

MCY4463 Junior Style Membrane Cartridges



Housing Cross Reference

Housing Style

MLL Series

Technical References

See Appendix for titles.

Ultipor® N ₆₆ ®	Fluorodyne® II
STRPUF-13	JVT-10/96
TR-680c	STRPUF-25
TR-700c	TR-1195

Description

Pall MCY4463 Junior style sterilizing grade membrane filter cartridges are available with either intrinsically hydrophilic Ultipor N₆₆ Nylon 6,6 membrane or low protein/low preservative binding Fluorodyne II hydrophilic modified PVDF membrane. Both membrane types are double layer pleated for added reliability. MCY4463 Junior style membrane filter cartridges are suitable for small batch liquid sterilizing filtration applications with flows up to 1-2gpm.

- · Hydrophilic PVDF or Nylon 6,6
- Sterilizing grade per FDA guidelines
- Double layer for reliability
- 100% integrity tested
- Low extractables
- · Broad chemical compatibilities
- General use Ultipor N₆₆ NR grade
- · Low preservative/low protein binding Fluorodyne II DFL grade
- Repeatedly steamable
- Manufactured for use in conformance with cGMP
- •ISO 9000 Certified Quality System
- · Pharmaceutical "P" optimized
- · Certificate of Test provided

Specifications

Materials

Membranes: (double layer)

- DFL: Hydrophilic PVDF
- NR: Nylon 6,6

Support/Drainage Layers:

- DFL: Polypropylene
- NR: Polyester

Core/Cage: Polypropylene

End Caps:

- DFL: Polypropylene
- NR: Polyester O-rings: Silicone1

NR: FDA listed materials per 21 CFR

Microbial Removal Rating²

0.2 µm, sterilizing grade

Dimensions (nominal)

- Lengths: 5.2 in. (133 mm)
- Diameters: 2.25 in. (57 mm)

Configuration

- · Single open ended cartridge
- · Single 116 O-ring
- Internal plug seal

Operating Conditions³

Max. Differential Pressure/Temp:

- •80 psid (5.5 bard) at 122°F (50°C)
- •55 psid (3.8 bard) at 180°F (82°C)

Autoclaving/Steaming

Autoclavable and Steamable in situ Cumulative Exposure Times:4 Fluorodyne II DFL:

- •30 hours at 257°F (125°C)
- 10 hours at 284°F (140°C) Ultipor N₆₆ NR:
- •16 hours at 257°F (125°C)
- •4 hours at 284°F (140°C)

Maximum Steaming Differential:

- •4.4 psid (0.3 bar)
- ² Assembly lot samples retain >10⁷cfu/cm² of Brevundimonas diminuta per mod. ASTM F838-83 and FDA guidelines.
- ³ Using compatible fluids.
- ⁴ Lab tests (1 hr. cycles) establish multi-cycle resistance. Filters should be qualified in actual use. Contact Pall for recommended procedures.

Liquid Service ProductsSmall Flow Cartridges

1-800-717-7255

or 516-484-5400 – Fax: 516-625-3610 pharmafilter @ pall.com www.pall.com

Specifications cont'd.

Quality/Bio-Safety

Integrity (100% Unit Release Test):

- Correlated to microbial retention. Biological Tests:
- Meets USP Biological Reactivity, In Vivo, for Class VI-121°C plastics. Effluent Quality Tests:⁵
- Meets Cleanliness per USP Particulates in Injectables.
- Non-Fiber-Releasing per 21 CFR

- Non-Pyrogenic per USP Bacterial Endotoxins (< 0.25 EU/ml)
- Meets Oxidizables and pH per USP Purified Water.

Autoclaving Resistance: Lot samples multi-cycle autoclave challenged.

Integrity Test Values

Forward Flow at 40 psi (2760 mbar):6

- DFL: $\leq 4.0 \, \text{cc/min}$
- NR: ≤4.6 cc/min

Pressure Drop vs. Liquid Flow Rate⁷

DFL: 0.7 psid (50 mbard)/lpm NR: 1.2 psid (83 mbard)/lpm

⁵ Per lot sample soak or rinse-up flush aliquots.

⁶ Allowable flow, water wet, air test gas.

⁷ Typical initial clean \(\Delta P\), water at 68°F (20°C), 1 cp. Pressure drop at other flows is directly proportional to flow. For assembly pressure drop, add filter cartridge value to housing value at specified flow rate. For assistance in sizing filter assemblies, contact your local Pall distributor.

Part Numbers / Ordering Information

Part Number 8 Media Type MCY4463DFLPH4 Fluorodyne II hydrophilic PVDF (double layer) MCY4463NRPH4 Ultipor N₆₆ hydrophilic Nylon 6,6 (double layer)

8 H4 suffix = Silicone O-ring material (standard). Buna-N, Ethylene Propylene and Fluorocarbon Elastomer O-rings also available. See Appendix for alternate O-ring polymer codes.

Note: For very small flows, a half-high cartridge (MCY2230) is available on special order (fits MLL2230 Junior housing; see MLL Junior data sheet). For additional information, contact your local Pall distributor.

Specifications and Availability: The information provided is a guide to the part number structure and possible options. Product availability may be subject to change without notice. All specifications are nominal. This literature was reviewed for accuracy at the time of publication. For current information on the products and test methodologies, consult your local Pall distributor.