



FILL4SURE™

CUSTOM SINGLE-USE FILLING
SOLUTIONS FOR BIOPROCESSING



THE SANISURE ADVANTAGE

Your Go-To Partner for Flow Path and Closed-System Solutions

Created from the merger of six companies leading the market in their fields of expertise, SaniSure is unmatched in our ability to provide you with a uniquely diversified and vertically integrated portfolio of highly innovative proprietary solutions, custom assemblies, and engineered components.

We apply our decades-deep product and application expertise in a consultative manner, working with you to resolve your most challenging flow path needs, supported by our industry-leading, in-house design and manufacturing capabilities.

While larger companies cannot offer the flexibility, and smaller companies lack the depth of capabilities, we stand apart as the best of both worlds—unparalleled flexibility combined with end-to-end capabilities and deep vertical integration to help you de-risk, grow and innovate.



FLOW PATH & CLOSED SYSTEM EXPERTS

FILL4SURE™

Fill4Sure sets the highest standard for drug product filling. Fully customized, Fill4Sure ensures your drug product has The Best Home a Drug Can Get™ for greater security, efficiency and repeatability in your drug product filling.

CUSTOMIZED. OPTIMIZED. SECURE.

Simplify your precision and efficiency with Fill4Sure, our entirely custom single-use filling solution. Designed with your needs at the core, Fill4Sure assemblies are uniquely optimized to meet the specific requirements of your drug products and processes.

- Tailor-made assemblies
- Customer-driven design
- A vast validated library of components and proprietary solutions offers a fast, complete, end-to-end, tested solution from a single supplier
- Open architecture allows full flexibility and compatibility with your existing process
- Product quality assurance with 10^{-6} SAL (Sterility Assurance Level)
- SaniSure's proprietary filling solutions offer an end-to-end fluid management solution
- Global manufacturing and supply network delivers efficiency, flexibility and supply security



Fill-Finish as Easy as 1,2,3

1

Collaborative Design

Working with you, our specialist team designs Fill4Sure assemblies around your drug products and processes.

2

Secure Production

Fill4Sure assemblies are manufactured, assembled and packaged in SaniSure Class 7 cleanrooms, with 100% in-line inspection, all lot traceable and available with 10^{-6} SAL.

3

Thorough Implementation & Documentation

Fill4Sure assemblies are “plug and play”, requiring very minimal set-up. SaniSure includes certificates of conformance and irradiation, and full Custom Designed Assemblies validation packages.

CUSTOMER-DRIVEN DESIGN

A Fill4Sure assembly is created completely custom for you. With our vast library of sterile, validated components we can uniquely create the optimal single-use filling assembly for your drug products and processes.

Components are available in polypropylene, polyethylene, PVDF, polysulfone, fluoropolymers, polycarbonate and other materials based on individual application needs.

Fill4Sure Assembly Features

- Complete product traceability
- Vast library of validated components
- Support with internal validation protocols
- Non-irradiated or irradiated options for process flexibility (sterility assurance optional)



Flexible 2D Surge Bag Systems

- Multi-layer structure with inert PE Fluid contact layer for very low extractables and leachables
- Highly transparent film materials for enhanced visual inspection of process fluids
- Available with and without bag vent port
- No animal derived components
- Customizable for 1-12 Filling Ports
- Allow multi-line filling without the introduction of downstream line splitting



OEM & Custom Single-Use Filling Needles

- Made without adhesives or oils for minimal particle generation
- Customizable nozzles remediate unfavorable drug product results during filling
- Designed to adhere to FDA and EU GMP standards
- Available as:
 - Non-irradiated
 - Gamma-irradiated to a minimum of 25 kGy



Silicone Overmolded Tubing Connections

- Provide optimal fluid dynamics and reduce component-driven bug traps and turbulences
- Increased connection strength enhance assembly integrity and ensure drug product security throughout prolonged filling operations



