LENNTECH
info@lenntech.com Tel. +31-152-610-900
www.lenntech.com Fax. +31-152-616-289

LifeASSURE™ PNA Series

Bioburden & Fine Particle Reduction Filters

LifeASSURE™ PNA Filter Series

3M Purification's LifeASSURE™ PNA series filters feature a unique asymmetric polyethersulfone (PES) membrane with the Advanced Pleat Technology (APT) construction. This design results in a robust filter that is optimised for both long service life and fast flowing applications, while providing 0.2 µm or 0.45 µm rated filtration for superior reduction of microorganisms*. LifeASSURE™ PNA series are pre-filters or bioburden reduction grade filters. LifeASSURE™ PNA series filters help bioprocess, pharmaceutical, biologicals and diagnostic reagent processors meet high standards for microorganism and fine particle control. Combined with 3M Purification's range of particle control and sterilising grade filter cartridges, i.e. LifeASSURE™ PDA020, LifeASSURE™ PNA filters offer processors a complete solution for rigorous contaminant control while maintaining long service life and low operating costs.

Features and Benefits

Hydrophilic asymmetric polyethersulfone membrane
- Ensures easy wet-out and low protein binding while providing fast flow rates

Advanced Pleat Technology design
- Allows maximum fluid and contaminant access to filter surface area for high throughput

100% Integrity tested prior to release
- Ensures consistent performance to specification

21 CFR materials of construction
- Passes USP Biological Reactivity for Class VI Plastics Test

Regulatory Support File
- Eases validation and regulatory submissions

Applications

- Media and fermenter feed streams
- Serum and blood fractions
- Diagnostics
- Biologicals
- Chromatography column protection
- Cell culture fluids
- Large volume parenterals (LVP)
- Reagents and Buffers
- Ophthalmics
- High purity DI water and WFI systems
- Bulk pharmaceutical chemicals
- Orals and topicals

Durable Design

The LifeASSURE™ PNA filter membrane and cartridge design innovations result in a highly durable filter cartridge, capable of secure operation through numerous cycles of steam sterilisation and chemical-based cleaning and sanitation protocols.

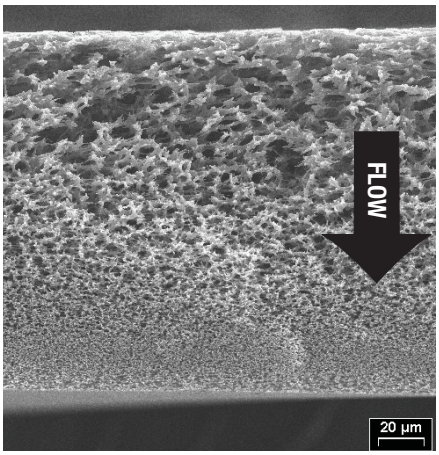
Advanced Technologies

Highly Asymmetric Membrane

LifeASSURE™ PNA series filters incorporate a single layer PES membrane with a high degree of asymmetry (Figure 1). When viewed in cross-section, the membrane contains larger pores on the upstream surface that gradually taper to smaller pores towards the downstream surface. Compared to conventional membranes with a symmetric pore structure, this structure provides greater contaminant capacity, since it presents greater open spaces (void volume) in which to retain these contaminants. This increase in capacity leads directly to longer service life. In addition, the asymmetric structure provides less resistance to flow, resulting in a lower pressure drop when compared at a constant flow rate to competitive filters, allowing a user to employ fewer LifeASSURE™ PNA filters for any given flow rate.

* LifeASSURE™ PNA filters are not sterlising grade filters as defined in FDA Guidance.

Figure 1: SEM Photograph Showing the LifeASSURE™ PNA Membrane



Advanced Pleat Technology Design

LifeASSURE™ PNA filters feature 3M Purification's Advanced Pleat Technology (APT) design for extended service life. This design technology maximises the useful surface area of the filter while maintaining open flow paths between the media pleats (refer to Figure 2). By employing the APT construction, the LifeASSURE™ PNA filter provides lower pressure drops, longer service life and lower overall operational costs.

Media Support Design

LifeASSURE™ PNA filters employ a filter media support design that helps provide a faster fluid flow versus pressure drop compared to competitive filters. This unique 3M Purification development combines the high flowing PES membrane with special, optimised support layers upstream and downstream of the membrane. When combined with the previously mentioned Advanced Pleat Technology, this feature greatly increases flow per cartridge and results in lower overall operational costs.

