Virtual Tour of Central Processing

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DISCLOSURES 2024 Consultations • PDI (Professional Disposables International) Honoraria • PDI Other • Kinnos, Ideate Medical

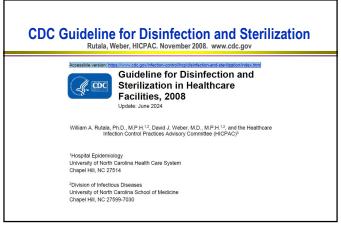
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Reprocessing Reusable Medical Devices

Learning objective-understand the key steps in the sterilization process

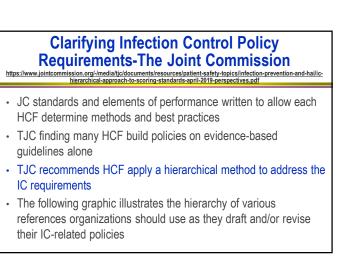
- Point-of-use treatment
- Preparing dirty instruments for transport
- Cleaning and decontamination
- Inspection
- Packaging
- Sterilization

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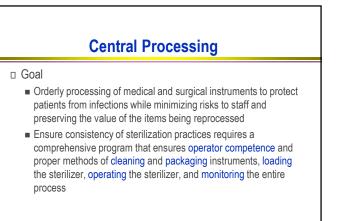
Medical/Surgical Devices WA Rutala, DJ Weber, and HICPAC, www.cdc.gov EH Spaulding believed that how an object will be disinfected depended on the object's intended use (developed 1968). CRITICAL-medical/surgical devices which enter normally sterile tissue or the vascular system or through which blood flows should be sterile. SEMICRITICAL-medical devices that touch mucous membranes or skin that is not intact require a disinfection process (high-level disinfection [HLD]) that kills all microorganisms but high numbers of bacterial spores. NONCRITICAL-medical devices that touch only intact skin require low-level disinfection.









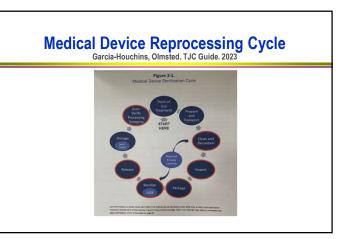


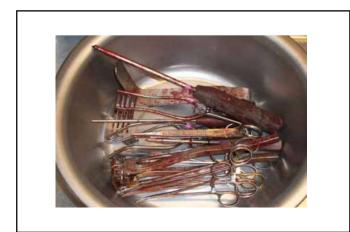
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Central Processing Physical Facilities

□ Facility ideally divided into three (or four) areas:

- Decontamination-reusable items are received, sorted, and decontaminated; negative pressure; 10AC/hr. Personnel wear gloves when handling contaminated instruments; face masks, eye protection, and gowns/aprons when splashing may occur.
- Packaging-used for inspecting, assembling, and packaging clean, but not sterile, material.
- Sterilization and storage-limited access area with a controlled temperature and relative humidity.



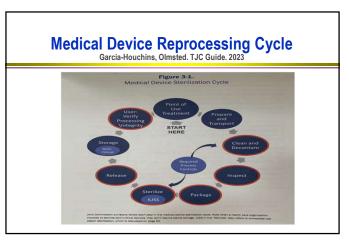


Point-of-Use (takes place at the procedure site) May include (per MIFU) Flushing lumens with sterile water or wiping tissue and blood from instruments during the procedure to remove gross soil Placing items in transport product to prevent drying or start the breakdown of soil Options for keeping used instruments and devices moist • Applying or soaking devices in compatible spray, gel, foam or liquid detergent • Placing instruments in a container or bag designed to maintain moisture • Covering the devices with a cloth moistened with water

