maxill u·test PCD

Process Challenge Device for Sterilization Monitoring

Indications for Use

A PCD (Process Challenge Device) is used in a sterilization monitoring quality assurance program to challenge the efficacy of the sterilization process. The PCD simulates an equal or greater challenge than the most difficult instrument/item routinely processed in a sterilization cycle. Each day and each cycle used requires the use of a PCD. Adding a more rigorous approach to testing follows best practice within the risk management of the theory of routine practice principles of infection prevention and control.

Reusable device is manufactured with lightweight, durable aluminum and lasts for an unlimited number of cycles without changing its performance.

The PCD has two testing properties:

1. Daily routine testing of a sterilizer for each selected cycle
2. Qualifying / re-qualifying a sterilizer in the event of any disruption to its regular activities as well as under the following specific circumstances:
   a) Introduction and installation of a new sterilizer
   b) Circulation of a 'loaner' sterilizer (also referenced in d)
   c) Post any environmental changes in the area housing the sterilizer
   d) Relocation of the sterilizer
   e) Repairs / alterations to the sterilizer
   f) Sterilization failures
   g) Any professional judgment that suspects an issue in the function of the sterilizer

The maxill u-test PCD is intended to be used to challenge BI (Biological Indicator) and CI (Chemical Indicator - Type 5 and / or Type 6) sterilization tests:

Evaluation of the results of the BI and CI remain the same with the use of a PCD. Continue to follow the MIFU (Manufacturer's Instructions for Use) of the BI and CI. Continue to follow the sterilizer's instructions for use as well as the regulatory bodies' frequency of testing for both BI and CI. Use of a PCD does not alter the frequency of testing. Best practice indicates a BI in a PCD and control BI are to be tested and logged daily in the morning/first load of the day with routine daily use. Best practice indicates a CI Type 5 or 6 in a PCD is to be tested and logged daily in every cycle type used that day with routine daily use.

Note: An air detection PCD is also required for the challenge of a Type 2 Chemical Indicator (a.k.a. BDS (Bowie Dick Simulation)) for pre-vacuumed sterilizers. The maxill u-test PCD design is not a suitable test for challenging air detection and does not support the testing parameters for a Type 2 chemical indicator.

Sterilizer's Instructions for Use

A sterilizer's instructions for use includes a section on quality assurance and typically will identify areas in the sterilization chamber that are most difficult for steam to reach during sterilization and / or to react to all three parameters of sterilization: time, temperature and pressure. Identify the most challenging location in each sterilizer in use. A challenging area can also be created by tucking the PCD under and between non-sterile packages that are already positioned in the sterilizer prior to the commencement of sterilization.

Daily Use Procedural Steps

PCD for Chemical Indicator (CI) Type 5 / 6

1. Unscrew the cap on the PCD and insert a CI into the hollow chamber. Replace the cap, taking care not to over-tighten. If the cap is tightened it can be difficult to remove after the sterilization process.
2. Place the PCD in the appropriate size sterilization pouch and position in a challenging area (identified by the sterilizers instructions for use) in the chamber amongst non-sterile packs. Process the load as per cycle selection.
3. Upon full cycle completion (do not interrupt the drying time) and ensuring caution in handling the hot PCD, open the cap, read and log the CI results.

PCD for Biological Indicator (BI)

1. Unscrew the cap on the PCD and insert a BI into the hollow chamber. Replace the cap, taking care not to over-tighten. If the cap is tightened it can be difficult to remove after the sterilization process.
2. Place the PCD in the appropriate size sterilization pouch and position in a challenging area (identified by the sterilizers instructions for use) in the chamber amongst non-sterile packs. Process the load as per cycle selection.
3. Upon full cycle completion (do not interrupt the drying time) and ensuring caution in handling the hot PCD, open the cap and follow regular incubation steps for the BI, log the results once determined.

Qualifying / Re-Qualifying Procedural Steps

See *indications for use* for circumstances that require a sterilizer to be qualified / re-qualified to prove they are fit for introduction for new or existing usage.

The qualifying / re-qualifying steps include three BI tests to be performed consecutively in an empty test load with the Type 5 CI and BI placed in a PCD, process and incubate. Once confirmed that all three BI's as well as chemical and mechanical testing display a 'pass' then the sterilizer can move to a fourth challenge in a full test load. Again, the CI and BI are required to be placed in a PCD for the fourth load and with all three (BI, CI and mechanical) meeting testing criteria, the sterilizer can be utilized.

A sterilizer is not fit for use if any quality assurance indicators conclude a failed outcome.

Record Keeping

As part of quality assurance, document the use of a PCD on all log sheets and in all infection prevention and control written polices and procedures.

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