Keywords
- sterilisation
- chemical indicator
- process challenge decive system
- PCD

ZENTRAL STERILISATION

Which Chemical Indicators Should be Used in a Process Challenge Device System (PCD)?

U. Kaiser

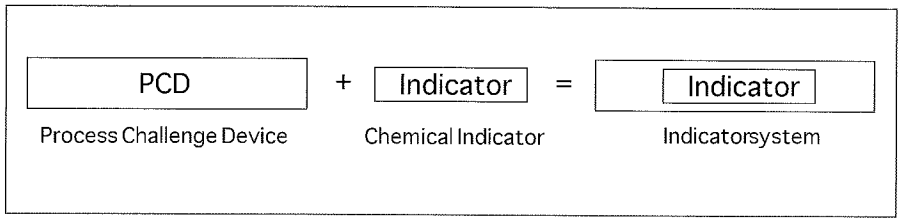

Fig. 1

Chemical indicator systems consisting of a Process Challenge Device (PCD) with an indicator inside are always calibrated with an especially selected indicator (Fig. 1).

In the event of non-availability of the original indicator strip the validation has been carried out with, is it possible to use any other Class D or Class 5 or 6 integrating indicator?

The sensitivity of a PCD depends on various factors. One is the free effective capsule volume determined by the capsule volume minus the volume of the indicator. The volume of the chemical indicator (CI) does not depend only on its outside dimensions, but also on the porosity of the carrier of the CI. For a user it is very difficult to produce another CI with exactly the same inner volume. Small volume differences of only 20 – 30 µl may heavily influence the indicator system's sensitivity.

However, more important is the CI-substrate-specification. A class 5 or 6 indicator has to show the critical parameters for a steam sterilization process according to EN-ISO 11140-1: temperature, time and water (created by condensation). A class 5 or 6 indicator and a class 2 indicator may have identical stated values (SV) referring to the parameters above defined in the standard. However, inside a PCD there is never steam or water or non-condensable gas (NCG) alone. In reality, there is always a mixture of gases, there may even occur a colour change of a CI or a total kill of a biological indicator (BI) within these mixtures. The so called partial pressure of NCG and steam influences the colour changing behaviour of a CI and is different for all CIs made by different manufacturers. The colour change characteristic is influenced by the partial pressure of steam and NCG but is not defined in any standard. As a consequence the change of a CI substrate will change the sensitivity of a PCD system, even if all hardware PCD components and the SV remain unchanged.

Even if exactly the same PCD is used with different CIs, remarkable sensitivity changes are observed, already reported by several publications (1–4). Therefore a class 2 indicator system, consisting of a PCD and a CI inside, should always be calibrated and used with the originally calibrated components. The new development of Medical Device Simulators (MDS) and Batch Monitoring Systems (BMS) for which standards are currently under development, take these phenomena into consideration. ✦

Literatur

1. A.C.P. de Bruijn, A.W. van Drongelen: Performance Evaluation of Hospital Steam Sterilizers Using the European Helix Test. Zentr Steril 2005;1: 26–33.
2. U. Kaiser: Value of chemical Indicators of class 6 according to the standard draft ISO-EN/CD 11140-1 for the monitoring of steam sterilization processes. Zentr Steril 2004; 6: 395–396.
3. U. Kaiser: Simple Method to Assess Efficacy of Sterilisation Processes for Hollow Instruments. Zentr Steril 1999; 6: 393–395.
4. D. Kaiser, U. Kaiser, H. Vogel: A Quantitative Description of Air Removal from Hollow Devices in Steam Sterilization Processes. Zentr Steril 2006; 4: 282–288.

* Dr. Ulrich Kaiser, gke-GmbH, Auf der Lind 10, 65529 Waldems, Germany; E-mail: office@gke.de