

Packing Products using the CF-45 for Shipping to Cellular Therapy Laboratory

Purpose This procedure provides direction for packing Cellular Therapy products for shipping freshly collect products to the Cellular Therapy Laboratory (CTL)

Proper configuration is required to ensure the CF-45 shipping container is able to cool toward or maintain a 2-8C environment during shipment or transport for a maximum of 30 hours.

Related Documents Post Collection Quarantine of HPC Collections, HPC0154

Materials

- CF-45 shipping container
- 1-inch insulated panels
- Inner box with inner sleeves
- Plastic bag, large (provided with shipping container)
- 2 Blood Shipper Ice (BSI) containers, filled to fill line (approximately 32 oz.), frozen solid
- Gel packs, 8 oz each, stabilized at 1-6C
- Absorbent pads
 - 9 x 9 inch (4) – each absorbs 500 mL
 - OR**
 - 18 x 14 inch (2) – each absorbs 1000 mL
- Re-sealable plastic bag for product
- Hematopoietic Progenitor Cells, Apheresis (Label), HPC 020 or equivalent
- HPC Product/Tube Chain of Custody, HPC 025 (Vitalant locations only)

Delayed Shipment If transport is delayed (e.g., inclement weather) and product will not arrive within 30 hours, perform the following.

Non-Vitalant clients:

- If product has been packed in the shipping container, replace the Blood Shipper Ice in the container prior to shipping to reset the transit time limit to 30 hours.
 - If product has not been packed in the shipping container, store product at 2-8C until able to pack and ship.
-

Continued on next page

Delayed Shipment (continued)

Vitalant locations:

- Quarantine the product according to Post Collection Quarantine of HPC Collections, HPC0154. Mark quarantine box on HPC Product/Tube Chain of Custody, HPC 025.
- Replace the Blood Shipper Ice in the container prior to shipping to reset the transit time limit to 30 hours. Document ice replacement on HPC Product/Tube Chain of Custody, HPC 025.
- Determine if the BSI ice pack still contains ice and record on HPC 025. Refer to the table below.

If ice	Then
is present	Record Yes on HPC 025.
is not present	<ul style="list-style-type: none"> ▪ Record No on HPC 025. ▪ Take temperature. ▪ Record in Comments section on HPC 025: <ul style="list-style-type: none"> ▪ temperature ▪ possible reason for ice not present

Blood Shipper Ice (BSI) Guidelines

Blood Shipper Ice (BSI) must be filled to fill line, frozen solid, and have the plug/cap secured.

- DO NOT store BSI containers in freezers colder than -35C.
- When stored colder than -20C, leave ice at ambient room temperature for at least 20 minutes prior to packing.

Before Packing Begins

Prepare packing materials prior to packing the CF-45 shipping container.

NOTE: Contact Cellular Therapy Laboratory for replacement materials, if necessary.

- Inspect materials, as appropriate, for evidence of damage, leakage, and proper fit.
 - Discard and replace unacceptable materials.
- Replace worn CF-45 shipping containers.
- Replace worn inner boxes and inner sleeves.
- CF-45 shipping containers should be at ambient temperature prior to packing.
- Gel packs should be stabilized at 1-6C.
- Verify BSI containers are frozen solid.

Packing Limits

Refer to the following table for the required number of Gel packs per Cellular Therapy component volume.

NOTE: The maximum product volume for the CF-45 shipping container is 2000 mL.

Product Volume	Total number of 8 oz Gel Packs (1-6C)
< 100 mL	8
100 - < 580 mL	6
580 – 2000 mL	4

Packing

Perform the following steps to pack product in the CF-45 shipping container.

NOTE: Products should not remain out of controlled storage longer than 30 minutes during the packing process.

Step	Action
1	Obtain the following materials. <ul style="list-style-type: none"> Plastic bag (provided with shipping container) 2 BSI containers, filled to fill line (approximately 32 oz.), each frozen solid 4 to 8 gel packs, 8 oz. each, stabilized at 1-6C Absorbent pads <ul style="list-style-type: none"> 9 x 9 inch (4) OR <ul style="list-style-type: none"> 18 x 14 inch (2)
2	Place plastic bag inside the inner box.
3	Place 2 (9 x 9 inch) or 1 (18 x 14 inch) absorbent pad(s) inside plastic bag, absorbent side up.
4	Within the plastic bag, place the frozen solid BSI containers on each end of the cardboard sleeve, positioned between the sleeve and the inner box wall.
5	Place half of the gel packs (up to 4) on top of the absorbent pads to ensure minimum and maximum load criteria are met. <ul style="list-style-type: none"> Refer to Packing Limits block.
6	Inspect product to ensure bag integrity
7	Place product in a re-sealable plastic bag and place on top of gel packs. <ul style="list-style-type: none"> If sending peripheral blood sample tube, place in resealable plastic bag and place with product.

