100% SILICONE 2-Way (3-Way) Foley Balloon Catheter INSTRUCTIONS FOR USE SINGLE USE ONLY

INTENDED USE:

The 2-Way (3-Way) Foley Balloon Catheter is intended for use as a urinary catheter to pass fluids to and from the urinary bladder.

Patient target group

Patient who have difficulty urinating naturally.

Intended user

Trained paramedics.

FEATURES:

1. Transparent tube with X-ray opaque line, transparent for easy visual inspection and fluid observation, x-ray opaque for easy confirmation of intubated tubes using X-ray.
2. The soft and uniformly inflated balloon helps the tube sit comfortably against the bladder.
3. Smooth round shaft reduces the chance of trauma during insertion and withdrawal.
4. The tip of 3-Way Foley Balloon Catheter with an open hole, it could be used together with a guidewire for the difficulty in catheterization.
5. Firm yet flexible tip designed to aid insertion.
6. Recommended usage up to 90 days for 4833 series, of which balloon is more durable; recommended usage up to 29 days for 182X/1856/1830/4810/4822/4856 series.

SPECIFICATION:

Cat. No.	Description	Apply to MRI	Symbols
182X series	2-way, X-ray opaque line, usage up to 29 days	Yes	MR
1856 series	2-way, Tiemann tip, usage up to 29 days	Yes	MR
1830 series	3-way, X-ray opaque line, Open tip, usage up to 29 days	Yes	MR
48xx series	2-way, Integrated balloon, usage up to 29 days	Yes	MR
4833 series	2-way, integrated long-term balloon, white tip, usage up to 90 days	Yes	MR
4856 series	2-way, Integrated balloon, Tiemann tip, usage up to 29 days	Yes	MR

INSTRUCTIONS ON ACCESSORIES:

Spigot: A plastic stopper for catheters, provided in an individually sterilized package.

PRE-TESTING:

Test that the balloon functions, and then pull back on the syringe to remove the fluid. Rationale: To ensure that balloon will inflate without leaking.

PROCEDURE:

1. Open the package and pour the antiseptic solution over cotton balls.
2. Lubricate the catheter with lubricant and generously lubricate the tip with lubricant. Keep the catheter on a sterile tray.
3. Position the fenestrated drape over the patient to expose the genitalia.
4. Cleanse the patient's meatus:

For female patients:

a. Separate the patient's labia minora with your non-dominant hand.
b. With your dominant hand, use forceps to pick up an absorbent ball that has been saturated with an antiseptic solution.
c. Cleanse the patient's meatus with one downward stroke of the forceps. Discard the absorbent ball in a plastic bag at the foot of the bed.
d. Repeat step c. at least three times.
e. Continue to hold the patient's labia apart until you insert the catheter.

For male patients:

a. Hold the patient's penis upright with your non-dominant hand. Hold the sides of the penis to prevent closing the urethra.
b. With your dominant hand, use forceps to pick up an absorbent ball that has been saturated with an antiseptic solution.
c. Cleanse the patient's meatus with one downward stroke of the forceps. Discard the absorbent ball.
d. Repeat step c. at least three times.
e. Continue to hold the patient's penis until you insert the catheter.

For pediatric patients:

a. Make sure before insertion that the end of the stylet is placed within the lumen, and that the tip of the stylet reaches the end of the catheter.
b. Catheterize the catheter with the aid of the stylet.
c. When urine flows out after the insertion, withdraw the stylet gently and slowly.
d. Keep the catheter straight to avoid difficulty in withdrawing the stylet.

5. Discard forceps in a plastic bag at the foot of the bed.
6. With your uncontaminated hand, pick up the catheter from the tray, and insert it gently into the meatus (6-8 inches, or until urine starts to flow).
7. Guide the catheter gently 2-3 inches beyond the point at which urine begins to flow. Rational: inserting the catheter further into the bladder ensures it is beyond the neck of the bladder.
8. Use a needleless syringe to inject the recommended fluid volume into the injection port.
9. Retract the catheter until you feel resistance.
10. Secure the catheter with one-inch tape.
    a. For females: tape the catheter to the side of the leg.
    b. For males: tape the catheter to the abdomen so as to prevent pressure on the penoscrotal angle.
11. Attach a drainage bag to the bed frame (not to the side rails).
12. Cleanse the patient's perineum of antiseptic solution.
13. Remove the drapes.
14. Change the catheter according to clinical symptoms for the individual patient, or as often as recommended by a physician.
15. The Foley catheter is generally simple to remove. Attach an empty syringe to the inflation valve, and withdraw the volume of water instilled. Gently retract the catheter.

