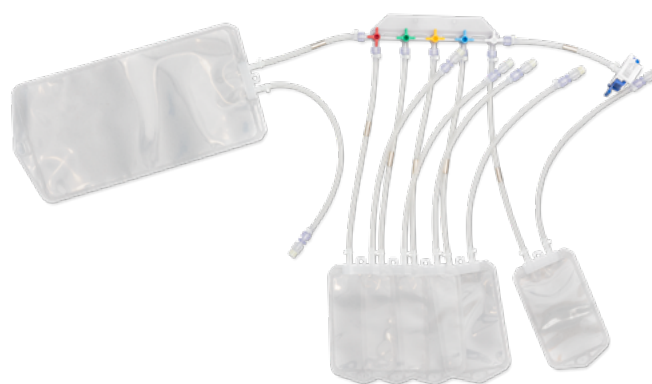


NovaSeptum® SURE Sterile Sampling Assemblies

Standard, closed, and sterile sampling assemblies for your single-use manufacturing processes

NovaSeptum® SURE single-use sterile sampling assemblies are designed to protect your single-use process from potential cross-contamination ensuring representative samples. This flexible sampling assembly can be easily integrated throughout your single-use manufacturing process via a standard AsepticQuik® S connector or C-Flex® tubing for heat welding. The closed assembly ensures your sample will be isolated from point of sample to analysis, reducing the risk of contamination. The NovaSeptum® SURE assemblies come as single or manifold designs in popular formats. They can also be customized to better fit your sampling requirements. Most of the standard assemblies are stocked and ready-to-ship, enabling fast delivery to your site.



Features

- Product design ensures process integrity and a representative sample from single-use manufacturing processes.
- Industry-standard C-Flex® tubing or AsepticQuik® S connection allows aseptic connection and disconnection to any single-use process.
- Range of options: standard or customized, single or manifold of 3 or 5 containers available in bags, bottles, accurate volume syringes, or conical tubes to suit your specific quality control requirements.
- Ideal for sterility, bioburden and endotoxin testing, chemical analysis, pH analysis and any other quality testing requirement.

Easy connection to your single-use process

NovaSeptum® SURE sterile sampling assemblies can be attached to any single-use system, making it versatile and convenient to collect samples from your existing process. The AseptiQuik® S genderless connector enables fast and easy fluid transfer. Alternatively use the C-Flex® tubing option to heat weld for a sterile connection or to connect via a luer or a SmartSite™ clean connector.



Monitoring your single-use process

Various container types tailored for your sampling need

We understand the importance of sampling **small volumes** in order to minimize cost and save high-value product. Our accurate volume syringe is designed to take small samples from 1 mL to 20 mL enabling operators to directly dispense sample products with milliliter accuracy. For **endotoxin testing**, our 15 mL conical tube, made from polystyrene, is ideal. For **larger volumes**, we offer 100 mL high purity bags, and 60 mL bottles.

Representative samples

Representativity is one of the most critical aspects of sampling. NovaSeptum® SURE sterile sampling assemblies are completely closed ensuring your sample and process are safe from cross-contamination.

Robust protection during transport, storage, and freezing

Our NovaSeptum® case is designed for high purity bags to protect your sample during freezing, storage, and transportation.

