

## Instruction for Use

### Suprapubic Drainage Catheter Set/ Foley Balloon Catheter Set

#### Device Description

The Suprapubic Drainage Catheter set/Foley Catheter set offers a simplified system for bladder drainage by suprapubic placement of a Foley catheter. The Foley catheter and Urine Collection Bag provide a closed system for collection of urine from the bladder. The tray comes with a trocar, which has a thumb guide to direct pressure during passage. The configurations available include:

| Family   | Accessories                           | Size(Fr) | Length (Cm) |
|--|---------------------------------------|----------|-------------|
| Suprapubic Drainage Catheter set/ Foley Balloon Catheter Set | Pigtail Straightener, Guide Wire,     | 10       | 40          |
|  | Metal Trocar/ Plastic Trocar, Scalpel | 12       | 42          |
|  | Blade/ Surgical Blade, UBC, Stop      | 14       |             |
|  | Cock Connector, Skin Stitching        | 16       |             |
|  | Clamp, Urine Bag, Metal               | 18       |             |
|  | Straightener                          | 20       |             |
|  |                                       |          | 22          |
|  |                                       | 24       |             |

#### Intended Purpose

The device is used for drainage of urine when the urethra is damaged or blocked, or when the patient is unable to use the intermittent catheter.

#### Intended User

This device should be administered to humans only by physicians authorized by the Competent Authority of the country in which the physician is practicing.

#### Medical Conditions to be Treated

- Bladder drainage in patients with urinary retention or obstruction
- Post-operative bladder drainage following urological or gynecological procedures
- Long-term urinary drainage in patients with neurogenic bladder or chronic urinary retention
- Management of urinary incontinence in selected patients
- Diversion of urine to prevent wound contamination in pelvic or lower abdominal surgeries

#### Performance Characteristics of the Device

Foley Balloon Catheter has a drainage lumen and inflation channel. It has an integrated balloon towards the tip of the Catheter which is symmetrical in shape, and when inflated, helps to maintain retention of the catheter in the bladder. The Catheter helps in drainage of urine from kidney and is collected in the Urine Collection Bag.

#### Indications:

- Acute and chronic urinary retention in a patient with contraindications to or complications from a transurethral catheter.
- Failed urethral catheterization
- Lack of urethral or perineal sensation where the risk of urethral injury or skin breakdown is increased

#### Contraindications

- Serious infections
- Haematuria
- Coagulopathy
- Uncooperative Patient

#### Precautions & Warnings

Carefully read all instructions for use and product labelling. The device shall only be applied for its intended use and in accordance with these instructions. Observe all cautions and warnings throughout these instructions. Failure to do so may result in complications.

##### Precautions:

- All medical staff is responsible for using the appropriate technique and deciding on the indication for use of this device based on own experience, training and medical judgment. The doctor must be trained in the proper use of the device.
- The Intended User of the device must be a Urologist specialized in the treatment of urinary system disorders and related urological procedures.
- Do not use the device if there is any indication that the sterility of the device has been compromised.

##### Warnings:

- All components of the Suprapubic Drainage Catheter set are for single use only.
- The product must not be re-used. Reusing single-use devices can lead to potentially serious consequences for the patient: Bio-contamination due to release of infectious agents from device into the body which further may result in Urinary Infection.
- This device should be administered to humans only by physicians authorized by the Competent Authority of the country in which the physician is practicing.

#### Groups of patients and diseases to be diagnosed

- Suprapubic Catheter is used for drainage of urine from bladder in patients diagnosed with kidney stone, urinary incontinence, urinary retention pelvic organ prolapses or other health conditions.
- The device is used in treatment of patients above the age group of 18yrs.
- The above-mentioned sizes not intended for use in infants and patients below the age of 18yrs.

#### Shelf-life and storage condition of the Product

The shelf life of Suprapubic Drainage Catheter set is 3 years (Indicated on product label with the following use-by date symbol).

Store the Suprapubic Drainage Catheter set at a temperature between 12-35<sup>o</sup> C and a Humidity range of 30-75%.

## Instruction for Use Suprapubic Drainage Catheter Set/ Foley Balloon Catheter Set

Store in a dry, cool place. Avoid extended exposure to sun light.

### Sterility – This product is Sterile unless the package has been opened or damaged

- The Suprapubic Drainage Catheter set have been sterilized by exposure to Ethylene Oxide. Sterility indicators are on each package. The imprinted label will change colour from blue to brown after ethylene oxide exposure. Do not use the product unless the sterility indicators are the correct colour.
- Exposure to high levels of Ethylene Oxide may result in presence of residual ETO which leads to Toxic Reaction in the body resulting in tissue damage of Urinary System.
- If the sterile package is damaged or possibly opened, do not use. Contact “Manufacturer or Distributor” and replace the product.
- The Suprapubic Drainage Catheter set are packed single. Product in each pack must be utilized immediately when opened. Product should not be re-sterilized.

### Directions for Use

- Open the package from the Chevron side (‘V’ Notch) of the pouch
- Apply local anesthetic to before introducing the catheter and confirm catheter location with aspirating urine.
- Make small incision to the skin
- Insert peel away sheath and advance it carefully.
- Remove the trocar and insert the foley catheter through sheath.
- Inflate the balloon of foley Catheter and fix the catheter in to bladder wall.
- Fix the catheter to skin with fixation disk.

### Removal Instructions

Remove the sheath by tearing down along the foley catheter.

### Disposal Instructions

Dispose of all equipment, in appropriate containers. After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

### Explanation of symbols used on label

| Symbol | Title of Symbol                 | Symbol | Title of Symbol              | Symbol | Title of Symbol         | Symbol | Title of Symbol                  | Symbol | Title of Symbol  |
|--------|---------------------------------|--------|------------------------------|--------|-------------------------|--------|----------------------------------|--------|--|
|        | Catalogue Number                |        | Unique Device Identifier     |        | Do not re-sterilize     |        | Country of Manufacture           |        | Medical Device   |
|        | Manufacturer                    |        | Date of manufacture          |        | Keep Dry                |        | Caution                          |        | Single Sterile barrier system with protective packaging inside |
|        | Batch Code                      |        | Use by Date                  |        | Keep Away from Sunlight |        | Do not re-use                    |        | Humidity Limit   |
|        | Sterilized using ethylene oxide |        | Consult Instructions for Use |        | Temperature Limit       |        | Do Not Use if Package is Damaged |        |  |



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### Bibliography

- Contraindications:  
<https://www.ncbi.nlm.nih.gov/books/NBK482179/#:~:text=Relative%20contraindications%20for%20suprapubic%20cystotomy,hardware%20of%20the%20pubic%20symphysis>
- Single Use Device:  
[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/956268/Single\\_use\\_medical\\_devices.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/956268/Single_use_medical_devices.pdf)
- EN ISO 15223-1:2021 – Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
- EN ISO 20417:2020 – Medical Devices – Information to be supplied by the manufacturer.