User Guide

Stericap™ PLUS System

Vacuum Driven Bottle-Top Filtration System

SCGPCAPRE

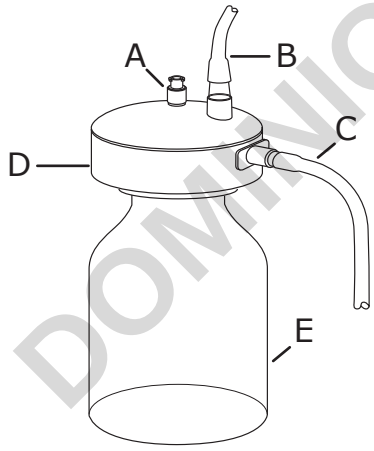
Introduction

The Stericap™ PLUS Vacuum Driven Bottle-Top Filtration System (Stericap™ PLUS System) 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 system can be used to fill vacuum rated bottles and other containers with inner neck diameters from 20 mm to 67 mm.

Each Stericap™ PLUS System package comes with 10 individually wrapped sterile filters and one reusable tube set.

CAUTION: The system 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 System



A. Vent port needle valve
B. Feed tube to reservoir
C. Vacuum tube to vacuum source
D. Stericap™ PLUS system
E. Receiver bottle (not supplied)

Materials Required

The user must supply the following materials:

- Vacuum source (with tubing)
- Sterile vacuum rated 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 "Product Ordering" section for catalogue numbers.

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 system if the package is damaged or the seal is broken.
- Do not re-sterilize or reuse the Stericap™ PLUS System; it is a single use system.
- Wear eye protection whenever using glass or plastic vessels under partial vacuum.
- If the system 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.

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Chemical Compatibility

The Stericap™ PLUS System is compatible with most aqueous solutions. Based on information from technical publications, materials suppliers, laboratory tests, and field evaluations, we believe that the agents listed below may or may not be used with Stericap™ PLUS System. However, because of the effects of variability in temperature, concentrations, duration of exposure, and other factors outside of our control, we do not provide or imply a warranty with respect to this information. Agents that are not listed should be tested prior to use, or contact Technical Service at SigmaAldrich.com/techservice for information.

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

Chemical	Stericap™ PLUS System
Aqueous solutions	•
Weak acids	•
Strong acids	Δ
Alcohols	Δ
Aldehydes	◇
Aliphatic amines	Δ
Aromatic amines	◇
Bases	•
Esters	◇
Hydrocarbons	◇
Ketones	◇
Strong oxidizing agents	◇

Key: • = Recommended, ◇ = Not recommended, Δ = Limited applications

How to Use the Stericap™ PLUS System

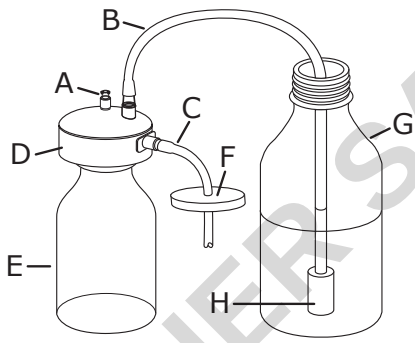
1. Remove a filter unit and the tube set from the packaging. Peel open their pouches using aseptic technique under a laminar flow hood, or in another sterile environment.

   CAUTION: This system is sterile when packaged. Check if the package is damaged or if the seal is broken. If you notice any damage, contact Technical Service SigmaAldrich.com/techservice 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.

3. Attach the blue vacuum port on the side of the system 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.



A. Vent port needle valve
B. Feed tube to reservoir
C. Vacuum tube to vacuum source
D. Stericap™ PLUS System
E. Receiver bottle (not supplied)
F. Millex®-FG$_{50}$ unit
G. Feed bottle
H. Tube weight

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

4. Hold the Stericap™ PLUS System onto the top of the receiver bottle and turn on the vacuum to begin filtration. Continue holding the system 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.

5. When the receiver bottle is almost full, detach the system 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®-FG$_{50}$ filter system, Cat. No. SLFG05010) to protect the vacuum line.

6. If more than one receiver bottle is being filled, proceed to Step 7. Otherwise, skip to Step 9.

7. With the vacuum source still on, hold the Stericap™ PLUS System upright and move the Stericap™ PLUS System onto the next bottle. Hold the unit over the bottle until a vacuum seal is established and the bottle starts filling.

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8. Repeat steps 4 through 7 until the desired number of bottle(s) are filled.

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

9. Turn off the vacuum source to end filtration. Then disconnect the vacuum and tube set from the filter system. Dispose of according to all applicable international, federal, state, and local regulations.

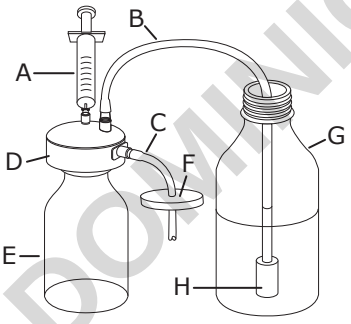
Autoclaving the Tube Set

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.



A. Vent port needle valve with 50 cc syringe
B. Feed tube to reservoir
C. Vacuum tube to vacuum source
D. Stericap™ PLUS System
E. Receiver bottle (not supplied)
F. Millex®-FG$_{50}$ unit
G. Feed bottle
H. Tube weight

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 System" section.

Specifications

Filter membrane	Express PLUS® PES
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 inHg
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 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 inHg 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 Association for the Advancement of Medical Instrumentation® (AAMI) practices and recommendations.

Audit Criteria

Toxicity: Fluid path component materials were tested and determined to be non-cytotoxic in accordance with United States Pharmacopeia (USP) <87>.

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

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Bacterial Retention: Samples were quantitatively retentive of a minimum *Brevundimonas diminuta* challenge concentration of 1×10^7 cfu per cm^2 using Health Industry Manufacturers Association (HIMA) methodology.

Product Ordering

Products can be ordered at SigmaAldrich.com/products.

Description	Catalogue Number
Stericap™ PLUS System with 0.22 µm Express PLUS® PES membrane. Each kit contains 10 units and 1 tube set.	SCGPCAPRE
Sterile receiver bottles (1 L, 12/pk)	S200B10RE
Vacuum/pressure pump	
115V, 60 Hz	WP6211560
220V, 50 Hz	WP6222050
100V, 50/60 Hz	WP6210060
50 cc syringe (5/pk)	XX1105005
Millex®-FG_{50} filter unit for vacuum line protection (10/pk)	SLFG05010

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Contact Information

For the location of the office nearest you, go to SigmaAldrich.com/offices.

Technical Assistance

Visit the tech service page on our web site at SigmaAldrich.com/techservice.

Standard Warranty

The applicable warranty for the products listed in this publication may be found at SigmaAldrich.com/terms.

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