



Instructions for use



optimummedical®

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Ugo Foley Catheter

PRODUCT REF / CONTENTS

UFC12	12CH (Fr)	Ugo Foley Catheter with 10mL empty syringe and 10mL sterile water prefilled syringe
UFC14	14CH (Fr)	Ugo Foley Catheter with 10mL empty syringe and 10mL sterile water prefilled syringe
UFC16	16CH (Fr)	Ugo Foley Catheter with 10mL empty syringe and 10mL sterile water prefilled syringe
UFC18	18CH (Fr)	Ugo Foley Catheter with 10mL empty syringe and 10mL sterile water prefilled syringe
OE-UFC12	12CH (Fr)	Ugo Foley Catheter [open-ended] with 10mL empty syringe and 10mL sterile water prefilled syringe
OE-UFC14	14CH (Fr)	Ugo Foley Catheter [open-ended] with 10mL empty syringe and 10mL sterile water prefilled syringe
OE-UFC16	16CH (Fr)	Ugo Foley Catheter [open-ended] with 10mL empty syringe and 10mL sterile water prefilled syringe
OE-UFC18	18CH (Fr)	Ugo Foley Catheter [open-ended] with 10mL empty syringe and 10mL sterile water prefilled syringe

PRODUCT DESCRIPTION

- All silicone Foley Catheter [2-way] with non-integrated 10mL balloon.
- 10ml syringe prefilled with sterile water for catheter balloon inflation (not for injection).
- Empty 10ml syringe for removal of existing catheter in situ.

INTENDED PURPOSE

Ugo Foley Catheter is intended for long term catheterisation of the urinary bladder and is appropriate for both transurethral and suprapubic use.

INDICATIONS FOR USE / INTENDED USER

Ugo Foley Catheter is a medical device indicated for continuous bladder drainage. Catheter insertion should always be carried out by appropriately trained Healthcare Professionals in accordance with local and national best practice policies.

CONTRAINDICATIONS

Do not use the **Ugo Foley Catheter** if the patient is sensitive or allergic to any of the device ingredients.

The **Ugo Foley Catheter** may be contraindicated or not be suitable for individuals who have:

- Acute urethritis
- Acute prostatitis
- Acute epididymitis

WARNINGS AND PRECAUTIONS

- Read all the warnings and instructions before use. Improper use can result in serious or fatal illness or injury.
- Do not use if the sterile packaging is damaged or unintentionally opened before use.
- Do not use the catheter if its damaged or irregularly shaped.
- Do not use after the expiry date.
- For single use only.
- Not compatible with MRI.
- Do not over inflate the balloon. Refer to outer unit pack or funnel of the catheter for balloon capacity.
- Inflate the catheter balloon only with sterile water.
- The pre-filled syringe with sterile water is for inflation of the balloon only. Not for injection.
- The empty syringe is for the deflation of the balloon before the removal of the catheter.
- The product is intended for use by trained Healthcare Professionals and an aseptic technique must be practiced.
- Do not use ointments and lubricants with a petroleum base. Use water soluble lubricants.
- Do not clamp catheter shaft. It may damage the catheter and prevent deflation.
- Patients should be regularly monitored as determined by a Healthcare Professional.
- Ensure local cleaning and hygiene protocols are followed to keep the catheter and meatus as clean as possible.
- During long-term use, the balloon inflation volume should be regularly monitored in case any clinical signs of deflation occur, such as bypassing of urine or urethral

pain. If necessary, the balloon volume should be adjusted.

- The balloon must be completely deflated before catheter removal.
- The retention time of the **Ugo Foley Catheter** should be decided by the medical care professionals according to the actual situation of using.
- **Ugo Foley Catheter** is supplied sterile by ethylene oxide after the packaging process.
- Do not reuse, reprocess or resterilise. Reuse, reprocessing or resterilisation may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in injury, illness or death of the patient. Reuse, reprocessing or resterilisation may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- The **Ugo Foley Catheter** must be disposed of according to national regulations for biological hazardous waste, including any consumables used with the device.
- The **Ugo Foley Catheter** is not made with natural rubber latex.

