[Product Name]
Infusion Pump

[Product Description]
Infusion Pump has a specially designed balloon-like reservoir that is filled with the drug or fluid intended for infusion. It exerts mechanical pressure thereby administering the liquid based medication through a flow restrictor tube creating the pre-determined flow rate. The mean flow rate of the device (CBI type, UCBI type, PCA type) shall have a tolerance of ±10 % compared to the nominal flow rate. The adjustable flow rate of the device (MCBI type, UMCBI type, MP type) shall have a tolerance of ±15 % compared to the nominal flow rate.

[Intended Use]
It is used for clinical infusion of liquid medicine.

[Type(s)/Specification(s)]
See attachment 1

[Indication]
Used for patients requiring intravenous, percutaneous, subcutaneous, intraoperative sites administration of medications. Medications that can be infused include analgesics, chemotherapeutics, antibiotics, antiviral drugs and infusion for re-hydration.

[Contraindications]
1) People allergic to the medication that is supposed to be infused, e.g. analgesic drugs.
2) People with severe disorder of respiratory and circulatory functions, shock or coma.
3) Cachexia patients.
4) Use for patients who do not possess the mental, physical or emotional capability to self-administer their therapy or who are not under the care of a responsible individual.

[Infusion Volume]
Not less than 90% of nominal volume.

[Tubing Length]
The total length of the infusion pump shall not be less than 110cm.

[Component(s)]

Type		Component
CBI		Bottle, protective cap, elastic reservoir, a filling port with check valve, liquid medicine filter, flow restrictor, clamp, tubing, connector and connector protector cap
MCBI	4 flow rate	Bottle, protective cap, elastic reservoir, a filling port with check valve, liquid medicine filter, flow restrictor, flow rate regulating device, clamp, tubing, connector and connector protector cap
	15 flow rate	
UCBI		Avoid light bottle, protective cap, elastic reservoir, a filling port with check valve, liquid medicine filter, flow restrictor, clamp, tubing, connector and connector protector cap
UMCBI	4 flow rate	Avoid light bottle, protective cap, elastic reservoir, a filling port with check valve, liquid medicine filter, flow restrictor, flow rate regulating device, clamp, tubing, connector and connector protector cap
	15 flow rate	
PCA		Bottle, protective cap, elastic reservoir, a filling port with check valve, liquid medicine filter, flow restrictor, bolus device, clamp, tubing, connector and connector protector cap
MP	4 flow rate	Bottle, protective cap, elastic reservoir, a filling port with check valve, liquid medicine filter, flow restrictor, bolus device, flow rate regulating device, clamp, tubing, connector and connector protector cap
	15 flow rate	

CBI: Continuous Basal Infusion Pump; MCBI: Multi-rate CBI
UCBI: Avoid light CBI (U:UV); UMCBI: Avoid light multi-rate CBI (U:UV)
PCA: Continuous Basal Infusion + Patient Controlled Analgesia Pump; MP: Multi-rate PCA

[Features]
1) The CBI pump (CBI type, UCBI type, MCBI type, UMCBI type) is controlled by a micro-flow restrictor tube to achieve the purpose of pain relief on demand. A liquid medicine filter is installed at the outlet of the tube to prevent the entry of particles into the patient's body.
2) The PCA type and Mp type has an additional bolus function, so that the patient can self-administer an extra dosage according to pain situation.
3) The Multi-rate type (MCBI type, UMCBI type, MP type) has an additional flow rate regulating device providing different flow rates to choose from. The flow rate can be adjusted at any time during the infusion.

ATTENTION: The adjustment of the flow rate may only be carried out with appropriate clinical approval.

[Instructions for filling and priming (use aseptic technique)]
1) Tear off the external packing and take out the infusion pump.
2) Remove cap from fill port and retain for later use.
3) The pump can be filled with a syringe or other filling device. Remove all air from the filling device and attach it securely to the fill port.
4) Fill the infusion pump with 10 ml of diluent first.
5) Remove the connector protector cap from the patient end of the tubing. Open the clamp in order to start priming. Fluid will begin to flow and fill the tubing. When all air has been expelled, replace the cap at the patient end and close the clamp. For the CBI type and UCBI type, it takes about 0.5min from the beginning of exhausting to the exhausting completed. Within 3 minutes; For the PCA type and MP type, the orange pressing disc keep it on during the exhaust process. It takes about 8 minutes roughly, and the maximum is 10 minutes; For the MCBI type and UMCBI type, the exhausting time was depended on the maximum flow rate. Like, the 1-2-3-4ml/h, 2-3-4-5ml/h, 2-4-6-8ml/h three specifications, it takes 4-7min. The maximum duration is within 10minutes generally. Then switch to the proper flow rate by clockwise rotation. (Note: The arrow should point to the maximum flow rate during exhausting. Otherwise, it is potential risk that the bubble exists in flow restrictor tube.)
6) Fill the remaining volume up with diluent and medication. Push down the syringe plunger until the volume is dispensed. Repeat as necessary. At completion, the medication will fill the tubing and reservoir.
7) Remove filling device from the fill port. Screw on the cap again.
8) Label the infusion pump with appropriate pharmaceutical and patient information.
9) PCA type and MP type: The orange pressing disc on the PCA button must be removed prior to use, otherwise flow rate will be too fast (see Figure 2). The PCA button allows patients to self-administer an extra dosage (bolus) in addition to the continuous drug infusion. Such operation shall be conducted under the guidance of medical personnel and the number of bolus doses shall be recorded in a treatment card to monitor the patient's pain level on the basis of given bolus doses.
10) The Multi-rate type (MCBI type, UMCBI type, MP type): Make sure that the flow rate regulating device is pointing to the correct flow rate before starting infusion. The selected flow rate is indicated by an arrow (see Figure 3).