Pre-Cleaning

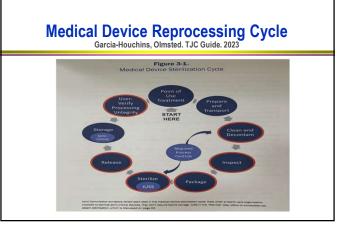
- Surgical instruments are pre-cleaned in the OR. Ideally, instruments should arrive in Central Processing free on visible contamination
- To keep instruments wet from OR to CP, many hospitals spray instruments with an enzymatic solution
- Wipe instruments clean and keep lumens flushed throughout surgery. Soiled instruments that will not be reused should be allowed to soak in a basin of sterile water for the remainder of the procedures
- Keep instruments moist (e.g., damp towel, foam) as it prevents hardening of soil

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Preparing Dirty Instruments for Transport Consider presence of sharps, distance, route, PPE Transport ASAP to the decontamination area Additional steps may be necessary if transporting the devices off-site for reprocessing



Cleaning/Decontamination

- Cleaning is defined as the process to physically remove organic material, such as blood, secretions, excretions, and microorganisms to prepare the medical device for decontamination
- Decontamination refers to the use of physical or chemical means to remove, inactivate or destroy BBP on a surface or item so it is no longer capable of transmitting disease and rendered safe for handling. Decontamination area allows work to flow from dirty to clean, sinks, countertops, airflow, temp, RH

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Disassembly

- Many medical devices may need to be disassembled before cleaning, especially those that are complex or have a number of parts
- □ Check the MIFU to see if the device requires disassembly.
- □ Some devices may require reassembly after cleaning but before sterilization; other may not.

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Cleaning

- Items must be cleaned using water with detergents or enzymatic cleaners before processing.
- Cleaning reduces the bioburden and removes foreign material (organic residue and inorganic salts) that interferes with the sterilization process.
- Cleaning and decontamination should be done as soon as possible after the items have been used as soiled materials become dried onto the instruments.

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Efficacy of Disinfection/Sterilization Influencing Factors

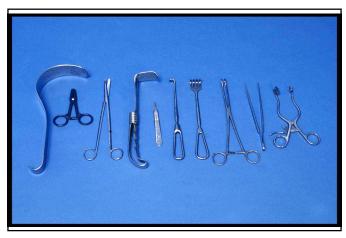
Cleaning of the object

- Organic and inorganic load present
- Type and level of microbial contamination

Concentration of and exposure time to disinfectant/sterilant

Nature of the object

Temperature and relative humidity



Bioburden on Surgical Devices Surgical Instruments Carry a Low Microbial Load (<100 CFU, 85%)

- Bioburden on instruments used in surgery (Nystrom, J Hosp Infect 1981)
 - 62% contaminated with <10¹
 - 82% contaminated with <10²
 - 91% contaminated with <10³
- Bioburden on surgical instruments (Rutala, Am J Infect Control 1997)
 - 72% contained <10¹
 - 86% contained <10²
- Bioburden on surgical instruments (50) submitted to CP (Rutala, AJIC 2014)
 - 58% contained <10</p>
 - 20% contained < 10²
 - 16% contained <5x10²
 - 6% contained <10³

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Cleaning Mechanical cleaning machines-automated equipment may increase productivity, improve cleaning effectiveness, and decrease worker exposure Utensil washer-sanitizer

- Ultrasonic cleaner
- Washer sterilizer
- Dishwasher
- Washer disinfector
- Manual

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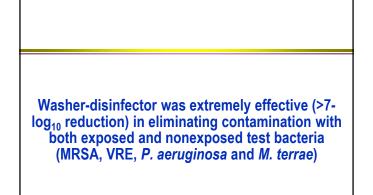
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Washer-Disinfector Rutala WA, Gergen MF, Weber DJ. ICHE 2014;35:883-885 □ Five Chambers (Reliance 777 automated multichamber washerdisinfector was used). The programmed cycle included 5 phases. Pre-wash: water/enzymatic is circulated over the load for 1 min Wash: detergent wash solution (150°F) is sprayed over load for 4 min Ultrasonic cleaning: basket is lowered into ultrasonic cleaning tank with detergent for 4 min Thermal and lubricant rinse: hot water (180-200°F) is sprayed over load for 1 min; instrument milk lubricant is added to the water and is sprayed over the load

