

**Biotech** 

#### USD3285

# Pall Kleenpak<sup>™</sup> Nova Capsules with Supor<sup>®</sup> EX Grade ECV Filter Membrane



## High Capacity, High Flow Rate Filter Capsules

Supor EX grade ECV filters are high capacity, high flow rate 0.2 µm sterilizing grade filters validated for the retention of *Brevundimonas diminuta* (ATCC 19146) at a challenge level of 10<sup>7</sup> colony forming units (CFU) per cm<sup>2</sup> membrane. A unique polyethersulfone (PES) membrane pairing ensures Supor EX grade ECV filters deliver highly efficient filtration of cell harvest material, process intermediates, growth media, buffers and final bulk biological process fluids. Supor EX grade ECV filters also deliver unrivalled efficiency with more viscous process streams.

Available in capsules with filter areas of 0.1 m<sup>2</sup> to 3 m<sup>2</sup>, in in-line and T-style configurations, and with a variety of inlet and outlet options, Kleenpak Nova capsules with Supor ECV membranes have a size and format to meet your process needs today and can scale as your process grows to meet your future needs without a change of membrane or materials.

#### Filtration. Separation. Solution.sm

## Key Features and Benefits

- Asymmetric PES membrane arranged in laid over pleat geometry for excellent flow rates and high capacity per unit membrane
- Low protein and preservative binding
- Available as 0.1 m<sup>2</sup>, 0.5 m<sup>2</sup>, 1 m<sup>2</sup>, 2 m<sup>2</sup> and 3 m<sup>2</sup> filter capsules for coverage of a broad range of fluid volumes
- Encapsulated format for minimized cleaning and low installation costs
- Easy integrity testing through Staubli vent valve
- Fluid compatibility over a broad pH range for use in multiple applications

## **Quality Standards**

A Certificate of Test provided with every filter documents the following:

- Filters are manufactured in a controlled environment
- Manufactured for use in conformance with cGMP
- Materials of construction meet USP<88> Biological Reactivity Test In Vivo for Class VI-121°C plastics
- Q.C lot release tests
  - Fabrication Integrity each filter has successfully passed a Forward Flow integrity test correlated to bacterial retention per modified ASTM F838-05
  - Lot sample bacterial retention tests with *Brevundimonas* diminuta (ATCC 19146) at a challenge level of 10<sup>7</sup> CFU/cm<sup>2</sup>
  - Effluent quality for cleanliness, TOC and water conductivity, pH and pyrogens per USP standard methods

## **Specifications**

#### **Materials of Construction**

| Filter Membrane              | Dual-layer hydrophilic polyethersulfone                   |
|------------------------------|---|
| Support and Drainage Layers  | Polypropylene   |
| Core, End Caps, Fin, Adapter | Polypropylene   |
| Cage                         | Polypropylene with TiO <sub>2</sub> whitener <sup>1</sup> |
| 0-rings                      | Silicone elastomer  |
| Sealing Technology           | Thermal bonding without adhesives                         |
| Housing Bowl                 | Polypropylene   |
| Housing Head                 | Polypropylene with TiO <sub>2</sub> whitener <sup>1</sup> |

<sup>1</sup> TiO<sub>2</sub> is an insoluble inorganic mineral filler that does not contribute to organic extractables

#### **Effective Filtration Area**

| Format                    | NP1L               | NP5L                | N(P/T)6             | N(P/T)7             | N(P/T)8             |
|---------------------------|--------------------|---------------------|---------------------|---------------------|---------------------|
| Nominal Filter Length     | 1 in.              | 5 in.               | 10 in.              | 20 in.              | 30 in.              |
| Effective Filtration Area | 0.1 m <sup>2</sup> | 0.52 m <sup>2</sup> | 1.04 m <sup>2</sup> | 2.08 m <sup>2</sup> | 3.12 m <sup>2</sup> |

#### **Operating Parameters**<sup>2</sup>

| Format                        | NP1L  | NP5L                           | N(P/T)6                        | N(P/T)7                        | N(P/T)8                        |  |  |
|-------------------------------|---|--------------------------------|--------------------------------|--------------------------------|--------------------------------|--|--|
| Maximum Differential Pressure | 4.1 bar (60 psi)<br>at 20 °C                                | 5.0 bar (72.5 psi)<br>at 40 °C | 3.0 bar (43.5 psi)<br>at 40 °C | 3.0 bar (43.5 psi)<br>at 40 °C | 3.0 bar (43.5 psi)<br>at 40 °C |  |  |
| Maximum Operating Pressure    | 5.2 bar (75.4 psi)<br>at 20 °C<br>4.0 bar (58 psi) at 40 °C | 5.0 bar (72.5 psi)<br>at 40 °C | 3.0 bar (43.5 psi)<br>at 40 °C | 3.0 bar (43.5 psi)<br>at 40 °C | 3.0 bar (43.5 psi)<br>at 40 °C |  |  |

<sup>2</sup> In compatible fluids which do not soften, swell or adversely affect the filter or its materials of construction

| Sterilization <sup>3</sup>           |   |                                   |                                |                                   |                                |
|--------------------------------------|---|-----------------------------------|--------------------------------|-----------------------------------|--------------------------------|
| Format                               | NP1L  | NP5L                              | N(P/T)6                        | N(P/T)7                           | N(P/T)8                        |
| Autoclave (G option only)            | 5 x 60 minute cycles<br>at 125 °C<br>1 x 60 minute cycle<br>at 135 °C | 5 x 60 minute cycles<br>at 125 °C | 3 x 60 minute cycles at 125 °C | 3 x 60 minute cycles<br>at 125 °C | 3 x 60 minute cycles at 125 °C |
| Gamma Irradiation<br>(G option only) | Maximum of 50 kGy   | Maximum of 50 kGy                 | Maximum of 50 kGy              | Maximum of 50 kGy                 | Maximum of 50 kGy              |

