

**DISPOSABLE INFUSION PUMP**

**DECEMBER - 2008**



**MEDICAL EQUIPMENTS**

**DISPOSABLE INFUSION PUMP**

Quality System Standard applied: **ISO 9001-2000**

Product Standard applied: **ISO 13485/2003**

CE Certified 94/42/EEC – Annex II section 3

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# COMPANY

The Company is incorporated with the joint investments of California International Co. Ltd. of USA and some domestic enterprises. It is an enterprise specially engaged in the development and production of hi-tech medical software and medical equipment. In May of 2000, the Group established itself in Zhuhai Hi-Tech Achievements Industrialization Base with an initial investment value of USD 12 million.



**Office**

Since its incorporation, The Company has swiftly grown into a model enterprise in the industry of medical apparatus in China by way of relying on technology and talented human resources and by following the concept of perfectionism, creative innovations and strenuous efforts. At the early stage of its incorporation, the Co. introduced complete sets of sophisticate technologies and modernized production lines from abroad and built up the purification workshop up to the 10,000 - class standards.

The Co. also utilizes the generally accepted testing approaches in the world to enable each link of the processes from R&D, designing, production and inspection to meet the international standards. The disposable infusion pumps are the first generation of products jointly developed and manufactured by The Company and some domestic and foreign medical specialists. The technical performances and parameters of some key parts and components meet or exceed the international advanced level. Through the clinic application, these products have won favourable remarks from the broad masses of medical workers as well as the patients, which fully demonstrates the outstanding business strength of The Company and its persistent efforts in relying on technologies and continuous innovations.



**10,000 Class  
Purification workshop**



**ETO Sterilization Room and  
Lab Center**

In March of 2002, the Board of Directors of The Company decided to make an additional investment of USD 25 million in the incorporation of The Company Group which is to be built into a modern conglomerate integrating R&D, production and marketing of products by undertaking the development of the second generation of products with higher technological contents and larger added values. In May of 2003, the investment to the Group will be accrued up to USD 37 million, and the construction project of The Company Technology Park T with land coverage of 15000 square meters will be completed.

Up to the present day, The Company has established comprehensive marketing networks and after-sale service systems in China, which further facilitates and improves the promotion of the products and services. Ever since, The Company has been following the concept that "Technology is to be human-oriented", and completed the establishment of a Product Software R&D Centre with powerful technological strength by gathering large numbers of elite professionals in the field of medical software development, bio-medical science and polymer compounds as well as many specialists in various engineering technologies, including over 80 senior experts in the five categories of mechanic designing & manufacture, chemistry, polymer technology, mechanic and electric integration, software development.



**Employee Dormitory**



**Multifunctional Building**

The senior engineers of the Group engaged in the R&D of medical polymer compounds are well-known specialists in bio-medical science in this country. They have rich and profound experience in the development of various polymer materials for special uses. In the meantime, the Group also possesses a team of senior engineers in cybernetics and engineering, who are well equipped with the capability to design and develop sophisticate medical apparatuses.

## DISPOSABLE INFUSION PUMP

The disposable infusion pump is a safe, effective and durable micro injector, which is driven by the balanced contraction of the medical silicone rubber reservoir, with the flow rate controlled by the flow rate controlling tubing. Besides the continued infusion, the product allows the patients to administer their own pain relief by pressing the button of PCA (Patients Controlled Analgesia) set. The product is mainly used in the analgesia after surgical operations or childbirth, in the therapy of chronic pains, in the analgesia for malicious tumor as well as some other therapies that involve the self-controlled micro injections. Currently there are 39 models of this product to meet the different needs of the patients.



### **Easy to operate**

The doctors may prescribe the dosage and choice the proper model of the Company infusion pump for different patients. When using the pump, besides the background continuous infusion, the patients can press the button of PCA (Patients Controlled Analgesia) set to administer their own pain relief when they are having pain.

### **More options**

Company disposable infusion pump can provide as much as injections for five days, ranging from 0.2ml/hr to 16ml/hr. It can be used for intravenous (IV) injection or epidural injection.

### **More reliable and precise**

The Disposable Infusion Pump contains a silicone rubber reservoir, together with plasticised PVC tubing, ABS tubing connector. The fluid path is latex free.

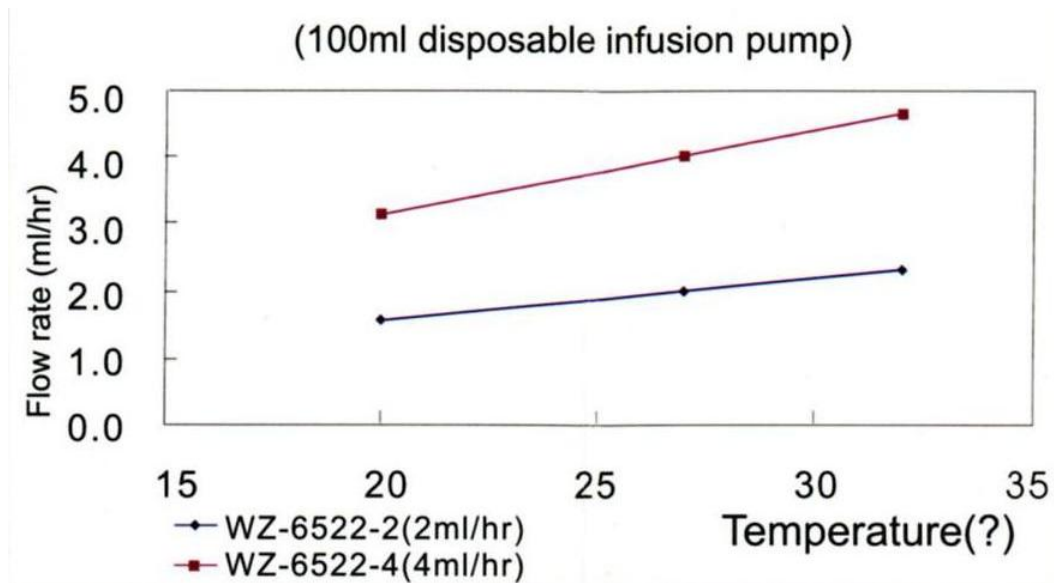
--- The flow rate controlling tubing (capillary tubing) is made by introducing the advanced technology of USA, which enables the accuracy of flow rate control to be within  $\pm 10\%$ .

