

Shanghai Zhengbang Medical Technology Co., Ltd. CE Technical Documentation	Document No.: IVC-CE-09-01	Edition: C2	Page: 1/4
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Disposable I.V. Catheter

Instruction for Use

[Product Name]

Disposable I.V. Catheter

[Model/Type]

Type	Specification
three-way (type A), three-way (type B), straight-through (type C), straight-through (type D)	16G(1.6×55 mm), 18G(1.3×48 mm), 18G(1.3×30 mm), 20G(1.1×48 mm), 20G(1.1×30 mm), 20G(1.1×25 mm), 22G(0.9×25 mm), 22G(0.9×19 mm), 24G(0.75×19 mm), 24G(0.75×15 mm), 26G(0.6×19 mm), 26G(0.6×15 mm)

[Structure]

The main raw materials of disposable I.V. catheter are acrylonitrile - butadiene - styrene, fluorinated ethylene propylene copolymer, polyvinyl chloride, polypropylene, austenitic stainless steel, polyethylene and isoprene rubber. Consists of the following components: protective cap, catheters, metal wedge, catheter seat, separating stopper, needle, needle seat, water stop clip, tube seat (A type), tube seat (B type), heparin cap (for liquid injection), end cap, air filtration membrane, exhaust seat. Infusion unit consists of tube seat (A type), tube seat (B type), catheter seat, heparin cap, and end cap. The Types are divided according to different infusion unit, and the specifications are divided according to the outer diameter and effective length of the catheter.

[Intended Purpose]

Disposable I.V. Catheter is intended to be inserted into the peripheral superficial venous blood system for short term use (no more than 72 hours) to administration and infusion.

[Intended Users]

It is only used by doctors or nurses trained and the use of this product must be in line with the relevant regulations of the medical department.

[Intended Patient Populations]

The patient needs continuous infusion via peripheral veins.

[Indications]

- a) If a patient is ill and has fluid loss related to decreased intake, surgery, vomiting, diarrhea, or diaphoresis, the patient may require IV therapy.
- b) To replace fluids and electrolytes and maintain fluid and electrolyte balance: The body's fluid balance is regulated through hormones and is affected by fluid volumes, distribution of fluids in the body, and the concentration of solutes in the fluid.

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- c) To administer medications, including chemotherapy, anesthetics, and diagnostic reagents: About 40% of all antibiotics are given intravenously.
- d) To deliver nutrients and nutritional supplements: IV therapy can deliver some or all of the nutritional requirements for patients unable to obtain adequate amounts orally or by other routes.

[Directions for use]

- 1) Before use, check whether the single package of the product is complete and whether the protective cover of the product falls off.
- 2) Open the single package, take out the intravenous indwelling needle, insert the infusion needle or injection needle matched with the infusion set into the heparin cap, or directly connect the lower end cap with the external cone locking connector of the infusion set.
- 3) Open the infusion set regulator to remove the air in the retention needle.
- 4) Remove the protective sleeve by rotation, rotate the appropriate puncture site, sterilize according to the conventional method, tie the tourniquet, and perform the venipuncture. The speed of needle insertion should be slow. Reduce the angle after seeing the return of blood, pull out a little needle tube gently, send the tube into the vein, and then pull out the needle tube and discard it in the sharps collection box, loosen the tourniquet, and fix it with sterile application.
- 5) After the infusion, pull out the infusion needle or injection needle from the heparin cap, use the syringe to inject the sterile anticoagulant for pipe sealing into the heparin cap, and close the water stop clamp on the retention needle hose.
- 6) For the next infusion, open the water stop clamp on the hose of the retention needle, first draw the point back with the syringe, and insert the intravenous infusion needle or injection needle directly into the heparin cap for infusion after seeing the blood return.
- 7) After the infusion, if no infusion is needed, the indwelling needle can be directly extracted from the vein according to the conventional method, and the waste can be discarded in the specified container.

[Contraindications]

None.

