Without measurement there is no control®

PARTICLE MEASURING SYSTEMS®
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BioCapt® Single-Use STS

Microbial Impactor

Lightweight settle-plate replacement for continuous monitoring of critical areas

The BioCapt® Single-Use STS (Safe Transfer Solution) Microbial Impactor is the ideal solution for sterile transfer of Biocapt Single Use (BCSU) plates into isolators equipped with Rapid Transfer Ports (RTP) to be used for viable air monitoring.

The system enables direct introduction of sterile, pre-filled, ready-to-use BCSU units into controlled environments, minimizing operator intervention and eliminating the need for additional decontamination procedures before loading.

By enabling efficient RTP-based transfer, the solution supports uninterrupted operation and increases operational efficiency while providing greater manufacturing flexibility by allowing additional consumables to be introduced into the isolator during production without interrupting operations. Its compact, organized transfer configuration frees up valuable space inside the isolator, improving workspace management and operator ergonomics

By minimizing handling steps and reducing direct operator manipulation of monitoring consumables, the BCSU STS supports enhanced contamination control strategies and helps lower the risk of manual handling errors or false positive events.

Overall, the system is designed to simplify sterile transfer logistics while preserving isolator integrity and supporting continuous production activities in highly controlled pharmaceutical environments.

BENEFITS

Test ready

- Fully prepared, pre-filled, sterile, validated, and disposable
- Samples efficiently between 25 and 50 LPM

Simplified Aseptic Handling

- Minimizes operator interventions in critical environments
- Reduces contamination risk while supporting safer, more efficient transfer and sampling
- Each Beta Bag provides 18 BioCapt® Single-Use devices (six triplets), reducing isolator transfers
- Double-bagged and supplied in boxes with two Beta Bags

Cost reduction and increased productivity

- RTP-based transfer enables in-process addition of BCSU devices without interrupting production, increasing flexibility and uptime.
- Higher quality assurance through continuous monitoring
- Eliminates time-consuming and operator-dependent steps such as disinfection, sanitization, and sterilization
- Eliminates uncertainty from settle plate results
- Minimizes isolator footprint with a compact transfer setup that improves ergonomics

FEATURES

- Patented radial slit design for efficient microbial collection
- Transfer techology based on Getinge DPTE-BetaBag® 190, a widely used solution for sterile transfer in isolators and RABS (10 connections, 190 mm port)
- Complies with ISO 14698-1 and ISO 17141
- Culture media stability validated up to 12 months
- Storage at room temperature or under refrigeration
- Improved lot traceability with three-dimensional QR codes
- Compatible with active air monitoring systems
- Proven microorganism recovery under stressed conditions after up to 4 hours of continuous air sampling at 25 LPM (PQ required)
- Culture media of Tryptone Soy Agar (TSA) + Neutralizers

APPLICATIONS

- Microbial monitoring of critical control points in aseptic manufacturing areas (Isolators, ISO 5/Class A)

BioCapt® Single-Use STS Microbial Impactor

DESIGN

The BCSU® STS is based on Getinge DPTE® transfer technology (DPTE-BetaBag® 190 with 10 L PU bag), a widely used solution for sterile transfer in isolators. It comprises a sterile flexible polyurethane Beta Bag that interfaces with a 190 mm Alpha Port on the isolator wall, enabling transfer of sterile consumables without compromising aseptic integrity.

The Biocapt ® Single-Use Impactor uses a radial slit design, patented and validated at the Centre for Applied Microbiology & Research (CAMR), a Health Protection Agency (HPA) at Porton Down. It achieves isokinetic sampling for minimal air turbulence in compliance with ISO 14698-1, and is ideal for sampling with a flow rate between 25 and 50 L/min.

