

Tangential Flow Depth Filtration® (TFDF®)

Introduction

SpectrumLabs.com offers a unique TFDF® filter that combines the benefits of the non-fouling nature of tangential flow filters with the benefits of high dirt capacity depth filters. Please refer to the following instructions for the care and use.

A. Materials of Construction

Housing: Polysulfone

Filter Media: HDPE 1-3um Pore Rating

HDPE 2-5um Pore Rating

Potting Material: Urethane

-All materials USP Class VI compatible

-Pore Ratings for reference only: Retention rating may vary based on application

B. Filter Preparation

TFDF® filters are shipped ready-to-use with no surfactant or storage agent. Filters wet readily with water and/or buffer.

C. Filter Sterilization

SpectrumLabs.com recommends using the filters with Pro-Connex® Ready-to-Use, Sterile Flow Paths that include the single-use MagLev pump and pressure sensors for perfusion applications. When needed, Sampler and MiniKros® filters (filters part numbers beginning with S and N) filters can be autoclaved one time using the conditions below:

NOTE: *KrosFlo® and KrosFlo® Max filters (filters beginning with K or X) have not been validated for autoclave cycles.*

1. Remove and discard all pouches, as these are not autoclavable; wet the membrane (optional).
2. Loosen all module connections to avoid damaging the module during the autoclave cycle.
3. Wrap all open ports of the connecting tubing with autoclave paper, making sure permeate cavity is open to steam penetration along with the inlet/retentate side.
4. Ramp up the autoclave by increasing the temperature by 1-2°C/min up to 121°C (15 psig)



Patent Pending



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5. Hold the autoclave at or above 121°C for 50 min, not to exceed 124.1°C.
6. Slowly ramp down the autoclave temperature by 1-2°C/min until room temperature.
7. Tighten all module connections.
8. Perform a module integrity test.

D. Integrity Test

Gross Leak Integrity Test

TFDF® filters are integrity tested prior to shipment and are extremely robust. When needed, an integrity test can be performed prior to use. The following pressure hold test is recommended to verify the integrity of a wetted filter.

1. With the bottom permeate port closed fully, wet the filter with water and ensure that permeate side outside of the fibers is flooded. Direct the upper permeate line to drain.
2. Close retentate line and introduce air into the filter via the inlet line with either pump or air source.
3. Do not exceed 1.0 psi.
4. Wait. If rapid bubbles do not appear in the permeate cavity within 2-3 seconds, then module is integral. Small bubbles will slowly start to form after a few seconds and will increase in strength to rapid bubbles over time. The first few seconds are key to see the gross failure.

NOTE: *The TFDF® media readily passes air so false negatives are a high probability. If rapid bubbles are seen in the first few seconds, redo wet-out procedure and integrity test to confirm gross integrity failure.*

E. Filter Operation

SpectrumLabs.com recommends the following operating parameters:

Pressure: Not to exceed 30psig inlet pressure.

NOTE: *As process pressures change, retention characteristics of the TFDF® filter might be affected.*

Flow: For mammalian cell perfusion, shear rates from 1500s⁻¹ to 3000s⁻¹ are recommended. For protein or virus clarification, shear rates of up to 8000s⁻¹ may be required for better performance.



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