HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER MATERNITY AND CHILDREN HOSPITAL

Department:	Infection Prevention and Control Department		
Document:	Multidisciplinary Policy and Procedure (MPP)		
Title:	Sterile Supplies and Equipment Management		
Applies To:	CSSD and Health Care Workers		
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1. PURPOSE:

1.1 To provide guidelines on the appropriate use of Central Sterile Supply Department (CSSD) services for the reprocessing of reusable items, proper storage, and event-related shelf life of all sterile items and equipment.

2. DEFINITONS:

2.1 Biological indicators (BIs) - test systems containing viable microorganisms providing a defined resistance to a specified sterilization process.

2.2 Chemical indicators - devices used to monitor the presence or attainment of one or more of the parameters required for a satisfactory sterilization process, or used in specific tests of sterilization equipment.

2.3 Containment device - reusable rigid sterilization container, instrument case, cassette, or organizing tray intended for use in health care facilities for the purpose of containing reusable medical devices for sterilization.

2.4 Contaminated - state of having been actually or potentially in contact with microorganisms.

2.5 Decontamination – according to OSHA, "the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens 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."

2.6 Decontamination area – area of health care facility designated for collection, retention, and cleaning of soiled and/or contaminated items.

2.7 Dust cover – protective plastic bag used to protect sterile items from environmental contamination such as moisture, dust, and lint; also known as a sterility maintenance cover.

2.8 Instructions for Use (IFU) – manufacturer's written instruction for use.

2.9 Labeling – any legend, work, or mark attached to, included in, belonging to, or accompanying any medical device or product.

2.10 Reusable medical device – device intended for repeated use on different patients, with appropriate decontamination and other processing between uses.

2.11 Shelf life – term is used with respect to a sterilized, medical device and the period of time during which the item is considered safe for use.

2.12 Sterile storage area – area of a healthcare facility designed to store clean and sterile items and protect them from contamination.

3. POLICY:

3.1 All reusable devices requiring in-house reprocessing will be reprocessed by CSSD in accordance with the Spaulding Classification system that segregates medical devices and places them in categories based on the risk of infection related to their use. The categories are as follows:

3.1.1 Critical Items

3.1.1.1 This category includes objects and items entering the vascular system and sterile tissue.

3.1.1.2 Examples of critical items are surgical and dental instruments, cardiac and blood catheters, implants and needles, blood compartments of hemodialysis equipment, laparoscopes, arthroscopes, and other scopes that are introduced into sterile tissues.

3.1.1.3 These items present a high risk of infection and require sterilization after each patient use.

3.1.1.4 All reusable items in this category must be processed by the CSSD.

3.1.2 Semi-critical Items

3.1.2.1 This category includes objects and items that come in contact with intact mucous membranes and non-intact skin but do not penetrate body tissues or the vascular system.

3.1.2.2 Examples of semi-critical items are non-invasive medical equipment, flexible and rigid fiber optic endoscopes, respiratory therapy and anesthesia equipment, endotracheal tubes, and cystoscopes.

3.1.2.3 These items require high level disinfection after each patient use.

3.1.2.4 Any reusable items in this category must be processed by CSSD.

3.1.3 Non-critical Items

3.1.3.1 This category includes items and objects that come in contact with intact skin only

3.1.3.2 Examples of non-critical items are bedpans, blood pressure cuffs, tourniquet cuffs, and crutches.

3.1.3.3 These items could potentially contribute to secondary transmission of microorganisms to healthcare workers' hands; therefore, they require cleaning with hospital-approved disinfectant at the point of use.

3.1.3.4 These items do not require CSSD service.

4. PROCEDURE:

4.1 The delivery of sterile healthcare products for use in patient care depends not only on the efficacy of the sterilization itself but also on the following factors:

4.1.1 Efficient facility design in terms of functional, controlled, one way traffic flow with defined work zones. Specific utility requirements per work zone must be in place and function as intended consistently.

4.1.2 Efficient trained personnel who are competent to perform the function of CSSD with the knowledge of the Department's reporting structure.

4.1.3 Effective and monitored infection prevention and control practices.

4.1.4 Effective quality control including process improvement systems that encompass all aspects of device reprocessing from point of use through sterilization to reuse. Relevant and effective documentation and reporting practices that enable traceability of each facility-sterilized medical device to the patient on whom it was used.

4.1.5 Cleaning and decontamination is the first important step of the sterilization process.

4.1.6 Observe standard precautions when handling contaminated items and instruments.

4.1.7 CSSD reprocess in accordance with the manufacturer's published IFU in conjunction with the IFU for the chemicals in use and the operator's manual for equipment in use.

4.1.8 Discard disposable single use devices (SUDs) at the point of use by the end user, since it will not be reprocessed by CSSD.

4.1.8.1 Consult Infection Prevention & Control (IP&C) for any unused SUDs which have expired.

4.1.9 End users spray reusable devices after use with a hospital-approved transport medium immediately at the point of use.

