

ugo.<sup>TM</sup>  
Foley catheter



Instructions for use

# Ugo Foley Catheter

100% silicone 2-way Foley catheter  
with integrated 5-10ml balloon

STANDARD LENGTH (420mm)

All-silicone Foley catheter suitable for transurethral and suprapubic catheterisation for up to 90 days.

## INSTRUCTIONS FOR USE

### 1. Intended use:

For long-term transurethral and suprapubic catheterisation for up to 90 days.

Silicone Foley catheters are used in bladder drainage of urine and/or for continuous irrigation of fluids by urethra or suprapubic placement and/or for installation of appropriate therapeutic agents into the bladder.

### 2. Indications for use of long-term catheterisation:

- Bladder outlet obstruction not correctable medically or surgically.
- Intractable skin breakdown caused or exacerbated by incontinence.
- Some patients with neurogenic bladder and retention.
- Palliative care for terminally ill or severely impaired incontinent patients for whom bed and clothing changes are uncomfortable.
- Preference of a patient who has not responded to specific incontinence treatments.

### 3. Contraindications:

#### 3.1. For transurethral catheterisation;

- Acute urethritis.
- Acute prostatitis.
- Acute epididymitis.

#### 3.2. For suprapubic catheterisation;

- Known or suspected carcinoma of the bladder.
- Suprapubic catheterisation is absolutely contraindicated in the absence of an easily palpable or ultrasonographically localised distended urinary bladder.
- Previous lower abdominal surgery.
- Coagulopathy (until the abnormality is corrected).
- Ascites.
- Prosthetic devices in lower abdomen i.e. hernia mesh.
- Pelvic fracture.

### 4. Cautions:

- Single-use device for single patient use.
- For transurethral catheterisation and suprapubic use only.
- Sterile contents if package is unopened and undamaged.
- Catheter size and balloon capacity are marked on labels and device.
- Select catheter size according to patient body type and intended procedure.
- Apply sterile and aseptic technique for the catheter insertion procedure.

- Visually inspect the catheter for imperfections prior to use.
- Lubricate catheter with water-based lubricant before insertion.
- Do not inflate catheter balloon above its stated capacity.
- Do not inflate catheter balloon until catheter is correctly in place.
- Do not aspirate or manually accelerate deflation of catheter balloon.

## 5. Product description:

- Manufactured from 100% Silicone.
- A Foley catheter is an indwelling, soft and flexible tube which is inserted into the bladder and left in place (in situ) by its inflatable balloon, to drain urine and/or for continuous irrigation of fluids by urethra or suprapubic placement and/or for installation of appropriate therapeutic agents into the bladder.
- Catheter size, by French gauge (Ch), and corresponding outside catheter diameter in millimetres (mm), is stated on product labels.
- The injection port of the catheter is color-coded according to its size reference.
- Catheter length in millimetres (mm) is stated on product labels.
- Catheter balloon inflation volume in millilitres (ml) is stated on product labels.

## 6. Product packaging:

- Each Foley catheter is individually wrapped in a sterile product pack.
- The Foley catheter is sterile if the product pack is unopened and undamaged.
- Catheter size and balloon inflation capacity are marked on labels and device.

## 7. Warnings:

- **THE CATHETER IS A SINGLE-USE DEVICES FOR SINGLE PATIENT USE.**
- **DO NOT REUSE OR RE-STERILISE .**
- The catheter balloon should only be inflated in patient, once the catheter is fully inserted and correctly placed in the bladder.
- Use only water-based lubricants to ease the insertion of the catheter.
- Do not over-inflate the balloon above its advised minimum/maximum volume inflation interval.
- Do not use product beyond intended continuous use.
- Do not use product after product expiry date.

## 8. Storing:

- Catheters should be stored in their original packaging and shelf cartons, in a clean and dry environment at normal room temperature, away from heat exposure and sunlight.
- Catheters in their single packaging should not be stored or handled in folded positions.

## 9. Use of the Ugo Foley Catheter:

The physician is responsible for writing the order for placement of a Foley catheter. The registered nurse, licensed practical nurse, advanced care partner, emergency medical technician or paramedic is responsible for placing an indwelling urinary or suprapubic catheter. The above personnel must have demonstrated the knowledge and skills to perform this procedure as evidenced by verification on a competency profile.

