



STA-PURE™ Fluid Sampling System

FOR SINGLE-USE ASEPTIC APPLICATIONS

Secure Sampling for Bioprocessing Fluids

Product Description

The GORE™ STA-PURE™ Fluid Sampling System is a fully disposable system for biopharmaceutical fluid sampling. It is delivered as a preassembled, presterilized, closed system that incorporates an intuitive lever-valve actuator. A wide variety of options allow you to customize the device to fit your application.

Quality Assurance

The GORE™ STA-PURE™ Fluid Sampling System is designed to meet the most demanding requirements of biocompatibility, and all components meet or exceed the test requirements of:

- USP Class VI for Plastics
- USP <661> Physiochemical Tests
- FDA 21 CFR 177
- EP 3.1.9. — Silicone elastomer for closures and tubing

Critical properties are controlled throughout the manufacturing process, which operates under a quality system based on applicable current Good Manufacturing Practices (cGMP). Additionally, GORE™ Silicone Tubing is animal derived component free (ADCF).

All GORE™ STA-PURE™ Fluid Sampling Systems are visually inspected and 100% tested for pressure resistance.

Materials of Construction

- Valve and housing . . . Polyetherimide (PEI)
- Gasket Platinum-cured silicone (PCS)
- Tubing Platinum-cured silicone (PCS) or Styrene ethylene butylene styrene (SEBS) TPE
- Collection container. . Bag: Multilayer polyethylene film (PE)
Bottle: Polyethylene terephthalate glycol (PETG)
Syringe: Natural polypropylene (PP)
Conical Tubes: Polystyrene (PS)

Chemical Compatibility Guidelines

	Acids		Bases		Salts	Alcohols	Ketones
	Strong	Weak	Strong	Weak			
PEI	Y	Y	Y	Y	Y	Y	N
PCS	N	Y	N	Y	Y	Y	Y
TPE — SEBS	Y	Y	Y	Y	Y	N	N

Y = Yes N = No



Benefits of GORE™ STA-PURE™ Fluid Sampling System

- Improves operator safety and delivery of fragile cell media via its needle-free, smooth, fluid transport valves
- Maximizes operator efficiency by eliminating assembly time and cleaning costs
- Connects to standard vessel ports and works with existing equipment
- Allows for increased versatility through a modular design and a full range of optional peripherals
- Enables multiple but discrete aseptic sampling from a single vessel port with the choice of single- and five-valve devices
- Provides quick validation and implementation with the use of USP Class VI materials and complete engineering and microbial test package
- Ability to fit any process protocol (CIP/SIP-compatible, customized configurations and collection container options)

Typical Applications

- Monitoring cell count and development
- Sampling for purity, pH and ingredient concentration
- QC retains and sterile transfers
- Small volume (10 milliliter) to large volume (1 liter) sampling





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Typical Physical Properties

PEI Valve and Housing		
Property	Test Method	Specifications
Heat deflection temperature at 66 psi (DTUL)	ASTM D648	210°C
Izod impact, notched, 23°C	ASTM D256	3 cm — kg/cm
Biocompatibility	USP Class VI and FDA 21 CFR	Compliant

Platinum-Cured Silicone Tubing		
Property	Test Method	Specifications
Durometer hardness, Shore A	ASTM D2240	48 to 58
Temperature range	—	-80 to 200°C
Biocompatibility	USP Class VI and FDA 21 CFR	Compliant

SEBS Thermoplastic Elastomer Tubing		
Property	Test Method	Specifications
Durometer hardness, Shore A	ASTM D2240	64
Temperature range	—	-45 to 135°C
Biocompatibility	USP Class VI and FDA 21 CFR	Compliant

Multilayer PE Film Bag		
Property	Test Method	Specifications
Temperature range	—	-80 to 60°C
Gamma stability	Suggested maximum	50 kGy
Biocompatibility	USP Class VI and FDA	Compliant

PETG Bottle		
Property	Test Method	Specifications
Heat deflection temperature at 66 psi	ASTM D648	170°C
Maximum use temperature	—	70°C
Gamma stability	Suggested maximum	50 kGy
Biocompatibility	USP Class VI and FDA 21 CFR	Compliant

Performance Properties

Property	Specifications
Tubing burst pressure (open valve)	40 psi/2.67 bar
Device burst pressure (closed valve)	>150 psi/10.35 bar
Temperature (external to face)	-20°C to 135°C
Flow rate	>15 ml/sec @ 0.4 bar

Microbial Ingress/Egress Resistance

As measured by independent lab immersion protocol with *B. diminuta* culture: no growth after two weeks

Standard Product Ordering Information

Standard configurations of the GORE™ Fluid Sampling System are listed in the table below. To order, contact a Gore representative. For custom solutions, see **Custom Product Design and Ordering Information** below.