[Warning and Precautions]

- 1) It is forbidden to use when the protective cap is falling off ,or the small package is damaged and wet or beyond the validity period;
- 2) This product is for single use only, please destroy it after use;
- 3) This product is not suitable for high-pressure injection system, otherwise it may cause product leakage or damage;
- 4) Before use, please check the needle point and needle tube, if the tip of the needle has barbs or burrs, can not be used;
- 5) When the needle tube is removed from the catheter, it is prohibited to insert the needle tube into the catheter, otherwise it may cause the catheter to be damaged;
- 6) It is suggested that the number of puncture of heparin cap should not exceed 30 times;

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- 7) The vein-detaining time of this product is not more than 72 hours;
- 8) The use of this product must be in line with the relevant regulations of the medical department, and it is only used by doctors or nurses trained;
- 9) This product contains DEHP.
- 10) According to the research data at home and abroad, the clinical doctors and nurses should pay attention to the interaction between product and the injected drugs, which leads to the change of the efficacy;
- 11) The product does not contain natural latex;
- 12) There are metal parts inside the product, which may affect the inspection of nuclear magnetic resonance.

Serious incident report

Any serious incident which causes the death of a patient or user, or a serious injury or deterioration of health, 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.

[Expiry]

Five years.

[Production Date]

Refer to the package label

[Storage conditions]

Products shall be protected from heavy pressure, direct sunlight and rain and snow during transportation;

It shall be stored in a ventilated, dry and non-corrosive gas environment. Keep away from fire sources and inflammables.

[Sterilization Method]

Sterilized using ethylene oxide

[Symbol Description]



Caution; Indicates the need for the user to consult the instructions for use for important cautionary information, such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.



Authorized representative in the European Community; Indicates the Authorized representative in the European Community



CE Mark: conforms to essential requirements of the Medical Device Regulation 2017/745 (EU)



Date of manufacture; Indicates the date when the medical device was manufactured



Manufacturer; Indicates the medical device manufacturer, as defined in Medical Device Regulation 2017/745 (EU)



Use-by date; Indicates the date after which the medical device is not to be used

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Do not re-use; Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure



Do not use if package is damaged; Indicates a medical device that should not be used if the package has been damaged or opened



Sterilized using ethylene oxide; Indicates a medical device that has been sterilized using ethylene oxide.



Batch code; Indicates the manufacturer's batch code so that the batch or lot can be identified.



Unique device identifier; Indicates a carrier that contains Unique Device Identifier information



Fragile, handle with care; Indicates a medical device that can be broken or damaged if not handled carefully.



Keep away from sunlight; Indicates a medical device that needs protection from light sources.



Keep dry; Indicates a medical device that needs to be protected from moisture.



Do not re-sterilize; Indicates a medical device that is not to be re-sterilized.



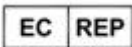
Consult instructions for use or consult electronic instructions for use; Indicates the need for the user to consult the instructions for use.



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Importer, Indicates the entity importing the medical device into the locale

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Disposable I.V. Catheter

Instruction for Use

[Product Name]

Disposable I.V. Catheter

[Model/Type]

Type	Specification
LY-A, LY-B, LY-C	16G(1.6×55 mm), 18G(1.3×48 mm), 18G(1.3×30 mm), 20G(1.1×48 mm), 20G(1.1×30 mm), 20G(1.1×25 mm), 22G(0.9×25 mm), 22G(0.9×19 mm), 24G(0.75×19 mm), 24G(0.75×15 mm), 26G(0.6×19 mm), 26G(0.6×15 mm)

[Structure]

Disposable I.V. Catheter consists of heparin cap, end cap, three-way tube seat, straight tube seat, extension tube, water stop clip, separated stopper, metal wedge, catheter seat, catheter, needle, needle seat and protective cap. Infusion unit consists of three-way tube seat, straight tube seat, heparin cap, and end cap. The Types are divided according to different infusion unit, and the specifications are divided according to the outer diameter and effective length of the catheter.

[Intended Purpose]

Disposable I.V. Catheter is intended to be inserted into the peripheral superficial venous blood system for short term use (no more than 72 hours) to administration and infusion.

[Intended Users]

It is only used by doctors or nurses trained and the use of this product must be in line with the relevant regulations of the medical department.

