

Opticap® XL Capsules and Opticap® XLT Capsules



User Guide

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Sterilization by Autoclave

WARNING: DO NOT IN-LINE STEAM STERILIZE. NEVER USE A DEFORMED CAPSULE.

- Appropriate autoclave validation studies should be performed to achieve sterilizing conditions.
- For devices with filling bell, remove the protective cap from the filling bell before autoclaving.
- Remove dust cover (bag) and protective caps if present, before autoclaving.
- High and low point bleed valves must be open during autoclaving.
- Opticap® XL capsules must be oriented so that flow indicator arrows are pointing down during autoclave cycle.
- Opticap® XLT capsules must be oriented such that the t-line inlet and outlet connectors are the lowest points during the autoclave cycle to minimize condensate formation. **DO NOT AUTOCLAVE OPTICAP® XLT CAPSULES IN A HORIZONTAL POSITION.**
- Use plastic sanitary flange clamps or three piece stainless steel clamps to minimize stress during autoclaving. Fittings will distort if the flange or hose barb clamps are over torqued.
- For additional autoclaving information, request Technical Brief Opticap® Autoclaving Guidelines, TB072.

The following values are the maximum cycle parameters recommended for this product.

Opticap® XL and Opticap® XLT Capsule Autoclaving Specifications

| Media | Catalog Number | Time (Min.) | Temp (°C) | Cycles |
|----------------------------------|----------------|-------------|-----------|--------|
| Aervent® | KTGRA | 30 | 135 | 30 |
| Hydrophobic Durapore® | KVGBA | 30 | 126 | 20 |
| Durapore® 0.45 µm | KPHLA | 60 | 126 | 3 |
| Durapore® 0.45 µm with prefilter | KVHLA | 60 | 121 | 3 |
| Durapore® 0.22 µm | KVGLA | 60 | 126 | 3 |
| Durapore® 0.1 µm | KVWLA | 60 | 126 | 3 |
| Multilayer Durapore® | KHGLA | 60 | 126 | 3 |
| Multimedia Durapore® | KVSSA | 30 | 123 | 3 |
| | KVSXA | 30 | 123 | 3 |
| | KVSCA | 30 | 123 | 3 |
| | KV19A | 30 | 123 | 3 |
| | KV06A | 30 | 123 | 3 |
| Multimedia Durapore® | KV03A | 30 | 123 | 3 |
| | KV03A | 30 | 123 | 3 |
| Millipore Express® SHC | KHGEA | 60 | 126 | 3 |
| Millipore Express® SHR | KHVEA | 60 | 126 | 3 |
| Millipore Express® SHR-P | KVEPA | 60 | 126 | 3 |
| Millipore Express® SHF | KGEPA | 60 | 126 | 3 |
| Millipore Express® PHF | KPGEA | 60 | 126 | 3 |
| Lifegard™ | KP15 | 30 | 121 | 3 |
| | KP20 | 30 | 121 | 3 |
| Polysep™ II | KGW1 | 30 | 121 | 3 |
| | KGW2 | 30 | 121 | 3 |
| | KGW3 | 30 | 121 | 3 |
| | KGW6 | 30 | 121 | 3 |
| | KGW9 | 30 | 121 | 3 |
| Milligard® | KWSS | 30 | 121 | 3 |
| | KWSC | 30 | 121 | 3 |
| | KW03 | 30 | 121 | 3 |
| | KW06 | 30 | 121 | 3 |
| | KW19 | 30 | 121 | 3 |
| Milligard® LPB | KWLS | 30 | 121 | 3 |
| | KWLC | 30 | 121 | 3 |
| | KWL3 | 30 | 121 | 3 |
| | KWL6 | 30 | 121 | 3 |
| | KWL9 | 30 | 121 | 3 |
| Clarigard® | K030 | 30 | 126 | 3 |
| | K010 | 30 | 126 | 3 |
| | K005 | 30 | 126 | 3 |
| | K003 | 30 | 126 | 3 |
| | K002 | 30 | 126 | 3 |