Advanced Performance

Figure 2: Advanced Pleat Technology

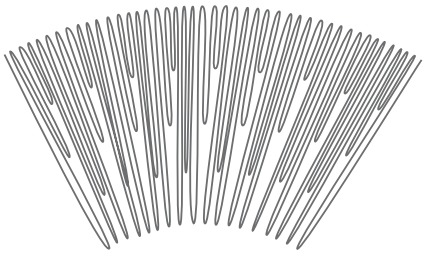


Table 1: Log Reduction Value

Series	Microorganism	Typical Log Reduction Value
PNA020	*B. diminuta*	LRV > 7
PNA045	*S. marcescens*	LRV > 8

Extended Service Life

LifeASSURE™ PNA filters can reduce the cost of filtration in both batch and continuous operation modes. In continuous operation mode, service life is measured either by the volume filtered or the number of days in service, before becoming permanently blocked. Filters that provide longer service life not only reduce direct operational costs, but also reduce indirect filter costs as well (filter change-out/ installation labour, downtime between change-outs, filter flushing, etc.). The LifeASSURE™ PNA filter's unique combination of a highly asymmetric PES membrane, the Advanced Pleat Technology design and upstream/downstream supports all work together to maximise the volume of product that can be processed. LifeASSURE™ PNA filters also provide cost reduction in batch process applications. As demonstrated in Table 3 (on the following page), the filter's high flow rate as compared to alternative filters can lead to a reduction in the number of filters needed to process a given batch volume.

Advanced Microbiological Control

The primary purpose of a membrane filter cartridge in many applications is to effectively control contaminating microorganisms. LifeASSURE™ PNA filters provide superior reduction of microorganisms, even at challenge concentrations that far exceed those experienced by most operations. The LifeASSURE™ PNA020 series membrane has been shown to provide Log Reduction Values (LRV) in excess of 7 with *B. diminuta* (ATCC 19146) when challenged at a concentration of 10^7 CFU/cm² or greater. The LifeASSURE™ PNA045 series membrane has been shown to provide an LRV in excess of 8 for *S. marcescens* (ATCC 14756) when challenged at a concentration of 10^6 CFU/cm² or greater.

Fast Flow Rates at Low Pressure Drops

3M Purification has combined three key technological advances to provide fast flow rates per unit of pressure drop. These three technologies, Advanced Pleat Technology (APT) design, an upstream and downstream support design and a unique, highly asymmetric microporous membrane, afford users with faster process flow rates using fewer filters as compared to alternative filters.

As the example in Table 2 illustrates, the pressure drop at a given flow rate for LifeASSURE™ PNA020 filters can be significantly lower compared to competitive filters. Since filter change-out is usually tied to a terminal differential pressure drop (typically between 1.38 bar and 2.41 bar), employing filters that exhibit a lower initial pressure drop can result in longer filter service life.

Alternatively, in a new system, when determining the number of filters needed to provide a desired flow rate at a given pressure drop, faster flowing filters will result in smaller, more economical systems. Consider the example in Table 3.

As the example in Table 3 illustrates, the nearest competitor requires significantly more 30" filters to provide the same flow rate and pressure drop when compared to the LifeASSURE™ PNA020 filter. Employing the LifeASSURE™ PNA020 filter in new applications can help users reduce both capital cost (smaller housing assemblies can be used) and operating costs (fewer filters are needed to deliver a required flow rate).

Table 2: Initial Clean Pressure Drop (water) for a 30" Filter Flowing at 76 l/min

Product	Pressure Drop
LifeASSURE™ PNA020 Series	152 mbar
Competitor A	352 mbar
Competitor B	241 mbar
Competitor C	365 mbar

Table 3: The number of 30" filters needed to provide a 170 l/min flow with a clean pressure drop of 69 mbar

Product	No. of Filters
LifeASSURE™ PNA020 Series	5 filters
Competitor A	12 filters
Competitor B	8 filters
Competitor C	12 filters