4.1.9.1 Place used devices in a covered receptacle in the soiled utility room.

4.1.9.2 Segregate these devices per set with the heavier items on the bottom, and must be transported immediately to CSSD in a covered receptacle. Never leave these items unattended.

4.1.10 End user is responsible to transfer to the main CSSD any new devices delivered to the organization with the original packaging, product insert, the most recent IFU, and the "transfer memo" form.

4.1.11 Reprocess or handle all devices whether loaned or owned by the organization in the same manner

4.1.12 Sterility is "event-related" based on handling, storage practices, and packaging degradation.

4.1.13 Provide hand hygiene facilities in convenient locations.

4.2 Packaging

4.2.1 An effective packaging material for steam sterilization processing should:

4.2.1.1 Allow for adequate air removal;

4.2.1.2 Provide an adequate barrier to microorganisms or their vehicles;

4.2.1.3 Resist tearing and can withstand normal handling;

4.2.1.4 Allow for a method of sealing that results in a complete seal that is tamper-evident and provides seal integrity;

4.2.1.5 Allow for ease of aseptic presentation;

4.2.1.6 Be free of toxic ingredients and non-fast dyes;

4.2.1.7 Be non-linting; and

4.2.1.8 Capable to withstand high temperature.

4.2.2 During storage, transport, and prior to use in CSSD, packaging materials should be held at room temperature (20°C to 23°C) and at relative humidity ranging from 30% to 60%.

4.2.3 Examine regularly all packaging materials, woven or non-woven, for defects and extraneous matter prior to use.

4.2.4 Keep wrappers snug to prevent low spots that could collect condensate on the exterior of the package; however, care should be taken not to wrap too tightly, because strike-through could occur

4.2.5 Package labels (e.g., process indicators, labels for product identification, lot number, and expiration labels) should be capable of remaining securely affixed to packages throughout the course of their handling from sterilization to the point of use.

4.2.5.1 If a marking pen is used to label paper/plastic pouches, the labeling information should be written only on the plastic side of the pouch.

4.2.5.2 If a marking pen is used to label any device to be sterilized in the hospital, the ink should be non-toxic, and the labeling information should be written on the indicator tape or affixed labels

4.2.6 Package closures must allow the steam sterilization process to occur, avoid constriction of the package, and maintain package integrity

4.3 Handling and Inspection

4.3.1 Minimize handling of all sterile items.

4.3.2 Inspect all sterile packages for tears, punctures and abrasions prior to storage and use. If your inspection reveals any of the above, do not use this package.

4.3.3 Notify and return to CSSD any sterile packs found to be wet. CSSD will recall all other packs sterilized in that particular load.

4.3.4 Return to the decontamination area for reprocessing if an item is dropped on the floor or place on a patient's bed but were not use.

4.3.5 Return all recalled items to the decontamination area for decontamination prior to re-sterilization.

4.4 Sterile Storage Area

4.4.1 Store sterile supplies in a way that sterility will not be compromised. Maintain a clean and dry storage area with low traffic volume.

4.4.2 Covered or closed shelving is preferred in a clean area with limited access, positive air pressure, and effective ventilation.

4.4.3 Storage shelves or cabinets must be 18 inches from the ceiling, 8 to 10 inches from the floor, and 2 inches from the outside wall. They must be away from sprinklers and air vents; and temperature and humidity must be controlled.

4.4.4 Do not store sterile packs under sinks, exposed pipes, floors, or window sills.

4.4.5 Minimize the handling of sterile items to reduce and prevent the risk of packages from being crushed, bent, compressed or punctured. Utilize the first in, first out principle.

4.4.6 Affix sterilization date and sterilization load number to each package prior to issuing supplies sterilized in-house.

4.4.7 Inspect all sterile items for package integrity and/or expiration dates prior to storage.

4.4.8 Use sterility maintenance covers (dust covers) to protect sterilized devices/items that are used less than once a month to maintain sterility.

4.4.9 Cover sterile packs with dust covers at the CSSD prior to distribution.

4.4.10 Consult with IP&C with regards to the use of items beyond the expiration use by date.

4.5 Shelf Life of Devices Sterilized In-house by CSSD and/or Commercially

4.5.1 The shelf life for all sterile items is 'event-related'

4.5.1.1 Event-related sterility refers to the sterility based on the proper handling, storage, and packaging degradation. The items or supplies are considered sterile only if the following are met:

4.5.1.1.1 No barrier tears, compressions, abrasions, punctures, moisture, dirt, bending, or damage in any way.

4.5.1.1.2 Each package must have not been opened and/or resealed.

4.5.1.1.3 The package must be properly opened without contaminating the contents.

4.5.1.2 If the packaged item does not have an expiration date and does not contain fluids antimicrobial agents, special coating or other materials, medication, or movable tips/parts that are subject to deterioration or degradation over time, which reducing the effectiveness or quality of the product, the event-related expiration date applies.

4.5.1.3 Consider any package that is not intact (i.e., with compromised integrity) as contaminated and must not be used. These items must be returned in their original packaging to CSSD office for reprocessing.

