



PharmaLink® BioClosures

Platinum cured silicone or biopharmaceutical grade TPE

Manufactured from USP Class VI, platinumcured silicone elastomer or from PharmaLink[®] biopharmaceutical grade TPE, Italprotec Industries BioClosures 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.

PharmaLink[®] BioClosures 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 conta mination 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
- * 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 PharmaLink[®] BioClosures have a Master File with the U.S. Food and Drug Administration



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

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

> Italprotec's BioClosures 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.



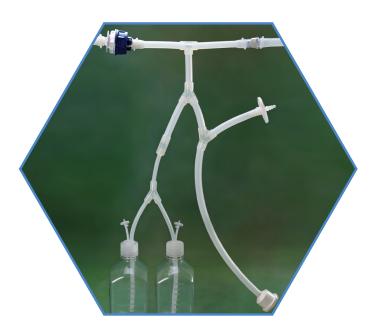
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Single-use process molded manifolds

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

Each manifold is custom made using platinumcured, Class VI silicone tubing or PharmaLink® TPE tubing, molded fittings, filters, bottles, labels and tracking options, and other components.

Contact an Italprotec Industries representative today to discuss your application.

Italprotec's BioClosures are part of a complete line of products for the Pharmaceutical, Biomedical, Cosmetic, and Food industries. Items available include

- * 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; rubber-covered FEP and EPDM hose
- * Sanitary fittings and complete hose assemblies including molded silicone ends
- * Identification & Lifecycle Analysis System from Italprotec Industries



Data and features are approximate and subject to change without notice