Fluorodyne™ EX

GRADE EDF FILTER SERIES

High-capacity sterility control with exceptional value

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 10^7 CFU/ cm^2 membrane (ATCC 19146), Fluorodyne EX EDF grade filters are suitable 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 safer practices within your process.

High capacity

Fluorodyne EX grade EDF filters feature a MachV asymmetric polyethersulfone (PES) membrane prefilter layer with high capacity for optimized throughput performance.

Faster processing

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

High yields, low extractables

The downstream polyvinylidene fluoride (PVDF) sterilizing grade layer allows for sterilization in wet or dry conditions and supports low leachables and low protein adsorption.

Fig 1. Fluorodyne EX grade EDF filters are available in a range of sizes and styles.

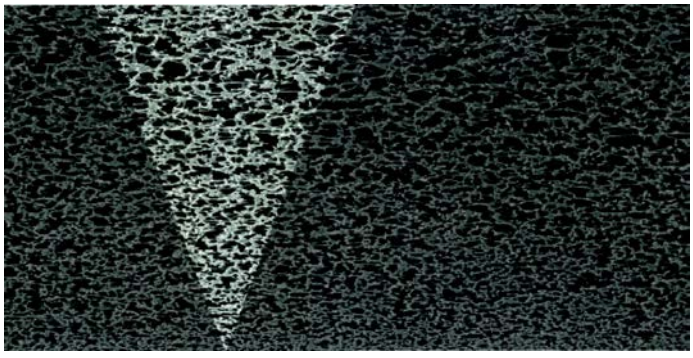


Fig 2. Scanning electron microscopy (SEM) of highly asymmetric membrane prefilter layer.

Allegro™ systems: the single-use solution

Cross-contamination elimination, 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 different approach.

Allegro single-use systems featuring Kleenpak™ filter capsules and sterile connectors eliminate the need for cleaning and associated validation efforts, and can reduce major capital investments, increase flexibility and support safer products.

We provide 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 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 Cytiva 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 to more 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 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

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

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 lock inlet, male slip luer outlet

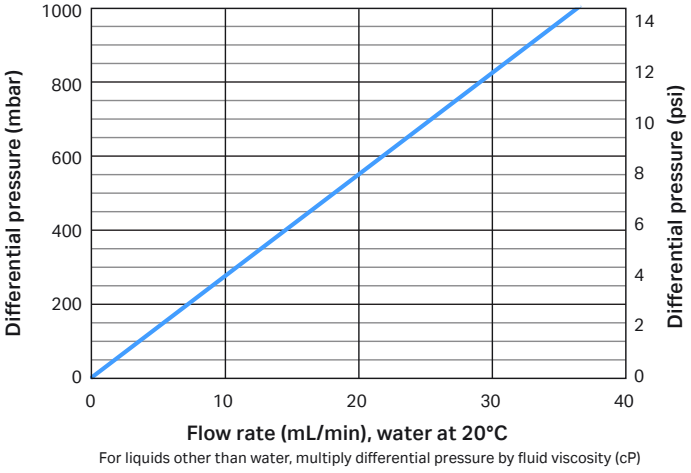


Fig 3. Typical liquid flow vs differential pressure.

Ordering information [3]

Product code: 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 [4]	
Maximum operating temperature and pressure	1.4 bar (20 psi) at 20°C

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

Sterilization [5]

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

[5] Pre-sterilized Mini Kleenpak 20 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

< 2.5 mL

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 $in.^2$)

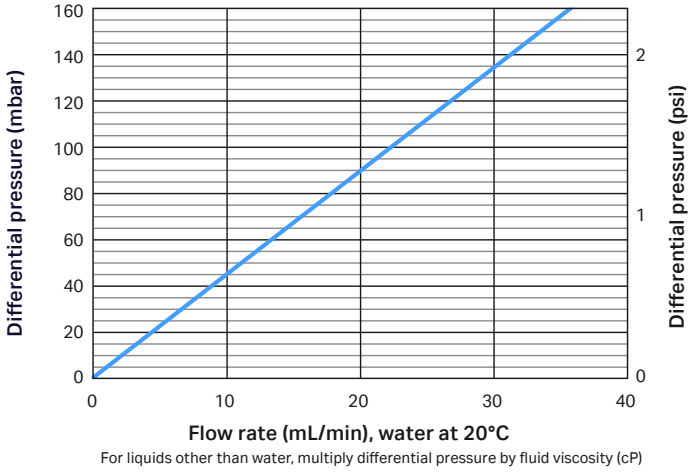


Fig 4. Typical liquid flow vs differential pressure.

