

# OriGen Cryostore Freezing Bag

**CAUTION:** US Federal law restricts the sale and use of this device by or on the order of a physician.

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1. Day, John and McLelann, Mark Cryopreservation and Freeze-drying protocols *Cryopreservation of Animal and Human Cell Lines*, Humana Press New Jersey. 1995 (p179-188)

**Instructions for Use:** Caution: These instructions should be read and understood by all personnel before using the device.

**Intended Use:** The Cryostore bag is intended to be used for freezing of blood components. For single use only

**Sterile:** Sterilized by Radiation. The fluid path is sterile and non-pyrogenic.

Product Code	Freeze volume, ml, Min. - Max.	Max Capacity, ml
CS 25	5 - 25	25
CS 50	10 - 30	50
CS 250	30 - 70	250
CS 500	55 - 100	500
CS 750	80 - 190	750
CS 1000	120 - 275	1000
CS2000	180 - 450	2000

The freeze volume recommendation is based on horizontal freezing in a standard cassette (internal thickness of approximately 0.37 inches (0.9cm). If the bag is frozen in another manner, the optimum fill volume must be determined by the user.

**Fluid Transfer:**

**Use aseptic technique.**

1. Close roller clamps on transfer tube, if required. Hang the bag or lay it flat on the counter, do not suspend by the donor tube.
2. Remove luer cap from the appropriate lead and attach to transfer tubing
3. Open clamp(s) and allow blood components to enter freezing bag . Add cryoprotectant according to institutional protocol. The product should be cooled before adding cryoprotectant.
4. **Caution:** Remove as much air as possible from the bag. After air has been removed, close clamp.

5. Using a dielectric or RF sealer, heat seal donor tubing close to the bag. After sealing, pressure test the seal by gently compressing the bag and checking the port for leaks. Cut the sealed tube so that the stub is shorter than the spike port tops. This will help prevent damage from abrasion by the cassette. **Caution: Do not use a metal clip to seal tubing.**
6. **Sterile Docking (SCD):** Note that only the softer tubes above the “Y” connectors can be sterile docked.

#### Label Placement:

**Caution: Do not write on bag or adhere label stickers to bag as this may cause the bag to burst on re-warming.**

1. The pouch pocket can be used for labeling. The pouch pocket may be intermittently sealed with a conventional heat or RF sealer. Do not seal this pocket completely closed.

#### Freezing Precautions

**Caution:** Always follow your Institutions’ protocol for freezing. The following is recommended as a starting point only.

1. **DMSO Caution:** Polycarbonate parts such as syringes and connectors have varying degrees of resistance to 100% DMSO. Dilute DMSO down to 60% concentrations or less before administering to avoid degrading Polycarbonate and PVC parts.
2. **Exterior Dry:** Before freezing, ensure that the bag and cassette surfaces are completely dry. Moisture may cause frost adhesion between the bag and the cassette making removal of the bag from the cassette difficult.
3. **Freezing Protocol:** When using rate-controlled freezing, follow institutional protocol to maintain a consistent freezing profile. A controlled freezing rate of -1 to -3 °C/min. is recommended (1). When using a constant temperature freezer, an insulating sleeve can help reduce rate of freezing and provide an even shape to the frozen bag.
4. **Overwrap:** A clear, cryogenic overwrap bag is available from Origen. For more information on the **Origen O-Wrap**, see [www.origen.com](http://www.origen.com).
5. **Use Cassette:** The Cryostore bag is fragile and easily abraded when frozen, handle with care when outside of the cassette. The use of a protective cassette during storage is always recommended.
6. **Thermal Cycling:** The bag is suitable for freezing in mechanical freezers or in Liquid Nitrogen (LN). When stored in LN, ensure that the

storage temperature does not fluctuate, as thermal cycling of the bag may cause breakage of the bag when frozen. When freezing in the liquid phase, consider the possibility of viral transmission between samples.

7. **Breakage Precaution:** Storage at LN temperatures causes the Cryostore bag to become rigid, and while rare, breakage can occur from storage conditions and many other factors. Breakage of the Cryostore bag is usually related to impact when the bag is frozen, or expansion of the contents which occurs below -40 °C. If breakage of the Cryostore bag is a problem at your institution, use a different cryoprotectant or protocol, an overwrap bag, or switch to the Origen FEP Permalife bag (formerly the Cryobag CA).

#### Thawing recommendations

**Caution:** Always follow your Institutions protocol for thawing. The following is recommended as a starting point only.

1. **Re-warming burst danger:** If the bag has been stored in the liquid phase of the LN tank, LN seeping inside the bag may cause the bag to burst during thawing. In this case, move the bag in the vapor phase of the LN tank or a mechanical freezer for a minimum of 12 hours before completion of thawing.
2. **Remove the bag from the cassette** prior to thawing, and inspect it for breakage or leaks. If the bag does not easily release from the cassette, warm the cassette before removing the bag.
3. **Thaw** the bag in a 37 °C to 40 °C water bath with gentle agitation (1). Observe the container carefully during thawing. If the bag begins to swell, it is likely that LN has seeped into the bag during storage. Using an aseptic technique, puncturing through the Spike port may help save the sample.
4. **DMSO** can be toxic to cells at room temperature. Remove the bag from the water bath as soon as the sample liquefies. Process the sample and begin re-infusion as soon as possible after thawing

**Note:** Twist off top portion to open Spike Ports.