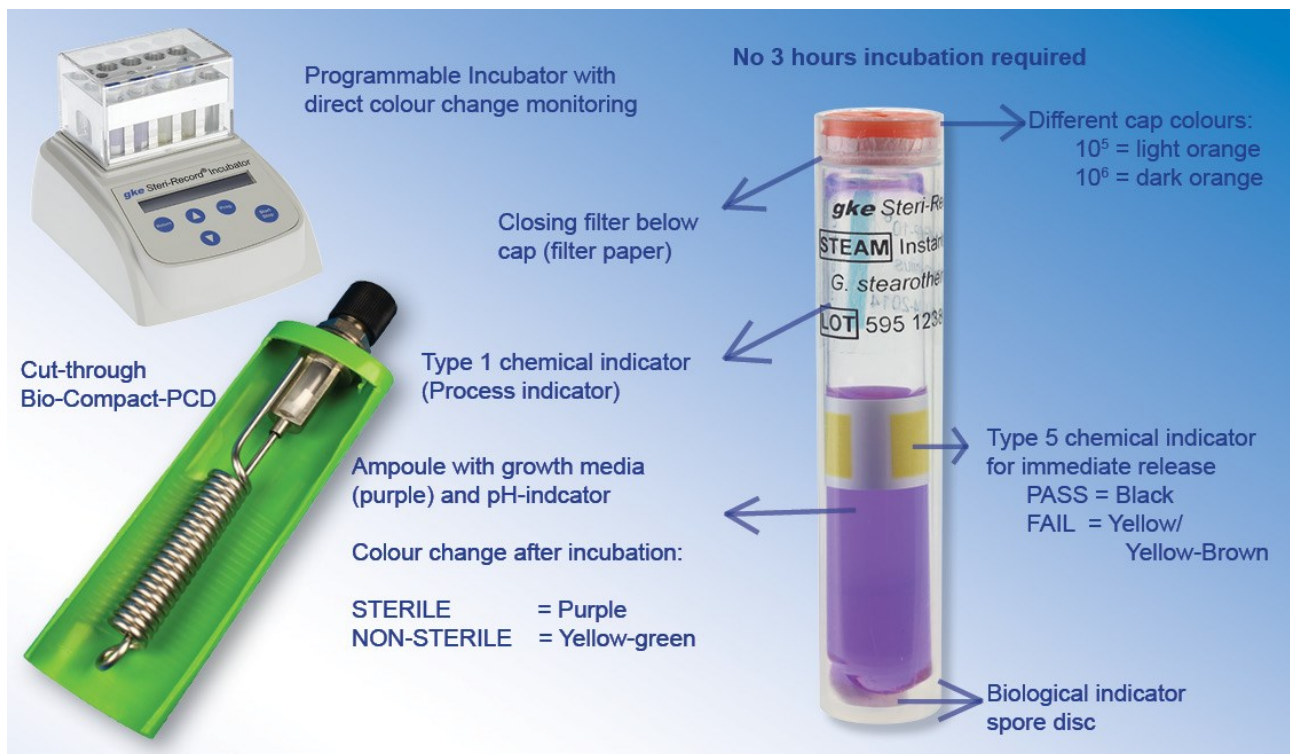


gke Steri-Record[®] Instant-Mini-Bio-Plus self-contained biological indicators (SCBI) for immediate release



Application

The *gke Steri-Record*[®] Instant-Mini-Bio-Plus self-contained biological indicators (SCBI) are used for validation and routine monitoring and allow an immediate release of the load in steam sterilization processes without having to wait for the result after incubation.

The Instant-Mini-Bio-Plus SCBIs can be used for routine monitoring inside packs or containers. They have also been designed to be used inside a *gke Steri-Record*[®] Bio-Compact Process Challenge Device (Bio-C-PCD[®]). Special adaptations have been made to the SCBI so it can be used together with a PCD as a type 2 indicator according to EN ISO 11140-1 which reaches 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. Depending on the process used and on the load configuration an appropriate Bio-C-PCD[®] should be selected.

Product Description

The *gke Steri-Record*[®] Instant-Mini-Bio-Plus SCBI uses a plastic vial with a minimized internal volume containing a biological indicator spore plate and a glass ampoule with a growth medium and pH-indicator inside.

The outside label of the SCBI contains a type 1 chemical indicator according to EN ISO 11140-1 to check, if the SCBI has been in a sterilization process.

The Instant-Mini-Bio-Plus SCBI also contains a type 5 chemical indicator inside the SCBI 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 since the type 5 indicator provides equivalent or better information about the result of the sterilization process according to the above chemical indicator standard.

The specially designed and patented *gke Steri-Record*[®] Bio-C-PCD[®] construction consists of a large initial internal volume with a stainless steel tube inside and a minimal capsule volume at the closed end. It can be used only with the specially designed Mini-Bio-Plus SCBIs as described before, to create a high sensitive Hollow Load PCD. Conventional SCBIs cannot be used because of the lower sensitivity for air removal and steam penetration inside the PCD.

For incubation of the Instant-Mini-Bio-Plus SCBIs **gke Steri-Record®** incubators with different versions are available (see separate data sheet).



gke Incubator

Performance Characteristics

Instant self-contained biological indicator:

The Instant-Mini-Bio-Plus SCBI complies with the standard EN ISO 11138-1 + 3 and meets the performance characteristics published in the current United States Pharmacopeia (USP) and European Pharmacopeia (EP).

The incubation time of the Instant-SCBIs has been optimized, so that they can be fully interpreted within 24 hours. The SCBIs do not contain additional enzymes and do not require fluorescent light for evaluation. Therefore, standard incubators can be used.

