

## INSTRUCTIONS FOR USE- FOR FILTERS SOLD IN THE UNITED STATES OF AMERICA

### Applications & Intended use

*The Mar Cor Purification (Mar Cor) Posiclear™ filter is intended to remove bacteria, endotoxin, and particulate matter from water used for dialysis. It is intended for use in dialysis water treatment systems as a final stage of filtration after RO or DI treatment to help control bacteria and endotoxin levels in purified water distribution systems. This filter is not intended as a primary means of water purification.*

1. **CAUTION:** *When used as a medical device, Federal (USA) law restricts this device to sale by or on order of a physician.*
2. **CAUTION:** *This filter is not intended as a primary means of water purification. To obtain water of adequate quality for hemodialysis, it is necessary to use this filter in conjunction with other devices such as Reverse Osmosis (RO) or Deionization beds (DI). This filter should be placed following these devices as a final stage in the purification cascade.*
3. **CAUTION:** *The Mar Cor Posiclear™ filter is not compatible with bleach, formaldehyde, or ozone. Exposure to these disinfecting agents may damage the filter membrane and negatively affect filter performance.*
4. **CAUTION:** *When installing a Mar Cor Posiclear™ filter into a dialysis water system, ensure that the water flow through the filter will not exceed the maximum flow rating. In cases of higher flows, multiple filters can be used in parallel (a duplex arrangement of 2 filters in parallel, a triplex arrangement of 3 filters in parallel, etc).*
5. **CAUTION:** *The pressure drop across the filter(s) should be monitored regularly. This pressure drop is a key measurement of filter performance. Typical filter pressure drops are low (a few PSI). A pressure drop higher than 15 PSI is unusual and may indicate the filter is clogging and in need of replacement.*
6. **CAUTION:** *The Mar Cor Posiclear™ filter should be replaced every 6 months or whenever the pressure drop across the filter exceeds 15 PSI.*
7. **CAUTION:** *All cartridges should be inspected before use to determine if any unanticipated damage has occurred to the filter cartridge during storage; this includes inspection of the O-rings/gaskets to confirm that they have not dried out, become cracked, or exhibit a loss of elasticity that would prevent normal sealing during operation.*
8. **CAUTION:** *All cartridges must be stored in their original packaging and can not become wet, either directly or from condensing moisture.*

### Installation instructions

- **Housing type:** The Mar Cor Posiclear™ filter should only be used in “222” style filter housings (10” or 20”). In order to comply with AAMI RD-62, the filter housing should be opaque and the material of the housing should be compatible with the intended disinfection method.<sup>1</sup>
- **Pressure monitoring:** The filter housings should be equipped with pressure gauges to monitor pre-and post filter pressures. This pressure drop across the filter is a key measurement of filter performance and should be checked regularly. A pressure drop in excess of 15 PSI is unusual and may indicate the filter is clogging and in need of replacement.
- **Flow guidelines:** The Mar Cor Posiclear™ filter has a maximum flow limit:  
20” filter = 8 gallons per minute (GPM)  
10” filter = 4 gallons per minute (GPM)

**CAUTION:** *When installing a Mar Cor Posiclear™ filter into a dialysis water system, ensure that the water flow through the filter will not exceed the maximum flow rating. In cases of higher flows, multiple filters can be used in parallel (a duplex arrangement of 2 filters in parallel, a triplex arrangement of 3 filters in parallel, etc).*

---

<sup>1</sup> ANSI/AAMI RD-62:2006

**Filter Cartridge Replacement Procedure** -- The following procedure should be used to replace the Mar Cor Posiclear™ Filter Cartridge. If multiple filters are in use (duplex or triplex arrangement), all cartridges should be replaced at the same time. This procedure should be completed at the end of a patient treatment day and prior to water system disinfection.

1. Turn off the flow through the filter by shutting off the water distribution pump or RO. Check that the pressure in the filter housing drops to zero.
2. If the filter housing(s) has ball valves before and after the housing(s), close the valves.
3. Remove the filter sump from the filter head.
4. Remove and dispose of old filter cartridge.
5. Inspect filter housing(s) O-ring or gasket for damage (replace as needed).
6. Wet the O-rings on the new filter. Install new filter cartridge in filter head (make sure the filter cartridge O-rings properly seat into the filter head).
7. Re-attach the filter sump to filter head being careful not to damage the filter housing's O-ring or gasket.
8. If applicable, repeat steps 3-7 for additional filter housings.
9. Open the filter ball valves (if closed in step 2).
10. Begin water flow through the filter by re-starting the RO or water distribution pump.
11. Observe and record the pressure drop using the pre & post filter pressure gauges. Pressure drop should be less than 15 PSI.
12. Initiate a disinfection procedure according to the water system user's manual.
13. Label filter housing showing the replacement date.
14. Complete documentation/logging of filter replacement according to facility protocols.

