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Learning Objectives

1. List what conditions must be followed when flash sterilization is used in selected clinical situations.
2. Develop a policy and procedure for the use of rapid-action biological indicators for the release of implants.
3. Develop a policy and procedure for the routine monitoring of each flash sterilization cycle.
4. List the documentation required for each flash load.

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SELF-STUDY Series

Flash sterilization:

Association of periOperative Registered Nurses (AORN) Recommended Practices for Sterilization in Perioperative Practice Setting 2006

by Martha Young, BS, MS, CSPDT

The Association of periOperative Registered Nurses (AORN) Recommended Practices for Sterilization in Perioperative Practice Settings were updated and became effective January 1, 2006. The AORN recommended practices for sterilization in perioperative settings should be part of your reference library and reviewed when establishing policies and procedures (see details for purchase on p. 40).

The AORN recommended practices "are intended as achievable recommendations representing what is believed to be an optimal level of practice."¹ Each healthcare facility will need to determine the degree to which the recommended practices can be implemented within their policies and procedures.

Purpose of Recommended Practice

"These recommended practices provide guidelines for the sterilization of surgical items (i.e., instruments, supplies, equipment, medical devices). The creation and maintenance of an aseptic environment has a direct influence on patient outcomes. A major responsibility of the perioperative registered nurse is to minimize patients' risks for surgical wound infections. The expected outcome of primary importance to this recommended practice is outcome O10, "The patient is free from signs of Infection." One of the measures for preventing surgical wound infections is to provide surgical items that are free of contamination at the time of use. This can be accomplished by subjecting them to a sterilization process. Steam, ethylene oxide (EO), low temperature gas plasma, peracetic acid, ozone, and dry heat are sterilization methods that are used in the health care environment. Sterilization of each item to be processed must be validated by the product manufacturer. Directions for sterilizing items should be reviewed in consultation with the manufacturers of the sterilizer and the item to be sterilized. Each sterilization method, and some instrumentation, has limitations; these limitations should be identified before purchasing and using any sterilizer. Sterilization provides the highest level of assurance that surgical items are free of viable microbes."¹

AORN defines flash sterilization as "a process designed for steam sterilization of patient care items for immediate use. This inservice will provide information about the AORN Recommended Practices IV for Flash Sterilization in Perioperative Practice Settings.

Recommended Practice IV

"Flash sterilization should be used in selected clinical situations and in a controlled manner. Use of flash sterilization should be kept to a minimum."

"Flash sterilization should be considered only if all of the following conditions are met:

- The device manufacturer's written instructions are available and followed.
- Items are disassembled and thoroughly cleaned with detergent and water to remove soil, blood, body fats, and other substances.
- Lumens are flushed with the cleaning solution and rinsed thoroughly.
- Items are placed in a sterilization container or tray in a manner that allows steam to contact all instrument parts.
- Measures are taken to prevent contamination during transfer to the sterile field.
- Documentation of cycle information and monitoring results is maintained to provide for tracking of the flashed item(s) to the individual patient."¹

AORN states that "Flash sterilization should be used only when there is insufficient time to process by the preferred wrapped or container method. Flash sterilization should not be used as a substitute for sufficient instrument inventory."¹ This statement can assist in the justification to increase instrument inventory to reduce and avoid flash sterilization.

The AORN recommended practices states: "Flash sterilization may be associated with increased risk of infection to patients because of pressure on personnel to eliminate one or more steps in the cleaning and sterilization process. It is essential that all steps in the sterilization process be performed in a conscientious manner."¹

The recommended practice also discuss the necessity for proper cleaning, decontamination, packaging and wrapping, handling and transportation of unwrapped packages and the use of specialized flash sterilization containers

and preparation of lumens. The AORN's *Recommended Practices for Cleaning and Caring for Surgical Instruments and Powered Equipment* is cited as a good reference along with the Association for the Advancement of Medical Instrumentation (AAMI) Recommended Practices for additional information.^{2,6}

In addition, the following Recommended Practices in this AORN Recommended Practices for Sterilization in Perioperative Practice Settings can be used to appropriately prepare and sterilize instruments:

