

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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FOR SINGLE-USE ASEPTIC APPLICATIONS

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



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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.



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