



Bioflo NY

- * Positive Zeta potential
- * Enhanced endotoxins retention
- * Easy integrity testing in situ
- * Repeatedly steamable in situ and in an autoclave
- * Thermo-welded construction
- * EC-listed materials for Food contact
- * FDA-listed materials per 21 CFR
- * Bio-Safety per USP - Plastics
- * Low filter extractable even with solvents
- * Validation Guide available on request



The Bioflo NY filter element is manufactured using a highly positive charged, Nylon 6.6 membrane, its Zeta potential retains negatively charged fine particles even smaller than the pores size itself.

Tests have proven that the positive charged Nylon membrane provides an enhanced retention capability of sub-micron particles and especially on endotoxins in aqueous solution at defined conditions. The intrinsically water wettability of nylon and polyester allows easy integrity testability. Manufacturing is completed in a controlled environment. The filter is easily integrity tested to provide the quality level required in products for pharmaceutical and medical applications.

Materials of Construction

Filter media	Positive charged Nylon 6,6
Upstream supports	Polyester
Downstream supports	Polyester
Internal core	Polypropilene
External core	Polypropilene
End caps / adapters	Polyester

Food Safety

Bevflo TS filter element meets (EU) regulation 10/2011 and its amendements and regulations (EC) 1935/2004 and 1895/2005.

Quality Standards

Produced under a certified quality system to guarantee traceability of manufacturing records and integrity test results.

Bio Safety

Filter media and components pass USP Biological Reactivity and Chemical-Physical tests for Class VI plastics. The filter meets USP "Water for Injection" requirements and particle release and the effluent is Non - pyrogenic for USP Bacterial Endotoxins (< 0,25 EU/ml).

Operating Conditions

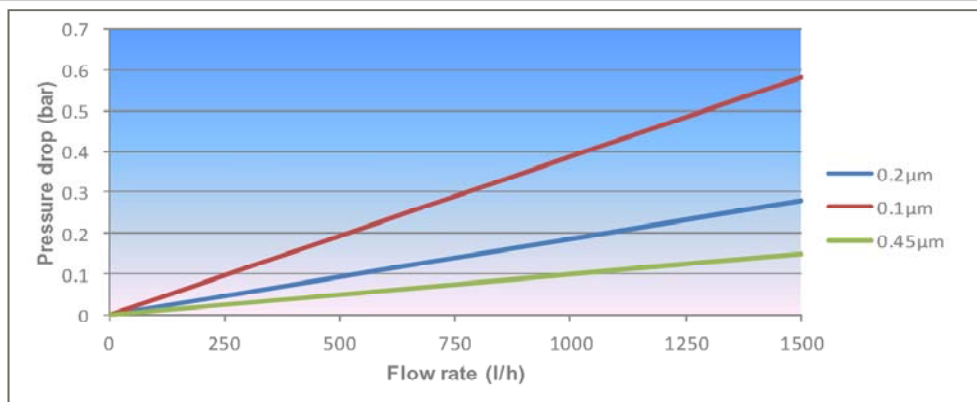
- max. continuous temperature 80°C
- max, cumulative time of steam sterilisation 5 hours at 140°C / 13 hours at 125°C / 20 hours at 121 °C
- sanitisation with hot water 80°C max
- sanitisation with chemicals Can be sanitised by standard chimica agents
- max. differential pressure 5.0 bar at 25°C / 2.5 bar at 80°C / 0.3 bar at 135°C
- recommended change out differential pressure 2.0 bar at 25°C
- recommended rinse up volume 3 liters / 10" cartridge

ABSOLUTE FILTRATION IN LIQUIDS	BACTERIAL RETENTION >10 ⁷ CFU/m ²	ACCEPTABLE LIMIT FOR DIFFUSER WITH WATER FOR 10" DIFFUSER (ml/min)
0.1 µm	Hydrogenophaga pseudo flava**	≤ 16 @ 2.8 bar
0.2 µm	Brevundimonas diminuta	≤ 16 @ 2.1 bar

*as for ASTM F838-05 ** bacterial retention with Acheleplasma laidlawii ≥ 10⁷

ENDOTOXINS RETENTION IN WATER
350 l/h flow rate / 10" cartridge 0.1µm, 0.2µm, 0.45µm

Water Flow Rate for 10" Cartridge



Ordering Guide

Name	Micron Rating	Nominal Length	End Cap Type	Seal Type	Special
Bioflo NY	0.1 µm 0.2 µm 0.45 µm	5"	03	S - Silicone E - EPDM	PH - Biological Grade, tested and preflushed with nopr pyrogenic water
		10"	04 - DOE		
		20"	07		
		30"	08		
		40"	28		

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