

Emflon™ II

FILTERS

Emflon™ II membranes deliver sterilizing-grade air filtration for use on process gas and vent applications. With a comprehensive validation and quality package, these gas filters are designed for use from clinical development through to licensed drug manufacture.

Emflon II filter medium, made from a proprietary modified polyvinylidene fluoride (PVDF), is inherently hydrophobic, chemically inert, and available in a wide range of filter styles. Designed to be gamma-compatible, these filters are the go-to choice for safeguarding cell cultures and drug product in a wide variety of single-use applications. Features of the filter medium include a double layer membrane for high filtration security and an exceptionally high surface area for economy of use and long service life.

Formats range from small disposable filter capsules to large plug-in cartridges with an effective filtration area of 1.98 m². All formats are manufactured from only two basic materials, PVDF membrane and polypropylene (PP). No glues, resins, binding agents, or loose fibers are used during manufacture. Each filter is integrity tested during manufacturing using the forward flow test.

Features and benefits

- Highly retentive Emflon II membrane for sterility assurance.
- High flow rates associated with low differential pressure enable the use of smaller filters, leading to reduction of installation and operating costs.
- Gamma irradiatable, autoclavable, or available pre-sterilized for maximum convenience.
- Integrity testable using the forward flow and bubble point test.
- Choice of filter format options for enhanced flexibility and scalability.

Applications

Emflon II filters are specifically designed for use in the following processes:

- Sterile process air or gases.
- Bioreactor and fermenter sterile air inlet.
- Bioreactor and fermenter exhaust (filtration).
- Venting of storage tanks.
- Particulate control of process gases in the electronics industry.
- Microbiological and particulate control during aseptic packaging.



Fig 1. Emflon II membrane in Kleenpak™ capsules

Quality

Emflon II pharmaceutical grade filters are designed and manufactured in conformance with current good manufacturing practice (cGMP), including 21CFR210 (Manufacturing, Processing, Packing or Holding of Drugs) and 21CFR211.72 (Finished Pharmaceuticals). All GMP grade filters are supported by batch release certificate, full traceability and are covered under our change control policy. Validation guides, extractables reports, and regulatory statements are available via our Regulatory Support website.

High quality standards:

- Validated in liquids using *Brevundimonas diminuta* (ATCC 19146) at a challenge level of 107 organisms/cm² of filter area.
- 100% integrity tested during manufacturing.
- Identified by a lot number and unique serial number for complete traceability of manufacturing history and for user traceability systems.
- Comprehensive batch and release testing supported, with a pharmaceutical certificate of test for each filter.
- Manufactured under a quality management system certified to ISO 9001:2015.

Emflon II membrane

IN AB STYLE CARTRIDGES



Fig 2. Emflon II membrane in AB style cartridges.

Technical specifications

Materials of construction

Membrane	Hydrophobic PVDF
Support and drainage layers	PP
End cap and core	PP
Outer shell	PP

Nominal dimensions

Lengths	254 mm (10 in.), 508 mm (20 in.), 762 mm (30 in.)
Diameter	70 mm (2.75 in.)

Maximum differential pressure

4.1 bar at 80°C

Steam sterilization

Emflon II filters can be repeatedly sterilized, enabling repeated use in vent or sterile air applications to minimize operating costs.

Procedure	Temperature	Maximum steam exposure time
<i>In situ</i> sterilization (normal flow direction)*	142°C	165 hours
Autoclave sterilization	125°C 140°C [†]	100 hours 50 hours [†]

* Emflon II filter cartridges can also be steam sterilized *in situ* in reverse direction of flow – please contact Cytiva for details.

[†] Values extrapolated from validation data.

Typical air flow rates

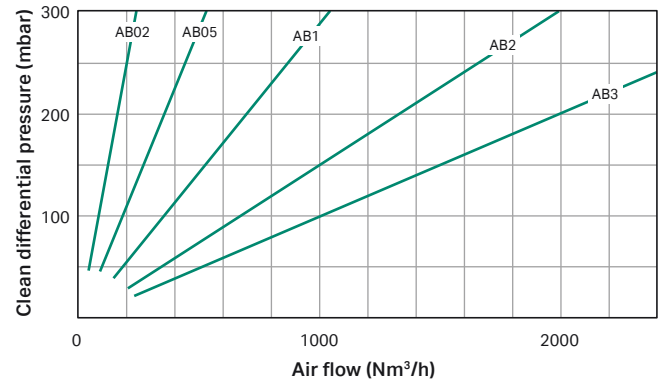


Fig 3. Pressurized air (2 bar gauge inlet) air flow vs differential pressure.

