



Life Sciences

USD 2561

Fluorodyne[®] EX Grade EDT Filters

Unrivalled Mycoplasma Control with Superior Value



Filtration. Separation. Solution.SM

Fluorodyne EX Grade EDT Filters

Pall's Fluorodyne EX grade EDT filter is a highly retentive mycoplasma control filter to be used where the sterility assurance and economical filtration of culture media or other hard-to-filter fluids is paramount.

A unique **three-layer construction** contributes to outstanding throughput, high flow rates and the superior retention of bacteria and mycoplasma during the filtration of process fluids.

The Pall patented Ultipleat® modular cartridge pleating design in combination with a narrow core ensures high effective filtration areas, small foot-print filter systems and improved process efficiencies. A complete validation package supports the assurance of safety within your process.



Built in Supor® Mach V pre-filtration

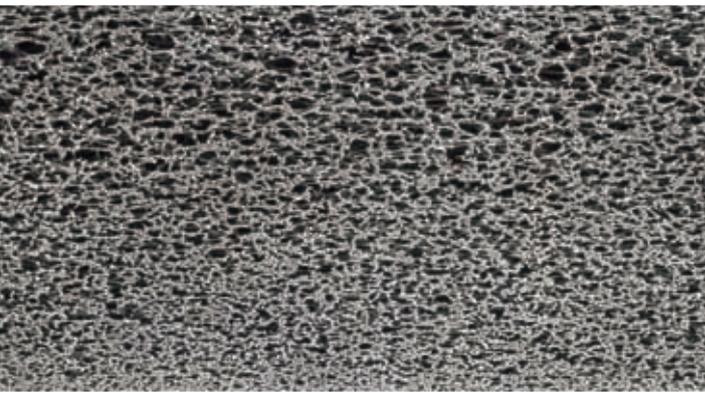
- ▶ The built-in proprietary pre-filtration layer is a highly asymmetric polyethersulfone membrane with a large dirt holding capacity for maximum flow and throughput performance.

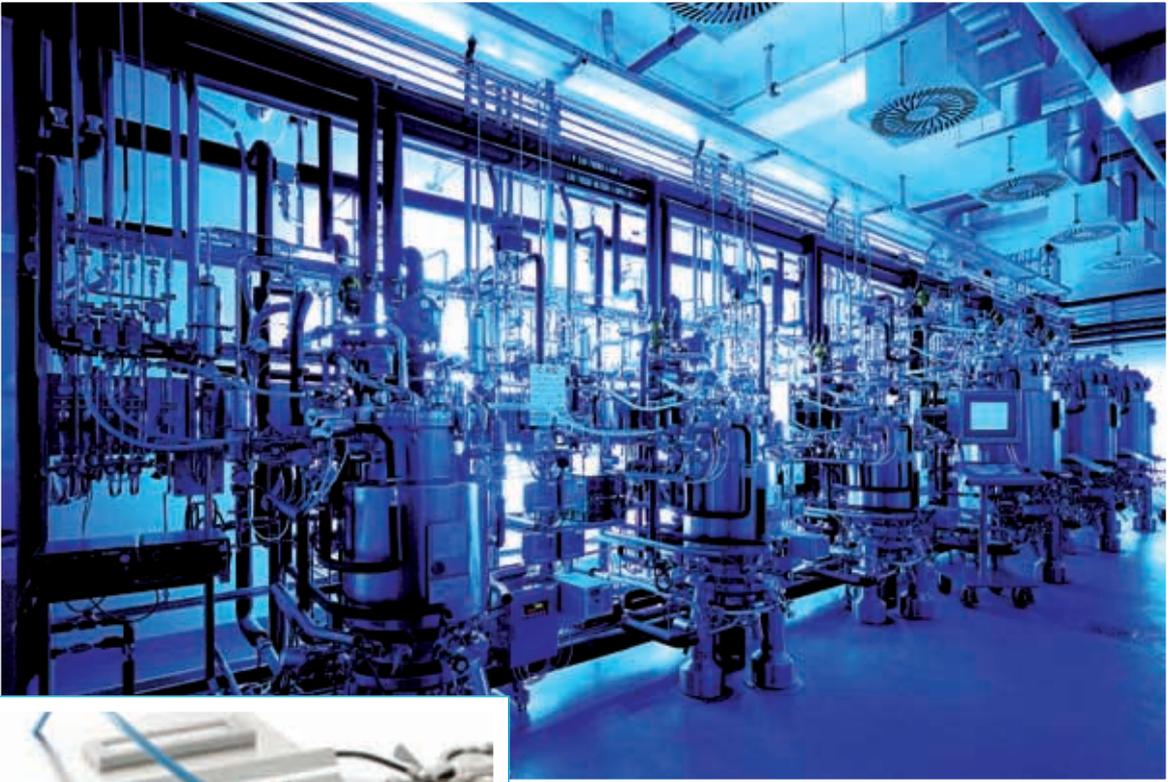
Ultipleat and narrow core design

- ▶ With a Pall patented Ultipleat construction in combination with narrow core design, Fluorodyne EX grade EDT filters achieve a maximum filtration area for high flow rates and throughput, enabling smaller filtration systems with easy and cost effective fluid processing.

