Fluorodyne® EX Grade EDT Filters

Unrivalled Mycoplasma Control with Superior Value
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® MachV 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.
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.

**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.
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

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
The Pall UpScale℠ 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 inInjectables
  - 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.
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.

Ordering Information(2)

Pall Part Number: EDT04725

(2) 25 discs per box

Typical Liquid Flow vs. Differential Pressure

For liquids other than water, multiply differential pressure by fluid viscosity (cP).
Mini Kleenpak Capsules with Fluorodyne EX EDT Media

**Materials of Construction**

<table>
<thead>
<tr>
<th>Filter Membrane</th>
<th>Prefilter Layer:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Hydrophilic asymmetric PES</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Final Filter Layers:</th>
<th>Support/Drainage</th>
<th>Capsule Shell</th>
<th>Filling Bell</th>
<th>Sealing Technology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrophilic PVDF</td>
<td>Polypropylene</td>
<td>Polypropylene</td>
<td>Polycarbonate</td>
<td>Thermal bonding without adhesives</td>
</tr>
</tbody>
</table>

**Operating Parameters**(1)

<table>
<thead>
<tr>
<th>Maximum Temperature</th>
<th>40 °C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum Operating Pressure</td>
<td>4.1 bar (60 psi) at 40 °C</td>
</tr>
<tr>
<td>Maximum Differential Pressure</td>
<td>4.1 bar (60 psi) at 40 °C</td>
</tr>
</tbody>
</table>

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

**Sterilization**(2)

<table>
<thead>
<tr>
<th>Autoclave</th>
<th>3 x 30 minutes at 135 °C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gamma Irradiation</td>
<td>Maximum of 50 kGy</td>
</tr>
</tbody>
</table>

(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

**Nominal Dimensions**

<table>
<thead>
<tr>
<th>Maximum diameter including valves</th>
<th>53 mm (2.1 in.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length - Code 2</td>
<td>105 mm (4.1 in.)</td>
</tr>
</tbody>
</table>

**Nominal Effective Filter Area (EFA)**

200 cm² (0.22 ft²)

**Ordering Information**(3)

Pall Part Number: KA02EDT2FT

(3) Filterability tool for sizing studies
Kleenpak Nova Capsules with Fluorodyne EX EDT Media

### Materials of Construction

<table>
<thead>
<tr>
<th>Component</th>
<th>Prefilter Layer:</th>
<th>Final Filter Layers:</th>
<th>Support/Drainage</th>
<th>Core/End Caps</th>
<th>Cage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filter Membrane</td>
<td>Hydrophilic asymmetric PES</td>
<td>Hydrophilic PVDF</td>
<td>Polypropylene</td>
<td>Polypropylene</td>
<td>Polypropylene</td>
</tr>
<tr>
<td>Prefilter Layer:</td>
<td>Hydrophilic asymmetric PES</td>
<td>Hydrophilic PVDF</td>
<td>Polypropylene</td>
<td>Polypropylene</td>
<td>Polypropylene</td>
</tr>
<tr>
<td>Final Filter Layers:</td>
<td>Hydrophilic PVDF</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Polypropylene</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Polypropylene</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Polypropylene with TiO₂</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(white colored)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>O-rings</td>
<td>Silicone elastomer</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sealing Technology</td>
<td>Thermal bonding without adhesives</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Housing Bowl</td>
<td>Polypropylene</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Housing Head&lt;sup&gt;(1)&lt;/sup&gt;</td>
<td>Polypropylene</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<sup>(1)</sup> Formulated with TiO₂ whitener which does not contribute to organic extractables

### Operating Parameters<sup>(3)</sup>

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Maximum Temperature</strong></td>
<td>40 °C</td>
</tr>
<tr>
<td><strong>Maximum Operating Pressure</strong></td>
<td>3 bar (44 psi) at 40 °C</td>
</tr>
<tr>
<td><strong>Maximum Differential Pressure</strong></td>
<td>3 bar (44 psi) at 40 °C</td>
</tr>
</tbody>
</table>

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

### Sterilization<sup>(4)</sup>

<table>
<thead>
<tr>
<th>Process</th>
<th>Temperature</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Autoclave “G” version</td>
<td>3 x 30 minutes at 135 °C</td>
<td></td>
</tr>
<tr>
<td>Gamma Irradiation “G” version</td>
<td>Maximum of 50 kGy</td>
<td></td>
</tr>
</tbody>
</table>

