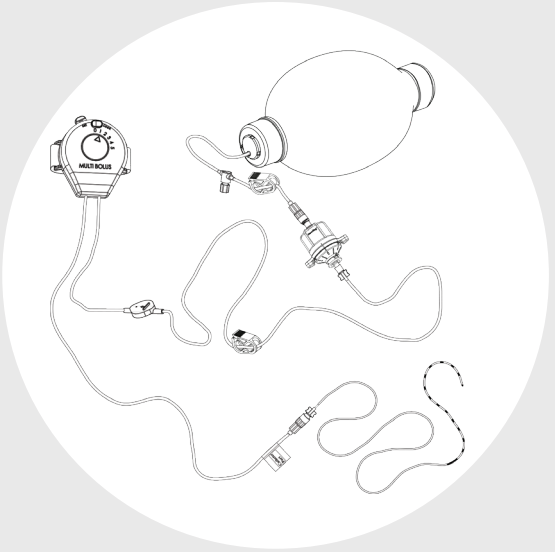
PHYSICIAN GUIDELINES AND INSTRUCTIONS



Ambu

Ambu® ACTion™ Fuser Pain Pump

Disposable Pain Management System

Rx Only

DESCRIPTION

The ACTtion™ Fuser pump provides continuous delivery of a local anesthetic solution through a catheter inserted directly into the surgical site.

ACTion™ FUSE PAIN PUMP CONTENTS

- Catheter [1,2]
- Regulating Set (infusing set) [1]
- Compression Unit (pump)
- Peel-off introducer [2]
- Surgical dressing
- 50/60 cc luer-lock syringe
- Medication stickers
- Pump stickers
- Carrying pouch
- Antimicrobial dressing (optional)
- Flow Splitter (optional)
- Sealed male/female cap (optional – when supplied, is loose in the regulating set sterile pouch)

[1] The Catheter and the Regulating Set comprise the Administration Set.
[2] The set might contain dual Catheters and dual Peel-off introducers or might not include them (depending on the Pain Pump version).

In the "Closed System" configuration, the compression Unit and the Regulating Set are connected and bonded and can't be set apart

CONTRAINDICATION

- ACTion™ Fuser is not intended for intravenous, intra-arterial use.
- ACTion™ Fuser is not intended for delivery of blood, blood products' or lipids.

FILLING THE PUMP

*For the **Closed System configuration**; start at below sub-clause #2.*

For the **Modular configuration**: the Compression Unit (the pump) is packed in a sterile pouch located in the main box or container. It can be filled away from the patient, i.e. in the pharmacy or other approved location.

1. Remove the compression Unit from the sterile package.
2. Close the "c" clamp positioned closed to the exit port (Figures 1a, 1b).
3. Remove the **colored** cap and fill the Compression Unit through the check valve using the 50/60 cc syringe included in the set.
4. Place the cap back on the inlet port of the check valve.
5. Complete the medication sticker and attached it to the tubing. Place the other medication sticker in the patient record or implant log.

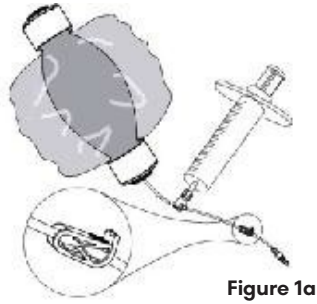


Figure 1a

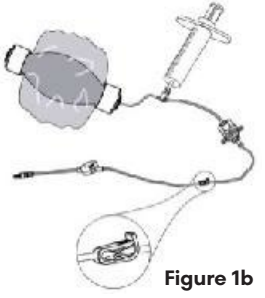


Figure 1b

NOTES

- Maximum volume
  1. For pumps of nominal volume, 200ml is 330ml
  2. For pumps of nominal volume, 400ml is 550ml.
  3. For pumps of nominal volume, 650ml is 650ml.

WARNING

- Use aseptic technique to fill the pump.
- After use, handle and discard in accordance with standard medical protocol.

CONNECTING THE ADMINISTRATION SET

The below three clauses (#1, #2, and #3) are referring ONLY to the "Modular" configuration

1. Remove the Regulating Set from the sterile packaging.
2. Remove the caps off from the regulator input port and from the compression unit tubing exit.
3. Connect the luer-lock connector of the compression unit tubing to the regulator input (see Figures 2, 3).

The below clause #4 is referring to ALL configurations

4. After the pump is primed, connect the male luer-lock connector of the regulating set exit port to the catheter inlet port (see Figure 2).
   When two catheters need to fed by the same pump, remove the FlowSplitter from the sterilepackaging and connect it to the set exit port (see Figure 3).
   Then remove the caps of the FlowSplitter exit ports and connect the catheters.

