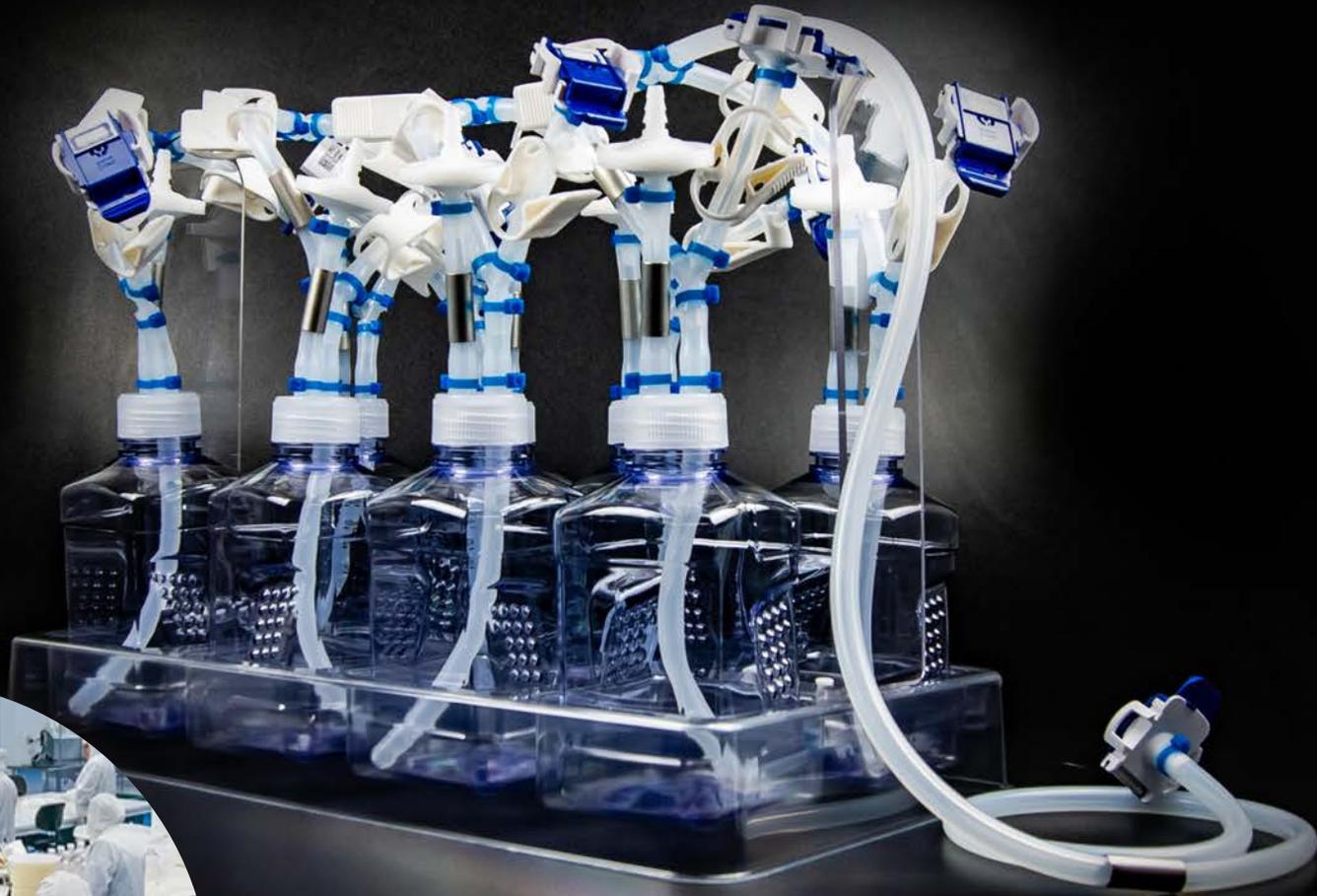


PharmaTainer™

The Best Home a Drug Can Get™



 **SANISURE**®
Solution Based Innovation

What We Do

Simplifying Sterile Manufacturing

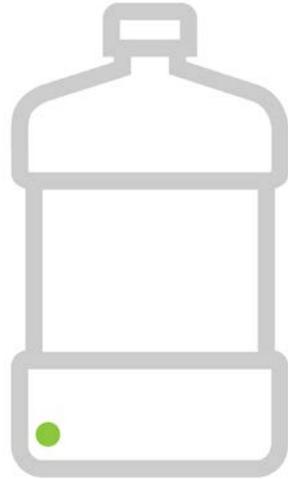
SaniSure is a global leader in simplifying single-use systems for sterile drug and vaccine manufacturing and other biotech applications. With the combination of industry-leading single-use technology (SUT) companies (Cellon, Silicone Altimex, TBL Performance Plastics, GL Engineering and Sani-Tech West) into SaniSure, our resources, capabilities, and ability to create value for customers is greater than ever and unmatched in the industry.

