

User Guide

Opticap® Small Scale 300 Capsules
Opticap® XL Capsules
Opticap® XLT Capsules
Opticap® T-line Capsules
Opticap® Inline Capsules

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Introduction

Opticap® Small Scale 300 capsules, Opticap® XL capsules, Opticap® XLT capsules, Opticap® T-line capsules, and Opticap® Inline capsules are self-contained, single-use, Inline (or T-line) filters with upstream vents and drain ports. Each capsule filter is supplied with a Certificate of Quality (CoQ) which summarizes lot release criteria and product specifications.

Delivery

Visually inspect capsules to ensure no damage occurred during shipping. The outer carton and the bags within the box that protect the filters should be intact and in good condition.

Unpacking

Opticap® XL capsules and Opticap® XLT capsules are available in autoclavable, gamma-compatible and sterile options. Sterile capsules have been presterilized by gamma irradiation. The radiation exposure label on the inner bag will be red to indicate gamma irradiation has been performed.

The Opticap® Small Scale 300 capsules, Opticap® T-line capsules, and Opticap® Inline capsules are available in autoclavable and gamma-compatible options.

Storage

Store filters in their original packaging at ambient temperature and away from direct sunlight.

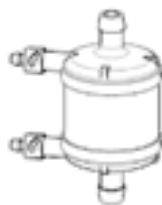
Installation

If the capsule is dropped, perform a visual inspection to confirm the capsule is not damaged. To minimize the risk of contaminating a sterilized capsule, handle the capsule housing with gloved hands. Do not touch the inlet and outlet of the capsule with ungloved hands.

Installing the Capsule

- Use tubing clamps to secure tubing to the hose barb connections.
- Sanitary flange connections should be finger tightened only. Do not overtighten as this may crack the fitting. Use caution when connecting an Opticap® capsule fitting to a stainless-steel fitting.

Opticap® Small Scale 300



Opticap® XL



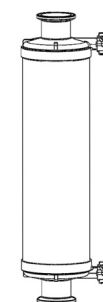
Opticap® XLT



Opticap® T-line



Opticap® Inline



- Install the capsule so that process flow follows the flow direction arrow on the capsule label.
- To minimize hold up volume in Opticap® XLT capsules and Opticap® T-line capsules, orient the capsule so that the T-line connector is at the lowest point.
- Install isolation valves at the inlet and outlet ports of the capsule to enable flushing, venting and draining.
- Install a pressure gauge near the inlet port before use.

NOTE

When first actuating the vent for Opticap® Small Scale 300 capsules, Opticap® T-line capsules, and Opticap® Inline capsules, use thicker gloves with a good grip. Avoid using mechanical tools to prevent vent damage.

Autoclaving

WARNING!

Do not inline steam sterilize. Never use a deformed filter capsule.

Proper autoclaving is essential to maintaining capsule integrity:

- Opticap® XL capsules and Opticap® XLT filter capsules can be autoclaved wet or dry.
- Opticap® Small Scale 300 capsules, Opticap® T-line capsules, and Opticap® Inline capsules *MUST BE* wet prior to autoclaving.

Validation of the sterilization process should reflect process conditions and confirm sterilizing conditions are achieved. The maximum autoclave sterilization cycle parameters for each membrane filter is listed on the CoQ and other product documentation.

- For Opticap® XL 150, XL 300, or XL 600 devices with filling bell, filling bell is a cover that goes over certain device formats used to ensure sterility. Remove the protective cap from the filling bell before autoclaving. Remove dust cover (bag) and protective caps if present, before autoclaving.
- Seal devices in autoclave pouches or protect inlet, outlet fittings and bleed valves (vent) with sterilization wrap. Capsule inlet and outlets must be unobstructed to allow maximum air displacement and steam flow but openings should be protected to prevent contamination ingress after sterilization. Failure to select the appropriate pouches or wraps can result in device damage or ineffective sterilization.
- Tubing with the largest possible inner diameter should be used. Tubing should not be crimped or bent. If tubing is connected to both the inlet and outlet openings it

should not form a continuous loop and *MUST BE* open and unobstructed to provide adequate steam flow.

- 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.
- High and low point bleed valves (vent) *MUST BE* open during autoclaving.
- Capsule orientation in autoclave: the flow indicator on Opticap® XL capsules and Opticap® Inline capsules should point down and the Opticap® XLT capsules and Opticap® T-line capsules must have the T-line inlet and outlet connectors at the lowest points during the autoclave cycle to minimize condensate formation.

NOTE

Do not autoclave Opticap® XLT capsules or Opticap® T-line capsules in a horizontal position.

- Hardware attached to the capsule must be supported during the autoclave cycle to prevent warping of the fitting. The capsule vents should not be supporting the weight of the capsule during the autoclave cycle.
- To minimize the possibility of filter damage through excessive differential pressures during autoclave sterilization, use an appropriate sterilization wrap or pouch and a slow exhaust profile where possible.

Filter Wetting

Refer to the wetting guide for each membrane filter for additional information. Wetting can be used to meet minimum flush requirements, prevent false integrity failures, and ensure the entire filtration area can be used for processing.

NOTE Opticap® capsule filters containing Durapore®, Multimedia Durapore®, Millipore Express®, Milligard® PES membranes *MUST BE* wetted prior to use and integrity testing.

Wetting Opticap® XL 150, 300, 600 and Opticap® Small Scale 300 Capsule Filters

- Close both bleed valves and the isolation valve downstream of the capsule.
- Wet the filter capsule by slowly introducing RO, DI or WFI water or buffer through the capsule inlet.
- Open the capsule downstream isolation valve and set the inlet pressure to 5 psig.
- Continue to flow the wetting fluid through the capsule at 1 L/min/0.1 m² for three minutes.

Wetting Opticap® XL and Opticap® XLT Capsule Filters

- Close both bleed valves and the isolation valve downstream of the capsule.
- Wet the filter capsule by slowly introducing RO, DI or WFI water or buffer through the capsule inlet.
- 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.

Wetting Opticap® T-line and Opticap® Inline Filters

- Close both bleed valves and the isolation valve downstream of the capsule.
- Wet the filter capsule by slowly introducing RO, DI or WFI water or buffer through the capsule inlet.
- 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.
- For optimal results perform the following before integrity testing: open the capsule downstream isolation valve and adjust flow to approximately 6.1 Lpm/10 inch of filter surface area with back pressure of 45 psi for a minimum of 10 minutes while maintaining a differential pressure of less than or equal 3 psi.

Flushing

Filter flushing before product processing is strongly recommended to minimize product binding to the membrane. Filter flushing will also reduce levels of extractable substances before processing. Filter capsules should be flushed after autoclaving or exposure to gamma irradiation. Refer to the CoQ or Emprove® Material Qualification Dossier (MQD) for the appropriate filter flush volumes.

Integrity Testing

NOTE Opticap® capsule filters containing Durapore®, Millipore Express®, Milligard® PES membranes *MUST BE wetted before integrity testing.*

Integrity testing specifications for different membrane filters are listed on the CoQ.

Pre-use, post-sterilization integrity testing is recommended for critical sterilizing filters to identify potential problems before processing. The integrity of all critical sterilizing filters should be confirmed after processing.

Filtration Operations

To start filtration, slowly wet the filter at low pressure and purge air to ensure the membrane is fully wet. To minimize the risk of filtration induced failures, ensure filtration processing conditions fall within the ranges specified on the CoQ for each filter.

Opticap® capsules with filling bell attachment:

- Do not use if filling bell is cracked.
- Do not remove filling bell from capsule.

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