



LYOGUARD®

FREEZE-DRYING TRAYS

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 membrane barrier 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.
 - LGT2000, 1/2" (12.7 mm) fill height = 1.2 L
 - LGT2000, 3/4" (19.0 mm) fill height = 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 membrane of the lower tray may condense onto external surfaces of trays stacked on top.

Loading into Dryer

Load GORE® LYOGUARD® 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 when filled with fluid.
- The GORE™ Membrane barrier is highly resistant to liquid penetration. Most solutions will roll off the membrane if incidental contact is made between the solution and the membrane.

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.

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 membrane barrier 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 along a corner, taking care not to cut into the rigid frame. Hold the tray by opposite, non-scored corners and flex tray to empty product contents through the scored corner.
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.

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