Our core manufacturing capabilities include injection molding, injection-stretch blow molding, cleanroom assembly, tubing extrusion, fabrication, needle manufacturing, and other proprietary technologies. With a global footprint of 5 manufacturing sites, we provide an unrivaled level of vertical integration and supply-chain security. Our founding companies have been at the forefront of SUT innovation for decades and have supported many clients through all phases of drug and vaccine development and



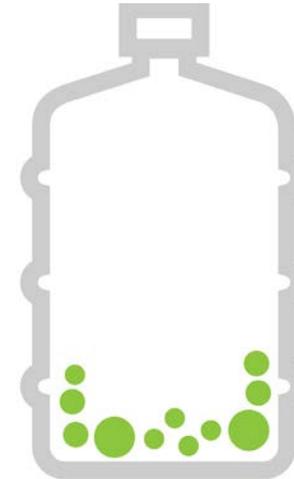
PharmaTainer™
Nothing Cleaner

Bottle Particle Load Comparison



PharmaTainer™

< 1.7% of the USP788 limits
Injection blow molding.



Next-Best Competitor

20x more particles than PharmaTainer™
Extrusion blow molding.

SaniSure's injection-stretch-blow molding technology has many valuable quality benefits, including dramatically lower particle counts, when compared to traditional extrusion blow molding.





Extractables

We have partnered with a leading bio-processing institute and several fully-accredited, third-party laboratories to provide one of the most extensive extractables packages in the industry today.



Control Over Product Contact Material

All PharmaTainer™ bottles are manufactured from 100% virgin ADCF approved medical grade resins with existing DMF files. This provides lot-to-lot consistency and enhanced change control. We also hold safety stocks for resins.



Extremely Low Particle Load

Our injection blow molded bottles are perfectly formed with no cutting needed. They improve on USP 788 limits with <1.7% particle limits per representative studies. The next cleanest bottle had 20x more particles.



No Detectable Endotoxins

Optional endotoxin testing for our bottles is based on a validated assay method using a 5% rinse volume and detection limit of 0.001 EU/ml. The method complies with current USP <85> and EP Bacterial Endotoxin Testing (BET) methodologies.



3 Layers of Poly Packaging

Bottles are packaged in an ISO Class 7 clean room for transfers. The innermost layer is vacuum sealed to provide assurance of sterility. The second bag is heat sealed and the third poly layer is taped closed.



Quality Assured

- Bottle Molding/ Capping in ISO Class 5
- ISO 9001 2015 certified
- Each bottle includes serial number and expiration date
- USP 787, ISO 10993 06, 10, 11,
- FDA CFR 21 compliant
- Animal-Derived-Component-Free (ADCF) components

PharmaTainer™

Nothing Stronger



No Seal Leakage

PharmaTainer™ bottles are made with a precision, flash and burr-free neck, eliminating the primary cause of seal failure. Our bottles passed a positive pressure test with freeze & thaw cycles from ambient to -80C.



