Nebraska Infection Control Network

Sterilization in a Healthcare Setting

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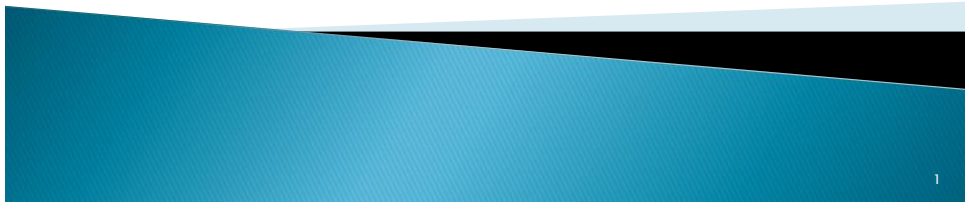
Director of Sterile Processing LSH/NSC



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Who is responsible?

- Round in the SPD
- Make the SPD team your ally
- Collaborate and support
- Define what processes are being performed
- IP should know the standards high level
- SPD management/team should know the standards in great detail (do they?)

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The Gospel according to ANSI/AAMI

- ST 79 – Steam sterilization
- ST 58 – Chemical sterilization and high level disinfection
- ST 91 – Flexible and semi-rigid endoscope processing
- ST 108 – Water for the processing of medical devices

- Lots of others if you perform sterilization by: EO, radiation, dry heat, etc. or sterilize tissue, linen, etc.

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Spaulding Classification

Dr Earl Spaulding defined categories the CDC uses to classify medical devices according to their use.

- **Critical** devices – those that are exposed to normally sterile areas of the body. These devices should be sterile when used thus requiring sterilization between uses.
- **Semi critical** devices – come in contact with intact mucous membranes during use thus they are to be either sterilized or high-level disinfection.
- **Noncritical** devices – only touching skin or come in contact with persons indirectly. These devices can be cleaned and then disinfected with an intermediate-level disinfectant, sanitized with a low-level disinfectant, or simply cleaned with soap and water.

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High Level Disinfection Rounds

Review practice

- Correct chemical for device (IFU)
- Consider ventilation requirements
- Monitor Minimum Effective Concentration (MEC) level (possibly temperature)
- Documentation
- Verification testing for residual soil
- Proper drying and handling post disinfection

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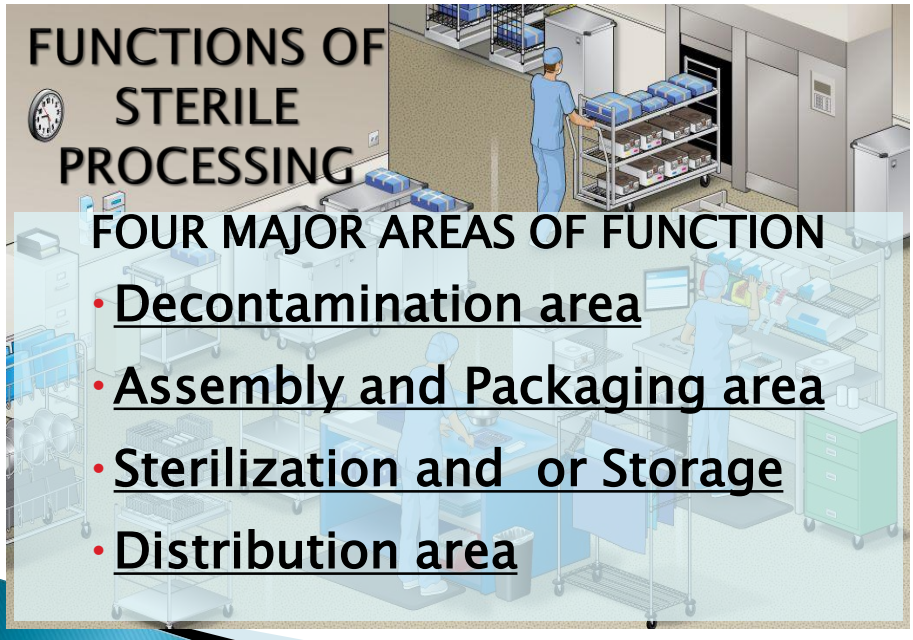

