

POLIFLO N6

DOUBLE LAYER ASYMMETRIC NYLON MEMBRANE CARTRIDGE FILTERS

Leaflet E-34-00



FLUXA

Fluxa
Filtri
S.p.A.

V.le A. De Gasperi, 88/B-20017 Mazzo di Rho (MI)
Tel. 0293959.1 (15 lines)
Fax 0293959.400-440-470
e-mail: info@fluxafiltri.com - www.fluxafiltri.com

Agent for South Italy:
Sire srl - Via Sannio, 9 - 80146 Napoli
Tel. 0817349254 - 0817349310
Fax 0817349317



Poliflo N6

Double Layer Asymmetric Nylon Membrane

Introduction

Fluxa Filtri Poliflo N6 cartridges feature a naturally hydrophilic twin layer nylon membrane with an asymmetric cross section. When compared with cartridges manufactured from similar membranes, they provide high flow rates, low clean pressure drops and exceptional removal characteristics. The membrane combines a narrow pore size distribution with a uniform thickness and high void volume, guaranteeing optimum performance at the specified pore size rating. The inherent stability of the membrane eliminates any risk of media migration and minimises the potential for particulate release even under impulse conditions.

Poliflo N6 cartridges are an economic yet cost effective way of providing accurately controlled microbial control as well as particle removal for a wide range of critical and non-critical process solutions. With good chemical compatibility and a high thermal stability, they are ideal for microbial stabilisation and cold sterilisation, in applications where the characteristics of a hydrophilic membrane are required.

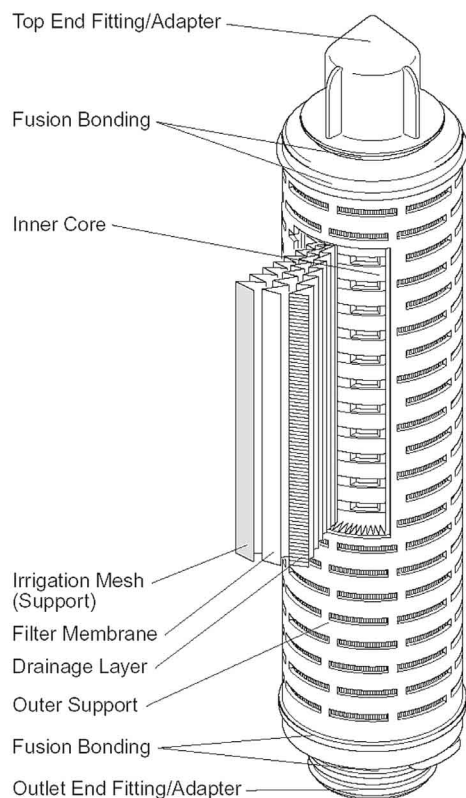
Features and Benefits

- Widely used nylon membrane validated to HIMA challenge standard for reliable sterilisation or critical filtration of liquids
- Fusion bonded for high integrity and minimal extractables
- Integrity testable to confirm cartridge integrity without destruction
- Exceptional particulate removal characteristics make Poliflo N6 an excellent choice for critical filtration such as microelectronics applications
- FDA approved materials of construction for biosafety
- Polypropylene hardware for high strength and integrity

Applications

Poliflo N6 cartridges are suitable for the sub-micronic filtration of a wide range of process liquids, in applications where the characteristics of a naturally hydrophilic membrane are required. Typical applications include:

- **Biopharmaceuticals** - for the sub-micronic filtration of ingredients, intermediates, make-up waters and final products, including sterilisation, clarification and the reduction of bioburden.
- **Electronics and Semiconductors** - for the sub-micronic filtration of process water and chemicals, including solvents, developers and photoresists. Applications typically include central water plant treatment and critical 'wet bench' point of use filtration.
- **Fine Chemicals** - for the clarification and sterilisation of a wide range of process chemicals.
- **Beverages** - for the clarification and sterilisation of various beverages, including the removal of yeast and spoilage organisms.
- **Pure water supply** - for use in de-mineralised and de-ionised water treatment systems, as either a resin trap sterilisation filter, or for bioburden reduction.



They will retain total integrity when autoclaved or repeatedly in-line steam sterilised at up to 125°C (257°F) and can be subsequently integrity tested. A guide to steam sterilisation and chemical sanitisation is available from Fluxa Filtri. Polypropylene hardware (excluding filter media and seals), ensures Poliflo N6 cartridges have minimal extractables and the optimum chemical characteristics consistent with the use of a nylon membrane (see 'Chemical Compatibility').

