

# Endotoxin-Retentive (Loop) Filters





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## **1 RESTRICTIONS ON USE**

Federal law restricts this device for sale by or on the order of a physician when used as a water treatment device for hemodialysis.

## **2 THEORY OF OPERATION**

The Endotoxin-Retentive Filters are the final purification process prior to distribution of the product water. They are sub-micron filters with the ability to remove bacteria and endotoxin. The filters are enclosed in an opaque housing to inhibit the proliferation of algae. Water flows through the filter, which traps bacteria and endotoxin.

## **3 INSTALLATION**

Locate and install the Endotoxin-Retentive Filter assembly on the wall (or on the floor near the wall for the Quad Stainless Steel Endotoxin-retentive Filter Housing for Heat Disinfection).

Inlet water supply piping should be equal or greater than the inlet piping on the ultra-filtration header.

Plumbing from outlet of the Endotoxin-Retentive Filter should be of equal or greater diameter as the outlet connection on the Endotoxin-Retentive Filter assembly.

Follow all local plumbing codes.

If you have selected a multi-cartridge version, ensure that all filters are always installed. Failure to do so will result in water bypassing the filter, which could lead to patient harm.

### **3.1 Wetting Procedure**

The wetting procedure is to slowly wet the filter and allow air to exit the system, while not over-pressurizing the filter.

Starting with the inlet and outlet isolation valves closed, open the outlet sample port.

**NOTE:** On assemblies with the outlet sample port AFTER the outlet isolation valve, the outlet isolation valve will need to remain open.

With the RO running, gradually open the inlet isolation valve. Throttle the valve to stay nearly closed, checking the pressure gauges to make sure they remain low.

Air will exit the outlet sample port. When a steady stream of water is seen exiting the outlet sample port, let it run for 5 more minutes.

After the 5 minutes, the inlet and outlet isolation valves can be opened fully and the outlet sample port should be closed.

## 4 MONITORING:

Monitor and record the pressure drop (delta pressure) across the filters daily. The delta pressure should be < 15 psi.

AmeriWater recommends that Endotoxin-Retentive Filters be replaced at least every 12 months\* or when delta pressures  $\geq$  15 psi.

*\* If the filter cartridge manufacturer recommends more frequent replacement, follow their recommendation for frequency of exchange.*

**WARNING: ENDOTOXIN-RETENTIVE FILTERS ARE ESSENTIAL TO PATIENT SAFETY AND SHOULD NEVER BE BYPASSED OR REMOVED DURING TREATMENT!**

## 5 HEAT DISINFECTION:

AmeriWater offers several options for systems that will use heat for disinfection:

0021035 – Single 20" Endotoxin Filter, 3/4" Inlet and Outlet  
0021036 – Single 20" Endotoxin Filter, 1" Inlet and Outlet  
0021037 – Dual 20" Endotoxin Filters, 1" Inlet and Outlet  
0021038 – Quad 20" Endotoxin Filters, 1.5" Inlet and Outlet

