wellead

Instruction For Use

Latex Foley Catheter

DESCRIPTION

Latex Foley Catheter is inserted through the urethra during urinary catheterization and into the bladder to drain urine, or for irrigating the bladder. It consists of shaft, drainage funnel, inflation funnel, irrigation funnel (if present), balloon and valve. Accessories for the Latex Foley Catheter include：Cap, Spigot, Prefilled syringes with purified water (5mL and 10mL), and Empty syringes (5mL and 10mL).

FEATURES

- Made from latex which is soft and comfortable
- Silicone coated
- Color coding for size identification
- Available with different types

INTENDED USE

Latex Foley Catheter is inserted into the bladder through urethra and are indicated for routine urine drainage or for routine post-operative drainage and irrigation bladder.

CLINICAL BENEFITS

- By urinary catheterization, urinary catheter indwelling and bladder irrigation, the Latex Foley Catheter can draw out urine in the bladder so as to alleviate the symptoms of patients, use with urine collection systems to measure the urine volume providing accurate data for medical diagnosis procedures, it also can be used to irrigate bladder, drain irrigation solution to realize adjuvant therapy function.
- The clinical benefit associated with the device is define as direct, it is applied for perioperative patient, and patient have urinary retention or bladder outlet obstruction.

PATIENT TARGET GROUP

Newborn, Infant, Child, Adult

The product can be used on perioperative patient and patient have urinary retention or bladder outlet obstruction.

INTENDED USER

Must be operated by trained professionals.

INDICATIONS

- Patient has acute urinary retention or bladder outlet obstruction
- Use for selected surgical procedures
- To assist in healing of open sacral or perineal wounds
- Patient requires prolonged immobilization
- To improve comfort for end of life care

CONTRAINDICATIONS

- Acute urethritis
- Acute prostatitis
- Acute epididymitis
- Allergy to latex
- Urethral injury or urethrostenosis
- Menstrual period

ADVERSE REACTIONS

- Bleeding
- Urethral swelling
- Urethritis
- Catheter-associated urinary tract infection (CAUTI)

DIRECTIONS FOR USE

Preparation:

- The following additional items might be required for catheterization:

✓ Sterile field, Sterile gloves, Items required for cleaning the patient meatus, (sterile, based on established techniques), Luer syringe with sterile water for balloon inflation (if not included), Empty syringe for balloon deflate (if not included), Sterile dressings, Urine drainage device.

- Before use, visually inspect the catheter to detect mechanical damages and check that no leakage occurs.
- Place male patients in supine position, female patients in lithotomy position.
- Wash and dry hands thoroughly.
- Using aseptic technique, remove the catheter from its pouch and place it on a sterile field.
- Put on sterile gloves and remove the catheter sleeve.
- Lubricate the tip and the shaft of the catheter with a water-based lubricant.
- Clean the opening of the urethra and the surrounding area, using established techniques.

Catheterization:

- Test the balloon function before operation with pre-filled syringe.
- With the uncontaminated hand, pick up the catheter from the sterile field.
- Generously lubricate the tip and shaft of the catheter. Do not use ointment and lubricants having petroleum base.
- Carefully insert catheter tip into the bladder (normally indicated by urine flow), and then a further 5-7cm to ensure balloon is inside the bladder.
- For catheters with Tiemann tip, the tip should be facing towards the ceiling or patients' face, assuming the patient is supine.
- After the catheter is inserted to the right place, remove the cap on pre-filled syringe and connect the syringe to the valve of Foley Catheter. Push the plunger steadily for continuous flow of purified water into catheter balloon with the volume marked on Foley Catheter funnel.
- Disconnect the syringe from the valve and dispose syringe by local regulations.
- Slowly retract the catheter until some resistance is felt to ensure that the balloon is correctly located within the bladder, before the bladder neck.
- Connect the catheter to a urine drainage device.
- Observe urine flow.

Catheter removal:

- For removal of the catheter, deflate the balloon by inserting the empty syringe into the inflation valve. Release the syringe plunger and allow the balloon to deflate. Only use gentle aspiration, if necessary, to deflate the balloon. The balloon should spontaneously deflate.
- Discard the catheter according to local regulations.

Catheter care:

- Ensure local cleaning and hygiene protocols are followed to keep the catheter and meatus as clean as possible. In particular, for long-term catheterization, in order to prevent infection, please refer to the relevant guidelines for catheter care，such as EAU Guidelines On Urological Infections and Guidelines For Prevention of Catheter-Associated Urinary Tract Infections 2009.
- Conduct hand hygiene immediately before and after any manipulation of the catheter and the urine drainage system. Wear disposable gloves when handling the system.
- Maintain unobstructed urine flow.
- Ensure that the catheter and collection tube do not kink.

Deflation Procedure：

Insert the syringe luer tip into the valve housing with a firm push/twist motion. Release syringe plunger and allow balloon to deflate. Use only gentle aspiration, if necessary, to deflate balloon. The balloon shall deflate spontaneously. lf deflation does not occur, proceed to the alternative methods listed below.

