WHAT TO DO

When Your Sterilization Quality Assurance Monitoring Fails?

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Dental hygienists are required to establish, document and maintain policies and procedures for the reprocessing and/or recall of reprocessed medical devices that may not have been sterilized. This includes quality assurance monitoring of the reprocessing procedure using biological indicator (BI) and chemical indicator (CI) process challenge devices (PCDs), as well as physical parameters. Each of these tests plays a critical role in monitoring the sterilization process and need to be evaluated after each cycle. Results of sterilizer monitoring must be fully documented and signed by the person(s) responsible.

It is important to realize that each of these tests has its limitations. The physical parameters indicate that time, temperature and pressure have been reached inside the sterilizer for the required duration, however, they do not exactly indicate if the desired temperature has been reached inside the centre of each package. External chemical indicators identify a processed package from an unprocessed package. Internal chemical indicators measure a number of variables inside the package which highlights the importance of placing these indicators in the least likely area to be penetrated by steam in order to verify if the centre of the package has been penetrated. The BI PCD is indicative of the most challenging test that proves highly resistant bacterial spores have been destroyed in the location of the test.

The CDHO practice advisors are often asked, "If the BI PCD test pack is the gold standard, why are we not placing a BI spore test inside every package." While this would truly be the only way we could know with certainty that no matter where your package is located in the sterilizer that viable microorganisms have been killed, it is not practical, and for this reason, CI are used inside all packages instead. All of these tools are used to alert you of any failures in your process.

Your CI PCD Failed and/or Physical Parameters Were Not Reached, Now What?

1. Inform the supervisor/owner of the practice.
   - The supervisor/owner will want to know the time and date of failure, sterilizer and load/cycle number in question, CI results, results of physical monitoring, BI results if available and any other information that may be useful in determining the problem.
2. The sterilizer should be taken out of service.
3. The cause of the failure should be investigated.
4. If the failure is confined to one load and can be immediately corrected, simply correct the problem and reprocess the load.
   - If a failed chemical indicator is found in one package, the contents of the package shall be reprocessed before use.
   - If a failed chemical indicator is found in multiple packages, the entire load should be reprocessed.
5. If the failure cannot be immediately corrected, recall and reprocess all items back to the last passed CI test.
6. If a major repair is done, requalify the sterilizer (*see yellow box near end of this article for instructions*).
7. Keep a log of all maintenance associated with any failed tests.

What To Do If Your Biological Indicator Process Challenge Device (BI PCD) Fails?

In the event a biological indicator process challenge device (BI PCD) yields positive results for bacterial growth (a failed test), the oral healthcare practitioner should follow the steps below to ensure the safety of your clients:

1. Inform the supervisor/owner of the practice.
    - The supervisor/owner will want to know the time and date of failure, sterilizer and load/cycle number in question, CI results, results of physical monitoring, BI results if available, and any other information that may be useful in determining the problem.
2. Investigate the problem.
    - Review cycle parameters (mechanical and chemical indicators) since the last negative biological indicator results to check for any operator errors such as overloading, failing to provide acceptable package separation, and using incorrect and/or excessive packaging material.
3. Temporarily quarantine all instruments back to previous negative BI test.
4. Retest the sterilizer with a second BI PCD test.
    - While waiting for the test results, the sterilizer should remain out of service.
5. If the repeat BI PCD test is negative for growth (successful test) and chemical and mechanical indicators indicate adequate processing, the sterilizer may be put back into service.
    - All items from the failed load should be resterilized.
6. If the repeat BI PCD test is positive for growth (failed test) and all sterilization procedures have been performed accurately, the sterilizer should remain out of service and be inspected and repaired. Prior to returning the sterilizer to service, it must be challenged with three biological indicator tests in three consecutive empty chamber cycles. All three tests must yield negative results.
    - Initiate recall protocol. All items from suspect loads dating back to the last negative BI should be recalled, to the extent possible, and reprocessed.
7. There must be a procedure for notification of the client in the event of a recall (e.g. positive biological indicator PCD).
8. Consult with your local public health unit for risk assessment and to determine if client notification is necessary.
9. Keep a recall log of all maintenance associated with a positive BI PCD test.

Recalling Instruments and Equipment

In the event that any one of the quality assurance indicators fails (physical parameters, biological indicator, external or internal chemical indicators), items in the package(s) must not be used until after investigation, the problem is corrected, and the package(s) are reprocessed.

A written protocol must be established to recall all inadequately sterilized devices and instruments. All items being reprocessed should be recorded and tracked in the event of any failed quality assurance indicators.

Recall Log

If the biological indicator is positive, loads are recalled back to the last successful BI, and the positive test is investigated. A Log should be kept of biological indicator results including all failed tests outlining the procedures for the recall of improperly reprocessed items. The recall log should include the following:

1. Circumstances (i.e. failed tests) that prompted a recall order
2. A list of medical devices, sterilizers, loads included in the recall
3. A list of supervisors, owners or public health units that were notified of the recall
4. A list of items that were ordered for recall but not collected (i.e. those that were already used on clients)
5. The corrective actions taken to resolve the issue and procedures implemented to prevent re-occurrence
6. The client notification procedures

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Qualifying and Requalifying Your Sterilizer

Sterilizers must be rigorously challenged on installation and rechallenged following disruptions to their normal activity. They should be installed according to the manufacturer's instructions by a qualified technician and must pass **three consecutive cycles** with the appropriate biological and chemical challenges placed in an **empty load**. Finally, the sterilizer should be **challenged** with at least **one full test load**, before the sterilizer can be put into routine service. A sterilizer should not be approved for use if any indicator(s) yield a failed test on any of the tests conducted for the purposes of **qualifying** or **requalifying** the sterilizer.

Sterilizers must be monitored with a test load and be fully **requalified** annually and under the following circumstances:

i) The purchase and installation of a new sterilizer or loaner sterilizer
ii) After construction or other environmental changes in the area
iii) The relocation of a sterilizer
iv) After the sterilizer is repaired or modified
v) After unexplained sterility failures

As you can see, reprocessing is a sophisticated process and failure in any one of the reprocessing steps can put your clients at risk. It is important to be knowledgeable of the reprocessing policies and procedures in your office and understand how and when to implement your recall protocols in the event of failure in any one of those steps.

Do not use any reprocessed instrument if there are any doubts about the sterility of instruments. CDHO

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RDH Expertise for RDHs

CDHO practice advisors provide confidential consultations to dental hygienists who seek assistance with issues that directly or indirectly affect the delivery of safe, competent, ethical dental hygiene care.

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