

## Life Sciences

USD 2461b

## Pall Supor<sup>®</sup> EKV Sterilizing Grade Filters

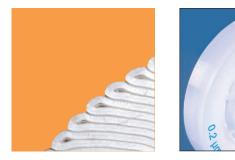
Filtration. Separation. Solution.sm

## Supor EKV Sterilizing Grade Filters

Pall Supor EKV filters are validated sterilizing grade membranes for the most cost effective filtration of a wide range of liquids such as buffers tissue, culture media, and others.

The incorporated PES membrane demonstrates very high compatibility over the whole pH range plus very low protein binding to ensure the maximum transmission of the active ingredients.

The patented Ultipleat<sup>®</sup> filter technology, combined with the optimized, built-in asymmetric prefilter for higher flow rates and throughput, allows very compact sizing for easy integration in disposable systems.

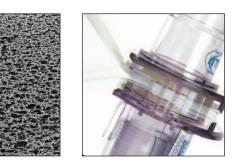














## Allegro<sup>™</sup> Systems: The Disposable Solutions

High flexibility, minimized cleaning, cleaning validation, enhanced sterility, and cost control, through the whole drug development cycle and during full manufacturing are clear industry targets.

The Allegro disposable systems, which incorporate Pall Kleenpak<sup>™</sup> capsules, are the answer to these requirements as they completely eliminate the need for cleaning and related validation, minimizing major capital investment, and offering very high flexibility while enhancing the quality of aseptic processing.

For liquids from several milliliters up to full production scale volumes, a wide range of Supor EKV filter products are available in disposable format and can thus be integrated into Allegro disposable systems.





Mini Kleenpak Syringe Filters Page 7



Mini Kleenpak 20 Capsules Page 8















Junior Filter Cartridges Page 14



Filter Cartridges

Page 15



### Save Time, Get Results

Supor EKV filters are available in a wide range of scalable, encapsulated formats which allow fast and easy scale-up, to bring your product to the market faster.

### Same materials\*

From syringe filters to production scale, all products incorporate the same membrane and the identical materials of construction.

\* Except Novasip Capsules. See material of construction tables for each product for further details.

# Quality

## Every Supor EKV pleated filter is:

- Integrity tested during manufacture
- Identified by lot and serial number for total traceability
- Supplied with a certificate of test confirming each filter:
  - Meets USP Biological Reactivity test *in vivo*, for class VI-121°C plastics
  - Meets cleanliness per USP Particulates in Injectables
  - Is Non-Fiber-Releasing
  - Is Non-Pyrogenic per USP Endotoxins (< 0.25 EU/mL)
  - Meets Total Organic Carbon and Water Conductivity per USP Purified Water.







# Mini Kleenpak Syringe Filters

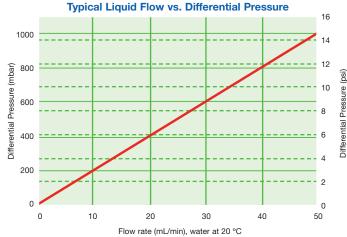
#### **Materials of Construction**

Hydrophilic PES
Polypropylene
Insert molding

#### **Operating Parameters**<sup>(1)</sup>

Maximum Operating	5.4 bar (80 psi) at 20 °C
Temperature and Pressure	2.1 bar (30 psi) at 60 °C

<sup>(1)</sup> In compatible fluids which do not soften, swell or adversely affect the filter or its materials of construction



For liquids other than water, multiply differential pressure by fluid viscosity (cP).

21 mm (0.8 in.)

29 mm (1.2 in.)

#### Typical Hold Up Volume

< 2.5 mL

#### Sterilization<sup>(2)</sup>

Pre-sterilized, subject to a minimum of 25 kGy of Gamma-irradiation

Pre-sterilized Mini Kleenpak syringe filters must not be re-sterilized
Mini Kleenpak syringe filters must not be sterilized *in-situ* by passing steam under pressure

## Nominal Effective Filter Area (EFA)

2.8 cm<sup>2</sup> (0.43 in<sup>2</sup>)

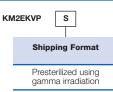
Capsule Length

Capsule Diameter

**Nominal Dimensions** 

### **Ordering Information**<sup>(3)</sup>

Pall Part Number:



(3) 50 filters per box

# Mini Kleenpak 20 Capsules

#### **Materials of Construction**

Filter Membrane	Hydrophilic PES
Housing, Vent Plug and Support Material	Polypropylene
Filling Bell	Polycarbonate
Sealing Technology	Thermal bonding without adhesives

#### **Operating Parameters**<sup>(1)</sup>

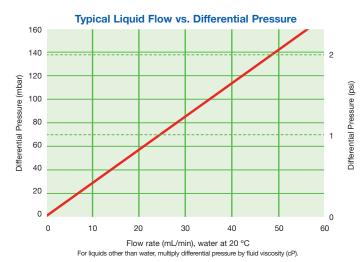
Maximum Operating	1.4 bard at 22 °C (20 psid)
Temperature and Pressure	

(1) In compatible fluids which do not soften, swell or adversely affect the filter or its materials of construction

• Mini Kleenpak 20 capsules must not be sterilized in-situ by passing steam

· Pre-sterilized Mini Kleenpak 20 capsules should not be re-irradiated

· Water wet Supor EKV capsules prior to steaming to retain full water wettability for



#### **Typical Hold up Volume**

< 2.5 mL

Sterilization<sup>(2)</sup>

Autoclave

(2)

Capsule Length	83 mm (3.3 in.)
Capsule Diameter	67 mm (2.7 in.)

#### Nominal Effective Filter Area (EFA)

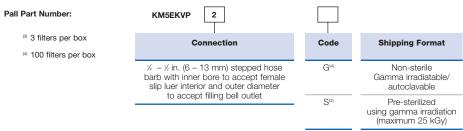
**Nominal Dimensions** 

20 cm<sup>2</sup> (3.1 in.<sup>2</sup>)

under pressure

integrity testing





1 x 60 minutes at 125 °C



Filter Membrane	Hydrophilic PES
Support/Drainage	Polypropylene
Capsule Shell	Polypropylene
Filling Bell	Polycarbonate
Sealing Technology	Thermal bonding without adhesives

#### **Operating Parameters**<sup>(1)</sup>

Maximum Temperature	40 °C
Maximum Operating Pressure	4.1 bar (60 psi) at 40 °C
Maximum Differential Pressure	4.1 bar (60 psi) at 40 °C

 $^{\scriptscriptstyle (1)}$  In compatible fluids which do not soften, swell or adversely affect the filter or its materials of construction

#### Sterilization<sup>(2)</sup>

Autoclave	3 x 60 minutes at 140 °C
Gamma Irradiation	Maximum of 50 kGy

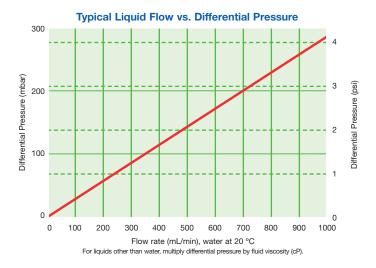
<sup>(2)</sup> • Pre-sterilized Mini Kleenpak capsules must not be re-sterilized.

 Mini Kleenpak capsules must not be sterilized *in-situ* by passing steam under pressure

 Water wet Supor EKV capsules prior to steaming to retain full water wettability for integrity testing

#### Typical Extractables in Water at 20 °C

< 5.0 mg per capsule



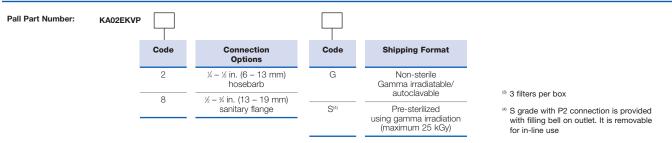
#### **Nominal Dimensions**

Maximum diameter including valves	53 mm (2.1 in.)
Length - Code 2	105 mm (4.1 in.)
Length - Code 8	73 mm (2.9 in.)

#### Nominal Effective Filter Area (EFA)

220 cm2 (0.24 ft2)

#### Ordering Information<sup>(3)</sup>





Filter Membrane	Hydrophilic PES
Support/Drainage	Polypropylene
End Cap, Core and Cage	Polypropylene
Capsule Shell	Polypropylene
Sealing Technology	Thermal bonding without adhesives

#### **Operating Parameters**<sup>(1)</sup>

Maximum Temperature	40 °C
Maximum Operating Pressure	5.2 bar (75 psi) at 20 °C 4.0 bar (58 psi) at 40 °C
Maximum Differential Pressure	4.0 bar (58 psi) at 40 °C