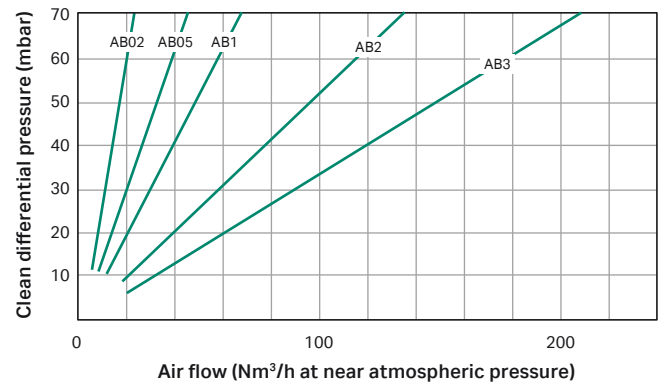


Fig 4. Vent filters air flow vs differential pressure.

Ordering information

Cartridge type	O-ring material	Area (m ²)	Product code
Single open ended plug-in style with double external 226 size O-rings and bayonet lock	Ethylene propylene	0.16	AB02V0022PVJ
	Fluorocarbon	0.33	AB05V0022PVJ
	Silicone	0.66	AB1V0028PVH
	Silicone	0.16	AB02V0022PVH4
	Silicone	0.33	AB05V0022PVH4
Single open ended plug-in style with double external 222 size O-rings and bayonet lock	Silicone	0.66	AB1V0023PVH4
	Silicone	1.32	AB2V0023PVH4
	Silicone	1.98	AB3V0028PVH4
Locating fin and single open ended plug-in style with double external O-rings and bayonet lock	Ethylene propylene	0.66	AB1V0027PVJ
	Ethylene propylene	1.32	AB2V0027PVJ
	Ethylene propylene	1.98	AB3V0027PVJ
Locating fin and single open ended plug-in style with double external O-rings and bayonet lock	Fluorocarbon	0.66	AB1V0027PVH
	Silicone	0.33	AB05V0027PVH4
	Silicone	0.66	AB1V0027PVH4
	Silicone	1.32	AB2V0027PVH4
	Silicone	1.98	AB3V0027PVH4

Emflon II membrane

IN SEALKLEEN™ AND JUNIOR STYLE CARTRIDGES



Fig 5. Emflon II membrane in junior style cartridges.

Technical specifications

Materials of construction

Membrane	Hydrophobic PVDF
Support and drainage layers	PP
End cap and core	PP
Outer shell	PP

Maximum differential pressure

Sealkleen™ and junior style cartridges	4.1 bar at 80°C
Junior SBF style cartridges	4.1 bar at 60°C

Steam sterilization

Emflon II filters can be repeatedly sterilized, enabling repeated use in vent or sterile air applications to minimize operating costs.

Procedure	Temperature	Maximum steam exposure time
<i>In situ</i> sterilization (normal flow direction)*	142°C	165 hours
Autoclave sterilization	125°C	100 hours
	140°C†	50 hours†
Autoclave sterilization – SBF filters only	140°C†	25 hours

* Emflon II junior and Sealkleen filter cartridges can also be steam sterilized *in situ* in reverse direction of flow – please contact Cytiva for details.

† Values extrapolated from validation data.

Typical air flow rates

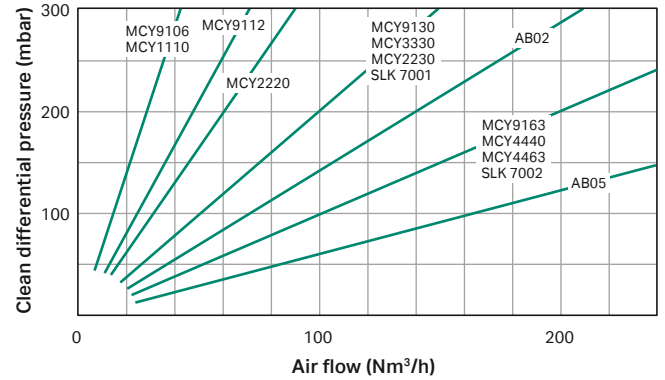


Fig 6. Pressurized air (2 bar gauge inlet) air flow vs differential pressure.

