



Biological Indicator Process Challenge Devices

‘Test Packs’ Used in Healthcare Facilities

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Many thanks to the team at 3M Health Care for working with Managing Infection Control to provide the following accredited course. IAHC SMM has awarded 1 contact point for completion of this continuing education lesson toward IAHC SMM recertification. The CBSPD has pre-approved this inservice for 1 contact hour for a period of five (5) years from the date of publication. This inservice is 3M Health Care Provider approved by the Californial Board of Registered Nurses, CEP 5770 for 1 Contact Hour.

This form is valid up to five years from the date of publication. Instructions for submitting results are on page 92.

Managing Infection Control and 3M Health Care will be working collaboratively to provide continuing education courses in monthly editions of Managing Infection Control.

Objectives

After completion of this self-study activity, the learner will be able to:

1. Define what a biological indicator process challenge device (BI test pack/PCD) is.
2. Discuss why biological indicator process challenge devices (BI test pack/PCDs) were developed.
3. Select an appropriate biological indicator process challenge device (BI test pack/PCD) for all steam and low temperature sterilization processes.
4. Develop a policy and procedure for the use of biological indicator process challenge devices (BI test pack/PCDs) for routine and qualification testing of steam and low temperature sterilization processes.

Test Questions

True or False

1. A biological indicator process challenge device (BI test pack/PCD) is the same as a challenge or test pack.
 2. A biological indicator process challenge device (BI test pack/PCD) should create a challenge to sterilant penetration that is less stringent than the load contents and placed in the least challenging area in the chamber.
 3. Biological indicator process challenge devices (BI test pack/PCDs) are the most important part of a sterilization process-monitoring program because they tell you spores are killed.
 4. The Association for the Advancement of Medical Instrumentation (AAMI) developed healthcare prepared biological indicator process challenge devices (BI test pack/PCDs) to test the ability of sterilants to penetrate the load.
 5. Commercially available disposable test packs can be used if they are shown to be equivalent to the AAMI “gold standard” packs.
 6. The same biological indicator process challenge device (BI test pack/PCD) can be used for flash and non-flash steam sterilization cycles.
 7. If a steam sterilizer is designed to be used for multiple types of cycles [gravity-displacement, dynamic air-removal (prevacuum or steam-flush pressure-pulse), flash], only one sterilization cycle type should be tested with an appropriate biological indicator process challenge device (BI test pack/PCD) at least weekly, preferably each day the sterilizer is used.
 8. Each type of tray configuration (e.g., open surgical tray, single-wrapped surgical tray, protective organizing case, rigid sterilization container) used for flash sterilization should be tested with an appropriate biological indicator process challenge device (BI test pack/PCD) at least weekly, preferable each day the sterilizer is used.
 9. The Association of periOperative Nurses (AORN) standards state that implantable medical devices should not be flash sterilized but if they are the implant must be used immediately after a negative biological readout.
 10. Low temperature sterilization processes should be monitored every load with an appropriate biological indicator process challenge device (BI test pack/PCD) to monitor the penetration of all critical parameters into the packages being processed.
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Introduction

You maybe looking at the title of this inservice and asking: *What is a process challenge device (PCD)?* A PCD is the new term for challenge or test packs. It is a term that is part of the International Standards Organizations (ISO) documents and is now used in the Association for the advancement of Medical Instrumentation (AAMI) recommended practices and standards. You will not routinely see this name as part of a commercially available challenge or test pack because it is a new term but be assured that commercially available products labeled as challenge or test pack are PCDs. For this inservice the term test pack/PCD will be used.

A test pack/PCD is “designed to simulate product to be sterilized and to constitute a defined challenge to the sterilization process, and used to assess the effective performance of the process”¹. In other words the test pack/PCD creates a challenge to the sterilization process representative of load contents but presents the worst case. In addition it is placed in the sterilizer in the location that creates the worst-case or greatest challenge to sterilant penetration.

