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. Our 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.

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OriGen Accessory Sets Instructions for Use

CAUTION: These instructions should be read and understood by all personnel before using the devices.

Intended Use: The accessories are intended to be used for fluid transfer. Follow your institution's protocol.

WARNING: Do not use if the packaging is open or the parts appear damaged in any way. Single use only. Always use aseptic techniques.

Sterile: The fluid path is provided sterile and non-pyrogenic as long as the package remains unopened and undamaged.

Materials: Product may contain phthalates and BPA. For a complete listing of products that contain trace phthalates and BPA contact OriGen. Contains no latex

Storage: Store in a cool, dry place.

CAUTION: Not all accessories are resistant to 100% DMSO: Prolonged exposure to pure DMSO can cause degradation of some polymers. Contact OriGen for a complete listing of DMSO resistant parts.

Spike Adapters & Manifold Sets

- 1. Close the clamp(s) if applicable.
- 2. Remove the clear cover from the spike.
- 3. Open the bag spike port and insert the spike through the membrane by pushing and then twisting the spike to break through the EVA membrane. Repeat as needed with remaining spikes.
- 4. Swab the needle-free valve or injection port face with an approved disinfectant (ex. 70% ethanol) or remove the luer caps as applicable.
- 5. Connect the syringe, bag, or other transfer container to the open end(s) of the Spike Adapter. If using the needle-free valve, push on a luer lock syringe or other luer lock device to actuate the valve, then twist to lock in place.
- 6. If replacing the luer caps, hand-tighten the caps on the luer. Take care to not over-tighten.
- 7. Open the clamp(s) as required, then remove or inject fluids.
- 8. Flush the Spike Adapter to remove residual fluid. **Note**: the volume retained in the spike is 1.8mL.
- 9. If using the needle-free valve, the valve can be accessed with a luer lock device multiple times if desired.
- 10. After use dispose of all components appropriately.

Cell Connect

1. Close the clamps.

- 2. Remove the clear cover from the spike.
- 3. Open the bag spike port and insert the spike through the membrane by pushing and then twisting the spike to break through the EVA membrane. Repeat with the remaining spikes as needed.
- 4. Remove the luer cap and attach other required product to the luers by twisting until secure. Repeat with remaining lines as needed.
- 5. Alternatively, the lines can be sterile welded to the desired connecting devices (bags).
- 6. Use a standard heat sealer or close the clamps to seal off any unused lines.
- 7. Open the clamps to the desired pathway to transfer solutions.
- 8. Turn the stopcock on the syringe so that fluid can be pulled through one side of the Cell Connect and into the syringe. Readjust the stopcock to push the solution out of the syringe and into the other

side of the Cell Connect. Close the clamp to that pathway. Repeat this process as needed per your institutional protocol

- 9. If air needs to be removed from the filled container, reverse the process only allowing air to be removed.
- 10. If the stopcock lever points to the "off" position (pointing towards the syringe), fluid will flow through the Cell Connect bypassing the syringe.
- 11. After use dispose of all components appropriately.

Syringes with Attached Tube

- 1. Sterile dock the tubing connected to the empty syringe to the product to be sampled.
- 2. Use the syringe to withdraw the required sample.
- 3. When fluid transfer is complete, hermetically seal the tubing using a tube sealer, twist off the syringe and place a syringe cap on the syringe or dispense sample into appropriate container.
- 4. Follow your facility's protocol for sample transfer, handling and testing.
- 5. After use dispose of all components appropriately.

Tube Adapters

- 1. If sterile docking, sterile weld the required portion of the Tube Adapter to the product.
- 2. Using aseptic technique, remove the cap from the luer and connect the desired product by twisting until secure. Repeat process as needed.
- 3. If clamps are present, open to allow fluid to transfer. Close clamps when transfer is complete. Repeat process as needed.
- 4. After use dispose of all components appropriately.