Nebraska Infection Control Network

Sterilization in a Healthcare Setting

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1

1

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.

2

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Objective

- Understa tion, it cesses and best pra s t re ster d items are provide use o ent

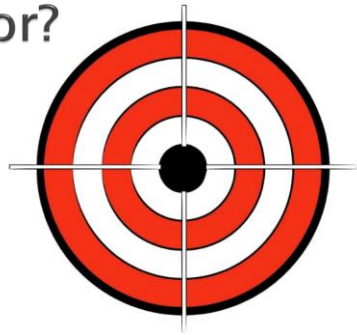
Objective

- Understand sterilization, its processes and best practices
- Understand that we can only provide the best chance at sterilization by following proper protocols and testing

What are we aiming for?

Sterility Assurance Level of 10^{-6}:

Less than or equal to one chance in a million of a single viable microorganism being present on a sterilized item



How are we achieving this?

- Assurance Testing Program
- Steam sterilization
- Low temperature chemical sterilization

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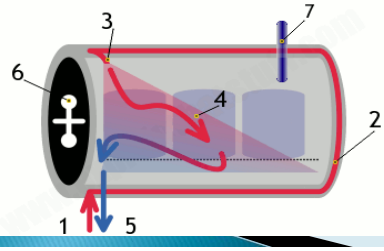
Steam Sterilizers/Autoclave

Steam is the workhorse of the SPD

- Most Common
- Least Expensive
- Most effective



1. Steam enters jacket
2. Steam warms jacket
3. Steam enters chamber
4. Steam sterilized contents
5. Steam exits via drain
6. Locked and sealed door
7. High pressure valve

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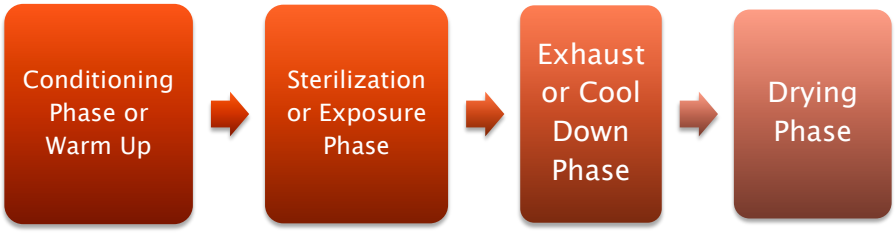
Sterilizer Phases



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Steam Sterilization

- 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
- The temperature of steam is affected by pressure

8

8

Low Temperature Chemical Sterilization
(Works by chemical flooding, contacting all surfaces)

- Vaporized Hydrogen Peroxide/Gas Plasma (VHP)
  - Most common and safest
  - Not as hard on certain items as steam, making their useful life longer
- Paracetic Acid (PAA)
  - Only for submersible items
  - Cannot be stored for later use

- Ethylene Oxide (EtO)
  - Outlawed in many states
  - At one time the most common, now obsolete
  - High toxicity requiring 10+ hour cycles for aeration

9

9

Other types of Sterilization

- Ozone
  - Safe alternative used in foreign countries
  - Not popular in US due to 4 hour process time
- Dry Heat
  - Longer process time than steam
  - Hard on some surfaces due to drying nature
  - Packaging challenges
- Ultraviolet Light (UV)
  - Gained popularity during COVID
  - Working on how to use and allow storage

10

10

Common Barriers to Sterilization

- Soil
  - Biofilms
  - Cross contamination
- Water and Air
- Improper processing practices
- Cycle failure
- Chemical concentration failure
- Handling & storage failure

11

Surgical instrument cycle

- The use
- Point of use cleaning/pre-treatment
- Transport
- Cleaning
- Inspection
- Sterilization
- Distribution/Sterile storage

