AcroPak™ 200 capsule with Supor™ and Supor EKV membrane

Instructions for Use

Introduction

Intended use

Cytiva Lab Filtration products are designed for professional laboratory applications only. These products are not approved for use in medical, clinical, surgical or other patient protection applications. They are also not suitable for use in Biopharmaceutical manufacturing or production.

Important

Employment of the products in applications not specified, or failure to follow all instructions contained in this Instructions for Use, can result in personal injury, damage to property or the product, or improper functioning of the product.

Description

AcroPak™ 200 capsule with Supor™ membrane is designed to provide high filtration area while maintaining a compact size. The result is an efficient, cost-effective product for the filtration of solutions in the 5 to 20 liter volume range.

All materials used to manufacture AcroPak 200 capsule have passed United States Pharmacopeia (USP) Biological Reactivity Test, *In Vivo* <88>. The membrane and housing are sealed using fusion technology, eliminating potential extractables that might be released from uncured sealing adhesives. As added assurance, the AcroPak 200 capsule with Supor membrane is gamma sterilized, non-pyrogenic, and provided with a removable filling bell (except sanitary flange option). These features assure sterile filtration of media without the risk of harmful extractables, which could adversely affect sensitive cell lines.

Applications

AcroPak 200 capsule quickly processes difficult-to-filter solutions, such as serum, serum supplemented culture media, and ascites fluid. Supor membrane has very high flow rates and consistently higher total solution throughputs because it has a higher porosity than most other membranes. Ideal in situations where rapid filtration or short processing times are essential.

Membrane

AcroPak 200 capsule is manufactured with patented Supor membrane, an inherently hydrophilic polyethersulfone membrane. The capsule consists of two layers: a prefilter and a 0.2 µm final filter. The unique Supor membrane structure provides fast flow rates, high throughput, low extractables and low protein binding. These characteristics make Supor membrane ideal for biological solutions and buffers. The built-in prefilter increases throughput and filter life when proteinaceous, viscous, or other difficult-to-filter liquids are being processed. Save time and money when scaling up your processes with our complete line of products that incorporate Supor membrane, from Acrodisc™ syringe filters to cartridges.

Operation

Using AcroPak 200 capsule with Supor membrane (aseptic technique)

Step	Action
1	Assemble filtration apparatus as shown in one of the following figures. All components of filtration apparatus downstream from the capsule must be pre- sterilized. ***Note:*** *For best results, perform filtration in a hood or other protected environment.*

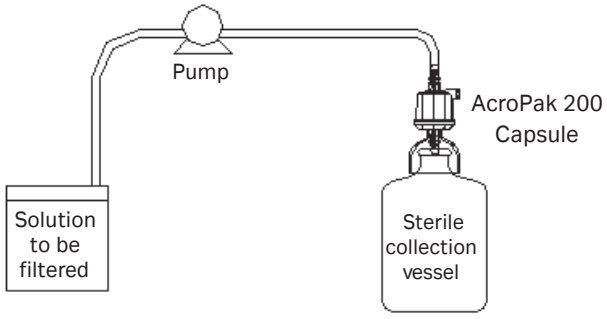

Fig 1. Positive filtration via peristaltic pump

Step	Action

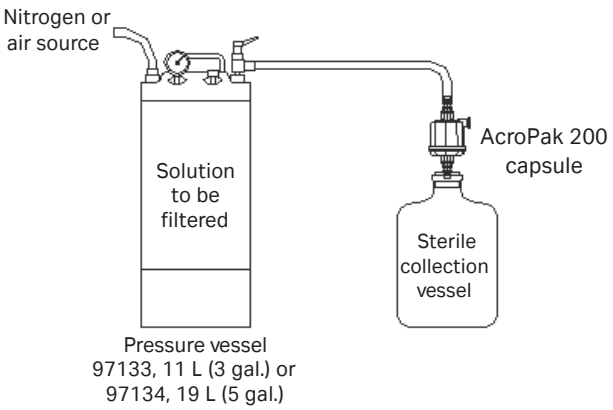

Fig 2. Positive filtration via pressure vessel

2 Aseptically remove the AcroPak 200 capsule with Supor membrane from bag and attach tubing to the inlet. Use hose clamps to secure tubing in place.

