

Instruction for Use

Foley Balloon Catheter

Device Description

Foley Balloon Catheter is a sterile single-use product. The Catheter has a drainage lumen and inflation channel. It has an integrated balloon towards the tip of the Catheter and a funnel with an inflation valve at the bottom of the Catheter. The capacity of the balloon can be found on the Catheter label. Foley Balloon Catheter is made of 100% silicone. The Catheter has a tip with two opposite drainage eyes. The valve of the Catheter can be operated with a Luer syringe tip. Each Silicone Foley Catheter is sterile and individually double-packed.

Family	Size (Fr)	Length (Cm)	Type	Catheter Hub Color
Foley Balloon Catheter (FBC)	10	33	Two way	Orange
	12	42	Three way	Red
	14			Yellow
	16			White
	18			Green
	20			Purple
	22			Blue
	24			Black

Intended Purpose

Used to drain the urine from the urinary bladder through urethral orifice.

Intended User

This device should be administered to humans only by physicians authorized by the Competent Authority of the country in which the physician is practicing.

Medical Conditions to be Treated

- Urinary retention due to urethral obstruction, benign prostatic hyperplasia (BPH), urethral stricture, or neurogenic bladder.
- Post-surgical urinary drainage after urological, gynecological, or abdominal surgeries.
- Monitoring urine output in critically ill patients.
- Management of gross hematuria through continuous bladder irrigation.
- Relief of bladder distension in cases of obstructive uropathy or trauma.

Performance Characteristics of the Device

The Foley balloon catheter is designed for temporary urinary drainage and is made entirely from silicone for flexibility and biocompatibility. It is available in various sizes to accommodate patient needs. The inflated balloon at the distal end secures the catheter in the bladder, allowing for effective urine drainage. Its tapered tip facilitates easy insertion, while the large lumen promotes optimal urine flow

Indications

- To relieve obstruction and facilitate urine drainage.
- For continuous bladder drainage during or after surgery.

Contraindications

Contraindications includes Prostatitis (relative), Pelvic/ urethral trauma, serious Urethritis, Serious urethral stricture, Blunt or sharp Urethral trauma

Precautions

- Ensure correct catheter size and balloon volume are selected before insertion.
- Inflate the balloon only after confirming the catheter tip is inside the bladder.
- Use aseptic technique during insertion and handling to prevent infection.
- Avoid excessive force during insertion or removal to prevent urethral injury.
- Regularly monitor catheter function, drainage, and balloon integrity.
- Do not reuse; device is **single-use and sterile**.

Warnings

- Do not use if the package is damaged or opened, as sterility may be compromised.
- Over inflation of the balloon may cause bladder or urethral trauma.
- Prolonged use increases the risk of infection, encrustation, and blockage; follow recommended indwelling duration.
- Improper placement or premature balloon inflation outside the bladder can lead to serious urethral injury.
- Use only by trained medical professionals under aseptic conditions.

Intended Patient Population

- The Foley Balloon Catheter can be used in patients of all age groups based on doctors' decision.

Shelf-life of the Product

- The shelf life of the Foley Balloon Catheter is 3 years (Indicated on product label with the use-by symbol and date). Store the Foley Balloon Catheter at dry, cool place. Avoid extended exposure to light.

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Sterility – This product is Sterile unless the package has been opened or damaged

- The Foley Balloon Catheter have been sterilized by Exposure to Ethylene Oxide. Sterility indicators are on each package. The imprinted label will change colour from blue to brown after ethylene oxide exposure. Do not use the product unless the sterility indicators are the correct color.
- If the sterile package is damaged or possibly opened, do not use. Contact “Distributor” and replace the product.
- The Foley Balloon Catheter are packed single. Product in each pack must be utilized immediately when opened. Product should not be re-sterilized.

Directions for Use

- Inspect product package for integrity and expiry and then remove product from package.
- Verify the catheter balloon inflation & deflation process, by gently inserting a syringe in catheter valve, never use more force than is required to make the syringe fit in the valve.
- Ensure the catheter is well lubricated then pass the deflated catheter through the urethra in to the bladder. Insert/Use the Foley Balloon Catheter in to the urethra as per current medical practices.
- Once position of catheter is confirmed, connect a syringe containing sterile water to the luer of the inflation lumen on the two- or three-pronged Y-fitting.
- Use the syringe to fill the balloon; make sure that the inflation of balloon with sterile water should not exceed the maximum balloon capacity. Refer balloon volume mentioned on pack & product.
- Connect the funnel drainage lumen of the two- or three-pronged fitting to drainage bag.
- If using a 3-way Foley catheter, the third lumen may be used to irrigate.
- Assure good drainage from the catheter.
- Secure the catheter to the skin.
- Irrigate only as needed.




















Removal Instructions

- Disconnect all drainage/Irrigation tubes from the catheter.
- Using syringe aspiration, deflate the balloon.
- Upon removal if noticed slowly or no deflation, reset the syringe gently. Use only gentle aspiration; vigorous aspiration may collapse the inflation lumen & preventing balloon deflation.
- If balloon ruptures occur, care should be taken to assure that all balloon fragments have been removed from the patient.
- Gently remove the catheter.

Disposal Instructions

Dispose of all equipment in appropriate containers. After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Explanation of symbols used on label

Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol
	Catalogue Number		Unique Device Identifier		Do not re sterilize		Country of Manufacture		Medical Device
	Manufacturer		Date of manufacture		Keep Dry		Caution		Single Sterile barrier system with protective packaging inside
	Batch Code		Use by Date		Keep Away from Sunlight		Do not re-use		Humidity Limit
	Sterilized using ethylene oxide		Consult Instructions for Use		Temperature Limit		Do Not Use if Package is Damaged		

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- Indications: <https://my.clevelandclinic.org/health/treatments/foley-catheter>
- EN ISO 15223-1:2021 – Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
- EN ISO 20417:2020 – Medical Devices – Information to be supplied by the manufacturer.