Talking about flash sterilization

AORN is working with partner organizations to address flash sterilization and infection prevention

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When it comes to preventing infection, perioperative professionals are at a crossroads. From one direction, regulatory agencies including the federal Centers for Medicare and Medicaid Services are instituting more stringent rules holding healthcare facilities responsible for surgical-site infections. From another direction, facilities face limited supplies and increasing pressures to handle more cases and reduce OR turnover time.

Flash sterilizers are used in the OR setting to sterilize instruments when there is insufficient time to process by the preferred wrapped or container method.

"Flash sterilization is the Band-Aid facilities sometimes use, but 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. In the end, resorting to flash sterilization may cause the facility more cost and put patients at risk," said Sheila Mitchell, RN, BSN, MS, CNOR, perioperative nursing specialist in AORN's Center for Nursing Practice and clinical editor of the 2008 Recommended Practices for Sterilization in the Perioperative Practice Setting.

"If facilities are using fl ash sterilization as a substitute for suffi cient instrument inventory, they may be putting patients at risk for increased surgical-site infection and may face a citation by The Joint Commission or other accreditation organizations," she advised.

Recognizing the challenges perioperative professionals face, AORN is working closely with The Joint Commission, the Association for the Advancement of Medical Instrumentation (AAMI), the Centers for Disease Control and Prevention, the Association for Professionals in Infection Control and Epidemiology (APIC) and others to ensure AORN's recommended practices and other guidelines are in line with accreditation and infection-control requirements from partner organizations. AORN is also working with partner organizations to better understand and measure the prevalence and practice of flash sterilization.

Advocating for safe flash sterilization practices
Because AORN's evidence-based standards and recommended practices are used by facilities to develop the infection prevention and control policies that are reviewed by accrediting bodies such as The Joint Commission, it is important for AORN to keep open communication with our partner organizations, said Sharon Giarrizzo-Wilson, RN, BSN/MS, CNOR, a perioperative nursing specialist in AORN's Center for Nursing practice.

Giarrizzo-Wilson says heightened attention to preventing surgical-site and healthcare-associated infections has led to a focus on sterilization practices by healthcare facilities, AORN, The Joint Commission and APIC. According to members of APIC's Practice Guidance Council, "the issue of flash sterilization has become routine in most invasive-procedure areas . . . due primarily to the lack of systematic fiscal revenue management based on supply and demand. This flash sterilization approach to daily OR cases has become a contributor to several surgical-site infections, and has been noted by outbreak investigations published in the literature and from personal consulting experiences," the council told AORN Connections.

AORN recommends that "use of fl ash sterilization be kept to a minimum. Flash sterilization should be used only in selected clinical situations and in a controlled manner," according to Recommended Practice IV of AORN's 2008 Recommended Practices for Sterilization in the Perioperative Practice Setting, which are included in AORN's 2008 Perioperative Standards and Recommended Practices.

This recommended practice is in agreement with the recommendations included in the American National Standards Institute (ANSI)/AAMI ST79:2006 Comprehensive Guide to Steam Sterilization and Sterility Assurance in Healthcare Facilities. "We work to make the recommendations from organizations consistent so people get the same information no matter which document they refer to. However, AORN's recommendations are written specifi cally for the needs of the perioperative nurse," explained Ramona Conner, RN, MSN, CNOR, manager of standards and recommended practices in AORN's Center for Nursing Practice. Conner is co-chair of the AAMI workgroup that developed ANSI/AAMI ST79:2006.

Understanding the survey process
Last year AORN's Giarrizzo-Wilson submitted questions to The Joint Commission Standards group, which has resulted in ongoing dialogue between AORN and The Joint Commission regarding surveying flash sterilization practices.

Currently The Joint Commission offers ongoing surveyor training in infection control and sterilization methods, including flash sterilization, through a regular column in the organization's internal biweekly newspaper. This is in addition to the detailed and specific education in infection control and sterilization that all Joint Commission surveyors obtain, explained Louise Kuhny, RN, MPH, MBA, CIC, senior associate director-standards interpretation for The Joint Commission.

"We work with a variety of government agencies and professional organizations, including AORN, to understand what the latest guidelines are. By all working together in terms of recommending policy, our common goal is to reduce the risk for infections and increase patient safety," Kuhny said.

