



Bioptimal™

Instructions for Use of Silicone Foley Catheter

STERILE EO

Sterilized using ethylene oxide



Do Not Use If Package Is Damaged



For Single Use Only



Keep From Direct Sunlight



Keep Dry

Please read all instructions, warnings and notes carefully before use.

Product Specifications:

The Silicone Foley Catheter can be divided into various specifications according to its outer diameter, (See Table 1). Doctors can choose different specifications according to the patient's bodily form and gender.

Table 1 – Models and specifications of Silicone Foley catheter

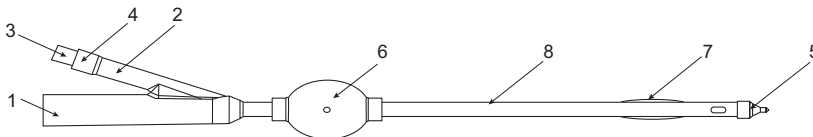
Models		Specifications
Soft Tip Type	FC3NS	4.7mm(14Fr)/5.3mm(16Fr)/6.0mm(18Fr)/6.7mm(20Fr)

This product has only one model and suitable for adult male and female. It is advisable to choose the appropriate specification according to the actual situation.

Product Performance:

The product uses the catheter to excrete urine. The balloon of the catheter can be inflated and fixed the catheter after water injection.

Structural Composition:



1- drainage funnel

2- inflation funnel

3- valve (one way)

4- snap ring

5- tip

6- air balloon

7- balloon

8- catheter body

Intended Use and Scope of Application:

This product is used for temporary urethral catheterization or indwelling catheterization.

Contraindication:

1. Acute urethritis
2. Acute prostatitis, epididymitis
3. Patients with injury of urethra or complete rupture of the urethra
4. Patients with silicone allergies

Possible Complications:

1. Urethral mucosa injury
2. Urinary tract infection
3. Collapse
4. Urinary retention

Usage Method:

1. Prepare Insertion:
 - i. Choose the proper specification of the product according to the patient's different conditions.
 - ii. The packing is opened from the opening and the catheter is taken out. Press the air hole of air balloon to check whether the gas path is normal.
 - iii. Use the syringe to make sure the balloon is able to be inflated and deflated.
2. Catheter insertion:
 - i. Insert the catheter into the bladder slowly through the urethra using tweezer. If the intubation is not smooth, press the hole of air balloon to inflate the balloon, then relief the inflated balloon to its original shape, continue to intubate until the urine is seen.
 - ii. Continue to insert another 3-5 cm after the urine is seen.

- iii. Follow the capacity indicating in drainage funnel, inject the water or physiological saline into the balloon from the valve (one way) to inflate the balloon and gently pull the catheter outwards. Encountering resistance can prove that the balloon has been fixed at the neck of the bladder.
- iv. The catheter is used in conjunction with other equipment or accessories, such as drainage bag.
- v. When removing the catheter, insert an empty syringe into the valve (one way) by letting the water drain out naturally. Alternatively, cut off the catheter body for rapid drainage, then remove the catheter accordingly.

Warning:

1. This product is only for single use. Reusing of used product is strictly prohibited. Used product should be properly disposed as medical waste or biohazardous waste according to local hospital protocol.
2. This product is sterilized with ethylene oxide and period of validity is 2 years.
3. Handle the product gently with care and do not pull it hard when used.
4. The water injection of the balloon should not exceed the maximum volume of the balloon.
5. This product should be operated by professional medical personnel.
6. Check the condition of package and confirm whether the product is in the validity period before use. Do not use if the product has expired or the package is damaged.
7. The injection volume of Foley balloon should not exceed the indicated volume at the tip of the catheter: 5-15ml or 20-30ml. During the procedures, the soft tip injection volume normally won't exceed 2.5ml.

Indwelling Time:

This product should not be retained in the body for more than 14 days.

Storage Environment:

The product should be stored in a ventilated, dry, non-corrosive room. Direct exposure to sunlight or strong artificial light with high UV components should be avoided and humidity level should not exceed 80%.

Validity Period:

2 years

PRODUCT INFORMATION

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