Material Conformity and Validation

The bio-safety of all materials used in the manufacture of Poliflo N6 cartridges is certified to 21CFR standard and conform with the requirements of USP Class VI. Poliflo N6 cartridges have been tested for bacterial retention in accordance with HIMA standards. The results which are documented in a Validation Guide (available on request), confirms that Poliflo N6 cartridges achieve an LRV (log reduction value) of greater than 7 (sterile grade). Fluxa Filtri procedures include regular LAL tests of the rinse water used for final flushing to confirm the absence of pyrogens. These tests ensure that Poliflo N6 cartridges are suitable for most critical process and pharmaceutical applications.

Cartridge Construction

Fluxa Filtri Poliflo N6 cartridges are manufactured from a naturally strong and flexible double layered asymmetric nylon membrane, fused together to give a homogeneous membrane which does not require casting on, or bonding to, a membrane support. With its asymmetric structure, the membrane provides excellent prefiltration and doubles the security in terms of particle retention. By combining these attributes with a high effective media area (0.7m² per 250mm module) and high integrity cartridge construction, Poliflo N6 cartridges provide high efficiency filtration while minimising processing costs.

Cartridge construction is based on a multi-layer combination of irrigation mesh, filter membrane and drainage material, which is precision pleated and thermally seam-bonded to maximise the available filtration area and ensure efficient flow throughout the cartridge. Final assembly is by thermal fusion bonding the cartridge components, including the filter media, outer support and core, to the end fittings. The optimised method of fusion bonding helps to guarantee cartridge integrity, eliminating the risk of by-passing or extractables such as resins derived from bonding agents.

Manufactured using injection moulded polypropylene inner and outer supports, Poliflo N6 cartridges are designed with the strength necessary to handle the high differential pressures which can be encountered during steam sterilisation and with hydraulic shock.

Range

Suitable for use in Fluxa Filtri filter housings and as direct replacements for existing cartridges, Poliflo N6 cartridges can be supplied with end fittings to suit most hardware installations without modification. They are available in single or multiple module units of 5, 10, 20, 30 and 40 inches, and in a choice of three absolute microbial ratings: 0.1, 0.2 and 0.45 micron. Each cartridge is supplied with all necessary seals or O-rings, chemically compatible with the liquid to be filtered.

Specifications

Materials of Manufacture

Filter Medium Nylon	(Twin Layer Asymmetric Section)
Irrigation Mesh (Support)	Polypropylene
Inner Core	Polypropylene
Outer Support	Polypropylene
End Fittings	Polypropylene
Sealing	Fusion Bonding

Cartridge Dimensions (Nominal)

Diameter:	70mm	(2.8")
Length: 1 Module (short)	125mm	(5")
1 Module	250mm	(10")
2 Modules	510mm	(20")
3 Modules	860mm	(30")
4 Modules	1020mm	(40")

Effective Filtration Area

Absolute Microbial Rating	EFA (Each 250mm Module)
0.1 micron	0.63m ² (6.9 ft ²)
0.2 micron	0.7m ² (7.5 ft ²)
0.45 micron	0.7m ² (7.5 ft ²)

Cartridge Treatment

Standard	Cleaned and flushed, without further treatment
Rinsed	Ultra-clean, pulse flushed to give a system resistivity of 18M..cm

Gaskets and O-rings

Ethylene Propylene Rubber, Silicone, Viton, Nitrile, or PTFE Encapsulated

Maximum Differential Pressure

Normal Flow Direction-Operating at:

20°C (68°F)	6.0 bar (87lb/in ²)
80°C (176°F)	4.0 bar (57lb/in ²)
100°C (212°F)	3.0 bar (43lb/in ²)
120°C (248°F)	2.0 bar (29lb/in ²)
125°C (257°F)	1.5 bar (22lb/in ²)

Operating Temperature

Maximum continuous 60°C (140°F)

Sterilisation

Autoclave and Multiple In-line Steam (at 1.38 bar) up to 121°C (250°F)

