DIRECTIONS FOR USE

CLEANING STERILIZATION

for all GKE Steri-Record® Mini-Bio-Plus self-contained biological indicators (SCBI) for formaldehyde sterilization processes

FORM

Art.-No.*	Product code	Quantity/ pack	Pop.	Colour of cap	Sterilization process	Colour change of				Incubation temperature	Biological indicator spores
						Outside Type 1 Indicator on label		Liquid Growth Media in SCBIs after sterilization and incubation			
						before	after				
						Sterilization		sterile	non-sterile		
325-601	B-F-MBP-10-6	10	10^6	Yellow	Formaldehyde	Yellow	Brown	Purple (no change)	Yellow-green	55-60 °C	*G. stearothermophilus*
325-605		50									

Art.-No.*	Product Code	Quantity	Product description
224-002	I-C	1	Crusher for SCBI activation if no GKE Steri-Record® Incubator is used.

(*) To all article numbers a 3-digit alpha code is added. The additional letter code refers to the language and/or customized and plug version. It is only added on the outside label, the inside of the pack is identical to the article numbers on the above tables.

Application

The GKE Steri-Record® Mini-Bio-Plus self-contained biological indicators (SCBI) are used for validation and routine monitoring of formaldehyde sterilization processes. After sterilization the SCBIs can be incubated by the user without a microbiological laboratory. For routine monitoring the SCBI cannot be used inside packs or containers since no sterility information is available after opening the package or container. Therefore, the SCBIs shall be used inside a Process Challenge Device (PCD) as a type 2 indicator system according to EN ISO 11140-1 which has the required sensitivity to check the internal lumens of a minimal invasive surgical (MIS) instrument. Seven Bio-C-PCD®s with different air removal characteristics are available. The sensitivity of these Bio-C-PCD®s can be selected to simulate the load. The validation of the Bio-C-PCD® according to the load can be achieved by using the test method described in DIN 58921. For more information see data sheet/ directions for use (Bio-C-PCDs).

Product description

The GKE Steri-Record® Mini-Bio-Plus SCBI consists of a plastic vial with a minimized internal volume containing a biological indicator spore disc and a glass ampoule with a liquid growth medium and pH-indicator inside. For formaldehyde sterilization processes, filter paper is used as a carrier and closing filter below the cap. The label of the SCBI contains a chemical indicator according to EN ISO 11140-1 type 1 to check if the SCBI has been in a sterilization process.

Performance characteristics

All GKE biological indicators comply with the standard EN ISO 11138 series and meet the performance characteristics published in the current United States Pharmacopeia (USP) and European Pharmacopeia (EP). The specifications of population and D-value for each lot are documented in the certificate which is delivered in each package.

The SCBIs for Low Temperature Steam Formaldehyde (LTSF) sterilization processes contain in the growth medium substances, decomposing remaining absorbed formaldehyde, so that the pretreatment with Na_2SO_3 according to EN ISO 11138-5 is not required anymore and the results can be obtained much faster.

The incubation time has been optimized, so that Mini-Bio-Plus SCBIs can be fully interpreted quicker. The SCBIs do not contain additional enzymes and do not require fluorescent light incubators for evaluation. If the incubation time exceeds the recommended time, the colour of the media does not change back if SCBIs containing *G. Stearothermophilus* are used. As soon as a colour change to yellow occurred, the result is valid and has to be documented as growth. If the sterilization process is unable to kill the spores, in most cases the colour change will already occur within 5-8 hours.

Handling Information

If the SCBI is used inside a Bio-C-PCD®, please refer to the separate directions for use (DFU) for Bio-C-PCD®s.