Unique hybrid construction

- ▶ The downstream PVDF sterilizing grade layers allow for sterilization in wet or dry conditions and contribute to low extractables and low protein adsorption.





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2D matrix marking

- ▶ High area “AB-Style” EDT grade filter formats are laser marked, allowing for filter module serial numbers and lot codes to be read electronically, helping to save time and reduce the potential for human error when recording important filter information.



Allegro™ Systems: Disposable Solutions

Elimination of cross-contamination, assured sterility, reduction of manufacturing time and costs, and greater flexibility are clear objectives for the biopharmaceutical industry. These drivers, coupled with increasing titers in drug manufacturing, require new approaches.

Pall Allegro single-use systems, which incorporate Pall Kleenpak™ filter capsules, provide the solution to these industry drivers. Allegro single-use systems eliminate the need for cleaning and associated validation efforts, minimize major capital investments, increase flexibility and provide high assurance of product safety.

Pall provides 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 full range of scalable products in the Fluorodyne EX grade EDT filter range and Pall Allegro product platform, single-use systems incorporating EDT grade filters can be used to process several milliliters up to large production scale volumes.

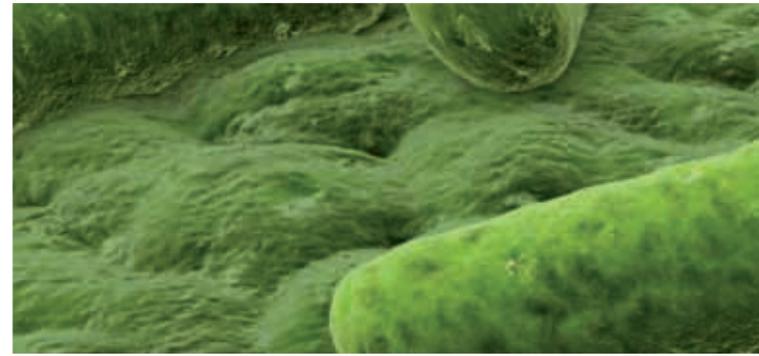


Filter Validation Package

The performance of Fluorodyne EX grade EDT filters is supported by a comprehensive validation package. Its mycoplasma and bacterial removal capabilities are documented with data generated from studies with industry standard bacteria and mycoplasma typically associated with human, plant and animal derived material.



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Brevundimonas diminuta (ATCC* 19146)

- ▶ This bacterium is the standard challenge organism for qualifying sterilizing grade filters. *B. diminuta* is a well-suited model organism, as it penetrates 0.45 µm rated filters, is easy to culture to a high concentration and has demonstrated proven reliability in the laboratory.
 - Fluorodyne EX grade EDT filters produce sterile effluent when challenged with $> 10^7$ cfu *B. diminuta* per cm² effective filtration area.

If specific process validation is required, the performance of the filter should be proven with *B. diminuta* or a relevant bioburden isolate.



Acholeplasma laidlawii (ATCC 23206)

- ▶ This mycoplasma has been used as a standard challenge organism model for 0.1 μm rated filters for almost 30 years. It was selected based on recognition as a penetrant of 0.2 μm sterilizing grade filters in water, serum and soy-derived culture media. It is ubiquitous, being isolated from environmental, animal and human sources and is easy to culture relative to many other mycoplasma.
- Grade EDT provides ≥ 10 log removal efficiency

Mycoplasma orale (ATCC 23714)

- ▶ This mycoplasma was selected as a human-associated isolate and typical contaminant of serum-supplemented cell culture media. Its use as a challenge model is intended to address questions regarding the suitability of *A. laidlawii* as a predictive model for qualifying 0.1 μm rated filters where mycoplasma contamination may come from human operators.
- Grade EDT provides ≥ 10 log removal efficiency

The Pall UpScaleSM Program

Save time, get results

Fluorodyne EX grade EDT 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 small scale disc filters to high area filters, all products incorporate the same membrane and identical materials of construction.

Quality

Every Fluorodyne EX EDT 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 (TOC) and water conductivity per USP purified water.






