

MYCAP[™] Bottle Assemblies

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, are gamma irradiated and ready for immediate use.



| Features | Benefits |
|--|--|
| – Ready-to-use | Save time Eliminate errors |
| – Single-use | No contamination risk |
| One-For-All silicone closure | Universal validation Robust & reliable performance |
| One-piece construction | Integral closure Easy to handle |
| Easy customization | Configure MYCAP[™] to your process needs |

Applications

MYCAP[™] is ideal for critical fluid-handling applications.

 $\mathsf{MYCAP}^{\mathsf{m}}$ bottle assemblies are gamma irradiated and ready for immediate use for:

- Buffer and Media Storage
- Buffer and Media Addition
- Bioreactor Feeds
- Sample Collection
- Bulk Harvest
- Product Pooling
- Bulk Intermediate Hold

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 $MYCAP^{m}$ 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.

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 μ m/m³ and 5.0 μ m/m³ particles are within the ISO Class 7 acceptance criteria, per ISO 14644-1.

Quality Assurance

 $MYCAP^{M}$ 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

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.

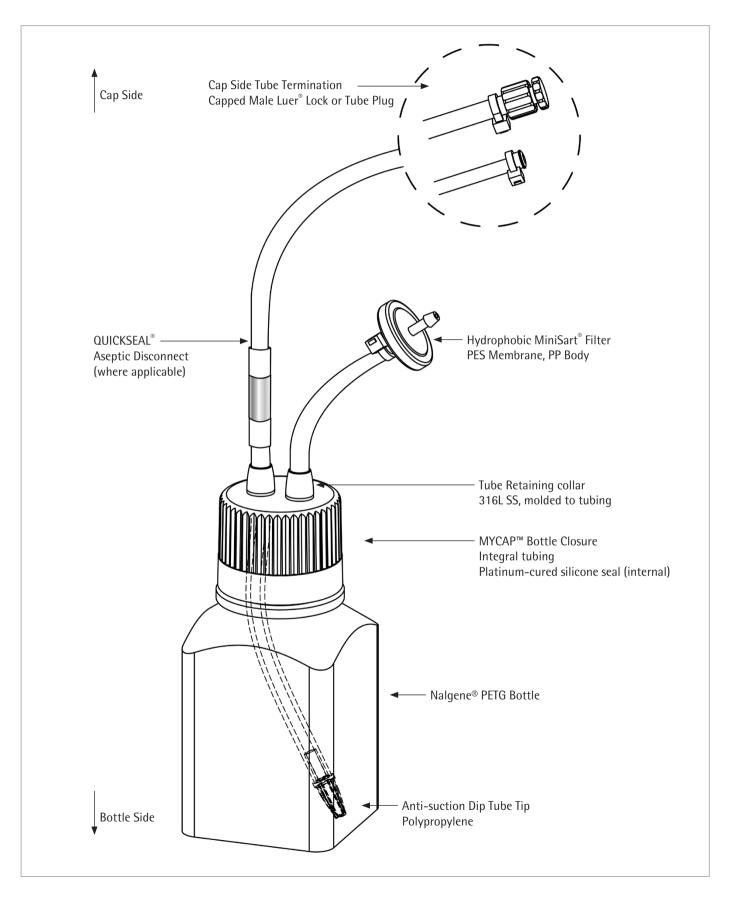
Technical Data

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 Outlet, Air vent - 25 mm PES membrane MiniSart® |
| Fittings | Luer [®] Lock or tube plug |
| Sterilization | Gamma Irradiated |
| | |

C-Flex[®] is a registered trademark of Saint-Gobain Performance Plastics Corporation Luer[®] is a registered trademark of Becton Dickinson Dow Corning[®] is a registered trademark of Dow Corning Corporation LpH[®], Vesphene[®] Spor Klenz[®] are registered trademarks of STERIS Corporation Nalgene[®] is a registered trademark of ThermoFisher Scientific

