

Mycap[®] Manifold Bottle Assemblies for Media



Product Information

Mycap[®] bottle closures are a one-piece, ready-to-use aseptic fluid transfer system.

The single-use design features integral tubing and a robust platinum-cured silicone seal.

Mycap[®] bottle assemblies include PETG square media bottles, Sartopore[®] 2 filter, are gamma irradiated and ready for immediate use.

Features & Benefits

| Features | Benefits |
|---------------------------------|---|
| Ready-to-use | Save time Eliminate errors |
| Single-use | No contamination risk |
| One-for-all silicone closure | Universal validation Robust and reliable performance |
| One-piece construction | Integral closure Easy to handle |
| Easy customization | Configure Mycap [®] to your process needs |
| Sartopore [®] 2 Filter | Sterile filter media into media bottle |

Applications

Mycap® for Media make media distribution and storage quicker and easier than ever before. Mycap® for Media includes six bottles.

Manifolds include a Sartopore® 2 filter for sterile filtration directly into easy-to-handle bottles. Simply connect the filter inlet to your bulk media source to sterilize media as the bottle fills.

Cut the Quickseal® aseptic disconnect after filling and your aseptic media distribution is complete, without ever having to go into a biosafety cabinet.

Choose tube welding or aseptic connector for convenient aseptic connection and dispense sterile media at point-of-use, including bioreactors.

Reduce Risk and Improve Performance

With Mycap® bottle closures, every use is its first use.

There is no risk of batch-to-batch or product-to-product cross-contamination.

Mycap® bottle assemblies pass studies of container closure by bacterial immersion.

One-For-All Closure System

At last – a truly universal bottle closure system.

All Mycap® closure systems are constructed using the same high-performance, platinum-cured silicone seal regardless of the tubing material, tubing size, port configuration, bottle type or bottle size.

Ease validation and reduce regulatory work by implementing Mycap® throughout the production process.

Easy Implementation

Alternative bottle closure systems include a number of reusable components which are costly to implement and manage.

Regulatory agencies demand a scientifically sound validation strategy for parts cleaning to avoid non-host or batch-to-batch contamination. The physical condition and life cycle of reused parts must be closely monitored to ensure cleaning efficacy.

Select pre-assembled and single-use Mycap® bottle assemblies to bypass the burden of validation and parts management.

Reliable Performance

The platinum-cured silicone seal of Mycap® is suitable for a range of applications.

The closure to the bottle is secure so long as the seal maintains its physical properties. Silicone maintains its elastomeric properties from -70° to 260° Celcius.

Validation demonstrates a leak-free seal when Mycap® are installed with torque force from 4in-lbs to 60in-lbs.

Technical Data

Specifications

| | |
|----------------|---|
| Elastomer Seal | Platinum-cured silicone |
| Tubing | Platinum-cured silicone or C-Flex® formulation 374 |
| Cap Material | Polycarbonate (not fluid contact) |
| Bottle Style | PETG Square bottle |
| Tube Ports | Inlet: Sartopore® 2 Media Filter Air vent - 25 mm PES membrane Minisart® |
| Fittings | Outlet: Aseptiquik® S or tube plug |
| Sterilization | Gamma Irradiated |

Manufacturing Environment

Mycap® bottle closures are constructed and packaged in an ISO 7 clean-room.

Monthly cleaning with a schedule of LpH®, Vesphene® and Spor Klenz® reduce and control viable organisms. Viable organisms are measured quarterly to monitor the effectiveness of the clean-room management and cleaning procedures, and to be compliant to EU GMPs and ISO 14698.

Line clearance, weekly cleaning of equipment and work surfaces, and monthly cleaning of the clean-room reduce and control non-viable particles. Non-viable readings are re-taken weekly to ensure 0.5 µm/m³ and 5.0 µm/m³ particles are within the ISO Class 7 acceptance criteria, per ISO 14644-1.

Quality Assurance

Mycap® bottle assemblies are manufactured in accordance with the key principles of cGMP.

Each Mycap® bottle closure is issued with a unique lot number on its Certificate of Compliance. The lot number provides full traceability to all components used and operations performed.

The Certificate of Conformance for Mycap® bottle assemblies reports compliance to:

- USP <87>: Biological reactivity tests, in Vitro
- USP <88>: Biological reactivity tests, in Vivo
- USP <788>: Particulate matter
- USP <85>: Endotoxin
- Sterility Assurance (SAL) 10⁻⁶ per ISO 11137

