

## STERILIZATION MONITORING

All sterilization processes in the Cambrian College Dental Clinic are routinely and strictly monitored using specific physical, biological and chemical indicators, as outlined below. These indicators evaluate both the sterilization conditions and the procedure's effectiveness, in accordance with the following:

- indicators are used only for the sterilizer type and cycle for which they were designed and validated
- indicators are used and stored in accordance with the manufacturer's instructions
- indicators are not used beyond their expiration date
- indicator results are interpreted only by trained and qualified staff

### PHYSICAL INDICATORS:

**Physical indicators** are the gauges or displays on the sterilizer that indicate the cycle time, temperature and pressure. In the Cambrian College Dental Clinic:

- All sterilizers are the same model: *Tuttnauer EZPlus* table top autoclaves. These sterilizers utilize steam flush pressure pulse technology and include printers.
- These sterilizers print results and/or record digitally after each cycle is complete.
- The print outs are used for verifying that the physical parameters required for sterilization have been met for each load.
- Once the sterilization print outs from each load are checked by the Dental Clinic

Technologist, they are then recorded in the *Sterilization Monitoring Record*.

### CHEMICAL INDICATORS:

**Chemical indicators (CI)**, internal and external, use sensitive chemicals to assess physical conditions such as time, temperature and presence of steam. There is no hierarchical significance in the classes of indicators (see table below), as they simply measure different variables.

- Internal (inside the package) and external (outside the package) chemical indicators are used with every instrument package to ensure the package is subject to the sterilization process.
- Chemical indicators are used to detect sterilizer malfunction/failures resulting from improper loading of the sterilizer, incorrect packaging, deficiencies of the sterilizing process, or malfunction of the sterilizer itself.
- Chemical indicators involve the use of a heat-sensitive chemicals that change colour when exposed to certain conditions. A simple visual colour change shows the package has been exposed to physical conditions present during the sterilization process.
- **Chemical indicators signify that the package has undergone a sterilization cycle, although they do not ensure that sterilization has been achieved.**

In the Cambrian College Dental Clinic, each instrument package has an:

- **External Type 1 Process Indicator** on the outside of the package and is used to distinguish between processed and unprocessed items.
- **Internal Type 4 Multi-variable Indicator** on the inside of the package. These indicators react to two or more critical parameters (time and temperature) of the sterilization process and indicate exposure to the sterilization cycle at stated values of the chosen parameters.

## **BIOLOGICAL INDICATORS:**

Biological indicators determine whether sterilization has occurred. The Biological Indicators (BI) or “spore test” is the gold standard for monitoring sterilization. The BI test contains bacterial spores which are highly resistant to heat. The spores used are more resistant and present in greater numbers than the common microbial contaminants found on patient care items. A passed BI indicates that live spores have been killed and, therefore, indicates that all other microorganisms have also been killed.

**In the Cambrian College Dental Clinic, BI testing is done in the first load of each day using a BI Process Challenge Device (PCD), for each sterilizer, and with each type of cycle. Items of the processed load are quarantined and not released until the results of the BI PCD test are available.**

The Dental Clinic Technologist is responsible for conducting the BI PCD test and logging the results in the *Sterilization Monitoring Record*.

### **Biological Indicator Process:**

1. The sterilizer number, cycle number, and processing date is recorded on the BI label.
2. A BI PCD test pack is placed in the chamber with a full load of items to be sterilized. This PCD includes a BI spore test and a Type 5 CI added in the area of the package where steam would have most difficulty penetrating, as indicated by the manufacturer’s instruction manual. **This is completed once a day, at the same time of day, for each type of cycle** (i.e. wrapped, plastics, handpieces, etc.)
3. The load is processed according to the manufacturer’s instructions.
4. Upon cycle completion, the BI is removed from the PCD test pack, prepared and incubated for 24 hours. A control BI, from the same lot as the test indicator, not processed through the sterilizer, is 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).
5. Both BI (the sterilized one and the control) are incubated for 24 hours.
6. After the 24 hours have passed, the result of the BI test is verified for spore growth (visual color change from purple to yellow).
7. The Type 5 CI results are also checked and the sterilizer print outs are reviewed, verifying that the physical parameters required for sterilization have been met.
8. Once the packages have completely dried, the Dental Clinic Technologist verifying that the:
  - **External (Class I) chemical indicators** on each package have changed colour appropriately

- **Internal (Class IV) chemical indicators** on each package have changed colour appropriately.

**9. Items of the processed load are quarantined and not released until the results of the BI PCD test are available. The instruments are stored in a locked cabinet labelled *Instruments in Quarantine*.**

10. If the results of the BI indicate a pass and all physical parameters have been met (time, temperature, pressure), the instruments are 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 must be repackaged with new indicators and re-sterilized.)

11. The results are recorded in the Sterilization Monitoring Record by the Dental Clinic Technologist, *including the date and time of sterilization, sterilizer number, sterilizer cycle, and location of the PCD within the cycle. The sterilization #, cycle # and location is recorded at the completion of the sterilization cycle. Once the results from the BI's are visible (24hrs) the results are noted in the SMR*

12. After the results are documented, the BI is disposed of according to the MIFU. Used BI's are disposed of in the puncture resistant sharps container.

13. The results of all sterilization monitoring tests are retained for 10 years as per the CDHO Records Regulation

#### **Verification Chairsides:**

In addition to verification in the reprocessing area, the Class I and IV Chemical Indicators must be checked once more at chairside prior to client use (*Refer to Routine Practices: Unit Preparation Procedure in the Program Procedure Manual*). In the event that the external or internal chemical indicators indicate inadequate processing, items in the package must not be used (*refer to the Instrument Recall Policy in this manual*).

The integrity of the packaging is also inspected. In the event the packaging is compromised, (sterilization bags not properly sealed, torn/punctured, no labelling information visible), the contents are no longer considered sterile. **Compromised instruments and the packaging must be returned to the Reprocessing Area and the Dental Clinical Technologist is to be informed immediately.**

During client care, the instrument cassette contents identification code, cycle, sterilizer number, and date is recorded in the Record of Treatment of the client record (*Refer to the Instrument Recall Policy in this manual*). For sterilized instruments and equipment used in Radiography (XCP kits, panorex bite blocks) and cotton pliers used in dispensing clinical supplies, the cycle, sterilizer number, and date is recorded in the Dental Clinic Instrument Log, kept in the radiography area.

**References:** CDHO Infection Prevention and Control (IPAC) Guidelines, 2018. [www.cdho.org](http://www.cdho.org)  
Public Health Ontario, 2015. *Infection Prevention and Control for Clinical Office Practice*. p. 55-56. Retrieved from [www.publichealthontario](http://www.publichealthontario)