[Intended Patient Populations]

The patient needs continuous infusion via peripheral veins.

[Indications]

- If a patient is ill and has fluid loss related to decreased intake, surgery, vomiting, diarrhea, or diaphoresis, the patient may require IV therapy.
- To replace fluids and electrolytes and maintain fluid and electrolyte balance: The body's fluid balance is regulated through hormones and is affected by fluid volumes, distribution of fluids in the body, and the concentration of solutes in the fluid.
- To administer medications, including chemotherapy, anesthetics, and diagnostic reagents: About 40% of all antibiotics are given intravenously.

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- d) To deliver nutrients and nutritional supplements: IV therapy can deliver some or all of the nutritional requirements for patients unable to obtain adequate amounts orally or by other routes.

[Directions for use]

- 1) Before use, check whether the single package of the product is complete and whether the protective cover of the product falls off.
- 2) Open the single package, take out the intravenous indwelling needle, insert the infusion needle or injection needle matched with the infusion set into the heparin cap, or directly connect the lower end cap with the external cone locking connector of the infusion set.
- 3) Open the infusion set regulator to remove the air in the retention needle.
- 4) Remove the protective sleeve by rotation, rotate the appropriate puncture site, sterilize according to the conventional method, tie the tourniquet, and perform the venipuncture. The speed of needle insertion should be slow. Reduce the angle after seeing the return of blood, pull out a little needle tube gently, send the tube into the vein, and then pull out the needle tube and discard it in the sharps collection box, loosen the tourniquet, and fix it with sterile application.
- 5) After the infusion, pull out the infusion needle or injection needle from the heparin cap, use the syringe to inject the sterile anticoagulant for pipe sealing into the heparin cap, and close the water stop clamp on the retention needle hose.
- 6) For the next infusion, open the water stop clamp on the hose of the retention needle, first draw the point back with the syringe, and insert the intravenous infusion needle or injection needle directly into the heparin cap for infusion after seeing the blood return.
- 7) After the infusion, if no infusion is needed, the indwelling needle can be directly extracted from the vein according to the conventional method, and the waste can be discarded in the specified container.

[Contraindications]

None.

[Warning and Precautions]

- 1) It is forbidden to use when the protective cap is falling off ,or the small package is damaged and wet or beyond the validity period;
- 2) This product is for single use only, please destroy it after use;
- 3) This product is not suitable for high-pressure injection system, otherwise it may cause product leakage or damage;
- 4) Before use, please check the needle point and needle tube, if the tip of the needle has barbs or burrs, can not be used;
- 5) When the needle tube is removed from the catheter, it is prohibited to insert the needle tube into the catheter, otherwise it may cause the catheter to be damaged;
- 6) It is suggested that the number of puncture of heparin cap should not exceed 30 times;
- 7) The vein-detaining time of this product is not more than 72 hours;
- 8) The use of this product must be in line with the relevant regulations of the medical department, and it is only used by doctors or nurses trained;

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- 9) This product does not contain DEHP;
- 10) According to the research data at home and abroad, the clinical doctors and nurses should pay attention to the interaction between product and the injected drugs, which leads to the change of the efficacy;
- 11) The product does not contain natural latex;
- 12) There are metal parts inside the product, which may affect the inspection of nuclear magnetic resonance;
- 13) Suggested disinfection method: After selecting the puncture point, disinfect the skin in a circular shape from the inside to the outside with the puncture point as the center. Before puncturing the heparin cap, the puncture site of the heparin cap should be circularly disinfected from the inside to the outside, until the entire heparin cap puncture site is covered.

Serious incident report

Any serious incident which causes the death of a patient or user, or a serious injury or deterioration of health, 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.

[Expiry]

Five years.

[Production Date]

Refer to the package label

[Storage conditions]

Products shall be protected from heavy pressure, direct sunlight and rain and snow during transportation;
It shall be stored in a ventilated, dry and non-corrosive gas environment. Keep away from fire sources and inflammables.

