



# Bioptimal™

## Instructions for Use of Silicone Foley Catheter



**Read Instruction Manual Before Use**

STERILE | EO

**Sterilized using ethylene oxide**



**For Single Use Only**



**Do Not Re-sterilize**



**Keep Dry**



**Do Not Use If Package Is Damaged**



**Keep From Direct Sunlight**

## 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 different body conditions of pediatric, male and female.

Table 1 – Models and specifications of Foley catheter

Models		Specifications
Standard Type	FC2N	2.0mm(6Fr)/2.7mm(8Fr)/3.3mm(10Fr)/4.0mm(12Fr)/4.7mm(14Fr)/5.3mm(16Fr)/6.0mm(18Fr)/6.7mm(20Fr)/7.3mm(22Fr)/8.0mm(24Fr)/8.7mm(26Fr)/9.3mm(28Fr)/10.0mm(30Fr)
	FC3N	2.0mm(6Fr)/2.7mm(8Fr)/3.3mm(10Fr)/4.0mm(12Fr)/4.7mm(14Fr)/5.3mm(16Fr)/6.0mm(18Fr)/6.7mm(20Fr)/7.3mm(22Fr)/8.0mm(24Fr)/8.7mm(26Fr)/9.3mm(28Fr)/10.0mm(30Fr)
Female Type	FC2NW	2.0mm(6Fr)/2.7mm(8Fr)/3.3mm(10Fr)/4.0mm(12Fr)/4.7mm(14Fr)/5.3mm(16Fr)/6.0mm(18Fr)/6.7mm(20Fr)/7.3mm(22Fr)/8.0mm(24Fr)/8.7mm(26Fr)/9.3mm(28Fr)/10.0mm(30Fr)
	FC3NW	2.0mm(6Fr)/2.7mm(8Fr)/3.3mm(10Fr)/4.0mm(12Fr)/4.7mm(14Fr)/5.3mm(16Fr)/6.0mm(18Fr)/6.7mm(20Fr)/7.3mm(22Fr)/8.0mm(24Fr)/8.7mm(26Fr)/9.3mm(28Fr)/10.0mm(30Fr)

## 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. Foley catheter (2-way) can be used for bladder drainage, and Foley catheter (3-way) also can be used for bladder irrigation.

## Structural Composition

Model	Structural Composition
FC2N	Main pipe of Foley catheter (two way) , Valve
FC3N	Main pipe of Foley catheter (three way) , Valve
FC2NW	Main pipe of Foley catheter (two way) , Valve, Advancer
FC3NW	Main pipe of Foley catheter (three way) , Valve, Advancer

## Intended Use and Scope of Application:

This product is used for temporary urethral catheterization or indwelling catheterization and bladder irrigation.

## Contraindication:

1. Acute urethritis
2. Acute prostatitis, epididymitis
3. Menstrual period of women
4. Patients with complete rupture of the urethra
5. Patients with urethral stricture, unable urethral catheterization and silicone allergies

## Possible Complications:

1. Urethral mucosa injury
2. Urinary tract infection
3. Collapse
4. Urinary retention
5. Difficulty in extubation
6. Inadequate drainage

## Usage Method:

1. Prepare:
  - 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. The operator's hands and the patient should undergo routine disinfection. The operator should wear gloves.
2. The usage method of standard type Foley catheter (FC2N, FC3N):
  - i. The catheter is inserted into the bladder through the urethra, and the drainage area is covered with sterile gauze or compound cloth to prevent contamination from external environment.
  - ii. Injection water or physiological saline is injected into the balloon from the valve, filling the balloon and fixing the catheter.
  - iii. The Foley catheter is connected with a drainage catheter, and the flow rate is controlled by a flow regulating device or a catheter clip.
3. The usage method of female type Foley catheter (FC2NW, FC3NW):
  - i. Female type Foley catheter (FC2NW, FC3NW) is equipped with an Advancer. Open the product package, and check whether the Advancer is pushed smoothly and the Foley balloon is normal. Lubricate the catheter body, then return the catheter to the

Advancer housing.

- ii. Insert the tip of the catheter into the urethral orifice, and then place the front end of the Advancer against the external urethral orifice to locate the catheter. Adjust the angle of the catheter to ensure that the catheter is coaxial with the urethra, which can reduce the friction with the urethra in the process of pushing the catheter (See Fig.1).

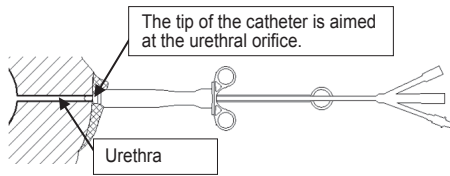
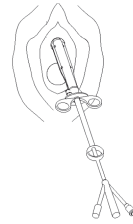


FIG.1



- iii. Push the catheter into the bladder at constant speed and slowly with the Advancer. Keep pushing 3-5 cm after you see the urine (See Fig.2). If the Advancer is pushed to the maximum position and still has no urine, remove the Advancer and continue to push the catheter 3 to 5 cm until the urine is seen.

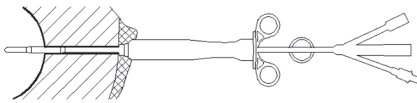
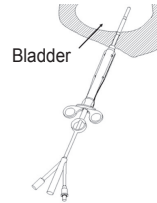


FIG.2



- iv. The catheter is gently drawn outward after filling the Foley balloon with the syringe. The resistance can prove that the balloon has been fixed at the neck of the bladder, and finally the Advancer is removed. (See Fig.3)
- v. Injection water or physiological saline is injected into the balloon from the valve, and then gently pull the catheter outwards. Encountering resistance can prove that the balloon has been fixed to the neck of the bladder. (See Fig.4)

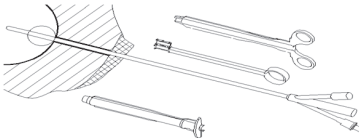


FIG.3

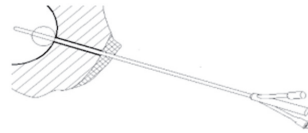


FIG.4

- vi. The following operations are consistent with the standard type Foley catheter.

#### 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. Do not use lubricants with oil matrix.
7. 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.
8. If the female type Foley catheter cannot be pushed normally during the process of using Advancer, disassemble the Advancer. Replace the Advancer with tweezers according to the usage method of standard type catheter.
9. 0.9% sterilized physiological saline can be used in the irrigation lumen of the catheter to irrigate the bladder.

#### 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.

#### Validity Period:

2 years

#### PRODUCT INFORMATION

For further information or assistance relating to the BIOPTIMAL products, please contact:

#### Legal Manufacturer:

#### BIOPTIMAL INTERNATIONAL PTE LTD

Add: 36 Jalan Tukang, Singapore 619266  
Tel: +65-6213-5777  
Fax: +65-6213-5737  
Email: sales@bioptimalg.com

#### EU Representative:

#### Shanghai International Holding Corp. GmbH (Europe)

Add: Eiffeustrasse 80, 20537 Hamburg, Germany  
Tel: +49-40-2513175  
Fax: +49-40-255726  
Email: shholding@hotmail.com

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