

# Mycap<sup>®</sup> Bottle Assemblies



## Features

- Ready-to-use
- Single-use
- One-For-All silicone closure
- One-piece construction
- Easy customization

## Benefits

- Save time Eliminate errors
- No contamination risk
- Universal validation Robust & reliable performance
- Integral closure Easy to handle
- Configure Mycap<sup>®</sup> to your process needs

## Product Information

Mycap<sup>®</sup> 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<sup>®</sup> bottle assemblies include Nalgene<sup>®</sup> square media bottles, are gamma irradiated and ready for immediate use.

## Applications

Mycap® is ideal for critical fluid-handling applications.

Mycap® 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® 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 µm/m<sup>3</sup> and 5.0 µm/m<sup>3</sup> 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<sup>-6</sup> 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

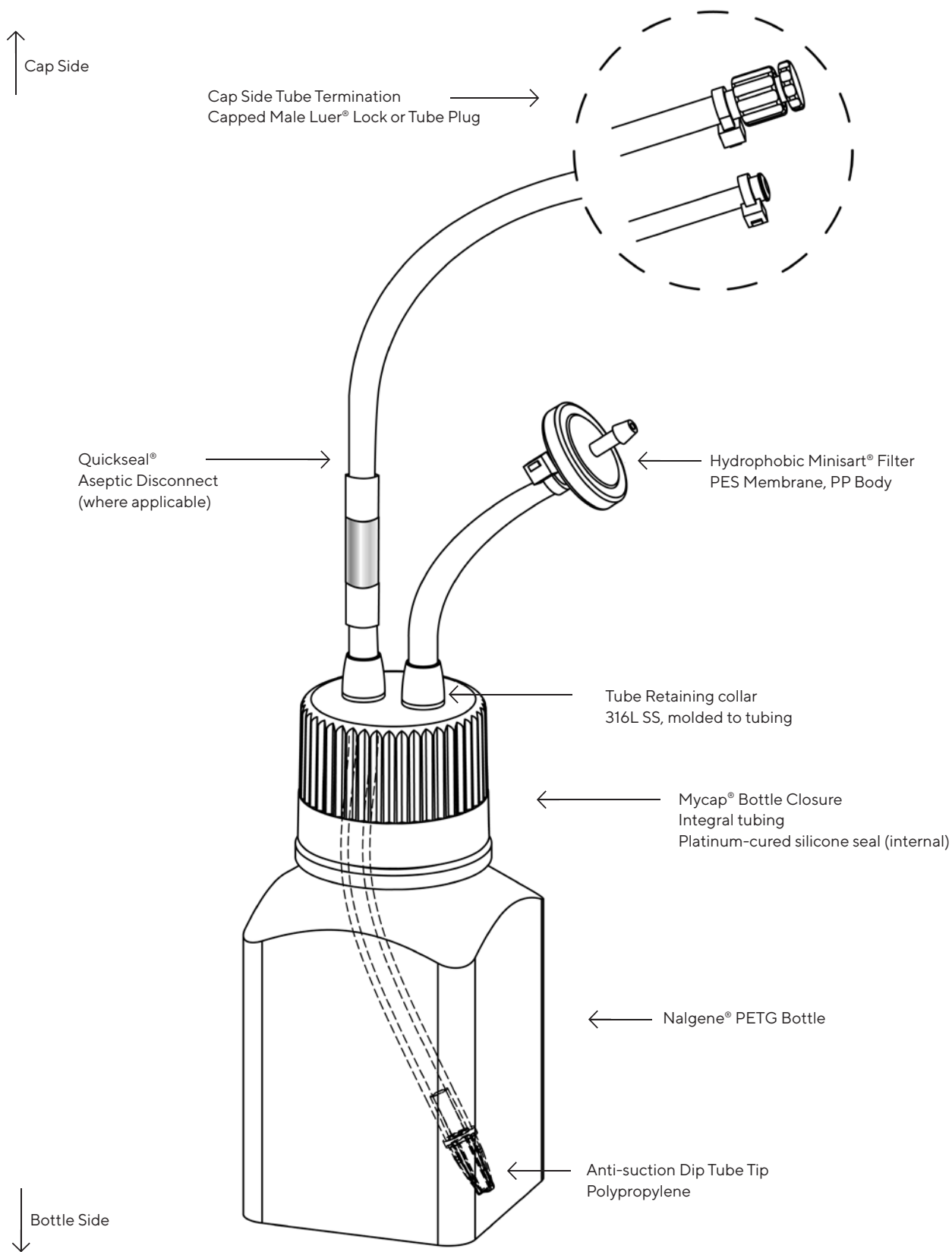
Luer® is a registered trademark of Becton Dickinson