While The Joint Commission standards do not specifically address fl ash sterilization, this practice is included within the Surveillance, Prevention and Control of Infection Standard of the accreditation organization's Comprehensive Accreditation Manual for Hospitals. It is listed within standards IC.2.10, IC.3.10, IC.4.10 and IC.5.10., which are grouped into four basic categories: risk assessment, goals and objectives, intervention and evaluation. Kuhny added that "interventions need to be based on relevant scientifi c guidelines for infection prevention and control activities, including those offered by AORN."

Evaluation is a critical step in this compliance program, she emphasized. "Facilities need to have a data-driven process to make sure what they do is working."

Focusing on measurement

The emphasis on evaluation to measure the prevalence of fl ash sterilization is also a current focus for AORN and researchers at The Joint Commission, according to Nancy Kupka, DNSc, MPH, RN, project director in The Joint Commission's department of health services research, division of quality measurement and research.

"Flash sterilization is interesting because it has been around for so long. People just assume there isn't a problem with this sterilization method, but our surveyors say fl ash sterilization continues to be a problem, due to breaks in sterile process ranging from inconsistent use of fl ash sterilization to improper cleaning of instruments before sterilization and improper use of biological indicators," Kupka said.

Surveyors are expected to evaluate areas where anesthesia is administered, so fl ash sterilizers in operating room areas are often included in a survey, Kupka noted. "When surveyors talk to OR staff about fl ash sterilization, they are likely going to note any

inconsistencies between what staff say and what an OR flash sterilization log shows."

All facilities need to be keeping an accurate, detailed record of fl ash sterilization activity. This is particularly important for ambulatory surgery centers because "the frequency of fl ash sterilization goes up in smaller facilities with tighter budgets," stressed AORN's Giarrizzo-Wilson.

While there are currently no national benchmarking data established for fl ash sterilization, AORN recommends that facilities should be benchmarking internally within their facilities because they need to know why they are flashing, particularly if they are flashing on a routine basis.

At a minimum, Giarrizzo-Wilson recommends that facilities need to document the following:
- Patient's name
- Surgery or procedure performed
- Item(s) and number fl ashed
- Exposure time and temperature

"Keeping accurate records for fl ash sterilization helps to build internal benchmarks needed to evaluate how frequently the process is used and determine the need to change existing practices," she stressed.

Giarrizzo-Wilson also encouraged members to enter their flash cycle data into AORN's Perioperative Nursing Dataset (PNDS) Dashboard by visiting, aorn.org/ PracticeResources/PNDS/PNDSDashboard/.

"Providing this information can help AORN contribute to a national benchmark for flash sterilization, which can provide all perioperative professionals with an evidencebased understanding for how often fl ash sterilization is being used in the perioperative environment," Giarrizzo-Wilson noted.

Tracking prevalence

In addition to focusing on benchmarking, AORN is also working with The Joint Commission's Kupka and Marguerite Jackson, PhD, RN, FAAN, chair of the APIC Scientific Research Council, to propose a study on the prevalence of flash sterilization in hospitals.

"We are all involved in infection prevention and interested in developing strategies that will help decrease surgical-site infection and promote infection prevention and control," acknowledged Joan Blanchard, RN, MSS, CNOR, CIC, perioperative specialist in AORN's Center for Nursing Practice.

The proposed survey, which is still in development, will query hospital staff about a number of issues related to fl ash sterilization, including when and why this sterilization method is being used, who is training for and practicing flash sterilization and what instruments are being flashed, said Kupka.

"Is flash sterilization being done for legitimate reasons, such as dropping an instrument? Or is it being used because a facility does not have enough instruments in their inventory?" she wondered. "Nobody really understands to what extent this is a problem. We suspect the reasons why, but this proposed study will give us the first opportunity to quantify what is going on."

As AORN continues to work with APIC, The Joint Commission and other partner organizations to help facilities increase awareness and gain a better understanding for flash sterilization practices, Blanchard hopes perioperative professionals will be encouraged to interact more with infection control professionals in their own facilities.

"Infection control professionals have the latest information on infection control guidelines and measurement, which perioperative professionals can use to establish best practices for flash sterilization and other infection control practices," Blanchard advised.

