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Learning objectives

1. Define what a process challenge device (PCD) is.
2. Select an appropriate biological indicator process challenge device (BI PCD) for routine and sterilizer qualification testing of all steam sterilization processes.
3. Select the appropriate Class 5 integrating indicator (Class 5 CI PCD) to routinely monitor loads that do not contain implants.
4. Develop a policy and procedure for the correct use of a Bowie-Dick PCD (BD PCD) for routine and qualification testing of steam sterilizers.

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SELF-STUDY Series

Process challenge devices for steam sterilization cycles

by Martha Young, BS, MS, CSPDT

A process challenge device is the International Standards Organization (ISO) term that is now being used in the Association for the Advancement of Medical Instrumentation (AAMI) recommended practices and standards. This term replaces the word challenge or test pack that has been used in the past. For short it is referred to as a "PCD".

You will not routinely find the term PCD used in the labeling of commercially available challenge or test packs because it is a new term but be aware that the term "test" or "challenge pack" on that product is interchangeable with the term "PCD".

In 2003, AAMI published a Technical Information Report TIR, AAMI TIR31, *Process challenge devices/test packs for use in health care facilities*. This TIR provides technical information to health care facilities in the selection and use of process challenge devices (PCDs). This TIR specifically addresses biological indicator (BI) PCDs but does have Annex B which discusses the Bowie-Dick test pack. In addition, at the time this TIR was published, there were no test or challenge pack or PCD standards for hydrogen peroxide gas plasma or ozone sterilization. Information about the use of test or challenge packs/PCDs in these processes is provided by the sterilizer manufacturer.

The AAMI TIR31, 2003 defines a process challenge device (PCD) as¹:

"Item 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."

For this in-service the term PCD does refer to test or challenge pack and will discuss biological indicator PCDs (BI PCDs), Class 5 integrating indicator PCDs (Class 5 CI PCDs), and Bowie-Dick PCDs (BD PCDs).

Biological Indicator PCDs

A BI PCD consists of a BI and may include a chemical indicator. These indicators are placed inside a package that creates a challenge to the sterilization process and that is representative of the most difficult item to sterilize in the load.

The BI PCD is the greatest challenge to the sterilization process because spores are the only currently accepted system capable of integrating all the physical parameters responsible for lethality of a sterilization process to tell you spores were

killed.^{2,3} Chemical indicators, such as Class 5 integrating indicators are not an acceptable monitor for determining the effectiveness of a sterilization process.^{4,5}

Steam Sterilization

Routine Testing

Routine testing should be done at least weekly, but preferably every day that the sterilizer is in use.^{1,6-9} 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.^{1,6-8}

Each load containing implantable medical devices should be monitored with a BI (early read-out or spore growth) and whenever possible, quarantined until the results of the BI testing are available.^{1,6-8}

For the 270°F to 275°F (132°C to 135°C) dynamic-air-removal or 250°F (121°C) gravity-displacement steam sterilization cycles use one of the following PCDs:

- AAMI 16-towel routine BI PCD
- Commercially available BI PCD of equivalent performance to the AAMI 16-towel routine BI PCD
- BI in a package that is representative of the load (i.e., protective organizing case or rigid sterilization container)

For routine testing the AAMI BI PCD is placed flat or horizontal. Commercially available BI PCDs should be placed according to the instructions for use. A BI in a package that is representative of the load should be placed as it normally would be.

All BI PCDs are placed in a full chamber on a rack or shelf near the drain which is the least favorable to sterilization and the greatest challenge to the BI.

For 270°F to 275°F (132°C to 135°C) gravity-displacement or dynamic-air-removal flash steam sterilization processes, in addition to testing each type of cycle used, each type of tray configuration (e.g., open surgical tray, single-wrapped surgical tray, protective organizing case, rigid sterilization container) should be tested separately with the appropriate BI PCD.^{1,7} This testing should also be done at least weekly, but preferably every day that the sterilizer is in use.^{1,6-9} Following are examples of BI PCDs that are appropriate but must be representative of the tray configurations being processed:

- BI in open perforated or mesh bottom surgical tray
- BI in wrapped perforated or mesh bottom surgical tray
- BI in protective organizing case in area(s) that creates the greatest challenge to air removal and sterilant penetration
- BI in rigid sterilization container in area(s) that creates the greatest challenge to air removal and sterilant penetration

Porous items such as a towel or foam should be included in the BI PCD if routinely used. It is not necessary to add instruments to the BI PCD since an empty tray is a greater challenge because it minimizes heat-up time, because there is less mass in the tray, which minimizes the lethality of the processes.

For example, if flash sterilization is routinely done in a rigid sterilization container for 5 minutes in a 270°F to 275°F (132°C to 135°C) gravity-displacement steam sterilizer, then the BI PCD to routinely use would include a BI in an empty rigid sterilization container run in the same cycle parameters. It would not be as great a challenge or representative of the load to run a BI in a perforated or mesh bottom tray.