For routine (daily to every load and every load that contains an implantable medical device) and qualification testing (after a sterilizer is installed, relocated, after sterilizer malfunctions, or a sterilization process failure and after any major repairs), a test pack/PCD contains biological indicators (BIs) and chemical indicators (CIs). CI test packs/PCDs are available for limited use testing also, but will not be discussed in this inservice.

BI test packs/PCDs are an important part of monitoring the sterilization process. If the BI is killed in a test pack/PCD that represents the worst case or greatest challenge to the sterilization process, then other items in the hospital load were probably effectively sterilized. Let’s take a journey through the history of test packs/PCDs, review the appropriate test packs/PCDs for testing all steam and low temperature sterilization processes, and examine how to use test packs/PCDs for routine and qualification testing of steam and low temperature sterilization processes.

History

In 2003, the Association for the Advancement of Medical Instrumentation (AAMI) published a Technical Information Report (TIR), AAMI TIR31, 2003 *Process challenge devices/test packs for use in health care facilities*, to provide technical information to healthcare facilities in the selection and use of process challenge devices (PCDs). TIRs are developed when there is an immediate need for information and when the field or technology is rapidly evolving.

A TIR is different than a standard or recommended practice because it does not require the formal process of committee approval, public review, and resolution of comments. In addition a standard or recommended practice is formally reviewed usually every five years to reaffirm, revise or withdraw

the standard or recommended practice. A TIR is approved for distribution by a technical committee and the AAMI Standards Board and, after five years, a technical committee can decide if the TIR should be removed from circulation.

In the early days of steam sterilization, “practitioners considered proper sterilization of surgical supplies in hospitals an art rather than a science.”¹ This was because the outcome of the sterilization process depended on the skill of the individual operator in manipulating the sterilizer valves by hand and reading the gauges of early gravity type steam sterilizers. Even at that time, it was identified that a need existed for a dependable type of sterilizer detector that could identify whether an adequate temperature was reached in the load during the period of exposure to the steam. Sterilizer technology advanced with the introduction of the recording thermometers in the discharge pipe system (i.e., drain), considered the coolest part of the chamber. Additional temperature monitors included temperature tubes and self-registering or lag thermometers that were placed in large, dense fabric packs.

These monitors were adequate until the introduction of the prevacuum steam sterilizers. At that time it became important to assess the ability of the vacuum system to remove air and allow steam to penetrate porous loads.¹ Fabric packs were thought to be the most resistant to air removal and steam penetration so in 1980 the AAMI organization designed a 12 x 12 x 20 inch heterogeneous challenge pack with one or more BIs and optional CIs in the geometric center of the pack to be used in an empty chamber for testing after a sterilizer is installed, relocated, after sterilization failures, and major repairs, as well as for routine testing in a fully loaded sterilizer. Because the materials in this pack were no longer readily available, in 1988 the 16-towel challenge pack was developed.^{1,2}

In 1985 the need for a test pack to challenge the ethylene oxide (EO) sterilization process was identified.¹ At that time, AAMI developed an EO challenge pack consisting of two BIs placed inside two disposable syringes, a plastic item, and a rubber item (EO absorbents) placed inside the center of four folded and stacked towels, wrapped and taped.^{1,6} This EO challenge pack was developed to represent a greater challenge to the sterilizer than a typical load. It is used for qualification testing by sterilizer manufacturers and by the health care facilities for installation testing, periodic quality assurance (quarterly) testing, after major redesign, relocation, corrective maintenance and after a sterilization process failure.

In addition, a test pack was developed for routine testing that consisted of one BI inside of a disposable syringe and a CI, placed in the folds of a single absorbent towel which is placed inside a peel pouch.^{1,6} This routine EO test pack represents a typical sterilizer load and is used with a fully loaded chamber.

Both the AAMI steam and EO challenge and routine test packs became the “gold standards” that manufacturers, who introduced commercial, pre-assembled, disposable test packs, used as reference test packs to demonstrate equivalency in performance for premarket notification [510(k)] submissions to the FDA.¹ The AAMI ST46, 2002 *Steam sterilization and sterility assurance in health care facilities* recommended practice states:

“Commercially available disposable test packs may be used only if they are shown to be equivalent in scientific experiments. Manufacturers of disposable test packs should provide written information regarding the instructions for use, storage, handling, and testing of their products.”

