

DIRECTIONS FOR USE



GKE Steri-Record® Helix-PCD Testset | Helix-PCDs

for validation and routine monitoring of sterilization processes



STEAM **FORM** **VH2O2**

Product | Art.-No.

200-017, 200-153, 200-510, 200-302, 200-154, 200-452, 200-303, 200-205, 200-304, 200-305, 200-405, 200-505, 200-605, 200-013, 200-150, 200-100, 200-075, 200-050, 200-025, 200-016, , 200-325, 200-350, 200-510, 200-425, 200-025, 200-450, 200-475, 200-525, 200-550, 200-575

Application

The GKE Steri-Record® process challenge devices (PCDs) and Testsets have been developed to test the penetration characteristics of the sterilization agent to ensure penetration inside hollow devices e.g. minimal invasive surgical (MIS) instruments and tubes. For a successful sterilization process the sterilizing agent must contact all inside and outside surfaces of the goods to be sterilized. Air and other non-condensable gases (NCG) must be removed from inside of hollow devices before they can be sterilized. Experience has demonstrated that most hollow devices and MIS instruments are more difficult to sterilize than porous loads (e.g. Bowie-Dick-Test).

Sterility inside hollow devices cannot be checked with parametric release and can only be correctly detected by using microbiological methods with direct inoculation. The results have to be checked in a microbiological laboratory after sterilization. This procedure is only meaningful for validation but not for routine monitoring. To circumvent direct inoculation alternatively a PCD can be used with biological or chemical indicators for steam, ethylene oxide, formaldehyde and hydrogen peroxide sterilization processes. The PCDs have different sensitivities and simulate simple solid instruments up to complex hollow devices.

The air removal and sterilant penetration characteristics in the PCD depends very much on the sterilizer and program used. For routine monitoring, the Helix-PCD should be selected which has just been successfully sterilized and is more difficult to sterilize than instruments. GKE offers various test sets for testing.

Information for formaldehyde sterilization processes:

The helix-PCD 200-150 can be used with a chemical indicator (213-202) as a Process Monitoring System (PMS). This PMS represents a test for heavily wrapped and hollow sterilization goods. The indicator has been tested under the following conditions:

15 gas pulses	between 53 and 200 mbar for 15 s each
Total plateau time	60 min
Evaporating solution	2% formaldehyde in water
Temperature	60 °C

There are various sterilization programs on the market. Before using the batch monitoring with other sterilization programs, validate the test using biological indicators. For sterilization cycles without pressure difference processes, the PCD may not be suitable because of insufficient gas penetration. In this case seal indicator in one or more pouches without using a PCD.

Information for hydrogen peroxide (plasma) sterilization processes:

The process monitoring system (PMS) for hydrogen peroxide (plasma) ensures that the H₂O₂ gas penetrates into the most difficult locations of the load. The air removal and hydrogen peroxide penetration conditions differ depending on the sterilization process used. Therefore, GKE does not offer a fixed combination of biological or chemical indicator strip and process challenge device (PCD) but the selection of the PCD depends on the effectiveness of the hydrogen peroxide/plasma sterilization process and on the requirements of the load. It must be secured that the selected PCD represents the most difficult penetration characteristics of the load.

For selecting the appropriate test device your local sales partner or the GKE laboratory may support you. After the right PCD is selected it can be ordered separately as a single PCD for routine monitoring together with biological or chemical indicators. In contrast to steam sterilization processes the penetration characteristics of H₂O₂ in hydrogen peroxide sterilization processes into tubes become less difficult if the diameter of the tubes increases. Tube diameters below 4 mm are extremely difficult to be sterilized in hydrogen peroxide sterilization processes. Since hydrogen peroxide/plasma sterilization processes are currently not standardized there are several different processes with different process parameters on the market. Therefore, it is recommended to validate a PMS once using biological indicators before routine monitoring with chemical indicators.

If the indicator is left close to any product which has been in a H₂O₂ sterilizer or even in the surrounding of the H₂O₂ chemicals, they are integrating the H₂O₂ and providing a pass overnight or over a longer period depending on the concentration. Therefore we recommend to keep the indicators always completely separate from H₂O₂ and insert the H₂O₂ indicators just before they are put in the sterilizer and be taken out immediately at the end of the sterilization process.

The GKE hydrogen peroxide chemical indicators change its colour from blue to green or red to yellow. Under the same process conditions biological indicators (Geob. Stearothermophilus 10⁶ CFU per strip) are inactivated. Since hydrogen peroxide/plasma sterilization processes are currently not standardized there are several different processes with different process parameters on the market. Therefore, it is recommended to validate a PMS once using biological indicators before routine monitoring with chemical indicators.

Product Description

The Helix-PCDs can be used in steam, formaldehyde and hydrogen peroxide sterilization processes. The GKE Steri-Record® PCD-Testsets contain different hollow test devices, consist of a tube with metal capsule, that can accommodate biological or chemical indicators with dimensions of 6 x 40 mm. The test devices are made of tubes with different lengths and inner diameters. Three different testsets are offered.

