

### Evolve Cell Culture Bags

**Note:** These instructions should be read and understood by all personnel before using the device. Always follow your institution's protocol and always use aseptic techniques.

**Intended Use (USA):** The Evolve bag is intended for use in cell culture.

**Intended Use (EU):** For Research Use Only. Not for clinical, household, or other uses. End-user must determine the suitability of the product(s) for their particular use.

**Indications:** This device does not have any specific clinical indications for use and is not intended to treat, mitigate, cure, or diagnose any specific clinical disease state. The device is also not validated for use with specific types of cells or blood components. It is the responsibility of the user/institution to validate the use of Evolve in a particular clinical treatment.

**Contraindications:** This device does not have any specific clinical contraindications. Uses outside of cell culture have not been validated by OriGen.

**Device Description:** The Evolve bag is made of Ethyl Vinyl Olefin (EVO) and contains no BPA or latex. The bag can be supplied with tubing sets that can include, but are not limited to, the following components: EVA/PVC coextruded tubing, PVC tubing, Y-connectors, needle-free valves, female luers, male luers and/or caps.

Part Number	Store Flat Surface Area (cm <sup>2</sup> )	Recommended Fill Volume (mL)
EV120 + F-M12	130	70 – 120
EV1000N	300	100 – 500
EV3000N	750	500 - 2000

#### WARNINGS:

For single use only. Do not reuse this product. Cleaning and re-sterilization may damage the bag. Do not use if the packaging is open or the product is damaged. Writing on the bag is not recommended. Do not suspend bag by ports at any time.

#### Directions for Use:

##### Manual fluid transfer using luer adapters:

1. Close all clamps.
2. Remove luer adapter cap from the appropriate lead and attach to the cell product bag.
3. Open clamp to allow fluid transfer. Use caution when filling and manipulating a filled bag.
4. When transfer is complete, close clamp.
5. If desired, seal tubing on used lead with an RF seal; cut and discard tubing.
6. If replacing the luer caps, be careful not to over-tighten the luer cap.
7. Needle-Free injection site may be used for additives or sampling and is accessed with a standard male luer connector. The luer connectors may be swabbed with alcohol before use, if desired.

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7. Needle-Free injection site may be used for additives or sampling and is accessed with a standard male luer connector. The luer connectors may be swabbed with alcohol before use, if desired.

8. For EV1000N and EV3000N: If suspending bag to gravity drain, always hang by all hanger holes.
- a. Note: The hermetically sealed spike ports on the EV1000N and EV3000N bag sizes may be used for fluid removal. For use: twist off the top section and spike the port to puncture the membrane.

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

**Sterile:** Sterilized by radiation. The fluid path is sterile and non-pyrogenic, as long as the package remains unopened and undamaged.

**Packaging:** The Evolve Bag is packaged singly in a protective packaging.

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

**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**

Please contact OriGen in the case of any defect or issue with the bag from point of receipt through disposal, including alleged claims of deficiencies related to quality, identity, durability, reliability, safety, effectiveness of performance of the product. 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 reesterilization 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.

#### **Manufactured by:**

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