DIRECTIONS FOR USE

CLEANING STERILIZATION

STEAM

GKE Steri-Record® Mini-Bio-Plus Activation Control (AC) Instant-SCBI

Art.-No.*	Product code	Quantity/ pack	Pop.	Sterilization process (STEAM)	Colour of SCBI cap	Colour change of					Colour of liquid growth media		
						Type 5 Indicator inside SCBI			Outside Type 1 Indicator on label		before activation sterilization and incubation	after activation, sterilization and incubation	
						before	after		before	after			
						Sterilization							
							Pass	Fail				sterile	non-sterile
324-585	B-S-AC-MBP-I-10-5-SV4	50	10^5	132-134°C	Light orange	Yellow	Black	Yellow-Brown	Blue	Brown	Colourless	Purple	Yellow-green
324-580		100											
324-685	B-S-AC-MBP-I-10-6-SV4	50	10^6		Dark orange								
324-680		100											
324-535	B-S-AC-MBP-I-10-5-SV5	50	10^5	121-124°C	Light green	Yellow	Blue	Yellow-Green					
324-530		100											
324-635	B-S-AC-MBP-I-10-6-SV5	50	10^6		Dark green								
324-630		100											

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

Application

Activation Control (AC) Instant-SCBI (self-contained biological indicators) are used to monitor steam sterilization process efficacy allowing safe incubation and evaluation by the user without using a microbiological laboratory. The result can be observed instantly after the sterilization process by checking the type 5 chemical indicator (CI) inside the SCBI.

There is a common possible handling error to forget activation before incubation. This is particularly dangerous because it is impossible to discover this error visually. Non-activated and activated SCBIs nearly look alike. The **GKE Activation Control Instant-SCBI** is the first SCBI worldwide where non-activated and activated SCBIs are distinguishable by colour after incubation.

The SCBI contains a colourless growth medium which is only changing its colour after being crushed after sterilization in order to get the spores in contact with growth medium. **This is called "ACTIVATION".**

The activation becomes visible that the colourless growth medium gets in contact with the pH-indicator, changing the liquid in the ampoule purple indicating the activation.

The SCBI may be used as well inside a GKE Steri-Record® Process Challenge Device (Bio-C-PCD®) which is designed to represent the most demanding penetration conditions of the load. Different PCDs with different penetration sensitivities are available.

Product Description

The GKE Steri-Record® AC-Instant-SCBI consists of:

1. plastic vial and lid containing:
   - crushable colourless medium glass ampoule with TSB
   - inoculated spore disc *Geob. Stearothermophilus* with a population of 10^5 or 10^6 CFU/ampoule
   - pH-indicator (outside of glass ampoule).
2. type 1 chemical indicator outside on the label of the vial to check if the SCBI has been in a sterilization process.
3. type 5 chemical indicator inside the vial

Performance Characteristics

The GKE Steri-Record® AC-Instant-SCBI complies with the standard EN ISO 11138-1 + -3 for biological indicators and meets the performance characteristics published in the current United States and European Pharmacopeia. The specifications of population, D-value and z-value for each lot are documented in the certificate which is delivered in each package.

The AC-Instant-SCBI contain a type 1 indicator outside and different type 5 indicators (121/134°C) according to EN ISO 11140-1 inside the SCBI-vial. The indicator enables the user to interpret the sterilization result immediately at the end of the process. The specifications of the type 5 indicator are also included in the certificate in the package.

Handling Information

1. Place the AC-Instant-SCBI outside of the load inside a self-made or in a GKE Bio-C-PCD® representing the worst- case load configuration and run the sterilization process.
2. After sterilization remove the SCBI from the PCD package or Bio-C-PCD®. Cool SCBI down at room temperature for 15 min.
3. 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. However, the chemical indicator is a process indicator, unable to determine a successful sterilization process.
4. Check the chemical type 5 indicator inside of the SCBI vial:

   For 121-124°C SCBIs:

   - If all three bars have turned to blue, the sterilization process has been successful.

   

   - If the bars remain yellow or yellow-green and have not turned to blue completely, it indicates a potential failure of the sterilization process.

   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.

   To prove the result of the chemical indicator with the biological indicator, continue with 5.

5. **Activation of the AC-Instant-SCBI:**
   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 the 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. **After being activated, the liquid growth medium will change colour to purple.** 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 the SCBI is not activated, the growth medium remains colourless.
6. Vitality Test: After sterilization additionally mark, activate and incubate a non-sterilized SCBI of each SCBI batch.
7. Incubate the sterilized SCBIs together with the non-sterilized SCBI (6.) with the cap upwards at 55-60 °C according to EN ISO 11138-1.
8. Observation of growth: After 12 hours observe the colour change of the liquid growth media 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. Based on the GKE performance test results, a reduced incubation period of 24 hours is sufficient for GKE-Steam-SCBIs. The test report is available on request.
   Any change in colour of the growth medium inside 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. This procedure is not necessary for routine operation. It is advised to incubate the vials no more than 5 days. Storage of the vials for documentation purposes does not make sense.
9. 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 medium to yellow-green, the SCBI has not been activated (no colour of the liquid) or 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.
10. 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.

11. 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. 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.

Documentation sheets for SCBIs and AC-Instant-SCBIs are available for download:
https://www.gke.eu/en/documentation-system-video.html

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 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 Mini-Bio-Plus AC-SCBI® in the original package at 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, especially with hydrogen peroxide vapor coming from hydrogen peroxide sterilized goods.
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. All type of Mini-Bio-Plus SCBI must not be used in dry heat sterilization processes. The glass ampoules explode and the plastic vial will melt.
4. Bio-C-PCD® and AC-SCBI® 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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