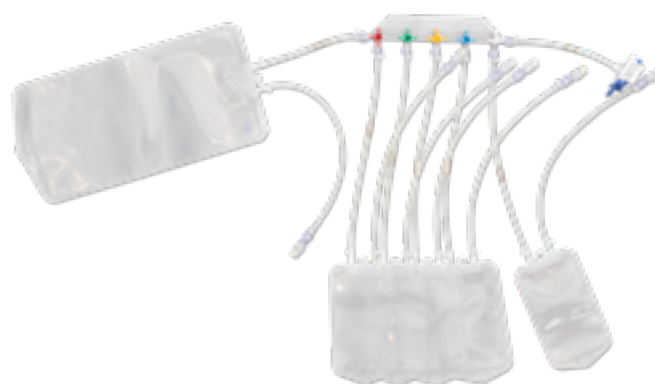


# NovaSeptum® SURE Sterile Sampling Assemblies

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.

\* This test is not applicable for the conical tube designs

## 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  | Tube Transfer (High Temperature)  |
|---|--|---|---------------------------|--|---|
| Sampling Unit Volume                                | 100 mL   | 60 mL   | 15 mL                     | 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)  | N/A   |
| <b>Temperature Range ( Storage)</b>                 |  |   |                           |  | -80 to 125 °C (-112 to 257 °F)  |
| 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 37 °C (-4 to 99 °F)                                     |   |
| AseptiQuik® S designs                               |  | 4 °C and 40 °C (39 °F and 104 °F)   |                           |  |   |
| <b>Materials of Construction</b>                    |  |   |                           |  |   |
| Drainage Sampling Bag                               |  | Polyethylene film (PureFlex™ film)  |                           |  | N/A   |
| Fluid Contact Layer                                 | Polyethylene film (PureFlex™ film)   | Polyethylene Terephthalate Glycol   | Polystyrene               | Polycarbonate, platinum-cured silicone, medical silicone fluid | Polycarbonate, platinumcured silicone, medical silicone fluid   |
| AseptiQuik® S connector                             |  | Polycarbonate   |                           |  |   |
| Cap   | N/A  | Polypropylene   | Polyethylene              | N/A  | N/A   |
| <b>Fittings</b>                                     |  |   |                           |  |   |
| AseptiQuik® S Inlet Tubing                          | TPE (Thermoplastic elastomer)  | Cap and TPE tubing  | Cap and 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 |
| Outlet Tubing for AseptiQuik® S and C-Flex® designs | 3-piece Luer-Lok™ containing a male, female, and an injection site   |   |                           |  |   |
| <b>Autoclaving***</b>                               | Not autoclavable   |   |                           |  | yes   |
| <b>Biological Reactivity</b>                        | 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> Class VI ( <i>in vivo</i> ), USP<87> ( <i>in vitro</i> ), ISO 10993-5 ( <i>in vitro</i> ). |   |                           |  |   |
| <b>Integrity Testing</b>                            | Units are integrity tested at regular intervals during manufacturing.  |   |                           |  |   |
| <b>Assembly Condition</b>                           | Assembled under ISO 8 classified cleanroom in a facility certified to ISO 14644-1 standards.   |   |                           |  |   |

|  | High-purity Bag   | Bottle                         | Conical Tube               | Syringe | Tube Transfer (High Temperature) |                  |
|--|---|--------------------------------|----------------------------|---------|----------------------------------|------------------|
| <b>Bacterial Endotoxin</b>   | Aqueous extraction contains < 2.15 EU per device as determined using the Limulus Amebocyte Lysate (LAL) test. |                                |                            |         |                                  |                  |
| <b>Sterilization</b>   |   |                                |                            |         |                                  |                  |
| C-Flex® Tubing Designs   | Gamma irradiation at 25-40 kGy according to ISO 11137   |                                |                            |         |                                  |                  |
| AseptiQuik® S Connector Designs  | Gamma irradiation at 25-40 kGy according to ISO 11137   |                                |                            |         |                                  |                  |
| <b>NovaSeptum® Case</b>  |   |                                |                            |         |                                  |                  |
| <b>Materials of Construction</b>   |   |                                |                            |         |                                  |                  |
| Case   | Amorphous Polyethylene Terephthalate (APET) noble   |                                |                            |         |                                  |                  |
| Maximum Pressure Conditions  | 0.50 bar  |                                |                            |         |                                  |                  |
| Operating Temperature  | -80 to 37 °C (-112 to 98.6 °F)  |                                |                            |         |                                  |                  |
| <b>Miscellaneous Accessories</b>   |   |                                |                            |         |                                  |                  |
| <b>Materials of Construction</b>   |   |                                |                            |         |                                  |                  |
| Volume Indicator Ruler, Crimped Tube Protector Caps  | PVC   |                                |                            |         |                                  |                  |
| <b>Operating Temperature</b>   |   |                                |                            |         |                                  |                  |
| Volume Indicator Ruler   | -15 to 55 °C (5 to 131 °F)  |                                |                            |         |                                  |                  |
| Crimped Tube Protector Caps  | -20 to 60 °C (-4 to 140 °F)   |                                |                            |         |                                  |                  |
| <b>Dimensions</b>  | <b>Thickness (µm)</b>   | <b>Volume (mL)</b>             | <b>Length x Width (mm)</b> |         |                                  |                  |
| 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    |         |                                  |                  |
| <b>NovaSeptum® Manual Crimping Tool</b>  |   |                                |                            |         |                                  |                  |
| <b>Materials of Construction</b>   |   |                                |                            |         |                                  |                  |
| 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. |   |                                |                            |         |                                  |                  |
| ** Freeze samping bottle vertically.   |   |                                |                            |         |                                  |                  |
| *** Autoclaving can only be performed on empty bags.   |   |                                |                            |         |                                  |                  |
| <b>Ordering information</b>  |   |                                |                            |         |                                  |                  |
| <b>Case</b>  |   |                                |                            |         |                                  |                  |
| Device Description   | Sample Volume (mL)  | Length x Width (open)          | Height                     | Qty/Pk  | Compatible Bag Cat. No.          | Cat. No.         |
|   | 100   | 442 x 275 mm (17.4 x 10.8 in.) | 36 mm (1.4 in.)            | 25      | 5744-10100<br>AC714-10100        | <b>NSF-10100</b> |
| <b>Accessories</b>   |   |                                |                            |         |                                  |                  |
| Device Description   | Volume (mL)   | Qty/Pk                         | Cat. No.                   |         |                                  |                  |
|   | NovaSeptum® Manual Crimping Tool  | 1                              | <b>A100</b>                |         |                                  |                  |
|   | NovaSeptum® Manual Crimping Tool Spare Part Kit   | 1                              | <b>A104</b>                |         |                                  |                  |
| Crimped Tube Protector Caps  |   | 100                            | <b>NSTP-3X6</b>            |         |                                  |                  |
| Volume Indicator Ruler for High Purity Bags  | 100   | 50                             | <b>NSRULER-10100</b>       |         |                                  |                  |

