

<i>gke</i> – Technical Information	TI 730-076-EN	
Influence of indicator capsule construction on the sensitivity of Helix-PCDs	Version 01	
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Helix Process Challenge Devices (Helix-PCDs) consist of a tube, which is at one end closed with a capsule hosting a chemical indicator. The sensitivity to detect insufficient air removal, leaks or non condensable gases (NCG) in steam depends besides the material on all geometric dimensions of the test system:

### 1. Tube length

Tubes become more difficult to penetrate steam the longer they are. One end closed tubes are almost equal to penetrate as tubes at double length with both ends open.

### 2. Tube diameter

In contrast to what most of experts believe, tubes at the same length become more difficult to penetrate when the diameter increases (a 1 mm diameter tube is much easier to penetrate than an 8 mm diameter tube of the same material and length). The scientific background of this phenomenon is described in the publication of U. Kaiser and J. Gömann: "Investigation of Air Removal from Hollow Devices in Steam Sterilization Processes" of 1998 and in the publication of D. Kaiser: "A Quantitative Description of Air Removal from Hollow Devices in Steam Sterilization Processes" of 2006, both published in CentralSterilization.

This phenomenon can be reproduced using the *gke-Steri-Record*<sup>®</sup> PCD-Test-Set-D-10 containing 10 different Helix-PCDs with different length and diameter.

### 3. Volume, diameter and length of the internal indicator capsule area

The capsule at the end of a tube should not modify the sterilant penetration characteristic of a tube in front. The square root of the capsule area should be equal or less of the tube square root to minimize the influence of the capsule itself. If the capsule square root is larger than the tube diameter, the sterilant penetration becomes less difficult.

#### a) Influence of air removal

Air in large capsule volumes is compressible and decompressible during pressure changes and allow a quite simple air removal inside capsule and tube, if a large capsule volume and tiny tube volume is combined. It is possible that a tube without indicator capsule will not be penetrated while the same tube with a big capsule volume at the end will be easily penetrated.

A Helix-PCD construction with indicator capsule volumes of 10 ml and more is absolutely unusable to monitor the penetration inside of tubes.

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**b) Influence to measure non condensable gases (NCG)**

The larger the volume of an indicator capsule is, where a chemical indicator is hosted inside, the more NCG volume is necessary to fill the capsule. As a consequence the sensitivity of a Helix-PCD is increasing the lower the free capsule volume is. In those areas of the capsule volume where NCG are present, the indicator will not change. When minimal invasive surgical (MIS) instruments are sterilized, it is very important that Helix-PCDs used as Batch Monitoring Systems (BMS) can determine small amounts of NCG.

**c) Graduated response**

The longer the area of the free capsule volume is, which is filled with a chemical indicator strip, the better is the graduated response, if NCG are present in the capsule. It is important that the indicator strip is covered all over the length with indicator substrate to detect NCG in different regions of the capsule.

**4. Sensitivity of a Helix System depending on the positioning of the indicator strip**

Inside the capsule of a Helix-PCD NCG are most likely present close to the end of a tube or at the end of a capsule volume. Therefore the indicator strip has to be designed in such a way that the indicator substrate is positioned at the worst-case penetration location at the end of the capsule.

Test systems on the market where the indicator substrate is in the middle area of the capsule and is not distributed to the end of the capsule, are blind for NCG at the worst case penetration location.

All *gke* PCD test systems have a graduated response over the whole volume of the capsule. Depending on the indicator colour change in each segment of the indicator the amount of NCG can be determined.