If flash sterilization is done in open perforated or mesh bottom surgical trays and rigid sterilization containers then a BI PCD representative of each of those types of packaging should be routinely run. Remember to always use a BI PCD that is representative of the most challenging tray configuration and to test all the different tray configurations used routinely.

In flash sterilization cycles the BI PCD is placed in an empty load, on the bottom rack or shelf, over the drain. 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.⁷

For table top steam sterilizers, each type of sterilization cycle used (e.g., unwrapped instruments, wrapped instruments, packs) should be tested with the same type of package or tray and items routinely processed.⁹ Examples of appropriate BI PCDs for specific cycles:

- Unwrapped instrument cycle – BI in unwrapped perforated or mesh bottom instrument tray;
- Wrapped instrument cycle or peel pouches – BI in empty wrapped instrument tray or peel pouch (include porous items if applicable);
- Wrapped pack cycle – BI in wrapped pack that is representative of the load (include porous items if applicable).

Place the BI PCD on its edge if it is a small pack or flat if it is a tray or large pack. Place in the coldest area of the sterilizer, normally the center, front of the chamber in a full load. Full load testing is the greatest challenge because of the limited amount of sterilant that enters the chamber.

If a positive BI is obtained a recall must be done because the sterilization process was not effective.⁶

As stated in AAMIST46, section 7.5.4.4 Positive biological indicator results (p. 50):

“b) Because a sterilization failure has occurred, items processed in that sterilizer, dating from the sterilization cycle having the last negative BI to the next cycle showing satisfactory BI challenge results, should be considered nonsterile. They should be retrieved, if possible, and reprocessed. (See 7.9)

A recall can be avoided by monitoring each load with a BI PCD and quarantining the load until the BI results are negative at 1 or 3 hours.

Sterilizer Qualification Testing

The BI PCD used for routine testing can also be used for sterilizer qualification testing whenever:^{1,6-8}

- a sterilizer is installed or relocated
- after a sterilizer malfunction
- after a sterilization process failure
- after a major repair
 - › A major repair is a repair outside the scope of normal maintenance. This includes weld repairs of the pressure vessel, replacement of the chamber door or major piping assembly, or rebuilds or upgrades of controls. Normal preventive maintenance, such as the rebuilding of solenoid valves, is not considered major repair.

For qualification testing each cycle type used [gravity-displacement, dynamic air-removal (prevacuum or steam-flush pressure-pulse), flash], should be tested but it is not necessary to test each type of tray configuration used.^{1,6-8} For sterilizer qualification testing a BI PCD is run in three consecutive empty cycles in the 270°F to 275°F (132°C to 135°C) dynamic-air-removal, 250°F (121°C) gravity-displacement and 270°F to 275°F (132°C to 135°C) gravity-displacement steam sterilization cycles. If all BIs are negative the sterilizer can be placed into routine use.

Table-top steam sterilizer qualification testing is done to ensure the sterilizer is installed correctly and has the correct utilities to function consistently and properly. For qualification testing each type of sterilization cycle used (e.g., unwrapped instruments, wrapped instruments, packs) should be tested with the same type of package or tray and items routinely processed.⁹ Qualification testing with a BI PCD is done in a fully loaded chamber as this creates the greatest challenge to the limited amount of sterilant that enters the chamber of a table top sterilizer. Run three consecutive full cycles, one right after the other. If all BIs are negative the sterilizer can be placed into routine use.

Class 5 Integrating Indicator PCDs

A Class 5 integrating indicator PCD consists of a Class 5 CI in a package that creates a challenge to the sterilization process and that is representative of the most difficult item to sterilize in the load. This PCD may also contain a BI.

Routine Testing

The Class 5 integrating indicator in the PCD is only used for routine testing and as an additional monitoring tool but not as a replacement for the use of a BI in a PCDs.⁶ AAMI ST46, 2002: *Steam sterilization and sterility assurance in health care facilities* states in 7.4.2.3(b)(2):

“NOTE-Multiple-parameter CIs and integrating CIs provide more information about the process than do single-parameter indicators. The results of Class 5 integrating indicators may serve as the basis for the release of processed items, excluding implants. These indicating indicators must be used within an appropriate challenge test pack. Using Class 5 integrating indicators for this purpose does not replace the use of BIs as described in 7.4.3.”

