

# Prostak<sup>™</sup> Microfiltration Modules

User Guide

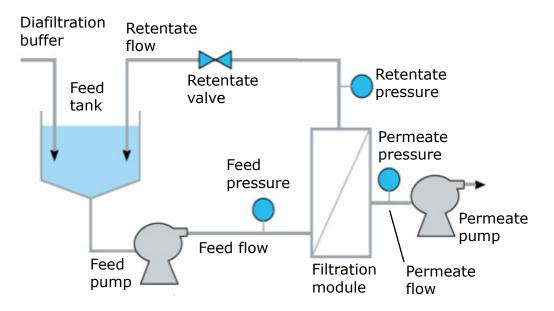
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# Introduction

This user guide provides installation and maintenance procedures for Prostak<sup>™</sup> tangential flow, microfiltration (MF) devices in two-pump Prostak<sup>™</sup> MF systems that include a feed or cross flow pump and a permeate flow control pump.

A typical Prostak<sup>™</sup> MF filter two-pump TFF system with permeate control (low temperature at constant flux) is shown below.



### Abbreviations

CIP	Clean in place		
in-lb	Inch pounds (torque)		
L	Liters		
L/m <sup>2</sup>	Liters per square meter		
LMH	Liters per square meter per hour		
LPM	Liters per minute		
MF	Microfiltration		
mL	Milliliter		
NMWL	Nominal molecular weight limit		
ppm	Parts per million		
PVDF	Polyvinylidene fluoride		
RO/DI	Reverse osmosis and deionization water		
SDS	Sodium dodecyl sulfate		
SIP	Steam in place		
TFF	Tangential flow filtration		
ТМР	Transmembrane pressure		
WFI	Water for injection		

### Catalog Number and Specifications

The  $\mathsf{Prostak}^{\mathsf{TM}}$  MF modules are available in hydrophilic and hydrophobic membranes.

#### Catalog numbers

Pore Size	Catalog Number					
(µm)	2 Stack	4 Stack	10 Stack	20 Stack		
Durapore®	Hydrophilic PV	DF Membrane				
0.10	PSVV AG0 21	PSVV AG0 41	PSVV AG1 01	SK2P 127 E1		
0.22	PSGV AG0 21	PSGV AG0 41	PSGV AG1 01	SK2P 484 E0		
0.45	PSHV AG0 21	PSHV AG0 41	PSHV AG1 01	SK2P 242 E9		
0.65	PSDV AG0 21	PSDV AG0 41	PSDV AG1 01	SK2P 446 E0		
Durapore®	Hydrophobic P	VDF Membrane				
0.22	—	—	—	SK2P 344 W2		
0.45	SK2P 012 W6	_		SK2P 013 W4		
PZHK Mem	PZHK Membrane: Hydrophobic PVDF					
200*				SK2R B30 A1		

\*Nominal molecular weight limit in kiloDaltons

Specifications

	pH Range		
Membrane	Short Duration (≤1 hour cycle)	Continuous	
Durapore <sup>®</sup> Hydrophilic PVDF Membrane	1-11	2-10	
Durapore <sup>®</sup> Hydrophobic PVDF Membrane	1-13	2-13	
PZHK Membrane	1-15	2-13	

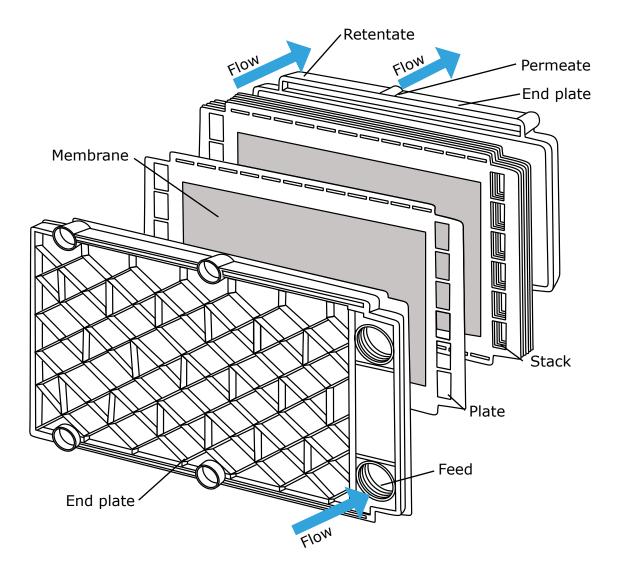
# **Installing the Modules**

A stainless steel Prostak<sup>TM</sup> holder (catalog number PSKPMF001) is available.

