INSTRUCTION FOR USE FOR THE NELATON CATHETER

Product Name : Nelaton Catheter

Brand Name : Ultramed Nelaton Catheter

Manufacturer's Name : Ultra for medical products (Ultramed) Co (U.M.I.C) S.A.E

Manufacturer's Address : Part no. (304 : 310) and part no. 312 - Arab El Awamer - Industrial zone – Abnoub - Assiut, Egypt.

- *Description of the Device:*

- A Nelaton catheter is a flexible PVC tube inserted into the bladder through the urethra (or a Mitrofanoff) to drain urine.
- Because it has no retention balloon, the Nelaton catheter cannot remain in situ unaided and is used only for temporary bladder drainage. It is designed for cases where the patient requires periodic assistance with bladder drainage
- It is commonly used for one-time it is used once and then thrown away.
- It is designed for intermittent use and is removed once the bladder is empty (inserted temporarily to drain the bladder, then removed) in patients who cannot naturally empty their bladder. During the procedure, urine drains through the catheter into a urine collection bag to which the catheter should be attached through a universal drainage funnel catheter.
- The catheter's flexibility and smooth, closed distal end make insertion and removal more comfortable, reducing patient trauma. It features 2 small drainage eyelets at the tip to allow efficient urine flow.
- Nelaton catheters are made from non-toxic, non-irritant, medical-grade PVC and include a radio-opaque line for X-ray visibility.
- One end has a universal color-coded drainage funnel connector for easy attachment to a urine collection bag and for simple size identification.
- Standard overall lengths are 400 mm for males and 200 mm for females.
- The duration of use is intermittent and typically less than 60 minutes (commonly 10–20 minutes), classifying it as a transient-use device.
- Its simple design, transient-use time, and well-established material contribute to a low risk profile and support its safe and effective performance for routine urinary drainage and sampling.
- Its design fulfills the requirements of ISO 20696.
- The Nelaton catheter is a well-established medical device used for many years across multiple brands. It is CE-marked (since 2008), approved by the Ministry of Health, sterilized with ethylene oxide (EO), and intended for single use.
- Sizes range from 6 to 24 FG, and each catheter is individually packaged in a peel pouch.
- Nelaton catheter is used as medical device for many years under different brands.
- Packaging in PE bags in Single box according to the table below:
- For Male Catheter

Size/Type	Pcs. Qty. of Bag	Pcs. Qty. of Box	Boxes Qty. of Carton	Pcs. Qty. of Carton	Carton Dimensions
06-10 FG	35	175	16	2800	63*48*56 cm
12-16 FG	25	125	16	2000	
18-24 FG	25	125	8	1000	63*48*28 cm

- For Female Catheter

Size/Type	Pcs. Qty. of Bag	Pcs. Qty. of Box	Boxes Qty. of Carton	Pcs. Qty. of Carton	Carton Dimensions
06-24 FG	25	125	10	1250	69*34*31cm

Material Used:

- DEHP free P.V.C (Poly Vinyl Chloride) medical grade

Intended purpose:

- Nelaton catheter is a medical device that is primarily used for urinary drainage from the bladder. It is often used when patients require assistance to empty their bladder. such as in cases of urinary retention, neurological conditions affecting bladder control and monitoring urinary output especially post-surgery, anesthesia. the catheter it is inserted and removed once the bladder is drained.

Variants:

Nelaton Catheter Male			Nelaton Catheter Female		
Size FG	Color Code	Ref. Code	Size FG	Color Code	Ref. Code
6	Light green	3001-6	6	Light green	3002-6
8	Blue	3001-8	8	Blue	3002-8
10	Black	3001-10	10	Black	3002-10
12	White	3001-12	12	White	3002-12
14	Dark green	3001-14	14	Dark green	3002-14
16	Orange	3001-16	16	Orange	3002-16
18	Red	3001-18	18	Red	3002-18
20	Yellow	3001-20	20	Yellow	3002-20
22	Purple	3001-22	22	Purple	3002-22
24	Light blue	3001-24	24	Light blue	3002-24

Clinical Indications:

- Post-operative Urinary Retention: After certain surgeries, such as urological, gynecological, or abdominal surgeries to provide an alternate way temporarily to avoid any medical complications.
- When bladder or urethral trauma occurs—such as during gynecologic surgery or obstetric procedures—bladder drainage may be required to prevent complications. In cases where urethral catheterization is clinically appropriate and urethral integrity has been assessed, a gently inserted, well-lubricated catheter may be used to maintain bladder drainage and support healing.