**Materials of construction**

Membrane	Positive charge modified nylon 6,6
Membrane support layer	Polyester
Pleat support and drain layers	Polypropylene
Core, cage, end caps and adapter	Polypropylene
End cap reinforcing ring	316 stainless steel
O-rings	Silicone

**Description of the membrane cartridge**

Mar Cor Posiclear™ membrane filters are positive charge modified, pleated nylon 6,6 membrane filters. The positive charge treatment assists in retention of negatively charged biological contaminants such as endotoxin. Mar Cor Posiclear™ filters are 100% integrity tested following manufacture to ensure they are defect free. Mar Cor Posiclear™ filters are manufactured in a controlled environment using an ISO 9001 registered quality system. An identification system permits traceability of all raw material components. All materials of construction are 21 CFR listed and have passed USP Class VI Biological Tests for Plastics at 121° C.

**Routine monitoring**

**CAUTION:** The pressure drop across the filter(s) should be monitored regularly. This pressure drop is a key measurement of filter performance. Typical filter pressure drops are low (a few PSI). A pressure drop higher than 15 PSI is unusual and may indicate the filter is clogging and in need of replacement.

**Replacement frequency**

**CAUTION:** The Mar Cor Posiclear™ filter should be replaced every 6 months or whenever the pressure drop across the filter exceeds 15 PSI.

**Cleaning/disinfection recommendations**

The Mar Cor Posiclear™ filter should be disinfected whenever the water distribution system is disinfected.

Disinfectant compatibility:

- **Hot water:** The Mar Cor Posiclear™ filter is compatible with hot water disinfection systems (periodic hot water flushing of up to 90 degrees C).
- **Peracetic acid based disinfectants:** Disinfect the filter with a 1% to 2% Minncare or Renalin<sup>2</sup> solution. Total chemical exposure time over the life of the filter should not exceed 60 hours (at maximum strength dilution – 2%).

**CAUTION:** The Mar Cor Posiclear™ filter is not compatible with bleach, formaldehyde, or ozone. Exposure to these disinfecting agents may damage the filter membrane and negatively affect filter performance.

**Troubleshooting guidelines**

Increasing pressure drop across the filter(s) is the primary indicator of filter performance issues. Pressure drops in excess of 15 PSI indicate that the filter should be replaced. Consistent failure to achieve typical filter life (6 months) due to increasing pressure drop is unusual. Potential causes include:

- Exposure to bleach or ozone. Investigate water system disinfection protocol.
- Exposure to unusually large bacteria or endotoxin load. May be caused by use post deionizer (DI) tanks. The Mar Cor Posiclear™ filter is appropriate for use downstream of DI tanks; however, this is often a bacteria rich environment and typical filter life-span in this application may not reach 6 months.

<sup>2</sup> Minncare and Renalin are trademarks of Minntech Corporation

**Warranty and limitation of liability**

1. Mar Cor warrants that the Mar Cor Posiclear™ has been manufactured in accordance with its specifications and in compliance with Good Manufacturing Practices and other applicable industry standards and regulatory requirements. If provided with the lot number of the defective product, Mar Cor will by replacement, credit, or repair remedy manufacturing defects in Mar Cor Posiclear™ filters, which are discovered at the time the filter is first placed into use.
2. The warranty under paragraph 1 above is in lieu of, and to the exclusion of any other warranty, whether written or oral, express or implied, statutory or otherwise and there are no warranties or merchantability or other warranties, which extend beyond those described in paragraph 1 above. The remedy set out in paragraph 1 above is the sole and exclusive remedy available to any person due to defects in the Mar Cor Posiclear™ and neither Mar Cor nor the manufacturer shall be liable for any consequential, special or incidental loss, damage, injury, or expense arising directly or indirectly from the use of the Mar Cor Posiclear™, whether as a result of any defect therein or otherwise.
3. Neither Mar Cor nor the manufacturer shall be liable for any misuse, improper handling, non-compliance with warnings, precautions, and instructions set forth in these Instructions for Use, damage arising from events after the Mar Cor Posiclear™ filter is delivered to the buyer, failure or omission to inspect the Mar Cor Posiclear™ before use in order to insure that the Mar Cor Posiclear™ is in proper condition, or any warranty given by independent distributors or dealers.

Manufactured by:

3M Purification, Inc.  
400 Research Parkway  
Meriden, CT 06450

Distributed by:

Mar Cor Purification.  
14550 28<sup>th</sup> Ave N  
Plymouth, MN 55447  
800-633-3080



Mar Cor Purification  
4450 Township Line Road  
Skippack, PA 19474-1429  
Tel: (484) 991-0220  
Toll Free: (800) 346-0365  
Fax: (484) 991-0230

Mar Cor Purification  
14550 28th Avenue North  
Plymouth, MN 55447  
Tel: (484) 991-0220  
Toll Free: (800) 633-3080  
Fax: (763) 210-3868

Mar Cor Purification  
1119 Paulsun Street  
San Antonio, TX 78219  
Tel: (210) 227-3601  
Toll Free: (800) 268-5035  
Fax: 210) 227-0735

Mar Cor Purification  
160 Stedman Street  
Lowell, MA 01851  
Tel: (978) 453-9600  
Toll Free: (800) 633-3080  
Fax: (978) 453-1223

Mar Cor Purification  
6351 Orangethorpe Ave.  
Buena Park, CA 90620  
Tel: (714) 736-9990  
Toll Free: (800) 633-3080  
Fax: (714) 736-9402

Visit [www.mcpur.com](http://www.mcpur.com) for more information or call **1-800-633-3080**

©2011 Mar Cor Purification. All rights reserved. P/N:3027274 Rev.B