UNDESIRABLE SIDE EFFECTS

- Reported adverse reactions associated with Foley catheters include but are not limited to: Septicaemia, Urethritis, Urinary tract infection and encrustations, bladder spasms, and abdominal discomfort.
- If difficulty is encountered aspirating the balloon with a syringe, a rare and infrequently reported event, the leg of the catheter with the valve should be cut with a sharp scissors at the bifurcation or rupture the balloon according to established procedures reported in medical literature. Should it be necessary to rupture the balloon, care must be taken to remove all fragments from the patient's bladder.
- Incorrectly positioned catheters can cause urethral damage if the balloon is inflated contrary to instructions within the urethra.
- Irritation of the urethral mucosa, blockage of the catheter due to encrustation and catheter induced infections are documented complications with some catheter materials and patient's. The patient should be routinely monitored in accordance with accepted procedures and the catheter shall be removed after a suitable interval as determined by a Healthcare Professional or other suitably qualified personnel.
- Long term use of catheter has the risk of urinary tract infection, sphincter relaxation and urethral relaxation.
- Any serious incident or malfunction that has occurred in relation to the **Ugo Foley Catheter** should be reported to the manufacturer and the Competent Authority of the Member State in which the user and/or patient is established.

HOW TO USE

Preparation:

- The following additional items are required for catheterisation:
- Sterile field, sterile gloves, items required for cleaning the patient meatus (sterile, based on established techniques), dressings and urine drainage device.
- Before use, visually inspect the catheter to detect for any mechanical damages and check that no leakage occurs.
- Place male patient's in supine position, female patient's in lithotomy 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 the catheter sleeve.
- Lubricate the tip and the shaft of the catheter with a water-based lubricant.
- Clean the opening of the urethra and the surrounding area, using established techniques.

Catheterisation:

- With the uncontaminated hand, pick up the catheter from the sterile field.
- Carefully insert catheter tip into the bladder (normally indicated by urine flow), and then a further 3 cm to ensure balloon is also inside the bladder.
- Advance the catheter further to ensure that the balloon is located beyond the bladder neck, within the bladder.
- Inflate the catheter balloon with sterile water, at the discretion of the Healthcare Professional.
- Use the syringe to inflate the balloon with the required fluid volume (marked on the catheter funnel).
- Slowly retract the catheter until some resistance is felt to ensure that the balloon is correctly located within the bladder, before the bladder neck.
- Connect the catheter to a urine drainage device.
- Observe urine flow.

Catheter removal:

- For removal of the catheter, deflate the balloon by inserting the empty syringe into the valve. Release the syringe plunger and allow the balloon to deflate.

An implant card must be supplied to the patient with the Ugo Foley Catheter.

CATHETER CARE

- Ensure local cleaning and hygiene protocols are followed to keep the catheter and catheter site as clean as possible.
- Conduct hand hygiene immediately before and after any manipulation of the catheter and the urine drainage system. Wear disposable gloves when handling the system.
- Maintain unobstructed urine flow.
- Ensure that the catheter and collection tube do not kink.

LONG-TERM USING CARE

- The patient should wash their hands before and after any catheter operation.
- The area around the catheter is rinsed with a mild soap box at least twice a day.
- The patient drinking 2 to 3 litres of water a day can help wash the catheter and keep the urine clear.
- The patient should regularly drain urine bags.
- The patient should always keep the drainage system closed.

STORAGE AND HANDLING

- Store between -15 and 49°C (5-120°F) until expiry date.
- Store in a dark, cool and dry place.
- Keep dry.
- Keep out of direct sunlight.
- Protect product from moisture and excessive heat.
- Avoid prolonged exposure to ultraviolet, sunlight and fluorescent light.
- Unopened packs have a 5-year shelf life.
- Do not use after expiry date.
- Catheters should not be stored folded.
- Store in manner preventing crushing.

DISPOSAL

Ugo Foley Catheter must be disposed of according to local policies and waste disposal procedures, including any accessories / consumables used with the device.

REF **UFC12/UFC14/UFC16/
UFC18/OE-UFC12/
OE-UFC14/OE-UFC16/
OE-UFC18**



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EC REP

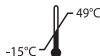
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