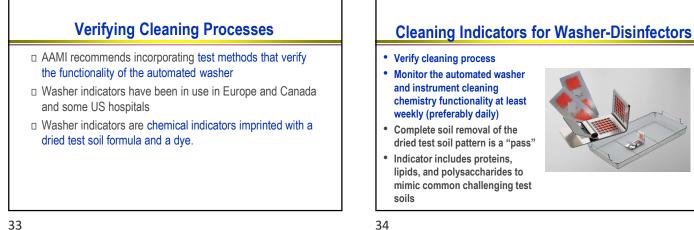
Drying: blower starts for 4 min and temperature in drying chamber at 180-240°F



	/al/Thermal Inacti	ivation of Inoculu	m (Exposed) or	n Instrument
,	Rutala WA, Gergen I	MF, Weber DJ. ICHE 2	014;35:883-885	
WD Conditions	Organism	Inoculum	Log Reduction	Positives
Routine	MRSA	2.6x10 ⁷	Complete	0/8
Routine	VRE	2.6x10 ⁷	Complete	0/8
Routine	P aeruginosa	2.1x10 ⁷	Complete	0/8
Routine	M terrae	1.4x10 ⁸ (8.1)	7.8	2/8
Routine	GS spores	5.3x10 ⁶ (6.7)	4.8	11/14
No Enz/Det	VRE	2.5x10 ⁷	Complete	0/10
No Enz/Det	GS spores	8.3x10 ⁶ (6.9)	5.5	8/10



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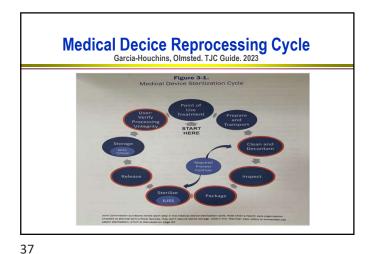
IS THERE A STANDARD TO DEFINE WHEN A DEVICE IS CLEAN?

- □ There is currently no standard to define when a device is "clean", cleanliness controlled by visual
- Detential methods: level of detectable bacteria; protein (6µg/cm²) based on Bradford's reagent or ninhydrin; endotoxin; ATP; lipid; carbohydrate; hemoglobin
- □ This is due in part to the fact that no universally accepted test soils to evaluate cleaning efficiency and no standard procedure for measuring cleaning efficiency
- □ At a minimum, a cleaning process should: reduce the natural bioburden; remove organic/inorganic contaminants; provide devices that when sterilized have a SAL 10⁻⁶

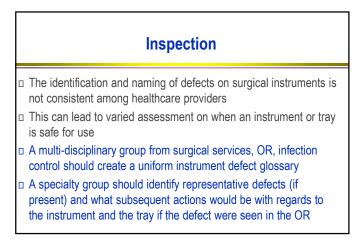
Cleaning Verification Tests AAMI Summit September 2023

- No cleaning verification products cleared by FDA
- □ Tests criteria-easy-to-perform (e.g., go-no go color change), rapid, sensitive, accurate, robust, relevant, not damaging
- □ Options:

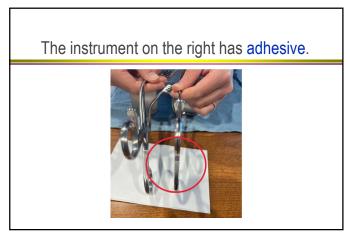
- Protein <6.4µg/cm²
- Carbohydrate <1.8µg/cm²
- Hemoglobin <2.2µg/cm²

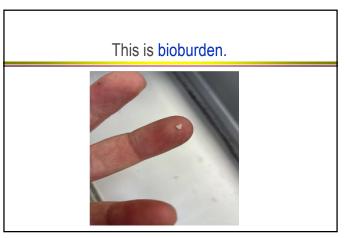


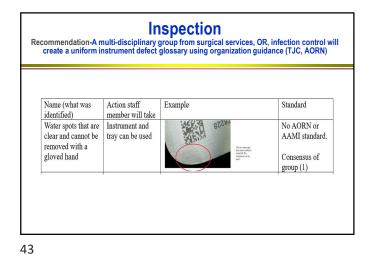
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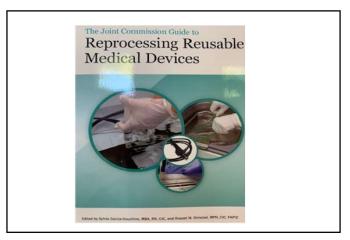