## 9.1 Directions for catheter selection:

- **ALWAYS FOLLOW LOCAL AND NATIONAL BEST PRACTICE DIRECTIONS IN EFFECT.**
- Identify the patient by use of two patient identifiers.
- Select catheter size and length by considering patient gender, patient body type, the procedure to be performed, and the potential risks involved.
- Catheter size needed for insertion into the urethra for transurethral catheterisation is often determined by the size of the urethra opening of the patient.
- Select the smallest catheter size suitable for the procedure to be performed. For urethral catheterisation, generally Ch 14, Ø 4.7mm is suitable for adult males, and Ch 12, Ø 4.0mm is suitable for adult females.
- A too big catheter may lead to urethral irritation and difficult placement.
- A too small catheter may lead to kinking and urinary leakage.

### 9.1.2 Directions for urethral catheterisation preparation:

- Apply sterile and aseptic technique for the catheter insertion procedure as per local best practice.
- Visually inspect product packing to ensure it is unopened and undamaged before use.
- Inspect catheter for any imperfections and/or surface deterioration prior to use.
- Identify, and assure, that volume contents of selected sterile water prefilled syringe, lies within the minimum/maximum balloon inflation interval of the catheter and does not exceed the stated maximum volume capacity of the balloon.
- Before insertion, apply sterile gloves and remove the covering sleeve from the catheter and lock the sterile water syringe into the inflation port of the catheter.
- **DO NOT PRE-INFLATE THE BALLOON PRIOR TO INSERTION.**

### 9.1.3 Directions for urethral catheter insertion:

- **ALWAYS FOLLOW LOCAL AND NATIONAL BEST PRACTICE DIRECTIONS IN EFFECT.**
- Male patients should be positioned in a supine position, female patients should be positioned in lithotomy position or in frog-leg pose.
- Using a suitable water-soluble sterile lubricant, insert the pre-filled syringe directly into the urethral meatus to lubricate the entire urethra prior to catheter insertion.

#### • Male insertion procedure:

Grasp the penis in an upright position and insert the catheter firmly into the meatus, advancing the catheter to the bifurcation at the "Y" of the catheter. If resistance in advancing the catheter is met at the prostate, ask the patient to cough. The return of urine does not assure that the catheter is placed correctly in males, since there is often residual urine in the penis. Inserting the catheter to the bifurcation of the "Y" is the standard approach for assurance of proper placement.

#### • Female insertion procedure:

Insert the catheter steadily into the meatus until urine flows, then advance the catheter some further 3-5 centimetres to make sure the catheter is well into the bladder before inflating the balloon.

- Instruct the patient to inform if any discomfort is felt with inflation of the balloon. If discomfort is felt, the catheter is most probably in the urethra and will need to be deflated and advanced.
- When correctly placed, inflate the balloon slowly using the entire contents of selected prefilled syringe suited for the catheter.

- Withdraw the catheter slowly to the point of resistance at the bladder neck.
- **DO NOT INFLATE THE BALLOON ABOVE ITS STATED MAXIMUM VOLUME CAPACITY.**
- If catheter placement is in question 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.
- Following completed procedure, the catheter should be secured as per local best practice.
- NEVER leave the catheter hanging to be pulled by the weight of the attached drainage bag.
- Periodic observations should be made to ensure that urine is flowing freely.
- If a standing column of urine is observed, check for correct positioning of the attached drainage bag and then for physical obstruction, such as kink in the tubing.
- If correct positioning of the drainage bag, or removal of physical obstruction, does not allow free flow, the drainage bag may have to be changed.

### 9.1.4 Directions for urethral catheter removal:

- **ALWAYS FOLLOW LOCAL AND NATIONAL BEST PRACTICE DIRECTIONS IN EFFECT.**
- Gently connect suitable empty syringe to the inflation arm of the catheter.
- Never use more force than is required to make the syringe “stick” in the valve.
- Use gentle aspiration, only if needed, to encourage deflation.
- Allow the pressure within the inflated balloon to push the plunger back and fill the syringe with water.
- Gently remove the catheter noting the length from the meatal opening to the tip of the removed catheter to indicate the length of when a possible replacing catheter is likely to be correctly placed in the bladder.
- **NEVER FORCE THE WATER INTO THE SYRINGE.**
- Vigorous aspiration may collapse the inflation lumen, preventing balloon deflation.
- Allow for 30 seconds for the balloon to deflate.
- If there is slow, or no deflation, reset 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.
- NEVER cut the catheter or its inflation/deflation lumen in attempt to deflate the balloon.
- Never clamp the catheter as this may cause lumen and functional damage. If flow-controlling is necessary, a catheter valve and/or a catheter plug (spigot) should be utilised.

