Georgia Regents Medical Center
Policy Library

Sterilization Policy

Policy Owner: Epidemiology

POLICY STATEMENT

The ability to sterilize instruments and equipment for use during operative or other invasive procedures is critical to promoting successful patient outcomes and preventing infections. This policy defines the standard for sterilization of reusable medical equipment and devices.

At a minimum, items requiring sterilization per manufacturer's instructions for use (IFU) or entering sterile body sites or systems are sterilized following the provisions below.

AFFECTED STAKEHOLDERS

Indicate all entities and persons within the Enterprise that are affected by this policy:

☐ Administrative Services
☒ Hired Staff
☐ Housestaff/Residents & Clinical Fellows
☐ Leased staff
☐ Medical Staff (includes Physicians, PAs, APNs)
☐ Patient Care Services (Nursing, PCT's, Unit Clerks)
☐ Professional Services (Laboratory, Radiology, Respiratory, Pharmacy; etc.)
☐ Vendors/Contractors
☒ Other: Those performing or using sterilized instrumentation, and those who oversee such processes.

DEFINITIONS

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bowie Dick</td>
<td>A diagnostic test of a sterilizer's ability to remove air from the chamber of a pre-vacuum steam sterilizer. The air-removal or Bowie-Dick test is not a test for sterilization.</td>
</tr>
<tr>
<td>Decontamination</td>
<td>The use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens and other pathogenic organisms on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal. Devices may also require high level disinfection or</td>
</tr>
</tbody>
</table>

Office of Compliance and Enterprise Risk Management Use Only
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Last Revision: 02/26/2016
Last Review: 03/18/2016
Next Review: 03/18/2019
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Sterilization is achieved by either physical (steam) or chemical sterilization. For all sterilization processes, strict adherence to work flow and the flow of supplies are required throughout the preparatory stages. Packaging occurs only in clean areas.

The reuse of a single-use, disposable product requires approval of the Disposable Product Reuse Taskforce and the Director of Hospital Epidemiology. Reprocessing will ONLY be done by the third party approved by the task force for reprocessing the product.

Instrument Decontamination and Transport for Reprocessing

1. Instruments are not decontaminated on the units because pathogens may be aerosolized during decontamination. All units, except for some Practice Sites and Operative Services, are to forward all instruments to Central Sterile Reprocessing or the Ambulatory Care Center (ACC) decontamination/sterilization area for decontamination, cleaning and sterilization.

2. When transporting reusable instruments to Central Sterile Reprocessing for decontamination, cleaning, and disinfection or sterilization, the instruments are transported in a biohazard-labeled bag, a biohazard-labeled puncture-resistant container with a closed lid, or appropriate transport cart (i.e., OR instrument carts). Before transporting instruments to Central Sterile Reprocessing, the following steps are taken:
   a. Nursing units/clinics do not rinse or clean (i.e., decontaminate) the instruments in any manner on the unit/clinic.
   b. All disposable needles and blades are removed and disposed in the appropriate sharps disposal receptacle. All other sharp instrumentation
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must be in a puncture resistant container even when placed into the case cart for transport.

c. The tray and/or instruments utilized on nursing units, ancillary departments or in ambulatory care clinics are placed in a biohazard-labeled bag or puncture-resistant containers. Used, peel-packed instruments are placed in the small, biohazard-labeled specimen bags.

d. Spray the instruments with the approved, ready-to-use proteolytic enzymatic cleaner.

e. Seal (or tie) the bag securely or secure the lid on the puncture-resistant container and place the bagged or containerized instruments in the Soiled Utility Room or transport to Central Sterile Reprocessing.

f. Containers for proteolytic enzymatic cleaners may be supplied to departments with a high use of sterilized instruments. Instruments should be transferred to a soiled utility room in a biohazard-labeled container and placed in the proteolytic enzymatic cleaner. Central Sterile Reprocessing will deliver the premixed proteolytic enzymatic cleaner and container on a daily basis.

3. Instruments are decontaminated and cleaned according to manufacturer’s instructions for use prior to preparing for sterilization.

a. The healthcare worker who performs the decontamination process is required to wear special gloves, masks, protective eyewear, gown, and hair cover and work in a room under negative pressure.

