INSTRUCTION FOR USE FOR LATEX FOLEY BALLOON CATHETER

Product Name	:	**Latex Foley Balloon Catheter**
Brand Name	:	Ultramed Latex Foley Balloon Catheter
Manufacturer's Name	:	Ultra for medical products (Ultramed) Co (U.M.I.C) S.A.E
Manufacturer's Address	:	Part No. (304:310) & part no. (312) – Industrial Area, Arab El Awamer – Abnoub - Assiut – Egypt.

Description of the Device*:*

- A Foley catheter is a flexible tube with an inflatable balloon at its distal tip for retention in the urinary bladder where it usually functions as a therapeutic device for urine retention and is used for short-term urine drainage.
- In the 2-way catheter, the proximal end consists of one drainage funnel and one inflation funnel with an access port.
- In the 3-way catheter, the proximal end includes one drainage funnel, one inflation access port, and one irrigation access port which is used to instill sterile fluids into the bladder to flush out blood and blood clots after urinary tract surgery.
- The distal end is rounded and closed, with two lateral eyes to facilitate urine drainage.
- The inflation access port is fitted with a Non-Return Valve (NRV), allowing controlled inflation and deflation of the balloon. The drainage funnel is designed for connection to a urine collection bag to enable continuous drainage of urine from the bladder. In the 3-way catheter, an additional irrigation access port is provided to allow bladder irrigation.
- The inflation access port with NRV is equipped with a colored sleeve for easy identification of the catheter size. The drainage funnel connector is printed with the catheter size and the maximum balloon capacity volume.
- The drainage funnel fulfills the requirements of ISO 80369
- Its design fulfills the requirements of ISO 20696.
- Some pediatric balloon catheters include a stylet in order to facilitate insertion if needed.
- The device is supplied sterile and packed in a soft blister with medical-grade paper. Catheter sizes range from 6 to 24 FG for the Latex Foley Balloon Catheter with 2 ways, and catheter sizes range from 16 to 24 FG for the Latex Foley Balloon Catheter with 3 ways.
- Lengths vary between 27 cm and 40 cm, depending on the size. The device is an indwelling urinary catheter, intended to remain in place to allow continuous drainage of urine from the bladder.
- Latex Foley Balloon Catheter is made from natural latex rubber and is coated with medical-grade silicone to provide a smooth surface, improve patient comfort, and minimize tissue irritation.
- Latex Foley Balloon Catheter is a short-term use device and has been used as a medical device for many years under different brands.
- The catheter must not be used for more than 14 days.
- This product is CE marked since 2008.
- The product is sterilized using EO (Ethylene Oxide).
- This product is for single use.
- Product is available in various sizes to fit the intended patient population. Sizes: 6 to 24 FG.
- Individually packed in a single Peel Pouch

Material Used:

- Natural latex rubber
- Silicone coated
- (PVC) medical grade in the valve.

Intended purpose:

A Foley Catheter is inserted into the bladder to drain urine. Used for short-term use urethral catheterization for routine drainage of the bladder or for routine post-operative drainage and irrigation of the bladder. Device maximum use duration is not more than 14 days. There is a balloon on the end of the catheter that holds it in place.

Variants:

Trade Name	REF (Product ID Number)
Silicone coated latex Foley Balloon catheter Size 6 FG / 2-way	3006-6/2
Silicone coated latex Foley Balloon catheter Size 8 FG / 2-way	3006-8/2
Silicone coated latex Foley Balloon catheter Size 10 FG / 2-way	3006-10/2
Silicone coated latex Foley Balloon catheter Size 12 FG / 2-way	3006-12/2
Silicone coated latex Foley Balloon catheter Size 14 FG / 2-way	3006-14/2
Silicone coated latex Foley Balloon catheter Size 16 FG / 2-way	3006-16/2
Silicone coated latex Foley Balloon catheter Size 18 FG / 2-way	3006-18/2
Silicone coated latex Foley Balloon catheter Size 20 FG / 2-way	3006-20/2
Silicone coated latex Foley Balloon catheter Size 22 FG / 2-way	3006-22/2
Silicone coated latex Foley Balloon catheter Size 24 FG / 2-way	3006-24/2
Silicone coated latex Foley Balloon catheter Size 16 FG / 3-way	3006-16/3
Silicone coated latex Foley Balloon catheter Size 18 FG / 3-way	3006-18/3
Silicone coated latex Foley Balloon catheter Size 20 FG / 3-way	3006-20/3
Silicone coated latex Foley Balloon catheter Size 22 FG / 3-way	3006-22/3
Silicone coated latex Foley Balloon catheter Size 24 FG / 3-way	3006-24/3

