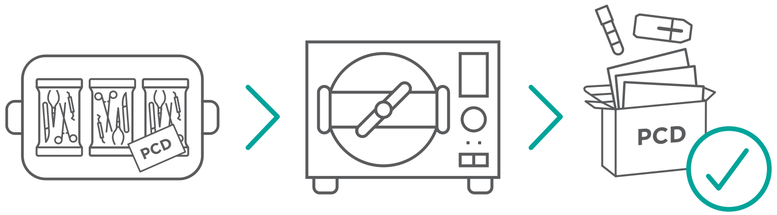

Sterilization efficiency
without concessions:
Safety guaranteed
with Terragene
PCDs
Terragene®
terragene.com


# With Terragene PCDs, every sterilization process is a promise kept.

A Process Challenge Device (PCD) is a device used to evaluate the effective performance of a sterilization process by providing a challenge to the process that is equal to or greater than the challenge posed by the most difficult-to-sterilize item that is routinely processed.

Before developing the PCDs, healthcare facilities used BI and CI to monitor the instrument packages they processed. The contents of these packages were, and still are, wrapped with packaging materials to preserve the sterilized contents until use. The facility did not know the outcome of the sterilization assurance monitors within the package until the package was opened, which could occur hours or days after processing. Information on the effectiveness of the sterilization process was needed as soon as possible after completing the sterilization cycle and removing the load from the sterilizer. Therefore, PCDs were developed for use together with BI and CI to provide a means to evaluate the effectiveness of the sterilization process at the end of the sterilization cycle without compromising the sterility of the contents of instrument packages.

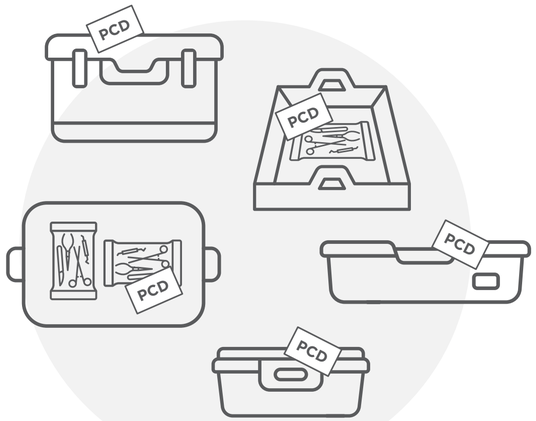
PCD helps you to monitor the performance of the sterilization process and should be placed in the sterilizer in the location that creates the worst-case or greatest challenge to sterilant penetration.

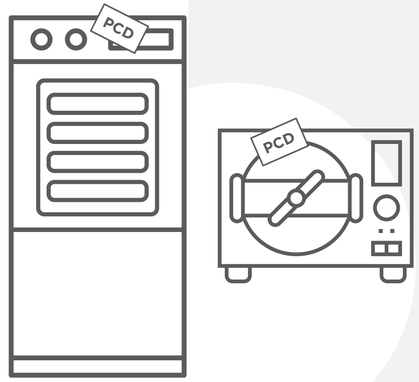



# When the PCD approves, you know it’s safe.

PCDs replicate the toughest sterilization challenges, validating your process.

Immediate results: Know the outcome at the end of the sterilization cycle without opening the packages.




# Every load, every day, every test: Trust never takes a break.

The PCD should be used for:
**Routine monitoring**: daily, in every load or every load that contains an implant.
**For qualification testing**: after the sterilizer is installed or after malfunctions are suspected, or after any major repairs.

There are different PCD configurations depending on the material it is intended to simulate, the process for which it was designed to monitor, with chemical indicators (CI), biological indicators (BI) and configurations that include both indicators. This is why, when selecting a PCD, it is recommended to take into account what type of process you want to monitor and what type of load you want to reprocess. It is advisable to follow the PCD manufacturer's instructions for use to choose the correct challenge for your process.

Different PCD configurations.

