

Millidisk® Barrier Filter

Facilitate post-sterilization pre-use integrity testing of sterile filtration systems

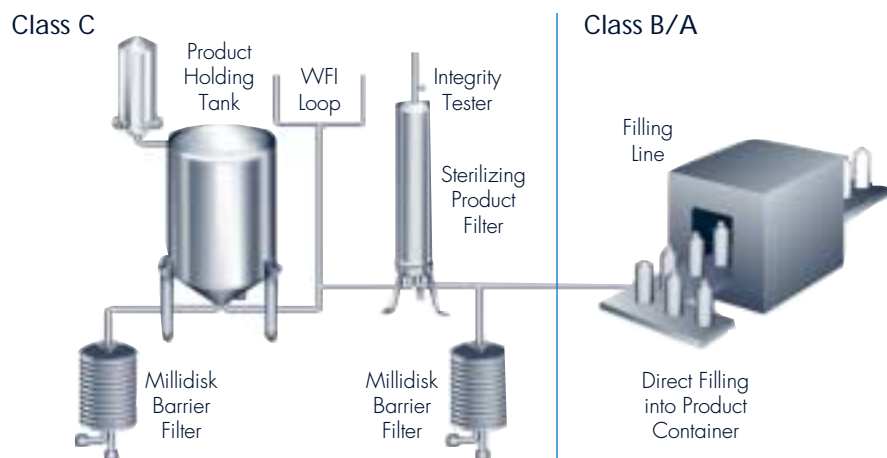


- ▶ Unlimited flushing volume
- ▶ Increase of process yield
- ▶ Assured downstream sterility
- ▶ Quality and reliability
- ▶ One size for all applications

The Millidisk Barrier Filter was developed to facilitate in-line post steam-in-place (SIP), pre-use integrity testing of single and/or redundant liquid filter systems. The unique combination of hydrophilic and hydrophobic sterilizing-grade Durapore® membrane in one filter unit allows for steam penetration, condensate removal, filter drying, filter wetting and filter integrity testing without compromising the sterility of the steam sterilized or autoclaved system.

Regulatory authorities in Europe have introduced new guidance with respect to filter integrity testing, specifically regarding post SIP, pre-use testing of sterilizing-grade liquid filters. The European GMP directive of 1997 for human and veterinary medicinal products, annex 1, point 85 states: "The integrity of the sterilized filter should be verified before use and should be confirmed immediately after use by an appropriate method such as bubble point, diffusive flow or pressure hold test." The Millidisk Barrier Filter is the best choice for meeting this recommendation.

Operation Overview



The Millidisk Barrier Filter is installed on the downstream side between the sterilizing-grade liquid filter housing and the condensate line for SIP systems, as shown above. During the SIP cycle the sterilizing-grade liquid filter, the Millidisk Barrier Filter, the filling line (or holding tank) and all connecting piping is sterilized. During the integrity test process, both wetting liquid and air are removed to the drain through the Millidisk Barrier Filter maintaining the sterility of the downstream system.

Unlimited Flushing Volume

The Millidisk Barrier Filter eliminates the need for a traditional pressure vessel set-up and the limited flush volumes associated with it. Using the Millidisk Barrier Filter, unlimited volumes of both gas and water may be flushed through to the system drain.