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5 basic principles of Asepsis

- Principle one: know what is dirty
- Principle two: know what is clean
- Principle three: know what is sterile
- Principle four: keep the three conditions separate
- Principle five: remedy contamination immediately

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Physical Design of Sterile Processing

- Should incorporate clear separation of clean and dirty
  - Restricted lines and signage
- One way work flow from dirty to clean
- Decontamination should be under negative air pressure in relation to other work areas
- Clean and Sterile Storage should be under positive pressure.

Work Area	Temperature	Humidity	Air Exchanges	Air Pressure
Decontamination	60°F- 65°F	30-60%	10	Negative
General Work Areas	68°F-73°F	30-60%	10	Positive
Sterile Storage	75°F or lower	Not exceed 70%	4	Positive
Sterilization Equipment Room	75°F-85°F	30-60%	10	Positive

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Environmental maintenance of Sterile Processing

- Minimize the amount of contaminates such as dust, lint, and bacteria in work areas. (monitor during construction or breakouts)
- Food and beverages should not be allowed in the work areas.
- Floors should be cleaned (wet mopped) at least daily. Floors should never be swept or dust mopped because dust will rise and fall on items such as instruments.
- Horizontal work surfaces such as counters and tables should be cleaned at least daily.
- The decontamination area should have separate dedicated cleaning equipment such as mops and buckets.
- Establish cleaning frequency for vents, lights, walls, ceilings, equiment, etc. (IFUs and AAMI standards can assist with recommendations

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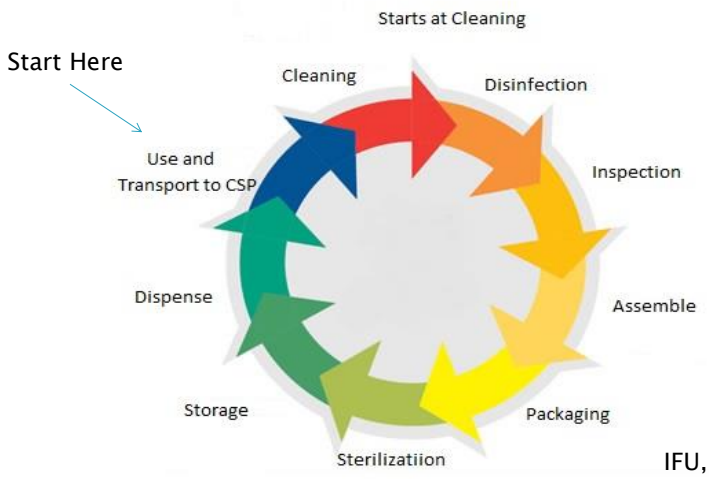
The Processing Cycle



IFU, IFU, & IFU

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When Should Instruments Be Cleaned?

- After each use
- After they have been opened in a sterile field, but not used
- When new instruments are received at the facility
- When used instruments are returned from being repaired/refurbished
- When instruments are contaminated
- When loaner instruments are received

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Instrument Point of use Cleaning and Transport Considerations

- Prevent soil from drying and forming biofilm
  - AMAP Wipe soils from instruments after each use as surgery progresses and at the end of the case
  - Disassemble instruments AMAP, and unclamp and open jaws
  - Multiple commercial products
- If instruments are initially soaked in a basin:
  - Avoid prolonged exposure and never in saline
  - Do not transport with items soaking in any solution
    - Could cause splashes/exposures
- Label instruments in need of repair or sharpening so they can be segregated and sent for repair

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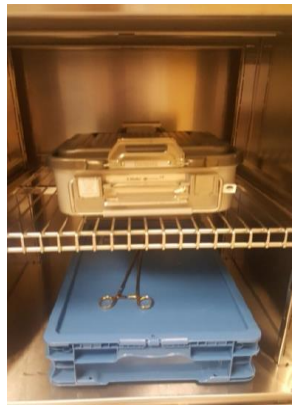
Transport