Packaging Procedure
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1. Items packaged for sterilization are wrapped in a sterile wrap, placed in a peel pouch, or placed in an appropriate container system. Peel pouches are not used for multiple instruments, heavy instrumentation, or instruments with sharp edges.

2. Instruments placed in a container system are sterilized following the manufacturer’s directions.

3. Packaging is secured and contains a chemical indicator externally and internally.

4. Package wrapping contains the following:
   a. Product identification;
   b. Date of sterilization, sterilizer number, load number; and
   c. An event-related label stating, “sterile unless opened, damaged, or wet”.

Sterilization Methods/Procedure

1. Physical (Steam) Sterilization
   a. Steam sterilization is a process that achieves sterility by having time, temperature, pressure, and saturated steam present in the correct parameters to cause microbial death. Steam sterilization is the process preferred if no contraindications for use exist.
   b. Immediate Use Steam Sterilization (IUSS) is defined as rapid steam sterilization of an unwrapped object at 270°F (132°C) or as per manufacturer’s instructions for use in a gravity/displacement sterilizer. A 3 – 10 minute cycle may be used depending on the item being sterilized. IUSS is intended for emergent use only (i.e., an instrument is dropped or inadvertently contaminated and a sterile replacement is not available), and is not to be used to compensate for an inadequate instrument supply. IUSS is performed only in areas with restricted traffic and the physical configuration of the department provides for direct delivery of the sterilized items to the point of use. IUSS only takes place after proper cleaning,
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decontamination, and inspection occurring in an approved setting. Instruments must be placed in the appropriate (validated for IUSS), closed container for IUSS, and not packaged and stored for later use.

i. IUSS is not recommended for implantable devices (e.g., wires, screws, and joint replacements). If there is no other alternative in an emergency, then a biological indicator must be processed with the item. The item should then be quarantined on the sterile field until the results of the biological test are known.

ii. Records are maintained on all instruments subject to IUSS, along with patient information to allow for traceability.

2. Chemical Sterilization

There following chemical sterilization processes are approved for use at GRMC.

a. Peracetic acid (Steris System 1E; when reprocessing equipment and devices for immediate use. Devices must remain in the reprocessing tray until they reach the point of use and personnel remove them from the tray to the sterile field using sterile gloves and towels to maintain sterility.)

b. Hydrogen peroxide gas plasma (Sterrad and Sterrad NX system)

Sterilization using gluteraldehyde is not approved for use at GRMC.
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Quality Monitoring

Documentation of quality monitoring for sterility assurance is retained for 6 years.

<table>
<thead>
<tr>
<th>Type</th>
<th>Sterilization Process</th>
<th>Process Monitors</th>
<th>Frequency of Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical</td>
<td>Steam – Gravity Displacement Cycle</td>
<td>Mechanical printout</td>
<td>Each load</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bowie Dick™</td>
<td>Daily</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Chemical tape</td>
<td>Each pack</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Chemical indicator</td>
<td>Each pack</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Biological, <em>Bacillus stearothermophilus</em></td>
<td>Daily while in use and each load containing an implant</td>
</tr>
<tr>
<td></td>
<td>Steam – Dynamic Air Removal Cycle (i.e. Pre-vacuum)</td>
<td>Mechanical printout</td>
<td>Each load</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bowie Dick™</td>
<td>Daily</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Chemical tape</td>
<td>Each pack</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Chemical indicator</td>
<td>Each pack</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Biological, Process Challenge Device</td>
<td>Daily while in use and each load containing an implant</td>
</tr>
<tr>
<td></td>
<td>Peracetic acid (Steris)</td>
<td>Mechanical printout</td>
<td>Each load</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Computer monitored diagnostic cycle</td>
<td>Daily if in use</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Chemical indicator</td>
<td>Each load</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Spore strips, <em>Bacillus stearothermophilus</em></td>
<td>Daily while in use</td>
</tr>
<tr>
<td></td>
<td>Hydrogen peroxide gas plasma (Sterrad)</td>
<td>Mechanical printout</td>
<td>Each load</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Chemical tape</td>
<td>Each pack</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Chemical indicator</td>
<td>Each pack</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Biological, <em>Bacillus stearothermophilus</em></td>
<td>Daily while in use</td>
</tr>
</tbody>
</table>

* Microbiology use weekly spore strips (*Bacillus stearothermophilus* and *Bacillus subtilis*) per CAP guidelines.
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Temperature and humidity are monitored daily in all areas if required, and logs are maintained in the department.

