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# Instructions for Use

# Meatal Dilator Pediatric

BLUENEEM®
Clinicians Trust. Patients Wellbeing

## Intended Purpose & Duration
Intended to be used for adult assisted dilation of urethra for paediatric patients for less than 02 hours.

## Indications For Use & Contraindications
Indicated to be used for adult assisted dilation of urethra paediatric patients as per prescription by physician. No known contraindications.

## Potential Complications
Potential complications include but not limited to UTI and pain.

## Warnings And Precautions
- Do not reuse the device. Reuse or resterlization can compromise the structural integrity of the device and may cause serious harm to the patient. It can also cause severe patient infection and harm due to contamination.
- Do not use if package is opened or damaged or expired. Do not use the product if there is suspect that the device is not sterile. Device is not intended for permanent use.
- User should use the device only after getting necessary training from physician how to use.
- After usage, dispose of the device as per local regulatory guidelines for bio-hazardous medical waste or as informed by physician during training.

## Instructions For Use
**IMPORTANT NOTE:**
**PROCEDURE MUST BE PERFORMED BY TRAINED ADULTS/GUARDIANS OR TRAINED TECHICIANS/NURSES ONLY.**

1. **Cleaning the genitalis:** Clean the infant patient genitals thoroughly with antiseptic soap and water. Once cleaned, genitals should be mopped dry by a clean piece of towel. Clean the vestibule of genitalia by Povidone iodine solution-soaked gauze piece. Pull back the foreskin (if any) while cleaning for male patient
2. **Instill xylocaine jelly in urethra:** For this purpose, thoroughly clean the nozzle of xylocaine gel by soap and water, decontaminate it with Povidone iodine solution and then introduce the tip of nozzle into urethral orifice and apply some jelly along the tip and shaft of the dilator
3. **Insertion**: After instilling some xylocaine jelly in urethra, with foreskin pulled back for male patients, gently insert the Dilator. Hold through the rear end. Do not touch the tip or shaft of the dilator
4. **Advancing:** As you advance the dilator inside the urethra, be gentile, slow and insert only up to the prescribed length by the physician.
5. Slowly and gently remove the dilator and insert again for better dilation as necessary.
6. Once the dilator is removed, urine starts to flow gradually. Safely dispose off the dilator following the procedure for safe disposal of medical waste.

   **Note:** Observe any signs of discomfort in the patient. Stop the procedure if major discomfort or pain is observed. Consult the physician for further guidance.

## Intended population group
Paediatric patients who are prescribed for urethral dilation assisted by adults on prescription by physician/healthcare professional.

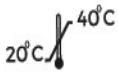
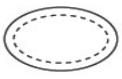
## Supply and Storage
The device is packed in primary pack made of polyethylene and the secondary package made of polyethylene and Tyvek. Supplied sterilized by Ethylene Oxide gas in peel open package. Device shall be stored at temperature range from $20^0$C to $40^0$C and away from direct sunlight.

## 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.

## 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 |
|---|---|
|  | Do not re sterilize |
|  | Do not use if package is damaged and consult instructions for use |
|  | Consult instructions for use |
|  | Temperature limit |
|  | Keep away from sunlight |
|  | Do not re-use |
|  | Not made with natural rubber latex |
|  | Sterilized using ethylene oxide |
|  | Non-pyrogenic |
|  | Keep dry |
|  | Medical device |
|  | Single sterile barrier system with protective packaging inside |
|  | Does not contain DEHP |
|  | Unique device identifier |
|  | Date of Manufacture |
|  | Use-by date |
|  | Batch code |

| | |
|---|---|
|  | Catalogue number |
|  | Authorized Representative in the European Community/ European Union |
|  | Manufacturer |
|  | Caution |
|  | 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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