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Millipak® Final Fill Filters

Maximize recovery and enhance protection of your high value product

Millipak® Final Fill capsule filters are designed for reliable filtration of small volume, high value solutions. In final filling, it is critical to maximize product recovery and maintain sterility.

The filter's stacked disc design minimizes hold-up volume over standard pleated devices, increasing product recovery.

These user-friendly filters feature a multi-purpose port that simplifies venting, integrity testing and sampling, and is validated to maintain an aseptic flow path even after multiple actuations.

Millipak® Final Fill filters contain the proven and trusted Durapore® membrane in multiple pore sizes offering flexibility for your specific process needs.

Benefits

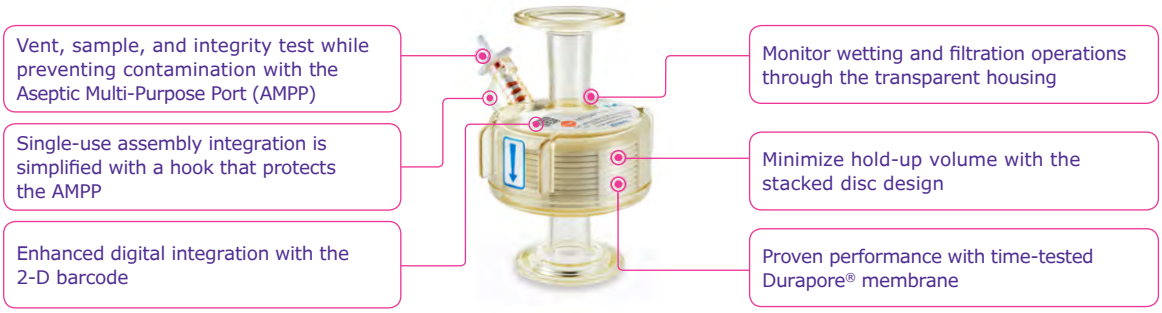
- Maximizes product recovery in final and high value filtration
- Simplifies operation and reduces risk of microbial and particulate contamination
- Contains Durapore® membrane for high flow rates, low binding and extractables, and broad chemical compatibility
- Improves integration into single-use assemblies

Membrane Pore Sizes

Available with particulate removal, bioburden reduction and sterilizing-grade Durapore® polyvinylidene fluoride (PVDF) membranes for both liquid and solvent applications.

- Hydrophilic Durapore® membrane: 0.1 µm, 0.22 µm, 0.45 µm, 5.0 µm
- Hydrophobic Durapore® membrane: 0.22 µm

Millipak® Final Fill Filters Design Features



Maximize Product Recovery

In applications like final filtration where maximizing product recovery is critical, the low hold-up volume of Millipak® Final Fill filters translates to more vials filled, as compared to traditional pleated filters. Millipak® Final Fill filters incorporate Durapore® membrane bonded to solid discs instead of the support material in pleated filters, resulting in lower hold-up volume and reduced risk of particulates, Figure 1. Consistent, high product recoveries are achieved across filtration areas from 100-1000 cm^2. Millipak® Final Fill filters maximize your product recovery, increasing the efficiency of this critical process step, Figure 2.

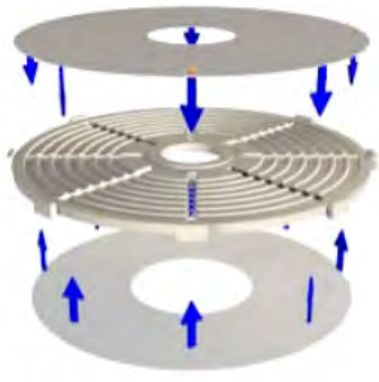


Figure 1
Membrane is bonded to solid discs instead of support material used in pleated filters, resulting in lower hold-up volume and reduced risk of particulates

