

BIOCLOSURE® SYSTEM ASSEMBLIES

SINGLE-USE; FOR BOTTLES, FLASKS AND CARBOYS



TPE
www.advantapure.com

BioClosure System Assemblies, made from AdvantaFlex® biopharmaceutical grade TPE, provide a ready to use, cost effective solution to reduce assembly time and eliminate cleaning validations. The Single-Use, closed cap systems feature a robust design to protect product integrity and decrease the risk of contamination. BioClosure System Assemblies are an ideal choice for bioprocessing applications such as aseptic sampling, cell growth and filling.

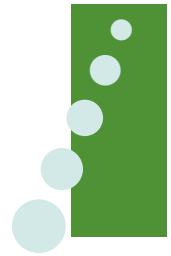
Full BPOG standardized extractables test protocol (six extraction solvents, tested to four different exposure times, out to 70 days) is in process with a fully-accredited, third-party test lab; applies to AdvantaFlex closures and tubing only.

KEY FEATURES

- All systems come preassembled with fluid transfer tubing for easy use
- Meets various ISO and USP standards, including Class VI
- Assembled and packaged in Class 7 (Class 10,000) ISO-certified clean rooms
- Easy connections – AdvantaFlex tubing is sterile weldable and heat sealable
- AdvantaFlex tubing is certified free of animal-derived ingredients
- Documented quality control; lot traceable with identification on bags
- AdvantaFlex validation and extractables test portfolios available upon request
- AdvantaFlex has a Master File with the U.S Food and Drug Administration (#28810)

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BioClosure Sterile Media Bottle Assemblies

- ▶ Available in five bottle capacities from 125 mL to 2 liter; square PETG bottles
- ▶ Validated sterility assurance of 10^{-6} via gamma irradiation per ISO 11137 method VDmax 25
- ▶ AdvantaFlex® tubing supplied with plugged end and dip tube to bottom of bottle with angled cut for easy transfer
- ▶ 0.2 um filter for sterile gas venting
- ▶ Custom lengths and configurations available upon request
- ▶ Also available in platinum cured silicone



APPLICATIONS

- Aseptic Sampling
- Media/Buffers Storage
- Sterile Filling
- Vaccine Production
- Process R&D

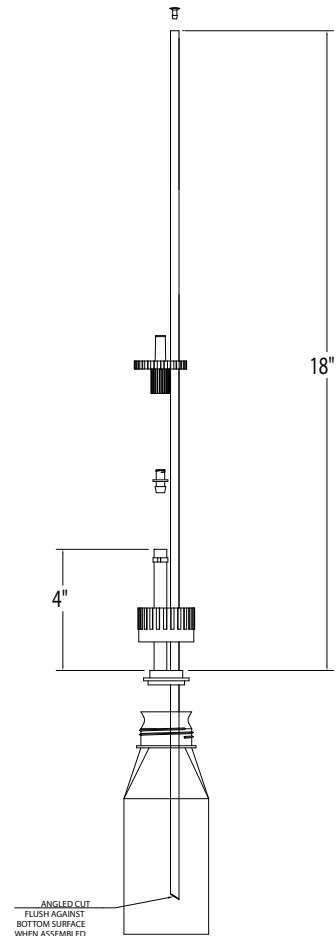
TYPE

SPECIFICATIONS

for BioClosure Sterile Media Bottle Assemblies

Product Number	Bottle Capacity
AFBA2-38-0012	125 mL
AFBA2-38-0025	250 mL
AFBA2-38-0050	500 mL
AFBA2-38-0100	1000 mL (1 Liter)
AFBA2-53-0200	2000 mL (2 Liter)

All AdvantaFlex BioClosure Sterile Media Bottle Assemblies are supplied with one (1) 1/8" I.D. x 1/4" O.D. dip tube line and one (1) 1/4" I.D. x 7/16" O.D. vent line.