--- The reservoir is made of medical silicone rubber material. With the balanced contraction of the reservoir, it provides a balanced pressure for continuous infusion.

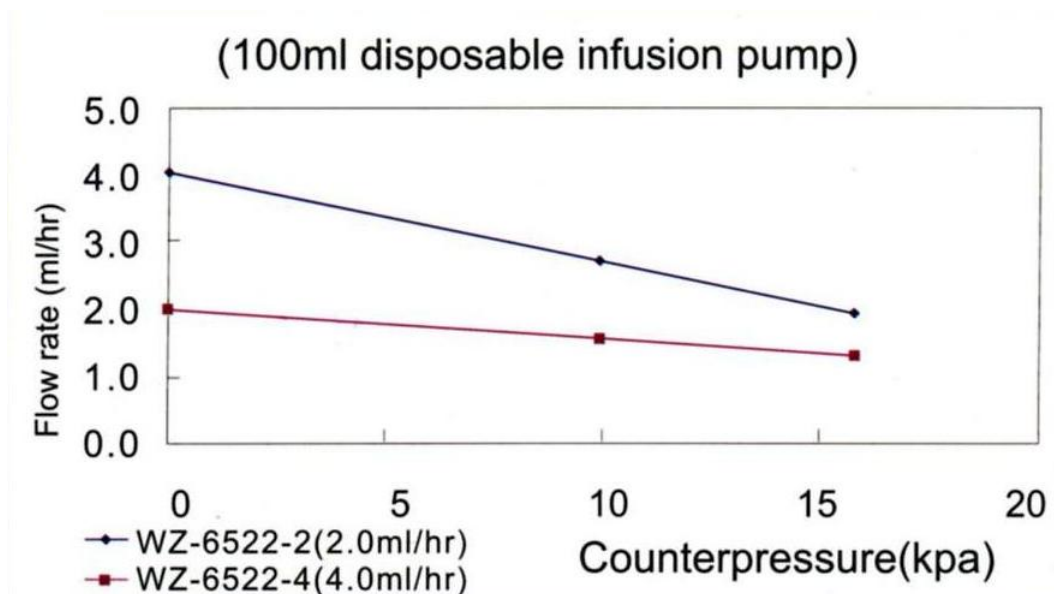
--- The catheter is made of medical plastic PVC materials, with the interior in triangular shape. It is good at resisting pressure and bends, and will not be blocked even if twisted.

--- The filter can effectively screen off the air bubbles, germs and particles of foreign substances.

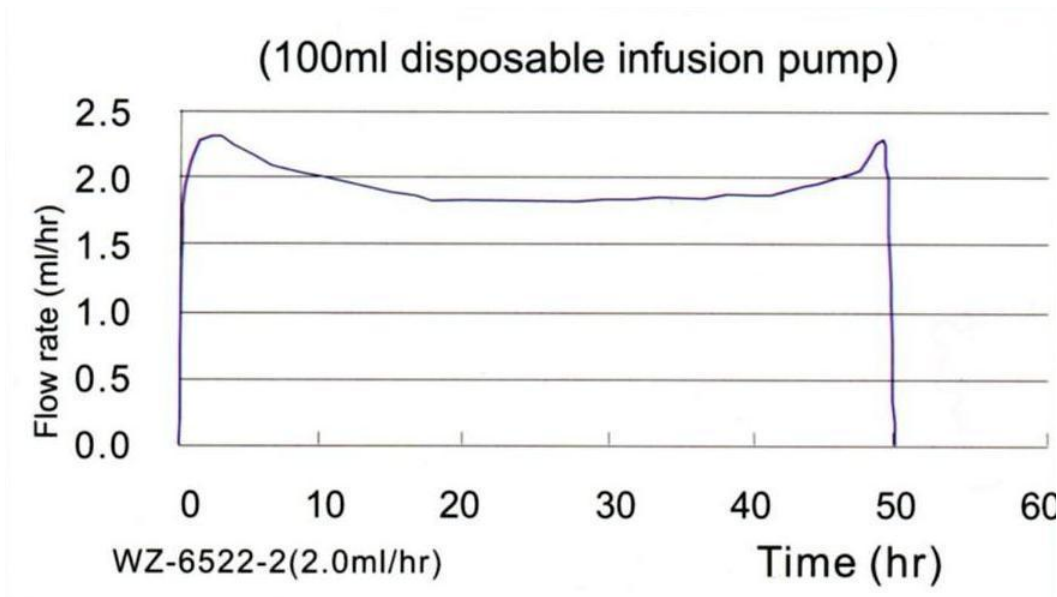
**The following graph indicates the regulation of flow rate changes caused under different temperatures.**



**The following graph indicates the regulation of flow rate changes under different pressures at 23°C**



**The following graph indicates the regulation of flow rate changes during the infusion process**



**Frequently Asked Questions**

**1. How does the pump work?**

- The Company Disposable Infusion Pump is driven by the balanced contraction of the medical silicone rubber reservoir, with the flow rate controlled by the Flow Rate Controlled Tubing. When the pump starts work, a small dose of the medication will be continuously injected into the patient's body.
- The pump can be used for intravenous (IV) injection and epidural injection
- The pump can provide as much as injection for five days, ranging from 0.2ml/hr to 16ml/hr
- The accuracy of flow rate control is within + - 10%.

**2. What is the benefit of using the Company Disposable Infusion Pump?**

Doctors traditionally treated the pain control with intramuscular injections of analgesics. Doses of intramuscular analgesics were often inadequate and spaced far apart enough so that the medication wore off before the patients received the next dose. Pain would usually build up before the next dose of pain reliever was given.

If the patients use the Company Disposable Infusion Pump to control their pain, it can continually micro inject the pain medication into the patient's body. Moreover, when the patients feel pain or discomfort, they can self-control the additional doses by pressing the button of PCA administration set instead of having to call the nurse and waiting for the pain relief to be given to them.

**3. What is PCA and the PCA administration set?**

The PCA is Patient-Controlled Analgesia. It has become an acceptable and highly effective means of relieving post-operative pain.