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.

Instant-SCBIs shall be used for steam processes of 132-137°C only and contain a type 5 indicator according to EN ISO 11140-1. The indicator enables the user to interpret the result immediately at the end of the process. The result of a type 5 indicator provides a much higher probability of sterility compared to the result of a SCBI incubation after 3 hours where the probability of < 99 % is achieved after this minimal incubation time only.

Special test systems using Bio-C-PCDs and **gke SCBIs inside:**

Bio-C-PCD®s with **gke** SCBIs inside can simulate porous loads and hollow devices simultaneously. A special Bio-C-PCD® to simulate the hollow load device described in EN 867-5 is available as well.

Additional Bio-C-PCD®s are available to simulate different load configurations and may be validated according to the test method described in DIN 58921.

Operational Description

The Instant-SCBI must be placed inside the most difficult penetration condition of packs or containers but in hollow devices like MIS instruments they cannot be placed inside. In this case a Bio-C-PCD® with an Instant-SCBI inside is used to simulate MIS instruments. This alternative offers for the first time the possibility to check sterility inside hollow instruments. Instant-SCBIs in PCDs can be directly evaluated with the result of the chemical type 5 indicator and incubated at the end of the cycle without having to open packs or containers.

After the sterilization process the Instant-SCBIs are taken out of the load or the Bio-C-PCD® and are activated by crushing the glass ampoule. After they are incubated according to the directions for use, the colour of the liquid will indicate a pass or fail of the sterilization process. If the colour has not changed, this indicates a pass of the process, a colour change indicates a fail.

Benefits

- First worldwide PCD-system (type 2 indicator) with a special internal volume design hosting the Instant-SCBI, which simulates hollow devices.
- Immediate release at the end of the steam sterilization process by checking the colour change of the type 5 chemical indicator with an increased probability of the result at the end of the process. In addition the proof of the biological indicator result will be available after incubation.
- Cost reduction using SCBIs with direct incubation by the user instead of using a microbiological laboratory.
- Instant-SCBIs can be incubated on completion of each cycle without having to open any packs or containers when used in Bio-C-PCD®s.
- Simple handling and traceability of test results.
- The labels on the SCBI are self-adhesive and can be removed for external documentation.
- The combination of Mini-Bio-Plus SCBI and specially designed Bio-C-PCD®s allows correct testing of hollow lumen instruments.
- Several Bio-C-PCD®s are available to simulate different loads.
- A special oval and round Bio-C-PCD design for use in small table-top or large sterilizers.
- Cost-effective due to multiple use of the Bio-C-PCD® without losing sensitivity. All important parts are made of stainless steel or thermal resistant polymers to guarantee long-term durability.
- The Mini-Bio-Plus SCBI can be easily removed and evaluated immediately on completion of each cycle because all outside parts consist of highly thermal resistant polymers that protect hands from high temperatures.

Order Information

Instant-Mini-Bio-Plus (MBP) self-contained biological indicators (SCBI)

Art.-No.*	Product code	Quantity/ pack	Pop.	Sterilization process	Colour of cap	Colour change of				Incubation tempera- ture	Biological indicator spores
						Outside Type 1 Indicator on label		Growth Media in SCBIs after steriliza- tion and incubation			
						Before	After	sterile	non-sterile		
324-551	B-S-MBP-I-10-5-SV4 Instant-MBP-SCBI	10	10 ⁵	Steam 132-137°C	Light orange	Blue	Brown	Purple	Yellow- Green	55-60°C	<i>G. Stearo- thermophilus</i>
324-555		50									
324-550		100									
324-651	B-S-MBP-I-10-6-SV4 Instant-MBP-SCBI	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 <i>gke Steri-Record</i> [®] incubator is used.
224-004	I-PC	1	Plastic Crusher for SCBI activation if no <i>gke Steri-Record</i> [®] incubator is used.

gke Steri-Record[®] process challenge devices (Bio-C-PCD[®]s) for Instant-Mini-Bio-Plus SCBIs

Art.-No.*	Product code	PCD-Version**	Penetration Characteristics***
300-031	B-PM-OCPCD-0	oval	very low requirements for air removal
300-032	B-PM-RCPCD-0	round	
300-033	B-PM-OCPCD-1	oval	minimal requirements for air removal
300-034	B-PM-RCPCD-1	round	
300-035	B-PM-OCPCD-2	oval	low requirements for air removal
300-036	B-PM-RCPCD-2	round	
300-037	B-PM-OCPCD-3	oval	air removal less difficult than Hollow load test according to EN 867-5
300-038	B-PM-RCPCD-3	round	
300-039	B-PM-OCPCD-4	oval	air removal equal to Hollow load test according to EN 867-5
300-040	B-PM-RCPCD-4	round	
300-041	B-PM-RCPCD-5		air removal more difficult than Hollow load test according to EN 867-5
300-042	B-PM-RCPCD-6		air removal much more difficult than Hollow load test according to EN 867-5

Incubators with aluminum block for Mini-Bio-Plus SCBIs

Art.-No.*	Product code	Description of incubator
610-120	I-57-AB-MBP	Incubation temperature: 57°C fixed
610-121	I-V-AB-MBP	Variable temperature selection
610-122	I-V-T-AB-MBP	Variable temperature selection and programming of the incubation time

* 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 tables.

** It is recommended to use the round versions in large and the oval versions in small sterilizers.

*** PCDs for routine monitoring need to be validated according to the load using the test method DIN 58921.

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