For the 270°F to 275°F (132°C to 135°C) dynamic-air-removal or 250°F (121°C) gravity-displacement steam sterilization cycles the Class 5 integrating indicator should be in the same type of test pack or PCD as the routine BI PCD used. The Class 5 CI PCD is placed flat or according to the product instructions for use in a full chamber on a rack or shelf near the drain which is the least favorable to sterilization and the greatest challenge to the BI. The Class 5 CI PCD is opened at the end of the cycle and if the CI has reached its endpoint the load can be released. If a BI is included it should be incubated. Implants should not be released until the BI results are known.⁶⁻⁸

For 270°F to 275°F (132°C to 135°C) gravity-displacement or dynamic-air-removal flash steam sterilization processes, the Class 5 integrating indicator PCD should be in the same type of test tray configuration or PCD as the routine BI PCD. The Class 5 CI PCD is placed in an empty load, on the bottom rack or shelf, over the drain. In addition, any visible Class 5 integrating indicator in any tray configuration processed can be used as both an internal chemical indicator and to release the load if the load does not contain an implantable medical device.

Remember that the Association of periOperative Nurses (AORN) 2005 *Standards, Recommended Practices, and Guidelines* states⁸:

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

Patient outcomes included a higher degree of risk of infection because:¹⁰

- “First, they are left behind at surgery, so if there are microorganisms on them, these will remain in the body. Infections associated with implants may not be evident for up to a year after surgery.
- Second, the placement of an implant often means the removal of tissue, with interrup-

See SELF-STUDY SERIES on page 38

Answers
1. a
2. b
3. a
4. a
5. b
6. b
7. a
8. b
9. a
10. a

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tion of blood supply and significant manipulation of the tissues immediately adjacent to the implant, creating an area of potential safety for microorganisms to multiply, further increasing the risk of infection.

- Third, because there is interrupted blood supply, antibiotics cannot easily get to the microorganisms if they do multiply enough to cause a clinical infection.
- Fourth, the implant itself may be vital to continuing function of a body system, such as would occur with a total joint replacement, vascular graft, or intraocular lens placement. An infection may not be curable with the implant in place, and removing it could cripple or kill the patient."

In addition:

"The mortality rate (deaths) associated with infected total hip replacements approaches 50%, from the infection itself and from the complications associated with the resulting impaired mobility, such as blood clots and pneumonia."¹⁰

For the above reasons, an implant should not be flash sterilized or released for patient use before the BI result is known.

The AORN standard also states:⁸

"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."

Class 5 integrating indicator PCDs may be used as an additional routine monitoring tool to release loads that do not contain implantable medical devices but they do not replace the use of BI PCDs and do not respond the same as BIs to inadequate time at temperature and defined failure conditions of superheated steam and incomplete chamber air removal.¹¹ In addition, a recall is based on the results of the BI PCD.⁶ This recall occurs no matter what the results are of the Class 5 integrating indicator PCD.

Sterilizer Qualification Testing

Class 5 integrating indicators are not to be used for sterilizer qualification testing (see BI PCD section).

Bowie-Dick PCD's

A Bowie-Dick (BD) PCD consists of a Class 2 chemical indicator test sheet placed inside a package that creates a challenge to air removal and steam penetration. The BD PCD can be either an:

- AAMI BD towel pack
- Commercially available BD PCD of equivalent performance to the AAMI BD towel pack. The BD PCD is used in 270°F to 275°F (132°C to 135°C) dynamic-air-removal sterilizers to

demonstrate that the sterilizer has no air leaks, the vacuum system is adequately removing air from the chamber, that the steam is capable of penetrating the package and not too dry or too wet or does not contain a level of non-condensable gases that would interfere with effective sterilization.^{6,12}

When evaluating BD test results according to the AAMI ST46 *Good Hospital Practice: Steam Sterilization and Sterility Assurance*, 2002 document (p. 52), unsatisfactory test results occur when:⁶

"Any unexpected color change, such as the center of the test sheet being paler or a different color than the edges (i.e., there is a nonuniform color change) indicates that there was an air pocket present during the cycle due to sterilizer malfunction."

Any indication of a malfunction must be reported to the supervisor on duty whose immediate responsibility is to assure that the test results have been interpreted correctly.⁶ Comparing the results with past results for the same sterilizer over a recent period of time of weeks or months will assist in detecting subtle changes in the test sheet.¹¹ The supervisor then determines if the sterilizer needs to be retested, serviced, or remain in use.⁶

Routine Testing

The BD PCD is run routinely each day before the first processed load in the 270°F to 275°F (132°C to 135°C) dynamic-air-removal sterilizer.^{6,8} A warm up cycle should be run prior to running the BD PCD to properly heat the sterilizer.⁶ The BD PCD "should be placed horizontally, in the front, bottom section of the sterilizer rack, near the door and over the drain, in an otherwise empty chamber".⁶ The exposure time is 3.5 minutes, but if half-minute exposure times are not available, then the time should never exceed 4 minutes.⁶

Sterilizer Qualification Testing

The BD PCD used for routine testing can also be used for sterilizer qualification testing whenever:^{6,8}

- a sterilizer is installed or relocated
- after a sterilizer malfunction
- after a sterilization process failure
- after a major repair
 - › A major repair is a repair outside the scope of normal maintenance. This includes weld repairs of the pressure vessel, replacement of the chamber door or major piping assembly, or rebuilds or upgrades of controls. Normal preventive maintenance, such as the rebuilding of solenoid valves, is not considered major repair.