The PCA administration set allows the patients self-administer the additional medication. When patients feel pain and discomfort, they can press the button of the PCA administration set. A small dose of the additional medication will be injected into patients' body.

**4. Is the Basal + PCA bolus series infusion pump appropriate for children?**

If a child is mature enough to understand that after pressing the button the pain is relieved, then he may be a candidate for the pump.

There is no set age when a child can routinely be given the pump, but it has been successfully used for post-surgical pain control in children as young as 6 and 7

### **5. Can the patients become addicted?**

No! Studies have shown that patients using PCA often use less medication during their hospital stay. Usually a patient uses the machine for only a few days, and then oral medication is enough to relieve his pain.

### **6. Are there any side effects?**

As there is with any medication, patients may feel some side effects. A small number of people feel nauseated, have some itchiness, or have difficulty passing urine. If any of these symptoms occur, the patient should notify his nurse.

## **Patient's Guide to Pain Control After Surgery**

### **1. Why is pain control so important?**

In addition to keeping you comfortable, pain control can help you recover faster and may reduce your risk of developing complications after surgery. If your pain is well controlled, you are likely to start walking and doing your breathing exercises sooner. These activities will help you get your strength back. You may also avoid some problems, such as pneumonia and blood clots, that can occur after surgery.

### **2. What is the role of the anaesthesiologist in controlling your pain?**

Working with you, an anaesthesiologist will choose the type of pain control that you will receive after surgery. Anaesthesiologists understand the actions of potent analgesic (pain-killing) drugs and special nerve block techniques. Before the anaesthesiologist recommends a treatment, he or she will review your medical history, check the results from your laboratory tests and physical exam, and consider the type of surgery you are having. Types of pain-control treatments are described below.

After surgery, you will be visited daily by a pain-specialist anaesthesiologist and a clinical nurse specialist who will make sure that you are comfortable, adjust your therapy if needed, and monitor you for any side effects.

### **3 Types of pain control treatments**

The anaesthesiologist will recommend one of several types of pain-control treatments. You may also receive a combination of treatments, depending on your needs and the type of surgery you are having.

All of these treatments are safe; however, side effects of itching, nausea, and drowsiness can occur. These side effects are common with narcotic pain medicines regardless of how the medicines are given.

Don't worry about getting "hooked" on pain medicines. Studies show that this kind of addiction is very rare after surgery (unless you currently have a drug abuse problem). Please discuss any concerns you may have with your anaesthesiologist before your surgery.

### **Patient-controlled Analgesia (PCA)**

The "basal +PCA bolus" series pumps continuously injects pain medicine into an intravenous (IV) catheter (small plastic tube) that has been inserted into your arm. When you still feel pain, you can simply press a button on PCA administration set to request additional pain medicine. In this way, you receive prompt pain relief when you need it.

You will not be able to give yourself too much pain medicine because the amount is limited to the specification of the disposable infusion pump.

## Patient-controlled Epidural Analgesia

Patient-controlled epidural analgesia uses a "basal +PCA bolus "series pumps to deliver pain-control medicine into a catheter placed into your back.

The catheter will be inserted into the "epidural space," the area between the vertebrae and a sac filled with spinal fluid. The pump will be attached to the catheter so that you can give yourself additional pain medicine by pressing the button on PCA administration set.

Patients who receive epidural analgesia typically have less pain when they take deep breaths, cough, and walk, and they may recover more quickly. For patients with medical problems such as heart or lung disease, epidural analgesia may reduce the risk of serious complications such as heart attack and pneumonia.

Although side effects from epidural analgesia are uncommon, they can occur. Most of these are minor and short term, and may include headache, lowered blood pressure, or numbness and weakness in your legs. All of these side effects can be treated and managed.

## Nerve blocks and regional anaesthesia

Pain relief in a specific part of your body may be provided by local anaesthetics using a regional or local nerve block. For example, your dentist uses a nerve block to numb your mouth before drilling your teeth.

Your anaesthesiologist may recommend performing your surgery using a nerve block or regional anaesthesia rather than general anaesthesia. The part of your body that will be operated on will remain numb for a period of time after surgery, but the rest of your body will be unaffected.

Nerve blocks and regional anaesthesia have fewer side effects than general anaesthesia, which can cause nausea and vomiting, lingering drowsiness and a sore throat from a breathing tube.

Often, patients who receive this type of pain control require little or no additional medications to feel comfortable. With some types of surgery, such as lower abdominal, gynaecological, or orthopaedic surgery, epidural anaesthesia may be recommended. The epidural catheter can be maintained to relieve pain after surgery.

## 4 Pain pills

In the past, patients were only given pain pills when they asked for them. This process often delayed the delivery of pain medicine. As a result, the patient's pain often got worse. Today, pain pills are typically ordered on a schedule. Once the infusion pump has been stopped, your nurse will give you the pain pills at scheduled times.

Additional medicine will be ordered in case the scheduled medicines do not control your pain. The doctors and nurses will ask you how the pain medicine is working and change the medicine, its dose, or its timing if needed.

## 5 What can you do to help keep your pain under control?

Most importantly, you can help the doctors and nurses "measure" your pain. While you are recovering, your nurses will ask you to rate your pain on a scale of 0 to 10 with "0" being "no pain" and "10" being "the worst pain you can imagine." Reporting your pain as a number helps the doctors and nurses know how well your treatment is working and whether to make any changes. Don't worry about being a "bother." Your doctors and nurses want and need to know about any pain that is not under control.



