



PharmaLink® BioSystems

For pharmaceutical & biotech processing applications

Eliminate production stoppages for sterilization, reduce the risk of leaks and contamination, and increase efficiency by incorporating BioSystems from Italprotec Industries. PharmaLink® BioSystems simplify cleaning validations-use once and discard.

Each system is custom made using platinum-cured, Class VI silicone tubing or reinforced hose or TPE Class VI biopharmaceutical grade tubing to meet sealing and welding application requirements.

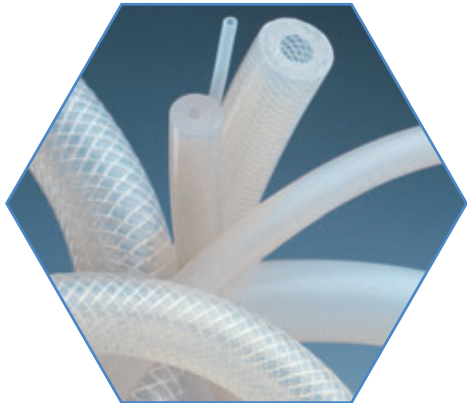
Add fittings, stoppers and container closures, filters, sensors, bottles, labels, tracking options and other components. BioSystems are not intended for implantation or continuous steam applications.

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 and autoclaving
- * 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
- * Available with validated sterility assurance of 10⁻⁶ via gamma irradiation per ISO 11137 method VDmax 25
- * 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
- * The silicone and thermoplastic elastomer compounds used to make BioSystems have a Master File with the U.S. Food and Drug Administration



Build Your System From ...

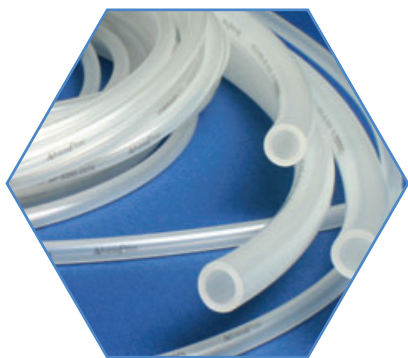


Silicone Tubing & Hose

Silicone Tubing & Hose Low-volatile grade, platinum-cured silicone tubing and braid-reinforced hose is clean-room manufactured by PharmaLink® for pharmaceutical and biotech applications.

Both the tubing and hose 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.

Tubing size range: .030" through 1" I.D. (.76mm through 25.40mm I.D.)
Hoses size range: .063" through 1" I.D. (1.59mm through 25.40mm I.D.)

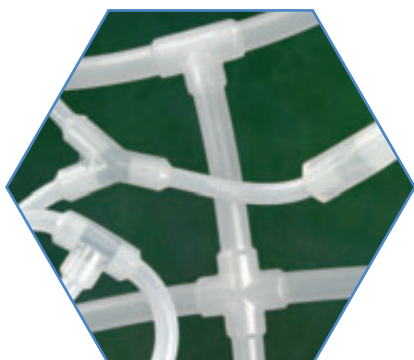


Pharmaceutical Grade TPE Tubing

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

TPE tubing 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.)



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 TPE tubing, they allow for one material contact surface throughout the system.

Connection sizes vary depending on style.

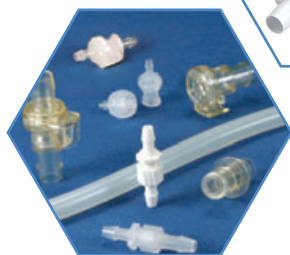
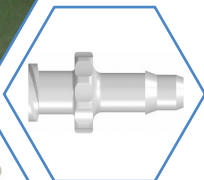
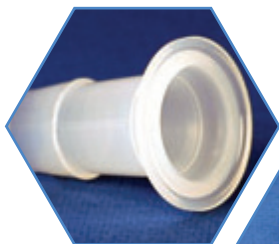
Size range: .188" to 1" I.D. (4.76mm to 25.40mm I.D.)





Tubing Sets

If you're not sure 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 you specify. Sizes to 1" I.D.



Connections

• Barbed fittings

come in Tri-Clamp, Y, T, elbow and reducer styles and Luers. 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 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.

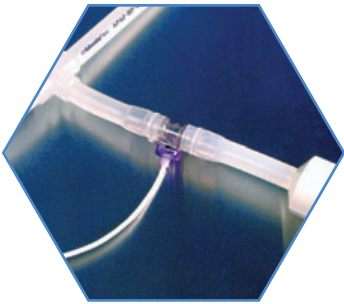
• Quick connects

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

Filters

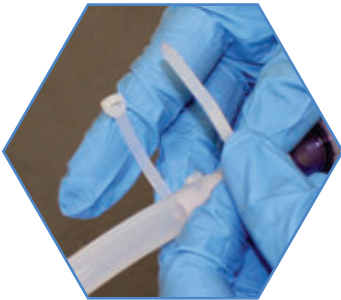
Filters Choose from a variety of styles, sizes, and manufacturers for your Single-Use System.





Sensors

Single-Use in-line sensors offer realtime 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

- **Cable Ties**

are quick and easy to apply; no tools are needed. For added security, it is recommended that two ties be used at each attachment.



- **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.



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.)

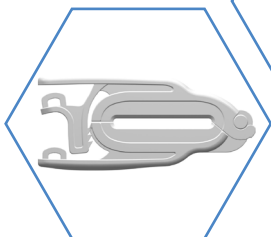
Vise clamp for tubing 1" and larger

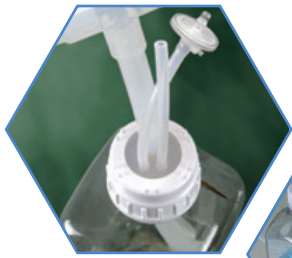


- **Tri-Clamp connection clamps**

come in durable plastic and 304 stainless steel.

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





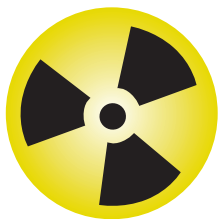
Bottles

Laboratory and sampling bottles can also be incorporated into your system. For bottle stoppers and container closures, see PharmaLink BioClosures below.



BioClosures

Italprotec'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 platinum-cured, Class VI silicone or TPE biopharmaceutical tubing. Stopper size range: most sizes from #2 to #12; other styles custom made.



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 Italprotec'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 our facilities 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.

