

NovaSeptum® GO Sterile Sampling Systems

A secure and flexible system for sampling fluids throughout sterile and aseptic processes

To demonstrate the safety and integrity of your product, you need a standard-setting sampling solution that provides the flexibility to sample throughout your entire process. It is critical that samples are representative and the sampling system minimizes the risk of both sample or process contamination.

Our NovaSeptum® GO sterile sampling system is designed to meet the needs of sampling throughout aseptic and sterile processes. The innovative closed design isolates your sample from collection to analysis, maintaining sample integrity while reducing the possibility of sample loss. When not in use, the locking capability provides an extra level of confidence, keeping your sample safe and process under control.

Benefits

- Sampling actuation evidence and control ensures process integrity and a representative sample
- Closed, easy to use and validate, the system improves operational efficiency and reduces risk of contamination
- Presterilized, eliminating the need for cleaning and/or sterilization between samples
- Preconfigured or configure on site
- Accommodates a wide range of holders and sampling configurations for adaptable, flexible sampling throughout your process

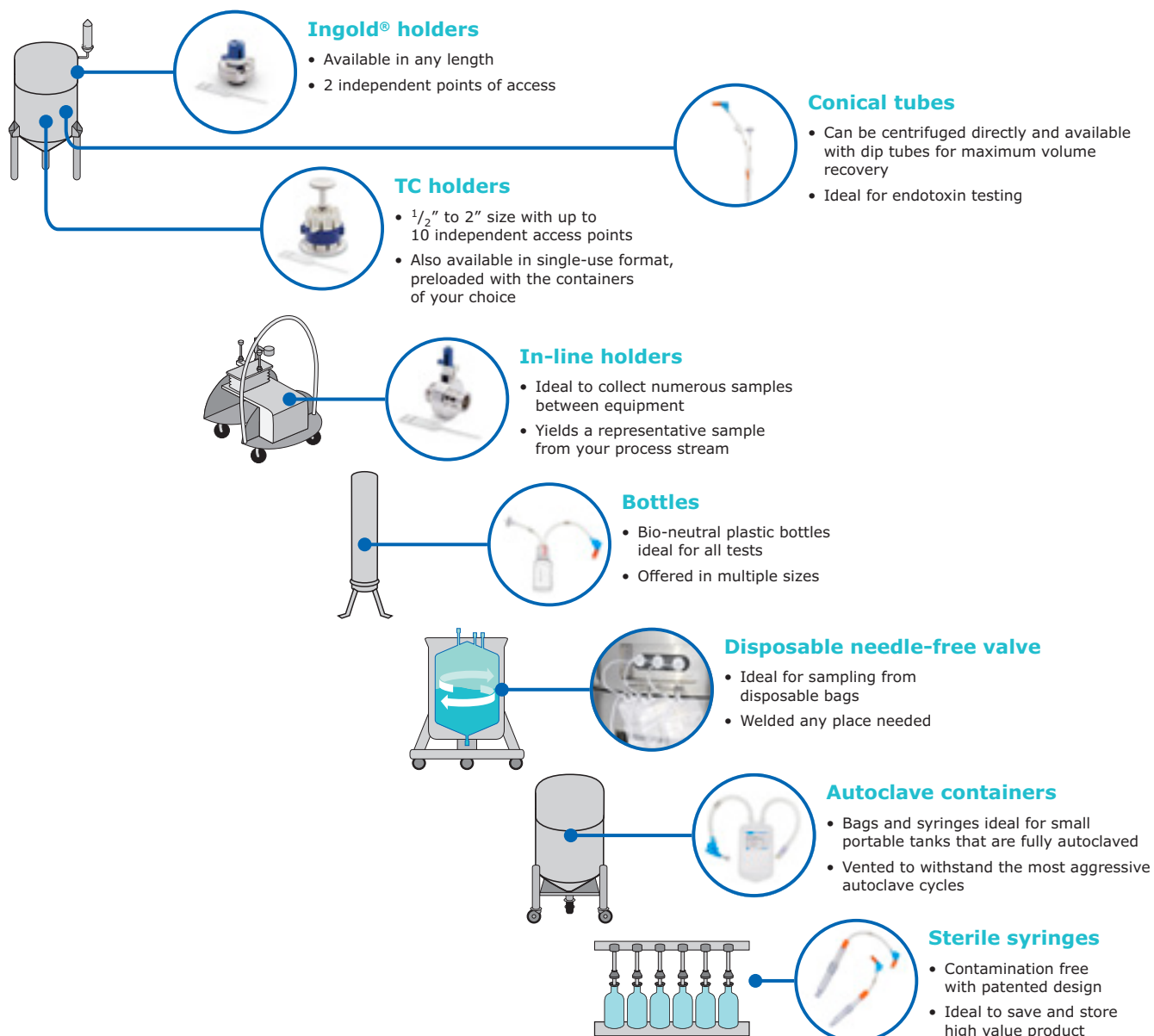


NovaSeptum® GO system compared to other sampling systems

	NovaSeptum® GO systems	Other single-use sampling methods	Traditional sample valves	Tube welding
Closed and presterilized	✓	✓		
User configurable	✓			
Ready to use/Pre-assembled	✓	✓		
Sample anywhere: Ingold®, In-line, and custom holders	✓			
Representative sample: No dead leg, flush, or sample dilution	✓	✓		
Patented accurate volume closed syringes	✓			
Single-use system compatible	✓			✓
Autoclavable	✓		N/A	N/A

Sampling anywhere—made easy

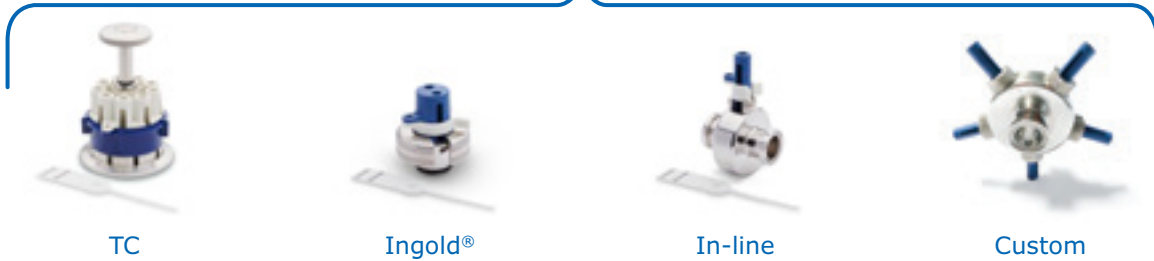
Anatomy of a sampling plan



Your sampling plan, our solution: For Fast and Flexible Implementation

Standard or custom, standalone or preloaded options

Pick your holder



Pick your single or multi sampling unit