### System Components

Item	Description	Material of Construction	Catalog Number	Quantity per kit	Quantity Needed
Sanitary gaskets	Short sanitary gasket kit for use without holding plates.	Silicone	PSKP02200	Twelve for permeate. Twelve for feed/ retentate.	Two of each per module. Two of each per end plate.
	Tall sanitary gasket kit for use with gasket holding plates.	Silicone	PSKP0220P	Sixteen for permeate. Sixteen for feed/ retentate.	Two of each per module. Two of each per end plate.
		EPDM	PSKP0210P	Sixteen for permeate. Sixteen for feed/ retentate.	Two of each per module. Two of each per end plate.
Gasket support	Gasket support plate for non- steaming applications.	Polycarbonate	PSKPMFG06	Six	One per module. One per end plate.
plates (optional)	Gasket support plate for steaming applications.	Polysulfone	SK2P007W8	Six	One per module. One per end plate.

Exploded view of 10 ft.<sup>2</sup> Prostak™ module



#### Assembling the Process Scale Holder

Refer to the illustrations on the following pages.

For horizontal installation, use tall sealing gaskets and a gasket support plate.

For vertical installation, the use of gasket support plates is optional. If the gasket support plates are not used, use the short gaskets to seal the interfaces between the modules and holder. If the gasket support plates are used, pair them with the tall gaskets.

- 1. Start with feed or retentate side plate depending on system design. Typically, the feed connection plate is the first plate.
- 2. For vertical orientation, install the short gaskets at the corresponding open ports on the module.

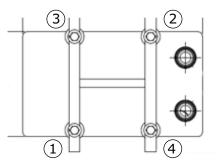
For horizontal orientation, install the tall gaskets in the gasket support plate to align with open ports on the module and install against the module.

- 3. Install the next module.
- 4. For vertical orientation, if the gasket support plates are not used, install the short gaskets at the corresponding open ports on the module. If the gasket support plates are used, install the tall gaskets into the plate and then place the plate on the module over the corresponding holes and fit the plate and gaskets to the module. Some rocking is normal. Make adjustment ments to ensure a good seal.

For horizontal orientation, install the tall gaskets in the gasket support plate to align with open ports on the module and install against the module.

- 5. To install additional modules, repeat steps 2–4.
- 6. Align the feed or retentate side plate against the last installed module and gaskets.
- 7. To seal gaskets between the modules and the endplates, use a torque wrench to uniformly tighten between 50–100 in-lb.

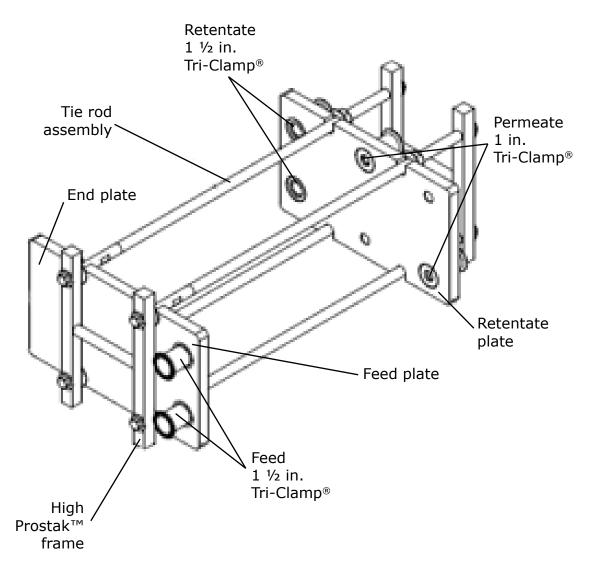
To torque uniformly across the nuts, tighten in the order indicated in the following illustration:



Note: Over torquing could cause the device to crack.

If the seal fails, disassemble the holder, verify that the gaskets are seated correctly, and examine the modules.

Exploded view of Prostak<sup>™</sup> holder



# **Using the Modules**

Note: Prostak<sup>™</sup> MF modules must be operated while under compression from the holder assembly to ensure that the modules seal properly. The compression is supplied by applying torque to the nuts on the threaded tie rods of the holder assembly.

#### Flux Excursion

This process determines the critical flux point, which is the optimal operation condition for an assembly of  $Prostak^{TM}$  MF modules for use in a clarification-type application.

Following flux excursion, execute a process simulation (see <u>Process</u> <u>Simulation</u>) in which the process is run to the desired volume reduction. Maintain sufficient feed volume to reach the required concentration factor (10–15X for example).