For sterilizer qualification testing a BD PCD is run in three consecutive empty cycles. If the test sheets show a uniform color change and the BI PCDs show negative results, the sterilizer can be put into routine use.

Summary

A process challenge device is the new term that replaces the word challenge or test pack. A PCD is an "item 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."¹¹ It is commonly referred to as a PCD. A PCD can contain a BI (BI PCD), a Class 5 integrating indicator (Class 5 CI PCD) which may also contain a BI, or a Bowie-Dick test sheet (BD PCD). The BI PCD and BD PCDs are used for routine and sterilizer qualification testing. The BI PCD is used to release implantable medical devices. The Class 5 CI PCD can be used to routinely release loads that do not contain implantable medical devices. The Class 5 CI PCD is not used for sterilizer qualification testing. All these PCDs are monitoring tools used to evaluate the effectiveness of the steam sterilization process. If used as designed and in the appropriate cycles and situations the outcome of the sterilization process can be improved. **HPN**

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References

1. Association for the Advancement of Medical Instrumentation. Process challenge devices/test packs for use in health care facilities. AAMI TIR31:2003.
2. Pflug, Irving J. and Odlaug, Theron E. Biological Indicators in the Pharmaceutical and Medical Device Industry. Parenteral Science and Technology. Sept/Oct:1986.
3. PDA Journal of Pharmaceutical Science and Technology. March/April, Vol 58, No. 2:2004.
4. International Standard. Sterilization of health care products-Requirements for validation and routine control-Industrial moist heat sterilization. ISO 11134:1994.
5. Association for the Advancement of Medical Instrumentation and International Standard. Medical Devices-Validation and routine control of ethylene oxide sterilization. ANSI/AAMI/ISO 11135:1994.
6. Association for the Advancement of Medical Instrumentation. Steam sterilization and sterility assurance in health care facilities. ANSI/AAMI ST46:2002.
7. Association for the Advancement of Medical Instrumentation. Flash Sterilization: Steam sterilization of patient care items for immediate use. ANSI/AAMI ST37:1996.
8. Association of periOperative Nurses. Standards, Recommended Practices, and Guidelines. AORN:2006.
9. Association for the Advancement of Medical Instrumentation. Steam sterilization and sterility assurance using table-top sterilizers in office-based, ambulatory-care medical, surgical, and dental facilities. ANSI/AAMI ST42:1998.
10. Schultz, Janet K. Monitoring and Load Release for Implants Sterilized by Steam Within Healthcare Facilities. Managing Infection Control. Jan:2004.
11. Schneider, Phil, et al. Performance of Various Steam Sterilization Indicators Under Optimum and Sub-Optimum Exposure Conditions, in Disinfection. American Journal of Infection Control. Supplement 2, Vol. 33, No. 2, June:2005.
12. Hancock, Charles, et al. Bowie-Dick Testing. Health Purchasing News. Oct:2005.

Continuing Education Test-February 2006

Process challenge devices for steam sterilization cycles used in healthcare facilities

CIRCLE THE CORRECT ANSWER

1. A process challenge device (PCD) is the same as a challenge or test pack.
 - a) True
 - b) False
2. A biological indicator process challenge device (BI PCD) should create a challenge to sterilant penetration that is less stringent than the load contents and be placed in the least challenging area in the chamber.
 - a) True
 - b) False
3. Biological indicator process challenge devices (BI PCDs) are the most important part of a sterilization process-monitoring program because they integrate all the parameters of the sterilization process and tell you spores are killed.
 - a) True
 - b) False
4. Commercially available disposable PCDs can be used if shown to be equivalent to the AAMI recommended health care prepared packs.
 - a) True
 - b) False
5. The same biological indicator process challenge device (BI PCD) can be used for flash and non-flash steam sterilization cycles.
 - a) True
 - b) False
6. 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 PCD) at least weekly, preferably each day the sterilizer is used.
 - a) True
 - b) False
7. 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 PCD) at least weekly, preferably each day the sterilizer is used.
 - a) True
 - b) False
8. A Class 5 integrating chemical indicator process challenge pack (Class 5 CI PCD) can be used to release loads containing implantable medical devices.
 - a) True
 - b) False
9. Class 5 integrating chemical indicators do not detect steam sterilization process failure conditions as often as a BI.
 - a) True
 - b) False
10. One Bowie-Dick process challenge pack (BD PCD) is placed on the sterilizer rack or shelf, near the door and over the drain, in an otherwise empty chamber for both routine and sterilizer qualification testing.
 - a) True
 - b) False

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