MYCAP® Single 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 Nalgene® square media bottles, Sartopore® 2 filter, are gamma irradiated and ready for immediate use.

Features

- Ready-to-use
- Single-use
- One-For-All silicone closure
- One-piece construction
- Easy customization
- Sartorpore® 2 Filter

Benefits

- Save time
  Eliminate errors
- No contamination risk
- Universal validation
  Robust & reliable performance
- Integral closure
  Easy to handle
- Configure MYCAP®
  to your process needs
- 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 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 AseptiQuik® aseptic connector for convenient aseptic connection and dispense sterile media at point-of-use, including bioreactors.

Reduce Risk & 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 torqueforce 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	Nalgene® PETG 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 ISO14698.

Line clearance, weekly cleaning of equipment and work surfaces and monthly cleaning of the cleanroom reduce and control non-viable particles. Non-viable readings are taken weekly to ensure 0.5 µm/m^3 and 5.0 µm/m^3 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 ISO11137
- USP <381>: Extractables
- 21CFR177.2600: Extractables

Shelf Life

MYCAP® bottle closures, components and component resins have shelf-life that exceeds 2 years.

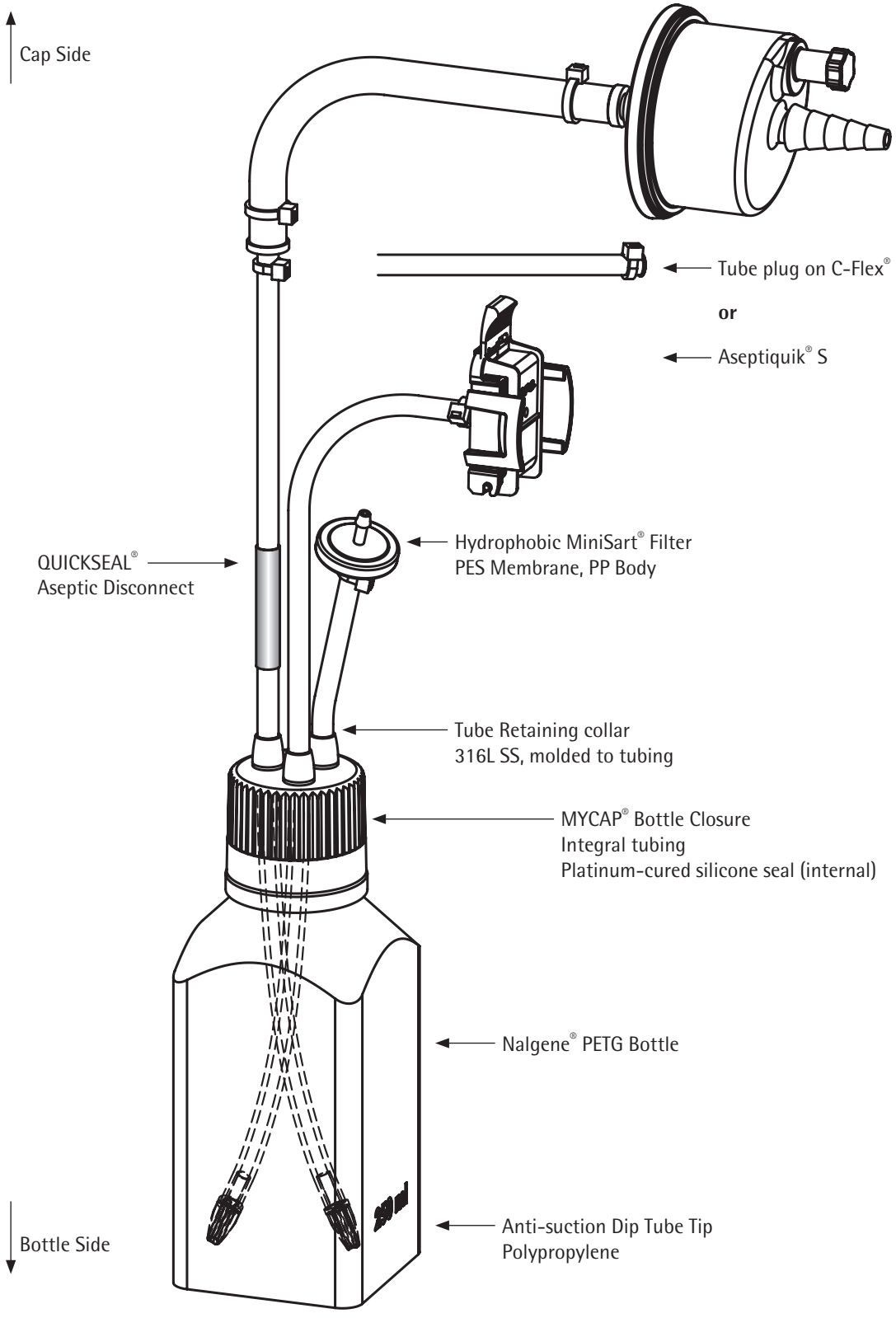
TSE|BSE Risk

The components and materials used in construction of MYCAP® bottles 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 & BSE transmitters.

