Prosys®

OPEN ENDED

All-Silicone Foley Catheter

Prosys® All-Silicone Open Ended Foley Catheter with sterile water filled syringe for balloon inflation and empty syringe for balloon deflation*. For urethral and suprapubic use, with two peelable product record labels.

DIRECTIONS FOR USE

Intended Use:

Prosys® All Silicone Open Ended Foley Catheter should be used by a trained healthcare professional for drainage and/or irrigation of the patient's bladder by inserting the catheter into the vesical cavity of the bladder through the urethra or anterior abdominal wall.

Indications:

For continuous bladder drainage and/or instillation of appropriate therapeutic agents into the bladder and/or bladder irrigation.

Clinical Benefits:

- Urine drainage from patients with urinary retention/ obstruction or incontinence
- Assisting with the healing of open wounds in patients with incontinence
- Clinical diagnosis, such as obtaining uncontaminated urine samples for bacterial culture, accurate measurement of urine output in critically ill patients and peri/post operative urine measurement due to immobility
- The catheter can also be used for urethrography or cystography

Contraindications:

- Acute urethritis
- Acute prostatitis
- Acute epididymitis

Contents:

- 100% Silicone Foley Catheter
- 10ml syringe prefilled with sterile water for catheter balloon inflation (not for injection)
- Empty 10ml syringe for removal of existing catheter in situ*

Description:

- Manufactured from 100% silicone (latex-free)
- Available in standard lengths
- Available as 2-way Foley Catheter
- The catheter charriere/diameter size, balloon volume infill size, catheter name and type along with the product reference code are printed on the paper film pouch, with additional information such as expiry date and batch number recorded on each outer unit pack as well as on the shelf box. The individual unit pack has 2 peel-off sticky labels stating the appropriate details for placing in the catheterised patient's case records/notes

Warnings:

- The **prefilled syringe** containing sterile water, is to **inflate** the catheter **ONLY** and is **NOT** for injection usage
- Syringes are for single use only
- The **empty syringe** is for **deflation of the previous indwelling catheter** prior to its removal*
- Patients should be fully assessed by an appropriately trained healthcare professional prior to catheter insertion
- Patients with indwelling catheters should be monitored in accordance with local and national policy

Packaging:

- Each catheter is individually supplied in a sterile pack
- The catheter and its components are guaranteed to be sterile unless the pack is open or is damaged
- The products are for single use only. NEVER re-sterilise or reuse

Storage Recommendations:

- Store in a cool, dry place, away from direct sunlight and sources of heat
- Avoid prolonged exposure to ultraviolet, sunlight and flourescent light
- Do not store folded

Use of the **Prosys®** All Silicone Foley Catheter

- The product can be used on patients with acute urinary retention who are not able to drain urine through urethra
- Catheter insertion should always be carried out in accordance with local and national best practice policies by appropriately qualified and trained healthcare professionals
- Strict adherence to aseptic technique is required
- Hand hygiene policies are essential to minimize the risk of catheter associated urinary tract infection
- Any additional products used to facilitate catheter insertion should be sterile
- Prior to use the catheter should be removed from the packaging and placed on a sterile field
- The outer packaging includes traceability labels that can be used to record the details of the catheter in the patient record

Precautions:

- Catheters and syringes are for single use only and, therefore, should be correctly disposed of after being used once only
- Do not use if the package has been previously opened or is damaged as this means that sterility has been compromised
- Always check the catheter charriere size and balloon capacity which is marked on the outer unit pack and funnel of the catheter

- Always deflate the balloon slowly using the empty syringe provided to avoid the catheter tubing collapsing in on itself*
- **Balloon Safety:** the balloon shall not leak and shall not occlude the lateral drainage holes
- The catheter should be removed after a recommended period of 12 weeks, or suitable intervals according to national best practice guidelines as determined by appropriately qualified healthcare personnel
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the local competent authority

Potential Complications:

- In rare cases, deflating the balloon, usually too quickly, with the syringe may result in the collapsing of the catheter inflation lumen. Should this occur, seek a suitably trained medical professional for assistance. Do not attempt to rupture the catheter balloon by over inflating it as this could cause further damage to the bladder. Should the chosen corrective methods require rupturing, it is important that all fragments are carefully removed
- Catheters that are not correctly positioned in the bladder may cause irritation, pain and mucosal damage especially if the balloon is inflated whilst in the urethra
- Blockage caused by encrustation, infections or spasms affecting urinary drainage may occur
- Never clamp the catheter as this may cause damage. If necessary, use a catheter valve or catheter plug
- Do not use petroleum-based lubricants as these are not water-soluble. If necessary, only water- based lubricants should be used

Catheter Care:

- Wash the area where the catheter enters the body with mild soap and warm water at least once a day removing any encrustation or debris that may have dried around or on your catheter
- Avoid using talcum powder or oil-based creams around the catheter
- Seek help if any of the following occurs:

  There has been no urine draining into the bag for 2-3 hours, especially if the bladder is still full. This is likely to indicate that the catheter may have become blocked.

  If there is new pain in the lower abdomen, pelvis, back or legs. Urine has changed colour i.e. it has become cloudy, bloodstained or has obvious blood clots in it.

  Urine has a strong, foul (sometimes fishy) odour.

  The patient develops a fever, nausea, vomiting or unwell feeling.

  Urine is leaking from the insertion site indicating that it is bypassing the catheter.

  Experience irritation, tenderness, swelling or redness at the catheter insertion site.

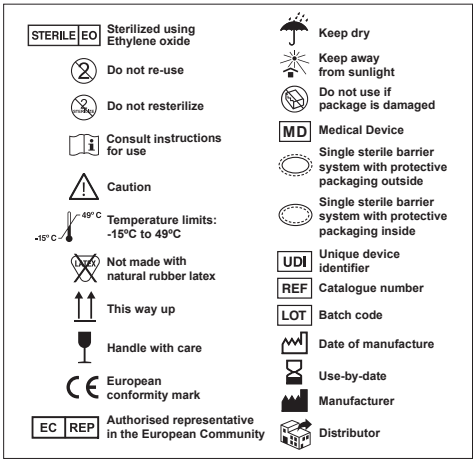
Catheter Removal:

- The balloon must be completely deflated before catheter removal
- **NEVER** cut the catheter or inflation channel in an attempt to deflate the balloon
- Deflate the balloon by using an empty syringe
- Loosen the plunger in the syringe by moving it up and down several times
- With the plunger compressed **almost** to the bottom of the syringe, gently attach it to the catheter valve
- Allow the pressure in the balloon to force the water slowly back into the syringe in a free flowing manner
- If the balloon fails to deflate, reposition the patient and/or **gently** aspirate to remove the water. If this fails seek the advice of an appropriate healthcare professional
- Gently remove the catheter noting the length from the meatal opening to the tip of the removed catheter to indicate the length of when the replacement catheter is likely to be in the bladder. **WARNING:** Always slowly insert the new catheter a further 3cm into the bladder before inflating the balloon to ensure it is not inflated in the bladder neck or in the urethra. Gently retract the catheter to ensure the inflated balloon is securely and snugly positioned at the bladder neck

* Additional empty syringe only provided in Prescription Foley Catheter packs of 1 unit

The flow shall meet the requirements of Table below:

Size (Ch/Fr)	12	14	16	18
Drainage Flow, ≥mL/min	50	70	100	100
Irrigation Flow, ≥mL/min	/	/	25	25



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