

Packing Cellular Therapy Products using the CF-45 Shipping Container 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 2C – 8C environment during shipment or transport for a maximum of 30 hours.

Materials

- CF-45 shipping container
- 1 inch insulated panels
- Inner box with inner sleeves
- Plastic bag, large (provided with shipping container)
- 2 BSI Ice containers, filled to fill line (approximately 32 oz.), frozen solid
- Gel packs, 8 oz. each, stabilized at 1-6C
- 4 Absorbent pads, blue plastic-backed Biosorb
- Re-sealable plastic bag for product
- Hematopoietic Progenitor Cells, Apheresis (Container Label), HPC 020 or equivalent

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 Ice is frozen solid.
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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 Ice containers, filled to fill line (approximately 32 oz.), each frozen solid ▪ 4 to 8 gel packs, 8 oz. each, stabilized at 1-6C ▪ 4 Absorbent pads, blue plastic-backed Biosorb (each absorbs 500 mL)
2	Place plastic bag inside the inner box.
3	Place 2 absorbent pads inside plastic bag, absorbent side up.
4	Within the plastic bag, place the frozen solid BSI Ice 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.
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 absorbent pads 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.

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Packing (continued)

Step	Action
12	Place additional shipping 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 (Container 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