- In case of acute vulvovaginitis only when causes acute urinary retention, such as in cases of severe vulvar or labial edema or intense pain preventing normal voiding.
- Neurogenic bladder dysfunction, including patients with spinal cord injury, multiple sclerosis, or other neurological disorders requiring intermittent catheterization.
- Bladder Investigations by Monitoring urine output for critically ill persons.
- Intermittent urinary catheterization when the person cannot naturally void their bladder or when bladder function is impaired.
- Urinary incontinence that can be managed by intermittent catheter such as overflow incontinence (Meddings et al., 2015).
- Urinary retention and inability to spontaneously void, including:
  - Acute urinary retention without bladder outlet obstruction (Meddings et al., 2015).
  - Acute urinary retention with bladder outlet obstruction due to noninfectious, non-traumatic diagnosis such as benign prostatic hypertrophy: If acute prostatitis or urethral trauma is present, consult a urologist to determine catheter type and/or placement (Meddings et al., 2015).
- Chronic urinary retention with/or without bladder outlet obstruction, as a temporary alternative to an indwelling catheter (Meddings et al., 2015) for less than 60 minutes.
- Collection of random urine samples for specimens, if impossible by other collection strategies (Meddings et al., 2015).
- Assessment of post-void, residual urine volume if a bladder scanner is unavailable. (Gould et al., 2009; Meddings et al., 2015).
- For catheterization of continent urinary diversions through the urethra (neobladder) or the stoma (urostomy or ileoconduit). The Nelaton catheter is indicated for patients with continent urinary diversions or ileal bladder substitutes who are unable to achieve spontaneous voiding due to mechanical outlet obstruction (e.g. kinking, anastomotic stricture, or prostatic tissue regrowth). It provides intermittent drainage of urine until spontaneous voiding is restored or definitive corrective treatment is performed.
- Diagnostic or monitoring purposes, including temporary bladder emptying or monitoring urine output in selected clinical situations.
- Intermittent catheterization in pediatric patients requiring temporary bladder drainage.
- Temporary bladder emptying during radiological or urodynamic examinations.
- Emergency bladder decompression in acute urinary retention when rapid relief is clinically required.
- bladder emptying prior to or during surgical or diagnostic procedures when required by the clinician. Many surgeons prefer to drain the bladder prior to gynaecological operation.

Contraindications:

- Do not use in patients with known allergy or hypersensitivity to PVC or any component of the catheter.
- Do not use in patients with suspected or confirmed urethral injury or trauma, including pelvic fracture or visible blood at the urethral meatus.

- Do not use in patients with known urethral strictures, severe urethral narrowing, or anatomical abnormalities that prevent safe passage of a straight catheter without causing additional injury.
- Do not use in patients with acute or severe urinary tract infection (UTI), acute urethritis, epididymitis, or severe urethral infection, as catheterization may increase complications.
- Do not use following recent urethral or bladder surgery unless catheterization is specifically approved by the treating surgeon as insertion may interfere with healing or damage surgical sites.
- Do not use in the presence of urethral stones or any obstructive lesion that may prevent safe insertion.
- Do not use in cases of gross hematuria of unknown cause until evaluated by a urologist.
- Do not use in patients with severe coagulation disorders, where even minimal urethral trauma may cause significant bleeding.
- Do not use if catheter insertion meets significant resistance or causes pain, suggesting possible obstruction, stricture, or creation of a false passage as inserting a catheter into this area can cause significant damage or introduce infections.
- Do not use after certain types of urological surgeries, such as those involving the urethra or bladder, the use of a Nelaton catheter might be contraindicated and the insertion could interfere with the healing process or exacerbate surgical wounds
- Do not use in men with significant prostate enlargement like prostatitis, especially if accompanied by bladder outlet obstruction, where catheterization may worsen obstruction or infection. Specially the male urinary sphincter may create resistance when passing a urinary catheter, particularly for older men with prostatic hypertrophy. If acute prostatitis or urethral trauma is present, consult a urologist to determine catheter type and/or placement (Meddings et al., 2015). But it is indicated for bladder drainage in cases of acute urinary retention. Use with caution in situations where urethral resistance, infection, or trauma is suspected. If catheter passage is difficult or if urethral injury or acute prostatitis is present, consult a specialist to determine the appropriate catheter type or method of placement.
- Do not use in situations where spasticity, incontinence despite anticholinergic therapy,
- or an unhygienic environment would prevent a clean and safe catheterization procedure (Queensland Health, 2013). (Do not use a Nelaton catheter if the patient has severe spasticity, persistent incontinence despite treatment, or if the environment is not clean enough to perform safe and hygienic intermittent catheterization) A Nelaton catheter should not be used for intermittent catheterization in patients whose clinical or environmental conditions prevent safe and hygienic catheter insertion. This includes individuals with severe spasticity that makes catheter placement difficult or traumatic, as well as those with persistent, uncontrolled incontinence that remains despite appropriate therapy, since continuous urine leakage can compromise cleanliness and increase infection risk. Use is also contraindicated in settings where the environment does not allow for proper clean technique. Even when intermittent catheterization is clinically indicated,