- Goal: minimize exposure to microorganisms
- Transport in an enclosed system (Bins with lids, enclosed or covered carts, rigid sterilization container systems, and impermeable bags; when sharps or needles may be present container must be impervious.)
- Carts/containers must be identified as biohazardous and cleaned between use
- Outside departments need to transport often and ASAP after instrument use is complete



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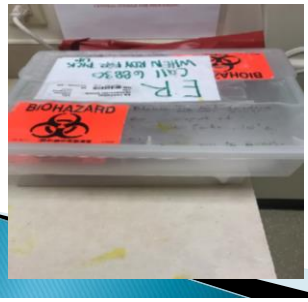
Perform rounds or audits to ensure containers are in compliance

- Adhesive residue and paper labels prevent proper cleaning and disinfection



- Paper labels cannot be cleaned or disinfected
- Labels are confusing

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Decon Rounds

The down and DIRTY

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Environmental Rounding

- Under sink storage is prohibited

- Tape is not to be used; prohibits cleaning and disinfection

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Personnel Safety: Eyewash Stations

- Available in decontamination area
- Accessible within 10 seconds
- Must not be blocked
- Routine maintenance and checks are completed and logged

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Cleaning Verification

- AAMI ST79: 2017
- Mechanical cleaning equipment performance should be tested each day it is used and all results should be recorded. (7.6.4.5)
- Health care personnel should perform verification testing on all mechanical cleaning equipment. (13.2)
  - Methods of testing: (13.2)Monitor critical parameters. Use a test device intended for the equipment being tested. Direct testing of individual devices.
- Test each day-the equipment is used and after major repairs. (13.2)

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Are we following the manufacturers instructions for use (IFU)

- How do staff know how to clean instruments or other medical devices and what type of solution to use to clean with?
- Length of time for wash/soak
- How do they know if and item needs taken apart for cleaning and to what level?
- IFUs for equipment
  - Sterilizers, washers, dryers

oneSOURCE document site

Instructions For Use

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Sink Use

- Appropriate cleaning and decontamination solution
- Proper dilution
  - Water lines in the sink and med cup to measure, or automatic dosing system
- If using dosing system, must calibrate to ensure proper dosing is dispensing

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Attire in the Decontamination Area

- Bouffant caps
- Face shield
- Fluid resistant mask to protect nose and mouth
- Fluid resistant gown
- Gloves
  - Thicker than exam gloves
  - Long cuffs are ideal
- Impervious shoe covers

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Brushes

- Use disposable when possible
- If not disposable, decontaminate often, at least daily
- Rusted brushes and brushes with worn bristles should be discarded immediately

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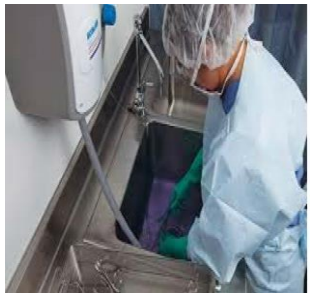
Brush Under Water

- Ensure detergent can reach every part of the device
- Brush instruments under water to prevent aerosolization
- Lumened instruments need to be cleaned with proper size brush



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What does ST79: 2017 say?- Decontamination

- Additional chemicals should not be used following rinsing unless recommended in manufacturer's IFU. 7.4.1
- Brushes should be clean. 7.4.1 (Discard worn brushes)
  - Use appropriate brush bristle type and size –e.g. brush for lumen must contact all sides of the lumen and extend beyond the end of the lumen.
  - Should be disinfected or sterilized at least once a day.
- Cloths should be clean and non-linting. 7.4.1
- Final rinse water should be of the quality specified in IFU. 7.4.1 & AAMI ST108

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Sonic/Washer-Disinfector

- Avoid mixed metals in Sonic
- Single levels
- Proper weight limits for pans
- Correct wash cycle for type of instruments

