Fluorodyne™ EX

GRADE EDT FILTERS

Remarkable mycoplasma control with exceptional value

The Fluorodyne™ EX grade EDT filter is a highly retentive mycoplasma control filter for use where sterility and economical filtration of culture media or other hard-to-filter fluids is paramount.

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

The patented Ultipleat modular cartridge pleating design combined with a narrow core enables high effective filtration areas, small footprint filter systems and improved process efficiencies. A complete validation package supports safety within your process.

Built in Supor™ pre-filtration

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

Ultipleat and narrow core design

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

Exceptional hybrid construction

The downstream polyvinylidene fluoride (PVDF) sterilizing grade layers allow for sterilization in wet or dry conditions and contribute to low extractables and low protein adsorption.

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

2D matrix marking

High area “AB-Style” EDT grade filter formats are laser marked, allowing 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, 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 different approaches.

Allegro single-use systems, which incorporate Kleenpak™ filter capsules, provide a solution to these industry drivers. Allegro single-use systems eliminate the need for cleaning and associated validation efforts, reduce major capital investments, increase flexibility and support 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 wide choice of scalable products in the Fluorodyne EX grade EDT filter range and Allegro product platform, single-use systems incorporating EDT grade filters can be used to process volumes from 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 is reliable in the laboratory.

Fluorodyne EX grade EDT filters produce sterile effluent when challenged with > 10^7 cfu *B. diminuta* per cm^2 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 several decades. It was selected based on its 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 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 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

Fluorodyne EX EDT membrane in 47 mm disc filters

Materials of construction	
Filter membrane	Prefilter layer: hydrophilic asymmetric PES
	Final filter layers: hydrophilic PVDF

Sterilization	
Autoclave	1 × 60 minutes at 135°C

Recommended integrity test
< 5170 mbar

Typical effective filter area (EFA) [1]
12.5 cm^2 (1.9 $in.^2$)

[1] When used in a Cytiva standard test housing. Contact us for housing details.

Typical liquid flow vs differential pressure

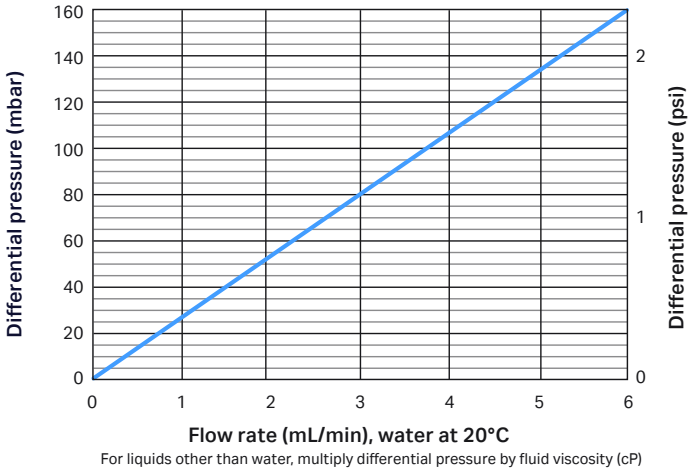


Fig 2. Typical liquid flow vs differential pressure for 47 mm disc filters.

Ordering information [2]

Product code: EDT04725

[2] 25 discs per box

Fluorodyne EX EDT membrane in Mini Kleenpak capsules

Materials of construction	
Filter membrane	Prefilter layer: hydrophilic asymmetric PES
	Final filter layer: hydrophilic PVDF
Support/drainage	Polypropylene
Capsule shell	Polypropylene
Filling bell	Polycarbonate
Sealing technology	Thermal bonding without adhesives

Operating parameters [3]	
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

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

Sterilization [4]	
Autoclave	3 × 30 minutes at 135°C
Gamma irradiation	Maximum of 50 kGy

[4] 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	
Maximum diameter including valves	53 mm (2.1 in.)
Length – code 2	105 mm (4.1 in.)

Nominal effective filter area (EFA)
200 cm^2 (0.22 ft^2)

Typical liquid flow vs differential pressure

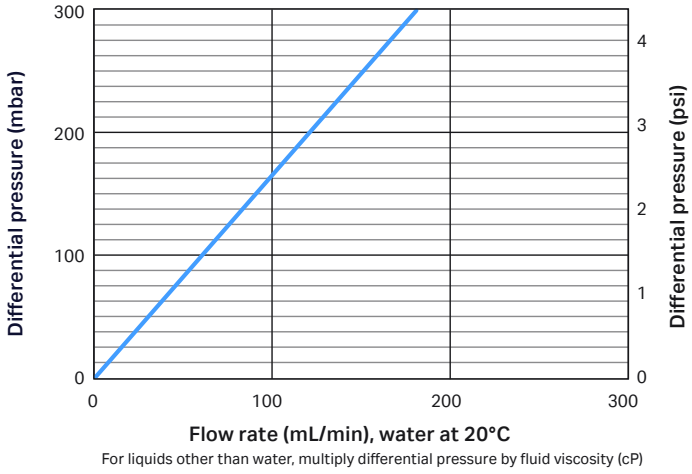


Fig 3. Typical liquid flow vs differential pressure for Mini Kleenpak capsules.

