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Romsons®

URO CATH®

(3-WAY FOLEY BALLOON CATHETER)
(Natural Rubber Latex-Silicone Coated)

REF GS-1094

℞ ONLY

INSTRUCTIONS FOR USE

The device is biocompatible, Non-Toxic, Non-Pyrogenic , Sterile, Single Use.

⚠ **Caution :** Carefully read all instructions prior to use. Observe all warnings & precautions noted throughout these instructions. Failure to do so may result in complications. To be administered by an expert qualified medical professional.
This device is Sterile & Ready for Use. Sterility is guaranteed – if pack is undamaged. The device is for Single Use Only.

Device Description : Silicone coated latex foley balloon catheter for atraumatic penetration, with inbuilt symmetrical balloon, ensuring on inflation a straight distal tip, for good sphincter action to prevent any leakage & with excellent drainage through large lateral eyes. Distally located funnel connector for fixation to urine bag's tapered connector. Robust and well controlled, syringe luer operated non-return valve (NRV) for inflation / deflation of the balloon. Funnel connector is printed with size and maximum balloon capacity volume. NRV end is size color coded.

Population of Use: Adult & Paediatrics.
Intended User : To be administered by an expert qualified medical professional , Urologist & Trained nurse .

Intended Use: Used for short-term use Urethral catheterization for urine drainage. Device maximum use duration is not more than 14 days.
Preferred Route of Administration: is Urethral passage of male / female
Contents : Uro Cath-3 Way (Foley Balloon Catheter), Sterile Unit packed in pealable unit pack.

Size : FG: 6, 8, 10, 12, 14, 16, 18, 20, 22, 24.

Material of Construction : Natural Rubber Latex (Silicone Coated), Polypropylene, Acrylobutadiene Styrene+Polyoxymethylene+Stainless Steel, Master Batch.

Storage : Store in a cool & dry place.

Indications : Acute Urinary retention, Urinary Incontinence, etc.

Contraindications : Use in patient with a known allergic reaction to any of the product components, Urethral trauma, infection at site, severe phimosis, urethral meatus, urethral strictures, traumatic injury to the lower urinary tract.

Potential Complications / Risks : Leaking of urine out of the catheter, Blood in the urine, Kinking of the Catheter, allergic reactions to latex, CAUTI, Injury to urethra, Encrustation when catheter is indwelled for longer duration.

Warnings : This device is intended for Single use only.
DO NOT resterilize and /or reuse the device, as this can compromise the device performance (functionality) and may cause inadequacy, deterioration of the device technical factor, rendering the device non-functional and unfit for intended use and also this may increase the risk of cross contamination due to several aspects including inappropriate reprocessing.
Device is not MRI safe.
Do NOT use petroleum based lubricants or ointments, such as Vaseline.Re-use of single use device creates a potential risk for patient or user. It may lead to contamination and / or impairment of functional capability.
Contamination and / or limited functionality of the device may lead to injury, illness of the patient.

Precautions :
(i) Check the integrity and functionality of the uro cath before use. Do not use if the Unit Pack is open or damaged.
(ii) Determine patient's condition and vitals status During device application / Operation.
(iii) Check the patency of the Catheter Tip before use.
(iv) Wash the area where the catheter enters the body with mild soap and warm water at least once a day.
(v) Check the patency of the lateral eye before use.
(vi) Check the inflation & deflation mechanism of device.
(vii) This product contains natural rubber latex.
(viii) Destroy / Dispose the device & its accessories after single use as bio-medical waste as per applicable laws.
(ix) Do not Resterilize. Do not Re-use. Discard after single use.

Adverse Events : Allergic reaction to latex, CAUTI.

General Instructions : To be administered by an expert qualified medical professional. Use maximal sterile barrier precautions during administration. (These are only the guidelines & hence, user's medical experience / expertise in important).

Use Instructions :
(1) Check the packing carefully, if found damaged / pierced discard the piece.
(2) Wash up and scrub hands and preferably use pre sterile protective gloves.
(3) Peel opens the pack and remove the device aseptically. Check the inflation & deflation mechanism of device. Check device integrity.
(4) Prepare the part by scrubbing, while patient is lying flat.
(5) Apply small amount of jelly on to the urethral orifice by.
(6) Open the catheter package and lubricate about 2 inches of the tip of the catheter with the water-soluble lubricant. Do NOT use petroleum jelly, such as Vaseline.
(7) Hold the penis upright little stretched (male) or spread the labia (female) as per case & insert and advance the catheter gently into the urethra.
(8) Check the placement of Urine outflow without blood).
(9) As designated, inject appropriate volume of distilled water to inflate the balloon through the non-return valve, with the help of a suitable volume syringe.
(10) Connect the proximal end of catheter to the Urine Collecting Bag.
<u>For Catheter removal</u>
(11) Gently connect suitable empty syringe to the inflation arm of the catheter.
(12) Use gentle aspiration, only if needed, to encourage deflation.
(13)Allow the pressure within the inflated balloon to push the plunger back and fill the syringe with exited water.
(14) While Replacing the Catheter, remove the catheter and note the length from the meatal opening to the tip of the removed catheter so as to indicate the inserted length.
(15) This will help in replacing of the catheter.

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CE 2460

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Basic UDI DI : 8902120A004RE

REF	Catalogue Number	MD	Medical Device		Do Not Reuse		Consult Instructions for Use
LOT	Batch Code	IN	Country of Manufacture				Keep away from sunlight
	Date of Manufacture	STERILE EO	Sterilized Using Ethylene oxide		Do Not Re-sterilize		Keep Dry
	Use by date	EC REP	Authorized Representative in the European Union		Do not use if package is damaged and consult instruction for use		Caution
		UDI	Unique device Identifier				
	Manufacturer		Single Sterile barrier system		Temperature Limit	LATEX	Contains or presence of natural rubber latex