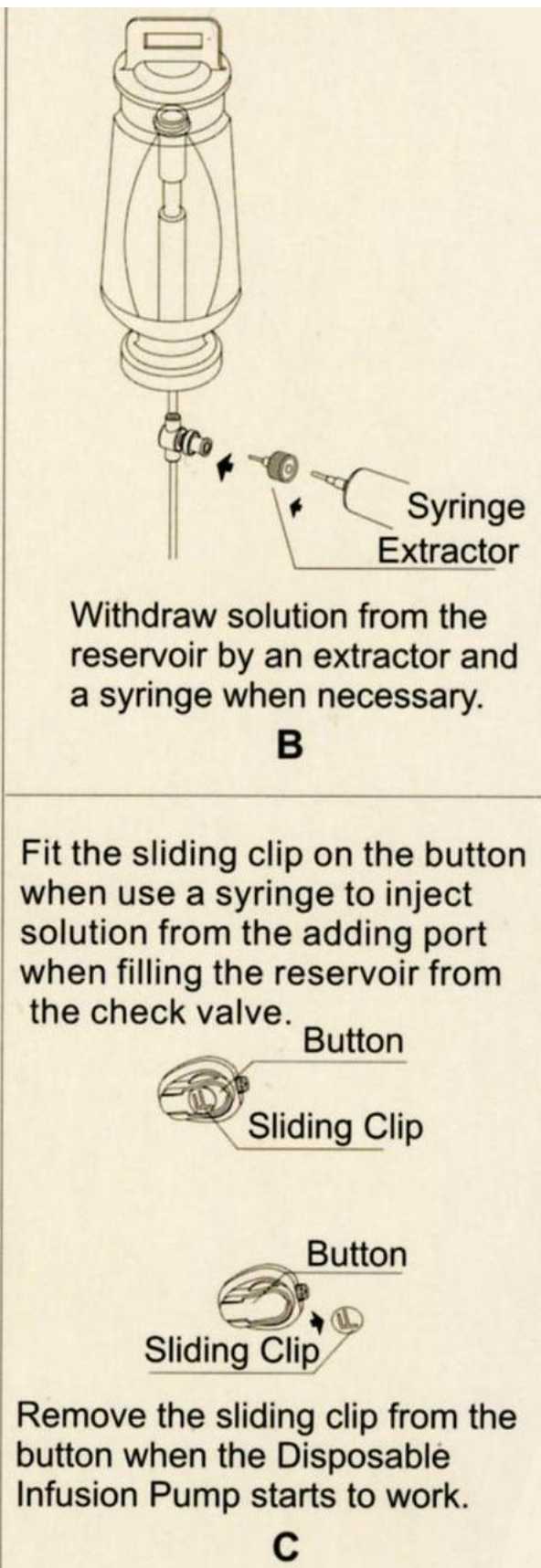
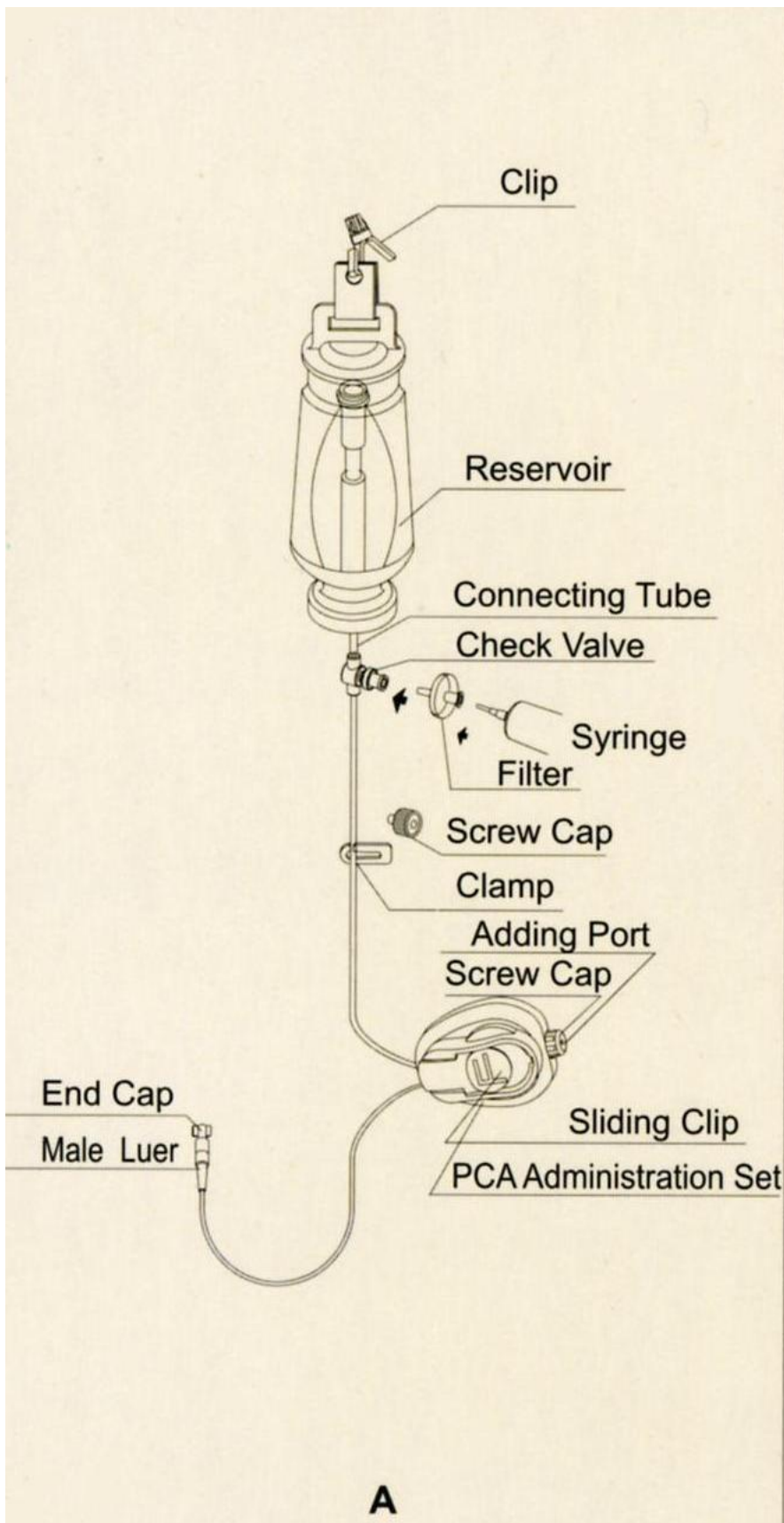
## Specification list

