*IFU­* of Latex Foley Catheter



DESCRIPTION

Latex Foley Catheter is available in one way, 2-way and 3-way types. They are made from latex; consist of shaft, drainage funnel, inflation funnel, irrigation funnel (if present), balloon and valve. The product is sterile and intended for single use only.

INDICATIONS

Latex Foley Catheter is used in bladder drainage of urine and/or continuous irrigation of fluids by urethra placement.

Only for transurethral catheterization operated by qualified training medical staff.

MODEL and SPECIFICATION

|  |  |
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| type | model |
| one-way | 12Fr, 14Fr, 16Fr, 18Fr |
| Pediatric, 2-way | 6Fr, 8Fr, 10Fr |
| Female(standard), 2-way | 16Fr, 18Fr |
| Male(standard), 2-way | 12Fr, 14Fr, 16Fr, 18Fr, 20Fr, 22Fr, 24Fr, 26Fr, 28Fr, 30Fr |
| 3-way | 16 Fr, 18 Fr, 20 Fr, 22 Fr, 24 Fr |

Balloon volvume: 3mL, 3~5mL, 5mL, 10mL, 5~10mL, 15mL, 5~15mL, 20mL, 30mL, 40mL,30~50mL,50mL,60mL,80mL

CONTRAINDICATIONS

• acute urethritis

• acute prostatitis

• acute epididymitis

WARNING

• Do not over inflate the balloon. Refer to outer unit pack or funnel of catheter for balloon capacity.

• Inflate catheter balloon with sterile water.

• The product is intended for use by physicians trained and aseptic technique must be practiced.

• Do not use petroleum-based lubricants.

• Do not use if package has been opened or damaged.

• Do not clamp catheter shaft. It may damage catheter and prevent deflation.

• Do not use needle to inflate balloon. Use Luer syringe.

• For single patient use only.

• Do not use after the expiry date.

• This is a disposable product for single use, any re-sterilization or reuse of the product can result in hazard to the patient.

• Precautions shall be taken when discarding device and disposal of the device shall be made in accordance with applicable national regulations for biological hazardous waste.

ADVERSE REACTIONS

Reported adverse reactions associated with Foley Catheter are: Septicemia, Urethritis, Urinary tract infection and encrustations, bladder spasms, abdominal discomfort, abdominal discomfort, etc.

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| USE IN CONJUNCTION WITH OTHER MEDICAL DEVICES |
| Pre-loaded stylet, Syringe with sterile aqueous glycerin solution, empty syringe and urine bag |

DIRECTIONS FOR USE

- The leakage or deflation of balloon should be tested prior to use.

- Generously lubricate tip and shaft of the catheter.

- Carefully insert catheter tip into the bladder (normally indicated by urine flow), and then a further 3 cm to ensure balloon is also inside it.

- Using the syringe set inflate balloon. Recommended volume is marked on funnel of catheter.

- For deflation, cut off the inflation funnel above the valve, or using a syringe without needle push into valve to facilitate drainage.

**Notice:** The catheter retained in human body should be replaced once time no more than 7 days. and the same type/model should be continuously used in a single same patient not more than 30 days.

CAUTION

- For single use only.

- Sterile if package is unopened or undamaged.

- The size and balloon capacity are marked on outer unit pack and funnel of catheter.

- patients with allergy to natural latex are prohibited.

STORAGE CONDITIONS

- Store in a dark, cool and dry place.

- Avoid freezing and excessive heat.

SHELF-LIFE

3 years

DISPOSABLE

The device shall be disposed in accordance with applicable national regulations for biological hazardous waste

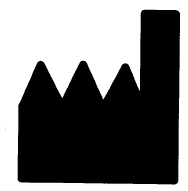
【Symbol and illumination】

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| --- | --- | --- | --- |
| **Symbol** | **Introductions** | **Symbol** | **Introductions** |
|  | Batch Code |  | “Do not reuse" are "single use, "Use only once |
|  | Warnings and Precautions |  | EO sterilization |
|  | Damaged packing, please do not use |  | Do not re-sterilized |
|  | medical device |  | Manufacture Date |
|  | Manufacturer Name Address |  | Name and Address of European Union Representative |
|  | CE Symbol, Notify Body number |  | Usedby |
|  | Protect from heat and radioactive sources |  | Use no hooks |
|  | Put upside |  | Unique Device Identifier |

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