



INFECTION CONTROL hotline

Surgeons, nurses, materials managers and vendors must be aware of how long it takes to reprocess instruments according to each manufacturer's instructions.

source notes



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about this column

This column presents answers and practical guidance to some of the most commonly asked questions of suppliers and educators in the infection control and sterile processing communities. To submit a question to the column, e-mail Bob Kehoe, executive editor, at rkehoe@healthforum.com.



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Are instruments sterile or did they just get hot?

Flash sterilization of instruments raises many concerns if not done properly, as stated in AAMI and CSA Standards, VA Directive 7176, AORN Recommended Practices and The Joint Commission's Position Statement issued June 15, 2009. It is critical that the device manufacturer's validated reprocessing instructions be followed and to not flash implants, except in cases of emergency when no other option is available.

What is the definition of flash sterilization?

Flash sterilization is defined by the Association for the Advancement of Medical Instruments (AAMI) as a "process designed for the steam sterilization of patient care items for immediate use."

Why do so many health care facilities flash sterilize instruments?

Two common reasons for flash sterilization include lack of inventory and lack of communication. Lack of inventory may be attrib-

utable to case volumes requiring the same instruments, scheduling back-to-back blocks that require the same instruments, vendors not delivering loaner instruments in time or SPD not reprocessing instruments in time, as well as the surgeon's personal instruments being used. Lack of communication may be due to surgeons not contacting vendors with enough time to deliver instruments when loaners are used, the OR not contacting the sterile processing department with enough time to reprocess instruments, as well as staff and vendors having limited

knowledge regarding best practices such as not knowing how long it takes to properly reprocess instruments.

How long does it take to reprocess instruments?

Today's instruments are much more complex than instruments of say five to 10 years ago, with very detailed cleaning, packaging and sterilization instructions provided by the device manufacturers as required by the Food and Drug Administration (FDA). These validated instructions must be available and carefully followed by trained staff. The process can easily take two to three hours, including time to soak, clean, rinse and inspect instruments; time to assemble, package and sterilize instruments; and time to unload, cool and distribute instruments.

Surgeons, nurses, materials managers and vendors must be aware of how long it takes to reprocess instruments according to each manufacturer's instructions and plan accordingly.

How has flash sterilization changed over the years?

Traditionally, flash sterilization has been recommended for emergency use only (for example, a dropped instrument) using an unwrapped tray or pan and processed in gravity displacement steam sterilizer at 132C/270F for three or 10 minutes depending on the type of instrument. Today, flash sterilization has been expanded for use in prevacuum cycles and a variety of packaging systems, including protective organizing cases, single-layer wrap and sealed sterilization containers.

Although some sterilization standards do not recommend flashing large instruments sets (CSA and VA Directive 7176), the use of prevacuum cycles permits users this opportunity, whereas traditional gravity cycles will only get many of today's complex instruments hot (Medtronic Midas Rex, SYNTHES Complex Sets and Smith & Nephew).

Other examples of instruments that cannot be sterilized in traditional gravity flash

cycles, but can be processed in prevacuum cycles if the cycle time is extended include DePuy Hand Innovations (10 minutes), Stryker Spine sets (15 minutes), Abbott Spine sets (15 minutes), Scientix SACP System (18 minutes), Aesculap S4 Spine set (10 minutes) and DePuy large bone sets (5 to 8 minutes).

How do flash sterilization recommendations vary among organizations?

Flash sterilization recommendations vary slightly from organization to organization. For example, Canadian standard Z314.03-09 states: "Flash sterilization should only be employed in situations where individual items (dropped instruments, for example) require immediate sterilization."

VA Directive 7176 states: "Flash sterilization will not be performed for the purpose of routine sterilization of surgical instruments. The flash sterilizer may be used during a surgical procedure for an unanticipated event. It is not recommended for large trays of instruments, such as loaner trays. It is not recommended that items with lumens, such as suction tubes and power equipment, be flash sterilized due to their complex makeup."

