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Disposable Infusion Pump

ISO9001 & ISO13485

Instructions for Use

■Major components

Constituted of the subassemblies such as store device, power device, filter, flux-control device and outflux device.

■Applied Scope

Used for injection after operation or the injection of analgesic.

■Function

Capacity: mL

Flow rate: mL/h

■Directions for use

* Open the package, and take out the unidirectional filter and the pump.

* Remove the cap A and cap B, and then fix the unidirectional filter in the intake for the infusion.

* Through the unidirectional filter, inject the prepared infusion into the pump. Then remove the filter and vertically place the pump. Deflate the air in the infusion from the inlet valve.

* Exhaust air in the catheter, when there is the exudation of the infusion in the orifice of outflowing. Then after connecting the catheter for anaesthesia (or needle base), it can be used for injection to the spinal epidural cavity or the vein for a therapy.

* It is allowed to add some more infusion when necessary.

■Caution

* For single use only.

* Sterilized with ETO with a valid period of 2 years.

* There is no microbe and no pyrogen in the product.

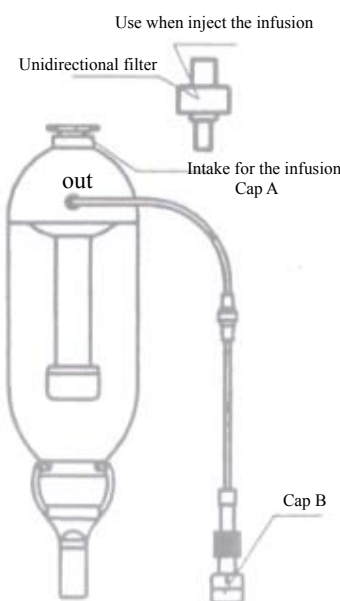
* Don't use if the package is damaged, and discard after use.

* Store at shady, dry and clean place with a normal temperature.

* Lot. No.:

* Mfg. Date.:

* Exp. Date.:



Disposable Infusion Pump Instruction

CE₀₄₃₄

[Name]: Disposable infusion pump

[Specification and Type]:CBI,

CBI+PCA-60/100/150/200/275ml

[Infusion volume]: not less than 85% of nominal capacity

[Characteristics]:

continually dosing + self-control dosing (CBI+PCA);
not only features continually dosing but self-control
dosing, namely , the patient may self control the
dosage depending on ache.

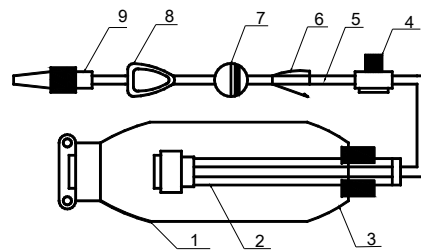
[Product structure]: The main product contains one-way
valve plus drug plant、 elastic force store liquid plant、
liquid drug filter、 limit to velocity of flow plant、 give
liquid by oneself to control plant (or no)、 tube、 conical
fitting and so on.

[Dosing parameters]

Nominal Capacity	Continually dosing volume	Self-control dosing volume	interval
100ml	2.0ml/hour	0.5ml/time	15min
150ml	4.0ml/hour	0.5ml/ time	10min
200ml	5.0ml/hour	0.5ml/ time	10min

[Instruction]:

1. Take infusion pump out of external packing.
2. Remove the skull protector of dosing mouth, clip on the stanching clip, suck the well prepared fluid in an injector, then infuse it in a drug bag via an infusing wye;
3. On the completion of dosing (if any gas found inside pump body, turn the pump upside down such that gas may be exhausted out of the pump), unclose the stanching clip, take down Luer joint cap for exhaust purpose during which the **pressing disc** will not be removed (if exhaust time needs to be shortened, an injector may be employed to such in about 5ml fluid from pump when the handgrip lies down horizontally; infuse the fluid via the wye mouth on the handgrip for an instant exhaust), after observing for 5 minutes, if no air bubble is yet found inside the catheter , remove the **pressing disc** and fasten the clip for standby application.



Drawing 1. Structural presentation of infusion pump

1. Protection bottle
2. reservoir
3. skull protector
4. Infusion wye
5. Major catheter for transfusion
6. Stanching clip
7. PCA filter
8. PCA button
9. Luer joint

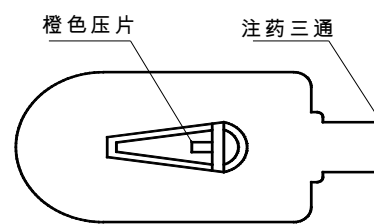


图 2 PCA 按钮示意图

Drawn 2: PCA button schematic drawing

Note: The pressing disc must be removed prior to use, or the flow velocity will be over fast.

The key PCA serves as a function key by which patients may self control the additional dose on the basis of sustained medication (determined with dose per hour) . Such case must be undertaken under the guidance of medical personnel and a treatment card should be filled in so as to understand and analyse the state of illness on the basis of adding times of PCA.

[contraindication]

It is forbidden for application for those people who are allergic to an analgesic or sufferers of a respiratory disease, severe disturbance of circulatory function, shock or severe pain; in these cases it sees no satisfied effects as for common conditions. It should be cautious in application for the elderly.

[adverse side effects]

The instrument should make no direct contact with the patient. The indirect contact with the patient is made through fluid, so the likely adverse side effect is caused by the fluid.

1. Nausea and vomitus: Drugs which include opium like morphine and demerol and non-steroidal nti-inflammatory drugs like Ketorolac are usually applied by the venous system. The nausea and vomitus as the most side effects

are caused by low dosage of opium medicines, which are also likely relating to the operation or the application of other medicines.

2. Pain and itch of skin: In case of the application of morphine hydrochloride, the occurrence rate of pain and itch is dose dependent.

3. Gastrointestinal dysfunction: Patients who take the opium medicines may have ileus which mostly occurs after operations of the epigastrium and lasts for 24 hours. The occurrence of ileus also relates to factors like operation.

[Notices]:

1. Use within the period of validity of sterilization, and package in a damaged condition is forbidden for use.

2. Fluid injected into the reservoir must be diluted by a rational proportion, it is forbidden to inject undiluted fluid directly in vivo to the patient.

3. Inject a specified dosage into pump, and no excess is allowable for fear of affecting the use effect or resulting in rupture of the sacculus.

4. The marked flow rate is tested at room temperature $23^{\circ}\text{C}\pm 2^{\circ}\text{C}$ with the medium of distilled water. The flow rate may vary due to the difference of medicine recipe, concentration, temperature, hanging height of main body, viscosity of fluid and injection pressure, which shall be observed in real time such that grasping the individual differences of patients and understand the demands of each sufferer.

5. In 1 to 2 hours of inception of product application, the flow rate may be faster than the marked (but still falling in the scope as set in product standards), which is determined by physical performances of silica capsule, if any gases found in silica capsule, they could be exhausted after several decades of minutes under the action of silica gel.

6. This product has been subject to Ethylene Oxide sterilization, with validity of 2 years.

7. This product is only for Disposable Use and it shall be melt down immediately after application.

8. You must read and understand the use method and

functions of the product to ensure a safe and effective use.

9. The fluid shall be prepared by combining the flow rate set for this product and the needs of sufferer to prevent the sufferer from unnecessary pain or medical accident due to improper concentration or mixture ratio.

STERILE	EO
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Manufactured by Z. S. Medical Device Co., Ltd

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