12

12

Instrument Point of use Cleaning and Transport to SPD

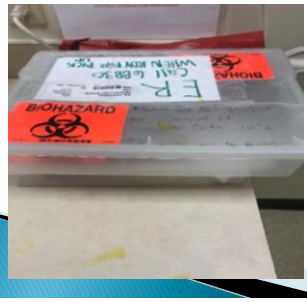
- Prevent soil from drying and forming biofilm
  - Wipe DURING and after case
  - DO NOT use saline for cleaning
  - Disassemble instruments, unclamp and open jaws
  - Use a commercial products or wet towels after case to keep from drying
- For transport:
  - Do not transport with items soaking in any solution
    - Could cause splashes/exposures
  - Lidded, leak proof, puncture resistant
  - Bins/carts must be labeled biohazard
- Label instruments in need of repair or sharpening so they can be segregated and sent for repair

13

13

Ensure POU cleaning and transport are in compliance

- Enlist OR management help for OR team education and auditing
  - Are instruments POU cleaned with sterile water
  - Is blood allowed to dry
  - Is a wet towel or commercial product used to prevent drying after transport
  - Are proper transport containers available and used properly



Container considerations:
- Adhesive residue and paper labels prevent proper cleaning and disinfection
- Labels must be clear with easy identification between clean and contaminated

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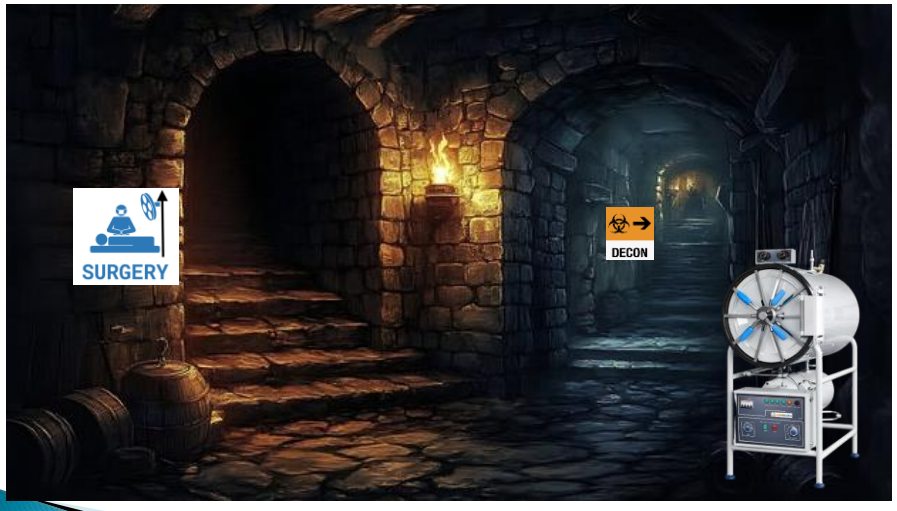
SPD



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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 Equiq Rom	75°F–85°F	30–60%	10	Positive

17

17

EVS for Sterile Processing

- Who is responsible and are they properly trained
- Floors should be cleaned (wet mopped) at least daily. Floors should not be swept or dust mopped
- The decontamination area should have separate dedicated cleaning equipment or strict cross contamination protocols in place
- Horizontal work surfaces such as counters and tables should be cleaned at least daily.
- Light fixtures, air vents, ceilings should be cleaned on a facility determined schedule (typically 6 months)
- Other surfaces including walls, cabinets and racks should be cleaned “regularly”.

18

18

Always follow the (IFU)

- Do staff clean instruments or other medical devices based on IFU
  - Disassembly
  - Lumens, cavities, caps, etc.
  - Pre-rinse, soak, rinse times

- Are IFUs for instruments compatible with automatic equipment
  - Sonic, washers, dryers, sterilizers
- Are IFUs accessible

oneSOURCE document site

19

Deconcontamination

Manual Cleaning
"3 sink process"

Will always perform

Mechanical Cleaning
Is best practice if allowed by IFU and equipment is available