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You Can't Sterilize Dirt

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Various Types of Sterilization

- Steam (high temp)
  - Most common
  - Least expensive
  - IUSS process
- Hydrogen peroxide gas plasma
  - Low temperature
- 100% Ethylene Oxide (EO)
  - most states have outlawed its use
  - 12-13 hour process
- Ozone
  - Good alternative
  - 4 hour process
  - Hasn't caught on yet due to the length of time for sterilization

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Steam Sterilization

- Steam sterilization is saturated steam under pressure
- Steam kills microorganisms by heating them and causing coagulation and denaturing of the cell proteins
- For steam to be effective it must contact the microorganisms for a specific amount of time and temperature

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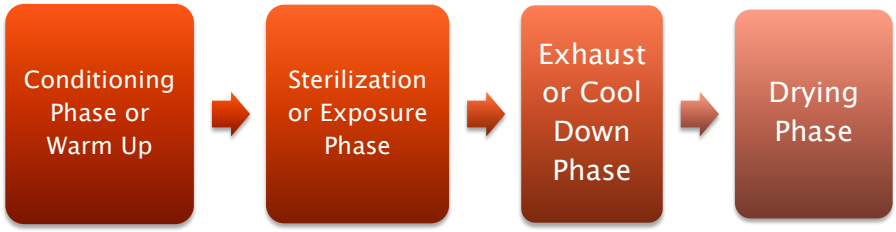
Sterilizer Phases



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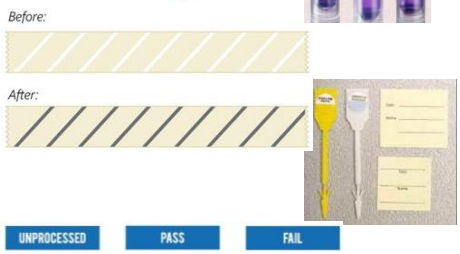
Monitoring Steam Sterilization

- Physical Monitoring
  - Exposure Time, Proper Temp and pressure Recorded accurately
- Chemical Integrator
  - External CI (class I)
    - Outside of packaged goods
    - Measures one parameter of sterilization
  - Internal CI (class IV or V)
    - Placed inside each packaged item
    - Measures all parameters of sterilization
- Air Removal (Bowie Dick, Dart)
  - Testing completed daily for dynamic air removal sterilizers
- Biological Indicators
  - Used for daily monitoring of sterilizer efficacy tests
- All the above are part of
  - monitoring
  - load release
  - recall of sterilization loads



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Biological Indicators (BI): Frequency of Usage

Mission	Frequency	Source
Routine chemical sterilization	At least daily, preferably in every cycle	AAMI ST58 Section 9.5.4.3
Routine steam sterilization	At least weekly, preferably daily	AORN Guidelines for Perioperative Practice 2018 Sections XXh.1– XX.h.4 AAMI/ANSI ST79
Sterilization loads containing implantable devices	Each load	AAMI/ANSI ST79
Ethylene Oxide	Every load	Manufacturer Instructions for Use
Low temperature hydrogen peroxide gas plasma, routine	At least daily on each cycle type, preferably with each load	Manufacturer Instructions for Use

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Best Practice: Monitor Every Load

- By monitoring every load you will: Provide the same level of care to every patient; from a standard of care to best practice.
- Achieve consistency of use across all sterilization modalities.
- Reduce the time needed to identify and recall loads in the event of a positive BI (if rapid BIs are used).

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Sterilization Rounding

Environment
- Clean
- Staff attire
- Air

Processes
- ⇨ Wrapping
- ⇨ Loading
- ⇨ Cooling

Paper trail
- Cycle parameters
- Load contents
- Validation testing

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Multi-Level Trays

- Must be within the weight limits
- Must have a CI on every level
- May need extended exposure time
- May need extended dry time
- What determines these
  - The IFU

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Peel Pouches

- Use tip protectors
- Place in position of use
- Tips should face the plastic side
- Hinged instruments should be open
- ½" around the instrument in pouch to edge
- Remove excess air
- Place any labels on plastic side only
- Sealed edge must not have creases

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Sterilizer Cart Loading

- Must follow the sterilizer capacity levels
- Must adhere to the weight limits of containers or wrapped items
- Any peel pouches should be placed on their side paper to plastic side
- Must be on top shelf if mixed load
- Textile or wrapped items above container items
- Lightest to heaviest from top to bottom
- Nothing can hang over the edges of the cart

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Don't Overload

There's no way these can end well!