For flux excursion, use the smallest area module with equivalent process scale flow path.

Perform the experiments so that the permeate is looped back to the feed vessel.

Develop transmembrane pressure (TMP) versus flux data at a given cross flow:

- 1. Increase the feed pump speed to the desired cross flow rate while simultaneously and slowly increasing the permeate pump speed to the desired flux level.
- 2. Record inlet, outlet, and permeate pressures over a 20–30 minute period.
- 3. Monitor stability of TMP.
- Note: A rapid increase in TMP indicates a flux limit in which polarization of the membrane occurs. The last stable flux before the flux limit is called the "critical flux."
- 4. Take samples of feed and permeate at the end of 20–30 minute period and analyze for protein concentration and rejection.
- 5. If TMP is stable, increase flux to the next level in 10–15 LMH increments.
- 6. Repeat steps 3–5 at increasing flux settings until the critical flux is obtained.

Steps 1–6 may be repeated at a different cross flow.

Note: The smallest Prostak<sup>™</sup> MF module is a 2-stack (0.17 m<sup>2</sup>). This requires 12–14 L of feed product for a critical flux determination operated at full recycle.

The data obtained from the flux excursion study results in the critical flux point and can be presented in several valid formats:

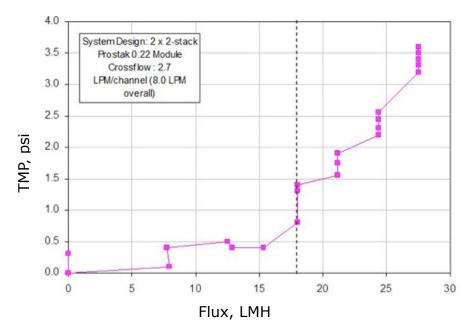
- TMP vs flux
- Flux and TMP vs time
- Permeability vs time

The next experiment is capacity determination:

- Operate at 50 to 75% of the critical permeate flux as determined in the last section. Operate at the same feed flowrate that was used to find the critical permeate flux.
- Start with proper feed stock volume to attain estimated L/m<sup>2</sup> at target concentration factor.
- Monitor TMP as a function of throughput.
- Determine capacity based on predetermined TMP limit (5–10 psi).
- Repeat steps 1–3 at other flux points.

The following graph represents plotting data for a critical flux point. The feed was a mammalian perfusion culture, and the clarification tool was Prostak<sup>TM</sup> MF, 0.22 (GVPP). The critical flux was 18 LMH.

#### Sample critical flux chart

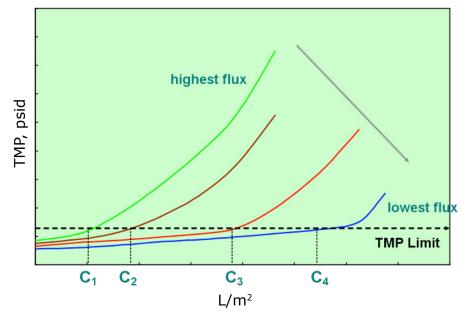


#### **Process Simulation**

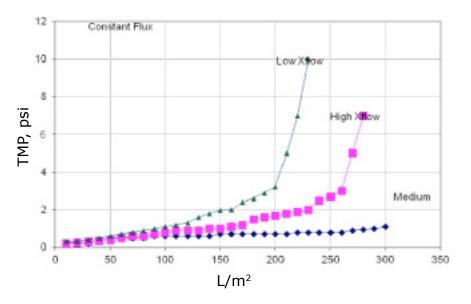
- 1. Operate at constant flux (somewhat below the critical flux) and at a constant cross flow rate.
- 2. Start with proper feed stock volume to attain estimated  $\mbox{L/m}^2$  at target concentration factor.
- 3. Monitor TMP as a function of throughput.
- 4. Determine capacity based on a predetermined TMP limit (5-10 psi).
- 5. Repeat steps 1–3 at other flux points.