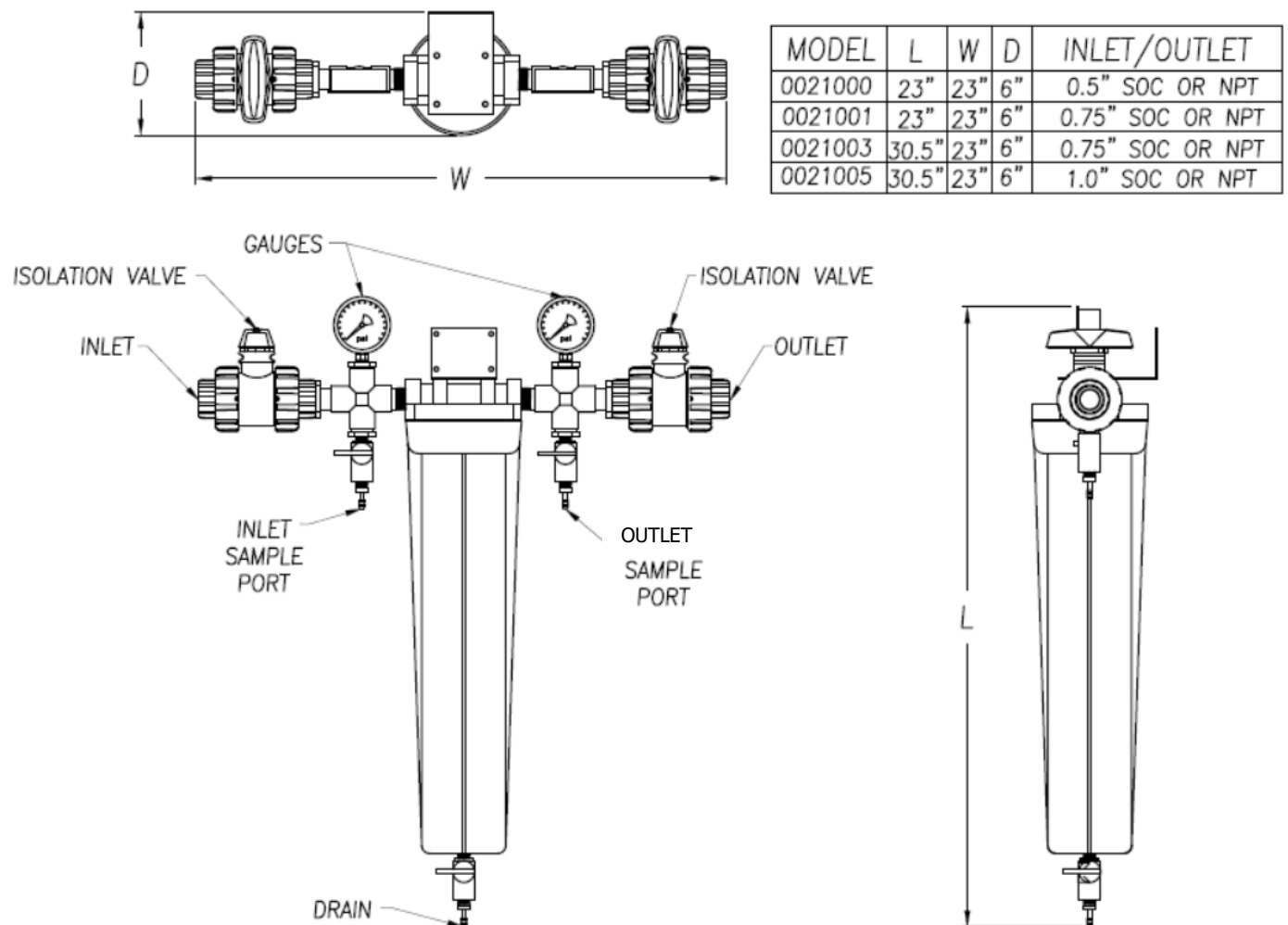
These have been specifically designed with heat disinfection in mind. Failure to use one of these with a heat disinfection system will lead to a breakdown of the materials and a potential hazard to the patient.



