

Sterile Foley Balloon Catheter (3 Way)

DEVICE INTENDED USE:

Tubular device intended for being introduced into the vesicle cavity through the urethra in order to provide drainage and flushing of the bladder. The Foley Balloon Catheters are intended to drain urine from the urinary bladder and for bladder wash. The device is for short term use and not to exceed 30 days of use.

DEVICE DESCRIPTION:

The Foley catheter is also called as an indwelling catheter that provides drainage of urine from the urinary bladder. It is a sterile, single-use, disposable device that is prescribed by a physician or an urologist. It is inserted and removed by an experienced or skilled health care professional. It consists of a flexible shaft with two opposing eyelets in the proximal tip for urine entry, one internal lumen for urine drainage, a second lumen for balloon inflation and in case of three way Foley catheter a third lumen for bladder irrigation; a retention balloon; an adjustable retainer ring; a self-sealing balloon inflation.

DEVICE CATALOGUE NO. AND AVAILABLE SIZE :

Catalogue No.	Sizes
FBC3LE	16Fr,18Fr,20Fr,22Fr,24Fr,26Fr,28Fr,30Fr

BASIC UDI:

8905159FBCL6G

a. Foley Balloon Catheter specification (Three Way)

Foley Balloon Catheter specification (Three Way)								
Designated Size FG/Ch/Fr	16	18	20	22	24	26	28	30
Outside Diameter ±0.33 (mm)	5.3	6.0	6.7	7.3	8.0	8.7	9.3	10.0
Effective length Min mm	275	275	275	275	275	275	275	275
Drainage lumen Flow rate of Foley balloon Catheter ml/min	100	100	100	100	100	100	100	100
irrigation lumen Flow rate of Foley balloon Catheter ml/min (For 3- way)	25	25	25	30	30	30	NA	NA

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Test volume recovered %	80	80	80	80	80	80	80	80
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INDICATIONS:

Sterile Foley Balloon Catheter is used for the drainage of urine from urinary bladder and also used for irrigation of bladder.

INTENDED USER:

Urologist or any other Healthcare Professionals

TARGET PATIENT POPULATION:

- Patients with urinary Incontinence,
- Patients undergoing urological surgeries or any long term surgeries
- Patients treated for short term urinary bladder drainage

DEVICE SHELF LIFE:

5 years from the data of manufacture printed on the Product Single Use Packaging Label and Sales Packaging Label.

DEVICE STORAGE:

Store at 5°Celsius to 40° Celsius temperature, dry place and away from sunlight

METHOD OF STERILIZATION:

Sterilized by EO (Ethylene Oxide).

WARNINGS AND PRECAUTIONS:

1. Do not use after the expiry date printed on the label.
2. Do not use if Package is opened or damaged.
3. This is a Single Use device
4. Do not Re-use the Product. Reusing of the product can cause urinary tract infection.
5. Do not Re-sterilize. Re sterilization of the product can cause urinary tract infection.
6. Do not use ointment or lubricants having petroleum base on catheter if used it will damage the catheter visually and the product quality.
7. Use only sterile water or normal saline for inflation of the balloon.
8. The device is for short term use and not to exceed 30 days of use. Exceeding 30 days of use can cause urinary tract infection.
9. It is made of Natural rubber latex and might cause allergic reactions including Latex Allergy – Anaphylaxis if the user is allergic to latex.
10. Device should not be stored in direct sunlight.
11. Sterility guaranteed until package is opened or damaged.
12. Visually inspect the product for any imperfections or surface deterioration prior to use.
13. Do not use by unskilled or untrained personnel

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CONTRA INDICATIONS:

- Foley Balloon Catheter is made of Natural rubber latex, which might cause allergic reactions including Latex Allergy – Anaphylaxis if the user is allergic to latex.
- Foley balloon catheters contraindicated in the presence of traumatic injury to the lower urinary tract (eg: urethral tear/Trauma)

POTENTIAL ADVERSE EFFECTS:

1. The balloon can break while the catheter is being inserted. In this case, the healthcare provider will remove all the balloon fragments.
2. The healthcare provider shall check the balloon inflation before inserting the catheter into the urethra. If the balloon does not inflate after it is placed into the bladder, it will be discarded and replaced with a new catheter.
3. 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.
4. If urine flow is blocked, the Foley catheter will be discarded and replaced with a new catheter.

