IFU of Foley Balloon Catheter

Manufactured by Mais India Medical Devices Pvt. Ltd.

General Device Description: The device Foley balloon catheter is a flexible tube that is often passed through the urethra and in to the bladder to drain urine. 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 in to a collection bag. The other lumen has a valve on the outside end connects to a balloon at the tip; the balloon is inflated with sterile water when it lies inside the bladder, in order to stop it from slipping out.

Product Name: Foley Balloon Catheter

Brand Names: (1) FOLEDRAIN™ (2) MAISURO-SILICO™ (3) INTRAVENO™

Variants:

1. Foley Balloon Catheter (Latex Siliconised)
2. Foley Balloon Catheter (Silicone)

Types:

1. 2-Way Foley Balloon Catheter
2. 3-Way Foley Balloon Catheter

Intended Use:

The Foley balloon catheters are used to drain urine from the bladder into urine bag.

Material of construction:

Component	Material
Foley Catheter	Latex/ Silicone
Non-Return Valve	PP+ SS+ Silicone
Sleeve	PVC Sheet

Indications:

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

Contra-indications:

- Known allergies to any components of the catheter.
- Improper positioning of catheter leads to urethral pain or discomfort.
- Urethral trauma or strictures.
- Severe phimosis.
- Active infection at the insertion site.

Intended Patient Population:

All Patient age groups such as – Neonates, Paediatrics & Adults.

Intended User:

Qualified doctor or a paramedic

Use environment:

Proper healthcare setup

Size specifications: (6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30) FR.

Instruction for use:

1. Inspection:

- Prior to use, inspect the device for any visible defects, such askinks, or leaks.
- Check the expiration date and ensure the packaging is intact. If the packaging is damaged or the expiration date has passed, do not use.

2. Catheterization:

- Perform hand hygiene and wear sterile gloves.
- Clean the patient genital area with aseptic techniques.
- When inserting the catheter use water-based lubricant at site of insertion.
- Gently insert the catheter into the urethra until it reaches the bladder.
- Use needle free syringe to inflate the balloon at catheter tip with sterile water/Saline to keep it in place.
- Check for the urine flow from drainage funnel and connect it to the Urine bag.

3. Catheter Removal:

- Perform hand hygiene and wear sterile gloves.
- Attach the syringe to the balloon port and allow the water to drain out completely.
- Gently remove the catheter as per patient comfort.
- Dispose the catheter as per institutional and local regulatory guidelines for bio-hazardous medical waste disposal.

Intended Clinical Benefits to the patients:

Direct Clinical Benefits: -

- Enables continuous and effective drainage of urine from the bladder, providing immediate relief of urinary retention.
- Ensures reliable and accurate measurement of urinary output for patient monitoring.
- Maintains bladder decompression, thereby reducing the risk of overdistension and associated complications.
- Provides a controlled pathway for urine drainage, supporting consistent bladder emptying.
- Allows intravesical administration of medicinal agents when clinically indicated.

Indirect Clinical Benefits: -

- Supports clinical assessment of renal function and fluid balance based on urine output monitoring.
- Contributes to perioperative patient management by reducing the likelihood of bladder-related complications.
- Minimizes the need for repeated catheterization, thereby reducing urethral trauma and patient discomfort.
- Assists healthcare professionals in identifying changes in patient condition through variations in urine output.
- Supports maintenance of patient hygiene and helps reduce complications associated with urinary incontinence.

Clinical Safety:

- Universal Funnel connector for secure connection with urine bag.
- Device Design and Material Safety.
- Biocompatible products,
- Our device is a single use device,
- Our product is non-toxic, sterile & non-pyrogenic.

Performance characteristics:

- Made from latex & silicone provides flexibility and durability.
- Come in various sizes to accommodate different patient needs, measured in French units (Fr).
- Single use sterile product minimizes the risk of infection.
- Catheter lumen design ensures efficient urine drainage without blockages.

Accessories which can be used with the device:

Device is not provided with any accessories but a **Foley Balloon Catheter** can be used with urine bags.

