

OriGen PermaLife Bag Instructions for Use (English, EN)

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



Intended Use: PermaLife Bags are intended for use in:

- protecting, storing and freezing cells and tissues;



<Volume>

- cell culture.



<Volume>

Device Description: PermaLife bag is made of pure fluorinated ethylene propylene (FEP) and contains no phthalates, BPA or latex. The bag can be supplied with an FEP port and a needle-free valve (NFV), or with tubing sets that can include, but are not limited to, the following components: PVC tubing, Y-connectors, luers and caps.

| Bag Size | Working Volume, mL | Freezing Volume, mL | Width, cm | Length, cm |
|----------|--------------------|---------------------|-----------|------------|
| PL07 | 10 | 7 | 3 | 6.3 |
| PL30 | 40 | 30 | 8.9 | 6.1 |
| PL70 | 100 | 70 | 8.9 | 9.7 |
| PL120 | 150 | 120 | 8.9 | 14 |
| PL240 | 300 | 240 | 14 | 19.3 |
| PL325 | 450 | 325 | 14 | 25.9 |
| PL500 | 750 | 500 | 29.21 | 18 |
| PL750 | 1000 | 750 | 29.21 | 26.5 |
| PL1000 | 1500 | 1000 | 29.21 | 35 |
| PL2000 | 3000 | 2000 | 47 | 45 |

Bag size can be identified by the PLXXXX at the beginning of the product code, where XXXX is the freezing volume listed above. Freeze volume recommendation is based on horizontal freezing in a cassette (internal thickness of approximately 0.81in [0.9cm]). If the bag is frozen in another manner, the optimum fill volume must be validated by the user.



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 the expiration date.



- **Handle with Care during Cell Culture:** Do not crease, fold, squeeze, or aggressively handle the bags.
- **Needle-free Access:** Use a standard male luer taper device to access the NFV valve. Do not use a needle or non-luer taper
- **Handle with Care while Freezing:** Most bag breakages occur during transport or when handling frozen product. Use care to avoid impacts when handling the 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:** ABS, PVC, and polycarbonate parts such as syringes and spikes have varying degrees of resistance to 100% DMSO. If using DMSO, dilute to 60% concentration or less before transferring into PermaLife.
- **Re-warming burst danger:** If stored in liquid phase of LN tank, migration of LN into PermaLife may cause bag to burst during thaw. Move bag into vapor phase of LN tank or mechanical freezer for minimum of 4 hours before thawing.
- For freezing, store in vapor phase of LN or place in overwrap prior to placing in direct submersion of LN.

Directions for Use:

PermaLife Fluid Transfer Instructions (PL bags without SCD tubing):

1. For cell culture, transfer fluids and media into PermaLife according to your institutional protocol.
2. Aseptically open pouch and remove PermaLife
3. Remove green vent cap on the needle-free valve, if present.
4. Swab face of NFV before use. Actuate NFV with male luer device, such as syringe. Push and twist to lock in place.

PermaLife Fluid Transfer Instructions (PL bags with SCD tubing):

1. Aseptically open pouch and remove PermaLife
2. PVC tubes on PermaLife can be sterile docked.
3. Transfer cellular product to PermaLife utilizing SCD welding or luer connection.
4. An oxygen rich environment allows oxygen to permeate into PermaLife as FEP is gas permeable

Freezing:

1. Transfer fluids into PermaLife and add cryoprotectant according to your institutional protocol.
Note: Certain cell cultures and cryoprotectants may expand during freezing causing bag breakage. Always validate your freezing protocol.
2. Remove all air from bag before freezing.
3. Place PermaLife in overwrap if submerged in Liquid LN.
4. Remove SCD tubing or Spike Port by twisting male luer lock and replace with standard male luer cap. PVC is not compatible with freezing.
5. Before freezing, ensure outside of bag and inside of cassette are dry. Moisture may cause bag to adhere to cassette while frozen.
6. Breakage Precaution: Storage at LN vapor temperatures causes the PermaLife bag to become rigid, and while rare, breakage can occur. Please contact OriGen if breakage problem persists.

Thawing:

1. Thaw bag per your institution's protocol. It is recommended to remove from cassette prior to thaw. Observe during thawing
2. If bag begins to swell, it may indicate LN has seeped into bag during storage. If this occurs, slightly open one of the ports to reduce the chance of bag bursting.
3. Cryoprotectants may be toxic to cells at room temperature. Wash DMSO/cryoprotectant from product, and begin to infuse as soon as possible.

Sterilization: Sterilized by Ethylene Oxide. The fluid path is sterile and non-pyrogenic



Packaging: PermaLife is packaged singly in a pouch.

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.

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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 letter. All complaints should be accompanied by the name(s), reference(s), and batch 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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| EC | REP |
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CE marked since 13 January 2003.

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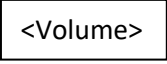

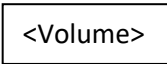
Other ISO 15223-1 Harmonized Symbols:

REF - Catalogue Number/Product Code

LOT - Batch/Lot Number

MD - 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 in box are the validated freeze volume. |
|   | Processing Bag | Indicates that the product is intended for processing blood components or cells. Values in box are the validated working volume. |