To guarantee sterilization of porous goods, solid instruments and hollow devices, like tubes and endoscopes, test devices are used. These test devices are called “Process Challenge Devices” (PCD) and are used in many standards today. To simulate cotton packs, paper packs are used. In sterilization processes working with sterilization gases, PCDs show, if the sterilization gas penetrates the most difficult location of the instruments to be sterilized. To secure the gas penetration of the PCD chemical or biological indicators are used to monitor the presence of the sterilizing agent at the most difficult location. Such a PCD with an indicator inside is called “type 2 indicator system” according to the standard EN ISO 11140-1 and checks in addition to the critical variables all penetration characteristics of a sterilization process.

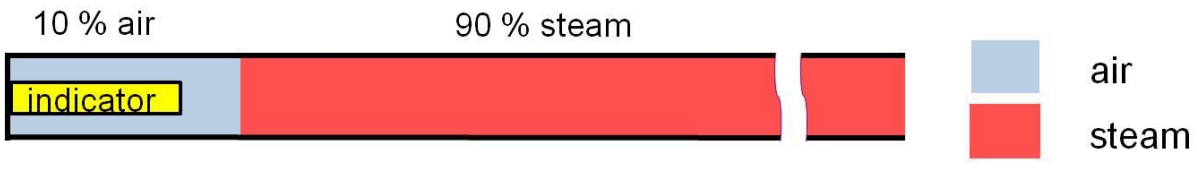
In steam sterilization processes before steam injection all remaining air in the sterilizer, the instruments and/or PCDs has to be removed. Air removal is carried out using pressure difference air removal processes. If steam/air mixtures are present, there is a high risk that steam condenses inside of lumen instruments and the remaining air is blocking steam penetration at locations most difficult to reach.

In tubes or endoscopes the most difficult air removal location is in the geometrical center, but there is no capsule hosting indicators.

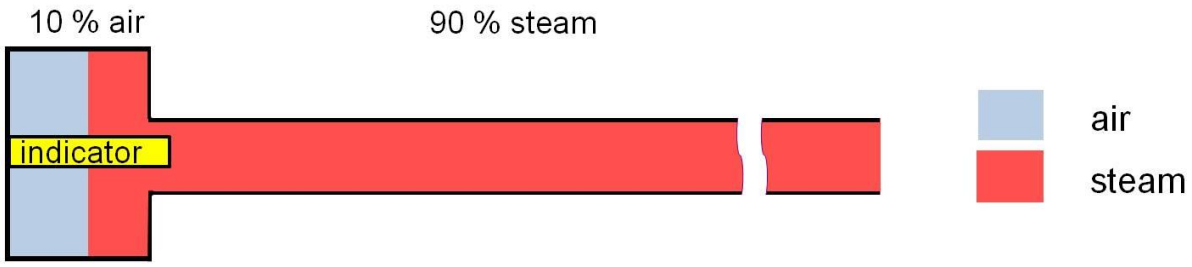
Since it is very difficult to place indicators in the geometrical center of tubes, in the European standard EN 867-5 (new: EN ISO 11140-6) the tube has been cut in the middle and closed. The closed end has the same penetration characteristics as in the middle of a tube both ends open, with the advantage that biological or chemical indicators can be inserted at the end closed with a cap.

For hollow devices a PCD „Hollow load“ has been defined in the above standard which consists of a 1,5 m Teflon tube with 2 mm diameter, closed at one end. The closed end is most difficult to penetrate with steam. A biological or chemical indicator has to prove there, that steam penetrates the most difficult location at the end.

It is absolutely important that at the indicator location the volume and free cross-section conforms with the cross-section of the PCD tube, otherwise during pressure changes for air removal, carried out in steam sterilization processes, steam could easily get into the capsule without a guarantee that an instrument simulated by the PCD has been penetrated.



If the capsule at the end has a larger cross-section and volume than the test tube at the same length, with a single pressure change steam can get into the test capsule and pretend a good penetration result, since in reality tubes or instruments don't have such volume expansions in the middle where the location is most difficult to sterilize.