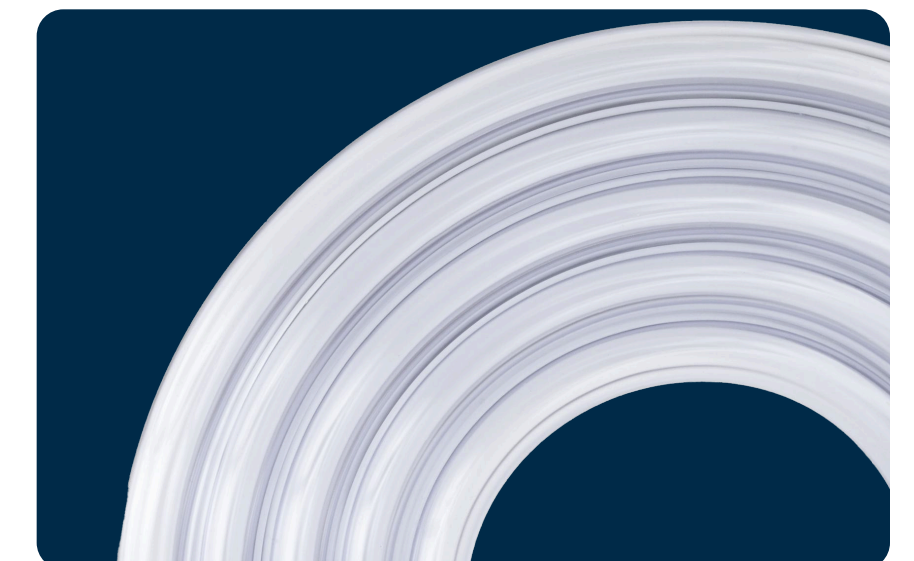
Independent Fill Lines

- High-throughput, multi-needle filling
- Superior fluid dynamics ensure process pumps can perform optimally and accurately



Custom Ported RTP Bags

- Maximize large batch filling while retaining a grade A filling environment
- A number of custom RTP bag porting options available



Precision Peristaltic Tubing

- Designed to integrate all tubing types for specific drug product considerations and filling accuracy

OPTIMIZED FOR YOUR PRODUCTS AND PROCESSES

Secure Fill-Finish

Experience total confidence in the security of your drug during the filling process with your sterility-ensured Fill4Sure custom assembly.

Routinely tested for bioburden, particulates and endotoxins, where further security is needed, our validation experts can provide lot-release testing to meet your quality requirements.

Designed for Total Confidence

- 100% custom design uniquely safeguards product quality
- Reduces your validation burden
- Supports internal validation protocols
- Provides product quality assurance with 10^{-6} SAL (Sterility Assurance Level)



EXPERTS
FLOW PATH & CLOSED
SYSTEM

Validation Testing

SaniSure's single-use solutions are fully supported by our experienced validation testing specialists.

We offer bioprocessing expertise and tailored validation packages to help reduce your regulatory burden.

Our validation testing team will design your validation studies using the most up-to-date, industry-recognized standards alongside our fully qualified testing partners. We provide a bespoke results assessment to ensure your specific quality assurance requirements are met. Our decades of expertise in biopharmaceutical equipment manufacture ensure that your validation data analysis is rigorous and can be trusted.

Protocols can cover one-off testing or lot-release testing, and include standards such as:

- Endotoxin (USP <85>)
- Particulate (USP <788>)
- Bioburden (USP <88>)
- Leak/integrity (pressure decay)
- Extractable and leachable (BPOG/USP 665/USP <661>)
- Sterility (10^{-6} SAL/ USP <71>)

SECURE SOLUTIONS FOR LIFE-SAVING BIOPHARMACEUTICALS

As a trusted partner for biopharmaceutical companies worldwide, SaniSure delivers solutions that enable confident scaling from bench-top single-needle assemblies all the way up to full commercial, multi-needle assemblies.

Biopharma Processes

mRNA Manufacturing
Monoclonal Antibodies (mAbs)
Plasmid DNA (pDNA)
Viral Vectors

Advanced Therapies

Cell Therapy
Gene Therapy

Custom Applications

Small, bench-top single-needle filling setups
Full commercial, multi-needle assemblies
Clinical Trial Batch Filling

INTEGRATE SEAMLESSLY

Proprietary Solutions



Mixed4Sure™



One2Fill™



RC-40™



Custom Assemblies

Engineered Components



Bottles & Stability Vials



Cap2V8® Bottle & Cap Assemblies



Diversified Tubing Portfolio



aSURE™ Instrument Tees



Closed System Vessels



2D & 3D Bags



Validated Library of Fittings, Clamps & Other Components



Precision Filling Needles



sanisure.com

Americas

1020 Flynn Road
Camarillo, CA 93012
United States

+1 800 726 4835

SalesSupport-US@sanisure.com

Asia-Pacific

Suite 708, German Center
88 Keyuan Road
Pudong District, Shanghai, PRC

+86 21 68771098

SalesSupport-CN@sanisure.com

Europe, Middle East, & Africa

ZAE Robert Steichen
16, rue Héierchen
L4940 Bascharage
Grand Duché du Luxembourg

+352 26 33 731

SalesSupport-EU@sanisure.com