Ordering information [6]

Product code: KM5EDFP 2 S

Connection	Shipping format
¼ to ½ in. (6 to13 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

[6] 3 filters per box

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 end caps	Polypropylene
Filling bell	Polycarbonate
Sealing technology	Thermal bonding without adhesives

Operating parameters [7]	
Maximum operating temperature	40°C
Maximum differential pressure	4.1 bar (60 psi) at 38°C

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

Sterilization [8]	
Autoclave 'G' option	3 × 30 minutes at 135°C
Gamma irradiation 'G' option	Maximum of 50 kGy

[8] 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

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)

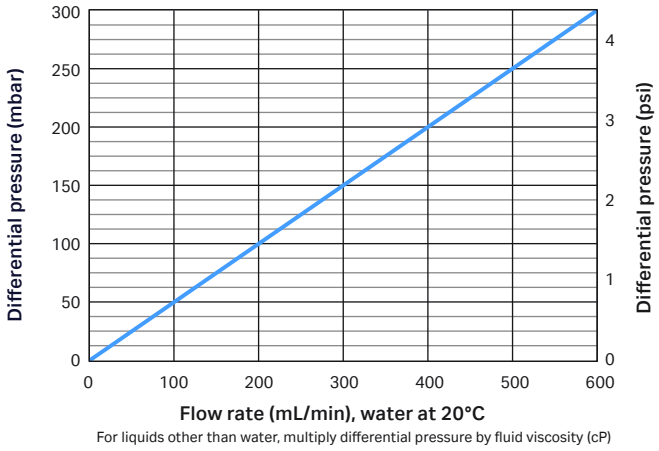


Fig 5. Typical liquid flow vs differential pressure.

Ordering information [9]

Product code: KA02EDFP ☐ ☐

Code	Connection options	Code	Shipping format
2	¼ to ½ in. (6 to 13 mm) hosebarb	G	Non-sterile gamma irradiatable/ autoclavable
8	½ to ¾ in. (13 to 19 mm) sanitary flange	S [10]	Pre-sterilized using gamma irradiation

[9] 3 filters per box
[10] 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 [11]	
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

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

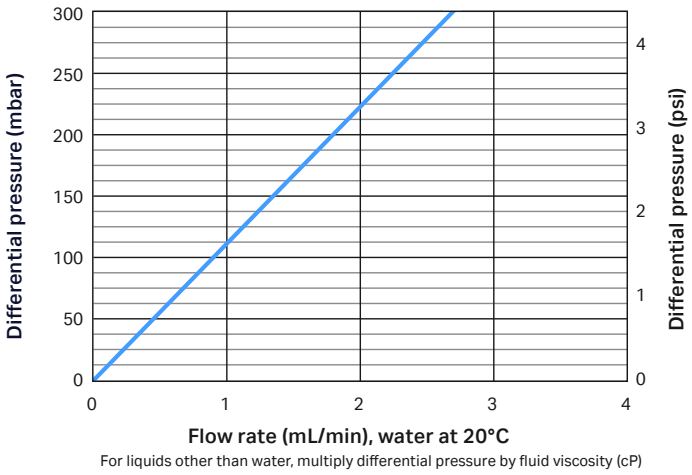
Sterilization [12]	
Autoclave 'G' option	5 × 60 minutes at 125°C
Gamma irradiation 'G' option	Maximum of 50 kGy

[12] 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

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)



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

Fig 6. Typical liquid flow vs differential pressure.

Ordering information

Product code: 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

High-area filter cartridges

Materials of construction	
Filter membrane	Prefilter layer: hydrophilic asymmetric PES
	Final filter layer: hydrophilic PVDF
Support/drainage	Polypropylene
Core and end caps	Polypropylene
Cage	Polypropylene with TiO_2 whitener [13]
O-rings	Silicone elastomer
Sealing technology	Thermal bonding without adhesives

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

Operating parameters [14]	
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

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

Sterilization	
Autoclave or *in situ* steam [15]	5 × 60 minutes at 135°C

[15] Maximum differential pressure 1 bar in forward direction.

Typical extractables in water at 20°C [16]
< 50 mg after 4 hours extraction (per 254 mm module)

[16] Tested on elements without pre-flushing.

