NEPHROS

Instructions for Use Part #: **70-0110H / 70-0120H**

Nephros EndoPur Endotoxin Filter (Flat)

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 Filter (Flat) is a hollow fiber ultrafilter that retains bacteria and endotoxin from fluid.

Indications for Use: The EndoPur Endotoxin Filter intended use is to filter water used with 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 continuous use up to one year. Once it completes its useful life or maximum number of disinfection cycles, 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 Filter should be installed as part of the dialysis water distribution loop after the Reverse Osmosis (or Deionization) treatment system in a clinical environment.

To achieve the desired flow rate needed for the distribution loop, it may be necessary to install multiple filters in appropriate filter sizes. Install one or more branch tees to run multiple filters in parallel.

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 Filter is intended for a maximum differential water pressure of 30 psi (2 bar).

Replacement: It is recommended to establish a regular maintenance schedule for replacing the filter. The filter should be replaced when the maximum differential pressure of 30 psi (2 bar) is exceeded or the maximum disinfection cycles are reached.

Filter Installation & Removal

New Install: If it is the first time a reusable housing is being installed with an endotoxin retentive filter, refer to the Housing Installation section before proceeding with the instruction below.

Note: Personnel installing filters must be properly trained per this IFU.

- Wash hands and place on clean 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, remove the old filter, and discard per facility protocol.
- Wash and sanitize hands and place on clean disposable gloves.
- Open a new EndoPur Endotoxin Filter 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.
- Open the bleed valve located at the top of the housing cap to fully purge the air from inside the housing/bowl. All air must be fully purged from the filter bowl/housing at this time to achieve sufficient flow rates.
- Open the upstream fluid source and prime the new filter by opening the outlet test valve. Purge it of any additional trapped air for 3-5 minutes.
- Close the outlet test valve and bleed valve, dry housing of any fluid from purging and verify the housing and cover are properly sealed.

Operation & Disinfection

- After installation of a new filter, it is recommended to disinfect the system as per standard clinic procedure.
- The EndoPur Endotoxin Filter is compatible with the following disinfection cycles with no degradation in safety or efficacy:

Disinfection Method	Maximum Cycles[1]
1% MinnCare	52
1% Bleach	52
Hot Water ≤ 85°C[2]	52

- Disinfection should be carried out as per standard clinic procedures. No special precautions or procedures are required for disinfection and the filter should be treated as an extension of the distribution system.
- Following chemical disinfection the fluid must be tested for residual disinfectant per standard procedure. Verification in absence of chemical residuals are required to proceed.
- Continue to rinse the EndoPur Endotoxin Filter until verifying the absence of chemical residuals as required per clinic procedures.
- Pressure drop across the EndoPur Endotoxin Filter maybe higher than a typical endotoxin filter. This increase in pressure is due to a tighter membrane pore size. The EndoPur Filter should not provide any noticeable flow velocity reduction during standard operation.
- The filter should be replaced and discarded when maximum differential pressure of 30 psi (2 bar) is exceeded.

Integrity Testing

Note: If multiple filters are installed (as shown in Diagram B: Parallel Housing and Filter Installation) 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 installed, connected, and primed.
- Turn off the fluid source valve and open the inlet test valve to bleed off any residual pressure.
- A pressure gauge must be installed to monitor the inlet filter pressure in order to carry out this test. Connect an air source (compressed air or air pump) to the inlet test port as shown in Housing and Filter Installation Example.
- Do not exceed 30 psi to prevent damage to the filter membrane.
- Open outlet test valve, ensure that the inlet test valve is open, 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.

(1) When the filter completes its useful life or maximum number of disinfection cycles it should be replaced and discarded. (2) Based on the following cycle timing: ramp-up to 85°C for 1.5–2 hours, hold at 85°C for 2 hours, then cool down to room temperature for 1–1.5 hours, with a maximum differential pressure of 8 psi at 85°C.