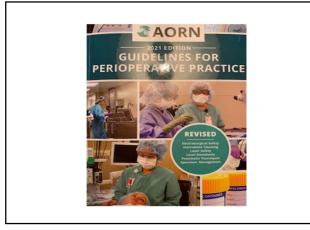












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Scissor blades or forceps tips or teeth may be misaligned or ratchet performance affected Adequate lighting and magnification equipment can aid the inspection process Should be process for accessing maintenance/refurbishing resources so staff is empowered to take instruments out of circulation Stained instruments may indicate a problem with process such as detergent residues, salts and other elements, poor water or steam quality or lack of sterilizer/washer maintenance

Inspection

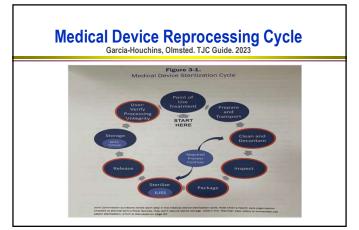
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AORN Guidance

AORN Guideline for Perioperative Practice. 2021

- □ 6.2.4. When an item or items are found to be contaminated, take the following corrective actions, at a minimum:
 - remove the contaminated item(s),
 - remove any other items that may have come in contact with the contaminated item(s),
 - $\hfill \ensuremath{\bullet}$ change the gloves of any team member who may have touched the contaminated item(s), and
 - take any additional corrective actions required after thoughtful assessment and informed decision making based on the specific factors associated with the individual event.

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- □ Arranged in tray/basket according to guidelines
 - Hinged instruments opened
 - Items with removable parts should be disassembled
 - Heavy items positioned not to damage delicate items
- Several choices to maintain sterility of instruments: rigid containers, peel pouched; sterilization wraps

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Multiple layers are still common practice due to the rigors of handling

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Loading

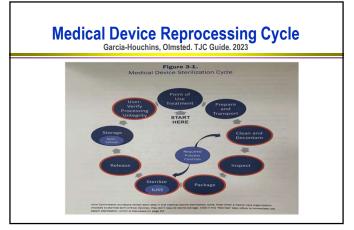
- All items to be sterilized should be arranged so all surfaces will be directly exposed to the sterilizing agent
- □ Other basic principles:
 - Allow for proper steam circulation
 - Nonperforated containers should be placed on their edge
 - Peel packs should be placed on edge

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Packaging/Load Configuration

- Packaging materials should be compatible with the sterilization process
- Packaging (rigid containers, peel pouches, wraps) should provide a barrier to microorganisms and moisture and should be sufficiently strong to resist punctures and tears.
- Items should be placed loosely into the basket, shelf, or cart so as not to impede contact between the sterilant and the microorganism.

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Sterilization

Complete elimination or destruction of all forms of microbial life. It is accomplished by physical or chemical processes.

Sterilization of "Critical Objects" Rutala, Weber, HICPAC. November 2008. <u>www.cdc.gov;</u> Rutala et al. AJIC 2019;47:A3-A9

Heat resistant

Steam sterilization

- Heat sensitive
- Ethylene oxide
- Hydrogen peroxide gas plasma
- Ozone and hydrogen peroxide
- Vaporized hydrogen peroxide

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		Steam Steriliza		
		er, HICPAC. November 2008. v		
	Item	Minimum exposure	Minimum drying time	
	Wrapped instruments	4 min	30 min	
	Textile packs	4 min	5 min	

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Immediate Use Steam Sterilization

- "Flash" originally defined as sterilization of an unwrapped object at 132°C for 3 min at 27-28 lbs pressure in gravity
- "Flash" used for items that must be used immediately and sterilized unpackaged (not sterile once removed from sterilizer)
- "Flash" is an antiquated term and replaced by "immediate use steam sterilization"

