



Mixed4Sure™

Bottom Mount

The Best Home a Drug Can Get™

Single-use, small-volume, comprehensive, and out-of-the-box mixing platform for biopharmaceutical mixing steps

**FIRST BOTTLE
MIXING SYSTEM FOR
COMMERCIAL
BIOMANUFACTURING**

Distributed by:
Acuity Process Solutions
Web: acuityprocess.com
Phone: 508-809-5099



Mixed4Sure™



FIRST BOTTLE MIXING SYSTEM

for commercial biomanufacturing.

Changing the standards of small-volume mixing:

- Reducing the risks of undesirable effects in mixing
- Less financial investment
- Reduced set-up time
- Enhanced flexibility in mixing processes between 500ml–20L



Heating/Cooling Finger



pH Sensor



Conductivity Sensor



1.5" Powder Addition Port

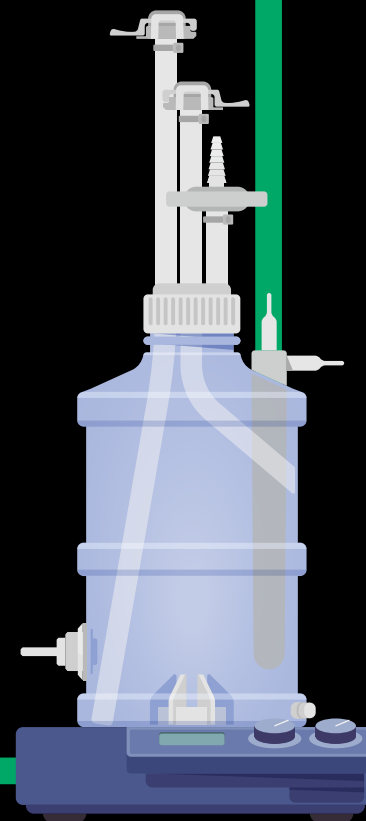
Mixed4Sure™



2X

lower shear forces than in comparable bag mixing systems.

In downstream mixing steps shear forces can have undesirable effects on your sensitive protein, such as degradation and aggregate formation. Mixed4Sure™ has been demonstrated to create shear forces that are ½ that of a comparable mixing system, and a magnitude of 4 lower than the forces leading to protein degradation.



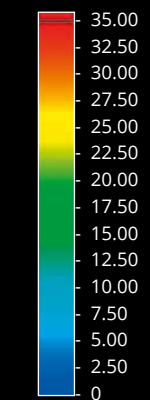
Shear Forces

Computational Fluid Dynamics

- Provides a mathematical simulation of fluid flows in a system.
- CFD demonstrated enhanced turnover in the corners of the vessel.
- All volumes and speeds resulted in shear forces $\sim 10^3 \text{ s}^{-1}$ (significantly lower than the 10^7 - 10^8 where protein degradation occurs).*

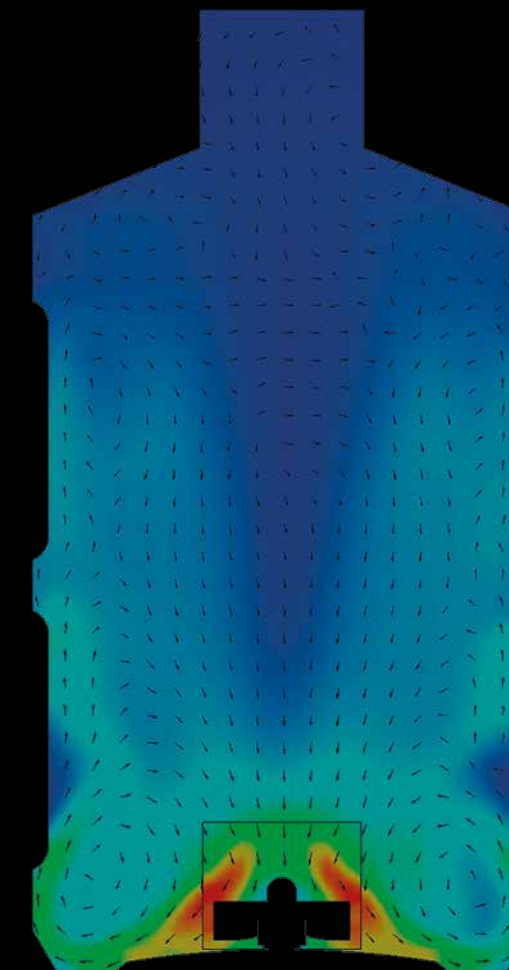
* Thomas, C. R, and D. Geer. 2011. "Effects of shear on proteins in solution." *Biotechnology Letters*, 443-456.

