

USE GUIDELINES FOR GORE® STA-PURE® FLEXIBLE FREEZE CONTAINER AND ACCESSORIES



GORE STA-PURE Flexible Freeze Container with Barrier Wrap and Hard-shell Carrier

Overview

Single-use GORE STA-PURE Flexible Freeze Containers are intended for storing and transporting biopharmaceutical intermediates, after freezing at -86°C (123°F). Unlike other containers which may become brittle and fragile when frozen, GORE STA-PURE Freeze Containers* are resistant to cracks, leaks or breaks during cold-chain handling.

Specially fitted disposable Hard-shell Carriers,** suitable for plate or blast freezers, are available as accessories. They are designed to maximize freezer space, make handling easier and further protect tubing in the Container Assembly. If carbon dioxide (CO_2) or oxygen (O_2) permeation are a concern in the application, an optional vacuum heat-sealable secondary Barrier Wrap is available to minimize ingress. The Wrap fully encloses the Container Assembly, including tubing.

The Carrier and Barrier Wrap are optional. The decision to use the accessories is entirely application dependent and at the discretion of the customer. This guide provides use instructions for the Container Assembly, Barrier Wrap and Carrier.

See the GORE STA-PURE Flexible Freeze Container Data Sheet and Validation Guide for additional information. Contact Gore for tubing and connector options.

Product Information

The Hard-shell Carriers for GORE STA-PURE Flexible Freeze Containers include two parts: a high-density polyethylene (HDPE) lid and an HDPE base with a separate internal compartment for tubing and connectors. The lid and the base are attached and secured with cable ties (provided) for shipment.

The Barrier Wrap is a linear low-density polyethylene (LLDPE) laminate that is intended to be vacuum heat-sealed around the filled Freeze Container Assembly in the Carrier prior to freezing. Barrier Wrap permeability information is provided in Table 1. Container and accessory information is provided in Table 2.

TABLE 1. Barrier Wrap Permeability Information

	Permeability (Nominal)	Test Method
Oxygen (O_2)	< 0.0003 (cc/100in ² /24 hours)	ASTM D3985
Carbon Dioxide (CO_2)	< 0.0645 (cc/100in ² /24 hours)	ASTM F2476
Water	< 0.001 (g/100in ² /24 hours)	ASTM F1249

TABLE 2. Product Information

Container Size	Freezer Type	Container Maximum Fill Volume	Carrier Dimensions Width (W) x Length (L) x Height (H) [†]	Carrier Part Number	Barrier Wrap Dimensions	Barrier Wrap Part Number
Stability	Suitable for blast or plate freezers	50 mL	Not applicable	Not applicable	16 x 9 in (40.6 x 22.9 cm)	11010511
Sample	Suitable for blast or plate freezers	50 mL	Not applicable	Not applicable	18 x 17 in (47.7 x 43.2 cm)	10971719
Small	Blast Plate	2.5 L	13.5 x 23.5 x 3.0 in (34.3 x 59.7 x 7.6 cm)	11010512 (FIGURE 1)	33 x 14 in (84.0 x 35.6 cm)	10986994
		2.5 L	13.5 x 23.5 x 2.65 in (34.3 x 59.7 x 6.7 cm)	11010513 (FIGURE 2)	29 x 12 in (73.3 x 30.5 cm)	11010510
Medium	Blast Plate	5.0 L	23 x 18.5 x 5.5 in (58.4 x 47 x 14 cm)	10982759 (FIGURE 3)	28 x 16 in (71.1 x 41 cm)	10971720
		4.25 L	27 x 15 x 2.65 in (68.6 x 38.1 x 6.7 cm)	10986997 (FIGURE 4)	33 x 14 in (84 x 35.6 cm)	10986994
Large	Blast Plate	12.0 L	28.5 x 22.5 x 5.0 in (72.4 x 57.2 x 12.7 cm)	10982760 (FIGURE 5)	27 x 27 in (68.6 x 68.6 cm)	10971721
		10.0 L	27 x 21 x 2.65 in (68.6 x 53.3 x 6.7 cm)	10986998 (FIGURE 6)	33 x 20 in (84 x 51 cm)	10986995

NOTE: See Validation Guide for Container dimensions.

[†] Estimate based on Containers filled to maximum volume.