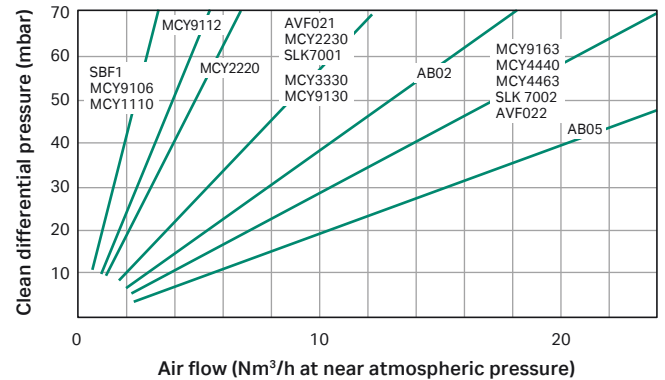


Fig 7. Vent filters air flow vs differential pressure.

Ordering information

Sealkleen style cartridges

Cartridge type	Diameter	O-ring material	Nominal length	Area (m ²)	Product code
Single open end with patented flange seal, supplied with a separate O-ring seal	56 mm (excluding flange)	Elastomer	66 mm	0.11	SLK7001V002PV
			133 mm	0.22	SLK7002V002PV

Junior style cartridges

Cartridge type	Diameter	O-ring type	O-ring material	Nominal length	Area (m ²)	Product code
Single open end with patented flange seal, supplied with a separate O-ring seal	56 mm	209	Ethylene propylene	66 mm	0.11	MCY2230V002PVJ
			Fluorocarbon	133 mm	0.22	MCY4463V002PVH
			Silicone	66 mm	0.11	MCY2230V002PVH4
				133 mm	0.22	MCY4463V002PVH4
Single open ended with four locking tabs, double external O-rings	56 mm	-	Ethylene propylene	32 mm	0.045	MCY1110V002PVJ
						MCY1110V002PVJ50*
				57 mm	0.09	MCY2220V002PVJ
				82 mm	0.14	MCY3330V002PVJ
			Silicone	106 mm	0.19	MCY4440V002PVJ
				57 mm	0.09	MCY2220V002PVH4
				106 mm	0.19	MCY4440V002PVH4
Single open ended, double external O-rings	42 mm	-	Ethylene propylene	51 mm	0.035	SBF1V002PVJ
			Silicone	51 mm	0.035	SBF1V002PVH4

* Box of 50.

Emflon II membrane

IN MINI KLEENPAK™ 20 CAPSULES



Fig 8. Emflon II membrane in Mini Kleenpak™ 20 capsules

Technical specifications

Materials of construction

Membrane	PVDF
Capsule	PP

Dimensions (nominal)

Housing diameter	68 mm (2.7 in.)
Inlet/outlet hose barb length	83 mm (3.3 in.)
Nominal effective filtration area	20 cm ² (0.022 ft ²)

Operating conditions ¹

Maximum operating temperature and pressure 2.0 bar (29 psi) at 20°C

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

Sterilization ²

Gamma-irradiation	Maximum 50 kGy
Autoclave	131°C, 3 × 60 minute cycles

Warning: pre-sterilized Mini Kleenpak 20 capsules (as supplied on some single-use systems) should not be re-sterilized. Contact Cytiva in regards to re-sterilizing gamma-irradiated Mini Kleenpak 20 capsules. The capsules must not be sterilized *in situ* by passing steam under pressure. Do not autoclave after use if heat labile chemical contaminants are present on the filter.

² The figures are maximum allowable figures determined by testing under controlled laboratory conditions to the length of time indicated. Actual operating conditions may affect the filter's long term response to sterilization. Filters should be qualified for each process application.