Ordering information [5]

Product code: KA02EDT2FT

[5] Filterability tool for sizing studies

Fluorodyne EX EDT membrane in 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 (white colored)
O-rings	Silicone elastomer
Sealing technology	Thermal bonding without adhesives
Housing bowl	Polypropylene
Housing head [6]	Polypropylene with TiO_2 whitener

[6] Formulated with TiO_2 whitener which does not contribute to organic extractables

Operating parameters [7]

Maximum temperature	40°C
Maximum operating pressure	3 bar (44 psi) at 40°C
Maximum differential pressure	3 bar (44 psi) at 40°C

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

Sterilization [8]

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

[8] 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 m^2 per 254 mm module (9.7 ft^2 per 10 in. module)

Typical extractables in water at 20°C [9]

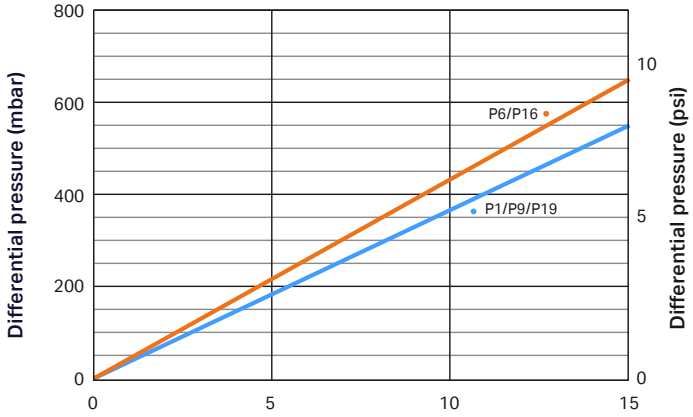
< 50 mg after 4 hours, extraction (per 254 mm module)

[9] 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.)

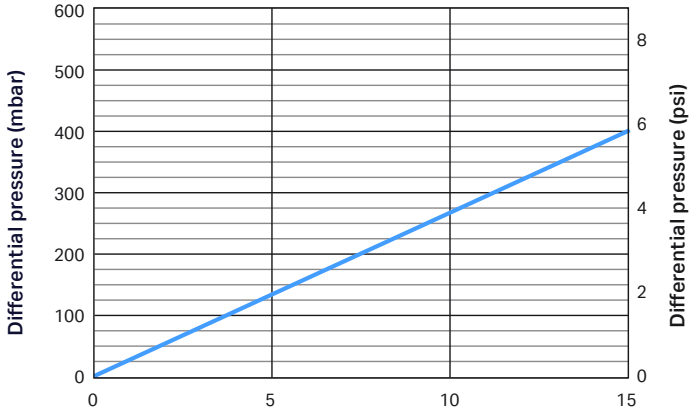
Typical liquid flow vs differential pressure



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

Fig 4. Typical liquid flow vs differential pressure for Kleenpak Nova (NP) in-line capsules.

Typical liquid flow vs differential pressure



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

Fig 5. Typical liquid flow vs differential pressure for Kleenpak Nova (NT) T-style capsules.

Ordering information

Product code: N [ ] [ ] **UEDT 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
G	Non-sterile gamma irradiatable/ autoclavable
S	Pre-sterilized using gamma irradiation (minimum 25 kGy)

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

Code	Connection options
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 [(10)]	½ in. (13 mm) single barb hose barb inlet and outlet
16 [(10)]	1 to 1½ in. sanitary flange inlet and ½ in. (13 mm) single barb hose barb outlet
1H [(11)]	1 to 1½ in. sanitary flange inlet and outlet, with ½ in. sanitary port on inlet
1H9 [(11)]	1 to 1½ in. sanitary flange inlet and 1 in. (25 mm) single barb hose barb outlet with ½ in. sanitary port on inlet

[(10)] For in-line (code P) only
[(11)] For T-style (code T) only

Fluorodyne EX EDT membrane in AB-style 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
O-rings	Silicone
Sealing technology	Thermal bonding without adhesives

Operating parameters [12]	
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

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

Sterilization	
Autoclave	5 × 60 minutes at 135°C
In situ steam	5 × 60 minutes at 135°C

Typical extractables in water at 20°C [13]
< 50 mg after 4 hours extraction (per 254 mm module)

[13] Tested on elements without pre-flushing.

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)

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

Nominal effective filter area (EFA)
9500 cm^2 (10.2 ft^2) per 254 mm (10 in.) module

Typical liquid flow vs. differential pressure

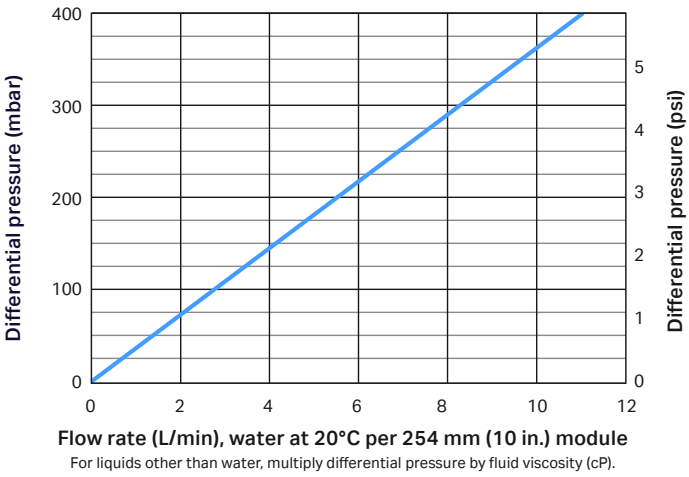


Fig 5. Typical liquid flow vs differential pressure for AB-style filter cartridges..

Ordering information

Product code: AB [ ] **UEDT** [ ] **P** **H4**

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

Code	Filter media
7	Code 7 double o-ring bayonet lock and fin

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

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