

Stericap™ PLUS

Vacuum Driven Bottle-Top Filtration System

User Guide

(Catalogue Number SCGP CAP RE)

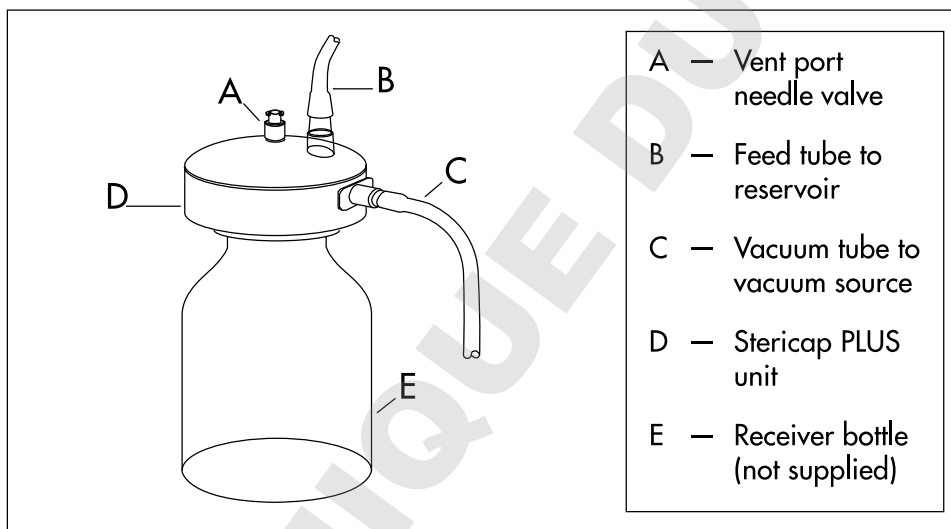
Introduction

The Stericap PLUS filter unit (Millipore cat. no. SCGP CAP RE) is a vacuum driven, disposable, universal bottle-top sterile filtration system used in the preparation of buffers, tissue culture media, microbiological media, and other biological fluids. The unit can be used to fill vacuum rated bottles and other containers with inner neck diameters from 20 to 67 mm.

Each Stericap PLUS package comes with 10 individually wrapped sterile filter units and one reusable tube set.

CAUTION: The unit is not compatible with strong acids, bases, polar solvents, aromatic solvents, most chlorinated solvents, or concentrated alcohols. See the “Chemical Compatibility” section for details.

Diagram of the Stericap PLUS Filter Unit



Materials Required

The user must supply the following materials to use the Stericap PLUS filter unit:

- Vacuum source (with tubing)
- Sterile receiver bottles or vessels with an inner neck diameter of 20–67 mm

Optional equipment (to re-prime in the event of air locking)

- 50 cc syringe

See “Ordering Information” section for catalogue numbers for these products.

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Guidelines for Use

- Use aseptic technique. To ensure sterility of filtered fluid, filtration should take place under a laminar flow hood or other sterile environment.
- To ensure sterility, do not use this unit if the package is damaged or the seal is broken.
- Do not resterilize or reuse the Stericap PLUS filter unit; it is a single use device.
- Wear eye protection whenever using glass or plastic vessels under partial vacuum.
- If the unit has slowed or stopped flowing because of an air lock, follow steps in "Recovering from an Air Lock Event" section.
- Do not overfill the receiver bottle, which could force liquid into the vacuum source and cause damage.

Chemical Compatibility

The Stericap PLUS units are compatible with most aqueous solutions. Based on information from technical publications, materials suppliers, laboratory tests, and field evaluations, Millipore believes that the agents listed in the following chart are safe to use with Stericap PLUS units. However, because of the effects of variability in temperature, concentrations, duration of exposure, and other factors outside of our control, Millipore does not provide or imply a warranty with respect to this information. Agents that are not listed should be tested prior to use, or call Millipore Technical Service for information.

