

PRODUCT SPECIFICATION

PRODUCT NAME : MALE INCONTINENCE DEVICE (U-DRAIN)

Special Features

- Comfortable, easy to use, one piece catheter
- Provides snug fit without constriction
- It is provided with an individual adhesive strip with every catheter for proper fixing.

Product Information

Material : Natural Rubber Latex
Colour : Pale Yellow, the colour may vary due to storage time and conditions.
Sterilization : Non Sterile.
Labeling : Shall comply with the corresponding labelling specification and customer requirement.
Shelf Life : 3 years from the date of manufacture.
Storage condition : Shall be stored in cool dry place and away from direct light.

Packaging Details

Pouch	1 pc
Inner Box	50 pcs
Master Carton	600 pcs (12 inner boxes)
20 feet container	2,50,800 pcs (418 Cartons)
40 feet HC container	6,09,000 pcs (1015 Cartons)

Certifications : CE
ISO 9001:2008
ISO 13485: 2003

Physical Dimensions

Sizes	Total Length	Diameter
Small	180 ± 10 mm	25±3 mm
Medium	200 ± 10 mm	30 ± 3 mm
Large	220 + 10 mm	35 ± 3 mm
Ex-Large	220+10mm	40 ± 3 mm

Directions for Use:

Usage of Product : **Male Incontinence Device (U-Drain)** is used by men as an alternative to an indwelling device. U-drain is affixed over the penis and directs urine in to a collection device.

Male Incontinence

Device Sizing : You can determine the diameter of the penis by measuring the circumference (c) of the penis in millimetres with measuring tape and apply this formula: circumference times 7 and divided by 22. $(Cx7)/22$.

Preparation for use : Ensure selection of Male Incontinency Device with correct size.

How to use

Proper application of a Male Incontinence Device is crucial to ensure successful use.

- Make sure any residual adhesive or creams have been completely removed
- Wash the penis thoroughly with soap and water and dry completely.
- If indicated, apply a skin protectant and wait until it has fully dried before applying the external Male Incontinence Device.
- During the application of the Male Incontinence Device, leave the foreskin down and in its natural position.
- In order to avoid skin irritation it is not recommended to shave pubic hair. It would be advisable to trim long pubic hair and/or use a hair guard. If you do not have a hair guard, a paper towel with a hole cut in the middle can be used during device application and removed once it is in place.
- Continually monitor for penis constriction and for any kinks that may occur in the Male Incontinence Device collection tube.

Removal

- Wear times can vary based on the type of Male Incontinence Device being used and patients skin sensitivity. Common wear times are between 12 and 72 hours and should be re-evaluated periodically.
- Unless otherwise indicated by the manufacturer, remove the device daily for cleaning and skin inspection.
- Removal of the device is easily done by soaking with a warm washcloth for 30 seconds.

Cautions for Use

- Users should consider the circumstances of use in deciding whether to remove
- Isolated cases of allergic reactions to latex product or powder have been reported. If you experience a reaction to this product, discontinue use immediately and seek medical help.
- Many problems with Male Incontinence Device commonly are attributed to equipment malfunctions and user error. Many problems can be avoided with proper hygiene and knowledge of Male Incontinence Device application.

Storage Condition

- The atmosphere must always be conducive to the storage of the Male Incontinency Device.
- Male Incontinency Device before opened for use shall be stored in dark, cool and dry place.
- Male Incontinency Device need to avoid area with excessive heat. The storage areas need to be controlled below 40°C/ 104 °F.
- Male Incontinency Device need to be stored at the areas with good air ventilation.
- Male Incontinency Device need to be shielded from direct sunlight and fluorescent lighting.
- Male Incontinency Device need to be stored far away from any energy radiating and heat generating equipment.

Expiration Date

The shelf life of the Male Incontinency Device is 3 years from the date of manufacture.