DIRECTIONS FOR USE

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

VH2O2

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		Growth Media in SCBIs after sterilization and incubation			
						before	after				
						Sterilization		sterile	non-sterile		
327-601	B-V-G-MBP-10-6 (on glass fiber carrier)	10	10^6	Light grey	Hydrogen peroxide	Blue	Green	Purple	Yellow-green	55-60°C	*G. Stearothermophilus*
327-605		50									
327-610		100									
337-601	B-V-T-MBP-10-6 (on Tyvek® carrier)	10		White							
337-605		50									
347-601	B-V-ST-MBP-10-6 (on stainless steel carrier)	10		Dark grey							
347-605		50									
357-601	B-V-P-MBP-10-6 (on PET carrier)	10		Purple							
357-605		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 inside packs or containers for validation of hydrogen peroxide/plasma sterilization processes. After sterilization the SCBIs can be incubated by the user without a microbiological laboratory. SCBIs cannot be used inside packs for routine monitoring. For routine monitoring the SCBI shall be used inside a GKE Steri-Record® Bio-Compact Process Challenge Device (Bio-C-PCD®) as an indicator system 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 meet the requirement of 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.

There are various hydrogen peroxide/plasma sterilization processes on the market with different penetration and kill kinetics characteristics of the sterilization agent. Depending on the process used and on the load configuration an appropriate Bio-C-PCD® and H_2O_2-SCBI should be selected.

The resistance of an H_2O_2-SCBI heavily depends on the carrier used inside, even using exactly the same BI spore batch. Therefore, a carrier should be used which is also used for the instruments being sterilized.

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 growth medium and pH-indicator inside. 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.

The SCBIs are available with glass fiber, Tyvek®, stainless steel and PET carriers.

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 SCBI for hydrogen peroxide are supplied with different carriers with the consequence having completely different resistance characteristics by using identical *G. stearothermophilus* spores. The D-value that is tested under the defined sterilization conditions is described in the certificate which is included in each package. Since the resistance of the spore on Tyvek® is much higher it is a sign that the kill of the same germs in a hydrogen peroxide sterilization process depends not only on the process conditions of the sterilizer but also heavily on the material where the medical devices are made from. Therefore, it is recommended to use glass fiber for polar materials, e.g. stainless steel instruments and Tyvek® for non-polar plastic materials.

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 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

1. Place the SCBI outside of the load preferably inside a PCD representing the worst-load configuration ,e.g. in Bio-C-PCD®s and run the sterilization process. Please check that no glue residues from the SCBI label remain in the Bio-C-PCD®. Please use benzine for cleaning.
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. 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 (colour change see table above). To check sterilization success the biological indicator has to be incubated.
4. After sterilization additionally mark, activate and incubate a non-sterilized SCBI of each SCBI batch (vitality test).
5. After activation incubate the SCBIs together with a non-sterilized SCBI with the cap upwards at 55 - 60 °C for 48 hours (100% sterility assurance level) unless other times are requested by local laws and guidelines. According to FDA a sterility assurance level of 97 % is sufficient (30 hours incubation time).

   The European Pharmacopeia (EP) requires an incubation time of 7 days since alive but damaged spores need a longer time for growth. The GKE growth medium is optimized so that an incubation time of 7 days is not necessary. Currently a new standard will be published to measure the reduced incubation time (RIT).

6. Observation of growth:
   After 12 hours observe the colour change of the 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 is not necessary and does not increase the probability of sterility. Storage of the vial for documentation purposes does not make sense.
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 growth media, the incubator has not been switched on, the wrong incubation temperature is selected 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 or check if a wrong sterilization process has been selected. 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 the MDD and 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 ampoule may explode and the 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. If the open end of the Bio-C-PCD®s is not in lowest position during sterilization hot condensate may be collected inside and may come out of the Bio-C-PCD® during removal from the sterilizer burning your skin.
6. Do not open the mounting screw of the Bio-C-PCD®. An unscrewed Bio-C-PCD® cannot be reassembled and must be replaced by a new one.
7. 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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