

EndoPur Endotoxin 10" Filter Flat- Instructions for Use

INTRODUCTION

Information on this sheet must be read before the use of this device to ensure safe and effective operation in a clinical or hospital environment.

Recommended Storage: Between 5 and 35°C (41 and 95°F).

INDICATIONS

Intended Use: The EndoPur Endotoxin 10" Filter Flat is a hollow fiber ultrafilter that retains bacteria and endotoxin from fluid.

Indications for Use: The EndoPur Endotoxin 10" Filter Flat is intended to be used to filter water used in hemodialysis devices. It assists in providing hemodialysis quality water. The device is not a complete water treatment system, but serves to remove biological contaminants. Therefore it must be used in conjunction with other water treatment equipment (Reverse Osmosis, Deionization, etc.).

Use Life: The device is intended for long term continuous use. Once it completes its useful life, the filter should be replaced and discarded. Do not attempt to sterilize or reuse it.

Location: Due to its size and flow capacity, the EndoPur Endotoxin 10" Filter Flat should be installed as part of the dialysis water distribution loop after the Reverse Osmosis treatment system in a clinical environment.

To achieve the required flow rate for the distribution loop, it may be necessary to install more than one EndoPur Endotoxin 10" Filter Flat. Install one or more branch tees to run multiple filters in parallel.

CONTRAINDICATIONS

Heat sterilization is contraindicated for use with polypropylene housings that are not rated for disinfection temperatures above 80°C.

WARNINGS & PRECAUTIONS

Caution: When used as a medical device, federal law (USA) restricts this device to sale by or on the order of a physician.

Pressure: The EndoPur Endotoxin 10" Filter Flat is intended for a maximum differential water pressure of 30 psi (2 bar).

Replacement: The filter should be replaced if the flow rate begins to noticeably decrease and the maximum differential pressure is exceeded. As long as it is flowing the EndoPur Endotoxin 10" Filter will continue to filter microbiological contaminants. However, it is recommended to establish a regular maintenance schedule for replacing the filter.

FILTER INSTALLATION & REMOVAL

New Install: If it is the first time a reusable cartridge type filter is being installed as an endotoxin retentive filter, please refer to the second page of these instructions for installation guidance under *Housing Installation* section before proceeding with the instruction below.

Note: Prior to handling a new filter wash hands and wear disposable gloves.

- Turn off the fluid source upstream of the filter and vent any excess pressure from the housing via its bleed valve or outlet test valve.
- Remove the housing bowl/cover and remove the old filter.
- Open a new EndoPur Endotoxin 10" Filter Flat blister pack and aseptically remove the filter.
- Insert the O-ring end of the filter into the head of the housing. It may be necessary to use a twisting motion to ensure that the filter is firmly in place and the O-rings seat properly.
- Re-attach the housing bowl/cover.

Note: Air must be fully purged from the filter bowl/housing to achieve sufficient flow rates.

- Open the bleed valve (located at the top of the housing cap) to fully purge the air from inside the housing/bowl. After removing, sanitize hands and replace with clean gloves.
- Open the upstream fluid source and prime the new filter by opening the outlet test valve for a few minutes to purge it of any additional trapped air.
- Close the outlet test valve and bleed valves, and verify there are no leaks.

OPERATION & DISINFECTION

- Following installation, it is recommended to disinfect the system as per standard clinic procedure.
- The EndoPur Endotoxin 10" Filter Flat is compatible with the following disinfectants for 1 year of weekly exposures with no degradation in safety or efficacy:
 - 1% MinnCare
 - 1% Bleach
 - 85°C Water
- Disinfection should be carried out as per standard clinic procedures, and no special precautions or procedures are required. The filter should be treated as an extension of the distribution system.
- Following chemical disinfection the fluid must be tested for residual disinfectant with appropriate test strips (or other means). Continue to rinse the EndoPur Endotoxin 10" Filter Flat until you can verify absence of chemical residuals as required per clinic procedures.
- The pressure drop across the EndoPur Endotoxin 10" Filter Flat is minimal and should not provide any noticeable flow rate reduction.
- If the flow rate degrades significantly, replace the filter.