Typical air flow rates ³

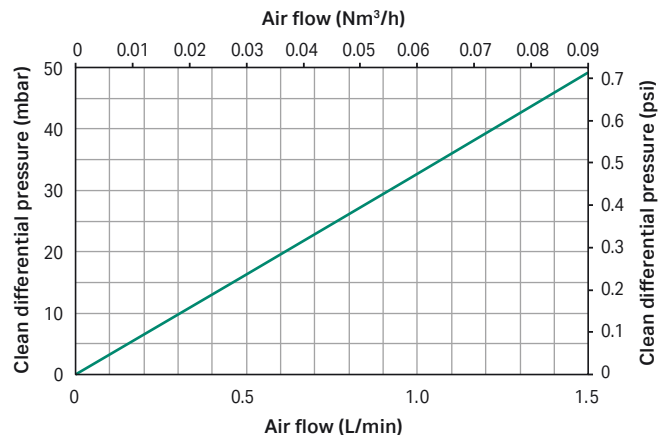


Fig 9. Vent conditions for Mini Kleenpak 20 capsules.

³ For gases other than air or nitrogen, contact us.

Ordering information

Connections	Sterilization	Quantity per box	Product code
1/4 to 1/2 in. (6 to 13 mm) hose barbs	Non-sterile, gamma-irradiatable/autoclavable	3	KM5V002P2G
		100	KM5V002P2G100

Emflon II membrane

IN MINI KLEENPAK™ CAPSULES



Fig 10. Emflon II membrane in Mini Kleenpak capsules.

Technical specifications

Materials of construction

Membrane	Hydrophobic PVDF
Support and drainage layers	PP
End cap and core	PP
Outer shell	PP

Dimensions (nominal)

Maximum diameter (including valves)	67 mm (2.6 in.)
Length with hose barb connections (Code 2)	105 mm (4.1 in.)
Length with sanitary connections (Code 8)	73 mm (2.9 in.)
Nominal filtration area	230 cm ² (0.25 ft ²)

Sterilization

Gamma-irradiation maximum dosage (G option only)	Up to 50 kGy
Autoclave sterilization:	
Gamma-irradiated filters	1 one-hour cycle at 125°C for the purpose of post-use decontamination
Non gamma-irradiated filters	Up to 3 one-hour cycles at 125°C

Operating conditions ¹

Maximum operating pressure	4.1 bar (60 psi) at 38°C
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¹ In air/nitrogen gas service or other compatible fluids, which do not soften, swell, or adversely affect the filter or its materials of construction.

Typical air flow rates ^{2, 3}

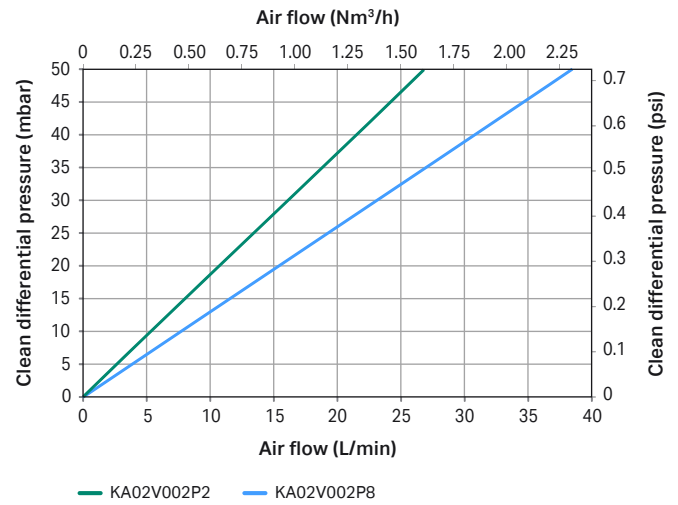


Fig 11. Vent conditions for Mini Kleenpak capsules.

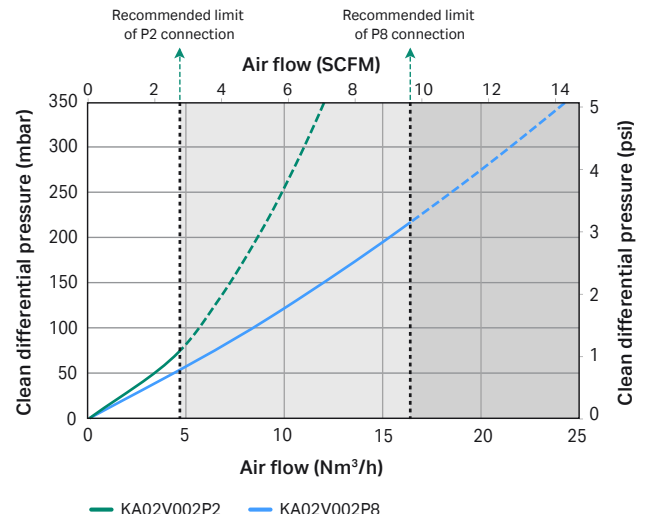


Fig 12. Operating conditions (2 bar) for Mini Kleenpak capsules.

