	The Johns Hopkins Hospital INTERDISCIPLINARY CLINICAL PRACTICE MANUAL	<i>Policy Number</i> IFC033
	<i>Subject</i> Flash Sterilization of Implantable Items	<i>Effective Date</i> 11/13/03
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		<i>Supersedes</i> 10/01

KEYWORDS

Flash Sterilization, Implantable, Biological Indicator, Chemical Integrator, Rapid Readout

PATIENT CARE OBJECTIVES


Flash sterilization of implantables is not recommended. It shall be used only in emergent situations when there is insufficient time to sterilize an item by the preferred prepackaged method. When flash sterilization is absolutely necessary, strict adherence to the procedure outlined in this policy must be followed.

RESPONSIBILITIES

1. Operating Room (OR) Staff
 - Sterilize implantables only in emergent situations.
 - 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.
 - Run the appropriate biological indicator (B.I.) with each implantable item that is being sterilized.
 - Do not release the item unless the B.I. has been read as negative.

PROCEDURES

1. FLASH OF IMPLANTABLES BY OR STAFF
 - Inspect implantables for defects, organic soil and/or debris. Follow the manufacturer's instructions for removing organic soil and debris before sterilizing. Even those items without visible soil shall be washed before sterilization. For lumened and teathed instruments, brushes shall be required to clean lumens thoroughly.
 - Handle the implantables according to the manufacturer's recommendations.
 - Arrange the items in the sterilization pan to maximize sterilization effectiveness, i.e., disassemble all parts, open all instruments.
 - For items that will be transported to another room through a semi-restricted hallway, place the items in a rigid covered flash container and follow the manufacturer's directions for sterilization.
 - Place a chemical integrator in each pan before being flash sterilized.
 - Complete the flash sterilization log.
 - Sterilize all implantable items for 10 minutes at 270 °F (unless the manufacturer specifies otherwise) using a gravity cycle.
 - Run the appropriate Rapid Readout biological indicator (B.I.) with each load of implantables being flash sterilized. Using the gravity cycle, a one hour Rapid Readout shall be used.
 - At the conclusion of the sterilization cycle, verify that the sterilization time, pressure and temperature has been met, and document on the graph/computer printout your initials and the room to which the implants are being delivered.


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- Before placing the implantables on the field, check the chemical integrator to make sure it has reached the safe level. Place the implants on a separate table until the BI has been read.
- Label the B.I. after the completion of the flash sterilization cycle and after adequate cool down with the following information: patient's name, date, sterilizer number and OR number. Label a control B.I. with the patient's name, date and OR number.
- Activate the sterilized and control B.I.'s by following the manufacturer's instructions, making sure the vials are completely closed and the caps are properly sealed.
- Place the Rapid Readout B.I. in the incubator with an activated control. At the completion the incubation period, place the sterilized B.I. in the designated well and read the results. At no time can the B.I. be read in less than one hour. The machine will automatically tell you if the results are positive or negative. This shall be completed before the items are released for implantation. Place the control B.I. in the reader well and read the results.

DOCUMENTATION

The following shall be documented after the B.I. and control are read:

1. Patient information (name, history #), implant type, autoclave number, date, time and signature of the person flash sterilizing the implant(s).
 - B.I. is negative: document that the B.I. is negative and that no follow-up is needed.
 - B.I. is positive: document that the B.I. is positive and that follow up is needed. Record the name of the person completing the follow-up. Complete Report of Patient/Visitor Event form and notify the Department of Hospital Epidemiology and Infection Control, Risk Management and the operator. **Do not release the item for implantation.**
 - Control B.I. is positive: document that the Control is positive.
 - Control B.I. is negative: document that the Control is negative. It must be assumed that the test biological indicators from that lot are nonviable or that improper incubation occurred; therefore, the test results must be considered invalid. Flash again using B.I. and B.I. Control from a different lot. Do not release the item until the control has tested positive.
2. On the nurse's notes:
 - Implant type, sterilization time, pressure, temperature, results of the sterilized Rapid Readout B.I and control B.I. and the time it was run.
 - Record the date, time and signature of the person flash sterilizing the implant(s).
 - If the results of the sterilized B.I. are positive, the name and time that the operator was notified and any follow up to be performed must be documented.

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SUPPORTIVE INFORMATION

REFERENCES

Association for the Advancement of Medical Instrumentation. (2000). Standards and Recommended Practices: Part 1 Sterilization in Health Care Facilities.

Association for Professionals in Infection Control. Text of Infection Control and Epidemiology, Chapter 55, 2000.

Association of Operating Room Nurses, Inc. (2000). Standards and Recommended Practices Guidelines.

Joint Commission on Accreditation of Healthcare Organizations (2001). Accreditation Standards for Acute Care Facilities.

SEE ALSO

Interdisciplinary Clinical Practice Manual

- Sterilization, IFC031 <http://www.insidehopkinsmedicine.org/icpm/ifc031sterilization.pdf>

SPONSOR

- Medical Care Evaluation Committee

DEVELOPERS

- Sterilization Standards Committee
- Hospital Epidemiology and Infection Control

COMMUNICATION & EDUCATION

This policy will be communicated to the appropriate JHHS personnel via the following channels:

1. Nurse educators and Central Sterile Management to review with staff involved in the cleaning, decontamination, assembly, sterilization, and storage of implantable items.
2. Nurse educators and Central Sterile Management to review with staff involved in the documentation of sterilized implantable items within the nursing notes and the flash implantables log sheets.
3. Medical Staff and Nursing publications.
4. This policy will be placed in the Interdisciplinary Clinical Practice Manual on the JHH Intranet site <http://www.insidehopkinsmedicine.org/icpm>. Paper distributions will be made to the Functional Unit Nursing offices in the event of web access difficulty.
5. Placement of policy on-line at www.Hopkins-HEIC.org.

REVIEW CYCLE	• Three (3) years	MEDICAL BOARD	Approval Date: 5/13/03 Effective Date: 11/13/03
VICE PRESIDENT FOR MEDICAL AFFAIRS			

Date:			