CE 0123

Disposable Infusion Set

Instruction for Use

[Product Name]

Disposable Infusion Set

[Model/Type]

Model	Type	Infusion needle specification
Disposable Infusion Sets Disposable Infusion Sets with Needle	SYS-1, SYS-2, SYS-3, SYS-4, SYG-3, SYG-4	0.45×16mmRWLB; 0.5×19mmRWLB; 0.55×19mmRWLB; 0.6×22mmTWLB; 0.7×25mmTWLB; 0.8×27mmTWLB; 0.9×28mmTWLB; 1.2×32mmTWSB.

[Structure]

Disposable Infusion Sets consist of protective cap, closure-piercing device (Plastic steel closure-piercing device, plastic closure-piercing device with air-inlet and air filter, double plastic closure-piercing device with a common air-inlet and air filter, double plastic closure-piercing device with separate air-inlet and air filter, plastic closure-piercing device with air filter and closure) ,air filter, drip chamber (blow drip chamber with top two-way drip tube; blow drip chamber with top two-way drip tube and bottom two-way drip tube), tubing, flow regulator, injection site, fluid filter, intravenous needle and infusion paste.

[Performance characteristics]

This product has physical, chemical and biological requirements.

[Intended Purpose]

This product is indicated for the delivery of fluids from a container to a patient's vascular system through an infusion needle under the action of gravity.

[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.

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) Take off protective cap of the male conical fitting, connected with intravenous needle;
2) Take off protective cap of closure-piercing device, close flow regulator, Connect the closure-piercing device to the desired infusion container;
3) Open the flow regulator, liquid medicine in infusion container inflow to tubing; keep the 2/3 liquid in drip chamber, drain the air in soft tubing, then turn off flow regulator;
4) Disinfection of skin and intravenous injection is carried out according to the requirement of intravenous injection;
5) When there is blood in the soft tubing of the intravenous needle, open the flow regulator immediately;
6) Fixed intravenous needle, adjust infusion speed, intravenous infusion;
7) When dosing, use a syringe to extract the desired medication, use iodine disinfection the latex cap above the drip chamber, inject the medication into drip chamber by syringe.

[Contraindications]

None

[Warning and Precautions]

1) This product is DEHP free;
2) Clinical staff should pay attention to its possible toxicity to high risk population(newborn, pregnant and lactating women and adolescent males) ,try to choose alternative products;
3) This product is not suitable for infusion of fat soluble liquids and medicine such as fat emulsion;
4) According to the research data at home and abroad, the clinical doctors and nurses should pay attention to the interaction between the PVC tubing and the injected drugs, which leads to the change of the efficacy;
5) This product is prohibited for infusion of incompatible medicines with PVC;
6) It is forbidden to use when the protective cap is falling off ,or the small package is damaged or beyond the validity period;
7) Before use, please check the needle point and needle tube, if the tip of the needle has barbs or burrs, or needle bends greater than 25°， may not be used;
8) This product is for single use only, please destroy it after use;
9) This product is only suitable for gravity infusion, not suitable for blood transfusion or blood components.
10) Each 20 drops or 60 drops of distilled water in this product dropper is equal to 1ml±0.1ml;

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

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 resterilize; Indicates a medical device that is not to be resterilized.

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

Contains or presence of phthalate": bis (2ethylhexyl) phthalate (DEHP)

Stacking layer limit, n represents layer limit

Shanghai Zhengbang Medical Technology Co., Ltd
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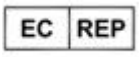

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Importer，Indicates the entity importing the medical device into the locale

CE 0123

Disposable Infusion Sets (Stop Fluid Function)

Instruction for Use

[Product Name]

Disposable Infusion Sets (Stop Fluid Function)

[Model/Type]

Model	Type	Infusion needle specification
Disposable Infusion Sets (Stop Fluid Function)	SYS-1G, SYS-3G, SYS-4G, SYG-4G	0.45×16mmRWLB; 0.5×19mmRWLB; 0.55×19mmRWLB; 0.6×22mmTWLB; 0.7×25mmTWLB; 0.8×27mmTWLB; 0.9×28mmTWLB; 1.2×32mmTWSB

[Structure]

Disposable Infusion Sets (Stop Fluid Function) consist of protective cap, closure-piercing device (Plastic steel closure-piercing device, plastic closure-piercing device with air-inlet and air filter, double plastic closure-piercing device with a common air-inlet and air filter, double plastic closure-piercing device with separate air-inlet and air filter, plastic closure-piercing device with air filter and closure） ,air filter, drip chamber, stop fluid film, tubing, flow regulator, injection site, and intravenous infusion needle.

