

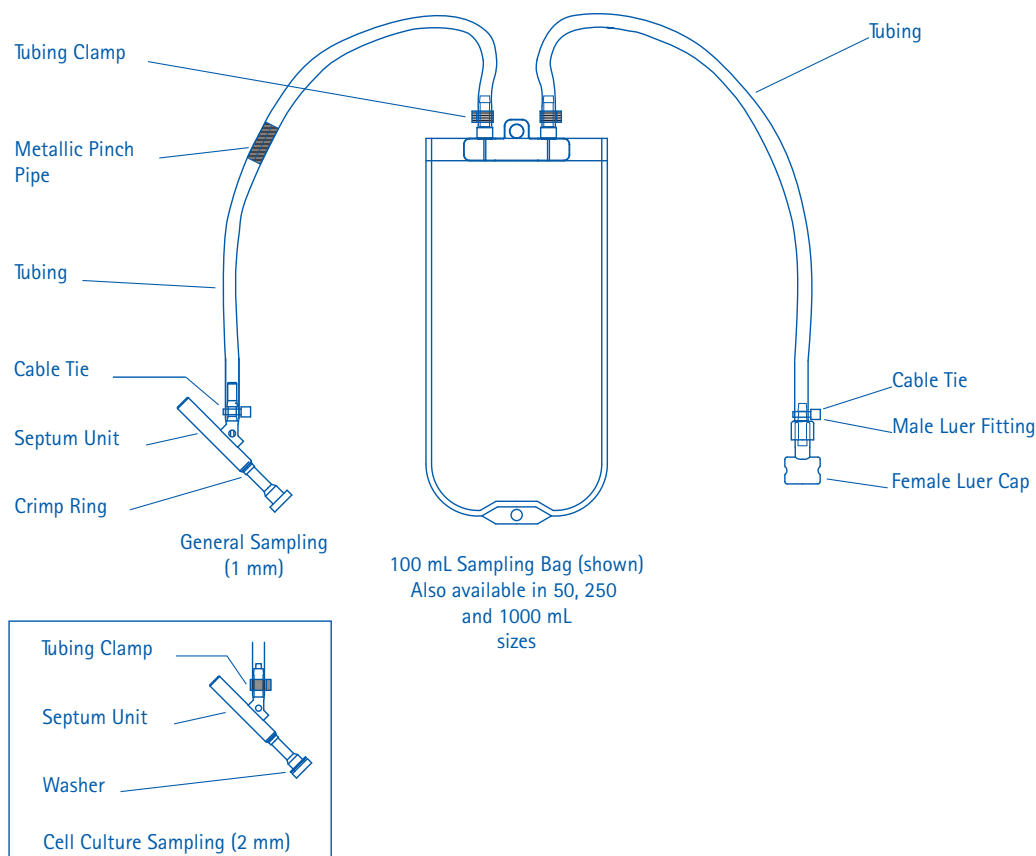
Specification Sheet

NovaSeptum® Autoclavable Sampling Unit

Product Description

The NovaSeptum® autoclavable sampling unit is intended for applications where the unit can be connected to a vessel that needs to be sterilized by autoclave. This sampling unit is available with a 1 mm needle for general sampling or a 2 mm needle for cell culture sampling and must be used with a NovaSeptum® holder. For single-use only, it is important to note that the needle may only penetrate the septum once to ensure proper sealing. A certificate of quality is included in each box.

NovaSeptum® Sampling Unit Configuration



Autoclavable Sampling Ordering Information

Sample Volume (mL)	Sampling Unit	Needle Size (mm)	Qty/Pk	Catalogue No.
50	Single	1	50	1221-60050
100	Single	1	50	1221-60100
250	Single	1	50	1221-60250
1000	Single	1	50	1221-61000
50	Single	2	50	2221-60050
100	Single	2	50	2221-60100
250	Single	2	50	2221-60250
1000	Single	2	50	2221-61000

Specifications

Materials of Construction	
Sampling Bag Fluid Contact Layer	Polypropylene film
Septum	Medical grade, platinum-cured silicone
Septum Body	
1 mm	Green polyester
2 mm	Blue polyester
Septum Cannula	ASTM® 316 L stainless steel
Tubing	Medical grade, platinum-cured silicone
Metallic Pinch Pipe	Nickel plated brass
Male Luer Fitting, Female Luer Cap	Polypropylene
Cable Tie	Nylon
Tubing Clamp, Crimp Ring and Washer	Stainless steel

Dimensions	
Volume*	Sampling Bag Dimensions (length x width)
50 mL	150 x 80 mm
100 mL	180 x 80 mm
250 mL	245 x 80 mm
1000 mL	310 x 140 mm

* Do not fill the sampling unit with more than the maximum sample volume. Use the flow rates in the User Guide to determine when the sampling unit is filled.

Environmental	
Maximum Bag Pressure Conditions	Withstand 0.3 bar (4.35 psi) at 25 °C (77 °F)
Operating Temperature	-20 °C to 125 °C (-4 °F to 257 °F)
Traceability	The product and packaging label includes the catalogue and lot number as well as the expiration date.
Sterilization	Beta Irradiation (e-beam) minimum 25 kGy according to ISO-11137
Autoclaving Guidelines	<p>An autoclave not adjusted to the NovaSeptum® Sampling System may cause product failure. It is the responsibility of the end-user to validate the autoclave so that product failure does not occur.</p> <p>The critical part in the autoclave cycle is the drop down in vacuum. The vacuum causes an expansion of the sterile air inside the tubes, which will expand the bags. The air volume is approximately the same for all sampling systems, however, a unit with a larger bag volume gives greater expansion possibilities for the air inside, and therefore the effect will be more apparent in the smaller units. If the drop down into vacuum is made too fast this may cause problems such as blow-up of the sampling bag. The most critical cycle is the post-vacuum due to the higher chamber temperature, which enhances the expansion of the air.</p> <p>To avoid this:</p> <ul style="list-style-type: none"> • A ramp of 150 mbarg/min into vacuum is recommended for both pre- and post-vacuum cycles. • A vacuum cycle below -500 mbarg is not recommended.
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	This product is manufactured in a clean room environment complying with class 8 according to ISO* 14644-1.
Packaging	Five sampling units are packaged in two sealed bags and then placed in 5 * 5 units in a plastic bag for a total of 25 units in each bag. Two bags, containing a total of 25 units are placed in a cardboard box for a total of 50 sampling units per box.



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