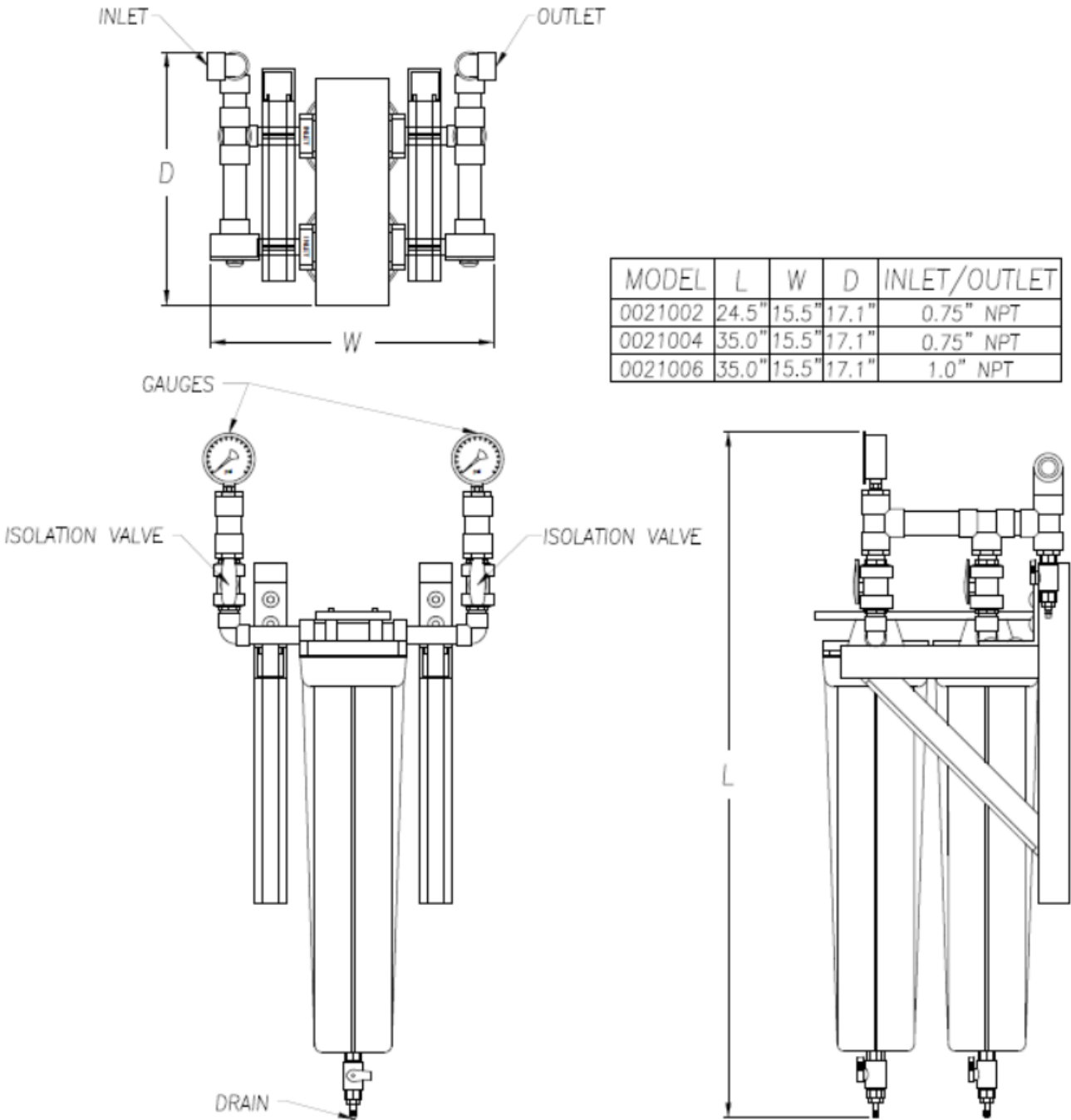
**This symbol indicates a possible hot surface. Touching parts of any system showing this label should be avoided during a heat disinfection cycle. Failure to do so could lead to burns.**

