Postoperative Pain Management Infusion System

INSTRUCTIONS FOR USE

CE marking : 2009
Products references:

<table>
<thead>
<tr>
<th>Reference</th>
<th>Catheter</th>
<th>Needle</th>
<th>Pump (CE marked accessory)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>Frenestrated</td>
<td>Diameter</td>
</tr>
<tr>
<td></td>
<td></td>
<td>area length</td>
<td>(mm)</td>
</tr>
<tr>
<td>INSP-S-127-250_C</td>
<td>1</td>
<td>127</td>
<td>1</td>
</tr>
<tr>
<td>INSP-S-127-250_D</td>
<td>1</td>
<td>127</td>
<td>1</td>
</tr>
<tr>
<td>INSP-S-254-250_C</td>
<td>1</td>
<td>254</td>
<td>1</td>
</tr>
<tr>
<td>INSP-S-254-250_D</td>
<td>1</td>
<td>254</td>
<td>1</td>
</tr>
<tr>
<td>INSP-S-63-250_C</td>
<td>1</td>
<td>63</td>
<td>1</td>
</tr>
<tr>
<td>INSP-S-63-250_D</td>
<td>1</td>
<td>63</td>
<td>1</td>
</tr>
<tr>
<td>INSP-D-127-250_C</td>
<td>2</td>
<td>127</td>
<td>1</td>
</tr>
<tr>
<td>INSP-D-127-250_D</td>
<td>2</td>
<td>127</td>
<td>1</td>
</tr>
<tr>
<td>INSP-D-254-250_C</td>
<td>2</td>
<td>254</td>
<td>1</td>
</tr>
<tr>
<td>INSP-D-254-250_D</td>
<td>2</td>
<td>254</td>
<td>1</td>
</tr>
<tr>
<td>INSP-D-63-250_C</td>
<td>2</td>
<td>63</td>
<td>1</td>
</tr>
<tr>
<td>INSP-D-63-250_D</td>
<td>2</td>
<td>63</td>
<td>1</td>
</tr>
</tbody>
</table>

Product sterilized by ethylene oxide
Sterile product as long as the packaging has not been opened, damaged or broken.
Single use only
Latex free

WARNING: Do not re-sterilize
WARNING: Do not refill or re-use
Re-use of the device could result in inaccurate flow rate, increased risk of infection or other improper functioning of the device.
WARNING: Store in a cool and dry place at room temperature. Avoid extreme temperatures and humidity. Avoid abrupt or repeated storage temperature change.
WARNING: Conserve in the original packaging. Do not remove from pack until ready for use.
WARNING: Check the integrity of the packaging before use.
WARNING: Shelf life – Use before expiration date indicated on the package.
Before starting patient infusion, ensure you fully understand the infusion characteristics of the system and its components. The complete Postoperative Pain Relief Infusion System consists of a pump kit and a catheter kit. The pump kit comprises a pump made of an elastomeric balloon inside a rigid, transparent container and an infusion line with a Female Luer-Lock connector; a 50 mL with male luer lock syringe and a transport bag. Instructions for use of the pump kit are provided separately. Make sure to read it completely before use.

The catheter kit comprises a combined stainless steel needle and Pebax / stainless steel catheter, a removable male luer lock connector and a female luer lock 5mL syringe. This device may be contaminated after use. The needle part should be considered as a sharp device according to 2010/32 UE directive. Dispose of these devices with other sharp or contaminated devices according to validated medical protocols and any other applicable regulations after use.

INSTRUCTIONS FOR USE

The PainKwell System is to be used for the continuous infusion of local anaesthetic directly into the surgical site for acute postoperative pain control.

CONTRAINDICATIONS

The PainKwell system is not intended for intravenous, intra-arterial or epidural drug delivery. It is not intended for the delivery of blood, blood products, lipids, or oil based medications, i.e. iodized ethyl ester of fatty acid obtained from poppy seed oil etc., etoposide or fatty emulsion medications.

POSSIBLE SIDE EFFECTS

Ensure the infused medication is not toxic for the site. Recent studies have shown a link between anaesthetic / pain pumps and post arthroscopic glenohumeral chondrolysis on shoulder joint. The PainKwell catheter should be placed with caution and the infusion rate should be kept as low as possible in order to obtain the desired effect. When used in distal end extremities [nose, finger, toe, penis, etc.] high flow rates may induce ischemic injury or necrosis when used in such places.

METHOD Under aseptic conditions

1. Medication procedures
   - Determine the medication and volume as prescribed by the surgeon. Medications used with this system should be administered in accordance with instructions provided by the drug manufacturer.