[Performance characteristics]

This product has physical, chemical and biological requirements.

[Intended Purpose]

This product is indicated for the delivery of fluids from a container to a patient's vascular system through an infusion needle under the action of gravity.

[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.

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) Open the small package and remove the infusion sets;
2) Turn off the flow regulator, remove the protective cap of closure-piercing device, insert the closure-piercing device into the infusion bottle（bag）;
3) Squeeze the drip chamber, let the fluid into drip chamber and put the fluid level into 1/2-2/3 height of the drip chamber;
4) Open the flow regulator, drain the air in soft tubing, then turn off flow regulator, do the venepuncture;
5) Slowly open the regulator and adjust the infusion rate according to need;
6) When changing the infusion, close the regulator, remove closure-piercing device and insert it into the replacement bottle, and do the following operation.

   a. When the fluid level of drip chamber is normal, the stop fluid film does not close the infusion channel, please follow the above article 5;

   b. When the fluid level of drip chamber reduce or the stop fluid film close the infusion channel, please follow the above article 3 and 5;
7) After the infusion is finished, the stop fluid film will automatically close the infusion channel ,then remove the infusion needle from the human body.

[Contraindications]

None

[Warning and Precautions]

1) This product is DEHP free;
2) Clinical staff should pay attention to its possible toxicity to high risk population(newborn, pregnant and lactating women and adolescent males) ,try to choose alternative products;
3) This product is not suitable for infusion of fat soluble liquids and medicine such as fat emulsion;
4) According to the research data at home and abroad, the clinical doctors and nurses should pay attention to the interaction between the PVC tubing and the injected drugs, which leads to the change of the efficacy;
5) This product is prohibited for infusion of incompatible medicines with PVC;
6) When there is sediment in the infusion tube during infusion, the infusion should be stopped immediately.
7) It is forbidden to use when the protective cap is falling off ,or the small package is damaged or beyond the validity period;
8) Before use, please check the needle point and needle tube, if the tip of the needle has barbs or burrs, or needle bends greater than 25°， may not be used;
9) This product is for single use only, please destroy it after use;

10) This product is only suitable for gravity infusion, not suitable for blood transfusion or blood components.
11) 20 drops from the drip tube is equivalent to 1ml±0.1ml;
12) 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;
13) This product does not have the anti - blood returning effect. The clinical use should follow the standard of intravenous infusion same as the ordinary infusion sets, and this product can't replace nurses' normal patrol;
14) Verified by laboratory: when infusing the fluid that has similar specific gravity and viscosity of fluid with distilled water, saline solution, 5% glucose, 20% glucose, 50% glucose, 20% mannitol injection, 20% fat emulsion injection, nitroglycerin injection and 50% ethanol solution, the stop fluid performance can meet the requirements of clinical use;
15) If the stopping fluid performance is influenced by the tilting Angle of the infusion, and the maximum tilt angle should not be greater than 40°;
16) Minimum height of drip chamber distant from patient should be not less than 0.5 m, because of the patient position change and other factors affecting patients venous pressure, we advise that height of drip chamber distant from the infusion needle should be not less than 0.8 m; When the fluid level reaches the stop fluid film, the retention time of the stop fluid performance can be 30min.

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

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 resterilize; Indicates a medical device that is not to be resterilized.

