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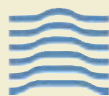
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## Learning objectives

1. Understand the definition of an implant and the importance of sterility for implants
2. Learn the processes and activities required when an implant is to be used
3. Understand the basics of flash sterilization and its use for implants
4. Understand the positions of professional organizations on using flash sterilization for implantable devices
5. Learn how to reduce infection risk when flash sterilization is unavoidable

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## Implant sterilization: Basic questions and answers

by Ronald R. Rahl, RN, BSN, MPA

People are living longer and more productive lives thanks to advances in healthcare and nutrition. Many of us have reached the age at which body parts require assistance or even replacement. The resulting increase in demand for surgical procedures to implant heart valves, pacemakers, hip joints and other permanent devices leads to an associated increase in the number of implants requiring sterilization in sterile processing departments and operating rooms. In order to ensure that every implant is safe for every patient, central services and O.R. staff must have a basic understanding of the topic.

### What is an implant?

The Food and Drug Administration defines an implant as a "device that is placed into a surgically or naturally formed cavity of the human body if it is intended to remain there for a period of 30 days or more." There is a long list of items such as heart valves, arterial shunts and artificial joints included in this definition. But the list also includes commonly used items such as screws and metal plates.

All implants must be sterile at the time of use because a non-sterile implantable device may have severe consequences for the patient. Even one pathogenic organism at an avascular surgical site (an area without blood supply) can cause a serious infection. Imagine the complications that can occur from an infection caused by a non-sterile heart valve, for example.

### What are the sterilization requirements for implants?

Most implants arrive at the hospital packaged and pre-sterilized. The manufacturers of these implants undertake painstakingly detailed sterilization validations to ensure that the item is sterile. When a non-sterile implantable device is received, however, it is very important to follow the manufacturer's instructions for sterilization of that specific device.

Though every steam sterilizer manufacturer must validate the sterilization effectiveness of their equipment's programmed sterilization cycles, the effectiveness of cycles for each medical device, including implants, must also be validated. Many steam sterilizers are able to meet the FDA requirements for implants within

their menu of standard cycles. However, some implants may have special requirements, especially those that have been included with instruments sets such as total hip replacement sets.

### What steps should be taken when an implant is used?

First, ensure that the implant packaging has maintained its integrity. Check to make sure there are no puncture points, tears in wraps or pouches, or damaged filters (if applicable), and that there are no other signs of damage to the packaging. Confirm that the implant will function properly.

When the device is placed in a patient, thoroughly document all identification and placement details. Without this critical information, follow-up is difficult and critical updates concerning the implant may be missed. Documentation should occur at the time of implantation, by the surgical team. The Association of Peri-Operative Registered Nurses (AORN)<sup>1</sup> states that the following information must be documented in the patient record:

- Placement and location of implant
- Name of the manufacturer or distributor
- Lot and serial number
- Type and size of implant
- Expiration dates, if applicable
- Any other information required by the FDA.

In addition, the Association for the Advancement of Medical Instrumentation (AAMI)<sup>2</sup> states that any implants used and sterilized by the healthcare facility must be traceable back to the sterilization cycle in which it was processed. Typically this is done by recording the sterilization load number or other unique cycle identification number in the patient record.

It is the responsibility of the sterile processing department to ensure that all the implants sterilized within their hospital are sterile and that all sterility assurance monitoring of each cycle is appropriately completed. However, there are situations in which unexpected trauma cases or late delivery of an implant set for a planned surgical procedure may result in a need so urgent that the standard sterilization cycle would take too long. This is when the O.R. may turn to flash sterilization to process the implant quickly.

## How long has flash sterilization been in use?

As long as steam sterilization has existed, flash sterilization has been an option. The original flash sterilization cycle was a gravity cycle performed at high temperatures (270°F) for an abbreviated time. The items were placed in a mesh tray and were not wrapped. Items that were sterilized in this manner were never meant to be stored. All flash-sterilized items were, and are still, for immediate use only.

As time progressed, the development of pre-vacuum and steam-flush pressure-pulse (SFPP) cycles made sterilizers more efficient. Along with these advanced cycles came new ways to flash sterilize. More complex instrumentation and even implants began to be flash-sterilized as people became more confident in the method. Today, O.R. staff must be aware of exactly which devices are being flash-sterilized and which sterilization cycle and exposure time should be used for each item.

## What do professional organizations say about flash sterilization of implants?

Just because we *can* do something doesn't mean we *should*. Both AORN and the Centers for Disease Control and Prevention agree that implants should never be flash-sterilized. Though flash sterilization cycles are complete and efficacious, the many inherent opportunities for contamination of the implant following flash sterilization warrant this precaution. Proper scheduling, planning and inventory management will prevent the need for flash sterilization of implants.

AAMI, on the other hand, recognizes that there are times when flash sterilization of a screw or metal plate must be performed. In these emergency cases, implants may be flash-sterilized if the quality control procedures for standard sterilization are followed, aseptic transport can be ensured, and the proper documentation for flash sterilization is performed so that the load's contents can be traced directly to the patient for whom they are used.

## What are the steps required when flash sterilization cannot be avoided?

Prior to sterilization of any implant, ensure that the implant is functioning and that it has been properly decontaminated. Next, place the implant in an unwrapped mesh tray. Then, in order to assure proper quality control, place both a biological indicator and a chemical indicator in the tray next to the implant.