### A. Basal Model

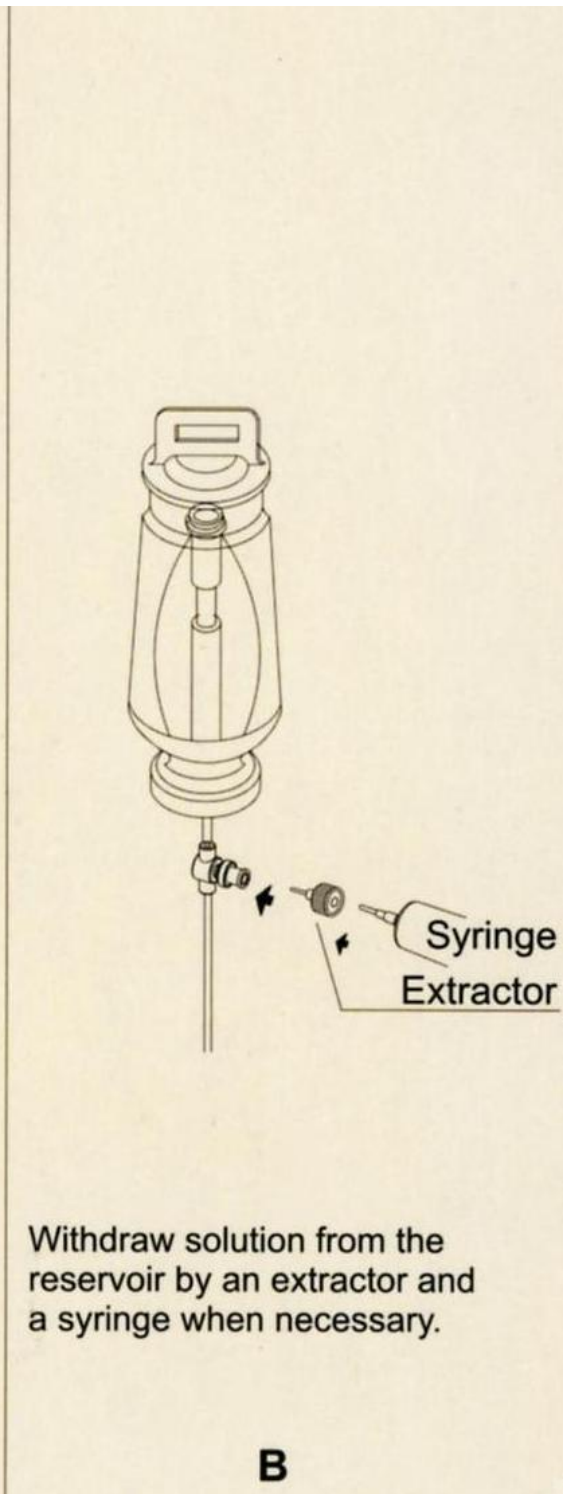
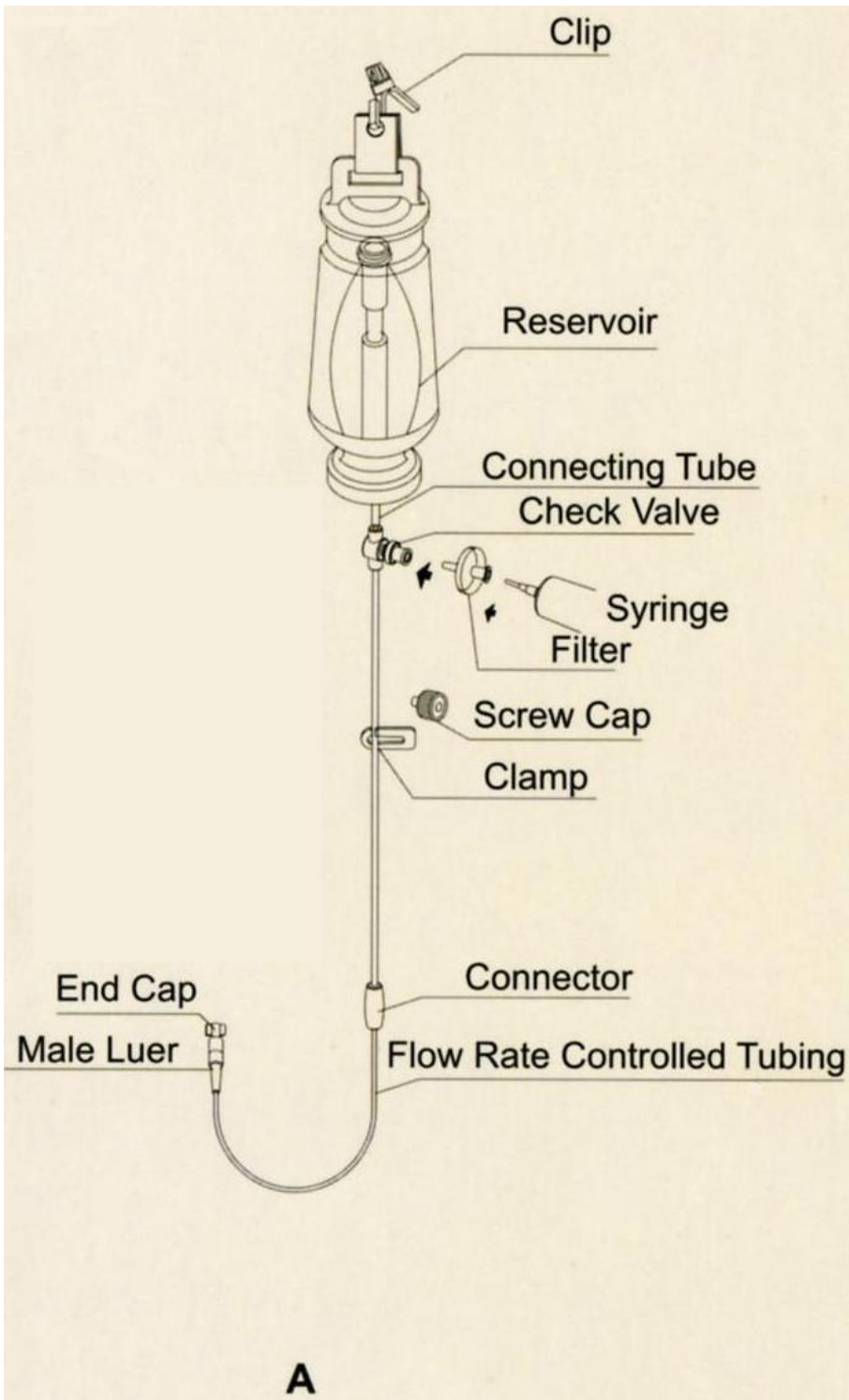
<u>Specification</u>	<u>Maximum Capacity</u>	<u>Basal Rate</u>	<u>PCA Bolus</u>
WZ-6522-1	100 ml	1.0 ml/hr	-----
WZ-6522-2	100 ml	2.0 ml/hr	-----
WZ-6522-3	100 ml	3.0 ml/hr	-----
WZ-6522-4	100 ml	4.0 ml/hr	-----
WZ-6522-5	100 ml	5.0 ml/hr	-----
WZ-6522-6	100 ml	6.0 ml/hr	-----
WZ-6522-7	100 ml	7.0 ml/hr	-----
WZ-6522-8	100 ml	8.0 ml/hr	-----
WZ-6522-9	100 ml	9.0 ml/hr	-----
WZ-6522-10	100 ml	10.0 ml/hr	-----
WZ-6522-01	275 ml	1.0 ml/hr	-----
WZ-6522-02	275 ml	2.0 ml/hr	-----
WZ-6522-03	275 ml	3.0 ml/hr	-----
WZ-6522-04	275 ml	4.0 ml/hr	-----
WZ-6522-05	275 ml	5.0 ml/hr	-----
WZ-6522-06	275 ml	6.0 ml/hr	-----
WZ-6522-07	275 ml	7.0 ml/hr	-----
WZ-6522-08	275 ml	8.0 ml/hr	-----
WZ-6522-09	275 ml	9.0 ml/hr	-----
WZ-6522-013	275 ml	13.0 ml/hr	-----
WZ-6522-016	275 ml	16.0 ml/hr	-----

