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## Learning Objectives

1. Discuss the reasons medical device manufacturers recommend extended steam sterilization cycles.
2. Describe an effective quality assurance program for extended cycles.
3. Discuss implementing a procedure to collect and document device reprocessing instructions.

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# Extended steam sterilization cycles

by Susan Flynn, BESC, CSPDT

**S**terile processing departments across the country are devoting energy to managing extended steam sterilization cycles. Steam sterilization cycles with exposure times greater than the traditional four minutes in a 270°F dynamic-air removal sterilization cycle are commonly referred to as extended cycles. Exposure times are recommended by the Medical Device Manufacturer and these times have increased in recent years due to the increase in weight and complexity of instrumentation and containment devices used in healthcare facilities. This self-study article will discuss some of the issues related to managing an increasing number of steam sterilization cycles.

### Reprocessing instructions

Knowing which medical devices require extended sterilization times is a good first step. How does your department manage this data? Having a system to collect, document, implement and audit recommended medical device reprocessing protocols is important. Software designed for sterile processing departments can be a helpful tool both to document recommended exposure and drying times for individual instruments or sets and to provide technicians with the correct cycle information as trays are assembled.

The Food and Drug Administration (FDA) requires manufacturers of reusable medical devices to provide instructions on how to prepare the device for the next patient. FDA reviewers review 510K submissions to be sure the labeling includes reprocessing instructions.<sup>1</sup> The reprocessing instructions:

- should include cleaning;
- should include validated sterilization or disinfection (high, medium or low level) instructions, as appropriate for the intended use of the device;
- should be reasonable (e.g. gamma radiation sterilization wouldn't be specified for a device used in hospitals since

this technology is not available in health care settings);

- should be understandable;
- must be comprehensive;
- must include only legally marketed devices (e.g. sterilizers) and accessories (e.g. liquid chemical sterilants and disinfectants).

When developing and validating reprocessing guidelines, one resource device manufacturers turn to is the Association for the Advancement of Medical Instrumentation's (AAMI's) Technical Information Report (TIR), "*Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers*", AAMI TIR12:2004. While the TIR encourages manufacturers to test commonly available hospital sterilization cycles, they are given the option to adjust those parameters that can be controlled by health care personnel (e.g. exposure time in the case of steam sterilization) if needed to achieve the desired sterility assurance level (SAL).<sup>2</sup> The increasing complexity and weight of instrumentation used in orthopedic and neurological procedures and the use of multi-level containment devices both create a challenge to air removal and steam penetration. This has led to medical device manufacturers validating a confusing variety of steam sterilization exposure times and left end-users with the task of managing these extended cycles.

When collecting device reprocessing instructions, don't forget loaners! Hospitals are increasingly relying on loaner instrumentation to equip surgeons with state-of-the-art orthopedic instrumentation. Capturing reprocessing instructions might include implementing a Policy and Procedure on Loaner Instrumentation that requires the vendor to provide written disassembly, cleaning, and sterilization instructions.

ANSI/AAMI ST79:2006 "*Comprehensive guide to steam sterilization sterility as-*

surance in health care facilities" recommends developing and implementing procedures for insuring correct cycle selection. Additionally, compliance should be checked using process audits.<sup>3</sup>

### Monitoring extended steam cycles

In addition to implementing measures to insure technicians select the correct extended cycle, you may have wondered about how to monitor extended steam sterilization cycles. Concerns have been raised about the use of currently available sterilization process monitors in extended steam sterilization cycles. For example, Dr. Michelle Alfa wrote: "Despite the requirement by the medical device manufacturer for longer cycles, there has not been the concurrent development of the appropriate chemical indicator (CI) and biological indicator (BI) challenge packs to adequately monitor these extended steam sterilization cycles."<sup>4</sup>

As there are currently no standards or recommended practices that provide guidance on the assembly of a process challenge device for extended cycles, we need to use the available monitoring tools and apply the existing guidance provided in ANSI/AAMI ST79:2006. Best practice would include a three-pronged approach:

- the use of Product Quality Assurance Testing;
- verifying the sterilization process is functioning well by conducting Routine Sterilizer Efficacy Monitoring;
- and releasing each load using the recommended monitoring tools.

Let's review each of these approaches.

### Product quality assurance testing

Periodic product quality assurance testing of routinely processed items is recommended because the Biological Indicator Process Challenge Devices (BI PCDs) used for routine and qualification testing present a known challenge to the sterilization process but do not necessarily reflect the same challenge as items routinely processed. This is particularly true of items that require an extended sterilization cycle. Product testing is therefore a key element of the quality assurance program for extended cycle items. In addition to conducting product testing on newly purchased or

loaner sets before permitting routine reprocessing, testing should also occur when "major changes are made in packaging, wraps, or load configuration, such as dimensional changes, weight changes, or changes in the type or material of packaging or wrapper."<sup>3</sup> Product testing is conducted both to verify the effectiveness of the sterilization process and to avoid wet packs.

