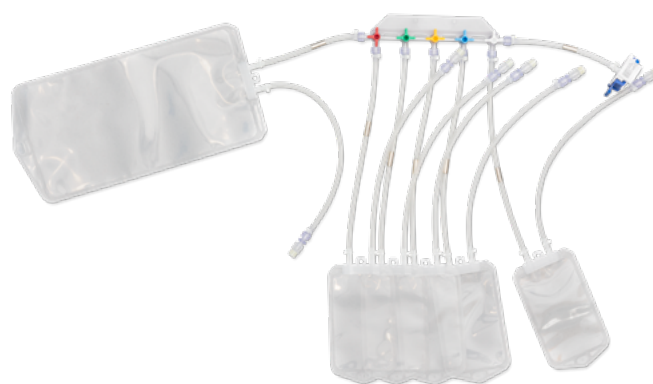


NovaSeptum® SURE Sterile Sampling Assemblies

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 high purity bags from 50 to 1000 mL 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	50 to 1000 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 to 50 °C (39 to 122°F)		4 to 60 °C (39 to 140°F)	4 to 37 °C (39 to 99 °F)	N/A
AseptiQuik® S designs	4 to 40 °C (39 to 104 °F)			4 to 37 °C (39 to 99 °F)	4 to 40 °C (39 to 104 °F)
Storage Temperature (containers only)					
C-Flex® designs**	50 to 250 mL: –20 °C (–4 °F), or –80 °C (–112 °F) when used with a NovaSeptum® Case, to 50°C (122°F)	–80 to 50°C (–112 to 122 °F)	2 to 60 °C (35 to 140 °F)	min –80 °C (–112 °F)	N/A
AseptiQuik® S designs	1000 mL: –20 to 50°C (–4 to 122°F)	Freeze sampling bottle vertically. To freeze the 500 mL size, do not fill more than 400 mL.			
Autoclaving***		Not autoclavable			yes: up to 1h at 125 °C (257 °F)
Graduations	N/A	10 mL (60 mL size)	0.5 mL (15 mL size) 2.5 mL (50 mL size)	0.2 mL (5 mL size) 1 mL (20 mL size)	N/A
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	N/A
Tubing	Thermoplastic elastomer (TPE)	Thermoplastic elastomer (TPE)	Thermoplastic elastomer (TPE)	Silicone	Silicone
AseptiQuik® S connector			Polycarbonate		
Cap	N/A	Polypropylene	Polyethylene	N/A	N/A
Dip Tube	N/A	N/A	LDPE (Low Density Polyethylene)	N/A	N/A

	High-purity Bag	Bottle	Conical Tube	Syringe	Tube Transfer (High Temperature)
Fittings					
AseptiQuik® S Inlet Tubing	TPE (Thermoplastic elastomer) tubing	TPE tubing	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
C-Flex® Inlet	3-piece Luer-Lok™ containing a male, female, and an injection site				N/A
Outlet	Tubing with 3-piece Luer-Lok™, containing a male, female and an injection site	Cap	Cap	N/A	AseptiQuik® S High Temperature (AQS-HT) connector
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> Systemic Injection (<i>in vivo</i>) , USP <87> Cytotoxicity Elution Test (<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				

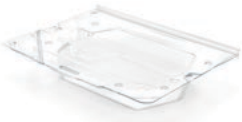
*Do not fill the sampling unit with more than the maximum sample volume. Refer to the User Guide to determine your sampling procedure.

