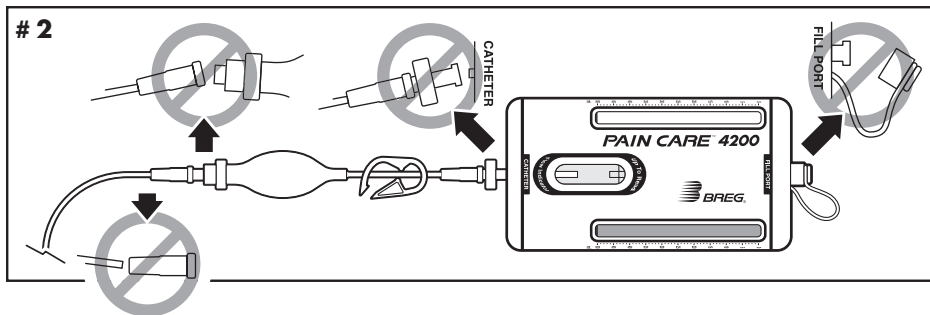
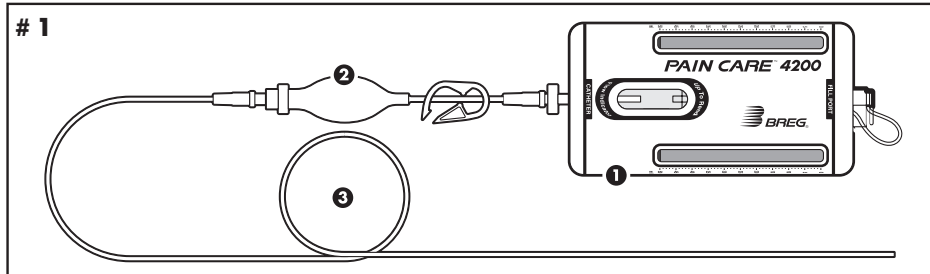


PAIN CARE® 4200

PATIENT INSTRUCTIONS



WARNING: READ CAREFULLY BEFORE OPERATION



BREG's Pain Care® 4200 is a portable infusion pump designed to deliver pain medicine directly to the surgical site. The medicine is continuously delivered (approximately 2 cc's per hour) through a tiny tube called a catheter, which is placed inside the wound by your physician/licensed health care provider during surgery. Your physician/licensed health care provider has filled the Pain Care® 4200 with a numbing medicine and has attached it to the catheter tube. This procedure is similar to the way a dentist numbs your mouth to fill a cavity or pull a tooth. Other pain control therapies such as pain pills and narcotics taken by mouth go throughout the entire body and often cause side effects such as drowsiness, disorientation, nausea, constipation, and vomiting.



WARNINGS

- 1 ONLY A PHYSICIAN/LICENSED HEALTH CARE PROVIDER MAY APPLY THE PAIN CARE® 4200.
- 2 ONLY A PHYSICIAN/LICENSED HEALTH CARE PROVIDER MAY PRESCRIBE THE MEDICATION USED IN THE PAIN CARE® 4200.
- 3 THE PHYSICIAN/PRESCRIBING HEALTH CARE PROVIDER MUST ENSURE THAT THE PATIENT UNDERSTANDS CONTRAINDICATIONS FOR THE PRESCRIBED MEDICATION, RELATED SYMPTOMS AND THE RISK OF INFECTION SHOULD THE DEVICE OR ITS INSTALLATION BE COMPROMISED. THE PATIENT MUST BE INFORMED OF ACTIVITIES THAT MAY INCREASE INFECTION INCIDENCE (E.G. BATHING, SHOWERING, BANDAGE COMPROMISE, CATHETER/CONNECTOR COMPROMISE).
- 4 USE STERILE TECHNIQUE AT ALL TIMES DURING IMPLANTATION OF THE CATHETER, WHILE FILLING THE FLUID RESERVOIR WITH THE LOCAL ANESTHETIC AND UPON REMOVAL OF THE CATHETER. IF STERILE TECHNIQUE IS VIOLATED A RISK OF INFECTION EXISTS.
- 5 DISPOSABLE – SINGLE PATIENT USE ONLY. DISCARD AFTER USE. (2)
- 6 ONLY REFILL THE DEVICE PER PHYSICIAN/LICENSED HEALTH CARE PROVIDER ORDER AND INSTRUCTION.
- 7 MEDICATIONS USED WITH THE PAIN CARE® 4200 SHOULD BE IN ACCORDANCE WITH INSTRUCTIONS PROVIDED FROM THE DRUG MANUFACTURER. THE PHYSICIAN/LICENSED HEALTH CARE PROVIDER SHOULD REFERENCE THE DRUG MANUFACTURER INSERT OR "PHYSICIANS' DESK REFERENCE" FOR DOSAGE RECOMMENDATIONS AND INFORMATION.
- 8 IF ANY LUER LOCK CATHETER CONNECTIONS DISCONNECT FROM THE PAIN CARE 4200, DO NOT RECONNECT. IF THE CATHETER EXITS THE SURGICAL SITE, DO NOT RE-INSERT. INFECTION COULD RESULT IF RECONNECTED. CONSULT YOUR PHYSICIAN/LICENSED HEALTH CARE PROVIDER FOR REMOVAL INSTRUCTIONS.
- 9 AVOID DROPPING THE PAIN CARE 4200. IF THE PAIN CARE IS COMPROMISED (E.G. CRACK, LEAK, BREAK OR DISCONNECT) CONTACT YOUR PHYSICIAN/LICENSED HEALTH CARE PROVIDER.
- 10 PATIENTS WITH KNOWN ALLERGIES OR COMPLICATIONS TO MEDICINE USED IN THE PAIN CARE UNIT SHOULD NOT USE THIS DEVICE. CONTACT A PHYSICIAN IMMEDIATELY IF ANY OF THE FOLLOWING OCCUR: BREATHING DIFFICULTY, HEART RATE FLUCTUATIONS, RASH, HIVES, EXCESSIVE SWEATING OR NAUSEA.

