Helix-PCDs have been used for more than 20 years in standards for monitoring formaldehyde, ethylene oxide and steam sterilization processes. The Helix-PCD used today for steam sterilization processes is described in the European standard EN 867-5 (new: EN ISO 11140-6) as a hollow load helix test. It consists of a 1.5 m long PTFE tube with an inner diameter of 2 mm and an outer diameter of 3 mm and a capsule made of pure PTFE with a mass of 10 g, which has a free inner volume of 0.28 to 0.31 ml and whose cross-section must be uniformly distributed over a length of 4 cm in order to accommodate a standard biological indicator strip according to EN ISO 11138-3.

Helix-PCDs measure the presence of non-condensable gases (NCG) in steam. These gases may be present due to inadequate air removal or leakage, or they may enter the sterilizer together with the incoming steam.

In practice, the PCD described in the standard is only used for comparative measurements, since a capsule made of pure PTFE is not suitable for daily routine monitoring. The above-mentioned standard therefore defines that alternative PCD systems with other materials can be used, if the sensitivity of these PCDs is equal to the original, that the materials used are stable in the steam sterilization process and have no negative effect on the growth of biological indicators.

The sensitivity of a Helix-PCD depends on the materials used and the geometry of the tube and capsule.

These influences are described below:

1. Material properties of tube and capsule

a. Heat capacity and weight

The heat capacity of metals and different plastics can differ considerably. For example, polypropylene, which is often used for PCDs available on the market, has a heat capacity that differs by a factor of 2 from the PTFE (Teflon) PCD described in EN 867-5 (new: EN ISO 11140-6). There are other materials where these values differ by a factor of 10. Heat capacity and weight influence the amount of condensate that accumulates on the outer and inner surfaces of the PCD.

b. Thermal conductivity

The thermal conductivity of metal and plastics is extremely different (approx. factor 100). It influences the ratio of the condensation of steam on the surfaces of the capsule and tube in relation to the inner surfaces by a factor of up to 10.

c. Thermal and corrosion stability

The materials used in steam sterilization processes must be both thermally stable and corrosion-resistant. Many metals corrode and many plastics (not PTFE) are getting soft in steam sterilization processes at 134°C and lose their dimensional stability. As a result, there is a risk that the screw connection of the capsule will leak.

The Helix-PCD described in EN 14180 is only intended for formaldehyde sterilization processes and is made of polypropylene from most companies. It is therefore not suitable for steam sterilization processes due to insufficient thermal stability.

2. Geometric properties of PCD and indicator

a. Tube length

Tubes become more difficult to penetrate steam the longer they are.

b. Tube diameter

In contrast to the widespread belief that tubes of the same length with a larger diameter are easier to penetrate and sterilize, steam penetration of tubes of the same length and the same material with a small diameter is easier to penetrate than with large ones. This applies to tubes up to a diameter of approx. 10 mm and was published by Kaiser and Gömann in Central Service in 1998 ("Investigation of Air Removal from Hollow Devices in Steam Sterilization Processes"). The results can be verified by own tests by using the GKE Steri-Record® PCD testset, art. no. 200-017, consisting of 13 different Helix-PCDs with tubes of different lengths and diameters.

c. Combination of different lengths and tube diameters

GKE has patented a procedure in which different tube lengths and diameters are combined in one PCD. Therefore the sensitivity of the systems can be varied to a high degree and it is possible to design the PCDs suitable for the application and to avoid the mechanical sensitivity of plastic tube models.

d. Volume of the indicator capsule

The volume of the indicator capsule influences the sensitivity of the helix system even more than the above-mentioned tube dimensions. Indicator capsules with a small volume can therefore be filled with even minimal amounts of NCG, whereas the same amount of NCG in a large-volume capsule does not result in a measurable filling quantity. Thus the sensitivity of a PCD system can be massively influenced.

The free capsule volume is calculated from the empty volume of the capsule minus the volume of the indicator holder and minus the volume of the indicator itself. The indicator volume itself cannot be calculated by the dimensions of the indicator strip alone, but is highly dependent on the porosity of the indicator holder. Filter paper, for example, has an internal pore volume of approx. 40 - 50%, which must be added to the total volume. This means that the free capsule volume changes significantly when indicators with different carrier materials are used.

There are PCDs on the market with a capsule volume of more than 12 ml to which a 1 m long PTFE tube is connected. This large capsule volume allows the tube to be penetrated in overpressure cycles in sterilization processes without a vacuum pump. If the tube would be sterilized in the same process without this capsule, air removal and therefore steam sterilization inside the tube would not be possible. The large capsule volume acts as an "air pump".

In order not to falsify the air removal characteristics of a tube, the free diameter of the indicator capsule must be equal to or smaller than the free diameter of the connected tube. If the capsule volume is larger, the air removal and steam penetration of the system is simplified and therefore falsifying the test result.

e. Diameter and length of the indicator capsule

The geometric properties of the indicator capsule, i.e. diameter and length, influence the progress of air removal and steam penetration, which can be showed by chemical indicators with several indicator bars. This enables a graduated result of the quality of air removal and steam penetration.

f. Design of the indicator strip

Since the closed end of the indicator capsule is most difficult to penetrate, the sensitivity can be varied considerably by positioning the chemical indicator bar differently. There are indicators on the market that only have an indicator bar in the middle area and are therefore blind for NCG at the end of the capsule. Other indicators have an indicator dot which is outside the middle of the indicator strip. Depending on how the indicator is positioned in the capsule, the sensitivity of the entire test system can be manipulated either consciously or unconsciously. Indicator strips that have several bars along the entire length of the carrier are most suitable because they provide graduated information about air removal and steam penetration.

3. Characteristics of the indicator substrate

Type 5 and 6 indicators according to EN ISO 11140-1 must detect the critical parameters temperature, time and the presence of condensate. The standard does not require type 5 and 6 indicators to detect NCG in steam. The indicators are only additionally tested in dry heat to indicate the complete absence of steam. In practice, the capsule of a PCD contains neither pure steam nor NCG, but always a mixture of both. Such a mixture is technically defined by the partial pressures of all gases. The detection characteristics for these gas mixtures are not specified in the above-mentioned standard and vary greatly depending which chemical components of the indicator substrate are used for detection. Therefore the sensitivity of the Helix system is heavily influenced by the chemistry of the chemical indicator. If indicator strips from different manufacturers are used in a helix system, this will result in different sensitivities of the entire system. Therefore type 5 or 6 indicators cannot be used in Helix-PCDs. For such a test, the specification resulting from the combination of PCD (e.g. Helix) and indicator used is always relevant. According to EN ISO 11140-1 such a combination is a type 2 indicator system. These type 2 indicator systems may also have the characteristics of a type 5 or 6 indicator, but type 5 or 6 indicators cannot detect NCG.

4. Comparison of the original PTFE helix system with alternative helix systems developed for routine monitoring

In order to prove the comparability of a so-called Bowie Dick simulation test with the original Bowie-Dick cotton pack, EN ISO 11140-4 requires the use of a special test sterilizer and describes a test method which ensures that the simulation test and the original Bowie Dick test have the same sensitivity.

The requirements of this standard are also used to compare alternative helix tests with the original PTFE helix system. Only with such a test sterilizer the required highly precise reproducible results be provided. This requires a huge effort of testing. Since the alternative helix test systems have different materials and different geometric dimensions, they must be adapted to have the same characteristics as the original. For this purpose, the manufacturer must consult a test laboratory, which issues a corresponding test report and a certificate of conformity.