## Sampling assemblies. All sampling units are manifolded.

| Products   | Description                                       | Sample Volume (mL) | Sampling Unit | Connection Type                          | Qty/Pack                | Cat. No.    |
|--|---|--------------------|---------------|--|-------------------------|-------------|
| NovaSeptum® SURE Tube Transfer (High Temperature)            | Tube transfer                                     |                    |               | 2mm trigger + AseptiQuik® S-HT connector | 50                      | AC561-40014 |
| NovaSeptum® SURE High Purity Bag Sampling Assemblies         | 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                                   | 3x100              | Manifold      | AseptiQuik® S connector                  | 10                      | AC713-10100 |
|  | High Purity Bag                                   | 3x100              | Manifold      | Inlet C-Flex® tubing                     | 12                      | 5743-10100  |
|  | High Purity Bag                                   | 5x100              | Manifold      | AseptiQuik® S connector                  | 7                       | AC714-10100 |
|  | High Purity Bag                                   | 5x100              | Manifold      | Inlet C-Flex® tubing                     | 5                       | 5744-10100  |
| NovaSeptum® SURE Bottle Sampling Assemblies                  | Bottle  | 60                 | Single        | AseptiQuik® S connector                  | 30                      | AC871-80060 |
|  | Bottle  | 3x60               | Manifold      | AseptiQuik® S connector                  | 9                       | AC873-80060 |
|  | Bottle  | 3x60               | Manifold      | Inlet C-Flex® tubing                     | 9                       | 5843-80060  |
|  | Bottle  | 5x60               | Manifold      | AseptiQuik® S connector                  | 5                       | AC874-80060 |
|  | Bottle  | 5x60               | Manifold      | Inlet C-Flex® tubing                     | 5                       | 5844-80060  |
| NovaSeptum® SURE Accurate Volume Syringe Sampling Assemblies | Accurate Volume Syringe                           | 3x5                | Manifold      | AseptiQuik® S connector                  | 9                       | AC463-90005 |
|  | Accurate Volume Syringe                           | 3x5                | Manifold      | Inlet C-Flex® tubing                     | 8                       | 5443-90005  |
|  | Accurate Volume Syringe                           | 5x5                | Manifold      | AseptiQuik® S connector                  | 5                       | AC464-90005 |
|  | Accurate Volume Syringe                           | 5x5                | Manifold      | Inlet C-Flex® tubing                     | 5                       | 5444-90005  |
|  | Accurate Volume Syringe                           | 3x20               | Manifold      | AseptiQuik® S connector                  | 6                       | AC463-90020 |
|  | Accurate Volume Syringe                           | 3x20               | Manifold      | Inlet C-Flex® tubing                     | 6                       | 5443-90020  |
|  | Accurate Volume Syringe                           | 5x20               | Manifold      | AseptiQuik® S connector                  | 4                       | AC464-90020 |
|  | Accurate Volume Syringe                           | 5x20               | Manifold      | Inlet C-Flex® tubing                     | 5                       | 5444-90020  |
|  | NovaSeptum® SURE Conical Tube Sampling Assemblies | Conical Tube       | 15            | Single                                   | AseptiQuik® S connector | 35          |
| 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   |   | 3x15               | Manifold      | AseptiQuik® S connector                  | 10                      | ACC73-80015 |
| Conical Tube   |   | 3x15               | Manifold      | Inlet C-Flex® tubing                     | 10                      | 5C43-80015  |
| Conical tube with dip tube                                   |   | 5x15               | Manifold      | Inlet C-Flex® tubing                     | 8                       | 5D44-80015  |
| Conical Tube   |   | 5x15               | Manifold      | Inlet C-Flex® tubing                     | 8                       | 5C44-80015  |
| Conical Tube   |   | 5x15               | Manifold      | AseptiQuik® S connector                  | 8                       | ACC74-80015 |

### To place an order or receive technical assistance

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