Install



Collect sample



Clean and sterile cut detaches sample container for QC lab



Specific Sampling Demands Require Specific Sampling Solutions

Representative sampling

Ensuring the sample and product are safe from cross contamination is a key component of representative sampling. The NovaSeptum® GO sampling system significantly reduces the risk of both process and sample contamination compared with traditional sampling methods. The system's locking tag confirms actuation occurred prior to use, and the safety ring prevents accidental actuation during processing. This system is ideally suited for sampling for sterility testing, bioburden testing*, endotoxin testing, chemical analysis, pH analysis, sample retains, and applications requiring very low affinity for proteins, complex carbohydrates, or small molecules.

High Viscosity Cell Culture Sampling

Sampling can become a challenge with high viscosity cell culture solutions. For this reason, all NovaSeptum® GO sampling units are designed with a universal 2 mm diameter needle size, enabling significantly higher flow rates while reducing shear for cell culture sampling as well as all other applications.

Autoclavable Manufacturing Processes

When integrating a sampling solution into a fully autoclavable manufacturing set-up, specific parameters and materials need to be considered. The NovaSeptum® GO sampling system for autoclavable applications are suitable for integration into processes that require autoclave sterilization.

Sample Size and Quantity

Every manufacturing process has specific requirements for both the number of samples and sample volume. The NovaSeptum® GO sampling system offers options to meet all your sampling needs, including preloaded sampling systems and multi-sampling manifolded options, available as standard off-the-shelf products.

Accurate, Small Volume of Samples

Small-volume sampling of high value products is important to minimizing product waste and economic loss. Our NovaSeptum® GO AV syringe can accurately sample from 1-20 mL volumes enabling operators to confidently dispense small volumes directly.

