Instructions for use

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Product Name

Sterile Transfusion Sets for Single Use

Description

The disposable infusion enteral giving sets is used to deliver fluids into the gastrointestinal system of a patient who is physically unable to eat and swallow.

Model and class

IEGS-1

Main structure and properties

The Infusion enteral giving sets are consist of protective cap, piercing device, air filter, integral air-inlet, drip chamber, tube, flow regulator, gastroesophageal conical fitting, protective cap of conical fitting and so on.

Indications

1. Open the small package of the product, pull out the protective cap of the piercing device, and insert the piercing device into the stopper of the nutrient solution bottle or bag.
2. Hang the nutrient solution bottle or bag upside down, loosen the flow regulator, squeeze the drop, so that the liquid level in the drop is controlled at about 2/3, exhaust the air in the tube, fill the entire pipeline with nutrient solution or liquid food, and close the flow regulator.
3. Connect the gastroesophageal conical fitting with the gastroesophagus, open the flow regulator, adjust the delivery speed of enteral nutrient solution or liquid food, until the required speed, then the delivery can be carried out.

Intended purpose

The device is used to deliver fluids into the gastrointestinal system of a patient who is physically unable to eat and swallow.

Intended user: Trained medical institution nursing staff.

Intended patient population:

① Age group: non-limited, include newborn to geriatric;

② Weight range: all

③ Health: Patients who are unable to eat autonomously due to their physical condition need to receive nutrient solution or fluid food through an intestinal infusion device.

Contraindications

Nutrient liquid or liquid food such as fat soluble liquid and fat lotion shall not be transfused. Prohibit the infusion of nutrient solutions that are incompatible with PVC.

Warnings

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 product tube is made of PVC material. if the product 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.

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

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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