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Immediate Use Steam Sterilization

- "Immediate Use" is defined as the shortest possible time between a sterilized item's removal from sterilizer and aseptic transfer to sterile field; now same time-temp (132°C, 4min)
- The same critical reprocessing steps (such as cleaning, decontaminating, and transporting) must be followed
- A sterilized item intended for immediate use is not stored for future use.
- Sterilization process monitoring is essential
- Instruments inventories should be adequate to meet surgical volumes and permit the time to complete all critical elements of reprocessing



Sterilization of "Critical Objects" Rutala, Weber, HICPAC. November 2008. <u>www.cdc.gov;</u> Rutala et al. AJIC 2019;47:A3-A9

Heat resistant

Steam sterilization

Heat sensitive

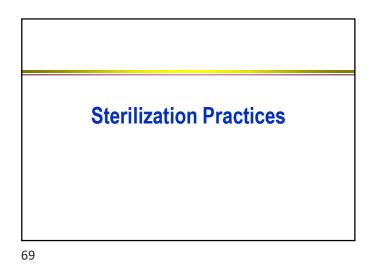
- Ethylene oxide
- Hydrogen peroxide gas plasma
- Ozone and hydrogen peroxide
- Vaporized hydrogen peroxide

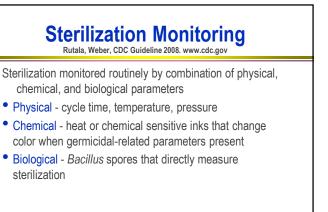
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Conclusions All sterilization processes effective in killing spores Cleaning removes salts and proteins and must precede sterilization

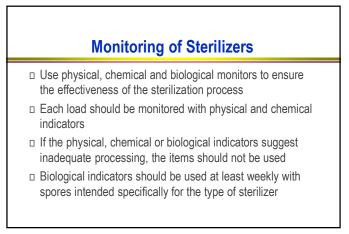
• Failure to clean or ensure exposure of microorganisms to sterilant (e.g. connectors) could affect effectiveness of sterilization process

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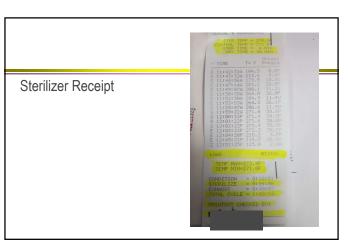


Monitoring of Sterilizers

Internal Chemical Indicator

- Validates the sterilant penetrated the pack or tray
- Advantage of the pack control monitor is that it is inside each pack in multiple locations
- Detect local problem

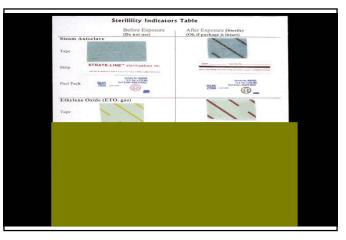
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Biological Indicators

- · Select BIs that contain spores of **Bacillus atrophaeus**
- Rationale: Bls are the only sterilization process monitoring device that provides a direct measure of the lethality of the process

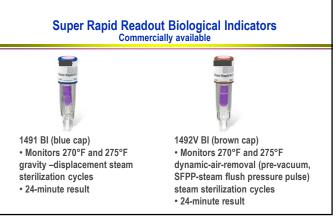


Biological Monitors Rutala, Weber, CDC Guideline 2008. www.cdc.gov

- Steam Geobacillus stearothermophilus
- Dry heat B. atrophaeus (formerly B. subtilis)
- ETO B. atrophaeus
- · New low temperature sterilization technologies
 - HP gas plasma G. stearothermophilus
 - HP/Ozone -G. stearothermophilus
 - VHP- G. stearothermophilus

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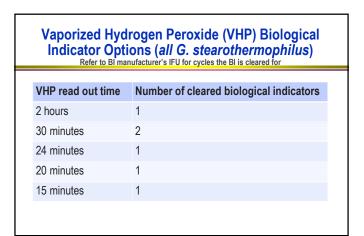




