

**OriGen CryoStore Freezing Bag**  
**Instructions for Use**  
**(English, EN)**

**Note:** These directions should be read and understood before using. Always follow your institution's protocol.



**Intended Use:** The CryoStore bag is intended to freeze blood components

**Device Description:** CryoStore bag is made of Ethylene Vinyl Acetate (EVA) and contain no phthalates, BPA or latex. The bag can be supplied with tubing sets that may include the following components: EVA/PVC coextruded tubing, EVA tubing, Y-connectors, needle-free valves, luers and caps. Multi-Chamber & FLEX bags have two to five chambers that can be sealed to create separate chambers.

Bag Size	Freeze Volume (mL), Min-Max
CS28	10 - 25
CS50	10 - 30
CS250	30 - 70
CS400	55 - 100
CS500	55 - 100
CS750	80 - 190
CS1000	120 - 275
CS2000	180 - 450





Multi-Chamber and FLEX Bag Volumes:

Bag Size	Freeze volume, (mL), Min-Max.
CS24	16 – 24
CS25	10 - 25
CS20	20 - 30
CS30	20 - 30

Bag size can be identified by the CSXXXX at the beginning of the product code, where XXXX is a number value as above. Freeze volume recommendation is based on horizontal freezing in a cassette (internal thickness of approximately .37in [0.9cm]). The optimum fill volume must be validated by the user, if frozen in another configuration.



**WARNING:**

- **Single Use Only:** Cleaning and re-sterilization may damage bag, which may cause bacterial or viral contamination. 
- Do not re-sterilize 
- Do not use if packaging is damaged. 
- Do not use after expiration date 
- **Handle with Care:** Most bag breakages occur during bag movement while frozen. Use care to avoid impacts when removing, transporting, re-racking, and thawing bags.
- **Cassettes:** Use of cassettes during freezing is recommended. Cassettes should be appropriately sized and should not distort the bag.

- **Always debubble:** large air bubbles present during freezing may expand rapidly during thawing and could cause localized pressure to break the bag.
- **DMSO Caution:** Some plastics have varying degrees of resistance to 100% DMSO. If using DMSO, dilute to less than 60% concentration before use.
- **For Multi-Chamber and FLEX Bags,** carefully place seal and cut between chambers to avoid puncturing adjacent chambers.
- **For FLEX Bags,** donor tube is not compatible with freezing. Seal bag and remove tubing before freezing.
- **Re-warming burst danger:** If stored in liquid phase of liquid nitrogen LN tank, migration of LN into CryoStore may cause bag to burst during thaw. Move the bag into vapor phase freezer for minimum of 4 hours before thawing.

### **Directions for Use:**

#### CryoStore, Multi-Chamber, and FLEX Bag Fluid Transfer Instructions:

1. Use aseptic technique.
2. Close roller or pinch clamps on tube as needed.
3. Do not hang by donor tube while filling.
4. If replacing caps on tube sets, tighten until connection is secure. Do not over-tighten.
5. Sterile Docking: (SCD) only PVC tube above the “Y” connectors can be sterile docked.
6. Transfer fluids into CryoStore and add cryoprotectant following your institutional protocol. Product should be cooled before adding cryoprotectant as some cryoprotectants generate heat when added.  
**Note:** Certain cell cultures and cryoprotectants may expand during freezing causing bag breakage. Always validate your freezing protocol.
7. Remove all air from bag before freezing.

#### CS30M9 & CS24M9 Fluid Transfer Instructions:

1. Use aseptic technique.
2. Close roller or pinch clamps on all lines except line with pre-attached syringe.
3. Remove air from bag by retracting plunger attached syringe.
4. Close roller or pinch clamp on syringe line.
5. Hold Multi-Chamber bag with donor tube at the highest point, then transfer fluids into CryoStore bag and add cryoprotectant following your institutional protocol allowing the furthest chambers to fill first.
6. Remove all air from bag before freezing.

#### CryoStore Sealing Instructions:

1. First Seal: Seal donor tube as close to stub tube as possible.
2. Gently compress bag to check the tube for complete seal. Place second seal above fluid seal
3. If donor tube is printed, segments can be made with donor tubing. Seal on printed X's for approximately 100µL segments.
4. Remove excess tubing by cutting through the second seal  
**Note:** Donor tube should not be sealed above the spike ports to protect from potential impact while frozen.
5. Components on tube sets are not suited for freezing. Only bag and donor tube are validated for cryopreservation.