² For gases other than air or nitrogen, contact your local Cytiva representative.

³ Recommended flow limits have been based on a maximum velocity of 25 m/s through the capsule. Tubing sizes should also be considered.

Ordering information

Product	Product code
¼ to ½ in. hose barb, gamma-irradiated	KA02V002P2S
¼ to ½ in. hose barb, non-irradiated	KA02V002P2G
½ in. sanitary flange, gamma-irradiated	KA02V002P8S
½ in. sanitary flange, non-irradiated	KA02V002P8G

Emflon II membrane

IN KLEENPAK™ CAPSULES



Fig 13. Emflon II membrane in Kleenpak capsules.

Technical specifications

Materials of construction

Membrane	Hydrophobic PVDF
Support and drainage layers	PP
End cap and core	PP
Outer shell	PP
Vent and drain valve O-rings	Ethylene propylene (EPDM)

Dimensions (nominal)

	KA1 capsule	KA2 capsule	KA3 capsule
Maximum diameter (including valves)	90.5 mm (3.6 in.)	90.5 mm (3.6 in.)	105.5 mm (4.2 in.)
Length with hose barb connections	158 mm (6.2 in.)	198 mm (7.8 in.)	210 mm (8.3 in.)
Length with sanitary flange	117 mm (4.6 in.)	157 mm (6.2 in.)	174 mm (6.8 in.)

Sterilization

Gamma-irradiation maximum dosage (G option only)	Up to 50 kGy
Autoclave sterilization:	
Gamma-irradiated filters	1 one-hour cycle at 125°C for the purpose of post-use decontamination
Non gamma-irradiated filters	Up to 3 one-hour cycles at 125°C

Warning: Kleenpak filters must not be steam-sterilized *in situ* by passing steam through under pressure. The figures are maximum allowable figures determined by testing under controlled laboratory conditions to the total number of hours indicated. Actual operating conditions may affect the filters' long-term response to sterilization. Filters should be qualified for each process application.

Operating conditions ¹

Maximum temperature	40°C
Maximum operating pressure	3.5 bar (50 psi) at 40°C

¹ In air/nitrogen gas service or other compatible fluids, which do not soften, swell, or adversely affect the filter or its materials of construction.

Typical air flow rates ^{2, 3}

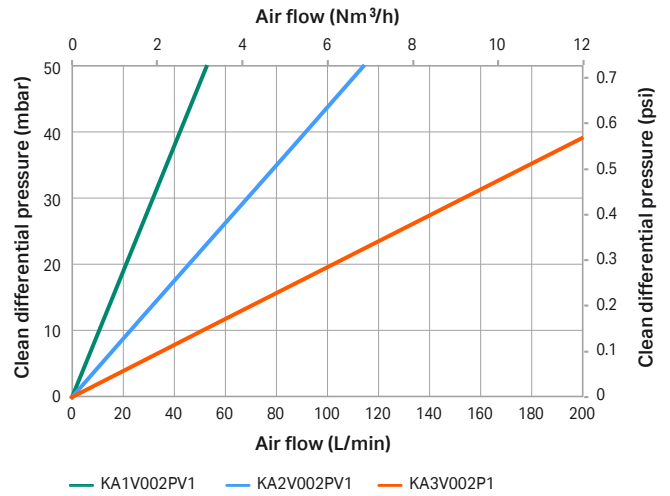


Fig 14. Sanitary flange connections: vent conditions.