Latex Foley Balloon Catheter 2 way		Latex Foley Balloon Catheter 3 way	
Size FR/CH	Ref. Code	Size FR/CH	Ref. Code
6	3006-6/2	16	3006-16/3
8	3006-8/2		
10	3006-10/2	18	3006-18/3
12	3006-12/2		
14	3006-14/2	20	3006-20/3
16	3006-16/2		
18	3006-18/2	22	3006-22/3
20	3006-20/2		
22	3006-22/2	24	3006-24/3
24	3006-24/2		

Clinical Indications:

Based on clinical practice guidelines including the American Urological Association (AUA).

1. **Urinary Retention**

According to the American Urological Association (AUA), Foley catheters may be used for the management of:

- Acute urinary retention, defined as sudden and complete inability to void.
- Chronic urinary retention or incomplete bladder emptying associated with urinary frequency, overflow incontinence, or impaired renal function.
- Retention due to bladder outlet obstruction, such as benign prostatic enlargement, urethral strictures, or impaired detrusor contractility.
- Retention complicated by bilateral hydronephrosis, often associated with long-standing obstruction.
- Gross hematuria with clot retention, which may require a 3-way catheter for continuous bladder irrigation.
- Urosepsis associated with incomplete bladder emptying.
- High voiding pressures or functional outlet obstruction.
- High bladder storage pressures in neurogenic bladder conditions.
- In case of absence of intermittent catheterization, the Foley catheter can be used as alternative.

2. **Perioperative and Surgical Use**

(Aligned with AUA recommendations for perioperative bladder management)
Foley catheters are indicated for:

- Temporary bladder drainage during perioperative and postoperative care in urological, gynecologic, obstetric, or abdominal surgeries.
- Preoperative bladder emptying for procedures requiring decompression of the bladder.
- Lengthy or complex surgical procedures where bladder overdistension is anticipated.
- Continuous bladder irrigation using a 3-way catheter after genitourinary surgery to prevent urethral obstruction from blood clots.
- Temporary drainage in cases of bladder or urethral trauma identified during surgery.

3. **Urinary Incontinence**

(Consistent with AUA guidance that indwelling catheters be used only when clearly justified)
Foley catheters may be used for:

- Severe urinary incontinence when alternative management methods are unsuitable or contraindicated.
- Perioperative management of patients with urinary incontinence when required for surgical care.
- Comfort and hygiene care for terminally ill patients.
- Management of stage III–IV sacral, buttock, or perineal pressure ulcers in incontinent patients requiring moisture control.

4. **Neurogenic Bladder and Pediatric Use**

(Aligned with AUA recommendations for neurogenic bladder management)
Indications include:

- Neurogenic bladder dysfunction, such as in spinal cord injury or multiple sclerosis, when intermittent catheterization is not feasible or temporary drainage is required.
- Pediatric temporary bladder drainage.

5. **Continent Urinary Diversions**

According to AUA-aligned clinical practice:

- Catheterization of neobladder, ileal conduit substitutes, or other continent urinary diversions when spontaneous voiding is not possible due to outlet obstruction or impaired reservoir emptying.
- Temporary catheterization until spontaneous voiding or definitive treatment is achieved.

6. **Urine Collection and Monitoring**

Foley catheters may be used for:

- Urine specimen collection when alternative methods are impractical.
- Temporary drainage required for diagnostic, radiologic, or urodynamic studies.

7. **Supportive and Special Clinical Situations**

According to AUA-referenced clinical practice, Foley catheters may be used for:

- Temporary bladder drainage in patients unable to void due to paralysis, trauma, or impaired bladder function.
  Short-term drainage in select clinical conditions.