- Step 1. Aspire by slowly pulling back on syringe plunger handle to force deflation. lf this does not work, proceed to Step 2.
- Step 2. Try inflating the balloon with 5mL/cc of air or 2-3ml of sterile water, if it could be inflated then slowly aspirate it and repeat 5-8 times until the fluid in balloon is deflated completely. lf this does not work, proceed to Step 3.
- Step 3. Use scissors to sever the side arm below the valve or cut the catheter shaft at some safe distance from the meatus and the balloon of catheter shall drain spontaneously. Before cutting the catheter, the proximal catheter must be fixed to prevent the catheter from retracting into the urethra. lf this does not work, proceed to Step 4.
- Step 4. Use scissors to sever the inflating cavity longitudinally in the direction of the urethral orifice, use a micro-rigid guidewire to penetrate deep into the inflating cavity to the direction of the balloon to puncture the balloon, and the fluid in the balloon shall flow out spontaneously. lf this does not work, proceed to Step 5.
- Step 5. Doctors need to puncture the balloon and take out the catheter by bladder puncture under B-ultrasound.

PRECAUTIONS / WARNINGS

PRECAUTIONS

- Do not over inflate the balloon. Refer to outer unit pack or funnel of catheter for balloon capacity.
- The retention time of Latex Foley Catheter should be decided by trained professionals according to the actual situation of using. Suggest to use less than 14 days.

WARNINGS

- Read all warnings and instructions before use. Improper use can result in serious or fatal illness or injury.
- The product must be operated by trained professionals.
- The whole catherization process need to use aseptic technique.
- Do not use if the sterile packaging is damaged or unintentionally opened before use.
- Do not use if it’s damaged or irregularly shaped.
- Do not use after the expiry date.
- For single use only.

- This product is applicable to magnetic resonance imaging (MRI) examinations without affecting imaging findings.
- This product contains Latex and might cause allergy. Doctors need to decide if the patient can use latex catheters according to patient's allertic history.
- Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in injury, illness or death of the patient. Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- Inflate catheter balloon with sterile distilled water.
- Do not use ointment and lubricants having petroleum base. Use silicone oil or water soluble lubricants.
- Do not clamp catheter shaft. It may damage catheter and cause non deflation.
- Do not use needle syringe to inflate balloon. Use Luer syringe without needle.
- Be careful that the balloon cannot contact with sharp edges.
- Dispose of product and packaging in accordance with hospital administrative and/or local government policy.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the local competent authority of the user's place.

MRI SAFETY INFORMATION

A patient with the Latex Foley Catheters with the Welllead Valve may be safely scanned under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 2,000-Gauss/cm (20-T/m)
- 2.0 W/kg whole body average SAR for 60 minutes of continuous RF(a sequence or back-to-back series/scan without breaks)

STORAGE CONDITIONS

- Store in a cool and dry place, keep away from sunlight. Protect product from moisture and excessive heat.
- Avoid prolonged exposure to ultraviolet, sunlight and fluorescent light.
- Store in manner preventing crushing.

APPENDIX:

The Key Performance Characteristics of the Latex Foley Catheter

a) The Key Performance: Flow

Test Method: According to Appendix E of ISO 20696-2018

The flow is not less than the following table 1:

Table 1

Specifications (Fr)	6	8	10	12	14	16	18	20	22	24	26	28	30
Drainage Flow, ≥mL/min	10	15	30	50	70	100	100	100	100	100	100	100	100
Irrigation Flow, ≥mL/min	/	/	/	/	/	25	25	25	30	30	30	/	/

b) The Key Performance: Balloon Safety

Test Method: According to Appendix C of ISO 20696-2018

The catheter balloon is inflated with water to maximum stated capacity and immersed in simulated urine for 14 days. Then according to the table 2 below, the weight is selected to hang under the catheter according to the specifications, and after 1min, the balloon shall not leak or block the drainage hole.

Table 2

6Fr~8Fr	10 Fr	12 Fr	14 Fr	16 Fr and above
0.3Kg	0.45 Kg	0.6 Kg	0.7 Kg	1.0 Kg

MEANING OF SYMBOLS ON PACKAGE

	**Date of manufacture**		**Use-by-date**		**Batch code**
	**Do not re-use**		**Consult instructions for use**		**Do not use if package is damaged**
	**Sterilized using ethylene oxide**		**Do not resterilize**		**Single sterile barrier system with protective packaging inside**
	**Medical Device**		**Manufacturer**		**Authorized representative in the European Community**
	**CE Marked Product**		**Keep dry**		**Keep away from sunlight**
	**Importer**		**This way up**		**Fragile, handle with care**
	**Contains or presence of natural rubber latex**		**Catalogue number**		**MR Conditional**

wellead

Instruction For Use

UKCA 0086 **UKCA Marked Product**

UKRP **UK Responsible Person**

CH REP **Authorized representative in Switzerland**

UDI Unique Device Identifier

STERILE R **Sterilized using irradiation**

WELL LEAD MEDICAL CO., LTD.
Address: C-4 Jinhu Industrial Estate, Hualong, 511434 Panyu, Guangzhou, PEOPLE'S REPUBLIC OF CHINA
E-mail: info@welllead.com.cn www.welllead.com.cn
Tel: +86 20 84758878

EC REP Shanghai International Holding Corp. GmbH (Europe)
Address: Eiffestrasse 80, 20537 Hamburg, GERMANY

CH REP QS Engineering AG
Address: Rütihof 1, CH 8820 Wädenswil, Switzerland

UKRP SUNGO Certification Company Limited
Address: 3rd Floor, 70 Gracechurch Street, London, EC3V 0HREngland, United Kingdom

Version and date: WLIFU-01-001-02E/ Dec 30, 2024