

SINGLE-USE MOLDED MANIFOLDS

FOR PRODUCT SAMPLING & STORAGE APPLICATIONS



Single-Use Molded Manifolds are custom made to meet your product sampling and storage needs in drug and vaccine production.

Manufactured from AdvantaFlex® biopharmaceutical grade TPE or platinum-cured Class VI silicone, molded manifolds eliminate the need for barbed fittings while providing a seamless transition from tubing to connection for a continuous, unrestricted flow. Designs range from simple molded sanitary ends to complex configurations with varying lengths of tubing and several molded connections.

Single-Use Molded Manifolds are not intended for implantation or continuous steam applications.



KEY FEATURES

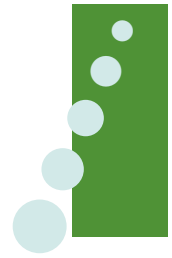
- Eliminates leaks, entrapment, and contamination issues associated with barbed fittings
- Custom manufactured with Y's, T's, crosses, reducers, mini and standard Tri-Clamps®, stoppers and other container closures, and tubing
- Components are permanently molded into one, Single-Use manifold
- Provides a smooth inner surface without seams or crevices for even, uninterrupted flow
- One **animal-derived-ingredient-free** material contact surface throughout
- Reduces end-user component inventory and assembly labor time and expense
- Single-Use reduces the risk of cross contamination
- Also reduces downtime by eliminating certain cleaning validation requirements
- Provides flexibility in facility design—changes are less costly than with hard piping
- Sterilizable by autoclave and gamma radiation—available with **validated sterility assurance** of 10⁻⁶ per ISO 11137 method VDmax 25
- Each material retains its temperature resistance properties after molding
- Imparts no taste or odor to critical streams
- Molded and packaged in Class 7 (Class 10,000) ISO-certified clean rooms
- Documented lot traceable with identification on bags
- Documented quality control
- Experienced engineers available for technical assistance
- DocuLink® (patent pending) manifold assembly identification permanently molds a part number and/or lot number onto a manifold for quick visual reference and to track the part back to its origins (silicone only; see back page)
- Optional RFID tags easily attach to assemblies for identification purposes providing reliable electronic data storage and current status of assemblies from inception to disposal
- The silicone and thermoplastic elastomer compounds used to make Single-Use Molded Manifolds have a Master File with the U.S. Food and Drug Administration

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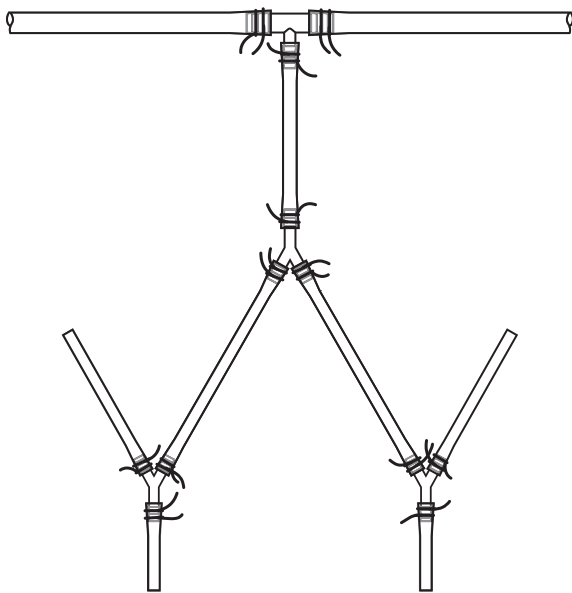
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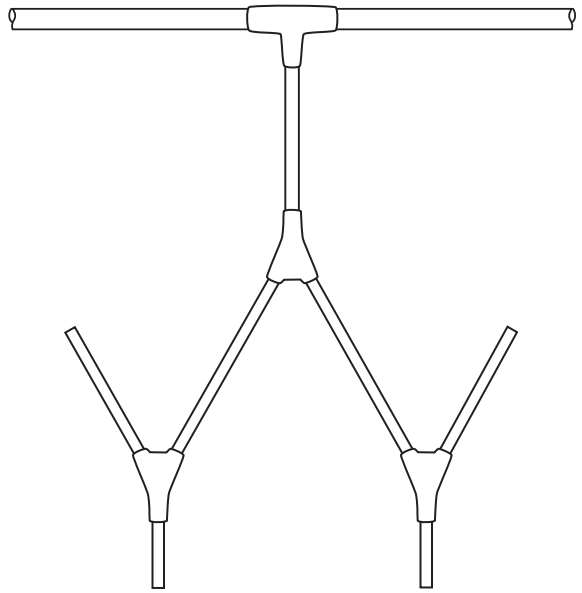


This example of an assembly made from tubing and barbed fittings is comprised of nine separate pieces of tubing of varying sizes and lengths, plus four fittings that require insertion into the tubing at three points each, with double cable ties installed at each connection for secure attachment.