Contraindications:

- Do not use in patients with known hypersensitivity or allergy to any materials used in the catheter.
- Do not use in patients with suspected or confirmed urethral injury or compromised urethral integrity, including pelvic fracture, straddle injury, traumatic injury to the lower urinary tract, visible blood at the urethral meatus, known or suspected urethral false passage, radiation-induced urethral injury, or a history of urethral reconstruction or urethroplasty, until appropriate urological or radiologic evaluation (e.g., retrograde urethrogram) has been completed.
- Do not use in patients with urethral obstruction or anatomical abnormalities that may prevent safe catheter insertion, including severe phimosis, urethral meatal abnormalities, urethral strictures, severe urethral narrowing, urethral calculi, or other obstructive lesions.
- Do not use if catheter insertion meets significant resistance or causes pain, suggesting obstruction, stricture, or creation of a false passage; catheterization must be stopped immediately in such cases.
- Do not use in patients with acute or severe infection or inflammation of the urinary tract or surrounding genital area, including acute urinary tract infection, acute urethritis, epididymitis, or active infection, inflammation, or severe skin breakdown at or around the urethral meatus, unless urgent bladder decompression is clinically required.
- Do not use in patients who have undergone recent urethral or bladder surgery, unless catheterization is specifically approved by the treating surgeon.
- Do not use in patients with known or suspected bladder rupture, gross hematuria of unknown origin pending appropriate urological evaluation, or conditions associated with a high risk of bleeding, including severe coagulation disorders or fragile irradiated tissues.
- Do not use in patients with very low bladder volume or poor bladder compliance, where indwelling catheterization may increase the risk of bladder injury or other complications.
- Do not use in patients for whom safe and appropriate catheterization cannot be ensured, including those with severe spasticity, limited manual dexterity, persistent uncontrolled urinary incontinence despite appropriate therapy, absence of a suitably trained caregiver, or environmental conditions that do not permit clean and safe catheterization.

- Do not use when intermittent catheterization or other appropriate urinary management methods are clinically feasible, due to the increased risk of complications associated with indwelling Foley catheter use.
- Do not use in patients with suspected acute prostatic injury or severe prostatic trauma.
- Do not use when aseptic insertion and maintenance technique cannot be ensured.
- Do not use more than the recommended duration of use.
- Do not inflate the retention balloon unless flow has been observed and the catheter is fully advanced into the bladder.
- Do not use if correct intravesical placement cannot be confirmed prior to balloon inflation

Device Limitation:

- ❖ Do not use suction tool or equipment to drain because the catheter is designed to drain the urine through gravity power.
- ❖ Do not use the Foley catheter for any purpose other than urinary bladder drainage.
- ❖ Do not use the Foley catheter for treating or curing underlying urological conditions but it is intended solely to facilitate urine drainage

Patient Target Group:

- ❖ No specific requirements or restrictions on use for patient population.
- ❖ It is used for male and female patients.
- ❖ It is used for all ages pediatrics and adults.
- ❖ Pediatrics (Sizes 6: 12 FG) & Adults (Sizes: 14-24 FG).
- ❖ Patients who are unable due to paralysis or physical injury to use either standard toilet facilities or urinals**.**

Intended User:

To be used by an expert qualified medical professional, Skilled or Trained Personnel ***(In-Charge)***

Application site in the body:

A Foley catheter is a flexible tube that is inserted through the urethra to help drain urine from the bladder. It is a type of indwelling catheter, meaning one that is kept in place so that urine is continuously drained from the bladder.

Replacement Frequency:

- Change the device immediately upon suspected contamination.
- Do not use the device more than 14 days.
- The catheter should be removed or exchanged after appropriate time intervals determined individually
- for each patient, based on clinical indications such as infection or obstruction as well as current guidelines for prevention of infection**.**

Clinical benefits:

The clinical benefits derived from the device are achieved indirectly. The device itself provides a safe and reliable conduit for continuous urinary drainage from the bladder, helping to relieve urinary retention, monitor urinary output, and maintain bladder decompression in various clinical situations.

- ✓ Provide a smooth surface to reduce friction
- ✓ resistance to kinking
- ✓ Better flow properties
- ✓ Reducing the incidence of urethritis and the rates of encrustation and infection

- ✓ Lower rate of insertion failure

Intended Use Environment:

- The device is intended for use by trained healthcare professionals in sterile clinical environments where aseptic technique is required. Typical use settings include hospitals, operating rooms, emergency departments, intensive care units (ICUs), critical care units, and other healthcare facilities providing urinary catheterization for patients requiring sterile urinary drainage, particularly those at increased risk of infection.

