	The Johns Hopkins Hospital Interdisciplinary Clinical Practice Manual Infection Control	<i>Policy Number</i>	IFC031	
		<i>Effective Date</i>	10/01/2010	
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	<i>Subject</i>	Sterilization and High Level Disinfection of Products	<i>Page</i>	1 of 6
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Keywords: Sterilization, implantable devices, flash sterilization, vacuum sterilizers, biological indicators

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I. OBJECTIVES


This policy shall standardize the Johns Hopkins Hospital sterilization processes and minimize the use of flash sterilization.

II. DEFINITIONS

Sterilization	The use of a physical or chemical procedure to destroy all microbial life, including highly resistant bacterial spores.
Flash Sterilization	Flash sterilization is the processes by which surgical instruments are sterilized for immediate use should an emergency situation arise during the surgery. (Appendix A and Appendix B)
Products	Surgical instruments, utensils, implantable items and other supplies used for procedures requiring sterility.

III. RESPONSIBILITY

- A. JHH/JHU/JHMI Staff
 1. Shall follow the processes detailed within this policy.
 2. Check that external and internal indicators turned the appropriate color to indicate sterility prior to use on a patient
- B. Manager, Central Sterile Processing (CSP)
 1. Ensure employee compliance with this policy.
 2. Notify Hospital Epidemiology Infection Control (HEIC), Risk Management and the operator when biological indicator test results are positive.
 3. Perform follow-up as outlined in this policy.
 4. Verify compliance daily.
 5. Monitor compliance of all sterilizer testing.
 6. Report non-compliance.
- C. Central Sterile Processing Staff
 1. Shall follow the processes detailed within this policy.
- D. Operating Room (OR) Staff
 1. Flash sterilize implantables only in emergent situations.

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2. Ensure that special items being supplied by vendors are made available to the hospital prior to the day of surgery or with sufficient lead-time to allow time for processing through standard methods.
 3. Run the appropriate biological indicator (B.I.) with each implantable item that is being sterilized.
 4. Do not release the item unless the B.I. has been read as negative.
- E. Department of Hospital Epidemiology and Infection Control (HEIC)
1. Review and revise the policy at least every 3 years.
 2. Present the policy to the HEIC Committee for review and approval as appropriate.
 3. Act on reports of sterilization malfunction and overuse of flash sterilization.
 4. Assist with decisions regarding sterilization and high-level disinfection.
- F. Areas with Sterilizers
1. Biological Indicator testing records must be maintained


IV. PROCEDURE

A. DECONTAMINATION AREA


1. Personnel Restrictions
 - a. Only properly attired personnel may enter the decontamination area.
2. Configuration
 - a. Separate with a physical barrier the decontamination area from the areas where all other processing activities are performed.
3. Attire
 - a. Wear both a fluid resistant cover gown (tied in the back) and heavy-duty gloves during the decontamination process.
 - b. Completely cover all head and facial hair with a surgical-type hair covering.
 - c. Wear mask and goggles or a face shield to protect against splashes or sprays.
4. Hand hygiene
 - a. Thoroughly clean hands. Wash and dry hands or use an alcohol-based gel for hand cleaning upon leaving the decontamination area and before performing any assignment in a different area.
5. Cleaning Process
 - a. Washer Decontaminator
 - i. Maintain standard Water Temperatures:
 - Wash cycle: 140-160 degrees F
 - First tap water rinse: 150 degrees F
 - Final rinse: 181-190 degrees F
 - b. Manual Cleaning
 - i. Use three stainless steel sinks for the manual cleaning process.
 - ii. Sinks must be large and deep enough to immerse completely any article processed.
 - iii. If three sinks are not available for this process, the following steps must be used:
 - Place item to be cleaned in sink and wash with detergent.
 - Rinse equipment in clean water.
 - When finished, empty sink and wipe sink surfaces with a combined detergent-disinfectant.
 - Rinse sink twice with hot tap water
 - Wipe sink surfaces with a detergent-disinfectant a second time
 - c. Repair Logs
 - i. Maintain records of repairs on all sterilizers for 7 years.