Obtaining written recommended reprocessing instructions from the medical device manufacturer is a critical first step in conducting product testing. ANSI/AAMI ST77:2006, "Containment devices for reusable medical device sterilization", specifies the information manufacturers should include in their Instructions for Use provided to users. This information should include "the most challenging area of the containment device for the placement of internal CIs and BIs for routine monitoring and product testing."<sup>5</sup> When checking with medical device manufacturers for current recommended reprocessing instructions, be sure to ask whether they can recommend BI and CI placement locations.

The testing procedure is discussed in AAMI ST79, section 10.9. Place multiple BIs and CIs in the areas that create the greatest challenge for air removal and steam penetration, wrap/close the tray as you normally would, label it as a product test, and run in a standard load according to the medical device manufacturer's instructions. After the sterilization cycle, open the pack or tray and inspect the pack for moisture. Retrieve the BIs and CIs, noting their position in the containment device, and either reprocess or discard the contents of the test sample. Incubate the BIs, read the CIs and record all results. The set must be dry, BIs must be negative and the CIs must reach their endpoint result before the medical device is placed into routine use.

Conducting product testing is consistent with guidance provided in ANSI/AAMI ST77:2006 with respect to the division of responsibilities. ST77 discusses minimum labeling, safety, performance and testing requirements for containment devices. Containment devices include rigid sterilization containers, cassettes, cases, and organizing trays. This document is not an end-user docu-

ment. It was developed to provide **manufacturer** requirements. Manufacturers are responsible for validating that products are compatible with the specified sterilization method. Health care personnel are responsible for using the containment device in the recommended sterilization method and performing tests to verify items can be sterilized by the specific sterilizers and methods used within their facility.

### Routine sterilizer efficacy monitoring

Routine sterilizer efficacy monitoring is establishing a regular pattern of testing the efficacy of the sterilizer to ensure medical devices are effectively sterilized. For sterilizers larger than 2 cubic feet, AAMI ST79:2006 recommends monitoring a full load weekly, preferably daily, with a BI PCD. The PCD is the AAMI 16-towel pack or an FDA cleared, commercially available disposable BI PCD. In addition, routine sterilizer efficacy monitoring includes the use of a Bowie-Dick (BD) test to evaluate the efficacy of air removal and steam penetration in dynamic-air-removal steam sterilizers. This daily Bowie-Dick testing is conducted in an otherwise empty chamber each day the sterilizer is used, before the first processed load.

### Routine load release

AAMI ST79:2006 divides routine load release into two sections: nonimplants and implants. The sterilization monitoring tools used to release a **nonimplant load** include the sterilizer's physical monitors, external and internal chemical monitoring of packages, and the optional use of a PCD (i.e. test pack) containing one of: a biological indicator (BI); a BI and a Class 5 integrating indicator; a BI and an enzyme-only indicator; a Class 5 integrating indicator; or an enzyme-only indicator. When monitoring extended cycles, particular attention should be paid to reading the chart or sterilizer printout. Be sure all staff knows how to interpret the printout and is taking the time to verify the desired cycle parameters (exposure time, temperature, dry time, etc.) were met at the end of each cycle. Initialing the chart or printout, as recommended by AAMI ST79, permits later identification of the operator.

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As you're reviewing routine load release for extended cycles, it may be a good time to incorporate some new guidance on chemical indicator placement in your department's Policies and Procedures. Each year the Association of periOperative Registered Nurses, AORN, publishes an updated Standards, Recommended Practices, and Guidelines. Of special interest to sterile processing personnel, the 2007 edition includes updated content in the "Recommended Practices for Selection and Use of Packaging Systems for Sterilization" section. The document recommends the use of a Class 3, 4, or 5 internal chemical indicator within each package. Recommended Practice IV within this section states:

- "Two chemical indicators/integrators should be placed inside rigid containers, one in each of two opposite corners of the inside basket. Multi-level containers should have a chemical indicator/integrator placed in two opposite corners (e.g., one in each of two corners) of each level.
- A chemical indicator/integrator should be placed on each level of multi-level wrapped sets."<sup>6</sup>

Should you implement this recommended practice, be sure to advise your colleagues in the Operating Room so they'll begin to retrieve and interpret these additional CIs. Figures 1 and 2 depict this recommended chemical indicator/integrator placement within rigid containers.