[Sterilization Method]

Sterilized using ethylene oxide

[Symbol Description]



Caution; Indicates the need for the user to consult the instructions for use for important cautionary information, such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.



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Use-by date; Indicates the date after which the medical device is not to be used

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Do not use if package is damaged; Indicates a medical device that should not be used if the package has been damaged or opened



Sterilized using ethylene oxide; Indicates a medical device that has been sterilized using ethylene oxide.



Batch code; Indicates the manufacturer's batch code so that the batch or lot can be identified.



Unique device identifier; Indicates a carrier that contains Unique Device Identifier information



Fragile, handle with care; Indicates a medical device that can be broken or damaged if not handled carefully.



Keep away from sunlight; Indicates a medical device that needs protection from light sources.



Keep dry; Indicates a medical device that needs to be protected from moisture.



Do not re-sterilize; Indicates a medical device that is not to be re-sterilized.



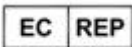
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Disposable I.V. Catheter

Instruction for Use

[Product Name]

Disposable I.V. Catheter

[Model/Type]

Type	Specification
Z-S, Z-G, Y-S, Y-G, Y-GS	16G×55 mm, 18G×48 mm, 18G×30 mm, 20G×48 mm, 20G×30 mm, 20G×25 mm, 22G×25 mm, 22G×19 mm, 24G×19 mm, 26G×15 mm

[Structure]

Disposable I.V. Catheter consists of protective cap、catheter unit、needle unit、extension tube、water stop clip and infusion unit, and catheter unit consists of catheter、metal wedge、separated stopper and catheter seat;needle unit consists of needle and needle seat, and infusion unit consists of straight needle-free infusion port, Y-type needle-free infusion port, heparin cap, straight tube seat, Y-type tube seat and end cap.The Types are divided according to different infusion unit, and the specifications are divided according to the outer diameter and effective length of the catheter.

[Intended Purpose]

Disposable I.V. Catheter is intended to be inserted into the peripheral superficial venous blood system for short term use (no more than 72 hours) to administration and infusion.

[Intended Users]

It is only used by doctors or nurses trained and the use of this product must be in line with the relevant regulations of the medical department.

[Intended Patient Populations]

The patient needs continuous infusion via peripheral veins.

[Indications]

- If a patient is ill and has fluid loss related to decreased intake, surgery, vomiting, diarrhea, or diaphoresis, the patient may require IV therapy.
- To replace fluids and electrolytes and maintain fluid and electrolyte balance: The body's fluid balance is regulated through hormones and is affected by fluid volumes, distribution of fluids in the body, and the concentration of solutes in the fluid.
- To administer medications, including chemotherapy, anesthetics, and diagnostic reagents: About 40% of all

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antibiotics are given intravenously.

- d) To deliver nutrients and nutritional supplements: IV therapy can deliver some or all of the nutritional requirements for patients unable to obtain adequate amounts orally or by other routes.

[Directions for use]

- 1) Before use, check whether the product package is complete and whether the protective cap is off;
- 2) Open the single package and take out the I.V. Catheter, for the product of Z-G、 Y-G, insert the infusion needle or injection needle into the heparin cap; for the product of Z-S、 Y-S, let the needle - free infusion port connect with the male conical fitting of infusion devices firmly; for the product of Y-GS, let infusion needle or injection needle connect with the heparin cap or let the needle - free infusion port connect with the male conical fitting of infusion devices fitting firmly;
- 3) Open the flow regulator, drain the air in the I.V. Catheter;
- 4) Remove the protective cap by rotating, choose suitable puncture site, after disinfection by conventional method, bind the tourniquet and do the vein puncture .The inserting needle speed should be slow, after seeing the flashback ,please reduce Angle and gently pull out needle tube a little; put the catheter into the vein, take out the needle, and discard it into the sharps collection box, then loosen the tourniquet and fixed with sterile apply;
- 5) After the infusion is finished, for the product of Z-G、 Y-G、 Y-GS, firstly disinfect the heparin cap, then Inject the heparin diluent or saline into the heparin cap with a needle syringe. After the I.V. Catheter is filled with the heparin diluent or saline, push the wheel of the positive pressure generating device to the end, fasten the protective cap of it, then remove the needle syringe. For the product of Z-S 、 Y-S, use a syringe to extract heparin diluent or ,saline, Inject from the infusion port (by the syringe without needle) .After the I.V. Catheter is filled with the heparin diluent or saline, push the wheel of the positive pressure generating device to the end, fasten the protective cap of it, then remove the needle syringe;
- 6) When doing the infusion again, disinfect the infusion port of the I.V. Catheter, push back the wheel of the positive pressure generating device, after seeing the flashback, connect the heparin cap or needle-free infusion port with the infusion device and then do the infusion;
- 7) After infusion is finished, if no infusion is required, it can be removed from the vein by the conventional method and discarded the product to the designated container.