Ultrasonic

Washer/Disinfector

20

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
- Shoe covers

21

21

Manual Decontamination per IFUs

- 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

22

22

Brushes, Sponges and Cloths– oh my

- Use Non-linting items
- 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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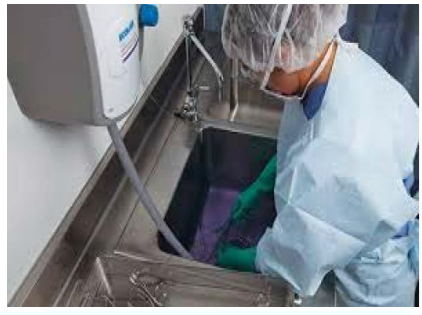
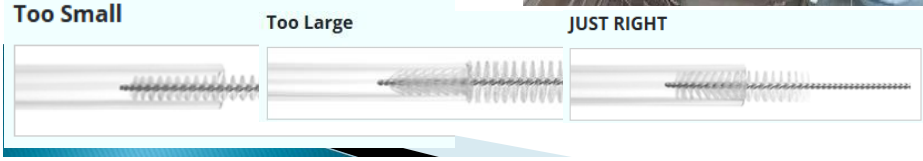
Clean Under Water

- 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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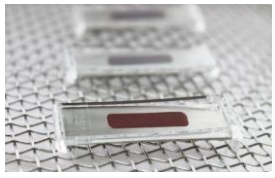
Cleaning Verification

- Mechanical cleaning equipment (Washer/Disinfector and ultrasonic) performance should be tested each day it is used and after major repairs with results recorded
- Testing should monitor critical parameters. Use a test device intended for the equipment being tested.



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Barriers to automated cleaning devices

- Crowding/Stacking/Shielding
  - Too much in pans can block cleaning solutions
  - Overcrowding can prevent cavitation in ultrasonic
- Silicone and plastic
  - Hinders the action of cavitation
- Improper pans/trays
  - IFU for pans/trays used must be approved for use in the automated cleaning device per the container's IFU

26

26

Inspection

- Train staff to identify potentials for hidden biofilms:
  - Pitting
  - Rust
  - Cracks
  - Gouges/scrapes/burrs
- Use lighted magnification
- Use boroscopes

27

27

Packaging

- Correct selection for items by IFUs (for item, packaging, and sterilizer)
- Appropriate CI included per IFU and by AAMI ST79
- Correct instrument arrangement
- Locks and valves open
- Appropriate labeling

28

28

Loading for Sterilization

- Adhere to the weight limits (both individual containers and sterilizer max load)
- Any peel pouches should be placed on their side, paper to plastic side
- Peel pouches and wrapped items should not be on self below rigid containers
- Lightest to heaviest from top to bottom
- Nothing can hang over the edges of the cart
- Circulation is critical to all sterilization, space between items is needed

29

29

Don't Overload

There's no way this can end well!

30

30

Unloading a Completed Sterilizer

- Sterilized items should remain on wire rack out of direct airflow to cool
- Pores in packaging stay open until cooled properly
- Handling items prior to proper cool could allow microorganisms to be wicked into package causing contamination
- Items should be cooled to a facility determined temperature (usually room temperature-80°F)
- Temperature should be checked with a temperature sensing device (infrared thermometer)

31

31

Monitoring Sterilization

(for both steam and low temp chemical sterilizers unless noted)

- Develop facility specific plan at or above Standards requirements
- Leak Test (typically weekly)
  - Measures jacket, chamber and external piping integrity
- Physical
  - Shows required exposure time, temperature and pressure (steam) or concentration (VHP) for every load
  - Reviewed, signed off with date and time and recorded

MACHINE NAME : ST1
CYCLE COUNTER : 30366
PROCESS START : 2026.04.07 13:11:53

PARAMETERS
Program: P3 - vacLoad 4\45
Exposure Temp: 270.0
Exposure Time: 00:03:30

