

POSINYL Nylon 6,6 membrane

- Positive Zeta potential
- Enhanced endotoxins retention
- Easy integrity testable in situ
- Repeatedly steamable in situ and in autoclave
- Thermowelded construction
- EC-listed materials for Food contact
- FDA-listed materials per 21 CFR
- Bio-Safety per USP—Plastics
- Low filter extractables even with solvents



POSINYL filter element is manufactured using a highly positive charged, Nylon 6,6 membrane; its Zeta potential retains negative 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. The intrinsically water wettability of nylon and polyester allows easy integrity testability. Manufacturing is completed in a controlled environment; each filter is integrity tested to provides the quality level required in products for pharmaceutical and medical applications.

MATERIALS OF CONSTRUCTION

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Filter media	Positive charged nylon 6,6
Upstream supports	polyester
Downstream supports	polyester
Internal Core	polypropylene
External Cage	polypropylene
End caps / Adapters	polyester

FOOD-SAFETY

POSINYL filter element materials meet (EU) regulation 10/2011 and its amendments, regulations (EC) 1935/2004 and 1895/2005.

BIO-SAFETY

Filter media and components pass USP CLASS VI Biological Reactivity and Chemical-Physical tests for USP plastics.

Specific for "PH" grade: the filter meets USP "Water for injection" requirements for particle release and the effluent is Non-Pyrogenic per USP Bacterial Endotoxins (< 0,25 EU/ml).

QUALITY STANDARDS

Produced under a certified Quality System to guarantee traceability of manufacturing records and integrity testing results.

OPERATING CONDITIONS

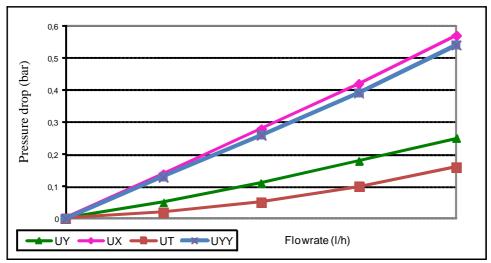
- max. continuous temperature	80 °C	
- max. cumulative time of steam sterilization	5 hours at 140°C / 13 hours at 125°C / 20 hours at 121 °C	
- sanitization with hot water	80 °C max	
- sanitization with chemicals	Can be sanitized by standard chemical agents	
- max. differential pressure	5,0 bar at 25 °C—2,5 bar 80 °C—0,3 bar 135 °C	
- recommended change out differential pressure	2,0 bar at 25 °C	
- recommended rinse up volume	3 liters/cartridge 10"	

CODE	ABSOLUTE FILTRATION RATING IN LIQUIDS	BACTERIAL RETENTION OF MICRO-ORGANISM >10 ¹⁰ CFU/ 10" CARTRIDGE*	ACCEPTABLE LIMIT FOR DIFFUSION FLOW TEST WITH WATER FOR 10" CARTRIDGE (ml/min)
UX	0,1 μm	Hydrogenophaga pseudoflava**	≤ 16 @ 2,8 bar
UY	0,2 μm	Brevundimonas diminuta	≤ 16 @ 2,1 bar
UYY	0,2 μm Double membrane	Brevundimonas diminuta	≤ 16 @ 2,1 bar

*as per ASTM F838-05

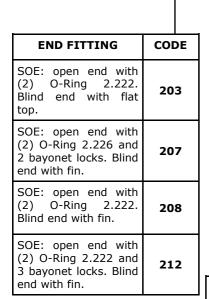
** bacterical retention with Acholeplasma laidlawii ≥ 108

WATER FLOW RATE FOR 10" CARTRIDGE



POSINYL ORDERING INFORMATION

<u>UY</u> -



PZE -

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CODE	ABSOLUTE FILTRATION RATING micron
UX	0,1
UY	0,2
UT	0,45
UYY	0,2 Double membrane

<u>SB</u>

CODE	GASKETS	
s	Standard	Silicone

<u>S</u>

CODE	PACKING TYPE	
SB	Single box	

CODE	NOMINAL LENGTH
1	10"
2	20″
3	30″
4	40"
05	5″
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CODE	PRODUCT GRADE
РН	Biological Grade; tested and prefluxed with non-pyrogenic water. Quality Certification in the box.
РНН	Biological Grade; tested and prefluxed with non-pyrogenic water. Quality Certification, with serial number, in the box.

Data contained in this bulletin are informative and subject to change without notice. User is responsible for determining whether the product is fit for particular purpose and suitable for User's method of application.



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