2. Priming the reservoir with medication
   - See instruction for use provided with the pump.

3. Placing the catheter within the wound
   - 1. Uncoil the needle/catheter prior to handing to the surgeon.
   - 2. The needle bending can be adjusted by the SURGEON: Bend needle to desired curvature with protective sheath in place, then discard sheath.
   - 3. Working from within the wound cavity, pass the needle from the deepest part of the wound up into the fat layer and bring the needle out of the tissues so that it is fully visible. Then make a second pass of the needle back through the fat layer and tunnel it over 5-8cm so that it emerges through the skin 5-8cm from the wound edge.
   - 4. Remove the small tab in the luer twist lock connector [Fig.1] by unscrewing two full turns - and discard. The connector is now ready to receive the catheter. Push cut end of catheter fully [approx. 2cm] into the hole and screw the twist lock connector on tightly. Verify the connection is locked by gently pulling the catheter. Do not tighten excessively.
   - 5. Fill the 5ml syringe with infiltration mixture, expelling all air, and attach it to the twist lock connector. Prime the catheter using gentle pressure from the syringe so that it fills with infiltration mixture and contains no trapped air. A continuous row of droplets should appear through the catheter fenestrations indicating all air is expelled. Remove syringe and screw temporary end cap onto the connector.
   - 6. Coil catheter tubing on the skin surface and secure catheter to the skin by applying occlusive dressing over inserention site and coiled catheter tubing. Remove end cap from the twist lock connector and connect the primed pump line. The pump line is already secured to the pump. The system is now sealed from the pump to the inside of the wound and is ready for use.
   - 7. Set the flow regulator to the desired rate according the instruction for use enclosed with the pump.

4. Connect catheter tubing to the skin surface and secure catheter to the skin by applying occlusive dressing over inserention site and coiled catheter tubing. Remove end cap from the twist lock connector and connect the primed pump line. The pump line is already secured to the pump. The system is now sealed from the pump to the inside of the wound and is ready for use.

5. Place pump, now attached to the pump line and catheter, in draw-string bag and attach to a secure site.

6. Enter medication data onto adhesive label [supplied] and adhere around tubing.

NOTE:

Infusion should be started as soon as possible once the pump is primed.

The PainKwell™catheter is supplied with a male luer lock connector. It can only be connected to an infusion line which terminates in a female luer connector.
INFORMATION FOR POSTOPERATIVE USE

N.B. IT IS NOT RECOMMENDED TO USE THIS DEVICE FOR MORE THAN 5 DAYS

Changing the infusion rate: See instruction for use enclosed with the pump.

Removing the catheter: Catheter should be removed as soon as the infusion is complete. Any delay could result in removal difficulties.
1. Remove dressing from catheter site.
2. Grasp catheter close to skin and gently slide it from skin. Do not cut or pull hard to remove catheter. If catheter resists or stretches, stop pulling. Wait 30 to 60 minutes and try again. Movements of patient should release the catheter.
3. Verify the presence of black mark at the distal end of the catheter.
4. Place bandage over the catheter insertion site.

Daily Use
- Use the carrying pouch [supplied separately] for convenience and to protect the pump from damage during daily activities. The pouch can be worn around the waist or over the shoulder.
- Use the enclosed Patient Guidelines Booklet for patient education.
- Fill in the patient booklet according to his clinical state and medicine used.
- To monitor medication delivery, check the evolution of the filling of the pump. The medication volume moves very slowly, so re-check in a few hours.
- During use make sure:
  - The pump is emptying and the catheter and tubing are not kinked.
  - All connections are secure and there is no leakage from the connections.
- Do not immerse the pump in liquid. When showering, keep the pump outside the shower or put it in a waterproof bag.
- PainKwell™ does not require periodic maintenance. Dispose of according to local protocols.

Disclaimer of Warranties
ISOMed and Peak Medical Limited warrants that reasonable care has been used in the manufacture of this device and that it was free from defects in workmanship or materials at the time of shipment from ISOMed or Peak Medical. ISOMed and Peak Medical's sole obligation shall therefore be to repair or replace any device which it determines was defective at the time of shipment. Because no product is completely effective under all circumstances, and because the actual use and handling of this device is beyond our control, ISOMed and Peak Medical can not warrant for a good effect or against a bad effect in the application and use of this system. The buyer therefore assumes all liability arising from any cause for damages resulting from use or misuse of this product. ISOMed and Peak Medical therefore give no warranty of merchantability or fitness for a particular purpose. ISOMed and Peak Medical shall not be liable for incidental or consequential loss, damage or expense resulting from the use or application of this product. This warranty is in lieu of all other warranties, whether implied, express, oral or written, and no individual has the authority to vary the terms of this warranty.

Manufactured by ISOMED For PEAK MEDICAL Limited

ZAE Les Pointes , 230 rue des grands prés 60230 CHAMBLY FRANCE Phone :+33 130 284 307 Fax :+33 139 379 661 www.fbmedical.fr

Unit 4 Manor Farm Barns Cornbury Park , Finstock OX7 3DG ENGLAND FREEPHONE [UK] 0800 6520424 www.painkwell.com

Caution
1. Make sure there are no bends or twists in the infusion line or the connected catheter. Bends and twists can cause fluctuations in the infusion rate.
2. The infusion rate will vary with changes in the viscosity of the medication due to density, temperature, etc. Please keep these factors in mind when using.
3. Any modifications to the infusion rate must be made by duly qualified personnel. The key associated with the regulator should only be entrusted to such persons.
4. Do not use excessive pressure when priming the catheter.
5. Store the product in a cool, dry place away direct sunlight and excess humidity.
6. Take extra precaution when using electric cauter instruments in the proximity of the catheter.
7. Do not submit patient to an MRI scan when catheter is in place.