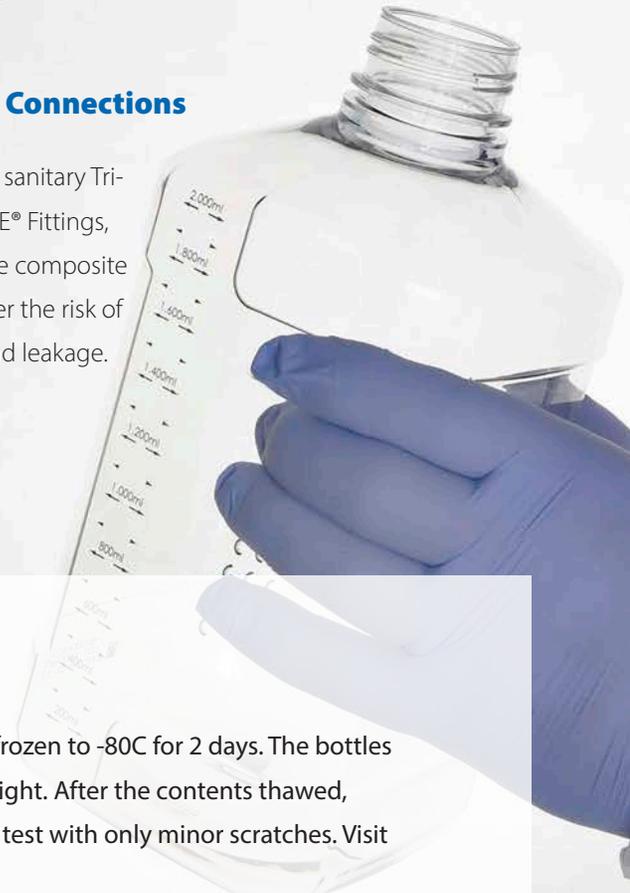
Filling & Shipping Kits

Custom shipping solutions with up to 5 bottle filling and sampling lines. A rack for the manifold and protective caps for freezing provides unrivaled secure delivery.



Secure & Reliable Connections

Both over-molding sanitary Tri-Clamps and aSURE® Fittings, with their one-piece composite gasket design, lower the risk of contamination and leakage.



PharmaTainer™ Strength The Drop Test

10L PC PharmaTainer™ gamma irradiated bottles were filled to nominal volume and frozen to -80C for 2 days. The bottles were then dropped two times in a row onto a flat concrete surface from 1,100mm height. After the contents thawed, leak tests were performed on the sides, base and closure. All bottles passed the drop test with only minor scratches. Visit sanisure.com/pharmatainer to learn more.

Getting the Drug There **Safely and Securely**

Our out-of-the box custom filling, freezing & shipping kits provide a plug and play solution for our customers. The kits can include a filling line, sampling and protection caps for tubing and vent filter protection. We also provide shipping systems with temperature tracking. Our unique box concept allows easy handling of complex manifolds.



Protection Caps

To protect tubing and vent filters during freezing and for shipment.



Box Concept

For easy handling of complex bottle-assembly manifolds.



Shipping System

Our shipping boxes are available with temperature tracking sensors for reliable temperature monitoring.



4 Key Components

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

Bottles/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.



Mixing

How do you mix at 50L and below? SaniSure manufactures a range of novel mixing products to meet your bio-processing needs.



Tubing

Stocked tubing sizes with many formulations to fit your specific application.

Our portfolio includes platinum cures silicone, Cellgyn® (TPE), and Pharm-A-Line™ I (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.



PharmaTainer™ Bottles and Caps



Redundant Seal Technology

Precision molded closures and necks have robust threads that provide secure engagement between cap and bottle. Closures seal at two points – inside the neck and on the rim of the neck – to provide a leak-proof seal.



Leading in Traceability

Each container is printed with a unique serial number, lot number, expiration date and machine readable data matrix to provide unrivaled traceability



Many Sizes in Stock

10mL, 125mL, 500mL, 1L, 2L, 5L, 10L, and 20L containers are kept in stock in multiple warehouses throughout the world.



Hose-Barbed Caps

For aseptic filling and venting operations we manufacture a range of 2, 3 and 4 port caps in polypropylene (autoclavable*/ irradiation stable).

*Ported caps should be fitted lose on bottle during the autoclave cycle.



Cap2V8® Caps

Overmolded cap system that provides an added level of security due to the composite (one piece) cap design.



Torque is Key

Contact us to receive the recommended torque values to be applied to ensure a seal between the bottle and closure in both non-freezing and freezing applications.

Mixed4Sure™ Mixing



Mixed4Sure® Pronto

An aseptic, closed mixing system for low shear to vigorous mixing. Compatible with 5, 10, 20, or 50 liter carboys, the Mixed4Sure Pronto is a suspended, magnetically coupled mixing system which is driven by a common stir plate. It is essentially a stir bar, suspended inside the container.



Mixed4Sure® Bottom Mounted Mixer

A revolutionary new magnetically driven mixing system coming soon! The technology excels at low volume mixing, and is available with several impeller options.



Gamma-Stable Stir Bars and other Custom Solutions

SaniSure has developed a full range of gamma-irradiation compatible stir bars for bioprocessing and several other solutions for volumes of 50 liters or less. Our unique stir-bar design outperforms the competition in terms of low particle generation.

TPE and Silicone Tubing



Pharma-Clear® Silicone Tubing

Our Pharma-Clear® silicone tubing has a trusted reputation as the premier choice in the industry. We specialize in critical pump and transfer tubing as well as braided silicone hose for higher pressure applications.



