

INSTRUCTION FOR USE

Sterile Syringes For Single Use

Without Needle



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1. Intended use

This product is used for medical equipment connecting 6% Luer taper joint, or for washing human wounds or cavities in surgery and gynecology of medical institutions, or for extracting liquid to prepare drugs or transfer drugs.

- 1) Intended users: medical professionals, including doctors, nurses, etc.
- 2) Intended use environment: The device is mainly used in medical institutions.
- 3) Intended patient population:
 - ① Age group: unlimited, including newborns to the elderly;
 - ② Weight range: all;
 - ③ Health range: people who need to use syringes to complete relevant treatment.
- 4) The type of body part or tissue with which it interacts:

The device does not come into direct contact with the patient's skin, tissue or blood path.

- 5) Intended clinical efficacy:

Through the use of syringes to achieve the effect of adjuvant therapy.

2. Product Description

Sterile syringes can be divided into three-piece syringe and two-piece syringe (including syringes for tuberculin). Three-piece syringe include a barrel, plunger and rubber plug. The two-piece syringe includes a barrel and plunger.

All materials of the product meet medical requirements, the concentration of CMR and or endocrine disrupting substances does not exceed 0.1% by weight, and does not contain radioactive substances.

The biological, chemical and physical properties of the products meet the requirements of the product standards.

Syringes Volume:

Three-piece syringe :1mL, 2mL, 2.5mL, 3mL, 5mL, 10mL, 20mL, 25mL, 30mL, 35mL, 50mL, 60mL;
Two-piece Syringe :1mL, 2mL, 5mL, 10mL, 20mL, 30mL, 35mL, 50mL, 60mL.

Clear scale range, capacity tolerance in accordance with ISO 7886-1(latest edition), measurement functions meet the requirements of Table 1:

The product is sterilized by ethylene oxide.

This product is not a combination of pharmaceutical devices.

This product is a class Is sterile medical device, not implantable.

Basic UDI-DI: 69541527202101sJZQ4E

The full UDI-DI record is available in the EUDAMED database.

CE Marking: CE 0123 – Conformity assessed under MDR by Notified Body TÜV SÜD Product Service GmbH Certification Body.

Table 1

Nominal capacity of syringe V mL	Tolerance on any graduated capacity		Precision	
	Less than half nominal capacity	Equal to or greater than half nominal capacity	less than half nominal capacity	Equal to or greater than half nominal capacity
$V < 2$	$\pm(1.5\% \text{ of } V + 2\% \text{ of discharge volume})$	$\pm 5\% \text{ of discharge volume}$	$\leq 5.1\%$	$\leq 2.1\%$
$2 \leq V < 5$	$\pm(1.5\% \text{ of } V + 2\% \text{ of discharge volume})$	$\pm 5\% \text{ of discharge volume}$		
$5 \leq V < 10$	$\pm(1.5\% \text{ of } V + 1\% \text{ of discharge volume})$	$\pm 4\% \text{ of discharge volume}$		
$10 \leq V < 20$	$\pm(1.5\% \text{ of } V + 1\% \text{ of discharge volume})$	$\pm 4\% \text{ of discharge volume}$		
$20 \leq V < 30$	$\pm(1.5\% \text{ of } V + 1\% \text{ of discharge volume})$	$\pm 4\% \text{ of discharge volume}$		
$30 \leq V < 50$	$\pm(1.5\% \text{ of } V + 1\% \text{ of discharge volume})$	$\pm 4\% \text{ of discharge volume}$		
$V \geq 50$	$\pm(1.5\% \text{ of } V + 1\% \text{ of discharge volume})$	$\pm 4\% \text{ of discharge volume}$		

3. Instructions for use

- 1) Please use it in time after opening the aseptic packaging;
- 2) Fill the syringe, correctly adjust and read the scale of the required drug dosage;
- 3) According to the needs of the purpose, it should be correctly used for the use of connecting other medical devices, flushing or preparing drugs;
- 4) After use, please destroy according to the medical device waste disposal regulations;
- 5) This device is sterile medical device and can be used independently;

4. Contraindications

- 1) High-pressure injection is prohibited;
- 2) Drugs incompatible with polypropylene and polyethylene syringes are prohibited;
- 3) This product should not be used with incompatible chemicals.

5. Precautions and warnings

- 1) If sterile packaging is damaged or accidentally opened, the scale is not clear or incomplete, there are foreign bodies or product damage, do not use;
- 2) Expired prohibited use;
- 3) This product is for one-time use only, and repeated use is prohibited;
- 4) Use the syringe immediately after it is filled with medicine;
- 5) Avoid moisture, heat and pollution;

6) Waste shall be disposed of in accordance with relevant medical device disposal regulations and other provisions;

7) A notice to the user and/or patient informing them that they should report any serious incidents related to the equipment to the competent authorities of the manufacturer and user and/or the Member State in which the patient resides;

8) As indicated in the ISO Syringe Standard (ISO7886-1), syringe manufacturers are not required to prepare compatibility tests for all drugs that may be injected;







9) The use of this product must meet the requirements of the relevant operating norms and relevant regulations of the medical department. It is limited to trained doctors, nursing staff and other professional medical personnel, and non-professional personnel are prohibited to use it.









6. Validity period, production date and/or expiration date

Validity period: 5 years. The production date and/or expiration date are detailed on the packaging.

7. Storage, transportation and maintain

The product should be stored in a cool, dry, clean, well-ventilated environment without corrosive gas, and prevent direct sunlight and rain and snow from wetting.

Drawing	Meaning
	"CE mark"
	"DO NOT USE IF PACKAGE IS DAMAGED"
	"STERILE" by EO sterilization
	"DO NOT REUSE", "single use", "Use only once"
	"Sterile barrier system/sterile packaging"
	"Non-sterile protective packaging with sterile barrier system inside"

	" LATEX FREE"
	"DATE OF MANUFACTURE"
	"Consult instructions for use"
	"CAUTION"
	"Keep away from sunlight"
	"Fragile,handle with care"
	"Expiry date"
	"MANUFACTURER"
LOT	"BATCH CODE"
EU REP	"Authorized representative in the European Community"
CH REP	"Authorized representative in the Switzerland"

8. Handling of Adverse Events

In the event of a serious incident (e.g., needle breakage, sterility breach, patient injury), Report immediately to Email: zhzb@kdlchina.com;

National Competent Authority: Use the EU portal: <https://www.adrreports.eu>

Provide: device name, UDI, batch number, description of incident, and patient outcome.

EU REP

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CH REP

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