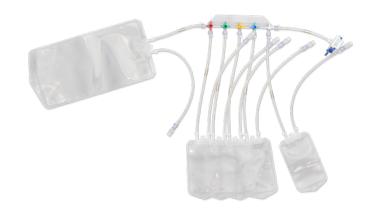


NovaSeptum® SURe Sterile Sampling Assemblies

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 AseptiQuik® 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 manifold with five containers in popular formats. These 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 AseptiQuik® S connection allows aseptic connection and disconnection to any single-use process.
- Range of options: manifolds of 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	
Sampling Unit Volume	100 mL	60 mL	15 mL	5 and 20 mL	
Maximum Pressure Conditions (at 25 °C)*	0.30 bar (4.35 psi)	0.30 bar (4.35 psi)	0.50 bar (7.25 psi)	0.50 bar (7.25 psi)	
Temperature Range (Stora	age)				
C-Flex® designs	-80 (when used with a NovaSeptum® Case) to 50 °C (-112 to 122 °F)	−80 to 50 °C (−112 to 122 °F)**	2 to 60 °C (35 to 140 °F)	-20 to 50 °C (-4 to 122 °F)	
AseptiQuik® S designs		4 °C and 40 °C	(39 °F and 104 °F)		
Materials of Construction					
Drainage Sampling Bag		Polyethylene fil	m (PureFlex™ film)		
Fluid Contact Layer	Polyethylene film (PureFlex™ film)	Polyethylene Terephtalate Glycol	Polystyrene	Polycarbonate, platinum- cured silicone, medical silicone fluid	
AseptiQuik® S connector		Polyc	arbonate		
Tubing	Thermoplastic elastomer (TPE)	TPE	TPE	Silicone	
Сар	N/A	Polypropylene	Polyethylene	N/A	
Fittings					
AseptiQuik® S Inlet Tubing	TPE	Cap	Сар	Female and male Luer-Lok™	
Outlet Tubing for AseptiQuik® S and C-Flex® designs	3-piece Luer-Lok™ containing a male, female, and an injection site				
Autoclaving***	Not autoclavable				
Biological Reactivity	All component materials, in contact with sampling liquid				
Integrity Testing	Units are integrity tested at regular intervals during manufacturing.				
Assembly Condition	Assembled under ISO 8 classified cleanroom in a facility certified to ISO 14644-1 standards.				
Bacterial Endotoxin	Aqueous extraction contains < 2.15 EU per device as determined using the Limulus Amebocyte Lysate (LAL) test.				
Sterilization					
C-Flex [®] Tubing Designs	Beta irradiation at 25–70 kGy according to ISO 11137	Gamma irradiation at 25-40 kGy according to ISO 11137	Gamma irradiation at 25-40 kGy according to ISO 11137	Beta irradiation at 25-70 kGy according to ISO 11137	
AseptiQuik® S Connector Designs	Gamma irradiation at 25-4	0 kGy according to ISO 1113	7		

NovaSeptum® Case					
Materials of Construction					
Case	Amorphous Polyethylene Tereph	thalate (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 Crim	nping Tool				
Materials of Construction					
Body	Aluminum				
Lower Die	Vanadis with hardened special s	urface treatment			
Upper Die	Vanadis with hardened special s	urface 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.

Ordering information

Case

Device Description	Sample Volume (mL)	Length x Width (open)	Height	Qty/Pk	Compatible Bag Cat. No.	Cat. No.
T.	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.
1	NovaSeptum® Manual Crimping Tool		1	A100
Maria	NovaSeptum® Manual Crimping Tool Spare Part Kit		1	A104
Crimped Tube Protector Ca	ps		100	NSTP-3X6
Volume Indicator Ruler for	High Purity Bags	100	50	NSRULER-10100

^{**} Freeze samping bottle vertically.

^{***} Autoclaving can only be performed on empty bags.

Sampling assemblies. All sampling units are manifolded.

Products	Sample Volume (mL)	Connection Type	Qty/ Pack	Cat. No.
NovaSeptum® SURe High Purity Bag Sampling Assemblies	100	Inlet C-Flex® tubing	5	5744-10100
		AseptiQuik® S connector	8	AC714-10100
NovaSeptum® SURe Bottle Sampling Assemblies	60	Inlet C-Flex® tubing	5	5844-80060
		AseptiQuik® S connector	5	AC874-80060
NovaSeptum® SURe Accurate Volume Syringe Sampling Assemblies	5	Inlet C-Flex® tubing	5	5444-90005
		AseptiQuik® S connector	5	AC464-90005
66868	20	Inlet C-Flex® tubing	5	5444-90020
		AseptiQuik® S connector	4	AC464-90020
NovaSeptum® SURe Conical Tube Sampling Assemblies	15	Inlet C-Flex® tubing	8	5C44-80015
		AseptiQuik® S connector	8	ACC74-80015

To place an order or receive technical assistance

Please visit: SigmaAldrich.com/offices

For additional information or place an online order, please visit SigmaAldrich.com/sterilesampling

Merck KGaA Frankfurter Strasse 250 64293 Darmstadt, Germany