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

Contains or presence of phthalate": bis (2ethylhexyl) phthalate (DEHP)

Stacking layer limit, n represents layer limit

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

CE 0123

Disposable Infusion Set (TPE material)

Instruction for Use

[Product Name]

Disposable Infusion Set (TPE material)

[Model/Type]

Model	Type	Infusion needle specification
Disposable Infusion Set (TPE material)	TSYS-1E, TSYS-3E, TSYG-3E, TSYG-4E	0.45×16mmRWLB; 0.5×19mmRWLB; 0.55×19mmRWLB; 0.6×22mmTWLB; 0.7×25mmTWLB; 0.8×27mmTWLB; 0.9×28mmTWLB; 1.2×32mmTWSB

[Structure]

Disposable Infusion Set (TPE material) consists of protective cap of closure-piercing device, device with air-inlet(air filter),closure-piercing device, tubing, water stopper, drip tube, drip chamber, flow regulator, injection site(optional), fluid filter， male conical fitting， protective cap of male conical fitting（optional)， intravenous needle for single use（optional)， intravenous needle consists of connecting base, tubing, needle handle, needle tubing and protective cap.

[Performance characteristics]

This product has physical, chemical and biological requirements.

[Intended Purpose]

This product is indicated for the delivery of fluids from a container to a patient's vascular system through an infusion needle under the action of gravity.

[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.

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 package is damaged or not. If the product is in good condition， use after opening the sealing package；
2) Turn off the flow regulator, remove the protective cap of closure-piercing device, insert the closure-piercing device into the infusion bottle, and open the air-inlet cap (or insert the air-inlet needle)；
3) Invert the infusion bottle, squeeze the drip chamber with the hand, and put the fluid into the drip chamber about 1/2;
4) Release the flow regulator, place the fluid filter on the level, exhaust the air, and then the infusion will start;
5) When there is a small amount of fluid, pull the intravenous infusion needle out and the infusion will be over;
6) Infusion operation should be carried out and monitored by professional nurses；
7) When using the double closure-piercing products, attention should be paid to the prohibition of infusion.

[Contraindications]

None

[Warning and Precautions]

1) During infusion, large bubbles should not enter into the body with the liquid;
2) When the infusion was finished, the liquid level is forbidden to be lower than the bottom of drip chamber of infusion sets to prevent the gas from entering into the human blood vessel;
3) Do not use hand or non-sterilized goods to touch parts of contacting with the fluid and piercing into the body;
4) This product is not suitable for blood transfusion or blood products;
5) This product is for single use only, please destroy it after use；
6) Product specifications and packaging quantity are seen in the bag certificate, production lot number and Exp are seen in the seal;
7) When Opening the package , please use it immediately；
8) It is not allowed to be used when the package is damaged or the protective cap is off;
9) 20 drops from the drip tube is equivalent to 1ml±0.1ml;
10) The injection site is used for dosing medicine， please disinfect before use；
11) The specification of venous needle is seen in the small package;
12) This product is only suitable for gravity infusion；
13) Our company had made a medicine compatibility study on taxol, nitroglycerin, amiodarone hydrochloride，cephalosporin injection and fat emulsion injection by simulating the clinical conditions， the maximum

adsorption value of taxol was 1.5%，the maximum adsorption value of nitroglycerin was 2.6%，the maximum adsorption value of amiodarone hydrochloride was 3.3%， the maximum adsorption value of cephalosporin injection was 1.3%，the maximum adsorption value of fat emulsion injection was 0.6%；

14) Our company had not made other medicine compatibility study，information about other medicines infusion is unknown；
15) This product does not have the anti - blood returning effect. The clinical use should follow the standard of intravenous infusion same as the ordinary infusion sets, and this product can't replace nurses' normal patrol；
16) This product should be used in a fixed place, and the use during the exercise will affect the performance of automatic stopping fluid, such as walking back and forth , in the the ambulance；
17) Minimum height of drip chamber distant from patient should be not less than 0.5 m, because of the patient position change and other factors affecting patients venous pressure, we advise that height of drip chamber distant from the infusion needle should be not less than 0.8 m；
18) We advise that tilt angle is less than 30°;

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

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 resterilize; Indicates a medical device that is not to be resterilized.

