

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 or re-sterilization 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.

OriGen Biomedical, Inc.

7000 Burleson Rd, Bldg D
Austin, TX, USA 78744
Tel: +1 512 474 7278
Fax: +1 512 617 1503
Email: sales.us@origen.com

European Representative

Advena Ltd.
Tower Business Centre
2nd Flr, Tower Street,
Swatar, BRK 4013 Malta



www.origen.com

LC44. R05: 2019-01, OriGen Biomedical, Inc. All Rights Reserved

OriGen TissueVault Tissue Freezing Bag

Instructions for Use

Indications

The OriGen TissueVault Tissue Freezing Bags are indicated for use in freezing cells and tissues. For single use only. Contraindicated for other uses.

Sterile

Products are sterile, singly packed. Sterilized with Radiation.

WARNING: Re-sterilization may damage the product. Re-use may cause contamination or viral transmission between tissues.

Product Characteristics

Materials:

The OriGen TissueVault is made of EVO copolymer. This material is easily sealed and remains flexible in liquid nitrogen. Contains no phthalates, BPA, or latex.

The TissueVault is supplied as a flat pouch with one end open, and is designed to freeze solid tissue and bone.

Gas permeable:

The TissueVault bag is gas permeable, but water vapor transmission rates are very low. Gas transfer rates for O₂, H₂O and CO₂ under ideal conditions are as follows:

	TV0918	TV1430
Oxygen	79.2g/day	429g/day
CO ₂	654g/day	3.5 kg / day
H ₂ O	4.4 g / day	2.28 g / day

Cryogenic storage:

The Origen TissueVault may be used in any freezing environment down to -196°C (-322°F). See cautions for direct liquid nitrogen storage under 'Freezing', below.

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 package and drop the TissueVault on the sterile field or pick it out of the pouch using aseptic technique.
3. Transfer the tissue(s) into the bag.
4. Heat seal the open end using an impulse or RF sealer. EVO is very easy to seal, and requires only a low temperature setting on the sealer. A seal temperature of only 200°F (93°C) is required to seal the material. The resulting seal should be clear, allowing for easy inspection of the seal. Also, test the seal by attempting to squeeze residual air from the bag. If you can, re-seal.
5. The outside of the TissueVault bag may be wiped with alcohol if desired.

Freezing

1. The TissueVault bag will withstand freezing temperatures down to liquid nitrogen, -196°C (-321°F).
2. Make certain the outside of the container is dry before freezing in a cassette. Frost may cause the bag to adhere to the cassette.
3. Freeze the specimen per your institutional protocol.

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

CAUTION: It is not known if a virus can penetrate the bag wall when stored in liquid phase or liquid nitrogen.

Thawing

1. Remove the bag from the cassette prior to thawing and inspect it for breaks or leaks. If the bag does not easily release from the cassette, warm the cassette to release the bag.

CAUTION: Migration of liquid nitrogen (LN) into the bag during storage may cause the bag to burst during re-warming. During re-warming, LN will gasify much quicker than it can escape through the bag walls. Monitor the TissueVault carefully for swelling during re-warming.

2. Many institutions thaw the bag in a 37 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, puncture the O-wrap to vent pressure.
3. Some cryoprotectants can be toxic to cells at room temperature. Follow your Institutional protocol and begin tissue recovery as soon as possible after thawing

Precautions

1. Use caution when handling the bag to prevent breakage. When the bag contents are frozen, it is much easier to damage the bag through impact.
2. Use caution with solvents that come in contact with the bag. While EVO is resistant to most solvents, test on a sample bag before using on clinical products.
3. Wash out cryoprotectants before patient administration.

Contraindications

There are no known contraindications for the use of the bag when used as directed.

Caution:

These instructions should be read by all personnel before using the device.