3 Loosen vent plug and slowly begin to fill capsule. Tighten vent as soon as all excess air escapes the capsule and liquid reaches the level of the vent.

4 Gradually increase flow rate or pressure to the desired value. Do not exceed the maximum operating parameters listed in the specifications section of this product information insert.

When filtration is complete, fluid can be followed by an air purge to minimize hold-up of solution in the capsule.

Note:
The AcroPak 200 capsule is designed for single use only.

Integrity testing

Step	Action

1 Assemble bubble point apparatus as shown in the figure below.

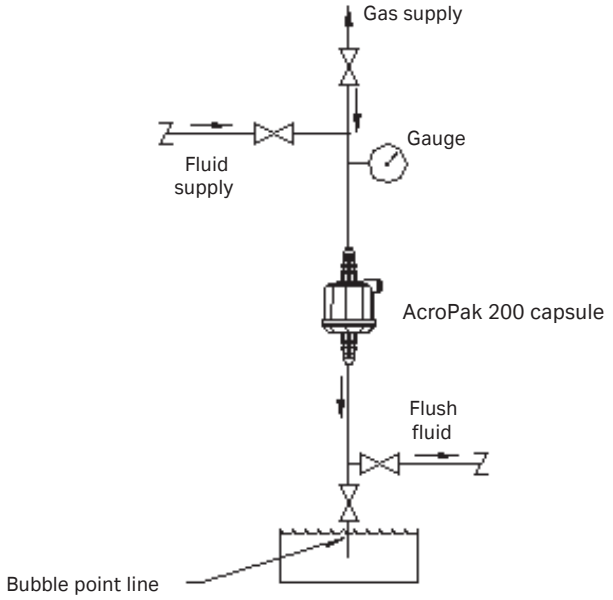

Fig 3. Bubble point test apparatus

2 Loosen vent plug and slowly begin to fill capsule. Tighten vent as soon as all excess air escapes the capsule and liquid reaches the level of the vent.

Step	Action

3 Flush the filter with 0.2 µm filtered water for at least one minute to assure wetting.

4 Turn off liquid flow and turn on gas supply.

5 Pressurize the filter assembly to 0.3 bar (30 kPa, 5 psi). Hold for 30 seconds and watch for a steady stream of bubbles.

6 If no bubbles are observed at the bubble point line, increase the pressure at a rate of 10 psi/minute up to 50% of the bubble point. Hold for 30 seconds and watch for a steady stream of bubbles.

7 If no bubbles are observed at the bubble point line, increase pressure to 80% of bubble point at the previous rate and hold for 30 seconds, again watching for a steady stream of bubbles.

8 If no bubbles are observed, continue to increase pressure to minimum bubble point value and observe for 30 seconds. If a steady stream of bubbles is not observed before the minimum bubble point value is reached, the unit is considered integral.

Specifications

Materials of construction

Parameter	Specification
Filter media	Supor membrane (hydrophilic polyethersulfone)
Housing, vent plug, and support material	Polypropylene
Sealing technology	Thermal bonding
Filing bell	Polycarbonate

Dimensions (nominal)

Parameter	Specification
Housing length	
• 12941 and 12094	• 10.5 cm (4.1 in.)
• 12093	• 10.1 cm (4.0 in.)
• 12095	• 7.3 cm (2.9 in)
Housing diameter	• 5.3 cm (2.1 in.) without vent • 6.7 cm (2.6 in.) with vent

Inlet and outlet connection

Part number	Specification
12941 and 12094	6.4 to 12.7 mm (¼ to ½ in.) stepped hose barb inlet and outlet
12093	1/4 in. MNPT inlet/6.4 to 12.7 mm (¼ to ½ in.) stepped hose barb outlet
12095	13 mm (½ in.) sanitary flange inlet and outlet

All capsules with tapered hose barb outlet have filling bell attached to outlet.

Biological safety

Materials of construction pass United States Pharmacopeia (USP) Biological Reactivity Test, In Vivo <88>.