CAUTION: Perform filter binding analysis before filtering very dilute proteins, hormones, or drug solutions.

Chemical	Stericap PLUS Filter Unit
Aqueous solutions	●
Weak acids	●
Strong acids	▲
Alcohols	▲
Aldehydes	○
Aliphatic amines	▲
Aromatic amines	○
Bases	●
Esters	○
Hydrocarbons	○
Ketones	○
Strong oxidizing agents	○

Key: ● = Recommended, ○ = Not recommended, ▲ = Limited applications

How to Use the Stericap PLUS Filter Unit

1. Remove a filter unit and the tube set from the packaging. Peel open their pouches using aseptic technique under a laminar flow hood, or in another sterile environment.

CAUTION: This unit is sterile when packaged. Check if the package is damaged or if the seal is broken. If you notice any damage, contact Millipore Technical Service before using.

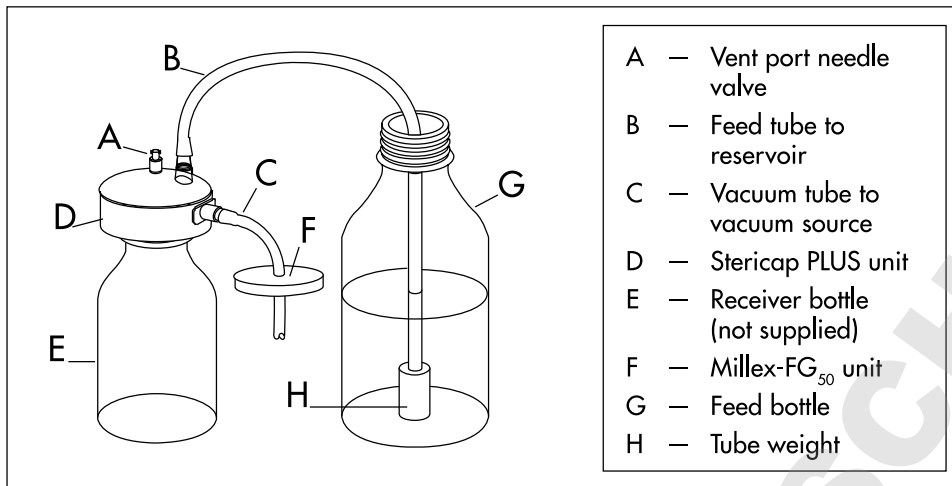
2. Connect the feed tube to the barbed fitting marked "Inlet" on the clear dome top of the device. Place the other end of the tube into the solution you want to filter, with the tube weight at the bottom of the feed container.

NOTE: The tube set is reusable. Keep tube weight at the bottom of the feed bottle to prevent air from entering the tube set and creating an air lock.

How to Use the Stericap PLUS Filter Unit, continued

- Attach the blue vacuum port on the side of the unit to a regulated vacuum source. (The universal tubing adapter provided with each system fits most vacuum hoses.) If you use a water aspirator as the vacuum source, use a check-valve or in-line catch flask to prevent the system from accidentally drawing water into the receiving bottle.

▲WARNING: Wear eye protection whenever using glass or plastic vessels under partial vacuum.



- Hold the Stericap PLUS unit onto the top of the receiver bottle and turn on the vacuum to begin filtration. Continue holding the unit until the vacuum source secures the filter unit into place and the flow starts into the receiver bottle.

NOTE: A small amount of air collected at the top of the dome is normal, and will not affect filtration. If too much air enters the housing and filtration stops, go to the “Recovering from an Air Lock Event” section for instructions on re-priming.

- When the receiver bottle is almost full, detach the unit from the bottle top by simply tilting it very slightly to lift the gasket off of the bottle. Breaking the vacuum seal on the downstream will temporarily stop the flow.