MYCAP[™] Bottle Assembly Anatomy



Ordering Information

Series A MYCAP[™] Bottle Assemblies

- Optimized Tube Lengths including dip tube for fluid transfer
- Includes Nalgene® PETG Media Bottle
- Platinum-Cured Silicone Tubing (Dow-Corning® PHARMA-50)
- Gamma Irradiated
- Individually Double Bagged

| Part Number | Description | Bottle Size | Port 1 | Port 2 | Qty/Pack |
|----------------|---|-------------|---|---|----------|
| MYCAPNGPG0030A | 2 port MYCAP™ bottle closure with 30mL bottle | 30 mL | Tube Size: 1/8" ID × 1/4" OD Cap Side: 3.75"; capped male Luer [®] fitting Bottle Side: To Bottom; dip tube tip | Tube Size: $\frac{1}{8}$ " ID $\times \frac{1}{4}$ " OD Cap Side: 3"; Minisart [®] hydrophobic PES filter Bottle Side: None | 1 |
| MYCAPNGPG0060A | 2 port MYCAP™ bottle closure with 60mL bottle | 60 mL | Tube Size: $\frac{1}{8}$ " ID × $\frac{1}{4}$ " OD Cap Side: 3.25"; capped male Luer [®] fitting Bottle Side: To Bottom; dip tube tip | Tube Size: $\frac{1}{8}$ " ID $\times \frac{1}{4}$ " OD Cap Side: 3"; Minisart [®] hydrophobic PES filter Bottle Side: None | 1 |
| MYCAPNGPG0125A | 2 port MYCAP™ bottle closure with 125mL bottle | 125 mL | Tube Size: 1/8" ID × 1/4" OD Cap Side: 8"; capped male Luer [®] fitting Bottle Side: To Bottom; dip tube tip | Tube Size: $\frac{1}{8}$ " ID $\times \frac{1}{4}$ " OD Cap Side: 3"; Minisart [®] hydrophobic PES filter Bottle Side: None | 1 |
| MYCAPNGPG0250A | 2 port MYCAP™ bottle closure with 250 mL bottle | 250 mL | Tube Size: 1/8" ID × 1/4" OD Cap Side: 6.5"; capped male, Luer [®] fitting Bottle Side: To Bottom; dip tube tip | Tube Size: $\frac{1}{8}$ " ID $\times \frac{1}{4}$ " OD Cap Side: 3"; Minisart [®] hydrophobic PES filter Bottle Side: None | 1 |
| MYCAPNGPG0500A | 2 port MYCAP™ bottle closure with 500 mL bottle | 500 mL | Tube Size: 1/8" ID × 1/4" OD Cap Side: 11.25; capped male Luer [®] fitting Bottle Side: To Bottom; dip tube tip | Tube Size: $\frac{1}{8}$ " ID × $\frac{1}{4}$ " OD Cap Side: 3"; Minisart [®] hydrophobic PES filter Bottle Side: None | 1 |
| MYCAPNGPG1000A | 2 port MYCAP™ bottle closure with 1000 mL bottle | 1000 mL | Tube Size: 1/8" ID × 1/4" OD Cap Side: 9.5"; capped male, Luer [®] fitting Bottle Side: To Bottom; dip tube tip | Tube Size: $\frac{1}{8}$ " ID × $\frac{1}{4}$ " OD Cap Side: 3"; Minisart [®] hydrophobic PES filter Bottle Side: None | 1 |

Series B MYCAP[™] Bottle Closures

- Optimized Tube Lengths including dip tube for fluid transfer
- Includes Nalgene® PETG Media Bottle
- C-Flex[®] tubing (formulation 374)
- Gamma Irradiated
- Individually Double Bagged