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Kleenpak Capsules
Coming Soon



Kleenpak Nova
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47mm Disc Filters with Fluorodyne EX EDT Media

Materials of Construction

Filter Membrane

Prefilter Layer:
Hydrophilic asymmetric PES

Final Filter Layers:
Hydrophilic PVDF

Sterilization

Autoclave

1 x 60 minutes at 135 °C

Recommended Integrity Test

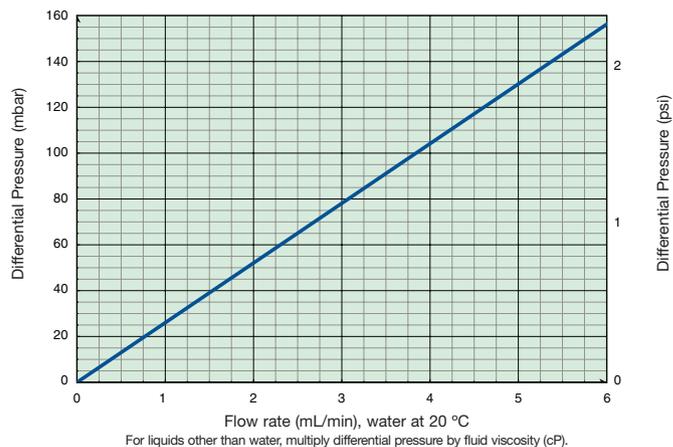
< 5170 mbar

Typical Effective Filter Area (EFA)⁽¹⁾

12.5 cm² (1.9 in.²)

⁽¹⁾ When used in Pall standard test housing. Refer to Pall for housing details.

Typical Liquid Flow vs. Differential Pressure



Ordering Information⁽²⁾

Pall Part Number: EDT04725

⁽²⁾ 25 discs per box

Mini Kleenpak Capsules with Fluorodyne EX EDT Media

Materials of Construction

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

Operating Parameters⁽¹⁾

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

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

Sterilization⁽²⁾

Autoclave	3 x 30 minutes at 135 °C
Gamma Irradiation	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

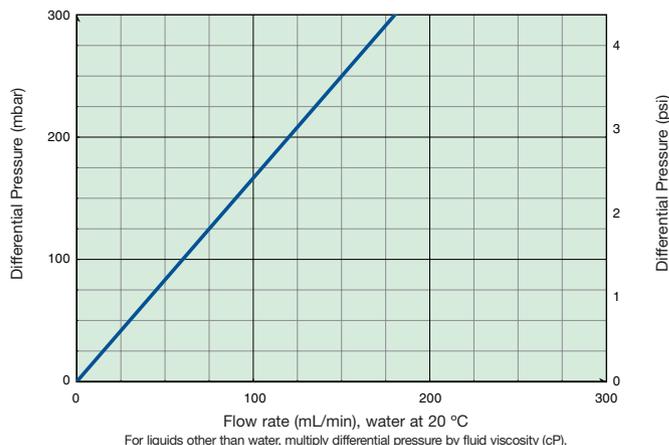
< 20 mg for the non-irradiated filter capsule

Ordering Information⁽³⁾

Pall Part Number: KA02EDT2FT

⁽³⁾ Filterability tool for sizing studies

Typical Liquid Flow vs. Differential Pressure



Nominal Dimensions

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

Nominal Effective Filter Area (EFA)

200 cm² (0.22 ft²)

Kleenpak Nova Capsules with Fluorodyne EX EDT Media

Materials of Construction

Filter Membrane	Prefilter Layer: Hydrophilic asymmetric PES
	Final Filter Layers: Hydrophilic PVDF
Support/Drainage	Polypropylene
Core/End Caps	Polypropylene
Cage	Polypropylene with TiO ₂ (white colored)
O-rings	Silicone elastomer
Sealing Technology	Thermal bonding without adhesives
Housing Bowl	Polypropylene
Housing Head ⁽¹⁾	Polypropylene

⁽¹⁾ Formulated with TiO₂ whitener which does not contribute to organic extractables

Typical Extractables in Water at 20 °C⁽²⁾

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

⁽²⁾ 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 (6.1 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.)

Operating Parameters⁽³⁾

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

⁽³⁾ In compatible fluids which do not soften, swell or adversely affect the filter or its materials of construction

Sterilization⁽⁴⁾

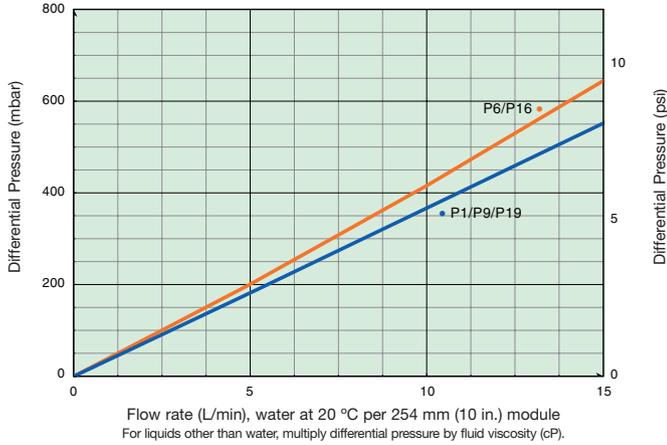
Autoclave "G" version	3 x 30 minutes at 135 °C
Gamma Irradiation "G" version	Maximum of 50 kGy