### B. Basal + PCA Bolus Model

<u>Specification</u>	<u>Maximum Capacity</u>	<u>Basal Rate</u>	<u>PCA Bolus</u>
WZ-6523C-1	100 ml	0.2 ml/hr	0.2ml/15min
WZ-6523C-2	100 ml	1.0 ml/hr	0.5ml/30min
WZ-6523C-3	100 ml	1.0 ml/hr	0.5ml/15min
WZ-6523C-4	100 ml	2.0 ml/hr	0.5ml/15min
WZ-6523C-4.25	100 ml	0.5 ml/hr	0.5ml/8min
WZ-6523C-5	100 ml	1.0 ml/hr	1.0ml/15min
WZ-6523C-6	100 ml	2.0 ml/hr	1.0ml/15min
WZ-6523C-7	100 ml	3.0 ml/hr	1.0ml/15min
WZ-6523C-8	100 ml	4.0 ml/hr	1.0ml/15min
WZ-6523C-9	100 ml	5.0 ml/hr	1.0ml/15min
WZ-6523C-10	100 ml	2.0 ml/hr	2.0ml/15min
WZ-6523C-13	100 ml	5.0 ml/hr	2.0ml/15min
WZ-6523C-02	275 ml	1.0 ml/hr	0.5ml/30min
WZ-6523C-04	275 ml	2.0 ml/hr	0.5ml/15min
WZ-6523C-05	275 ml	3.0 ml/hr	0.5ml/15min
WZ-6523C-09	275 ml	5.0 ml/hr	1.0ml/15min
WZ-6523C-013	275 ml	5.0 ml/hr	2.0ml/15min
WZ-6523C-016	275 ml	8.0 ml/hr	2.0ml/15min



**BASAL Series**



## DISPOSABLE CENTRAL VENOUS CATHETER KIT

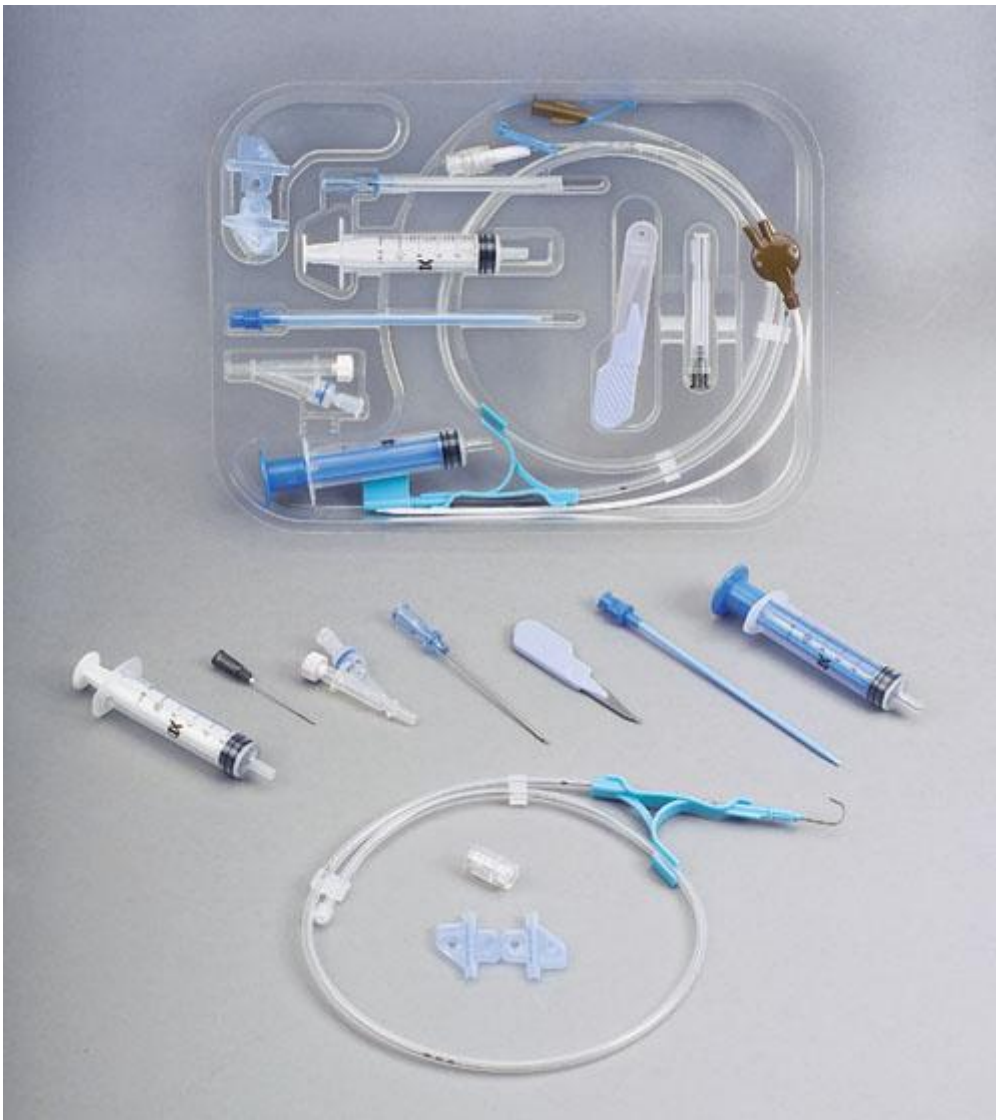
Central venous catheterization allows for an adequate therapy of critically ill patients during complex therapeutic interventions, especially in anesthesia, intensive care and emergency medicine. The tip of the central catheter should always be placed in the vena cava superior. By way of an unchangeable central venous inlet, a simple and painless approach is realized to do the therapies involving IV-class medicines, the fully parental venous nutrition, the injection of highly penetrative or irritating solutions, the blood transfusion, the taking of blood samples, the monitoring of central venous pressure, etc

