinfection – Flexible Endoscopes

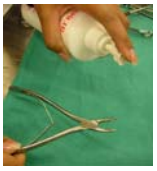
- Process flexible scopes according to the manufacturer IFU – DO NOT SKIP STEPS!
- Rinse thoroughly
- Purge with medical grade air and alcohol
- Store hanging
- Establish hang time

Automated Processing of Endoscopes

- Liquid Chemical Sterilization
  - Sterilization claim indicates the process has been validated to kill bacterial spores
  - Use immediately
- High Level Disinfection
  - Most AERs provide an additional cleaning cycle in addition to HLD
  - Must use flush tubes for your specific scopes

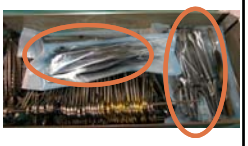
Inspection and Assembly

- Inspection
- Lubrication
- Weight
- Lumens
- Open & disassembled



Assembly - Accessories

- Trays
- Tray liners
- Peel pouches
- No rubber bands
- Tip protectors
- Color code tape



Packaging – Peel Pouches

- Chemical Indicator (CI) should be included in each pack
- Refer to IFU for using double peel packs
- Seal pack correctly
- Labeling only on plastic side of pouch
- Use tip protectors as required
- Do not use expired peel packs

Packaging – Sterilization Wrap

- Choose the correct size and weight for device
- Single vs. double wrap
- Woven wrap
- Manufacturers IFU

Packaging – Rigid Containers

- Provide great protection
- Costly
- Filters and arrows/locks
- Cleaning chemistries
- Inspection and maintenance
- Manufacturers IFU
- IUSS

Steam Sterilization

- Variety of sterilizers in use: table top, larger units
- Types of cycles
  - Gravity
  - Pre-vacuum
  - IUSS
  - Express

Sterilizer Loading

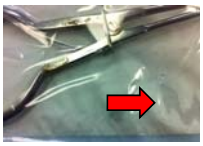
- All instrument trays flat
- Basins tilted
- Peel packs on their side
- Spacing between packages
- In table top sterilizer follow IFU for loading
- Don't overload!

Sterilizer Unloading

- Remove cart from chamber and allow to cool on cart
- If no cart:
  - Open door slightly and let items sit in chamber
  - Remove aseptically
  - Place on open cart or shelf to cool
  - Do not handle until completely cool

Wet Packs

- Wet packs are not acceptable
- Wet packs could be an indication that the sterilizer should be serviced or replaced

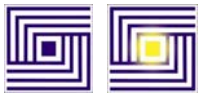


Sterility Assurance Goal

- Ensure processed instruments and devices are safe for patient use
  - Verifies proper functioning of sterilizers
  - Identifies processed items from non-processed
  - Confirms sterilant penetration

Steam Sterilization Monitoring

- Bowie Dick Testing
  - Air removal testing
- Physical Monitors
  - Sterilizer charts and printouts
- Chemical Monitors
  - Internal indicators
- Biological Monitors
  - Directly determines whether conditions have been met to kill the resistant organisms in the self-contained vial



Bowie Dick Test

- Daily air removal test for pre vacuum sterilizers
- Performed first empty load each day the sterilizer is used
- If first test fails, run again

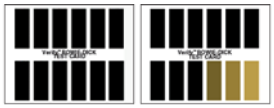
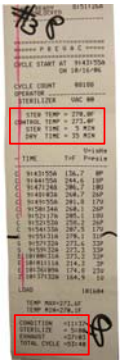


Figure 1: Pass Figure 2: Typical Failure

Physical Monitors

- Use as part of load release criteria
  - Should be evaluated and sign by a qualified technician
- Sterilizer charts and printouts are used to show conditions within the sterilizer for a particular load
  - Conditioning time
  - Sterilization time and temperature
  - Dry time
  - Pressure within chamber



Chemical Monitors

6 Types of Chemical Monitors

- Type 1 – Process Indicator
- Type 2 – For use in specific tests
- Type 3 – Single Parameter Indicator
- Type 4 – Multi Parameter Indicator
- Type 5 – Integrating Indicators
- Type 6 – Emulating Indicators

Biological Monitors

- According to AAMI ST79, BI monitoring to be done weekly, preferably daily and with all implant loads
- BIs are to be run in full loads
- Loads should be quarantined until BI results are known
- Incubate the BI, run with the load along with a control of the same lot
  - Processed BI should be Negative
  - Control should be Positive

Load Release Criteria "Non-implants"

- According to AAMI ST79, Section 10.6.2:

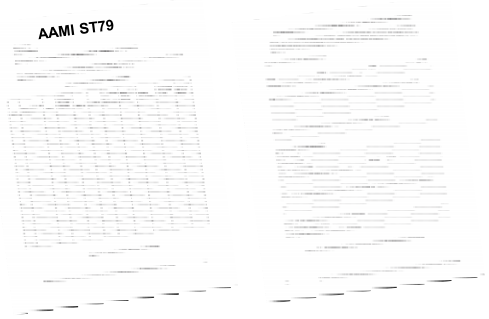
  "Load release should be an active decision that is based on evaluation of all available data from the sterilization process for the particular load. The decision to release a load should be made by an experienced, knowledgeable person at the conclusion of the sterilization cycle. Loads that do not meet the criteria for release should be clearly identified so that they are not mistakenly distributed.