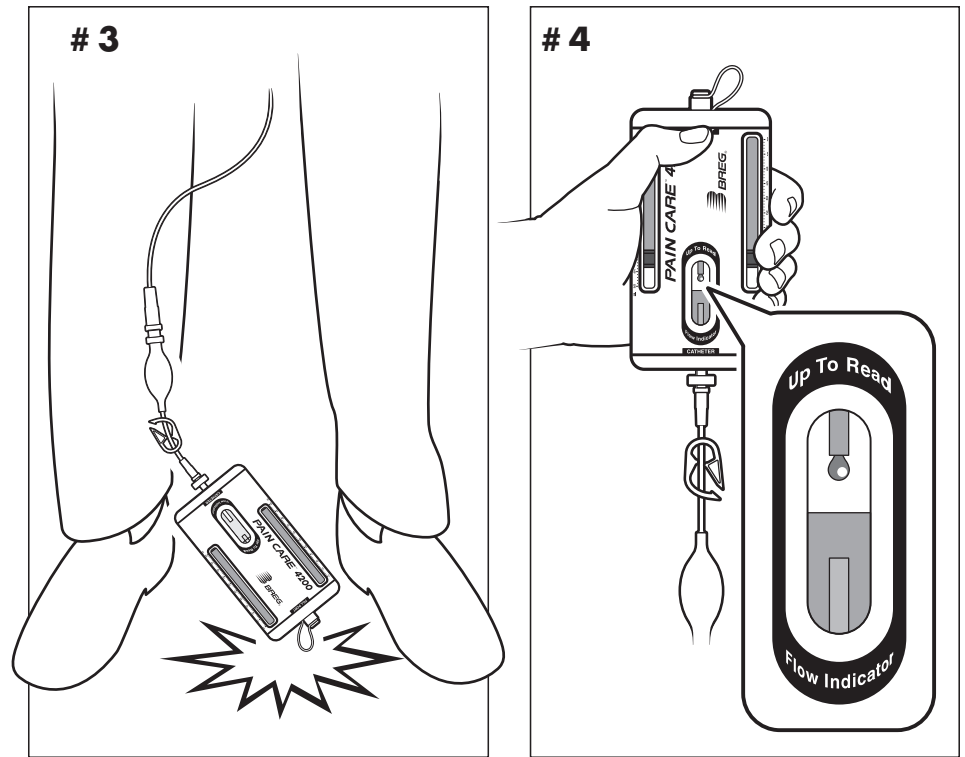
If more medicine is needed to decrease pain, simply squeeze the Bolus Bulb on the *Pain Care*® 4200 one time and an additional 4-6 cc's (0.14-0.21 fluid ounces) of numbing medicine will be injected directly into your wound site through the catheter. How often the Bolus Bulb is used per day is to be determined by your physician/licensed health care provider.

The *Pain Care*® 4200 has a capacity of 200 cc's (7 fluid ounces). This device is designed to provide approximately 100 hours of continuous treatment. How often the Bolus Bulb is used for an increase in the delivery of your pain medication will vary depending upon a number of factors. Such as, the frequency you have been directed to squeeze the Bolus Bulb, the surgery performed, individual pain tolerance, the effectiveness of the numbing medicine prescribed by your physician/licensed health care provider and how much pain medicine you take orally.

No part of the *Pain Care*® 4200 should be disconnected, and the system should remain intact for the entire duration of your therapy. This is important: if any part of the unit becomes disconnected, do not reattach. Infection could result.