| Media | Catalog Number | Time (Min.) | Temp (°C) | Cycles |
|---|-----------------|-------------|-----------|--------|
| Polygard® CR | KRK1 | 30 | 126 | 3 |
| | KRK3 | 30 | 126 | 3 |
| | KRK5 | 30 | 126 | 3 |
| | KR01 | 30 | 126 | 3 |
| | KR03 | 30 | 126 | 3 |
| | KR05 | 30 | 126 | 3 |
| | KR10 | 30 | 126 | 3 |
| | KR25 | 30 | 126 | 3 |
| | KR50 | 30 | 126 | 3 |
| | KR75 | 30 | 126 | 3 |
| Polygard® CN | KR99 | 30 | 126 | 3 |
| | KN03 | 30 | 126 | 3 |
| | KN06 | 30 | 126 | 3 |
| | KN12 | 30 | 126 | 3 |
| | KN25 | 30 | 126 | 3 |
| | KN50 | 30 | 126 | 3 |
| | KN1H | 30 | 126 | 3 |
| KN3H | 30 | 126 | 3 | |
| Gamma Stable and Pre-Sterilized Capsules that can be autoclaved: | | | | |
| Hydrophobic Durapore® | KVGBG/ KVGBS | 30 | 123 | 3 |
| Durapore® 0.22 µm | KVGLG/ KVWLS | 60 | 123 | 3 |
| Durapore® 0.1 µm | KVGLG/ KVWLS | 60 | 123 | 3 |
| Multilayer Durapore® | KHGLG/ KHGLS | 60 | 123 | 3 |
| Millipore Express® SHC | KHGEG/ KHGES | 60 | 123 | 3 |
| Millipore Express® SHR | KHVEG/ KHVES | 60 | 123 | 3 |
| Millipore Express® SHR-P | KVEPG/ KVEPS | 60 | 123 | 3 |
| Millipore Express® SHF | KGEPG/ KGEPS | 60 | 123 | 3 |
| Millipore Express® PHF | KPGEG/ KPGES | 60 | 123 | 3 |
| Millipore Express® HPF | KHPSG/ KHPS | 60 | 123 | 3 |

Installation

- Orient the capsule in the process so that process flow follows the flow indicator arrow on the capsule label. See Figure 1.

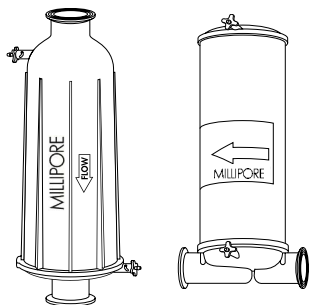


Figure 1. Flow indicator arrows

- To minimize holdup volume in the Opticap® XLT capsule, orient the capsule so that the t-line connector is at the lowest point.
- Isolation valves should be attached to the inlet and outlet ports of the capsule to allow flushing, venting and draining operations.
- If using the Opticap® XLT capsules with the optional gauge port, install gauge prior to use.

Filter Wetting

NOTE: Opticap capsules with Durapore®, Multimedia Durapore® or Millipore Express® membranes **MUST** be wetted prior to use and integrity testing.

Close both bleed valves, and the isolation valve located downstream of the capsule.

Wet the filter capsule by slowly introducing RO, DI or WFI water or buffer through the capsule inlet port. (Product may be used, if a product-based integrity test has been validated.) Open the high point bleed valve until liquid starts flowing out of the valve. Close the valve when the flow of liquid becomes steady and free of air. Open the capsule downstream isolation valve and adjust flow to approximately 1 Lpm/ft² of filter surface area for a minimum of 5 minutes.

Opticap® XL 150, 300 and 600 capsules with Millipore Express® membranes:

Open the capsule downstream isolation valve and set the inlet pressure to 5 psig. Continue to flow the wetting fluid through the capsule for a total of three minutes.

Proper wetting can also be used to meet minimum flush requirements, to prevent false integrity failures, and to ensure full use of the available filtration area.

Filter Flushing—Hydrophilic Membranes

Filter flushing before product processing is strongly recommended as a preconditioning step. It will prevent adverse reactions such as excessive product binding or precipitate formation, which can occur between process fluid and dry filter material. Flushing also allows the filter to be properly wet, which is key to overall filter performance.

Flushing is beneficial to filtrate quality and will eliminate most of the filter extractable substances from the process. When the filter is subjected to autoclaving, flushing after autoclaving is highly recommended.