Cellgyn® TPE Tubing

We stock a full range Cellgyn® TPE sizes. Cellgyn® has been qualified to weld with a wide range of competitors, such as C-Flex®, and we have invested heavily in extractables and regulatory testing to save you time and money in the validation process.



Molded Sanitary Ends

For the cleanest and most secure sanitary connections available, consider our extensive portfolio of over- molded sanitary hoses. With inhouse tooling capabilities and an extensive library of tooling, we have the expertise to meet your needs with industry-leading quality and delivery times. Ask about our range of sizes and materials.

Bioprocess Fittings



aSURE® Fittings (Patented)

Our aSURE® technology enables us to make sanitary fittings with a gasket built in. aSURE® Fittings are ideal for applications where bioburden reduction and seal integrity are critical. No more misalignment + no need to touch the gasket after sterilization = lower risk.



Bio-Pharma Components

We manufacture and stock a vast range of single-use fittings and Tri-Clamp adapters. Vertical integration with in-house tool/die manufacturing and generations of molding experience results in enhanced flexibility and control of supply. As a world-class provider of stock and custom injection-molded components/connectors, let us strengthen your supply chain.



Bio-Ease®+ Clamps

Our patented Bio-Ease®+ sanitary clamps are suitable for autoclave and gamma-irradiation sterilization. We stock an extensive inventory of sizes up to 4" TC. Please contact us to learn more about the strongest, most trusted non-metallic sanitary clamp on the market.

Extractables & Biocompatibility

Testing

SaniSure has completed state-of-the-art extractables and biocompatibility testing for multiple product lines, including PharmaTainer™

SaniSure contracted with The BioProcess Institute to conduct a thorough and independent extractables study for many products which were tested in accordance with USP <665> extractables protocols and USP Class VI and ISO 10993 biocompatibility protocols. Extractables testing was conducted with three solvents (Ethanol/Water, Acid, Base), and 21-day and 70-day timeframes. The components were qualified based on the current USP <665> draft, which has strong alignment with BPOG's end-user best practices, with additional testing included to provide the best assessment of the materials' capabilities. To assess potential extractables based on their intended use, SaniSure's components were either pre-treated with gamma irradiation (at maximum dose), autoclaved (at 130°C), and/or aseptically welded (tubing), and then subjected to the extraction studies. The test protocols for biocompatibility included USP<87> and ISO 10993-05 for in vitro Cytotoxicity, and USP<88>, ISO 10993-06, -10, and -11 for in vivo testing.

Products Tested Include:

- PharmaTainer™ PET and Polycarbonate containers
- Pharma-Clear® LH Tubing
- Pharma-Clear® 65 Tubing
- Cap2V8® Molded Cap Systems
- Pharma-Clear® R Platinum-Cured Braided Hose (Inner Tubing Tested)

Visit sanisure.com/get-report
to request the full study.

Customized Fluid Management Solutions For Sterile Manufacturing

For sterile drug and vaccine manufacturing applications, SaniSure has a dedicated team of engineers to develop and manufacture custom single-use assemblies that are tailored to fit your needs. With proprietary "Drawing Tracker" software, SaniSure is able to achieve industry-leading traceability, quality, and efficiency in the custom-assembly design process. Contact us today to discuss your application and to learn more about the drawing tracker system.



Plan

Application Specific
Consultation
Conceptual Design

Design

SolidWorks
AutoCAD
3-D Printing
Fabrication

Prototype

Build
Autoclave/ Irradiate
Pressure Testing
Accelerated Aging
Various Characterization Tools

Produce

High Quality Standards
Redundant Assembly Sites: US & EU
Collaborative Demand Planning
Application Support