[Contraindications]

None.

[Warning and Precautions]

- 1) It is forbidden to use when the protective cap is falling off ,or the small package is damaged and wet or beyond the validity period;
- 2) This product is for single use only, please destroy it after use;
- 3) This product is not suitable for high-pressure injection system, otherwise it may cause product leakage or damage;
- 4) Before use, please check the needle point and needle tube, if the tip of the needle has barbs or burrs, can not be used;

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- 5) When the needle tube is removed from the catheter, it is prohibited to insert the needle tube into the catheter, otherwise it may cause the catheter to be damaged;
- 6) It is suggested that the number of puncture of heparin cap should not exceed 30 times;
- 7) The vein-detaining time of this product is not more than 72 hours;
- 8) The use of this product must be in line with the relevant regulations of the medical department, and it is only used by doctors or nurses trained;
- 9) This product does not contain DEHP;
- 10) According to the research data at home and abroad, the clinical doctors and nurses should pay attention to the interaction between product and the injected drugs, which leads to the change of the efficacy;
- 11) The product does not contain natural latex;
- 12) There are metal parts inside the product, which may affect the inspection of nuclear magnetic resonance;
- 13) Suggested disinfection method: After selecting the puncture point, disinfect the skin in a circular shape from the inside to the outside with the puncture point as the center. Before puncturing the heparin cap, the puncture site of the heparin cap should be circularly disinfected from the inside to the outside, until the entire heparin cap puncture site is covered. Before using the needle-free infusion port, please use 75% alcohol cotton ball to cover the entire needle-free infusion port surface and side. Hold the infusion port in the left hand, press the thumb and index finger of the right hand on the side, rotate and wipe with the left hand, and sterilize the needle-free connector for about 30 seconds, repeat at least 3 times.

Serious incident report

Any serious incident which causes the death of a patient or user, or a serious injury or deterioration of health, 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.

[Expiry]

Five years.

[Production Date]

Refer to the package label

[Storage conditions]

Products shall be protected from heavy pressure, direct sunlight and rain and snow during transportation;

It shall be stored in a ventilated, dry and non-corrosive gas environment. Keep away from fire sources and inflammables.

[Sterilization Method]

Sterilized using ethylene oxide

[Symbol Description]



Caution; Indicates the need for the user to consult the instructions for use for important cautionary information, such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.



Authorized representative in the European Community; Indicates the Authorized representative in the European Community

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Use-by date; Indicates the date after which the medical device is not to be used



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Do not use if package is damaged; Indicates a medical device that should not be used if the package has been damaged or opened



Sterilized using ethylene oxide; Indicates a medical device that has been sterilized using ethylene oxide.



Batch code; Indicates the manufacturer's batch code so that the batch or lot can be identified.



Unique device identifier; Indicates a carrier that contains Unique Device Identifier information



Fragile, handle with care; Indicates a medical device that can be broken or damaged if not handled carefully.



Keep away from sunlight; Indicates a medical device that needs protection from light sources.



Keep dry; Indicates a medical device that needs to be protected from moisture.



Do not re-sterilize; Indicates a medical device that is not to be re-sterilized.



Consult instructions for use or consult electronic instructions for use; Indicates the need for the user to consult the instructions for use.



