

<i>gke</i> - Technical Information	730-097-EN	
Material Characteristics of Process Challenge Devices (PCDs)	Version 03	
	Created	29.10.2009 JM
	Changed	17.07.2017 UK
	Checked	17.07.2017 UK
	Released	17.07.2017 UK
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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 such high temperatures. Therefore the standard for the helix system EN 867-5 requests a seal test at 134°C. Under such high temperatures polypropylene capsules may deform and loose their seal properties and volume dimensions.

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:

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Table 1: Characteristics of materials used PCDs

PCD	<i>gke</i> Compact-PCD		Original Helix-PCD according EN 867-5	plastic Helix-PCD, e.g. for FO sterilization
	Inside material	Outside casing		
Material	Stainless steel V4A	Plastic material, highly thermo resistant	PTFE Polytetrafluoro- ethylene	PP Polypropylene
Application	Hollow device construction and screw cap in all <i>gke</i> Compact-PCDs	<i>gke</i> PCD outside casing	PCD according to standard, indicator pin and tubes of <i>gke</i> 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/cm ³	1,78 g/cm ³	2,16 g/cm ³	0,905 g/cm ³
specific gravity g/ml	(much) heavier than water	heavier than water	heavier than water	lighter than water
Colour	silver	can be colourized, e.g. blue for <i>gke</i> -BDS Test	white	transparent or colourized, 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 describing the requirements on a Helix-PCD contains a description of a special test to check the leak tightness, see ***gke*** TI 730-091 EN.