Endotoxin Sampling

Made from polystyrene, the 15mL Novaseptum® GO conical tube is designed for endotoxin sampling. The tube is clearly calibrated enabling accurate measurement of a small sample volume in a convenient format for QC testing.

NovaSeptum® GO Sterile Sampling options



High purity bag single and multi-sampling units are available from 50 to 1000 mL.



Autoclavable bag single sampling units are available in 50, 100, 250 and 1000 mL.



Bottle single and multi-sampling units are available in 60 to 500 mL.



Conical tube single and multi-sampling units are available in 15 mL and 50mL, with or without Dip Tube, in different tubing materials (C-Flex® and Thermoplastic)



Transfer units are available in different tubing materials (Thermoplastic, Silicone, and C-Flex®).



AV single and multi-sampling units are available in 5 mL and 20 mL syringe sizes.



Single-use holder is available pre-loaded with high purity or autoclavable bags, bottles or AV syringe.

* This test is not applicable for the conical tube designs

Sterile Transfer

Transferring liquid from one sterile process into another can increase the risk of cross contamination of the sample or the manufacturing process. The NovaSeptum GO design ensures safe, sterile liquid transfer, minimizing risk of contamination.

Robust Protection During Transport, Storage and Freezing

The NovaSeptum® case provides extra protection for your high purity bag from sampling to transport and storage, and while freezing your samples.



A Step-By-Step Guide to Sampling with the NovaSeptum® GO System

Step 1: Load the NovaSeptum® GO triggers into the magazine and lock into place. Attach the bag rack to the loaded magazine (optional). Then attach the bag rack with loaded magazine onto the NovaSeptum® GO holder base and lock into place. (Note: Holder base may be left secured onto a tank or piping.) If preloaded, start at Step 2.



Step 2: Attach the loaded NovaSeptum® GO holder base to a NovAseptic® connector on either your tank or piping. If configuring on site, attach the first actuation locking tag to prevent accidental actuation.



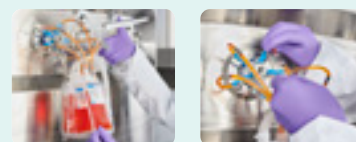
Step 3: Perform standard CIP/SIP.



Step 4: To begin sampling, remove the locking tag, then turn the safety ring to actuate first trigger. Press the NovaSeptum® GO trigger to enable needle to puncture the silicone diaphragm to begin sampling. When sampling is complete, release the NovaSeptum® GO trigger, place it in the lock position, and return safety ring to lock position.



Step 5: Using the NovaSeptum® manual crimping tool, crimp the metal pinch pipe to seal and separate the inlet tubing. The NovaSeptum® manual crimping tool provides a safe, secure cut without risk of contamination.



Step 6: The NovaSeptum® GO sampling container is ready for shipment to the laboratory.



Connect Easily and Securely

Whether you are connecting to an existing process or designing a sampling solution for a new procedure, NovaSeptum® GO system has a broad range of connectors and holders to facilitate the integration of the NovaSeptum® GO sampling units into the process.

**NovAseptic®
Connectors**



Single-Use Connectors

Reduce labor associated with cleaning or handling with NovaSeptum® single-use connectors. The needle-free sampling valve brings capabilities for NovaSeptum® sampling integration into your larger single-use process assemblies. Our NovaSeptum® needle-free single-use sampling assemblies are part of our Mobius® Select Component Library providing you with the perfect balance of off-the-shelf speed and custom flexibility to meet your single-use processing needs.

Needle-Free Single-Use Sampling Valve



**NovaSeptum® GO
Multi-Use Holders**



Validating Performance of your NovaSeptum® GO Sterile Sampling System

Let our validation experts help you develop a robust validation plan to help ensure your NovaSeptum® GO sterile sampling system performs reliably within your predefined process conditions.

We will work with you to understand your process, and then by using our in-depth knowledge of our products, help you assess the risk of your application and recommend the appropriate level of testing to mitigate this risk. Test results will demonstrate the NovaSeptum® GO sampling system's ability to maintain content sterility and integrity as well as operator safety under your specific process conditions, even after long storage periods or extreme operating parameters.

