Ultipor® N66 Sterilizing-grade Filter Cartridges

Sterilizing-grade Filters for Large-scale Applications

Pall **Ultipor** N66 sterilizing-grade filter cartridges feature high-strength pure Nylon 6,6 membranes for higher sterility assurance. In wide use for almost 20 years, these filters have a proven record of performance in the production of sterile biologicals and pharmaceuticals. High-area pleated into single open-ended (SOE) AB sanitary style cartridges, **Ultipor** N66 sterilizing-grade filter cartridges are available with ratings from 0.45 µm for LVPs, reagents and viscous fluids, 0.2 µm for sterile products and intermediates, 0.1 µm for sterilization and mycoplasma removal from biologicals, to 0.04 µm for sterilization and virus reduction from biologicals.

Features and Benefits

- Intrinsically water wettable
- Fixed pores, non-shedding
- Resin and surfactant-free
- Broad solvent compatibility
- Low filter extractables
- High-area for long-life
- High protein recovery from most protein solutions
- Repeatedly steamable in situ

Note: *These filters are also available in* ***Kleenpak*** *Nova capsule format.*

Quality and Bio-Safety*

Integrity

- Every filter integrity tested during manufacture. Test correlated to microbial retention

Biological Tests

- Meets USP Biological Reactivity Test, in vivo, for Class VI-121 °C Plastics
- Meets Cleanliness per USP Particulates in Injectables
- Non-Fiber-Releasing per 21 CFR
- Non-Pyrogenic per USP Bacterial Endotoxins (< 0.25 EU/mL)
- Meets Total Organic Carbon and Water Conductivity per USP Purified Water, pH per USP Sterile Purified Water

Steam Resistance

- Lot samples multi-cycle autoclave challenged

** Per lot samples soak or rinse-up flush aliquots.*

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Technical Specifications

Materials of Construction

Membranes	Nylon 6,6, double-layer
Supports, Drainage and End Caps	Polyester
Core and Cage	Polypropylene
O-ring	Silicone[1]

[1] Other polymers available.

Microbial Removal Ratings[2]

NR, NF	0.2 µm sterilizing-grade
NT	0.1 µm mycoplasma sterilizing-grade
ND	0.04 µm rated, sterilizing-grade (Typical MuLV, HIV (retrovirus) T_R 10^5)

[2] Lot samples retain > 10^7 cfu/cm² of an appropriate challenge organism per mod. ASTM F838-83 and FDA guidelines; **NR, NF, NT, ND:** *Brevundimonas diminuta*; NT also retains > 10^7 cfu/cm² *Acholeplasma laidlawii mycoplasma.*

Nominal Dimensions

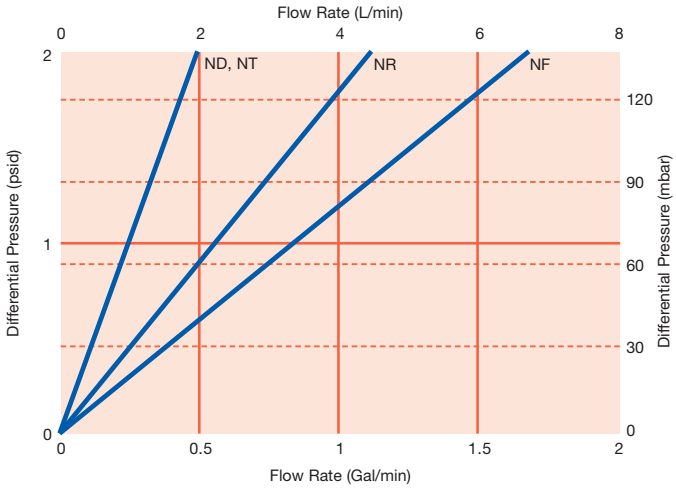
Lengths	10 in. (254 mm), 20 in. (508 mm), 30 in. (762 mm), 40 in. (1016 mm)
Diameter	2.75 in. (70 mm)

Operating Conditions[3]

Maximum Differential Pressure and Temperature	5.5 bard (80 psid) to 50 °C (122 °F) 4.1 bard (60 psid) to 80 °C (176 °F) 2.1 bard (30 psid) to 125 °C (257 °F)

[3] Using compatible fluids.

Typical Liquid Flow Rates[4]



[4] Typical initial clean media ΔP 10 in. (254 mm) element; water at 20 °C (68°F); viscosity 1 cP. For assistance in filter assembly sizing and housing selection, contact your local Pall distributor.

Configuration (AB Code 7)[5]

Double 226 O-ring adapter
Fin end with bayonet lock

[5] Alternate adapter codes available.

Autoclavable or steamable in situ[6]

Cumulative Steam Exposure	16 hours (1-hour cycles) at 121 °C (250 °F)
	4 hours (1-hour cycles) at 140 °C (284 °F)

[6] Laboratory tests to establish multi-cycle resistance. Filters should be qualified in actual use. Contact Pall for recommended procedures.

Aqueous Extractables (NVR) per 10 in. (254 mm) Element

Typically	15 – 25 mg

Ordering Information

AB □ □ □ □ □ □

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

Code[7]	Removal Rating	Nominal Filter Area[8]	Forward Flow[9] mL/min at mbar (psi)
NF	0.2 µm	0.79 m² (8.5 ft²)	12 at 2760 (40)
NR	0.2 µm	0.46 m² (5.0 ft²)	8 at 2760 (40)
NT	0.1 µm	0.79 m² (8.5 ft²)	14 at 5175 (75)
ND	0.4 µm	0.81 m² (8.7 ft²)	25 at 3440 (50)

[7] Code 7 adapter is standard (except 05 length is Code 2 with flat cap).
[8] Per 10 in. (254 mm) element.
[9] Forward Flow allowable limit for one 10 in. (254 mm) cartridge at given test pressure, water wet, air test gas. Please contact Pall for method details and test parameters.

Code	Filter Grade
P	Pharmaceutical*
Omit	General Use

* Pall pharmaceutical-grade filters are designed for use in conformance with CGMP in Manufacturing, Processing, Packing or Holding of Drugs (21CFR210) and CGMP for finished Pharmaceuticals (21CFR211.72) including batch release certificate and full traceability.

Code	Gasket Option
H4	Silicone

Other materials available on request.