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# Ultipor N66 and N66 Posidyne membranes

IN AB, JUNIOR AND SEALKLEEN™ STYLE FILTER CARTRIDGES

Ultipor Nylon 66 filters have a highly controlled pore distribution across removal ratings from as low as 0.1 µm up to 1.2 µm. This enables reliable contaminant removal for a diversity of fluids, whether used in prefiltration or sterilizing grade filtration applications. Being inherently hydrophilic without chemical modifications to achieve wettability, they have low extractables in water and they wet easily for integrity testing.

N66 Posidyne membrane has a positive zeta potential as well as all the characteristics and inherent performance of our Ultipor N66 membrane. The positive charge is functional over a pH range of 3 to 10 in aqueous solutions, and enables N66 Posidyne filters to retain negatively charged contaminants much smaller than the rated pore size.



Fig 1. AB style filter cartridges.

## Applications

Both membrane types are offered in different grades for particulate removal, bioburden reduction, mycoplasma removal, and sterilizing filtration applications. Sterilizing grade filters using Ultipor Nylon 66 membrane are particularly suitable for filtration of small molecule, low fouling fluids, including small and large volume parenterals.

Application	Ultipor N66 filter grade	N66 Posidyne filter grade	Absolute removal rating	Removal efficiency
<b>Bioburden reduction</b>	NI	NIZ	0.1 µm	Typical <i>Brevundimonas diminuta</i> $T_R > 10^{10}$
	NA	NAZ	0.2 µm	Typical <i>B. diminuta</i> $T_R > 10^{4-6}$
	NBA	NBAZ	0.2 µm (with 0.45 µm prefilter layer)	
	NB	NBZ	0.45 µm	Typical <i>Serratia marcescens</i> $T_R > 10^{4-6}$
<b>Particulate removal</b>	NL	NLZ	0.45 µm	Samples retain $> 10^7/cm^2$
	NX	NXZ	0.45 µm	<i>S. marcescens</i>
	-	NNXZ	0.45 µm	
	NK	NKZ	0.65 µm	$\beta > 5000$ ( $> 99.98\%$ efficiency)
<b>Sterilizing grade</b>	NH	NHZ	0.8 µm	
	NN	NNZ	1.2 µm	
	NF	NFZ	0.2 µm	Retains <i>B. diminuta</i> at $10^7$ CFU/cm <sup>2</sup> effective filter area
<b>Mycoplasma removal</b>	NR	-	0.2 µm	
	NT	NTZ	0.1 µm	Removal of <i>Acholeplasma laidlawii</i> mycoplasma with a typical $T_R > 10^{11}$ and retention of <i>B. diminuta</i> at $10^7$ CFU/cm <sup>2</sup> effective filter area

## Pharmaceutical grade quality

- Every filter cartridge is integrity tested by the forward flow method during manufacture. Results from forward flow testing for sterilizing grade filters are continually validated against bacterial challenge.
- Each filter is identified with a unique serial number by which every production stage can be traced. Batch traceability is likewise fully ensured.
- Filtrate quality meets required standards for the following parameters:
  - Oxidizable materials per United States Pharmacopeia (USP)
  - Bacterial endotoxins per USP
  - Particulates
  - pH shift
- Routine steam autoclave testing.
- Manufactured according to GMP.

## Specifications

### Maximum differential pressure

Up to 50°C	5.3 bar
50°C to 80°C	4.0 bar
> 100°C*	0.3 bar

\* i.e., during steam sterilization.

### Filter area and typical flow rate per 254 mm (10 in.) nominal length AB cartridge

Ultipor N66 filter grade	N66 Posidyne filter grade	Filter area per 254 mm (10 in.) nominal length cartridge <sup>†</sup>	Typical clean water flow rate for 254 mm (10 in.) nominal length cartridge per 100 mbar <sup>†</sup>	Absolute removal rating
NI	NIZ	0.80 m <sup>2</sup>	3.1 L/min	0.1 µm
NA	NAZ	0.84 m <sup>2</sup>	10.0 L/min	0.2 µm
NBA	NBAZ	0.47 m <sup>2</sup>	5.5 L/min	0.2 µm
NB	NBZ	0.82 m <sup>2</sup>	16.7 L/min	0.45 µm
NL	NLZ	0.82 m <sup>2</sup>	10.0 L/min	0.45 µm
NX	NXZ	0.82 m <sup>2</sup>	5.6 L/min	0.45 µm
-	NNXZ	0.47 m <sup>2</sup>	6.8 L/min	0.45 µm
NK	NKZ	0.82 m <sup>2</sup>	25.0 L/min	0.65 µm
NH	NHZ	0.73 m <sup>2</sup>	38.5 L/min	0.8 µm
NN	NNZ	0.74 m <sup>2</sup>	62.5 L/min	1.2 µm
NF	NFZ	0.79 m <sup>2</sup>	5.0 L/min	0.2 µm
NR	-	0.47 m <sup>2</sup>	3.1 L/min	0.2 µm
NT	NTZ	0.70 m <sup>2</sup>	1.4 L/min	0.1 µm

<sup>†</sup> For filter area and clean water flow rates of AB cartridges other than 254 mm (10 in.) cartridges, multiply figures by the number of equivalent 254 mm (10 in.) modules.

