Millipore_®

User Guide

Millipak® Final Fill Filters

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Introduction

Millipak® Final Fill Filters have a unique stacked disc design to minimize hold-up volume and maximize recovery of high value products. Designed for final fill processing, they can be used alone or integrated with assemblies, isolators or in a redundant filtration operation. All Millipak® Final Fill filters are made with Durapore® PVDF membranes. For more details, visit our website.

This user guide applies to filters with catalog numbers beginning with MFVL, MFGL, MFHL and MFSL.

Membrane		Millipak [®] Final Fill Filter				
Pore Size (µm)	Catalog Number Prefix	20	40	60	100	200
		Filtration Area (cm²)				
		100	200	300	500	1000
0.1	MFVL			$\sqrt{}$	√	
0.22	MFGL	$\sqrt{}$		$\sqrt{}$		
0.45	MFHL					
5.0	MFSL	n/a	n/a		n/a	

General Guidelines

Avoid dropping the filter

If a Millipak® Final Fill Filter drops onto a hard surface, perform a pre-use integrity test to ensure that the filter was not damaged.

Use sterile technique

Some Millipak® Final Fill Filters are shipped sterilized. To prevent contaminating the filter, handle the outside of the housing only. Do not touch the inlet or outlet fittings of a capsule with ungloved hands.

Orient filter correctly

Optimum performance of the filter occurs when the flow is in the forward direction (inlet to outlet). Position the filter so that the Aseptic Multi-Purpose Port (AMPP) is at the top for easier wetting and venting.

Millipak® Final Fill Filters with hose barb connections

Use tubing clamps to secure tubing to the hose barb connections. This prevents tubing from slipping off the hose barb when under pressure.

Millipak® Final Fill Filters with sanitary flanges

Do not overtighten the sanitary flange. Fingertightening is sufficient. Overtightening may crack the fitting. Use caution when connecting a plastic Millipak® Final Fill fitting to a stainless steel fitting.

Unpacking

Inspection

Visually inspect the filters upon receipt to ensure no damage occured during shipping. The outer carton and the bags within the box that protect the filters should be intact and in good condition.

Unpacking

Millipak® Final Fill Filters are shipped double bagged. Carefully tear open the outer bag, then tear open the inner bag.

Millipak® Final Fill Filters are shipped with the following:

Certificate of Quality

Provides detailed product properties and performance data, lot release criteria, product audit criteria, and in-process testing results.

Durapore Wetting Guide

Provides guidance on wetting the filter to ensure optimum performance.

Gamma Indicator

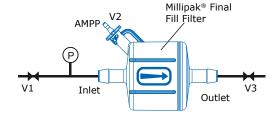
Indicates filter has been sterilized by gamma irradiation for sterilized products.

Storing the Filter

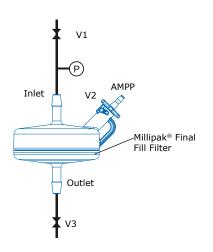
Store filters in their original packaging, away from direct sunlight, at room temperature. Note the use by date of the filter. Integrity test all Millipak® Final Fill Filters before use to ensure no damage occurred during shipping or storage.

Installation

- 1. Install the filter so the process flow is in the forward direction (from inlet to outlet). Millipak® Final Fill Filter 100 and 200 have a flow direction arrow on the filter body. The inlet port is labeled on all Millipak® Final Fill Filters. All filters may be installed either vertically or horizontally.
- Install a user supplied pressure gauge to the inlet side of the filter. Attach isolation valves on the inlet and outlet lines of the filter to allow flushing, venting and draining.
- Attach process lines to the inlet and outlet ports of the filter. Install the Millipak® Final Fill Filter with the AMPP at the highest point. Attach tubing to the AMPP and direct this tubing to drain or waste.



Millipak® Final Fill Filter Horizontal Installation (Millipak® Final Fill Filter 100 and 200 with the flow direction arrow shown)

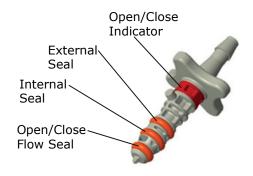


Millipak® Final Fill Filter Vertical Installation (Millipak® Final Fill Filter 20, 40, 60 without flow indicator arrow shown)

Operating the Aseptic Multi-Purpose Port

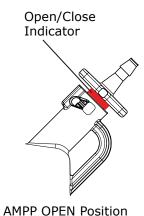
Millipak® Final Fill Filters feature an Aseptic Multi-Purpose Port (AMPP). The AMPP can be used as a vent, sampling port and/or an integrity tester connection.

The port features a unique, three O-ring design to ensure fluid contact surfaces remain isolated.

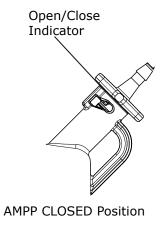


Millipak® Final Fill Filters AMPP

To open the port, rotate the port handle counterclockwise half a turn. The red open/closed indicator should be visible.



To close the port, rotate the port handle clockwise half a turn. The red open/closed indicator should not be visible.



Wetting and Integrity Testing

Flushing is beneficial to filtrate quality. Complete wetting is critical to performing an accurate integrity test.

Wetting

Refer to the <u>Wetting Instructions for</u>
<u>Filter Units with Durapore® Membrane</u>
for guidance on wetting the filter.

Integrity Testing

Refer to the Certificate of Quality included with the filter for specifications.

Sterile Filtering

To start filtration, slowly wet the filter at low pressure and purge all air. This ensures that all of the effective membrane area is used and the membrane is fully wetted prior to the start of filtration. To minimize the risk of filtration induced failures, ensure that the filtration process is compliant with all published filter specifications.

Warranty

The applicable warranty for the products listed in this publication may be found at www.millipore.com/terms (within the "Terms and Conditions of Sale" applicable to your purchase transaction).

We provide information and advice to our customers on application technologies and regulatory matters to the best of our knowledge and ability, but without obligation or liability. Existing laws and regulations are to be observed in all cases by our customers. This also applies in respect to any rights of third parties. Our information and advice do not relieve our customers of their own responsibility for checking the suitability of our products for the envisaged purpose.

For worlwide contact information and technical assistance please visit: www.sigma-aldrich.com

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