Autoclave Sterilization Guidelines

TRAY HANDLING DURING STERILIZATION

GORE LYOGUARD Trays can be steam-sterilized once using a customer-validated autoclave cycle. Users are responsible for validating their own sterilization techniques and processes. Irradiation or electron beam 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 laminate.
- 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 trays from packaging. The tray should be oriented with the laminate facing up. The laminate side is the top of the tray (Figure 1).
- Install the crossbar support tightly across the top of the tray to prevent the laminate from sagging during autoclaving. See detailed crossbar installation instruction on the next page.
- 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 laminate 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).

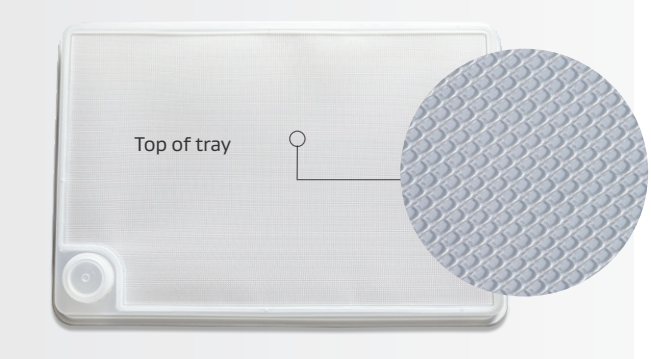


Figure 1. Correct tray orientation shown. Inset: Laminate

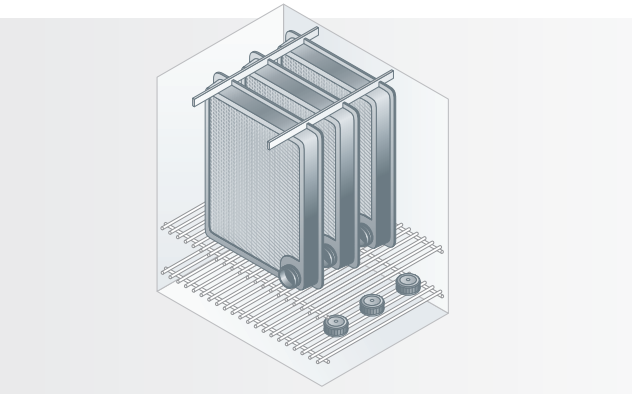


Figure 2. Trays shown in a vertical orientation with screw caps top side up

- The maximum pressure change should not exceed 1 psi/minute (0.069 bar/min).
- Exposure time in the autoclave should not exceed 30 minutes. Total time in autoclave may be longer.

Installing the Crossbar

It is recommended to use the crossbar support accessory to help prevent the laminate 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 laminate (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 laminate (Figure 5).
- Remove the crossbar after sterilization.

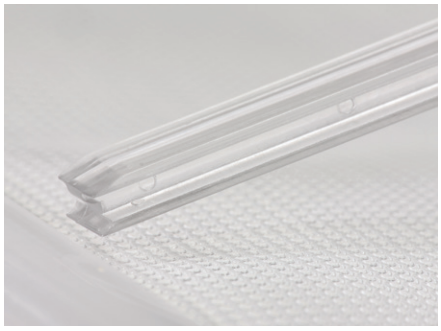


Figure 3. Locate the top of the crossbar

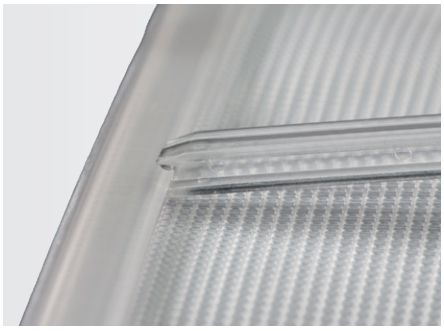


Figure 4. Insert crossbar into top of tray, across the center of the tray

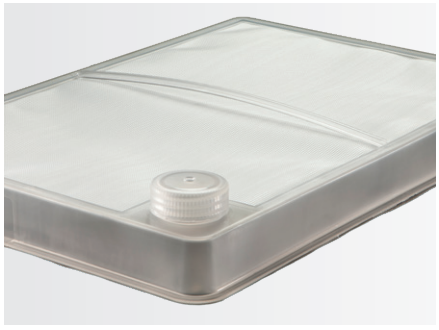


Figure 5. Properly installed crossbar should bow upwards

Ordering Information

Foil Pouches and Crossbar are available as accessories to the GORE LYOGUARD Trays

Part	Part Number	Minimum Order Quantity	Accessories Sold Separately
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

Gore PharmBIO Products

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

GORE LYOGUARD 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.

The GORE LYOGUARD Tray is neither classified nor regulated as a medical device and is not subject to FDA regulation.

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 of our products in the specific applications, since the performance of the product can only be judged when all necessary operating data is available. Gore's terms and conditions of sales apply to the purchase and sale of the product.

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