

# NEPHROS

Instructions for Use Part #: 70-0288 / 70-0289

## Nephros S100 In-Line

### Introduction

Information on this sheet must be read before the use of this device to ensure safe and effective operation.

**Sterility:** These devices are sterilized by ethylene oxide.

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

### Indications

**Description:** The Nephros S100 In-Line filters are disposable point-of-use microfilters used to filter EPA-quality drinking water. The filters retain bacteria. By retaining bacteria in water for washing and drinking, the filters may aid in infection control. The filters produce water that is suitable for cleaning of equipment used in medical procedures and washing of surgeon's hands. The filters come in two configurations: Quick Connect (QC) and 1/2" NPS Thread.

**Use:** The device is intended for single use.

Once installed the filter is intended to be used for up to 3 months. After such time the unit should be replaced and discarded. Do not attempt to sanitize or re-sterilize it.

### Contraindications

**Medical:** The filters are not intended to provide water that can be used as a substitute for USP sterile water.

**Chemical:** The S100 In-Line filters retain bacteria. To obtain chemically pure water it is necessary to use the filter in conjunction with other devices such as DI beds or RO systems.

### Warnings & Precautions

**Pressure:** The S100 In-Line filters are intended for a maximum incoming water pressure of 75 psi (5 bar).

**Temperature:** The S100 In-Line filters are rated for a maximum incoming water temperature of 60°C (140°F).<sup>(2)</sup>

**Cyclic Use:** The S100 In-Line filters are rated for a maximum of 5,000 on/off cycles.

**Replacement:** The filter should be replaced when the flow rate begins to noticeably decrease. It is recommended that one establish a maintenance schedule of replacing the filter at least every 3 months, dependent on water quality.

**Water Monitoring:** After installation of an S100 In-Line filter, periodic monitoring of the water for bacteria is recommended.

### Installation & Removal

**Note:** For first-time installation, please refer to the S100 In-Line installation guide. Prior to handling a new filter it is recommended that one wash their hands and wear disposable gloves.

- Open a new filter blister pack.
- Mark the label with the installation date.
- If installing the threaded version of the filter, turn off the water supply valve. For the QC version it is not necessary to turn off the water valves before disconnecting the filter as the female quick connectors have internal shut off valves.
- Disconnect the inlet of the used filter followed by the outlet.

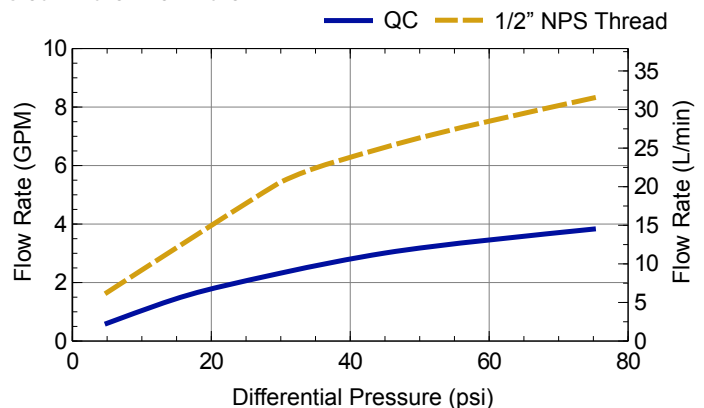
- Seal the used filter ports with the caps to minimize water leakage.
- Remove the used filter from its mounting clip and discard appropriately.
- Place the new filter in the clip making sure the flow direction arrow points towards the water outlet.
- Connect the outlet line to the filter followed by the inlet line.

**Note:** Prolonged exposure of the filter to alkyl dimethyl benzyl ammonium chloride (ADBAC) may result in cracks to the external housing. It is recommended not to use ADBAC based cleaners.

### Operation

After a new S100 In-Line filter is installed, water should be run through the filter for approximately 20 seconds to purge it of trapped air. The pressure drop across the S100 generally reduces the flow rate by about ¼ of the rate without a filter. The filter should operate for up to 3 months of normal use with minimal degradation in flow. If the flow rate degrades significantly, the filter should be replaced.

### Clean Water Flow Rate



















### Specifications

<b>Sterilization Method</b>	Ethylene Oxide
<b>Max Inlet Pressure</b>	75 psi (5 bar)
<b>Max Inlet Temperature<sup>(2)</sup></b>	60°C (140°F)
<b>Material</b>	Polysulfone
<b>Pore Size</b>	0.1 micron
<b>Bacterial Retention<sup>(1)</sup></b>	> 10 <sup>9</sup> (B. diminuta)
<b>Expected Life</b>	Up to 3 months

(1) S100 filters have been validated by a 3rd-party certified laboratory, in accordance with ASTM F838-20 "Standard Test Method for Determining Bacteria Retention of Membrane Filters Utilized for Liquid Filtration," with total bacteria retention as defined by "Sterilizing Grade" filter. Nephros S100 Validation Report: NEPH061521. For additional reference see: FDA "Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice," September 2004.

(2) The maximum allowable hot water flow rate for 1/2" NPS threaded configuration is 2.5 GPM at 60°C (140°F).

Symbol	Symbol Title	Standard Reference	Standard Title	Explanatory Text
	<b>Manufacturer</b>	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	
	<b>Use by Date</b>	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	
	<b>Batch Code</b>	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	
	<b>Part Number</b>	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.
	<b>Sterilization by Ethylene Oxide</b>	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	
	<b>DO NOT Resterilize</b>	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	
	<b>DO NOT Use if Package Is Damaged and Consult Instructions for Use</b>	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	
	<b>Consult Instructions for Use</b>	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	
	<b>Medical Device</b>	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.
	<b>Unique Device Identifier</b>	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.
	<b>Fragile, Handle with Care</b>	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	
	<b>Rain</b>	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	
	<b>Keep Away from Sunlight</b>	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	
	<b>Temperature</b>	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	
	<b>This Way Up</b>	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	
	<b>Stacking Load</b>	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	

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