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

Stacking layer limit, n represents layer limit

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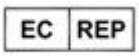

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Importer，Indicates the entity importing the medical device into the locale

CE 0123

Disposable Precise Filtration Infusion Set with Needle

Instruction for Use

[Product Name]

Disposable Precise Filtration Infusion Set with Needle

[Model/Type]

Model	Type	Infusion needle specification
Disposable Precise Filtration lnfusion Set with Needle	PF-S, PF-G	0.45×16mmRWLB; 0.5×19mmRWLB; 0.55×19mmRWLB; 0.6×22mmTWLB; 0.7×25mmTWLB; 0.8×27mmTWLB; 0.9×28mmTWLB; 1.2×32mmTWSB

[Structure]

Disposable Precise Filtration lnfusion Set with Needle consists of protective cap, closure-piercing device (Plastic steel closure-piercing device, plastic closure-piercing device with air-inlet and air filter, plastic closure-piercing device with air filter and closure） , air filter, drip chamber unit (blow drip chamber with top two-way drip tube; blow drip chamber with top two-way drip tube and exhaust pipe; injection drip chamber type), tubing, water stopper, flow regulator, injection site, Precise fluid filter(filter medium aperture: 2.0μm, 3.0μm, 5.0μm) and intravenous needle.

[Performance characteristics]

This product has physical, chemical and biological requirements.

[Intended Purpose]

This product is indicated for the delivery of fluids from a container to a patient's vascular system through an infusion needle under the action of gravity.

[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.

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]

When using the product of double puncture device, we should pay attention to the taboo of drug infusion.

1. Open the small package, take out the infusion set, and tighten the connection seat of infusion needle.

2. Close the regulator, remove the protective sleeve of the puncture device, and insert the puncture device and air inlet needle (if any) into the infusion container.

3. Introduce the liquid medicine into the dropper, and fill the dropper with about 1/2-2/3 of the liquid medicine.

4. Open the regulator, clear the air in the catheter, close the flow regulator, and then perform venipuncture.

When it is necessary to add medicine, the injection needle of the inhaled medicine syringe can be directly inserted into the injection part of the medicine liquid, and the medicine can be injected into the precise filter infusion set.

[Contraindications, precautions, warnings and suggestive notes]

1) This product is DEHP free;
2) Clinical doctors and nurses should pay attention to choosing alternative products as much as possible based on the possible toxicity of high-risk groups such as pregnant women, lactating women and men before puberty;
3) This product is not suitable for infusion of fat soluble liquid such as fat emulsion;
4) The clinical medical staff should pay attention to the interaction between the drug and the infusion, which will lead to the change of efficacy;
5) This product is forbidden to be used for infusion of drugs incompatible with PVC;
6) Stop infusion immediately when sediment is found in the infusion tube during infusion;
7) If the protective sleeve falls off, the small package is damaged or beyond the validity period, it is strictly prohibited to use it;
8) Before use, please check the needle tip and the needle tube. If the needle tip has barb, burr or the needle tube is bent more than 25 °, it shall not be used;
9) It can only be used once and destroyed after use;
10) This product is only suitable for gravity infusion, not for blood transfusion or blood components;
11) Every 20 or 60 drops of distilled water in the burette is equal to 1ml ± 0.1ml;
12) The use of this product must meet the requirements of the relevant operation specifications and regulations of the medical department, and it is only used by trained doctors or nursing personnel.

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

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 resterilize; Indicates a medical device that is not to be resterilized.

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

Contains or presence of phthalate": bis (2ethylhexyl) phthalate (DEHP)

Stacking layer limit, n represents layer limit

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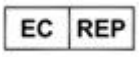

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Importer，Indicates the entity importing the medical device into the locale

CE 0123

Disposable Precise Filtration Infusion Set（TPE Material, Stop Fluid Function）

Instruction for Use

[Product Name]

Disposable Precise Filtration Infusion Set（TPE Material, Stop Fluid Function）

[Model/Type]

Model	Type	Optional Infusion needle specification
Disposable Precise Filtration Infusion Set (TPE Material, Stop Fluid Function)	TPF-2.0S1A, TPF-2.0S1E, TPF-2.0S3A, TPF-2.0S3E, TPF-2.0G4A, TPF-2.0G4E, TPF-3.0S1A, TPF-3.0S1E, TPF-3.0S3A, TPF-3.0S3E, TPF-3.0G4A, TPF-3.0G4E, TPF-5.0S1A, TPF-5.0S1E, TPF-5.0S3A, TPF-5.0S3E, TPF-5.0G4A, TPF-5.0G4E	0.45×16mmRWLB; 0.5×19mmRWLB; 0.55×19mmRWLB; 0.6×22mmTWLB; 0.7×25mmTWLB; 0.8×27mmTWLB; 0.9×28mmTWLB; 1.2×32mmTWSB