 $^{\scriptscriptstyle (1)}$  In compatible fluids which do not soften, swell or adversely affect the filter or its materials of construction

#### Sterilization<sup>(2)</sup>

Autoclave	5 x 60 minutes at 125 °C, slow exhaust
Gamma Irradiation	Maximum of 50 kGy

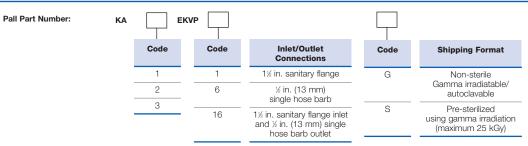
Pre-sterilized Kleenpak capsules must not be re-sterilized

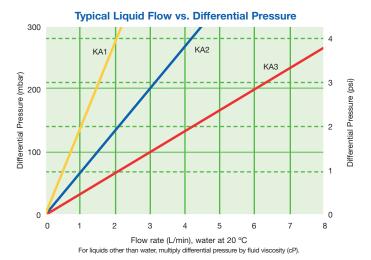
 Kleenpak capsules must not be sterilized *in-situ* by passing steam under pressure
Water wet Supor EKV capsules prior to steaming to retain full water wettability for integrity testing

#### Typical Extractables in Water at 20 °C

KA1 / KA2	< 5 mg per capsule		
КАЗ	< 10 mg per capsule		

#### **Ordering Information**





#### **Nominal Dimensions**

	KA1		KA2		KA3	
Diameter incl. Valves	94 mm	(3.7 in.)	94 mm	(3.7 in.)	105 mm	(4.1 in.)
Length - Code 1	117 mm	(4.6 in.)	157 mm	(6.2 in.)	174 mm	(6.8 in.)
Length - Code 6	157 mm	(6.2 in.)	197 mm	(7.7 in.)	210 mm	(8.3 in.)
Length - Code 16	137 mm	(5.4 in.)	177 mm	(7.0 in.)	192 mm	(7.6 in.)

#### Nominal Effective Filter Area (EFA)

KA1	375 cm <sup>2</sup> (0.4 ft <sup>2</sup> )
KA2	750 cm <sup>2</sup> (0.8 ft <sup>2</sup> )
КАЗ	1500 cm <sup>2</sup> (1.6 ft <sup>2</sup> )



Filter Membrane	Hydrophilic PES	
Support/Drainage	Polypropylene	
End Cap, Core and Cage	Polypropylene	
Capsule Bowl	Polyetherimide	
Sealing Technology	Thermal bonding without adhesives	
Housing Head	Polyetherimide with TiO <sub>2</sub>	
Operating Parameters <sup>(1)</sup>		
Maximum Temperature	60 °C	
Maximum Operating Pressure	6.5 bar (94 psi) at 40 °C 2.0 bar (29 psi) at 60 °C	
Maximum Differential Pressure	4.1 bar (60 psi) at 60 °C	

 $^{\scriptscriptstyle (1)}$  In compatible fluids which do not soften, swell or adversely affect the filter or its materials of construction

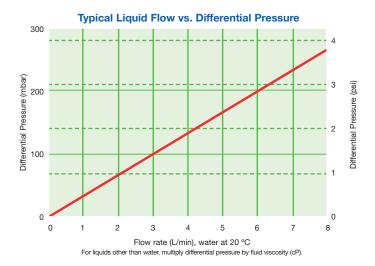
#### Sterilization<sup>(2)</sup>

Autoclave	5 x 60 minutes at 125 °C, slow exhaust
In-Line	5 x 60 minutes at 125 °C

 $^{\scriptscriptstyle (2)}$  Water wet Supor EKV capsules prior to steaming to retain full water wettability for integrity testing

#### Typical Extractables in Water at 20 °C

< 10 mg per capsule



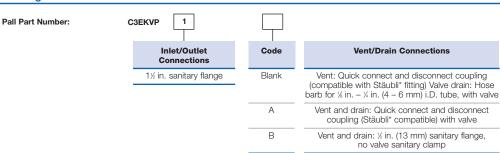
#### **Nominal Dimensions**

Diameter incl. Valves	123 mm (4.8 in.)
Overall Length	157 mm (6.2 in.)

