INSTRUCTIONS FOR USE

Doc. No.: SSIPL/IFU/SFC/01, Rev. No.:00, Dt. 12.08.2023

NAME OF PRODUCT: Silicone Foley Balloon Catheter

PRODUCT DESCRIPTION:

A flexible tube with an inflatable balloon on its distal tip and two/three lateral eyes. Drainage funnel and one inflation access port with NRV at proximal end in 2-way catheter, 3-way catheter having an additional irrigation access port at proximal end. Drainage funnel is meant for connection to urine bag to drain urine from bladder. Inflation access port with NRV has coloured sleeve for easily identification of size of catheter. Device is packed in soft blister (PP & PE) transparent film at one side and printed medical crepe paper on other side.

INTENDED PURPOSE:

Used for short- & long-term urine drainage.

INDICATIONS:

Routine drainage of the bladder or for routine post-operative drainage and irrigation of the bladder.

INTENDED USER:

Urologist and trained/registered healthcare professional only.

TARGET PATIENT POPULATION:

Infants, Paediatrics and Adults

CONTRAINDICATIONS:

- Use in patient with a known allergic reaction to any of the product components
- Urethral trauma
- Infection at site
- Severe phimosis
- Urethral strictures
- Traumatic injury to the lower urinary tract

WARNINGS

- The use of this product is restricted to a Doctor or qualified Paramedic
- Do Not resterilize
- Do Not use petroleum based lubricants or ointments, such as Vaseline
- Do Not reuse the device if reused it will lead to CAUTI

PRECAUTIONS AND CAUTIONS

- Prior to use read entire instructions for use, failure to do so may result in severe patient injury.
- If the patient is allergic to iodine or betadine, use an alternate cleanser.
- **STERIMED DISCLAIMS ANY RESPONSIBILITY FOR POSSIBLE CONSEQUANCES RESULTING FROM IMPROPER USE.**
- The product should not be reprocessed.
- Carefully check the product and packaging before use, improper transport and handling may cause structural and functional damage to Device or packaging.
- The product is Guaranteed Sterile if the package has not been opened or damaged.
- For single use only and discard after use.
- Store in a Cool and dry place.
- Do not expose to heat or direct sunlight.
- The product should be used immediately after opening the packaging.

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- Always use sterile technique when inserting a Foley catheter.
- Empty the urine 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 prevent infection.
- When transporting patient, maintain position of drainage bag below the level of the patient's bladder.
- **Device are MRI Conditional due to present of SS Spring in NRV and Items may safely enter into the MRI scanner room only, patient should not be scanned unless the device is positively identified as MRI conditional and the condition for safe use are met.**
- Perform inflation and deflation test of balloon with air prior to use.
- In the event of change in performance of device like obstruction of flow of urine observed the catheter should be replaced with new catheter.

ADVERSE EVENTS:

- CAUTI
- Urethral trauma

CLINICAL BENEFITS:

- Provide a slippery surface to reduce friction
- Superior resistance to kinking
- Better flow properties
- Reducing the incidence of urethritis and the rates of encrustation and infection
- Lower rate of insertion failure
- Siliconised catheters may be less likely to cause urethral side effects in men
- The risk of a burning sensation in the urethra is less in the Silicone catheter

RESIDUAL RISKS:

- Anaphylaxis
- CAUTI, injury to bladder and Allergic reaction

INSTRUCTIONS FOR USE:

- Check the packing carefully, if packing is found damaged, torned or pierced discard that piece.
- Verify that the patient is not allergic to iodine or betadine. If the patient is sensitive or allergic to iodine or betadine, use an alternate cleanser.
- Use the smallest size catheter that is appropriate.
- Explain the procedure to the patient and wash your hands or perform hand hygiene.
- Maintain the patient's privacy and dignity.
- Consider washing the patient's genital area before the procedure if visibly soiled. Done non-sterile gloves, wash patient's genital area thoroughly with foam body cleanser or Ready cleanse wipes.
- Remove gloves and wash hands.

