



Unomedical

100% Silicone Foley Catheter

- (da) Foley kateter 100 % Silikone
- (sv) Foley kateter 100% Silikon
- (no) Foley kateter 100% Silikon
- (fi) 100% Silikoni Foley katetri
- (de) 100% Silikon Foleykatheter
- (nl) 100% silicone Foley katheter
- (ru) Катетер Фолея 100% силикон
- (fr) Sonde de Foley 100% Silicone
- (pl) Cewnik Foley, 100 % silikonu
- (es) Sonda Foley 100% silicona
- (pt) Sonda Foley 100% silicone
- (it) Catetere Foley 100% Silicone
- (gr) 100% Καθετήρας Σιλικόνης Foley
- (tr) 100% Silikon Foley Sonda
- (cs) 100% silikonový Foley katétr
- (sk) 100% silikónový Foley katéter
- (cn) 100% 硅胶导尿管
- (tw) 100%矽膠導尿管

Instructions for Use

DESCRIPTION

The 100% Silicone Foley Catheters are available as 2-way Foley catheters (with bladder fixation balloon, catheter tip and shaft with x-ray line, drainage funnel, inflation funnel, and inflation valve) and 3-way Foley catheters (with additional irrigation funnel).

Variants of the 2-way Foley catheters are available in male, female and pediatric sizes (with stylets for pediatric sizes), with Tiemann tip, and with pre-filled syringe containing sterile aqueous glycerin solution for balloon inflation.

The catheter external diameter (Ch/Fr) and the balloon inflation volume (ml/cc) are printed on the proximal end of the drainage funnel.

The products are manufactured from Silicone. Additional materials are Polyvinyl chloride, Polypropylene, Acrylonitrile-butadiene-styrene and stainless steel. The products are sterile and intended for single use only.

INDICATIONS

The 100% Silicone Foley Catheters are indicated for transurethral drainage of urine from the bladder and/or continuous irrigation of fluids. The standard 2-way Foley catheters (sizes 12 to 18) can also be used for replacement of suprapubic catheters for drainage of the bladder (exchange only).

The adult 2-way catheters can be retained in the human body for up to 90 days, 3-way catheters for up to 30 days. **Pediatric sizes (Ch/Fr 6, 8, 10) can be retained for up to 30 days if using sterile aqueous glycerin solution for balloon inflation. If sterile water is used for balloon inflation a retention time of only 14 days is recommended.**

CONTRAINDICATIONS

For transurethral catheterization

- Acute urethritis
- Acute prostatitis
- Acute epididymitis

For suprapubic use

- Instable supra pubic stoma/track
- Immature suprapubic stomas (formed within past 4 weeks)
- Known or suspected carcinoma of the bladder
- Absence of an easily palpable or ultrasonographically localized distended urinary bladder
- Previous lower abdominal surgery
- Coagulopathy (until the abnormality is corrected)
- Ascites
- Prosthetic devices in lower abdomen, e.g. hernia mesh
- Pelvic fracture

WARNINGS AND PRECAUTIONS

- Do not use after the expiry date.
- The product is intended for use by physicians or suitably trained health care professionals and aseptic technique must be practiced.
- Do not use petroleum-based lubricants.
- Do not use if package has been opened or damaged.

- Do not clamp the catheter shaft. It may damage the catheter and prevent deflation.
- Catheters not positioned correctly may cause injury if the balloon is not correctly located in the bladder.
- Do not use needles to inflate the balloon. Use a Luer syringe (Luer slip or Luer lock).
- The pre-filled syringe (if included) is for inflation of the balloon only. Not for injection.
- Inflate catheter balloon only with sterile water or 10% sterile glycerine solution.
- Do not overinflate the balloon. Refer to product label or catheter funnel for balloon capacity.
- Patients should be regularly monitored as determined by a physician.
- 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.
- If deflation does not occur, established procedures should be followed and must be performed by a physician or suitably trained health care professional.
- This is a disposable product for single use. Any resterilization or reuse of the product can result in hazard to the patient.
- Disposal of the device shall be made in accordance with applicable national regulations for biological hazardous waste.
- If the suprapubic stoma/track is unstable, and there is a risk of losing the track do not replace the suprapubic catheter with a Foley catheter with closed tip. In this case we recommend using a Foley catheter with an open tip and usage of a guide wire to aid the suprapubic exchange.

ADVERSE REACTIONS

Reported adverse reactions associated with Foley Catheters are: Septicemia, Urethritis, Urinary tract infection and encrustations, bladder spasms, and abdominal discomfort.

POTENTIAL COMPLICATIONS

Possible complications known to be associated with indwelling catheters include irritation of the urethral mucosa, blockage of the catheter due to encrustation, and catheter induced infections. Patients should be routinely monitored in accordance with accepted procedures and the catheter shall be removed after a suitable interval as determined by a physician or other suitably qualified personnel.

