

Disposable Urethral Catheter Set

一、 Product name, model and specification

Product name: Disposable Urethral Catheter Set

Model specification: According to the model of the catheter

二、 Name, address, production address, contact information and after-sales service unit of the registered person/manufacturer

1. Name: Hunan Zhenheyikang Medical Instrument Co., LTD

2. Address: NO.6 Building Jingxiang Energy, No.55 Xianguang east road,Gaoxin district Xiangtan, Hunan

3. Production address:NO.6 Building, NO.8 Building,3rd and 4th floor Jingxiang Energy, No.55 Xianguang east road,Gaoxin district Xiangtan, Hunan,NO 19 Chutian Road, Yuetang District, Xiangtan City, Hunan

4. Contact number:+86 17711627084

5. After-sales service unit:Hunan Zhenheyikang Medical Instrument Co., LTD

三、 **Manufacturing License NO** : Hunan Medical Products Administration
Production Licence No.20150013

四、 **Product Registration Certificate No、 Product Technical Requirements No:**
HNFDA Certified 20182140022

五、 Structure and composition, scope of application

The product's basic configuration: disposable latex / silicone catheter, disposable drainage bag, disposable medical rubber examination gloves, iodine cotton ball, plastic tweezers, medical gauze block, tissue, tissue and auxiliary configuration plastic test tube, disposable polyethylene film gloves, alcohol cotton ball, silicone oil ball, tray, disposable sterile soluble syringe (without needle). After ethylene oxide and provided sterile.

The products are used for catheterization and drainage of clinical patients in medical institutions. The internal components of iodinated cotton balls and alcohol cotton balls are suitable for disinfection of hands, skin and mucous membranes.

六、 **Use method:** open the bag can be used.

七、 Contraindications, precautions, warnings and reminders

Product contraindications: allergic to latex / silicone material; patients with severe urethral infection

Matters needing attention:

1、 Do not use damaged packaging, expired products, and destroy them after use.

2、 Strict aseptic operation, the balloon is recommended to inject sterile water, the injection amount should not exceed the marked volume.

3、Ensure that the catheter is firmly connected to the drainage bag to prevent falling off and avoid urine overflow. If the tube is found to loosen, drain the residual fluid in the balloon with a syringe to check the margin. Reinject new saline or sterile water by balloon-labeled volume.

4、The catheter should be left in humans for no more than 7 days, allergic reaction, should be stopped immediately and treated.

5、This product is only intended for medical staff operation.

八、 Interpretation of graphics, symbols, abbreviations and other contents used in medical device labels



一次性使用



参考使用说明书



包装破损切勿使用



环氧乙烷灭菌



无菌

九、 Installation and use instructions or illustrations

1、This product does not need to be installed. firstly check the integrity of the package before using, and open the package after confirming that the package is not damaged.

2、Wearing sterile gloves to disinfect the balls with tweezers according to the routine disinfection process of catheterization.

3、Lubricate the catheter with a silicone oil ball (no petroleum matrix lubricant) and keep it loose if used.

4、The catheter was gently inserted into the urethra, so that the external port of the catheter was placed in the tray. The insertion depth of female patients was generally 4~6cm, and that of male patients was generally 15-20cm. When urine outflow, 2~4cm was inserted to ensure that the balloon was inserted into the bladder.

5、Prepare saline or sterile water, inject saline or sterile water not exceeding the calibration capacity of the syringe, and then inject it into the balloon through the one-way valve. After removing the syringe, pull the catheter gently outward to get the swollen balloon stuck in the bladder.

6、If the bacteria culture is used, take the middle section of urine for testing.

7、Connect the drainage bag connector to the catheter excretion interface for urinary catheterization.

8、When the catheter was removed after surgery, normal saline or sterile water was extracted from the balloon, and then the catheter was removed.

十、 Product maintenance and maintenance methods, special storage, transportation conditions, methods

Products should be stored in relative humidity $\leq 80\%$, non-corrosive gas and well-ventilated indoor, ordinary transport, in the transportation, storage process should be kept clean and pollution-free, strictly prohibited rain and snow immersion.

十一、 Date of production, shelf life or expiration date

Valid for two years, production batch number, production date, expiry date please refer to the small package or qualification label.

十二、 Accessories list, including accessories, appendix, lossitage replacement cycle and replacement method description

This product has no accessories

十三、 Date and version of preparation or revision of the specification

This specification was revised in February 2023, version 2023.