



GL45 MYCAP™ Bottle Closures

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.



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™
to your process needs

Applications

MYCAP™ is ideal for critical fluid-handling applications.

Attach to glass bottles with GL45 threaded closures, autoclave and 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 closures 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 closures 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.

GL45 MYCAP™ bottle closures can be field installed without use of any instruments or tools. A survey of random operators found the average torque applied by hand is just under 16in-lbs. 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/m³ and 5.0 µm/m³ particles are within the ISO Class 7 acceptance criteria, per ISO 14644-1.

Quality Assurance

MYCAP™ bottle closures 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 GL45 MYCAP™ bottle closures reports compliance to:

- USP <87>: Biological reactivity tests, in Vitro
- USP <88>: Biological reactivity tests, in Vivo
- USP <788>: Particulate matter
- USP <85>: Endotoxin

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 closures 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.

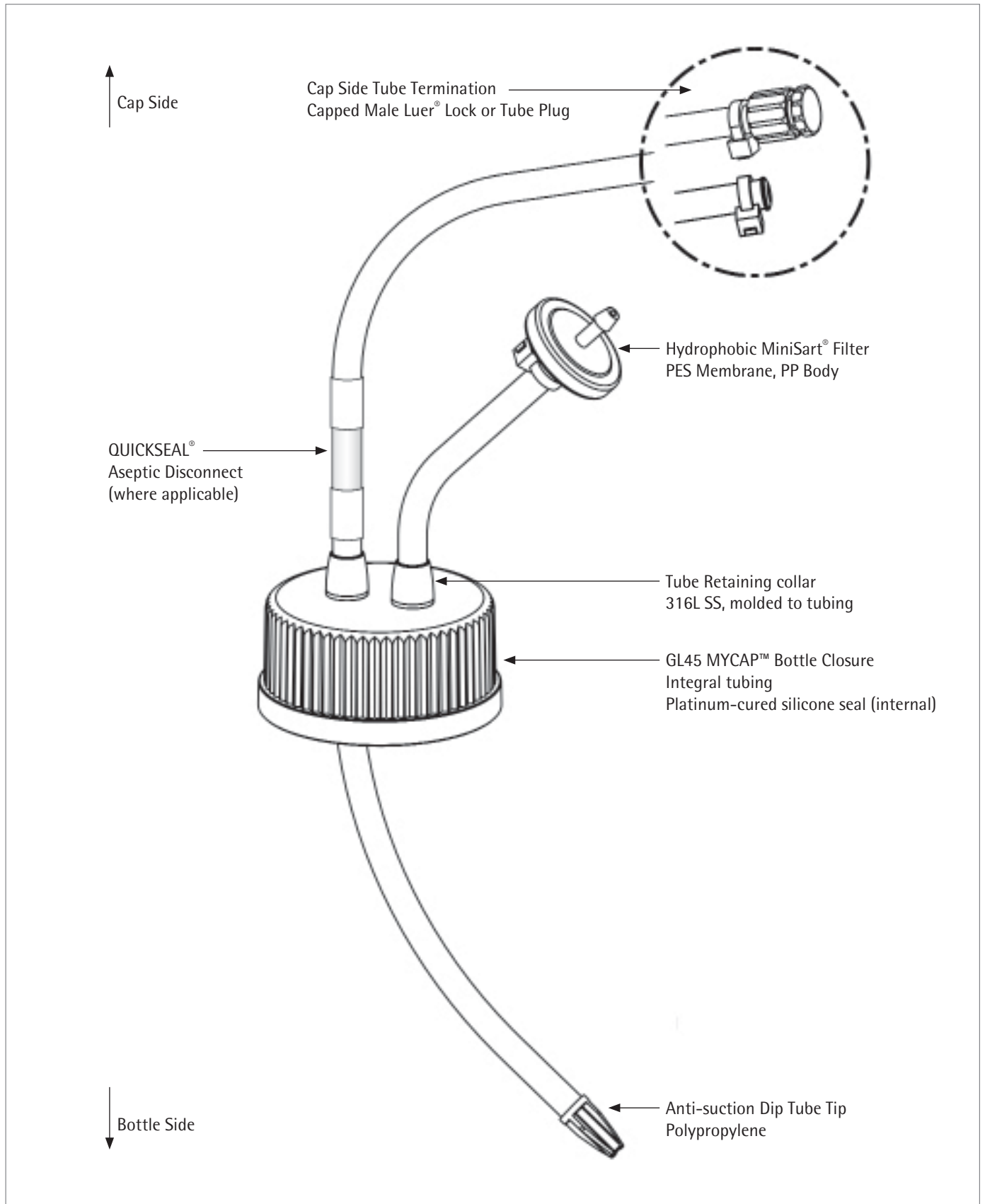
Technical Data

Specifications

Elastomer Seal	Platinum-cured silicone
Tubing	Platinum-cured silicone or C-Flex® formulation 374
Cap Material	Polycarbonate (not fluid contact)
Closure Style	GL45
Tube Ports	Inlet Outlet, Air vent - 25 mm PES membrane MiniSart®
Fittings	Luer® Lock or tube plug
Sterilization	Autoclavable

C-Flex® is a registered trademark of Saint-Gobain Performance Plastics Corporation
Luer® is a registered trademark of Becton Dickinson
Corning® and Pyrex® are registered trademarks of Corning Incorporated
Dow Corning® is a registered trademark of Dow Corning Corporation
LpH®, Vesphene® Spor Klenz® are registered trademarks of STERIS Corporation

MYCAP™ Bottle Closure Anatomy



Ordering Information

Series A GL45 MYCAP™ Bottle Closures

Universal Design Features:

- Optimized Tube Lengths for Corning® Pyrex® Round Media Storage Bottles (PN: 1395-xxx)
- Bottle not included
- Platinum-Cured Silicone Tubing (Dow-Corning® PHARMA-50)
- Non-sterile
- Autoclavable

Part Number	Description	Bottle Size	Cap Size	Port 1	Port 2	Qty/Pack
MYCAP13950100A	2 port GL45 MYCAP™ bottle closure	100 mL	GL45	Tube Size: 1/8" ID × 1/4" OD Cap Side: 8.25"; 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	5
MYCAP13950250A	2 port GL45 MYCAP™ bottle closure	250 mL	GL45	Tube Size: 1/8" ID × 1/4" OD Cap Side: 6.75"; 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	5
MYCAP13950500A	2 port GL45 MYCAP™ bottle closure	500 mL	GL45	Tube Size: 1/8" ID × 1/4" OD Cap Side: 11"; 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	5
MYCAP13951000A	2 port GL45 MYCAP™ bottle closure	1000 mL	GL45	Tube Size: 1/8" ID × 1/4" OD Cap Side: 9.25"; 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	5
MYCAP13952000A	2 port GL45 MYCAP™ bottle closure	2000 mL	GL45	Tube Size: 1/8" ID × 1/4" OD Cap Side: 14"; 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	5

Series B GL45 MYCAP™ Bottle Closures

Universal Design Features:

- Optimized Tube Lengths for Corning® Pyrex® Round Media Storage Bottles (PN: 1395-xxx)
- Bottle not included
- C-Flex® tubing (formulation 374)
- Non-sterile
- Autoclavable (tubing may deform or melt during autoclave - exercise caution)

Part Number	Description	Bottle Size	Cap Size	Port 1	Port 2	Qty/Pack
MYCAP13950100B	2 port GL45 MYCAP™ bottle closure	100 mL	GL45	Tube Size: 1/8" ID × 1/4" OD Cap Side: 14.5"; tube 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	5
MYCAP13950250B	2 port GL45 MYCAP™ bottle closure	250 mL	GL45	Tube Size: 1/8" ID × 1/4" OD Cap Side: 19"; tube 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	5
MYCAP13950500B	2 port GL45 MYCAP™ bottle closure	500 mL	GL45	Tube Size: 1/8" ID × 1/4" OD Cap Side: 17.25"; tube 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	5
MYCAP13951000B	2 port GL45 MYCAP™ bottle closure	1000 mL	GL45	Tube Size: 1/8" ID × 1/4" OD Cap Side: 21.5"; tube 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	5
MYCAP13952000B	2 port GL45 MYCAP™ bottle closure	2000 mL	GL45	Tube Size: 1/8" ID × 1/4" OD Cap Side: 20.25"; tube 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	5

Series C GL45 MYCAP™ Bottle Closures

Universal Design Features:

- Optimized Tube Lengths for Corning® Pyrex® Round Media Storage Bottles (PN: 1395-xxx)
- Bottle not included
- Platinum-Cured Silicone Tubing (Dow-Corning® PHARMA-50)
- QUICKSEAL® aseptic disconnect
- Non-sterile
- Autoclavable

Part Number	Description	Bottle Size	Cap Size	Port 1	Port 2	Qty/Pack
MYCAP13950100C	2 port GL45 MYCAP™ bottle closure	100 mL	GL45	Tube Size: 1/8" ID × 1/4" OD Cap Side: 8.25"; 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	5
MYCAP13950250C	2 port GL45 MYCAP™ bottle closure	250 mL	GL45	Tube Size: 1/8" ID × 1/4" OD Cap Side: 6.75"; 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	5
MYCAP13950500C	2 port GL45 MYCAP™ bottle closure	500 mL	GL45	Tube Size: 1/8" ID × 1/4" OD Cap Side: 11"; 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	5
MYCAP13951000C	2 port GL45 MYCAP™ bottle closure	1000 mL	GL45	Tube Size: 1/8" ID × 1/4" OD Cap Side: 9.25"; 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	5
MYCAP13952000C	2 port GL45 MYCAP™ bottle closure	2000 mL	GL45	Tube Size: 1/8" ID × 1/4" OD Cap Side: 14"; 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	5

Series D GL45 MYCAP™ Bottle Closures

Universal Design Features:

- Optimized Tube Lengths for Corning® Pyrex® Round Media Storage Bottles (PN: 1395-xxx)
- Bottle not included
- C-Flex® tubing (formulation 374)
- QUICKSEAL® aseptic disconnect
- Non-sterile
- Autoclavable (tubing may deform or melt during autoclave - exercise caution)

Part Number	Description	Bottle Size	Cap Size	Port 1	Port 2	Qty/Pack
MYCAP13950100D	2 port GL45 MYCAP™ bottle closure	100 mL	GL45	Tube Size: 1/8" ID × 1/4" OD Cap Side: 14.5"; QUICKSEAL® at 2.25"; tube 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	5
MYCAP13950250D	2 port GL45 MYCAP™ bottle closure	250 mL	GL45	Tube Size: 1/8" ID × 1/4" OD Cap Side: 19"; QUICKSEAL® at 2"; tube 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	5
MYCAP13950500D	2 port GL45 MYCAP™ bottle closure	500 mL	GL45	Tube Size: 1/8" ID × 1/4" OD Cap Side: 17.25"; QUICKSEAL® at 2.25"; tube 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	5
MYCAP13951000D	2 port GL45 MYCAP™ bottle closure	1000 mL	GL45	Tube Size: 1/8" ID × 1/4" OD Cap Side: 21.5"; QUICKSEAL® at 2.25"; tube 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	5
MYCAP13952000D	2 port GL45 MYCAP™ bottle closure	2000 mL	GL45	Tube Size: 1/8" ID × 1/4" OD Cap Side: 20.25"; QUICKSEAL® at 2"; tube 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	5

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