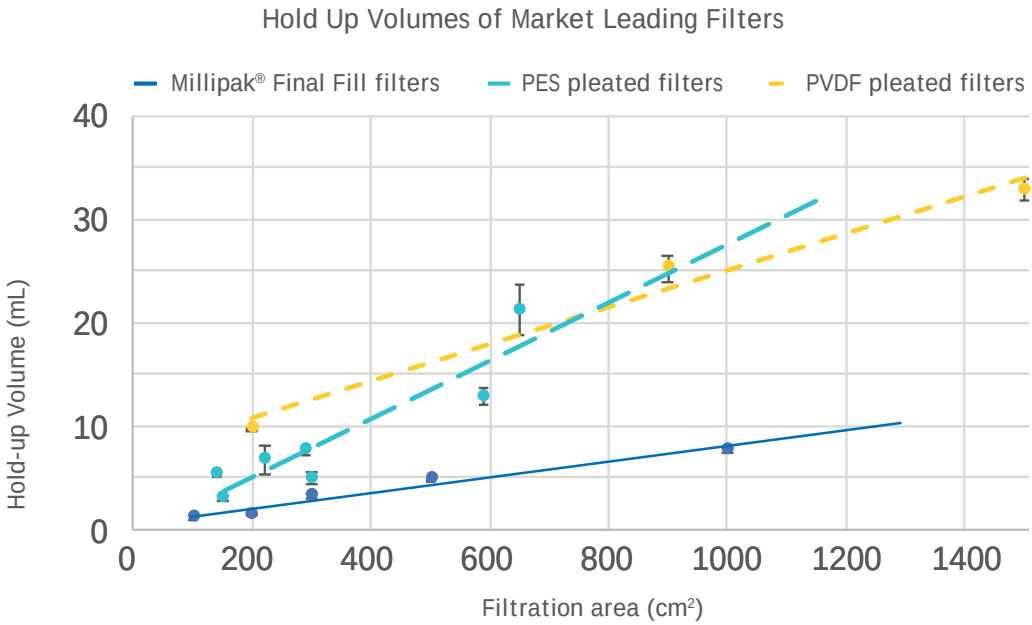


Figure 2
Hold-up volume of Millipak® Final Fill filters as compared to pleated polyethersulfone (PES) or polyvinylidene fluoride (PVDF) filters of different areas. Values represent the mean and standard deviation from replicate tests.

Robust Protection Combined with Ease of Use

The Aseptic Multi-Purpose Port (AMPP) has been designed for ergonomic use with gloves, and visible ‘open’ and ‘closed’ locking positions. It contains three O-rings – the lower O-ring seals the flow path when the AMPP is closed, and two upper O-rings maintain an aseptic area that prevents cross-contamination between the environment and flow path. This sterile boundary is maintained after heavy microbial challenge and multiple actuations keeping your process safe from contaminant exposure. This is critical in final fill, and also for sterility assurance in redundant filtration trains where the flow path downstream of the redundant filter must not be compromised.

Filter venting, integrity testing and sampling can all be performed through the single AMPP, lowering the risks associated with multiple filter connection points and streamlining process design.

Figure 3
Aseptic Multi-Purpose Port (AMPP).

Scalable

Multiple filter sizes enable easy scale up and sizing. All Millipak® Final Fill filter capsules are available as non-sterilized (gamma irradiation and autoclave compatible) or sterilized by gamma irradiation.

Size Format / Durapore® Membrane	20 (100 cm²)	40 (200 cm²)	60 (300 cm²)	100 (500 cm²)	200 (1000 cm²)
0.1 µm	√	√	√	√	√
0.22 µm	√	√	√	√	√
0.45 µm	√	√	√	√	√
5.0 µm			√		√
0.22 µm phobic	√		√		√

Mobius® Single-use Solutions

Millipak® Final Fill filters are part of the Mobius® library. This provides you with the flexibility to design single-use assemblies that meet your specific processing requirements.

The Emprove® Program – Your Fast Track through Regulatory Challenges

The Emprove® Program, complements our product portfolio, and provides three types of dossiers to support different stages of development and manufacturing operations such as qualification, risk assessment, and process optimization. This program consolidates comprehensive product-specific testing, quality and regulatory information, making it readily available to our customers to simplify their compliance needs.

