

Pegasus™ Protect

VIRUS PREFILTRATION MEMBRANE

Process-scale virus filter prefiltration

Pegasus™ Protect virus prefiltration combines with Pegasus Prime virus filtration to deliver an innovative gamma-sterilized pre-filter and virus filter combination. Together, these can simplify process development, validation and operations while saving time and delivering improved process economy.

Process developers can quickly deliver a robust, scalable virus filtration process using a low sample volume, supporting of successful virus validation. This choice supports clinical manufacturing with a solution that is easy to use and versatile enough to work alone or with integrated and automated single-use systems.

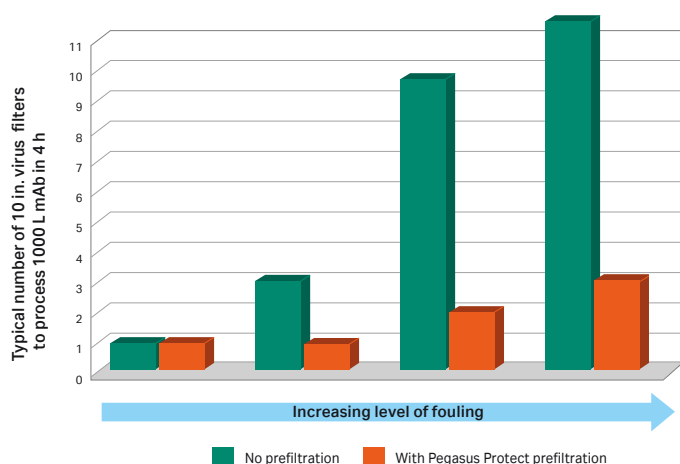


Fig 1. Impact of Pegasus Protect prefiltration on required virus filters per batch.



Fig 2. AB style filter and Kleenpak Nova capsule.

Features and benefits

Features

Removes filter plugging of Pegasus Prime substances

Benefits

- Reduce plugging of Pegasus Prime virus filters
- Smaller virus filter sizing
- Reduced cost of goods
- Shorter processing times
- Increased robustness to natural process fluid variation

The scale-up range provides a consistent prefilter-to-virus filter area ratio at all scales

- Consistent performance
- Controlling scaling risks
- Faster, simple scale-up

Scalable solutions

Prefiltration area and flowrate are critical variables that may affect the performance of Pegasus Protect prefiltration and Pegasus Prime virus removal filters when used in combination.

To control these variables, Pegasus Protect prefilters are available in a range of formats, designed to maintain a consistent prefilter to virus-filter ratio. This control enables predictable and consistent performance at scales from initial Microdisc capsule scale trials to clinical manufacturing.

Lab scale	Capsule format	Area
Pegasus Protect prefiltration	Microdisc	3.9 cm ²
Pegasus Prime virus filter	Microdisc	2.8 cm ²
Area ratio		1.4 : 1

Development scale		Area
Pegasus Protect prefiltration	Kleenpak	286 cm ²
Pegasus Prime virus filter	Mini Kleenpak	205 cm ²
Area ratio		1.4 : 1

Full scale		Area
Pegasus Protect prefiltration	20 in. Kleenpak Nova	1.4 m ²
Pegasus Prime virus filter	10 in. Kleenpak Nova	1.0 m ²
Area ratio		1.4 : 1

Specifications

Materials of construction	Filter cartridges	Kleenpak Nova capsules
Filter membrane	Nylon	Nylon
Support and drainage	Polyester	Polyester
Endcap and adaptor	Polyester	Polyester
Core and cage	Polypropylene	Polypropylene
O-rings	Silicone elastomer	Silicone elastomer
Capsule hardware	-	Polypropylene
Valve seals	-	Silicone elastomer

Retention ratings

Pore size	0.2 µm nominal
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Effective filter area (EFA) (Nominal)

254 mm (10 in.)	0.7 m ²
508 mm (20 in.)	1.4 m ²
762 mm (30 in.)	2.1 m ²

Operating parameters

Maximum temperature	40°C	40°C
Maximum pressure	5.4 bar (76 psi) at 20°C	5.4 bar (76 psi) at 20°C 3.0 bar (43.5 psi) at 40°C
Maximum differential pressure	5.4 bar (76 psi) at 20°C	3.0 bar (43.5 psi) at 40°C

