

3M Purification

0.1 μm rated Polyethersulfone Membrane Filters
for Biopharmaceutical Processes



LifeASSURE™ PDA010 Series

Capsules and Cartridges





3M Purification’s LifeASSURE™ PDA010 series 0.1 µm filters combine two asymmetric polyethersulfone (PES) membrane layers with the Advanced Pleat Technology design. This combination results in a robust filter that is optimised for both high throughput and fast flow applications while offering 0.1 µm rated filtration for the control of mycoplasma in pharmaceutical fluid streams. The hydrophilic PES membrane provides for direct integrity testing and is ideal for applications where low protein binding is critical.

LifeASSURE PDA010 series membrane technology

LifeASSURE PDA010 series 0.1 µm filters incorporate two layers of PES membrane. The upstream layer (figure 1) is highly asymmetric providing high loading capacity thereby protecting the downstream layer (figure 2). The downstream membrane contains a robust, centrally located, retention zone. Together, both membrane layers result in a filter with multiple filtration zones providing high contaminant capacity, fast flow rates and excellent removal of mycoplasma.

Applications

LifeASSURE™ PDA010 series filters are recommended for applications that require high log reduction value (LRV) of mycoplasma as required in many biopharmaceutical processes.

They are suitable for:

- Cell culture media
- Media additives
- Serum filtration
- Intermediate process filtration
- Buffers

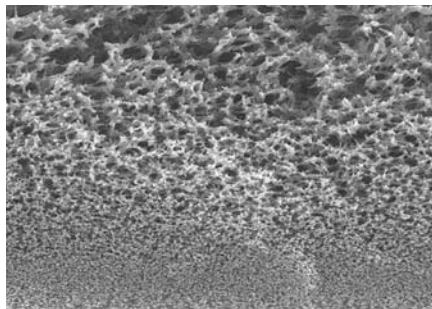


Figure 1: LifeASSURE™ PDA010 series upstream layer

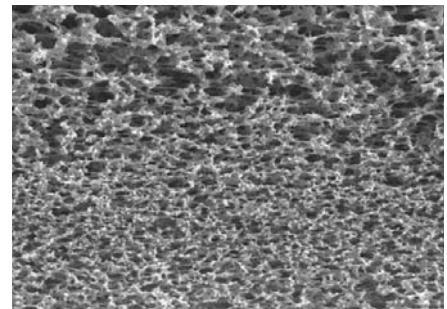


Figure 2: LifeASSURE™ PDA010 series downstream layer

Advanced Pleat Technology design

LifeASSURE PDA010 series filters also feature the Advanced Pleat Technology design to extend service life. This design technology maximises the useful surface area of the filter while maintaining open flow paths between media pleats (figure 3). By employing the Advanced Pleat Technology design, the LifeASSURE PDA010 series filter provides low pressure drops, longer service life and overall cost-effective filtration.

Features

LifeASSURE™ PDA010 series filter cartridges are recommended for the removal of mycoplasma and other small micro-organisms that can pass through a 0.2 µm rated sterilising-grade filter while offering excellent flow rates for biopharmaceutical process liquids such as cell culture media and buffers.

- Validated for bacterial (*Brevundimonas diminuta*) retention per ASTM F838-05 (2013)
- Greater than 7 log reduction of *Acholeplasma laidlawii* (≤ 1 bar) on an area basis (cm²)
- 100% integrity tested in the manufacturing process and correlated to bacterial retention
- Traceability – Each filter is permanently labelled with grade, lot number and serial number
- Membrane stable over wide pH range and suitable for acid and basic buffers
- Low protein binding