Device Lifetime:

- The device is intended for **short-term use only**, with a maximum continuous use period **not exceeding 14 days** as determined by clinical need

Sterility status and Method of sterilization:

- Latex Foley Balloon Catheter supplied in sterile state and sterilized using Ethylene oxide**.**

Information on medical device intended to be used with other devices:

- The proximal end of the 2-way Foley catheter consists of one drainage funnel intended for connection to a urine collection bag and one inflation funnel with an access port for connection to a syringe. The 3-way Foley catheter includes these same two funnels (drainage and inflation) and, in addition, incorporates a dedicated irrigation access port intended to be connected to a syringe for bladder irrigation.

Performance Characteristics:

- **2way & 3way Latex Foley Balloon Catheter**:
  - The first lumen: is for drainage of urine.
  - The second lumen: has a non-return valve that is for inflation of balloon for fixing the catheter and deflation of balloon for removal.
  - The third lumen (in case of 3way catheter): is for introduction of irrigating solutions into the bladder.
- **Atraumatic, soft, rounded, closed tip with two lateral eyes**: for efficient drainage.
- **Color coded plain connector**: for easy identification of catheter size
- **Soft and rounded tip**: to prevent trauma during application.
- Soft, kink-resistant natural latex Foley Catheter
- Flow rate according to Clause 6.5 &Annex E of EN ISO 20696:2018 shall be Not less than the Minimum Average of flow rate

Outer Diameter (FG)	Average flow rate (minimum)
6	10 ml/min
8	15 ml/min
10	30 ml/min
12	50 ml/min
14	70 ml/min
16, 18, 20, 22 and 24	100 ml/min

- Catheter often pediatric sizes, have an insertion guidewire that provides stabilization during catheterization of patients with the smaller size catheters

Risks Associated with reuse

Re-use of the device may create a potential risk to the patient, including contamination and/or impairment of the device function.

Instruction for Use:

BEFORE USE	
Step	**Instruction**
1	The patient must be informed of the reason for the procedure, the associated risks, and must give their consent; they should also be offered the option of having a chaperone.
2	A full explanation of the procedure must be provided, and sufficient time should be allowed for the patient to ask questions.
3	Clean gloves and an apron must be worn to reduce the risk of infection.
4	All sterile equipment must be collected before the procedure, including sterile gloves, cleaning solution, water-based lubricant, a urine collection bag, and the Foley catheter.
5	Ensure the catheter size is appropriate as larger catheters increase the risk of urethral trauma. **Foley Catheter Size Selection** A Foley catheter is available in a range of sizes. The size is measured in French (FG) units. A Foley catheter size ranges from 6 Fr to 24 Fr for adults and pediatrics. These are the factors considered by medical professionals when choosing a Foley catheter size for their patient: 1. **Patient Anatomy**: The size of the Foley catheter must match the dimension of the patient's urethra. 2. **Age and Gender**: Females and children generally require smaller catheters, but the specific size will depend on the individual's anatomy and age. Recommended Foley catheter sizes according to age are generally as follows: 6 FG for newborns, 8 FG for children aged 3 months to 4 years, 10 FG for 6-year-old children, 12 FG for 8-year-old children, and 14 FG for adolescents (>12 years). These values represent typical clinical recommendations based on age. However, the final selection of catheter size must always be determined by the physician or qualified healthcare professional, who must consider additional patient-specific factors such as urethral anatomy, gender, underlying medical condition, required drainage volume, and anticipated frequency of catheterization. Therefore, the appropriate catheter size may vary from the standard age-based recommendations.
6	The catheter must be visually inspected for any signs of damage before use.
7	A waterproof pad must be placed under the patient to prevent soiling of bed linens.
8	Drape the patient with one drape under the buttocks and another over the patient exposing the perineum or penis.
9	The patient must be positioned comfortably, preferably in a supine or semi-upright position with the knees raised.
10	For some women, the supine lithotomy position can be very uncomfortable or even dangerous. For example, patients in the last trimester of pregnancy may faint with decreased blood supply to the fetus in this position. Patients with arthritis of the knees and hips may also find this position extremely uncomfortable. Catheterization may also be accomplished with the patient in the lateral to Sim's position (three-quarters prone).
11	Apply sterile gloves and inspect the perineal region for erythema, drainage, and odor, and assess the perineal anatomy. Wash and disinfect the area around the urethral orifice with

BEFORE USE	
Step	**Instruction**
	warm water and soap or a perineal cleaner according to agency policy. It is important to avoid transferring bacteria onto the catheter from surrounding areas. Assessing the perineal area allows determination of its condition and identification of anatomical landmarks to assist with insertion.
12	After preparing the urethral area, hand hygiene must be performed again, and sterile gloves must be applied.
13	The catheter must be opened from its peel-open package and used immediately, taking care not to contaminate or drop it.
14	The catheter tip must be lubricated with sterile water-based lubricant; petroleum-based lubricants must be avoided.
15	If lignocaine gel is used, approximately five minutes must be allowed for the anaesthetic effect before insertion.

