



USER MANUAL

Helisafe® Plus

Compact PCD for use in small sterilizers according to DIN EN 13060 type B
and steam sterilizers according to DIN EN 285

Area of application

The application extends to steam sterilizers of the standards DIN EN 285 and DIN EN 13060 type B. In accordance with the recommendations of the Robert Koch Institute, each sterilization batch must be tested using the batch control system as a process control. According to the DGSV recommendations, steam sterilization at 134 °C should be given preference over sterilization at 121 °C due to its low dependence on influencing factors.

The Helisafe® Plus is supplied with 400 indicators.

Specification

The indicator only changes color from ochre to gray-brown to black depending on time and temperature when exposed to saturated steam.

134 °C



Dry heat does not discolor the indicator, so there is no falsification of the result.

The indicators are available as a block of 25 pre-punched strips.

Fitting the helix test specimen

The indicator holder capsule is removed from the Helisafe® Plus by turning it half a turn to the left. An indicator is folded together at the center crease with the printed side facing inwards and pushed into the gap with the crease in front. The test specimen is screwed together and placed next to the items to be sterilized near the door and in the lower part of the chamber.



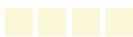





Gehäuse mit
PTFE Schlauch

Indikator

Indikator-
Aufnahmekapsel

Assessment of the indicator

At the end of the program, the indicator is removed from the test specimen and assessed for perfect colour change using the following table. The indicator is self-adhesive. For this purpose, the backing layer is removed at the punching and the indicator is glued into the batch control documents for verification.

Appearance of the indicator	Notes on the assessment
 evenly yellow	Indicators in the initial state
 uniformly black	Proper course of the sterilization process
 Color gradation light-dark	The gradient can occur in different color intensities. It occurs when the test specimen has not been completely vented. The amount of residual air leads to insufficient steam condensation, which is indicated by a color gradient on the indicator. This can be caused by leaks, insufficient venting, e.g. incorrect program, or an excessive proportion of inert gases in the steam.
 uniformly gray	Die Restluftmenge führt zu einer unzureichenden Dampfkondensation, was durch einen Farbverlauf auf dem Indikator angezeigt wird.
 uniform yellow with a reddish tinge	Dies kann durch Undichtigkeiten, unzureichende Entlüftung, z.B. durch ein falsches Programm, oder einen zu hohen Anteil an Inertgasen im Dampf verursacht werden.
 Protective layer of the indicator fields has come loose	Moisture was present in the test specimen before or during venting. Possible causes may be that <ul style="list-style-type: none"> the test specimen is not completely dry, the sterilizer is not preheated or overloaded, the load has not been conditioned

Please note

To prevent the indicator from being unnecessarily affected by environmental influences, it should only be removed from the packaging immediately before use. The indicator blocks must be kept sealed in the pressure seal bag and not near a heat source, e.g. on the sterilizer.

Storage conditions

Temperature range 5 °C to 25 °C and 30 % to 60 % relative humidity.