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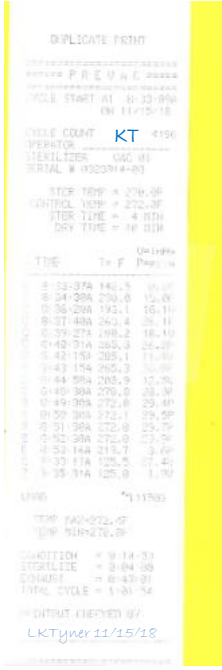
AAMI ST79 13.3.3 Sterilizer Records

- The process critical parameters: (time and temperature) should be provided on the recording chart, printer, or tape
  - Reviewed
  - Signed
  - dated



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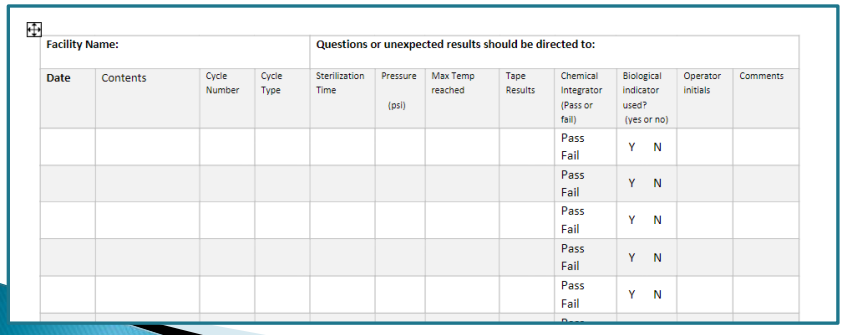
- For each sterilization cycle, the following information should be recorded:
  - the load number
  - the specific contents of the lot or load, including quantity, and a specific description of the items (type/name of instrument sets);
  - the exposure time and temperature, if not provided on the sterilizer recording chart
  - operator identification
  - the results of biological testing
  - the results of Bowie-Dick testing
  - the response of the CI in the challenge pack if used
  - any reports of inconclusive or nonresponsive CIs found later in the processed devices



Facility Name:				Questions or unexpected results should be directed to:							
Date	Contents	Cycle Number	Cycle Type	Sterilization Time	Pressure (psi)	Max Temp reached	Tape Results	Chemical Integrator (Pass or fail)	Biological indicator used? (yes or no)	Operator initials	Comments
								Pass Fail	Y N		
								Pass Fail	Y N		
								Pass Fail	Y N		
								Pass Fail	Y N		
								Pass Fail	Y N		

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Unloading a Completed Sterilizer

- Sterilized items should remain on wire rack where air circulates to cool items
- Items should be cooled to set temperature usually room temperature
- A minimum of 30 minutes for dry time may take longer depending on set density
- Pores in packaging stay open until cooled properly
- Handling items prior to proper cool could allow microorganisms to be wicked into package causing contamination
- Temperature should be checked with a temperature sensing device (infrared thermometer)

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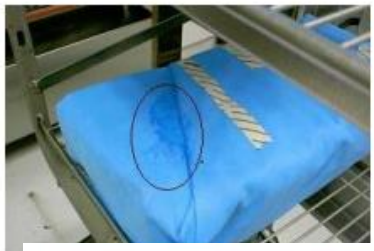
What is a Wet Pack?