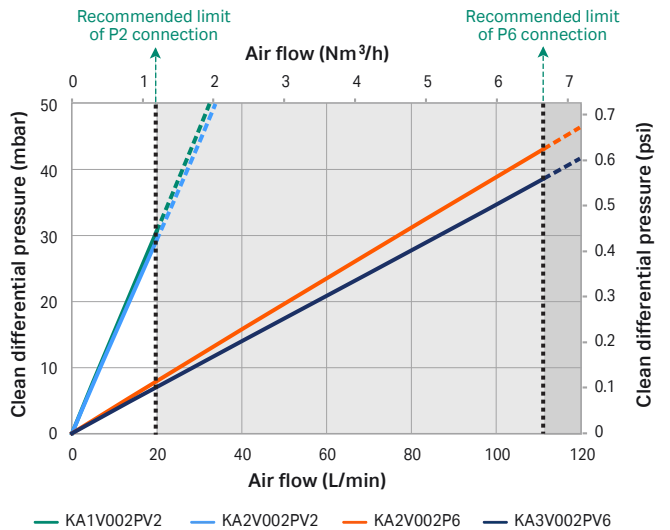


Fig 15. Hose barb: vent conditions.

Ordering information

Product	Nominal filtration area	Irradiation	Product code
1½ in. sanitary flange	380 cm ² (0.41 ft ²)	Gamma-irradiated	KA1V002PV1S
		Non-irradiated	KA1V002PV1G
	820 cm ² (0.88 ft ²)	Gamma-irradiated	KA2V002PV1S
		Non-irradiated	KA2V002PV1G
	1700 cm ² (1.83 ft ²)	Gamma-irradiated	KA3V002PV1S
		Non-irradiated	KA3V002PV1G
¼ to ½ in. hose barb	380 cm ² (0.41 ft ²)	Gamma-irradiated	KA1V002PV2S
		Non-irradiated	KA1V002PV2G
	820 cm ² (0.88 ft ²)	Gamma-irradiated	KA2V002PV2S
		Non-irradiated	KA2V002PV2G
½ in. hose barb	820 cm ² (0.88 ft ²)	Non-irradiated	KA2V002PV6G
		1700 cm ² (1.83 ft ²)	Gamma-irradiated
	Non-irradiated		KA3V002PV6G

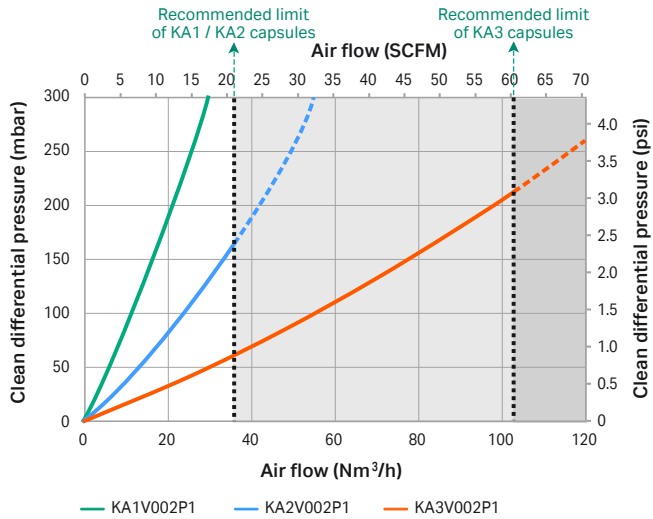


Fig 16. Sanitary flange connections: 2 bar operating pressure.

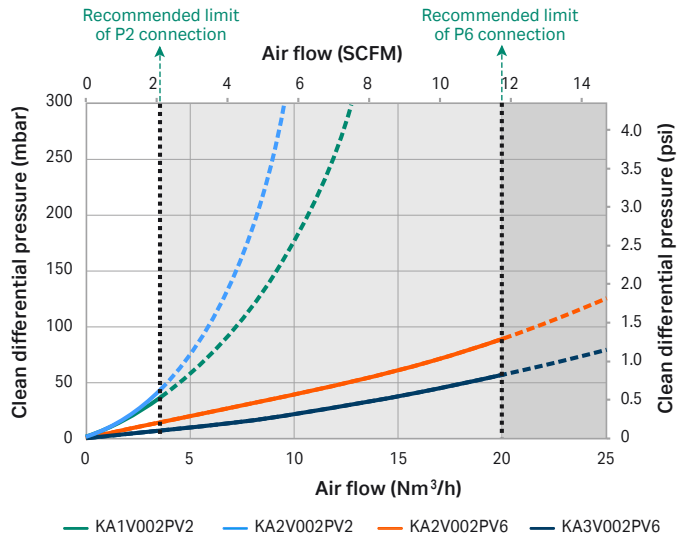


Fig 17. Hose barb connections: 2 bar operating pressure.

