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. Once a filter completes its useful life, 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:** The filter should be replaced when the flow rate begins to noticeably decrease. 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

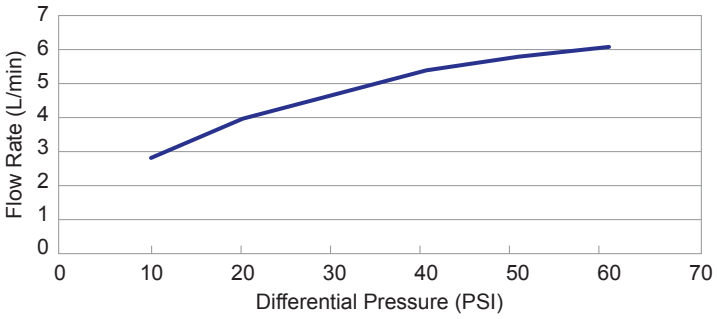
- For first time installation, it is necessary to remove the aerator from the faucet outlet and replace it with the aerator adapter.
- If necessary, use one of the rings supplied with the aerator adapter to convert it to the correct aerator thread.
- The following steps are recommended prior to attaching 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 rate degrades significantly, the filter should be replaced.

**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 15223-1:2021, 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