Kleenpak™ Capsules with Emflon® II Membrane Assemblies

Gamma-irradiation Tolerant Air and Gas Filters for Disposable Systems























Kleenpak capsule filters containing with hydrophobic polyvinylidenedifluoride (PVDF) Emflon II membranes are especially designed for the sterile filtration of air and gas. These compact filter capsules provide high air flows, resist blocking in wet applications, and provide 100% removal of bacteria and viruses from air and gases, even in the presence of high humidity and moisture.

Kleenpak capsules are manufactured using gamma-irradiation tolerant materials and offer the very highest standard of filtration security and user convenience. These filters can be integrated within gamma-irradiatable or gamma-sterilized complex systems such as bioreactors, filter assemblies, or transfer sets where venting is required.

Pre-sterilized Option

These Kleenpak filters can be supplied sterilized by a validated gamma-irradiation process reducing time and costs. Filter capsules are then double-bagged and the outlet is covered with a protective cap for extra security.

Gamma-irradiatable Option

These capsules can also be supplied non-sterile, allowing the connection to tubing or any other type of equipment prior to gamma irradiation. This allows users to have a sterilized processing system without the need for aseptic connections and the associated risks of contamination.

Custom-made Sets

We are happy to work with end-users to provide custom-designed processing systems which will integrate one or more of our capsule ranges.

Features and Benefits

- Highly retentive Emflon II membrane
- · High flow-rates associated with low Delta P enable the use of small filters reduction of installation and operating costs
- · Gamma-irradiatable or pre-sterilized for maximum convenience
- Integral molded connections
- · Fully integrity testable using the forward flow test

High Quality Standards

- Validated in liquids with 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 with a unique serial number for complete traceability of manufacturing history and for user traceability systems
- · Each filter supplied with a Certificate of
- · Comprehensive validation guide available
- Manufactured under a Quality Management System certified to ISO 9000
- Meets USP Biological Reactivity Tests in vivo, in accordance with USP Class VI plastics at 121 °C

Kleenpak Capsules with Emflon II Membrane Assemblies

Technical Specifications

Materials of Construction

| Membrane | Hydrophobic PVDF |
|--------------------------------|---------------------------|
| Support and Drainage Layers | Polypropylene |
| End Cap | Polypropylene |
| Core and Cage | Polypropylene |
| Outer Shell | Polypropylene |
| Vent and Drain - Valve O-rings | Ethylene Propylene (EPDM) |

Nominal Dimensions

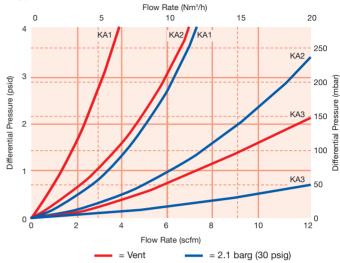
| | KA02 | KA1 | KA2 | KA3 |
|-------------------------------------|--|--|---|--|
| Maximum Diameter (Including Valves) | 51 mm | 94 mm | 94 mm | 109 mm |
| | (2.0 in.) | (3.7 in.) | (3.7 in.) | (4.2 in.) |
| Length with Hose Barb | 104 mm | NA | NA | NA |
| Connections (Code 2) | (4.1 in.) | - | - | - |
| Length with Sanitary | NA | 11.7 cm | 15.8 cm | 17.4 cm |
| Connections | - | (4.6 in.) | (6.2 in.) | (6.8 in.) |
| Nominal Filtration Area | 200 cm ² (0.21 ft ²) | 500 cm ² (0.5 ft ²) | 1000 cm ² (1.0 ft ²) | 1500 cm ² (1.5 ft ²) |

Operating Conditions(1)

| | KA02 | KA1/KA2/KA3 | |
|----------------------------------|---|---|--|
| Maximum Operating Temperature | - | 40 °C | |
| Maximum Operating Pressure | 4.1 barg (60 psig) at 38 °C (100 °F) | 3.5 barg (50 psig) at 38 °C (100 °F) | |
| Maximum Differential Pressure | 2.1 bard (30 psid) at 80 °C (176 °F) | Assessment and a second | |

⁽ⁱ⁾ 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)



⁽²⁾ For gases other than air or nitrogen, contact your local Pall representative.

Sterilization

| Maximum Dosage (G option only): Up to 50 kGy | | |
|---|--|--|
| | | |
| | | |

Gamma-irradiated Filters

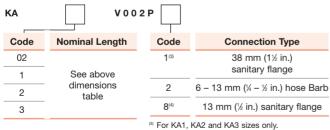
One 30-minute cycle at 125 °C

Non Gamma-irradiated Filters

3 x 1 hour cycles at 125 °C

Warning: Kleenpak filters must not be in situ steam-sterilized 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.

Ordering Information



| | Code | Sterilization Status |
|------|------|----------------------|
| | S | Gamma-irradiated |
| | G | Non-irradiated |
| 3arb | | |

For KA1, KA2 and KA3:
For KA02 size only.