# Find the perfect PCD for every process.

| PRODUCT SKU | BIOLOGICAL INDICATORS | CHEMICAL INDICATOR | 510K NOTIFICATION |
|---|---|---|---|
| PCD224-C | BT224 (20 min) | IT26-C (moving front) | K191021 |
| PCD224-2 | BT224 (20 min) | PCDBI-2-RC (color change) | K191021 |
| PCD222-C | BT222 (1 h) | IT26-C (moving front) | K163646 |
| PCD222-2 | BT222 (1 h) | PCDBI-2-RC (color change) | K163646 |
| PCD220-C | BT220 (3 h) | IT26-C (moving front) | K163646 |
| PCD220-2 | BT220 (3 h) | PCDBI-2-RC (color change) | K163646 |
| PCD26-C | - | IT26-C (moving front) | K191021 |
| PCD26-2 | - | PCDBI-2-RC (color change) | K191021 |

Terragene recommends these PCDs as part of a kit consisting of 25 PCD + 25 BIs to be used as a positive control.

# Global standards, unmatched precision: FDA-cleared.

To monitor steam sterilization processes (sterilizers larger than 56,6 liters), ANSI/AAMI ST79:2017 recommends a PCD composed by a 16-towel system. This pack is considered the representative standard for the appropriate worst-case challenge for steam sterilization cycles. The design of the original test package was developed by Perkins in the 1960s and since then it has been evaluated and redesigned to allow users to assemble an appropriate challenge package with standardized materials readily available in healthcare facilities. Any commercially pre-assembled PCD that has demonstrated equivalence to the 16-towel PCD and is approved by the FDA can be used with the security of a more automated assembly that reduces errors or differences from a manually assembled package.

The package described in ANSI/AAMI ST79:2017 is composed of 16 surgical towels with average dimensions 42.2 x 66.8 cm. Before packing the towels, they must be "pre-conditioned" by leaving them for a minimum of 2 hours at 18-24°C and humidity above 35%. The BI and CI should be placed between towel 8 and 9 in the center of the package. In its entirety this device should weigh approximately 3 pounds (1.36kg) and the approximate density should be 0.176 kg/l. This system should not be wrapped by other material and should be adjusted with tape to a height of approximately 6 inches. ANSI/AAMI ST79:2017 recommends the use of any commercial PCD that demonstrates the same performance as the package described above.

According to ANSI/AAMI ST79:2017, routine monitoring should be performed in a loaded chamber. The PCD should be:
a) placed flat (layers of towels horizontal if the 16 towel PCD is being used, porous card horizontal if a commercial porous card system is being used) on the sterilizer cart, before the cart is loaded with other packs, in the area of the sterilizer chamber and load that is least favorable to sterilization (i.e., the area representing the greatest challenge to the BI).
b) placed so that it is not on top of or underneath a package or sideways on the sterilizer cart.

The sterilizer manufacturer should identify the exact location of the area least favorable to sterilization in the instruction manual and instruct users to place the test pack at this location. This area varies with sterilizer design, but is normally in the front, bottom section of the sterilizer, near the drain.

Moreover, each day that test BIs are run, at least one BI that is from the same lot and that has not been exposed to the sterilant should be incubated as a control.

The use of this type of device offers the advantage of early release according to the CI result within the PCD when non-implantable load is processed. Even in case of emergencies, ANSI/AAMI ST79:2017 enables the release of implantable loads only with the CI result.

For monitoring table top sterilizers (less than or equal to 2 cubic feet), no universally accepted standardized PCDs is described by ANSI/AAMI ST79:2017. Therefore, this recommended practice suggests that a representative package that is to be routinely processed through the sterilizer be used as the PCD. The 16-towels pack was not tested in these sterilizers because it doesn't fit in the chamber. Therefore, a commercial PCD with dimensions compatible with table top sterilizers and validated against the 16-towels pack offers the advantage of a well-known challenge suitable in a wider range of chamber volumes.

PCDs can also be used for qualification tests. During this test each type of cycle used should be tested. To perform qualification tests, a PCD runs on three empty cycles. As part of the qualification process, accepted results of the CI and BI within the PCD accompanied with measurement records must be recorded.

Terragene offers a complete line of PCDs that present a challenge equivalent to the test pack (16-towel PCD) described in ANSI/AAMI ST79:2017 and approved by the FDA for safe use in the healthcare sector.

**Regulated Precision**

Products cleared by FDA. Products present a challenge to the steam sterilization process equivalent to the user-assembled BI challenge test pack (16-towel PCD) described in ANSI/AAMI ST79:2017

**Error Reduction**

Automated systems eliminate human errors.

**Versatility**

Suitable for sterilizers of all sizes.


Maximize safety.
Optimize your process.
Trust Terragene.
Contact us today to learn more and transform your sterilization process.
Scan QR code for more information
Terragene®