Disposable infusion pump
(Light-resistant product which is PVC(DEHP) material)

[Name]: Disposable infusion pump
[Type]: SZB-CX-B、SZB-CZ-B、SZB-DX-B、SZB-DZ-B
nominal volume: 50ml～600ml
nominal flow rate:

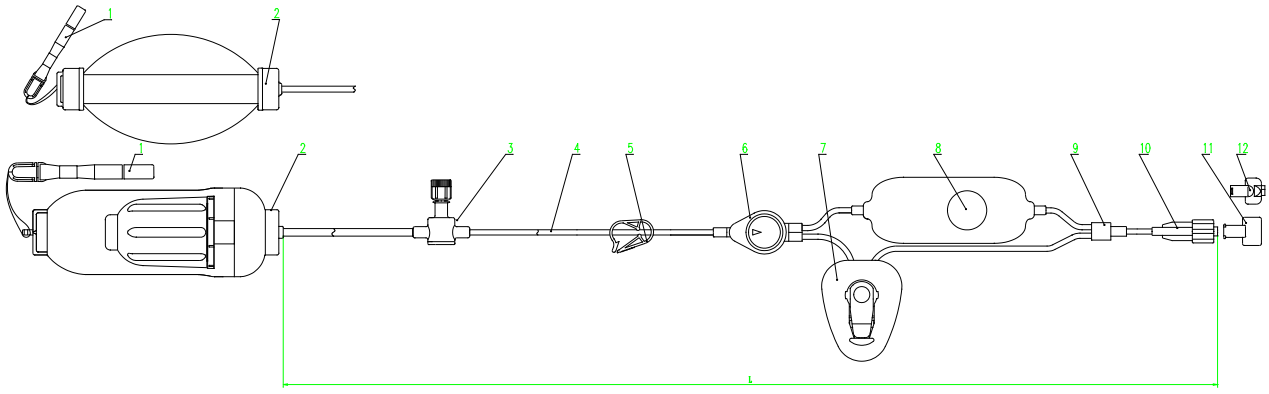
SZB-CX-B、SZB-CZ-B	1 ～ 600ml/h
SZB-DX-B、SZB-DZ-B	0 ～ 600ml/h

nominal bolus volume: 0.5mL/time or 1.0mL/time
nominal bolus refill time: 15min or 7.5min
residual volume: ＜10%

[Product structure and components]: The typical full structure consists mainly of Strap, Silicone liquid storage device(two shapes: soft bottle and hard bottle), Single-way filling port, Tubing, Clamp, Filter, Self-control device(PCA), Multiple regulator device, Transparent three way stopcock, Luer lock, Protective cap.

[Tubing length]: The tubing length L of the product is 110cm±15cm. (See typical structure)

Typical structure



1.Strap 2.Silicone liquid storage device(two shapes: soft bottle and hard bottle) 3.Single-way filling port 4.Tubing 5.Clamp 6.Filter 7.Self-control device(PCA) 8.Multiple regulator device 9.Transparent three way stopcock 10.Luer lock 11/12.Protective cap

***Please note that the shape of parts may change. Self-control device(PCA) and Multiple regulator device are optional parts.**

[Performance characteristics of the device]: It uses the flexibility of the silicon reservoir to allow for a constant minimal drop control through the capillary catheter, in order to achieve for continuous (fixed or adjustable) flow and/or for bolus applications.

[CMR/endocrine-disrupting substances]: This product has CMR substances precipitation: DEHP.

[Clinical benefits]：

1. Product use time：≤7day(if＞7 day, the risk is not evaluated)

2. The mean flow rate shall have a tolerance of ±15% compared to the nominal flow rate. The adjustable flow rate shall have a tolerance of ±20%. At least 80% of the nominal volume shall be delivered at an instantaneous flow rate within ±50% of the nominal flow rate.

[Device connection instructions]: All device fittings of this medical device can be connected to other medical devices or accessories shall conform to ISO 80369-1, ISO 80369-6 or ISO 80369-7, as appropriate for the intended application.

[Sterile]: The product is sterilized by EO

[Shelf life]: 5 years.

[Target population]: Adults and children

[Intended user]: The intended user is qualified trained physician.

[Intended purpose]: Disposable infusion pump is used for continuous (fixed or adjustable) and/or self-control infusion in clinical infusion therapy. It is applicable to the administration of analgesic drugs for intraoperative, postoperative, labor, as well as analgesic chemotherapy for cancer patients.

[Instruction for use]:

1 - First inspect the integrity of the package, and then take product from the sterile package, and inspect the integrity of product.

2 - Verify clamp is closed, remove the cap from the filling port and fill the balloon reservoir with the drug using a syringe (we recommend using a luer lock type syringe).

3 - When filling drug, please make sure there is no air in syringe, then infuse the medicine. (The balloon reservoir can exhaust itself. If there is few air, it can exclude after a while later.)

4 - When balloon reservoir is filled up with the correct liquid volume, disconnect the syringe and close the filling port with the cap.

5 - After medicine has been added, open the clamp, remove the yellow card from the self-control(PCA), and press the PCA button 1~2 times, in order to speed up the liquid flow through the tubing. When the medicine flows from the end, close the clamp and screw the tubing end with the protective cap.

