Instructions for Use

1. Product Name

Silicone Catheter

2. Intended Use

Silicone Catheter is used for temporary urethral catheterization or indwelling catheterization and bladder irrigation.

3. Intended User

Professional medical staff

4. Intended Patient Populations

Adults, Children, Elderly

5. Intended Use Environment

It is used in multiple clinical departments. For example, urology, gynecology, etc

6. Component

Type	Component
Single-lumen	It is made of catheter connector,catheter, imaging line, bullets, guidewire (optional)
Double-lumen	It is made of catheter 2-way connector,catheter, imaging line, bullets, check valve,guidewire (optional), saccule(optional)
Triple-lumen	It is made of catheter 3-way connector,catheter, imaging line, bullets, check valve,guidewire (optional), saccule(optional), flush taper joint (with protective cap) (optional)

7. Type and Specification

Type	Spec.（Fr/Ch）	O.D.（±0.3 3mm）	Effective length L（≧mm）	Flow rate（≧ml/min）	
				Drainage funnel	Trrigation funnel
Single-lumen	6	2.0	150	10	/
	8	2.7	150	15	/
	10	3.3	150	30	/
	12	4.0	360	50	/
	14	4.7	360	70	/
	16	5.3	150/360	100	/
	18	6.0	150/360	100	/
	20	6.7	150/360	100	/
	22	7.3	150/360	100	/
	24	8.0	150/360	100	/
	26	8.7	150/360	100	/
Double-lumen	6	2.0	150	10	
	8	2.7	220	15	/
	10	3.3	220	30	/
	12	4.0	360	50	/
	14	4.7	360	70	/
	16	5.3	220/360	100	/

	18	6.0	220/360	100	/
	20	6.7	220/360	100	/
	22	7.3	220/360	100	/
	24	8.0	220/360	100	/
	26	8.7	220/360	100	/
Triple-lumen	6	2.0	150	10	/
	8	2.7	220	15	/
	10	3.3	220	30	/
	12	4.0	360	50	/
	14	4.7	360	70	25
	16	5.3	220/360	100	25
	18	6.0	220/360	100	25
	20	6.7	220/360	100	25
	22	7.3	220/360	100	30
	24	8.0	220/360	100	30
	26	8.7	220/360	100	30

8. Contraindications

For transurethral catheterization

1) Acute urethritis
2) Acute prostatitis
3) Acute epididymitis
4) Allergic to the material (Silicone)

For suprapubic catheterization

1) Known or suspected carcinoma of the bladder
2) Suprapubic catheterisation is absolutely contraindicated in the absence of an easily palpable or ultrasonographically localised distended urinary bladder
3) Previous lower abdominal surgery
4) Coagulopathy (until the abnormality is corrected)
5) Ascites
6) Prosthetic devices in lower abdomen e.g. hernia mesh
7) Pelvic fracture

9. Indications

1) When patients with acute dysuria caused by various reasons, indwelling catheterization is required as an emergency measure to alleviate patients' dysuria, such as acute urinary retention caused by prostatic hyperplasia, and urinary retention caused by obstruction caused by urethral stones.
2) All kinds of operations take more than one hour, and indwelling catheterization is required to facilitate anesthesiologists to record the patient's output. After surgery, patients often need to stay in bed, cannot urinate on the ground. Patients have no sense of urination after anesthesia, if not indwelling catheterization may cause a large amount of urine retained in the bladder, causing serious complications such as hydronephrosis.
3) Indwelling catheterization is required when rescuing critically ill patients, such as shock patients, the purpose of indwelling catheterization is to record the patient's output and determine whether the intravenous infusion is

too little or too much.

4) Postoperative indwelling catheterization is required after surgery on various urethra. If the urinary catheter is not placed after urethral surgery, the surgical bruise may be narrowed again during the healing process, leading to surgical failure. Wait for the wound to heal completely and then remove the urethral after shaping to achieve good surgical results.

10. Used together with Other Devices

The product is connected with urine bags or syringes.

