

# Instruction Manual of Syringes for Single Use

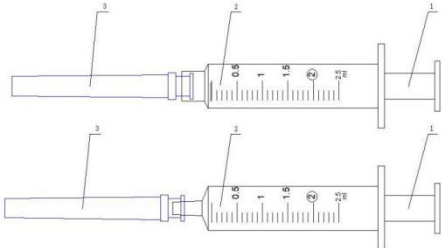

**IMPORTANT:** Read this instruction manual carefully before use the product, and keep it in a convenient location for easy consultation.

## Device description

The Syringes for Single Use consists of Barrel, Plunger, Piston and Needle, made of plastic or other materials and intended for the aspiration and injection of fluids after filling by the end-users.

The initial packaging is dialysis bag (dialysis paper +PE film), the middle package is white cardboard or grey cardboard (400g), and the outer package is five layers of corrugated carton.

The Syringes for Single Use is for single use only, It is provided sterile. The sterilization method is EO sterilization.

	
<p style="text-align: center;">Drawing of Disposable Sterile Syringes (1-Plunger+piston 2-Barrel 3 hypodermic needle)</p>	<p style="text-align: center;">Picture of Syringes for Single Use</p>

## Performance characteristics

- 1) The maximum available capacity is 10% larger than the nominal capacity.
- 2) Ethylene oxide residue  $\leq 10\mu\text{g/g}$ .
- 3) Acidity: the PH value of the syringe extraction solution and the same batch, the difference between the PH value shall not exceed 1.0.
- 4) Should be sterile, no pyrogen, no hemolytic reaction
- 5) Dead space

Nominal capacity of syringe (ml)	Maximum dead space (ml)
$V < 2$	0.07
$2 \leq V < 5$	0.07
$5 \leq V < 10$	0.075

$10 \leq V < 20$	0.10
$20 \leq V < 30$	0.15
$30 \leq V < 50$	0.17
$V \geq 50$	0.20

## Intended purpose

Syringes for single use are intended to inject drug for patients. And syringes are intended for use immediately after filling and are not intended to contain the medicament for extended periods of time.

## Indication

General purpose injection and aspiration of medical fluids, or pharmaceuticals.

## Patient target group

This device is suitable for children and adult patients.

Age: no restrictions for age of the patients;

Weight: no restrictions for weight of the patients;

Health: Patients who need aspiration and injection of fluids.

Nationality: multiple;

Patient status: PATIENT is not the OPERATOR;

## Intended users

Professional medical staff, include physicians, nurse, therapist and other relevant staff with medical science.

## Contraindications

- 1) The product with contains medical rubber, do not use if allergic to rubber.
- 2) The product is prohibited from High-pressure injection, and the drugs that indicate incompatible with polypropylene and Polycarbonate hypodermic syringe.
- 3) The product cannot be used with incompatible chemicals.

## Warnings

- Expel all the air in barrel from the needle upwardly, in case gas boit come into being if air be injected into human body blood vessels or tumor come into being if gas be injected into subcutaneous.
- Use immediately after opening the unit package. After use, dispose of properly and safely to eliminate risk of infection.
- Handle with care to avoid needle sticks.

## Precautions

- Do not use if packaging is damaged or unintentionally opened or contaminated before use.
- Do not use if the protective cap is parted or foreign matter is found.
- Do not re-sterilize. Contents are sterile unless package is opened or damaged.
- It has a valid period of five years, do not use after the expiration date.
- Read these instructions completely prior to use.
- For single use only. Discard any open, unused product.
- The products cannot be reused. The repetition use may cause cross infection, even serious illnesses such as hepatitis, HIV and other infectious disease.
- It should be used by special trained person, and the skin should be correctly sterilized
- Product must be stored in the original sealed pouch.
- Do not use for high pressure injection of contrast media.
- Do not store at extreme temperature and humidity. Avoid direct sunlight.
- Handle with care to avoid needlesticks.
- Keep hands behind needle at all times during use and disposal.

## Notice to the user/patient

If there any serious incident that has occurred in relation to the device, please reported to the manufacturer and the competent authority in your country immediately.

## Potential Adverse Reactions

- 1) Pain
- 2) Injection site infection
- 3) Injection site bleeding
- 4) Vascular injuries
- 5) Redness











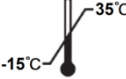






## Direction for use











- 1) First, check the validation period and completeness of package before using;
- 2) Tear the package and take out the syringe with needle;
- 3) Screw the needle into syringe tightly.
- 4) Push and pull plunger till it is well lubricated;
- 5) Remove protective cap of needle, then do as sterile operation requirements
- 6) Discard the used device into the specific medical waste bin after use.

## Storage conditions

Store at -15° C~40° C, keep away from sunlight, keep dry.

### Explanation of Symbols

	Medical device
	Caution
	Do not re-use
	Single sterile barrier system
	Sterilized by ethylene oxide
	Do not re-sterilize
	Do not use if the package is damaged
	Consult instructions for use
	Not contains or presence of natural rubber latex
	Non-pyrogenic
	Temperature limitation
	Humidity limitation
	Keep away from sunlight
	Keep dry
	Fragile, handle with care
	This Way UP
	Model number

	Reference number
	Batch code
	Expiry date
	Date of manufacture
	Country of manufacture
	Unique Device Identifier
	Manufacturer
	Authorized representative in the European Community / European Union
 0197	CE mark acc. Regulation (EU) 2017/745 by Notified Body 0197
	Manufacturer Logo

**Jiangsu Eyoung Medical Devices Co., Ltd.**



No. 1 Dongtang Road, Zhenglu Town, Tianning District, Changzhou City, 213115 Jiangsu, China.

Tel: [+86-519-85619978](tel:+86-519-85619978)

Fax: [+86-519-86059978](tel:+86-519-86059978)



**Shanghai International Holding Corp. GmbH (Europe)**

Eiffestrasse 80, 20537 Hamburg, Germany