Phase/ Prog Time	Temp	Pressure
PURGE		
00:00:01	168.4	-0.010
00:00:39	216.4	0.466
CONDITIONING		
00:01:30	226.4	0.209
00:02:00	240.6	0.764
00:02:26	254.1	1.221
00:03:09	201.2	-0.182
00:03:26	205.1	-0.334
00:04:00	234.2	0.558
00:04:35	254.3	1.217
00:05:22	180.4	-0.508
00:05:40	193.6	-0.678
00:06:00	204.6	-0.212
00:07:05	254.6	1.220
00:07:41	191.4	-0.402
00:08:00	198.3	-0.643
HEAT-UP		
00:08:10	200.5	-0.671
00:10:00	258.4	1.359
00:12:00	271.1	1.912
EXPOSURE		
00:12:22	271.8	1.948
00:14:00	271.9	1.956
00:15:57	272.0	1.959
EXHAUST		
00:16:23	271.8	1.949
00:17:02	186.3	-0.446
DRYING		
00:17:30	203.4	-0.682
00:17:44	204.9	-0.781
00:18:00	204.0	-0.835
00:19:08	199.7	-0.794
00:20:00	201.1	-0.775
00:22:00	203.3	-0.770
00:24:00	205.5	-0.766
00:26:00	202.0	-0.749
00:26:13	201.5	-0.746
00:27:04	199.6	-0.921
00:28:00	200.6	-0.950
00:30:00	210.0	-0.960

32

32

Chemical Indicators (CI)

- Type 1: External CI
  - Outside of packages
  - Measures one parameter
  - Example: Tape and locks

- Type 2: Bowie-Dick
  - For dynamic air removal sterilizers
  - Testing completed daily, prior to use, in an empty chamber
  - Measures efficacy of air removal and steam penetration

- Type 3-6: Internal CI
  - Placed inside each packaged item
  - Measures parameters of sterilization
    - Type 3= one parameter
    - Type 4= multi-parameters
    - Type 5= All parameters (integrating indicator)
    - Type 6= All parameters (emulating indicator

33

33

Biological Indicators (BI)

- Proves lethality was achieved for the cycle (but only proves lethality for the test vial)
- Each day a test is performed, an unprocessed vial from the same lot must be incubated to prove viability of spores
- Most standards have minimum of weekly test and with every load containing an implant
  - Many facilities use daily tests and all loads with implants or every load monitoring
- Testing is performed in a full load and is required for each cycle type used
- A failed BI requires a recall to the last negative BI in that sterilizer

34

34

Best Practice: Monitor Every Load

- By monitoring every load you will: Provide the same level of care to every patient
- Achieve consistency of use across all sterilization modalities. No falling through the cracks of cycles needing tested
- Reduce the time needed to identify and recall loads in the event of a positive BI
- Any instruments that may have been used on a patient should be reported to risk management, IP, and the surgeon

- Con: expensive in money and resources

35

35

Sterilization Process Failures

- Develop policy/process allowing for clinical judgment based on failure type (Wet, CI, BI)

- 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 IP to track patients who had an item from any recalled loads used in their surgery.

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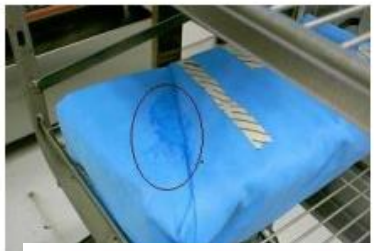
36

Wet Pack (1 item) or Wet Load (2 or more items)



- Can be External or Internal
- 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 (cooling in cold airflow or changing weather outside)

37

37

Sterilizer Qualification Testing

- Required when there are major repairs or the steam has been shut down
  - Run 3 Biological Tests
  - Run 3 Air Removal Tests

38

38

Sterilization Expirations: Make sure to look at the IFU for each product used and make an appropriate facility policy

39

39

ST79:2017 Instrument air vs. Compressed air

2.56 instrument air: Medical gas that falls under the general requirements for medical gases as defined by NFPA 99, is **not respired**, is compliant with the ANSI/ISA 7.0.01, and is **filtered** to 0.01 microns**, free of liquids and hydrocarbon vapors**, and **dry** to a dew point of -40ºC (-40ºF).