Before the sterilized implant can be used, the cycle printout and all other chemical indicators within the load must be examined and the results deemed acceptable. Often, the bio-

logical indicator result will not be available at the time the implant is taken into the O.R. As indicated in the AAMI ST46 guideline, staff must document that the implant was released for surgery prior to knowing the results of the biological indicator. This is for any implant, whether it is sterilized in the sterile processing department or flash-sterilized in the O.R. suite.

Even if O.R. staff knows that the item will not be implanted before the results of the biological indicator are available, this doesn't meet the requirements for the monitoring process. All flash-sterilized items should be treated as an early release and documented appropriately at the time the implant is sent to the O.R. (For an example of early release documentation forms, please see the ANSI/AAMI ST46:2002, Annex C, pages 73 and 74.)



Containers protect implants from environmental contaminants during transport.

## How can the risk associated with flash sterilization of implants be reduced?

The best way avoid risk is to never flash-sterilize surgical implants. However, if it is unavoidable some measures may be taken to reduce infection risk:

- Reduce the environmental contamination potential by using an approved flash sterilization container system
- Ensure that all personnel are thoroughly trained and competent in performing flash sterilization duties
- Verify that correct manufacturer instructions are being followed for each implant device
- Perform regular audits of your flash sterilization records
- Continue to strive for the overall reduction of flash sterilization.

## How can we avoid flash-sterilizing implants?

Basically, the solution is to think and plan well ahead in order to anticipate all surgical needs and allow time for required sterilization processes.

- Obtain pre-sterilized implants whenever possible
- Establish, communicate and enforce policies that support the use of loaner sets containing implants that can be properly processed and sterilized using standard sterilization cycles
- Establish accountability and consequences for the late receipt of sets
- Ensure that surgical inventory can support the scheduled cases and communicate any special needs well in advance of the case
- Establish an "expedite process" to flag and prioritize needed implants.

## Summary

As the demand for implant procedures increases, a high level of patient safety can be maintained through proper inspection, documentation, sterilization and sterility assurance monitoring practices, inventory management, and the overall reduction of flash sterilization activities.

In order to perform these tasks well, CS and O.R. staff must also participate in ongoing training programs, and should update their education as industry and hospital requirements change and staff turnover occurs. In addition, regular audits should be performed by managers to ensure that the staff understands the importance of proper implant sterilization and has mastered the required skills. **HPN**

## About the Author

Ronald R. Rahl, RN, BSN, MPA is a senior clinical education specialist for STERIS Corporation. He manages STERIS clinical education specialists, and with them provides sterilization and infection control education, clinical support, and troubleshooting services to healthcare professionals.

Rahl has over 26 years of experience as a registered nurse and has worked in a variety of specialties. He served as a commissioned officer in the United States Air Force for over twenty years and during that time managed the largest operating room in the Department of Defense, at Wilford Hall Medical Center in San Antonio, TX.

## References:

1. AORN Standards, Recommended Practices and Guidelines, Addition "Recommended Practices for Documentation of Preoperative Nursing Care," 2005.
2. AAMI ST46: 2002 "Steam sterilization and sterility assurance in health care facilities."

See SELF-STUDY SERIES on page 46

Answers	1. c
	2. b
	3. a
	4. b
	5. e
	6. a
	7. a
	8. a
	9. a
	10. b

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# Implant sterilization: Basic questions and answers

CIRCLE THE CORRECT ANSWER

1. Which of the following items are all considered implants by the FDA?
  - a) Heart valve, bandage and battery pack
  - b) Hip joint, syringe and neurostimulator
  - c) Heart valve, hip joint and pacemaker
  
2. Which of the following do not require documentation when using an implant?
  - a) Placement and location of implant
  - b) Number of implant procedures performed by the doctor
  - c) Lot and Serial number of implant
  - d) Unique identifying number of the sterilization cycle/load
  
3. Flash sterilization is an efficacious sterilization process.
  - a) True
  - b) False
  
4. AORN allows the flash sterilization of implants when a justifiable emergency case exists.
  - a) True
  - b) False
  
5. When should the recommended Early Release documentation be completed when flash sterilizing?
  - a) When the sterile processing department releases an implant prior to knowing the biological response
  - b) When implantation will most likely occur prior to the biological indicator's incubation time being completed
  - c) When implantation of a flash sterilized items will most likely occur after the incubation period is completed
  - d) A and B only
  - e) A, B and C
  
6. The best way to reduce flash sterilization of implants is to not flash sterilize any implants.
  - a) True
  - b) False
  
7. All of the following but \_\_\_\_\_ reduce the risk associated with flash sterilization of implants.
  - a) Documentation of placement and location of implant
  - b) Using flash sterilization container systems
  - c) Using pre-sterilized implants
  - d) Maintain higher inventory levels of flash sterilized implants
  
8. When flash sterilization of an implant cannot be avoided, place the implant in an unwrapped mesh tray and place both a biological indicator and a chemical indicator in the tray next to the implant.
  - a) True
  - b) False
  
9. The first steps to take when an implant is used are to ensure that the implant packaging has maintained its integrity and to confirm that the implant will function properly.
  - a) True
  - b) False
  
10. AAMI does not require an implant to be traceable back to the sterilization cycle in which it was processed.
  - a) True
  - b) False

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