Mixer SHEAR RATE S ⁻¹			
RPM	200	450	600
5L	1.710×10^3	6.335×10^3	9.536×10^3
10L	1.419×10^3	5.103×10^3	7.687×10^3
20L	1.385×10^3	5.126×10^3	8.631×10^3



Velocity (in/s)

Cut Plot 7: contours



Mixed4Sure™



10x

lower CapEx compared
to a bag mixing system.

Double-walled or jacketed stainless-steel containers can cost many tens of thousands of dollars, and the corresponding mixing drive can further increase the capital expenditure associated with a mixing step. Mixed4Sure™ dramatically reduces the hardware cost by integrating with common, standard mixing plates and is the only hardware required for the system.



CapEx Saving

\$4,000



Mixing Plate \$4,000

~\$40,000



Drive unit ~\$13,000
Jacketed tank ~\$29,000

Mixed4Sure™



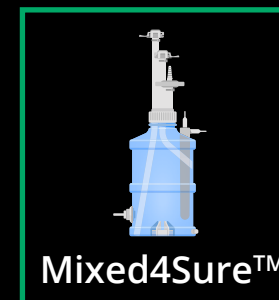
10x

quicker set-up time than bag mixing systems. (~20 min vs. 2 min)

Cycle-time optimization is a key requirement in all biomanufacturing unit operations. Mixed4Sure™ represents the next step in single-use implementation by offering true out-of-the-box operation. The Mixed4Sure™ is unpacked, placed on the mixing plate, connected to the fluid inlet, and optionally connected to the heating/cooling finger. It is ready for filling in under 2 minutes.



Time Saving



Mixed4Sure™



Bag Mixing



Mixed4Sure™



120X

lower minimum mixing volume
than in bag mixing systems. (50ml vs. 6L)

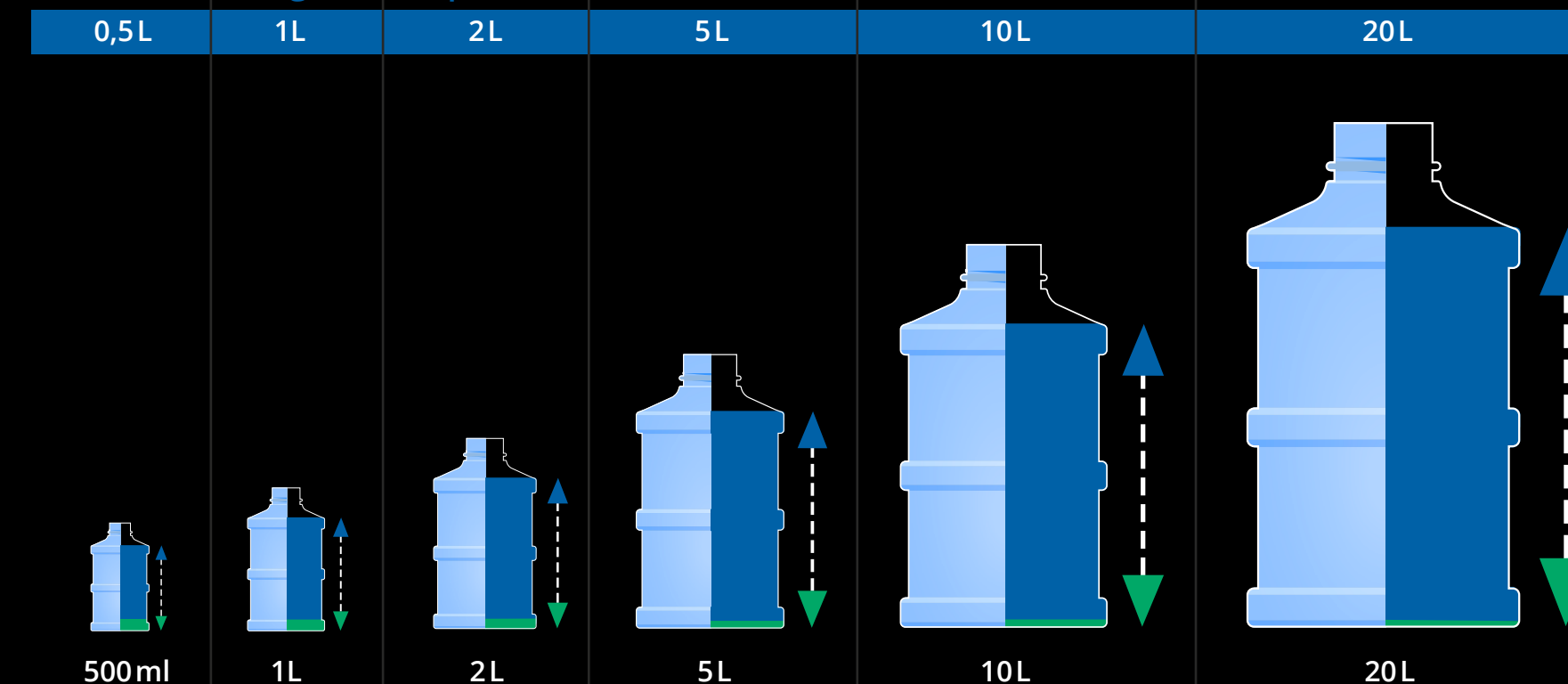
No matter what volume your mixing step requires Mixed4Sure™ offers the ability to continuously mix at all process volumes from 50ml – 20L. Furthermore, you can maintain mixing and fluid homogeneity during offload down to 50ml, which ensures the consistency of your drug is maintained to the last drop.