3.3.6.1.1 Design considerations

- ✓The decontamination area/room should have **instrument air**

7.6.4.2 Manual Cleaning

- ✓h) thoroughly rinse and dry a nonlinting cloth or **instrument air**

40

40

Sterile Processing hurdles

- Low staffing
- Small space
- Lack of quality training and education
- Usually not enough instrument set inventory to support Operating Room
- Loaners arriving too late to be processed appropriately
- Items with complicated IFU cleaning process: (many have 70+ steps)
- Overwhelming for staff to keep up

Audit Check List Items

- POU Cleaning being performed
- Transport safe and labeled
- PPE used and appropriate
- IFUs for processing followed
- Cleaning tools per standards (brushes, etc.)
- Auto-dosing systems calibrated per IFU
- Water volume and temperature measured
- SPD appropriate utilities available (critical water and instrument air)
- Appropriate equipment validation testing performed per policy and recorded
- Equipment cleaning and service per IFU and recorded

- Instruments not over crowded in trays
- Proper baskets and trays in Ultrasonic and W/D with proper arrangement
- Inspection performed (needed actions taken)
- Appropriately Packaged with proper CIs per IFU/Standards
- Packages labeled appropriately
- Sterilizers loaded appropriately
- Load cooled appropriately with hands-free temp
- Sterilizer records maintained
- Sterilizer to patient tracking
- BI practices followed and recorded
- Separation maintained between Dirty, Clean, and Sterilized (basic principles of asepsis)

43

43

- Proper storage
- Basic Environmental items (no storage under sink, no adhesives, bottom shelf liners)
- Safety (eye wash, shower?, hand wash sinks)
- Air handling appropriate, monitored, and recorded
- IUSS policy/process

44

44

Standards, Recommendations and Guidelines

AAMI
Advancing Safety in Medical Technology

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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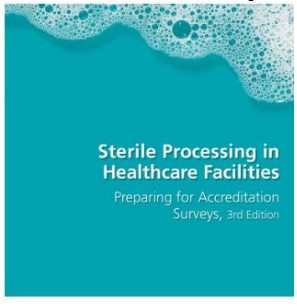
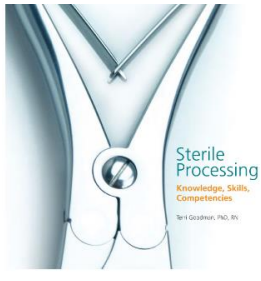
Resources

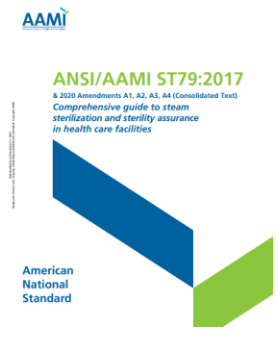
Sterile Processing in HC Facilities: Preparing for Accreditation Survey



Sterile Processing: Knowledge, Skills, Competencies



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



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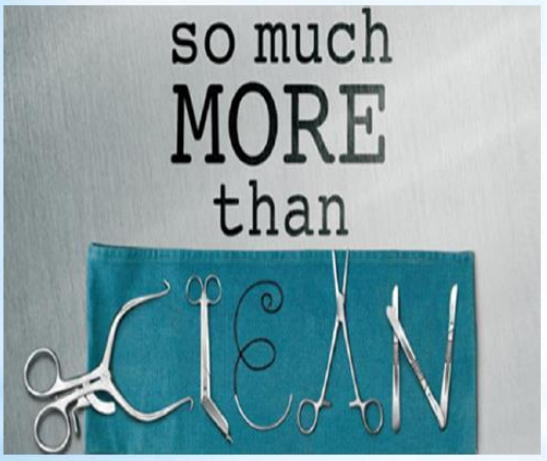

Thank you!
Questions

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