CONTRAINDICATIONS:

1. Urethral injury or stricture.
2. Recent urethral or bladder surgery.
3. Prior transurethral resection of the prostate with a large tissue defect.
4. Significant symptoms of urinary obstruction prior to treatment.
5. History of abdominoperineal resection for rectal cancer, rectal, stenosis, or other major rectal pathology.

WARNINGS AND PRECAUTIONS:

1. Do not use ointments of lubricants having a petroleum base.
2. Following aseptic catheterization. Inflate the retention balloon with only sterile distilled water through a needleless syringe. Glycerol/glycerin, any other fluid, air, carbon dioxide, and any other gas are not recommended to be inflated the balloon.
3. Inflate the balloon slowly according to volume indicators.
4. If a balloon does not deflate, do not cut the balloon port proximal to the inflation valve. Urological consultation is recommended if non-deflation persists.

5. Before removing the stylet, inflate the balloon and keep the catheter smooth to decrease process resistance.
6. Do not use sharp instruments to operate a Foley catheter to avoid damage to the catheter resulting in malfunction.
7. Drinking more water to prevent urinary tract infection, obstruction, and urinary crystallization is recommended.
8. Instruction for use shall be read and abided by carefully. Medical advice shall always be followed depending on the patient's clinical symptoms.
9. Use the needleless syringe to fill the balloon. It is recommended the balloon's fluid volume be daily checked to prevent the slip from its position, and then re-inflate with recommended volume in order to avoid the rupture of the balloon.
10. Patients with indwelling catheters should be monitored in accordance with local and national medical policy.
11. Strict adherence to aseptic technique and hand hygiene are essential to minimize the risk of catheter-associated urinary tract infection.
12. Withdraw the stylet gently and slowly to avoid the rupture, kink, or damage at the junction.

ADVERSE EVENTS:

1. Urinary tract, kidney or blood infection
2. Urethral injury
3. Skin breakdown
4. Bladder stone(s)
5. Hematuria

DISPOSING OF THE DEVICE:

Dispose of this device only according to your country's regulations for similar types of medical waste.

STORAGE:

The product should only be stored in a cool, dry environment.

STERILIZATION:

1. The Silicone Foley Balloon Catheter is a single-use item and is supplied sterile.
2. Sterilization is effected by E.O. Gas, as indicated on the label.
3. Please see the label on the sterilized peel-pouch for the expiration date.
4. Do Not re-sterilize or reuse. Reused catheters may cause inflammation and bacterial infection.
5. Sterile only if the package has not been opened, damaged, or broken.

MRI Safety Information

This device is MR conditional

MR Conditional

Non-clinical testing demonstrated that this device is MR Conditional. A patient with this device can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla only
- Maximum spatial gradient magnetic field of 1,850-Gauss/cm (18.5-T/m).
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg (Normal Operating Mode).

MRI-REALATED HEATING

Under the scan conditions defined, this device is expected to produce a maximum temperature rise of 1.5℃ after 15-minutes of continuous scanning.

ARTIFACT INFORMATION

In non-clinical testing, the image artifact caused by the device extends approximately 53-mm from this device when imaged with a gradient echo pulse sequence.

Notice

If any serious incident has occurred concerning this device please report it to Fortune Medical Instrument Corp. and the competent authority.

GRAPHICAL SYMBOLS FOR MEDICAL DEVICE LABELING

Symbols	Indication	Symbols	Indication
	Manufacturer		Do not re-use
	Caution		Do not re-sterilize
	Authorized representative in the European Community		Avoid sharp tool
	Consult instructions for use		Catalogue number
	Keep dry		Date of manufacture
	Keep away from sunlight		Use-by date
	Do not use if package is damaged		Batch code
	Sterilized using ethylene oxide		MR Conditional
	Single sterile barrier system with protective packaging inside		Medical device
	Importer	-	-

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