C-Flex® is a registered trademark of Saint-Gobain Performance Plastics Corporation
Luer® is a registered trademark of Becton Dickinson
LpH®, Vesphene® Spor Klenz® are registered trademarks of STERIS Corporation
Nalgene® is a registered trademark of ThermoFisher Scientific
Sartopore®, Minisart®, QUICKSEAL® and MYCAP® is a registered trademark of Sartorius-Stedim Biotech
AseptiQuik®, is a registered trademark of Colder Products Company

Ordering Information

Single Bottle with Aseptiquik® S



Before Media Fill

After Media Fill

Single Bottle with C-Flex® for Aseptic Connections via Tube Welding

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

Article Number	Description	Bottle Size	Port 1	Port 2	Port 3	Qty/Pack
MCMD1000010204W	1000 mL Square Media Bottle; 1/8 × 1/4 C-Flex® Tubing	1000 mL	Size 4 Sartopore® 2 capsule filter; 0.2 µm; 1/4 – 1/2 barb inlet; QUICKSEAL®; dip tube to bottom	Tube Plug; dip tube to bottom	Minisart® hydrophobic PES vent filter	1
MCMD0500010204W	500 mL Square Media Bottle; 1/8 × 1/4 C-Flex® Tubing	500 mL	Size 4 Sartopore® 2 capsule filter; 0.2 µm; 1/4 – 1/2 barb inlet; QUICKSEAL®; dip tube to bottom	Tube Plug; dip tube to bottom	Minisart® hydrophobic PES vent filter	1
MCMD0250010204W	250 mL Square Media Bottle; 1/8 × 1/4 C-Flex® Tubing	250 mL	Size 4 Sartopore® 2 capsule filter; 0.2 µm; 1/4 – 1/2 barb inlet; QUICKSEAL®; dip tube to bottom	Tube Plug; dip tube to bottom	Minisart® hydrophobic PES vent filter	1

Single Bottle with Aseptiquik® S for Aseptic Connections

Universal Design Features
– Optimized Tube Lengths including dip tube for fluid transfer
– Sartopore® 2 0.2 µm Filter at Inlet for Sterile Media Fill
– Includes Nalgene® PETG Media Bottle
– Gamma Irradiated
– Individually Double Bagged

Article Number	Description	Bottle Size	Port 1	Port 2	Port 3	Qty/Pack
MCMD1000010204A	1000 mL Square Media Bottle; 1/8 × 1/4 Silicone Tubing; Aseptiquik® S	1000 mL	Size 4 Sartopore® 2 capsule filter; 0.2 µm; 1/4 – 1/2 barb inlet; QUICKSEAL®; dip tube to bottom	Aseptiquik®; dip tube to bottom	Minisart® hydrophobic PES vent filter	1
MCMD0500010204A	500 mL Square Media Bottle; 1/8 × 1/4 Silicone Tubing; Aseptiquik® S	500 mL	Size 4 Sartopore® 2 capsule filter; 0.2 µm; 1/4 – 1/2 barb inlet; QUICKSEAL®; dip tube to bottom	Aseptiquik®; dip tube to bottom	Minisart® hydrophobic PES vent filter	1
MCMD0250010204A	250 mL Square Media Bottle; 1/8 × 1/4 Silicone Tubing; Aseptiquik® S	250 mL	Size 4 Sartopore® 2 capsule filter; 0.2 µm; 1/4 – 1/2 barb inlet; QUICKSEAL®; dip tube to bottom	Aseptiquik®; dip tube to bottom	Minisart® hydrophobic PES vent filter	1

Single Bottle with Aseptiquik® S on C-Flex® for Aseptic Connections

Universal Design Features
– Optimized Tube Lengths including dip tube for fluid transfer
– Sartopore® 2 0.2 µm Filter at Inlet for Sterile Media Fill
– Includes Nalgene® PETG Media Bottle
– Gamma Irradiated
– Individually Double Bagged

Article Number	Description	Bottle Size	Port 1	Port 2	Port 3	Qty/Pack
MCMD1000010204B	1000 mL Square Media Bottle; 1/8 × 1/4 C-Flex® Tubing w/Aseptiquik® S	1000 mL	Size 4 Sartopore® 2 capsule filter; 0.2 µm; 1/4 – 1/2 barb inlet; QUICKSEAL®; dip tube to bottom	Aseptiquik®; dip tube to bottom	Minisart® hydrophobic PES vent filter	1
MCMD0500010204B	500 mL Square Media Bottle; 1/8 × 1/4 C-Flex® Tubing w/Aseptiquik® S	500 mL	Size 4 Sartopore® 2 capsule filter; 0.2 µm; 1/4 – 1/2 barb inlet; QUICKSEAL®; dip tube to bottom	Aseptiquik®; dip tube to bottom	Minisart® hydrophobic PES vent filter	1
MCMD0250010204B	250 mL Square Media Bottle; 1/8 × 1/4 C-Flex® Tubing w/Aseptiquik® S	250 mL	Size 4 Sartopore® 2 capsule filter; 0.2 µm; 1/4 – 1/2 barb inlet; QUICKSEAL®; dip tube to bottom	Aseptiquik®; dip tube to bottom	Minisart® hydrophobic PES vent filter	1

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