PALL Life Sciences

USD 2556a

Fluorodyne® EX Grade EDF Filter-

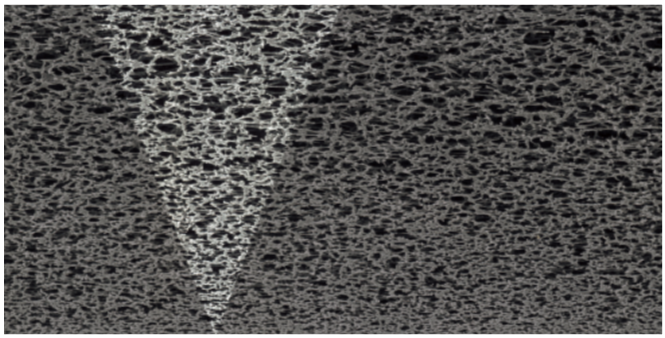
High-Capacity Sterility Control with Superior Value

Filtration. Separation. Solution.SM

Fluorodyne EX Grade EDF Filter Series

Fluorodyne EX grade EDF filters are high capacity, low protein binding sterilizing grade filters. Incorporating a built-in prefiltration layer and validated to retain *Brevundimonas diminuta* at a concentration of $\geq 10^7$ CFU/ cm^2 membrane (ATCC♦ 19146), Fluorodyne EX EDF grade filters are ideal for the sterile filtration of cell harvest material and challenging intermediate and final bulk biological process fluids.

A complete validation package for Fluorodyne EX grade EDF filters supports the assurance of safety within your process.



Scanning Electron Microscopy (SEM) of highly asymmetric membrane pre-filter layer

Highest Capacity

- Fluorodyne EX grade EDF filters feature a Mach*V* asymmetric polyethersulfone (PES) membrane pre-filter layer with high capacity for maximum throughput performance.

Faster Processing

- Combining Pall-patented Ultipleat® cartridge construction with a narrow core design, Fluorodyne EX grade EDF filters achieve a maximum filtration area for high flowrate, enabling smaller filtration systems for rapid and cost effective fluid processing.

High Yields, Low Extractables

- The downstream polyvinylidene fluoride sterilizing grade layer allows for sterilization in wet or dry conditions and ensures low leachables and low protein adsorption.

Allegro™ Systems: The Single-Use Solution

Cross-contamination elimination, assured sterility, reduction of manufacturing time and cost, and an improvement in flexibility are clear objectives for the biopharmaceutical industry. These factors, coupled with increasing titers in drug manufacturing, may demand a new approach.

Allegro single-use systems featuring Kleenpak™ filter capsules and sterile connectors eliminate the need for cleaning and associated validation efforts, minimize major capital investments, increase flexibility and provide high assurance of product safety.

We provide full support for our single-use systems including training and validation services, to facilitate their use from upstream bioreactor, to final formulation and filling.

With a comprehensive range of scalable products in the Fluorodyne EX grade EDF filter series and Pall Allegro product platform, single-use systems incorporating Fluorodyne EX grade EDF filters can be used to process volumes from 50 mL up to several thousand liters.

The Pall UpScale℠ Program

Save Time, Get Results

Fluorodyne EX grade EDF filters are available in a wide range of scalable, encapsulated formats that allow for fast and easy scale-up, helping you rapidly deliver your products to the market.

Same Materials

From laboratory-scale filters to production-scale assemblies, all Fluorodyne EX grade EDF filter products incorporate the same membrane and identical materials of construction, eliminating the need to requalify filter units as processes are scaled up.

