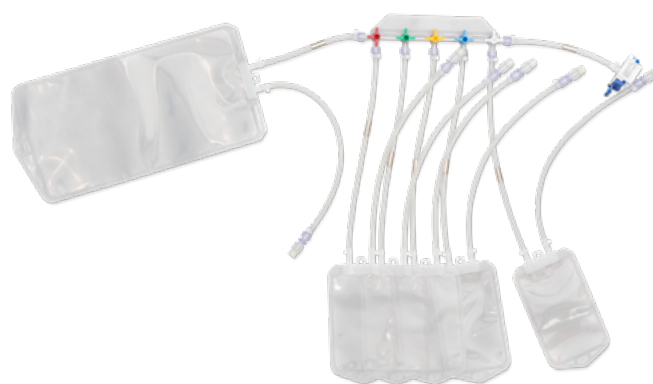


NovaSeptum® SURE Sterile Sampling Assemblies

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 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 AseptiQuik® 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.

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 |

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.

| | 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 | | | | |

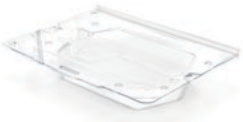
*Do not fill the sampling unit with more than the maximum sample volume. Refer to the User Guide to determine your sampling procedure.

**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


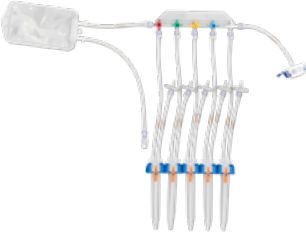
| Device Description | Sample Volume (mL) | Length x Width (open) | Height | Qty/Pk | Compatible Bag Cat. No. | Cat. No. |
|---|--------------------|-----------------------------------|-----------------|--------|--|------------------|
|  | 50 100 | 442 x 275 mm (17.4 x 10.8 in.) | 36 mm (1.4 in.) | 25 | 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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