¹ For gases other than air or nitrogen, contact your local Cytiva representative.

² Recommended flow limits have been based on a maximum velocity of 20 m/s through the capsule. Tubing sizes should also be considered.

Emflon II membrane

IN KLEENPAK™ NOVA CAPSULES



Fig 18. Emflon II membrane in Kleenpak Nova capsules.

Technical specifications

Materials of construction

Membrane	Hydrophobic PVDF
Support and drainage layers	PP
End cap and core	PP
Outer shell	PP

Sterilization

Gamma irradiation maximum dosage:	
Gamma-irradiated filters (S version)	Supplied pre-sterilized to a minimum of 30 kGy

Gamma irradiation maximum dosage:	
Non-gamma irradiated filters (G version)	Up to 50 kGy

Autoclave sterilization:	
Gamma-irradiated filters	1 one-hour cycle at 125°C for the purpose of post-use decontamination only

Non gamma-irradiated filters	Up to 3 one-hour cycles at 125°C
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Warning: Kleenpak Nova filters must not be steam sterilized *in situ* by passing steam through under pressure as this may cause rupture of the filter assembly and pose a risk to personnel and equipment. Do not autoclave after use if heat-labile chemical contaminants are present. During autoclaving, ensure the filter is not subjected to excessive weight or mechanical loading, as deformation may occur at elevated temperatures.

Typical air flow rates

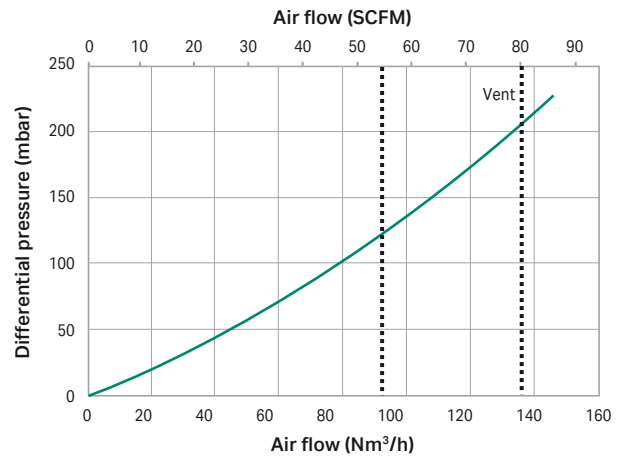


Fig 19. Air flow vs differential pressure in NP6V002P1S.

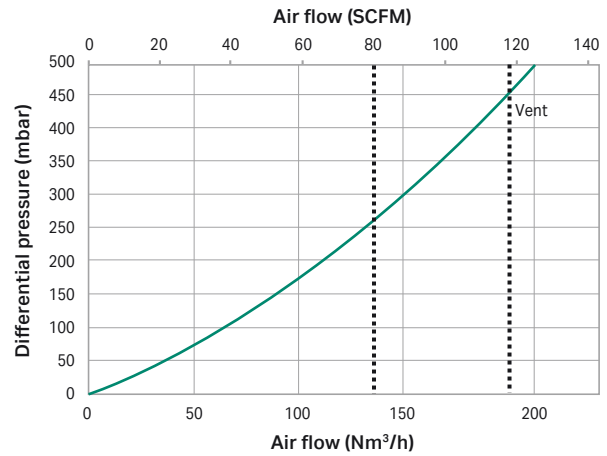


Fig 20. Air flow vs differential pressure in NP6V002P19G.