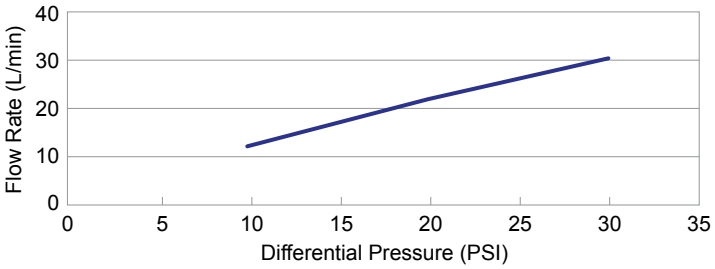
Nephros EndoPur Endotoxin Filter (Flat), (continued)

- When water stops flowing 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 10 seconds.
- Monitor the pressure gauge and determine the pressure drop for a period of 1 minute.
- 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.

Housing Installation

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

Clean Water Flow Rate 10" Segment[4]



Specifications

Max Differential Pressure	30 psi (2 bar)
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

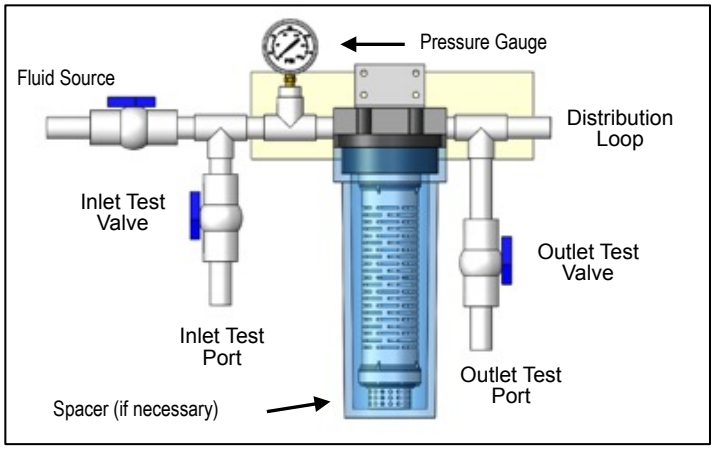
Note: EndoPur Endotoxin Filter is only to be installed in reusable cartridge filter housings that comply with AAMI/ANSI/ISO 26722 for material compatibility (or made from 316 Stainless Steel or made from pure polypropylene with no fillers, colorants, plasticizers or lubricants) and accepts 10" or 20" 222 O-ring head cartridge filters.

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.

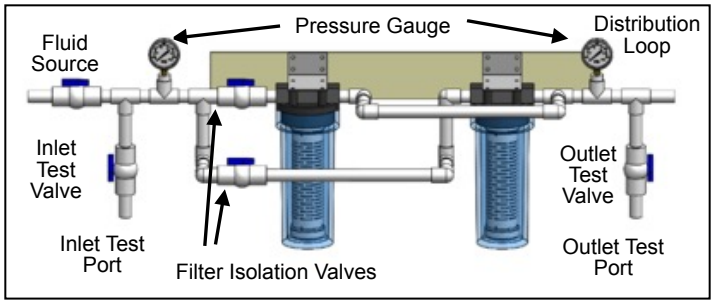
Examples of standard installations with a single and multiple EndoPur Endotoxin Filters with cartridge housings are shown in Diagrams (A) and (B) below. Bleed valves are not shown.

For higher flow rates to be achieved, multiple housings may need to be installed in parallel as shown in Diagram B.

(A) Single Housing and Filter Installation



(B) Parallel Housing and Filter Installation



(4) Maximum Flow Rate per 10" Segment = 2.5 GPM.