| Part Number | Description | Bottle Size | Port 1 | Port 2 | Qty/Pack |
|----------------|---|-------------|---|---|----------|
| MYCAPNGPG0030B | 2 port MYCAP™ bottle closure with 30mL bottle | 30 mL | Tube Size: $\frac{1}{8}$ " ID × $\frac{1}{4}$ " OD Cap Side: 15.75"; capped male Luer [®] fitting Bottle Side: To Bottom; dip tube tip | Tube Size: $\frac{1}{8}$ " ID × $\frac{1}{4}$ " OD Cap Side: 3"; Minisart [®] hydrophobic PES filter Bottle Side: None | 1 |
| MYCAPNGPG0060B | 2 port MYCAP™ bottle closure with 60mL bottle | 60 mL | Tube Size: 1/8" ID × 1/4" OD Cap Side: 15.25"; capped male Luer [®] fitting Bottle Side: To Bottom; dip tube tip | Tube Size: $\frac{1}{8}$ " ID × $\frac{1}{4}$ " OD Cap Side: 3"; Minisart [®] hydrophobic PES filter Bottle Side: None | 1 |
| MYCAPNGPG0125B | 2 port MYCAP™ bottle closure with 125mL bottle | 125 mL | Tube Size: 1/8" ID × 1/4" OD Cap Side: 14"; capped male Luer [®] fitting Bottle Side: To Bottom; dip tube tip | Tube Size: $\frac{1}{8}$ " ID × $\frac{1}{4}$ " OD Cap Side: 3"; Minisart [®] hydrophobic PES filter Bottle Side: None | 1 |
| MYCAPNGPG0250B | 2 port MYCAP™ bottle closure with 250 mL bottle | 250 mL | Tube Size: 1/8" ID × 1/4" OD Cap Side: 18.5"; capped male, Luer [®] fitting Bottle Side: To Bottom; dip tube tip | Tube Size: $\frac{1}{8}$ " ID × $\frac{1}{4}$ " OD Cap Side: 3"; Minisart [®] hydrophobic PES filter Bottle Side: None | 1 |
| MYCAPNGPG0500B | 2 port MYCAP™ bottle closure with 500 mL bottle | 500 mL | Tube Size: 1/8" ID × 1/4" OD Cap Side: 17.25; capped male Luer [®] fitting Bottle Side: To Bottom; dip tube tip | Tube Size: $\frac{1}{8}$ " ID $\times \frac{1}{4}$ " OD Cap Side: 3"; Minisart [®] hydrophobic PES filter Bottle Side: None | 1 |
| MYCAPNGPG1000B | 2 port MYCAP™ bottle closure with 1000 mL bottle | 1000 mL | Tube Size: 1/8" ID × 1/4" OD Cap Side: 21.75"; capped male, Luer [®] fitting Bottle Side: To Bottom; dip tube tip | Tube Size: $\frac{1}{8}$ " ID $\times \frac{1}{4}$ " OD Cap Side: 3"; Minisart [®] hydrophobic PES filter Bottle Side: None | 1 |

Series C MYCAP[™] Bottle Assemblies

- Optimized Tube Lengths for including dip tube for fluid transfer
- Includes Nalgene® PETG Media Bottle
- Platinum-Cured Silicone Tubing (Dow-Corning[®] PHARMA-50)
- QUICKSEAL[®] aseptic disconnect
- Gamma Irradiated
- Individually Double Bagged

| Part Number | Description | Bottle Size | Port 1 | Port 2 | Qty/Pack |
|----------------|---|-------------|--|---|----------|
| MYCAPNGPG0030C | 2 port MYCAP™ bottle closure with 30mL bottle | 30 mL | Tube Size: $\frac{1}{8}$ " ID × $\frac{1}{4}$ " OD Cap Side: 3.75"; OUICKSEAL® at 1.75"; capped male Luer [®] fitting Bottle Side: To Bottom; dip tube tip | Tube Size: 1/8" ID × 1/4" OD Cap Side: 3"; Minisart [®] hydrophobic PES filter Bottle Side: None | 1 |
| MYCAPNGPG0060C | 2 port MYCAP™ bottle closure with 60mL bottle | 60 mL | Tube Size: $\frac{1}{8}$ " ID × $\frac{1}{4}$ " OD Cap Side: 3.25"; QUICKSEAL® at 2.25"; capped male Luer [®] fitting Bottle Side: To Bottom; dip tube tip | Tube Size: 1/8" ID × 1/4" OD Cap Side: 3"; Minisart [®] hydrophobic PES filter Bottle Side: None | 1 |
| MYCAPNGPG0125C | 2 port MYCAP™ bottle closure with 125mL bottle | 125 mL | Tube Size: 1/8" ID × 1/4" OD Cap Side: 8"; OUICKSEAL® at 2"; capped male Luer [®] fitting Bottle Side: To Bottom; dip tube tip | Tube Size: 1/8" ID × 1/4" OD Cap Side: 3"; Minisart [®] hydrophobic PES filter Bottle Side: None | 1 |
| MYCAPNGPG0250C | 2 port MYCAP™ bottle closure with 250 mL bottle | 250 mL | Tube Size: 1/8" ID × 1/4" OD Cap Side: 6.5"; QUICKSEAL® at 3"; capped male Luer [®] fitting Bottle Side: To Bottom; dip tube tip | Tube Size: $\frac{1}{8}$ " ID $\times \frac{1}{4}$ " OD Cap Side: 3"; Minisart [®] hydrophobic PES filter Bottle Side: None | 1 |
| MYCAPNGPG0500C | 2 port MYCAP™ bottle closure with 500 mL bottle | 500 mL | Tube Size: $\frac{1}{8}$ " ID × $\frac{1}{4}$ " OD Cap Side: 11.25; QUICKSEAL® at 2"; capped male Luer [®] fitting Bottle Side: To Bottom; dip tube tip | Tube Size: $\frac{1}{8}$ " ID $\times \frac{1}{4}$ " OD Cap Side: 3"; Minisart [®] hydrophobic PES filter Bottle Side: None | 1 |
| MYCAPNGPG1000C | 2 port MYCAP™ bottle closure with 1000 mL bottle | 1000 mL | Tube Size: $1/8"$ ID × $1/4"$ OD Cap Side: 9.5"; QUICKSEAL® at 2"; capped male, Luer [®] fitting Bottle Side: To Bottom; dip tube tip | Tube Size: 1/8" ID × 1/4" OD Cap Side: 3"; Minisart [®] hydrophobic PES filter Bottle Side: None | 1 |