Flux, J (LMH)	Capacity, C (L/m2)
$J_1 = J_{Highest}$	C <sub>1</sub>
J <sub>2</sub>	C <sub>2</sub>
J <sub>3</sub>	C <sub>3</sub>
$J_4 = J_{Lowest}$	C <sub>4</sub>

*TMP versus capacity: as operating flux increases, obtainable capacity through the filter increases.* 



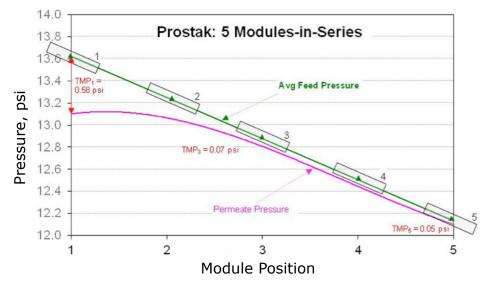
Higher cross flow does not always equate to higher capacities, as shown below.



TMP versus Capacity at Three Different Cross-Flow Rates

The path length with  $Prostak^{M}$  MF modules, five in series, demonstrates a pressure drop that must be considered while scaling.

Pressure versus module position



#### Flushing

Flush Prostak<sup>™</sup> modules with water for injection (WFI), reverse osmosis water, deionization (RO/DI) water, or a buffer:

- Before and after filtering process solutions and suspensions
- Before cleaning
- After each cleaning, depyrogenation, or sanitization (to remove chemical agents used in that step)
- Note: If using hydrophobic membranes, including PZHK membranes, flush using a solution of 60/40 (% volume) of isopropyl alcohol or 50/50 ethanol in water before flushing with WFI or RO/DI water.

Air integrity tests must be performed using membranes that are **water wet only**. Before wetting with water, flush with isopropyl alcohol or ethanol.

- 1. Direct permeate and retentate lines to drain to ensure that no fluid is returned to the cleaning tank during flushing.
- 2. Close the drain valves.
- 3. Add clean, warm water (40–50 °C) or buffer to the cleaning tank.
- Note: After use, perform a preliminary flush with isotonic fluid. Pure (nonisotonic) water can cause solutes present in the system to precipitate.

Module Size	Module Area (m <sup>2</sup> )	Flush Volume (L)
2 stack	0.17	60
4 stack	0.33	95
10 stack	0.84	190
20 stack	1.7	380

Recommended flushing volumes for Prostak<sup>™</sup> MF modules

Note: These volumes are recommended for installations of one to five modules installed in series to ensure thorough removal of residual product or cleaning agent.

- 4. Open all permeate valves and open the retentate valve.
- 5. Set the pump speed and flowrate to the lowest setting.

6. Turn the pump on and increase the pump speed to the following flow rates:

Recommended flow rates

Module Size Flow Rate (LPM)		Module Area (m <sup>2</sup> )	Inlet Parameter
2 stack	7–9	0.17	Adjust the
4 stack	10-14	0.33	pump speed to reach the flow
10 stack	20-30	0.84	rate. (Retentate
20 stack	40-60	1.7	pressure ~5 psi.)

The recommended settings are for one to five modules in series; a midpoint setting is recommended.

7. Adjust the retentate valve to maintain at least a 5 psi retentate pressure.

It is important to adjust pump rate and to manage retentate and permeate valves to develop a 20–30% conversion of feed (cross flow) to permeate flow. Conversion is the percentage of feed flow rate that is converted to filtrate.

Flush hydrophobic membrane Prostak<sup>™</sup>modules, including PZHK, at a higher pressure because of their lower intrinsic permeabilities. Adjust the inlet or feed pressure at the entrance of the Prostak<sup>™</sup> holder to 60–80 psi while maintaining flow rate as recommended in step 6.

- 8. Continue flushing for approximately 5–7 minutes at the above conditions.
- 9. Shut down the pump before the water/cleaning tank is empty to avoid running the pump dry.

#### Clean in Place (CIP)

Cleaning is required under the following conditions:

- The system has been exposed for a period of time to process fluids
- The system is to undergo membrane regeneration, system sanitization, depyrogenation, or storage
- 1. Direct permeate and retentate lines back to the cleaning tank.
- 2. Close the tank drain valve and open the retentate line or valve (and permeate valve, if present).
- 3. If the system has a variable-speed pump, set it to the lowest speed and flow rate.
- 4. Fill the tank with clean, warm water (40–50 °C).
- 5. Add a cleaning agent to the tank (see the following table.)

_	mbrane Type	Cleaning Agent	Concentration	Temperature (°C)	рН
-	<b>rophilic</b> apore®	Sodium hypochlorite (NaOCl)	600 ppm	40-50	<11
Dura	<b>rophobic</b> apore® PZHK	Sodium hydroxide (NaOH)	0.1 N to 0.5 N	40-50	up to 13

Recommended cleaning agents and conditions

Note: Do not exceed a concentration of 900 ppm NaOCI. 600–650 ppm NaOCI is sufficient for most applications.