CAUTION: Do not let the receiver bottle overflow with liquid or foam. This will cause fluid to advance into the vacuum line, and could damage the vacuum pump or house vacuum system. Be sure to use a vacuum trap or in-line hydrophobic membrane filter (e.g., Millex[®]-FG₅₀ filter unit, Millipore cat. no. SLFG 050 10) to protect the vacuum line.

- If more than one receiver bottle is being filled, proceed to Step 7. Otherwise, skip to Step 9.
- With the vacuum source still on, hold the Stericap PLUS unit upright and move the Stericap PLUS unit onto the next bottle. Hold the unit over the bottle until a vacuum seal is established and the bottle starts filling.
- Repeat steps 4 through 7 until the desired number of bottles is filled.

NOTE: The total filtration volume of the Stericap PLUS membrane will depend on the solution being filtered. If the membrane becomes fouled before filtration is finished, continue with a new Stericap PLUS unit.

- Turn off the vacuum source to end filtration. Then disconnect the vacuum and tube set from the filter unit. Discard Stericap PLUS filter unit appropriately.

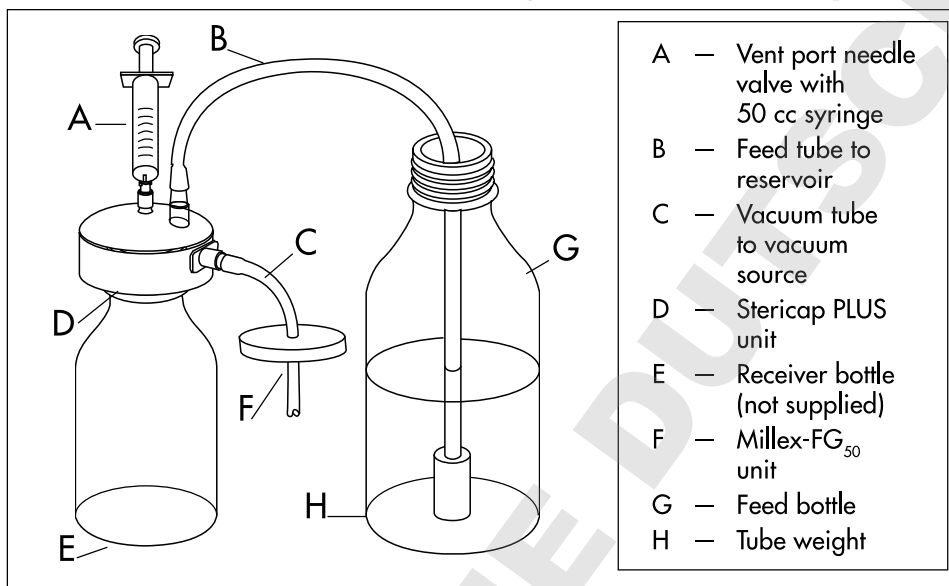
Autoclaving the Tube Set

The tube set can be autoclaved up to 10 times using a 15-minute cycle at 121 °C each time. After the first autoclave cycle, the tubing may lose some of its transparency and the tube weight may appear lighter in color. However, these changes will not affect the function of the tube set.

Recovering From an Air Lock Event

If the feed tube is inadvertently removed from the feed bottle during filtration, or if a sufficient quantity of air otherwise enters the housing and empties it of liquid, filtration will stop. It will be necessary to re-prime the upstream portion of the device using the vent valve at the top center of the dome.

1. Leave the vacuum source on and connected to the device in order to protect the membrane.
2. Attach a 50 cc syringe to the vent port needle valve's female Luer-Lok® connector on the top center of the dome.
3. Twist the needle valve counterclockwise slightly (1 to 1 1/2 turns) to open.



4. Pull on the syringe plunger to remove the air from the housing and re-prime the feed tube and housing with as much liquid as possible so that the membrane surface is fully submerged again.

NOTE: A small pocket of air at the top of the dome is normal and will not affect filtration.

