Emflon™ II membrane

IN KLEENPAK™ CAPSULES

Gamma-compatible, sterilizing-grade air filtration

For single-use installations, from upstream to final formulation and fill, Emflon™ II membrane is the go-to gas filter for safeguarding cell cultures and drug product from adventitious bacterial and viral contamination.

Kleenpak™ capsules with Emflon II membrane delivers scalable, gamma-compatible, sterilizing-grade air filtration for use on process gas and vent applications. With a comprehensive validation and quality package, Kleenpak capsules with Emflon II membrane are designed for use from clinical development through to licensed drug manufacture.

Features and benefits

- Highly-retentive Emflon II membrane for sterility assurance
- High flow rates associated with low differential pressure enable the use of small filters – 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 connection options for enhanced flexibility

Biological tests

- Meets USP biological reactivity tests *in vivo*, in accordance with USP class VI plastics at 121°C

Fig 1. Kleenpak capsules.

High quality standards

- Validated in liquids with Brevundimonas diminuta (ATCC 19146) at a challenge level of 10^7 organisms/cm^2 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/release testing supported with a pharmaceutical certificate of test for each filter
- Validation guide available
- Manufactured under a quality management system certified to ISO 9001:2015

Technical specifications

Materials of construction	
Membrane hydrophobic	Hydrophobic polyvinylidene fluoride (PVDF)
Support and drainage layers	Polypropylene
End cap and core	Polypropylene
Outer shell	Polypropylene
Vent and drain valve O-rings:	Ethylene propylene (EPDM)

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.

Specifications

Nominal dimensions

	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 connections	117 mm (4.6 in.)	157 mm (6.2 in.)	174 mm (6.8 in.)
Nominal filtration area	380 cm^2 (0.41 ft^2)	820 cm^2 (0.88 ft^2)	1700 cm^2 (1.83 ft^2)

Typical air flow rates [2, 3]

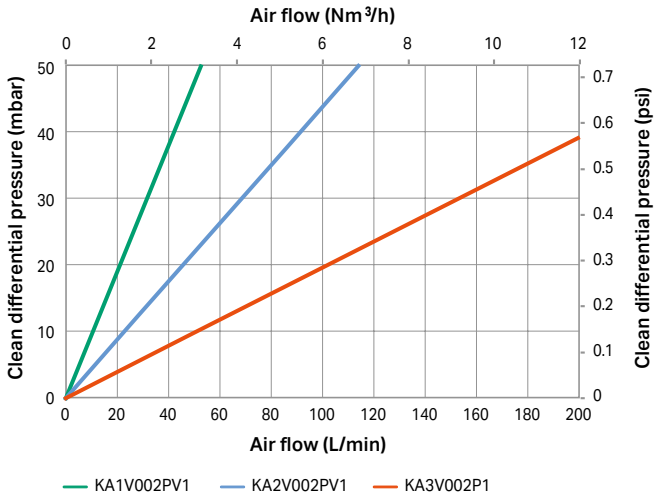

Fig 2. Sanitary flange connections: vent conditions.

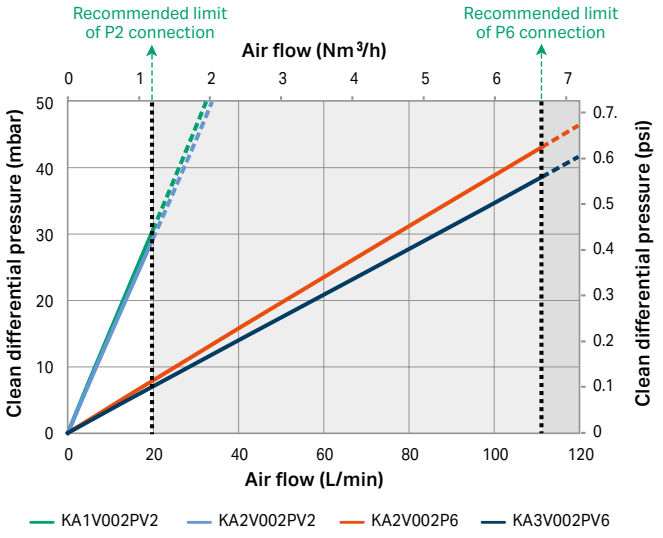

Fig 3. Hosetail: vent conditions.

