



# LYOGUARD®

FREEZE-DRYING TRAYS

## Autoclave Sterilization Guidelines

### Tray Handling During Sterilization

GORE® LYOGUARD® Freeze-Drying Trays can be steam-sterilized once using a customer-validated autoclave cycle. Users are responsible for validating their own sterilization techniques and processes. Irradiation sterilization methods should not be used because they can degrade the mechanical and barrier properties of the tray.

#### Tray Handling

- Always handle trays by the fill port and frame only.
- Protect tray from heavy or sharp objects as they may damage the membrane.
- Wear sterile gloves or use sterile instruments when handling the tray after sterilization. Do not touch the inner surfaces to minimize the risk of contamination.

#### Sterilization

- Remove GORE® LYOGUARD® Trays from packaging. The tray should be oriented with the membrane facing up. The membrane side is the top of the tray (Figure 1).
- Install the crossbar support tightly across the top of the tray to prevent the membrane barrier from sagging during autoclaving. See detailed crossbar installation instruction on page 2.
- Remove screw caps from the spout before sterilization.
- Place screw caps top-side up in a single layer in the sterilizer. Do not stack (Figure 2).
- Trays can be placed horizontally or vertically in the sterilizer.
  - For horizontal placement, place the trays so that each tray sits flat on a shelf with the membrane barrier facing up. Avoid stacking trays directly on top of one another.
  - For vertical placement, place the trays vertically in the sterilizer, so they rest on the short edge of the plastic frame. To minimize distortion of the plastic frame, trays should be sufficiently supported to remain vertical during the entire autoclave cycle (Figure 2).
- Ensure that temperatures in the autoclave chamber do not exceed 125°C (275°F).
- The maximum pressure change should not exceed 1 psi/minute (0.069 bar).
- Time in the autoclave should not exceed 30 minutes.

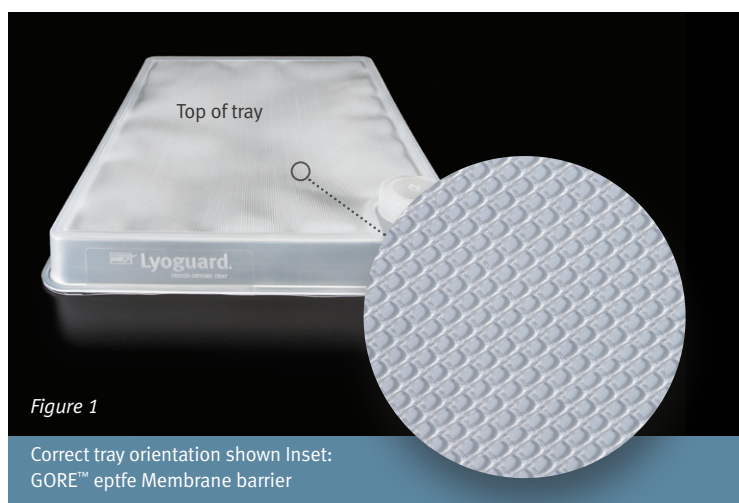


Figure 1

Correct tray orientation shown Inset:  
GORE™ eptfe Membrane barrier

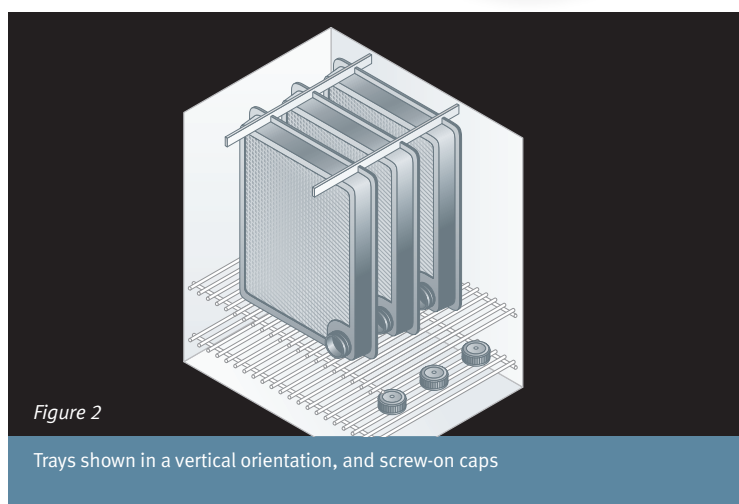


Figure 2

Trays shown in a vertical orientation, and screw-on caps



# LYOGUARD®

**FREEZE-DRYING TRAYS**

## Autoclave Sterilization Guidelines

### Installing the Crossbar

It is recommended to use the crossbar support accessory to help prevent the membrane barrier from sagging during sterilization.

