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ZHEJIANG RUNQIANG MEDICAL INSTRUMENTS CO.,LTD

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Epidural Anesthesia-Pain Management United Kit

Product name: Anesthesia kit
Model: AS-E
Product Feature and Components: Consists mainly of epidural needle, epidural catheter, introducer, catheter adapter, filter(optional) and low resistance syringe (optional).
Scope of Application: Epidural puncture and injection of liquid drugs into the epidural space.
Instruction for Use:

1. Remover product from aseptic packaging and inspect the integrity of product.
2. Properly disinfect the puncture site and perform the local anesthesia in the puncture site.
3. A common method is to apply epidural puncture. Connect low resistance syringe to epidural syringe to epidural needle seat and use negative pressure test to detect whether or not epidural needle enters epidural space. Stylet blade should be withdrawn before contact with ligamentum flavum. Operator can position needle through needle markings.
4. Anesthetic injection should be injected at a uniform speed based on diffusion rate of medication. At the same time patient needs to be closely monitored according to requirements for epidural anesthesia.
5. Insert epidural catheter into epidural space through needle. Catheter can be inserted to designed position through catheter marketing. When the catheter reaches normal position, carefully withdraw epidural needle from ear end of catheter. In the process of needle withdrawal, attention should be paid to prevent undesired withdrawal of catheter from epidural space.
6. Connect catheter to catheter adapter, and secure catheter against drop or twist.
7. Before filling epidural catheter with medication, first test the precision of position for detection with proper dosage. Then inject anesthetic with dosage according to standards of normal dosage for epidural anesthesia. Make sure that anesthesia is correctly applied to the site requiring anesthesia.
8. Withdraw catheter smoothly and gently after anesthesia is completed. Do Not withdraw catheter force or rapidly in order to prevent breakage of catheter inside patient’s body and harm to patient.

Contraindication:
Absolute contraindications: patient refusal, coagulopathy, therapeutic anticoagulation, skin infection at injection site, raised intracranial pressure, hypovolemia.
Relative contraindications: Uncooperative patients, pre-existing neurological disorders, fixed cardiac output states, anatomical abnormalities of vertebral, prophylactic use of low dose heparin.
Complications/Risks: Hypotension, inadvertent high epidural block, local anesthetic toxicity, full spinal anesthesia, epidural hemorrhage, infection, respiration inhibition, nausea and vomiting, lower back pain, headache after spinal puncture, nerve damage, damages by puncture and procedure-carried pollution, cardiac arrest, hypothermia, paraesthesia, urnary retention, pruritus, epidural vein catheter placement, abscess, anterior spinal artery syndrome, cauda equine syndrome, inadvertent puncture of blood vessels

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with intravascular injection of local anesthesia, accidental dural puncture, block failure.

Notices of Warning:

1. For single patient and single-use only. NOT to be re-sterilized or reused, in which case performance of device can be affected, and risk of cross infection is increased.
2. Inspect the integrity of packaging before use. No Not use if any single packaging is amaged.
3. For safety reason, devise is to be operated by anesthesiologist only. No oeration by non-anesthesiologist isallowed.
4. Manipulation of uncture should be smooth and gentle. No rude operation is allowed.
5. To safeguard against accident, forceful pentration of needle has to be avoid in case bigger resistane is encountered durIng puncture process.
6. In case with needle bent during operation, Do Not straighten needle for continue operation.
7. Needle has to be discarded and destroyed after use.
8. Sterilized with EO. Disinfection is valid for 2 years.
9. To be used before expiry date on sealed package.
10. Residual quantity is approximately 0.15ml(tested with distilled water). Effect of residual quantity should be taken into account in the process of injection.
11. Anesthetic catheter should be removed slowly and smoothly. NO forcible and quick withdrawal is allowed. To avoid risk of breaking the catheter, do NOT withdraw catheter through the needle.
12. WARNING: There is no evidence that common drugs can weaken the structure of polyurethane material. However, if catheter is used for injection of new drug, doctors should consider whether or not the drug can weaken the structure of polyurethane material.
13. WARNING: To meet environmental protection requirements, the used products should be collected at centrailized location in accordance with regulations by local authorities for disposal of medical waste. NO damage to environment in destruction of waste material has to be made.
14. WARNING: In pediatric application, attention needs to be paid to risks from children’s non-cooperation, refusal and activities.