#### Nominal Effective Filter Area (EFA)

1500 cm2 (1.6 ft2)

#### **Ordering Information**



# Kleenpak Nova Capsules

#### **Materials of Construction**

Filter Membrane	Hydrophilic PES
Support/Drainage	Polypropylene
Core/End Caps	Polypropylene
Cage	Polypropylene with TiO <sup>2</sup> (white colored)
O-rings	Silicone elastomer
Sealing Technology	Thermal bonding without adhesives
Housing Bowl	Polypropylene
Housing Head*	Polypropylene

\*Formulated with TiO<sub>2</sub> whitener which does not contribute to organic extractables

#### **Operating Parameters**<sup>(1)</sup>

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

<sup>(1)</sup> In compatible fluids which do not soften, swell or adversely affect the filter or its materials of construction

#### Typical Extractables in Water at 20 °C

< 25 mg after 4 hours extraction (per 254 mm module)

\*Tested on elements without pre-flushing

#### **Nominal Dimensions**

	In-line			
	NP6	NP7	NP8	
Maximum Diameter including valves 154 mm (6.1 in.)		154 mm (6.1 in.)	154 mm (6.1in.)	
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.)	

#### Sterilization<sup>(2)</sup>

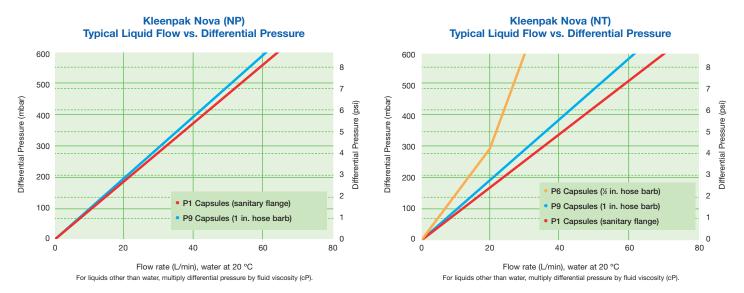
Autoclave:	1 x 60 minutes at 135 °C
Gamma irradiation:	Maximum of 50 kGy

Pre-sterilized Kleenpak Nova capsules must not be re-sterilized
Kleenpak Nova capsules must not be sterilized *in-situ* by passing steam under pressure

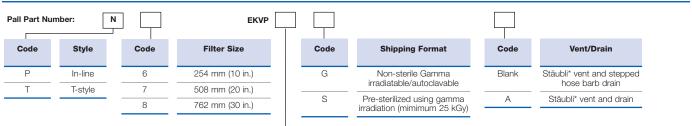
Water wet Supor EKV capsules prior to steaming to retain full water wettability for integrity testing

#### Nominal Effective Filter Area (EFA)

0.6 m<sup>2</sup> per 254 mm module (6.5 ft<sup>2</sup> per 10 in. module)



#### **Ordering Information**



Code	Connection Options
1	1 - 1% in. sanitary flange inlet and outlet
9	1 in. (25 mm) single barb hose barb inlet and outlet
19	1-1% in. sanitary flange inlet and 1 in. (25 mm) single barb hose barb outlet
6(1)	½ in. (13 mm) single barb hose barb inlet and outlet
16(1)	1-1% in. sanitary flange inlet and $%$ in. (13 mm) single barb hose barb outlet
1H <sup>(2)</sup>	1 – 1½ in. sanitary flange inlet and outlet, with ½ in. sanitary port on inlet
1 H9 <sup>(2)</sup>	1-1% in. sanitary flange inlet and 1 in. (25 mm) single barb hose barb outlet, with $%$ in. sanitary port on inlet

<sup>(1)</sup> For P-style only

(2) For T-style only

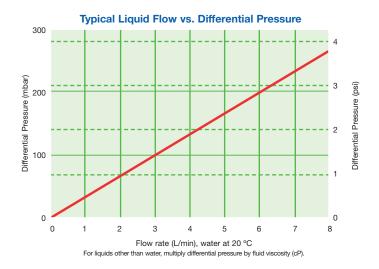


Filter Membrane	Hydrophilic PES
Support/Drainage	Polypropylene
End Cap, Core and Cage	Polypropylene
Sealing Technology	Thermal bonding without adhesives
O-rings	Silicone Elastomer

#### **Operating Parameters**<sup>(1)</sup>

Maximum Differential Pressure	5.2 bar (75 psi) at 40 °C

 $^{\scriptscriptstyle (1)}$  In compatible fluids which do not soften, swell or adversely affect the filter or its materials of construction



