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

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 therefore be to repair or replace any device which it determines was defective at the time of shipment. Because no product is completely effective under all circumstances, and because the actual use and handling of this device is beyond our control, OriGen cannot warrant for a good effect or against a bad effect in the application and use of this device. The buyer therefore assumes all liability arising from any cause for damages resulting from use, misuse, use other than as intended, or resterilization of this product. OriGen therefore gives no warranty of merchantability or fitness for a particular purpose. OriGen shall not be liable for incidental or consequential loss, damage or expense resulting from the use or application of this product. This warranty is in lieu of all other warranties, whether implied, express, oral or written, and no individual has the authority to vary the terms of this warranty.

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1. "Teflon Film: the Ultimate Bio-compatible Substrate" DuPont Technical Bulletin, DuPont Company, Wilmington DE, USA

Instructions for Use
PermaLife Cell Storage/Freezing Bag

Indications: OriGen PermaLife Cell Storage bags are indicated for protecting, storing and freezing cells and tissues.

Contraindications: Contraindicated for other uses.

For single use only. The fluid path remains sterile and non-pyrogenic as long as the package is unopened and undamaged.

Stock Nr. ➔	PL 07	PL 30	PL 70	PL 120	PL 240	PL 325
1 cm Volume	7	30	70	120	240	325
Max Vol., ml	12	50	145	265	725	1100
Width, cm	3.0	8.9	8.9	8.9	14.0	14.0
Length, cm	6.3	6.1	9.7	14.0	19.3	25.9
Area, cm^2	38	108	172	248	540	725
O2 , ml‡	44	126	199	288	627	842
CO2 , ml ‡	98	281	444	643	1400	1879
N2 , ml ‡	19	54	86	124	270	363
H2O, g ‡	0.03	0.08	0.12	0.17	0.38	0.51

Permeability is in ml (g) per 24 hours at 25°C for 1mil thickness FEP film

Product Characteristics

Materials: The OriGen PermaLife bag is made of pure FEP film. (Note that Teflon® is the registered trademark of DuPont FEP) (1). Contains no Phthalates, BPA, or latex.

The PermaLife bag is gas permeable. Estimated gas transfer rates are noted above. Due to the very low water transmission rate, humidified incubators are not needed during cell expansion.

Method of Use

1. Examine the packaging to make certain the packaging is undamaged and unopened.
2. For use on a sterile field, aseptically open the outer pouch and drop the PL bag on the sterile field or pick it out of the pouch using aseptic technique.
3. **If a green vent cap is present, on the needle-free valve remove and discard.**
4. The needle-free valve attached to the bag may be opened with any male luer device, such as a syringe. Press the tip of the syringe against the blue center to open the valve. Push and twist to lock in place.
5. Swab the face of the luer valve before use, if desired.
6. Transfer the cells and media into the bag.
7. Placing the PermaLife bag in an oxygen rich environment will allow oxygen to be transferred into the bag, as the bag is gas permeable. If the bag is suspended, both sides will be available for gas transfer.

Freezing

1. The PermaLife bag may be used in any freezing environment down to -200°C (-390°F).

   CAUTION: The PermaLife bag has not demonstrated to be virus-impermeable. Immersion in the liquid phase of liquid nitrogen (LN) could allow virus migration between samples immersed in the liquid. To prevent virus migration, storage in LN vapor is recommended.
2. Replace the luer-actuated valve with a standard male luer cap to fit better in a cassette.
3. Dry the exterior of the bag and freeze the specimen per your institutional protocol.

   CAUTION: Freezing and solidification of the contents makes the PermaLife bag more susceptible to damage. It is strongly suggested that the bag be placed in a freezing cassette for storage. Handle carefully when frozen.

Thawing

CAUTION: If LN migrates into the bag, it may burst on re-warming. Allow the bag to rest in vapor phase before re-warming.

1. Thaw the specimen per your institutional protocol, or in a 37°C to 40°C water bath with gentle agitation. Observe the container carefully during thawing. If the bag begins to swell, it may indicate that liquid nitrogen has seeped into the bag during storage. If this occurs, slightly open one of the ports to vent pressure and prevent the bag from bursting.
2. Process the sample and begin re-infusion as soon as possible after thawing

Precautions

1. Use caution when handling the bag to prevent punctures. When the bag contents are frozen, it is much easier to damage the bag through impact and abrasion.
2. Use caution with solvents that come in contact with the bag. While FEP is resistant to almost all solvents, some solvents may cause the connectors to crack, or may be absorbed through the bag.
3. Wash out cryoprotectants before patient administration.