

BIOCLOSURE® SYSTEMS

PLATINUM CURED SILICONE OR BIOPHARMACEUTICAL GRADE TPE



Manufactured from USP Class VI, platinum-cured silicone elastomer or from AdvantaFlex® biopharmaceutical grade TPE, AdvantaPure's BioClosure Systems offer the utmost in purity. They're biologically safe and work with vessels of glass, metal or plastic. Stoppers, caps, inserts for True Unions and GL45's, and other styles, with or without tubing, are available. 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.

BioClosure Systems are not intended for implantation or continuous steam applications.



KEY FEATURES

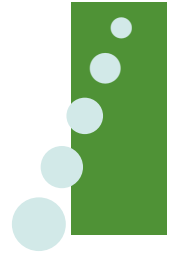
- Ideally suited for pharmaceutical, biotech and laboratory environments
- Silicone elastomer meets USP Class VI, FDA CFR 177.2600, ISO 10993, European Pharmacopoeia 3.1.9 and other industry standards
- Assembled and packaged in Class 7 (Class 10,000) ISO-certified clean rooms
- Both silicone and TPE are certified free of animal-derived ingredients
- Documented lot traceable
- For single or repeated use – sterilizable through autoclave or gamma radiation
- Single use applications reduce cleaning and validation requirements and costs, plus cross contamination risks
- Smooth, gap-free surfaces for a true seal and a secure environment
- Longer life expectancy, more consistent performance, and higher purity than parts made from other rubber materials
- Resistant to cracking and particle migration
- No taste or odor transfer
- Excellent chemical resistance properties
- Silicone withstands temperatures ranging between -100°F (-73.3°C) and 400°F (204.4°C)
- Select stopper sizes available; other silicone closures custom manufactured
- Certain styles available manufactured from AdvantaFlex® biopharmaceutical grade TPE (thermoplastic elastomer)
- For use with flexible container systems, laboratory apparatus and bottles, and sampling and storage receptacles of glass, plastics, or metal
- Available with tubing installed
- Validation and extractables test portfolios available upon request
- The silicone and thermoplastic elastomer compounds used to make BioClosure Systems have a Master File with the U.S. Food and Drug Administration

SILICONE/TPE

www.advantapure.com

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■ AdvantaPure's BioClosure Systems are manufactured from silicone or TPE that's free of animal-derived ingredients. Your processes stay biologically safe.



■ Choose from silicone stoppers, caps, inserts for True Unions and GL45's, and other styles, with or without tubing. Certain styles are available in TPE.

SILICONE/TPE



■ A securely sealed bioprocessing system is crucial. That's why BioClosure Systems are manufactured with strict tolerance requirements.



SILICONE STOPPER SPECIFICATIONS



Product Number	Size	Top Diameter		Bottom Diameter		Height	
		(in.)	(mm)	(in.)	(mm)	(in.)	(mm)
APSTOPPER-2	2	0.794	20.17	0.640	16.26	1.000	25.40
APSTOPPER-4	4	1.039	26.39	0.808	20.52	1.000	25.40
APSTOPPER-6	6	1.269	32.23	1.051	26.70	1.000	25.40
APSTOPPER-7	7	1.453	36.91	1.188	30.18	1.000	25.40
APSTOPPER-8	8	1.627	41.33	1.318	33.48	1.000	25.40
APSTOPPER-10	10	2.000	50.80	1.685	42.80	1.000	25.40
APSTOPPER-12	12	2.686	68.22	2.000	50.80	1.500	38.10

NOTE: Sizes 2 through 8 are packaged and sold in increments of 10 pieces per size. Sizes 10 and 12 are packaged and sold in increments of 5 pieces per size.

■ Silicone bottle stoppers in sizes 2 to 12 are available with tubing already attached to speed your installation, reduce multiple product inventories, and save labor costs.

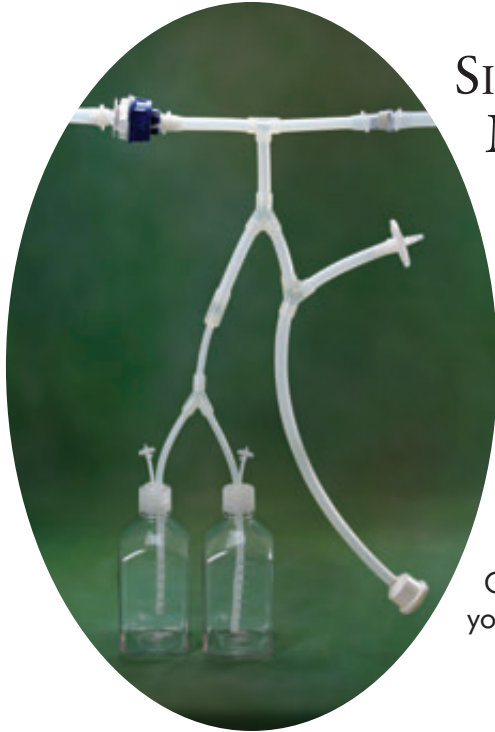
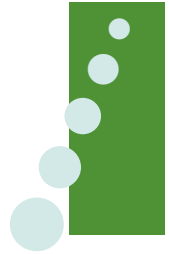
■ Use as a disposable item to reduce cross contamination risks, cleaning requirements, and validation time and costs.



SILICONE/TPE

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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.

SILICONE/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

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for Your Benefit

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