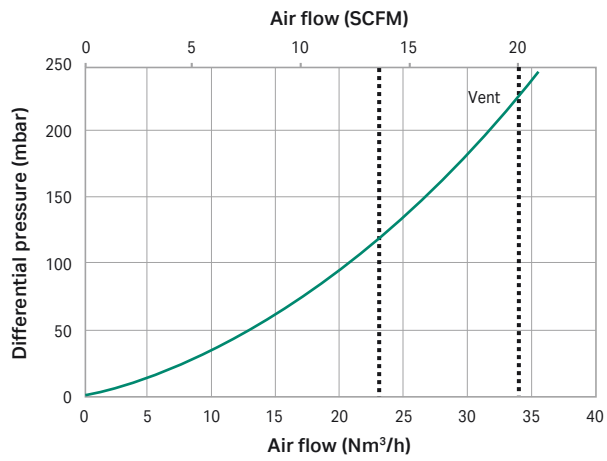


Fig 21. Air flow vs differential pressure in NP6V002P6G.

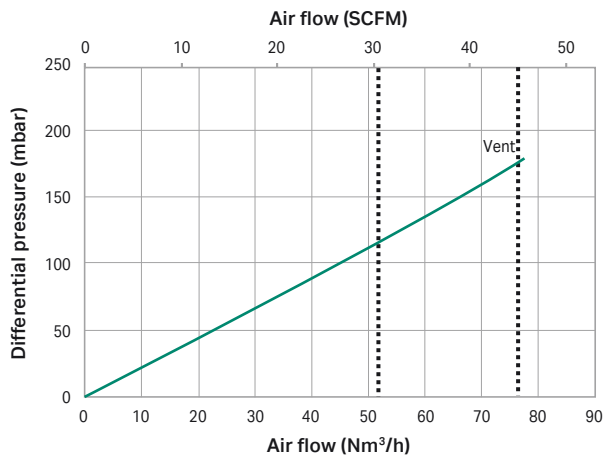


Fig 22. Air flow vs differential pressure in NP5V002P1S.

Ordering information

Connector	Nominal length	Area (m ²)	Irradiation	Product code
1 to 1½ in. sanitary flange inlet and outlet	213 mm	0.32	Gamma-irradiated	NP5V002P1S
			Non-irradiated	NP5V002P1G
	332 mm	0.64	Gamma-irradiated	NP6V002P1S
			Non-irradiated	NP6V002P1G
	598 mm	1.28	Non-irradiated	NP7V002P1G

Emflon II membrane

IN AUTOCLAVE VENT FILTER (AVF) STYLE CARTRIDGES

Technical specifications

Materials of construction

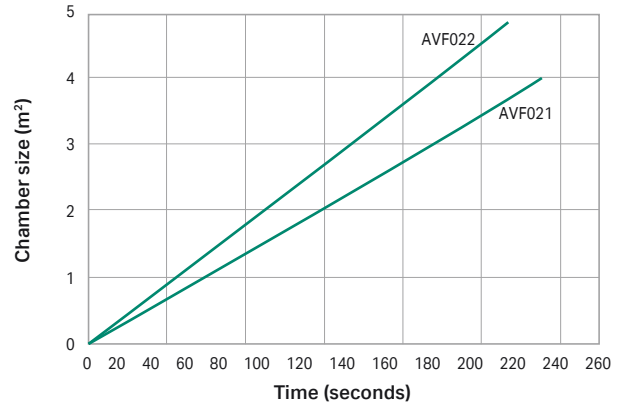
Membrane	Hydrophobic PVDF
Support and drainage layers	PP
End cap and core	PP
O-ring	Ethylene propylene or silicone

Sterilization

Steam sterilization	Repeated autoclave sterilization up to 140°C
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Performance characteristics

Microbial retention	Validated with <i>Pseudomonas diminuta</i> in aerosol and liquid challenge tests Aerosol bacteriophage (T1) challenge supports extrapolated gas removal performance
Operation	Effective in wet or dry air; performance independent of airflow rate
Integrity testing	100% integrity tested during manufacturing using the forward flow test



For conversion from cubic metres to cubic feet multiply by 35.3.
For conversion from cubic feet to cubic metres divide by 35.3.

Fig 23. Vacuum break time of AVF021V002PVJ and AVF022V002PVJ in vent service.

Ordering information

Cartridge type	Diameter	O-ring material	Nominal length	Area (m²)	Product code
½ in. BSPP male connection with O-ring	56 mm	Ethylene propylene	87 mm	0.11	AVF021V002PVJ
			150 mm	0.22	AVF022V002PVJ
		Silicone	87 mm	0.11	AVF021V002PVH4



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