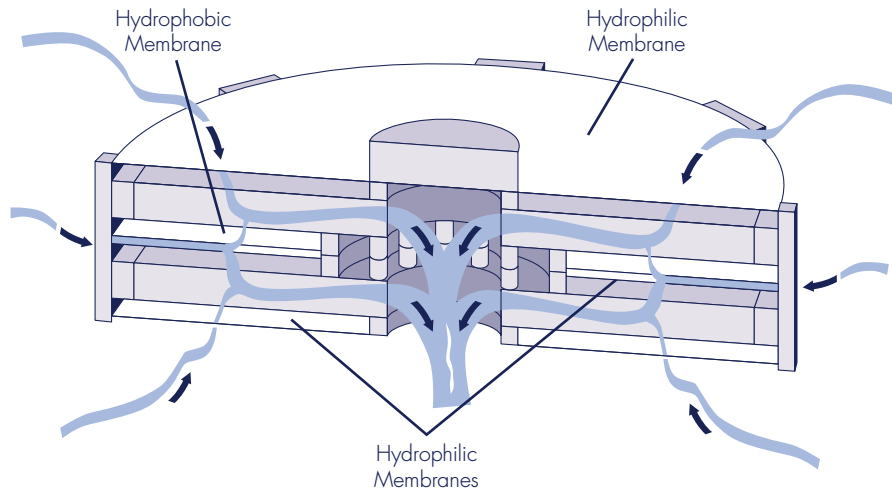
Increase Process Yield

Using the Millidisk Barrier Filter during the sterilization and integrity testing process increases product yield by eliminating the need to discharge the first production volume that typically contains filter extractable substances. Performing post-SIP, pre-use integrity testing requires wetting the filter with water. Filter extractable substances are eliminated when this water is flushed to the drain through the Millidisk Barrier Filter.

Assured Downstream Sterility

Each lot is tested for bacterial retention following ASTM[®] guidelines for thermal and hydraulic stress resistance. The Millidisk Barrier Filter is 100% integrity tested in both forward and reverse directions prior to packaging.

Millidisk Barrier Filter Flow Path and Membrane Distribution



Quality and Reliability

Each Millidisk Barrier Filter comes with a Certificate of Quality that states that the filter has met Quality Assurance lot release requirements. A validation guide is available to comply with regulatory requirements. The Millidisk Barrier Filter is manufactured in a facility whose Quality Management System is approved by an accredited registering body to the ISO® 9001 Quality Systems Standard. Every Millidisk Barrier Filter is labeled with its catalogue number, lot number and serial number.

One Size for All Requirements

The Millidisk Barrier Filter can be used for all process systems containing sterilizing-grade liquid filters ranging from the smallest area up to filtration areas representing 5-round 10" applications.

Specifications	
Materials of Construction	Hydrophilic and hydrophobic Durapore® PVDF membrane, polysulfone support structure, silicone O-rings
Filtration Area <i>Millidisk 40 Format</i>	2000 cm ² (310 in ²)
Operating Conditions	
<i>Maximum Inlet Pressure</i>	6.2 bar (90 psi) at 25 °C
<i>Maximum Differential Pressure</i> <i>Product Qualification Values</i>	<i>Forward:</i> 4.1 bar (60 psi) at 25 °C 1.7 bar (25 psi) at 80 °C 340 mbar (5.0 psi) at 123 °C <i>Reverse:</i> 690 mbar (10 psi) at 25 °C
<i>In-Process Value</i>	The maximum forward differential pressure during this operation should not exceed 1.4 bar (20 psi) at 25 °C so that the pores of the hydrophobic Durapore membrane are not intruded when wetting
Sterilization	May be autoclaved at 126 °C for 60 minutes up to 4 times or steamed-in-place at 135 °C for 60 minutes up to 4 times
Integrity Testing <i>Bubble Point</i>	≥1280 mbar (18.5 psi) in 70/30% IPA/water at 23 °C
Bacterial Retention	Millidisk Barrier Filter units are qualified for quantitative retention of <i>Brevundimonas diminuta</i> at a challenge level of 10 ⁷ cfu/cm ² when tested in accordance to ASTM F838-83 methodology
Bacterial Endotoxin	An aqueous extraction contains < 0.5 EU/mL bacterial endotoxin as determined by the LAL test
Toxicity	Component materials meet the requirements of the USP Class VI Biological Test for Plastics and the USP General (Mouse) Safety Test
Typical Flow Rate	7.6 L/min (2.0 gpm) at 1.0 barg (14 psi) with water at 25 °C

Ordering Information

Description	Qty/Pk	Catalogue No.
Millidisk Barrier Filter	3	MCGB L4S 03

To Place an Order or Receive Technical Assistance

For additional information call your nearest Millipore office:

In the U.S. and Canada, call toll-free
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In the U.S., Canada and Puerto Rico,
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