AAMI ST 79 states: "Flash sterilization of instrumentation should only be considered if all the following conditions are met: a) Workplace practices ensure proper cleaning and decontamination, inspection and arrangement of instruments into the recommended sterilizing trays or other containment devices before sterilization; b) The physical layout of the department or work area ensures direct delivery of sterilized items to the point of use (the sterilizer opens into an area either within or directly adjacent to the procedure room); c) Procedures are developed, followed and audited to ensure aseptic handling and personnel safety during transfer of the sterilized items from the sterilizer to the point of use; and d) The item is needed for use immediately following flash sterilization."

AORN Recommended Practices, 2010

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

Is it OK to flash sterilize implants?

First, we should define what a medical implant is. According to the FDA, a medical implant is "a device that is placed into a surgically or naturally formed body cavity with the intention of remaining there for a period of 30 days or more." Next, keeping in mind that AORN says flash sterilization may be associated with increased risk of infection, let's review what different organizations say about flashing implants.

CSA Standard Z314.03-09 states: "Flash sterilization shall not be used to sterilize implants unless specific instructions are provided by the device manufacturer. In many health care facilities, flash sterilization has been used as a convenience to compensate for inadequate inventories of instruments or implantables. These practices should be changed and use of the unwrapped method should be restricted to unplanned or emergency situations. It should be the goal of each health care facility to minimize the use of flash sterilization."

VA Directive 7176 states: "Implantable devices will not be sterilized by flash sterilization. Examples of implants include K-wires, screws, plates, vascular graphs, heart valves, merlex mesh, mercelen mesh, internal pacemakers, penile implants, breast implants and joints (knees, hips and shoulders). AAMI ST79 states: "Implantables should not be flash sterilized. The possible consequences to the patient placing even a minimally contaminated device in an essentially avascular environment and leaving it there at the conclusion of the procedure are potentially severe."

AORN RP, 2010 edition, states: “Flash sterilization should not be used for implantable devices except in cases of emergency when no other option is available. Implants are foreign bodies and they increase the risk of surgical-site infection. Careful planning, appropriate packaging and inventory management in cooperation with suppliers can minimize the need to flash sterilize implantable medical devices.”

How should health care facilities document flash sterilization?

Documentation of cycle information and monitoring results (physical printout, chemical indicator and biological indicator results) should be maintained in a log (electronic or manual) to provide tracking of the flashed items to the individual patient. Sterilization records should include the information on

each load, including the items processed, the patient receiving the items, the cycle parameters used, the date and time of cycle, the operator information and the reason for flash sterilization. These records should be regularly reviewed to reduce or eliminate flash sterilization.

Special note: While monitoring results may indicate the cycle chosen was accomplished, they do not indicate if the cycle chosen was enough to sterilize the device or to just get it hot. As stated in The Joint Commission position statement on steam sterilization issued last year, “Steam sterilization of all types, including flashing, must meet parameters (time, temperature and pressure) specified by both the manufacturer of the sterilizer, the maker of any wrapping or packaging, and the manufacturer of the surgical instrument.”

If the sterilizer operator fails to reconcile

the instrument device parameters with the packaging validated parameters and/or sterilizer manufacturer programmed cycles, you can be sure the flashed instruments will get hot. But will they be sterile?

How long do exposed instruments remain sterile in the OR?

There was a study performed on wrapped instruments a few years ago at Miami Valley Hospital in Dayton, Ohio, and published in *The Journal of Bone and Joint Surgery* that looked at three groups of 15 sterilized instrument trays in three separate ORs over a period of four hours.

The first group of instruments was opened and left uncovered in a locked OR. The second group of instruments was left uncovered in an OR with single person traffic flowing in and out from a non-sterile corridor every 10 minutes. The third group of instruments was covered immediately with a sterile towel in a locked OR. The purpose of the study was to determine the rate of contamination of opened sterile trays and to assess the results of a placing a sterile towel over exposed instruments in a controlled OR environment with no surgery being performed.

Cultures were taken immediately after opening all 45 trays every 30 minutes during a four-hour period. Three trays showed positives right away, which was attributed to improper or incomplete processing. Interestingly, none of the 15 opened trays that was covered with a sterile towel showed any contamination. However, 30 percent of the opened trays without a sterile towel did become contaminated. Surprisingly, light traffic did not appear to contribute to contamination. While this study did not address flash sterilized instruments in particular, the results do warrant concern for sterilizing unwrapped trays and opening sterilized wrapped trays before they are needed. **MMHC**

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