- A pack, container, or peel pouch that contains moisture after sterilizer completion to include proper dry time.
- Causes of wet pack?
  - A clogged drain
  - Improper steam supply
  - Incorrect loading of the sterilization cart
  - Incorrect packaging
  - Sets over the 25# weight limit
  - The water quality of the steam
  - Temperature flux during changing weather outside

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Sterilization Process Failures

Work with SPD

At what point do you report a process failure to infection control?

- Notify SPD management, follow facility policy (ANSI/AAMI ST79 13.7.5, Table 4, Figure 10)
- If root cause is immediately able to be determined, reprocess affected items or entire load as needed (possible QI report)
- If cause is not able to be identified immediately, quarantine the load and work through facility policy. (QI report)
- If failure is a positive BI, quarantine the load, recall all released items back to the last negative BI, notify IC to track patients who had an item from any recalled loads used in their surgery.

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What is a Recall?

- A Recall is when a positive BI has been Identified after incubation and you have distributed instruments to various places to include storage, clinics, and the Operating Room
- You must retrieve all instruments from loads back to the last negative BI
  - How do you know what to recall?
- Any instruments that may have been used on a patient must be reported to the doctor, patient safety, IP
- This process is very tedious
- A very good reason to run a BI on every load

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Compliance Items

- Instrument Air
- Quality Water
- Instrument Tape
- Package Outdating
- Equipment Maintenance logs
- Autoclave Qualification Testing
  - Required when there are major repairs or the steam has been shut down
    - Run 3 Air Removal Tests
    - Run 3 Biological Tests

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Standards, Recommendations and Guidelines

AAMI
ANSI American National Standards Institute
AORN
APIC Spreading knowledge. Preventing infection.™
U.S. Food and Drug Administration Protecting and Promoting *Your* Health
OSHA Occupational Safety and Health Administration www.osha.gov
CDC CENTERS FOR DISEASE CONTROL AND PREVENTION
ISO International Organization for Standardization
CMS CENTERS for MEDICARE & MEDICAID SERVICES
SGNA Society of Gastroenterology Nurses and Associates, Inc.

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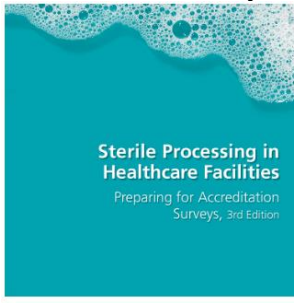
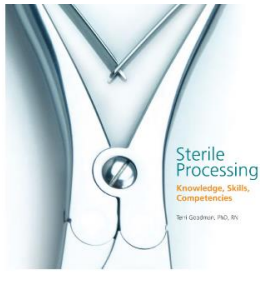
Resources

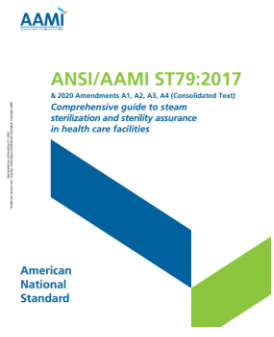
Sterile Processing in HC Facilities: Preparing for Accreditation Survey



Sterile Processing: Knowledge, Skills, Competencies



Comprehensive Guide To Steam Sterilization And Sterility Assurance In Health Care Facilities



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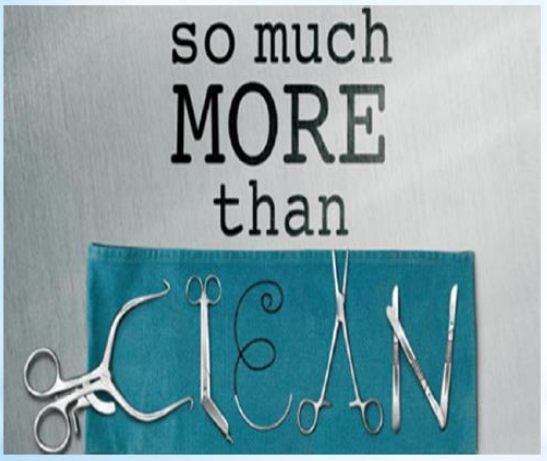

Thank you!
Questions

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