Sterilizer Monitoring: Process Challenge Devices

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What is a Process Challenge Device (PCD)?

"A test device intended to provide a challenge to the sterilization process that is equal to or greater than the challenge posed by the most difficult item routinely processed." (1, 2) In other words, a PCD is used to confirm that a sterilizer has effectively sterilized ALL items processed in that cycle. One example of a PCD is a set of instruments with a Biological Indicator (BI) spore test and a Class V indicator strip inserted inside the package. This package is then placed in a routine load with other instrument pouches or wrapped cassette to challenge and test the sterilization process. If these two tests show that all spores have been killed in the BI test, all critical variables have met or exceeded the performance requirements according to the Class V indicator results, and that all physical parameters (time, temperature and pressure) have been verified, you can be confident that the sterilization process has been effective and that the sterilizer is working properly. It is important to note that a PCD should only be used for the sterilizer type and sterilization cycle for which it is intended. (2)

The three types of PCDs most commonly encountered in practice are:

1. Air detection PCD (Bowie-Dick test pack)
2. A biological PCD test pack
3. A chemical indicator PCD test pack

Air Detection PCD (Bowie-Dick test pack)

If a dental hygiene practice has a pre-vacuum sterilizer, then a Bowie-Dick test pack (Class II chemical indicator) must be performed in an empty sterilizer at the beginning of each day it is used. The manufacturer's instructions for use (MIFU) of both the sterilizer and PCD will indicate where the test pack should be placed in the sterilizer. This is usually on the bottom shelf of the sterilizer cart over the drain. It is critical to confirm the type of sterilizer you have since this test is **only** required for prevacuum sterilizers. (2)

An air detection PCD can be purchased commercially and is used to assess if air has been properly evacuated and whether any air leaks are present. Once the cycle containing the air-detection PCD has passed, record the results and dispose of test pack. This log should be retained for 10 years as per the CDHO's Records Regulation. If you have a pressure-pulse sterilizer, please follow the manufacturer's instructions for relevant sterilization monitoring tests.

A Biological Indicator PCD test pack

A Biological Indicator (BI) test pack is used for routine monitoring of table-top sterilizers. It is placed in the sterilizer chamber containing a routine load each day (same time every day) the sterilizer is used and for each type of cycle (e.g. *gravity displacement at 121°C*; *dynamic air removal at 132°C to 135°C*). The purpose of a biological PCD is to provide a direct measure that viable micro-organisms have been killed. (2)

A BI PCD test pack can be one that is commercially prepared or prepared in office. To prepare your own, consider all packages routinely sterilized and choose the one that is most challenging to sterilize. This would be considered a package containing an instrument with a lumen or a hollow centre (e.g. ultrasonic handpieces or slow speed handpieces), or the package that has the most instruments. Assemble the package as you normally would and add a BI spore test and a chemical indicator strip (Class V or higher) in the area of the package where steam would have most difficulty penetrating. Seal the package and label it as "PCD". Place the BI PCD test pack in a routinely loaded chamber in the areas that will be coolest during the cycle. To determine the coolest areas, MIFU should be followed since results will vary with each sterilizer being used. Run the cycle as you normally would. (4)

Upon cycle completion, remove the BI from the PCD test pack, prepare and incubate for the recommended time as indicated by the MIFU. A control BI, from the same lot as the test indicator not processed through the sterilizer, should be prepared and incubated with the test BI; effective sterilization is indicated

when the control BI yields positive results for bacterial growth while the sterilized BI yields negative results. (4)

The chemical indicator should also be checked. If the results indicate a pass and all physical parameters have been met (time, temperature, pressure), the instruments may be released for use. Once the PCD test pack has been opened, it is no longer sterile, and therefore, all items within the PCD test pack shall be repackaged with new indicators and resterilized. Although instruments can be released based on the results of the chemical indicator (Class V or higher), best practice is to quarantine the load until results of the BI are available. (4, 5)

A log should be kept documenting the date and time of sterilization, sterilizer number, sterilizer cycle, and location of the PCD within the cycle. Once results are available and documented, the BI may be disposed according to MIFU. The results of all sterilization monitoring tests shall be recorded and retained for 10 years as per the CDHO Records Regulation.

It is important to note that **challenging** and **rechallenging the sterilizer** in three consecutive cycles using a BI PCD must be done annually and under the following conditions: (2)

i) The purchase and installation of a new sterilizer
ii) The relocation of a sterilizer
iii) After a sterilizer is repaired
iv) A loaner sterilizer
v) Unexplained sterility failures

"For dynamic air removal and gravity displacement sterilizers, the test shall be run in an otherwise empty chamber." (2) This test should be done for all cycles.

Chemical Indicator PCD test pack

A Chemical Indicator PCD test pack measures 2 or more variables for the area in the sterilizer in which it is placed. If your sterilizer has a printer/USB, and you are unable to quarantine your instruments, you need to place a CI PCD test pack containing a chemical indicator strip (Class V or higher) in every subsequent load after the BI PCD test pack load. (1, 2)

If your sterilizer does not have a printer/USB, plan to replace it with one that does. In the meantime, evaluate and document the physical parameters (time, temperature, pressure) manually, and use a Class V chemical indicator in each package. (2)

The easiest way to make your own chemical indicator test pack is to, once again, choose the instrument pack that is most challenging to sterilize (containing lumens or with the most instruments) and insert a chemical indicator strip (Class V or higher) in the area of the package where steam would have most difficulty penetrating. Seal the package and label it "PCD". (4)

Once the load containing a chemical indicator PCD test pack has been sterilized, check to see that the Class V or VI chemical indicator within the PCD has passed and all physical parameters (time, temperature, pressure) have been met. Once confirmed, the instruments may be released for use. As soon as the CI PCD test pack has been opened, it is no longer sterile and therefore, all items within the PCD test pack should be repackaged with new indicators and resterilized. (2)

Robust and detailed procedures for documenting the entire reprocessing process, and for recalling items that have been released prior to knowing the BI results, should be a part of your office infection control policy. (5)

This information is current as of the date of publication.

References

1. MDRAO. Medical Device Reprocessing Manual. 4th ed. Scarborough: Brown Brook Company; cJune 2017.
2. CSA Group. CAN/CSA Z314-18: Canadian Medical Device Reprocessing. Toronto, ON: CSA Group; 2018.
3. CSA Group. CSA Z314.0-13: Medical device reprocessing , general requirements. Toronto, ON: CSA Group; 2013.
4. CSA Group. SPE 1112-14: User handbook for medical device reprocessing in community health care settings. Toronto, ON: CSA Group; 2014.
5. Ontario Agency for Health Protection and Promotion (Public Health Ontario). Provincial Infectious Diseases Advisory Committee. Best practices for cleaning, disinfection and sterilization of medical equipment/devices. 3rd ed. Toronto, ON: Queen's Printer for Ontario; May 2013. CDHO

To ensure you are using the required indicators for your sterilizer process, check out the CDHO Decision Tree available on next page and on our website under "IPAC Guidelines and Resources."