### **Superb material with best biological compatibilities**

The flexible polyurethane material features favorable biological compatibility and dual protection against infections. The catheter is detective under the X-ray.

### **Less intima damage, irritation and reduces perforation risk**

An integral catheter tip, which is more pliant than the catheter body, minimizes the damages to the blood vessel walls during the insertion process.



**Fewer risks in puncture**

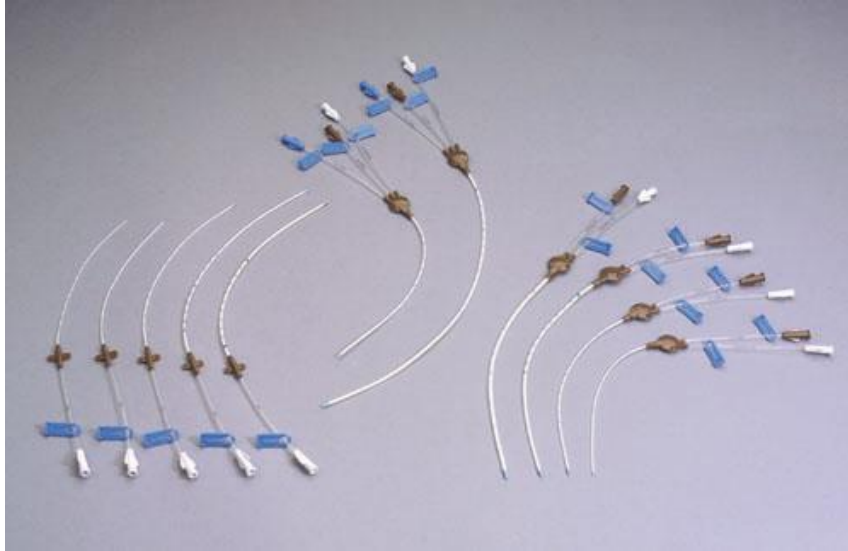
The Introducer Syringe with a check valve allows a spring-wire guide to be placed directly through the syringe into the vessel lumen so there's less trauma, less blood exposure risk, and virtually no chance for air embolism.

**More efficient placements**

The guide wire advancer helping you easily straighten the J-tip of the spring-wire guide and insert it with one hand, advancing it to the proper position with your thumb.

**More accurate placements**

A centimeter-marked spring-wire guide (.025", .032" and .035" diameters available) lets you know how much wire you have inserted and helps you avoid entering the heart. And catheter centimeter markings aid in determining insertion depth.



**The Center Venous Catheter Kit**

**Single Lumen**

Cat#	Specification	Description					
		Catheter	Catheter Clamp	Guide wire	Vessel Dilator	Introducer needer	Other Components
CVC-1121	22GX5cm	22GX5	22G	0.018"X50	4FX5	20GX4.5	<b>Standard Kit</b>  The Y connector  The 5ml syringe  The 7# syringe needle  The PET tray  The surgery scalpel(11#)
CVC-1123	22GX10cm	22GX10		0.021"X50			
CVC-1132	20GX8cm	20GX8					
CVC-1134	20GX13cm	20GX13	20G	0.025"X50	5.5FX7	19GX4.5	
CVC-1144	18GX13cm	18GX13	18G				
CVC-1145	18GX16cm	18GX16		16G	0.035"X60	6.5FX10	
CVC-1155	16GX16cm	16GX16	0.035"X70				
CVC-1156	16GX20cm	16GX20					
CVC-1157	16GX30cm	16GX30	14G	0.035"X60	7.5FX10	18GX7	
CVC-1165	14GX16cm	14GX16		0.035"X70			
CVC-1166	14GX20cm	14GX20					
CVC-1167	14GX30cm	14GX30					

## Double Lumen

Cat#	Specification	Description					
		Catheter	Catheter Clamp	Guide wire	Vessel Dilator	Introducer needler	Other Components
CVC-2145	4FX16cm	4FX16	18G	0.018"X50	5.5FX7	20GX4.5	The same as above
CVC-2154	5FX13 cm	5FX13	16G	0.021"X50	6.5FX10		
CVC-2155	5FX16 cm	5FX16					
CVC-2175	7FX16 cm	7FX16	7F	0.035"X60	8.5FX10	18GX7	
CVC-2176	7FX20 cm	7FX20		0.035"X70			
CVC-2177	7FX30 cm	7FX30		0.035"X60			
CVC-2186	8FX20 cm	8FX20	8F	0.035"X60	9FX10		