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Product name: Disposable infusion pump
Model: SZB-CX
Product Feature and Scope of Application: Single use medical device for the clinical treatment of pain. The elasticity of the silicone allows a constant control of flow through the catheter capillary ensuring a safe and effective infusion during therapy. Non-toxic and pyrogenic. Free of latex components and phthalates (DEHP). The models in PVC may be incompatible with some pharmacological solutions: Refer to the package insert of the drug and the relevant information.

Warnings

- **Medications or fluids must be administered per instructions provided by the drug manufacturer. Physician is responsible for prescribing drug based on each patient's clinical status (such as age, body weight, disease state of patient, concomitant medication, etc).**
- **There is no alarm or alert when flow interruption occurs, therefore life-supporting medications whose usage may cause serious injury or death due to stoppage or under-delivery are not recommended for infusion with the device.**
- **There is no indicator of pump infusion status, therefore use caution where over-delivery of medications could result in serious injury or death.**
- **It is the responsibility of the healthcare provider to ensure patient is educated in the proper use of the system.**

Cautions

- Do not use if package is open, damaged or a protector cap is missing
- The pump is sterile, non-pyrogenic and single use only. Do not re-sterilize, refill or reuse. Reuse of the device could result in the following risks:

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- Improper functioning of the device (i.e. inaccurate flow rate)
- Increased risk of Infection
- Occlusion of the device (i.e. impedes or stops infusion)
- Product uses Di (2-ethylhexyl) phthalate (DEHP) plasticized PVC:
- Certain solutions may be incompatible with the PVC material used in the administration set. Consult drug package insert and other available sources of information for a more thorough understanding of possible incompatibility problems.

- Do not remove from package until ready to use.
- Do not fill less than minimum or exceed maximum fill volume of pump.
- Clamp is provided to stop the infusion. Do not remove or break clamp. Do not use clamp as an intermittent delivery device.
  - Roll tubing between fingers to promote flow if clamped for extended time.
- The labeled flow rate and fill volume for each pump are identified on the fill port.
- Avoid contact of cleaning agents (like soap and alcohol) with the filter because leakage may occur from the air eliminating vent.
- Do not tape over filter(s) as this could block the air vent and impede the infusion.
- Do not immerse the pump in water. Take care to protect the pump during any activities which could cause the pump and filter to get wet, such as showering.
- Do not use a microwave, oven or water bath to warm the fluid.
- In the event of any leakage form the pump, or administration set, close tubing clamp. Replace pump if necessary.
  - Do not discard the pump and contact Runqiang Technologies for product return instructions.
  - Flow rates may vary due to:

Fill Volume
- Filling the pump less than labeled (nominal) fill volume results in faster flow rate.
- Filling the pump greater than labeled (nominal) fill volume results in slower flow rate.

Viscosity and/or drug concentration
- The pump labeled flow rates are based on the use of nominal saline as the diluent.
- Addition of any drug or use of another diluent may change viscosity and result in increased or decreased flow rate. Use of 5% dextrose will result in 10% longer delivery time.

Pump Position – place approximately 40cm (16 inches) below the catheter site
- Positioning the pump above this level increases flow rate
- Positioning the pump below this level decreases flow rate

Temperature
- Temperature will affect solution viscosity, resulting in faster or slower flow rate.
- The flow controller (located distal to the filter) should be close to, or in direct contact with the skin (31 degrees C/88 degrees F).
- The tubing should go under the patient’s clothing.
- Flow rate will increase approximately 1.4% per .6 degrees C/1 degree F increase in temperature and will decrease approximately 1.4% per .6 degrees C/1 degree F decrease in temperature.

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- If stored in the refrigerator or freezer, allow pump to reach room temperature before using. It may take several hours for a pump to reach room temperature, depending on fill volume.
- To ensure flow rate accuracy, do not place heat or cold therapy in close proximity to the flow controller tubing.