Standard systems	Part number	Composition
Single-valve, 0.75-inch mini sanitary end	ACS-1134-G	PEI body 0.125 inch ID x 0.25 inch OD PCS tubes 100 ml PE bags
Five-valve, 1.50-inch sanitary end	ACS-1135-G	
Aseptic separation accessories	Part number	Composition
GORE™ Crimp & Cut Tool	ACS-9073	Jaws & Blade — Ni-anodized, hardened 316L SS
1.25-inch crimp collars	AMS-4391	304 SS
Safety and convenience accessories	Part number	Composition
Lever-lock collar for five-valve device	ACS-1136	PC
0.75-inch custom-fit flanged gasket for one-valve device	ASIL075FL	PCS
1.50-inch custom-fit flanged gasket for five-valve device	ASIL150FL	PCS
Safety caps for separated tube-ends using crimp collars	VRR-125X375-6WH	PVC
2-inch connection adapter for five-valve device	ACS-9074	PEI
Tear-away lever closure shrink-sleeve for one-valve device	XCC48515P	PET
Tear-away lever closure shrink-sleeve for five-valve device	XCC82575P	PET
Gamma sterilization	GAMMA	standard gamma irradiation range provided: 20-35 kGy
Ratchet clamp	340TCSP	PP

Custom Product Design and Ordering Information

Gore offers you the ability to create a customized GORE™ STA-PURE™ Fluid Sampling System by designing the device itself and adding options to further customize your system. To order, contact a Gore representative.

- 1. Choose device type**
 - Single-valve 0.75-inch mini-sanitary end
 - Five-valve 1.5-inch sanitary end
- 2. Choose tubing**
 - Clear platinum-cured silicone
 - Color-indicated platinum-cured silicone (red, yellow, blue, green, black)
 - Clear SEBS thermoplastic elastomer (heat sealable)
- 3. Choose tubing length**
 - 12-inch standard
 - Custom lengths available (recommended 4-inch minimum)
- 4. Choose straight, split or custom manifolds with legs**
 - Straight tubing leg: standard
 - Overmolded Y: provides two containers per leg
 - Overmolded manifolds: provides three or more containers per leg
- 5. Choose collection containers:**
 - Film Bags (PE): from 50 to 500 ml
 - Bottles (PETG): from 30 to 500 ml
 - Syringes (PP): from 10 to 60 cc
 - Conical Tubes (PS): 15 ml
- 6. Choose container outlets for bags or bottles**
 - Luer and Cap
 - Needle-free syringe port and cap
 - ePTFE Vent
 - PP Plug
 - Crimped or heat sealed end
- 7. Safety and convenience options (from table above)**



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Sterilization

It is the end-user's responsibility to validate a sterilization method when using the GORE™ STA-PURE™ Fluid Sampling System. The end-user should conduct testing if sterilization conditions vary and/or if minor property changes could affect application performance.

Recommended sterilization methods include:

- Radiation — up to 50 kGy / 5 mRad maximum
- Steam — recommended maximum 2 SIP cycles prior to use

Shelf Life

When stored in the original unopened packaging at standard conditions, GORE™ STA-PURE™ Fluid Sampling Systems have a recommended shelf life of five years from the production date. When gamma irradiated, these systems have a recommended shelf life of one year from the production date.

Accessories

The patent-pending GORE™ Crimp & Cut Tool's ergonomic design simplifies mechanical, aseptic separations in elastomeric tubing components of a fluid sampling system. The unique jaws and cutting blade provide high strength and redundant seals on each separated tubing end.



Contact Us

For detailed selection criteria, technical assistance and installation guidelines, please contact a Gore representative. To learn more about the GORE™ STA-PURE™ Fluid Sampling System and to watch an online demonstration, visit www.gore.com/fluidsampling.

To the best of our knowledge, the information contained herein is accurate. Final determination of the suitability of any information or material for the use contemplated and the manner of use is the sole responsibility of the user. The above information gives typical properties only.

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