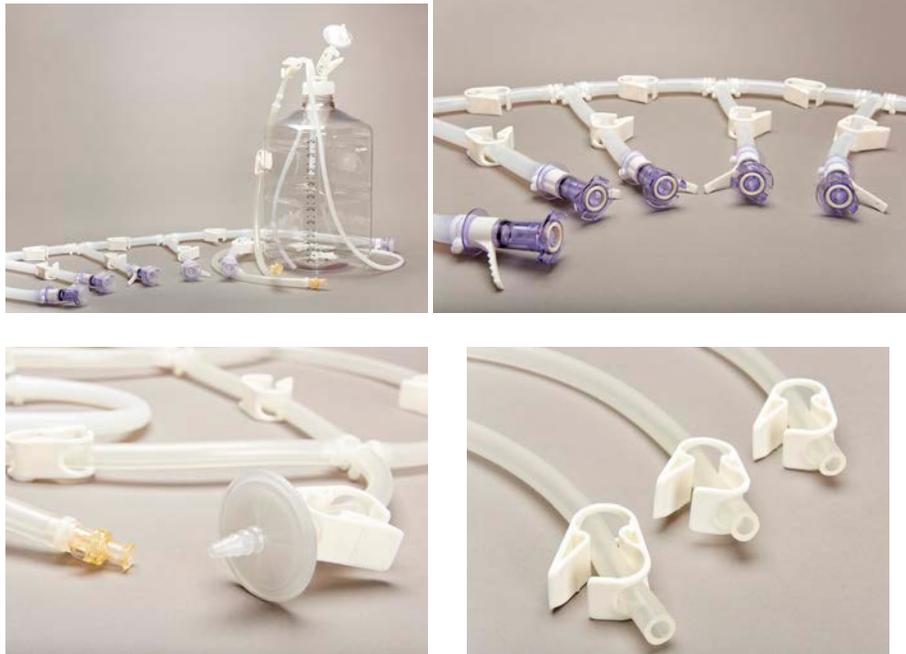
Use

PharmaTainer™

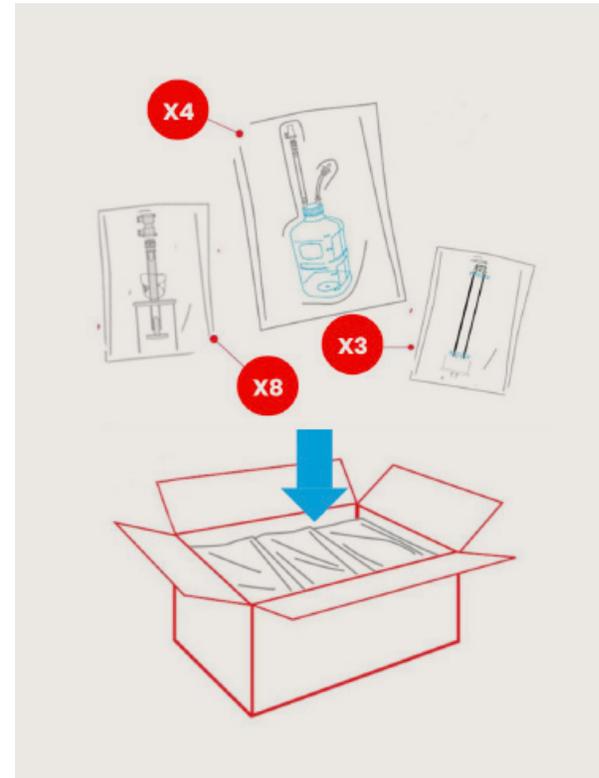
PharmaTainer™ Kits

Customized Assembly Kits

Whatever the application requires, we can consult and collaborate to develop the appropriately tailored custom assembly kit. Each kit is designed and manufactured to meet your specific requirements.



Bottle Assemblies/Transfer Sets



Bioreactor Assembly Kits
One bioreactor. One run. One kit.

Sizing Charts

Bulk Packed Bottles and Carboys (Sterile)

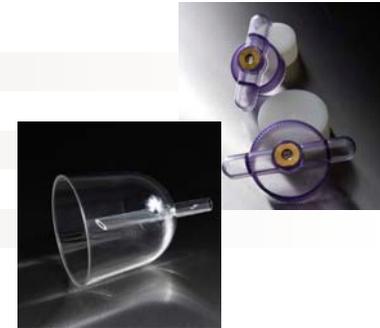
Part Number	Description	Units/Carton
100125-05	125ml PET Bottle	100
200125-05	125ml Polycarbonate Bottle	100
100250-05	250ml PET Bottle	60
200250-05	250 ml Polycarbonate Bottle	60
100500-05	500ml PET Bottle	60
200500-05	500ml Polycarbonate Bottle	60
101000-05	1L PET Bottle	30
201000-05	1L Polycarbonate Bottle	30
102000-05	2L PET Bottle	20
202000-05	2L Polycarbonate Bottle	20
105000-01	5L PET Carboy	6
205000-01	5L Polycarbonate Carboy	6
110000-01	10L PET Carboy	2
210000-01	10L Polycarbonate Carboy	2
120000-01	20L PET Carboy	2
220000-01	20L Polycarbonate Carboy	2