Endotoxin level

< 0.25 EU/mL utilizing Limulus Amebocyte Lysate (LAL) test

Typical water flow rate (1cp)

Part number	Specification
12941 and 12093	300 mL/min/0.1 bar (207 mL/min/psi)
12094 and 12095	350 mL/min/0.1 bar (241 mL/min/psi)

Operating specifications

Parameter	Specification
Hold-up volume (with air purge)	≤ 6 mL
Maximum operating pressure[1]	60 psi at ambient temperature
Maximum operating temperature[1]	60°C (140 °F) at 2.1 bar (210 kPa, 30 psi)

[1] In compatible fluids which do not soften, swell or adversely affect the filter or its materials of construction.

Recommended integrity test minimum bubble point - water

Part number	Specification
12941 and 12093	≥ 3.5 bar (350 kPa, 51 psi)
12094 and 12095	≥ 3.32 bar (332 kPa, 48 psi)

Bacterial retention

Lot samples retain a minimum 10^7 cfu/cm^2 of *B. diminuta* per modified ASTM F838, current revision.

Sterilization

Sterilized by gamma irradiation and individually packed.

Ordering information

Part number	Description	Pkg
12941	AcroPak 200 capsule with Supor membrane, sterile, 0.8/0.2 µm, tapered hose barb inlet/tapered hose barb outlet with filling bell	3/pkg
12093	AcroPak 200 capsule with Supor membrane, sterile, 0.8/0.2 µm, 1/4 in. MNPT inlet/tapered hose barb outlet with filling bell	3/pkg
12094	AcroPak 200 capsule with Supor EKV membrane, sterile, 0.2 µm, tapered hose barb inlet/tapered hose barb outlet with filling bell	3/pkg
12095	AcroPak 200 capsule with Supor EKV membrane, sterile, 0.2 µm, 13 mm (1/2 in.) sanitary flange inlet/outlet connection	3/pkg

Complementary products

Supor EKV products with prefilter

Part number	Description	Pkg
12247	AcroPak 20 with Supor EKV membrane, sterile, 20 cm^2 EFA	3/pkg

Standard Supor products with prefilter (0.8/0.2 µm)

Part number	Description	Pkg
4658	Acrodisc syringe filter with Supor membrane, sterile, 32 mm, 5.8 cm^2 EFA	50/pkg
4638	VacuCap™ 60 PF vacuum filter with Supor membrane, sterile, 60 mm, 30 cm^2 EFA	10/pkg
4628	VacuCap 90 PF vacuum filter with Supor membrane, sterile, 90 mm, 60 cm^2 EFA	10/pkg
12202	AcroPak 20 with Supor membrane, non-sterile, 20 cm^2 EFA	3/pkg
12203	AcroPak 20 with Supor membrane, sterile, 20 cm^2 EFA	3/pkg
12991	AcroPak 500 capsule with Supor membrane, sterile, 500 cm^2 EFA (0.8/0.2 µm)	1/pkg
12992	AcroPak 1000 capsule with Supor membrane, sterile, 1000 cm^2 EFA (0.8/0.2 µm)	1/pkg
12675	AcroPak 1500 capsule with Supor membrane, sterile, 1500 cm^2 EFA (0.8/0.2 µm)	1/pkg

Other sterile products with Supor membrane, 0.2 µm

Part number	Description	Pkg
4602	Acrodisc syringe filter with Supor membrane, 13 mm EFA	75/pkg
4652	Acrodisc syringe filter with Supor membrane, 32 mm EFA	50/pkg
4480	AcroCap™ positive pressure device, 15 cm^2 EFA	10/pkg
4632	VacuCap 60 vacuum filter, 60 mm, 30 cm^2 EFA	10/pkg
4622	VacuCap 90 vacuum filter, 90 mm, 60 cm^2 EFA	10/pkg
12995	AcroPak 500 capsule with Supor membrane, 500 cm^2 EFA (0.2/0.2 µm)	1/pkg
12996	AcroPak 1000 capsule with Supor membrane, 1000 cm^2 EFA (0.2/0.2 µm)	1/pkg
12686	AcroPak 1500 capsule with Supor membrane, 1500 cm^2 EFA (0.2/0.2 µm)	1/pkg

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