<sup>(4)</sup> • 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)

### Nominal Dimensions

<table>
<thead>
<tr>
<th>Component</th>
<th>NP6</th>
<th>NP7</th>
<th>NP8</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>In-line</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maximum Diameter including valves</td>
<td>154 mm (6.1 in.)</td>
<td>154 mm (6.1 in.)</td>
<td>154 mm (6.1 in.)</td>
</tr>
<tr>
<td>Length with hose barb inlet/outlet</td>
<td>397 mm (15.6 in.)</td>
<td>644 mm (25.4 in.)</td>
<td>895 mm (35.2 in.)</td>
</tr>
<tr>
<td>Length with sanitary inlet/outlet</td>
<td>335 mm (13.2 in.)</td>
<td>584 mm (23.0 in.)</td>
<td>834 mm (32.8 in.)</td>
</tr>
<tr>
<td><strong>T-style</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maximum Diameter including valves</td>
<td>240 mm (9.5 in.)</td>
<td>240 mm (9.5 in.)</td>
<td>240 mm (9.5 in.)</td>
</tr>
<tr>
<td>Length</td>
<td>349 mm (13.7 in.)</td>
<td>598 mm (23.5 in.)</td>
<td>848 mm (33.4 in.)</td>
</tr>
</tbody>
</table>

### Typical Extractables in Water at 20 °C<sup>(2)</sup>

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

<sup>(2)</sup> Tested on elements without pre-flushing

<sup>(1)</sup> Formulated with TiO₂ whitener which does not contribute to organic extractables

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

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

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<sup>(1)</sup> Formulated with TiO₂ whitener which does not contribute to organic extractables
### Ordering Information

**Pall Part Number:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Style</th>
<th>Code</th>
<th>Filter Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>P</td>
<td>In-line</td>
<td>6</td>
<td>254 mm (10 in.)</td>
</tr>
<tr>
<td>T</td>
<td>T-style</td>
<td>7</td>
<td>508 mm (20 in.)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>8</td>
<td>762 mm (30 in.)</td>
</tr>
</tbody>
</table>

**Shipping Format**

- G: Non-sterile gamma irraditatable/autoclavable
- S: Pre-sterilized using gamma irradiation (minimum 25 kGy)

**Vent/Drain**

- Blank: Stäubli* vent
- A: Stäubli* vent and drain

Connection Options

- 1: 1 – ½ in. sanitary flange inlet and outlet
- 9: 1 in. (25 mm) single barb hose barb inlet and outlet
- 19: 1 – ½ 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 – ½ in. sanitary flange inlet and ½ in. (13 mm) single barb hose barb outlet
- 1H(1): 1 – ½ in. sanitary flange inlet and outlet, with ½ in. sanitary port on inlet
- 1H9(2): 1 – ½ in. sanitary flange inlet and 1 in. (25 mm) single barb hose barb outlet, with ½ in. sanitary port on inlet
- 1H9(2): 1 – ½ 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**
- **Maximum Differential Pressure (Forward Direction):**
  - 5.5 bar (80 psi) at 40 ºC
  - 4.0 bar (58 psi) at 80 ºC
- **Maximum Differential Pressure (Reverse Direction):**
  - 2.0 bar (30 psi) at 40 ºC

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

(2) Tested on elements without pre-flushing

**Typical Liquid Flow vs. Differential Pressure**

**Integrity Test Values (Air test gas, water wet)**
- Values for 254 mm (10 in.) filter at 20 ºC
  - Max. allowable Forward Flow (air test gas) Water wet 32 mL/min at 4475 mbar (65 psi)

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

**Ordering Information**
- **Pall Part Number:** AB EDT P
- **Nominal Lengths:**
  - 1: 254 mm (10 in.)
  - 2: 508 mm (20 in.)
  - 3: 762 mm (30 in.)
- **Filter Media:**
  - Code: 7
  - Pall code 7 double O-ring bayonet lock and fin
- **O-ring Material:**
  - Code: 4
  - Silicone elastomer
  (Other materials available on request)
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