"As perioperative professionals face increased challenges to prevent and control infection, it is more important than ever to establish open dialogue with infection control professionals. These partnerships can help each us to provide positive outcomes for safer patient care."

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Table 4

TYPICAL MINIMUM CYCLE TIMES FOR DYNAMIC AIR-REMOVAL STEAM STERILIZATION[1]				
Item	**Exposure time at 270° F (132° C)**	**Minimum drying time**	**Exposure time at 275° F (135° C)**	**Minimum drying time**
Wrapped instruments	4 min	20 to 30 min	3 min	16 min
Textile packs	4 min	5 to 20 min	3 min	3 min
Wrapped utensils	4 min	20 min	3 min	16 min

1. Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST79:2006 Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities. *Arlington, VA: Association for the Advancement of Medical Instrumentation; 2006. Reprinted with permission.*

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.

IV.a 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.[1,2] (PNDS: I70, I98)

Proper decontamination is essential in removing bioburden and preparing an item for sterilization by any method. Failures in instrument cleaning have resulted in transmission of infectious agents.[3]

IV.a.1. Items to be flash sterilized should be subjected to the same decontamination processes as described in AORN's "Recommended practices for cleaning and care of surgical instruments and powered equipment."[2]

IV.a.2. Flash sterilization should be performed only if all of the following conditions are met:

- The device manufacturer's written instructions on cycle type, exposure times, temperature settings, and drying times (if recommended) 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 brushed and flushed under water with a cleaning solution and rinsed thoroughly.
- Items are placed in a closed sterilization container or tray, validated for flash sterilization, in a manner that allows steam to contact all instrument surfaces.
- Measures are taken to prevent contamination during transfer to the sterile field.

Flash-sterilized items are to be used immediately and not stored for later use.[3]

Table 5 provides examples of typical flash sterilization parameters.

IV.b. Packaging and wrapping (eg, textiles, paper/plastic pouches, nonwoven wrappers) should not be used in flash sterilization cycles unless the sterilizer is specifically designed and labeled for this use. (PNDS: I70, I98)

Cycle parameters vary according to sterilizer design.

IV.b.1. Sterilizer manufacturers' written directions should be followed and reconciled with the packaging manufacturer's instructions for sterilization.[3]

IV.c. Process challenge devices (PCDs) should be used with routine process monitoring devices (ie, chemical indicators, biological indicators, physical monitoring devices).[3] (PNDS: I70, I98)

Process challenge and process monitoring devices provide information to demonstrate that conditions for sterilization have been met.

Table 5

EXAMPLES OF TYPICAL FLASH STEAM STERILIZATION PARAMETERS[1]

Type of sterilizer	Load configuration	Time	Exposure Temperature	Drying Times
Gravity displacement	Metal or nonporous items only (ie, no lumens)	3 minutes	270° F–275° F (132° C–135° C)	0 to 1 minutes
	Metal items with lumens and porous items (eg, rubber, plastic) sterilized together. Complex devices (eg, powered instruments requiring extended exposure times). Manufacturer instructions should be consulted.	10 minutes	270° F–275° F (132° C–135° C)	0 to 1 minute
Dynamic air-removal (prevacuum)	Metal or nonporous items only (ie, no lumens)	3 minutes	270° F–275° F (132° C–135° C)	N/A
	Metal items with lumens and porous items sterilized together	4 minutes 3 minutes	270° F (132° C) 275° F (135° C)	N/A N/A

- The sterilizer manufacturer's instructions for use of express cycles should be followed. One sterilizer manufacturer provides an express flash cycle that permits flash sterilization with a single-ply wrapper to help contain the device to the point of use. This cycle is not recommended for devices with lumens. Express cycles should only be used if the sterilizer is designed with this feature.
- Steam-flush pressure-pulse: See manufacturers' written instructions for time and temperature.
- This table does not include specific instructions for rigid flash sterilization containers. The container manufacturer's instructions should be followed.

REFERENCE

1. Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST79:2006 Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities. *Arlington, VA: Association for the Advancement of Medical Instrumentation; 2006:60-72. Adapted with permission.*

IV.c.1. Each sterilization cycle should be monitored to verify that parameters required for sterilization have been met.[3]

IV.c.2. The sterilizer operator should use physical monitoring devices to verify cycle parameters for each load.[3]

Physical monitoring devices (eg, printouts, graphs, gauges) can indicate immediate sterilizer failure. Physical monitors record cycle parameters (ie, time, temperature) for each cycle.