## 6 SYSTEM DRAWINGS

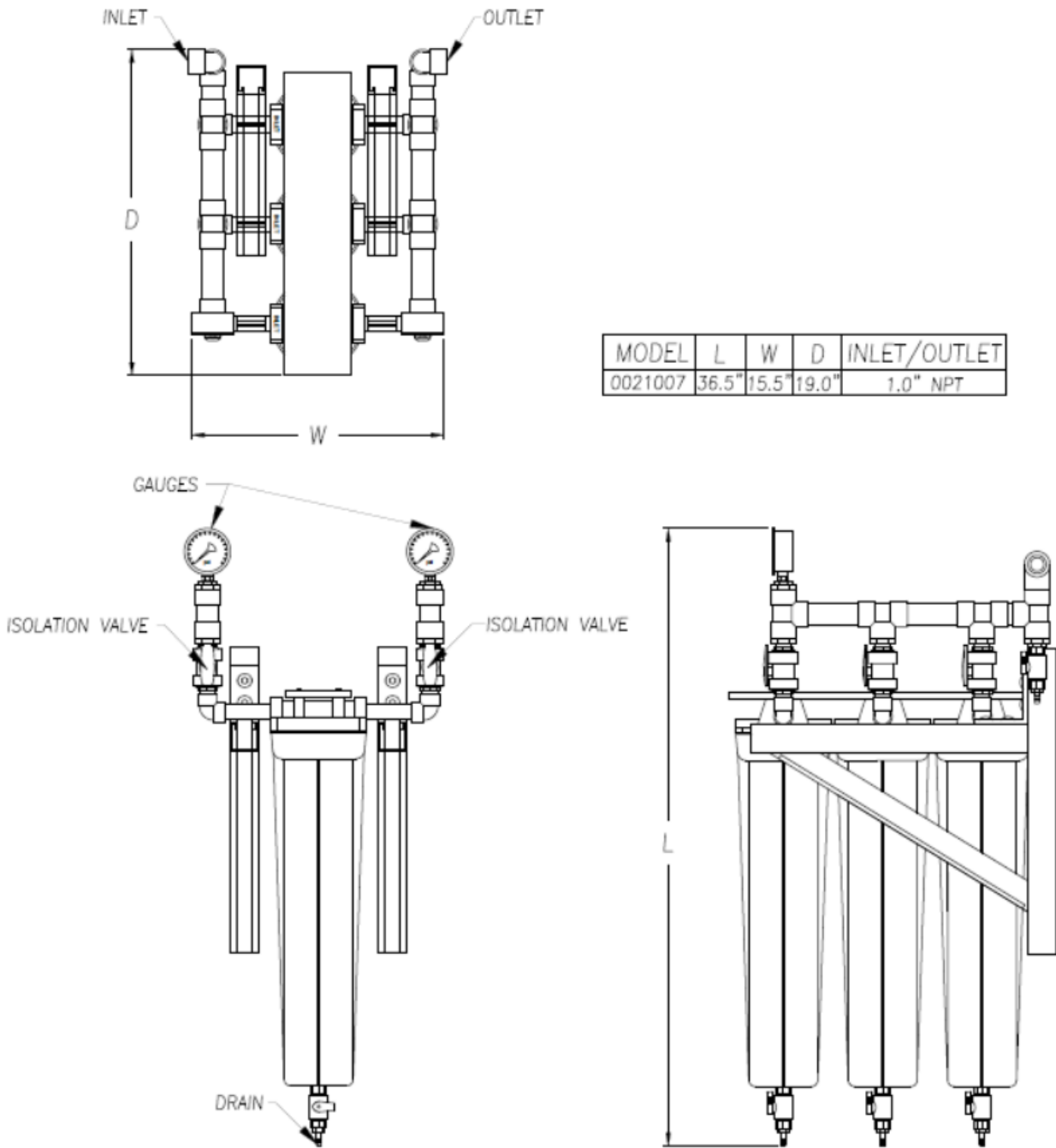
### SINGLE POLYETHELENE ENDOTOXIN-RETENTIVE FILTER HOUSING



**DUAL POLYETHELENE ENDOTOXIN-RETENTIVE FILTER