## Triple Lumen

Cat#	Specification	Description					
		Catheter	Catheter Clamp	Catheter	Catheter Clamp	Catheter	Catheter Clamp
CVC-3154	5.5FX13 cm	5.5FX13	16G	0.021"X50	6.5FX10	20GX4.5	The same as above
CVC-3155	5.5FX16 cm	5.5FX16					
CVC-3175	7FX16 cm	7FX16	7F	0.035"X60	8.5FX10	18GX7	
CVC-3176	7FX20 cm	7FX20		0.035"X70			
CVC-3177	7FX30 cm	7FX30		0.035"X70			

## DISPOSABLE EPIDURAL-SPINAL COMBINED ANESTHESIA KITS

The disposable epidural-spinal combined anaesthesia kits integrate the advantages of epidural anaesthesia and spinal anaesthesia for better and faster aesthetic effects and smaller dosage. The time length of anaesthesia can be prolonged at discretion, and the toxic side effects of the drugs can be reduced. The pen-point spinal anaesthesia needle causes little damages to the epidural, which greatly reduces the loss of CSF and minimizes the pains after the spinal anaesthesia. The combined technology makes possible the more flexible and more effective aesthetic plans, and the doctors can freely and flexibly control the parts and depth under aesthetic effects as well as the time length of anaesthesia as may be required by the operations. It also creates a new approach for the anaesthesia in obstetric applications.



### **Specially designed epidural puncture needle**

The specially processed needlepoint makes the puncture smoother and the handle feeling better. It does not cause epidural damages, has smooth interiors and is easy for tube placement.

### **Pen-point type spinal needle**

The 25G pen-point type spinal needle cause less epidural damage and minimizes the possibility of leakage of CSF. The fully transparent needle handle makes it easy to observe the backflow of the CSF.



### **Epidural catheter**

The round-shaped flexible and soft catheter with high strength and three side holes makes it easier to be placed in position and makes the medicine more evenly distributed.

### **Filter**

The 0.2um filter can effectively filter off the germs and foreign substances that might possibly exist.

### **Low-resistance syringe**

The specially designed disposable injector features smoothness, low resistance and highly sensitive to the negative pressure in the epidural chamber.

The microelectronic infusion pump is high technological medical infusion devices that can be apply on postoperative analgesia, child delivery, and therapy of chronic pain which safely and effectively delivers medication. Besides the regular continuous infusion, a PCA (patient controlled analgesia) set is equipped with programmable presets for individual clinical requirement that patients can administer additional analgesic when necessary.

--Easy programming modes: PCA only, Basal plus PCA, Continuous Basal

--The capacity of infusion reservoir cassette: 100ml & 250ml

--Basal flow rates from 0-20 ml/hr (in 0.1ml steps from 0 to 10ml/hr, in 1.0 step from 10ml/hr to 20ml/hr).

--Patient controlled bolus volume from 0-20ml (in 0.1ml steps from 0 to 10ml/hr, in 1.0 step from 10ml/hr to 20ml/hr).

--Bolus lockout time from 3 minutes to 5 hours.

--Volumetric accuracy: +/-10%.

--Concentration of medication: 0-999ug/ml or 0-99.9ml.

--One hour limit: 0-60ml/hr (in 1ml steps)

--Infusion history report, including effective PCA times, PCA volume given and total volume give.

## Easy operations

--Comprehensible, step-by-step programming instructions with the simple keypad design make the product easy to learn and use.

--The memory chips will restore preset program time when there is no power source so that infusion operations can normally be resumed with previous settings after batteries are replaced.

## Safe and reliable

--Security password restricts unauthorized operation.

--Automatic self-check whenever pump switches on minimized risk of error.

--One-hour limit ensure patients' safety.

--Strict settings on alarming prompts:

a. Infusion reservoir cassette lock released

b. One hour time limit reached

c. Low battery (Voltage below 2.3v)

d. Motor error

e. Fluid in infusion reservoir cassette running low (less than 2ml)

f. PCA set unplugged





## INSULIN PUMP

The Company insulin pump, which is driven by high-precision micro motor controlled by computer programming, is mainly used in the therapy for diabetes, with good effects in controlling the blood glucose of the diabetics and reducing the risk of complications of diabetes.

### Better blood glucose control is very important

In 1993, landmark Diabetes Control and Complications Trials (DCCT) got an exciting results from their largest long-term research that the diabetics who achieved a better blood sugar control had a tremendous decrease in their risk for the long-term complications of diabetes.

- Risk of diabetic eye disease was decreased by 76%
- Risk of diabetic nerve disease was decreased by 60%
- Risk of diabetic Kidney disease was decreased by 56%,



### The most safe, precise, and flexible insulin delivery device.

The Company insulin pump is made up of a reservoir filled with insulin, a small battery operated pump over 40 days and high-precision micro motor controlled by double computer chips. The reservoir delivers insulin to the diabetic body through a infusion set, which is a sterilized tube with a needle at the end. Normally, the needle can be buried under the skin of the abdomen for two or three days. According to the results of blood glucose monitoring, the diabetics can program the pump to continuously deliver insulin 24 hours.

### Make the diabetic's daily life more convenience and flexibility

The pump uses only short-acting insulin which is much more predictable than long-acting insulin. Its variability is less than 3%. Combined with basal infusion and bolus infusion, it makes the diabetics be free of rigid injection and meal schedules. For example, when a diabetic do exercise, he can reduce the basal rate so that his blood glucose does not drop too low. Or when the diabetic is sick or has an infection, he can increase the basal rate to prevent his blood glucose from going up too high.

### The parameters of The Company insulin pump

Model	The Company IP-101
Size (mm)	75 x45 x 19
Weight (g.)	53 ; <sup>a</sup> Empty 62 ; <sup>a</sup> With battery
Reservoir Type	300 unit / 3ml
Basal increment	0.1u
Basal Interval	60 min
Basal Delivery	Every 5 min.
Temp Basal	+/- 25% between 0-250% for 1 to 24 hrs, ie, +/- 25% of all current basal
Bolus Increments	0.1 u < 10u, 1.0 u > 10
1 u Bolus Duration	6 sec.
Bolus Amounts	0.1 to 87
Battery	3.6V DC
Battery Life	6 weeks
Memory	50 boluses, 50 day totals, 50 alarms
Water?	Watertight
Guarantee	4 year