- Locate the top of the bar. The top side has a slanted edge. The bottom has a lip which fits into the edge of the tray (Figure 3).
- Gently slide the lip of the bar into the center of the long edge of the tray. Be careful to not damage the membrane barrier (Figure 4).
- Slide the other end of the crossbar into the other side of the tray. The crossbar is designed to fit tightly across top of the tray. When installed properly, it should bow upward slightly, away from the membrane (Figure 5).
- Remove the crossbar after sterilization.

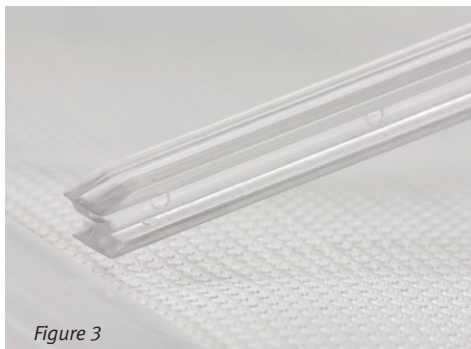


Figure 3

Locate the top of the crossbar

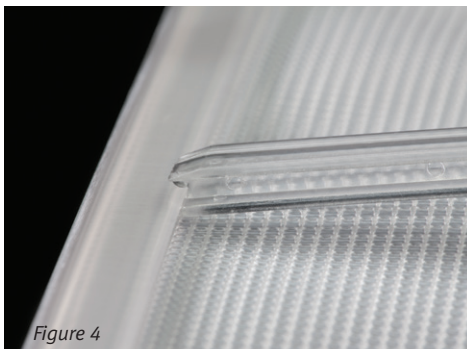


Figure 4

Insert crossbar into top of tray, across the center of the tray



Figure 5

Properly installed crossbar should bow upwards

### Ordering Information

| Part       | Part Number | Minimum Order Quantity |                                                                               |
|------------|-------------|------------------------|-------------------------------------------------------------------------------|
| Tray       | LGT2000     | 15 Trays (1 box)       |                                                                               |
| Foil Pouch | FP30031     | 50 Pouches             | Foil pouches are recommended for product stored in trays after lyophilization |
| Crossbar   | P229        | 10 Bars                | Crossbars are recommended for use during autoclaving                          |

*Accessories Sold Separately*

### Gore PharmBIO Products

Our technologies, capabilities and competencies in fluoropolymer science are focused on satisfying the evolving product, regulatory and quality needs of pharmaceutical and bioprocessing customers, and medical device manufacturers.

GORE® LYOGUARD® Freeze-Drying Trays, like all products in the Gore PharmBIO Products portfolio, are tested and manufactured under stringent quality systems. These high-performance products provide creative solutions to our customers' design, manufacturing, and performance-in-use needs.

[gore.com/pharmbio](http://gore.com/pharmbio)

#### AMERICAS | W. L. GORE & ASSOCIATES, INC.

402 Vieve's Way • Elkton, MD 21921 • USA  
Phone: +1.410.392.4100 • Toll-free (US): 1.800.294.4673  
Email: [pharmbio@wlgore.com](mailto:pharmbio@wlgore.com)

#### EUROPE | W. L. GORE & ASSOCIATES, GMBH

Wernher-von-Braun-Strasse 18 • 85640 Putzbrunn, Germany  
Phone: +49.89.4612.3456 • Toll free: 0.800.4612.3456  
Email: [pharmbio\\_eu@wlgore.com](mailto:pharmbio_eu@wlgore.com)

All technical information and advice given here is based on our previous experiences and/or test results. We give this information to the best of our knowledge, but assume no legal responsibility. Customers are asked to check the suitability and usability in the specific applications, since the performance of the product can only be judged when all necessary operating data are available. The Gore terms and conditions of sale apply to the purchase and sale of the product.

GORE, LYOGUARD, and designs are trademarks of W. L. Gore & Associates.  
© 2015-2018 W. L. Gore & Associates, Inc.