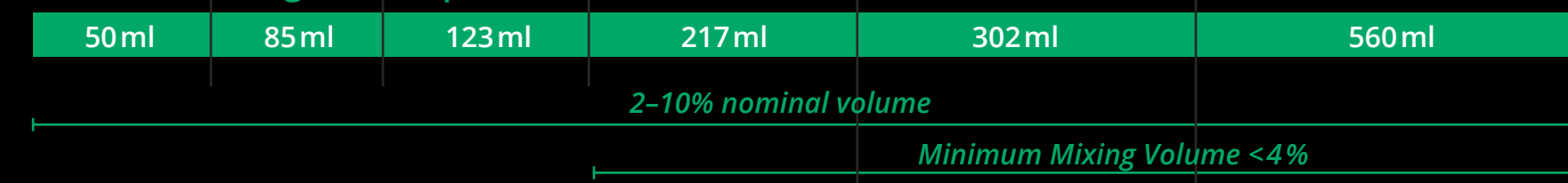
Minimum Mixing Volume

Continuous Volume 50ml–20L

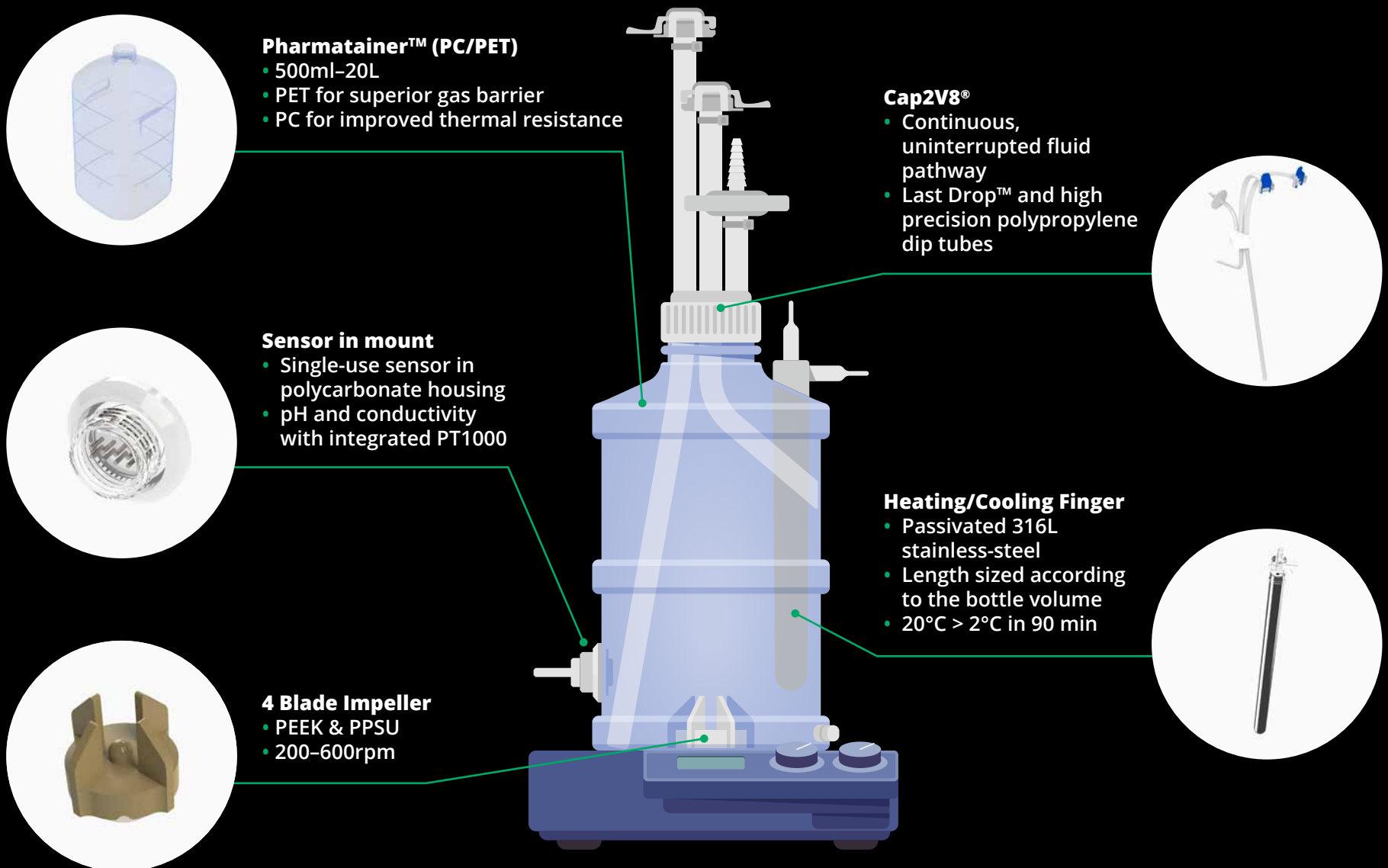
Maximum Mixing Volume per bottle size:



Minimum Mixing Volume per bottle size:



Mixed4Sure™ Bottom Mount



Mixed4Sure™ Bottom Mount-Extractables

MATERIAL LIST			
ITEM	QTY	DESCRIPTION	LONG TERM FLUID CONTACT SURFACES
1	1	20L PHARMATAINER BOTTLE, POLYCARBONATE	PC or PET
2	1	Cap2V8-70-Y-3DC W/ 2 PORTS @ 3/8" ID X 5/8" OD TUBING	
		1/4" ID X 1/2" OD TUBING, CELLGYN	
3	1	50mm 0.2µm HYDROPHOBIC VENT FILTER, GAMMA STABLE	
4	2	3/8" HB X ASEPTIQUIK S CONNECTOR, POLYCARBONATE	Polycarbonate
5	1	MLS X SWABABLE VALVE, POLYCARBONATE	Polycarbonate
6	1	LUER CAP, POLYCARBONATE	
7	1	PG 13.5 ADAPTER, POLYCARBONATE	
8	1	PG 13.5 PLUG, POLYPROPYLENE	
9	1	Ø14 O-RING, RED SILICONE	
10	1	1.9" BOTTOM MIXER KIT, PEEK/RADEL	PEEK & PPSU
11	1	10-32-3/8" SCREW, POLYCARBONATE	
12	1	111 O-RING, PLATINUM CURED SILICONE	Silicone
13	1	COOLING FINGER HEAD, POLYCARBONATE	
14	2	1/4" BONDABLE BARBS, POLYCARBONATE	
15	1	O-RING, RED SILICONE	
16	1	.924" ID X 1" OD COOLING FINGER TUBE, 316L 20RA EP SS	Stainless Steel 316L Passivated
17	4	COOLING FINGER COIL, POLYCARBONATE	
18	2	6mm RIGID TUBE, POLYPROPYLENE	Polypropylene
19	3	STD. CABLE TIE, NYLON	
20	1	HAMILTON SENSOR PORT KIT, POLYCARBONATE	Polycarbonate, Polyethylene & Silicone
21	2	SMALL CAP PLUG, VINYL	

Extractables for all long-term fluid contact surfaces

USP <665> compliant

Ordering Information

Product code	MOC	Volume	Check valve/ sample port	Powder Port	Heating/ Cooling Finger	Sensors (pH & Conductivity)
SS64004S	PC	500ml	✓			
SS64020S	PC	1L	✓			
SS64021S	PC	2L	✓			
SS64039S	PET	500ml	✓			
SS64049S	PET	1L	✓			
SS64050S	PET	2L	✓			
SS64000S	PC	5L	✓			
SS64005S	PC	10L	✓			
SS64010S	PC	20L	✓			
SS64035S	PET	5L	✓			
SS64040S	PET	10L	✓			
SS64045S	PET	20L	✓			

Product code	MOC	Volume	Check valve/ sample port	Powder Port	Heating/ Cooling Finger	Sensors (pH & Conductivity)
SS64001S	PC	5L	✓	✓		
SS64006S	PC	10L	✓	✓		
SS64011S	PC	20L	✓	✓		
SS64036S	PET	5L	✓	✓		
SS64041S	PET	10L	✓	✓		
SS64046S	PET	20L	✓	✓		

