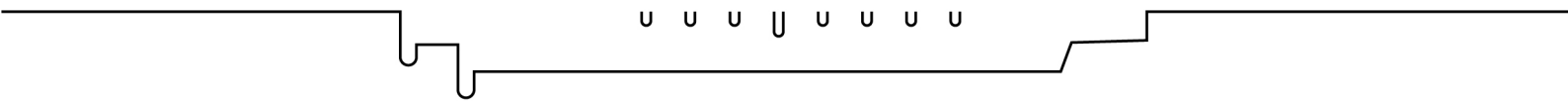
Guangdong Kindly
Medical Device Group Co.,Ltd.

INSTRUCTION FOR USE

Sterile Syringes For Single Use

With Needle



1. Intended use

This product is mainly used for intradermal, subcutaneous, muscle or intravenous injection of liquid medicine.

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: people who need to complete drug injection by using a syringe.

4) The body part or type of tissue with which it interacts:

The device will come into direct contact with the patient's skin, tissues and blood paths;

Body parts: subcutaneously or intravenously.

5) Intended clinical benefits:

① Provide sterile injections when used properly;

② Widely available;

③ Low cost.

2. Product description

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

All materials of the product meet the medical requirements, the concentration of CMR substances and endocrine disrupting substances shall not exceed 0.1% by weight, and it 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.

Hypodermic needle specifications: 14G, 16G, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G.

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

The product was sterilized by ethylene oxide.

This product is not a combination product of medicine and equipment.

This product is a Class IIa sterile medical device, not implantable.

Basic UDI-DI: 69541527202102aJZQYQ

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 nomial capacity	less than half nomial capacity	Equal to or greater than half nomial capacity
V < 2	±(1.5% of V + 2% of discharge volume)	±5% of discharge volume	≤ 5.1%	≤ 2.1%
2 ≤ V < 5	±(1.5% of V + 2% of discharge volume)	±5% of discharge volume		
5 ≤ V < 10	±(1.5% of V + 1% of discharge volume)	±4% of discharge volume		
10 ≤ V < 20	±(1.5% of V + 1% of discharge volume)	±4% of discharge volume		
20 ≤ V < 30	±(1.5% of V + 1% of discharge volume)	±4% of discharge volume		
30 ≤ V < 50	±(1.5% of V + 1% of discharge volume)	±4% of discharge volume		
V ≥ 50	±(1.5% of V + 1% of discharge volume)	±4% of discharge volume		

3.Instructions for use

1) Only for medical professionals to inject medicine for patients who need injection;
2) Use in time after opening aseptic package;
3) Connect the hypodermic needle and remove the needle cap;
4) Fill the syringe, correctly adjust and read the scale with required dose of medicine;
5) A syringe draws or injects liquid and uses it immediately;
6) In order to achieve the purpose of destruction, the sterile syringe can be inserted into the destruction device or separated from the syringe with pliers after use, the needle can be directly put into the puncture resistant container, the syringe and needle should be burned, disinfected or buried after incineration;
7) This product is a sterile medical device and can be used independently;

4. Contraindications

1) Ban high-pressure injection,
2) It is forbidden to use drugs incompatible with polypropylene and polyethylene hypodermic syringes.
3) This product should not be used with incompatible chemicals.

5. Precautions and warnings

1) If the sterile packaging is damaged or opened accidentally, the protective sleeve of the injection needle falls off, the scale printing is unclear or incomplete, there are foreign bodies or the product is

damaged, it is forbidden to use;

2) No use after expiration;

3) This product is only for one-time use only, reuse is forbidden, and it is destroyed after use;

4) Waste should be disposed of in accordance with provisions such as the Clinical Waste Management Ordinance and should be protected from needle-stick injuries;

5) Use immediately after the main package is removed, and inject drugs immediately when filling;

6) If the needle is damaged, do not use it;

7) Avoid moisture, heat and pollution;

8) A notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established;

9) Not recommended for ophthalmic injection;

10) The syringe should be used immediately after aspirating the liquid. As shown in the ISO Syringe standard (ISO7886-1), there is no requirement for syringe manufacturers to prepare for compatibility tests for all medicine that may be injected;

11) The use of this product must comply with the relevant operation specifications and regulations of the medical department. It is only used by trained doctors, nursing staff and other professional medical personnel, and non-professional personnel are forbidden to use it.

12) Some patients may suffer from redness, swelling, pain, bleeding, papules and redness after injection.

13) It is not advisable to puncture continuously or repeatedly at the same site to reduce pain at the puncture site and to prevent thrombophlebitis.

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	“CE mark”
	"DO NOT USE IF PACKAGE IS DAMAGED"
STERILE EO	"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"
	"BATCH CODE"
	"Authorized representative in the European Community"
	"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: zhzjb@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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