#### Typical Extractables in Water at 20 °C

< 10 mg per filter

#### Sterilization<sup>(2)</sup>

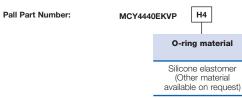
Autoclave	5 x 60 minutes at 125 °C, slow exhaust
In Situ Steam	30 x 60 minutes at 125 °C

 $^{\mbox{\tiny (2)}}$  Water wet Supor EKV capsules prior to steaming to retain full water wettability for integrity testing

#### Nominal Effective Filter Area (EFA)

1500 cm<sup>2</sup> (1.6 ft<sup>2</sup>)

#### **Ordering Information**





Filter Membrane	Hydrophilic PES
Support/Drainage	Polypropylene
Core/End Caps	Polypropylene
Cage	Polypropylene with TiO <sup>2</sup> (white colored)
O-rings	Silicone elastomer
Sealing Technology	Thermal bonding without adhesives

#### **Operating Parameters**<sup>(1)</sup>

Maximum Differential Pressure	5.5 bar (80 psi) at 40 °C
(Forward Direction)	4.0 bar (58 psi) at 80 °C
Maximum Differential Pressure (Reverse Direction)	2.0 bar (30 psi) at 40 °C

 $^{\scriptscriptstyle (1)}$  In compatible fluids which do not soften, swell, or adversely affect the filter or its materials of construction

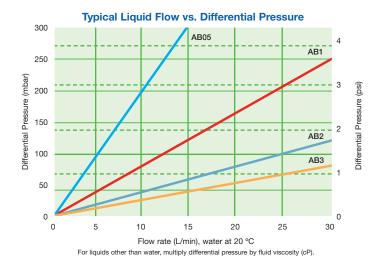
#### Sterilization<sup>(2)</sup>

Autoclave	30 x 60 minutes at 125°C, slow exhaust
In Situ Steam	30 x 60 minutes at 125 °C 5 x 60 minutes at 142 °C

 Water wet Supor EKV capsules prior to steaming to retain full water wettability for integrity testing

#### Typical Extractables in Water at 20 °C<sup>(3)</sup>

- < 25 mg after 4 hours extraction (per 254 mm module)
- <sup>(3)</sup> Tested on elements without pre-flushing



#### **Integrity Test Values:**

Values for 254 mm (10 inch) filter at 20°C		
Max. allowable Forward Flow	Water wet 17 mL/min	
(air test gas)	at 2760 mbar (40 psi)	

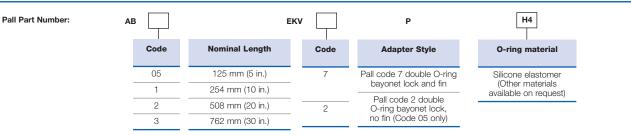
Contact Pall for multi-element integrity test values and recommended test procedures

#### Nominal Effective Filter Area (EFA)(4)

0.6 m<sup>2</sup> per 254 mm module (6.5 ft<sup>2</sup> per 10 in. module)

0.26 m<sup>2</sup> per 125 mm module (2.8 ft<sup>2</sup> per 5 in. module)

<sup>4)</sup> 5 in. filters are standard pleated.



#### **Ordering Information**



#### New York - USA

+1 516 484 5400 phone +1 516 801 9548 fax biotech@pall.com e-mail

#### Portsmouth - Europe

+44 (0)23 9230 3303 phone +44 (0)23 9230 2506 fax BioPharmUK@europe.pall.com e-mail

Filtration. Separation. Solution.sm



#### Visit us on the web at www.pall.com/biopharmaceutical

Pall Corporation has offices and plants throughout the world in locations including: Argentina, Australia, Austria, Belgium, Brazil, Canada, China, France, Germany, India, Indonesia, Ireland, Italy, Japan, Korea, Malaysia, Mexico, New Zealand, Norway, Poland, Puerto Rico, Russia, Singapore, South Africa, Spain, Sweden, Switzerland, Taiwan, Thailand, United Kingdom, the United States and Venezuela. Distributors are located in all major industrial areas of the world.

Because of developments in technology these data or procedures may be subject to change. (AL), Pall, Allegro, Kleenpak, Novasip and the Allegro design are trademarks of Pall Corporation. Filtration. Separation. Solution. and the UpScale logo are service marks of Pall Corporation. Stabilis is a trademark of Statibili.Part Numbers quoted above are protected by the Copyright of Pall Corporation. Is indicates a trademark registered in the USA. © 2008, Pall Corporation.