

# From Concept



## To Prototype

Optimize your design by leveraging our flexibility and ability to produce prototypes in small quantities.



## To Production

validated cleanrooms.



## Quality Assured

ISO 9001:2008, 21 CFR, Parts 210 and 211, cGMP Gamma-Irradiation Validation is performed assuring SAL 10<sup>-6</sup> per ANSI/ AAMI/ISO11137-2 (VDmax27.5)



## SINGLE-USE **COMPONENT** AND SYSTEM MANUFACTURER

SaniSure is a global, innovative, manufacturer and integrator of cGMP sterile, customizable singleuse products such as bottles, carboys, flasks, centrifuge tubes, tube sets and manifold assemblies for the biopharmaceutical industry, focusing on innovative solutions. SaniSure's mission is to combine our deep expertise, integrity, and industry knowledge to produce customized solutions and to maximize efficiencies, minimize costs and alleviate risks in the production of biopharmaceutical processes.



Phone (877) 777-3005

SaniSure can supply the innovative solutions you need for a successful biomanufacturing facility.

SaniSure® can help you design aseptic solutions for transfer, cell growth, sampling, mixing, filling and storage. Use our innovative products and solutions to reduce assembly time, eliminate cleaning validations, protect product integrity and decrease the risk of contamination.



Cap2v8° for Centrifuge Tubes

> The SaniSure Cap2v8 one-piece molded tube and cap system provides for aseptic transfer, storage and sampling within 15 mL, 50 mL and 500 mL centrifuge tubes. The SaniSure CAP2V8 centrifuge tubes are available with C-Flex®, AdvantaFlex®, PVC and PharMed®, in addition to custom tubing sizes, lengths and accessories. The design reduces the chance of contamination and product loss associated with barbed fittings.

## SaniSure® Gamma Stable Stir Bar



The SaniSure Stir Bars are the ideal product for a biopharmaceutical container (carboy, media bottle, solution bottle, bag, Erlenmeyer flask, etc.) where a product needs to be both agitated and stay in suspension and where traditional mixers can be potentially harmful to cell growth. They are available as sterile or non-sterile parts. The stir bars are manufactured from a PVDF, gamma stable, animal-derivative, component-free material. They are lightweight, provide lower particulate shedding, are lot traceable and meet USP Class VI requirements.

# Cap2v8° Bottle **Assemblies**

The SaniSure Cap2v8 one-piece molded tube and cap system provides for aseptic transfer, storage and sampling for sterile PETG media bottles, GL45 glass bottles and Cap2v8 custom bottle solutions. The SaniSure CAP2V8 bottle assemblies are available with C-Flex®, AdvantaFlex®. PVC and PharMed<sup>®</sup>, in addition to custom tubing sizes, lengths and accessories. The design reduces the chance of contamination and product loss associated with barbed fittings.



Mixed4Sure uses a magnetically coupled suspended mixing device inside a closed 5, 10, 20 or 50 liter container to provide an aseptic closed mixing system for low shear to vigorous mixing. Mixed4Sure eliminates the risk of the unpredictable results associated with the use of a normal stir bar. This product is available in polypropylene or polycarbonate, depending on container size, and is customizable to meet your needs.





SaniSure can provide single-use tubing assemblies integrated from various tubing, connectors, clamps, filters, filling nozzles and other components specific to your requirements. Assemblies can be provided double bagged, gamma irradiated, sterile, ready to use or prepackaged, and autoclaved at your facility. Let SaniSure help you reduce internal labor and assembly costs while improving internal inventory management and overall operational efficiency.





SaniSure offers Custom Plastic Assemblies or Components available in polypropylene, PE, PVDF, polysulfone, fluoropolymers, polycarbonate and other materials based on individual application needs. SaniSure can help to design, develop and optimize your specific process to help improve production efficiency and decrease overall production costs. These solutions include dip tubes, containers, sanitary flanges, mixing devices and many other machined components. Bottle and container assemblies are also available in a wide variety of materials.

## SaniSure® CLAMP



The SaniSure CLAMP is the very first sanitary clamp design to offer a fast, safe and secure way to connect plastic to plastic, plastic to stainless steel, and stainless steel to stainless steel for sanitary fittings. The SaniSure CLAMP works by providing conforming compression on tri-clamp fittings, which results in an even clamping force on the entire fitting surface — something a traditional "rigid" clamp design can't achieve.

# Cap2v8° Shaker Flask



The SaniSure Cap2v8 one-piece molded tube and cap system provides for aseptic transfer, storage and sampling for sterile shaker flasks and with our last drop™ technology you are guaranteed to remove all of your product from the flask. The SaniSure CAP2V8 bottle assemblies are available with C-Flex®, AdvantaFlex®, and PharMed®, in addition to custom tubing sizes, lengths and accessories. The design reduces the chance of contamination and product loss associated with barbed fittings.

### **Accessory Kit** for Glass **Bioreactor**



SaniSure prefabricates bioreactor accessory kits that are customized to your needs. Bioreactor accessory kits are assembled and packaged in our ISO Class 7 cleanroom, and are provided double bagged and ready to open and use. These pre-assembled kits can be customized to any validated components currently specified on your bioreactor design. Customize with different types of tubing, filters, fittings, connectors, sampling accessories and clamps to meet your requirements. We can also supply customized accessory kits for single use bioreactors.

#### SaniSure® **Proprietary** Process Components



SaniSure has created a variety of inventive, proprietary solutions to help meet customers' needs. With more than 150 years of combined design and engineering experience, we are uniquely suited to work with you to find solutions to your processing issues. Our design team can handle issues from your process development group through to the most stringent requirements of your GMP process group. As an integral part of our solution-based innovation process, our quality management team is capable of meeting your regulatory requirements.