these factors may render the procedure unsafe or ineffective and therefore should be considered contraindications.

- Do not use if limited dexterity and poor technique is available or in the absence of an appropriately trained caregiver (Queensland Health, 2013; Vahr et al., 2013).
- Do not use the Nelaton catheter for long-term or continuous bladder drainage, as it is not designed for indwelling use.
- Do not use in case of low bladder volume/compliance
- Do not use in case of high intravesical pressure, which would require continuous free drainage to avoid renal damage (Vahr et al., 2013).

Device Limitations:

- Do not use to introduce substances through the catheter into the bladder because it is not typically designed or intended for.
- Do not use for short term or long term catheterization because it is typically used for transient time catheterization, meaning they are inserted and removed once the bladder is drained as it is designed without retention balloon.
- Do not use suction tool or equipment to drain because the catheter is designed to drain the urine through gravity power.

Patient Target Group:

- No specific requirements or restrictions on use for patient population or user group defined by the manufacturer.
- 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).

Application site in the body:

- The Nelaton catheter is inserted through the urethra, with the tip positioned within the urinary bladder for temporary or intermittent drainage. This allows urine to drain effectively. Because it has a straight, closed, rounded tip with side holes (“eyes”), it is designed to be atraumatic to the urethral mucosa.

Replacement Frequency:

- Change the device immediately upon suspected contamination.
- The duration of use is intermittent and typically less than 60 minutes (commonly 10–20 minutes).

Intended User:

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

Clinical benefits:

- The Nelaton catheter provides safe, atraumatic, and effective temporary bladder drainage by allowing gentle, controlled emptying of the bladder without the risks associated with long-term indwelling catheters. Its smooth, rounded tip and lateral drainage eyes minimize urethral irritation, making it suitable for intermittent catheterization across a wide range of clinical situations. By enabling reliable bladder emptying, it helps prevent overdistention, urinary stasis, discomfort, and potential upper urinary tract complications.

The device supports post-operative recovery by reducing the risk of urinary retention, assists in managing neurogenic bladder dysfunction, and allows accurate monitoring of urine output when clinically required. It facilitates diagnostic and procedural workflows by enabling temporary bladder emptying or sterile urine collection when other methods are not feasible. For patients with urinary diversions or temporary mechanical outlet obstruction, it provides an effective means of intermittent drainage until normal voiding is restored or further treatment is performed. Additionally, by reducing reliance on indwelling catheters, the Nelaton catheter may help lower the risk of catheter-associated complications while offering a simple, low-trauma solution for bladder management.

Use Environment:

- Hospital, Emergency Room, Critical care room

Life time of device:

- The Nelaton catheter is a single-use, disposable medical device intended for one-time use only. It must not be reused, reprocessed, or sterilized for subsequent use. Reuse can compromise the catheter's structural integrity, increase the risk of urethral trauma, and elevate the risk of infection. After use, the catheter should be safely discarded in accordance with local clinical waste disposal regulations.

Sterility status and Method of sterilization:

- The Nelaton Catheter is supplied in sterile state and sterilized using ethylene oxide.

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

- Nelaton Catheter is designed to be connected with a urine Collection bag, its universal connector is designed to be compatible with the Urine Collection bag in-let connector.

Performance Characteristics:

- Soft, frosted and kink resistant tube.
- Atraumatic, soft, rounded, closed tip to prevent trauma during application, with two lateral eyes for efficient drainage.
- Color coded plain connector for easy identification of size.
- 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

- Radiopaque line for X-Ray visualization; for accurate placement and prevent misplacement of tube.
- Standard overall lengths are 400 mm for male type and 200 mm for female type.
- Sizes range from 6 to 24 FG, and each catheter is individually packaged in a peel pouch.