- ✓ Recommended Practice I
 - Cleaning and decontamination
- ✓ Recommended Practice II
 - Packaging
- ✓ Recommended Practice III
 - Steam sterilization
- ✓ Recommended Practice XIV
 - Quality control program

The AORN recommended practices also stress the importance of following written instructions for sterilization process parameters from the medical device and sterilizer manufacturer. Table 3 on p. 633 of the recommended practice provides examples of typical flash sterilization cycle parameters that may not apply to all the devices being processed.¹ With the variety of steam sterilization cycle times, temperatures and dry times it is important to obtain in writing from the medical device manufacturer the appropriate parameters and adjust your sterilization process to accommodate the parameters to ensure effective sterilization. If the medical device manufacturer's instructions for sterilization are different from those recommended by the sterilizer manufacturer, the medical device manufacturer's instructions should be followed.

The AORN recommended practices IV also states:

“Flash sterilization should not be used for implantable devices. Implants are foreign bodies, and they increase the risk of surgical site infections. Careful planning, appropriate packaging, and inventory management in cooperation with suppliers can minimize the need to flash sterilize implantable medical devices. **When an implantable device is sterilized at a health care facility, a biological indicator should be run with the load and the implant should be quarantined until the results of the biological indicator are known.** If an emergency situation makes flash sterilization unavoidable, **a rapid-action biological monitoring device should be used along with a class 5 chemical integrator. The implant should not be released until the rapid-action indicator provides a negative result.** After the rapid-action negative result is obtained, the implant can be released for use in the immedi-

ate situation. If the implant is not used, it cannot be saved as sterile for future use. Resterilization of the device is required. If the biological indicator is later determined to have a positive result, the surgeon should be notified as soon as the results are known.”¹

The risk of infection and negative patient outcomes that can result are addressed by Janet Schultz in Monitoring and Load Release for Implants Sterilized by Steam Within Healthcare Facilities in *Managing Infection Control*, Jan 2004:

- “First, they are left behind at surgery, so if there are microorganisms on them, these will remain in the body. Infections associated with implants may not be evident for up to a year after surgery.
- Second, the placement of an implant often means the removal of tissue, with interruption of blood supply and significant manipulation of the tissues immediately adjacent to the implant, creating an area of potential safety for microorganisms to multiply, further increasing the risk of infection.
- Third, because there is interrupted blood supply, antibiotics cannot easily get to the microorganisms if they do multiply enough to cause a clinical infection.
- Fourth, the implant itself may be vital to continuing function of a body system, such as would occur with a total joint replacement, vascular graft, or intraocular lens placement. An infection may not be curable with the implant in place, and removing it could cripple or kill the patient.”⁷

In addition:

“The mortality rate (deaths) associated with infected total hip replacements approaches 50%, from the infection itself and from the complications associated with the resulting impaired mobility, such as blood clots and pneumonia.”⁷

The AORN Recommended Practice IV is very clear that implants should not be flash sterilized or released for patient use before the rapid-action biological indicator (enzyme-based early-readout biological indicator is the term used by AAMI) result is known.^{1,3}

This AORN recommended practice also states that “each cycle should be monitored to verify that parameters required for sterilization have been met.”

Recommendations include:

- Record physical parameters of time and temperature for each cycle and verify by the sterilizer operator before the items are transferred to the point of use.
- Monitor the sterilizer function with mechanical (now referred to as physical), chemical and biological indicators to meet all monitoring standards.^{3,5}

- Monitor flash sterilization cycles daily with devices according to manufacturers' written instructions.
- Use sterilization process monitoring devices with each load to be flash sterilized.^{3,5}
- Documentation should be traceable to each patient
 - ✓ Information on each load
 - Device(s) processed
 - Patient receiving item(s)
 - Reason for flash sterilization

AORN Recommended Practice IV states that the routine use of monitoring devices, including biological indicators, provide information to demonstrate that conditions for sterilization have been met. More information about the use of these devices is discussed in Recommended Practice XIV and in the AAMI/ANSI ST46 *Steam sterilization and sterility assurance in health care facilities* and the AAMI/ANSI ST37 1996 *Flash Sterilization: Steam sterilization of patient care items for immediate use* recommended practice.^{3,5}