LifeASSURE™ PNA Series Cartridge Construction

Materials of Construction		
Membrane	Polyethersulfone (PES)	
Support Layers	Polypropylene	
Inner Core, Outer Cage, End Cap Adapters	Polypropylene	
Encapsulated Adapter Reinforcing Ring	Polysulfone	
O-rings	Various polymers available: Silicone, Fluorocarbon, EPR, Nitrile, Fluoropolymer Encapsulated Fluorocarbon	
Nominal Filter Dimensions		
Effective Filtration Area	0.79 m² per 10" equivalent length	
Filter Diameter	70 mm	
Filter Lengths	10" (254 mm), 20" (508 mm), 30" (762 mm), 40" (1016 mm)	
Operating Parameters		
Typical Water Flow Rate	PNA020 PNA045	17 l/min per 100 mbar 49 l/min per 68.9 mbar
Maximum Differential Pressure (Forward)	5.5 bar at 25 °C 1.7 bar at 80 °C	
Maximum Differential Pressure (Reverse)	0.69 bar at 25 °C	
Maximum Forward Flow Diffusion at 25 °C per 10" filter	PNA020 PNA045	≤ 51 cc/min at 2.07 bar ≤ 35 cc/min at 1.52 bar
Typical Gravimetric Extractables (per 10" filter)	< 10 mg after a 20 liter flush	
Non-Fibre Releasing	"non-fibre releasing" filter as defined in 21 CFR 210.3 (b) (6)	
Downstream Cleanliness/Effluent Particle Level	Meets USP <788> for WFI (Particles >10um = <12/ml, Particles >25um = <2/ml)	
Bacterial Endotoxin	<0.125 EU/ml	
Total Organic Carbon	Meets USP <643>	
Conductivity	Meets USP <645>	
Steam Resistance: 135 °C	20 cycles, 30 min. cycles	
NaOH Resistance: (conc. 1M at 65 °C)	100 hours	

Prefiltration Selections

Many applications employ a prefilter and final filter in series to achieve maximum performance and economy. Prefilters are used to help protect and extend the life of more expensive final filters. 3M Purification offers a number of premium prefilter choices including the Betafine™ XL pleated polypropylene filter series and the Betapure™ NT-P depth filter series. Betafine™ XL filters also feature 3M Purification's Advanced Pleat Technology maximising the accessible filter area and supplying exceptionally high flow rates. Those preferring depth-style filters can select from 3M Purification's Betapure™ NT-P prefilter family series which employs an advanced media design that enhances flow while extending service life.

Also, the LifeASSURE™ PNA filter itself can be employed as a prefilter to sterilising grade membrane filters in a variety of applications. 3M Purification final, sterilising grade filters include the LifeASSURE™ PDA filter series and the LifeASSURE™ PSA filter series.

For more information on the different prefilters and final filters series, please contact your 3M Purification representative or distributor.

3M Purification Filter Housings

3M Purification offers a full range of sanitary style filter housings which can be used with LifeASSURE™ PNA. Consult 3M Purification for additional detail.

LifeASSURE™ PNA Series Filters Ordering Guide

Filter Cartridge Grade	Configuration	Length	End Modification	O-Ring/ Gasket Material
PNA020 - 0.20 micron **PNA045** - 0.45 micron	**F -** APT Pleat	**01** - 10” **02** - 20” **03** - 30” **04** - 40”	**B** - 226 O-rings, bayonet lock & spear **C** - 222 O-rings & spear **F** - 222 O-rings & flat cap **J** - 226 O-rings, bayonet lock, flat cap	**A** - Silicone **B** - Fluorocarbon **C** - EPR **D** - Nitrile **K** - Fluoropolymer Encapsulated Fluorocarbon

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PNA020 F 01 B	PNA045 F 01 B
PNA020 F 01 C	PNA045 F 01 C
PNA020 F 01 F	PNA045 F 01 F
PNA020 F 01 J	PNA045 F 01 J
PNA020 F 02 B	PNA045 F 02 B
PNA020 F 02 C	PNA045 F 02 C
PNA020 F 02 F	PNA045 F 02 F
PNA020 F 02 J	PNA045 F 02 J
PNA020 F 03 B	PNA045 F 03 B
PNA020 F 03 C	PNA045 F 03 C
PNA020 F 03 F	PNA045 F 03 F
PNA020 F 03 J	PNA045 F 03 J
PNA020 F 04 B	PNA045 F 04 B
PNA020 F 04 C	PNA045 F 04 C
PNA020 F 04 F	PNA045 F 04 F
PNA020 F 04 J	PNA045 F 04 J