Instruction for Use

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Product Name

Sterile burette infusion sets for single use

Product description

The Sterile burette infusion sets for single use is consist of protective cap,closure-piercing device, air filter, drip chamber, graduated burette,tubing, flow regulator,fluid filter, intravenous infusion needle or injection needle, male conical fitting. All parts and materials used in this can meet medical requirement. Sterilized by EO, it characterized with sterile, pyrogen-free, easy to use and safe.

Model

BIS-NFSVF-1, BIS-NFSVF-2, BIS-NFSVC-1, BIS-NFSVC-2
BIS-NCSVF-1, BIS-NCSVF-2, BIS-NCSVC-1, BIS-NCSVC-2

Main structure and properties

The sterile Sterile burette infusion sets for single use products include protective cap of closure-piercing device, closure-piercing device, air inlet with closure, air filter, tubing, flow regulator, injection site, air inlet with air filter and closure, Upper cover of graduated burette, graduated burette, shut-off valve, Lower cover of graduated burette, drip tube, drip chamber, fluid filter, male conical fitting, protective cap of male conical fitting or hypodermic needle.

Medical condition(s)

Routine medical scenarios.

Principle of Operation

In the infusion system formed by the principle of atmospheric pressure and hydrostatic pressure, the liquid in the infusion bottle flows into the drip bucket from the infusion hose. When the pressure of the water column in the drip bucket is greater than the venous pressure in the body, the liquid in the infusion bottle flows into the vein from the hose.

Intended purpose

The Sterile burette infusion sets for single use is used for human body Intravenous infusion, it is suitable for children infusion and occasions requiring precise control of infusion dose.

Intended users: Professional medical staffs, include physicians, nurse, therapist and other relevant staffs with medical science;

Intended patient population:

Suitable for intravenous infusion of drugs in infants and young children or special adult patients who require precise control of infusion volume, especially in infants and young children or patients with heart and kidney failure, as well as in patients who require small doses, multiple drugs, and short intervals of infusion.

The combination of the device with product

Used together with the liquid medicine, the quantitative liquid medicine is injected into the human vein through the infusion needle.

Instructions:

1.Open the unit packaging of the product, take out the Sterile burette infusion sets for single use device, remove the protective cap of piercing device, and insert piercing device into the medicine bottle or medicine bag.

2. Close the flow regulator below the graduated burette and open the closed air inlet with closure on the upper cover of the burette.

3.Hang the medicine liquid bottle or bag upside down, squeeze the graduated burette until the medicine liquid entering the burette reaches the required infusion capacity mark, and close the flow regulator above the burette.

4. loosen the flow regulator, squeeze the drip chamber, and control the liquid level in the drip chamber at about 2/3. After exhausting the air in the tube, fill the entire tube with medicine liquid, and close the flow regulator.

5.If the infusion set is equipped with an hypodermic needle, pull out the protective sleeve of the hypodermic needle, insert the hypodermic needle into the human vein, open the flow regulator, and adjust the delivery speed of the drug solution until the desired speed is reached, then the infusion can be carried out.

6.If the infusion set is not equipped with an hypodermic needle, open the unit package of the hypodermic needle, install the hypodermic needle on the male conical fitting at the end of the infusion set, and follow the steps of 4 and 5.

(At 20℃, 20Drops of distilled water equals 1ml or 60 drops of distilled water equals 1ml.)

Contraindications/Warning:

1.The product operating instructions should be read carefully before using the product. Check the integrity of the packaging, the single package is damaged and damp, the protective sleeve is detached, there are foreign objects inside, and it is forbidden to use.

2. This product is used disposable, destroyed after use; reuse may cause cross-infection or other injury.

3. Expiration date exceeded，prohibited use。

4. Products are not allowed to be stored in places with high temperatures, humidity and direct sunlight.

5. The drip chamber and tube of Sterile burette infusion sets for single use device products are made of PVC material, If the packaging label shows that the product material contains DEHP, possible toxicity attention should be paid to the high-risk population (neonates, prepubertal male, pregnant and lactating women). Fat-soluble liquids and medicines such as fat emulsion should not be infused. prohibited to infusion PVC-incompatible medicines.

6. Do not discard the infusion set after use at will. Dispose of the infusion set product after use in accordance with the regulations of the user's location.

【Symbol】

	Manufacturer		CE mark and Identification number of Notified Body
	Authorised Representative in the European community		Unique Device Identification
	Importer		Batch code
	Medical Devices		Date of manufacture, made in China

	Caution			Use by
	Consult instructions for use			Keep dry
	Do not reuse			Keep away from sunlight
	Sterilized using EO, single sterile barrier system			Fragile, handle with care
	Dot not re-sterilize			Keep upright during transport
	Do not use if package is damaged			Catalogue number
	contains latex			latex free
	contains phthalate			phthalate free
	Do not use if the packaging is damaged. Follow the instructions carefully.			Protect from sunlight
	Temperature limits			luftfeuchte begrenzung
	Drops permillilitre			Liquid filterwith pore size

Incident Reporting

The user and/or patient shall report any serious incident that has occurred in relation to the device to Anhui Easyway Medical Supplies Co., Ltd and the competent authority of the EU Member State in which the user and/or patient is established.

Environmental protection

After using this product, the disposal of medical device waste complies with relevant regulations and environmental protection requirements.

Storage method and service life

1.This product is valid for five years from the date of sterilization.

2.This product should be protected from direct sunlight, rain and snow. Product should be stored in a relatively humid less than 80%, non-corrosive gases, cool, dry, well ventilated, and clean environment.

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