4.5.1.4 Inspect the integrity of sterile packs regularly, prior to storage and use.

4.5.1.5 CSSD must conduct an annual hospital-wide audit and contacts each unit to ensure compliance in sending reusable devices that have not been used within the parameters of their existing packaging degradation. Refer to CSSD hospital policy.

4.6 Distribution

4.6.1 Handling and inspection

4.6.1.1 Handle sterile supplies in such a way as to avoid compromising or contaminating the package.

4.6.1.2 Care should be taken to avoid dragging, sliding, crushing, bending, compressing, or puncturing the packaging, or otherwise compromising the sterility of the contents

4.6.1.3 Inspect packaging for integrity and labeling before an item is stored and/or issued.

4.6.2 Distribution containers and/ or carts

4.6.2.1 Cover all clean or sterile items being transported in uncontrolled environments or use an enclosed cart with a solid bottom shelf

4.6.2.2 Arrange items that are placed inside plastic or paper bags or boxes for transport within the containers so as to prevent them from being crushed, damaged or contaminated.

4.6.2.3 Reusable carts should have an enclosable opening. Clean reusable covers for carts after each use.

4.6.2.4 Decontaminate and dry transport carts after each use and before they are used for transporting another load of sterile supplies.

4.6.2.5 Follow manufacturer's written IFU on distribution and decontamination procedures for automated cart distribution systems and pneumatic systems.

4.7 Quality Assurance Testing

4.7.1 Perform quality assurance testing of reprocessed items on an ongoing basis.
4.7.2 Provide effective decontamination protocols
4.7.3 Include chemical indicators (CIs) in each package and must be sterilant specific. These are read by the end users after opening the sterile pack but before use.
4.7.3.1 In textile packs wrapped in woven or non-woven materials, the CIs are placed in between the layers of a folded surgical gown within the pack, between multiple layers of draping material or between layers of surgical towels.
4.7.3.2 In an instrument set, the CIs should be placed among the instruments that are placed on stringers.
4.7.3.3 In containment devices, the CIs should be placed in the areas recommended by the containment device manufacturer.
4.7.3.4 In multilayered instrument sets in containment devices, the CIs should be placed in the locations determined by the product manufacturer
4.7.4 Place biological indicators (BI) that are sterilant specific near the drain as per the manufacturer's IFU and run in every load.
4.7.5 Incubate and read BI that has been run/ processed in the sterilizer in accordance with the manufacturer's published instructions.

4.8 **"Sterility is Event Related" dependent upon:**
4.8.1 Appropriate & effective handling and storage [end user responsibility] and
4.8.2 **Packaging degradation [CSSD responsibility- every 4 years even if the packaging is intact]**
4.8.3 CSSD reprocesses items stored sterile but not utilized in 4 years, based on Event Related Sterility (ERS) guidelines.
4.8.4 All end users must use the form provided to log your items returned to CSSD this week for reprocessing
4.8.4.1 re: OR areas only, the tray inventory provided will be utilized for this purpose. Peel items will need to be listed by hand on the form provided.
4.8.4.2 All items must be returned to the CSSD office in the original packaging
4.8.4.2.1 * Do NOT open the item at source.
4.8.4.2.2 * Do not return to CSSD via the main CSSD decontamination window.
4.8.4.3 All items requiring reprocessing will be returned to you within 2- 3 days.
4.8.4.3.1 * Please remember you have not used them in 4 years.
4.8.4.3.2 * Please reconsider the need to have this item sterile on the shelf since it has not been used in 4 years
4.8.4.4 Should there be any items no longer required to be kept sterile on your units, CSSD will require an e-mail from the Nurse Manager asking CSSD to remove them from circulation.
4.8.4.5 Should the packaging integrity be compromised in any way it must be returned to CSSD for reprocessing at the time.
4.8.4.5.1 * This would include the item being bent, crushed, torn, stained, wet, having a visible foot print on it, abraded, resealed with scotch tape etc.
4.8.4.5.2 * When in doubt page the CSSD for point of use consultation. Do not open it until we arrive!
4.8.4.6 When this annual process has been completed, it is the end user responsibility to notify the CSSD via e-mail that the process is complete.
4.8.4.6.1 * This includes units who do not require inventory reprocessing for that year.

5. MATERIALS AND EQUIPMENT:

5.1 **Forms and Records:**
5.1.1 N/A
5.2 **Materials and Equipment**

5.2.1 N/A

6. RESPONSIBILITIES:

6.1 CSSD and Health Care Workers

7. APPENDICES:

7.1 N/A

8. REFERENCES:

8.1 GCC Infection Prevention and Control Manual. 3rd Edition. 2018.
8.2 Association for Professionals in Infection Control (APIC) and Epidemiology, Inc. (2014). Chapter 107: Environmental services. In APIC Text of infection control and epidemiology (4th ed.).
8.3 Hospital's administrative policy on management of spills of hazardous material.

9. APPROVALS:

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