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 Nelaton catheter.
5	Ensure the catheter size is appropriate as Larger catheters increase the risk of urethral trauma. **Nelaton Catheter Size and Selection** A Nelaton catheter is available in a range of sizes. The size of intermittent catheters is measured in French (FG) units. A Nelaton catheter size ranges from 6 Fr to 24 Fr for adults and pediatrics. These are the factors considered by medical professionals when choosing a Nelaton catheter size for their patient: 1. **Patient Anatomy**: The size of the Nelaton 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. 3. **Usage**: The medical condition that has mandated the use of a Nelaton catheter and the amount of content that needs to be drained. 4. **Frequency**: A smaller size may be chosen to minimize urethral irritation if it will be used frequently. 5. **Medical Condition**: Certain medical conditions may require larger or smaller catheters, such as cases of urinary retention, bladder obstruction, or strictures. Recommended Nelaton 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

BEFORE USE	
Step	**Instruction**
	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 patient with drape one under the buttocks and one on top of and 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 Sims 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 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	Sterile lubricating gel must be instilled into the urethra using the prefilled syringe (6 mL for females and 11 mL for males) according to NHS guidelines.
16	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	

DURING USE	
Step	**Instruction**
17a	**Female catheterization:** 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.
17b	**Male catheterization:** 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 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 forcepts 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.
18	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. • 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 to prevent the backflow of urine and decrease the risk for infection. • Never leave the catheter hanging to be pulled by the weight of the bag.
19	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.

AFTER USE	
Step	**Instruction**
20	Once the bladder is completely empty, the catheter must be removed slowly and disposed of safely according to clinical waste protocols.
21	The perineal area must be cleaned, and all used materials must be disposed of appropriately.
22	Hand hygiene must be performed to prevent microbial transmission.

- ***Warnings:***

- Do not use the device if the packaging is damaged or has been previously opened. failure to comply may expose the patient to risks such as contamination from a non-sterile product, reduced functionality due to device damage, and potential irritation or discomfort, moreover improper handling or use of an unsterile catheter may introduce bacteria into the urethra.
- For single use only.
- Do not reuse, reprocess or re-sterilize the catheter. Reuse may cause serious infection, cross contamination, or device failure.
- Do not use ointments or lubricants containing petroleum.
- The product must be used only by qualified physicians or trained healthcare professionals who are experienced and fully understand the clinical and technical aspects of the device.
- Store at temperatures up to 30 °C ± 2 °C and relative humidity up to 65% ± 5%. Avoid excessive heat and protect from direct sunlight and moisture.
- Dispose of the device in accordance with the disposal instructions provided in the Instructions for Use.
- Do not force the catheter during insertion. If resistance is encountered, stop immediately. Forcing the catheter may cause urethral trauma, bleeding, perforation, or the creation of a false passage. The catheter must always be inserted gently and correctly to avoid injury to the urethra or bladder. If difficulty persists, consult a healthcare professional.
- Do not leave the catheter in place. This device is intended for intermittent use only and is not designed for indwelling catheterization because it does not contain a retention balloon.
- Prolonged or frequent catheterization may cause irritation, urethral inflammation, or infection. Follow the schedule prescribed by a healthcare professional.
- Use caution in patients with urethral strictures, enlarged prostate, or anatomical abnormalities as catheter insertion may be difficult or may cause injury.
- Stop using the catheter and seek medical attention if the patient experiences severe pain, bleeding, fever, or signs of infection.
- Ultramed will not assume any responsibility in case of any incidental or consequential damages resulting from reuse of the product.

- ***Cautions:***

- Caution should be exercised Before use in case of (According to NHS guidelines):
  - Previous urethral trauma/fractured pelvis
  - Known history of urethral stricture

- Previous difficulty with catheterization.
- A history of Radical Prostatectomy or Bladder Reconstruction
- Urethral reconstruction surgery
- Implantation of urethral sphincter/penile rods
- Undiagnosed haematuria
- A history of lower urinary tract cancers
- Undiagnosed urethral discharge
- Congenital abnormalities (e.g. Hypospadias or epispadias)
- Consent is not given
- A patient has been given unsealed sources of radiation (e.g. Iodine 131 for thyroid cancer).

Advice in these circumstances can be obtained from the Urology Nurse Specialists or the on call Urology Registrar.