With decades of experience, we can save you valuable time and resources and mitigate your risk throughout your production process.

Specifications

NovaSeptum® GO Sterile Sampling Units

	High Purity Bag	Autoclavable Bag	Bottle	Conical Tube	Syringe	Tube Transfer
Sampling Unit Volume (mL)	50 to 1000	50 to 1000	60, 125, 250, and 500	15 and 50	5 and 20	N/A
Dip Tube	N/A	N/A	N/A	LDPE (Low Density Polyethylene)	N/A	N/A
	N/A	N/A	N/A	Inox 316L	N/A	N/A
TTP clip	N/A	N/A	N/A	Polypropylene	N/A	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	0.30 bar (4.35 psi)	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)	0.50 bar (7.25 psi)
Temperature Range	50 mL to 250 mL: -80 (when used with a NovaSeptum® Case) to 50 °C (-112 to 122 °F) 1000 mL: -20 to 50 °C (-4 to 122 °F)	-20 to 125 °C (-4 to 257 °F)	-80 to 50 °C (-112 to 122 °F) Freeze sampling bottle vertically. To freeze the 500 mL size, do not fill more than 400 mL.	15mL: 2 to 50 °C (36 to 122 °F) 50mL: 2 to 50°C (36 to 122 °F)	Single 5 mL: -80 to 134 °C (-12 to 273 °F) Single 20 mL: -80 to 121 °C (-112 to 250 °F) Multi: -20 to 50 °C (-4 to 122 °F)	Thermoplastic elastomer (TPE): -20 to 50 °C (-4 to 122 °F) Silicone: -50 to 95 °C (-58 to 203 °F) C-Flex®: -73 to 132 °C (-99 to 270 °F)
Centrifugation recommended speed (to be used with Centrifuge Caps sold as an accessory)	N/A	N/A	N/A	1000xg RCF (15 mL) and 3000xg RCF (50 mL)	N/A	N/A
Trigger	Septum: Platinum-cured silicone; Body: Polyester; Cannula: ASTM 316 L Stainless steel					
Sampling Bag	Polyethylene film (PureFlex™ film)	Polypropylene	N/A	N/A	N/A	N/A
Fluid Contact Layer	Polyethylene film (PureFlex™ film)	Polypropylene film	Polyethylene Terephthalate Glycol	Polystyrene, 15mL Polypropylene, 50mL	Polycarbonate, platinum-cured silicone, medical silicone fluid	N/A
Tubing	Thermoplastic elastomer (TPE)	Silicone	Thermoplastic elastomer (TPE)	Thermoplastic elastomer (TPE)	Silicone	Thermoplastic elastomer (TPE), silicone or C-Flex® tube
Dip Tube	N/A	N/A	N/A	LDPE (Low Density Polyethylene)	N/A	N/A
Insert	N/A	N/A	N/A	Inox 316L	N/A	N/A
TTP clip	N/A	N/A	N/A	Polypropylene	N/A	N/A
Bottle Cap	N/A	N/A	Polypropylene	N/A	N/A	N/A
Conical Tube Cap	N/A	N/A	N/A	polyethylene	N/A	N/A
Fittings						
Inlet Tubing	Septum with a 2 mm needle					
Outlet Tubing	Tubing: 3-piece Luer-Lok™, containing a male, female and an injection site	Tubing: Male Luer-Lok™ with female cap	Cap	Cap	Female and male Luer-Lok™	3-piece Luer-Lok™, containing a male, female and an injection site
Autoclaving**	No	Yes	No	No	Single: Yes Manifold: No	No
USP <88> Class VI	All component materials, in contact with sampling liquid, meet the criteria for Class VI testing based on USP <88> Biological Reactivity, <i>in vivo</i> .					
Integrity Testing	Units are integrity tested at regular intervals during manufacturing.					
Assembly	Assembled under ISO Clean Room Class 8 conditions in a facility certified to ISO 14644-1 standards.					
Sterilization	Beta irradiation at ≥25 kGy according to ISO 11137	Beta irradiation at ≥25 kGy according to ISO 11137	Gamma irradiation at ≥25kGy according to ISO 11137	Gamma irradiation at ≥25 kGy according to ISO 11137	Beta irradiation at ≥25 kGy according to ISO 11137	Beta irradiation at ≥25 kGy according to ISO 11137
Bacterial Endotoxin	Aqueous extraction contains <2.15 EU per device as determined using the Limulus Amebocyte Lysate (LAL) test.					