Quality

Every Fluorodyne EX grade EDF 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 after flushing
  - Is non-fiber-releasing
  - Is non-pyrogenic per USP endotoxins (< 0.25 EU/mL)
  - Meets Total Organic Carbon (TOC) and water conductivity per USP Purified Water after flushing

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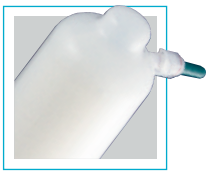


High Area Kleenpak Nova Capsules Page 10-11

Mini Kleenpak Syringe Filters

Materials of Construction

Filter Membrane	**Prefilter Layer:** Hydrophilic asymmetric PES **Final Filter Layer:** Hydrophilic PVDF
Housing, Vent Plug and Support Material	Polypropylene
Sealing Technology	Insert molding

Operating Parameters[1]

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

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

Sterilization[2]

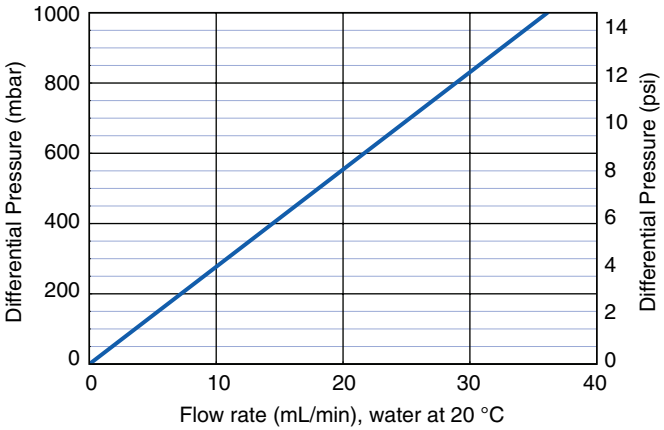
Pre-sterilized, subject to a minimum of 25 kGy of gamma irradiation

[2] • 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

Typical Hold up Volume

< 100 µL

Typical Liquid Flow vs. Differential Pressure



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

Nominal Dimensions

Capsule Length	21 mm (0.8 in.)
Capsule Diameter	29 mm (1.2 in.)

Nominal Effective Filter Area (EFA)

2.8 cm^2 (0.43 $in.^2$)

Connection

Female Luer-lok◆ inlet, male slip Luer outlet

Ordering Information[3]

Pall Part Number: KM2EDF **S**

Shipping Format
Pre-sterilized using gamma irradiation

[3] 50 filters per box

Mini Kleenpak 20 Capsules

Materials of Construction

Filter Membrane	Prefilter Layer: Hydrophilic asymmetric PES Final Filter Layer: Hydrophilic PVDF
Housing, Vent Plug and Support Material	Polypropylene
Filling Bell	Polycarbonate
Sealing Technology	Thermal bonding without adhesives

Operating Parameters[1]

Maximum Operating Temperature and Pressure	1.4 bar (20 psi) at 20 °C

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

Sterilization[2]

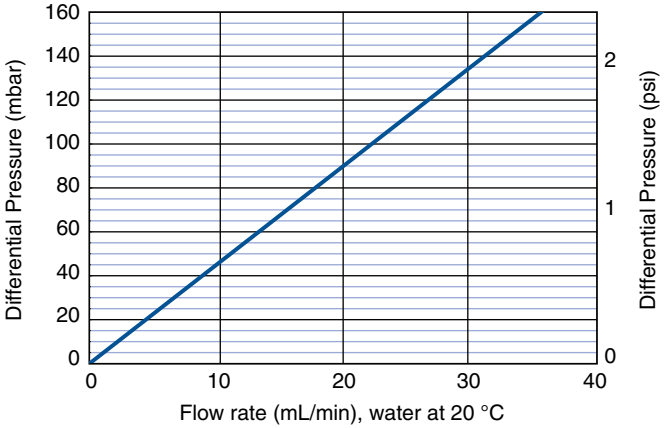
Pre-sterilized, subject to a minimum of 25 kGy of gamma irradiation

[2] • Pre-sterilized Mini Kleenpak 20 filters must not be re-sterilized
• Mini Kleenpak filters must not be sterilized in-situ by passing steam under pressure

Typical Hold up Volume

< 2.5 mL

Typical Liquid Flow vs. Differential Pressure



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

Nominal Dimensions

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

Nominal Effective Filter Area (EFA)

20 cm^2 (3.1 $in.^2$)

Ordering Information[3]

