# *FC NEWSLETTER, JANUARY, 2010*

**There has been increased demand for single use - disposable products in the biopharm industry --- This issue is dedicated to our disposables and assembly capabilities available through SAINT- Gobain products. The items highlighted are Bio-Simplex connection methods, flask systems, sterile bottle assembly and sampling manifold systems designed to handle your biopharm needs.**

**Flow Components is available to develop and provide solutions for a wide variety of disposable biopharmaceutical applications. -Phil Meese**

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# *Bio-Simplex® Connection Method*

## *Innovative Solutions for Today's Biopharmaceutical Manufacturers*

Bio-Simplex® technologies **eliminate the need for assembly infrastructure**. Bio-Simplex® overmolded technology is **"one-piece" construction**. The overmolding material is the same as the tubing; when molded together they become one, providing an integrally bonded connection with superior strength. Bio-Simplex® overmolding **maintains inner bore** diameters.

Bio-Simplex® overmolded connections intrinsically have **exceptional burst strength** that exceeds the burst pressure of the tubing.

**No mechanical fasteners** to fail, one-piece design.

Repeatable, **machine-driven** molding process.

**No hose barbs used.** Bio-Simplex® overmolds maintain bore diameters throughout connectors, eliminating entrapment areas.

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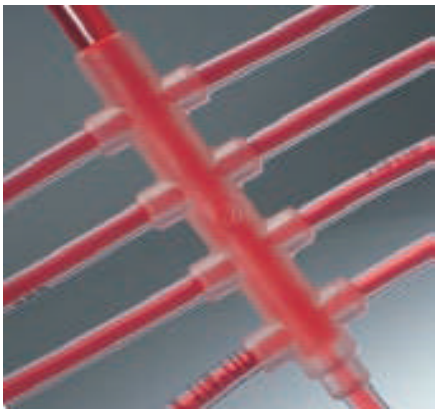
## *Bio-Simplex® Connections*



Bio-Simplex® Manifold—The heart of our fluid transfer system allows samples to be taken without compromising product sterility. Whether a single molded design (eight-port shown here) or a series of inline Tees, we can design to your exact specifications. One piece construction made from pharmaceutical C-Flex® resin and tubing to ensure an unobstructed fluid path, extremely low levels of extractables, and to provide a secure elastomeric seal against glass and plastic surfaces.

## *EZ Top® Container Closures*

One-piece construction. Made from pharmaceutical grade C-Flex® resin and tubing to ensure an unobstructed fluid path and extremely low levels of extractables, and to provide a secure elastomeric seal against glass and plastic surfaces.

Overmolded Tee —Totally seamless fluid path. Overmolding eliminates path obstruction, fluid holdup or loss, cell damage and connection failure.

Overmolded Cross — Similar technology to the Tee. Allows two additional seamless fluid paths

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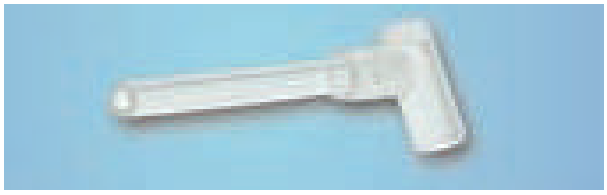
Overmolded Wye —Blends or divides fluid path. Overmolding holds tubing shape and maintains consistent fluid path through junction.



Overmolded Right Angle with Septum — Allows sample aspiration via needle through self-sealing septum port.

Bio-Simplex® FlexJoint™ — Eliminates tube kinking, holds shape after autoclaving. Unobstructed inner bore. Designed to accommodate angle deviation in hand-blown Spinner Flasks.

Flexible Tee with FlexJoint™ — Holds shape and maintains consistent fluid path.

## *Bio-Simplex® Connection Method:*

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- Custom-engineered for customer specific applications
- Economically designed for single use
- One-piece construction provides superior reliability and product integrity
- Made from C-Flex® pharmaceutical grade thermoplastic elastomers
- Eliminates manual assembly, tie wraps, hose barbs and other connecting devices
- Available with your choice of bottles, bags, syringes and filters