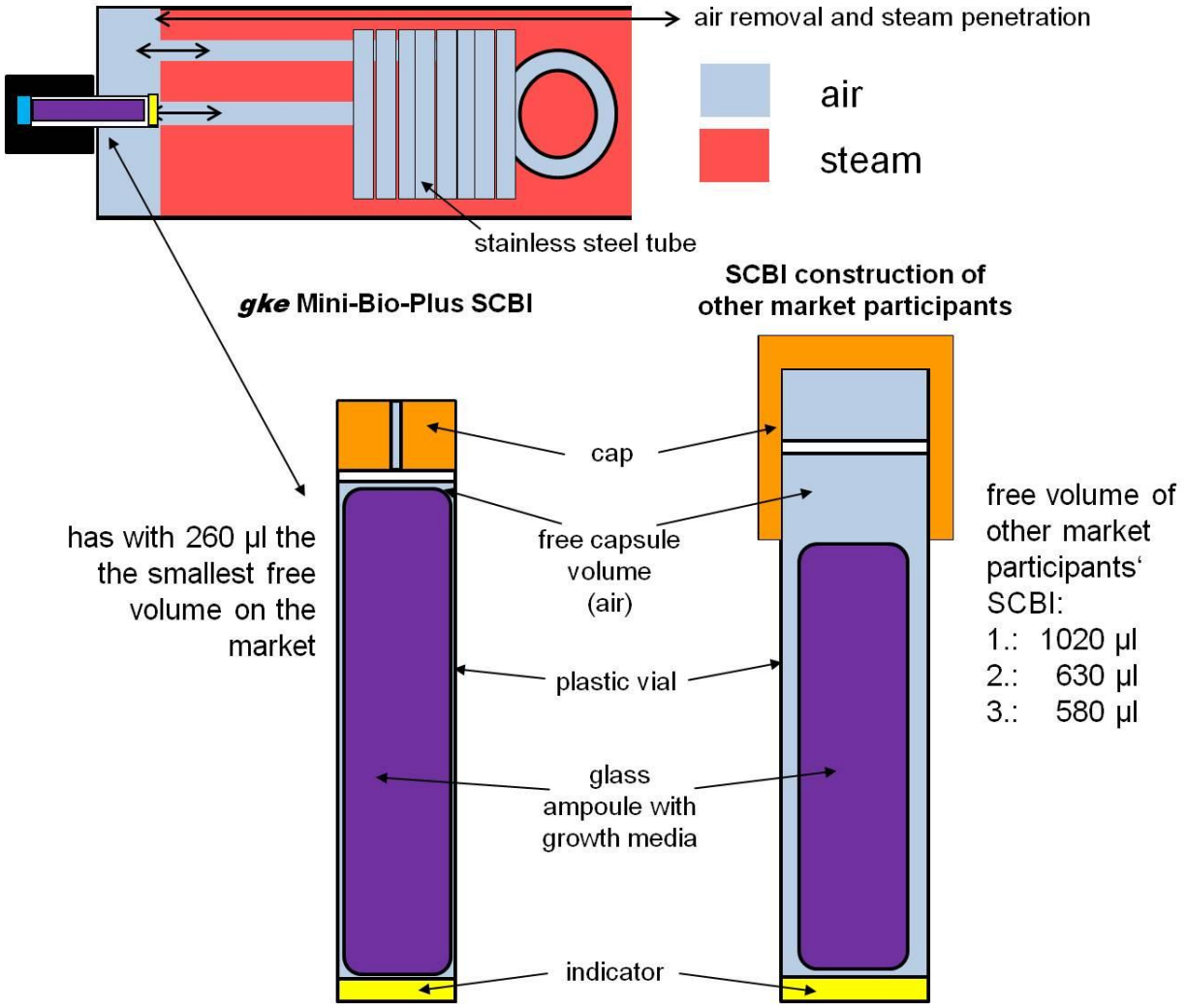


Unfortunately the above described basic conditions resulting from the gas law are often disregarded in PCDs sold in the market, where the cross-section of the capsule is a multiple of the PCD cross-section and therefore providing too easy penetration results and is not in accordance with tubes of the same length and diameter in reality and are therefore considered as dangerous.

The reference indicator in the above described standard contains a biological indicator strip according to EN ISO 11138-1 and -3 for steam sterilization processes. The disadvantage of this test method is that the PCD must not be opened after the sterilization process, but to be sent to a microbiological laboratory to be opened there under aseptic conditions and incubated to determine if the spores are inactivated. This procedure is time-consuming and cost-intensive.

To check the result of biological indicators faster, industry has developed so-called self-contained biological indicators (SCBI), which allow testing of the biological indicator locally in an incubator without using a microbiological laboratory. Unfortunately the SCBIs available on the market cannot be used in PCDs because their internal volume is too large which would falsify the results similar as described above.

To use SCBIs in such PCDs, GKE has developed an SCBI with minimal internal volume and has drastically reduced the whole PCD and SCBI volume (see below drawing). GKE offers 5 different PCD versions (GKE Steri-Record® Bio-C-PCD®s), which can be used with biological indicators for steam, hydrogen peroxide, formaldehyde and ethylene oxide sterilization processes. The Bio-PCD no. 4 with the GKE Steri-Record® Stearo-Mini-Bio-Plus conforms with the PCD "Hollow Load" according EN 867-5 (neu: EN ISO 11140-6). The GKE SCBIs are currently the only SCBIs worldwide on the market which can be used for this application because of their minimized volume. The PCD has been developed according to a patented procedure using a large volume at the open end and a small volume at the closed end, causing a higher sensitivity. The principle of the Bio-PCD construction is shown in the following drawing:


air removal and steam penetration
air
steam
stainless steel tube
gke Mini-Bio-Plus SCBI
SCBI construction of other market participants
has with 260 µl the the smallest free volume on the market
cap
free capsule volume (air)
plastic vial
glass ampoule with growth media
indicator
free volume of other market participants' SCBI:
1.: 1020 µl
2.: 630 µl
3.: 580 µl