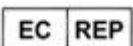
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Disposable I.V. Catheter

Instruction for Use

[Product Name]

Disposable I.V. Catheter

[Model/Type]

Type	Specification
FZ-S, FZ-G, FY-S, FY-G, FY-GS, FY-GG	18G (1.3×48 mm), 18G (1.3×30 mm), 20G (1.1×48 mm), 20G (1.1×30 mm), 20G (1.1×25 mm), 22G(0.9×25 mm), 22G(0.9×19 mm), 24G(0.7×19 mm), 26G(0.55×15 mm)

[Structure]

Disposable I.V. Catheter consists of protective cap, catheter unit, puncture resistant device, needle unit, extension tube, water stop clip and infusion unit, and catheter unit consists of catheter, metal wedge, separated stopper and catheter seat; needle unit consists of needle and needle seat; puncture resistant device consists of base and metal shrapnel, and infusion unit consists of straight needle-free infusion port, Y-type needle-free infusion port, heparin cap, straight tube seat, Y-type tube seat and end cap. The extension tube is made of polyurethane. Ethylene oxide sterilization, single use. The Types are divided according to different infusion unit, and the specifications are divided according to the outer diameter and effective length of the catheter.

[Intended Purpose]

Disposable I.V. Catheter is intended to be inserted into the peripheral superficial venous blood system for short term use (no more than 72 hours) to administration and infusion.

[Intended Users]

It is only used by doctors or nurses trained and the use of this product must be in line with the relevant regulations of the medical department.

[Intended Patient Populations]

The patient needs continuous infusion via peripheral veins.

[Indications]

- If a patient is ill and has fluid loss related to decreased intake, surgery, vomiting, diarrhea, or diaphoresis, the patient may require IV therapy.
- To replace fluids and electrolytes and maintain fluid and electrolyte balance: The body's fluid balance is regulated through hormones and is affected by fluid volumes, distribution of fluids in the body, and the concentration of solutes in the fluid.

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- c) To administer medications, including chemotherapy, anesthetics, and diagnostic reagents: About 40% of all antibiotics are given intravenously.
- d) To deliver nutrients and nutritional supplements: IV therapy can deliver some or all of the nutritional requirements for patients unable to obtain adequate amounts orally or by other routes.

[Directions for use]

- 1) Before use, check whether the single package of the product is complete and whether the protective cover of the product falls off.
- 2) Open the single package, take out the intravenous indwelling needle. For products of FZ-G, FY-G, and FY-GG models, insert the infusion needle matched with the infusion set into the heparin cap; For FZ-S and FY-S models, connects the needle-free infusion port of catheter to the outer cone locking joint of the infusion set firmly; For FY-GS model, insert the infusion needle matched with the infusion set into the heparin cap, connects the needle-free infusion port of catheter to the outer cone locking joint of the infusion set firmly. or directly connect the lower end cap with the external cone locking connector of the infusion set.
- 3) Open the infusion set regulator to remove the air in the retention needle.
- 4) Remove the protective sleeve by rotation, rotate the appropriate puncture site, sterilize according to the conventional method, tie the tourniquet, and perform the venipuncture. The speed of needle insertion should be slow. Reduce the angle after seeing the return of blood, pull out a little needle tube gently, send the tube into the vein, and then pull out the needle tube and discard it in the sharps collection box, loosen the tourniquet, and fix it with sterile application.
- 5) After the infusion, for FZ-G, FY-G, FY-GS, FY-GG models, disinfect the heparin cap first, and then inject the heparin diluent or physiological saline into the heparin cap by a syringe with needle, and wait for heparin diluent or physiological saline filling the entire I.V. Catheter, push the roller of the positive pressure generating device to the end, buckle the protective cover of the positive pressure generating device, and then withdraw the syringe with needle; For FZ-S, FY-S, FY-GS models, draw heparin diluent or physiological saline with a syringe, and inject it from the needle-free infusion port (needle-free syringe should be used when injecting), and wait until heparin diluent or physiological saline fills the entire I.V. Catheter, withdraw the syringe; and then push the roller of the positive pressure generating device to the end, buckle the protective cover of the positive pressure generating device.
- 6) For the next infusion, disinfect the joint end of the catheter, push back the roller of the positive pressure generating device, after seeing the blood return, connect the infusion set to the heparin cap or the needle-free infusion port for infusion.
- 7) After the infusion, if no infusion is needed, the indwelling needle can be directly extracted from the vein according to the conventional method, and the waste can be discarded in the specified container.

