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LEARNING OBJECTIVES

1. *Describe the difference between immediate use steam sterilization and Short Cycle steam sterilization*
2. *List the steps of Short Cycle validation*
3. *Define quality control needs and reporting*

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SELF-STUDY SERIES

Unmasking Short Cycle sterilization

by Arthur Henderson

During my 30-plus years in operating rooms and sterile processing departments, I believed that choosing the appropriate steam sterilization cycle was a simple task. Terminal steam sterilization is performed on wrapped or containerized instruments if you intend to store these critical medical devices for future use. Immediate-use steam sterilization (IUSS) allows us to use abbreviated cycles for devices that are to be quickly used for a specific case.

However, the introduction of Short Cycles used for ophthalmic device sterilization has challenged the simplicity of this thought process. These Short Cycles use terminal sterilization packaging but have shortened drying times, and the packaged instruments are typically used immediately, though they may be stored. So, should these new cycles be classified as a terminal sterilization process, an immediate-use process, or as something else? Let's see if we can make sense of this.

What is a Short Cycle?

Most healthcare facilities are familiar with terminal sterilization and IUSS. However, the newer Short Cycle defies previous categories. It's a type of terminal sterilization process, but it is unlike the traditional processes used in larger healthcare facilities.

Terminal steam sterilization uses steam to sterilize medical devices held within containers, pouches, and wrapped trays. The devices are dry at the end of the process, which allows them to be placed into storage. That dry condition is very important, since any residual moisture creates an opportunity for microorganisms to contaminate the pack. It also creates an opportunity for devices to be exposed to the corrosive properties of water, which can damage them and shorten their useful life.

In contrast, IUSS uses steam to sterilize medical devices held within containers validated specifically for this process. Devices are typically wet at the end of the sterilization cycle and are used immediately for a specific procedure. How do IUSS cycles differ from terminal sterilization cycles? Simply stated, they have shorter steam exposure times, drying times, or both.

After completing an IUSS cycle, it's important that the devices cool before they are used. Hot instruments can injure staff and patient tissues.

A Short Cycle is a term used by ophthalmic associations and ambulatory care facilities to describe a steam sterilization cycle that uses a shorter drying time than standard terminal sterilization cycles but achieves the same sterilization conditions as terminal sterilization cycles. However, items must be packaged in the same manner as if undergoing terminal steam sterilization, and they must be dry at the completion of the sterilization cycle.

Short Cycles are not included in the standards and guidelines of the Association for the Advancement of Medical Instrumentation (AAMI) or the Association of peri-Operative Registered Nurses (AORN). Instead, this is a cycle specific to ophthalmic instrumentation and is defined by the Centers for Medicare and Medicaid Services (CMS). CMS defines Short Cycles as "a sterilization cycle for a wrapped/contained load that meets the device manufacturer's instructions for

Table 1: Comparison of terminal, IUSS and Short steam sterilization cycles.

Parameter / Condition	Terminal Cycle	IUSS Cycle	Short Cycle
Exposure time	Full	May be shortened	Full
Dry time	Full	0-1 minute	Shortened
Moisture Retention	Dry	Wet	Dry
Storage	May be stored	No Storage	May be stored

use (IFU), is the equivalent of terminal sterilization, and is not IUSS if it includes use of a dry time and is packaged in a wrap or rigid sterilization container intended to be stored for later use."(See Table 1.)

When should you choose a Short Cycle?

As described by the CMS definition, the Short Cycle is an acceptable practice for the steam sterilization of ophthalmic instruments and instrument sets. These sets should contain only lightweight metallic instrumentation. Lightweight metallic instruments heat quickly and produce less condensate, which allows faster drying during the drying phase of a steam sterilizer. This allows for shorter dry times and faster steam sterilization cycles.

The Short Cycle can be used when the IFU of the instrument, containment device, and sterilizer all include the Short Cycle parameters. However, if any one of the above-mentioned IFU do not list the specific cycle parameters, it cannot be used. Furthermore, if the Short Cycle parameters are described as a "flash" or "unwrapped" sterilization cycle in any of those IFU, they are referring to an IUSS cycle and cannot be considered a Short Cycle. Table 2 illustrates some examples.

Short Cycle validation testing

It's difficult to find matching IFU for Short Cycles, especially when the sterilizer dry times are based on the most difficult-to-dry items. Many ophthalmic facilities choose to test and validate a shorter dry time for their ophthalmic instruments so that they can shorten their set turnaround time.

Section 5.7 of ANSI/AAMI ST8 "Hospital Steam Sterilizers" describes a moisture retention test that can be used to validate the ability of a sterilizer to provide dry packs. Healthcare facilities wishing to validate a shorter dry time often refer to this standard.

Hospitals choosing to use this standard as a reference should identify the worst-case load configuration for drying. This load will use the heaviest instrument sets within the containment device that is the hardest to dry. For example, a solid-bottomed container with 17 pounds of metal ophthalmic instrumentation would trap more steam condensate within it than a paper pouch with a single lightweight ophthalmic instrument. The former would be harder to dry and represent a worst-case configuration for drying.