Your therapy is complete when the medication reservoir is empty or when it is no longer needed for pain control. The total medication remaining can be viewed through the windows in front of the *Pain Care*® 4200.

- (# 1) The *Pain Care*® 4200 system consists of the continuous infusion pump, a bolus assembly, and a catheter.



- (# 2) Do NOT disconnect ANY of the caps or connections of the *Pain Care*® 4200, as infection could result. If any part of the device disconnects, call your physician/licensed health care provider as soon as possible.
- (# 3) Take care to correctly insert the *Pain Care*® 4200 into the carry case. The unit may be damaged if dropped.
- (# 4) To check for proper flow of medication, grasp the *Pain Care*® 4200 and hold it upright (Bolus Assembly pointing downward). View the flow indicator, proper flow is confirmed when drops of medication drip off the glass tube inside the flow indicator.

- (# 5) If you start to feel an increase of aching and discomfort at the surgery site, simply squeeze the Bolus Bulb assembly. This will inject approximately 4-6 cc of numbing medication into the surgery site. This additional dose should start to decrease your discomfort in 15 minutes.

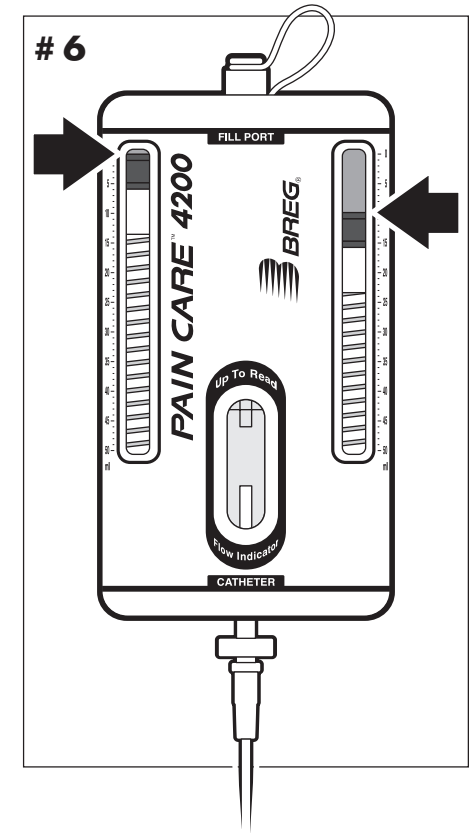
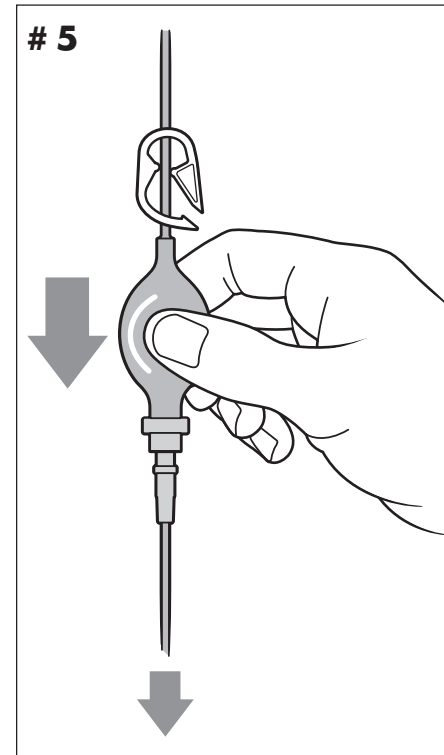
- Squeeze the Bolus Bulb slowly and firmly. Additional pressure is NOT needed to increase the rate of administration. Once the bulb is completely squeezed, release it. The bulb will gradually refill on its own.

- (# 6) Your therapy is completed when the medication reservoir is empty (as can be seen through the windows in the front of the case). The *Pain Care*[®] 4200 is designed to provide about 100 hours of continuous flow of pain medication. The continuous flow of pain relieving medication should control your pain.

- If you experience any problems with the *Pain Care*[®] 4200 unit such as leakage, the device becoming disconnected, or the tube pulling out of the wound site, contact your physician/licensed health care provider immediately. Do NOT attempt to reattach any part of the unit as infection could result.

- If you drop the *Pain Care*[®] 4200 and it cracks, breaks, or stops working, contact your physician/licensed health care provider immediately.

- Once the *Pain Care*[®] 4200 is empty the catheter tube must be removed. Contact your physician/licensed health care provider for instructions regarding catheter removal.



E/U authorized representative
MDSS
Burckhardtstrasse 1
D-30163 Hanover
Germany



2611 Commerce Way
Vista, CA 92081

800-321-0607
www.breg.com

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