B. Preparation Area

1. Configuration

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- a. Store clean supplies in closed cabinets. When this is not possible, store supplies on wire shelves with the bottom shelf being solid.
 - b. Use tables of sufficient size to facilitate the assembly of materials.
 - c. Maintain a clean environment.
 - d. Allow no exposed light fixtures, pipes, ducts, or cables that could collect lint and dust.
2. Attire
 - a. Wear clean surgical attire when working in the preparation, sterilization, and sterile storage areas.
 - b. Completely cover all head and facial hair (except eyebrows and eyelashes) with a surgical type-hair covering.
 - c. Remove all jewelry.
 - d. Review Surgical Attire Policy.
 3. Packaging (Appendix B)
 - a. Wraps
 - i. Wrap all packages separately.
 - ii. When double wrapping, all wrapped items must be double-wrapped by using one of the following:
 - Double-thickness woven or non-woven wrappers
 - Two non-woven wrappers - may be sealed
 - Peel-Pouches
 - b. Determination of Shelf Life of Packaged Items:
 - i. Inspect all packages before use.
 - ii. Do not use any packaged item if the package is torn, dropped, wet or damaged.
 - iii. Hospital sterilized items will have an indefinite shelf life and are to be considered sterile as long as integrity of the package has not been compromised.
 4. Personnel Restrictions
 - a. If only one person is to handle the supplies before and after decontamination, that person must remove decontamination attire and wash their hands or use an alcohol-based hand gel before entering the preparation area.
 - b. Traffic between the decontamination, preparation and assembly areas must be minimized.
 5. Transfer of Items into the Preparation Area
 - a. Clean items must be dry before transfer into the preparations area.
 - b. Equipment and supplies must not be shared among processing areas.
 6. Preparation of Articles
 - a. All jointed instruments must be open and/or unlocked.
 - b. Disassemble all instruments designed to be disassembled.
 - c. Instruments must not be held together with rubber bands.
 - d. If lubrication is necessary, use a nontoxic, water-soluble lubricant.
 - e. Place instrument sets in trays with wire mesh bottoms or in instrument container systems.
 - f. The total weight of the trays must not exceed 25 pounds or the weight specified by the manufacturer of the sterilizer or container system.
 - g. Hospital prepared linen packs must not be larger than 12" w x 12" h x 20" l and weigh no more than 12 lbs.
 - h. Absorbent towels or other moisture-absorbing material must be used to separate utensils nested in one package.
 - i. Align nested items so that air pockets are not created, condensate can drain out, and sterilant can circulate freely.
 - j. Place bowl, beakers, etc. upside-down or on side so steam can enter.
 7. Package Identification
 - a. Label every sterilized item with the following information:
 - i. Lot control/Production Label: Sterilizer Number, Load Number, designating the sterilization number, and the cycle number, year and date of sterilization (Julian date), and initials of processor.

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- ii. Item identification
- iii. Optional: list of package contents

C. STERILIZATION PROCEDURES:

- 1. See Appendix C

D. IMPLANTABLE DEVICES

- 1. High-vacuum: Validate every load in the Manufacturing Areas by obtaining the cycle parameters and the reading of the integrator before the load is released.
- 2. Flash Sterilization (Appendix A): Do not use flash sterilization for implantable items except in urgent situations in which patient care requirements preclude other sterilization methods (e.g. critical instrument is dropped and sterilized back-ups are not available). In such situations, use a sterilization time of 10 minutes and a rapid-readout biological indicator with the load. Special items being supplied by vendors must be made available to the hospital prior to the day of surgery or with sufficient lead-time to allow time for processing through standard methods.

E. NON-IMPLANTABLE DEVICES

- 1. Flash Sterilization (Appendix A): Do not use flash sterilization for non-implantable items except in urgent situations in which patient care requirements preclude other sterilization methods (e.g. critical instrument is dropped and sterilized back-ups are not available).

