Acro™ 50 vent filter with Emflon™ II membrane

Instructions for Use

DOMINIQUE DUTSCHER SAS

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

The Acro™ 50 vent filter with Emflon™ II membrane is made with a proprietary, low pressure drop, hydrophobic polyvinylidene fluoride (PVDF) membrane for use in air, gas and vent applications.

Emflon II membrane filters have a removal rating of 0.2 µm in liquid service[1]. The Emflon II filter can be integrity tested. These filters are stable to gamma irradiation up to 5 mRads, and are provided non-sterile. An autoclave cycle can also be used to render the filter sterile if needed.

Acro 50 vent filters are designed to connect easily to hoses of various sizes "in-line" or as a final filter. This lightweight device (< 27 grams) prevents crimping of tubing. It's hydrophobic PVDF membrane will not pass water unless its water breakthrough pressure is exceeded (see integrity testing below). Surfactants and solvents (i.e. alcohol) can be used to "wet-out" the membrane to enable filtration of aqueous solutions or to verify integrity of the device.

Sterilization

Autoclaving

Wrap the Acro 50 vent filter in autoclave paper and autoclave at 121°C (250 °F) for 20 minutes.

Note: *It might be necessary to remove residual condensation from the product before using (see installation integrity below). Reuse requires individual integrity testing and consideration for other problems including cross-contamination.*

Gamma irradiation

Specific cycles for sterilization and associated studies must be validated by the user. Cytiva recommends a maximum of 5 mRads (50 kilograys) gamma irradiation dosage. Higher levels can adversely affect filter performance.

Integrity testing

Bubble point method

Note: *An Integrity Test Kit is available to aid in this test. See* *Ordering information, on page 2*.

Step	Action
1	Fill a 10 mL or larger syringe with a fresh solution of 60/40 isopropanol/water.
2	Insert the syringe male luer into the Acro 50 vent filter, and orient the outlet in an upward direction.
3	Gradually (with low pressure) wet the Acro 50 vent filter membrane, allowing the Isopropanol/Water mixture to displace the air within the housing.
4	Flush the wetted filter with an additional 10 to 30 mL of 60/40 isopropanol/water at higher syringe pressure to assure thorough wetting (using less than a 10 mL flush can result in incomplete wetting).
5	Attach a syringe pressure gauge to an air-filled syringe or pressure vessel. Attach the Acro 50 vent filter and orient the filter in an upward direction.
6	By applying increasing pressure, gradually push the air into the filter while constantly watching for bubbles at the outlet of the Acro 50 vent filter.
7	Read pressure gauge at the moment rapid continuous bubbling appears to determine bubble point (see *Specifications, on page 2*).

[1] Lot samples of filters retain 10^7 cfu/cm^2 of *Brevundimonas diminuta* liquid challenge per modified ASTM F838, current revision and FDA guidelines.

Specifications

Parameter	Specification
Materials of construction	Filter media: Hydrophobic polyvinylidene fluoride (PVDF) Housing: Polypropylene
Filter diameter	50 mm
Effective filtration area	20 cm^2
Air flow rate	> 25 Lpm at 1 bar (100 kPa, 15 psi)
Maximum operating temperature	60°C (140 °F)
Maximum operating pressure	4.1 bar (410 kPa, 60 psi) at ambient temperature (20°C or 68 °F)
Inlet and outlet connections	Stepped hose barbs, 6.4 to 12.7 mm (¼ to ½ in.) diameter with slip luer ID in the hose barb
Endotoxin level	< 0.25 EU/mL using Limulus Amebocyte Lysate (LAL) test
Biological safety	Passes United States Pharmacopeia (USP) Biological Reactivity Test, *In Vivo* <88>
Bacterial retention	Lot samples retain 10^7 cfu/cm^2 of *Brevundimonas diminuta* per modified ASTM F838, current revision
Minimum bubble point	1.1 bar (110 kPa, 16 psi) using 60/40 isopropanol/water
Maximum autoclave stability	3 cycles at 131°C (268 °F) for 30 minutes

Ordering information

Part number	Description	Pkg
A50V002P2	Hose barb with vent, 0.2 µm	3/pkg
A50V002P2NV	Hose barb, no vent, 0.2 µm 100% integrity tested during manufacturing	100/pkg
A50V002NV300	Hose barb, no vent, 0.2 µm 100% integrity tested during manufacturing	300/pkg
4252	Integrity Test Kit (includes pressure gauge, 3-way stopcock, and 10 mL syringe)	1/pkg

All filters have membrane, pore size and lot number pad printed on each Acro 50 vent filter housing.

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