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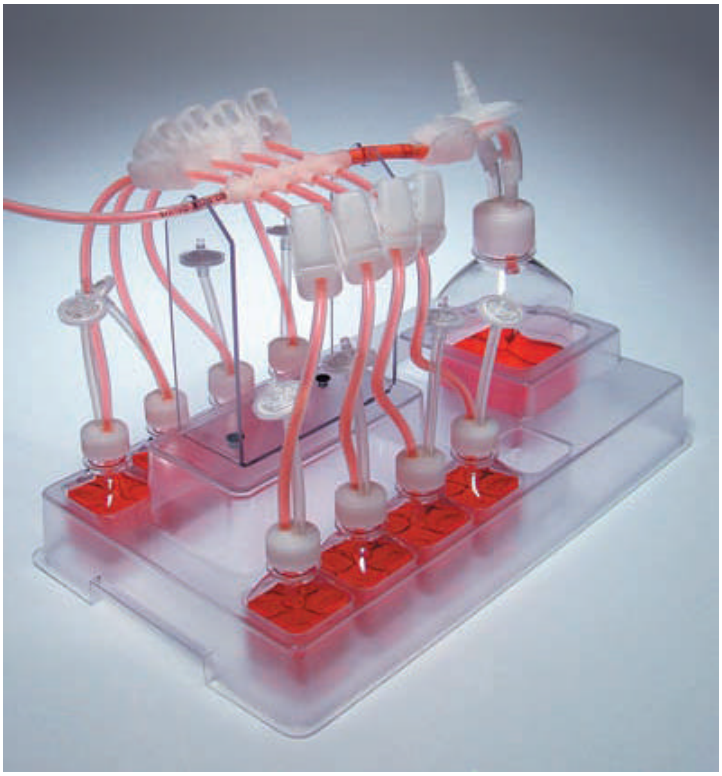
# Erlenmeyer Flask Systems

The number one choice of the biopharmaceutical industry in single-use Erlenmeyer Flask assemblies, BioSimplex™ Erlenmeyer Flask Closures are now available solo (Closure Assembly) or with a standard polycarbonate flask (System). Our Bio-Simplex™ Closure Assembly features the EZ Top® assembly, made from pharmaceutical grade C-Flex® thermoplastic elastomer (TPE) resin and tubing, and is engineered to ensure an unobstructed fluid path, extremely low levels of extractables and a secure elastomeric seal against plastic, glass and metal surfaces. The Closure Assembly includes C-Flex® tubing with a choice of either male Luer connections or CPC®quick disconnect fittings, a Bio-Simplex™ FlexJoint™, 0.2 µm vent filter and polypropylene cap. Economically designed for the single use market, both the Bio-Simplex™ Assembly and System eliminate cleaning and contamination from repeated use. They are easily used with sterile connecting devices and thermal tubing sealers.We offer standard 2 port configurations in 1, 2 and 3 Liter sizes, available as individually packaged Bio-Simplex™ Closure Assemblies or a complete packaged Bio-Simplex™ Erlenmeyer Flask System (Bio-Simplex™ Assembly, Erlenmeyer Flask and cap). Both come gamma irradiated. Customer-generated designs, sizes, packaging and other options — such as connectors, heat-sealed ends or alternate materials — are available as custom orders.

# Sterile Bottle Assembly Systems

Single-use technologies are playing a key role in the reduction in risk of cross-contamination in addition to time and cost benefits associated with assembly, cleaning and cleaning validation1. Bio-Simplex™ Sterile Bottle Assembly Systems are available in a range of commonly used sizes from 60mL to 2 Liter. Each sample bottle includes a 2 port EZ Top® Closure,made from C-Flex® pharmaceutical grade thermoplastic elastomer (TPE) resin and tubing, engineered to ensure an unobstructed fluid path, extremely low levels of extractables. Sample bottle assemblies are easily used with sterile connecting devices and thermal tubing sealers. Bio-Simplex™ Sterile Bottle Assembly Systems are sold as single items, each double bagged and gamma irradiated for a Sterility Assurance Level (SAL) of 10-6. Customer-generated designs, sizes, packaging and other options — such as connectors, heat-sealed ends or alternate materials — are available as custom orders.

# Sampling Manifold Systems



Single-use technologies are playing a key role in the reduction in risk of cross contamination in addition to time and cost benefits associated with assembly, cleaning and cleaning validation1. Economically designed for the single-use market, Bio-Simplex™ Sampling Manifold Systems are available with either four, six, eight or ten 60mL sampling bottles and an additional 500mL purge bottle at the end of the manifold. Each 60mL PETG bottle is connected to the Bio-Simplex™ manifold with 10 inches of tubing with a clamp, an EZ Top® container closure, a 0.2 µm vent filter and polyethylene cap. All EZ Top®s, tubing and manifolds are made from animal derived component free (ADCF) pharmaceutical grade C-Flex® thermoplastic elastomer (TPE) resin — engineered to ensure an unobstructed fluid path, a secure elastomeric seal against each bottle with extremely low levels of extractables. Bio-Simplex™ Sampling Manifolds are easily used with sterile connecting devices and thermal tubing sealers. They are sold double bagged and gamma irradiated. A carrying tray (as shown in the first photo), designed for up to ten 60mL sample bottles and one 500mL purge bottle is included.

**Ideal Applications:**

Our standard 4, 6, 8 or 10 bottle sampling manifolds provide ideal solutions for aseptic sampling, sterile additions, and for pulling samples to be retained. In the typical cell culture application, using the system provides a simple and easy mechanism for taking daily or periodic samples without breaking into the production line. This system also provides an ideal method to pull batch samples in the final formulation of your product. This sales literature provides details on our standard Sampling Manifold line.

**If you have a specific application that requires some modification or customization please contact Flow Components.**

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