

LGT2000 Technical Bulletin

HANDLING RECOMMENDATIONS FOR GORE® LYOGUARD® TRAYS

Caution: Please Read Before Removing GORE LYOGUARD Trays from Packaging

Please use care when removing trays from carton. To avoid possible damage to the trays, always handle by the fill port and frame only. Avoid grabbing bottom and top of tray surface during removal and normal handling. Pressure from fingertips and fingernails can cause damage to laminate and tray bottom.

Filling

1. Place the GORE LYOGUARD Tray on a flat surface.
2. Unscrew cap from fill port.
3. Fill appropriate volume of product into container using aseptic procedure.
 - Minimum recommended fill: 3/32" (2.4 mm)
approximate fill volume = 200 mL
 - Maximum recommended fill: 3/4" (19.0 mm)
approximate fill volume = 1.8 L
4. Replace the cap on fill port and tighten "hand tight".

Note: Stacking trays filled with liquid is not recommended because damage to the top tray surface may occur and vapors transmitted through the laminate of the lower tray may condense onto external surfaces of trays stacked on top. It is not recommended to freeze dry pure water within the LYOGUARD Tray. Freezing water is known to create "spikes" which tend to form in the center of the tray. These spikes can cause membrane damage. Purer water may be more likely to result in these spikes, as fewer solids are present.

Loading into Dryer

Load trays onto lyophilizer shelves in the same fashion as an open tray.

- It is recommended that GORE LYOGUARD Trays be carried in a horizontal orientation, supported from the bottom by a flat stainless steel sheet (or similar), when filled with fluid.
- The Gore laminate is highly resistant to liquid penetration. Most solutions will roll off the laminate if incidental contact is made between the solution and the laminate.

Removing from Dryer

Remove GORE LYOGUARD Trays from the lyophilizer in the same manner as an open tray. Trays containing dried product may be stacked on top of each other at alternating angles.

Post-lyophilization Product Storage

If dried product will be temporarily stored inside GORE LYOGUARD Trays, it is recommended to seal the trays inside a foil barrier pouch to prevent degradation of the dried product by ambient moisture. (Part Number FP30031).

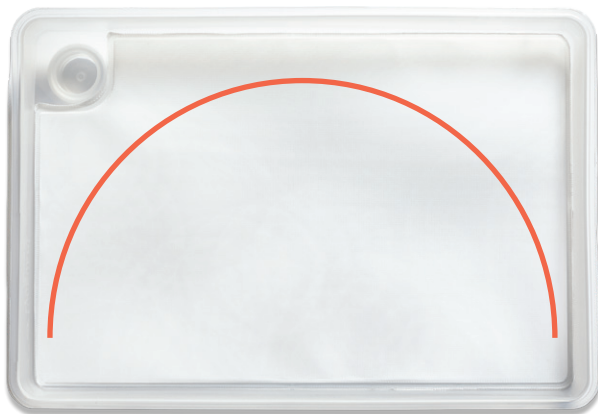
Gore does not have testing to support the long-term storage and transportation of product in trays while liquid, frozen, or in dry form. If product will be stored and/or transported in trays, process and product integrity validation are the responsibility of the user.

Product Sampling

1. Place tray on flat surface.
2. Remove fill port cap.
3. Insert sampling probe through fill port and collect samples from appropriate areas, exercising caution not to damage tray bottom or laminate with the sampling probe.
4. Replace fill port cap and tighten to "hand tight."

Product Recovery — Dried Powder Removal

1. Invert tray.
2. Using a sharp instrument, score the flexible film bottom with a single continuous cut in an arc shape from one end of the tray to another, taking care to stay away from the frame. Multiple cuts may cause film fragments to fall into the tray.



3. Product removal technique will vary, depending on dried cake characteristics.

Note: Film may be peeled away from some solid product cakes. Other cakes may be scooped from the tray top and, if needed, gently scraped from the film or internal tray surfaces. The most appropriate method will depend on the individual product.

Reconstituted Liquid Removal

1. Place tray on flat surface.
2. Remove fill port cap.
3. Add appropriate amount of diluent to tray.
4. Replace cap.
5. If needed, tray may be gently rocked to facilitate reconstitution.
6. Place tray on flat surface.
7. Remove fill port cap.
8. Insert product transfer tubing into fill port and transfer product. Tray may be gently tilted to facilitate complete liquid recovery.

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.

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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