INSTRUCTIONS FOR USE

FOLEY BALLOON CATHETER

***Please Read All Instructions Carefully (Sterile, for single use only)**

SMDPL/IFU/LFBC/01, Rev. No.:00, Dt. 10.08.2023

PRODUCT DESCRIPTION

A flexible tube with an inflatable balloon on its distal tip with one drainage funnel and one inflation funnel with access port in 2-way catheters, and one drainage funnel, one inflation access port & one irrigation access port in 3-way catheter at proximal end and lateral eyes at distal rounded closed end. Inflation access port fitted with Non-Return Valve (NRV) to inflate and deflate the balloon while drainage funnel is meant for connection to urine bag to drain urine from bladder. An extra irrigation access port provided in 3-way type catheter to irrigate bladder. Inflation access port with NRV has colored sleeve for easily identification of size of catheter. Device is packed in soft blister made up of Polypropylene (PP) & Polyethylene (PE) Film and medical crepe paper. Sizes range from 6 to 30 Ch./Fr. Lengths will vary between 20 and 45 cm. Some paediatric balloon catheters include a stylet in order to facilitate insertion if needed.

2 way (Silicon Coated) Male & Female (SMD 500 & SMD 500F):

Foley Balloon Catheter 2 Way made up of natural latex with an inflatable balloon on its distal tip for retention in the urinary bladder where it usually functions as a therapeutic device for urinary incontinence and used for short term urine drainage.

3 way (Silicon Coated) (SMD 501):

Foley Balloon Catheter 3 Way made up of natural latex with an inflatable balloon on its distal tip for retention in the urinary bladder where it usually functions as a therapeutic device for urinary incontinence and used for short term urine drainage along with irrigation of bladder.

2 way (Silicon Elastomer Coated) High Flow Male & Female (SMD 520 & SMD 520F):

Foley Balloon Catheter 2 Way made up of natural latex with an inflatable balloon on its distal tip for retention in the urinary bladder where it usually functions as a therapeutic device for urinary incontinence and used for short term urine drainage.

3 way (Silicon Elastomer Coated) High Flow (SMD 521):

Foley Balloon Catheter 3 Way made up of natural latex with an inflatable balloon on its distal tip for retention in the urinary bladder where it usually functions as a therapeutic device for urinary incontinence and used for short term urine drainage along with irrigation of bladder.

2 way (Silicon Coated) Coude/Tiemann Tip Male & Female (SMD 527 & SMD 527F):

Foley Balloon Catheter 2 Way made up of natural latex with an inflatable balloon on its distal Tiemann tip for retention in the urinary bladder where it usually functions as a therapeutic device for urinary incontinence and used for short term urine drainage.

3 way (Silicon Coated) Coude/Tiemann Tip (SMD 528):

Foley Balloon Catheter 3 Way made up of natural latex with an inflatable balloon on its distal Tiemann tip for retention in the urinary bladder where it usually functions as a therapeutic device for urinary incontinence and used for short term urine drainage along with irrigation of bladder.

INTENDED PURPOSE:

Used for short term urine drainage.

INDICATIONS:

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

CONTRAINDICATIONS

This device contains natural rubber latex, which may cause an allergic reaction. Usage of this device is contraindicated in individuals who are allergic to Latex. If the patient is sensitive or allergic to latex, replace the catheter with a silicone catheter. If the patient is allergic to iodine or betadine, use an alternate cleanser.

LIMITATIONS:

This device cannot be used in patients with insurmountable urethral passages and in patients with excessive urethral stricture.

INTENDED USERS:

Urologist and trained/registered healthcare professional

INTENDED PATIENT POPULATION:

It can be used in all patient population except in patients with known allergy to natural latex rubber or allergic to iodine or betadine.

PERFORMANCE:

Latex Foley Balloon Catheter is specifically designed to be easy on the body while offering consistent and reliable drainage. It is an indwelling catheter, meaning it is connected to the bladder through the urethra. The catheter also has two separate channels: one for draining urine and another helps to hold it in place with the help of a balloon. Its ability to stay in place and offer consistent drainage makes it suitable for patients who will require a catheter for short-term urine drainage from the bladder. An extra irrigation access port is provided in the 3-way type catheter to irrigate the bladder.

WARNINGS:

- This device should be used by a trained and registered healthcare professionalonly. It should not be used by unskilled and untrained personnel.
- Prior to using, read entire instructions for use. Failure to do so may result in severe patient injury.
- These products contain natural rubber latex which may cause allergic reactions.
- This is a single-use device and discards after single-use appropriately.
- Do not re-sterilize, do not reuse. Reuse of this device (or portions of this device) may create a risk of product degradation, which may result in device failure and/or cross-contamination, which may lead to infection or transmission of blood-borne pathogens to patients and users.
- Do not use lubricants or preparations with a petroleum base on products which contain latex, as they will damage the product and may cause the balloon to burst. For latex products, a water-based lubricant or gel may be used.
- The product is guaranteed sterile unless the unit packaging has been opened or damaged. Do not use if the package has tears or holes or if it is wet / seal is broken
- The product should be used immediately after opening the packaging.
- Needled syringe should not be used to inflate the balloon.
- Never use a needled syringe to puncture the catheter shaft for urine sampling. It may compromise the functioning of the catheter and may also lead to infection.
- Do not overinflate the Balloon. Do not apply too much pressure during inflation.
- If the balloon loses liquid, e.g. by diffusion of the filling liquid through the balloon membrane, the catheter can, with time, slide out of the bladder accidentally.