HOUSING**



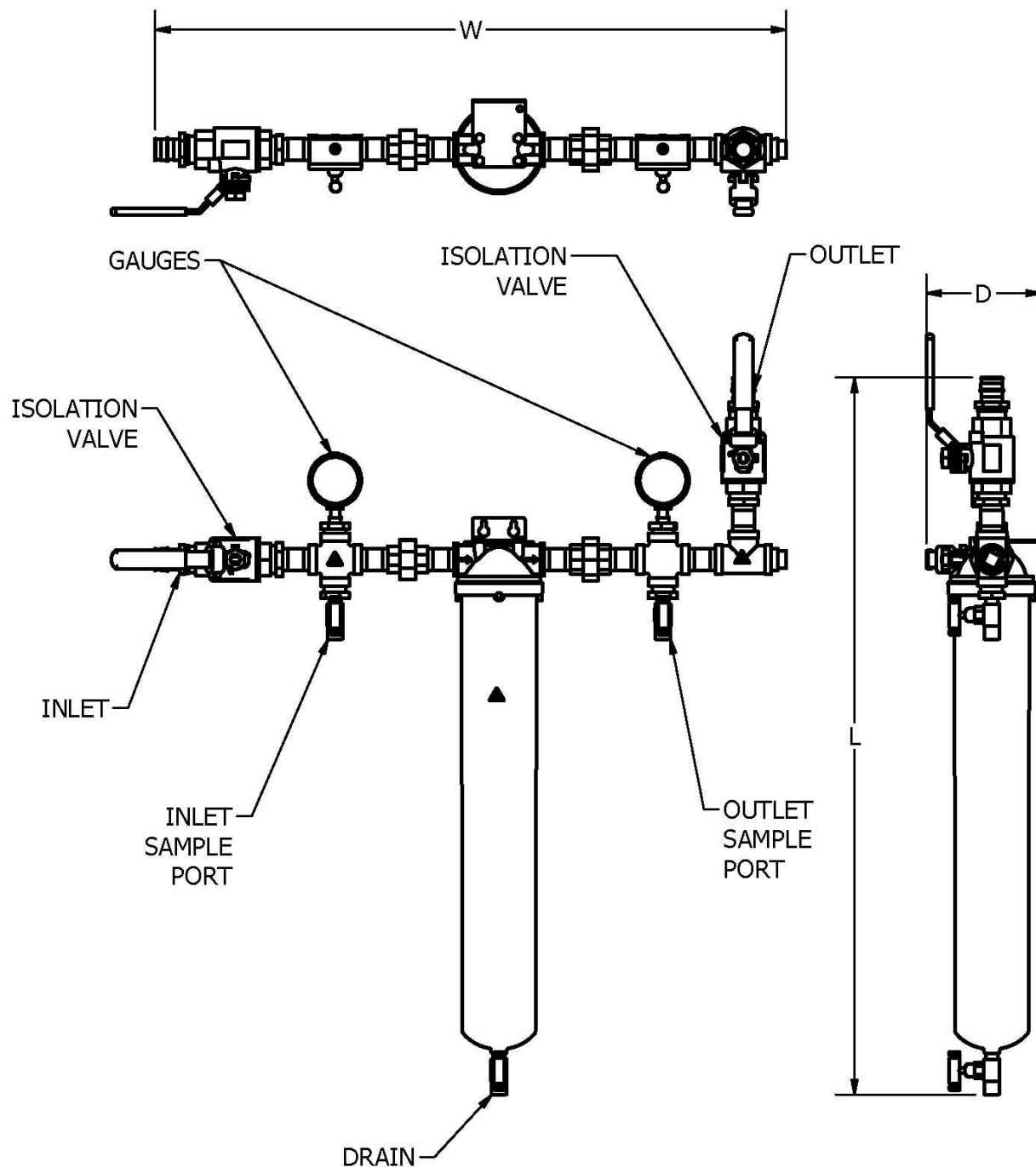
**TRIPLE POLYETHELENE ENDOTOXIN-RETENTIVE FILTER HOUSING**



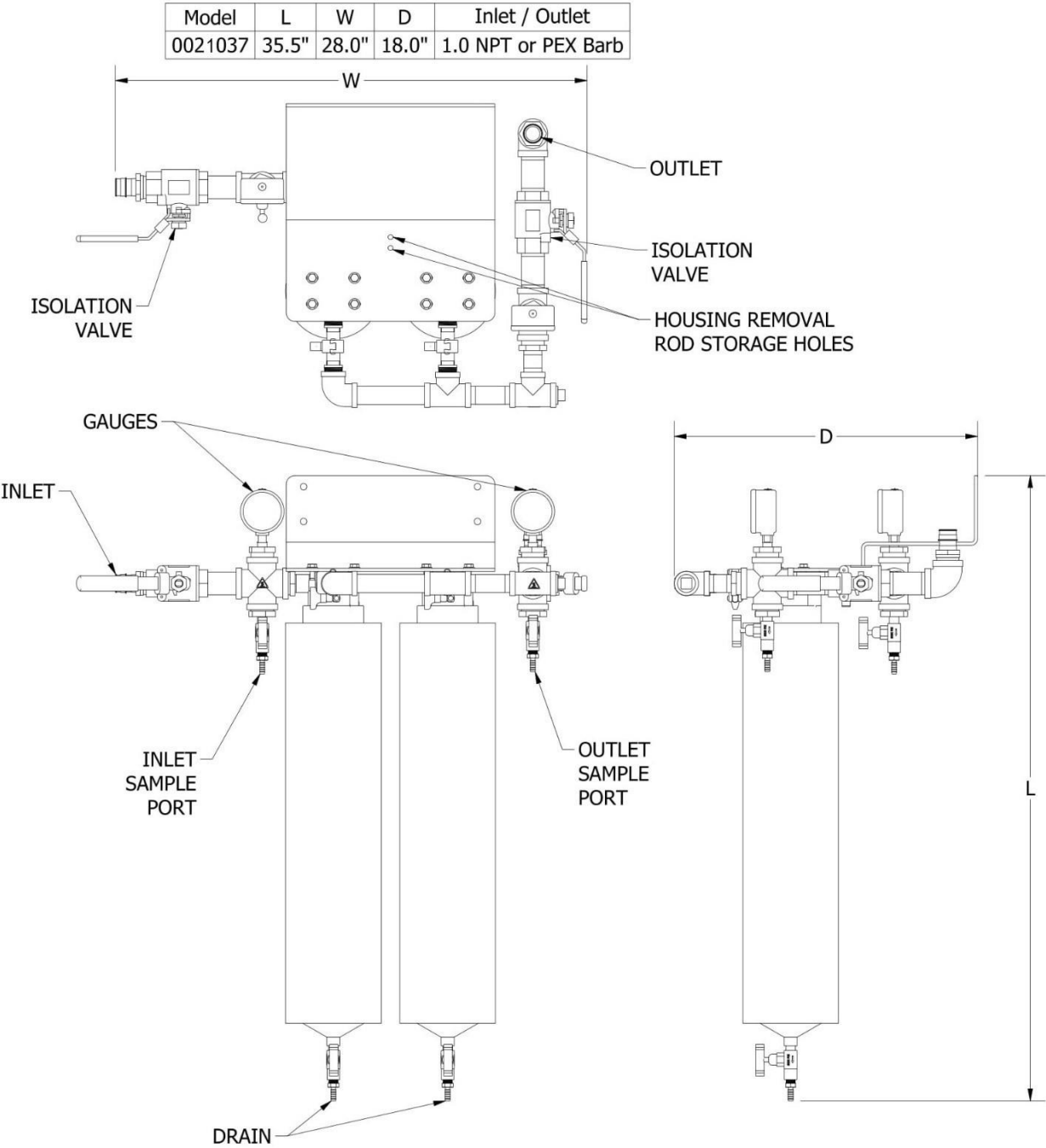


**SINGLE STAINLESS STEEL ENDOTOXIN-RETENTIVE FILTER HOUSING FOR HEAT DISINFECTION**

Model	L	W	D	Inlet / Outlet
0021035	35.5"	31.0"	6.0"	0.75 NPT or PEX Barb
0021036	35.5"	31.0"	6.0"	1.0 NPT or PEX Barb