- ❖ Use only under aseptic technique. Inadequate aseptic practice may lead to urinary tract infection. If contamination occurs, discard and use a new sterile catheter.
- ❖ Use adequate sterile, water-based lubrication during insertion to minimize urethral irritation and reduce the risk of injury. as insertion of the catheter without lubricant may cause some discomfort or pain, especially if the patient has a sensitive urethra or is unable to relax.
- ❖ Select the correct catheter size (FG) as recommended by a healthcare professional. because using the wrong size can lead to complications like discomfort or difficulty draining.
- ❖ Avoid kinking, bending or folding the catheter during insertion or drainage, ensure urine drains into a clean container kept below the level of the bladder to prevent backflow as this may obstruct urine flow and cause the bladder back flow.
- ❖ Do not expose the catheter to sharp objects that may damage the tubing or drainage eyelets.
- ❖ Monitor the patient during catheterization. If resistance is encountered, stop immediately the procedure. Reassess or Withdraw the catheter slightly and attempt gentle reinsertion after repositioning the patient. If resistance persists, do not force the catheter. Discontinue the procedure and consult a healthcare professional, as clinical evaluation may be required.
- ❖ Confirm proper placement in the bladder by ensuring urine flow once the catheter is inserted. If no urine is draining, assess for possible catheter misplacement or blockage.
- ❖ If the catheter becomes blocked or clogged, it must be replaced.
- ❖ If urine is thick or its flow is lower than expected, and medical causes have been ruled out, check the correct catheter size that is determined for the patient, Additionally, consult a urologist for guidance or for selecting an alternative drainage method. Insufficient bladder drainage, if not corrected promptly, may increase the risk of patient injury.
- ❖ Ensure the catheter is securely connected to any urine collection system to avoid leakage and potential contamination.
- ❖ Do not cut, alter, or modify the catheter. Any modification may compromise function and safety.
- ❖ A Sterile lubricating anaesthetic gel containing 2% Lignocaine may be used in both male and female catheterisation to minimise associated trauma, pain, discomfort and catheter-associated infection, however, this must be prescribed. A sterile lubricating gel with no

Lignocaine is a suitable alternative and has been shown to be as effective. If gel containing lignocaine is used must be prescribed prior to use.

- Caution is advised in using the lidocaine for patients with cardiovascular morbidity, hepatic insufficiency, or epilepsy. Lidocaine is contraindicated in patients with a known allergy to the product. Do not use lidocaine if there is urethral mucosal damage that could allow systemic absorption of the lidocaine.
- The only exception to this is for women in labour who are at an increased risk of toxicity. A sterile lubricating gel without anaesthetic must be used in all pregnant women according to NHS guidelines.
- If the sterile lubricating anaesthetic gel which contains a high dose lignocaine is used, then great care must be taken in both its application and observation of the patient post procedure. In traumatic or repeated catheterisations there is a risk that more of the gel is absorbed through the vascular membrane than expected with the potential for patient toxicity.
- Patients must be observed post procedure for signs of toxicity include loss of consciousness, fitting and cardiac arrest if lignocaine gel has been used.

- ***Precautions:***

- For urological use only.
- Do not aspirate urine through the drainage funnel connector.
- Carefully read all instructions prior to use. Observe all warnings & precautions noted throughout these instructions.
- Failure to do so may result in complications. This device is Sterile & Ready for Use. Sterility is guaranteed - if pack is undamaged.
- The device is for Single Use Only.
- Use the product immediately after opening the individual blister packing.
- Always ensure that proper hygiene practices are followed during insertion and care.
- Use sterile equipment, sterile gloves during the procedure.
- Ensure urine drains into a clean container kept below the level of the bladder to prevent backflow.
- Discard the set after single use.
- Determine patient's condition and vital status During device application / Operation.
- Destroy the device & its accessories after single use as bio-medical waste as per applicable laws.
- Check the expiry date prior to use. Do not Use the Device after Date of Expiry.
- Once the product has been opened, use it immediately. Do not procrastinate using it because if you do so, you allow its contamination.

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. 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:

To be used by an expert qualified medical professional. Use maximal sterile barrier precautions during administration Dispose the device after use as bio-medical waste as per applicable laws.

Conditions of Handling, Preservation and Storage:

- Not more than 5 cartons on each other.
- Nice Ventilated place.
- Out of Sunlight.
- Storage at room temperature up to 30°C ± 2°C.
- Humidity: 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: 622300425NEC3001P9

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
EC 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
30 °C ± 2	storage at room temperature up to 30 °C ± 2°C
	Cautions
LATEX	Latex Free

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

ISSUE/REV DATE: 01 -09- 2013 / 04.11.2025

Assiut Factory: Part no. (304:310) and part no. 312 - Arab El Awamer - Industrial zone – Abnoub - Assiut, Egypt.
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