**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

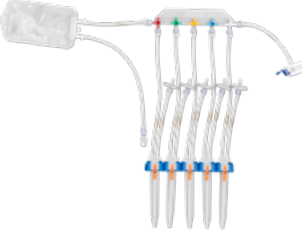
Device Description	Sample Volume (mL)	Length x Width (open)	Height	Qty/Pk	Compatible Bag Cat. No.	Cat. No.
	50 100	442 x 275 mm (17.4 x 10.8 in.)	36 mm (1.4 in.)	25	AC711-10050 AC711-10100 5741-10100 AC713-10100 5743-101003 5744-10100 AC714-10100 AC714-10050	NSF-10100
	250	442 x 275 mm (17.4 x 10.8 in.)	42 mm (1.6 in.)	25	AC711-10250 AC714-10250	NSF-10250

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	50	50	NSRULER-10050
	100	50	NSRULER-10100
	250	50	NSRULER-10250
	100	50	NSRULER-11000

Sampling assemblies

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
	Silicone Tube	140 mm		1 mm trigger + AseptiQuik® S-HT connector	40	AC561-30140
	Silicone Tube	140 mm		2 mm trigger + AseptiQuik® S-HT connector	40	AC561-20140
	NovaSeptum® SURE High Purity Bag Sampling Assemblies High Purity Bag	50	Single	AseptiQuik® S connector	30	AC711-10050
	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	250	Single	AseptiQuik® S connector	21	AC711-10250
	High Purity Bag	1000	Single	AseptiQuik® S connector	18	AC711-11000
	High Purity Bag	3 x 100	Manifold	AseptiQuik® S connector	10	AC713-10100
	High Purity Bag	3 x 100	Manifold	Inlet C-Flex® tubing	12	5743-10100
	High Purity Bag	5 x 50	Manifold	AseptiQuik® S connector	5	AC714-10050
	High Purity Bag	5 x 100	Manifold	AseptiQuik® S connector	7	AC714-10100
	High Purity Bag	5 x 100	Manifold	Inlet C-Flex® tubing	7	5744-10100
	High Purity Bag	5 x 250	Manifold	AseptiQuik® S connector	5	AC714-10250
	NovaSeptum® SURE Bottle Sampling Assemblies Bottle	60	Single	AseptiQuik® S connector	30	AC871-80060
	Bottle	3 x 60	Manifold	AseptiQuik® S connector	9	AC873-80060
	Bottle	3 x 60	Manifold	Inlet C-Flex® tubing	9	5843-80060
	Bottle	5 x 60	Manifold	AseptiQuik® S connector	5	AC874-80060
	Bottle	5 x 60	Manifold	Inlet C-Flex® tubing	5	5844-80060

Products	Description	Sample Volume (mL)	Sampling Unit	Connection Type	Qty/ Pack	Cat. No.
NovaSeptum® SURE Accurate Volume Syringe Sampling Assemblies 	Accurate Volume Syringe	3 x 5	Manifold	AseptiQuik® S connector	9	AC463-90005
	Accurate Volume Syringe	3 x 5	Manifold	Inlet C-Flex® tubing	8	5443-90005
	Accurate Volume Syringe	5 x 5	Manifold	AseptiQuik® S connector	5	AC464-90005
	Accurate Volume Syringe	5 x 5	Manifold	Inlet C-Flex® tubing	5	5444-90005
	Accurate Volume Syringe	3 x 20	Manifold	AseptiQuik® S connector	6	AC463-90020
	Accurate Volume Syringe	3 x 20	Manifold	Inlet C-Flex® tubing	6	5443-90020
	Accurate Volume Syringe	5 x 20	Manifold	AseptiQuik® S connector	4	AC464-90020
	Accurate Volume Syringe	5 x 20	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	3 x 15	Manifold	AseptiQuik® S connector	10	ACC73-80015
	Conical Tube	3 x 15	Manifold	Inlet C-Flex® tubing	10	5C43-80015
	Conical tube with dip tube	5 x 15	Manifold	Inlet C-Flex® tubing	8	5D44-80015
	Conical Tube	5 x 15	Manifold	Inlet C-Flex® tubing	8	5C44-80015
	Conical Tube	5 x 15	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	5 x 50	Manifold	Inlet C-Flex® tubing	8	5C44-80050
	Conical Tube with dip tube	5 x 50	Manifold	Inlet C-Flex® tubing	8	5D44-80050



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