Pall Part Number: **KM5 EDF P** **2** **S**

2 – Connection	S – Shipping Format
¼ – ½ in. (6 – 13 mm) stepped hose barb. Inner bore to accept female slip luer interior and outer diameter to accept filling bell outlet	Pre-sterilized using gamma irradiation

[3] 3 filters per box

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Mini Kleenpak Capsules

Materials of Construction

Filter Membrane	Prefilter Layer: Hydrophilic asymmetric PES Final Filter Layer: Hydrophilic PVDF
Support/Drainage	Polypropylene
Capsule Shell	Polypropylene
Core and Endcaps	Polypropylene
Filling Bell	Polycarbonate
Sealing Technology	Thermal bonding without adhesives

Operating Parameters[1]

Maximum Operating Temperature	40 °C
Maximum Differential Pressure	4.1 bar (60 psi) at 38 °C

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

Sterilization[2]

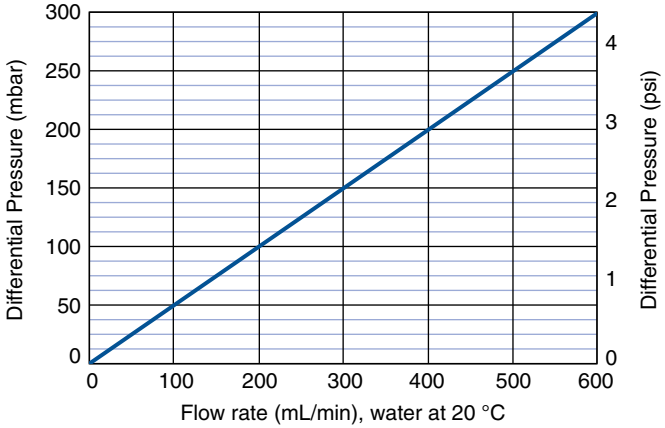
Autoclave 'G' option	3 x 30 minutes at 135 °C
Gamma Irradiation 'G' option	Maximum of 50 kGy

[2] • *Pre-sterilized Mini Kleenpak capsules must not be re-sterilized.*
• *Mini Kleenpak capsules must not be sterilized in-situ by passing steam under pressure*

Typical Extractables in Water at 20 °C

< 5 mg for the non-irradiated filter capsule

Typical Liquid Flow vs. Differential Pressure



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

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)

230 cm^2 (0.25 ft^2)

Ordering Information[3]

Pall Part Number: **KA02EDFP** ☐ ☐

Code	Connection Options
2	¼ - ½ in. (6 - 13 mm) hosebarb
8	½ - ¾ in. (13 - 19 mm) sanitary flange

Code	Shipping Format
G	Non-sterile gamma irradiatable/ autoclavable
S[4]	Pre-sterilized using gamma irradiation

[3] *3 filters per box*

[4] *'S' option with Code 2 connection is provided with filling bell on outlet. It is removable for in-line use*

Kleenpak Capsules

Materials of Construction

Filter Membrane	Prefilter Layer: Hydrophilic asymmetric PES Final Filter Layer: Hydrophilic PVDF
Support/Drainage	Polypropylene
End Cap, Core and Cage	Polypropylene
Capsule Shell	Polypropylene
Sealing Technology	Thermal bonding without adhesives

Operating Parameters[1]

Maximum Operating 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

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

Sterilization[2]

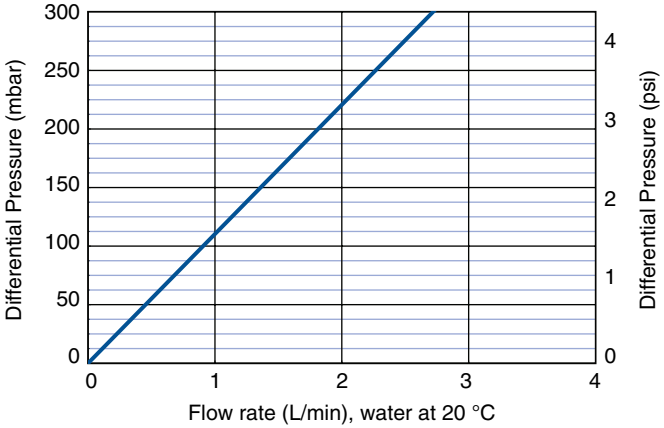
Autoclave 'G' option	5 x 60 minutes at 125 °C
Gamma Irradiation 'G' option	Maximum of 50 kGy