1. Place the SCBI outside of the load inside a self-made or commercial PCD[1] representing the worst-load configuration, e.g. in a Bio-C-PCD® and run the sterilization process.
2. After sterilization remove the SCBI from the package or Bio-C-PCD®. Activate and incubate the SCBI for low temperature sterilization processes immediately after taking them out of the process, otherwise remaining absorbed sterilizing agent in the vial can inactivate the biological indicator after the sterilization process. Use the crusher in the middle of the aluminium block of the GKE incubator by inserting the SCBI and push it in sideward's direction to 2nd hole until the interior glass ampoule is broken. Do not crush the glass ampoule until the vial is at room temperature because the hot glass ampoule may burst the plastic vial. If no GKE incubator is used, activate the SCBI with the crusher (art. no. 224-002). The spore plate inside the SCBI must be moistened by the liquid.
3. Check the chemical type 1 indicator on the label for proper colour change (yellow → brown). If there is no colour change, the vial has been exchanged by accident or sterilization process did not occur. The chemical indicator is a process indicator, unable to determine a successful sterilization process.
4. After sterilization additionally mark, activate and incubate a non-sterilized SCBI of each SCBI batch (vitality test).
5. After activation incubate the sterilized SCBIs together with the non-sterilized SCBI with the cap upwards for 24 h at 55-60 °C (100% sterility assurance level). For 97% sterility assurance 16 h are sufficient unless other times are requested by local laws and guidelines. According to FDA a sterility assurance level of 97 % is sufficient, for a 100 % sterility assurance level a longer incubation time has to be considered.

[1] If the SCBI is used without a PCD, it cannot represent the load and is scientifically not recommended.

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6. Observation of growth:

   After 12 hours observe the colour change of the liquid growth media in the plastic vial hourly. If no colour change occurs after the incubation time the sterilization process has been successful. Any change in colour of the vials coming out from the sterilizer is indicative for alive organisms demonstrating non-successful sterilization processes. The colour change is listed in the table above. An incubation time beyond the mentioned incubation time does not increase the probability of sterility and is not necessary. If the vials are incubated longer, the liquid could dry out.

7. The previously marked vitality test shall change colour demonstrating growth after one day incubation time latest. If this test does not show colour change of the liquid growth media, the incubator has not been switched on or the SCBI batch has a malfunction. In this case the sterilization has to be repeated with a new biological indicator batch.

8. If any sterilized test vial shows a colour change, stop the tested sterilization process and repeat the test with a larger quantity of Mini-Bio-Plus vials. If the sterilization process fails again, the sterilization process was not successful. Then check the sterilizer for malfunctions. After repair check the sterilization process again with Mini-Bio-Plus SCBI.

9. Keep record of the results on the GKE documentation sheet (see documentation information) with time, date and batch number of the sterilization cycle, time and date of the incubation start and incubation duration with a result. Include name and signature of the responsible person.

Documentation Information

According to the specifications of MDR, the release must be documented in a way that compliance with all necessary release conditions can be proven. This requirement can be implemented by e.g. archiving the program data and the test results.

A documentation sheet is available for download:
https://www.gke.eu/en/documentation-system-video.html
(Documentation Sheet SCBIs Sterilization.pdf).

To link batch monitoring and sterilized goods, GKE offers a documentation system with a hand labelling device. The documentation label contains the date of production, expiry date, lot and content number as well as the user's initials. Those labels are placed on all sterile goods and also onto the documentation sheet. After using the sterile goods in the operating room the labels are removed and are placed onto the patient documentation sheet (all labels are double self-adhesive). This easy process offers a cost effective documentation system for all sterilized goods used on a patient in the operating room.

In case of a nosocomial infection the result of the used sterile instruments can be traced back. This procedure fulfils the requirements of the quality standard EN ISO 13485 for batch-oriented documentation.

Storage and Disposal

1. For longer periods store all Mini-Bio-Plus SCBIs in the original package between 5-30°C with a humidity of 5-80% RH and avoid exposure to light.

2. The vapour of chemicals especially hydrogen peroxide may change the chemical indicator on the label before or after sterilization. Therefore, do not store them together with other chemicals.

3. Sterilized vials may be disposed with normal waste.

Safety Precautions

1. The indicators shall not be used after expiry date.

2. Do not activate the SCBI by crushing the inner glass ampoule until the vial is at room temperature! The hot glass ampoule inside may burst the plastic vial and may leak during incubation.

3. Mini-Bio-Plus SCBI must not be used in dry heat sterilization processes. The glass ampoules explode and plastic vial will melt.

4. Bio-C-PCD® and Mini-Bio-Plus SCBIs are closely adjusted to achieve the required sensitivity of the type 2 indicator system. If the test device is used with other SCBIs or PCDs, GKE cannot guarantee proper results.

5. SCBIs are not able to check liquid sterilization processes. GKE Stearo-Ampoules should be used for this application.

For further technical details please contact your local dealer or the GKE application laboratory. We will assist you with any technical questions. Also visit our website www.gke.eu for more information.

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