Shelf Life

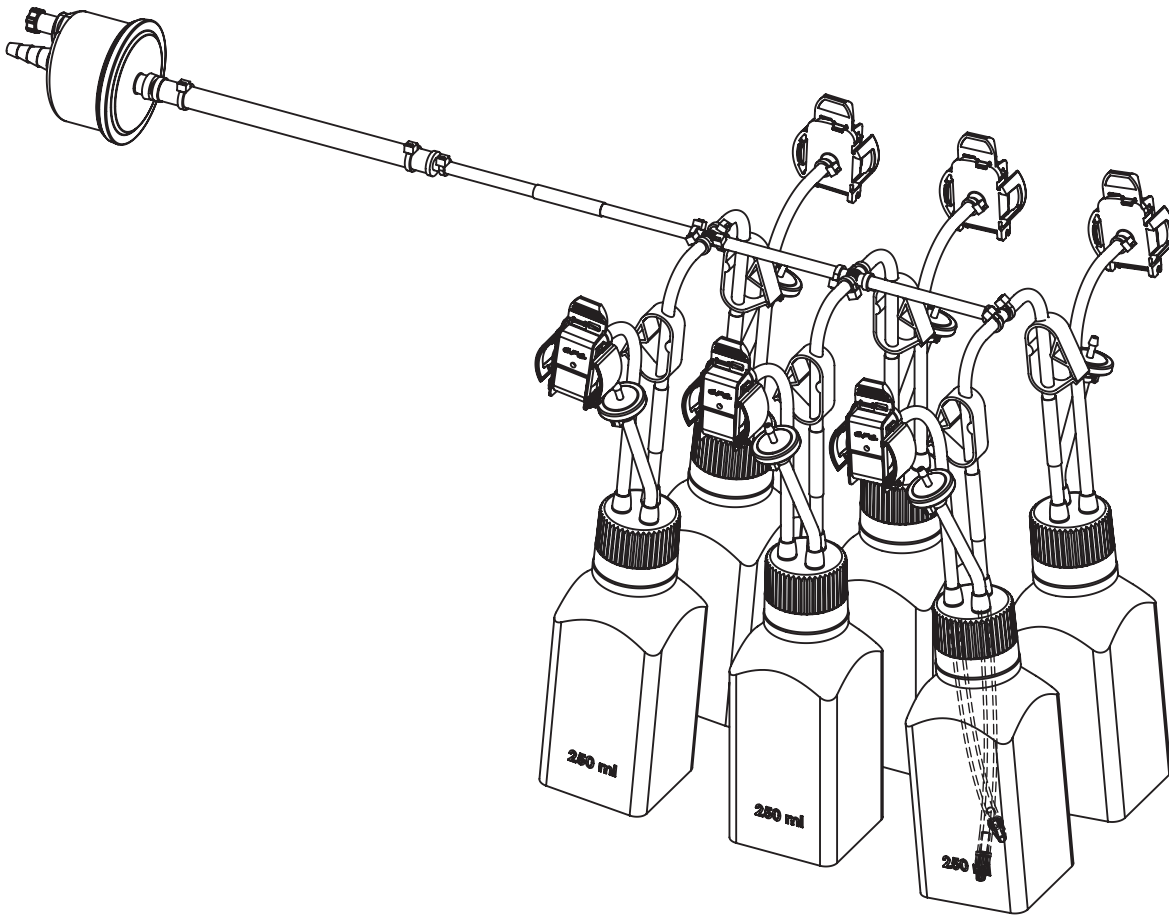
Mycap® bottle closures, components and component resins have shelf life that exceeds two years.

TSE|BSE Risk

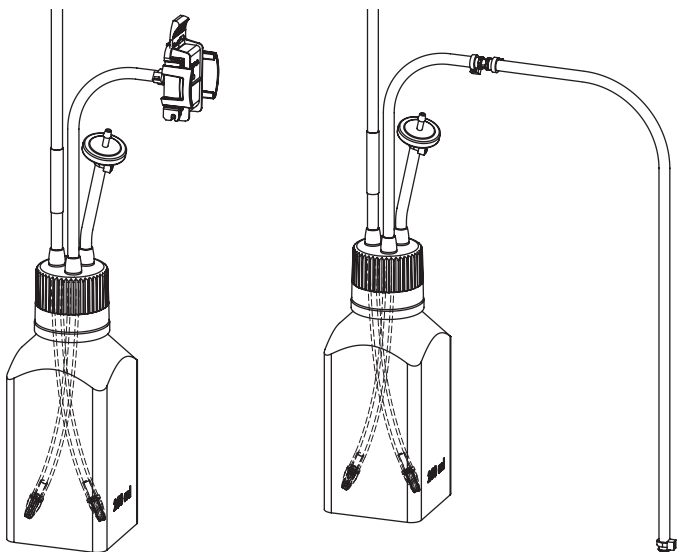
The components and materials used in construction of Mycap® bottle assemblies are treated at high temperatures and undergo chemical reactions which far exceed the stringent requirements laid down in the documents CPMP|BWP|1230|98 and WHO|CPS|VPH|95.145 and |or|EMA|410|01, rev 3. These processing conditions are considered sufficient to inactivate TSE and BSE transmitters.