[2] • *Pre-sterilized Kleenpak capsules must not be re-sterilized*
• *Kleenpak capsules must not be sterilized* ***in-situ*** *by passing steam under pressure*

Typical Extractables in Water at 20 °C

< 10 mg per capsule

Typical Liquid Flow vs. Differential Pressure



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

Nominal Dimensions

Capsule Length	157 mm (6.2 in.)
Capsule Diameter including valves	94 mm (3.7 in.)

Nominal Effective Filter Area (EFA)

750 cm^2 (0.8 ft^2)

Ordering Information

Pall Part Number: **KA2 EDF P** [1] [ ]

Inlet/Outlet Connections	Code	Shipping Format
1½ in. sanitary flange	G	Non-sterile gamma irradiatable/ autoclavable
	S	Pre-sterilized using gamma irradiation

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High Area Filter Cartridges

Materials of Construction

Filter Membrane	Prefilter Layer: Hydrophilic asymmetric PES Final Filter Layer: Hydrophilic PVDF
Support/Drainage	Polypropylene
Core/End Caps	Polypropylene
Cage	Polypropylene with TiO_2 whitener[1]
O-rings	Silicone elastomer
Sealing Technology	Thermal bonding without adhesives

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

Operating Parameters[2]

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

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

Sterilization

Autoclave or In Situ Steam[3]	5 x 60 minutes at 135°C

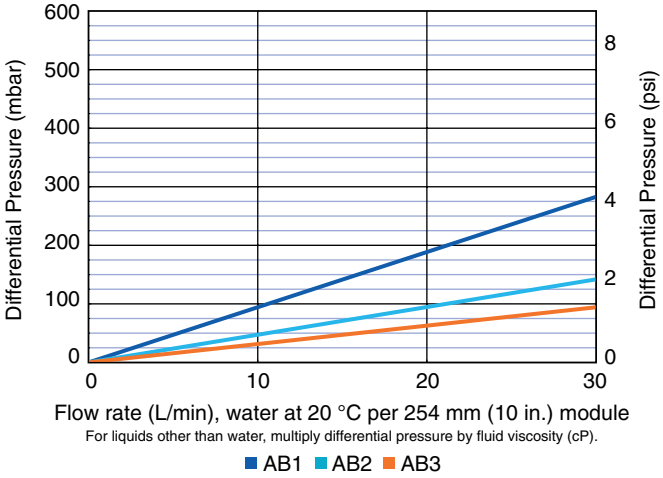
[3] Maximum differential pressure 1 bar in forward direction

Typical Extractables in Water at 20 °C[4]

< 50 mg after 4 hours extraction (per 254 mm module)

[4] Tested on elements without pre-flushing

Typical Liquid Flow vs. Differential Pressure



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

Values for 254 mm (10 in.) filter at 20°C	
Max. allowable Forward Flow (air test gas)	Water wet 30 mL/min at 2760 mbar (40 psi)

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

Nominal Effective Filter Area (EFA)

1.1 m^2 per 254 mm module (11.8 ft^2 per 10 in. module)

Ordering Information

Pall Part Number: AB [ ] UEDF [7] P [H4]

Code	Nominal Length
1	254 mm (10 in.)
2	508 mm (20 in.)
3	762 mm (30 in.)

