# **Supor**<sup>™</sup> EX

# GRADE ECV FILTER MEMBRANE IN KLEENPAK™ NOVA 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 cm² membrane. An innovative polyethersulfone (PES) membrane pairing enables Supor EX grade ECV filters to efficiently filter cell harvest material, process intermediates, growth media, buffers and final bulk biological process fluids. Supor EX grade ECV filters also facilitate efficiency with more viscous process streams.

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

#### 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, 0.5, 1, 2 and 3 m<sup>2</sup> filter capsules for coverage of a broad range of fluid volumes
- Encapsulated format to reduce cleaning and installation costs
- Easy integrity testing through Stäubli™ vent valve
- Fluid compatibility over a broad pH range for use in multiple applications



Fig 1. Supor EX grade ECV filter membranes in Kleenpak Nova capsules.



## Quality standards

A certificate of test provided with every filter documents the following:

- · Filters are manufactured in a controlled environment
- Filters are manufactured for use in conformance with cGMP
- Materials of construction meet USP <88> Biological Reactivity Test in vivo for Class VI-121°C plastics
- · Quality control lot release tests
  - Fabrication integrity each filter has 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, total organic carbon (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>
O-rings	Silicone elastomer
Sealing technology	Thermal bonding without adhesives
Housing bowl	Polypropylene
Housing head	Polypropylene with TiO <sub>2</sub> whitener <sup>(1)</sup>

 $<sup>^{(1)}\</sup>text{TiO}_2$  is an insoluble inorganic mineral filler that does not contribute to organic extractables.

#### Effective filtration area (EFA)

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.
EFA	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 (2)

Format	NP1L	NP5L	N(P/T)6	N(P/T)7	N(P/T)8
Maximum differential pressure	4.1 bar (60 psi) at 20°C	5.0 bar (72.5 psi) at 40°C	3.0 bar (43.5 psi) at 40°C	3.0 bar (43.5 psi) at 40°C	3.0 bar (43.5 psi) at 40°C
Maximum operating pressure	5.2 bar (75.4 psi) at 20°C 4.0 bar (58 psi) at 40°C	5.0 bar (72.5 psi) at 40°C	3.0 bar (43.5 psi) at 40°C	3.0 bar (43.5 psi) at 40°C	3.0 bar (43.5 psi) at 40°C

<sup>&</sup>lt;sup>(2)</sup> In compatible fluids which do not soften, swell or adversely affect the filter or its materials of construction.

#### Sterilization (3)

Format	NP1L	NP5L	N(P/T)6	N(P/T)7	N(P/T)8
Autoclave (G option only)	5 × 60-min cycles at 125°C 1 × 60-min cycle at 135°C	5 × 60-min cycles at 125°C	3 × 60-min cycles at 125°C	3 × 60-min cycles at 125°C	3 × 60-min cycles at 125°C
Gamma irradiation (G option only)	Maximum of 50 kGy	Maximum of 50 kGy	Maximum of 50 kGy	Maximum of 50 kGy	Maximum of 50 kGy

<sup>🕮</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 (4)

Format	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 10 in. capsule	< 150 mg per 10 in. capsule	< 150 mg per 10 in. capsule
Post gamma irradiation at 50 kGy	< 2 mg per capsule	< 15 mg per capsule	< 25 mg per 10 in. capsule	< 25 mg per 10 in. capsule	< 25 mg per 10 in. capsule

<sup>(4)</sup> Tested on elements after 24 h extraction.

#### Integrity test values (air test gas, water wet) (5)

Format	NP1L	NP5L	N(P/T)6	N(P/T)7	N(P/T)8
Maximum allowable forward flow at 2760 mbar (40 psi)	2.4 mL/min	11 mL/min	21 mL/min	37 mL/min	54 mL/min

<sup>&</sup>lt;sup>(5)</sup> Values correct at 20°C. Contact us 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	1.4 mL/min	8.5 mL/min	17 mL/min	34 mL/min	51 mL/min
differential pressure					

### Nominal dimensions

In-line	NP1L	NP5L	NP6	NP7	NP8	
Maximum diameter 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 - 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 128 mm (5.0 in.) inlet/outlet		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 - 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

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Code	Description	Code	Nominal filter length	Nominal filter area	Code	Inlet/outlet configurations	Code	Format	Code	Vent and drain options
P	In-line	1L <sup>(6)</sup>	1 in.	0.1 m <sup>2</sup>	1	1 to 1½ in. sanitary flange inlet and outlet	Blank	Non-sterile, autoclavable	Blank	Stäubli vent and stepped hose barb drain
<u>T</u>	T-style	5L <sup>(6)</sup>	5 in.	0.5 m <sup>2</sup>	9	1 in. (25 mm) single barb hose barb inlet and outlet	G	Non-sterile, autoclavable/ irradiatable	Α	Stäubli vent and drain
		6	10 in.	1 m²	19	1 to 1½ in. sanitary flange inlet and 1 in. (25 mm) single barb hose barb outlet	S	Pre-sterilized by irradiation		
		7	20 in.	2 m <sup>2</sup>	6 <sup>(6)</sup>	½ in. (13 mm) single barb hose barb inlet and outlet				
		8	30 in.	3 m²	16 <sup>(6)</sup>	1 to 1½ in. sanitary flange inlet and ½ in. (13 mm) single barb hose barb outlet				
					1H <sup>(7)</sup>	1 to 1½ in. sanitary flange inlet and outlet, with ½ in. sanitary port on inlet				
<sup>(6)</sup> In-line o					1H9 <sup>(7)</sup>	1 to 1½ in. sanitary flange inlet and 1 in. (25 mm) single barb hose barb outlet, with ½ in. sanitary port on inlet				

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