The AAMI ST41, 1999 *Ethylene oxide sterilization in health care facilities: Safety and effectiveness* recommended practice states:

“NOTE-Commercially available test packs for routine biological monitoring should not be used for challenge testing unless the manufacturer’s specifications indicate that the commercial test pack has been validated against the AAMI challenge test pack.”

In 2003, when the PCD TIR 31 *Process challenge devices/test packs for use in health care facilities* was published there were no published standards for test packs/PCDs for hydrogen peroxide gas plasma or ozone sterilization. Information about the use of test packs/PCDs in those processes is provided by the sterilizer manufacturer.

Figure 1: Instructions to Assemble an AAMI Routine 16-Towel BI Test Pack/PCD²

<p>Components:</p> <ol style="list-style-type: none"> 1. One or more BIs (one or two test vials and one control vial from the same lot) and one Class 4 or Class 5 CI. 2. Sixteen clean, preconditioned, reusable huck or absorbent surgical towels, in good condition, each approximately 16 in x 26 in (41 cm x 66 cm).
<p>Preparation:</p> <ol style="list-style-type: none"> 1. Fold each towel lengthwise into thirds and then fold widthwise in the middle. Stack towels one on top of another, with folds opposite each other, to form a stack that is approximately 9 in wide, 9 in long, and 6 in high (23 cm x 23 cm x 15 cm). 2. Place the BIs and CI between the eighth and ninth towels in the approximate geometric center of the pack. 3. Tape the pack in a manner that will yield the pack approximately 6 in (15 cm) high. 4. Label as a BI test pack/PCD
<p>Test Procedure:</p> <ol style="list-style-type: none"> 1. Place the test pack flat in a full chamber (routine testing) or an empty chamber (qualification testing) on a rack or shelf near the drain. 2. Run the load according to the sterilizer manufacturer’s instructions. 3. At the end of the cycle, cool the test pack according to the manufacturer’s instructions. 4. Read the CI and record the results. 5. Incubate the test vial and a control vial from the same lot each day a test vial is incubated. Read and record the results.

Test Packs/PCDs for Steam Sterilization

A BI test pack/PCD for steam consists of a biological indicator containing *Geobacillus stearothermophilus* spores (formally called *Bacillus stearothermophilus*) and a Class 4 or Class 5 CI. The BI test pack/PCD should create a challenge to the sterilization process that is representative of the most difficult item to sterilize in the load. As stated in the history section of this inservice, AAMI developed a 16-towel challenge and routine BI test pack/PCD that health-care facilities can prepare from readily available materials. Since the preparation of these BI test packs/PCDs was time consuming, costly, and pack performance could vary depending on the source of materials and how the packs are prepared, commercial, pre-assembled BI test packs/PCDs were developed and made available.

Routine Testing

Routine testing of steam sterilizers should be done at least weekly, but preferably every day that the sterilizer is in use.^{1-3,5} If a sterilizer is designed to be used for multiple types of cycles [gravity-displacement, dynamic air-removal (prevacuum or steam-flush pressure-pulse), flash], each sterilization cycle type should be tested.¹⁻³

Each load containing implantable device should be monitored and whenever possible, quarantined until the results of the BI testing are available.^{1-3,5} The Association of periOperative Nurses (AORN) 2005 *Standards, Recommended Practices, and Guidelines* states:

“Implantable medical devices should not be flash sterilized because of possible patient complications.”

The AORN standard also state:

“If an implantable device is sterilized on-site at health care facilities, AAMI recommends that health care personnel quarantine the device and await the outcome of biological monitoring of the device’s sterilization cycles before releasing the item for patient use. If an implantable medical device is flash sterilized, the device must be used immediately after a negative biological readout. If not used, the device must be reprocessed before future use.”