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

**Autoclaving can only be performed on empty containers.

NovaSeptum® Case

Materials of Construction

Case Amorphous Polyethylene Terephthalate (APET) noble

Dimensions (length x width x height)

50, 100 mL 442 x 275 x 36 mm (17.4 x 10.8 x 1.4 in.)

250 mL 442 x 275 x 42 mm (17.4 x 10.8 x 1.6 in.)

Maximum Pressure Conditions 0.50 bar up to 250 mL

Operating Temperature -80 to 37 °C (-112 to 98.6 °F)

Needle-Free Sampling Valve

Materials of Construction

Mounting Plate, Sliding Plate, Hanger, and Holder Stainless steel in compliance with ASTM 316

O-ring Silicone

Environmental

Operating Temperature 2 to 60 °C (35 to 140 °F)

Traceability N/A

Sterilization Gamma irradiation between 25 kGy and 45 kGy

Component Material Toxicity All wetted components comply with USP <88> Biological Reactivity Tests for Class VI plastics

Endotoxin Level <2.15 EU/device for all wetted components

Assembly Welded in a Mobius® assembly

Packaging N/A

NovaSeptum® GO Holder

Materials of Construction

Wetted Materials Stainless steel 316L, EN 1.4435

Magazine GF reinforced polysulfone (PSU) for 5 and 9 shot TC holders.
Polyphenylene sulfide (PPS) for 1 shot TC, Ingold®, and in-line holders.

Safety ring Polysulfone for 5 and 9 shot TC holders.
Polyester for 1 shot TC, Ingold®, and in-line holders.

Autoclavable/Steam-in-Place Yes

Tube Standards

TC and Ingold® N/A

In-line TC, Butt-end ASTM A270, DIN 11850 (Part 2)

Design Pressure: 6 bar(g) (87 psi)

Design Temperature: -80 °C to 135 °C (-112 °F to 275 °F)

NovaSeptum® GO Bag Racks

Materials of Construction

Mounting Plate, Sliding Plate, Hanger, and Holder	Stainless steel in compliance with ASTM 316
Manifold Holder	Polyacetale copolymer
Wing Screw	Stainless steel in compliance with A2/A4
Screw and Locking Nut	Stainless steel in compliance with A4

Port Plugs

Material of Construction	Platinum-cured silicone (wetted part) + polyester for the pin
Operating Temperature	0 to 134 °C (32 to 273 °F)

Miscellaneous Accessories

Materials of Construction

Volume Indicator Ruler, Crimped Tube Protector Caps	PVC
First actuation locking tag	Polyamide and stainless steel
Conical Tube Sterile Centrifuge cap	Polypropylene (15mL),HDPE (High Density Polyethylene) 50mL

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)
First actuation locking tag	0 to 134 °C (32 to 273 °F)

Dimensions	Thickness (µm)	Volume (mL)	Length x Width (mm)	
Volume Indicator Ruler	200 ±20	50	160 ±1	30 ±1
	200 ±20	100	169 ±1	30 ±1
	200 ±20	250	202 ±1	30 ±1
	200 ±20	1000	325 ±1	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