Storage

- Storage of a filled pump for more than 8 hours prior to starting infusion may result in a slower flow rate

Catheter/Access Devices

- When administering through a central or peripheral catheter, follow instructions provided by the catheter manufacturer. Connected to the epidural catheter.

Note: Product does not contain Di (2-ethylhexyl) phthalate (DEHP) plasticizer in its PVC tubing.

Indications

The pump is indicated for continuous delivery of medications through epidural catheter routes.

Contraindications

The pump is not intended for blood, blood products, lipids, fat emulsions, or Total Parenteral Nutrition (TPN).

Note: Follow standard protocols and applicable regulations for filling pump.

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1. Close the clamp.
2. Remove the cap from the fill port and retain for later use.
3. The pump can be filled with a syringe or similar device. Remove all air from the filling device and attach filled syringe to fill port.
4. Firmly grasp the syringe with both hands and push down on the plunger continuously until the volume is dispensed. Do not handle the pump while filling, as the syringe tip may break. Repeat as necessary.

Caution: Do not fill less than the minimum or exceed maximum fill volume.

5. Remove filling device from the fill port.
6. Securely replace fill port cap. Ensure that the distal end cap on the tubing is snug.
7. Label with appropriate pharmaceutical and patient information.
8. Connected the pump tubing lock to epidural catheter adaptor.

Priming the Administration Set

Use Aseptic Technique

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Note: In order to avoid the risk of precipitation within the tubing, the pump can be prefilled and primed with a small amount of diluent so that the medication is not in the pump tubing until the infusion is started. This technique can be used for any medication prone to precipitation, such as fluorouracil (5-FU).

Caution: It is important to completely prime the pump tubing. Failure to do so may prevent the pump from infusing.

1. Remove distal end cap.
2. Open clamp to start priming.
3. When all air has been removed from the entire tubing and fluid flow is observed at end of the distal luer, the administration set is primed.
4. Close clamp and replace distal end cap until ready for use.

If administration set does not prime, follow these steps:

1. Attach a luer adapter or stopcock to the distal luer.
2. Attach a small syringe (10ml preferred) to the other side of the adapter and pull back on the syringe to create suction.
3. Continue to create suction until all air is removed from the tubing and fluid flow is observed from the distal luer. Repeat as necessary.
4. Disconnect syringe and luer adaptor or stopcock, and observe pump for complete priming.

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5. If this does not work, check to see if something else is impeding flow, such as medication precipitate, clamp is closed or kinked tubing.

Starting Infusion

Note: Patient must be educated on proper use of product by healthcare provider.

1. Allow the pump to reach room temperature before using.
2. Verify that the clamp on the tubing is closed.
3. Cleanse patient's catheter injection site.
4. Attach the pump tubing to the access device
5. Tape the flow controller (not the filter) to the patient's skin.
6. Begin Infusion by opening the clamp; fluid delivery will start immediately.
    - If tubing is kinked, roll kinked portion of the tubing between fingers to restore shape of tubing and promote fluid flow.

End of Infusion

- Infusion is complete when the elastomeric membrane is no longer expanded.
- Close clamp, disconnect and dispose of the pump according to your institution's protocol.

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Technical Specifications

Delivery Accuracy: When filled to labeled (nominal) volume, pump flow rate accuracy is ±20% of the labeled (nominal) flow rate when infusion is started 0-8 hours after fill and delivering normal saline as diluent at 31 degrees C/88 degrees F with the pump positioned 40 cm (16 inches) below the catheter site.

Notes:

- Latex is not in fluid pathway or in contact with human.
- Length of tubing is approximately 115 +- 15 cm (40 +- 5 inches)

Storage Conditions

Store under general warehouse conditions. Protect from light sources and heat. Keep dry.

Table 1: Delivery Time/Volume Information

Caution:

- Filling the pump less than the labeled (nominal) volume results in faster flow rate.
- Filling the pump greater than the labeled (nominal) volume results in slower flow rate.