The AAMI 16-towel routine BI test pack/PCD (see Figure 1 for instructions for preparation) can be used for the 270°F to 275°F (132°C to 135°C)

Table 1: BI Test Packs/PCDs for 270°F to 275°F (132°C to 135°C) Dynamic-Air-Removal or 250°F (121°C) Gravity Displacement Steam Sterilization Cycles *

Type of Tray Configuration or Load	BI Test Pack/PCD
Wrapped surgical tray*, with or without porous item (towel, foam pad, etc)	BI in wrapped surgical tray* (include porous items if in patient care tray) or an AAMI 16-towel BI test pack/PCD or commercially available test pack/PCD of equivalent performance if appropriate for cycle parameters
Mixed wrapped load	BI in AAMI 16-towel test pack/PCD or commercially available test pack/PCD of equivalent performance
Protective organizing case	BI in protective organizing case in area(s) that creates the greatest challenge to air removal and sterilant penetration or an AAMI 16-towel test pack/PCD or commercially available test pack/PCD of equivalent performance if shown in product testing to be appropriate
Rigid sterilization container	BI in rigid sterilization container in area(s) that creates the greatest challenge to air removal and sterilant penetration or an AAMI 16-towel test pack/PCD or commercially available test pack/PCD of equivalent performance if shown in product testing to be appropriate

*Perforated or mesh bottom trays

Table 2: BI Test Packs/PCDs for Different Cycle/Tray Configurations for Flash Sterilization Cycles

Type of Cycle	Type of Tray Configuration	BI Test Pack/PCD
Gravity	Open surgical tray	BI in open surgical tray
Gravity	Wrapped surgical tray, with or without porous item (towel, foam pad, etc)	BI in wrapped surgical tray (include porous items if in patient care tray)
Gravity	Protective organizing case	BI in protective organizing case in area(s) that creates the greatest challenge to air removal and sterilant penetration
Gravity	Rigid sterilization container	BI in rigid sterilization container in area(s) that creates the greatest challenge to air removal and sterilant penetration
Dynamic-air-removal	Open surgical tray with or without porous item (towel, foam pad, etc)	BI in open surgical tray (include porous items if in patient care tray)
Dynamic-air-removal	Wrapped surgical tray, with or without porous item (towel, foam pad, etc)	BI in wrapped surgical tray (include porous items if in patient care tray)
Dynamic-air-removal	Protective organizing case	BI in protective organizing case in area(s) that creates the greatest challenge to air removal and sterilant penetration
Dynamic-air-removal	Rigid sterilization container	BI in rigid sterilization container in area(s) that creates the greatest challenge to air removal and sterilant penetration

dynamic-air-removal or 250°F (121°C) gravity displacement steam sterilization cycles (see Table 1 for appropriate BI test packs/PCDs for these cycles). This test pack/PCD is placed flat in a full chamber on a rack or shelf near the drain. This AAMI 16-towel test pack/PCD is not an appropriate BI test pack/PCD for flash cycles. See Table 2 for the appropriate BI test packs/PCDs for flash cycles.

For flash sterilization cycles, a health-care facility should make their own BI test pack/PCD that is representative of the load contents and contains a BI and a Class 4 or Class 5 CI.^{1,3} Each type of tray configuration (e.g., open surgical tray, single-wrapped surgical tray, protective organizing case, rigid sterilization container) and each type of cycle (e.g., gravity-displacement, prevacuum, steam-flush pressure-pulse, flash cycle with single wrapper) in routine use should be tested separately with the appropriate BI test pack/PCD.^{1,3} See Table 2 for the appropriate BI test pack/PCDs for different cycle/tray configurations for flash sterilization cycles. The BI test pack/PCD is placed in an empty load, on the bottom rack, over the drain if processing in a flash cycle. Empty load testing is a greater challenge because it minimizes heat-up time, because there is less mass in the load, which minimizes the lethality of the processes.³

Challenge Testing

The BI test pack/PCD used for routine testing can also be used for qualification testing by the health care facility whenever a sterilizer is installed, relocated, after a sterilizer malfunction, after sterilization process failures, and after any major repairs.¹⁻³ For qualification testing, each cycle type used [gravity-displacement, dynamic air-removal (prevacuum or steam-flush pressure-pulse), flash] should be tested. For qualification testing a BI test pack/PCD is run in three consecutive empty cycles.

