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Fig. 1: Mini-Bio-Plus SCBI inside Bio-PCD

Mini-Bio-Plus self-contained biological indicators (SCBI) and Bio Process Challenge Devices

Application

The Mini-Bio-Plus self-contained biological indicators (SCBI) are used inside packs or containers for validation and routine monitoring of steam, ethylene oxide, formaldehyde and hydrogen peroxide/plasma sterilization processes. After sterilization the SCBIs can be incubated by the user without a microbiological laboratory.

The Instant-Mini-Bio-Plus SCBI allows an immediate release of the load in steam sterilization processes without having to wait for the result after incubation.

The SCBI is designed to be used inside a Bio Process Challenge Device (Bio-PCD). Special adaptations have been made to the SCBI so it can be used together with a PCD as an indicator system which reaches the required sensitivity to check the internal lumens of a minimal invasive surgical (MIS) instrument.

Seven Bio-PCDs with different air removal characteristics are available. The sensitivity of these Bio-PCDs can be selected to meet the requirement of the load. The validation of the Bio-PCD according to the load can be achieved by using the test method described in DIN 58921.

Bio-PCDs can be used in all four sterilization processes mentioned above, if the correct SCBI is inserted.

There are various hydrogen peroxide/plasma sterilization processes in 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-PCD and H_2O_2-SCBI type should be selected.

Product Description

The Mini-Bio-Plus SCBI uses 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. For steam, ethylene oxide and formaldehyde sterilization processes, filter paper is used as carrier and closing filter below the cap. For hydrogen peroxide/plasma sterilization processes different material (glass fiber, Tyvek, stainless steel or PET) is used. For a better recognition of the different SCBI versions they each have different colored caps (see table).

The 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.

Additionally the Instant-Mini-Bio-Plus SCBI also contains a type 5 chemical indicator inside the SCBI allowing the result of steam sterilization processes to be instantly evaluated at the end of the 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 Bio-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 only be used with specially designed Mini-Bio-Plus SCBIs to create a high sensitive Hollow Load PCD. Conventional SCBIs cannot be used because of lower sensitivity for air removal and steam

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penetration inside the PCD.

Performance Characteristics

Self-contained biological indicators:

All 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 SCBIs for hydrogen peroxide sterilization processes are supplied on glass fiber or tyvek carrier with the consequence having completely different resistance characteristics although identical G. stearothermophilus spores are used. The D-Value that is tested under the defined sterilization conditions is described in the certificate which is included 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 of all Mini-Bio-Plus SCBIs has been optimized, so that steam Mini-Bio-Plus SCBIs can be fully interpreted within 24 hours and ethylene oxide, hydrogen peroxide and formaldehyde Mini-Bio-Plus SCBIs within 48 hours incubation time. 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, 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.

While Mini-Bio-Plus SCBIs may be used for all steam sterilization processes of 121-137°C, two versions of Instant-SCBIs shall be either used for processes of 121-124°C or 132-137°C 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 chemical 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-PCDs and SCBIs inside:

Bio-PCDs with SCBIs inside can simulate porous loads and hollow devices simultaneously.

Additional Bio-PCDs are available to simulate different load configurations and may be validated according to the test method, described in DIN 58921.

Operational Description

The 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 a SCBI inside is used to simulate MIS instruments. This alternative offers for the first time the possibility to check sterility inside hollow instruments. SCBIs in PCDs can be directly incubated at the end of the cycle without having to open packs or containers.

After the sterilization process the SCBIs are taken out of the load or the Bio-C-PCD® and are activated by crushing the glass ampoule. After they are incubated correctly according to the directions for use, the colour of the liquid will indicate a pass or

Fig. 2: Instant-Mini-Bio-Plus SCBI for steam, standard SCBI for steam, formaldehyde, hydrogen peroxide (glass fiber carrier) and ethylene oxide sterilization processes.

fail of the sterilization process. If the colour has not changed, this indicates a pass of the process, a colour change indicates a fail.