Ordering Information


General Fluid and Cell Culture Sampling

Device Description	Sample Volume (mL)	Sampling Unit	Needle Size (mm)	Qty/Pk	Cat. No.
	50	Single	2	50	E711-10050
	100	Single	2	50	E711-10100
	250	Single	2	50	E711-10250
	1000	Single	2	50	E711-11000
	5 x 50	Multi	2	5	E714-10050
	5 x 100	Multi	2	5	E714-10100
	5 x 250	Multi	2	5	E714-10250
	50	Single	2	40	E221-00215
	100	Single	2	40	E221-00216
	250	Single	2	40	E221-C0243
	1000	Single	2	40	E221-C0244
	60	Single	2	40	E871-80060
	5 x 60	Multi	2	5	E874-80060
	125	Single	2	25	E871-80125
	5 x 125	Multi	2	4	E874-80125
	250	Single	2	20	E871-80250
	5 x 250	Multi	2	3	E874-80250
	500	Single	2	12	E871-80500
	15	Single	2	40	EC71-80015
	5 x 15	Multi	2	8	EC74-80015
	15	Single	2	40	ED71-80015
	5 x 15	Multi	2	8	ED74-80015
	15	Single	2	40	5C41-80015
	5 x 15	Multi	2	8	5C44-80015
	15	Single	2	40	5D41-80015
	5 x 15	Multi	2	8	5D44-80015
	50	Single	2	40	EC71-80050
	5 x 50	Multi	2	8	EC74-80050
	50	Single	2	40	ED71-80050
	5x50	Multi	2	8	ED74-80050
	50	Single	2	40	5C41-80050
	5 x 50	Multi	2	8	5C44-80050
	50	Single	2	40	5D41-80050
5 x 50	Multi	2	8	5D44-80050	
	5	Single	2	50	E461-90005
	5 x 5	Multi	2	5	E464-90005
	20	Single	2	40	E461-90020
	5 x 20	Multi	2	5	E464-90020





Transfer Units

Device Description	Volume (mL)	Needle Size (mm)	Tubing	Tubing Connector	Qty/Pk	Cat. No.
	N/A	2	500 mm TPE	3-piece Luer-Lok™	50	E511-10014
	N/A	2	500 mm Silicone	3-piece Luer-Lok™	50	E521-10014
	N/A	2	1000 mm C-Flex®	3-piece Luer-Lok™	50	E541-00020

Case

Device Description	Sample Volume (mL)	Length x Width (open)	Height	Qty/Pk	Compatible with Bag Cat. No. (single)	Bag Cat. No. (multi)	Cat. No.
	50	442 x 275 mm	36 mm	25	E711-10050	E714-10050	NSF-10100
	100	(17.4 x 10.8 in.)	(1.4 in.)		E711-10100	E714-10100	
	250	442 x 275 mm	42 mm	25	E711-10250	E714-10250	NSF-10250
		(17.4 x 10.8 in.)	(1.6 in.)				

NovaSeptum® GO Holders*

Device Description	No. of Sampling Ports	TC Size	Tube Size (O.D.ø)	Cat. No.
In-line TC Holder EP+Glass Blasted, Fully Machined 	1	25 mm (.5 in.)	.5 in. (ASTM)	EP12/127x94-3D5
			.75 in. (ASTM)	EP12/191x158-3D5
			13 mm (DIN)	EP12/130x100-3D5
			19 mm (DIN)	EP12/190x160-3D5
In-line Butt-end Holder EP+Glass Blasted, Fully Machined 	1	N/A	.5 in. (ASTM)	EP12/127x94-3D4
			.75 in. (ASTM)	EP12/191x158-3D4
			13 mm (DIN)	EP12/130x100-3D4
			19 mm (DIN)	EP12/190x160-3D4
TC Holder EP+Glass Blasted, Fully Machined 	1	25 mm (.5 in.)	N/A	ET12/2-3D0
	5	50.5 mm (1.5 in.)	N/A	ET52/5-3D0
	9	64 mm (2 in.)	N/A	ET92/6-3D0
Device Description	No. of Sampling Ports	Ingold® Insertion Length	Cat. No.	
Ingold® Holder EP+Glass Blasted, Fully Machined 	2	22	EG22/380x252-3D0	
	2	46	EG22/380X490-3D0	
	2	52	EG22/380X550-3D0	







*Contact your local representative to discuss custom configurations.