- ⁽⁴⁾ • Pre-sterilized Kleenpak Nova capsules must not be re-sterilized
- Kleenpak Nova capsules must not be sterilized in-situ by passing steam under pressure

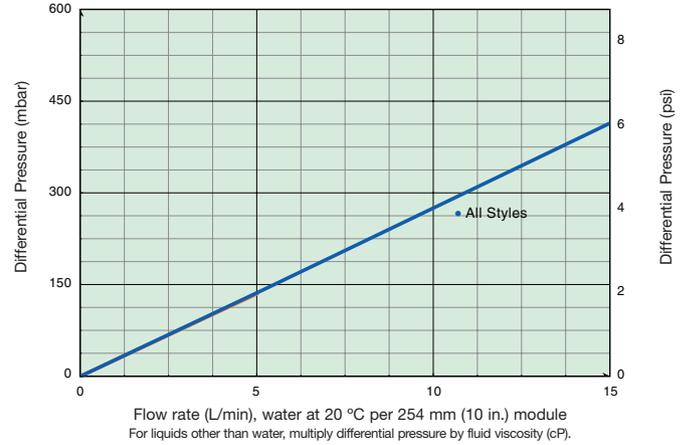
Nominal Effective Filter Area (EFA)

0.95 m² per 254 mm module (9.7 ft² per 10 in. module)

Kleenpak Nova (NP) Typical Liquid Flow vs. Differential Pressure



Kleenpak Nova (NT) Typical Liquid Flow vs. Differential Pressure



Ordering Information

Pall Part Number:

<input type="checkbox"/>								
N	Code	Style	Code	Filter Size	Code	Shipping Format	Code	Vent/Drain
	P	In-line	6	254 mm (10 in.)	G	Non-sterile gamma irradiatable/ autoclavable	Blank	Stäubli* vent and stepped hose barb drain
	T	T-style	7	508 mm (20 in.)	S	Pre-sterilized using gamma irradiation (minimum 25 kGy)	A	Stäubli* vent and drain
			8	762 mm (30 in.)				

Code	Connection Options
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

AB-Style Filter Cartridges with Fluorodyne EX EDT Media

Materials of Construction

Filter Membrane	Prefilter Layer: Hydrophilic asymmetric PES
	Final Filter Layers: Hydrophilic PVDF
Support/Drainage	Polypropylene
Core/End Caps	Polypropylene
Cage	Polypropylene
O-rings	Silicone
Sealing Technology	Thermal bonding without adhesives

Operating Parameters⁽¹⁾

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

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

Sterilization

Autoclave	5 x 60 minutes at 135°C
In Situ Steam	5 x 60 minutes at 135°C

Typical Extractables in Water at 20 °C⁽²⁾

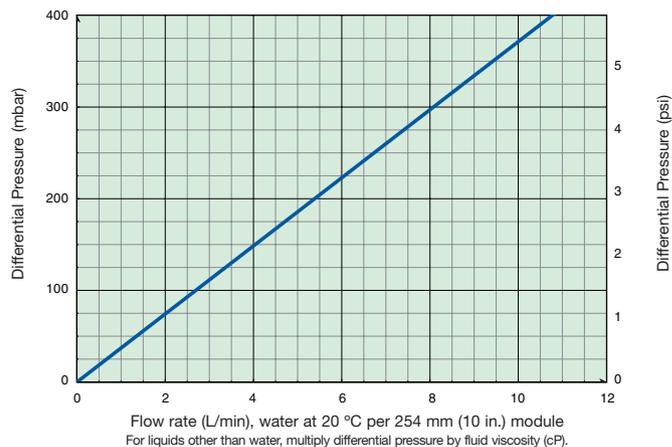
< 50 mg after 24 hours extraction (per 254 mm module)

⁽²⁾ Tested on elements without pre-flushing

Ordering Information

Pall Part Number:	AB	EDT	P	H4
	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
	Code	Code	Filter Media	O-ring Material
	1	7	Pall code 7 double O-ring bayonet lock and fin	Silicone elastomer (Other materials available on request)
	2			
	3			
	Nominal Length			
	254 mm (10 in.)			
	508 mm (20 in.)			
	762 mm (30 in.)			

Typical Liquid Flow vs. Differential Pressure



Integrity Test Values (Air test gas, water wet)

Values for 254 mm (10 in.) filter at 20 °C

Max. allowable Forward Flow (air test gas)	Water wet 32 mL/min at 4475 mbar (65 psi)
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Contact Pall for multi-element integrity test values and recommended test procedures

Nominal Effective Filter Area (EFA)

9500 cm² (10.2 ft²) per 254 mm (10 in.) module



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