Millipore®

User Guide

Opticap® XL Capsules and Opticap® XLT Capsules

Contents

The life science business of Merck KGaA, Darmstadt, Germany operates as MilliporeSigma in the U.S. and Canada.

MERCK

Introduction

Opticap® XL and XLT capsules are self-contained, single-use, in-line (or T-line) filters with upstream vents and drain ports. Each capsule filter is supplied with a Certificate of Quality 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 and 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.

Storage

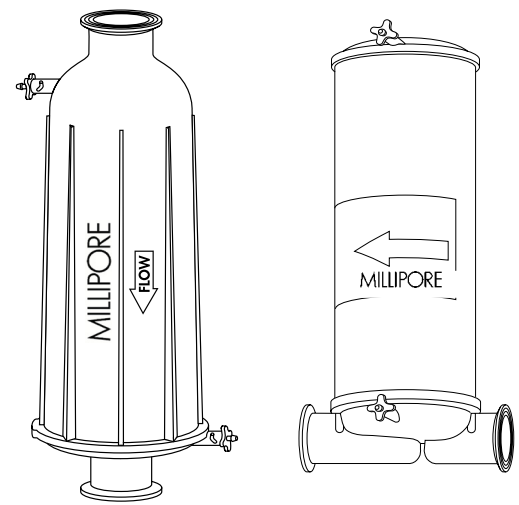
Store filters in their original packaging at ambient temperature away from direct sunlight.

Installation

If the capsule is dropped, perform a visual inspection to confirm the capsule was 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 the Opticap® capsule fitting to a stainless-steel fitting.



Opticap® XL (left) and XLT (right) capsules with flow direction arrows

- 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, 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 operations.
- Install a pressure gauge near the inlet port before use.

Autoclaving

Proper autoclaving is essential to maintaining capsule integrity. Filter capsules can be autoclaved wet or dry. 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 are listed on the Certificate of Quality and other product documentation.

Warning

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

- 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.
- Seal devices in autoclave pouches or protect inlet and outlet fittings 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 MUST be open during autoclaving.
- Capsule orientation in autoclave: the flow indicator on Opticap® XL capsules should point down and the Opticap® XLT capsules must have the T-line inlet and outlet connectors at the lowest points during the autoclave cycle to minimize condensate formation.

Warning

Do not autoclave Opticap® XLT 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

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

Note

Opticap® capsule filters containing Durapore®, Multimedia Durapore® or Millipore Express® membranes MUST be wetted prior to use or integrity testing.

Wetting Opticap® XL and XLT Capsule Filters

1. Close both bleed valves and the isolation valve downstream of the capsule.
2. Wet the filter capsule by slowly introducing RO, DI or WFI water or buffer through the capsule inlet.
3. 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.
4. Open the capsule downstream isolation valve and adjust flow to approximately 1 Lpm/ft^2 of filter surface area for a minimum of 5 minutes.

Wetting Opticap® XL 150, 300 and 600 Capsule Filters

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

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 Certificate of Quality or Emprove® Program Material Qualification Dossier for the appropriate filter flush volumes.

Integrity Testing

Integrity testing specifications for different membrane filters are listed on the Certificate of Quality.

Pre-use, post-sterilization integrity testing is recommended to identify potential problems before processing. In medicinal product manufacturing, filter integrity testing post-use is a standard step in GMP manufacturing.

Note

Opticap® XL and XLT capsules containing Durapore® or Millipore Express® membranes MUST be wetted before integrity testing.

Sterile Filtering

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 Certificate of Quality for each filter.

Opticap® capsules with filling bell attachment:

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

We provide information and advice to our customers on application technologies and regulatory matters to the best of our knowledge and ability, but without obligation or liability. Existing laws and regulations are to be observed in all cases by our customers. This also applies in respect to any rights of third parties. Our information and advice do not relieve our customers of their own responsibility for checking the suitability of our products for the envisaged purpose.

For technical assistance please visit:
www.sigmaaldrich.com

For additional information and documentation please contact:
Merck KGaA, Darmstadt, Germany
Corporation with General Partners
Frankfurter Str. 250
64293 Darmstadt, Germany
Phone: + 49 6151-72 0

For requests from USA and Canada please contact:
MilliporeSigma
A subsidiary of Merck KGaA, Darmstadt, Germany
400 Summit Drive
Burlington, MA 01803 USA
Phone: 1-800-645-5476

MK_UG1011EN Rev 3 03/2024