[Structure]

Disposable Precise Filtration Infusion Set (TPE Material, Stop Fluid Function) consists of protective cap of closure-piercing device, device with air-inlet (air filter), closure-piercing device, tubing, water stopper, drip tube, drip chamber, auto-stopping fluid device, flow regulator, injection site(optional), Precise fluid filter(filter medium aperture: 2.0μm, 3.0μm, 5.0μm), male conical fitting, protective cap of male conical fitting (optional), intravenous needle for single use（optional）, intravenous needle consists of connecting base, tubing, needle handle, needle tubing and protective cap.

[Performance characteristics]

This product has physical, chemical and biological requirements.

[Intended Purpose]

This product is indicated for the delivery of fluids from a container to a patient's vascular system through an infusion needle under the action of gravity.

[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.

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 package is damaged or not. If the product is in good condition， use after opening the sealing package；
2) Turn off the flow regulator, remove the protective cap of closure-piercing device, insert the closure-piercing device into the infusion bottle, and open the air-inlet cap (or insert the air-inlet needle)；
3) Invert the infusion bottle, squeeze the drip chamber with the hand, and put the fluid into the drip chamber about 1/2;
4) Release the flow regulator, place the fluid filter on the level, exhaust the air, and then the infusion will start;
5) When there is a small amount of fluid, pull the intravenous infusion needle out and the infusion will be over;
6) Infusion operation should be carried out and monitored by professional nurses；
7) When using the double closure-piercing products, attention should be paid to the prohibition of infusion.

[Contraindications]

None

[Warning and Precautions]

1) During infusion, large bubbles should not enter into the body with the liquid;
2) When the infusion was finished, the liquid level is forbidden to be lower than the bottom of drip chamber of infusion sets to prevent the gas from entering into the human blood vessel;
3) Do not use hand or non-sterilized goods to touch parts of contacting with the fluid and piercing into the body;
4) This product is not suitable for blood transfusion or blood products;
5) This product is for single use only, please destroy it after use；
6) Product specifications and packaging quantity are seen in the bag certificate, production lot number and Exp are seen in the seal;
7) When Opening the package , please use it immediately；
8) It is not allowed to be used when the package is damaged or the protective cap is off;
9) 20 drops from the drip tube is equivalent to 1ml±0.1ml;
10) The injection site is used for dosing medicine， please disinfect before use；
11) The specification of venous needle is seen in the small package;
12) This product is only suitable for gravity infusion；

13) Our company had made a medicine compatibility study on taxol, nitroglycerin, amiodarone hydrochloride，cephalosporin injection and fat emulsion injection by simulating the clinical conditions， the maximum adsorption value of taxol was 1.5%，the maximum adsorption value of nitroglycerin was 2.6%，the maximum adsorption value of amiodarone hydrochloride was 3.3%， the maximum adsorption value of cephalosporin injection was 1.3%，the maximum adsorption value of fat emulsion injection was 0.6%；
14) Our company had not made other medicine compatibility study，information about other medicines infusion is unknown；
15) This product does not have the anti - blood returning effect. The clinical use should follow the standard of intravenous infusion same as the ordinary infusion sets, and this product can't replace nurses' normal patrol；
16) This product should be used in a fixed place, and the use during the exercise will affect the performance of automatic stopping fluid, such as walking back and forth , in the the ambulance；
17) Minimum height of drip chamber distant from patient should be not less than 0.5 m, because of the patient position change and other factors affecting patients venous pressure, we advise that height of drip chamber distant from the infusion needle should be not less than 0.8 m；
18) We advise that tilt angle is less than 30°;
19) The blood-contaminated products must be disposed of in a method that complies with the established biohazard-free disposal procedures

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;

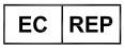
It shall be stored in a ventilated, dry and non-corrosive gas environment. Keep away from fire sources and inflammables.

[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

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 resterilize; Indicates a medical device that is not to be resterilized.

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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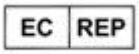

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