



LYOGUARD®

FREEZE-DRYING TRAYS

Autoclave Sterilization Guidelines

Tray Handling During Sterilization

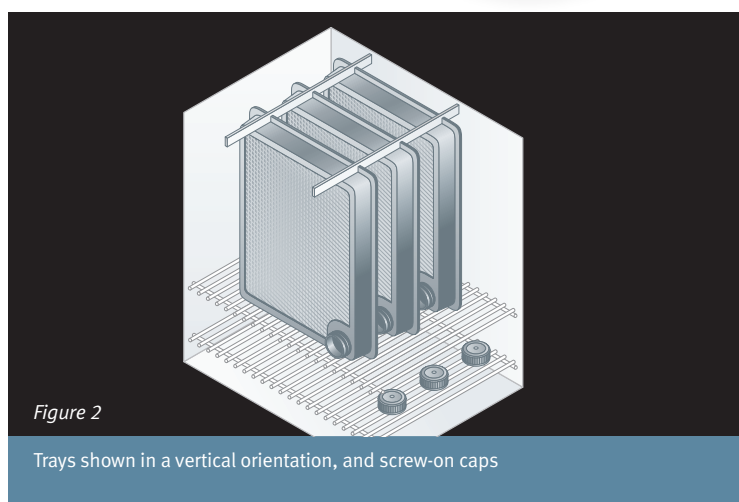
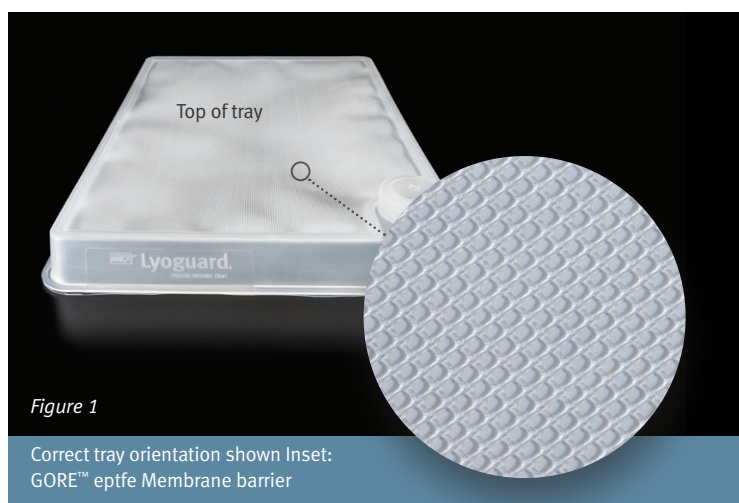
GORE® LYOGUARD® Freeze-Drying Trays can be steam-sterilized once using a customer-validated autoclave cycle. Users are responsible for validating their own sterilization techniques and processes. Irradiation sterilization methods should not be used because they can degrade the mechanical and barrier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





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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.

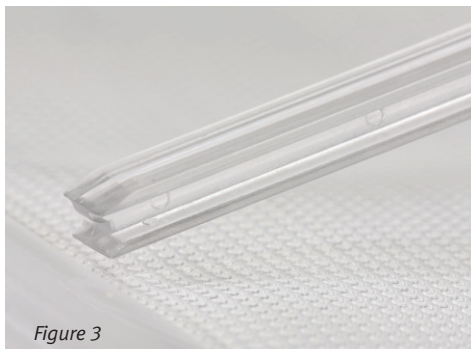


Figure 3

Locate the top of the crossbar

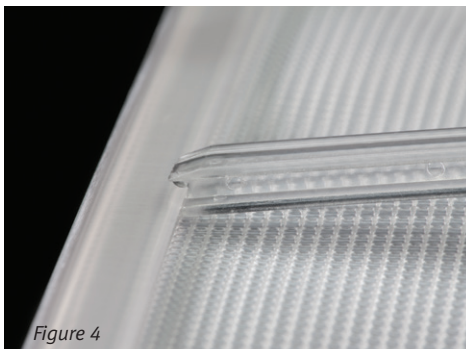


Figure 4

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

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