Insertion Procedures

- Visually inspect the product for any imperfections or surface deterioration prior to use. If any damage is noted or the package has been opened, do not use.
- Done protective eye wear.
- Using aseptic technique, open the outer plastic wrap to form a sterile field and place the under pad beneath the patient, plastic side down.
- Position the sterile fenestrated drape around the patient's genitalia.
- Apply sterile gloves and use strict sterile technique for the Foley insertion procedure.
- Before insertion, dispense the lubricating gel into the tray, pour cleansing solution over three cotton balls.
- **Remove the plastic sleeve from the catheter and lock the sterile water syringe into the inflation port and Urine Collection Bag into Drainage port. DO NOT PRE-INFLATE THE BALLOON PRIOR TO INSERTION.**
- Using the dominant, sterile hand to handle the catheter, cover the tip of the catheter with lubricant. Insert the foley through the urethra into the bladder.

- Instruct the patient to inform the nurse 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. Inflate the balloon slowly, using the entire 10 cc of sterile water. Withdraw the catheter slowly to the point of resistance at the bladder neck.

Female Insertion Procedure

- Position female patient into a frog-leg pose.
- Separate the labia using the non-dominant hand and visualize the meatus. Grasp one cotton ball with the forceps, wipe one side of the labia from top to bottom and discard the cotton ball away from the sterile field. Repeat on the opposite side and then wipe down the middle using the third cotton ball. Then wipe the area with the dry cotton balls.
- Insert the catheter approximately three inches, wait to see if urine flows, then advance another inch before inflating balloon.
- For unconscious female patient's or those with decreased sensation (i.e., paralyzed), insert the catheter slightly further than three inches, to make certain the catheter is in the bladder.

Male Insertion Procedure

- Position male patients into a supine pose.
- Retract the foreskin, if present, and hold the shaft of the penis with the non-dominant hand. Grasp one solution-soaked cotton ball with the forceps. Using a circular motion, wipe the glans from the meatus outward. Discard the cotton ball away from the sterile field. Repeat with two more cotton balls. Then wipe the area dry with the dry cotton balls.
- Grasp the penis in an upright position and insert the lubricated catheter firmly into the meatus, advancing the catheter to the bifurcation at the 'Y' of the catheter. A slight lean toward the umbilicus may be necessary if resistance in advancing the catheter is met at the prostate.
- The return of urine does not assure that the catheter is placed correctly in males, since there is residual urine in the penis. Inserting the catheter to the bifurcation of the Y is the standard for assurance of proper placement.
- If the foreskin was retracted, reposition it after placement.
- If catheter placement is in question (i.e., no urine returns or unable to fully insert the catheter) 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.

Complete the procedure

- **Secure the catheter to the patient's thigh with hospital approved catheter securement device to prevent movement, irritation, and decrease risk of infection.** To improve urine flow, some men may need to have the catheter secured slightly upward.
- **Position the bag to avoid urine reflux into the bladder, kinking, or gross contamination of the bag.**
- **Keep the bag below the level of the bladder at all times to prevent the back flow of urine and decrease the risk for infection**.
- Never leave the catheter hanging to be pulled by the weight of the bag.
- **Do not leave the bag laying on the floor unless necessary due to patient positioning (i.e., Trendelenburg position in the Operating Room).**
- Periodic observations of the system should be made to ensure that urine is flowing freely. If a standing column of urine is observed, check for correct positioning of the bag and then for a physical obstruction, such as a kink in the tubing.
- If correct positioning of the bag or removal of physical obstruction does not allow free flow, the bag may have to be changed.

Directions for removal

- Deflate the catheter balloon by negative pressure. Exercise the plunger of a leur-tipped 10 ml syringe by moving up and down within the syringe barrel. Pull back 0.5 ml air in the syringe to prevent adherence of the plunger to the end of the syringe barrel, then insert the syringe into the balloon port. Never use more force than is required to make the syringe "stick" in the valve. Use gentle aspiration, only if needed, to encourage deflation.
- NEVER FORCE THE WATER INTO THE SYRINGE. Vigorous aspiration may collapse the inflation lumen, preventing balloon deflation. Allow 30 seconds for the balloon to deflate.
- If there is slow or no deflation, re-seat 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.