Capsules meet the requirements of USP Oxidizable Substances Test after a water flush of:

Recommended Flush Volume (Liters) per Opticap® Capsule

| Membrane or Media | XL 150 XL 300 XL 600 | XL1 | XL2 | XL3 | XL4 | XL5 | XL 10 | XLT 10 | XLT 20 | XLT 30 |
|---|----------------------------|-----|-----|-----|-----|-----|-------|--------|--------|--------|
| Durapore® | -- | -- | 0.5 | -- | 0.5 | 0.5 | 1 | 1 | 2 | 3 |
| Multimedia Durapore® | -- | -- | -- | -- | -- | -- | 5 | 5 | 10 | 15 |
| Milligard® | -- | -- | 1 | -- | 1 | 2 | 5 | 5 | 10 | 15 |
| Milligard® LPB | -- | -- | 1 | -- | 1 | 2 | 5 | -- | -- | -- |
| Polysep™ | -- | -- | 1 | -- | 2 | 2 | 5 | 5 | 10 | 15 |
| Lifegard™ | -- | -- | -- | -- | -- | 2 | 5 | -- | -- | -- |
| Polygard® CN | -- | -- | -- | -- | -- | 2 | 5 | -- | -- | -- |
| Polygard® CR | -- | 1 | -- | -- | -- | 2.5 | 5 | -- | -- | -- |
| Clarigard® | -- | 1 | -- | -- | -- | 2 | 3 | 3 | 6 | 9 |
| Millipore Express® HPF, PHF*, SHF, SHC and SHR | 1 | -- | -- | 2 | -- | 2 | 2 | 2 | 4 | 6 |
| Multilayer Durapore® | | | | | | | 1.5 | 1.5 | 3.0 | 4.5 |

*Capsules with Millipore Express® PHF do not have an oxidizable substance specification, but should be flushed at the stated volumes.

Integrity Testing

Opticap® XL and XLT Capsules with Durapore®, Multimedia Durapore® Membrane or Millipore Express® Membranes

Pre-use, post-sterilization (autoclaving) integrity testing is recommended to identify potential problems prior to processing valuable product. Post-use integrity testing is a GMP requirement for many applications. Either a validated rinse procedure or a validated product-based integrity test is critical to minimize false failures.

Operating Conditions

Do not exceed maximum inlet pressure:

- 6.9 bar (100 psi) at 25 °C, intermittent, Millipore Express® HPF, SHF, SHC and SHR membranes only
- 5.5 bar (80 psi) at 25 °C
- 2.8 bar (40 psi) at 60 °C
- 1.0 bar (15 psi) at 80 °C

Do not exceed maximum differential pressures:

| Membrane or Media Type | Maximum Pressure | | | | | |
|--|------------------|------|---------|---------|-----|---------|
| | Forward | | | Reverse | | |
| | PSID | Bar | Temp °C | PSID | Bar | Temp °C |
| Durapore®, Multimedia Durapore®, Multilayer Durapore® | 15 | 1.0 | 80 | 50 | 3.5 | 25 |
| | 80 | 5.5 | 25 | | | |
| Millipore Express® SHF, SHC and SHR | 80 | 5.5 | 25 | 30 | 2.1 | 25 |
| Millipore Express® HPF XL3, XL5, XL10, XLT10, XLT20, XLT30 | 100* | 6.9* | 25 | | | |
| | 15 | 1.0 | 80 | | | |
| Millipore Express® HPF XL150, XL300, XL600 | 80 | 5.5 | 25 | 20 | 1.4 | 25 |
| | 100 | 6.9 | 25 | | | |
| | 15 | 1.0 | 80 | | | |
| Millipore Express® PHF | 80 | 5.5 | 25 | 20 | 1.4 | 25 |
| | 15 | 1.0 | 80 | | | |
| Milligard®, Milligard® LPB, Polysep™ II, Lifegard™ | 50 | 3.5 | 25 | None | | |
| Clarigard® | 70 | 4.8 | 23 | None | | |
| Polygard® CR | 80 | 5.5 | 23 | None | | |
| Polygard® CN | 70 | 4.8 | 25 | None | | |

* intermittent

Opticap® capsules with filling bell attachment:

- Do not use if filling bell is cracked.
- Do not remove filling bell from capsule.
- Remove protective vinyl cap before autoclaving.

General Limited Warranty

The applicable warranty for the products listed in this publication may be found at www.millipore.com/terms (within the “Terms and Conditions of Sale” applicable to your purchase transaction).

Technical Assistance

For more information, contact the office nearest you or visit the Technical Service page at www.millipore.com/techservice. Worldwide contact information is available at www.millipore.com/offices.