They should not be used in dry heat sterilization processes at all.

Benefits

- First worldwide indicator system with a special internal volume design hosting the gke Steri-Record SCBI which simulates hollow devices.
- Immediate release at the end of the steam sterilization process by checking the color

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.
- Special Mini-Bio-Plus SCBI design with minimized internal volume usable in Bio-PCDs for steam, ethylene oxide, formaldehyde and hydrogen peroxide/plasma sterilization processes.
- Mini-Bio-Plus SCBIs can be incubated on completion of each cycle without having to open any packs or containers when used in Bio-PCDs.
- 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-PCDs allows correct testing of hollow lumen instruments.
- Several Bio-PCDs are available to simulate different loads.
- A special oval and round Bio-PCD design for use in small table-top or large sterilizers.
- Cost-effective due to multiple use of the Bio-PCD without loosing 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.
- SCBIs also can be used for formaldehyde (LTSF) sterilization processes without pretreatment of the biological indicators with Na_2SO_3, described in EN ISO 11138-5.

Order Information

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

Art. No.	Product Code	Quality/ Pack	Pop.	Sterilization process	Color of Cap	Color 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				
						Sterilization		sterile	non-sterile		
324-501	B-S-MBP-10-5	10	10^5	Steam 121-137°C	Light blue	Blue	Brown	Purple	Yellow-green	55-60°C	*G. Stearo-thermophilus*
324-505		50									
324-510		100									
324-551	B-S-MBP-I-10-5-SV4 Instant-MBP-SCBI with type 5 indicator	10		Steam 132-137°C	Light orange						
324-555		50									
324-550		100									
324-651	B-S-MBP-I-10-6-SV4 Instant-MBP-SCBI with type 5 indicator	10	10^6		Dark orange						
324-655		50									
324-650		100									
324-601	B-S-MBP-10-6	10		Steam 121-137°C	Dark blue						
324-605		50									
324-610		100									
325-601	B-F-MBP-10-6	10		Formal-dehyde	Yellow	Yellow					
325-605		50									
327-601	B-V-G-MBP-10-6 on glass fiber carrier	10		Hydrogen peroxide	Light Grey	Blue	Green				
327-605		50									
327-610		100									
337-601	B-V-T-MBP-10-6 on tyvek carrier	10			Color-less						
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-T-MBP-10-6 on PET carrier	10			Light Green						
357-605		50									
326-605	B-E-MBP-10-6	50		Ethylene oxide	Red	Green	Green	Green	Yellow-Orange	33-37°C	*B. Atrophaeus*
326-610		100									

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Accessories

Art. No.	Quantity	Product Code	Product description
224-002	1	I-C	Crusher for SCBI activation if no gke Steri-Record incubator is used
224-004	1	I-PC	Plastic Crusher for SCBI activation if no gke Steri-Record incubator is used

gke Steri-Record process challenge devices (Bio-C-PCDs) for Mini-Bio-Plus SCBIs

Art. No.	Product Code	Product Code	Penetration Characteristics***	Image
300-031	B-PM-OCPCD-0	oval	minimal requirements for air removal	
300-032	B-PM-RCPCD-0	round		
300-033	B-PM-OCPCD-1	oval		
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 more difficult than Hollow load test according to EN 867-5	
300-040	B-PM-RCPCD-4	round		
300-041	B-PM-RCPCD-5	round	air removal much more difficult than Hollow load test according to EN 867-5	
300-042	B-PM-RCPCD-6	round		

Incubators****

For incubation of all SCBIs gke Steri-Record incubators with two different temperatures and programming versions are available. They contain an aluminum block for all SCBI. They are also available without aluminum block. Aluminum blocks suitable for Stearo-Ampoules and growth medium test tubes are available separately. Please order the correct plug on the power cord, available for Australia, Europe, Great Britain and USA.

Art. No.	Product Code	Description of incubator	Image
610-119	I-37-AB-MBP	Incubation temperature: 37°C fixed	
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.

**** For specification details see separate data sheet.

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