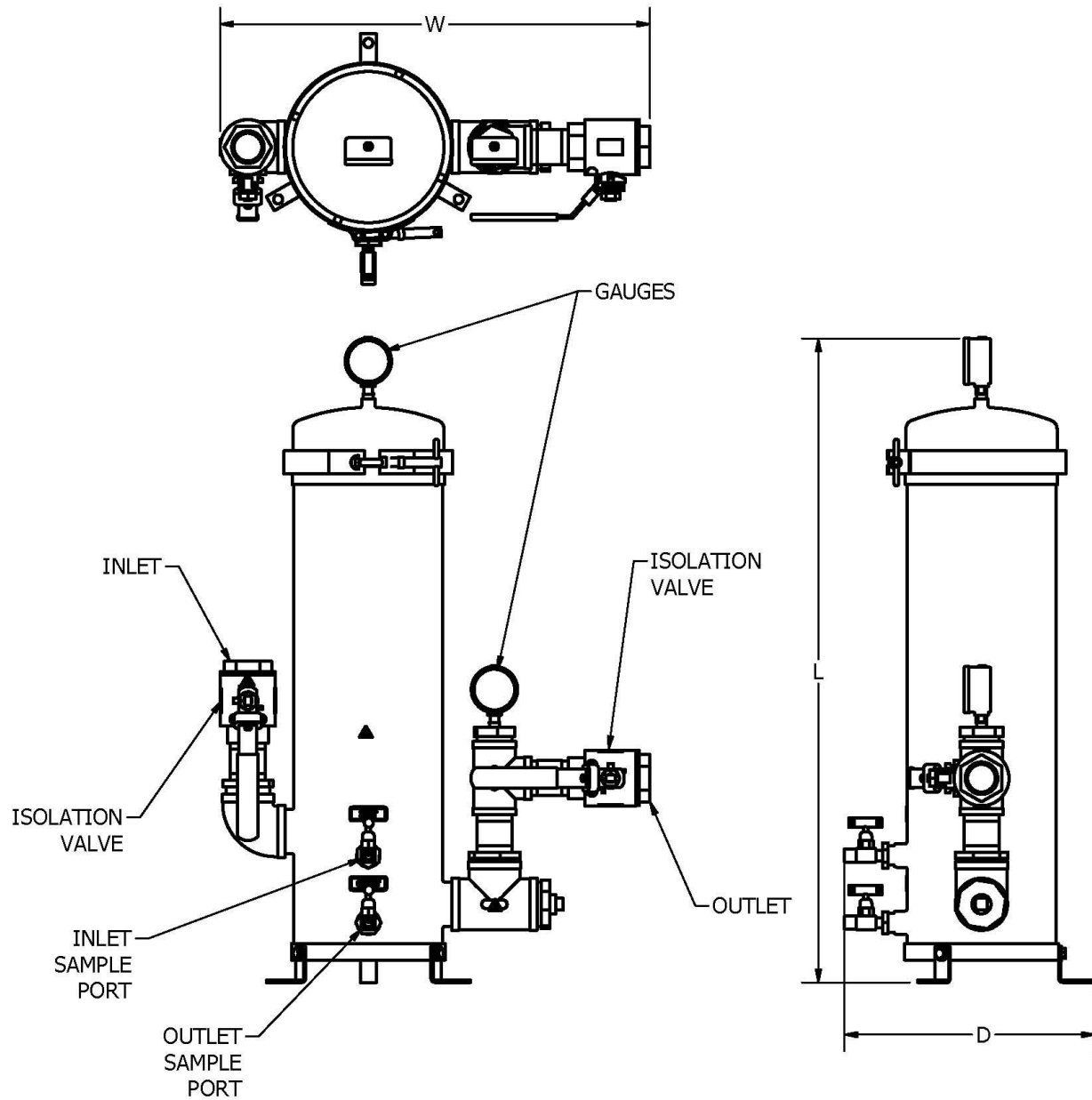


**DUAL STAINLESS STEEL ENDOTOXIN-RETENTIVE FILTER HOUSING FOR HEAT DISINFECTION**



**QUAD STAINLESS STEEL ENDOTOXIN-RETENTIVE FILTER HOUSING FOR HEAT DISINFECTION**

Model	L	W	D	Inlet / Outlet
0021038	35.5"	24.0"	14.5"	1.5 or 1.25 NPT



## 7 SPARE PARTS LIST

Part #	Name
041002	Sample Port – Plastic
041-0125	0.5" True Union Ball Valve - Plastic
041531806	0.75" True Union Ball Valve - Plastic
041-0133	1.0" True Union Ball Valve – Plastic
044-0109	0.75" NPT Stainless Steel Ball Valve*
044-0110	1.0" NPT Stainless Steel Ball Valve*
044-0113	1.5" NPT Stainless Steel Ball Valve*
42-0048	Sample Port – Stainless Steel*
43530710	Pressure Gauge, 0-100PSI
43-0031	Pressure Gauge, 0-100 PSI*
21SPH-12-222	Filter Housing, 2.5 X 12" – Plastic
21540116	Filter Housing, 2.5 X 20" – Plastic
21720548	Filter Housing Wrench for Plastic Sumps
21-0022	Housing, 2.5 X 20", Stainless Steel*
21-0042	Housing, Multi-Cartridge, (4) 20 Filters*
21530235	O-ring,Fltr,Hous,#10, # 12 & #20 "standard" & #10 & #20 "3g",blue/blk,.75 i/o
010-0113	O-ring, For Shelco Fltr House 21-0022, Heat Systems, Endotoxin
021-0015	O-RING,FLTR,HSG,FOR 21-0042
021-0016	O-RING,FLTR,HSG,FOR 021-0014
21-0021	Filter, Wrench, Housing 21-0022, ss, rod, heat systems

**NOTE:** Only parts with \* in their description are suitable for use with heat disinfection systems.

## 8 CONSUMABLE PARTS LIST

### SPECIFICATIONS

Model	Connection	For Housing	Maximum Flow (GPM)
20-3045	222 O-Ring	12"	5
20-3046	222 O-Ring	20"	10

The Pall cartridges, offered exclusively from AmeriWater, incorporate a patented covalent charge modified highly asymmetric hydrophilic polysulfone membrane, which provides retention of fine particles smaller than the membranes 0.2 micron rating.

### FEATURES:

- Materials of Construction: Polypropylene, Polysulfone.
- Hydrophilic media requires no pre-wetting.
- Extended life – cleanable, compatible with disinfection by PAA or heat.
- Patented highly asymmetric membrane provides higher flow rates at lower pressure drops (5 GPM at 2.4 PSI  $\Delta P$  per 10" length).