Compliance and Traceability

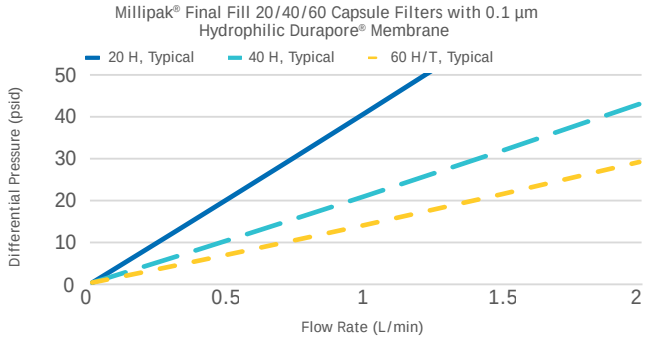
Millipak® Final Fill filters are designed, developed and manufactured in accordance with a Quality Management System approved by an accredited registering body to an ISO® 9001 Quality Systems Standard. Each unit is 100% integrity tested during manufacturing and includes a certificate of quality.

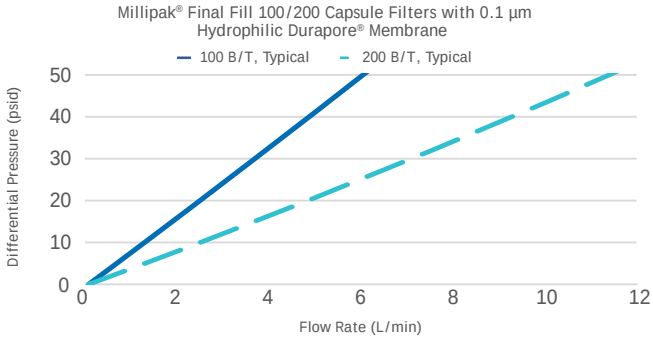
Specifications

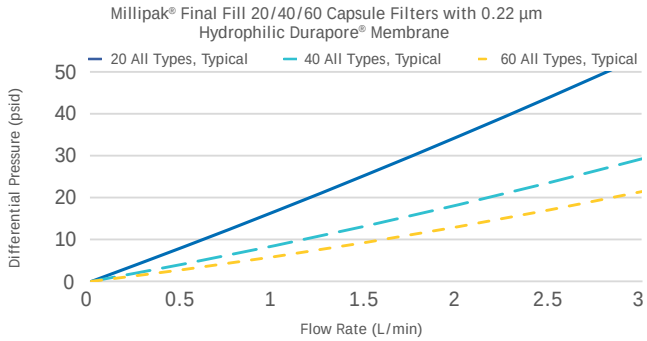
	Millipak® Final Fill 20	Millipak® Final Fill 40	Millipak® Final Fill 60	Millipak® Final Fill 100	Millipak® Final Fill 200
Nominal Dimensions					
Maximum length	8.1 cm (3.2 in.)	8.6 cm (3.4 in.)	10.9 cm (4.3 in.)	11.9 cm (4.7 in.)	14.5 cm (5.7 in.)
Body diameter	7.6 cm (3.0 in.)	7.6 cm (3.0 in.)	7.6 cm (3.0 in.)	7.6 cm (3.0 in.)	7.6 cm (3.0 in.)
Body diameter w/ anti-roll edges				8.1 cm (3.2 in.)	8.1 cm (3.2 in.)
Filtration Area	100 cm^2 (0.11 ft^2)	200 cm^2 (0.22 ft^2)	300 cm^2 (0.32 ft^2)	500 cm^2 (0.54 ft^2)	1000 cm^2 (1.08 ft^2)
Aseptic Multi-Purpose Port	3.2 mm (1/8 in.) hose barb				
Materials of Construction					
Filter membrane	Durapore® PVDF (polyvinylidene fluoride) membrane				
Support discs	Polysulfone				
Filter capsule	Polysulfone				
Aseptic Multi-Purpose Port (AMPP)	Polyethersulfone				
Aseptic Multi-Purpose Port (AMPP) O-rings	Silicone				
Hold-up Volume (mL)	20 psi above the Bubble Point Specification for 1 minute				
	1.1	1.5	3.2	4.8	7.2
Maximum Inlet Pressure	60 psi (4.1 bar) at 25 °C	80 psi (5.5 bar) at 25 °C			
Maximum Differential Pressure					
Forward:	60 psi (4.1 bar) at 25 °C	80 psi (5.5 bar) at 25 °C (0.1 µm, 0.22 µm, 0.45 µm, hydrophobic 0.22 µm) 50 psi (3.5 bar) at 25 °C (5 µm) 25 psi (1.7 bar) at 80 °C			
Reverse:	10 psi (0.7 bar) at 25 °C				
Bubble Point at 23 °C					
0.1 µm:	≥ 70 psi (4830 mbar) air with water*				
0.22 µm:	≥ 50 psi (3450 mbar) air with water				
0.45 µm:	≥ 26 psi (1790 mbar) air with water				
Hydrophobic 0.22 µm:	≥ 29 psi (2000 mbar) air with water ≥ 18 psi (1240 mbar) in 60/40% IPA/water ≥ 17 psi (1170 mbar) in 70/30% IPA/water				