## Filter area and typical flow rate per Sealkleen™ 7002 cartridge

Ultipor N66 grade product code	N66 Posidyne grade product code	Filter area per Sealkleen 7002 cartridge <sup>‡</sup>	Typical clean water flow rate Sealkleen 7002 cartridge per 100 mbar <sup>‡</sup>	Absolute removal rating
NA	NAZ	0.29 m <sup>2</sup>	3.2 L/min	0.2 µm
NB	NBZ	0.29 m <sup>2</sup>	5.2 L/min	0.45 µm
NL	NLZ	0.30 m <sup>2</sup>	3.3 L/min	0.45 µm
-	NNXZ	0.17 m <sup>2</sup>	2.7 L/min	0.45 µm
NK	NKZ	0.29 m <sup>2</sup>	8.8 L/min	0.65 µm
NN	NNZ	0.29 m <sup>2</sup>	21.0 L/min	1.2 µm
NF	NFZ	0.29 m <sup>2</sup>	1.8 L/min	0.2 µm
NR	-	0.17 m <sup>2</sup>	1.2 L/min	0.2 µm
NT	NTZ	0.26 m <sup>2</sup>	0.6 L/min	0.1 µm

<sup>‡</sup> For filter area and clean water flow rates of Junior and Sealkleen cartridges other than Sealkleen SLK7002, multiply figures given in the table by the appropriate factor (given in the Junior and Sealkleen cartridge ordering information table). For any questions, contact Cytiva.

## Materials of construction

All materials used meet the specification for Biological Safety per USP and are listed in the FDA Drug Master File.

Membrane layers:	
Ultipor N66	Nylon 66 and polyester support
N66 Posidyne	Modified Nylon 66 and polyester support
Support and drainage layers	
	Polyester
End-cap/adapters	
	Polyester
Internal core	
	Polypropylene
External cage	
	Polypropylene
Elastomeric O-ring seals <sup>§</sup>	
	Silicone as standard. Other materials on request.

<sup>§</sup> Applies to AB and Junior cartridges only. Sealkleen style cartridges contain an integral flange on the outlet adapter and seals are supplied with the housing.

## Sterilization

Ultipor N66 and N66 Posidyne filters can all be sterilized by steaming *in-situ* or by steam autoclave. For extended service in hot water, please consult Cytiva.

Temperature	Maximum recommended cumulative steam life
125°C	16 hours
140°C	4 hours

## Ordering information<sup>¶</sup>

### AB style cartridges

**Example part number:** AB1NF7PH4 represents a 254 mm (10 in.) filter, with 0.2 µm Ultipor N66 sterilizing grade filter membrane, with bayonet lock and fin end, and two silicone O-rings.

AB    P H4\*\*

Code	Nominal length
05	127 mm (5 in.)
1	254 mm (10 in.)
2	508 mm (20 in.)
3	762 mm (30 in.)
4	1016 mm (40 in.)

Ultipor N66 filter grade code	N66 Posidyne filter grade code	Absolute removal rating	Application
NI	NIZ	0.1 µm	Bioburden reduction
NBA	NBAZ	0.2 µm	
NA	NAZ	0.2 µm	
NL	NLZ	0.45 µm	
NX	NXZ	0.45 µm	Particulate removal
-	NNXZ	0.45 µm	
NB	NBZ	0.45 µm	
NK	NKZ	0.65 µm	
NH	NHZ	0.8 µm	Sterilizing grade
NN	NNZ	1.2 µm	
NR	-	0.2 µm	
NF	NFZ	0.2 µm	
NT	NTZ	0.1 µm	Mycoplasma removal

Code	Cartridge adapter style
2 <sup>¶¶</sup>	Bayonet lock adapter with double O-ring seal and flat end
7	Bayonet lock adapter with double O-ring seal and fin end


<sup>¶</sup> This is a guide to the part number structure only. For availability of specific options, please contact Cytiva.

\*\* Silicone seal. Other materials available upon request.

<sup>¶¶</sup> 127 mm (5 in.) cartridge length only.

## Junior style cartridges

**Example part number:** MCY4440NFPH4 represents a 106 mm length cartridge, with 0.2 µm Ultipor N66 sterilizing grade filter membrane with silicone O-rings.

 **P H4\*\***

Code	Nominal length	Flow rate multiplying factor
MCY4440	106 mm	0.83
MCY3330	82 mm	0.44
MCY2220	57 mm	0.27
MCY1110	32 mm	0.16

Ultipor N66 filter grade code	N66 Posidyne filter grade code	Absolute removal rating	Application
NI	NIZ	0.1 µm	Bioburden reduction
NBA	NBAZ	0.2 µm	
NA	NAZ	0.2 µm	
NL	NLZ	0.45 µm	
NX	NXZ	0.45 µm	
-	NNXZ	0.45 µm	
NB	NBZ	0.45 µm	
NK	NKZ	0.65 µm	Particulate removal
NH	NHZ	0.8 µm	
NN	NNZ	1.2 µm	
NR	-	0.2 µm	Sterilizing grade
NF	NFZ	0.2 µm	
NT	NTZ	0.1 µm	Mycoplasma removal

\*\* Silicone seal. Other materials available upon request.

## Sealkleen filter cartridges

**Example part number:** SLK7002NAP represents a 130 mm Sealkleen cartridge, with 0.2 µm Ultipor N66 bioburden reduction grade filter membrane.

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Code	Nominal length	Flow rate multiplying factor
SLK7002	130 mm	1.00
SLK7001	70 mm	0.50

Ultipor N66 filter grade code	N66 Posidyne filter grade code	Absolute removal rating	Application
NA	NAZ	0.2 µm	Bioburden reduction
NL	NLZ	0.45 µm	
-	NNXZ	0.45 µm	
NB	NBZ	0.45 µm	
NK	NKZ	0.65 µm	Particulate removal
NN	NNZ	1.2 µm	
NR	-	0.2 µm	Sterilizing grade
NF	NFZ	0.2 µm	
NT	NTZ	0.1 µm	Mycoplasma removal

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