

LifeASSURE™ PNA Series

Bioburden & Fine Particle Reduction Filters

LifeASSURE™ PNA Series Filters

3M Purification Inc.'s LifeASSURE™ PNA series filters feature a unique asymmetric polyethersulfone (PES) membrane with proprietary Advanced Pleat Technology (APT) construction. This design results in a robust filter that is optimized 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 filters help bioprocess, pharmaceutical, biologicals, and diagnostic reagent processors meet high standards for microorganism and fine particle control. Combined with 3M Purification Inc.'s range of particle control and sterilizing grade filter cartridges, LifeASSURE PNA series filters offer processors a complete solution for rigorous contaminant control while maintaining long service life and low operating costs.

Features & 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

Durable Design

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

ADVANCED TECHNOLOGIES

Highly Asymmetric Membrane

LifeASSURE PNA series filters incorporate a novel 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 series filters for any given flow rate.

Advanced Pleat Technology Design

LifeASSURE PNA series filters feature 3M Purification Inc.'s Advanced Pleat Technology (APT) design for extended service life. This design technology maximizes the useful surface area of the filter while maintaining open flow paths between the



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

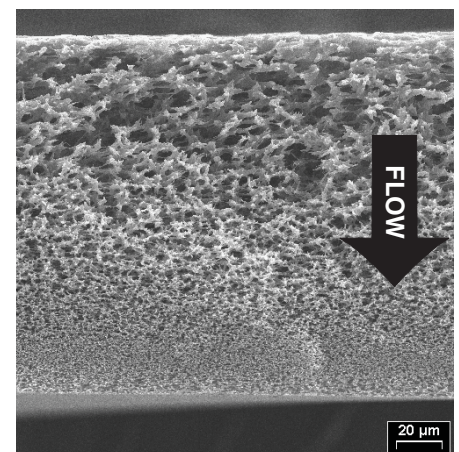


Figure 1. - SEM Photograph Showing LifeASSURE™ PNA Membrane

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

media pleats (refer to Figure 2). By employing the APT construction, the LifeASSURE™ PNA series filter provides lower pressure drops, longer service life, and lower overall operational costs.

Novel Media Support Design

LifeASSURE PNA series filters employ a novel filter media support design that helps provide a faster fluid flow versus pressure drop compared to competitive filters. This unique 3M Purification Inc. development combines the high flowing PES membrane with special, optimized 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

Extended Service Life

LifeASSURE PNA series 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 labor, downtime between change-outs, filter flushing, etc.). The LifeASSURE PNA series filter’s unique combination of highly asymmetric PES membrane, Advanced Pleat Technology design, and novel upstream/downstream supports all work together to maximize the volume of product that can be processed. LifeASSURE PNA series 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.

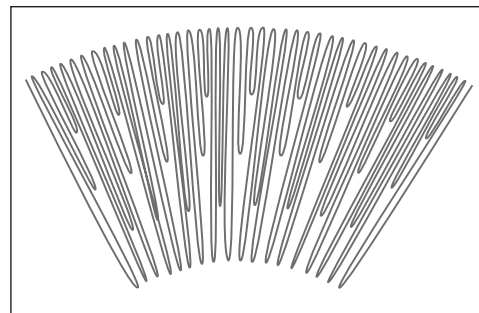


Figure 2. - Advanced Pleat Technology

Advanced Microbiological Control

The primary purpose of a membrane filter cartridge in many applications is to effectively control contaminating microorganisms. LifeASSURE PNA series filters provide superior reduction of microorganisms, even at challenge concentrations that far exceed those experienced by most operations. 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 10⁷CFU/cm² or greater. 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 10⁶CFU/cm² or greater.

Table 1.

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

Fast Flow Rates at Low Pressure Drops

3M Purification Inc. has combined three key technological advances to provide fast flow rates per unit of pressure drop. These three technologies, Advanced Pleat Technology (APT) design, a novel 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.

Table 2.