#### Multi-Chamber and FLEX Sealing Instructions:

1. Seals can be placed between chambers along the fluid channel following the arrow (Figure 1).
2. Seal and cut bottom channels prior to freezing.
  - a. Lay the bag flat to distribute cells between chambers
  - b. Do not put pressure on chambers, make one seal between each chamber ensuring full seal through the channel. Cut in the middle of the seal. Check for complete separation of chambers  
**Note:** Holding chambers instead of ports while sealing can cause fluid to distribute unevenly.

3. Multi-Chamber: Seal donor tube as close as possible to flange that attaches tubing to bag (Figure 2). If donor tube is printed, segments can be made with donor tubing. Seal on printed X's for approximately 100µL segments. Remove excess tubing by cutting through the seal.
4. Multi-Chamber: Components on tube sets are not suited for freezing. Only bag and donor tube are validated for cryopreservation.
5. Multi-Chamber: If donor tube is to remain attached, fold alongside the edge of the bag in the cassette
6. FLEX: Seal across film of bag to remove donor tube (Figure 3) Seal should be in line with bag outline. Remove excess tubing by cutting below seal.
7. FLEX: tubing is not compatible with freezing.

**Label Placement:**

1. User-applied labeling should be validated by the user/institution.
2. Pouch pocket can be used for additional labeling. Do not seal pocket completely closed.
3. Do not write on the body of the bag.

**Freezing:**

1. CryoStore is suitable for freezing in controlled-rate freezers or in liquid nitrogen vapor (LN). When using a controlled-rate freezer, follow institutional protocol to maintain a consistent freezing profile.
2. Before freezing, ensure outside of bag and inside of cassette are dry. Moisture may cause bag to adhere to cassette while frozen.
3. Breakage Precaution: Storage at LN temperatures causes CryoStore to become rigid, and while rare, breakage can occur. Bag breaks are usually related to impact when bag is frozen or due to contents expansion below -40°C. Contact OriGen if breakage problem persists.

**Thawing:**

1. Thaw bag following your institution's protocol. It is recommended to remove from the cassette prior to thaw. Observe during thawing.
2. Cryoprotectants may be toxic to cells at room temperature. Wash DMSO/cryoprotectant from product, and begin to infuse as soon as possible.
3. To open the spike ports, twist off the top portion and use an appropriate bag to drain the bag. Do not attempt to spike while frozen.

**Sterilization:** Sterilized by radiation. Fluid path is sterile and non-pyrogenic



**Packaging:** CryoStore can be packaged singly in a pouch, singly in a double pouch, with an overwrap in a pouch, or in a pouch of four or more. Pouches are placed in cartons which may include between one and 12 pouches. Alternate packaging may be available. Contact OriGen for more information.

**Storage:** Store in a cool, dry place.



**Disposal:** Dispose of bag after use per institutional protocol.

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

**Complaints:** Any user/customer who has a complaint or is dissatisfied with the quality, identification, reliability, safety, efficacy, and/or performance of the product should notify OriGen Biomedical or its authorized distributor. In the event of an incident or risk of a serious incident liable to result in, or to have resulted in, the death or serious deterioration in the health condition of a patient or user, OriGen Biomedical or its authorized distributor should be immediately warned by telephone, fax, or email. All complaints should be accompanied by the name(s), reference(s), and lot number(s) of the component(s) and the name and address of the claimant, the nature of the complaint with as much details as possible and the indication of a requested response.

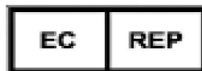
### Disclaimer of Warranties

OriGen Biomedical warrants that reasonable care has been used in the manufacture of this device and that it was free from defects in workmanship or materials at the time of shipment from OriGen. OriGen's sole obligation shall be to repair or replace any device which it determines was defective at the time of shipment. The buyer assumes all liability resulting from misuse, re-use, or any use other than as intended, including re-sterilization of this product. OriGen shall not be liable for incidental or consequential loss, damage or expense resulting from the use of this product. THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER IMPLIED, EXPRESS, ORAL OR WRITTEN.



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CE marked since 12 September 2007.

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Symbol Glossary at [www.origen.com/symbolglossary](http://www.origen.com/symbolglossary)

### Other ISO 15223-1 Harmonized Symbols:

	-	Catalogue Number/Product Code
	-	Batch/Lot Number
	-	Medical Device

### Non- harmonized Symbols:

	Quantity	Indicates the number of units in the associated packaging.
	Freezing Bag	Indicates that the product is intended for freezing at cryogenic temperatures. Values displayed to the right of the image indicate the validated <b>freeze</b> volume.