NEPHROS

Instructions for Use Part #: **70-0280 / 70-0281**

Nephros S100 Sink Filters

Introduction

Information on this sheet must be read before the use of this device to ensure safe and effective operation. Information applies to both spout and spray models.

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 Sink Spout and Spray Filters are disposable point-of-use micro-filters 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.

Use: These devices are intended for long-term, continuous use, over a 3-month period. Once a filter completes its useful life (3-months), the filter should be discarded and replaced. Do not attempt to sterilize or re-use 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 sink 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 sink filters are intended for a maximum incoming water pressure of 75 psi (5 bar).

Temperature: The S100 sink filters are rated for a maximum incoming water temperature of 60°C.

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

Installed Height: Once installed, the bottom of the filter must be at least 1 inch above the top rim of the sink. A filter must not be installed if its discharge is below this height.

Replacement: Once installed, the filter may be used for up to 3 months. If the flow rate decreases significantly prior to the 3 month replacement interval, the filter should be replaced. Replacement is recommended once a noticeable reduction in flow is observed. It is recommended to establish a maintenance schedule of replacing the filter dependent on water quality.

Water Monitoring: After installation of an S100 sink filter, periodic monitoring of the water for bacteria is recommended.

Installation & Removal

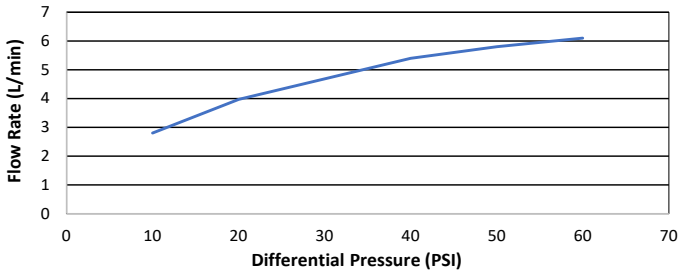
- A filter may be installed at any time, on or before the labeled expiration date. Once installed, the filter may be used for up to 3 months.
- For first time installation, it is necessary to remove the aerator from the faucet outlet and replace it with the aerator adapter.
- If necessary, use one of the rings supplied with the aerator adapter to convert it to the correct aerator thread.
- The following steps are recommended prior to attaching the filter.
- Measure the incoming water pressure by attaching a pressure gauge to the adapter and opening the faucet valves.
- Measure the pressure at a time of low facility water usage, hence the highest pressure (e.g. in the evening).
- Remove the filter from its package and insert the male quick connector into the aerator adapter.
- Make sure to push the filter in fully until the latch clicks and locks the filter in place.
- To remove a used filter, simply press the thumb latch on the aerator adapter and gently pull down on the filter to remove it.
- Discard the filter appropriately and replace it with a new one as previously described.

Note: 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. All S100 sink filters contain a bacteriostatic additive incorporated into the housing material in order to guard against surface touch contamination. In cases where the external housing of the filters might be subject to heavy surface contamination (e.g. rinsing of used surgical instruments), it is recommended to wipe down the exterior surface of the filters with 1% bleach. Do not remove the filters or immerse them in cleaning solution.

Operation

After a new S100 sink 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

Clean Water Flow Rate



Specifications

Sterilization Method	Ethylene Oxide
Max Inlet Pressure	75 psi (5 bar)
Max Inlet Temperature	60°C (140°F)
Material	Polysulfone
Pore Size	0.1 micron
Bacterial Retention(1)	> 10^9 (B. diminuta)
Expected Life	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.

NEPHROS

Symbol	Symbol Title	Standard Reference	Standard Title	Explanatory Text
	Manufacturer	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates the medical device manufacturer
		ISO 7000	Graphical symbols for use on equipment	
	Use by Date	ISO 15223-1	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	Graphical symbols for use on equipment	
	Batch Code	ISO 15223-1	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	Graphical symbols for use on equipment	
	Part Number	ISO 15223-1	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	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	Graphical symbols for use on equipment	
	DO NOT Resterilize	ISO 15223-1	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	Graphical symbols for use on equipment	
	DO NOT Use if Package Is Damaged and Consult Instructions for Use	ISO 15223-1	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	Graphical symbols for use on equipment	
	Consult Instructions for Use	ISO 15223-1	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	Graphical symbols for use on equipment	
	Medical Device	ISO 15223-1	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	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	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	Graphical symbols for use on equipment	
		ISO 780	Packaging — Distribution packaging — Graphical symbols for handling and storage of packages	
	Rain	ISO 15223-1	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	Graphical symbols for use on equipment	
		ISO 780	Packaging — Distribution packaging — Graphical symbols for handling and storage of packages	
	Keep Away from Sunlight	ISO 15223-1	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	Graphical symbols for use on equipment	
		ISO 780	Packaging — Distribution packaging — Graphical symbols for handling and storage of packages	
	Temperature	ISO 15223-1	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	Graphical symbols for use on equipment	
		ISO 780	Packaging — Distribution packaging — Graphical symbols for handling and storage of packages	
	This Way Up	ISO 780	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	Graphical symbols for use on equipment	
	Stacking Load	ISO 780	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	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