Component Specifications

NovaSeptum® SURE Sterile Sampling Assemblies

	High-purity Bag	Bottle	Conical Tube	Syringe	Tube Transfer (High Temperature)
Sampling Unit Volume	100 mL	60 mL	15 mL and 50mL	5 and 20 mL	N/A
Maximum Pressure Conditions (at 25 °C)*	0.50 bar (7.25 psi) up to 250 mL, 0.30 bar (4.35 psi) for 1000 mL and multi-sampling	0.50 bar (7.25 psi) for the single unit, 0.30 bar (4.35 psi) for the multi-sampling	0.50 bar (7.25 psi)	0.50 bar (7.25 psi)	0.5 bar (7.25 psi)
Operating Temperature					
C-Flex® designs	4 °C to 50 °C (39 °F to 122°F)		4 °C to 60 °C (39 °F to 140°F)	Single 5 mL: 4 to 134 °C (39 to 273 °F) Single 20 mL: 4 to 121 °C (39 to 250 °F) Multi: 4 to 37 °C (39 to 99 °F)	N/A
AseptiQuik® S designs		4 °C to 40 °C (39 °F to 104 °F)			4 to 125 °C (39 to 257 °F)
Minimum Storage Temperature (containers only)					
C-Flex® designs**	-80 °C (when used with a NovaSeptum® Case) (-112 °F) -20 °C (without a NovaSeptum® Case) (-4 °F)	-80°C(-112°F) Freeze samplingbottlevertically.	2 °C (35 °F)	-80 °C (-112 °F)	N/A
AseptiQuik® S designs					
Materials of Construction					
Drainage Sampling Bag		Polyethylene film (PureFlex™ film)			N/A
Fluid Contact Layer	Polyethylene film (PureFlex™ film)	Polyethylene Terephthalate Glycol	15 mL: Polystyrene 50 mL: Polypropylene	Polycarbonate, platinum-cured silicone, medical silicone fluid	Polycarbonate, platinumcured silicone, medical silicone fluid
AseptiQuik® S connector		Polycarbonate			
Cap	N/A	Polypropylene	Polyethylene	N/A	N/A
Fittings					
AseptiQuik® S Inlet Tubing	TPE (Thermoplastic elastomer)	Cap and TPE tubing	Cap and TPE tubing	Female and male Luer-Lok™ and Silicone tubing	Silicone tubing and Trigger Septum: Platinum-cured silicone; Body: Polyester; Cannula: ASTM 316 L Stainless steel
Outlet Tubing for AseptiQuik® S and C-Flex® designs	3-piece Luer-Lok™ containing a male, female, and an injection site				N/A

	High-purity Bag	Bottle	Conical Tube	Syringe	Tube Transfer (High Temperature)
Autoclaving***	Not autoclavable				yes
Biological Reactivity	All component materials, in contact with sampling liquid, meet the criteria for Biological Reactivity Testing. These tests can be any or a combination of the following test methods: USP<88> Class VI (<i>in vivo</i>), USP<87> (<i>in vitro</i>), ISO 10993-5 (<i>in vitro</i>).				
Integrity Testing	Units are integrity tested at regular intervals during manufacturing.				
Assembly Condition	Assembled under ISO Class 8 cleanroom according to ISO 14644-1 standard.				
Bacterial Endotoxin	Aqueous extraction contains < 2.15 EU per device as determined using the Limulus Amebocyte Lysate (LAL) test.				
Sterilization					
C-Flex® Tubing Designs	Sterilized by gamma irradiation at 25-40 kGy following ISO 11137 validation guidelines				
AseptiQuik® S Connector Designs	sterilized by gamma irradiation at 25-40 kGy following ISO 11137 validation guidelines				
NovaSeptum® Case					
Materials of Construction					
Case	Amorphous Polyethylene Terephthalate (APET) noble				
Maximum Pressure Conditions	0.50 bar				
Operating Temperature	-80 to 37 °C (-112 to 98.6 °F)				
Miscellaneous Accessories					
Materials of Construction					
Volume Indicator Ruler, Crimped Tube Protector Caps	PVC				
Operating Temperature					
Volume Indicator Ruler	-15 to 55 °C (5 to 131 °F)				
Crimped Tube Protector Caps	-20 to 60 °C (-4 to 140 °F)				
Dimensions	Thickness (µm)	Volume (mL)		Length x Width (mm)	
Volume Indicator Ruler	200 ±20	100		169 ±1 x 30 ±1	
Crimped Tube Protector Caps	1.00 ±0.25	N/A		12.7 ±2.00 x 8.00 ±0.25	
NovaSeptum® Manual Crimping Tool					
Materials of Construction					
Body	Aluminum				
Lower Die	Vanadis with hardened special surface treatment				
Upper Die	Vanadis with hardened special surface treatment				
Screws and Bearings	Stainless steel				

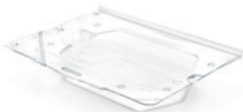
*Do not fill the sampling unit with more than the maximum sample volume. Refer to the User Guide to determine your sampling procedure.