Extractables

Minimal total extractables

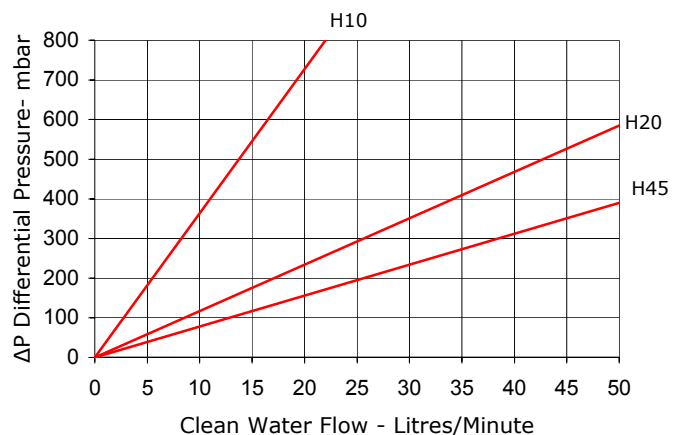
Integrity Testing

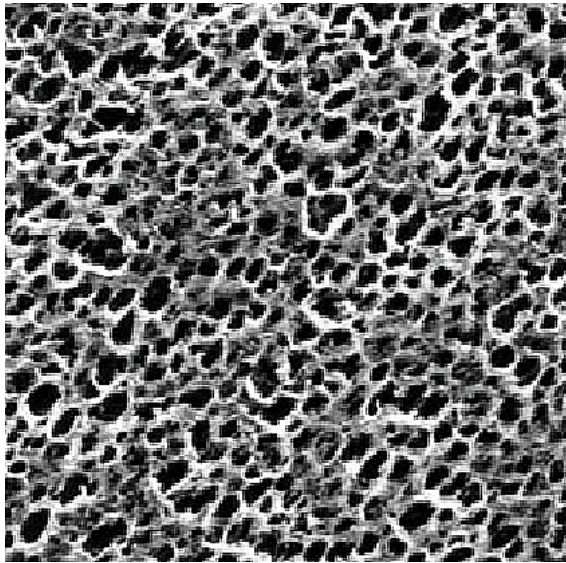
All cartridges are integrity tested prior to despatch. Details of testing by Bubble Point, Forward Flow Diffusion and Pressure Decay are available from Fluxa Filtri.

Test Conditions

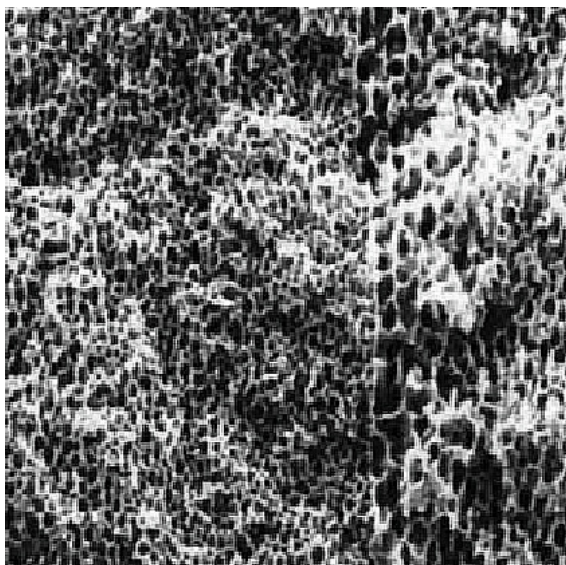
Typical Clean Water Flow Rate - Based on a 250mm (10") single module Fluxa Filtri housing exhibiting the differential pressure characteristics indicated below, for solutions with a viscosity of 1 centipoise. Other Solutions - For solutions with a viscosity greater than 1 centipoise, divide the indicated flow rate by the viscosity in centipoise.

Clean Water Flow Rates - Poliflo N6 Cartridges H10 - H45





Poliflo N6 A surface view (x750)
of nylon membrane filter
media



Poliflo N6. A cross section (x750)
through nylon membrane filter
media, showing the double
layer asymmetric structure

Quality Assurance

Poliflo N6 cartridges are manufactured under clean environmental conditions by staff fully gowned to minimise any risk of contamination during production. All cartridges are integrity tested, which is followed by drying in a vapour extraction oven and final packing in a sealed polythene bag. If required cartridges can be pulsed flushed with 18M..cm pyrogen free water, until full recovery of the system resistivity.

This ensures that all cartridges are fully traceable and allows users to maintain their own process records. Registered to ISO 9001, Fluxa Filtri procedures are subject to high standards of quality assurance.

Chemical Compatibility

Care must be taken to ensure that the cartridge and seals selected are chemically compatible with the application. Susceptibility to chemical attack varies considerably between solutions and is greatest at the extremes of the pH scale. It also varies according to the duration of exposure and operating temperature.

Prefilter Systems

In most applications it is necessary to install a prefiltration system upstream of Poliflo N6 cartridges. This normally takes the form of pleated or depth filters, which helps to extend the life of the Poliflo N6 cartridges by the bulk removal of particulate contaminants larger than the microbial rating of the membrane.

In fact, it may be desirable to fit several prefilters of gradually reducing filtration ratings, thereby optimising the efficiency and operating costs of the whole system. Choose the Fluxa Filtri Klearfil, Polyfil II or Microfil GP.

Technical Support

Fluxa Filtri has a team of laboratory and sales staff capable of assisting customers with the design of filtration systems and the selection of cartridges for existing installations.

