Instructions for Use en **Hydrophilic Intermittent Catheter**



Device description

CIC is a flexible, sterile catheter tube made of PVC with a closed atraumatic tip & two eyelets (in opposite direction) at the distal end with hydrophilic coating. It is inserted through the urethra up to the bladder to drain the urine. This device is available in following sizes, length and models.

| Size (Fr) | Length (cm) | Variants |
|---------------------|-------------|----------------|
| 10, 12, 14, 16 & 12 | 15 35 | Male Female |

Intended Purpose

Intended for intermittent drainage of urine from bladder for one time use.

Indications For Use & Contraindications

Clean intermittent catheterization (CIC) is indicated for individuals who have difficulty emptying their bladders effectively on their own. It is a valuable technique used in various medical conditions to maintain urinary health and prevent complications associated with urinary retention. Indicated for single use.

Contraindications include but not limited to Urethral stricture, Active Urinary tract infection, Severe urethral

trauma or injury, severe Urinary retention with high blood pressure.

Potential Complications

Urinary Tract Infections (UTIs), Bladder or Urethral Trauma, Urethral Stricture, Haematuria, Bladder Spasms, Incontinence, Psychological Impact.

Warnings And Precautions

- Ensure that you have received proper training and education on how to perform CIC procedure correctly. If Ensure that you have received proper training and education on now to perform CIC procedure correctly. If any doubt, seek guidance from a healthcare professional to reduce risk of infection.
 Wash your hands thoroughly with soap and water before starting the procedure.
 Check the catheter for any defects or damage before use. Do not use a catheter that appears to be compromised.
 Do not use the catheter if the integrity of the sealing is broken or damaged.
 Avoid using lubricant gel or oil-based products, as they can damage the catheter.
 Insert the catheter gently and slowly to minimize discomfort and reduce the risk of trauma.

- If you encounter resistance while inserting the catheter, do not force it. Consult with a healthcare professional for guidance.
- Be vigilant for signs of urinary tract infection (UTI), such as fever, increased frequency of urination, or cloudy urine. Seek medical attention if any signs of infection are present.
- Ensure that the bladder is fully emptied during each catheterization to reduce the risk of urinary retention or infection.
- If you notice any unusual bleeding during the procedure, stop immediately and seek medical advice.
- Keep a record of each catheterization, noting any difficulties or abnormalities. This information can be helpful for your healthcare provider.
- Ensure that all catheterization supplies and equipment are stored in a clean, dry place. Dispose of used
- catheters properly according to medical waste disposal protocols.

 Attend scheduled follow-up appointments with your healthcare provider to monitor your urinary health and address any concerns.

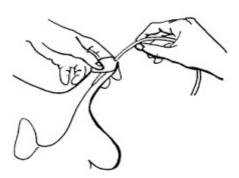
Instructions For Use

- Begin by thoroughly washing your hands with soap and water. Dry them with a clean towel.
 Lay out all the necessary supplies on a clean surface within easy reach.
 Find a comfortable and stable position. This could be sitting on a toilet, on the edge of a bed, or in a wheelchair with your feet flat on the ground.
- Open the catheter packaging, being careful to maintain sterility. Just activate the hydrophilic coating by wetting the catheter with cleaned water for a minimum of 10 sec.
- Ensure that you are placing a catheter in a clean and sterile environment. Avoid touching the catheter tip or allowing it to come into contact with any non-sterile surfaces.
- If your healthcare provider recommends it, use a clean cloth or antiseptic wipe to clean the urethral area from front to back. This step helps reduce the risk of infection.

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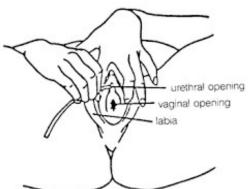
For Males

- 1. Hold the catheter near the tip with your dominant hand. With your non-dominant hand retract the foreskin (if present) and cleanse the glans, exposing the urethral opening.
- 2. Using your forefinger and thumb of your non-dominant hand squeeze the penis gently to open the urethral opening.
- 3. With the penis stretched and in the upright position, Slowly and gently insert the hydrophilic-coated catheter into the urethra and advance it until urine starts to flow.



For Females

- 1. Hold the catheter near the tip with your dominant hand. With your non-dominant hand gently spread the labia with two fingers. Cleanse around opening of urethra as instructed by your healthcare practitioner.
- 2. Slowly and gently insert the hydrophilic-coated catheter into the urethra.
- 3. For females, advance it about 2-3 inches.
- 4. If urine doesn't start flowing immediately, wait a moment. Sometimes, the flow will start after a slight pause.
- 5. If urine flow stops, adjust the position slightly and try to empty the bladder completely. You may need to reposition yourself or the catheter.
- 6. Once urine flow stops, slowly and gently withdraw the catheter. Be cautious to maintain sterility.
- 7. Dispose of the used catheter and any other disposable supplies according to your healthcare provider's instructions and local regulations for medical waste disposal.
- 8. If needed, clean the urethral area again using a clean cloth or antiseptic wipe.
- 9. Wash your hands thoroughly with soap and water.
- 10. Keep a record of each catheterization, noting any difficulties or abnormalities. This information can be helpful for your healthcare provider.



Supply and Storage

The device is assembled in protective tube and the secondary package made of polyethylene and Tyvek. Supplied sterilized by Ethylene Oxide gas in peel open package. Device shall be stored at temperature range from 20°C to 40°C and away from direct sunlight.

Report Any Serious Incident

If problems occur using this device or any serious incidents or adverse events, please contact our customer relations department or call to the contact provided in our manufacturing address and competent authority of the Member State in which the user and/or patient is established.

Reference:

These instructions for use are based on experience from physicians and (or) their published literature. Refer to your local Blueneem sales representative for information on available literature.

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Symbol Glossory And Definations

Standard Reference:

ISO 15223-1 Medical devices — Symbols to be used with information to be supplied by the manufacturer

| Symbol | Symbol Title |
|----------------------|---|
| STERRIZE | Do not re sterilize |
| ® | Do not use if package is damaged and consult instructions for use |
| i | Consult instructions for use |
| 2♂c Å ^{4♂c} | Temperature limit |
| 类 | Keep away from sunlight |
| 2 | Do not re-use |
| CATES . | Not made with natural rubber latex |
| STERILE EO | Sterilized using ethylene oxide |
| × | Non-pyrogenic |
| Ť | Keep dry |
| MD | Medical device |
| | Single sterile barrier system with protective packaging inside |
| DEHP | Does not contain DEHP |
| UDI | Unique device identifier |
| ~ | Date of Manufacture |
| | Use-by date |
| LOT | Batch code |

| REF | Catalogue number |
|---------------|---|
| EU REP | Authorized Representative in the European Community/ European Union |
| | Manufacturer |
| Ŵ | Caution |
| R only | Prescription |



- This device is to be sold by/on the directions of a physician. Sterile (ETO) if package is unopened or undamaged.
- Read all the instructions before use.
- On completion of the procedure, dispose off device and its components if any as per institutional and local regulatory guidelines for bio-hazardous medical waste dispose.



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