DURING USE	
Step	**Instruction**
Insertion procedure of the catheter Positioning of patient depends on gender	
16a	**Female catheterization:** Position female patient into a frog-leg pose. Ask patient to bear down gently (as if to void) to help expose urethral meatus. With one hand, part patient's labia to expose the urethral orifice. This process helps visualize urethral meatus and relax external urinary sphincter. Separate labia with fingers of non-dominant hand (now contaminated and no longer sterile). Using sterile technique and dominant hand, clean labia and urethral meatus from clitoris to anus, and from outside labia to inner labial folds and urethral meatus is the last swipe of the swab. If using prepackaged swabs, use a new swab for each cleansing stroke. If using cotton swabs and sterile forceps it is still one wipe one-way discard. Pick up catheter with sterile dominant hand 7.5 to 10 cm below the tip of the catheter. Holding catheter closer to the tip will help to control and manipulate catheter during insertion. Advance catheter 5 to 7.5 cm until urine flows from catheter, then advance an additional 5 cm. Insert the catheter approximately three inches, wait to see if urine flows, then advance another inch before inflating balloon. For unconscious female patient's or those with decreased sensation (i.e., paralyzed), insert the catheter slightly further than three inches, to make certain the catheter is in the bladder.
16b	**Male catheterization:** Position male patients into a supine pose. Hold penis perpendicular to body, avoid squeezing the penis, as this may make insertion of the catheter more difficult, ask patient to bear down gently (as if to void). Gently grasp penis at shaft and hold it at right angle to the body throughout procedure with non-dominant hand (now contaminated and no longer sterile). Ask patient to take a deep breath. This process helps visualize urethral meatus and relax external urinary sphincter. Using sterile

DURING USE	
Step	**Instruction**
	technique and dominant hand, clean urethral meatus in a circular motion working outward from meatus. If using prepackaged swabs, use a new swab for each cleansing stroke. If using cotton swabs and sterile forceps it is till one wipe one-way discard and slowly insert catheter through urethral meatus. Pick up catheter with sterile dominant hand 7.5 to 10 cm below the tip of the catheter. Holding catheter closer to the tip will help to control and manipulate catheter during insertion. Then slowly insert catheter through urethral meatus. Advance catheter 17 to 22.5 cm or until urine flows from catheter. The return of urine does not assure that the catheter is placed correctly in males, since there is residual urine in the penis. Inserting the catheter to the bifurcation of the Y is the standard for assurance of proper placement. If the foreskin was retracted, reposition it after placement. If catheter placement is in question (i.e., no urine returns or unable to fully insert the catheter) do not inflate the balloon and contact the physician. If resistance is met do not attempt forceful catheter insertion; apply continuous gentle pressure and ask the patient to take slow deep breaths to help relax or instruct the patient to try to void to open the sphincter and allow the catheter to pass.
17	While holding the catheter in place, slowly inflate balloon according to catheter size, using prefilled syringe. Observe the patient's facial expression during inflating noting any evidence of discomfort. If discomfort, STOP and deflate the balloon. The catheter balloon may be in the urethra. Likewise, if every indication suggests the balloon is in the bladder, keep gentle pressure on the syringe plunger with thumb, gently pull back on the catheter to confirm the balloon is inflated and the catheter will remain insitu. The size of balloon is marked on the catheter port. Inflating a balloon in a urethra can cause severe trauma.
18	**Note:** If patient experiences pain on balloon inflation, deflate balloon, allow urine to drain, advance catheter, and re-inflate balloon.
19	After balloon is inflated, pull gently on catheter until resistance is felt, and then advance the catheter again. Moving catheter back into bladder will avoid placing pressure on bladder neck.
20	The catheter must be connected to the urine collection bag, which must be positioned below the bladder level to prevent reflux, kinking, or accidental pulling. • Never leave the catheter hanging to be pulled by the weight of the bag.
21	When urine flow stops, the catheter should be withdrawn 2–3 cm. If urine flow restarts, the operator must wait briefly and then continue to withdraw the catheter slowly by an additional 1–2 cm.
22	**Complete the procedure** • Secure the catheter to the patient's thigh with hospital approved catheter securement device to prevent movement, irritation, and decrease risk of infection. To improve urine flow, some men may need to have the catheter secured slightly upward.

