



## Symbios GOPump™ Rapid Recovery Systems & GOBlock™ Continuous Peripheral Nerve Block System Disposable Infusion Pump Kit Warnings and Directions for Use

### Description/Indication:

The Disposable Infusion Pump Kit is a disposable, self-contained infusion system utilizing an inflatable elastomeric reservoir to mechanically provide percutaneous infusion of prescribed solutions at a pre-set rate for post-operative pain management. Kit components include an elastomeric pump, syringes and dressing(s), and may also include catheter needle(s) / introducer(s) and infusion catheter(s).

The components of the kit are disposable and intended for single use. These instructions are intended for use on all single and dual pumps with total volumes of 150ml-600ml.

### Pump Characteristics

Product	Reservoir Volume	Number of Catheters	Flow Rate	Approximate Infusion Time
GOPump Single	150 mL	1	2ml/hr	3 days
GOPump Dual	300 mL (150ml/side)	2	2ml/hr	3 days
GOPump Dual	600 mL (300ml/side)	2	2ml/hr	6 days
GOPump 'Y'	300mL (150ml/side)	1	2ml/hr	6 days
GOPump 'Y'	300mL (150ml/side)	1	4ml/hr	3 days
GOPump 'Y'	600mL (300ml/side)	1	6ml/hr	4 days
GOBlock	300mL (150ml/side)	1	4ml/hr	3 days
GOBlock	300mL (150ml/side)	1	6ml/hr	2 days
GOBlock	600mL (300ml/side)	1	6ml/hr	4 days
GOBlock	600mL (300ml/side)	1	8ml/hr	3 days
GOBlock	600mL (300ml/side)	1	10ml/hr	2.5 days

**Note:** Pump flow rates are accurate to within  $\pm 15\%$  of the rate shown above. Flow rates are listed for saline or water-based solutions. Solutions containing dextrose may flow as much as 20% slower than that shown above.

### Contraindications:

The Disposable Infusion Pump Kit is contraindicated for vascular drug delivery, delivery of blood, blood products, lipids or fat emulsions.

### Warnings:

1. Sterile technique should be used at all times during reservoir fill, catheter introduction and connection. Aseptic technique should be used for removal.
2. All medications used in conjunction with the Symbios GOPump™ & GOBlock™ should be administered in accordance with the drug manufacturer's labeling.
3. Do not refill pump. Do not fill pump reservoir(s) beyond the amount indicated on pump label.
4. Patient selection factors should include the ability and willingness of the patient to follow instructions.
5. Patient adverse reaction to anesthetic has been reported. If symptoms of anesthetic toxicity are identified, discontinue use. Consult the drug package insert for symptoms of anesthetic toxicity.
6. Do not place the catheter in joint spaces. Some studies suggest a possible association between continuous intra-articular infusions and subsequent development of chondrolysis.
7. Pump is for post-operative pain management. Do not use to provide surgical anesthesia or for chronic pain management.
8. Infusion times greater than six days are not recommended

### Instructions:

#### Fill Reservoir

1. Allow pump and fluid to come to room temperature before use.
2. Using sterile technique, remove the kit contents from the outer pouch, and place inner pouch in a sterile field.
3. Close the tubing clamp(s)
4. With the large syringe, draw up 60cc of physician-prescribed medication. Use approved techniques for removing medication from bottle, so that contaminants do not drop into fluid.
5. Remove all air from syringe and attach it securely to the fill port (150, 300 mL pumps) or to the extension tubing (600ml pump).
  - a. FOR 150ml & 300ml VOLUME PUMPS: Invert the pump and syringe, and push down on the syringe barrel with both

hands (see Figure). Do not hold the pump while depressing the syringe plunger.

- b. FOR 600ml VOLUME PUMPS: Inject the medication from the syringe into the pump, through the supplied tubing set.
6. Repeat the previous steps to fill each reservoir to the desired volume. Maximum fill volume is indicated on the front of the pump label.
7. Attach tethered fill port cap to each fill port.
8. Mark orange & white medication labels to indicate medication used.

#### Prime Pump Tubing

1. Open tubing clamps.
2. When air has been removed from the tubing and fluid is observed at the end of the luer lock, the administration set is primed
3. Place red cap at luer lock at end of tubing to secure fluid path.
4. Wrap the orange medication sticker around the tubing, below the clamp.

#### Prepare Syringe

1. Open the accessory pouch.
2. Remove end cap from the catheter connector, and discard.
3. Draw up 1 to 3 cc of sterile fluid into the 3cc syringe, and attach it to the catheter connector.

#### Insert Catheter

1. If using the introducer needle, remove and discard the protective sheath, and insert the needle 3 to 5 inches from incision.
2. Remove the needle, leaving the catheter introducer in place.
3. Thread the marked end of the catheter through the introducer into surgery site.
4. Pull the introducer out over the catheter, leaving the catheter in place.
5. Cover the catheter entrance site with the dressing provided, to secure the catheter to the skin.

NOTE: If using another manufacturer's catheter, refer to that manufacturer's DFU for use instructions

#### Prime Catheter

1. Open the catheter connector to a ninety-degree angle for catheter insertion.
2. Insert the free end of the catheter into the connector, following the manufacturer's instructions (included in this kit).
3. Inject fluid from the syringe through the catheter to verify a proper connection.

#### Attach Pump

**Important:** The catheter should be primed immediately prior to connecting with the end of the pump tubing.

1. Disconnect the 3cc syringe from the catheter connector/catheter.
2. Remove the end cap from end of the pump tubing, and attach the catheter connector
3. If using two catheters, repeat the above steps to insert and prime both, and attach to the pump.
4. Verify that the pump clamps are open.
5. Coil and tape any excess tubing, and the catheter connector, to the patient
6. Secure the pump to the patient by clipping it to the patient's gown/ace bandage/dressing, or place it into the carrying pouch

**NOTE:** In pumps with two elastomers, both sides may not deflate at the same rate.

#### After Infusion is Complete:

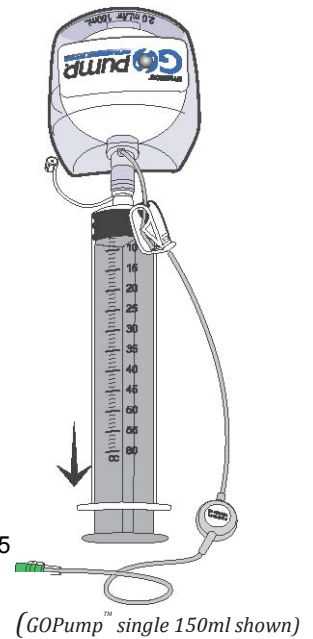
1. When the elastomeric membrane is no longer distended, the infusion is complete.  
**NOTE:** The membrane may not appear perfectly flat on all sides.
2. If instructed by physician, the catheter(s) may be removed by grasping it near the skin, and gently pulling it out.
3. Verify that the tip of the removed catheter is either blue or black, indicating that the entire catheter has been removed.  
Catheters used for GOBlock™ products may not have a blue or black tip.
4. Dispose of pump.

#### Sterility:

Unless otherwise noted, components of the Symbios Disposable Infusion Pump Kit are sterilized by ethylene oxide (EtO) methods. Do not re-sterilize, and do not use after expiration date.

#### Caution:

Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician.



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