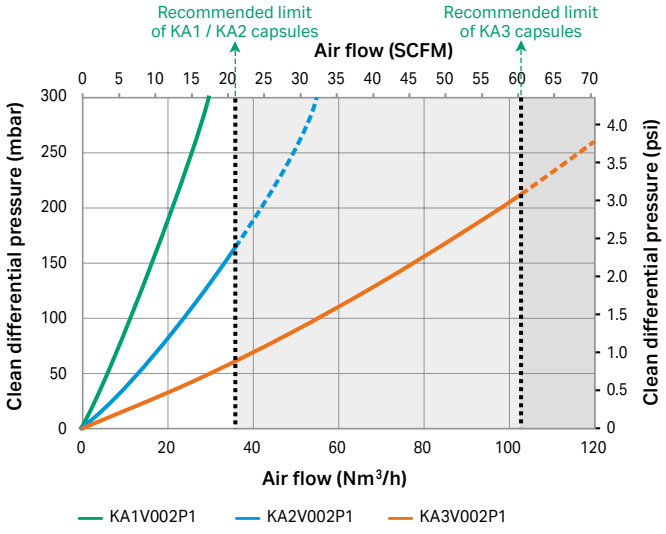

Fig 4. Sanitary flange connections: 2 bar operating pressure.

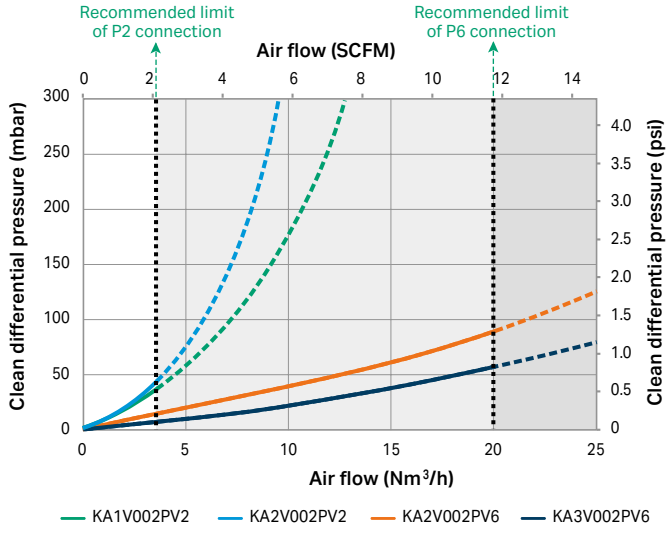

Fig 5. Hosetail connections: 2 bar operating pressure.

[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 20 m/s through the capsule. Customer tubing sizes should also be considered.

Ordering information

Product	Product code
Kleenpak capsule with Emflon II membrane, with 1½ in. sanitary flange, gamma-irradiated	KA1V002PV1S
Kleenpak capsule with Emflon II membrane, with 1½ in. sanitary flange, non-irradiated	KA1V002PV1G
Kleenpak capsule with Emflon II membrane, with ¼ to ½ in. hose barb, gamma-irradiated	KA1V002PV2S
Kleenpak capsule with Emflon II membrane, with ¼ to ½ in. hose barb, non-irradiated	KA1V002PV2G
Kleenpak capsule with Emflon II membrane, with 1½ in. sanitary flange, gamma-irradiated	KA2V002PV1S
Kleenpak capsule with Emflon II membrane, with 1½ in. sanitary flange, non-irradiated	KA2V002PV1G
Kleenpak capsule with Emflon II membrane, with ¼ to ½ in. hose barb, gamma-irradiated	KA2V002PV2S
Kleenpak capsule with Emflon II membrane, with ¼ to ½ in. hose barb, non-irradiated	KA2V002PV2G
Kleenpak capsule with Emflon II membrane, with ½ in. hose barb, gamma-irradiated	KA2V002PV6S
Kleenpak capsule with Emflon II membrane, with ½ in. hose barb, non-irradiated	KA2V002PV6G
Kleenpak capsule with Emflon II membrane, with 1½ in. sanitary flange, gamma-irradiated	KA3V002PV1S
Kleenpak capsule with Emflon II membrane, with 1½ in. sanitary flange, non-irradiated	KA3V002PV1G
Kleenpak capsule with Emflon II membrane, with ½ in. hose barb, gamma-irradiated	KA3V002PV6S
Kleenpak capsule with Emflon II membrane, with ½ in. hose barb, non-irradiated	KA3V002PV6G

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For local office contact information, visit cytiva.com/contact

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