- Set the feed pump (a peristaltic-tubing, multi diaphragm or rotary lobe) at a very low output setting. Increase pump speed to the recommended rate (see <u>Recommended flow rates</u>).
- 7. Recirculate the cleaning fluid for 30–60 minutes.
- 8. Using pump control and the retentate valve, set and maintain a minimum retentate pressure of 5 psi. Using both retentate and permeate valves achieve a 20 to 30 percent conversion of feed flow to permeate flow.
- Note: Check the concentration (starts at ~600 ppm) every 10–15 minutes of the cleaning period (30–to 60 minutes). Use a test kit that measures 100 to 1000 ppm for monitoring during cleaning. Use a kit to measure <1.0 ppm to determine complete removal of NaOCI after water flushing.

After cleaning hydrophobic membranes with NaOH, measure pH after flushing with water to determine if NaOH has been fully removed.

9. Shut down the recirculation pump and drain the system.

#### Sanitization

Perform sanitization after the Prostak<sup>™</sup> installation has been thoroughly cleaned and flushed to reduce bioburden.

The sanitization procedure, including pressures, flow rates, and volumes, is identical to the cleaning procedure (see <u>Clean in Place (CIP)</u>).

Flush modules after sanitization to remove chemical residue (see Flushing).

Note: Use sanitization agents and conditions that are suitable for the process requirements. Sanitization agents must comply with applicable local regulations.

Membrane Type	Sanitization Agent	Concentration	Temperature (°C)	рН	Time (min)
Hydrophilic	Chlorine (as NaOCl)	20–50 ppm (active chlorine)	20-50	6-8	30-60
Durapore®	Peracetic acid	100-200 ppm (0.25-0.40%)	10-40	3.5	30-60
Hydrophobic Durapore <sup>®</sup> and PZHK	NaOH	0.1N	40-50	13	30

Recommended	sanitization	agents	and	conditions

Note: 0.1 N NaOH is the recommended sanitization agent for the listed membranes but is not as effective as chlorine over a broad selection of microorganisms. All wetted (wetted with alcohol and rinsed with water) hydrophobic Prostak<sup>™</sup> modules can use all sanitization chemicals listed.

Hydrophobic Prostak<sup>TM</sup> modules pre-wetted with alcohol and rinsed with water can be sanitized using the chemicals in the above table.

See <u>Catalog Numbers and Specifications</u> for catalog number information.

#### Steam in Place (SIP)

Prostak<sup>™</sup> modules (Durapore<sup>®</sup> membrane) are the only hydrophilic and hydrophobic TFF devices that can be sterilized with steam.

Note: When steam sterilizing microporous modules repeatedly, avoid using Triton<sup>™</sup> X-100, Tween<sup>®</sup>-80, and sodium dodecyl sulfate (SDS) as cleaning agents. Residual amounts of these surfactants can cause premature failure of the Prostak<sup>™</sup> modules at steaming temperatures.

Systems should have a sterile vent on the feed or retentate manifold for pressure equalization during cooling.

Steam traps or ported diaphragm valves should be present on all low point drains to remove condensate and maintain steam pressure and temperature throughout the system.

Provide sufficient steam traps or ported diaphragm valves to ensure removal of steam condensate.

Avoid all dead-end circuits in the system piping.

Thoroughly clean and flush Prostak<sup>™</sup> systems and modules prior to steaming (see <u>Clean in Place (CIP)</u> and <u>Flushing</u>).

- 1. Connect the steam line to the highest point of the system. Open all low point steam condensate valves or connect steam traps to the low points.
- 2. Ensure that none of the manifolds to be steamed is blocked by closed valves or piping dead ends.
- 3. Introduce clean, filtered, and saturated steam into the system high point at 20 psi (1.4 bar) at 126 °C (259 °F). Allow steam vapor and condensate to flow through manifolds and all Prostak<sup>™</sup> modules.
- Note: Steam will pass through the membrane as a vapor; it is not necessary to steam the retentate and filtrate (permeate) sides of the Prostak<sup>™</sup> separately.
- 4. Allow condensate to drain out of the system through the low point valves or steam traps. After several minutes, the condensate rate decreases as the system warms to the steam temperature.
- Important: If steam traps are not available, close the low-point condensate valves to maintain 20 psi steam pressure, allowing a small amount of condensate (a wisp) to pass through these valves continuously via ported valves.
- 5. Maintain steam pressure for 1 hour at 20 psi (1.4 bar).
- 6. After completing steam cycle, open sterile vent valves, shut off the steam, and close the condensate valves.
- 7. Allow system to cool to ambient temperature prior to introducing process fluids.
- Note: PZHK and other hydrophobic modules must be re-wet with a mixture of 60/40 (% volume) isopropyl alcohol and water and then flushed (see <u>Flushing</u>) with sterile water (WFI) after steaming and before introducing aqueous process fluids.