Warnings:

- For use by trained healthcare professionals only.
- The product should not be reprocessed.
- Improper transport and handling may cause structural and/or functional damaged to device or packaging.
- The product is guaranteed sterile, non-pyrogenic and non-toxic if package is not opened or damaged.
- Do not clean or resterilize.
- Do not expose to heat or direct sunlight.
- Use the product immediately after opening the individual packing.
- Do not reuse, it may cause bacterial infection to the patient.
- Ensure the catheter is not used beyond its expiration date.
- Mais India disclaims any responsibility for possible consequences resulting from improper use.

Storage Conditions:
Store in a Cool & Dry Place. Keep away from sunlight
Temperature: 10^{o} C to 40^{o} C

Shelf life:
5 Years

Life Time
Once uses started, normally intended for continuous use less than 30 days.

Type of Sterilization:
ETO sterilization

Notice to Users and/ or Patients:
Any serious incident that has occurred in relation to the device, should be reported to the Manufacturer and the Competent Authority of the Member State in which the user and/or patient is established.

Cautions:
- Do not use if package is damaged.
- Discard after single use.

Limitations:
- Latex foley Catheter is intended for short term use, prolong use may lead to catheter associated urinary tract infection.
- Allergic reactions including Latex Allergy.

Potential Side Effects:
- Pain and discomfort
- Catheter associated urinary tract infection
- Allergic reactions including Latex Allergy.

Disposable instructions
The used device should be disposed of as 'hospital contaminated waste' - typically incinerated or as per safe hospital practices as improper disposal can lead to bio-hazard.

Duration of use:
Short Term Duration (less than 30 days)

Explanation of symbols used:

Symbols	Title of the Symbol	Symbols	Title of the Symbol
	Consult instructions for use (Indicates the need for the user to consult the instructions for use)		Latex free (Indicates a medical device that is Latex free)
	Caution (To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.)		Latex (Indicates a medical device that contain latex
REF	Reference number (Indicates the manufacturer's catalogue number so that the medical device can be identified)		Date of manufacture (Indicates the date when the medical device was manufactured)
LOT	Batch Number (Indicates the manufacturer's batch number so that the batch or lot can be identified)		Use-by date (Indicates the date after which the medical device is not to be used)
	Do not re-sterilize (Indicates a medical device that is not to be re-sterilized)	CE 0123	CE Mark (CE Marking with Notified Body Number)
STERILE EO	Sterilized using ethylene oxide (Indicates a medical device that has been sterilized using ethylene oxide)		Do not re-use (Indicates a medical device that is intended for one single use only)
	Non-pyrogenic (Indicates a medical device that is non- pyrogenic)		Keep away from sunlight (Indicates a medical device that needs protection from light sources)
	Do not use if packaging is damaged and consult instructions for use. (Indicates a medical device that should not be used if its packaging has been damaged or opened, and that the user should consult the instructions for use for additional information)	EU REP	Authorized representative in the European Union / European Community (Indicates the authorized representative in the European Union / European Community) OBELIS S.A. Boulevard Général Wahis 53, 1030 Brussels, Belgium Contact Number: +32(2)73 25 954 Email ID: regulatory@obelis.net Website: www.obelis.net

Symbols	Title of the Symbol	Symbols	Title of the Symbol
	Keep dry (Indicates a medical device that needs to be protected from moisture)		Manufacturer (Indicates the medical device manufacturer) Manufacturing Unit: 525P, Sector-37, Pace City II, Gurgaon, Haryana-122001, India. Contact Details.: +91 8527589990 Fax No.: 0124 404 7533 Email ID: info@maisindia.com Website:www.maisindia.com
STERILE EO	Single sterile barrier system (Indicates a single sterile barrier system)	IN	Country of manufacture (To identify the country of manufacture of products)
UDI	Unique Device Identifier (Indicates a carrier that contains Unique Device Identifier information)	MD	Medical device (Indicates the item is a medical device)
10°c 40°c	Temperature limit (Indicates the temperature limits to which the medical device can be safely exposed.		Fragile, handle with care (Indicates a medical device that can be broken or damaged if not handled carefully)
	This way up		

CE 0123

EU REP **Obelis S.A.**
Boulevard Général Wahis 53, 1030 Brussels, Belgium.

Manufactured by:
Mais India Medical Devices Pvt. Ltd.
525-P, Sector-37, Pace City-II,
Gurgaon, Haryana-122001 (INDIA)
Mfg. Lic. No.: MFG/MD/2019/000037

EDITION: 02, **REV.:** 02_20.05.2026