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

### Universal Design Features:

- 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	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 3.75"; capped male Luer® fitting <b>Bottle Side:</b> To Bottom; dip tube tip	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 3"; Minisart® hydrophobic PES filter <b>Bottle Side:</b> None	1
MYCAPNGPG0060A	2 port Mycap® bottle closure with 60mL bottle	60 mL	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 3.25"; capped male Luer® fitting <b>Bottle Side:</b> To Bottom; dip tube tip	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 3"; Minisart® hydrophobic PES filter <b>Bottle Side:</b> None	1
MYCAPNGPG0125A	2 port Mycap® bottle closure with 125mL bottle	125 mL	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 8"; capped male Luer® fitting <b>Bottle Side:</b> To Bottom; dip tube tip	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 3"; Minisart® hydrophobic PES filter <b>Bottle Side:</b> None	1
MYCAPNGPG0250A	2 port Mycap® bottle closure with 250 mL bottle	250 mL	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 6.5"; capped male, Luer® fitting <b>Bottle Side:</b> To Bottom; dip tube tip	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 3"; Minisart® hydrophobic PES filter <b>Bottle Side:</b> None	1
MYCAPNGPG0500A	2 port Mycap® bottle closure with 500 mL bottle	500 mL	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 11.25; capped male Luer® fitting <b>Bottle Side:</b> To Bottom; dip tube tip	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 3"; Minisart® hydrophobic PES filter <b>Bottle Side:</b> None	1
MYCAPNGPG1000A	2 port Mycap® bottle closure with 1000 mL bottle	1000 mL	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 9.5"; capped male, Luer® fitting <b>Bottle Side:</b> To Bottom; dip tube tip	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 3"; Minisart® hydrophobic PES filter <b>Bottle Side:</b> None	1

## Series B Mycap® Bottle Closures

### Universal Design Features:

- 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	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 15.75"; capped male Luer® fitting <b>Bottle Side:</b> To Bottom; dip tube tip	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 3"; Minisart® hydrophobic PES filter <b>Bottle Side:</b> None	1
MYCAPNGPG0060B	2 port Mycap® bottle closure with 60mL bottle	60 mL	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 15.25"; capped male Luer® fitting <b>Bottle Side:</b> To Bottom; dip tube tip	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 3"; Minisart® hydrophobic PES filter <b>Bottle Side:</b> None	1
MYCAPNGPG0125B	2 port Mycap® bottle closure with 125mL bottle	125 mL	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 14"; capped male Luer® fitting <b>Bottle Side:</b> To Bottom; dip tube tip	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 3"; Minisart® hydrophobic PES filter <b>Bottle Side:</b> None	1
MYCAPNGPG0250B	2 port Mycap® bottle closure with 250 mL bottle	250 mL	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 18.5"; capped male, Luer® fitting <b>Bottle Side:</b> To Bottom; dip tube tip	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 3"; Minisart® hydrophobic PES filter <b>Bottle Side:</b> None	1
MYCAPNGPG0500B	2 port Mycap® bottle closure with 500 mL bottle	500 mL	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 17.25"; capped male Luer® fitting <b>Bottle Side:</b> To Bottom; dip tube tip	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 3"; Minisart® hydrophobic PES filter <b>Bottle Side:</b> None	1
MYCAPNGPG1000B	2 port Mycap® bottle closure with 1000 mL bottle	1000 mL	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 21.75"; capped male, Luer® fitting <b>Bottle Side:</b> To Bottom; dip tube tip	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 3"; Minisart® hydrophobic PES filter <b>Bottle Side:</b> None	1

