

# 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

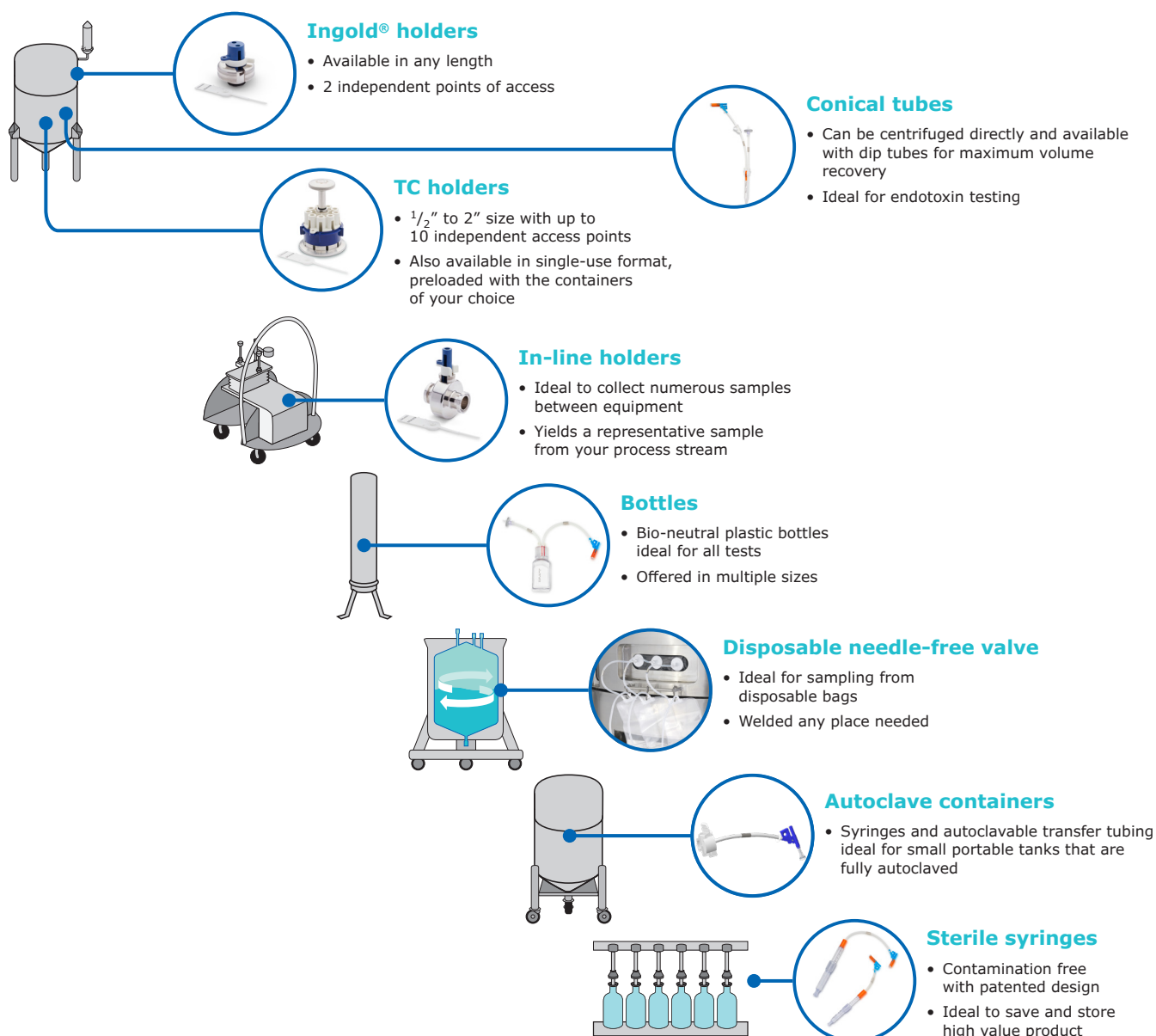


## NovaSeptum® GO system compared to other sampling systems

	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



TC



Ingold®



In-line



Custom

## Pick your single or multi sampling unit



Syringe



Conical  
Tube



Bottle



High purity bag



Single-use,  
preloaded



Multi-sampling  
option



## 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.

### 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.

### 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® SURE Tube Transfer (GO 2 mm trigger + AseptiQuik® S High Temperature\*\* connector) for autoclavable applications is suitable for integration into processes that require autoclave sterilization. This transfer set can be connected then with any NovaSeptum® SURE assembly after autoclave, adding flexibility and harmonization.

### 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.

## NovaSeptum® GO Sterile Sampling options



High purity bag single and multi-sampling units are available from 50 to 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 50 mL, 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®) and for autoclave application.



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 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.



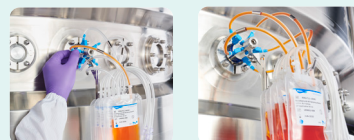
**Step 2:** Attach the loaded NovaSeptum® GO holder base to a NovAseptic® connector on either your tank or piping. If configuring on site, attach the first actuation locking tag to prevent accidental actuation.