Once the worst-case load has been identified, the desired dry time is determined. The desired dry time is the shortest time that consistently results in dry sets. Often, facilities will run several different dry times to find the right one for their facility.

What about the validation? All testing is done under a protocol with clearly defined test sets and acceptance criteria. The representative sets are prepared and weighed, and the sterilizer loaded. Immediately after the sterilization cycle, the sets are weighed, opened, and examined for residual moisture. There should be no visible moisture on the outside or inside of the containment devices. Additionally, if an absorbent wrapping material is used, it should not have increased in weight by more than 20% of its pre-sterilization weight. This procedure underscores the importance of knowing the weights of all your instrument sets.

The test is repeated two more times. All instruments and containment devices are cleaned, rinsed, and dried per the manufacturers' written IFU, before assembling them for each test cycle. The test is successful when every device in the load for every cycle meets the moisture criteria (none present). Failure of even one pack means the test fails.

All test records, including the test criteria and test results, must be maintained to support the use of the shortened drying time. If changes are made to the containment device, load configuration or instruments in the set, validation testing must be repeated.

Quality assurance for Short Cycles

Quality assurance is an essential part of sterilization. As with any steam sterilization cycle, Short Cycles use a combination of sterilization parameters, biological indicators and chemical indicators to evaluate the efficacy of the sterilization process. Short Cycles are held to the same testing standards as terminal cycles. Any time a failure occurs, it must be investigated and corrected per your facility's policies and procedures. Let's review the criteria necessary for quality assurance.

Sterilization parameters

Sterilization parameters are checked every time a sterilization or test cycle is run on the sterilizer. The cycle printout, recording chart or electronic record is reviewed to ensure that the correct temperature was reached for the required amount of time, all vacuum cycles reached their vacuum point, and the dry time lasted the right amount of time. Any documented cycle alarms and aborts must be recorded, along with the correction for the problem that caused them.

Air removal test/Bowie Dick test

Air removal/Bowie Dick tests are required each day that a vacuum-assisted or prevac steam sterilizer is used. The test pack is the only item placed in the sterilizer, without any items to be sterilized or other test packs. The test finds air leaks and other

Page 28

Table 2: IFU comparisons for appropriate use of a Short Cycle

Instrument IFU	Steam Sterilizer IFU	Containment Device IFU	Conclusion
Vacuum assisted 270°F 4 min exposure with 20-minute dry time	Prevac Instrument Cycle: 270°F 4 min exposure with 20-minute dry time	Sterilization Pouch / Prevac 270°F 4 min exposure with 20-minute dry time	All IFU list a 20-minute dry time. The 20-minute dry time can be used.
Gravity 275°F 10 min with 16-minute dry time	Gravity Wrapped Cycle: 275°F 10 min with 60 min air dry	Sterilization Wrap / Gravity 275°F 10 min with 16-minute dry	The sterilizer IFU requires a longer dry time than the instrument and pouch IFU. The longest dry time (60 minutes) must be used.
Vacuum assisted 270°F 4 min exposure with 6-minute dry time	Prevac Unwrapped Cycle: 270°F 4 min exposure with 1-minute dry time	Container / Vacuum assisted 270°F 4 min exposure with 6-minute dry time	The sterilizer IFU lists an Unwrapped Cycle, indicating that this is IUSS and can't be used as a Short Cycle.

Self-Study Test Answers: 1. A, 2. C, 3. C, 4. B, 5. A, 6. A, 7. C, 8. D, 9. D, 10. A

problems that prevent the sterilizer from getting good steam penetration during sterilization. Sterilizers that fail an air removal test typically need repairs.

Process challenge device/Biological indicator test pack

The process challenge device (PCD) or biological indicator (BI) test pack checks the lethality of the sterilizer. The sterilizer must kill a high population of bacterial spores placed within a pack that steam has trouble penetrating. A process challenge device is run with the first load of the day.

Process challenge devices must be placed in all loads that have implantable devices (medical devices placed in the body for more than 30 days). All loads with process challenge devices are placed in quarantine and shouldn't be used until the results of the BI are known.

A control BI must be incubated every day that a BI test is performed. The control BI shows that spores within the BIs used in the test are alive and that the incubator is functioning. Only tests with positive (growing) control BIs can be used.

A passing BI PCD test must have a negative BI from the PCD and a positive control BI. If the BI PCD test shows growth, then sterilization did not occur, so the items are considered not sterile and can't be used.

Chemical indicators

A chemical indicator (CI) strip is placed inside each pack, container, pouch, or wrapped item to be sterilized. A CI strip should also be placed on every level of multi-level trays. After sterilization, when the pack is opened, the CI is checked. A passing indicator shows that steam made it into the pack. A failing indicator shows that it did not, so the items are considered not sterile and can't be used.

