

SINGLE-USE TUBING ASSEMBLIES

FOR PHARMACEUTICAL & BIOPHARM PROCESSING APPLICATIONS



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

Each system is custom made using AdvantaSil® platinum-cured, Class VI silicone tubing or reinforced hose, or AdvantaFlex® Class VI biopharmaceutical grade TPE tubing to meet sealing and welding requirements. Add fittings, stoppers and container closures, filters, sensors, bottles, labels, tracking options and **now** GORE® STA-PURE® Pump Tubing, Series PCS, as the pump element.



KEY FEATURES

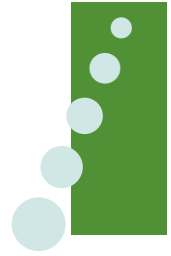
- Custom manufactured and assembled from a variety of components
- Reduces end-user assembly labor expense and time
- Reduces cross contamination risks
- Saves energy and resource costs by eliminating cleaning and autoclaving
- Reduces production downtime by eliminating certain cleaning validation requirements
- Well suited for long production cycles when GORE STA-PURE Pump Tubing is used as the pump element
- Provides flexibility and speed in facility design—system redesigns are implemented faster than with hard piping
- Less costly process development and design compared to systems of hard piping
- Assembled and packaged in ISO Class 7 cleanrooms
- Available with **validated sterility assurance** of 10^{-6} via gamma irradiation per ISO 11137 method VDmax 25
- Documented lot traceable with identification on packaging
- Documented quality control per ISO 9001:2015
- Experienced engineers available for technical assistance
- All AdvantaPure-manufactured tubing and molded components are **animal-derived-ingredient-free**
- Optional RFID tags easily attach to assemblies for identification purposes—provide reliable electronic data storage and current status of assemblies from inception to disposal

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Build Your Assembly From . . .

AdvantaSil® Silicone Tubing & Hose

Platinum-cured silicone tubing (called APST), ultra low temperature tubing (APLT), high pressure tubing (APHP), and braid-reinforced hose (APSH) are cleanroom manufactured by AdvantaPure for pharmaceutical and biopharm applications.

All four styles have undergone extensive physical, chemical, and biological testing and meet USP Class VI, FDA CFR 177.2600, ISO 10993, and European Pharmacopoeia 3.1.9 standards.

APST size range: .030" through 1" I.D.
(.76mm through 25.40mm I.D.)

APLT size range: .125" through .500" I.D. (3.18mm through 12.70mm I.D.)

APHP size range: .125" through 1" I.D. (3.18mm through 25.40mm I.D.)

APSH size range: .063" through 1" I.D. (1.59mm through 25.40mm I.D.)



AdvantaFlex® BioPharmaceutical Grade TPE Tubing

AdvantaFlex addresses the need for a flexible, translucent, heat sealable, weldable and moldable biopharmaceutical tubing without silicone oils. AdvantaFlex maintains its physical properties following sterilization processes and remains translucent for visible product flow.

AdvantaFlex is ideal for aseptic tubing welds and helps eliminate aseptic connectors and multiple contact surfaces. The tubing is made from FDA-approved ingredients and meets various ISO and USP standards, including Class VI, as well as European Pharmacopoeia 3.2.2.1 standards.

Size range: 1/8" to 1" I.D.
(3.18mm to 25.40mm I.D.)



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GORE® STA-PURE® Pump Tubing

AdvantaPure is pleased to offer GORE STA-PURE Pump Tubing for your Single-Use Process biotech and pharmaceutical applications.

As experts in molded connections, AdvantaPure can now overmold GORE STA-PURE Pump Tubing into a filling assembly as its pump element. Overmolding reduces the risk of failure at the connection, decreases the chance of contamination, and helps prevent lost batches of costly pharmaceutical and biopharm product.

Alternatively, connections may be made using barbed fittings and clamps.

NOTE: Assemblies that include GORE STA-PURE Pump Tubing cannot be gamma irradiated or be included in AdvantaPure's validated sterility assurance program.

Size range: 1/16" through 1" I.D.
(1.6mm through 25.40mm I.D.)

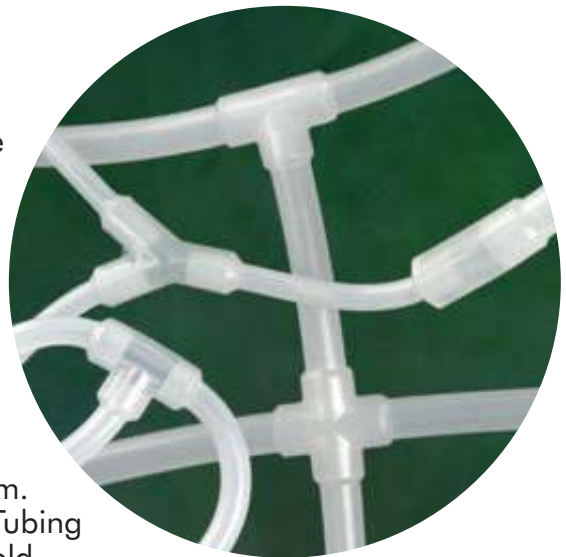


Manifolds

Single-Use molded manifolds provide a seamless transition between tubing and connections for a smooth, fluid contact surface with optimal flow. Molded connections include Y, T, cross, reducer, Tri-Clamp® and mini Tri-Clamp styles.

Made from AdvantaSil® silicone or AdvantaFlex® TPE, they allow for one contact material throughout the system. Additionally, GORE STA-PURE Pump Tubing can be integrated into silicone manifold assemblies as the pump element, providing longer production cycles. Connection sizes vary depending on style.

Size range: 1/8" to 1" I.D.
(3.18mm to 25.40mm I.D.)



Now Available with
GORE STA-PURE Pump Tubing

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Tubing Sets

If you're not sure molded manifolds are right for your application, let us manufacture your tubing sets. Assembled in ISO Class 7 clean-rooms, they're fabricated from tubing, fittings, clamps or cable ties, and accessories you specify.

Sizes to 1" I.D.



Connections

- *Barbed fittings* come in Tri-Clamp, Y, T, elbow and reducer styles. Materials include polypropylene, polyethylene and PVDF.

Size range: 1/8" to 1" hose I.D.
(3.18mm to 25.40mm hose I.D.)



- *Overmolded ends* are available in mini Tri-Clamp styles in AdvantaFlex TPE for a smooth fluid path.

Size range: 1/8" to 1/2" tubing I.D.
(3.18mm to 12.70mm tubing I.D.)



- *Aseptic connectors* reduce contamination risks and keep processing systems pure. Several easy-to-use styles are available.



Connections continue ►

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Contact an AdvantaPure representative or distributor today to start building your Single-Use Tubing Assembly.

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Connections *continued*

- **Quick connects** offer on-the-spot connections and come in several materials. Dependable and secure.



Filters

Choose from a variety of styles, sizes, and manufacturers for your Single-Use System.



Sensors

Single-Use in-line sensors offer real-time monitoring and control of critical processes. They eliminate the need for cleaning, maintenance and recalibration associated with traditional, reusable technologies. Choose from sensors for pressure, flow, temperature, conductivity, turbidity and UV absorbance.



Tubing-to-Fitting Attachments

- **Oetiker® Clamps** provide a 360° seal with both a smooth inner and outer surface. Made from stainless steel, Oetiker clamps are lightweight and compact yet robust—only one is needed at each attachment.

Size range: 5/32" to 1-9/16" nominal tubing O.D.



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Build Your Assembly From . . .

Clamps

- **Pinch clamps**
squeeze tubing closed
anywhere along a line.

One piece construction for
sizes up to 3/4" tubing O.D.
(19.05mm tubing O.D.)

Vise clamp for tubing 1" and larger

- **Tri-Clamp® connection clamps**
come in durable plastic and 304 stainless steel.

Size range: 1/2" to 4" (12.70mm to 101.60mm),
depending on material



Bottles

Laboratory and sampling bottles can also be
incorporated into your system.

For bottle stoppers and
container closures, see
BioClosure® Systems
on the next page.



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BioClosure® Systems

AdvantaPure's BioClosure Systems offer purity, secure seals and versatility in design. Stoppers, caps, True Union and GL45 inserts and other styles, available with or without tubing inserts, are manufactured from AdvantaSil® silicone or AdvantaFlex® biopharmaceutical TPE.

Stopper size range: most sizes from #2 to #12; other styles custom made



GammaTag® RFID Tags

GammaTag is the first read/write RFID tag that maintains data integrity after gamma irradiation. It provides reliable electronic data storage for Single-Use Tubing Assemblies and other bio-process components from inception to disposal.

GammaTag's key features:

- Uses read/write RFID technology to identify critical process components
- Record and access the current status of process components on the spot, or use simply for identification (part number, lot number, gamma sterilization date, etc.)
- Allows gamma radiation sterilization of a complete Single-Use Tubing Assembly for the cleanest possible product
- Available from NewAge Industries' Verigenics® division — learn more at www.verigenics.com



DocuLink®

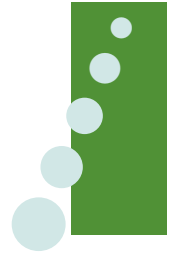
DocuLink (patent pending) is a service designed to save time and effort during document retrieval. It identifies a Single-Use assembly on the product itself, not only on the packaging from which it was removed, by encapsulating an affixed label into a molded silicone connection.

DocuLink can list the individual part number and lot number to allow quick lookup of documents such as certificates of compliance and certificates of analysis. DocuLink cannot fall off like other labels and handles clean-in-place (CIP), steam-in-place (SIP), autoclave and gamma irradiation processes.



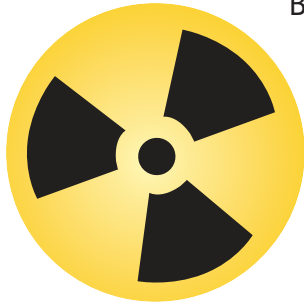
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Gamma Irradiation Services

Have your Single-Use Tubing Assembly gamma irradiated *before* it arrives at your location and save the additional inventorying, transportation costs, and transit time.



Bagged and labeled products are picked up from AdvantaPure's facility and conveyed to a local gamma irradiation service provider. Using Cobalt 60 radiation, microorganisms and bacteria are destroyed while your Single-Use assembly remains in its original packaging. Products are then returned to AdvantaPure for final inspection and shipment to your location.

Validated sterility assurance of 10^{-6} per ISO 11137 method VDmax 25 is available. Contact us for more information.

Bioreactor Tubing Kits

Another Single-Use item from AdvantaPure is Bioreactor Tubing Kits for benchtop bioreactors. The kits are custom manufactured and assembled from a variety of components—tubing, filters, connectors—to provide convenience and greater efficiencies over assembling on site. Choose from AdvantaSil® silicone tubing or weldable and sealable AdvantaFlex® TPE tubing. Visit www.advantapure.com/bioreactor-tubing-kits.htm.



Purity in Fluid Flow Systems®



Made in U.S.A.

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



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