QUALITY CONTROL TEST

Incubation	
At 32.5 ± 2.5 °C for 24 - 72 hours	Fertility (Growth Promotion) Test on Bacteria
At 32.5 ± 2.5 °C for 72 - 120 hours	Fertility (Growth Promotion) Test for Yeast and Mold
At 32.5 ± 2.5 °C and at 22.5 ± 2.5°C for seven days	Sterility control for absence of contamination

QUALITY CONTROL MICROORGANISMS

Organism (ATCC)	Inoculum (viable organisms)	Conditions	Recovery
E. coli (8739)	10-100	24 - 72 hours at 32.5 ± 2.5 °C	70% ≤ P_R% ≤ 200%
P. aeruginosa (9027)	10-100	24 - 72 hours at 32.5 ± 2.5 °C	70% ≤ P_R% ≤ 200%
S. aureus (6538)	10-100	24 - 72 hours at 32.5 ± 2.5 °C	70% ≤ P_R% ≤ 200%
B. spizizenii (6633)	10-100	24 - 72 hours at 32.5 ± 2.5 °C	70% ≤ P_R% ≤ 200%
C. albicans (10231)	10-100	72 - 120 hours at 32.5 ± 2.5 °C	70% ≤ P_R% ≤ 200%
A. brasiliensis (16404)	10-100	72 - 120 hours at 32.5 ± 2.5 °C	70% ≤ P_R% ≤ 200%
Environmental strain #1	10-100	24 - 72 hours at 32.5 ± 2.5 °C	70% ≤ P_R% ≤ 200%
Environmental strain #2	10-100	24 - 72 hours at 32.5 ± 2.5 °C	70% ≤ P_R% ≤ 200%

GENERAL INSTRUCTIONS

Only qualified laboratory personnel should handle the device using aseptic technique.

The culture media must be used only for the specific microbiological analysis , in accordance with applicable standards and procedures.

It is good practice to let the device reach room temperature before using.

Manual contamination (false positives) due to incorrect manipulation is essentially removed, as operation is a few simple steps: remove the lateral cap on the barb, connect to the vacuum source, and remove the lid. After sampling, the lid and lateral cap are replaced, and the BCSU is placed directly into an incubator. The Beta Bag contains 10 transport bags for transferring sampled BCSU units from the isolator to the laboratory.

After incubation, follow standard procedures to enumerate colonies on the unit's media; results must be interpreted by qualified personnel in context of use.

PRECAUTIONS

Do not utilize the device if:

- It is broken
- Media is past expiration date

DISPOSAL

On completion of work, all used or unusable preparations of this product and derivatives thereof are to be disposed of by autoclaving and/or by incineration.

Sterilize all biohazard waste before disposal. Dispose of waste in accordance with all applicable Federal, State, and local laws.

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BioCapt® Single-Use STS Microbial Impactor

PARAMETER	SPECIFICATION	
Air inlets	20 slits, 0.1 mm nominal width	
Flow rates	25 - 50 LPM recommended	
Material	Polystyrene	
Dimensions	120 mm exterior diameter 38.5 mm exterior height (with lid) 90 mm diameter agar surface	
Filling volume	30 ml	
Vacuum connectors	Hose Barb 11 mm OD and 31.5 mm long (includes removable cap)	
Transfer Technology	Based on the Getinge DPTE® (DPTE-BetaBag® 190)	
Number of connections to Alpha Port	up to 10	
Composition Medium[1]	**TSA**	**g/L of deionized water**
	Pancreatic digest of casein	15.00
	Soya peptone	5.00
	Sodium chloride	5.00
	Lecithin	0.70
	Polysorbate 80 (Tween 80)	5.00
	L-histidine	1.00
	Sodium thiosulphate	0.50
	Agar	15.00
Color of medium	Light yellow colored, clear to slightly opalescent	
Storage Temperature	2 - 25 °C until expiration date. Protect from light, excessive heat, moisture and freezing. Avoid fast change of temperature within the range	
pH at 25 °C storage	7.3 ± 0.2	
Packaging	Each Beta Bag contains a total of 18 BCSU devices, corresponding to 6 BCSU triplets packaged in a single bag. Each Beta bag is wrapped with 2 bags. Each box contains two Beta Bags	

[1] The medium can be adjusted and/or supplemented according to the performance criteria required

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