#### **Integrity Testing**

Integrity tests should be performed only on completely water-wet membranes. Hydrophobic and PZHK membranes should be thoroughly prewetted with a 60/40% (% volume) isopropyl alcohol and water mixture, followed by flushing with water (see Flushing). Prostak<sup>™</sup> modules with PZHK membranes should be thoroughly flushed with a 60/40 (% volume) of isopropyl alcohol and water, and then flushed with water (see Flushing).

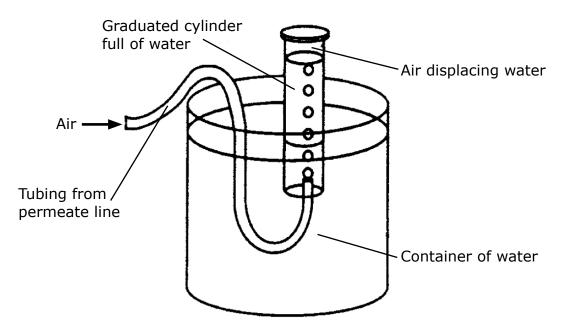
Perform only on a water-wet membrane.

Note: Ensure thorough wetting by recirculating water at 10-30 psi 0.7-2.0 bar) TMP for 5 minutes.

The presence of residual cleaning agents can significantly alter integrity test results.

Automated integrity testing instruments such as the Integritest<sup>®</sup> 5 Integrity Tester are suitable for TFF integrity testing.

- 1. Drain the system of water. Drain the retentate side of the system as thoroughly as possible.
- Note: Purge with filtered air at 1–2 psi (0.07–0.14 bar) if necessary to remove residual water.
- 2. Attach a regulated and filtered air supply to the feed or retentate piping, preferably at the high point of the system.
- 3. Isolate either the feed or the retentate piping by closing a valve or capping the piping if there is no valve. This enables pressurization of the filter feed channels.
- 4. Open the permeate line and keep it open.
- 5. Slowly raise the air pressure to the recommended value and wait 5 minutes to purge residual water in the permeate line.
- Note: Exceeding the recommended air pressure may cause displacement of water from the membrane pores and result in excessively high air flow (a false failure). Re-wet the membrane if this occurs.
- 6. After the diffusion air flow pressure stabilizes, measure and record the air pressure, temperature, and the air flow rate exiting the permeate line. The air flow rate may be measured with an air flow meter or by measuring the air displaced into a submerged and inverted volumetric cylinder as shown in the figure below:



- 7. Compare the measured air flow rate to the specified flow value in the following table. If the measured flow rate exceeds the specified flow value:
  - Confirm that the Prostak<sup>™</sup> module has been installed correctly and all mechanical and sanitary (TC) fittings are secure and air tight.
  - Rewet the module. Ensure thorough wetting by recirculating water at 10–30 psi (0.7 bar–2.0 bar) TMP for 5 minutes.
  - If a failure occurs, enhance and speed re-wetting by using ethanol or isopropyl alcohol in water. Flush out the alcohol solution with water by recirculating water at 10–30 psi (0.7–2.0 bar) TMP for 5 minutes.
  - Repeat steps 1–6. If the filter has been installed correctly and the air flow remains in excess of the specified value, contact technical services.

Pore Size	Maximum air flow through fully wetted membrane of an integral filter (cc/min)				
(µm)	2 stack	4 stack	10 stack	20 stack	Test psi
Prostak <sup>™</sup> MF o	pen-channe	l hydrophilio	PVDF mem	branes	
0.10	5	10	25	50	50
0.22	3	6	15	30	30
0.45	4	8	20	40	15
0.65	2.7	5.4	13.5	27	10
Prostak <sup>™</sup> MF o	pen-channe	l hydrophob	ic PVDF me	mbranes	
0.22	—	_	—	15	14
0.45	5	_	_	20	15
200*	_	_	_	40	15

#### *Prostak™ MF integrity test specifications*

\*Nominal molecular weight limit in kiloDaltons

#### Measurement of Normalized Water Permeability (NWP)

Establish the normalized water permeability (NWP) for each Prostak<sup>™</sup> MF module before the first product contact. Clean, flush, and integrity test new membranes before measuring NWP (see <u>Clean in Place (CIP)</u>, <u>Flushing</u>, and <u>Integrity Testing</u>).