BioClosure Sterile Erlenmeyer Flask Assemblies

- ▶ Available in two capacities: 1 and 2 liter; polycarbonate flasks
- ▶ Flasks fit standard shaking incubator systems and can be placed on any platform
- ▶ Validated sterility assurance of 10^{-6} via gamma irradiation per ISO 11137 method VDmax 25
- ▶ AdvantaFlex® tubing with MPC/sealing cap and dip tube to bottom of flask with angled cut for easy transfer
- ▶ 0.2 um filter for sterile gas venting
- ▶ Custom lengths and configurations available upon request
- ▶ Also available in platinum cured silicone



APPLICATIONS

- Cell/Microbial/Plant Cell Growth
- Media Preparation/Storage
- Process R&D

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SPECIFICATIONS *for BioClosure Sterile Erlenmeyer Flask Assemblies (flask included)*

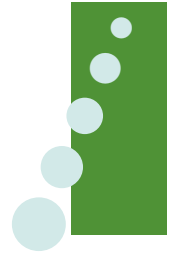
Product Number	Flask Capacity
AFFA2-53-0100x	1000 mL (1 Liter)
AFFA2-53-0200x	2000 mL (2 Liter)

All AdvantaFlex BioClosure Sterile Erlenmeyer Flask Assemblies are supplied with one (1) 1/8" I.D. x 1/4" O.D. dip tube line and one (1) 1/4" I.D. x 7/16" O.D. vent line.

Specify flat (F) or baffled (B) base.
Example: AFFA2-53-0100F

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BioClosure Cap Assemblies for AdvantaPure Carboys

- ▶ Available in five carboy cap capacities from 2.5 to 40 liter
- ▶ 2-port and 3-port closure configurations
- ▶ Fit carboys with 80mm and 120mm neck size
- ▶ Can be sterilized via gamma irradiation or autoclave
- ▶ AdvantaFlex® tubing with plugged end and fill line to bottom of carboy for easy transfer
- ▶ 0.2 um filter for sterile gas venting
- ▶ BioClosure assemblies for 20 liter and 40 liter carboys include an adapter cone
- ▶ Custom lengths and configurations available upon request
- ▶ Also available in platinum cured silicone



TYPE



■ Select from 2-port, molded AdvantaFlex cap assemblies (above) or 3-port, hose barb adapter styles (right)

APPLICATIONS

- Media/Buffer Storage
- Sterile Filling
- Vaccine Production
- Process R&D



SPECIFICATIONS *for 2-Port BioClosure Cap Assemblies for AdvantaPure Carboys, Molded Style*

Product Number	Carboy Capacity
AFCA2-83-0250	2.5 Liter
AFCA2-83-0500	5 Liter
AFCA2-83-1000	10 Liter
AFCA2-83-2000	20 Liter
AFCA2-83-4000	40 Liter

All 2-port, molded AdvantaFlex® BioClosure Cap Assemblies are supplied with one (1) 1/4" I.D. x 1/2" O.D. AdvantaFlex vent line and one (1) 1/4" I.D. x 1/2" O.D. AdvantaFlex fill line.

Note: 2-Port BioClosure Cap Assemblies are supplied non-sterile.

SPECIFICATIONS *for 3-Port BioClosure Cap Assemblies for AdvantaPure Carboys, 1/4" Hose Barb Adapter Style*

Product Number	Carboy Capacity
AFCA3-83x-0250-04	2.5 Liter
AFCA3-83x-0500-04	5 Liter
AFCA3-83x-1000-04	10 Liter
AFCA3-83x-2000-04	20 Liter
AFCA3-83x-4000-04	40 Liter

These 3-port BioClosure Cap Assemblies are supplied with one (1) 1/4" I.D. x 1/2" O.D. AdvantaFlex vent line and two (2) 1/4" I.D. x 1/2" O.D. AdvantaFlex fill lines.

Specify gamma sterilized, if required, when ordering. **Examples:**
A **non-sterile**, 10 Liter, 3-Port Cap Assembly is part number AFCA3-83-1000-04.
A **gamma sterilized**, 10 Liter, 3-Port Cap Assembly is part number AFCA3-83GS-1000-04.

SPECIFICATIONS *for 3-Port BioClosure Cap Assemblies for AdvantaPure Carboys, 1/2" Hose Barb Adapter Style*

Product Number	Carboy Capacity
AFCA3-83x-0250-08	2.5 Liter
AFCA3-83x-0500-08	5 Liter
AFCA3-83x-1000-08	10 Liter
AFCA3-83x-2000-08	20 Liter
AFCA3-83x-4000-08	40 Liter

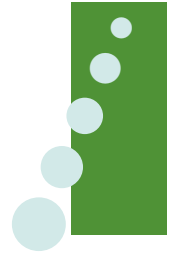
These 3-port BioClosure Cap Assemblies are supplied with one (1) 1/4" I.D. x 1/2" O.D. AdvantaFlex vent line and two (2) 1/2" I.D. x 3/4" O.D. AdvantaFlex fill lines.