The check valve is combined with a disposable syringe to inject sterilized distilled water into the saccule to expand it, or to extract the sterilized distilled water from the saccule and pull out the catheter.

The excretory cavity of the catheter connector is connected to the urine bag connector to discharge urine.

11. Performance Characteristics

Materials:

The catheter is made of silicone rubber, which has good biocompatibility and is less irritating to the patient's skin and urethral mucosa.

Function:

The catheter can be connected to a urine bag or syringe to facilitate urine collection and bladder flushing.

Double-lumen and triple-lumen catheters are equipped with a balloon to fix the catheter in the bladder to prevent it from falling off.

The triple-lumen catheter is also equipped with a flushing connector that can be used to inject drug solutions into the bladder.

Safety:

The catheter is sterilized with ethylene oxide to ensure sterility.

The catheter is soft and less irritating to the urethral mucosa, reducing patient discomfort.

The balloon capacity is clear to avoid damage caused by overinflation.

Contains a developing line to facilitate X-ray positioning and confirmation of position.

12. Use Method

The following usage methods are general usage methods. In actual clinical use, doctors can add and change the techniques based on experience.

1) Before use, wear sterile gloves to clean, wipe and routinely disinfect the external urethra and vulva of the human body.

2) Open the package under aseptic conditions, take out the urinary catheter from the sterilization bag, apply lubricant as needed (paraffin oil is contraindicated), and use a disposable syringe to confirm whether the saccule can expand and contract.

3) Insert the urinary catheter into the bladder along the urethra.

   Male: Slowly insert into the urethra about 15∽20cm, which is equivalent to 1/2 of the length of the urethra. After urine is seen flowing out, insert another 2cm.

   Female: Keep the labia open and slowly insert 4∽6cm into the urethra. After seeing urine flowing out, insert

another 5∽7cm.

4) Introduce the outflow urine into the urine bag.
5) When inserting the saccule part of the urinary catheter into the bladder, use a disposable syringe to inject sterile distilled water into the saccule to fill it up. Gently pull the catheter so that the saccule is pushed against the bladder neck to confirm that the urinary catheter will not be pulled out.
6) The silicone catheter body may contain a developing line that can clearly show the position of the catheter in the urethra and bladder under X-ray, making it easier for medical staff to confirm in real time whether the indwelling depth is appropriate (it needs to enter 5-6 cm after insertion into the bladder) and the drainage status.
7) After insertion, the catheter is fixed on the skin with a tape.
8) There should be no urine leakage at the connection between the urinary catheter and the urine bag.
9) Flush taper joint can be used to regularly inject medicinal liquid into the bladder according to the doctor's instructions.
10) When pulling out the urinary catheter, use a syringe to suck out the saccule's sterile distilled water.

13. Warnings and Precautions

1) This product is a single-use sterile device and is prohibited from being reused to avoid the risk of cross infection.
2) To ensure safety, please check all parts of the product to see if they are in good condition before use. If any abnormality is found, stop using the product.
3) To ensure safety, you must check the expiration date of this product before use. It is strictly forbidden to use expired products.
4) To ensure safety, please check that the packaging of this product is intact before use. If the packaging is damaged, the sterility will be affected, so please stop using it immediately.
5) To ensure safety, this product should be used immediately after opening the package. After use, be sure to follow the requirements of local medical regulations and properly dispose of medical waste. After use, the metal guide wire should be immediately placed in a sharps box that meets EU standards. When handling the metal guide wire, be sure to wear protective gloves and avoid direct contact with sharp objects to prevent punctures.
6) Do not over inflate the saccule. Refer to outer unit pack or funnel of catheter for saccule capacity.
7) Inflate catheter saccule only with sterile water or 10% sterile glycerine solution.
8) The pre-filled syringe or 10% sterile glycerine solution (if included) is for inflation of the saccule only. Not for injection.
9) The empty syringe (if included) is for deflation of the saccule before the removal of the catheter.
10) The product is intended for use by physicians trained and aseptic technique must be practiced.
11) Do not use petroleum-based lubricants.
12) Do not use if package has been opened or damaged.
13) Do not clamp catheter shaft. It may damage catheter and prevent deflation.
14) Do not use needle to inflate saccule. Use a Luer syringe (Luer slip or Luer lock).
15) For single patient use only.
16) Do not use after the expiry date.