Sizing Charts

Sterile Closures, Filling Bells, & Torque Adapters

Part Number	Description	Units/Carton
2595-PC28	28mm Torque Adapter	1
2595-PC48	48mm Torque Adapter	1
2595-PC70	70mm Torque Adapter	1
3070C1-01	70mm Cap, HDPE, Sterile, for PET Carboy	150
3070C2-01	70mm Cap, HDPE, Sterile, for PC Carboys	150
PIP530-10	Filling Bell, PharmaTainer™ PC Material, NS, 10 units	10



Individually Packed Bottles (Sterile)

Part Number	Description	Units/Carton
100125-01	125ml PET Bottle	48
100250-01	250ml PET Bottle	36
100500-01	500ml PET Bottle	36
101000-01	1L PET Bottle	24
102000-01	2L PET Bottle	14
200125-01	125ml Polycarbonate Bottle	48
200250-01	250 ml Polycarbonate Bottle	36
200500-01	500ml Polycarbonate Bottle	36
201000-01	1L Polycarbonate Bottle	24
202000-01	2L Polycarbonate Bottle	14



Sizing Charts

Sterile PharmaTainer™ Assemblies (Pre-Assembled & Irradiated - Ready to Ship)

With Cap2V8 Cap and Cellgyn® TPE Tubing

Part Number	Description	Units/Carton
CAP2V8-125PC-C-Y-2	125mL PharmaTainer™ Assembly w/ Cap2V8® Cap - 2 Ports: 1/8" X 1/4" Transfer and Vent	1
CAP2V8-500PC-C-Y-2	500mL PharmaTainer™ Assembly w/ Cap2V8® Cap - 2 Ports: 1/8" X 1/4" Transfer and Vent	1
CAP2V8-1000PC-C-Y-2	1L PharmaTainer™ Assembly w/ Cap2V8® Cap - 2 Ports: 1/8" X 1/4" Transfer and Vent	1
CAP2V8-2000PC-C-Y-2	2L PharmaTainer™ Assembly w/ Cap2V8® Cap - 2 Ports: 1/8" X 1/4" Transfer and Vent	1
CAP2V8-125PC-C-Y-2L	125mL PharmaTainer™ Assembly w/ Cap2V8® Cap - 2 Ports: 1/4" X 7/16" Transfer and Vent	1
CAP2V8-500PC-C-Y-2L	500mL PharmaTainer™ Assembly w/ Cap2V8® Cap - 2 Ports: 1/4" X 7/16" Transfer and Vent	1
CAP2V8-1000PC-C-Y-2L	1L PharmaTainer™ Assembly w/ Cap2V8® Cap - 2 Ports: 1/4" X 7/16" Transfer and Vent	1
CAP2V8-2000PC-C-Y-2L	2L PharmaTainer™ Assembly w/ Cap2V8® Cap - 2 Ports: 1/4" X 7/16" Transfer and Vent	1



Sterile PharmaTainer™ Assemblies (Pre-Assembled & Irradiated - Ready to Ship)

With Standard Cap and Cellgyn® TPE Tubing

Part Number	Description	Units/Carton
SG56711	125mL PharmaTainer™ Assembly - 2 Ports: 1/4" X 7/16" Transfer and Vent	25
SG56712	500mL PharmaTainer™ Assembly - 2 Ports: 1/8" X 1/4" Transfer and Vent	20
SG56713	1L PharmaTainer™ Assembly - 2 Ports: 1/8" X 1/4" Transfer and Vent	10
SG56714	2L PharmaTainer™ Assembly - 2 Ports: 1/8" X 1/4" Transfer and Vent	10



Sizing Charts

Stability Vials & Tubes

Part Number	Description	Units/Carton
100S10-49	10mL PET Stability Vial	245
200S10-49	10mL Polycarbonate Stability Vial	245



Custom Solutions

Contact us today to discuss a tailored solution for your application.

1.805.427.8418

sanisure.com/contact/

IMPORTANT: It is the user's responsibility to ensure the suitability and safety of SaniSure products for all intended uses. For a period of 90 days from the date of delivery, SaniSure 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 discretion, 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 LIMITED WARRANTY IS IN LIEU OF THE WARRANTIES OF MERCHANTABILITY, FITNESS FOR PARTICULAR PURPOSE AND ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED. No deviation is authorized. SaniSure assumes no obligations or liability for any advice furnished by it or for results obtained with respect to those products. All such advice is given and accepted at the user's risk. All specifications contained within this document are subject to change without notice. Please contact our quality department for the most up to date validation and information related to product-qualification.

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