5. Filtration should resume immediately. Return to step 4 of the “How to Use the Stericap PLUS Filter Unit” section.

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PR02269, Rev. A, 11/06

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Specifications

Filter membrane	Millipore Express® PLUS
Membrane pore size	0.22 µm
Effective filtration area	40 cm ²
Capacities	5–10 L (of typical cell culture media reconstituted from powder; e.g., DMEM with 10% serum)
Tube set length	3 ft
Sterilization method	Gamma irradiated
Storage temperature limit	-30 °C to 45 °C (-22 °F to 113 °F)
Maximum operating vacuum	25" Hg

Materials of Construction

Dome:	Clear styrene
Outlet frit:	Polypropylene (PP)
Collar:	Impact resistant styrene
Gasket:	Closed cell polyethylene foam
Membrane:	Polyethersulfone (PES)
Tube set:	Silicone
Vacuum adapter:	High density polyethylene (HDPE)
Tube weight:	Polyvinylidene fluoride (PVDF)
Vacuum port matrix:	Cellulose acetate
Vent cap:	PVDF

QC Release Criteria

Integrity: Each lot is air tested for reverse burst at 30" water during the manufacturing process to insure both membrane and housing integrity.

Filter Flow Rate: Samples exhibit an initial flow time of not more than 52 seconds to filter 500 mL of water at 25" Hg vacuum.

Sterility: The product is sterilized by means of gamma irradiation in a validated process. The dose is confirmed on a quarterly basis according to AAMI practices and recommendations.

Membrane Bubble Point: Membrane samples were tested according to an established procedure to determine the water bubble point of the filter media used in this product. Minimum observed water bubble point is 63 psi.

Audit Criteria

Toxicity: Membranes were tested and met the criteria for the current USP Class VI Biological Test for Plastics. Fluid path component materials were tested and determined to be non-cytotoxic in accordance with the current USP.

Pyrogens: An aqueous extraction from the unit contains less than 20 EU/device as determined using the Limulus Amebocyte Lysate (LAL) test according to the USP guidelines.

Bacterial Retention: Samples were quantitatively retentive of a minimum *Brevundimonas diminuta* challenge concentration of 1×10^7 cfu per cm² using HIMA methodology.

Product Ordering Information

This section lists the catalogue numbers for the Stericap PLUS Vacuum Driven Bottle-Top Filtration System and accessories. See the Technical Assistance section for information about contacting Millipore. You can also buy Millipore products on-line at www.millipore.com/purecommerce.

Description	Catalogue Number
Stericap PLUS filter unit with 0.22 µm Millipore Express PLUS membrane. Each kit contains 10 units and 1 tube set.	SCGP CAP RE
Sterile receiver bottles (1L, 12/pk)	SC00 B10 RE
Vacuum/pressure pump 115V, 60 Hz	WP62 115 60
220V, 50 Hz	WP62 220 50
100V, 50/60 Hz	WP62 100 60
50 cc syringe (5/pk)	XX11 050 05
Millex-FG ₅₀ filter unit for vacuum line protection (10/pk)	SLFG 050 10

Technical Assistance

For more information, contact the Millipore office nearest you. In the U.S., call **1-800-MILLIPORE** (1-800-645-5476). Outside the U.S., see your Millipore catalogue for the phone number of the office nearest you or go to our web site at www.millipore.com/offices for up-to-date worldwide contact information. You can also visit the tech service page on our web site at www.millipore.com/techservice.

Standard Warranty

Millipore Corporation ("Millipore") warrants its products will meet their applicable published specifications when used in accordance with their applicable instructions for a period of one year from shipment of the products. **MILLIPORE MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED. THERE IS NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.** The warranty provided herein and the data, specifications and descriptions of Millipore products appearing in Millipore's published catalogues and product literature may not be altered except by express written agreement signed by an officer of Millipore. Representations, oral or written, which are inconsistent with this warranty or such publications are not authorized and if given, should not be relied upon.

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