17) Patients should be regularly monitored as determined by a physician.
18) Ensure local cleaning and hygiene protocols are followed to keep the catheter and meatus as clean as possible.
19) The saccule inflation volume should be regularly monitored in case any clinical signs of deflation occur, such as bypassing of urine or urethral pain. If necessary, the saccule volume should be adjusted.
20) If deflation does not occur, established procedures should be followed and must be performed by a physician or suitably trained health care professional.
21) The maximum retention time of this product shall not exceed 28 days.
22) 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.

14. Adverse Reactions

1) Reported adverse reactions associated with Catheter are: Septicemia, Urethritis, Urinary tract infection and encrustations, bladder spasms, abdominal discomfort, abdominal discomfort, etc.
2) If difficulty is encountered aspirating the saccule with a syringe, a rare and infrequently reported event, the leg of the catheter with the valve should be cut with a sharp scissors at the bifurcation or the saccule ruptured according to established procedures reported in medical literature. Should it be necessary to rupture the saccule, care must be taken to remove all fragments from the patient's bladder.
3) Incorrectly positioned catheters can cause urethral damage if the saccule is inflated contrary to instructions within the urethra.
4) Irritation of the urethral mucosa, blockage of the catheter due to encrustation and catheter induced infections are documented complications with some catheter materials and patients. The patient should be routinely monitored in accordance with accepted procedures and the catheter shall be removed after a suitable interval as determined by a physician or other suitably qualified personnel.
5) The product is for one-time use. Medical personnel choose the retention time according to the actual clinical use. It is recommended that the silicone catheter should not exceed 28 days.

15. Potential Complications

Possible complications known to be associated with indwelling catheters include irritation of the urethral mucosa, blockage of the catheter due to encrustation, and catheter induced infections. Patients should be routinely monitored in accordance with accepted procedures and the catheter shall be removed after a suitable interval as determined by a physician or other suitably qualified personnel.

16. Clinical benefits

1) Provide a slippery surface to reduce friction
2) Superior resistance to kinking
3) Better flow properties
4) Reducing the incidence of urethritis and the rates of encrustation and infection
5) Lower rate of insertion failure
6) Siliconised catheters may be less likely to cause urethral side effects in men
7) The risk of a burning sensation in the urethra is less in the Silicone catheter

17. Shelf-life

Three years

18. Sterilization Method

Ethylene oxide

19. Storage and Transport Conditions

1) No heavy pressure, direct sunlight, rain or snow dipping, so as not to damage the device.
2) Handle with care during transport and avoid violent collision.
3) The product should be far away fire, heat source and corrosive gas, and please pay attention to good ventilation.
4) Store in a cool and dry place, and ensure that the room is well ventilated, no corrosive gas, and relative humidity does not exceed 80%.
5) Stock rotation on first in first out basis.

20. Production Date

See on the package.

21. Symbol Explanation

	Manufacturer		Date of manufacture
EU REP	Authorized representative in the European Community	LOT	Batch code
	Consult instructions for use or consult electronic instructions for use		Use-by date
	Do not resterilize		Caution
	Do not use if package is damaged and consult instructions for use	STERILE EO	Sterilized using ethylene oxide
	Do not re-use		Up
MD	Medical device	UDI	Unique device identifier
CE 2797	CE Marking	REF	Catalogue number
	Keep away from sunlight		Keep dry
	Fragile, handle with care	LATEX	Do not contain natural rubber latex
	Single sterile barrier system with protective packaging inside		

[Manufacturer]

Name: JIANGSU FEIYU MEDICAL APPARATUS CO., LTD.

Address: No.8 Xingda Road, Touqiao Town, Guangling District, Yangzhou City,Jiangsu Province,China

EU REP **[EU Representative]**

Name: Phoenix Medtech GmbH

Address: Koenigsberger Strasse 11, 64839, Muenster Hessen, Germany