Instruction for use

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Product Name

The sterile infusion sets for single use

Description

The sterile infusion sets are expected to establish a channel between the vein and the liquid medicine, which can filter the liquid, adjust the flow rate and add the drug function, so as to carry out intravenous infusion for patients.

Model and Class

SIS-ACNF-1111, SIS-ACNF-2111, SIS-AFNF-1111, SIS-AFNF-2111, SIS-ACNF-1211, SIS-ACNF-2211, SIS-ACNF-1121, SIS-ACNF-2121, SIS-ACNF-1222, SIS-ACNF-2222, SIS-ACNFLF-2111

SIS-ACNC-1111, SIS-ACNC-2111, SIS-AFNC-1111, SIS-AFNC-2111, SIS-ACNC-1211, SIS-ACNC-2211

Matching specifications and color codes for infusion needles and injection needles

Specification	0.7mm	0.8mm	0.9mm	1.1mm	1.2mm
Color code	Black	Dark Green	Yellow	Beige	Pink

Main structure and properties

The sterile infusion set products include protective cap of closure-piercing device, closure-piercing device, air inlet with air filter and closure, drip tube, drip chamber, fluid filter, tubing, flow regulator, injection site, check valve (If configured),male conical fitting, protective cap of male conical fitting or hypodermic needle. The device is intended to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into the vein.

Instructions

1.Open the unit packaging of the product, remove the protective cap of closure-piercing device, and insert closure-piercing device into the medicine bottle or medicine bag.

2.Hang the medicine liquid bottle or bag upside down, 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.

3.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.

4.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 2 and 3.

Intended purpose

The device is intended to administer fluids from a container to a patient's vascular system

through a needle or catheter inserted into the vein.

Intended user: Trained medical institution nursing staff.

Intended patient population:Patients who need intravenous fluids

Contraindications

1.Newborns, prepubertal men, pregnant and lactating women use DEHP-containing infusion sets with caution;

2.DEHP-containing infusion sets should not be used for infusion of fat-soluble liquids and drugs such as fat milk;

3.This product is forbidden to inject drugs that are incompatible with PVC.

Warnings

1. This product has been sterilized by ethylene oxide, sterile, pyrogen free, valid for 5 years.

2. This product is forbidden to be used in high pressure infusion system.

3. This product is only used by trained doctors or nursing staff.

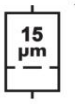
4. Check before opening, packaging damage, protective cover off, there are foreign bodies prohibited use.

5. This product is only for one-time use, immediately after opening, destroy after use.

6. Stored in the relative humidity is not more than 80%, no corrosive gas, clean environment.

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.

Anhui Easyway Medical Supplies Co.,Ltd
No. 8, Tianfeng Road, Yongfeng Industrial Area, Tianchang City, 239300 Anhui, China
www.easywaycompany.com

EU REP

Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany
Tel:+49-40-2513175

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