Table 3: BI Test Packs/PCDs for Table-Top Steam Sterilizers

Program/Load	Temperature	Time*	BI Test Pack/PCD
Unwrapped instruments on a tray or glassware	270°F-274°F (132°C-135°C)	≥3 min	BI in unwrapped instrument tray or glassware
Wrapped trays of instruments, instruments in peel pouches	270°F-274°F (132°C-135°C)	≥5 min	BI in a wrapped tray or peel pouch and include porous items if applicable
Packs, wrapped	250°F/121°C	≥30 min	BI in wrapped pack that is representative of the load, include porous items if appropriate
Liquids	250°F/121°C	≥15 min	BI suspended above a test container of the liquid

Table-Top Steam Sterilizers

There is no AAMI defined or universally accepted reference standard for BI test packs/PCDs for table-top steam sterilizers. The BI test pack/PCD should be representative of the same type of package or tray and items routinely processed in the table-top steam sterilizer and the most difficult to sterilize.

Routine Testing

AAMI ST 42, 1998 *Steam sterilization and sterility assurance using table-top sterilizers in office-based ambulatory-care medical, surgical, and dental facilities* recommends loads be monitored with a BI test pack/PCD at least once a week but preferable daily and each load containing implantable devices which should be quarantined, whenever possible, until the results of the biological indicator testing are available.⁴

Each type of sterilization mode or cycle used (e.g., unwrapped instruments, wrapped instruments, packs) should be tested. For example, an item packaged in multiple layers of absorbent materials creates a greater

Routine testing of the EO sterilizer should be done in each load to monitor the penetration of all the critical parameters.

challenge than an item in a peel pouch.⁴ So a BI test pack/PCD that consists of a wrapped pack containing absorbent material could be used to test a wrapped pack cycle. A BI test pack/PCD consisting of an instrument in a peel pouch with porous items, such as gauze, could be used to test both the wrapped instruments and peel pouch cycle. A BI in an unwrapped tray could be the BI test pack/PCD used to test the unwrapped instrument cycle.

Table 3 lists the BI test packs/PCDs that are appropriate for each type of sterilizer cycle that should be tested. Commercially available BI challenge or test packs (BI test packs/PCDs) may also be available. Place the BI test pack/PCD on its edge if it is a small pack or flat if it is a tray or large pack in the coldest area

of the sterilizer chamber as determined by the sterilizer manufacturer to create the most severe challenge to the sterilizer. Normally this is the center, front of the chamber.⁴

Challenge Testing

The BI test pack/PCD used for routine testing can also be used for qualification testing by the healthcare facility whenever a sterilizer is installed, relocated, after major repairs and after a sterilization process failure.⁴ Each type of sterilization mode or cycle used (e.g., unwrapped instruments, wrapped instruments, packs) should be tested. For qualification testing in a table-top sterilizer a BI test pack/PCD is run in three consecutive full cycles. Placement of the BI test pack/PCD is the same as for routine testing.

Test Packs/PCDs for Low Temperature Sterilization Ethylene Oxide (EO)

A BI test pack/PCD for EO consists of a biological indicator containing *Bacillus atropheus* spores (formally called *Bacillus subtilis var. niger*) and a Class 4 or Class 5 CI. The BI test

pack/PCD should create a challenge to the sterilization process that is representative of the most difficult item to sterilize in the load. As stated in the history section of this inservice, AAMI developed a challenge and routine BI test pack/PCD for EO sterilization processes that health-care facilities can prepare from readily available materials. Since the preparation of these BI test pack/PCDs was time consuming and pack performance could vary depending on how the packs are prepared and the source of the materials, commercial, pre-assembled BI test pack/PCDs were developed and made available.