## 9.2. Suprapubic Catheterisation:

### 9.2.1. Directions for suprapubic catheterisation preparation:

- The following additional items are required for suprapubic catheterisation:  
Sterile field, sterile gloves, items (sterile, based on established techniques) required for cleaning the patient meatus, syringe with sterile water or sterile aqueous glycerine solution for balloon inflation, sterile dressings and a urine collection device.
- Place patient in supine position.
- Wash and dry hands thoroughly.
- Using aseptic technique, remove the catheter from its pouch and place it on a sterile field.
- Put on sterile gloves and remove catheter sleeve.

### 9.2.2. Directions for suprapubic catheter removal:

- Remove existing securement devices or dressings at the puncture site.
- Clean and disinfect the area around the catheter using established techniques.
- Prior to removal of the catheter in situ, make a note of the length of visible catheter showing, as a guide for how far to insert the new catheter.
- For removal of the catheter in situ, deflate the balloon as described in section 9.1.4
- NEVER cut the catheter or its inflation/deflation lumen in attempt to deflate the balloon.
- Remove the catheter in situ by slowly pulling it gently in an upward direction.
- Upon removal, ensure the entire catheter has been removed.

### 9.2.3. Directions for suprapubic catheter reinsertion.

- Using a suitable sterile, water-soluble lubricating jelly, insert the prefilled syringe directly into the suprapubic site, ensuring the entire length is lubricated prior to catheter insertion.
- Gently insert the catheter until urine flows. Then advance a further 3-5cm to ensure correct placement within the bladder.
- When correctly placed, inflate the balloon using the entire contents of selected prefilled syringe suited for the catheter.
- Instruct the patient to inform if any discomfort is felt during inflation. If discomfort is felt, the catheter is most likely not positioned correctly within the bladder and will need to be deflated and advanced.
- Withdraw the catheter slowly to the point of resistance.

## 10. Patient care considerations:

- **ALWAYS USE STERILE AND ASEPTIC TECHNIQUE WHEN INSERTING A CATHETER.**
- **ALWAYS FOLLOW LOCAL AND NATIONAL BEST PRACTICE POLICIES IN EFFECT.**
- Document the catheterisation procedure, including the size of the catheter placed, the colour, volume, and clarity of urine returned after the initial placement, and patient response.
- If product outer packing provides traceability labels, such can be supplementary affixed to the patient journal.
- Record urine output as ordered.
- Blockage caused by encrustation, infections or spasms affecting the urinary flow and drainage may occur.
- Assess the patient for pain during and after procedure.
- If pain in the lower abdomen, pelvis, back or legs is experienced, contact the physician.
- If urine is changing colour i.e., becoming cloudy, bloodstained or contains obvious blood clots, contact the physician.
- If urine has – or develops - a strong and/or foul (sometimes fishy) odour, contact the physician.
- If patient experiences irritation, tenderness, swelling or redness at the catheter insertion area, contact the physician.

## 11. Infection control considerations:

- **ALWAYS FOLLOW LOCAL AND NATIONAL BEST PRACTICE POLICIES IN EFFECT.**
- Keep the genital area, where the catheter enters the body, cleansed by daily use of mild cleanser and warm water, removing any encrustation or debris that may have dried around the catheter or around the meatus.
- Wash hands or perform hand hygiene immediately before and after any manipulation

- of the catheter site, catheter or the drainage bag.
- A sterile, continuously closed drainage system should be maintained.
- Use of Foley catheters should not be unnecessarily extended in time of usage.
- Indications for continued Foley usage include: unresolved urinary retention and/or urinary tract obstruction.
- Provide patient and family education regarding the benefits of removing the Foley.
- Empty the attached drainage bag every 8 hours, or when the drainage bag is 2/3 full, to avoid traction on the catheter from the weight of the drainage bag and to prevent infection.
- Take care not to contaminate the catheter drainage port by touching the outlet parts of the drainage bag or allowing the drainage port to touch the floor when emptying.
- When transferring patient, maintain position of drainage bag below the level of the bladder, to prevent reflux of contaminated urine from the drainage bag to the bladder.
- For transurethral and suprapubic catheterisation, it is recommended that placed catheter is changed at suitable intervals in accordance with local and national best practice guidance as determined by a qualified healthcare professional and in line with manufacturers recommendations.
- Catheters are for single-use only and should be disposed of after use according to applicable local and national regulations and guidelines for biological waste and contaminated waste material handling.

<b>Manufacturer Ref</b>	<b>Size</b>	<b>OM Product Code</b>
3350	12CH	UFC12
3351	14CH	UFC14
3352	16CH	UFC16
3353	18CH	UFC18
3354	20CH	UFC20

# ugo.<sup>TM</sup>

Foley catheter

REF **3350/3351/3352/  
3353/3354**

CE 2460 **STERILEEO**



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