NEPHROS

Symbol	Symbol Title	Standard Reference	Standard Title	Explanatory Text
	**Manufacturer**	ISO 15223-1:2021, Clause 5.1.1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates the medical device manufacturer
		ISO 7000:2019, 3082	Graphical symbols for use on equipment	
	**Use by Date**	ISO 15223-1:2021, Clause 5.1.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates the date after which the medical device is not to be used.
		ISO 7000:2019, 2607	Graphical symbols for use on equipment	
	**Batch Code**	ISO 15223-1:2021, Clause 5.1.5	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates the manufacturer's batch code so that the batch or lot can be identified.
		ISO 7000:2019, 2492	Graphical symbols for use on equipment	
	**Part Number**	ISO 15223-1:2021, Clause 5.1.6	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates the manufacturer's part number, so that the medical device can be identified.
	**Sterilization by Ethylene Oxide**	ISO 15223-1:2021, Clause 5.2.3	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates a medical device that has been sterilized using Ethylene Oxide.
		ISO 7000:2019, 2501	Graphical symbols for use on equipment	
	**DO NOT Resterilize**	ISO 15223-1:2021, Clause 5.2.6	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates a medical device that is not to be resterilized.
		ISO 7000:2019, 2608	Graphical symbols for use on equipment	
	**DO NOT Use if Package Is Damaged and Consult Instructions for Use**	ISO 15223-1:2021, Clause 5.2.8	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates a medical device that should not be used if the package has been damaged or open.
		ISO 7000:2019, 2606	Graphical symbols for use on equipment	
	**Consult Instructions for Use**	ISO 15223-1, Clause 5.4.3	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates the need for the user to consult the instructions for use.
		ISO 7000:2019, 1641	Graphical symbols for use on equipment	
	**Medical Device**	ISO 15223-1:2021, Clause 5.7.7	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates that the item is a medical device.
	**Unique Device Identifier**	ISO 15223-1:2021, Clause 5.7.10	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates that the medical device contains a Unique Device Identifier.
	**Fragile, Handle with Care**	ISO 15223-1:2021, Clause 5.3.1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates that the device shall be handled with care.
		ISO 7000:2019, 0621	Graphical symbols for use on equipment	
		ISO 780:2015, Clause 4.3	Packaging — Distribution packaging — Graphical symbols for handling and storage of packages	
	**Rain**	ISO 15223-1:2021, Clause 5.3.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates that the device shall be kept away from rain and be kept in dry conditions.
		ISO 7000:2019, 0626	Graphical symbols for use on equipment	
		ISO 780:2015, Clause 4.4	Packaging — Distribution packaging — Graphical symbols for handling and storage of packages	
	**Keep Away from Sunlight**	ISO 15223-1:2021, Clause 5.3.2	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates that the device shall not be exposed to sunlight.
		ISO 7000:2019, 0624	Graphical symbols for use on equipment	
		ISO 780:2015, Clause 4.4	Packaging — Distribution packaging — Graphical symbols for handling and storage of packages	
	**Temperature**	ISO 15223-1:2021, Clause 5.3.7	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates the temperature limits in which the medical device can be safely exposed.
		ISO 7000:2019, 0632	Graphical symbols for use on equipment	
		ISO 780:2015, Clause 4.4	Packaging — Distribution packaging — Graphical symbols for handling and storage of packages	
	**This Way Up**	ISO 780:2015, Clause 4.4	Packaging — Distribution packaging — Graphical symbols for handling and storage of packages	Indicates the correct upright position of the distribution packages for transport and/or storage.
		ISO 7000:2019, 0623	Graphical symbols for use on equipment	
	**Stacking Load**	ISO 780:2015, Clause 4.5	Packaging — Distribution packaging — Graphical symbols for handling and storage of packages	Indicates the maximum stacking load which may be stacked on the distribution packages.
		ISO 7000:2019, 0630	Graphical symbols for use on equipment	

NEPHROS.COM

MANUFACTURER:
Nephros, Inc.
380 Lackawanna Place, South Orange, NJ 07079 USA
(201) 343-5202

ASSEMBLED AT:
MEDICA S.p.A.
Via Degli Artigiani, 7
41036 Medolla (MO), Italy