DURING USE	
Step	**Instruction**
	• Position the bag to avoid urine reflux into the bladder, kinking, or gross contamination of the bag. • Keep the bag below the level of the bladder at all times to prevent the back flow of urine and decrease the risk for infection. • Never leave the catheter hanging to be pulled by the weight of the bag. • Do not leave the bag laying on the floor unless necessary due to patient positioning (i.e., Trendelenburg position in the Operating Room). • Periodic observations of the system should be made to ensure that urine is flowing freely. If a standing column of urine is observed, check for correct positioning of the bag and then for a physical obstruction, such as a kink in the tubing. • If correct positioning of the bag or removal of physical obstruction does not allow free flow, the bag may have to be changed.

AFTER USE	
Step	**Instruction**
23	Insert syringe in balloon port and drain fluid from balloon. Verify balloon size on catheter to ensure all fluid is removed from balloon. A partially deflated balloon will cause trauma to the urethra wall and pain during removal. In case of NRV malfunction, cut the valve with scissors.
24	• Deflate the catheter balloon by negative pressure. Exercise the plunger of a leur-tipped 10 ml syringe by moving up and down within the syringe barrel. Pull back 0.5 ml air in the syringe to prevent adherence of the plunger to the end of the syringe barrel, then insert the syringe into the balloon port. Never use more force than is required to make the syringe "stick" in the valve. Use gentle aspiration, only if needed, to encourage deflation. • NEVER FORCE THE WATER INTO THE SYRINGE. Vigorous aspiration may collapse the inflation lumen, preventing balloon deflation. Allow 30 seconds for the balloon to deflate. • If there is slow or no deflation, re-seat the syringe gently. • If the retention balloon still does not deflate, reposition the patient to ensure catheter is not in traction or compressed within the bladder. • If this fails, contact the physician.
25	The catheter must be removed slowly and disposed of safely according to clinical waste protocols.
26	The perineal area must be cleaned, and all used materials must be disposed of appropriately.
27	Hand hygiene must be performed to prevent microbial transmission.

Warnings*:*

- For single-use only.

- Discard after single use, Reusing can be associated with Cross infection, Device Malfunction and Reactions to endotoxins as sterilization will not inactivate toxins produced by the breakdown of Gram-negative bacteria even if the bacteria themselves are killed.
- DO NOT re-sterilize and /or reuse the device, as this can compromise the device performance (functionality) and may cause inadequacy, deterioration of the device technical factors, rendering the device non-functional and unfit for intended use and also this may increase the risk of cross contamination due to several aspects including inappropriate reprocessing.
- The product should be used only by qualified healthcare professionals (qualified doctor or paramedic) who are experienced and have a thorough understanding of the clinical and technical aspects of product.
- Re-use of single use device creates a potential risk. It may lead to contamination and / or impairment of functional capability, Contamination and / or limited functionality of the device may lead to injury, illness of the patient.
- This product contains natural rubber latex, which may cause allergic reactions.
- Do not use ointment and lubricants having petroleum base, such as Vaseline, otherwise this may cause the balloon to rupture. But can be lubricated with water-soluble lubricants.
- Do not use if the packaging is damaged or has been previously opened.
- Storage Up to 30 ± 2 ℃, avoid excessive heat, protect from direct sunlight and moisture.
- The device should be disposed as per the safe disposal instructions as described in the instructions for use.
- Ultramed will not assume any responsibility in case of any incidental or consequential damages resulting from reuse of the product

Precautions:

- For urological use only.
- The patient must be routinely monitored by trained personnel according to recommended procedures.
- Always use sterile technique when inserting the catheter.
- Maintain proper hand hygiene before and after handling the catheter or drainage system.
- Adequately lubricate the catheter with a water-based lubricant prior to insertion to minimize urethral injury.
- A sterile lubricating gel containing 2% lignocaine may be used if prescribed. Avoid in patients with cardiovascular disease, hepatic insufficiency, epilepsy, or known allergy. For pregnant women, a lignocaine-free gel must be used. Observe patient's post-procedure for signs of toxicity, including seizures, loss of consciousness, or cardiac symptoms according to NHS guidelines.
- Use the right size of catheter
- Maintain a closed drainage system at all times to reduce infection risk. Avoid unnecessary disconnection.
- Ensure the catheter is securely connected to any urine collection system to avoid leakage or contamination.
- Do not use a needled syringe to inflate the balloon or puncture the catheter; this may compromise function and increase infection risk.
- Never overinflate the balloon or apply excessive pressure during inflation. Always inflate with sterile water.