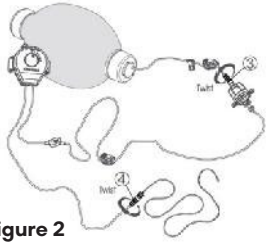


Figure 2

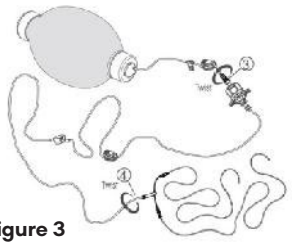


Figure 3

NOTES

- Verify that the luer-lock connectors are tightened.

PRIMING AND SETTING THE ADMINISTRATION SET

1. The regulator is secured at the maximum flow rate level (over 6 ml/hr or over 15 ml./hr depends on the set version) (See Figure 4).
2. Place the compression unit and the bolus so that exit port is positioned facing up and thebolus's tubes are positioned upwards (use the bolus's strip to hold it to the unit) and wait until medication flows through the catheter and most of the air bubbles have drained from the set and from the catheter (Note; the set filter automatically drains out any air bubble remaining in the set tubing) (see Figure 5).

3. Select the desired flow rate:
   a. Pull the Clamp of the Lock-Guard from the red locking ring and pull the Adjusting Ring out of the hub (see Figure 6).
   b. Select the desired flow rate by dialing the Adjusting Ring clockwise and aligning the digit on Ring with the line. Push the adjusting ring toward the regulator to secure the selected flow rate (See Figure 7).
4. To avoid locking of the flow rate in error and to better secure the selected flow rateplace the Clamp of the Lock-Guard between the red locking ring and the Adjusting Ring (See Figure 8a).
5. Permanently lock the flow rate prior to the patient being released; remove the Lock-Guard from the regulator, push the red locking ring toward the regulator body (See Figure 8b).

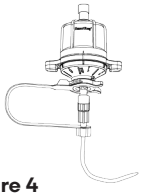


Figure 4

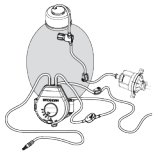


Figure 5

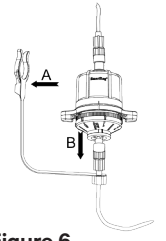


Figure 6

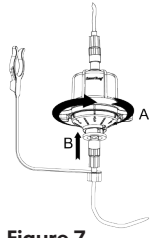


Figure 7

Lock-Guard

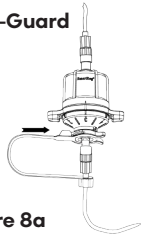


Figure 8a

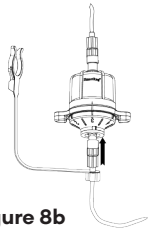


Figure 8b

NOTE

If applicable you may use the Red sealed cap to seal the exit port of the regulating set after priming when the pump is being pre-filled in advance;

a. Close the clamp on the reservoir tubing (see Figure 1).
b. Place the sealed cap at the exit port.

NOTES

- Approximate priming time for a 1-6 ml/hr set without bolus is 13 to17 minutes.
- Approximate priming time for a 5-15 ml/hr set without bolus is 6 to 8 minutes.
- Approximate priming time for a 1-6 ml/hr set with bolus is 65 to 75 minutes.
- Approximate priming time for a 5-15 ml/hr set with bolus is 35 to 40 minutes.

6. Select the MultiBolus volume by aligning the arrow with the digit by moving the lever. See figure (see Figure 9), secure the selected volume by turning the lock 180° (see Figure 10)
7. To permanently lock the bolus volume prior to the patient being released; push the lock downward (See figure 11)

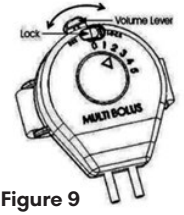


Figure 9

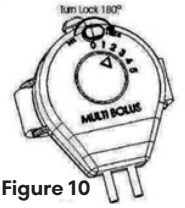


Figure 10

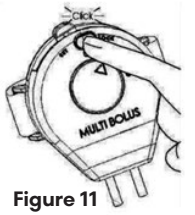


Figure 11

NOTES

- The digits on the Regulator represents flow rate in ml/hr.
- As long as the locking sleeve is in its original back position the flow rate can be reset multiple times as needed; simply pull out the adjusting ring, dial to the desired flow rate and push the adjusting ring in to secure.
- The digits on the MultiBolus represent volume in ml.