**with C-Flex® still connected only up to -67°C (-55 °F) instead of -80°C (-122 °F)

*** Autoclaving can only be performed on empty products.

Ordering information

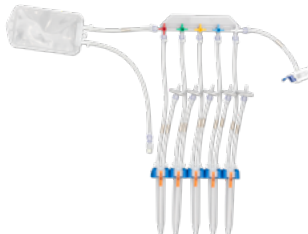
Case

Device Description	Sample Volume (mL)	Length x Width (open)	Height	Qty/Pk	Compatible Bag Cat. No.	Cat. No.
	100	442 x 275 mm (17.4 x 10.8 in.)	36 mm (1.4 in.)	25	5744-10100 AC714-10100	NSF-10100

Accessories

Device Description	Volume (mL)	Qty/Pk	Cat. No.
 NovaSeptum® Manual Crimping Tool		1	A100
NovaSeptum® Manual Crimping Tool Spare Part Kit		1	A104
Crimped Tube Protector Caps		100	NSTP-3X6
Volume Indicator Ruler for High Purity Bags	100	50	NSRULER-10100

Sampling assemblies. All sampling units are manifolded.

Products	Description	Sample Volume (mL)	Sampling Unit	Connection Type	Qty/ Pack	Cat. No.
NovaSeptum® SURE Tube Transfer (High Temperature) 	Silicone Tube	140 mm		2 mm GO trigger + AseptiQuik® S-HT connector	50	AC561-40014
NovaSeptum® SURE High Purity Bag Sampling Assemblies 	High Purity Bag	100	Single	AseptiQuik® S connector	40	AC711-10100
	High Purity Bag	100	Single	Inlet C-Flex® tubing	50	5741-10100
	High Purity Bag	3x100	Manifold	AseptiQuik® S connector	10	AC713-10100
	High Purity Bag	3x100	Manifold	Inlet C-Flex® tubing	12	5743-10100
	High Purity Bag	5x100	Manifold	AseptiQuik® S connector	7	AC714-10100
	High Purity Bag	5x100	Manifold	Inlet C-Flex® tubing	7	5744-10100
NovaSeptum® SURE Bottle Sampling Assemblies 	Bottle	60	Single	AseptiQuik® S connector	30	AC871-80060
	Bottle	3x60	Manifold	AseptiQuik® S connector	9	AC873-80060
	Bottle	3x60	Manifold	Inlet C-Flex® tubing	9	5843-80060
	Bottle	5x60	Manifold	AseptiQuik® S connector	5	AC874-80060
	Bottle	5x60	Manifold	Inlet C-Flex® tubing	5	5844-80060
NovaSeptum® SURE Accurate Volume Syringe Sampling Assemblies 	Accurate Volume Syringe	3x5	Manifold	AseptiQuik® S connector	9	AC463-90005
	Accurate Volume Syringe	3x5	Manifold	Inlet C-Flex® tubing	8	5443-90005
	Accurate Volume Syringe	5x5	Manifold	AseptiQuik® S connector	5	AC464-90005
	Accurate Volume Syringe	5x5	Manifold	Inlet C-Flex® tubing	5	5444-90005
	Accurate Volume Syringe	3x20	Manifold	AseptiQuik® S connector	6	AC463-90020
	Accurate Volume Syringe	3x20	Manifold	Inlet C-Flex® tubing	6	5443-90020
	Accurate Volume Syringe	5x20	Manifold	AseptiQuik® S connector	4	AC464-90020
	Accurate Volume Syringe	5x20	Manifold	Inlet C-Flex® tubing	4	5444-90020
NovaSeptum® SURE Conical Tube Sampling Assemblies 	Conical Tube	15	Single	AseptiQuik® S connector	35	ACC71-80015
	Conical Tube	15	Single	Inlet C-Flex® tubing	40	5C41-80015
	Conical tube with dip tube	15	Single	Inlet C-Flex® tubing	40	5D41-80015
	Conical Tube	3x15	Manifold	AseptiQuik® S connector	10	ACC73-80015
	Conical Tube	3x15	Manifold	Inlet C-Flex® tubing	10	5C43-80015
	Conical tube with dip tube	5x15	Manifold	Inlet C-Flex® tubing	8	5D44-80015
	Conical Tube	5x15	Manifold	Inlet C-Flex® tubing	8	5C44-80015
	Conical Tube	5x15	Manifold	AseptiQuik® S connector	8	ACC74-80015
	Conical Tube	50	Single	Inlet C-Flex® tubing	40	5C41-80050
	Conical Tube with dip tube	50	Single	Inlet C-Flex® tubing	40	5D41-80050
	Conical Tube	5x50	Manifold	Inlet C-Flex® tubing	8	5C44-80050
	Conical Tube with dip tube	5x50	Manifold	Inlet C-Flex® tubing	8	5D44-80050

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