FIGURE 1. Small blast freezer Carrier



FIGURE 2. Small plate freezer Carrier



FIGURE 3. Medium blast freezer Carrier



FIGURE 4. Medium plate freezer Carrier



FIGURE 5. Large blast freezer Carrier



FIGURE 6. Large plate freezer Carrier

* Patent EP3174514; additional patents pending in the US & EU.

** Patent pending

Use Guidelines for GORE® STA-PURE® Flexible Freeze Container and Accessories

IMPORTANT: If used, the Barrier Wrap and the Container Assembly must be placed in the Carrier prior to freezing.

- Open the outer TYVEK® packaging and remove the GORE STA-PURE Flexible Freeze Container Assembly from the plastic backing card. Wipe all surfaces with 70% isopropyl before packaging, if desired.

Filling

- Before inserting the empty Container Assembly into the Barrier Wrap, ensure that one of the fill/drain connectors is inserted into a poly bag. Secure the poly bag around the tubing with an appropriate fastener (FIGURE 7). Either of the two outside connectors on the Container Assembly can be used as the fill or drain connector.
- Then insert the empty Container Assembly into the Barrier Wrap through the opening, with tubing positioned along the side of the Wrap for accessibility to the fill line (FIGURE 8).
- Place the wrapped Container Assembly in the appropriate Carrier base.
- Fill the Container to the desired volume, up to the maximum fill volume (see TABLE 2 for Container maximum fill volumes). Disconnect the container from the filling line.
- Insert the disconnected tubing end, including the closure component (clamp, crimp sleeve, etc.), into a poly bag. Secure the poly bag around the tubing with an appropriate fastener.
- Make sure the Container, tubing and connectors are properly placed in the Carrier base after filling (FIGURE 9).
- FIGURES 10, 11, and 12 show proper placement of tubing in various Carriers.



FIGURE 7. Secure the poly bag around the tubing with an appropriate fastener



FIGURE 8. Place Container Assembly in Barrier Wrap



FIGURE 9. Position tubing in Carrier



FIGURE 10. Tubing placement, large plate/blast freezer Carrier (shown without Barrier Wrap)



FIGURE 11. Tubing placement, medium plate freezer Carrier (shown without Barrier Wrap)



FIGURE 12. Tubing placement, medium blast freezer Carrier (shown without Barrier Wrap)

Vacuum Heat-Sealing the Barrier Wrap

- Sealing parameters for PE-based materials will vary based on equipment. Customers should determine optimal process settings to achieve a seal. Fold any excess Wrap material to fit inside the Carrier base (FIGURE 13).



FIGURE 13. Folding the Barrier Wrap into the Carrier

- Secure Carrier lid to the Carrier base for freezing by inserting cable ties in the small holes at the lid's perimeter (FIGURE 14).
- For best results, use the plate freezer Containers in a plate freezer and the blast freezer Containers in a blast freezer.



FIGURE 14. Securing the Carrier with cable ties

Storage

- Blast freezer Carriers can be stacked for storage.
- For maximum protection, the GORE STA-PURE Flexible Freeze Container Assembly should be stored frozen in its respective Carrier. **NOTE: Tubes can become brittle when frozen; the Carrier minimizes the possibility of damage to the tubes during storage and handling.**

Draining

- Place the Carrier on a secure surface. Remove all cable ties from the Carrier and remove the lid. Open the Barrier Wrap at the tear notch (FIGURE 15).
- Remove the poly bag from the drain connector and connect the Container to drain and empty contents.



FIGURE 15. Opening the Barrier Wrap using the tear notch

Transportation Testing

- The system has been tested per ISTA-3E using the SUNOCO® THERMOSAFE® EF2700 insulated pallet shipper. See GORE STA-PURE Flexible Freeze Container Validation Guide for detailed information.
- The user is responsible for validating transport and shipping methods.
- The Carrier and Barrier Wrap have been tested for single-use only. Follow local regulations for disposal of Container Assembly, Carrier and Barrier Wrap.

Personal Protective Equipment

- No specific personal protective equipment is required when using the Container Assembly, Barrier Wrap or Carrier as outlined in this document.

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 STA-PURE Flexible Freeze Container, 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.

NOT INTENDED FOR USE in medical device or food contact applications or with radiation sterilization.

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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