Adapter Style: Pall code 7 double O-ring bayonet lock and fin (other fittings available on request)

O-ring material: Silicone elastomer (other materials available on request)

High Area Kleenpak Nova Capsules

Materials of Construction

Filter Membrane	Prefilter Layer: Hydrophilic asymmetric PES Final Filter Layer: Hydrophilic PVDF
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	Polypropylene with TiO_2 whitener[1]

[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 after 4 hours extraction (per 254 mm module)

[4] Tested on elements without pre-flushing

Nominal Effective Filter Area (EFA)

1.1 m^2 per 254 mm module (11.8 ft^2 per 10 in. module)

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

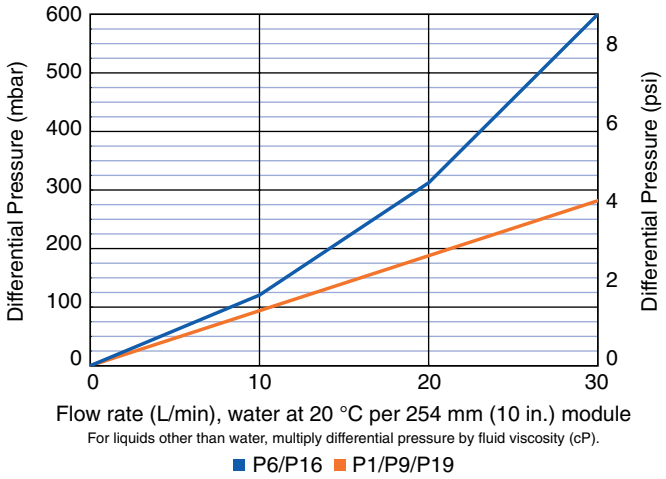
Values for 254 mm (10 in.) capsule at 20°C	
Max. allowable Forward Flow (air test gas)	Water wet 30 mL/min at 2760 mbar (40 psi)

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

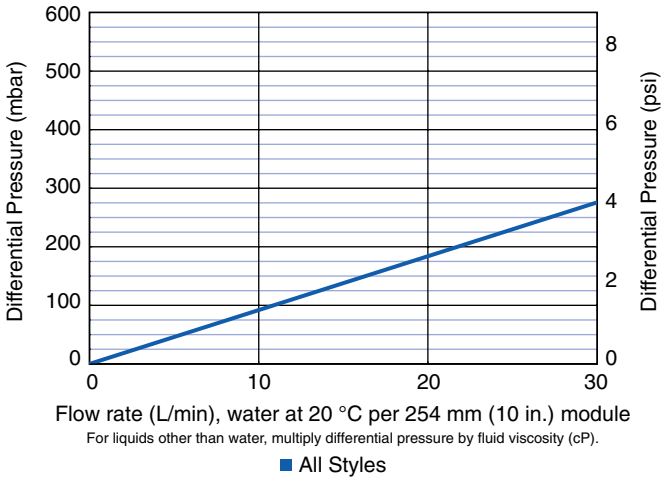
Nominal Dimensions

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

Pall Part Number: N ☐ ☐ UEDF P ☐ ☐ ☐

Code	Style
P	In-line
T	T-style

Code	Filter Size
6	254 mm (10 in.)
7	508 mm (20 in.)
8	762 mm (30 in.)

Code	Shipping Format
Blank	Non-sterile autoclavable
G	Non-sterile gamma irradiatable/ autoclavable
S	Pre-sterilized using gamma irradiation

Code	Vent/Drain
Blank	Stäubli◆ vent and stepped hose barb drain
A	Stäubli vent and drain

Code	Inlet/Outlet Connections
1	1 – 1½ in. sanitary flange inlet and outlet
9	1 in. (25 mm) single barb hose barb inlet and outlet
19	1 – 1½ 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 – 1½ in. sanitary flange inlet and ½ in. (13 mm) single barb hose barb outlet
1H[2]	1 – 1½ in. sanitary flange inlet and outlet, with ½ in. sanitary port on inlet
1H9[2]	1 – 1½ in. sanitary flange inlet and 1 in. (25 mm) single barb hose barb outlet with ½ in. sanitary port on inlet

[1] For In-line (Code P) only

[2] For T-style (Code T) only

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The information provided in this literature was reviewed for accuracy at the time of publication. Product data may be subject to change without notice. For current information consult your local Pall distributor or contact Pall directly.

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