

Instruction for Use

Urine bag with Connector

Device Description

A urine bag or collector is a medical device that is connected to an indwelling catheter. It is a drainage system comprised of tubing, connectors, an emptying system and mechanical supports it also includes a means to prevent urine backflow. The configurations of the device available are as mentioned:

Family	Size (Ltr)	Connector length(CM)
Urine bag with Connector	0.5	6.5
	1.0	
	2.0	
	2.5	

Intended Purpose

Urinary Drainage Bags are intended to be used for collecting urinary bladder output (diuresis) in hospitals, nursing homes and in home healthcare.

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

- Urinary incontinence requiring external urinary collection
- Urinary retention where continuous bladder drainage is necessary
- Post-operative urinary drainage following urological surgeries
- Bladder outlet obstruction caused by bladder or kidney stones
- Conditions requiring catheterization and continuous monitoring of urine output
- Patients unable to voluntarily control or effectively empty the bladder due to medical conditions or injury

Performance Characteristics of the device

The Urine bag connector is a medical device that is connected with an indwelling catheter. It is a drainage system comprised of tubing, connectors, an emptying system and mechanical supports. It also includes a means to prevent urine backflow.

Indications

- Urinary Incontinence
- Urinary Retention
- Surgery that made a Catheter necessary
- Health Condition that requires usage of Urine Bag.
- Patients who have undergone Catheterization, urological or gynecological surgery and Bladder and Kidney Stones

Contraindications

- Injury to the urethra

Precautions & Warnings

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

Precautions:

- The intended user of the device must be a Urologist specializing in the treatment of urinary system disorders and related urological procedures authorized by the Competent Authority of the country in which the physician is practicing.
- Each Physician is responsible for using the appropriate technique and deciding on the indication for use of this device.
- Confirm the information on the label and that the product has not reached its expiration date and there is no damage to the packaging or device.
- Store the Urine Bag with Connector at a temperature between 12-35°C and a Humidity range of 30-70%.
- Store in a dry, cool place. Avoid extended exposure to sun light.

Warnings:

- The device is intended for single use only.
- The product must not be re-used. Reusing single-use devices can lead to potentially serious consequences for the patient such as bio-contamination due to release of infectious agents from device into the body which further may result in Urinary Infection.
- Do not use the device if there is any indication that the sterility of the device has been compromised. If the sterile package is damaged or possibly opened, do not use. Contact "Manufacturer or Distributor" and replace the product.
- Do not reprocess or re-sterilize, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to failure which, in turn, may result in patient injury.

Intended Patient Population

The device can be used by patients of all age groups.

Shelf-life

The shelf life of the Urine Bag with Connector is 3 years (Indicated on product label with the following use-by symbol).

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

- The Urine Bag with Connector have been sterilized by exposure to Ethylene Oxide. Sterility indicators are on each package. The imprinted label will change color from blue to brown after ethylene oxide exposure. Do not use the product unless the sterility indicators are the correct color.

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- 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 in the Urinary System.
- If the sterile package is damaged or possibly opened, do not use. Contact “Manufacturer or Distributor” and replace the product.
- The Urine Bag with Connector are packed single. Product in each pack must be utilized immediately when opened. Product should not be re-sterilized.

Directions for Use

- The patients Urethral, pubic, and perineal areas are thoroughly cleansed and dried.
- The urine collection bags contain an adhesive backing, which is applied all around the urethral and genital area in case of female, but not the rectal area.
- In male, the bag is placed around the penis and attached to the perineal area, avoiding the rectum.
- Then the urine is allowed to drain and the bag is checked for a sufficient volume of urine.
- When the desired quantity is collected, the bag is carefully removed from the patient.
- The situations in which the health care provider must be contacted are as mentioned below:
 - Little or no urine flowing into the bag
 - Urine Leaking where the catheter enters to the body
 - Pain, burning or redness of the area where the catheter enters into the body
 - Bloody urine (a trace of blood is normal)
 - Cloudy or foul-smelling urine, or sandlike grains in your urine
 - Pain in your lower back or lower belly (abdomen)
 - If the catheter falls out
 - Fever of 100.4°F (38°C) or higher, or as directed by the provider
 - Shaking Chills










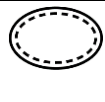


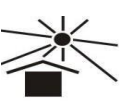

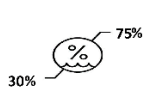


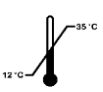

Removal Instructions

- Wash your hands well with soap and water to prevent infecting the urinary catheter and bag.
- If the short drainage tube is inserted into a pocket on the bag, take the drainage tube out of the pocket.
- Hold the drainage tube over a toilet or measuring container. Open the valve.
- Don't touch the tip of the valve or let it touch the toilet or container.
- Wash and disinfectant your hands again.

Disposal Instructions

Dispose the urine bag 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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Instruction for Use
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- Single Use Medical Device:
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.