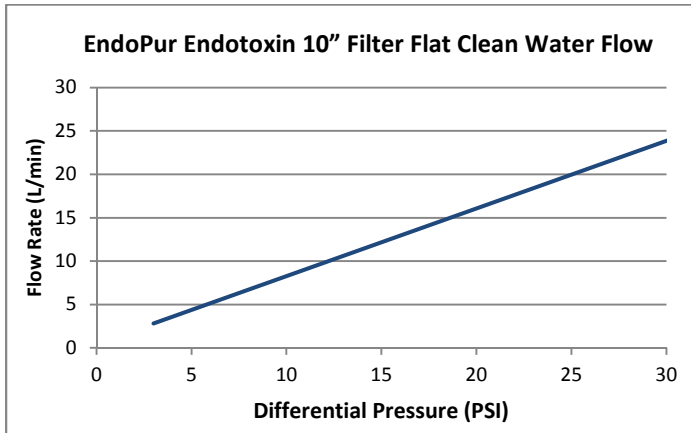
INTEGRITY TESTING

Note: If multiple filters are installed (as shown in *Parallel Housing and Filter Installation Example*) only one filter can be tested at a time and must be isolated using the filter isolation valve leading to all other filters. Once the filter is isolated, follow the instructions below

- The filter integrity can be verified with a pressure holding test after the filter has been properly primed and there are no connection leaks.
- Turn off the fluid source and open the inlet test valve to bleed off any residual pressure.
- Connect an air source (compressed air or air pump) to the inlet test port as shown in *Housing and Filter Installation Example*. Note that a pressure gauge must be installed to monitor the inlet filter pressure in order to carry out this test.
- Open both test valves, and pressurize the filter inlet; ensure the outlet test port is venting. Raise the air pressure to 15 psi at the filter inlet and allow water to exit from the outlet test port. Do not exceed 30 psi to prevent damage to the filter membrane.
- When water stops coming out from the outlet test port, close the outlet test valve and check for external leaks via pressure gauge.
- Open the outlet test valve and re-pressurize as necessary to reach 15 psi at the filter inlet.
- With the outlet test valve open, close the inlet test valve and allow the pressure to stabilize for 5 to 10 seconds.
- Monitor the pressure gauge and determine the pressure drop for a period of 1 minute.

EndoPur Endotoxin 10" Filter Flat- Instructions for Use

- If the pressure drops by more than 1 psi over a minute, check for leaks and repeat the test to confirm. If the filter fails, it must be replaced.
- Close the outlet test valve and remove air source. Open fluid source valve, purge air out of the housing/bowl using the bleed valve, and re-prime filter to return to operation.



Specifications	EndoPur Endotoxin 10" Filter Flat
Max Differential Pressure	30 psi (2 bar)
Filter Membrane	Medisulfone
Material	Polysulfone
MW cut-off	15 kDa
Bacterial Retention	> 10 ¹¹ (B. diminuta)
Virus Retention	> 10 ⁸ (PhiX-174)
Endotoxin Retention	> 10 ⁵ EU/ml
Expected Life	Up to 1 year

Medisulfone® is a registered trademark of Medica S.p.A.

Manufacturer:

Nephros Inc.
41 Grand Ave
River Edge, NJ 07661 USA
201-343-5202

HOUSING INSTALLATION

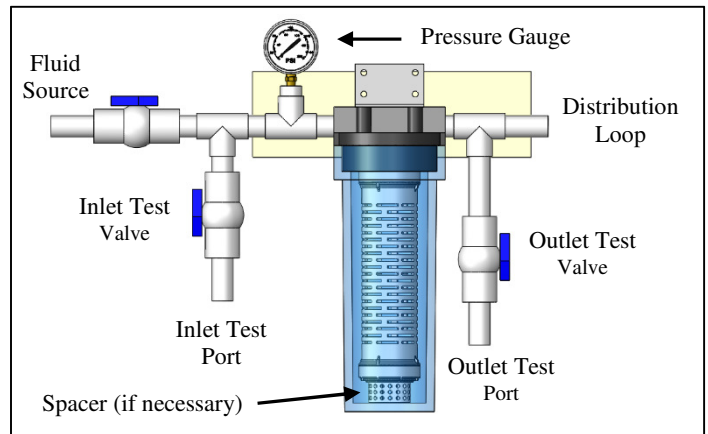
If no endotoxin retentive cartridge filter housings are currently installed, the initial install of the EndoPur Endotoxin 10" Filter Flat requires tapping into an existing section of the line between the fluid source and the distribution loop.

Note: EndoPur Endotoxin 10" Filter Flat is only to be installed in reusable cartridge filter housings that comply with AAMI/ANSI/ISO 26722 for material compatibility (or made from 316 Stainless Steel or made from pure polypropylene with no fillers, colorants, plasticizers or lubricants) and accepts 10" 222 O-ring head cartridge filters.

Note: A spacer may be required for longer housings to properly seat both O-rings and minimize the dead space areas (contact Nephros for acceptable spacers).

A typical installation of a single EndoPur Endotoxin 10" Filter Flat with cartridge housing is shown in the diagram below.

Housing and Filter Installation Example



In the instances that require higher flow rates, multiple housings may need to be installed in parallel as shown in the diagram below.

Parallel Housing and Filter Installation Example

