
Ultipor N66 membrane

IN KLEENPAK™ CAPSULES

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. Kleenpak™ filter capsule size KA3 with Nylon 66 (N66) filter membrane.

Applications

Both membrane types are offered in different grades for 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.

Table 1. Applications and removal ratings by membrane

Application	Ultipor N66 filter grade	N66 Posidyne filter grade	Absolute removal rating	Removal efficiency
Bioburden reduction	NL	NLZ	0.45 µm	Samples retain > 10 ⁷ /cm ² <i>Serratia marcescens</i>
Sterilizing grade	NF	NFZ	0.2 µm	Retains <i>B. diminuta</i> at 10 ⁷ CFU/cm ² effective filter area
Mycoplasma removal	NT	NTZ	0.1 µm	Removal of <i>Acholeplasma laidlawii</i> mycoplasma with a typical TR > 10 ¹¹ and retention of <i>Brevundimonas diminuta</i> at 10 ⁷ CFU*/cm ² effective filter area

* CFU – colony forming units

Clean and robust design

The Kleenpak filter capsule uses well-proven proprietary thermal bonding techniques for filter construction.

- It maintains high security against filter bypass, even under pulsed-flow conditions.
- The high strength design allows multiple autoclave cycles for extended use and maximum filter economy.
- The polyester shell provides long-term assurance of pressure and temperature ratings.
- The internal filter volume hold-up and dead space are minimized for maximum product recovery.
- A total absence of glues, binder resins, and surfactants results in very low filter extractables and extremely clean filtrate.
- All filter materials of construction meet the specifications for USP Class VI biological tests for plastics at 121°C.

Convenience to suit all needs

The self-contained design of each Kleenpak filter minimizes operator intervention, and exposure, during filter installation and change-out.

- Integrally molded inlet and outlet connections, available in sanitary and hose barb connections.
- Vent and drain connections with seal-protected threads and precision-molded valves.
- Available in four standard sizes for flexibility in batch size or flow rate requirements.

Pharmaceutical-grade quality

- Every single filter capsule is integrity-tested by the forward-flow method during manufacture. The results from forward-flow testing for sterilizing-grade filters are continually validated against bacterial challenge.
- Each filter has a unique serial number for full production and batch traceability.
- 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

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:	Nylon 66 and polyester support.
Ultipor N66	Charge-modified Nylon 66 with polyester support
N66 Posidyne	Nylon 66 with polyester support
Support and drainage layers	Polyester
End caps	Polyester
Core and cage	Polypropylene
Outer shell	Polyester
Vent and drain valve O-rings	Ethylene propylene

Connections (inlet and outlet)

KA1 and KA2 styles	38 mm (1½ in.) sanitary flange 6 to 13 mm stepped hose barb
KA3 and KA4 styles	38 mm (1½ in.) sanitary flange 14 mm hose barb

Nominal dimensions

Size code	KA1	KA2	KA3	KA4
Maximum diameter of bowl (including valves)	94 mm	94 mm	109 mm	109 mm
Nominal length including 1½ in. sanitary flange connection	117 mm	158 mm	174 mm	286 mm
Nominal length including stepped hose barb connection	158 mm	199 mm	-	-
Nominal length including hose barb connection	-	-	210 mm	325 mm

Operating characteristics¹

Maximum operating temperature	Maximum operating pressure	
	Liquid	Gas
40°C	5.2 barg	3.5 barg

¹ In compatible fluids which do not soften, swell or adversely affect the filter or materials of construction.

Sterilization

Ultipor N66 and N66 Posidyne membrane in Kleenpak capsules can be sterilized by steam autoclave. Pre-sterilized versions are available. Some non-sterile versions (denoted with a "G" at the end of the product code) can be sterilized by gamma-irradiation.

Steam autoclaving

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

Warning: Kleenpak filters must not be steam-sterilized *in situ* by passing steam through under pressure.

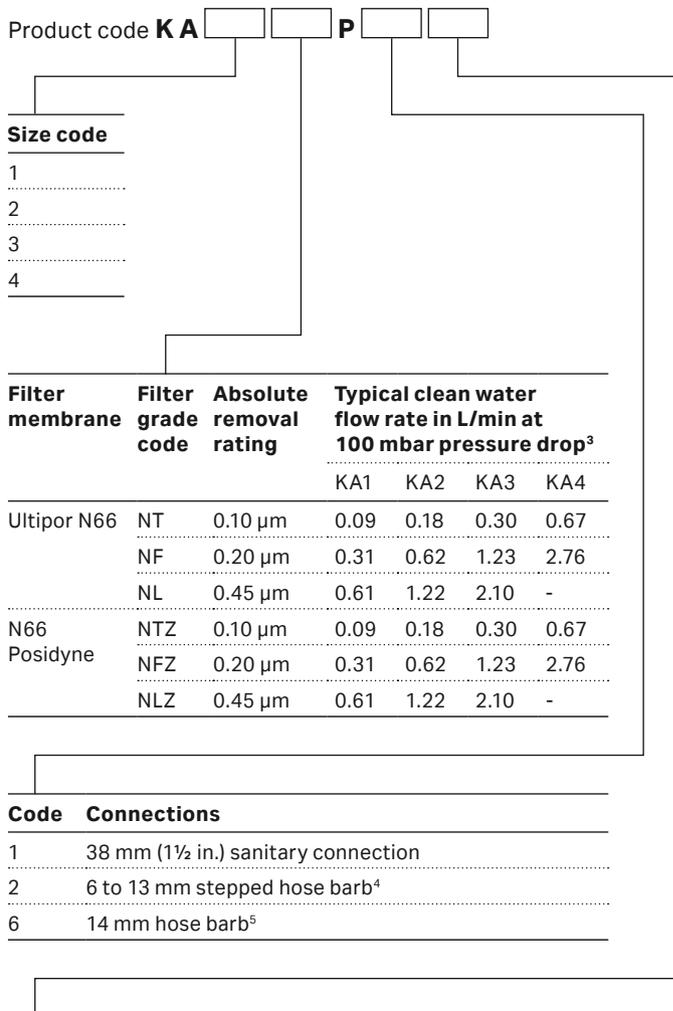
Gamma-irradiation

Maximum dosage	35 kGy
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Other technical data and ordering information²

To make your product code, fill in the relevant code from each section below.

EG: K A 1 NT P 1 G (Size 1, Ultipor N66 0.10 µm, 38mm sanitary connection, unsterilized)



Other connections available on request. Please contact us for details.

² This information is a guide to the product code structure and possible options. Please contact us for availability of specific options.

³ Sizes KA1 and KA2 only.

⁴ For products with sanitary connections and fluids of 1 cP viscosity. For other viscosities, divide the flow rate by viscosity in cP.

⁵ Size KA3 and KA4 only.

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CY55151-17Nov25-DF