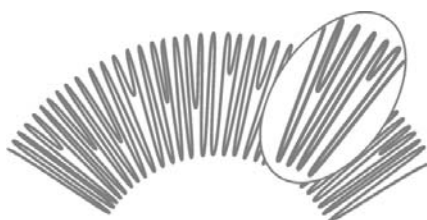
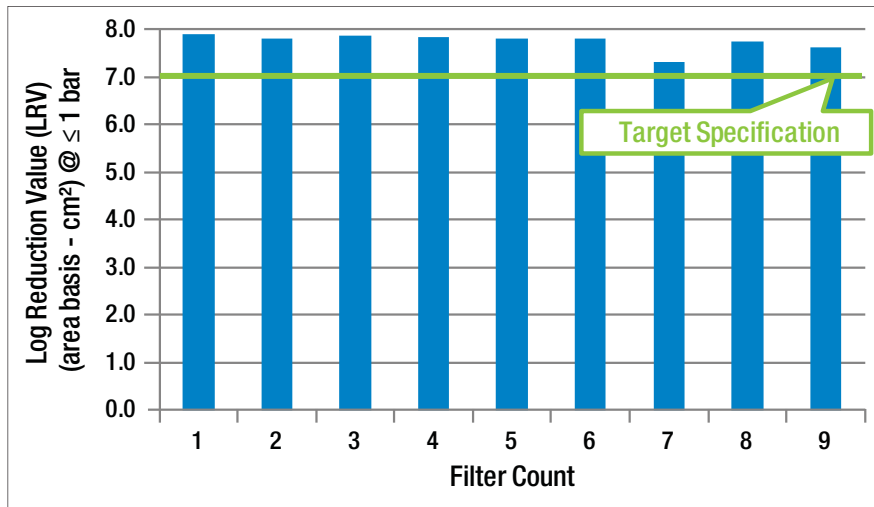
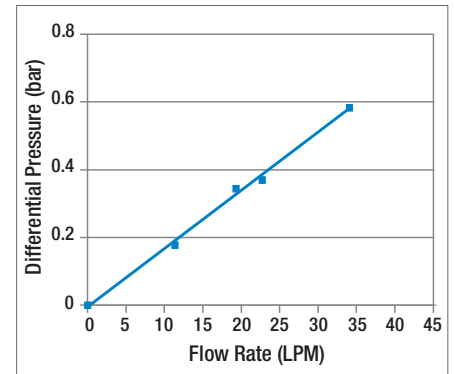


Figure 3: Advanced Pleat Technology design

Graph 1: Mycoplasma (*Acholeplasma laidlawii*) Retention



Graph 2: LifeASSURE™ PDA010 (0.1 µm) water flow rate - 10" Filter



Optimised for use in 3M Purification prefilter filtration solutions

LifeASSURE™ PDA010 series 0.1 µm rated polyethersulfone membrane filters are designed for use with other 3M Purification filters. There are two recommended types referenced in table 1 below.

Table 1: Filter combination selection

Prefilter type	Filter media	Typical applications
LifeASSURE™ PDA020 series filters	0.2 µm sterilising polyethersulfone	Buffers, media feeds, chromatography protection, final 0.2 µm sterilising filtration
Zeta Plus™ EXT series filters	Cellulosic depth filter	Cell culture debris clarification, concentrated protein feeds, serum, difficult to filter biological fluids
LifeASSURE™ PNA series filters	Polyethersulfone bioburden reduction 0.2 µm or 0.45 µm	Media fermenter feed streams, serum and blood fractions, chromatography protection

Robust filtration performance

In order to measure design robustness, LifeASSURE PDA010 series filter cartridges were subjected to multiple *in situ* steam sterilisation cycles or exposed to aggressive acid and alkaline fluids. Thermal cycling represents a severe test of structural integrity due to the elevated temperature exposure and expansion and contraction of filter components. Caustic compatibility is a desirable feature for chromatography column protection where caustic fluids used for column sanitisation and regeneration can be passed directly through LifeASSURE PDA010 series filters. Compatibility with acids provides filtration performance with aggressive buffers, column regeneration fluids and Clean-in-Place (CIP) protocols. Table 2 shows the results of these studies.

Table 2: Thermal and chemical compatibility

Test	Exposure condition	Post exposure integrity test result
<i>In situ</i> steam cycle (cartridges only)	20 cycles of 30 minutes at 135 °C	Pass
1 M sodium hydroxide	10 cycles of 60 minutes at 60 °C	Pass
1 M acetic acid	10 cycles of 60 minutes at 25 °C	Pass
1 M hydrochloric acid	10 cycles of 60 minutes at 25 °C	Pass

Performance engineered cartridge design

All-polypropylene structural components (end caps, adapters, media support, inner core and outer cage) used in the device fabrication offer excellent thermal and mechanical stability, broad chemical compatibility and low extractable levels. LifeASSURE™ PDA010 series filter cartridges are available in 5", 10", 20" and 30" lengths to match the dimension and sealing requirements of most currently available cartridge housings. The filters can also be supplied in a range of disposable capsule formats.

