

## PRODUCT SPECIFICATION

(Specification As per EN: 1616 1997 + A1:1999)

**PRODUCT NAME** : FOLEY BALLOON CATHETER

### Special Features

- Blockage-free balloon
- Elliptical side eye
- Maximum fluid flow
- Trauma-free catheterization
- Colour-coded valve sleeve

### Product Information

Material : Natural Rubber Latex, Siliconised Coating

Colour : Yellow

Design : Designed to ensure that the balloon material, tips and fluid channel provide the best possible performance and the highest degree of comfort to patients while in use.

Sterilization : Ethylene Oxide / Gamma as per customer requirement

Labeling : Shall comply with the corresponding labelling specification and customer requirement.

Shelf Life : 5 years from the date of manufacture.

Storage condition : Shall be stored in cool dry place and away from direct light.

### Packaging Details

Packing	2-Way	3-Way
Pouch	1 piece	1 piece
Inner Box	20 pieces for two way	10 pieces for three way
Master Carton	400 pieces (20 inner boxes)	200 pieces (20 inner boxes)
20 feet container	1,67,200 pieces (418 cartons)	83600 pieces (418 cartons)
40 feet HC container	4,06,000 (1015 cartons)	2,03,000 pieces (1015 cartons)

**Certifications** : CE  
ISO 9001 : 2008  
ISO 13485 : 2003

**Quality Standard** : EN1616

**1. Dimension of Foley Balloon Catheters**

**Outside Diameter (mm) (Tolerance $\pm$ 0.33mm)**

Size	8	10	12	14	16	18	20	22	24	26
Req. O.D ( $\pm$ 0.33 mm)	2.70	3.30	4.00	4.70	5.30	6.00	6.70	7.30	8.0	8.70

**2. A. Overall Length (mm)**

Size	8	10	12	14	16	18	20	22	24	26
Req.(Min)	220	220	360	360	360	360	360	360	360	360

**2. B. Effective Length (mm)**

Size	8	10	12	14	16	18	20	22	24	26
Req.(Min)	150	150	275	275	275	275	275	275	275	275

**3. Test Volume Recovered (%)**

Size	8	10	12	14	16	18	20	22	24	26
Req.(Min %)	55	55	80	80	80	80	80	80	80	80

**4. Flow Rate Of Foley Balloon Catheters (ml)**

Size	8	10	12	14	16	18	20	22	24	26
Req.(Min ml)	15	30	50	70	100	100	100	100	100	100

## Directions for Use:

### 1.1 How to Use

A Foley catheter is a flexible tube that is often passed through the urethra and into the bladder. The tube has two separated channels, or lumens, running down its length. One lumen is open at both ends, and allows urine to drain out into a collection bag. The other lumen has a valve on the outside end and connects to a balloon at the tip; the balloon is inflated with sterile water or normal saline when it lies inside the bladder, in order to stop it from slipping out.

### 1.3 Cautions for Use

- The product is for single use.
- Sterility guaranteed until package is opened or damaged.
- If you experience a reaction to this product, discontinue use immediately and seek medical help.
- There are several risks when using a Foley catheter (or catheters generally), including:
  - a) The balloon can break while the catheter is being inserted. In this case, the healthcare provider will remove all the balloon fragments.
  - b) The balloon might not inflate after it is in place. In some institutions, the healthcare provider will check the balloon inflation before inserting the catheter into the urethra. If the balloon still does not inflate after its placement into the bladder, it will be discarded and replaced with a new catheter.
  - c) If Urine stops flowing into the bag. The healthcare provider will check for correct positioning of the catheter and bag or for obstruction of urine flow within the catheter tube.
  - d) If Urine flow is blocked. The Foley catheter will be discarded and replaced with a new catheter.
  - e) The urethra begins to bleed. The healthcare provider will monitor the bleeding.
  - f) Introduction of an infection into the bladder. The risk of infection in the bladder or urinary tract increases with the number of days the catheter is in place.
  - g) If the balloon is opened before the Foley catheter is completely inserted into the bladder, bleeding, damage and even rupture of the urethra can occur. In some individuals, long-term permanent scarring and strictures of the urethra could occur.<sup>[5]</sup>
  - h) Catheters can be pulled out by patients while the balloon is still inflated, leading to major complications or even death.

### 1.4 Storage Condition

- The atmosphere must always be conducive to the storage of the Catheter
- Catheter before opened for use shall be stored in dark, cool and dry place.
- Catheter needs to avoid area with excessive heat. The storage areas need to be controlled below 40°C/ 104 °F.
- Catheter needs to be stored at the areas with good air ventilation.
- Catheter needs to be shielded from direct sunlight and fluorescent lighting.
- Catheter needs to be stored far away from any energy radiating and heat generating equipment.

### 1.5 Expiration Date

The shelf life of the Catheter is 5 years from the date of manufacture.