Many medical devices requiring extended steam sterilization cycles contain an implantable device.<sup>7</sup> The AAMI ST79:2006 criteria for releasing implant loads are more stringent than those for non-implant loads. Monitoring tools recommended to release implant loads are the sterilizer's physical monitors (i.e. a careful verification of cycle parameters), external and internal chemical monitoring of packages, and a PCD containing either a BI and a Class 5 integrating indicator or a BI and an enzyme-only indicator. Except in defined emergency situations, the implant should not be released until the results of the BI are available.

Process challenge devices (PCDs) should provide "a challenge to the process that is equal to or greater than the challenge posed by the most difficult item routinely processed".<sup>3</sup> At this time, neither medical device manufacturers nor monitoring products manufacturers offer

posure to saturated steam for extended periods of time. For example, wondering whether exposure to an extended cycle has any negative impact on the growth media provided in self-contained biological indicators is a valid question. Check with your suppliers to review the indications for specific monitoring products and to

ask whether they have done testing to investigate the effects of extended cycles on these products.

## Standards and recommended practices

Extended steam sterilization cycles are not yet addressed in user standards or recommended practices. The Association of periOperative Registered Nurses (AORN)'s Sterile Processing /Materials Management Specialty Assembly has issued a statement alerting users to concerns about extended cycles. The statement advises: "Each medical facility needs to make sure that all of their products used for sterilization (peel pouches, wrap,...) can withstand these longer steam sterilization cycles."<sup>9</sup> Contact your disposable packaging suppliers to see whether they have data supporting the use of their products in extended cycles.

Under the direction of the AAMI Sterilization Standards Committee, different working groups tackle various subjects. The Process Challenge Device Working Group is updating TIR 31:2003, "Process challenge devices/test packs for use in healthcare facilities". The update, which is currently in draft form, will harmonize the Technical Information Report (TIR) with the Process Challenge Device (PCD) guidance provided in AAMI ST79:2006 and add a section discussing extended steam sterilization cycles. A limited number of specific exposure times may be recommended. This limited

number of cycles would be of benefit both to health care facilities trying to manage the multitude of cycle times currently recommended by device manufacturers and to manufacturers of monitoring products trying to develop appropriate process challenge devices.

Unfortunately, a Technical Information Report (TIR) doesn't carry the weight of a standard. In due course, the Working



Figure 1: Placement of chemical indicators/integrators inside rigid container



Figure 2: Placement of chemical indicators/integrators in multi-level containers

a PCD designed to mimic the challenge posed by devices requiring extended cycles. Until such products are available, the BI PCD of choice for sterilizers larger than 2 cubic feet remains the AAMI 16-towel pack or an FDA-cleared, commercially available equivalent.

Another issue related to extended cycle load release is whether traditional monitoring products are compromised by ex-

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Group may push forward a proposal to turn the updated Process Challenge Device TIR document into a standard.

### Summary

Medical Device Manufacturers are increasingly recommending extended steam sterilization cycles. To ensure the sterility of complex and/or heavy devices, it is important that healthcare facilities follow these reprocessing recommendations. Implement a policy to collect, document, and audit reprocessing instructions, including those for loaner instrumentation. There are currently no guidelines on constructing a PCD to monitor extended sterilization cycles. Sterile process personnel must therefore use the tools that are available which include: the use of Product Quality Assurance Testing; verifying their sterilization process is functioning well by conducting Routine Sterilizer Efficacy Monitoring; and releasing each load using the recommended monitoring tools. An increased vigilance in verifying that the sterilizer print-out indicates the desired parameters were achieved and placing chemical indicators in each level of multi-level containers are practices you may wish to implement. **HPN**

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## Extended steam sterilization cycles

Circle the one correct answer:

1. The term "extended cycles" refers to steam sterilization cycles with exposure times longer than the traditional four minutes.  
A. True  
B. False
2. Manufacturers of reusable medical devices are required by the FDA to provide validated sterilization or disinfection instructions.  
A. True  
B. False
3. The FDA would approve reusable medical device instructions for reprocessing in healthcare facilities that include the use of a gamma sterilizer.  
A. True  
B. False
4. ANSI/AAMI ST79 recommends developing and implementing procedures for insuring correct cycle selection.  
A. True  
B. False
5. ANSI/AAMI ST79 provides guidance on the assembly of a special PCD for extended cycles.  
A. True  
B. False
6. The goal of Product Testing is to verify items can be effectively sterilized by the specific sterilizers and methods used within a healthcare facility.  
A. True  
B. False
7. Implantable devices never require extended steam sterilization cycles.  
A. True  
B. False
8. AORN recommends the placement of chemical indicators/integrators on each level of multi-level containers and wrapped sets.  
A. True  
B. False
9. Many companies offer FDA-cleared PCDs designed to monitor extended cycles.  
A. True  
B. False
10. When releasing loads processed in an extended steam sterilization cycle, carefully verify the sterilizer printout to verify the correct cycle parameters were achieved.  
A. True  
B. False

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