Routine Testing

Routine testing of the EO sterilizer should be done in each load to monitor the penetration of all the critical parameters of the process into the packages being processed, the condition of the sterilizer, and the expertise of the sterilizer operator (pack preparation and loading).^{1,6} The less frequently the sterilizer is monitored, the greater the opportunity for the occurrence of an unnoticed event that could lead to a sterilization process failure that could potentially affect patient outcomes.

Each load containing implantable devices should be monitored, and whenever possible, quarantined until the results of the biological testing are available.^{1,6}

An AAMI routine BI test pack/PCD (see Figure 2 on page 90 for preparation instructions) or an equivalent commercial disposable test pack/PCD should be used. This BI test pack/PCD should be placed in the center of a full sterilizer load.

Challenge Testing

A BI test pack/PCD challenge test pack is used by the EO sterilizer manufacturer for qualification testing and by the health care facility whenever the sterilizer is installed, for periodic quality assurance testing (quarterly), after major redesign, relocation, corrective maintenance or a sterilization process failure.⁶

An AAMI challenge BI test pack/PCD (see Figure 3 on page 90 for preparation instructions) or an equivalent commercial disposable test pack/PCD should be used. Placement of the test pack will depend on the type of testing performed. See Figure 4 on page 91 for this information.

Hydrogen Peroxide Gas Plasma

A BI test pack/PCD for the Hydrogen peroxide gas plasma sterilization process consists of a biological indicator containing *Geobacillus stearothermophilus* spores (formally called *Bacillus stearothermophilus*) and a CI. The BI test pack/PCD should create a challenge to the sterilization process that is representative of the most difficult item to sterilize in the load. At the time of the publication of

the AAMI TIR there were no published standards for test packs/PCDs used for challenge or routine monitoring of Hydrogen peroxide gas plasma.¹ A commercial, pre-assembled BI PCD is available. A healthcare facility prepared BI test pack/PCD could be prepared using a BI and CI in a package or tray routinely processed that is representative of the load and considered the most difficult to sterilizer.

Figure 2: Instructions to Assemble an AAMI Routine BI Test Pack/PCD⁶

Components:

1. Two BIs (one test vial and one control vial from the same lot) and one Class 4 or Class 5 CI.
2. One plastic syringe (approximately 20 cc).
3. A clean surgical towel, woven, 100% cotton.
4. A peel pouch or wrapper large enough to contain the test pack contents.

All components should be held at room temperature [18°C to 24°C (65°F to 75°F)] and a relative humidity of 35% for at least 2 hours prior to making the BI PCD).

Preparation:

1. Place one BI, according to the BI manufacturer's instructions, inside a plastic syringe of sufficient size that the plunger diaphragm does not touch the BI when the plunger is inserted into the barrel of the syringe. If there is a plastic protective tip guard on the syringe, remove it. One additional BI from the lots used for testing should be left unexposed to the sterilant and used as a positive control.
2. Place the syringe with the BI and the CI (outside the syringe) between the folds of the clean surgical towel, which has been folded lengthwise into thirds and then in thirds again to create nine layers.
3. Place these items inside one peel pouch or wrapper large enough to contain the test pack components.
4. Label as a BI test pack/PCD.

Test Procedure:

1. Place in the center of the load.
2. Upon completion of the cycle, the BI test pack/PCD should be handled according to the health care facility's protocol for minimizing worker exposure to EO (see sterilizer and BI test pack/PCD manufacturer's instructions).
3. Read the CI and record the results.
4. Incubate the test vial and a control vial. Read and record the results.

Figure 3: Instructions to Assemble an AAMI Challenge BI Test Pack/PCD⁶

Components:

1. Three BIs (two test vials and one control vial from the same lot) and one Class 4 or Class 5 CI.
2. Two plastic syringes (approximately 20 cc).
3. Four clean surgical towels, woven, 100% cotton, approximately 18 in by 30 in.
4. One adult plastic airway.
5. One 10 in-long section of amber latex tubing with an internal diameter of 3/16 in and a wall thickness of 1/16 in.
6. Two clean or one welded, woven or nonwoven wrappers, 24 in by 24 in.