Integrity test values (air test gas, water wet) [17]	
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)

[17] Contact us 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)

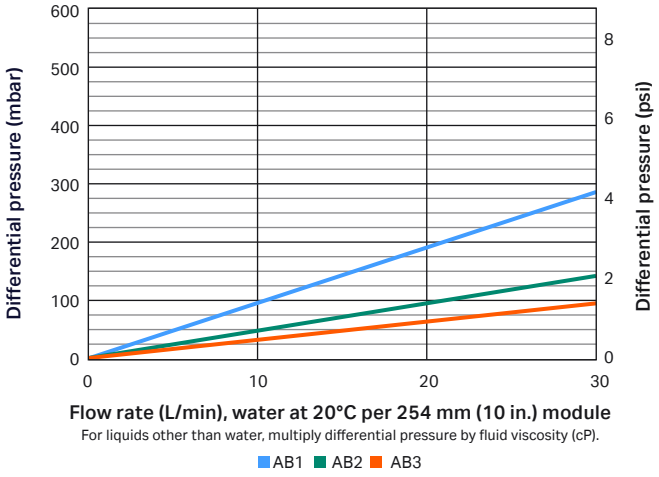


Fig 7. Typical liquid flow vs. differential pressure.

Ordering information

Product code: 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: 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 [18]
O-rings	Silicone elastomer
Sealing technology	Thermal bonding without adhesives
Housing bowl	Polypropylene
Housing head	Polypropylene with TiO_2 whitener [18]

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

Operating parameters [19]

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

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

Sterilization [20]

Autoclave (G option only)	1 × 60 minutes at 135°C
Gamma irradiation (G option only)	Maximum of 50 kGy

[20] 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 [21]

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

[21] 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) [22]

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)

[22] Contact us 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.)

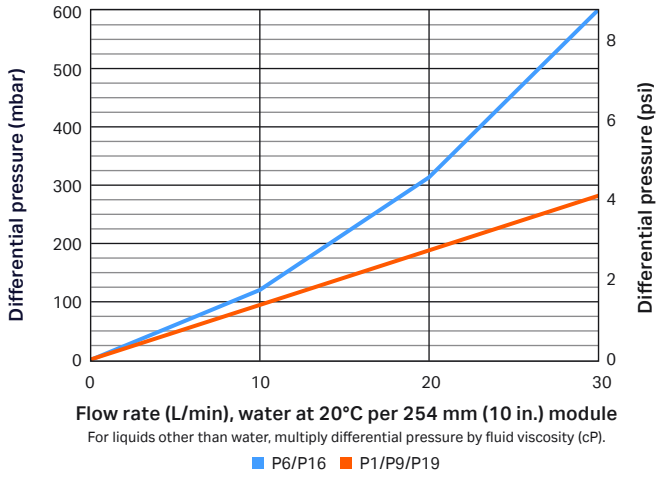


Fig 8. Kleenpak Nova in-line capsules (NP) typical liquid flow vs differential pressure

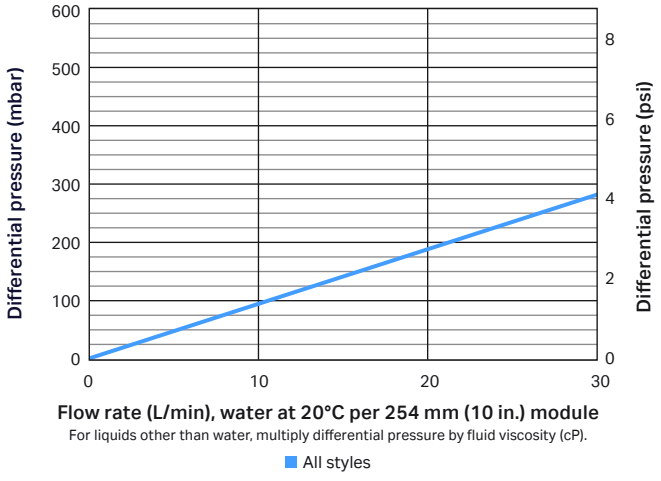


Fig 9. Kleenpak Nova T-style capsules (NT) typical liquid flow vs differential pressure.

Ordering information

Product code: 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 to 1½ in. sanitary flange inlet and outlet
9	1 in. (25 mm) single barb hose barb inlet and outlet
19	1 to 1½ in. sanitary flange inlet and 1 in. (25 mm) single barb hose barb outlet
6 [23]	½ in. (13 mm) single barb hose barb inlet and outlet
16 [23]	1 to 1½ in. sanitary flange inlet and ½ in. (13 mm) single barb hose barb outlet
1H [24]	1 to 1½ in. sanitary flange inlet and outlet, with ½ in. sanitary port on inlet
1H9 [24]	1 to 1½ in. sanitary flange inlet and 1 in. (25 mm) single barb hose barb outlet with ½ in. sanitary port on inlet

[23] For in-line (code P) only
[24] For T-style (code T) only

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