- Do not use normal saline as crystals could theoretically precipitate in the balloon, valve or balloon channel making deflation of the balloon difficult when removing or replacing the Foley.
- Verify proper placement in the bladder before balloon inflation. Resistance, lack of urine return, or curling of the catheter may indicate urethral misplacement. Improper inflation can cause urethral injury, fistula, or stricture.
- For male patients, ensure the catheter is fully inserted; it should remain in place without manual holding.
- Perform inflation and deflation tests of the balloon with air prior to use.
- Avoid forceful insertion. Stop and evaluate if resistance persists. Consult a urologist if catheter passage is difficult.
- Patients with spinal cord injury at or above T6 should be closely monitored for signs of autonomic dysreflexia. If catheter blockage or urinary retention is suspected, the catheter must be assessed and replaced without delay by trained healthcare personnel. Do not delay bladder decompression, even if vital signs appear stable. Ensure correct catheter placement before balloon inflation.
- Exercise caution in patients with altered lower urinary tract anatomy (e.g., post-surgery, bladder neck resection, sphincterotomy) or prior urethral trauma.
- Use caution in men with significant prostate enlargement or acute prostatitis, as catheterization may be difficult or increase risk of obstruction and infection.
- Expect some urine return if the catheter is correctly in the bladder. If none is observed, irrigate with normal saline (safer than sterile water if extravasated) and re-evaluate placement.
- Once the balloon is inflated, the catheter should be slightly mobile in the bladder. Restricted mobility may indicate incorrect placement.
- Always replace the foreskin in uncircumcised male patients to avoid paraphimosis.
- Consider bladder scan or ultrasound to confirm catheter placement and ensure bladder emptying.
- Empty the urine bag every 8 hours or when 2/3 full to prevent traction, leakage, or infection. Keep the bag below bladder level; avoid letting it hang or touch the floor unnecessarily.
- Use caution during patient repositioning, transfers, or turning to avoid pulling or dislodging the catheter. Secure the catheter and tubing appropriately.
- Special care is required during female catheterization due to anatomical variation; ensure proper visualization of the urethral meatus.
- Replace the catheter if encrustation, obstruction, leakage, change in performance of device or device malfunction occurs.
- Catheter use may cause urethral irritation, pain, discomfort, urethritis, stricture formation, or urinary tract infection. Monitor patients for fever, suprapubic or flank pain, cloudy urine, foul odor, or hematuria.
- Pediatric use: avoid stylet bending or kinking. “If a stylet is provided, it must be used only to facilitate insertion and must be removed immediately after correct catheter placement and before balloon inflation.”
- Ensure proper balloon deflation prior to removal. In case of NRV malfunction, cut the valve with scissors.
- Keep drainage tubing free of kinks or compression to maintain continuous gravity drainage.
- Evaluate insufficient urine flow for catheter size, obstruction, or patient hydration; consult a urologist if necessary.
- The catheter is MRI conditional due to the stainless-steel spring in the NRV. Only enter the scanner if the device is positively identified as MRI conditional and all safety conditions are met.
- Do not aspirate urine through the drainage funnel wall.

- Do not attempt catheterization if urethral injury is suspected.
- Do not use for more than 14 days.
- This device is sterile, single-use, and ready for use. Do not use if packaging is damaged or expired. Dispose of as biomedical waste according to applicable regulations

Potential Complications / Risks:

Improper connection to urine collection bags, leakage, blockage, kinking or bending of the catheter, deformation or damage of the tip, accidental Dislodgement, allergic reaction, complications from using an incorrectly sized catheter, urinary tract infection, pyuria, urethral trauma or irritation, mild hematuria, pain or discomfort during insertion or removal, bladder spasms, inflammation, bleeding, or urethral perforation. the formation of a false passage or difficulties in patients with urethral abnormalities such as strictures or obstructions if used by unskilled personnel, NRV malfunction, balloon encrustation. Most risks can be minimized by following proper aseptic technique, selecting the appropriate catheter size, ensuring adequate water-based lubrication, and monitoring the patient throughout the procedure