Note: The NWP measured at this point is used as a benchmark against which subsequent water permeability measurements are compared. These subsequent NWP measurements are performed after product processing and after product cleaning operations and are used to determine cleaning efficacy.

Prostak<sup>™</sup> MF modules exhibit high water permeability: >35 ->1000 LMH/ psi. When filtering water at high pressures, the permeate flow channels within the Prostak<sup>™</sup> module cannot accommodate the entire permeate flow. This flooding of permeate channels results in significant pressure losses between the membrane and the permeate port on the Prostak<sup>™</sup> holder. Although not harmful to the Prostak<sup>™</sup> module, this internal pressure drop causes the measured water permeability to be much less than the actual membrane permeability. As these internal pressure drops vary with the area of microporous membrane installed in a Prostak<sup>™</sup> MF module and holder, a permeability specification for multiple microporous Prostak<sup>™</sup> modules installed in series in a holder cannot be predicted. To establish the permeability specification for these modules, measure the water permeability of the installed modules in the Prostak<sup>™</sup> holder prior to the first use of the modules.

With particularly open membranes such as  $0.65 \ \mu m$  Durapore<sup>®</sup> it is nearly impossible to measure NWP accurately enough to use as an indicator of cleanliness. This procedure may be used to verify that no extreme plugging of the membrane has occurred and to wet membranes prior to air diffusion integrity testing; only run-to-run performance can be used to verify the effectiveness of the cleaning procedure.

- 1. Direct permeate and retentate lines back to the WFI or RO/DI water feed tank.
- 2. Close the tank drain and open the retentate and permeate valves.
- 3. Fill the tank with WFI or RO/DI water, ideally at 25 °C.
- 4. The permeate control pump is by-passed. Remove permeate tubing from usual peristaltic control pump. Using the feed, recirculation, pump controls and the retentate valve, set the following pressure values:

For Prostak<sup>™</sup>modules with microporous membranes:

Feed inlet pressure	10 psi (0.7 bar)
Retentate outlet pressure	5 psi (0.35 bar)

For Prostak<sup>™</sup>modules with PZHK and hydrophobic membranes:

Feed inlet pressure	25 psi (1.7 bar)
Retentate outlet pressure	15 psi (1 bar)

- 5. Recirculate the water for 5–10 minutes. Ensure that the pressure and temperature conditions are stable.
- 6. Record the permeate flow rate, inlet and outlet pressures, and the temperature of the water.
- 7. After the cycle is complete, shut down the feed, recirculation pump. Drain the system.
- 8. Calculate the NWP:
  - a. Measure: R Permeate flow rate in mL/min =  $\mathsf{P}_{\mathsf{in}}$ Feed Inlet pressure in psi = P<sub>out</sub> Retentate discharge pressure in psi = Permeate discharge pressure, if non-zero, in psi Pp = Т Water temperature in °C =
  - b. Determine the area of the filters installed in the system:

A = Total filter area in  $ft^2$ 

c. Using the measured temperature T, obtain the normalized water permeability correction factor, K, from the table that follows.

d. Use the following equation to calculate NWP:

$$NWP = \frac{R \cdot K}{A \cdot \left\{ \left[ \frac{P_{in} + P_{out}}{2} \right] - P_{p} \right\}} \text{ in mL/min / ft}^{2} / \text{ psi at 25 °C}$$

T (°F)	T (°C)	К	T (°F)	T (°C)	К	T (°F)	T (°C)	К
104.0	40	0.734	82.4	28	0.935	60.8	16	1.243
102.2	39	0.748	80.6	27	0.956	59.0	15	1.276
100.4	38	0.762	78.8	26	0.978	57.2	14	1.310
98.6	37	0.777	77.0	25	1.000	55.4	13	1.346
96.8	36	0.793	75.2	24	1.023	53.6	12	1.383
95.0	35	0.808	73.4	23	1.047	51.8	11	1.422
93.2	34	0.825	71.6	22	1.072	50.0	10	1.463
91.4	33	0.842	69.8	21	1.098	48.2	9	1.506
89.6	32	0.859	68.0	20	1.125	46.4	8	1.551
87.8	31	0.877	66.2	19	1.152	44.6	7	1.598
86.0	30	0.896	64.4	18	1.181	42.8	6	1.648
84.2	29	0.915	62.6	17	1.212	41.0	5	1.699

NWP Temperature	Correction	Factor	(K)
-----------------	------------	--------	-----

After the first use of the module, the NWP should be at approximately 80% of the original NWP. After repeated use (more than 5 times) the NWP should not vary more than 10% from run to run.

