Pall Corporation

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Kleenpak™ Nova Capsules with Supor® EAV Membrane

Description

Supor® grade EAV membrane filters are designed for effective bioburden and particle control of buffers and pharmaceutical or biological process fluids. A highly asymmetric single layer membrane incorporated in these filters ensures high throughputs and flow rates when utilized for the protection of downstream chromatography columns, ultrafilters or sterilizing filters.

Supor grade EAV membrane filters allow for reduced sizing of filter systems with improved process efficiencies when use of validated sterilizing grade filters is not essential, but reliable bioburden control is required. Supor grade EAV membrane filters are also effective prefilters for protection and extending the life of 0.2 µm sterilizing-grade and finer membrane filters where required.

Pall's range of Kleenpak™ Nova capsules are designed for use in medium to large scale production environments (100 L > 1000 L), often selected by the end user following scaling studies using smaller Kleenpak capsule formats. With the AB style cartridge format at its core, this capsule filter style can be supplied with the most comprehensive range of filter media.

Features and Benefits

- Hydrophilic, controlled asymmetric polyethersulfone (PES) membrane ensures high microbial and particulate reduction with outstanding service life
- Bacterial titer reduction in excess of 6 log for *Brevundimonas diminuta* ensures low bioburden levels in filtrate, regardless of bacteria or particle loading
- Broad pH compatibility for processing a wide range of buffers and other fluids
- High membrane area featuring Pall-patented cresent-shaped laid-over pleat construction combined with a narrow diameter core guarantees high flow rates, robustness and smaller multi-cartridge assemblies
- Kleenpak™ capsule formats eliminate housing cleaning and associated validation, for ease of use and integration into Allegro single-use disposable systems
- Low-binding polyethersulfone membrane for maximum transmission of proteins

Quality Standards

- 100% integrity tested
- Manufactured for use in conformance with cGMP
- Each filter is fully traceable by individual marked lot and serial number
- Manufactured under an ISO 9001 Certified Quality System
- Meets USP Biological Reactivity Test, *in vivo*, for Class VI-121 °C Plastics
- Certificate of Test provided confirms:
  - Fabrication Integrity
  - Bacterial Retention
  - Materials of construction
  - Effluent quality for cleanliness, TOC, water conductivity, pH and pyrogens

Specifications

Materials of Construction

Filter Membrane	Hydrophilic asymmetric PES
Support/Drainage	Polypropylene
Core/End Caps	Polypropylene
Cage	Polypropylene with TiO_2 whitener[1]
O-rings	Silicone elastomer
Sealing Technology	Thermal bonding without adhesives
Housing Bowl	Polypropylene
Housing Head	Polyetherimide with TiO_2 whitener

[1] *TiO_2 is an insoluble inorganic mineral filler that does not contribute to organic extractables*

Operating Parameters[2]

Maximum Operating Temperature	40 °C
Maximum Operating Pressure	3 bar (44 psi) at 40 °C
Maximum Differential Pressure	3 bar (44 psi) at 40 °C

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

Sterilization[3]

Autoclave (G option only)	1 x 60 minutes at 135 °C
Gamma irradiation (G option only)	Maximum of 50 kGy

[3] Pre-sterilized Kleenpak Nova capsules must not be re-sterilized. Kleenpak Nova capsules must not be sterilized in-situ by passing steam under pressure

Typical Extractables in Water at 20 °C[4]

< 50 mg per 254 mm (10 in.) module

[4] Tested on elements without pre-flushing

Nominal Effective Filter Area (EFA)

1.06 m^2 per 254 mm module (11.4 ft^2 per 10 in. module)

Integrity Test Values (air test gas, water wet)[5]

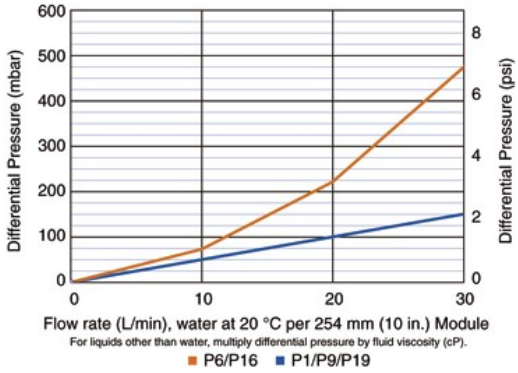
Max. allowable Forward Flow	Water wet 50 mL/min at 2060 mbar (30 psi)

[5] Values for 254 mm (10 in.) filter at 20°C. Contact Pall for multi-element integrity test values and recommended test procedures

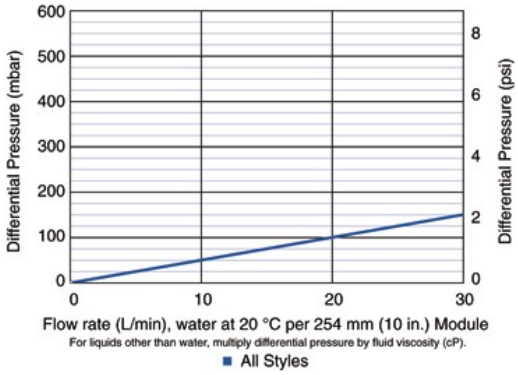
Nominal Dimensions

In-line	**NP6**	**NP7**	**NP8**
Maximum Diameter including valves	154 mm (6.1 in.)	154 mm (6.1 in.)	154 mm (6.1 in.)
Length with hose barb inlet/outlet	397 mm (15.6 in.)	644 mm (25.4 in.)	895 mm (35.2 in.)
Length with sanitary inlet/outlet	335 mm (13.2 in.)	584 mm (23.0 in.)	834 mm (32.8 in.)
T-style	**NT6**	**NT7**	**NT8**
Maximum Diameter including valves	240 mm (9.5 in.)	240 mm (9.5 in.)	240 mm (9.5 in.)
Length	349 mm (13.7 in.)	598 mm (23.5 in.)	848 mm (33.4 in.)

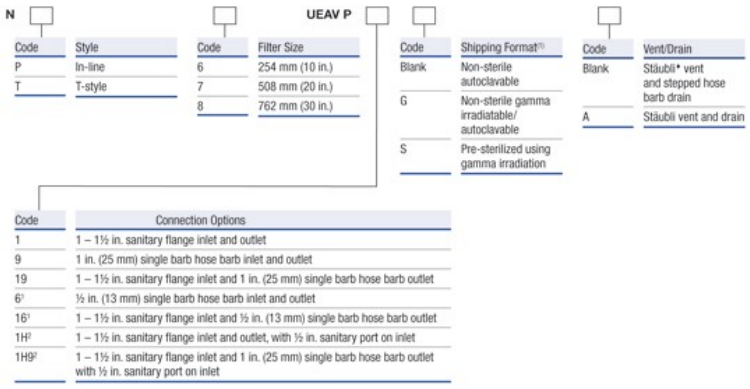
Kleenpak Nova In-line Capsules (NP) Typical Liquid Flow vs. Differential Pressure



Kleenpak Nova T-Style Capsules (NT) Typical Liquid Flow vs. Differential Pressure



Ordering Information



Contact Information

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Revision Date: 08/25/2010