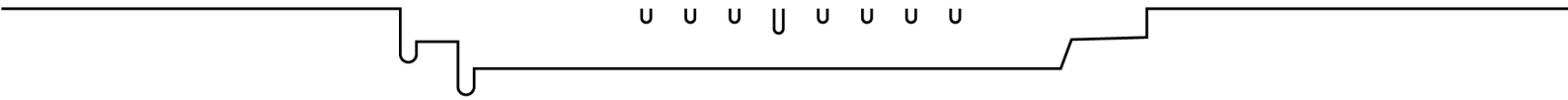
Guangdong Kindly
Medical Device Group Co.,Ltd.

INSTRUCTION FOR USE

Sterile Irrigation Syringe For Single Use



1. Intended use

For medical institutions surgery, gynecology irrigation of human body wound or cavity.

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 use irrigators to complete relevant treatment.

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

The device is for irrigation use only and does not come into direct contact with the patient's site or may only come into contact with the surface of the site.

5) Expected clinical efficacy:

Adjuvant therapy is achieved through the use of irrigators.

2. Product description

Flusher type is divided into: Type B, Type D;

Type D specification: 30mL, 35mL;

Type B specification: 50mL, 60mL.

Type D composition structure: barrel,plunger,rubber plug, butt fittings, of which the butt fittings is optional;

Type B composition structure: barrel,plunger, rubber plug, sheath, butt fittings, of which the cap and butt fittings are optional accessories.

All materials of the product meet medical requirements, the concentration of CMR substances 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 product meet the requirements of product standards.

Clear scale range, capacity tolerances refer to ISO 7886-1(latest edition), and measurement functions meet the requirements of Table 1.

The product is sterilized by ethylene oxide.

This product is a combination of non-pharmaceutical devices.

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

Basic UDI-DI: 69541527202201sJCQ2S

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) Use in time after opening sterile packaging;
2) Fill the irrigator, correctly adjust and read the scale of the required drug dosage;
3) After use, please destroy it according to relevant regulations on medical device waste treatment;
4) This device is sterile medical device and can be used independently.

4. Contraindications

1) High-pressure injection is prohibited;
2) Prohibit the use of drugs incompatible with polypropylene;
3) This product should not be used with incompatible chemicals.

5. Precautions and warnings

1) If the aseptic packaging is damaged or accidentally opened, the scale is not clearly printed or disabled which affects the use, foreign body 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) Avoid moisture, heat and pollution;
5) 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;

6) After inhaling liquid, please use the douche in time;

7) 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;

8) This product cannot be used for human injection;

9) After use, it shall be disposed of in accordance with relevant medical device disposal regulations.

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"
	"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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