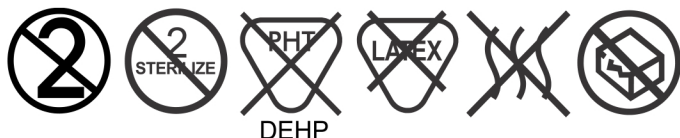


Rio™ Drug Reconstitution Transfer Device

STERILE R Rx only



Not made with DEHP or PVC
www.icumed.com/symbols-glossary

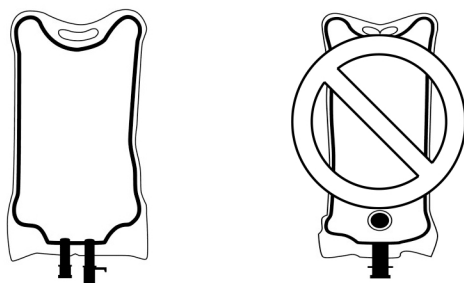
Directions for Use:

For single patient use, do not resterilize; Sterile, non-pyrogenic fluid path in unopened, undamaged, package and needle-free.

DESCRIPTION:

For reconstitution of liquid or lyophilized drugs (20 mm vials) and aseptic transfer into a multi-port LifeCare IV container system (up to 250 mL). Not for use with bags larger than 250mL or bags with a single down port. See below diagram.

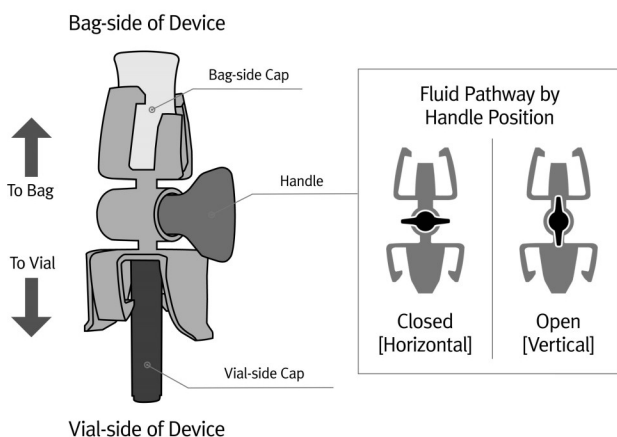
LifeCare IV Container Systems:



INDICATIONS FOR USE:

Rio™ Drug Reconstitution Transfer Device is indicated for single use reconstituting or mixing of liquid or lyophilized drug in a vial, and the aseptic transfer of the reconstituted drug into the multi-port LifeCare IV container system (IV bag) for patient infusion administration.

DIRECTIONS:



Assembly:

1. Remove vial cover and disinfect vial stopper with IPA using an aggressive circular motion for 3 seconds or per facility protocol.
2. Place vial upright on flat surface.
3. Using aseptic technique, open package and remove the device from its sterile package.
4. Ensure the device is in the closed [Horizontal] position. If not, turn handle so it is in the closed [Horizontal] position.

5. Remove vial-side cap from vial-side of device.
6. Firmly push the device straight down until it “clicks” securely onto vial.
7. Disinfect medication port on the LifeCare IV container system with IPA using an aggressive circular motion for 3 seconds or per facility protocol.
8. Remove bag-side cap from bag-side of device.
9. Spike the medication port on the LifeCare IV container system with the device until the device attaches securely onto IV bag.

Note: Do not remove the vial or IV bag once assembled and/or Do not refrigerate once assembled.

Activation / Reconstitution:

1. Turn and rotate the handle until it is in the open [vertical] position to open fluid pathway.
2. Hold IV bag with vial down.
3. Squeeze IV bag to transfer solution into vial until half full.

Note: Do not overfill vial.

4. (For lyophilized drug) shake or swirl to suspend drug in solution per manufacturer’s guidelines.

Note: Ensure drug is completely dissolved.

5. Hold IV bag with vial upside down.
6. Squeeze IV bag to transfer air into vial.
7. Release to drain drug from vial.
8. Repeat above steps as necessary until drug and solution are transferred from vial to IV bag.
9. If desired, turn and rotate the handle to the closed [horizontal] position to close fluid pathway upon emptying vial contents.

Note: Post reconstitution, the fluid pathway may be closed to prevent the reconstituted drug from entering the vial. Do not remove the vial or IV bag once assembled and/or Do not refrigerate once assembled.

Administration:

1. Remove IV bag administration port protector and attach administration set.
Note: Refer to manufacturer’s Directions for Use
2. Spike administration set per facility protocol.
3. Hang assembled system on IV pole and prime set per manufacturer’s Directions for Use or per facility protocol.

WARNING: DO NOT USE IN SERIES CONNECTIONS

4. Administer medication per medical instructions.
5. Use within specified time for drug stability.

Note: Refer to drug manufacturer’s packaging insert.

6. After use, dispose per facility protocol.

CAUTIONS:

- Use aseptic technique to maintain sterility upon device removal from packaging and cap removal.
- Do not disconnect medication vials from IV bag.
- Reuse negatively impacts performance/sterility, potentially resulting in product failure/contamination.
- Slight discoloration is a normal result of sterilization and does not affect the safety or sterility of the device.
- Do not use if packaged seal is open or damaged and avoid use beyond shelf life or expiration date to ensure sterility. Unopened and undamaged, sealed package should be stored at controlled room temperatures (20°C to 25°C) according to facility protocol.
- Disposal should be in accordance with facility protocol.
- Federal (USA) law restricts this device to sale by or on the order of a physician.