Summary

AORN Recommended Practice XVI stresses that “uniform perioperative nursing vocabulary should be used in the development of policies and procedures and documentation of nursing interventions related to sterilization.”¹ The 2006 AORN Recommended Practices for Sterilization in Perioperative Practice Settings states “these recommended practices should be used to guide the development of policies and procedures within individual perioperative practice settings.” In addition “policies and procedures establish authority, responsibility, and accountability and serve as operational guidelines.”¹ The goal of every perioperative nurse is to minimize patients' risk for surgical wound infections by providing surgical items that are free of contamination. Follow the AORN Recommended Practices for Sterilization in Perioperative Practice Settings when developing policies and procedures for flash sterilization. **NPN**

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See SELF-STUDY SERIES on page 40

ANSWERS	1. a
	2. b
	3. a
	4. b
	5. a
	6. a
	7. a
	8. b
	9. a
	10. a

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AAMI working group committees that are developing recommended practices.

References

1. Recommended Practices for Sterilization in Perioperative Practice Settings. Association of periOperative Registered Nurses. AORN Standards, Recommended Practices, and Guidelines. 2006.
2. AORN Standards, Recommended Practices, and Guidelines. Recommended Practices for Cleaning and Caring for Surgical Instruments and Powered Equipment. 2005.
3. The Association for the Advancement of Medical Instrumentation. Steam sterilization and sterility assurance in health care facilities. ANSI/AAMI ST46:2002.
4. The Association for the Advancement of Medical Instrumentation. Safe handling and biological decontamination of reusable medical devices in health care facilities and in nonclinical settings. ANSI/AAMIST35:2003.
5. The Association for the Advancement of Medical Instrumenta-

tion. Flash Sterilization: Steam sterilization of patient care items for immediate use. ANSI/AAMI ST37:1996.

6. The Association for the Advancement of Medical Instrumentation. Ethylene oxide sterilization in health care facilities: Safety and effectiveness. ANSI/AAMI ST41: 1999.
7. Janet Schultz. Monitoring and Load Release for Implants Sterilized by Steam Within Healthcare Facilities. Managing Infection Control. Jan 2004.

AORN Standards can be purchased through AORN using the following options:

1. Internet: www.aorn.org/bookstore/ordering.htm
2. Call: 1-800-755-2676 x 1 or 303-755-6304 x 1 (Monday-Friday, 8AM to 4:30PM mountain standard time)
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A CDROM of the standards is available for the first time this year.

Flash Sterilization: Association of periOperative Registered Nurses (AORN) Recommended Practices for Sterilization in Perioperative Practice Setting 2006

Continuing Education Test-April 2006

CIRCLE THE CORRECT ANSWER

1. Flash sterilization should only be used when there is insufficient time to process by the preferred method and not because there is insufficient instrument inventory.
 - a. True
 - b. False
2. Only consider using flash sterilization if the device manufacturer's written instructions are not available.
 - a. True
 - b. False
3. The same instrument preparation (disassembly, cleaning, flushing lumens) and the appropriate placement in containers and trays should be followed when flashing instruments as is used for the preferred wrapped method.
 - a. True
 - b. False
4. The same risk of infection to a patient is associated with flash sterilization as the preferred wrapped method.
 - a. True
 - b. False
5. Adjust your sterilization process to accommodate the parameters provided in writing by the medical device manufacturer to ensure effective sterilization.
 - a. True
 - b. False
6. Do not release a flashed implant until the rapid-action biological monitoring device is negative.
 - a. True
 - b. False
7. Routine testing of flash loads includes the use of physical monitors, chemical and biological indicators that meet all monitoring standards.
 - a. True
 - b. False
8. Do not document which patient received which items from each flash sterilization load.
 - a. True
 - b. False
9. The goal of every perioperative nurse is to minimize patients' risk to surgical wound infections by providing surgical items that are free of contamination.
 - a. True
 - b. False
10. Use the 2006 AORN Recommended Practices for Sterilization in Perioperative Practice Settings to develop policies and procedures to establish authority, responsibility, and accountability and serve as operational guidelines.
 - a. True
 - b. False

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