To assure sterility in steam sterilization processes it is necessary to monitor besides the physical data (pressure, temperature, time) which are recorded by the sterilizer itself, also the variables “air removal” and “steam penetration”. The last variables are not detected, if only temperature and pressure are recorded. Special test systems consisting of a process challenge device (PCD) and a suitable indicator strip can monitor air removal and steam penetration. The combination of both is a type 2 indicator system according EN ISO 11140-1.

One of the oldest PCD constructions is the so-called Helix-PCD consisting of a dead-end tube connected with a capsule. This capsule is provided with a screw cap to be able to insert an indicator strip into the PCD. After the screw cap is closed, the indicator is located at the place farthest away from the tube opening and is therefore most difficult to sterilize within the PCD.

The first Helix-PCD has been developed 30 years ago to monitor formaldehyde (FO) sterilization processes. FO sterilization processes use temperatures between 60°C and 80°C. The PCDs require a much lower thermal stability of 80°C only in comparison to steam sterilization processes which must be stable up to 134°C.

There are Helix-PCDs on the market which have been designed for FO processes but used in steam sterilization processes and are originally not designed for temperatures up to 140°C. Anyway, these helix PCDs are offered for steam sterilization processes because only the tube dimensions, but not the other material properties, are considered when testing the PCD.

GKE develops and produces PCDs for monitoring of various sterilization processes for more than 20 years. For steam sterilization processes GKE uses stainless steel capsules which seal and remain stable under high temperature conditions. In comparison to polypropylene capsules GKE PCDs don’t need to be exchanged producing reproducible results for a high number of cycles.

The following table provides an overview of the materials used in PCDs:

Table 1: Characteristics of materials used PCDs

PCD	GKE Compact-PCD® Inside material	GKE Compact-PCD® Outside casing	Original Helix-PCD according EN 867-5 (new: EN ISO 11140-6)	plastic Helix-PCD, e.g. for FO sterilization
Material	Stainless steel V4A	Plastic material, highly thermo resistant	PTFE Polytetrafluoro-ethylene	PP Polypropylene
Application	Hollow device construction and screw cap in all GKE Compact-PCDs	GKE PCD outside casing	PCD according to standard, indicator pin and tubes of GKE PCDs	Test capsule of Helix-PCD models for low temperature (e.g. FO) processes
Melting temp. ISO 11357	1.500°C	175°C	327°C	163°C
Max. temp. temporary	800°C	160°C	300°C	140°C Softening at approx. 120-135°C
Max. temp. permanently	> 450°C	150°C	260°C	100°C
Spec. density at 20°C	7,9 g/cm³	1,78 g/cm³	2,16 g/cm³	0,905 g/cm³
specific gravity g/ml	(much) heavier than water	heavier than water	heavier than water	lighter than water
Colour	silver	can be colorized, e.g. blue for GKE BDS Test	white	transparent or colorized, fades yellowish
Application (no of cycles)	routine monitoring min. 10.000 cycles		only for laboratory equivalent tests used	routine monitoring 100 – 400 cycles

This overview demonstrates that many of the Helix-PCDs on the market made of PP are only suitable to be used in processes with comparatively low temperature, e.g. in FO sterilization processes. Unfortunately such PCDs are also offered to be used in steam sterilization processes. These PCDs which are only limited or not suitable for steam sterilization are lighter than water (they float) and the material deforms, changing its internal volume just after a few cycles. If the PCD floats in water, it is mostly made of PP and not suitable for steam sterilization processes.

More critical than the optical change is the risk that after a short period the screw cap does not seal anymore because the material has deformed, and therefore the steam does not enter through the tube but directly through the (leaky) screw cap into the indicator capsule. Also the deformation can change the inner capsule volume so that the sensitivity of the PCD

can be changed. With such a PCD a reasonable test result concerning air removal and steam penetration is not possible anymore. Therefore the standard EN 867-5 (new: EN ISO 11140-6) describing the requirements on a Helix-PCD contains a description of a special test to check the leak tightness, see TI 730-091 EN.