All components should be held at room temperature [18°C to 24°C (65°F to 75°F)] and a relative humidity of 35% for at least 2 hours prior to making the BI test pack/PCD.

Preparation:

1. Fold the four surgical towels into thirds and then in half to create six layers per towel and then stack one on top of another.
2. Place each BI, according to the BI manufacturer's instructions, inside its own plastic syringe of sufficient size that the plunger diaphragm does not touch the BI when the plunger is inserted into the barrel of the syringe. If there is a plastic protective tip guard on the syringe, remove it. One additional BI from the lot used for testing should be left unexposed to the sterilant and used as a positive control.
3. Place the syringes with the BI and the CI (outside the syringe), the plastic airway and latex tubing in the center of the stack of folded cotton towels clean surgical towels.
4. Wrap the towels and tape.
5. Label as a BI test pack/PCD.

Test Procedure:

1. Place the BI test pack/PCD in the sterilizer load according to the testing being performed (see Figure 4).
2. Run the load according to the sterilizer manufacturer's instructions.
3. Upon completion of the cycle, the BI test pack/PCD should be handled according to the health care facility's protocol for minimizing worker exposure to EO (see sterilizer and BI test pack/PCD manufacturer's instructions for use).
4. Read the CI and record the results.
5. Incubate the test vial and a control vial. Read and record the results.

Figure 4: EO BI Test Pack/PCD Challenge Pack Placement for Type of Testing Performed⁶

Installation testing (testing performed between the time the EO sterilizer is installed and the time it is released for use in the health care facility)

- ▶ Run three consecutive empty cycles
- ▶ For an EO sterilizer with a chamber volume of less than 16 cubic feet, place one BI test pack/PCD in the front of the chamber near the door.

Periodic quality assurance testing (quarterly), after major redesign, relocation, or corrective maintenance

- ▶ Run three consecutive full cycles
- ▶ For an EO sterilizer with a chamber volume of less than 16 cubic feet, place one BI test pack/PCD in the front of the chamber near the door.
- ▶ Quarantine the loads until the BI results are available.

After a sterilization process failure

- ▶ Run one full cycle
- ▶ For an EO sterilizer with a chamber volume of less than 16 cubic feet, place one BI test pack/PCD in the front of the chamber near the door.
- ▶ Quarantine the loads until the BI results are available.

Routine testing

AAMI recommends that this routine testing be done daily in a full load or each day that the sterilizer is used.⁽¹⁾ AORN states that the BI testing should be performed at the same interval as other sterilizer testing in the facility (e.g., each load as for EO). According to the BI manufacturer the BI test pack/PCD should be placed with the spun-bonded polyethylene material side up on the top shelf of the load.

Challenge testing

A challenge test pack should be used by the manufacturer during installation testing and by the health care facility after major relocation, sterilizer malfunction, sterilization process failure, and any major repairs of the sterilizer.¹ Three consecutive empty cycles should be run.¹ Check with the sterilizer manufacturer for the appropriate BI test pack/PCD to use and its placement in the chamber.

Ozone

A BI test pack/PCD for the Ozone sterilization process consists of a biological indicator containing *Geobacillus stearothermophilus* spores (formally called *Bacillus stearothermophilus*) and a CI. The BI test pack/PCD should create a challenge to the sterilization process that is representative of the most difficult item to sterilize in the load. At the time of the publication of the AAMI TIR the ozone sterilization process was not being marketed in the United States so no published standards for test packs/PCDs used for challenge or routine monitoring of Ozone sterilization were available. The manufacturer recommends the preparation of a syringe pack. The BI is placed with the cap towards the opening or bevel of the syringe with the tip removed. The syringe containing the BI and a CI (outside of the syringe) is placed inside a peel pouch.