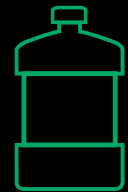
Ordering Information

Product code	MOC	Volume	Check valve/ sample port	Powder Port	Heating/ Cooling Finger	Sensors (pH & Conductivity)
SS64003S	PC	5L	✓		✓	✓
SS64008S	PC	10L	✓		✓	✓
SS64013S	PC	20L	✓		✓	✓
SS64038S	PET	5L	✓		✓	✓
SS64043S	PET	10L	✓		✓	✓
SS64048S	PET	20L	✓		✓	✓

Product code	MOC	Volume	Check valve/ sample port	Powder Port	Heating/ Cooling Finger	Sensors (pH & Conductivity)
SS64002S	PC	5L	✓	✓	✓	✓
SS64007S	PC	10L	✓	✓	✓	✓
SS64012S	PC	20L	✓	✓	✓	✓
SS64037S	PET	5L	✓	✓	✓	✓
SS64042S	PET	10L	✓	✓	✓	✓
SS64047S	PET	20L	✓	✓	✓	✓

Mixed4Sure™ – 4 Key Components

SaniSure® Manufactures 4 Key Components to Provide an Unparalleled Level of Quality and Assurance of Supply for our Assemblies



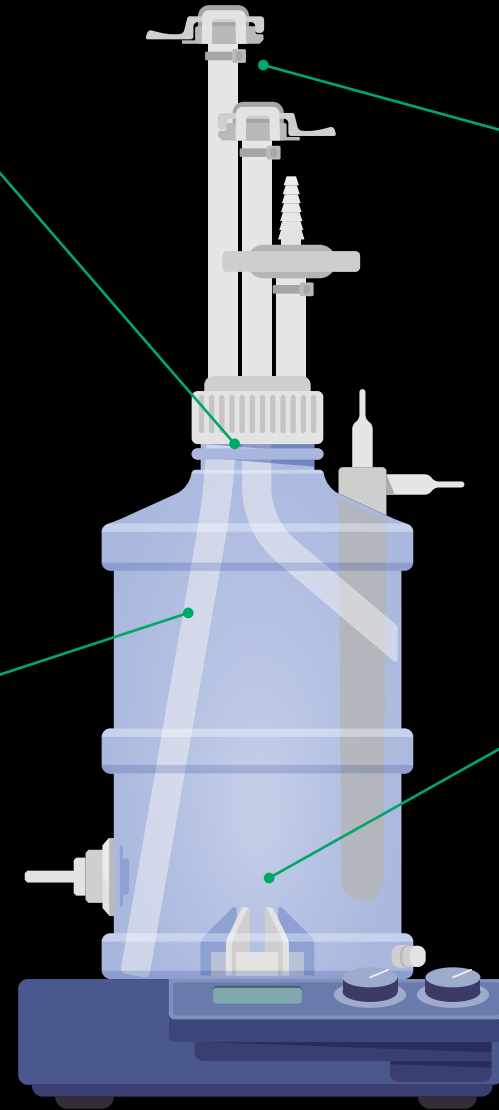
Bottle/Caps

- We are one of the leading manufacturers of 10ml to 20L bottles. PET is the best gas barrier and PC is ideal for freezing and/or high temperatures.



Tubing

- Stocked tubing sizes with many formulations to fit your specific application. Our portfolio includes platinum-cured silicone, CellGyn® (TPE), and Pharm-A-Line™ (TPV).



Fittings

- Single-use Sanitary connectivity – aSURE® with built-in gasket, Bio-Ease® clamps, instrument fittings, sanitary reducers, barbs, threaded adapters, fusion, site tubes, over-molded hoses, and more.



Mixing

- How do you mix at 20L and below? SaniSure® manufactures a range of novel mixing products to meet your bioprocessing needs.



SaniSure® is simplifying single-use technologies for sterile manufacturing in the single-use bioprocessing industry.

We are a global leader in the design and manufacturing of single-use systems and components for drug and vaccine manufacturing and other biotech applications.

Our core manufacturing capabilities include

- injection molding,
- injection-stretch blow molding,
- cleanroom assembly,
- tubing extrusion,
- fabrication,
- and other proprietary technologies.

We have a global footprint of 5 manufacturing sites worldwide to provide our customers with an unrivaled level of vertical integration and supply-chain security.

For more details, visit us at sanisure.com or [linkedin/sanisure.com](https://linkedin.com/sanisure.com)



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website to learn more
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