

## 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 validation<sup>1</sup>. 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 and a secure elastomeric seal between bottle and cap surfaces. Each system is equipped with a PETG bottle (2 Liter is poly-carbonate), a 0.2 µm vent filter, an 18" length of 1/8"ID x 1/4"OD C-Flex tubing with a plug end, notched dip tube to the bottom of the bottle and a polyethylene cap (polypropylene on 2 Liter). Economically designed for the single-use market, 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<sup>-6</sup>. Customer-generated designs, sizes, packaging and other options — such as connectors, heat-sealed ends or alternate materials — are available as custom orders.

<sup>1</sup>As noted in *Pharmaceutical Technology Europe*, January, 2006.



*Bio-Simplex™ Sterile Bottle Assembly Systems, in sizes from 60mL to 2 Liters, feature the EZ Top® Closure, filter, C-Flex® tubing, bottle and cap.*



*Closeup of a 125mL sterile bottle showing the EZ Top® Closure.*

BIO-SIMPLEX™ STERILE BOTTLE SYSTEMS	
60mL	SA24MM-60-2F
125mL	SA38MM-125-2F-DB
250mL	SA38MM-250-2F-DB
500mL	SA38MM-500-2F-DB
1000 mL (1L)	SA38MM-1L-2F-DB
2000 mL (2L)	SA38MM-2LPC-2F

*For more detailed specs on Bio-Simplex™ Sterile Bottle Assemblies, please see our product spec sheets.*

## Sterile Bottle Assembly Systems

- Sterile Bottle Assembly Systems include 18" of C-Flex<sup>®</sup> pharmaceutical grade thermoplastic elastomer (TPE) tubing with a plugged end.
- 1/8" ID x 1/4" OD C-Flex<sup>®</sup> tubing material is compatible with sterile connecting devices and tube welders.
- Standard polyethylene cap for 60mL-1L sizes; polypropylene cap for 2L size.
- PETG bottles in 60mL-1L sizes; Polycarbonate in 2L size.
- 0.2 μm 25mm vent filter allows sterile gas exchange.
- Thermal bond between stopper and tubing prevents compromise of product.
- EZ Top<sup>®</sup> closure of high purity C-Flex<sup>®</sup> pharmaceutical grade TPE provides integral seal to glass, plastic and metal. (See FLS-7201-0408-SGPPL-TPA)
- Provided gamma irradiated and double bagged.
- Bio-Simplex<sup>™</sup> Sterile Bottle Assembly Systems are available in standard 60, 125, 250 or 500 mL and 1 or 2 Liter sizes.
- Customer-generated designs, sizes, packaging and other options — such as connectors, heat-sealed ends or alternate materials — are available as custom orders.

Ez Top<sup>®</sup> and C-Flex<sup>®</sup> are registered trademarks.  
Bio-Simplex<sup>™</sup> and FlexJoint<sup>™</sup> are trademarks.

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**IMPORTANT:** It is the user's responsibility to ensure the suitability and safety of Saint-Gobain Performance Plastics tubing for all intended uses. Laboratory and clinical tests must be conducted in accordance with applicable regulatory requirements in order to determine the safety and effectiveness for use of tubing in any particular application.

For a period of 12 months from the date of first sale, Saint-Gobain Performance Plastics Corporation warrants this product to be free from defects in materials and workmanship. Our only obligation will be to replace any portion proving defective, or at our option, to refund the purchase price thereof. User assumes all other risk, if any, including the risk of injury, loss or damage, direct or consequential, arising out of the use, misuse, or inability to use, this product. THIS WARRANTY IS IN LIEU OF THE WARRANTIES OF MERCHANTABILITY, FITNESS FOR PARTICULAR PURPOSE, AND ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED. No deviation is authorized.

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