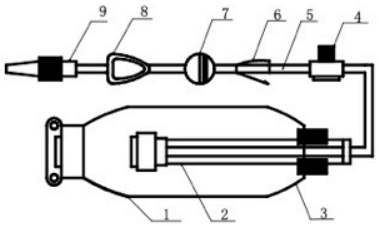

Figure 1: Schematic drawing of infusion pump
(1 Bottle; 2 Silica gel reservoir; 3 Protective cap cover;
4 A filling port with check valve; 5 Tubing; 6 Clamp; 7 Filter;
8 PCA button (PCA type and MP type only) or flow rate regulating device (Multi-rate type only); 9 Connector)

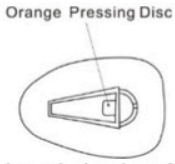

Figure 2: Schematic drawing of PCA button
Note: The orange pressing disc must be removed prior to use, otherwise flow rate will be too fast.

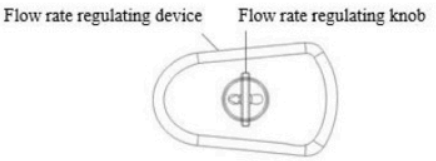

Figure 3: Schematic drawing of flow rate regulating device
Note: The flow rate indicated by the arrow is the selected flow rate.

[Starting Infusion (use aseptic technique)]
1) Allow the device to warm to room temperature before use, especially if it has been stored in the refrigerator or freezer.
2) Infusion should preferably be started 0-8 hours after filling. Prolonged storage of a filled pump beyond 8 hours may result in a longer delivery time.
3) Verify that the clamp on the tube is closed.
4) Clean patient access site as directed by the hospital/healthcare provider. Connect the tubing of the pump to the patient access site.
5) Start infusion by opening the clamp.

[Warnings and Precautions]
1) Do not use the product if expiry date has passed.
2) Do not use the product if the packaging has been opened or damaged.
3) The liquid-based drug filled into the reservoir must be diluted according to pharmaceutical manufacturer's instructions. Do not use liquid-based drugs without diluting them prior to injection into the patient´s body.
4) It is the responsibility of the user to ensure that the medication is prepared and administered in accordance with the drug manufacturer's instructions. Fill the drug liquid into the pump based on the specified dosage.
5) Infusion of blood and blood products is prohibited.
6) Do not infuse critical or life-supporting medications whose stoppage, interruption, over-delivery or under-delivery would likely cause serious injury or death.
7) Do not infuse any solution that is not compatible with the materials of the device (silicone, medical PVC, ABS). Refer to the pharmaceutical manufacturer's precautions and guidelines to ensure that the medications used will not interact with the device and possibly cause damage or leakage.
8) Do not exceed the maximal filling volume of the pump to avoid negative therapy effects or the breakage of the reservoir.
9) Avoid (soapy water, alcohol, etc.) cleaning agents contacting the filter and causing the filter to leak
10) The stated flow rate was tested at room temperature (23 ± 2°C) using water for injection. The flow rate may vary due to the differences in medication's composition, concentration, temperature, hanging height in relation to the patient, viscosity of the fluid as well as injection pressure and shall be observed in real time under given individual circumstances.
11) Within first 1-2 hours after start of infusion, the flow rate may be faster than stated.
12) Remaining air in the reservoir will be discharged automatically within several minutes due to silicone's physical property.
13) Do not fill the device with less than the nominal volume as that generally results in a lower flow rate.
14) Do not fill the device with more than nominal volume as that generally results in a faster flow rate or can cause breakage of the reservoir.
15) This product has been sterilized by ethylene oxide with shelf life of 5 years.
16) This product is for single use only. Please discard it immediately after use in accordance to local regulations.
17) It is mandatory to fully understand the mode of operation of the product before use to ensure safety and efficiency of use.
18) Consider the flow rate specified for this product and the prepared medication required by the patient to prevent the patient from unnecessary pain or a medical accident due to improper concentration or mixture ratio.
19) Not for neuraxial application connect.
20) This product should be used by medical staff. Non-medical staff should not use this product to avoid accidents.
21) Please inform the manufacturer and competent authority in case of any adverse events related to the device occur.

[Shelf-life]
Five years

[Sterilization Method]
Ethylene oxide

[Storage and Transport Conditions]
1) Store the product in a cool, dry and well-ventilated place and take care to moisture prevention.
2) Protection from the direct sunlight.

[Production Date]
See on the package.