Bacterial Retention for 0.1 µm and 0.22 µm	Quantitative retention of 10^7 CFU/cm^2 *Brevundimonas diminuta* ATCC® 19146 per ASTM® F838 methodology.				
Bacterial Endotoxin	Aqueous extraction contains < 0.25 EU/mL per device as determined using the Limulus Amebocyte Lysate (LAL) test, meeting requirements of USP <85>, EP 2.6.14 and JP 4.01.				
Total Organic Carbon (TOC)/Conductivity	Samples exhibited < 500 ppb TOC per USP <643> and < 1.3 µS/cm conductivity per USP <645> at 25 °C after sterilization and a water flush of:				
	1.0 L	2.0 L	2.0 L	3.0 L	5.0 L
Sterilization	Device integrity and retention was maintained after 3 autoclave cycles of 90 minutes at 126 °C. Devices can withstand a dose ≤ 40 kGy gamma exposure.				
Toxicity	Component materials meet the criteria for Class VI testing based on USP <88> Biological Reactivity, *in vivo*, USP <87> Biological Reactivity, *in vitro*, and ISO 10993-5 Tests for *in vitro* Cytotoxicity. This product also meets physicochemical specifications, as described in USP <661> Containers-Plastics.				
Particle Shedding	Effluent meets the acceptance criteria set forth in USP <788> for large volume parenterals.				
Non-Fiber Releasing	This product was manufactured with a Durapore® membrane which meets the criteria for a "non-fiber releasing" filter as defined in 21 CFR 210.3 (b)(6), validated based on large volume parenteral specifications as detailed in USP <788> Particulate Matter in Injections.				
Indirect Food Additive	All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177–182, based on information provided by raw material suppliers.				
Quality Management System	These products are manufactured in a facility which is certified to ISO® 9001:2015 Quality Management Systems.				

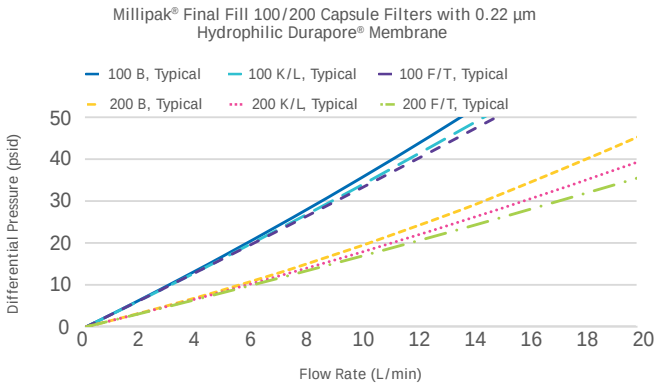
*Transient pressure excursion above the maximum differential and inlet pressures of the unit for integrity testing and capsule blow-down is acceptable.