PRECAUTIONS:

- Use the right size of catheter.
- Make sure to check the date of manufacturing and expiry.
- 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 the patient, maintain the position of the drainage bag below
- the level of the patient's bladder.
- Protrusion of the catheter stylet through the eye of a paediatric catheter during insertion may puncture or damage the urethra.
- Secure the catheter to the patient's thigh with hospital approved catheter securement device to prevent movement, and irritation, and decrease the risk of infection.
- Position the bag to avoid urine reflux into the bladder, kinking, or gross contamination of the bag.
- Always keep the bag below the level of the bladder to prevent the backflow 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 lying on the floor unless necessary due to patient positioning.

SIDE EFFECTS:

- Isolated cases of allergic reactions to latex products ranging from mild symptoms (rash; hives; flushing; itching; nasal, eye, and sinus irritation; asthma) to anaphylaxis have been reported.
- Incorrectly positioned catheters can cause urethral injury if the balloon is inflated within the urethra.
- It can lead to irritation of the urethral mucosa, pain and discomfort, urethritis and stricture formation, and blockage of the catheter due to encrustation leading to obstruction of urine flow and urinary retention.
- It can lead to fever, pain or burning on micturition, urinary urgency, urine leak, catheter-associated urinary tract infection and bleeding from the urethra.
- It can lead to genital skin lesions, ulceration, rashes, damage, irritation, or infection.
- Difficulty in the removal of stylet if the paediatric balloon catheter is bent or kinked in the urethra.
- Difficulty in the removal of the catheter in case of excessive aspiration of fluid from the balloon and/or failure to deflate.
- Accidental slide out of the catheter from the bladder due to loss of fluid from the balloon by diffusion of the filling liquid through the balloon membrane.

CLINICAL BENEFITS:

1. Reduce the risk of trauma to the urothelium
2. Safe long-term catheterization
3. Safe for long-term ureteral occlusion
4. No urinary leakage
5. Prevents the development of obstructive air-locks, and provides consistent and complete drainage of the bladder.

RESIDUAL RISKS:

- Anaphylaxis
- CAUTI, Injury to bladder and Allergic reaction

SUPPLY:

2 way (Silicon Coated)	SMD 500	
3 way (Silicon Coated)	SMD 501	
2 way (Silicon Elastomer Coated) High Flow,	SMD 520	
3 way (Silicon Elastomer Coated) High Flow	SMD 521	
2 way (Silicon Coated), Coude/Tiemann Tip	SMD 527	
3way (Silicon Coated), Coude/Tiemann Tip	SMD 528	
2 way Female (Silicon Coated)	SMD 500F	
2 way Female (Silicon Elastomer Coated) High Flow,	SMD 520F	
2 way Female (Silicon Coated), Coude/Tiemann Tip	SMD 527F	

DIRECTIONS FOR USE:

- Consider washing the patient's genital area before the procedure if visibly soiled. Use sterile gloves and wash the patient's genital area thoroughly with foam body cleanser or ready-cleanse wipes. Remove gloves and wash hands.
- Visually inspect the product package prior to use. Do not use the device if the unit package is damaged or opened.
- User can appropriately select the right size device to avoid any trauma to the patient.
- Remove the device from its unit packing using an aseptic technique.
- Apply sterile gloves and use the strict sterile technique for the Foley catheter insertion.
- Visually inspect the catheter for any mechanical damage.
- Perform inflation and deflation test of the Balloon with air, prior to use to check for any balloon leaks.
- Make sure that the balloon is emptied completely before inserting the catheter.
- Lubricate the catheter using a water-based lubricant or gel (with or without local anaesthetic as required).
- Using sterile techniques as per the institutional protocols, insert the catheter fully into the urethra ensuring that the balloon is beyond the bladder neck, and inflate the balloon with sterile water/saline to ensure the retention of the catheter.
- During inflation, properly hold the catheter valve with the thumb and index finger.
- Inflate the balloon appropriately with sterile water/saline only as per the label specified. (3 ml, 5 ml, 10 ml, 15 ml, 30 ml, 50 ml)
- Ensure urine flow from the drainage funnel and connect the urine bag with the connector.