NovaSeptum® Needle-free Sampling Valve


Device Description	Sampling Type	No. of Sampling Ports	TC Size	Tube Size (I.D.Ø)	Cat. No.
Needle-free Single-use Sampling Valve	N/A	1	N/A	3.2 mm (.125 in.)	Integrated in a Mobius® assembly




NovaSeptum® GO Preloaded Sampling Systems


Device Description	Sampling Type	Sample Volume (mL)	Sample Unit/Single-Use Holder	Qty/ pack	Cat. No.
	NovaSeptum® GO AV Accurate Volume Sampling Unit	20	5 Single Sampling Unit	4	E5SU461-90020
		5	5 Single Sampling Unit	6	E5SU461-90005
	NovaSeptum® GO High Purity Sampling Unit	50	5 Single Sampling Unit	6	E5SU711-10050
		100	5 Single Sampling Unit	6	E5SU711-10100
		250	5 Single Sampling Unit	5	E5SU711-10250
		1000	5 Single Sampling Unit	4	E5SU711-11000
	NovaSeptum® GO Bottle Sampling Unit	60	5 Single Sampling Unit	6	E5SU871-80060
		125	5 Single Sampling Unit	4	E5SU871-80125
		250	5 Single Sampling Unit	3	E5SU871-80250
		500	5 Single Sampling Unit	2	E5SU871-80500
	NovaSeptum® GO AV Accurate Volume Sampling Unit	20	9 Single Sampling Unit	2	E9SU461-90020
		5	9 Single Sampling Unit	3	E9SU461-90005
	NovaSeptum® GO High Purity Sampling Unit	50	9 Single Sampling Unit	3	E9SU711-10050
		100	9 Single Sampling Unit	3	E9SU711-10100
		250	9 Single Sampling Unit	3	E9SU711-10250
		1000	9 Single Sampling Unit	3	E9SU711-11000
	NovaSeptum® GO Bottle Sampling Unit	60	9 Single Sampling Unit	3	E9SU871-80060
		125	9 Single Sampling Unit	2	E9SU871-80125
		250	9 Single Sampling Unit	1	E9SU871-80250

NovaSeptum® GO Preloaded System Starter Kits


Device Description	Qty/Pk	Cat. No.	
	NovaSeptum® GO base/nut/locking tool 5-port TC50.5	1	EAT52/5-3D0
	NovaSeptum® GO base/nut/locking tool 9-port TC64	1	EAT92/6-3D0

Accessories

Device Description	Qty/Pk	Cat. No.	
	NovaSeptum® Manual Crimping Tool	1	A100
	NovaSeptum® Manual Crimping Tool Spare Part Kit	1	A104
Port Plugs	100	E202	
Crimped Tube Protector Caps	100	NSTP-3X6	
Locking Tag	100	ENSTAG	

Device Description	Sample Volume	Qty/Pk	Compatible with Conical tube Cat. No.	Cat. No.
	15	10	EC71-80015	NSCAP15
			EC74-80015	
			ED71-80015	
			ED74-80015	
			5C41-80015	
			5C44-80015	
			5D41-80015	
	5D44-80015			
	50	10	EC71-80050	NSCAP50
			EC74-80050	
			ED71-80050	
			ED74-80050	
			5C41-80050	
			5C44-80050	
5D41-80050				
5D44-80050				

Device Description	Volume (mL)	5D44-80050	Cat. No.
Volume Indicator Ruler for High Purity Bags	50	50	NSRULER-10050
	100	50	NSRULER-10100
	250	50	NSRULER-10250
	1000	50	NSRULER-11000

Device Description		Fits NovaSeptum® Holder	Cat. No.
 <p>NovaSeptum® bag racks are available for single and multi-sampling units</p>	For single sampling units	1-port holder, TC 25/NAC 18	A002
		5-port holder, TC 50.5	A003
		9-port holder, TC 64	A004
		Ingold® holder	A005
		5-port holder, TC 50.5 for NAC-USI, NAC-USM	A013
		9-port holder, TC 64 for NAC-USI, NAC-USM	A014
	For multi-sampling units	1-port holder, TC 25/NAC 18	A007
		5-port holder, TC 50.5 for NAC-A, NAC-D, NAC-I, NAC-S	A008
		9-port holder, TC 64 for NAC-A, NAC-D, NAC-I, NAC-S	A009
		Ingold® holder	A010
		5-port holder, TC 50.5 for NAC-USI, NAC-USM	A011
		9-port holder, TC 64 for NAC-USI, NAC-USM	A012
NovaSeptum® GO Fixture for TC Bag Rack			ET-BAGRACK-KIT

For additional information, visit

SigmaAldrich.com/sterilesampling

To place an order or receive technical assistance, visit

SigmaAldrich.com/offices

