

# BioCapt® Single-Use

Microbial Impactor

*Lightweight settle-plate replacement for continuous monitoring of critical areas*

*Without measurement there is no control*

The BioCapt® Single-Use Microbial Impactor is a lightweight, integrated air sampler designed to be used with both portable and remote monitoring systems in remote sampling settings. The impactor eliminates the risk of false positive results and final product contamination from microbial sampling interactions, while decreasing the cost of investigations. The single use sampling head enables manufacturers to monitor their full process, eliminating the risk of non-conclusive results by settle plates. The innovative design is a combination of media plate and sampling head into a single unit. This unique solution eliminates the handling risk, costs, and complications related to autoclaving and stainless steel head disinfection.

It is a sterile, ready-to-use unit already filled with medium, eliminating agar plate preparation and minimizing operator handling. The units are packed in a gamma irradiated double bag (3 units/double-bagged).

The single use impactor uses a radial slit design, 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 can be used for sampling at 25 - 50 LPM.

Manual contamination (false positives) from incorrect manipulation is greatly reduced as the operator must only follow three steps: remove the single use impactor unit from the bag, install it in a portable or continuous monitoring system and take off the lid. When sampling completes and after replacing the lid, the single use impactor gets directly placed into an incubator. Due to its design and weight, it can be handled easily with one hand.

By using the BioCapt Single-Use, it is possible to reduce the costs of investigations related to false positive results that could occur when using traditional agar plates.

## BENEFITS

### Test ready

- Fully prepared and disposable
- Eliminates agar plate preparation
- Samples efficiently at 25 or 50 LPM

### False-positive reduction

- Minimizes operator handling
- Eliminates unintended contamination
- Each set of three samplers is double-bagged and gamma irradiated

### Cost reduction and increased productivity

- Higher quality assurance through continuous monitoring (up to 4 hours)
- Eliminates time-consuming and operator-dependent cleaning and process steps like: disinfection, sanitization and sterilization
- Removes uncertainties of non-conclusive results from settling plates
- Risk reduction during the introduction and withdrawal of microbiological sampling plates in sterile production areas
- Reduced number of investigations

## FEATURES

- Culture media stability validated up to 12 months
- Storage either at room temperature or under refrigeration
- Improved lot traceability by use of three-dimensional QR codes
- Compatible with active air monitoring systems
- Extensive validation studies
- 100% inspection of critical dimensions during manufacturing process
- Leakage test ensuring perfect assembly
- Complies with ISO 14698-1 for highest microbiological and physical efficiencies
- Proven recovery of microorganisms under stressed conditions after 2 hours of continuous air sampling (25 LPM flow rates)
- Standard culture media of TSA and SDA

## APPLICATIONS

- Microbial air sampling monitoring in cleanrooms and associated controlled environments
- USP 797 environmental viable airborne particle testing
- Microbial monitoring of critical control points in aseptic manufacturing areas (Isolators, RABS, ISO 5/Class A)



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Specifications

<b>Materials</b>	Polystyrene
<b>Air inlets</b>	20 slits, 0.1 mm nominal width
<b>Flow rates</b>	25 - 50 LPM recommended
<b>Dimensions</b>	120 mm exterior diameter 38.5 mm exterior height (with lid) 90 mm diameter agar surface
<b>Filling volume</b>	30 ml
<b>Vacuum connectors</b>	Hose Barb 11 mm OD and 31.5 mm long (includes removable cap)
<b>Standard media</b>	Trypticase Soy Agar (TSA) or Sabouraud Dextrose Agar (SDA). SDA is available only with neutralizers.
<b>Additives</b>	Neutralizers Neutralizers and Pyruvate Neutralizers and Lactamator(R): for the inactivation of a wide range of beta-lactam antibiotics.



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