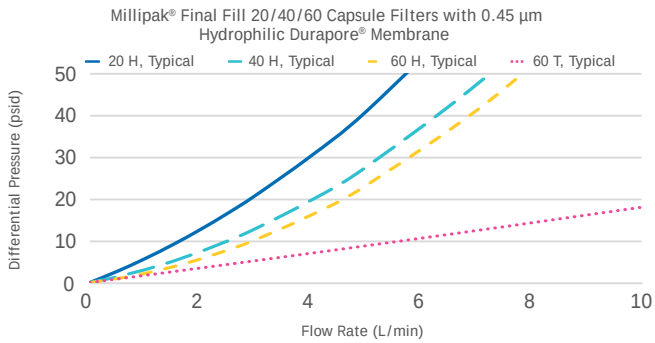
Typical Clean Water Flow Rates

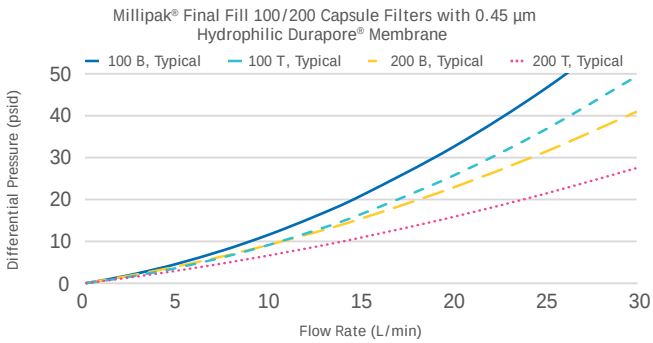


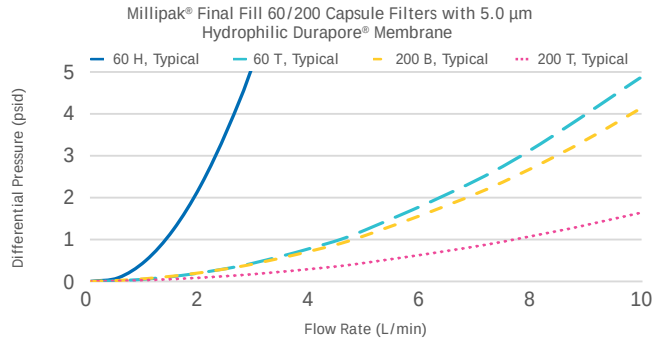












Legend

B = 13 mm (½ in.) stepped hose barb inlet and outlet

C = 19 mm (¾ in.) sanitary flange inlet and 6 mm (¼ in.) hose barb outlet

F = 19 mm (¾ in.) sanitary flange inlet and outlet

H = 6 mm (¼ in.) stepped hose barb inlet and outlet

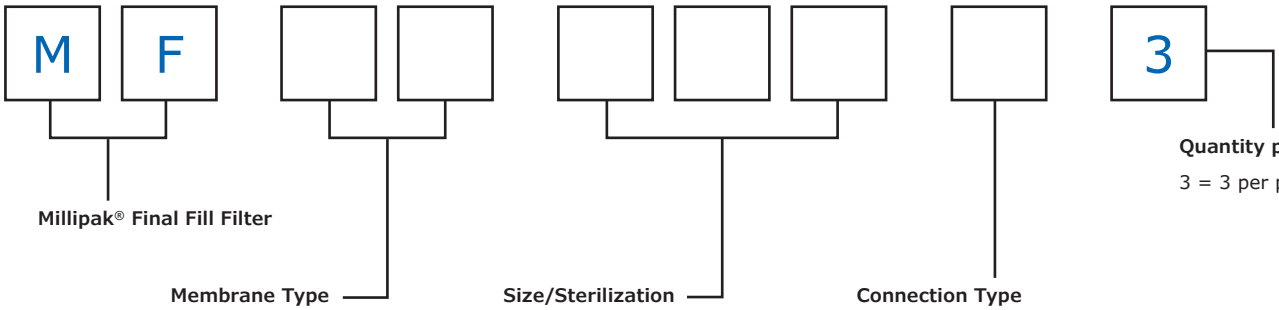
K = 19mm (¾ in.) sanitary flange inlett and 13 mm (½ in.) hose barb outlet