6 - The self-control device(PCA) is the function button that the patient can use to control the additional medicine when in continuous medicine infusion position. By pressing the PCA button, the patient can add a limited quantity of medicine in respect with doctor’s instruction, as he needs.

7 - The multiple regulator device should be used only by qualified trained physician, the key should be keep by specially-assigned person.

8 - To administer the drug to the patient, check there is no bubbles in the infusion line, remove the protective cap, attach the connector to the patient’s line and open the clamp.

9 - The flow rate will be a little faster (within the standard scope) during the 1~2 first

hours of use. That is due to the physical characteristic of the silicone material.

10 - In the test conditions, temperature(23±2)℃, relative humidity(50±5)% and atmospheric pressure of 86 KPa~106KPa, using purified water or distilled water for level infusion(the balloon reservoir and the end Luer lock is at the same level), mean flow rate infusion rate accuracy is±15%, the adjustable flow rate shall have a tolerance of ±20%.

11 - Flow rate may be affect due to:

1) Fill Volume

When using, please add the liquid according to the nominal volume, over or less of fill volume will lead to inaccurate infusion flow.

2) Viscosity and/or drug concentration

The flow rate of the product is calibrated with purified water or distilled water as the medium, infusion of overly viscous liquid will result in a slower flow rate.

3) Temperature

The flow rate of the product is calibrated in the temperature of (23+2)℃, the flow rate of the product will be faster when the operating temperature is high, slower conversely.

4) Atmospheric pressure

The flow rate of the product is calibrated under a standard atmospheric pressure condition, the flow rate of the product will be faster when atmospheric pressure is below standard or slower conversely.

5) Level infusion

The normal use of the product should be level infusion, when the balloon reservoir is higher than the end outlet will lead to a faster flow, slower conversely.

6) Storage

The product should be used in time after the fill volume, the flow rate of the product will be slower after a long time no use after filling.

[Indications]:

It is applicable to the administration of analgesic drugs for intraoperative and postoperative analgesia and labor analgesia, as well as analgesic chemotherapy for cancer patients.

[Contra-indications/Limitation]:

1 - This product is not intended for infusion of blood, blood products, lipids, fat emulsions, or Total Parenteral Nutrition (TPN).

2 - This product is forbidden for intramuscular injection.

3- The Newborns, pre-adolescent men, pregnant women and other high-risk groups should try to use other substitute products.

[Complications / Risks]:

Complications are different because of the different drugs used, mainly manifested in analgesia insufficiency, nausea and vomiting, lethargy, urinary retention, serious lower limb skin itching, or even lower limb numbness symptoms.

[Adverse Event Feedback and Measures]: A notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

[Notices and 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 - Check for package integrity before opening. Do not use if package is damaged.

3 - All components are sterile, non-toxic, non-pyrogenic.

4 - For single use only, discard after use.

5 - Please remove the yellow card on the PCA button before use.

6 - The scale on the pump housing is for reference only.

7 - Read all instructions before use for patient safety.

8 - Infuse the prescribed dosage of the product, over or less infusion would affect the result of the cure.

9 - Stored in a clean environment with good ventilation and no corrosive gases, avoid direct sunlight.

10 - With ISO80369-6 mark indicates that the connection port of the product complies with the ISO80369-6 standard, and with ISO80369-7 mark indicates that the connection port of the product complies with the ISO80369-7 standard, please be aware of the matching use.

11 - For clinical use, please inject the liquid according to the marked volume of the product.

12 - Light-resistant between the scope 290nm~450nm, the tubing should be less than or eaqul to 15%, other parts should be less than or eaqul to 35%.

13 - **Warning:** In order to meet the requirements of environmental protection, the used products should be collected in a centralized manner according to the regulations of the local medical waste disposal department. When medical waste is destroyed, the environment must not be damaged.

14 - **Warning:** After the clinical procedure is complete, dispose the product in accordance with environmental protection and local medical device waste regulations.

15 - **Warning:** Do not use if the product is contaminated or damaged.

[Key symbols]:

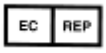
MD	Medical Device		Do not use if package is damaged		
	Single Sterile barrier system	STERILE EO	Sterilized using ethylene oxide		
LATEX	LATEX FREE	PHT DEHP	Contains DEHP		
UDI	Unique Device Identifier	CE 0123	European Conformity		
	Consult instructions for use		Caution	REF	Catalogue number
	Keep away from sunlight		Do not re-use	LOT	Batch code

	Manufacturer		Keep dry		Date of manufacture
	Authorized Representative in the European Community				Use-by date

[Storage and shipping]:

1. Stored in a clean environment with good ventilation and no corrosive gases.
2. Fragile, handle with care.
3. Avoid heavy pressure, direct sunlight, get wet in rain and snow, high temperature during transportation.

 **Zhejiang Runqiang Medical Instruments Co., Ltd.**
599 Ruifeng Street, Gaozhao District, Xiuzhou District 314031 Jiaxing City, Zhejiang Province PEOPLE'S REPUBLIC OF CHINA
Tel: +86-573-88106708 Fax: +86-573-88110618

 **Shanghai International Holding Corp. GmbH (Europe)**
Eiffestrasse 80, 20537 Hamburg Germany
Tel: +49-40-2513175 Fax: +49-40-255726