NOTE: The catheter tip should be examined prior to insertion of a paediatric catheter to ensure that the stylet is properly positioned in the tip of the catheter and did not protrude. Make sure that the tip of the stylet is not visible through the eye of the catheter. If one wishes to use the style for insertion, do not remove it from the catheter and try to re-insert it. Re-inserting the stylet is very difficult and may perforate and protrude through the catheter resulting in urethral injury upon insertion. The stylet should be removed before inflating the balloon. Make certain that the catheter does not move from the bladder after the removal of the stylet.

- The inflated balloon holds the catheter in the bladder. If the balloon loses liquid., by diffusion of the filling liquid through the balloon membrane, the catheter can, with time, slide out of the bladder accidentally. To prevent this danger, the inflation liquid should be withdrawn from these catheters at least once a week and the balloon should then be immediately re-inflated with the stated nominal filling volume.
- Sterile Latex Foley Balloon Catheter is recommended for use for up to 30 days only.

DIRECTIONS FOR REMOVAL:

- The patients with this catheter should be routinely monitored as per standard institutional protocol, and the catheter should be removed after a suitable interval as determined by the health care professional.
- To deflate the balloon before removal, use a syringe without a plunger. Aspirate the syringe gently to remove the inflation fluid. Do not use excessive aspiration on the syringe during deflation as this may cause a vacuum collapse of the inflation lumen which may impair normal drainage.
- 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 the 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 scissor at the bifurcation or the balloon ruptured according to established procedures reported in the medical literature. Should it be necessary to rupture the balloon, care must be taken to remove all fragments from the patient.

STERILITY:

This device is sterilized by ethylene oxide gas. Do not re-sterilize, do not reuse. Do not use it if the package is opened or damaged. Discard opened, unused catheters.

MATERIALS USED:

Latex Foley Balloon Catheter 2/3 way (Silicon Coated) (SMD 500 & SMD 501)

Component	Material	Specification/ Material Grade
Foley Catheter	Natural Rubber Latex	Medical Grade
PVC Sleeve	Poly Vinyl Chloride	Medical Grade
NRV (Non-Return Valve)	Polypropylene (PP) / Acrylonitrile Butadiene Styrene (ABS)	Medical Grade

STORAGE:

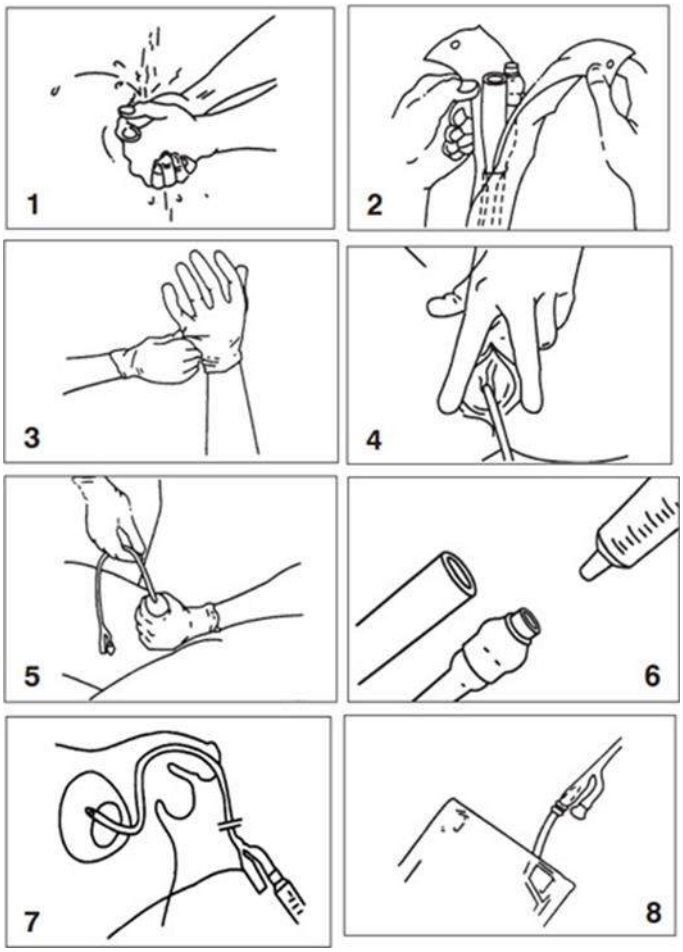
These products should be stored in their original box in a dry place between 5 °C - 45° C, preferably away from the direct and indirect source of light and heat. Do not use after expiry.

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.

SYMBOLS:

REF	**Catalogue No.**		**See instructions for Use**
	Cautions		**Keep Dry**
	Do not use it if the packaging is damaged.	5°C 45°C	**Keep in a dry place between 5°c to 45 °C**
	Single-Use	STERILIZE	**Do not Re-sterilize**
LOT	**Batch / Lot No.**	STERILE EO	**Ethylene Oxide Sterilized**
	Date of Mfg.	LATEX	**Made from Natural rubber Latex**
	Date of Exp.		**Sterile Barrier System**
	Avoid Direct Sunlight	MD	**Medical Device**
MR	**MR Conditional**	UDI	**Unique Device Identifier**



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

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