If the NWP decreases by more than 10% from run to run, the cleaning procedures being employed may not be adequate. Alternative cleaning agents and procedures should be investigated.

Due to the inherent variability of NWP measurements with high permeability Prostak<sup>™</sup> membranes, this test should be taken as only one marker of cleaning effectiveness. Monitoring the stability of in-process TMP values between batches is a more accurate determination of cleaning effectiveness over the lifetime of the device.

### Maintenance

The following steps are recommended to keep the holders in operational condition:

- 1. Clean nuts, washers, and tie rods before every use to ensure that they are free of particles. A 70/30 (% volume) mixture of a mild solvent such as isopropyl alcohol and water is generally effective.
- 2. Protect the tie rods from receiving blows that could damage the threads, which can lead to galling. Particular care should be taken when using a torque wrench near the tie rods.
- 3. To ensue proper sealing, replace worn-out nuts and tie rods.
- 4. When new nuts do not spin freely, refurbish the threaded rods with a 5/8 in-18 die.
- 5. A set of spare parts should be kept on hand at all times.

# Storage

Storage Time	Storage Method
More than six months	Dry the cleaned module and then flush the module with water and apply heated air (45 °C) at 2–6 psi (0.0138–0.4137 bar) for 6 hours.
	Dry the cleaned module and then flush the module with water and dry in a drying oven at 45 °C for five days.
More than a week but less than six months	Remove the modules from the holder and flush with the storage solution indicated in the table below.
Less than one week	Use 0.1 M phosphoric acid as a storage fluid.

#### *Prostak™ module storage solutions*

Storage Solution	Membrane Type	Concentration	рН	Time Period
Lysol <sup>®</sup> (10% solution)	All	10 mL/liter	7	1 year
NaHSO <sub>3</sub>	All	1.00 %	4-8	2 months
NaCl	All	5.00 %	4-8	1 day
Sodium azide	All	0.05%	4-8	3 months
NaOH	Hydrophobic only	0.1 N	13	6 months

Note: Use storage agents and conditions that are suitable for the process requirements. Storage agents must comply with applicable local regulations.

Wear appropriate protective equipment (rubber gloves and safety glasses) for handling the storage solution.

The storage preparation steps are very similar to the procedures for water flushing and chemical cleaning.

- 1. Direct permeate and retentate lines back to the cleaning tank.
- 2. Close the tank drain valve and open the retentate line or valve (and permeate valve, if present).
- 3. Set the feed, crossflow pump to the lowest speed and flow rate. Increase speed to reach flow rates in the following table:

Module Size	Flow Rate (LPM)
2 stack	38
4 stack	57
10 stack	132
20 stack	253

*Prostak™MF device storage flow rates* 

- 4. Fill tank with clean, warm water (40–50 °C). Fill the tank with the appropriate storage solution.
- 5. Turn the pump on and open the pump discharge valve, or increase the pump speed to the following approximate flow rates:
- 6. For Prostak<sup>™</sup> modules with microporous membranes, use the retentate control valve to adjust the retentate pressure to at least 5 psi (0.3 bar) while maintaining crossflow as specified in step 5.

For Prostak<sup>TM</sup> modules with PZHK membranes, adjust the feed pressure to 60–80 psi (4.1–5.5 bar) while maintaining the crossflow specified in step 3.

- 7. Recirculate the storage solution for five minutes.
- 8. If the filters will be stored for only 1–5 days before re-use, store them in the system:
  - Shut off the recirculation pump and clamp the lines to/from the holder or shut the feed, retentate, and permeate valves to keep the holder and filters full of storage solution.
  - Store the holder and filters at 4 °C if possible. Do not freeze the modules.
- 9. If the filters will be stored longer than 5 days:
  - Remove them from the holder.
  - Shut off the recirculation pump and drain the system.
  - Loosen the holder and remove the filters, which have been fully wetted with storage solution.
  - Place the filters in a liquid-tight container and fill the container with excess storage solution to immerse the filter.
  - Seal the container and store at 4 °C.

Suitable storage containers include molded polyethylene or polypropylene cans, pails, or tanks with locking and sealing lids.

# **Standard Warranty**

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

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