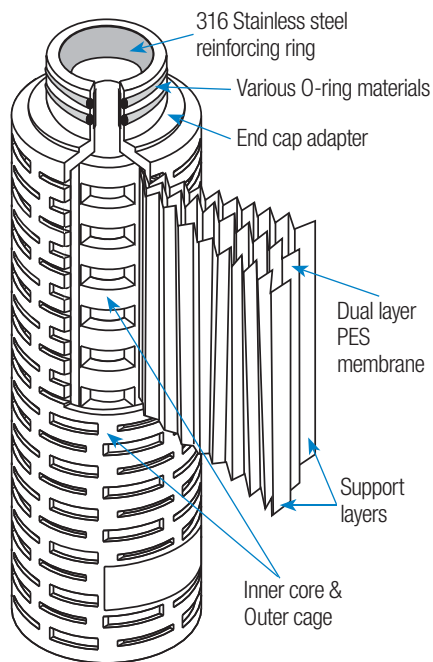
Mini-cartridges

For critical small volume applications, LifeASSURE PDA010 series filters are available in 2.5" and 5" mini-cartridges. Installed in 3M Purification 2.5" or 5" mini-cartridge housings or in existing competitor housings, LifeASSURE PDA010 series mini-cartridges offer low hold-up volume and economical small volume filtration.

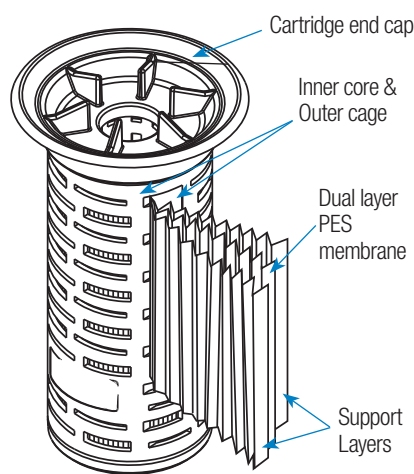
Gamma-compatible and sterile filter capsules

For critical applications where convenience and ease of use are desired, LifeASSURE PDA010 series filters are available in 2.5", 5", 10", 20" and 30" disposable capsules. The capsules are supplied with sanitary vent and drain ports as well as 1 1/2" sanitary flange connections. The 2.5" and 5" mini-capsules are available with your choice of 1/2" (13 mm) hose barb inlet/outlet connections or 1 1/2" sanitary flange connections.

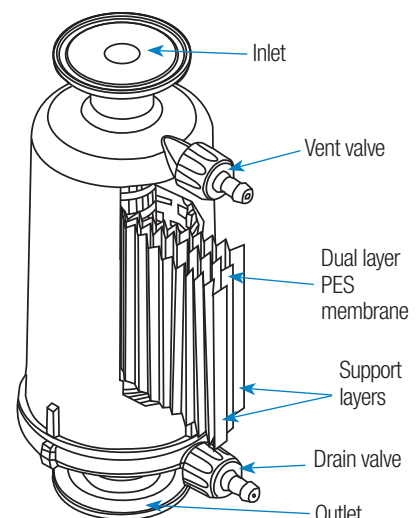
All capsules are available in both *gamma*-compatible and sterile formats. *Gamma*-compatible filter capsules are compatible with autoclaving or *gamma*-irradiation up to 45 kGy. Sterile filter capsules are ready for use without further sterilisation.



High surface area F-cartridge



Mini-cartridge



Capsule

Quality and reliability

LifeASSURE PDA010 series filters are manufactured in accordance with the ISO Quality Management Systems and are 100% integrity tested prior to shipment.

All materials of construction are listed for food contact per U.S. Code of Federal Regulations (CFR), Title 21 (parts 170-199) and comply with United States Pharmacopoeia (USP) Biological Reactivity <87> and <88> Class VI Biological Reactivity Tests.

All LifeASSURE PDA010 series cartridge and capsule filters are shipped with a Certificate of Quality affirming compliance with rigid manufacturing quality specifications. Supporting Drug Master File (DMF) documentation is on file with the United States Food and Drug Administration (FDA). LifeASSURE PDA series Validation Guides are available upon request.