[Contraindications]

None.

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[Warning and Precautions]

- 1) It is forbidden to use when the protective cap is falling off ,or the small package is damaged and wet or beyond the validity period;
- 2) This product is for single use only, please destroy it after use;
- 3) This product is not suitable for high-pressure injection system, otherwise it may cause product leakage or damage;
- 4) Before use, please check the needle point and needle tube, if the tip of the needle has barbs or burrs, can not be used;
- 5) When the needle tube is removed from the catheter, it is prohibited to insert the needle tube into the catheter, otherwise it may cause the catheter to be damaged;
- 6) The heparin cap is used together with the I.V. catheter and cannot be disassembled and used alone. It is suggested that the number of puncture of heparin cap and use of needle- free infusion port should not exceed 30 times;
- 7) The vein-detaining time of this product is not more than 72 hours;
- 8) The use of this product must be in line with the relevant regulations of the medical department, and it is only used by doctors or nurses trained;
- 9) This product does not contain DEHP;
- 10) According to the research data at home and abroad, the clinical doctors and nurses should pay attention to the interaction between product and the injected drugs, which leads to the change of the efficacy;
- 11) The product does not contain natural latex;
- 12) There are metal parts inside the product, which may affect the inspection of nuclear magnetic resonance.
- 13) Suggested disinfection method: After selecting the puncture point, disinfect the skin in a circular shape from the inside to the outside with the puncture point as the center. Before puncturing the heparin cap, the puncture site of the heparin cap should be circularly disinfected from the inside to the outside, until the entire heparin cap puncture site is covered. Before using the needle-free infusion port, please use 75% alcohol cotton ball to cover the entire needle-free infusion port surface and side. Hold the infusion port in the left hand, press the thumb and index finger of the right hand on the side, rotate and wipe with the left hand, and sterilize the needle-free connector for about 30 seconds, repeat at least 3 times.

Serious incident report

Any serious incident which causes the death of a patient or user, or a serious injury or deterioration of health, 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.

[Expiry]

Five years.

[Production Date]

Refer to the package label

[Storage conditions]

Products shall be protected from heavy pressure, direct sunlight and rain and snow during transportation;

It shall be stored in a ventilated, dry and non-corrosive gas environment. Keep away from fire sources and inflammables.

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[Sterilization Method]

Sterilized using ethylene oxide

[Symbol Description]



Caution; Indicates the need for the user to consult the instructions for use for important cautionary information, such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.



Authorized representative in the European Community; Indicates the Authorized representative in the European Community



CE Mark: conforms to essential requirements of the Medical Device Regulation 2017/745 (EU)



Date of manufacture; Indicates the date when the medical device was manufactured



Manufacturer; Indicates the medical device manufacturer, as defined in Medical Device Regulation 2017/745 (EU)



Use-by date; Indicates the date after which the medical device is not to be used



Do not re-use; Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure



Do not use if package is damaged; Indicates a medical device that should not be used if the package has been damaged or opened



Sterilized using ethylene oxide; Indicates a medical device that has been sterilized using ethylene oxide.



Batch code; Indicates the manufacturer's batch code so that the batch or lot can be identified.



Unique device identifier; Indicates a carrier that contains Unique Device Identifier information



Fragile, handle with care; Indicates a medical device that can be broken or damaged if not handled carefully.



Keep away from sunlight; Indicates a medical device that needs protection from light sources.



Keep dry; Indicates a medical device that needs to be protected from moisture.



Do not re-sterilize; Indicates a medical device that is not to be re-sterilized.



Consult instructions for use or consult electronic instructions for use; Indicates the need for the user to consult the instructions for use.

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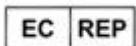
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Importer, Indicates the entity importing the medical device into the locale