STEAM

Instructions for Use

Instant-Mini-Bio-Plus SCBI for steam sterilization

1. Instant-Mini-Bio-Plus self-contained biological indicators (SCBI) for 121-124°C

Art.-No.	Product code	Quant. pack	Pop.	Cap Color	Color change						Incubation temp
					Type 5 Indicator inside SCBI			Outside Type 1 Indicators on label		Liquid growth media in SCBI after sterilization and incubation		
					before	after		before	after			
					Sterilization					Sterile	Non-sterile	
						Pass	Fail					
324-521	**B-S-MBP-I-10-5-SV5**	10	10^5	Light Green	Yellow	Blue	Yellow-Green	Blue	Brown	Purple (no change)	Yellow-green	55-60°C
324-525		50										
324-621	**B-S-MBP-I-10-6-SV5**	10	10^6	Dark Green								
324-625		50										

2. Instant-Mini-Bio-Plus self-contained biological indicators (SCBI) for 132-137 °C

Art.-No.	Product code	Quant. pack	Pop.	Cap Color	Color change						Incubation temp
					Type 5 Indicator inside SCBI			Outside Type 1 Indicators on label		Liquid growth media in SCBI after sterilization and incubation		
					before	after		before	after			
					Sterilization					Sterile	Non-sterile	
						Pass	Fail					
324-551	**B-S-MBP-I-10-5-SV4**	10	10^5	Light Orange	Yellow	Black	Yellow-Green	Blue	Brown	Purple (no change)	Yellow-green	55-60°C
324-555		50										
354-550		100										
324-651	**B-S-MBP-I-10-6-SV4**	10	10^6	Dark Orange								
324-655		50										
324-650		100										

Art.-No.	Product Code	Quantity	Product description
224-002	**I-C**	1	Crusher for SCBI activation if no GKE Incubator is used which already contains a crusher.

Application

The GKE Instant-Mini-Bio-Plus self-contained biological indicators (SCBI) are used for validation and routine monitoring of steam sterilization processes. The result can be observed instantly after the sterilization process checking the type 5 chemical indicator (CI) inside the SCBI. When the CI provides a pass result the load can be released. 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 GKE Bio-PCDs with different air removal characteristics are available. The sensitivity of these Bio-PCDs can be selected to simulate the load. The validation of the Bio-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

GKE offers two different Instant-SCBI depending on the temperature used (see table above).

1. 121-124 °C
2. 132-137 °C

The GKE Instant-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. It also contains a type 5 chemical indicator inside the vial allowing the result to be instantly evaluated at the end of the sterilization process. Therefore, it is not necessary to wait for the outcome of the SCBI incubation result since the type 5 indicator provides quicker information about the result of the steam sterilization process according to the above chemical indicator standard. The outside label of the SCBI contains a chemical indicator according to EN ISO 11140-1 type 1 to check if the SCBI has been in the correct sterilization process.

Performance characteristics

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

The incubation time has been optimized, so that Instant-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.

Both Instant-SCBI versions contain different type 5 indicators according to EN ISO 11140-1 inside the SCBI-vial. The indicator enables the user to interpret the result immediately at the end of the process. The specifications of the type 5 indicator are also included in the certificate in the package.

If the incubation time exceeds the recommended time, the colour of the media does not change back, as some conventional SCBI media do. 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

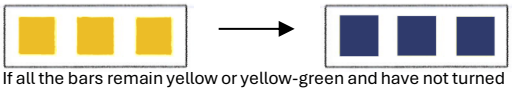
If the SCBI is used inside a GKE Bio-PCDs, please refer to the separate instructions for use (IFU) for Bio-PCDs.

1. Select the appropriate SCBI for the sterilization process used (121°C or 134°C).
2. Place the SCBI outside of a package inside a self-made or commercial PCD1 representing the worst-load configuration, e.g. in GKE Bio-PCDs and run the sterilization process.
3. After sterilization remove the SCBI from the Bio-C-PCD® or package. Cool SCBIs down at room temperature for 15 min.
4. Check the chemical type 1 indicator on the label for proper colour change (blue → 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.

5. Check the chemical type 5 indicator inside of the vial:

   For 121-124°C SCBIs:
   - If one single bar has turned to complete blue the sterilization process has been successful. Note that big amounts of condensate may influence the sensitive 121°C indicator colour negatively, so that some fields may occasionally not change colour completely. To avoid this, keep the SCBI upright during the process and make sure the SCBI has at least at room temperature before adding in the process.

     
   - If all the bars remain yellow or yellow-green and have not turned to blue, it indicates a potential failure of the sterilization process. In this case do not release the batch immediately but wait for the incubation result of the SCBI which still may be successful.

   For 132-137°C SCBIs:
   - If all three bars have turned to black the sterilization process has been successful.

     
   - If the bars remain yellow or brown and have not turned to black completely, it indicates a potential failure of the sterilization process. In this case do not release the batch immediately but wait for the incubation result of the SCBI which still may be successful.
6. In case the chemical indicator (see 5.) did not change to pass or due to load requirements the proof a of BI is required. For activation, use the crusher in the middle of the aluminium block of the GKE incubator by inserting the SCBI and push it in sidewards 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. If not moistened, gently shake the vial without moistening the sterile filter on top.
7. After sterilization additionally mark, activate and incubate a non-sterilized SCBI of each SCBI batch (vitality test).
8. After activation incubate the sterilized SCBIs together with the non-sterilized SCBI with the cap upwards at 55-60 °C according to EN ISO 11138-1. Based on the GKE performance test results, a reduced incubation period of 24 hours is sufficient for GKE-Steam-SCBIs. The validation 24h test report is available on request.
9. Observation of growth:
   After 12 hours observe the colour change of the growth media liquid in the plastic vial hourly. The vitality test should have already changed to yellow-green. If no colour change occurs after 24 hours the sterilization process has been successful. The colour change is listed in the tables on page 1. Any change in colour of the vials coming out from the sterilizer is indicative for alive organisms demonstrating non-successful sterilization processes. An incubation time beyond the mentioned incubation time is not necessary and does not increase the probability of sterility. If the vials are incubated longer than mentioned above, the liquid could dry out. The colour of the remaining crystals is still observable. If required, the incubation time can be extended by using para film to close the cap before incubation. However, this procedure is not necessary for routine operation. It is advised to incubate the vials no more than 5 days. Storage of the vial for documentation purposes does not make sense. **The end color of the type 5 indicator inside the SCBI will change to a less contrast after incubation. This does not change the result shown directly after sterilization.**
   It may be possible that the type 5 chemical indicator (CI) inside the vial shows a fail, but after incubation the biological indicator (BI) shows a pass later. This may happen, because the CI is more critical in detecting non-condensable gases inside the vial than the BI. Depending on the load configuration, solid loads can be released without risks, but hollow devices bear a risk if the air removal inside is not sufficient, and they are non-sterile inside the lumens.
10. 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 liquid, the incubator has not been switched on, the SCBI has not been activated or the SCBI batch has a malfunction. In this case the sterilization has to be repeated with a new biological indicator batch.
11. If any sterilized test vial shows a colour change of the growth media, do not release the tested sterilization process and repeat the test with a larger quantity of 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 Instant-Mini-Bio-Plus SCBI.
12. Keep record of the results 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. Also, the label on the SCBI itself can be removed and used for documentation.

Documentation Information

According to 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.

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

Storage and Disposal

1. For longer periods store all 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. SCBI must not be used in dry heat sterilization processes. The glass ampoules explode, and the plastic vial will melt.
4. Bio-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-healthcare.com for more information.

760-100 EN V05 07/2024