Ordering Information

Six-Bottle Manifold With Aseptiquik® S



Two Options for Aseptic Connection:





Before Media Fill



After Media Fill

Six-Bottle Manifold; Aseptic Connection by Tube Welding or Aseptic Connectors

Universal Design Features

- Optimized Tube Lengths including dip tube for fluid transfer
- Sartopore® 2 0.2 µm Filter at Manifold Inlet for Sterile Media Fill
- Includes PETG Square Media Bottle
- Gamma Irradiated
- Individually Double Bagged

| Article Number | Description | Bottle Size | Port 1 | Port 2 | Port 3 | Qty/ Pack |
|-----------------|---|-------------|--|--------------------------------------|---|--------------|
| MCMD1000060204B | 6 × 1000 mL Square Media Bottle; ½ × ¼ C-Flex® Tubing w/Aseptiquik® S | 1000 mL | (Manifold Inlet) Size 5 Sartopore® 2 capsule filter; 0.2 µm; ¼ - ½ barb inlet; Quickseal®; dip tube to bottom | Aseptiquik® S; dip tube to bottom | Minisart® hydrophobic PES vent filter | 1 |
| MCMD0500060204B | 6 × 500 mL Square Media Bottle; ½ × ¼ C-Flex® Tubing w/Aseptiquik® S | 500 mL | (Manifold Inlet) Size 5 Sartopore® 2 capsule filter; 0.2 µm; ¼ - ½ barb inlet; Quickseal®; dip tube to bottom | Aseptiquik® S; dip tube to bottom | Minisart® hydrophobic PES vent filter | 1 |
| MCMD0250060204B | 6 × 250 mL Square Media Bottle; ½ × ¼ C-Flex® Tubing w/Aseptiquik® S | 250 mL | (Manifold Inlet) Size 5 Sartopore® 2 capsule filter; 0.2 µm; ¼ - ½ barb inlet; Quickseal®; dip tube to bottom | Aseptiquik® S; dip tube to bottom | Minisart® hydrophobic PES vent filter | 1 |

Six-Bottle Manifold; Aseptic Connection With Aseptic Connector

Universal Design Features

- Optimized Tube Lengths including dip tube for fluid transfer
- Sartopore® 2 0.2 µm Filter at Manifold Inlet for Sterile Media Fill
- Includes PETG Square Media Bottle
- Gamma Irradiated
- Individually Double Bagged

| Article Number | Description | Bottle Size | Port 1 | Port 2 | Port 3 | Qty/ Pack |
|-----------------|---|-------------|---|--------------------------------------|---|--------------|
| MCMD1000060204A | 6 × 1000 mL Square Media Bottle; 1/8 × 1/4 Silicone Tubing; Aseptiquik® S | 1000 mL | (Manifold Inlet) Size 5 Sartopore® 2 capsule filter; 0.2 µm; 1/4 – 1/2 barb inlet; Quickseal®; dip tube to bottom | Aseptiquik® S; dip tube to bottom | Minisart® hydrophobic PES vent filter | 1 |
| MCMD0500060204A | 6 × 500 mL Square Media Bottle; 1/8 × 1/4 Silicone Tubing; Aseptiquik® S | 500 mL | (Manifold Inlet) Size 5 Sartopore® 2 capsule filter; 0.2 µm; 1/4 – 1/2 barb inlet; Quickseal®; dip tube to bottom | Aseptiquik® S; dip tube to bottom | Minisart® hydrophobic PES vent filter | 1 |
| MCMD0250060204A | 6 × 250 mL Square Media Bottle; 1/8 × 1/4 Silicone Tubing; Aseptiquik® S | 250 mL | (Manifold Inlet) Size 5 Sartopore® 2 capsule filter; 0.2 µm; 1/4 – 1/2 barb inlet; Quickseal®; dip tube to bottom | Aseptiquik® S; dip tube to bottom | Minisart® hydrophobic PES vent filter | 1 |

Six-Bottle Manifold; Aseptic Connection by Tube Welding

Universal Design Features

- Optimized Tube Lengths including dip tube for fluid transfer
- Sartopore® 2 0.2 µm Filter at Manifold Inlet for Sterile Media Fill
- Includes PETG Square Media Bottle
- Gamma Irradiated
- Individually Double Bagged


| Article Number | Description | Bottle Size | Port 1 | Port 2 | Port 3 | Qty/ Pack |
|-----------------|--|-------------|---|----------------------------------|---|--------------|
| MCMD1000060204W | 6 × 1000 mL Square Media Bottle; ½ × ¼ C-Flex® Tubing | 1000 mL | (Manifold Inlet) Size 5 Sartopore® 2 capsule filter; 0.2 µm; ¼ – ½ barb inlet; Quickseal®; dip tube to bottom | Tube Plug; dip tube to bottom | Minisart® hydrophobic PES vent filter | 1 |
| MCMD0500060204W | 6 × 500 mL Square Media Bottle; ½ × ¼ C-Flex® Tubing | 500 mL | (Manifold Inlet) Size 5 Sartopore® 2 capsule filter; 0.2 µm; ¼ – ½ barb inlet; Quickseal®; dip tube to bottom | Tube Plug; dip tube to bottom | Minisart® hydrophobic PES vent filter | 1 |
| MCMD0250060204W | 6 × 250 mL Square Media Bottle; ½ × ¼ C-Flex® Tubing | 250 mL | (Manifold Inlet) Size 5 Sartopore® 2 capsule filter; 0.2 µm; ¼ – ½ barb inlet; Quickseal®; dip tube to bottom | Tube Plug; dip tube to bottom | Minisart® hydrophobic PES vent filter | 1 |

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