**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**



**NovaSeptum® GO  
Multi-Use Holders**



## 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**



## 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	Bottle	Conical Tube	Syringe	Tube Transfer
Sampling Unit Volume (mL)	50 to 1000	60, 125, 250, and 500	15 and 50	5 and 20	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)	0.50 bar (7.25 psi)
Maximum Operating Temperature	50 °C (122 °F)	50 °C (122 °F)	50 °C (122 °F)	37 °C (99 °F)	Thermoplastic elastomer (TPE): 50 °C (122 °F) Silicone: 95 °C (203 °F) Silicone with AseptiQuik® S High Temperature: 4 to 40 °C (39 to 104 °F) C-Flex®: 132 °C (270 °F)
Minimum Storage Temperature (container only)**	50mL to 250mL: -20 °C (-4 °F) or -80 °C (-112 °F) when used with a NovaSeptum® Case 1000mL: -20 °C (-4 °F)	-80 °C (-112 °F) Freeze sampling bottle vertically. To freeze the 500 mL size, do not fill more than 400 mL.	2 °C (36 °F)	Single: -80 °C (-112 °F) Manifold: -20 °C (-4 °F)	Thermoplastic elastomer (TPE): -20 °C (-4 °F) Silicone: -50 °C (-58 °F) Silicone with AseptiQuik® S High Temperature: 4 °C (39 °F) C-Flex®: -73 °C (-99 °F)
Autoclaving***	No	No	No	Single 5 mL: up to 134 °C (-12 °F) Single 20 mL: up to 121 °C (250 °F) Manifold: No	No except AC561-40014: up to 125°C (257 °F)
Graduations	N/A	10 mL (60 mL size) 25 mL (125 mL size) 50 mL (250 mL size) 100 mL (500 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
Centrifugation recommended speed (to be used with Centrifuge Caps sold as an accessory)	N/A	N/A	1000xg RCF (15 mL) 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)	N/A	N/A	N/A	N/A
Fluid Contact Layer	Polyethylene film (PureFlex™ film)	Polyethylene Terephthalate Glycol	Polystyrene, 15mL Polypropylene, 50mL	Polycarbonate, platinum-cured silicone, medical silicone fluid	N/A
Tubing	Thermoplastic elastomer (TPE)	Thermoplastic elastomer (TPE)	Thermoplastic elastomer (TPE)	Silicone	Thermoplastic elastomer (TPE), silicone or C-Flex® tube
Dip Tube	N/A	N/A	LDPE (Low Density Polyethylene)	N/A	N/A
Insert	N/A	N/A	Inox 316L	N/A	N/A
TTP clip	N/A	N/A	Polypropylene	N/A	N/A
Bottle Cap	N/A	Polypropylene	N/A	N/A	N/A
Conical Tube Cap	N/A	N/A	Polyethylene	N/A	N/A
AseptiQuik® S High Temperature	N/A	N/A	N/A	N/A	Polycarbonate
Fittings					
Inlet Tubing	Septum with a 2 mm needle				
Outlet Tubing	Tubing: 3-piece Luer-Lok™, containing a male, female and an injection site	Cap	Cap	Female and male Luer-Lok™	3-piece Luer-Lok™, containing a male, female and an injection site or AseptiQuik® S High Temperature (AQS-HT) connector

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

\*\*Refer to the User Guide for storage and freezing instructions.

\*\*\*Autoclaving can only be performed on empty containers.

	High Purity Bag	Bottle	Conical Tube	Syringe	Tube Transfer
Biological Reactivity	All component materials, in contact with sampling liquid, meet the criteria for Biological Reactivity Testing. These tests can be any one or a combination of the following test methods USP<88> Systemic Injection Test ( <i>In Vivo</i> ), USP <87> Cytotoxicity Elution Test ( <i>In Vitro</i> ), ISO 10993-5.				
Integrity Testing	Units are integrity tested at regular intervals during manufacturing.				
Assembly	Assembled under Clean Room Class ISO 8 as specified in ISO 14644-1				
Sterilization	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	Beta irradiation at 25–70 kGy according to ISO 11137, Gamma irradiation at 25–40 kGy according to ISO 11137 for AQS design
Bacterial Endotoxin	Aqueous extraction contains <2.15 EU per device as determined using the Limulus Amebocyte Lysate (LAL) test.				

## 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 (15 mL), 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

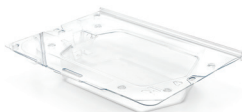
### General Fluid and Cell Culture Sampling

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

### 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	<b>E511-10014</b>
	N/A	2	500 mm Silicone	3-piece Luer-Lok™	50	<b>E521-10014</b>
	N/A	2	1000 mm C-Flex®	3-piece Luer-Lok™	50	<b>E541-00020</b>
	N/A	2	140 mm Silicone	AseptiQuik® S connector for High Temperature	50	<b>AC561-40014</b>

## 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	<b>NSF-10100</b>
	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	<b>NSF-10250</b>
		(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	4	E5SU711-10050
		100	5 Single Sampling Unit	4	E5SU711-10100
		250	5 Single Sampling Unit	4	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
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### Crimped Tube Protector Caps

### Locking Tag



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	
Volume Indicator Ruler for High Purity Bags	50	50	NSRULER-10050
	100	50	NSRULER-10100
	250	50	NSRULER-10250
	1000	50	NSRULER-11000

