



INSTRUCTIONS FOR USE NELATON / URETHRAL CATHETER

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

SMDPL/IFU/NC/01 Rev. No.:00, Dt. 12.08.2023

PRODUCT DESCRIPTION:

A flexible tube (catheter) used for the short-term drainage of urine. Unlike the Foley catheter, the Nelaton catheter has no balloon on its tip and thus cannot stay in situ unaided. The Nelaton catheter can be inserted into the bladder via the urethra or a Mitrofanoff. It is intended for short term use.

INTENDED PURPOSE:

For short term urine drainage from the bladder through urethral.

INDICATIONS:

Patient who are all unable to urinate under the following situation:

- Acute Urinary Retention or Obstruction
- Bladder Drainage
- Immobilization needed for trauma or surgery
- Patient is Critically ill and will require accurate output Measurement.

CONTRAINDICATIONS:

The Patients who have

- Blood at the meatus. Insertion of the catheter can worsen an underlying injury
- Gross hematuria
- Evidence of urethral infection
- Urethral pain or discomfort
- Low bladder volume/compliance

LIMITATION

N/A

INTENDED USER

Doctor or Trained healthcare professional.

INTENDED PATIENT POPULATIONS

Paediatrics & Adults.

DIRECTIONS FOR USE:

- Choose the appropriate size of device.
- Open the package from the peel-open area and remove the device.
- Connect the catheter to the Urine Collection Bag.
- 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 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.

WARNING:

The use of this product is restricted to a qualified Doctor or Healthcare professional only.

PRECAUTIONS AND CAUTIONS:

- Prior to using read entire instructions for use. Failure to do so may result in severe patient injury.
- **STERIMED DISCLAIMS ANY RESPONSIBILITY FOR POSSIBLE CONSEQUENCES FROM IMPROPER USE.**
- Do not clean or Re-use the device,
- For single Patient use only.
- Discard after Single use.
- The product should be used immediately after opening the packing.
- Do not use with a stylet or guide wire
- Do not use the device after expiry Date mentioned on the Label.
- If the patient is sensitive or allergic to PVC, do not use the device.

ADVERSE EFFECTS:

- Urinary tract infection
- Paraphimosis
- Urethral Injury
- Bladder spasm and pain

CLINICAL BENEFITS:

- UD is shown to be acceptable, cost-effective, simple, safe and feasible techniques for urethral dilation.
- Enhance patient safety and improve quality
- Reduced risk of UTI
- Shorter hospital stay
- The Nelaton catheter is a familiar simple at-hand device
- It is flexible, it could be used in irregular narrowing of airway
- Placement of the Nelaton catheter in subdural space is easier

RESIDUAL RISKS:

- Urinary tract infection
- Urethral infection
- Injury to urethra
- Allergy

SUPPLY:

Nelaton/Urethral Catheter
(PVC) SMD 502



Nelaton/Urethral Catheter (PU)
SMD 502 PU



Nelaton /Urethral Catheter
(Female) PVC SMD 502 F



Nelaton /Urethral Catheter
(Female) PU SMD 502 F PU



MATERIALS USED:

Nelaton/Urethral Catheter (PVC) (SMD 502):

Component	Material	Specification/Grade
Funnel Connector	Medical Grade PVC (Poly Vinyl Chloride) Compound	Medical Grade
Nelaton Tube (Catheter)	Medical Grade PVC (Poly Vinyl Chloride) Compound	Medical Grade

Nelaton/Urethral Catheter (PU) (SMD 502 PU):

Component	Material	Specification/Grade
Funnel Connector	PVC (Poly Vinyl Chloride) Compound	Medical Grade



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Nelaton Tube (Catheter)	Medical Grade Poly Urethane	Medical Grade
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Nelaton /Urethral Catheter (Female) PVC (SMD 502 F):

Component	Material	Specification/Grade
Funnel Connector	Medical Grade PVC (Poly Vinyl Chloride) Compound	Medical Grade
Nelaton Tube (Catheter)	Medical Grade PVC (Poly Vinyl Chloride) Compound	Medical Grade

Nelaton /Urethral Catheter (Female) PU (SMD 502 F PU):

Component	Material	Specification/Grade
Funnel Connector	PVC (Poly Vinyl Chloride) Compound	Medical Grade
Nelaton Tube (Catheter)	Medical Grade Poly Urethane	Medical Grade

STERILITY:

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

STORAGE:

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

DEVICE DISPOSAL:

Used Devices 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

SYMBOLS:



Catalogue No.



See instructions for Use



Cautions



Keep Dry



Do not use it if the packaging is damaged.



Sterile Barrier System



Single-Use



Do not Re-sterilize



Batch / Lot No.



Ethylene Oxide Sterilized



Date of Mfg.



Latex Free



Date of Exp.



Medical Device



Avoid Direct Sunlight



Keep in a dry place between 5°C to 45°C



Phthalate Free



Pyrogen Free



Unique Device Identifier



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EN ISO 13485:2016 Certified Company

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