General Instructions:

1. To be used by a trained and qualified healthcare provider and medical professional.
2. During operation, take all necessary sterile barrier precautions. After usage, dispose of the device as biomedical waste in accordance with the applicable laws

Conditions of Handling, Preservation and Storage:

- Not more than 5 cartons on each other.
- Store in a clean, dry, well-ventilated area.
- Out of Sunlight.
- Suitable temperature: Up to 30 ℃ ± 2℃.
- Humidity: Up to RH 65% (± 5)

Safe Disposal of single-use medical devices:

- Adopt adequate precautions for the elimination and disposal of the device and comply with the provisions of the laws in force on biologically hazardous waste.
- Single-use devices must be segregated from other reusable devices and, should not be returned to a Decontamination facility for reprocessing. Once discarded (used or unused) medical devices are considered to be special waste and should be managed as healthcare (clinical) waste. All medical devices that are to be disposed of, must in accordance with Health and Safety, Carriage of Dangerous Goods and Waste Regulations.
- Discarded devices should be placed in UN-type approved waste containers suitable for clinical waste (UN 3291); these should be rigid and puncture-proof. In general devices other than sharps should not be placed in sharps boxes as sharps waste is treated and disposed of in a different manner.
- Guidance on the type and color of the container should be sought from the Board Waste Management Officer. rigid water-tight containers are used for waste requiring incineration in a suitably permitted or licensed facility

Method of sterilization: Sterilized Using Ethylene Oxide

Shelf life: 5 years (from the date of manufacturing)

Basic UDI: 622300425LFC3006NW

Reporting of incident to Manufacturer & Competent Authority:

- For providing feedback on this product write to shady@ultramedumic.com
- In case of any serious incident occurred, please report it to the Ultra for medical products (Ultramed) Co (U.M.I.C) S.A.E and/or its Authorized Representative and to your national

authority. The contacts of national competent authorities (Vigilance Contact Points) and further information can be found on the following European Commission website: https://ec.europa.eu/growth/sectors/medical-devices/contacts_en

Details of symbols used in labels:

Symbol	Meaning
EU REP Obelis SA 53 Bd. Général Wahis B-1030 Brussels,Belgium Phone : 32.2.732.59.54 Fax : 32.2..732.60.03 E-mail: mail@obelis.net www.obelis.net	EU REP
CE 2803	CE Mark with notified body number 2803
STERILE EO	Sterilized by Ethylene Oxide
	For Single Use Only
LOT	Lot No.
	Date of Manufacturing
	Use by / Expiry date
REF	Catalogue No.
	Non- Pyrogenic
MD	Medical Device
UDI	Unique device Identifier
	Don't use if package is not intact
	Manufacturer’s address
PHT NON-DEHP	Phthalate-Free
	Read Instructions for Use
2 STERILIZE	Not to be re-sterilized
	storage at room temperature up to 30 ℃ ± 2℃
	Cautions
LATEX	The product contains Latex

Symbol	Meaning
	MR Unsafe
	Protect from rain / Keep Dry
	Protect from sunlight / Keep away from Sunlight
	Symbol for „This way Up“
	Symbol for „handle with Care“
	Don’t put more than 5 cartons upon each other

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Assiut Factory: Part No. (304:310) & part no. (312) – Industrial Area, Arab El Awamer – Abnoub - Assiut – Egypt. T**el**: 002-088-4964333 (500), 002-088-4964666 (600), 002-088-4964777 (700), 002-088-4964888 (800), 002-088-4964999 (900)
& Fax:002-088-4964222**& Mob:** 002-01001558853, 002-01068832355
Cairo Head Office: 64, Nakhla El Motaiy Triumph Square Heliopolis **Tel:** 022/4171621-4143794 **& Fax**: 022/4171613 **& Mob**: 01223988200
Assuit Office: 23, July Str. Tel: 088/2364111 – 2364222 **& Fax:** 088/2334964 & Mob. : 01223988202
Alexandria Office: 212Abd El salaam Airef Str, Luran **Tel:** 03/5856202– 5856458 **& Fax:** 03/5828988& **Mob:** 01223948666
E-mail: info@ultramedumic.com, **shady@elaggargroup.com** **Website:** **www.ultramedumic.com**