Recommended operating conditions

73 mbard (1.1 psid) or 7.3 L/min/10 in.⁽¹⁾

⁽¹⁾ When used with filter cartridges or Kleenpak Nova capsules with Pegasus Prime virus removal media at 2.1 bard (30 psid)

Steam autoclaving

Cumulative autoclave time	16 hours at 125°C ⁽²⁾ 4 hours at 140°C
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⁽²⁾ Laboratory tests (1-hour cycles). Contact us for recommended procedures
WARNING: Kleenpak capsules must not be steam sterilized *in situ* by passing steam through under pressure. Gamma pre-sterilized capsules should not be steam autoclaved. They have not been validated for steam autoclaving

Dimensions (nominal)	Filter cartridges	Kleenpak Nova capsules	
		In-line	T-style
Length	254 mm (10 in.)	335 mm (13.2 in.)	349 mm (13.7 in.)
	508 mm (20 in.)	584 mm (23.0 in.)	598 mm (23.5 in.)
	762 mm (30 in.)	834 mm (32.8 in.)	848 mm (33.4 in.)
Diameter including valves	n/a	154 mm (6.1 in.)	240 mm (9.5 in.)
Connection type	n/a	1 in. sanitary flange	

Ordering information

Filter cartridges

Product	Pkg	Product code
254 mm (10 in.) filter cartridges with Pegasus Protect prefilter membrane. Nominal area 0.7 m ²	1/pkg	AB1PRT7PH4
508 mm (20 in.) filter cartridges with Pegasus Protect prefilter membrane. Nominal area 1.4 m ²	1/pkg	AB2PRT7PH4
762 mm (30 in.) filter cartridges with Pegasus Protect prefilter membrane. Nominal area 2.1 m ²	1/pkg	AB3PRT7PH4

Kleenpak Nova filter capsules (in-line flow)

Product	Pkg	Product code
254 mm (10 in.) Kleenpak Nova filter capsules with Pegasus Protect prefiltration membrane. Nominal area 0.7 m ²	1/pkg	NP6LP RTP1G
508 mm (20 in.) Kleenpak Nova filter capsules with Pegasus Protect prefiltration membrane. Nominal area 1.4 m ²	1/pkg	NP7LP RTP1G
762 mm (30 in.) Kleenpak Nova filter capsules with Pegasus Protect prefiltration membrane. Nominal area 2.1 m ²	1/pkg	NP8LP RTP1G

Kleenpak Nova filter capsules (in-line flow) gamma sterilized

Product code	Pkg	Product code
254 mm (10 in.) Kleenpak Nova filter capsules with Pegasus Protect prefiltration membrane. Nominal area 0.7 m ² , gamma sterilized	1/pkg	NP6LP RTP1S
508 mm (20 in.) Kleenpak Nova filter capsules with Pegasus Protect prefiltration membrane. Nominal area 1.4 m ² , gamma sterilized	1/pkg	NP7LP RTP1S
762 mm (30 in.) Kleenpak Nova filter capsules with Pegasus Protect prefiltration membrane. Nominal area 2.1 m ² , gamma sterilized	1/pkg	NP8LP RTP1S

Kleenpak Nova filter capsules (T-style flow)

Product	Pkg	Product code
254 mm (10 in.) Kleenpak Nova filter capsules with Pegasus Protect prefiltration membrane. Nominal area 0.7 m ²	1/pkg	NT6P RTP1G
508 mm (20 in.) Kleenpak Nova filter capsules with Pegasus Protect prefiltration membrane. Nominal area 1.4 m ²	1/pkg	NT7P RTP1G
762 mm (30 in.) Kleenpak Nova filter capsules with Pegasus Protect prefiltration membrane. Nominal area 2.1 m ²	1/pkg	NT8P RTP1G

Kleenpak Nova filter capsules (T-style flow) gamma sterilized

Product	Pkg	Product code
254 mm (10 in.) Kleenpak Nova filter capsules with Pegasus Protect prefiltration membrane. Nominal area 0.7 m ² , gamma sterilized	1/pkg	NT6P RTP1S
508 mm (20 in.) Kleenpak Nova filter capsules with Pegasus Protect prefiltration membrane. Nominal area 1.4 m ² , gamma sterilized	1/pkg	NT7P RTP1S
762 mm (30 in.) Kleenpak Nova filter capsules with Pegasus Protect prefiltration membrane. Nominal area 2.1 m ² , gamma sterilized	1/pkg	NT8P RTP1S

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