IV.c.3. Biological (BI) and chemical indicators should be used to monitor sterilizer efficacy and assess compliance of monitoring standards established for gravity-displacement and dynamic air-removal sterilizers. Class 5 chemical integrating indicators should be used within each sterilizer container or tray.[3]

IV.d. Users should adhere to aseptic technique for flash-sterilized items during transport to the point of use. It is important that sterilization processing be carried out in a clean environment and that flash-sterilized devices are transferred to the point of use in a manner that prevents contamination.

IV.e. Rigid sterilization containers designed and intended for flash-sterilization cycles should be used. (PNDS: I70, I98)

Rigid flash-sterilization containers

- reduce the risk of contamination during transport to the point of use,
- facilitate ease of presentation to the sterile field, and
- protect sterilized items during transport

IV.f. Flash-sterilization containers should be used, cleaned, and maintained according to the manufacturer's written instructions.[3]

IV.f.1. Flash-sterilization containers should be opened, used immediately, and not stored for later use.

IV.f.2. Flash-sterilization containers should be differentiated from other types of containers.

IV.g. Flash sterilization should not be used for implantable devices except in cases of emergency when no other option is available.[12] (PNDS: I85, I138)

Implants are foreign bodies and they increase the risk of surgical site infection.[12] Careful planning, appropriate packaging, and inventory management in cooperation with suppliers can minimize the need to flash sterilize implantable medical devices.

IV.h. In an emergency, when flash sterilization of an implant is unavoidable, a rapid-action BI with a Class 5 chemical integrating indicator (or enzyme only indicator) should be run with the load.[3,12] (PNDS: I70, I98)

IV.h.1. The implant should be quarantined on the back table and should not be released until the rapid-action BI provides a negative result.

IV.h.2. If the implant is used before the BI results are known and the BI is later determined to have a positive result, the surgeon and infection prevention and control personnel should be notified as soon as the results are known.

IV.h.3. If the implant is not used, it cannot be saved as sterile for future use. Resterilization of the device is required if the implant is to be used later.[3,12]

IV.i. Documentation of cycle information and monitoring results should be maintained in a log (electronic or manual) to provide tracking of the flashed item(s) to the individual patient.[3,12] (PNDS: I112)

Documentation allows every load of sterilized items used on patients to be traced.

IV.i.1. Sterilization records should include information on each load, including

- the item(s) processed;
- the patient receiving the item(s);
- the cycle parameters used (eg, temperature, duration of cycle);
- the date and time the cycle is run;
- the operator information; and
- the reason for flash sterilization.[3]

Recommendation V

Ethylene oxide (EO) sterilization is a low-temperature process that is appropriate for heat- and moisture-sensitive surgical items when indicated by the device manufacturer.

Ethylene oxide at sterilizing temperatures kills microbes in hard-to-reach areas, and it does so with no damage to devices. Ethylene oxide is an alkylating agent that results in microbial death under controlled parameters. Ethylene oxide substitutes for hydrogen atoms on molecules needed to sustain life and, by attaching to these molecules, EO stops these molecules' normal life-supporting functions. Some of the key molecules that EO disrupts are proteins and DNA. Under low-temperature sterilizing conditions, so much EO is used that this disruption proves lethal to microbial life.[13]

V.a. Ethylene oxide should be used if alternate methods of sterilization are not available compatible with the medical devices being processed.[14]

Health care organizations use 100% concentrations of EO or EO in mixtures with inert diluent gases (eg, carbon dioxide, hydrochlorofluorocarbons [HCFC]) for EO sterilization procedures. Until the 1990s, chlorofluorocarbons (CFCs) were used as diluents for EO. Chlorofluorocarbons cause depletion of the ozone layer and are no longer produced in the United States. Hydrochlorofluorocarbons deplete the ozone layer, but to a lesser degree than CFCs.[14]

V.a.1. Users of HCFCs should be aware of and comply with federal, state, and local regulations regarding HCFC use in EO sterilizers.[15-17]

V.b. The manufacturer's written instructions should be reviewed to determine if a heat- or moisture-sensitive item is compatible with EO sterilization before attempting sterilization by this method. (PNDS: I122)