Specify gamma sterilized, if required, when ordering. **Examples:**
A **non-sterile**, 10 Liter, 3-Port Cap Assembly is part number AFCA3-83-1000-08.
A **gamma sterilized**, 10 Liter, 3-Port Cap Assembly is part number AFCA3-83GS-1000-08.

See next page for AdvantaPure Carboys.

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AdvantaPure Carboys

AdvantaPure Carboys are the ideal choice for advanced fluid handling and have been designed with the end-user in mind. The ergonomically designed body and handles allow the user to easily hold and manipulate the container during lifting, filling and pouring while the novel shape maximizes bench and shelf space. The user-friendly cap has molded finger grips allowing for easy cap removal and attachment while wearing gloves.

Carboys are available with or without spigots and have large levers that control two flow rates – one for continuous, locked flow and the other for faster, manual flow. The spout features 5/8" and 3/4" hose barbs and a standard internal luer tape to fit a male barb adapter.



Additional options provide flexibility in drainage, pump connection and automated equipment. Spigot fittings are available as 1/4", 3/8", 1/2" and 3/4" hose barb adapters, as well as a 3/4" sanitary Tri-Clamp connector.

Carboy container materials include:

Polypropylene (PP):

- Meets USP Class VI and FDA requirements
- Autoclavable (recommended cycle is 15 PSI for 20 minutes at 121°C)
- Easy to clean and good chemical compatibility to acids and bases
- Temperature range: -40°C to 121°C
- Good for media and buffer solutions
- Top molded handles; available with or without spigot
- Easy to read graduation marks certified to +/- 5% accuracy

TYPE

Dark Amber Polypropylene (DP):

- Meets USP Class VI and FDA requirements
- Autoclavable (recommended cycle is 15 PSI for 20 minutes at 121°C)
- Easy to clean and good chemical compatibility to acids and bases
- Temperature range -40°C to 121°C
- Amber color helps protect from UV and light that can alter contents in carboy
- Top molded handles; available with or without spigot
- Easy to read graduation marks certified to +/- 5% accuracy

PETG (PG):

- Meets USP Class VI and FDA requirements
- Can be gamma irradiated
- Easy to clean and good chemical compatibility to acids and bases
- Temperature range -40°C to 80°C
- Clear
- Good for media and buffer solutions
- Available with or without spigot
- Easy to read graduation marks certified to +/- 5% accuracy

HDPE:

- Meets USP Class VI and FDA requirements
- Highly chemical resistant to acids and bases
- Temperature range -50°C to 121°C
- Good for buffers and reagents
- Top molded handles; available with or without spigot
- Easy to read graduation marks certified to +/- 5% accuracy

Amber HDPE:

- Meets USP Class VI and FDA requirements
- Highly chemical resistant to acids and bases
- Temperature range -50°C to 121°C
- Excellent for storage of light sensitive materials
- Top molded handles; available with or without spigot
- Easy to read graduation marks certified to +/- 5% accuracy

Carboy capacities range from 2.5 Liter through 40 Liter; not all materials are available in all sizes. Please contact your AdvantaPure Technical Sales Representative at 888-755-4370 (in the U.S.) or 215-526-2151 for more details.

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SINGLE-USE PROCESS MOLDED MANIFOLDS

Eliminate production stoppages for sterilization, reduce the risk of leaks and contamination, and increase efficiency by incorporating Single-Use manifolds from AdvantaPure. Single Use products simplify cleaning validations—use once and discard.

Each manifold is custom made using platinum-cured, Class VI silicone tubing or AdvantaFlex® TPE tubing, molded fittings, **BioClosures**, filters, bottles, labels and tracking options, and other components.

Contact an AdvantaPure representative today to discuss your application.

TPE

Purity in Fluid Flow Systems®

AdvantaPure's BioClosure Systems are part of a complete line of products for the Pharmaceutical, Biomedical, Cosmetic, and Food industries. Items available include . . .



Made in U.S.A.

- Unreinforced, 50 Shore A, platinum-cured silicone tubing
- Braid-reinforced, platinum-cured silicone hose
- Wire and mesh reinforced, mandrel-wrapped, platinum-cured silicone suction hose
- Stainless steel overbraided PTFE hose and rubber-covered EPDM hose
- Sanitary fittings and complete hose assemblies including molded silicone ends
- Identification solutions including GammaTag®, Hose Track®, and the P•E•T Process Equipment Tracking® Identification & Lifecycle Analysis System from NewAge Industries' Verigenics® division

Address: NewAge Industries AdvantaPure®
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Southampton, PA 18966 U.S.A.



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for Your Benefit

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