- Three times the endotoxin retention of comparable products on the market.
- QUALITY ASSURED: Validated for use in dialysis water systems.
- FDA clearance under AmeriWater 510K for Water Purification Systems.

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## **WARNING**

This product can expose you to chemicals such as vinyl chloride (used in the production of PVC) or Nickel (used in the production of stainless steel), that are known to the State of California to cause cancer. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

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Dear Valued Customer,

California Proposition 65 (Prop 65) is the Safe Water and Toxic Enforcement Act of 1986. The State of California began enforcing amendments to California Prop 65 at the end of August 2018. Prop 65 requires manufacturers to provide a clear and reasonable warning to residents of California about chemicals used in products that they purchase that are included on the Prop 65 Chemical List. The chemicals included on the list are chemicals that are known to the State of California to cause cancer, birth defects, or other reproductive harm. One such chemical is Vinyl Chloride, a compound used to produce Polyvinyl Chloride (PVC). The AmeriWater system you have purchased may contain PVC or stainless steel parts.

While warnings are only required in the State of California, AmeriWater has initiated the use of Prop 65 labeling for all products to ensure compliance with California regulations. Please note that the above warning does not necessarily mean that the product that you have purchased is unsafe. Products that have been cleared for market by FDA have been determined to be safe and effective by the United States Food and Drug Administration. The warning is simply a requirement by the State of California. If you wish to obtain additional information, please visit: [p65warnings.ca.gov](http://p65warnings.ca.gov). You may also contact your AmeriWater representative if you have any questions.

Thank you for your understanding and we look forward to continuing to serve you.