Initial Clean Pressure Drop (water) for a 30" Filter Flowing at 20 GPM (76 lpm)	
LifeASSURE™ PNA020 Series Filters	2.2 psid (152 mbar)
Competitor A	5.1 psid (352 mbar)
Competitor B	3.5 psid (241 mbar)
Competitor C	5.3 psid (365 mbar)

As the example above illustrates, the pressure drop at a given flow rate for LifeASSURE PNA020 series filters can be significantly lower compared to competitive filters. Since filter change-out is usually tied to a terminal differential pressure drop (typically between 20 and 35 psid), 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 following example:

Table 3.

(The number of 30" filters needed to provide a 45 GPM flow with a clean pressure drop of 1 psid (170 lpm flow @ 69 mbar))	
LifeASSURE™ PNA020 Series Filters	5 filters
Competitor A	12 filters
Competitor B	8 filters
Competitor C	12 filters

As the example above illustrates, the nearest competitor requires significantly more 30" filters to provide the same flow rate and pressure drop when compared to the LifeASSURE™ PNA020 series filter. Employing the LifeASSURE PNA020 series 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).

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	
Nominal Filter Dimensions		
Effective Filtration Area	8.5 ft ² (0.79 m ²) per 10" equivalent length	
Filter Diameter	2.75" (70 mm)	
Filter Lengths	10" (254 mm), 20" (508 mm), 30" (762 mm), 40" (1016 mm)	
Operating Parameters		
Typical Water Flow Rate	PNA020	3.1 gmp/psid (17 lpm/100 mbar)
	PNA045	9 gmp/psid (49 lpm / 100 mbar)
Maximum Differential Pressure (Forward)	80 psid @ 77 °F (5.5 bar @ 25 °C)	
	35 psid @ 176°F (1.7 bar @ 80 °C)	
Maximum Differential Pressure (Reverse)	50 psid @ 77 °F (0.69 bar @ 25 °C)	
Maximum Forward Flow Diffusion at 25 °C per 10" filter	PNA020	≤ 51 cc/min @ 30 psig (2.07 bar)
	PNA045	≤35 cc/min @ 22 psig (1.52 bar)
Typical Gravimetric Extractables (per 10" filter)	<10mg after a 20 liter flush	
Non-Fiber Releasing	"non-fiber releasing" filter as defined in 21 CFR 210.3 (b) (6).	
Downstream Cleanliness/Effluent Particle Level	Meets USP <788> for WFI (Particles >10 micron = <12/ml, Particles >25 micron = <2/ml)	
Bacterial Endotoxin	<0.125 Eu/ml	
Total Organic Carbon	Meets USP <643>	
Conductivity	Meets USP <645>	
Steam Resistance: 275°F (135 °C)	20 cycles, 30 minute cycles	
NaOH Resistance: (conc. 1M @ 65 °C)	100 hours	

LifeASSURE™ PNA Series Filters

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 Inc. offers a number of premium prefilter choices including the Betafine™ XL series pleated polypropylene filter and the Betapure™ NT-P series depth filter. Betafine XL series filters (Literature 70-0201-8686-5) also feature 3M Purification Inc.'s Advanced Pleat Technology maximizing the accessible filter area and supplying exceptionally high flow rates. Those preferring depth-style filters can select from 3M Purification Inc.'s Betapure NT-P series prefilter family (Literature 70-0201-8721-0) which employs an advanced media design that enhances flow while extending service life.

Also, the LifeASSURE™ PNA Series filter itself can be employed as a prefilter to sterilizing grade membrane filters in a variety of applications. 3M Purification Inc. final, sterilizing grade filters include the LifeASSURE™ PDA series filter (literature 70-0201-8687-3) and the LifeASSURE™ PSA series filter (literature 70-0201-8893-7).

3M Purification Inc. Filter Housings

3M Purification Inc. offers a full range of sanitary style filter housings accomodating a single LifeASSURE PNA series filter. Consult 3M Purification Inc. for additional detail

LifeASSURE™ PNA Series Filters Ordering Guide

Filter Cartridge Grade	Configuration	Length	End Modifications	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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