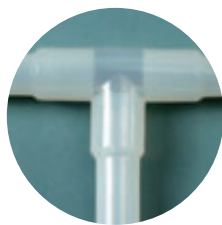
37 Components

An AdvantaPure Single-Use Molded Manifold is a complete unit, packaged in a sealed polybag and ready for use. Leaks, entrapment, and contamination concerns involved with barbed fitting connections are eliminated. Labor, numerous inventories, and time to assemble the manifold is unnecessary.



1 Component

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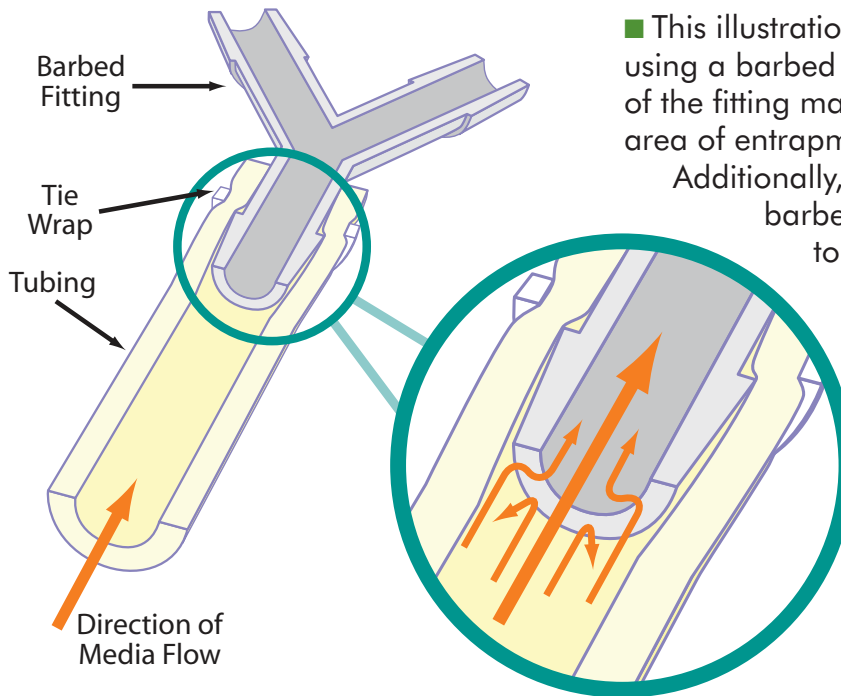
■ Select from a number of different crevice-free connections.



■ Molded mini and standard Tri-Clamp® fittings with protective backing cups may be incorporated into manifolds.



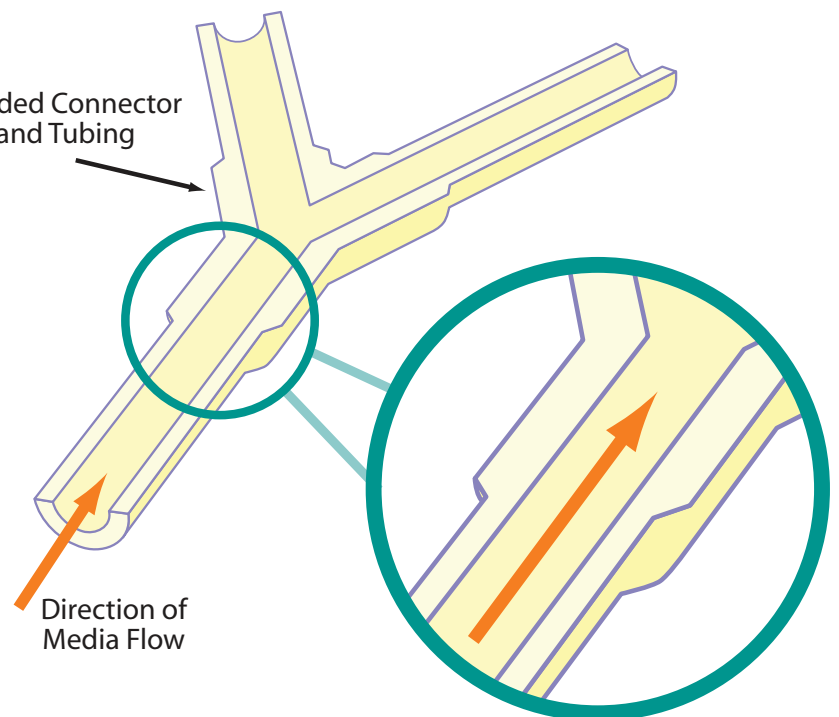
Comparative Advantages of Molded Manifold Interiors



■ This illustration of a tubing set assembly using a barbed fitting shows how the edge of the fitting may disrupt flow or create an area of entrapment and potential leakage. Additionally, cable ties used to secure barbed fittings have the potential to pierce bags and packaging.

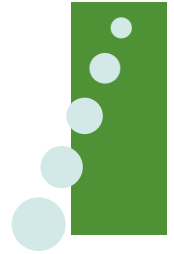
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■ The interior of a one-piece molded manifold connection provides a smooth inner surface and a seamless transition for a continuous, unrestricted, leak-proof flow. Molded manifolds reduce the risk of a wasted batch of costly product.



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Platinum-Cured Silicone

Low-volatile grade, platinum-cured silicone tubing is clean room produced and has undergone extensive physical, chemical, and biological testing. Called APST, it meets many USP standards, including Class VI, as well as FDA, ISO, European Pharmacopoeia, and 3-A standards. APST offers a complete validation package and is stocked in over forty sizes.



■ Manifolds are manufactured by molding straight sections of tubing or hose with connectors such as T's and Y's. Molded connectors provide a seamless transition for a continuous, unrestricted flow.

■ Standard size bottle stoppers are available solid or customized with tubing inserts to speed your installation, reduce multiple product inventories, and save labor costs.



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■ BioClosure® caps, inserts for True Unions and GL45's, and other container closures, available with or without tubing inserts, are also manufactured from platinum-cured, Class VI silicone.

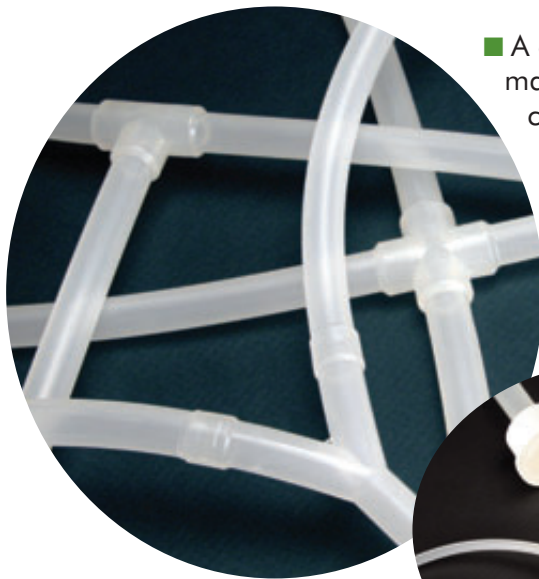


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AdvantaFlex® BioPharmaceutical Grade TPE

AdvantaFlex addresses the need for a flexible, translucent, sterilizable, heat sealable, weldable, and moldable biopharmaceutical tubing for fluid processing. The tubing is made from FDA-approved ingredients and meets various ISO and USP standards, including Class VI, and European Pharmacopoeia standards. A complete validation package is available, and fifteen popular sizes are stocked.



- A complete Single-Use Molded Manifold can be made from AdvantaFlex. Choose from T's, Y's, crosses, reducers, mini and standard Tri-Clamps® and BioClosure® container closures.



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- Excellent weldability and sealability allows leak-free, sterile connections for filling and sampling applications.



- Sealed Tubing Ends make it easy to maintain a sterile, closed system. Weld to bags or container closures for sampling and storage applications.

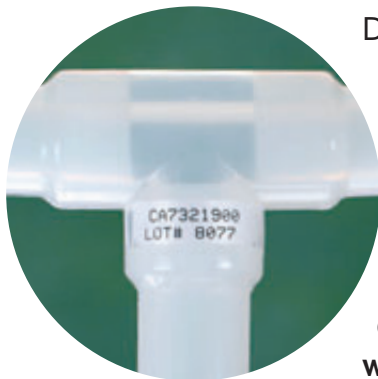
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Tubing Sets

If you're not sure that molded manifolds are right for your application, let us manufacture your tubing sets. Assembled in Class 7, ISO-certified clean rooms, they're fabricated from tubing, fittings, and accessories that you specify, such as filters, aseptic connectors and bottles.

Contact your AdvantaPure sales representative for information.



DocuLink (patent pending) visually identifies each manifold with a part number and/or lot number. The identification is permanently molded into the silicone connector.

Using DocuLink allows easy tracking of a manifold assembly back to its origins. It handles clean-in-place (CIP), steam-in-place (SIP), autoclave, and gamma irradiation processes.

Contact your AdvantaPure sales representative or visit www.advantapure.com/doculink.htm for information.

Purity in Fluid Flow Systems®



Made in U.S.A.

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