Continued on next page

Packing (continued)

Step	Action
8	Place the other half of the gel packs (up to 4) on top of product to ensure minimum and maximum load criteria are met. <ul style="list-style-type: none"> Refer to Packing Limits block.
9	Place 2 (9 x 9 inch) or 1 (18 x 14 inch) absorbent pad(s) on top of gel packs with absorbent side down.
10	Close plastic bag by twisting and folding over.
11	Place foam lid on top of closed plastic bag in CF-45 shipping container.
12	Place additional required documents on top of the inner box when prepared for shipping and/or transport.
13	<p>Seal the CF-45 shipping container and affix appropriate shipping container label, e.g., Hematopoietic Progenitor Cells, Apheresis (Label), HPC 020 or equivalent.</p> <p>The label includes the following:</p> <ul style="list-style-type: none"> The number of product bags in the shipping container. The total liquid volume of all of the product bags combined. The full name of the processing laboratory or transplant facility that will receive the HPC product. The address to include street, city, and state for delivery at any time of day. The full name and an appropriate telephone number of the contact person at the receiving facility who has knowledge of the product's transport. The full name of the shipping facility. The address to include the street, city, and state of the shipping facility. The full name and an appropriate telephone number of a contact person at the shipping facility who has complete knowledge of the product's transport.

Diagram
(9 x 9 inch pads)

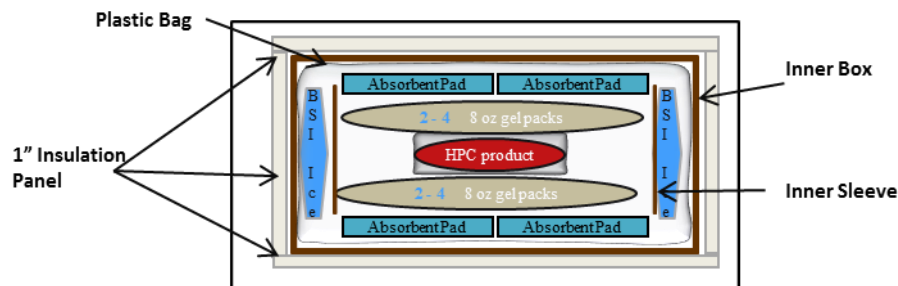
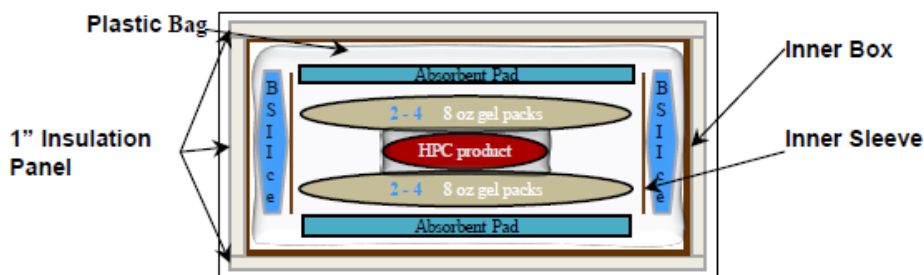


Diagram
(18 x 14 inch pads)



Revision History

The following table represents the revision history of this document.

Revision	Issued	Implemented	Reason
5			<ul style="list-style-type: none"> Revised for use with new absorbent pad.
4	MCR-24-014	3/25/24	<ul style="list-style-type: none"> Added Delayed Shipment block with reference to HPC0154.
3	MCR-23-072	09/05/23	<ul style="list-style-type: none"> Added Blood Shipper Ice (BSI) Guidelines block.
2	MCR-22-141	12/17/22	<ul style="list-style-type: none"> Defined Blood Shipper Ice (BSI).
1	MCR-20-055	10/1/20	<ul style="list-style-type: none"> Initial release. Information previously contained in HPP0201.