<sup>3</sup> 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 Non Volatile Residue (NVR) Extractables in Water at 20 °C<sup>4</sup>

| Format                                      | nat NP1L NP5L       |                     | N(P/T)6                        | N(P/T)7                        | N(P/T)8                        |  |
|---|---------------------|---------------------|--------------------------------|--------------------------------|--------------------------------|--|
| Post 1 x 60 minute autoclave cycle at 125°C | < 15 mg per capsule | < 75 mg per capsule | < 150 mg per<br>10 in. capsule | < 150 mg per<br>10 in. capsule | < 150 mg per<br>10 in. capsule |  |
| Post gamma irradiation at<br>50 kGy         | < 2 mg per capsule  | < 15 mg per capsule | < 25 mg per<br>10 in. capsule  | < 25 mg per<br>10 in. capsule  | < 25 mg per<br>10 in. capsule  |  |

<sup>4</sup> Tested on elements after 24 hr extraction

#### Integrity Test Values (Air test gas, water wet)\*

| Format  | NP1L       | NP5L      | N(P/T)6   | N(P/T)7   | N(P/T)8   |
|---|------------|-----------|-----------|-----------|-----------|
| Maximum Allowable Forward<br>Flow at 2760 mbar (40 psi) | 2.4 mL/min | 11 mL/min | 21 mL/min | 37 mL/min | 54 mL/min |

\* Values correct at 20 °C. Contact Pall for multi-element integrity test values or other fluid values and recommended test procedures

| Clean Water Flow Rates                                |           |           |          |          |          |  |  |  |  |  |
|---|-----------|-----------|----------|----------|----------|--|--|--|--|--|
| Format  | NP1L      | NP5L      | N(P/T)6  | N(P/T)7  | N(P/T)8  |  |  |  |  |  |
| Clean Water Flow at 100 mbar<br>Differential Pressure | 1.4 L/min | 8.5 L/min | 17 L/min | 34 L/min | 51 L/min |  |  |  |  |  |

### **Nominal Dimensions**

| In-Line                                | NP1L             | NP1L NP5L NP6     |                   | NP7               | NP8               |  |  |
|--|------------------|-------------------|-------------------|-------------------|-------------------|--|--|
| Maximum Diameter<br>Including Valves   | 154 mm (6.1 in.) | 154 mm (6.1 in.)  | 154 mm (6.1 in.)  | 154 mm (6.1 in.)  | 154 mm (6.1 in.)  |  |  |
| Length with Hose Barb<br>Inlet/ Outlet | -                | 275 mm (10.8 in.) | 397 m (15.6 in.)  | 644 mm (25.4 in.) | 895 mm (35.2 in.) |  |  |
| Length with Sanitary<br>Inlet / Outlet | 128 mm (5.0 in.) | 213 mm (8.4 in.)  | 332 mm (13.1 in.) | 584 mm (23.0 in.) | 834 mm (32.8 in.) |  |  |
| T-Style                                | -                | -                 | NT6               | NT7               | NT8               |  |  |
| Maximum Diameter<br>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.) |  |  |

## **Ordering Information**

| Ν | []   |             | []   | UECVP                       |                        | []    |  | []    |  | []    |  |
|---|------|-------------|------|-----------------------------|------------------------|-------|--|-------|--|-------|--|
|   | Code | Description | Code | Nominal<br>Filter<br>Length | Nominal<br>Filter Area | Code  | Inlet / Outlet<br>Configurations   | Code  | Format   | Code  | Vent and<br>Drain Options                |
|   | Р    | In-line     | 1L*  | 1 in.                       | 0.1 m <sup>2</sup>     | 1     | $1 - 1\frac{1}{2}$ in. sanitary flange inlet and outlet  | Blank | Non-sterile,<br>autoclavable                   | Blank | Staubli vent and stepped hose barb drain |
|   | T    | T-style     | 5L*  | 5 in.                       | 0.5 m <sup>2</sup>     | 9     | 1 in. (25 mm) single barb<br>hose barb inlet and outlet  | G     | Non-sterile,<br>autoclavable /<br>irradiatable | A     | Staubli vent<br>and drain                |
|   |      |             | 6    | 10 in.                      | 1 m <sup>2</sup>       | 19    | $1 - 1\frac{1}{2}$ in. sanitary flange inlet<br>and 1 in. (25 mm) single barb<br>hose barb outlet                              | S     | Presterilized by irradiation                   |       |  |
|   |      |             | 7    | 20 in.                      | 2 m <sup>2</sup>       | 6*    | 1/2 in. (13 mm) single barb hose barb inlet and outlet   |       |  |       |  |
|   |      |             | 8    | 30 in.                      | 3 m <sup>2</sup>       | 16*   | $1 - 1\frac{1}{2}$ in. sanitary flange inlet<br>and $\frac{1}{2}$ in. (13 mm) single barb<br>hose barb outlet                  |       |  |       |  |
|   |      |             | _    |                             |                        | 1H**  | $1 - 1\frac{1}{2}$ in. sanitary flange inlet<br>and outlet, with $\frac{1}{2}$ in. sanitary<br>port on inlet                   |       |  |       |  |
|   |      |             |      |                             |                        | 1H9** | 1 - 1% in. sanitary flange inlet<br>and 1 in. (25 mm) single barb<br>hose barb outlet, with $\%$ in.<br>sanitary port on inlet |       |  |       |  |