

SmartInfuser PainPump™ P49230

Medical Team Operation Instructions



C4202 Rev.2



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Medical Team Operation Instructions

SmartInfuser PainPump™ P49230

The SmartInfuser PainPump provides continuous delivery of a local anesthetic solution through a catheter inserted directly into the surgical site.

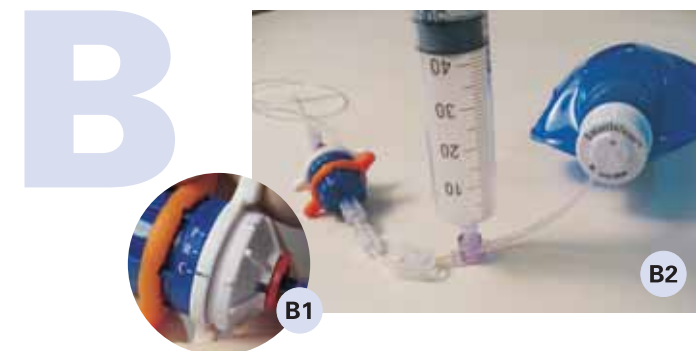
CONNECTING THE ADMINISTRATION SET



1. Remove the SmartInfuser Set and the SmartCatheter from the sterile packaging.
2. Connect the SmartCatheter to the regulating set with the luer lock connectors.
3. Remove the compression unit from the sterile packaging.
4. Remove the caps from the regulator input port and from the compression unit tubing exit port and connect the male luer-lock connector of the tubing to the regulator input port.

NOTE: Verify that the luer-lock connections are tightened.

FILLING THE PUMP



1. Position the SmartReg at C (closed, See Fig. B1).
2. Remove the cap and fill the pump through the check valve using 50/60 cc syringe (which is also included in the set, See Fig. B2).
3. Place the cap back on the check valve inlet port.
4. Complete the medication sticker and attach it to the regulating set. Place the other completed pump sticker on the patient record.

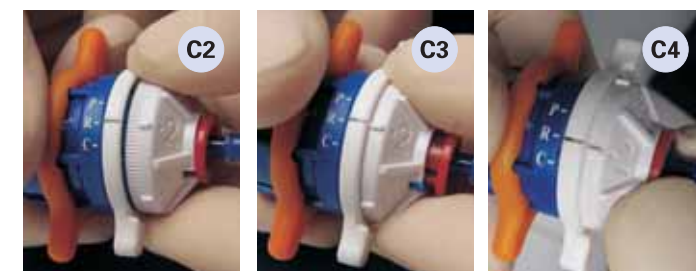
NOTE: The maximum volume is 500 ml

WARNING: Use aseptic technique to fill the bag. After use, handle and discard in accordance with standard medical protocols.

SELECT PUMP SETTING

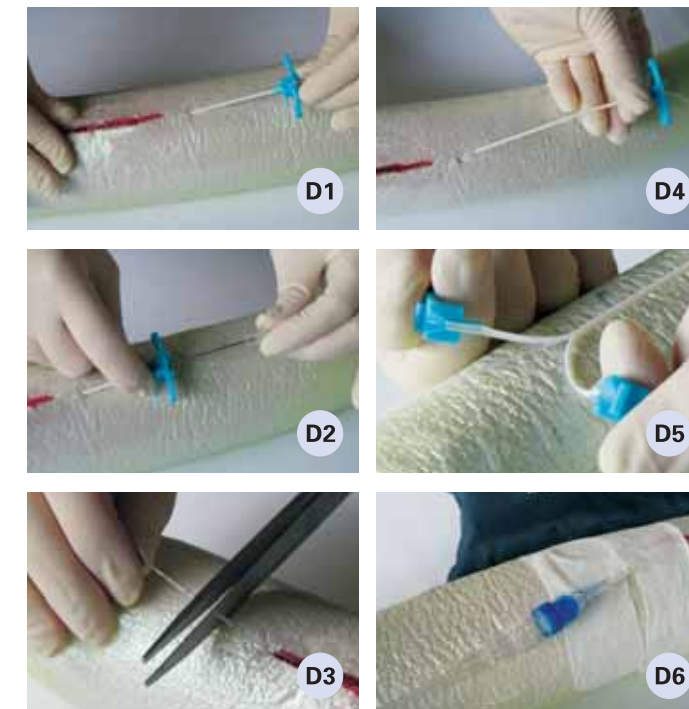


1. Position the SmartReg at P (priming). Hold the compression unit so that the exit port is positioned facing up. Tap the body of the SmartReg with one finger (See Fig. C1).
2. When all the air bubbles have drained from the set tube and from the catheter, position the SmartReg adjusting ring at R (regulating, See Fig. C2).
3. Select the desired flow rate by aligning the digit on the SmartReg adjusting ring with the line. Push the ring toward the regulator body to secure and to permanently lock out the Priming function (See Fig. C3).
4. To permanently set and lock the flow rate prior to the patient being released, push the red locking sleeve toward the regulator body (See Fig. C4).



PLACING THE SmartCatheter

D



1. While holding the T-handle, remove the protector from the introducer needle.
2. Insert the introducer needle through the skin to the wound site (at a distance of approximately 3 to 5 cm from the site) (See Figure D1).
3. While holding the T-handle, pull out the introducer needle (See Figure D2).
4. OPTIONAL: Cut the catheter infusion segment to the desired length (See Figure D3).
5. Insert the catheter through the opening of the introducer's T-handle to the wound site, and pull the introducer's T-handle all the way off the skin and pill it off the catheter (See Figure D4, D5).
6. Secure the catheter by coiling it close to the insertion site and applying a surgical dressing or tape (See Figure D6).

WARNING: Care should be taken during catheter placement to assure that occlusion will not occur during use and that catheter removal will not be impeded.

Ensure that the catheter tip has not been placed in a vein or artery!

ORGANIZING THE SYSTEM

E



Place the compression unit in the carrying pouch (See Figure E1, E2).

NOTES

1. The position of the regulator's adjusting ring determines the nominal infusion flow rate.
2. When saline liquid is used at 22°C, the regulator maintains an accuracy of $\pm 15\%$ of the selected flow rate and a stability of $\pm 5\%$ throughout the entire therapy. The viscosity of the solution affects the actual flow rate.
3. Actual infusion time may vary due to differences between nominal and actual flow rate and tolerances in the actual medication volume.