L = 38 mm (1 ½ in.) sanitary flange inlet and 13 mm (½ in.) stepped hose barb outlet

T = 38 mm (1 ½ in.) sanitary flange inlet and outlet

Ordering Information

Millipak® Final Fill Filters with Hydrophilic Durapore® 0.1 µm/0.45 µm Membrane



Millipak® Final Fill Filter

Membrane Type

VL = Durapore® 0.1 µm

HL = Durapore® 0.45 µm

Size/Sterilization

02G = 20, non-sterilized

02S = 20, sterilized by gamma irradiation

04G = 40, non-sterilized

04S = 40, sterilized by gamma irradiation

06G = 60, non-sterilized

06S = 60, sterilized by gamma irradiation

10G = 100, non-sterilized

10S = 100, sterilized by gamma irradiation

20G = 200, non-sterilized

20S = 200, sterilized by gamma irradiation

Connection Type

Millipak® Final Fill 20, 40, 60
H = 6 mm (¼ in.) stepped hose barb inlet and outlet

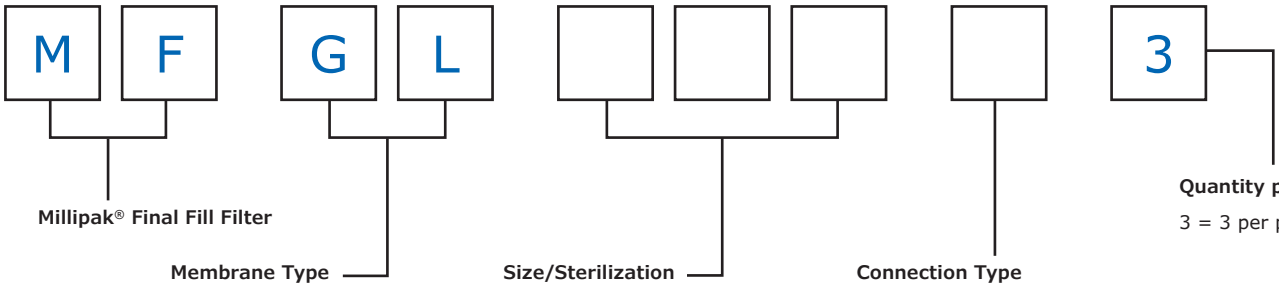
Millipak® Final Fill 100, 200
B = 13 mm (½ in.) stepped hose barb inlet and outlet

Millipak® Final Fill 60, 100, 200
T = 38 mm (1½ in.) sanitary flange inlet and outlet

Quantity per Pkg

3 = 3 per package

Millipak® Final Fill Filters with Hydrophilic Durapore® 0.22 µm Membrane



Millipak® Final Fill Filter

Membrane Type

GL = Durapore® 0.22 µm

Size/Sterilization

02G = 20, non-sterilized

02S = 20, sterilized by gamma irradiation

04G = 40, non-sterilized

04S = 40, sterilized by gamma irradiation

06G = 60, non-sterilized

06S = 60, sterilized by gamma irradiation

10G = 100, non-sterilized

10S = 100, sterilized by gamma irradiation

20G = 200, non-sterilized

20S = 200, sterilized by gamma irradiation

Connection Type

Millipak® Final Fill 20, 40, 60
C = 19 mm (¾ in.) sanitary flange inlet and 6 mm (¼ in.) hose barb outlet
H = 6 mm (¼ in.) stepped hose barb inlet and outlet

Millipak® Final Fill 60, 100, 200
L = 38 mm (1½ in.) sanitary flange inlet and 13 mm (½ in.) stepped hose barb outlet
T = 38 mm (1½ in.) sanitary flange inlet and outlet

Millipak® Final Fill 100, 200
B = 13 mm (½ in.) stepped hose barb inlet and outlet
K = 19 mm (¾ in.) sanitary flange inlet and 13 mm (½ in.) hose barb outlet