- *Rationale:* Releasing sterilized devices on the basis of all quality control measures is critical in providing safe and effective products for patient use."

Load Release "Implants"

- Biological Indicator must be run with each implant load
- Review physical monitors and CI from BI PCD
- Quarantine load until results of BI are known
- Early release of implants
  - Document
  - Must be traceable to the patient
  - Complete early release exception form and have signed by MD
  - Emergency must be clearly defined by policy

Sample – Early Release Documents



Positive Biological Indicators/Sterilization Recall

- Positive BI result or other suspected sterilization failure
- Use load log for recalling items in loads with questionable sterility
- Recall all items sterilized back to the last cycle with a negative (good) BI result
- Notify supervisor/administrator, infection prevention personnel and physician(s)
- Patient notification and intervention determined by administration, infection prevention and physician

Recordkeeping

Types of records that are required to be kept

- Sterilization logs
- Biological monitoring logs
- Equipment service logs
- IUSS

Transport and Storage

- Keep handling of sterile packages to a minimum
- Handle, transport and store in a way that does not compromise sterility maintenance

Improper Storage

Unacceptable Storage Solution

Loaner Instruments

- Unexpected instruments arrive when you are not prepared
- Expected instruments that don't arrive
- Not sure which company rep to call when there is a problem
- Delays in instrument processing
- Unclear or unavailable IFUs

Best Practice for Loaner Instrumentation

- Develop a communication procedure for loaner instrumentation
- Always follow IFU for cleaning and sterilization
- All loaner instrumentation must be cleaned and sterilized by the receiving facility
- Transport and store in a way that does not compromise packaging and sterility

Beware…

Equipment Maintenance

- Daily/routine cleaning
  - Clean chamber drain daily
  - Check door gasket
  - Clean chamber per manufacturers IFU
  - Refer to operator's manual
- PMs and maintenance
  - Maintenance should be done by qualified, trained technician
  - Regular PMs can keep equipment running correctly
  - Major repairs require re-qualification testing
  - Maintain all maintenance records

Environmental Cleaning

- Establish policies and procedures
- Cleaning must precede disinfection
- Emphasis on surfaces most likely to become contaminated
- Follow manufacturer's recommendations
  - Use
  - Contact time
  - Dilution rate
  - Disposal

Environmental Cleaning, continued

- Cleaning should flow from clean to dirty areas
- Horizontal surfaces should be cleaned and disinfected at the beginning and end of each shift
- Spills should be cleaned up immediately
- Floors should be cleaned and disinfected daily
- Biohazard waste should be removed frequently
- Walls, shelves, cabinets should be cleaned routinely

Additional Concerns

Bottles refilled from a Water Distiller without being cleaned and disinfected first

Not All Air is Equal

Is it Clean or Sanitized?

Will You Clean It?

Clean and Disinfect Routinely

Wash Between Each Patient

Continuing Education

- In-services from device and equipment manufacturers
- Clinical specialists
- Facility policies and procedures
- Annual competencies
- Regulatory agencies/guidelines
- Online learning
- Conferences and seminars
- Certification

References

- Association of the Advancement of Medical Instrumentation. (2013). *ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3:2010 & A4:2013 Comprehensive guide of steam sterilization and sterility assurance in healthcare facilities*. Arlington, VA: Author.
- Centers for Disease Control and Prevention. (2008). Guide for disinfection and sterilization in healthcare facilities. Retrieved from: http://www.cdc.gov/hicpac/pubs.html
- Centers for Disease Control and Prevention. (2016). Guide to infection prevention for outpatient settings: Minimum expectations for safe care (*version 2.3).* Retrieved from: https://www.cdc.gov/hai/settings/outpatient/outpatient-care-guidelines.html

References, continued

- International Association of Healthcare Central Service Material Management. (2016). *Central Service Technical Manual* (8th ed.). Chicago, IL: Author.
- Rechtoris, M. (2015). 50 things to know about the ambulatory surgery center industry. Retrieved from http://www.beckersasc.com/asc-turnarounds-ideas-to-improve-performance/50-things-to-know-about-the-ambulatory-surgery-center-industry.html
- Society of Gastroenterology Nurses and Associates. (2016). Standards of Infection Prevention in Reprocessing Flexible Gastrointestinal Endoscopes. Chicago, IL: SGNA.

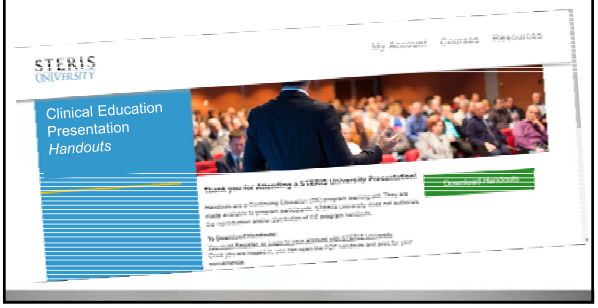
Questions

Evaluation and Registration

- Thank you for attending this CE activity
- Please complete and submit the evaluation form

Handouts

To access the handouts for this presentation, go to: university.steris.com/ic.




EDUCATION
STERIS
UNIVERSITY
university.steris.com
Playing a part in your professional development today
To help you achieve your career vision for tomorrow
One Integrated Approach to Healthcare.
STERIS