F. STORAGE OF STERILIZED ARTICLES

- 1. Storage of Sterile Items
 - a. Store items in a manner that prevents crushing or binding together.
 - b. Place lighter items on heavier ones.
 - c. Store items in closed cabinets. If this is not possible, store items on wire shelves in a restricted storage area with the bottom shelf being solid.
 - d. Maintain storage areas in a manner that prevents splashing from personnel or housekeeping.
 - e. Arrange sterile storage to facilitate stock rotation.
 - f. Store liquids below dry sterile goods or in a separate section.
 - g. Store materials 8"-10" from the floor and 18" -20" below the ceiling and/or sprinkler head.
 - h. Do not store sterile items under plumbing valves and traps.
 - i. If traffic is not restricted to personnel who are involved only in the dispensing functions, require other personnel to adhere to the attire guidelines.
- 2. Housekeeping
 - a. Wet vacuum or wet mop floors at least once daily and repeat as often as necessary during the day to keep them clean and free of dirt and dust.
 - b. Clean shelves weekly.
 - c. Clean walls and ceilings as necessary.
 - d. Clean vents and change filters quarterly or more frequently if necessary.
 - e. Do not sweep, dry mop or dry dust within the area


G. DISTRIBUTION OF STERILIZED ARTICLES

- 1. Delivery carts shall be covered during delivery.
- 2. Transportation carts shall be cleaned weekly with a disinfectant.

H. PERSONAL HYGIENE FOR PERSONNEL PERFORMING STERILIZATION PROCESSES

- 1. Provide hand washing facilities and alcohol-based hand gel in areas accessible to all personnel.
- 2. Clean hands frequently and thoroughly by either washing with a lotion soap or use of an alcohol-based gel.
- 3. Clean hands by washing or using alcohol-based gel before moving between work areas.
- 4. Hair, body, nails and uniforms of personnel must be clean at all times.
- 5. Report all personnel illness or infection to supervisor prior to beginning the workday.

I. INSERVICE EDUCATION FOR PERSONNEL PERFORMING STERILIZATION PROCESSES

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1. Provide in-service training programs for personnel involved in decontamination, processing, sterilization, storage, and the delivery of sterile supplies annually and more frequently as deemed necessary by the area supervisor.
 2. See Policy IFC032 Prion –Associated Diseases.
- J. PROCEDURE MANUAL FOR STERILIZATION PROCESSES
1. Provide written policy and procedure manuals covering work tasks in all areas performing sterilization processes.
 2. Update written policies at least every three years and forward to HEIC for approval.
- K. RECALL OF SUPPLIES
1. When directors and administrators of an area are notified of a recall of items in their area, they must notify Risk Management, HEIC and the operator of possible patient exposures to recalled items.

V. REPORTABLE CONDITIONS

- A. Report to HEIC:
1. Written report quarterly to the HEIC Committee of the amount of Flash Sterilization that has been performed and the reasons for the Flash Sterilization.
 2. Report to the HEIC department any failure of Biological Indicators and response to the event.
- B. Report in PSN: Any failures in procedures that may expose a patient to the possibility of infection.

VI. DOCUMENTATION

- A. Refer to Wilmer OR Flash Sterilization log (Appendix C).

VII. EDUCATION AND COMMUNICATION

- A. Nurse educators and Central Sterile Management shall review with staff involved in the cleaning, decontamination, assembly, sterilization, and storage of sterilized items.
- B. Sterilization Standards Committee will review and update protocol when there are changes in practice.
- C. Placement of policy on-line at www.hopkinsmedicine.org/heic
- D. This policy will be placed in the [Interdisciplinary Clinical Practice Manual on the JHH Intranet site](#). Paper distributions will be made to the Functional Unit Nursing offices in the event of web access difficulty.

VIII. SUPPORTIVE INFORMATION


See Also:

The Johns Hopkins Hospital Interdisciplinary Clinical Practice Manual

- [Policy IFC032 Prion –Associated Diseases](#)
- [Policy PAT009 Surgical Attire Policy](#)

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Sponsor:

- Medical Care Evaluation Committee

Developer:

- Hospital Epidemiology and Infection Control Committee

Review Cycle - Three (3) years **Medical Board** - Approval Date: 9/28/10; Effective Date: 10/1/10

Vice President for Nursing & Patient Services

Vice President for Medical Affairs

Date:

Date: