

SINGLE USE SYSTEMS

FOR PHARMACEUTICAL & BIOTECH PROCESSING APPLICATIONS



Eliminate production stoppages for sterilization, reduce the risk of contamination, and increase efficiency by incorporating single use systems from AdvantaPure. Single use systems, or SUS, simplify cleaning validations—use once and discard.

Each system is custom made using platinum-cured, Class VI silicone tubing and hose or AdvantaFlex® Class VI biopharmaceutical grade tubing for peristaltic pump applications. Add fittings, stoppers and container closures, filters, bags, bottles, labels and tracking options, and other components.

Single use systems are not intended for implantation or continuous steam applications.



KEY FEATURES

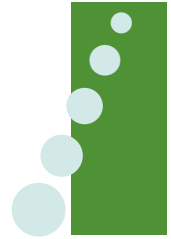
- Custom manufactured and assembled from a variety of components
- Reduces end-user assembly labor expense and time
- Reduces cross contamination risks
- Saves energy and resource costs by eliminating cleaning
- Reduces production downtime by eliminating certain cleaning validation requirements
- Provides 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 **Class 7 (Class 10,000) ISO-certified clean rooms**
- Gamma irradiation services available
- Documented lot traceable with identification on bags
- Documented quality control
- Experienced engineers available for technical assistance
- Tubing and molded connections provide a single, **animal-derived-ingredient-free** material contact surface
- Optional RFID tags easily attach to assemblies for identification purposes—provide reliable electronic data storage and current status of assemblies from inception to disposal

SUS

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Build Your System From . . .

Silicone Tubing & Hose

Low-volatile grade, platinum-cured silicone tubing and braid-reinforced hose is clean-room manufactured by AdvantaPure for pharmaceutical and biotech applications.

Both the tubing (called APST) and hose (APSH) have undergone extensive physical, chemical, and biological testing and meet USP Class VI, FDA CFR 177.2600, ISO 10993, European Pharmacopoeia 3.1.9, and 3-A standards.

APST size range: .030" through 1" I.D.
(.76mm 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, sterilizable, heat sealable, weldable, and moldable biopharmaceutical tubing for fluid processing. The unique properties of AdvantaFlex help it outlast similar tubing tested in peristaltic pumps by 6-10 times.

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.)



SUS

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Manifolds

Single use molded manifolds provide a seamless transition between tubing and connections for a continuous, leak-proof flow. Molded connections include Y, T, cross, reducer, Tri-Clamp®, and mini Tri-Clamp styles. Made from platinum-cured silicone or AdvantaFlex, they allow for one material contact surface throughout the system. Connections sizes differ depending on style.

Size range: .188" to 1" I.D.
(4.76mm to 25.40mm I.D.)



Connections

- *Barbed fittings* come in 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 Tri-Clamp and mini Tri-Clamp styles in Hytrel® and polypropylene materials.

Size range: 1/8" to 1-3/16" hose I.D.
(3.18mm to 30.16mm hose I.D.)



- *Aseptic connectors* reduce contamination risks and keep processing systems pure. Several easy-to-use styles are available. AdvantaFlex tubing can even be molded onto connectors (patent pending), providing a leak-free bond that eliminates tie wraps and their risk of piercing bags or packaging.

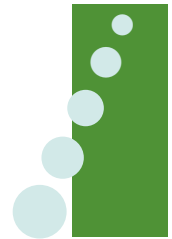


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Build Your System From . . .

Connections *continued*

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



Clamps

- **Pinch clamps** of polypropylene or polyester squeeze tubing closed anywhere along a line. One piece construction.



Sizes fit up to 3/4" tubing O.D.
(19.05mm tubing O.D.)

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

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



Filters

Choose from a variety of styles, sizes, and manufacturers for your single use system. Like aseptic connectors, AdvantaFlex tubing may be molded onto filters (patent pending) for a leak-free seal that eliminates tie wraps.



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Contact an AdvantaPure representative or distributor today to start building your single use system.

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Bags

AdvantaPure can supply bags from a number of leading manufacturers. Let us know what you need.



Bottles

Laboratory and sampling bottles can also be incorporated into your system. Select from HPDE and other materials.

For stoppers and container closures, see BioClosure Systems below.



BioClosure® Systems

AdvantaPure's new 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 platinum-cured, Class VI silicone or AdvantaFlex biopharmaceutical TPE.

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



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GammaTag® RFID Tags

GammaTag is the first read/write RFID tag that maintains data integrity after gamma sterilization. It provides reliable electronic data storage for single use systems and other bioprocess 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.)
- All critical packaging and labeling documentation resides on the component throughout its useful life
- Allows gamma radiation sterilization of a complete single use system for the cleanest possible product
- GammaTag's read/write ability makes it unique – data may be written directly on the tag, unlike read-only bar code labels
- Provides reliable identification without the potential hazards of leachables found in permanent markers
- Will not fall off during cold storage
- RoHS compliant
- Available from NewAge Industries' Verigenics™ division
- Learn more at www.verigenics.com



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DocuLink™

DocuLink (patent pending) is a service designed to save time and effort during document retrieval. It identifies a single use system on the product itself, not only on the bag from which it was removed, by use of a permanently-affixed label at a silicone connector.

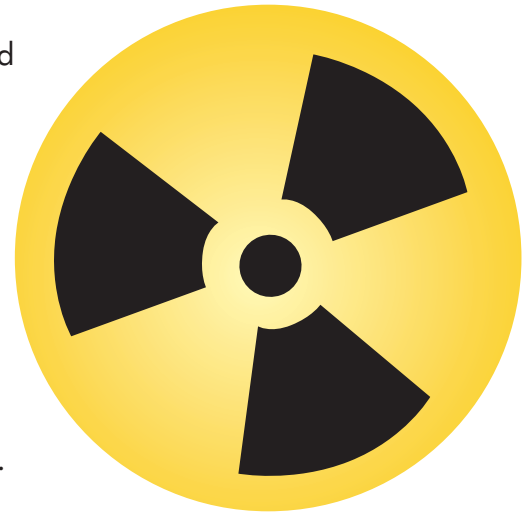


DocuLink can list the individual part number and lot number to allow quick lookup of documents such as certificates of compliance and certificates of analysis. DocuLink cannot fall off like other labels and handles clean-in-place (CIP), steam-in-place (SIP), autoclave, and gamma irradiation processes.

Gamma Irradiation Services

Have your single use system gamma irradiated *before* it arrives at your location and save the additional inventorying, transportation costs, and transit time.

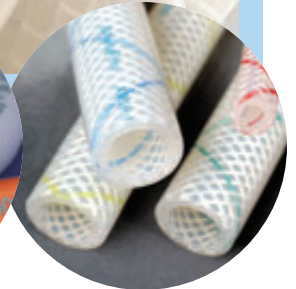
Bagged and labeled products are picked up from AdvantaPure's facility and conveyed to a local gamma irradiation service provider. Using Cobalt 60 radiation, microorganisms and bacteria are destroyed while your single use system remains in its original packaging. Products are then returned to AdvantaPure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



SUS

MORE ADVANTAPURE PRODUCTS

- Unreinforced platinum silicone tubing
- Braid-reinforced platinum silicone hose
- Stainless steel wire and polyester mesh reinforced wrapped platinum silicone hose
- Polyester mesh reinforced 4-ply platinum silicone hose
- PTFE hose with stainless steel overbraiding (with or without overjacketing)
- Rubber-covered FEP or EPDM hose
- AdvantaFlex® BioPharmaceutical Grade Tubing
- Stainless steel sanitary crimp fittings and complete hose assemblies including molded silicone ends
- Custom hose identification solutions – silicone encased labels with color striping, laser-etched stainless steel collars, tubing/hose printing, solid color exterior layers, and color tracer braid
- Identification solutions including GammaTag®, Hose Track®, and the P•E•T Process Equipment Tracking® Identification & Lifecycle Analysis System
- Special hose coverings, cleaning, and packaging



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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