Table 3: Integrity test parameters and recommended preconditioning flush

Minimum Bubble Point in 60%/40% Isopropyl alcohol (IPA) / H ₂ O					
2.69 bar					
Maximum forward flow air diffusion rate for water (cm ³ /min) at 4.14 bar and 25 °C					
Product	2.5"	5"	10"	20"	30"
Cartridge "Mini"	6.7	15	-	-	-
Cartridge "F"	-	17	38	71	104
Capsule	6.7	15	38	71	104
Recommended preconditioning flush volume (L)					
Product	2.5"	5"	10"	20"	30"
Cartridge "Mini"	7	13	-	-	-
Cartridge "F"	-	15	25	50	75
Capsule	7	13	25	50	75





Table 4: LifeASSURE™ PDA010 series filters specifications

	Cartridges		Mini-cartridges		Capsules				
	5 to 30"		2.5"	5"	2.5"	5"	10"	20"	30"
Filter rating	0.1 µm								
Materials of construction									
Cage, core, end caps and adapters	Injection moulded polypropylene								
Membrane	Polyethersulfone								
Membrane support layer	Polypropylene non-woven								
Encapsulated adapter reinforcing ring	Polysulfone	N/A		N/A					
	Cartridges		Mini-cartridges		Capsules				
	"F"	2.5"	5"	2.5"	5"	10"	20"	30"	
Filtration surface area (m ²)	5": 0.35 10": 0.78 *	0.12	0.26	0.12	0.26	0.78	1.56	2.35	
Typical water flow rate at 25 °C - lpm/0.1 bar	5": 8.8 10": 19.8 20": 35.7 30": 49.4	2.7	6.6	2.7	6.6	19.8	35.7	49.4	
	Cartridges		Mini-cartridges		Capsules				
	5 to 30"		2.5"	5"	2.5"	5"	10"	20"	30"
Operating parameters									
Maximum operation temperature	80 °C				40 °C				
Maximum differential pressure (bar)	Forward pressure: 5.5 at 25 °C ; 1.7 at 80 °C Reverse pressure: 2.4 at 25 °C				4.5 at 40 °C				
<i>In situ</i> steam conditions	Up to 135 °C				Do not <i>in situ</i> steam				
Autoclave conditions	Up to 126 °C								
<i>Gamma</i> sterilisation	<i>Gamma</i> -Compatible:		N/A		Minimum: 27.5 kGy Maximum: 45 kGy				
	Sterile:		N/A		Do not resterilise				
Sterility (sterile)	N/A				Meets current AAMI guidelines for sterility utilising a validated sterilisation cycle. DO NOT resterilise.				

* For multiple cartridge lengths, multiply by number of 10" equivalent lengths.

LifeASSURE™ PDA010 series cartridges - Ordering guide

Grade designation	Configuration	Height (inches)	End modification	O-ring material
PDA 010 - LifeASSURE PDA Series 0.1 µm	F - High area	50 - 5 01 - 10 02 - 20 03 - 30	B - 226 O-ring and spear J - 226 O-ring and flat cap	A - Silicone C - EPR

LifeASSURE™ PDA010 series mini-cartridges - Ordering guide

Grade designation	Configuration	Height (inches)	End modification	Package quantity
PDA 010 - LifeASSURE PDA Series 0.1 µm	M	01 - 2.5 02 - 5	AN - Flange seal	01 - 1 Pack

LifeASSURE™ PDA010 series capsules - Ordering guide

Grade designation	Configuration	Height (inches)	End modification	Vent O-ring option	Sterilisation	Package quantity
PDA 010 - LifeASSURE PDA Series 0.1 µm	C - Small Capsules	01 - 2.5 02 - 5	A - 1 ½" sanitary fitting B - 13 mm hose barb C - Inlet: 1 ½" sanitary Outlet: 13 mm hose barb D - Inlet: 13 mm hose barb Outlet: 1 ½" sanitary	A - Silicone	G - Gamma-compatible S - Sterile	1 - 1 Pack
	J - Large Capsules	01 - 10 02 - 20 03 - 30	A - 1 ½" sanitary fitting			



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