Sterilization Failure Procedure

Biological indicators are the most sensitive indicators to measure if sterilization has taken place. A positive biological indicator is considered evidence that inappropriate sterilization has occurred until proven otherwise. The test result is never thought of as a false positive test.

1. The sterilizer is taken out of service and checked for proper functioning by trained personnel.
2. All items processed in the sterilizer dating from the last negative biological indicator are retrieved and reprocessed.
3. If an item has been used, every effort is made to determine what department and patient were involved.
4. The department utilizing the sterilizer is to immediately notify Hospital Epidemiology of the sterilization failure. If any items were used on patients, the department where the items were used will notify the patient’s physician and Risk Management. That department will compile a list of patients on whom the items were used and submit the list to Hospital Epidemiology.
5. Once the sterilizer has been checked for proper functioning, three consecutive negative biological indicators and three Bowie Dicks (when indicated) are required prior to the sterilizer being reactivated. Until the final results are determined, no items are processed. Documentation regarding the results of these three negative biological indicators and three Bowie Dicks (when indicated) is maintained by the user department.
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Sterility Maintenance

1. When distributing items, the person releasing the pack should visually inspect the pack to ensure the packing has not been compromised; no tears, holes, stains. If noted, the pack should be re-processed.

2. When receiving sterile products from an internal processing department, outside vendors, or receiving items back into central sterile storage (that have not been opened/used), it is the responsibility of the individual accepting the product to check for packaging integrity and for signs of contamination (e.g. staining of packaging material).

3. Items should be rejected and/or reprocessed when sterility is questioned.

4. Items are never compressed, and handling is kept to a minimum to reduce damage to the integrity of sterile packages. Likewise, carts and bins are not overstocked to ensure sterility maintenance.

5. A product is considered sterile until some event occurs that compromises the sterility of the product. Sterility maintenance is an event-related process. Any sterile-wrapped product is considered sterile unless:
   a. The packaging is worn or damaged.
   b. The packaging becomes wet.
   c. The product is dropped on a contaminated surface or exposed to an unsafe environment.
   d. The lock/heat seals become loose.
   e. A manufacturer's expiration date has passed.

Sterile Item Storage

1. Sterile items are stored:
   a. At least eight (8) inches from the floor to permit Environmental Services to clean without splashing onto the packs on the bottom shelf; may also be
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stored in a closed cabinet. Bottom shelves or should be solid or items may be stored in bins to prevent contamination.

b. Eighteen (18) inches from the ceiling (particularly ceiling fixtures, i.e. sprinkler heads) to prevent impeding the sprinkler’s operation when activated as per fire code.

c. Eight (8) inches from outside walls to prevent condensation from the outside leaking through the wall and possibly contaminating packs.

d. With newly sterilized items stocked behind sterilized items with more recent expiration dates, if applicable (i.e. stock is rotated).

2. Storage occurs in a clean, dry, and vermin-free environment with limited access. Shelving and bins are kept clean and dust free.

3. Temperature is kept between 65 and 72°F and humidity is kept between 35 and 50%.

4. Storage of items on floors, window sills, within three (3) feet of sinks, and areas other than designated shelving, carts, or drawers is prohibited.

Training
It is the responsibility of each user department to provide training on decontamination, cleaning, disinfecting and sterilizing procedures. Documentation of such training is likewise required. Educational sessions occur annually as refresher courses and when any new product is introduced.

REFERENCES, SUPPORTING DOCUMENTS, AND TOOLS

Association for the Advancement of Medical Instrumentation (AAMI) (2010). The Joint Commission Comprehensive Accreditation Manual- 2014- IC.02.02.01 (EPs 1-5)

RELATED POLICIES
Disinfection Level Determination
Laryngoscope Reprocessing Policy
Prion Disease Prevention and Control Policy