SUPPLY:

The device is available in the below variants:

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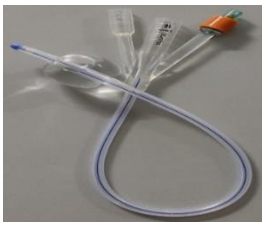
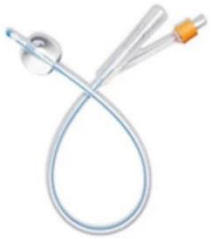
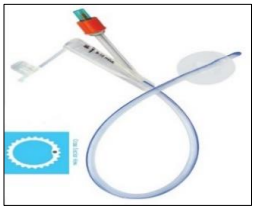
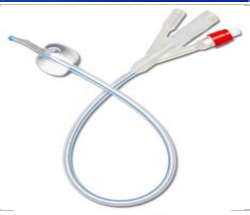
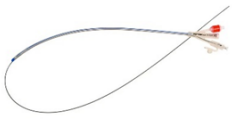
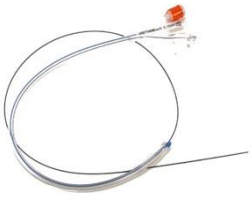
100% Silicone Foley Balloon Catheter 2-Way - SMD 517 BH		100% Silicone Foley Balloon Catheter 3-Way Open Tip - SMD 559	
100% Silicone Foley Balloon Catheter 3-Way - SMD 519		100% Silicone Foley Balloon Catheter 2-Way Four Eye - SMD 555	
100% Silicone Foley Balloon Catheter Star (Ribbed) 2-Way - SMD 553		100% Silicone Foley Balloon Catheter 2-Way Inline - SMD 562	
100% Silicone Foley Balloon Catheter 2-Way Coude / Tiemann Tip - SMD 556		100% Silicone Foley Balloon Catheter 3-Way Inline - SMD 563	
100% Silicone Foley Balloon Catheter 3-Way Coude / Tiemann Tip - SMD 557		100% Silicone Foley Balloon Catheter 2-Way Guidewire/Chancellor - SMD 560	
100% Silicone Foley Balloon Catheter 2-Way Open Tip - SMD 558		100% Silicone Foley Balloon Catheter 3-Way Guidewire/Chancellor - SMD 561	

MATERIAL USED:

Component	Material	Specification/ Material Grade
Shaft	Silicone Elastomer	Medical Grade
Balloon	Liquid Silicone Rubber	Medical Grade
Funnel	Liquid Silicone Rubber	Medical Grade
Sleeve	PVC	Medical Grade

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NRV	Polypropylene (PP)	Medical Grade

STORAGE:

These products should be stored in their original box in a dry place between 5°C to 45°C, preferably away from the direct and indirect source of light and heat. Do not use after expiry.

DISPOSAL:

Used catheters may be contaminated with infectious and/or other hazardous materials. Discard used catheters in the container meant for infectious waste. Unused expired catheters should be disposed of as per local regulations.

NOTE: Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

SPECIMEN SYMBOL

SYMBOL	DESCRIPTON	SYMBOL	DESCRIPTON	SYMBOL	DESCRIPTON	SYMBOL	DESCRIPTON
	**Catalogue No.**		**Batch / Lot No.**		**Date of Mfg.**		**Date of Exp.**
	**Cautions**		**See Instructions for Use**		**Sterilized by Ethylene Oxide gas**		**Do not Re-sterilize**
	**Do not use if packaging is damaged or opened**		**Phthalate Free**		**MRI Conditional**		**Avoid Direct Sunlight**
	**Do not Reuse**		**Keep Dry**		**CE Certified**		**Sterile Barrier System**
	**Medical Device**		**Keep in a dry place between 5°C to 45°C**		**Unique Device Identifier**		

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