WARNING

- Prior to connecting the regulation set exit port to the catheter verify that there is a slow drip from the exit port.
- The compression unit must not be connected directly to the catheter, as this can result in free flow of the anesthetics to the patient. Excessive anesthetics can result in a life-threatening condition.

PLACING THE CATHETER

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 12).
3. While holding the T-handle, pull out the introducer needle (See figure 13.
4. Cut the catheter infusion segment to the desired length (See figure 14). See also the Catheter instructions.
5. Insert the catheter through the opening of the introducer's T-handle to the wound site (See figure 15).
6. While holding the edge of the catheter, pull the introducer's T-handle all the way off the skin and peel it off the catheter (See figure 16).

7. Make sure the catheter's infusion tubing in its entirety is positioned in the wound site. The end of the infusion tubing is marked by a black band that should be positioned just below the skin surface.
8. Secure the catheter by coiling it close to the insertion site and applying a surgical dressing or tape (See figure 17).

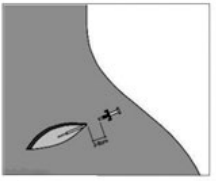


Figure 12

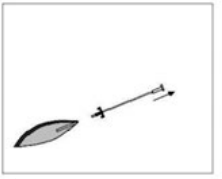


Figure 13

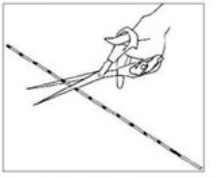


Figure 14

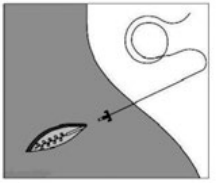


Figure 15

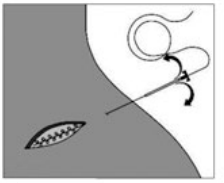


Figure 16

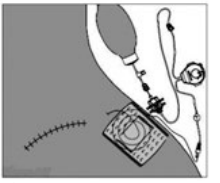


Figure 17

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!**
- Certain studies suggest a connection between intra-articular catheter placement when combined with the use of Bupivacaine (common trade names include Marcaine® and Sensorcaine®), especially in the shoulder, and the occurrence of chondrolysis. Certain studies also suggest the possibility of increased infection rates with intra-articular catheter placement. **The catheter placement is the ultimate decision of the physician; however, the company recommends not placing catheters intra-articularly.**

NOTES

- When Antimicrobial Dressing is included in the set, first place the Antimicrobial Dressing on the catheter insertion site and then place the surgical dressing.
- Read and follow the instructions for the antimicrobial dressing prior to placing it on the patient.

CAUTION

- Do not cover the filter of the ACTion™ Fuser.
- Sterile, unless sterile packaging is broken. Do not use the product if any damage has occurred to the sterile packaging.

ORGANIZING THE SYSTEM

1. Place the compression unit and the regulator in the carrying pouch and then zip the pouch closed. Verify that the tubing is free and no kinks have occurred (See figure 18).
2. Infusion is complete when the pump is no longer inflated (the compression unit's body will feel hard when touched at the middle) (See figure 19).

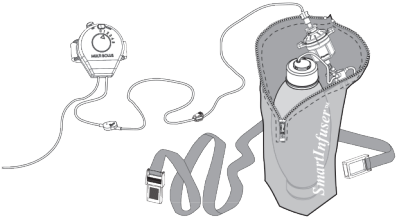


Figure 18

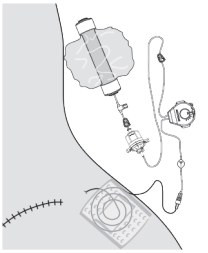


Figure 19

NOTES

- The position of the regulator's adjusting ring determines the nominal infusion flow rate.
- When saline liquid is used at 22° C, the regulator maintains an accuracy of ±15% of the selected flow rate and stability of ±5% throughout the entire therapy. The viscosity of the solution affects the actual flow rate.
- Actual infusion time may vary due to differences between the nominal and actual flow rate and tolerances in the actual medication volume.
- The maximum residual volume is 1.5% of the reservoir nominal volume for all versions except 4% for the Combined Compression Unit version
- The product is sterile if indicated with symbol on product pouch -
  STERILE R : Sterile by Radiation-
  STERILE EO : Sterile by Ethylene Oxide.

Ambu

Ambu, Inc.
6230 Old Dobbin Lane
Columbia, MD 21045
Tel. 800 262 8462
Fax 800 262 8673
ambuUSA.com

US: Rx only