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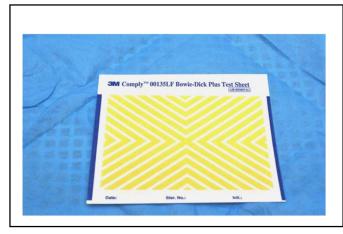




Process challenge device simulates an equal or greater challenge than the most difficult instrument/item routinely processed in a sterilization cycle











Recommendations Monitoring of Sterilizers Rutala, Weber, CDC Guideline 2008. www.cdc.gov

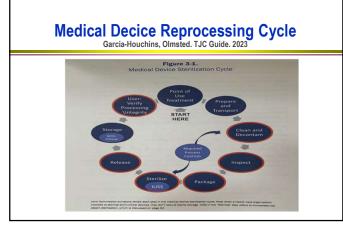
- Following a single positive biological indicator used with a method other than steam, treat as non-sterile all items that have been processed in that sterilizer, dating back to last negative biological indicator.
- Following a positive biological indicator with steam sterilization, objects, other than implantable objects, do not need to be recalled because of a single positive spore test unless the sterilizer or procedure is defective or inappropriate cycle settings. If additional spore tests remain positive, consider the items nonsterile and recall and reprocess the items from the suspect load.

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Recommendations Methods of Sterilization Rutala, Weber, CDC Guideline 2008. www.cdc.gov

- Steam is preferred for critical items not damaged by heat
- Follow the operating parameters recommended by the manufacturer
- Use low temperature sterilization technologies for reprocessing critical items damaged by heat
- Use immediately critical items that have been sterilized by peracetic acid immersion process (no long term storage)

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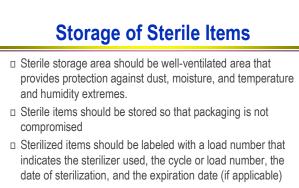




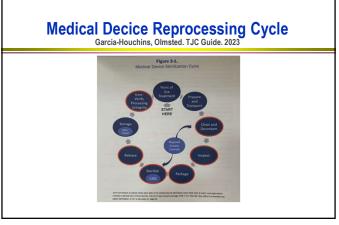
Storage of Sterile Items

- Event-related shelf life recognizes that the product remains sterile until an event causes it to become contaminated (e.g., tear, wetness). Packages should be evaluated before use for lose of integrity.
- Time-related shelf life (less common) considers items remain sterile for varying periods depending on the type of material used to wrap the item/tray. Once the expiration date is exceeded the pack should be reprocessed.

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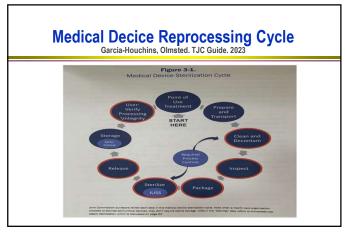
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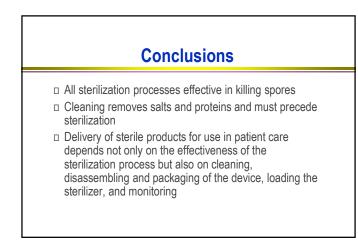






- Provide comprehensive and intensive training for all staff assigned to reprocess medical/surgical instruments
- $\hfill\square$ To achieve and maintain competency, staff should:
 - hands-on training
 - all work supervised until competency is documented
 - competency testing should be conducted at commencement of employment and regularly
 - review written reprocessing instructions to ensure compliance





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Rutala WA, Weber DJ. Disinfection and sterilization in health care facilities: An overview and current issues. Infect Dis Clin North Am 2016;30:609-637. Rutala WA and DJ Weber. CDC Guideline for disinfection and sterilization in healthcare facilities. 2008. www.cdc.gov Rutala WA, Weber DJ. 2016. Disinfection, sterilization and antisepsis: an overview. Am J Infect Control. 44:e1-e6. Rutala WA, Gergen MF, Weber DJ. Efficacy of a washer-disinfector in eliminating healthcare-associated pathogens from surgical instruments. Infect Control Hosp Epidemiol. 2014;35:883-885.

