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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 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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OriGen O-Wrap Freezing Bag

Instructions for Use: Caution: These instructions should be read and understood by all personnel before using the device. **Intended Use**: The OriGen O-Wrap is intended to contain other freezing bags to protect them in long term frozen storage. The O-Wrap bag is suitable for direct use in liquid nitrogen freezing applications. Contraindicated for other uses.

Sterile: Sterilized by radiation. Resterilization is not recommended. Reuse of this product can cause sepsis, viral transmission, hematological complications and patient death.

Contains no Phthalates, BPA or latex.

Product Code	W x L, cm	For Use with
OW0419	4 x 19	Cryovials
OW0909	9 x 9	CS 25, Pall
OW0918	9 x 18	CS 50
OW1430	14 x 30	CS 250, CS 500, CS750
OW1936	19 x 36	CS 1000
OW1950	19 x 50	Custom

<u>General</u>

After the biologic freezing bag is prepared and the sample is ready for freezing, place this bag in the appropriate size O-Wrap bag, sliding it all the way to the bottom, port side up.

1. Remove Air: Remove as much air as possible from the bag before sealing. This may be done with a vacuum sealer or applying gentle pressure with a gloved hand to the bag before sealing.

2. Heat Seal: Be sure to include any aliquots, samples and labels inside the bag before sealing. Move all components out of the

way of the top edge, expel excess air and seal the O-Wrap bag with any standard, impulse, or RF sealer.

3. Sealer settings: As temperature setting varies based on sealer performance, use these settings as a starting point.

75-95°C, 1 - 2 sec. heating, 3 - 5 sec. cooling.

The resulting seal should be clear and resist a firm tug. If not sealed, increase the temperature a bit and try again. Final clarity of the seal will be dictated by the smoothness of the covering strip. A smooth strip will yield a water-clear seal in the O-wrap.

BE CERTAIN THERE ARE NO FOLDS OR OVERLAPS IN THE EVO FILM WHEN SEALING.

This will insure that the O-Wrap fully protects your product during freezing and thawing.

- **4. Trim:** The O-Wrap bags are supplied with extra length to fit a range of different biologic bags. Once the bag is sealed the excess film may be trimmed and discarded.
- **5.** You may label the O-Wrap bag at this point (see labeling).
- **6.** Process per your institutional protocol.

CryoStore and Overwrap

- 1. The O-Wraps are ideally suited for the CryoStore bags and are A perfect fit inside your existing cassettes.
- 2. Slide the filled CryoStore bag into the O-Wrap, with the ports pointed up, all the way to the bottom. Be sure to include any aliquots or labels you wish to archive.
- 3. Remove as much air as possible and heat seal the top edge close to the bag.
- 4. Attach any required labeling at this point.
- 5. Open the metal cassette, and slide the sealed edge under while pushing the bag up to the top edge of the cassette. Keep the sealed edge folded under if possible.
- 6. Push the edges down in place around the cassette, tuck in any loose edges and close the cassette.
- 7. Process as normal.

Labeling

1. As the O-Wrap bag is not intended to come into contact with

the specimen, the user can write directly on the bag with a permanent marker or ball point pen. Be aware that many inks are alcohol-soluble, and that a post-freeze wipedown with alcohol may remove these marks.

- 2. Per your institutional protocol, ISBT 128 labeling may be used with the O-Wrap bags.
- 3. Alternatively, OriGen can provide self-adhesive labels for your use. Please contact us with your requirements.

Freezing Precautions

- 1. Always follow your institutions protocol for freezing of biological samples.
- 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. Use Cassette:** While the O-Wrap is very tough, the use of a protective cassette during cryogenic storage is always recommended.

Thawing recommendations

- **1. Caution:** Always follow your institutions protocol for thawing. The following is recommended **as a starting point only.**
- 2. **Re-warming burst danger:** If the O-Wrap bag has been stored in the liquid phase of the Liquid Nitrogen (LN) tank, LN seeping inside the bag may cause the bag to burst during thawing. If the bag has been stored in liquid phase, or it has not been properly sealed, move the bag in the vapor phase of the LN tank or a mechanical freezer for 12 hours, if possible, before thawing to room temperature.
- **3.** 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.
- **4.** Thaw the bag 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 through an improper seal during storage. Puncture the bag to prevent bursting if it begins to swell.
- **5.** Using sharp scissors, cut the O-Wrap bag along one of the edges and remove the inner bag.