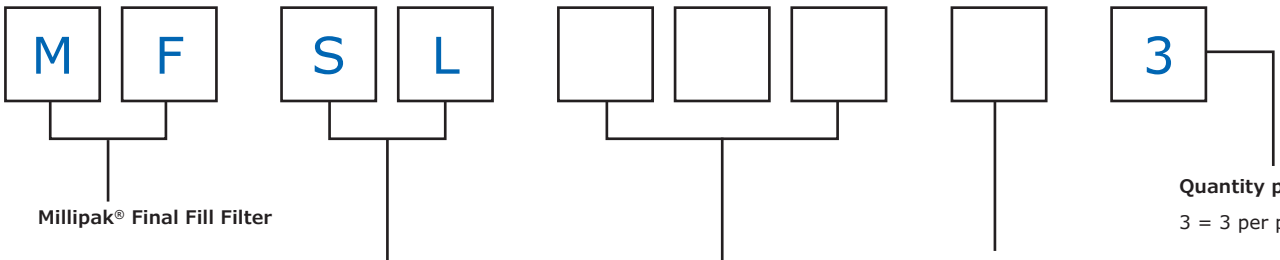
Millipak® Final Fill 20, 40, 60, 100, 200
F = 19 mm (¾ in.) sanitary flange inlet and outlet

Quantity per Pkg

3 = 3 per package

Ordering Information

Millipak® Final Fill Filters with Hydrophilic Durapore® 5.0 µm Membrane



Millipak® Final Fill Filter

Membrane Type

SL = Durapore® 5.0 µm

Size/Sterilization

06G = 60, non-sterilized

06S = 60, sterilized by gamma irradiation

20G = 200, non-sterilized

20S = 200, sterilized by gamma irradiation

Connection Type

Millipak® Final Fill 60
H = 6mm (¼ in.) stepped hose barb inlet and outlet

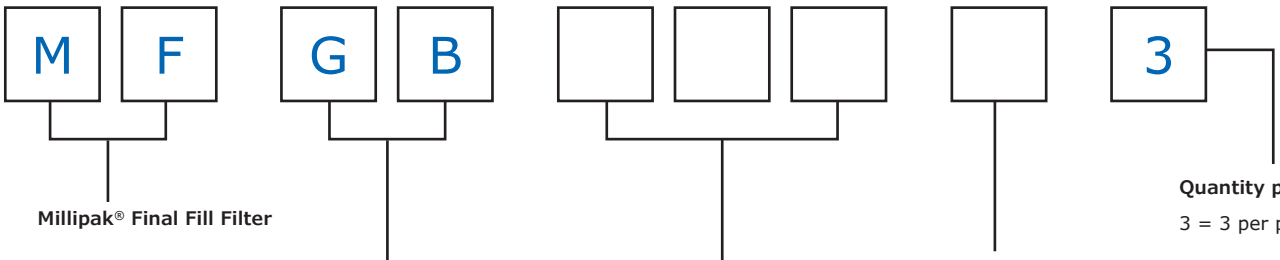
Millipak® Final Fill 200
B = 13 mm (½ in.) stepped hose barb inlet and outlet

Millipak® Final Fill 60, 200
T = 38 mm (1½ in.) sanitary flange inlet and outlet

Quantity per Pkg

3 = 3 per package

Millipak® Final Fill Filters with Hydrophobic Durapore® 0.22 µm Membrane



Millipak® Final Fill Filter

Membrane Type

GB = Hydrophobic Durapore® 0.22 µm

Size/Sterilization

02G = 20, non-sterilized

02S = 20, sterilized by gamma irradiation

06G = 60, non-sterilized

06S = 60, sterilized by gamma irradiation

20G = 200, non-sterilized

20S = 200, sterilized by gamma irradiation

Connection Type

Millipak® Final Fill 20, 60
H = 6 mm (¼ in.) stepped hose barb inlet and outlet

Millipak® Final Fill 200
B = 13 mm (½ in.) stepped hose barb inlet and outlet

Millipak® Final Fill 60, 200
T = 38 mm (1½ in.) sanitary flange inlet and outlet

Quantity per Pkg

3 = 3 per package

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