Sterile Process and Distribution CEU Information

CEU Applicant Name _____
 Address _____
 City _____
 State _____ Zip Code _____

The CBSPD (Certification Board for Sterile Processing and Distribution) has pre-approved this inservice for one (1) contact hour for a period of five (5) years from the date of publication. Successful completion of the lesson and post test must be documented by facility management and those records maintained by the individuals until re-certification is required. **DO NOT SEND LESSON OR TEST TO CBSPD.**

For additional information regarding CBSPD certification, contact: CBSPD, 121 State Hwy 31N, Suite 500, Flemington, NJ 08822 or call (908) 788-3847 or visit www.sterileprocessing.org.

IAHCSMM has awarded 1.5 Contact Points for completion of this continuing education lesson toward IAHCSMM recertification.

Nursing CEU Application Form

This inservice is 3M Health Care Provider approved by the California Board of Registered Nurses, CEP 5770 for (1) contact hour. This form is valid up to five years from the date of publication.

1. Make a photocopy of this form.
2. Print your name, address and daytime phone number and position/title.
3. Add your social security number or your nursing license number.
4. Date the application and sign.
5. Answer the CE questions.
6. Submit this form and the answer sheet to:
 Workhorse Publishing
 Managing Infection Control
 PO Box 25310, Scottsdale, AZ 85255-9998
7. Participants who score at least 70% will receive a certificate of completion within 30 days of Managing Infection Control's receipt of the application.

Application

Please print or type.

Name _____
 Mailing Address _____
 City, State, Country, Zip _____
 Daytime phone () _____
 Position/Title _____
 Social Security or Nursing License Number _____
 Date application submitted _____
 Signature _____

Offer expires August 2010

Routine testing

The sterilizer manufacturer recommends that routine testing of Ozone sterilizers should be done in each load to monitor the penetration of all the critical parameters of the process into the packages being processed, the condition of the sterilizer, and the expertise of the sterilizer operator (pack preparation and loading). The syringe BI test pack/PCD is the last thing placed in the load.

Challenge testing

As for other low temperature sterilization processes, challenge test pack should be used by the manufacturer during installation testing and by the health care facility after major relocation, sterilizer malfunction, sterilization process failure, and any major repairs of the sterilizer.¹ Three consecutive empty cycles should be run.¹ Check with the sterilizer manufacturer for the appropriate BI test pack/PCD to use and its placement in the chamber.

Summary

It is important to choose the appropriate BI test pack/PCD so that the sterilization process is challenged with a BI test pack/PCD that creates a challenge to the sterilization process that is similar to the load contents but the worst case scenario. For example, if the load contains a mixture of fabric packs, basin sets, and peel pouches, a BI test pack/PCD that consists of a BI in a peel pouch would not be the greatest challenge. An AAMI

Answer Key

- | | |
|------|-------|
| 1. T | 2. F |
| 3. T | 4. T |
| 5. T | 6. F |
| 7. F | 8. T |
| 9. T | 10. T |

Routine testing of the EO sterilizer should be done in each load (remove.) to monitor the penetration of all the critical parameters of the process.

16-towel pack or commercially available BI test pack/BCD would create a greater challenge.

In addition the BI test pack/PCD is placed in the sterilizer in the location that creates the worst-case or greatest challenge to sterilant penetration. For flash steam sterilization processes, test each type of tray configuration (e.g., open surgical tray, single-wrapped surgical tray, protective organizing case, rigid sterilization container). For all steam sterilization processes test each type of cycle (e.g., gravity-displacement, prevaccum, steam-flush pressure-pulse, flash cycle with single wrapper) in routine use with the appropriate BI test pack/PCD, which is also used for qualification testing. BI test packs/PCDs are the only monitoring tool that can demonstrate that spores are killed, which is the goal of the sterilization process. This is why a BI test pack/PCD is the most stringent test in a sterilization process monitoring program.

AAMI documents can be purchased through AAMI by credit card using the following four options:

1. Internet: <http://marketplace.aami.org/eseries/ScriptContent/Index.cfm>
2. Call: 1-800-332-2264, ext 217 or 1-703-525-4890, ext 217
3. Fax: 703-525-1424
4. Mail: AAMI, Customer Service Center, 1100 N. Glebe Road, Suite 220, Arlington, VA 22201-5762 ✉

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