Series D MYCAP[™] Bottle Assemblies

- Optimized Tube Lengths for including dip tube for fluid transfer
- Includes Nalgene® PETG Media Bottle
- C-Flex tubing (formulation 374)
- $\mathsf{QUICKSEAL}^{\circ}$ as eptic disconnect
- Gamma Irradiated
- Individually Double Bagged

| Part Number | Description | Bottle Size | Port 1 | Port 2 | Qty/Pack |
|----------------|---|-------------|---|---|----------|
| MYCAPNGPG0030D | 2 port MYCAP™ bottle closure with 30mL bottle | 30 mL | Tube Size: 1/8" ID × 1/4" OD Cap Side: 15.75"; QUICKSEAL® at 1.75"; plug at end Bottle Side: To Bottom; dip tube tip | Tube Size: 1/8" ID × 1/4" OD Cap Side: 3"; Minisart [®] hydrophobic PES filter Bottle Side: None | 1 |
| MYCAPNGPG0060D | 2 port MYCAP™ bottle closure with 60mL bottle | 60 mL | Tube Size: 1/8" ID × 1/4" OD Cap Side: 15.25"; QUICKSEAL® at 2.25"; plug at end Bottle Side: To Bottom; dip tube tip | Tube Size: 1/8" ID × 1/4" OD Cap Side: 3"; Minisart [®] hydrophobic PES filter Bottle Side: None | 1 |
| MYCAPNGPG0125D | 2 port MYCAP™ bottle closure with 125mL bottle | 125 mL | Tube Size: 1/8" ID × 1/4" OD Cap Side: 14"; OUICKSEAL® at 2"; plug at end Bottle Side: To Bottom; dip tube tip | Tube Size: 1/8" ID × 1/4" OD Cap Side: 3"; Minisart [®] hydrophobic PES filter Bottle Side: None | 1 |
| MYCAPNGPG0250D | 2 port MYCAP™ bottle closure with 250 mL bottle | 250 mL | Tube Size: $\frac{1}{8}$ " ID × $\frac{1}{4}$ " OD Cap Side: 18.5"; QUICKSEAL® at 2.5"; plug at end Bottle Side: To Bottom; dip tube tip | Tube Size: 1/8" ID × 1/4" OD Cap Side: 3"; Minisart [®] hydrophobic PES filter Bottle Side: None | 1 |
| MYCAPNGPG0500D | 2 port MYCAP™ bottle closure with 500 mL bottle | 500 mL | Tube Size: 1/8" ID × 1/4" OD Cap Side: 17.25; QUICKSEAL® at 2"; plug at end Bottle Side: To Bottom; dip tube tip | Tube Size: 1/8" ID × 1/4" OD Cap Side: 3"; Minisart [®] hydrophobic PES filter Bottle Side: None | 1 |
| MYCAPNGPG1000D | 2 port MYCAP™ bottle closure with 1000 mL bottle | 1000 mL | Tube Size: 1/8" ID × 1/4" OD Cap Side: 21.75"; QUICKSEAL® at 1.5"; plug at end Bottle Side: To Bottom; dip tube tip | Tube Size: 1/8" ID × 1/4" OD Cap Side: 3"; Minisart [®] hydrophobic PES filter Bottle Side: None | 1 |

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