DIRECTIONS FOR USE:



Use an appropriate size catheter depending upon the patient type age and size. Catheters that are too big or small are at risk of urethral trauma or leakage

➤ **Patient Preparation:**

- a. Prepare patient with packet of pre-saturated antiseptic swab sticks
Female Patient: With a downward stroke cleanse the right labia minora and discard the swab, repeat for left labia minora, and also cleanse the middle area between the labia minora
Male Patient: Cleanse the penis in a circular motion starting at the urethral meatus and working outward.
- b. Insert catheter into the urethral opening upward at approximately 30 degree angle until urine begins to flow. Inflate the balloon slowly using sterile water or normal saline to the volume recommended on the catheter. When catheter tip has entered bladder, urine will be visible in the drainage tube, insert catheter two more inches and inflate catheter balloon using entire adequate of sterile water or normal saline provided in the prefilled syringe (Note: Use of less than Adequate can result in asymmetrically inflated balloon)

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	<p>Properly inflated with recommended volume of sterile water or normal saline</p>
	<p>Improperly inflated with less than recommended volume of sterile water or normal saline</p>

- c. Once inflated, gently pull catheter until the inflated balloon is snug against the bladder neck
- d. Discard all materials in accordance with hospital protocol / Local regulatory requirement and remove contaminated Foley Balloon catheter.
- e. Perform hand hygiene
- f. Position hanger on bed rail at the foot of the bed and use green sheeting clip to secure drainage tube to sheet. Make sure tube is not kinked
- g. Indicate time and date of catheter insertion on provided labels and place designated labels on patient chart and drainage system

Procedure- Catheter Insertion:

- a. Insert Foley Catheter using aseptic technique and sterile equipment.
- b. Wash hands and wear clean gloves
- c. Perform Hand hygiene immediately before and after insertion.
- d. Use the smallest Foley catheter possible consistent with good drainage.
- e. Place under pad beneath patient, plastic or “shiny” side down
- f. Use the cleansing wipes to cleanse patient’s peri-urethral area
- g. Remove gloves and perform hand hygiene.
- h. Wear sterile gloves.
- i. Position fenestrated drape on patient appropriately
- j. Attach the sterile water or normal saline filled syringe to the inflation port
- k. Remove Foley Catheter from Sterile Wrap. Lubricate the Foley catheter

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Procedure: Foley Catheter Removal

- a. Perform Hand hygiene and wear sterile gloves
- b. Position patient and place waterproof pad under patient
- c. To deflate catheter balloon gently insert a Leuer lock or slip tip syringe in the catheter valve. Never use more force than is required to make the syringe “stick” in the valve.
- d. Allow the pressure within the balloon to force the plunger back and fill the syringe with water or normal saline. If slow or no deflation is noticed, re-seat the syringe gently.
- e. Use only gentle aspiration to encourage deflation if needed as vigorous aspiration may collapse the inflation lumen, preventing balloon deflation
- f. If the balloon will not deflate and if permitted by hospital protocol, the valve arm may be severed. If this fails, contact adequately trained professional for assistance, as directed by hospital protocol
- g. Should balloon rupture occur, care should be taken to assure that all balloon fragments have been removed for the patient
- h. Remove the catheter and dispose as per institutional and local regulatory guidelines for bio-hazardous medical waste disposal

MEDICAL BENEFITS:

1. Treat urinary incontinence
2. Used for complete draining of urine from bladder and bladder irrigation.
3. Remove urine from the bladder if nerve damage interferes with bladder control
4. It reduce or prevent incidence of urinary infection from urine
5. Prevents the bladder from overfilling
6. Can Improve patient quality of life
7. Labor induction in women at term

RESIDUAL RISK:


















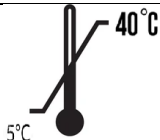


1. Anaphylaxis
2. Urinary tract infection
3. Bladder perforation

SIDE EFFECTS

1. Catheter associated urinary tract infection.
2. Pain and discomfort
3. Urethritis
4. Stricture formation
5. Irritation of the Urethra
6. Injury to the urethra
7. Bladder Spasm
8. Bladder Weakness

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SYMBOLS USED IN DEVICE SINGLE UNIT PACKAGING AND SALES PACKAGING					
	Manufacturer		Date of Manufacture		Keep away from Sunlight
	Authorized Representative in the European Community/ Authorized representative European Union		Use by Date/ Expiry Date		Keep Dry
	Contains presence of Natural Rubber Latex		Batch Code		Do not Re-use
	Sterilized using Ethylene Oxide		Do not use if package is damaged and consult instructions for use		Caution
	Do not resterilize		Medical Device		Unique Device Identifier
	Single sterile barrier system with protective packaging inside		One-Way Valve		Storage Temperature
	CE Mark Symbol		No: of units		

• In case of any adverse event noted, contact manufacturer (MRK Healthcare Pvt Ltd) or authorized representative and competent authority of the member state where user/ patient is established without any delay or within 24 hrs.

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Authorized EU REP

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Revision History

Rev. No.	Date	Reason for Revision
A	20-04-2022	Initial Release
B	09-08-2022	2 way and 3 way variant segregated as per TR comments
C	01-01-2023	Reviewed and Updated in accordance with Annex I, section 23.4 of EU MDR 2017/745.