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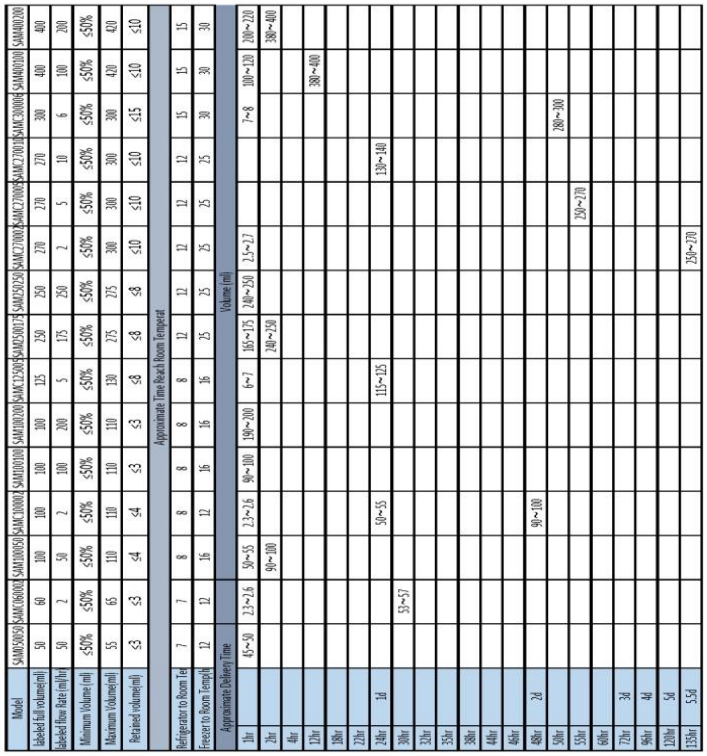

Model	SAM030050	SAM060060	SAM100050	SAM100060	SAM100080	SAM100100	SAM100200	SAM125060	SAM250130	SAM250175	SAM250250	SAM270060	SAM270080	SAM270100	SAM300080	SAM400100	SAM400200
Labeled Full volume(ml)	50	60	100	100	100	100	200	125	250	250	250	270	270	270	300	400	400
Labeled Flow Rate(ml/hr)	50	2	50	2	100	100	200	5	175	175	250	2	5	10	6	100	200
Minimum Volume(ml)	≤50%	≤50%	≤50%	≤50%	≤50%	≤50%	≤50%	≤50%	≤50%	≤50%	≤50%	≤50%	≤50%	≤50%	≤50%	≤50%	≤50%
Maximum Volume(ml)	55	65	110	110	110	110	110	130	275	275	300	300	300	300	300	420	420
Retained volume(ml)	≤3	≤3	≤4	≤4	≤4	≤3	≤3	≤8	≤8	≤8	≤8	≤10	≤10	≤10	≤15	≤10	≤10
Approximate Time Reach Room Temperat																	
Refrigerator to Room Tel	7	7	8	8	8	8	8	8	12	12	12	12	12	12	15	15	15
Freezer to Room Temp(h	12	12	16	16	12	16	16	16	25	25	25	25	25	25	30	30	30
Approximate Delivery Time	Volume (ml)																
1hr	45~50	2.3~2.6	50~55	2.3~2.6	90~100	90~100	190~200	6~7	165~175	240~250	2.5~2.7				7~8	100~120	200~220
2hr			90~100						240~250								380~400
4hr																	
12hr																380~400	
18hr																	
22hr																	
24hr					50~55			115~125						130~140			
30hr			53~57														
32hr																	
35hr																	
38hr																	
44hr																	
46hr																	
48hr					90~100										280~300		
50hr																	
55hr													250~270				
66hr																	
72hr																	
96hr																	
120hr																	
135hr														250~270			

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[Key Symbols]:


Do not reuse

Lot number


Expiry date

Ref number

Sterilised using ethylene oxide


Caution


Keep dry


Consult instructions for use


Do not use if package is damaged

Manufacturer

Authorized Representative in the European Community

[Storage and Shipping]:

1. Do not stack heavy load on top. Keep away from direct sunlight and rain.
2. Fragile. Handle with care.
3. Store in cool, dry, ventilated and clean environment with relative humidity below 80% and free of corrosive gases.

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