DIRECTIONS FOR USE - Transurethral catheterization

Preparation:

- The following additional items are required for catheterization:
 - Sterile field, sterile gloves, sterile water-based lubricant, Luer syringe with sterile water or sterile aqueous glycerin solution for balloon inflation (if not included). Items required for cleaning the patient meatus (sterile, based on established techniques)

- Urine drainage device
- Place male patients in supine position, female patients 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.
- Test the catheter for leakage or deflation of the balloon by inflating the balloon with the required volume (marked on the catheter funnel) of fluid prior to catheterization. Release the syringe plunger and allow the balloon to deflate. Only use gentle aspiration, if necessary, to deflate the balloon.
- 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.

Catheterization:

- With the uncontaminated hand, pick up the catheter from the sterile field.
- Carefully guide the catheter tip into the urethra and advance it further until the catheter tip and eyes reach the bladder (normally indicated by urine flow).
- 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 or sterile aqueous glycerin solution, at the discretion of the physician.
- 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 a Luer syringe into the inflation valve. Release the syringe plunger and allow the balloon to deflate. Only use gentle aspiration, if necessary, to deflate the balloon. The balloon should spontaneously deflate.
- Discard the catheter according to hospital protocol.

Catheter care:

- Ensure local cleaning and hygiene protocols are followed to keep the catheter and meatus as clean as possible.
- Wash hands in line with hygiene protocols 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.

- Always keep the urine drainage bag below the level of the bladder to allow urine to drain by gravity. Do not place the drainage bag on the floor.
- Empty the urine collecting bag using a separate container for each patient, avoid splashing, and prevent contact of the drainage funnel with the non-sterile collection devices.

DIRECTIONS FOR USE - Suprapubic use (Exchange only)

Preparation:

- The following additional items are required for catheterization:
 - Sterile field, sterile gloves, Items (sterile, based on established techniques) required for cleaning the patient meatus, Luer syringe with sterile water or sterile aqueous glycerin solution for balloon inflation (if not included), Sterile dressings
 - Urine drainage 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.
- Test the catheter for leakage or deflation of the balloon by inflating the balloon with the required volume (marked on the catheter funnel) of fluid prior to catheterization. Release the syringe plunger and allow the balloon to deflate. Only use gentle aspiration, if necessary, to deflate the balloon.

Removal of the catheter in situ:

- Remove existing securement devices or dressings at the puncture site.
- Clean and disinfect the area around the catheter using established techniques.
- For removal of the catheter in situ, deflate the balloon by inserting a Luer syringe into the inflation valve. Release the syringe plunger and allow the balloon to deflate. Only use gentle aspiration, if necessary, to deflate the balloon.
- Remove the catheter in situ by slowly pulling it in the upward direction.
- Upon removal ensure the entire catheter has been removed.
- Discard the old suprapubic catheter according to hospital protocol.

Placement of new catheter:

- Put on new sterile gloves.
- Clean the cystostomy site again.
- Gently insert the catheter down the cystostomy tract.
- Ensure that the catheter inflation balloon is fully inserted through the suprapubic tract into the bladder.
- Inflate the catheter balloon with sterile water or sterile aqueous glycerin solution, at the discretion of the physician. Inflate the balloon with 3-5ml of inflation fluid (adult sizes). Ask the patient if discomfort is experienced. In case of resistance very gently (balloon is still located within the bladder) advance the

catheter a little further or pull back a little (in case the catheter tip has moved into the bladder neck or urethra).

- Carefully retract the catheter against the inside of the bladder and further inflate the balloon to the nominal fluid volume (marked on the catheter funnel).
- Apply sterile dressing at the puncture site using established techniques.
- Connect the catheter to a urine drainage device.
- Observe urine flow.















Care of the suprapubic catheter site:

- Conduct hand hygiene immediately before and after any intervention using protective equipment, such as gloves.
- Clean the suprapubic catheter site daily with soap and water, ensuring local cleaning and hygiene protocols are followed.
- Observe the cystostomy site regularly for signs of infection.

STORAGE CONDITIONS

- Store in a dark, cool and dry place.
- Avoid freezing and excessive heat.

EXPLANATION OF SYMBOLS ON PACKAGE

	Catalogue number		Sterilized using ethylene oxide
	Do not re-sterilize		Batch code
	Do not use if package is damaged		Use-by date
	Do not re-use		Consult instructions for use
	Does not contain phthalate		Does not contain natural rubber latex
	Manufacturer		Keep dry
	Authorized representative in the European Community		Keep away from sunlight



Well Lead Medical Co.,Ltd.
C-4 Jinhu Industrial Estate
Hualong, Panyu, Guangzhou
511434 P.R.China



Shanghai Intl. Holding
Corp GmbH
Eiffestrasse 80
20537 Hamburg
Germany

Made in China

Distributed by



ConvaTec

ConvaTec Limited
First Avenue
Deeside Industrial Park
Deeside, Flintshire
CH5 2NU, UK

www.convatec.com

Sponsored in Australia by Conva Tec (Australia) Pty Limited
1800 339 412 Australia; 0800 441 763 New Zealand

Импортер/Представительство в России:

ЗАО «КонваТек», 115054, г. Москва, Космодамианская наб., д.52, стр.1.

Тел.: +7 495 663 70 30 Факс: +7 495 748 78 94