## Series C Mycap® Bottle Assemblies

### Universal Design Features:

- 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	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 3.75"; Quickseal® at 1.75"; capped male Luer® fitting <b>Bottle Side:</b> To Bottom; dip tube tip	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 3"; Minisart® hydrophobic PES filter <b>Bottle Side:</b> None	1
MYCAPNGPG0060C	2 port Mycap® bottle closure with 60mL bottle	60 mL	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 3.25"; Quickseal® at 2.25"; capped male Luer® fitting <b>Bottle Side:</b> To Bottom; dip tube tip	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 3"; Minisart® hydrophobic PES filter <b>Bottle Side:</b> None	1
MYCAPNGPG0125C	2 port Mycap® bottle closure with 125mL bottle	125 mL	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 8"; Quickseal® at 2"; capped male Luer® fitting <b>Bottle Side:</b> To Bottom; dip tube tip	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 3"; Minisart® hydrophobic PES filter <b>Bottle Side:</b> None	1
MYCAPNGPG0250C	2 port Mycap® bottle closure with 250 mL bottle	250 mL	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 6.5"; Quickseal® at 3"; capped male Luer® fitting <b>Bottle Side:</b> To Bottom; dip tube tip	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 3"; Minisart® hydrophobic PES filter <b>Bottle Side:</b> None	1
MYCAPNGPG0500C	2 port Mycap® bottle closure with 500 mL bottle	500 mL	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 11.25; Quickseal® at 2"; capped male Luer® fitting <b>Bottle Side:</b> To Bottom; dip tube tip	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 3"; Minisart® hydrophobic PES filter <b>Bottle Side:</b> None	1
MYCAPNGPG1000C	2 port Mycap® bottle closure with 1000 mL bottle	1000 mL	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 9.5"; Quickseal® at 2"; capped male, Luer® fitting <b>Bottle Side:</b> To Bottom; dip tube tip	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 3"; Minisart® hydrophobic PES filter <b>Bottle Side:</b> None	1

## Series D Mycap® Bottle Assemblies

### Universal Design Features:

- Optimized Tube Lengths for including dip tube for fluid transfer
- Includes Nalgene® PETG Media Bottle
- C-Flex tubing (formulation 374)
- Quickseal® aseptic 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	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 15.75"; Quickseal® at 1.75"; plug at end <b>Bottle Side:</b> To Bottom; dip tube tip	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 3"; Minisart® hydrophobic PES filter <b>Bottle Side:</b> None	1
MYCAPNGPG0060D	2 port Mycap® bottle closure with 60mL bottle	60 mL	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 15.25"; Quickseal® at 2.25"; plug at end <b>Bottle Side:</b> To Bottom; dip tube tip	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 3"; Minisart® hydrophobic PES filter <b>Bottle Side:</b> None	1
MYCAPNGPG0125D	2 port Mycap® bottle closure with 125mL bottle	125 mL	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 14"; Quickseal® at 2"; plug at end <b>Bottle Side:</b> To Bottom; dip tube tip	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 3"; Minisart® hydrophobic PES filter <b>Bottle Side:</b> None	1
MYCAPNGPG0250D	2 port Mycap® bottle closure with 250 mL bottle	250 mL	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 18.5"; Quickseal® at 2.5"; plug at end <b>Bottle Side:</b> To Bottom; dip tube tip	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 3"; Minisart® hydrophobic PES filter <b>Bottle Side:</b> None	1
MYCAPNGPG0500D	2 port Mycap® bottle closure with 500 mL bottle	500 mL	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 17.25; Quickseal® at 2"; plug at end <b>Bottle Side:</b> To Bottom; dip tube tip	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 3"; Minisart® hydrophobic PES filter <b>Bottle Side:</b> None	1
MYCAPNGPG1000D	2 port Mycap® bottle closure with 1000 mL bottle	1000 mL	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 21.75"; Quickseal® at 1.5"; plug at end <b>Bottle Side:</b> To Bottom; dip tube tip	<b>Tube Size:</b> 1/8" ID x 1/4" OD <b>Cap Side:</b> 3"; Minisart® hydrophobic PES filter <b>Bottle Side:</b> None	1




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