Wet packs

Failing cycle parameters, BIs and/or CIs are all considered evidence of sterilization failures. Another indicator of sterilization failure is residual moisture on packaged instruments after the cycle, also known as wet packs. Wet packs indicate a problem with loading, steam quality or sterilizer performance. Wet packs can be seen on the outside as pooling or wetness on the external surface of the pack. It can also be internal, visible as pooling or water drops on the instruments or items inside a pack when it is opened. If wet items are stored, residual moisture may dry before the pack is opened. In this situation, evidence of residual moisture shows up as water stains or rings. Each wet pack or moisture event must be investigated, and the root cause identified and corrected.

It's important to note that wet packs are still wet packs even if used immediately. In fact, using an item that is wet immediately after sterilization, whether wrapped or not, is defined as an IUSS event.

Short Cycles use abbreviated drying times and can produce wet packs if packaging material weights change, set configurations change, containment devices change, or if the steam supply becomes wet. If Short Cycle wet packs occur, identify the root cause and correct it, and then perform cycle validation again to ensure that the solution worked.

Documentation

All test results, sterility assurance failure investigations and wet pack reviews must be documented. The documentation should include the sterilizer used, results of the test, results of any investigation, the corrective actions taken, and the results of the corrective action.

These records are reviewed by surveyors, so it's important to ensure that they are accurate and complete. It's a good idea to routinely audit documentation practices to ensure that the documents are completed with all required signatures. It is equally important to ensure that all tests have been completed per facility policy and procedures. Surveyors need to confirm that policies and procedures reflect what is actually done in a department.

For example, some tests, such as leak tests, may provide data that should be evaluated for trends. It's also important to audit and document trends when wet packs have been investigated and corrective action has been taken.

Assure Short Cycle best practices

Short Cycles are terminal steam sterilization cycles with a validated dry time that yields dry, terminally packaged items that can be placed in sterile storage. These cycles are typically used for metal ophthalmic instruments that can dry more quickly because of their size and weight.

Before any decision is made to implement Short Cycles, sterile processing managers need to diligently review all applicable device, packaging, and sterilizer IFU to assure that they document the use of similar Short Cycle parameters. If IFU disagree, they must be reconciled. If necessary, a cycle validation should be completed using the department's most challenging Short Cycle loads to prove the effectiveness of shorter drying times. And since quality assurance is just as important for Short Cycles as for any other terminal sterilization process, a quality system should be put in place that includes cycle parameter checks, appropriate tests, trend audits and thorough documentation. A well-run Short Cycle program can help a department improve the efficiency and turnaround of its ophthalmic reprocessing practices. HPN

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1. Association for the Advancement of Medical Instrumentation; *ANSI/AAMI ST79:2017 & 2020 Amendments A1, A2, A3, A4 (Consolidated Text) Comprehensive guide to steam sterilization and sterility assurance in health care facilities*. Arlington, VA.

2. Association for the Advancement of Medical Instrumentation; *ANSI/AAMI ST8:2013/(R)2018 Hospital Steam Sterilizers.* Arlington, VA

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Unmasking Short Cycle sterilization

Circle the one correct answer:

1. **Why must packs be dry after steam sterilization?**
   a. It allows sterile storage
   b. It makes them lighter
   c. It protects packaging from degradation
   d. It allows immediate use

2. **What makes IUSS cycles different from terminal cycles?**
   a. Short dry time and long exposures
   b. Long dry time and short exposures
   c. Short dry time and short exposure times
   d. They are the same

3. **Which medical specialty uses Short Cycles?**
   a. Obstetrics
   b. Occupational Therapy
   c. Ophthalmic
   d. Orthopedic

4. **What type of cycle is a Short Cycle?**
   a. Ethylene oxide
   b. Terminal
   c. Immediate Use Steam Sterilization (IUSS)
   d. It is not a sterilization cycle

5. **A Short Cycle can be used when the device, sterilizer, and packaging IFU list the same cycle parameters.**
   a. True
   b. False

6. **Which standard describes validation of dry times?**
   a. ANSI/AAMI ST8
   b. ANSI/AAMI ST79
   c. ANSI/AAMI ST58
   d. ANSI/AAMI ST90

7. **Which criteria must be met for validation of short dry times?**
   a. Dry on the inside but outside moisture is okay
   b. Dry on the outside but inside moisture is okay
   c. Dry on the outside and inside
   d. Any moisture found dries in five minutes

8. **Which is a quality assurance test used for Short Cycles?**
   a. Protein test
   b. Wet pack test
   c. Competency test
   d. Process challenge device/Biological indicator test pack

9. **Where are chemical indicator strips placed?**
   a. Taped to the sterilizer rack
   b. Taped to the outside of a pack
   c. Placed above the sterilizer's drain
   d. Inside a pack/container to be sterilized

10. **A wet pack discovered after a terminal or Short Cycle is considered a sterilization failure.**
    a. True
    b. False

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