Operational Description (Testset)

The Testset is sterilized together with the load. At the end of the process the indicators are checked. As a result some PCDs show good penetration characteristics while some more demanding PCDs indicate fail conditions. The PCD that has passed with the highest hollow penetration resistance provides information about the best penetration characteristics of the process and may be used for routine monitoring. However it has to be demonstrated that this PCD has higher penetration characteristics than the load configuration. In case of doubt, validation according to DIN 58921 must be carried out.

The selected PCD is also available as single test device and can be used with the corresponding indicator strips for routine monitoring.

Performance Characteristics

The combination of a PCD and a biological or chemical indicator is a type 2 indicator system according to EN ISO 11140-1 consisting of a „specific test load“ (PCD) and „indicator“ (indicator strip). The Helix-PCD (Art.No. 200-150) is a hollow load test according to EN 867-5. This test has been validated by an accredited laboratory according to EN ISO 17025. For formaldehyde sterilization processes this test is described as the hollow load test in EN 14080, for steam sterilization processes in EN 13060 and EN 285.

Handling Information to select the appropriate PCD | for routine monitoring with the selected PCD

1. Select the right biological or chemical indicator for the sterilization process used.
2. Open the caps of the PCD(s) and make sure the seal ring in the cap in each PCD is in good condition.
3. If using chemical indicators, take out indicator strip from the card, number it with the PCD number and fold it that the indicator bars are inside and place it in the white holder with the fold toward the screw cap.
- 3a. Alternatively biological indicator strips but no self-contained biological indicators may be used. The strips have to be taken out of the glassine envelope. The PCDs are designed for standard spore strips of dimensions of 38 or 40 mm x 6 mm. The septic loading of the biological indicator is non-critical. (It is much easier to sterilize the germs of your fingers than the test germs on the strips.) It is recommended to pack the PCD into a sterilization pouch to prevent re-contamination by means of the tube after sterilization, if the biological indicators are not developed within one day.
4. Insert the white indicator holders into the PCDs and tighten the caps.
5. Place test devices close to the bottom and near the door of the chamber on a small stainless steel tray. The PCD does not require to be put into a pack, pouch or container.
6. Run the sterilization program.
7. On completion of the cycle remove the test devices carefully.
8. After cooling down, remove one chemical indicator strip after the other and adhere them onto the documentation evaluation sheet related to the PCD of the right number (available as download <https://www.gke.eu/en/testsets-templates.html>). Check the result:
 - If all four bars have turned to its final colour the sterilization process has been successful.
 - If one or more bars remain the original colour or have not turned to its final colour this indicates insufficient air removal and penetration.
9. At the end of the process condensate droplets may remain in the PCD. In this case open the test device when it is still warm, blow air through and leave it open for drying.
10. The person authorized will decide whether to release the batch or to re-sterilize the load.
11. If biological indicators are used, do not open the PCD and bring the PCD to a microbiological laboratory. The biological indicators have to be taken out aseptically and should be transferred in glass tubes with growth media. The glass tubes need to be marked with the numbers of the PCDs. After incubation record the result in the documentation sheet.

12. Select the PCD with the highest number that has been successfully penetrated. This PCD can be used for routine monitoring only if the PCD has higher penetration characteristics than the most difficult instrument in the load. In case of doubt the procedure in the standard DIN 58921 should be applied to validate the PCD against the load.
13. The indicator is self-adhesive and can be adhered onto the GKE documentation sheet with date, sterilizer and batch number and the signature of the person authorized to do so (see documentation information).

Maintenance Information for the PCDs

The Helix-PCDs can be used for more than 1.000 cycles. Make sure the silicon connector and the tube are in perfect condition. In the case of a blocked tube or leakage, replacement of the PCD is required.

Documentation Information

One documentation sheet (evaluation sheet) is included in each testset. The template is also available for download: <https://www.gke.eu/en/testsets-templates.html>

A documentation sheet for routine monitoring is available for download:

<https://www.gke.eu/en/documentation-system-video.html>. For each day and sterilizer one page is required. Adhere all the indicator strips and the BDS indicator strip for one day from the same sterilizer on the documentation sheet. To link batch monitoring and sterilized goods, GKE offers a documentation system with a label print device. The documentation label contains the date of production, expiry date, lot and content number as well as the user's initials. Those labels are placed on all sterile goods and also onto the documentation sheet. After using the sterile goods in the operating room the labels are removed and are placed onto the patient documentation sheet (all labels are double self-adhesive). This easy process offers a cost-effective documentation system for all sterilized goods used on a patient in the operation room. In case of a nosocomial infection the result of the used sterile instruments can be traced back. This procedure fulfils the requirements of quality standard EN ISO 13485 for batch related documentation.

Safety Precautions

1. In steam sterilizers batch monitoring systems are no replacements for the Bowie-Dick-Test to start with. The GKE-Bowie-Dick-Simulation test can be used.
2. This batch monitoring system does not replace the validation of the sterilization process after start-up, major repairs or changes of the load configuration (see EN ISO 17665-1, 11135-1, 25424 and 14937).
3. PCD and indicator strips are closely adjusted to achieve the required sensitivity. If the test device is used with other indicator strips, or GKE indicator strips are used with other test devices, GKE cannot guarantee proper results.

For further technical details please contact your local dealer or GKE directly. We will assist you with any technical questions. Also visit our website www.gke.eu for more information.

760-010 ED V01 03/2022