



Instructions for use

23324645 Version 1

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Intended purpose

The urine bag is intended to passively collect urine.

Indications

Urine bags are indicated for patients suffering from urinary incontinence and/or retention of any aetiology.

Warning

Re-use of the single use product is not recommended cross contamination may occur.

Reprocessing, washing, disinfection and/or (re)sterilisation may compromise product characteristics, causing additional risk of physical harm or infection to the user.

This leg bag is intended to be used while out of bed and moving about. Change to a bedside drainage bag with higher capacity while in bed and during sleep. Alternatively, leave your leg bag in place and attach a bedside drainage bag to expand the capacity of the overall urine collection system.

This product contains phthalates and should neither be used by children nor by pregnant or nursing women without consulting a health care professional.

Information

The bag is designed for single use.

The product has a capacity of 600/800 mL.

The printed volume indicator is only an indicative volumetric measurement scale.

The straps can be washed at temperature of 40°C/104°F or lower.

The products are intended to be stored in the box until removed for use, as the box protects the products and the label on the box contains important information like batch code, use-by date and a unique barcode.

The device does not have to be removed before an MR scan as it is MR safe.

Coloplast accepts no liability for any injury or loss that may arise if this product is used in a manner contrary to Coloplast's current recommendations.

Maximum number of allowable reuses

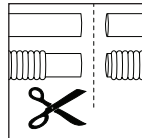
Straps should be replaced when the elasticity weakens.

How to use

Preparation

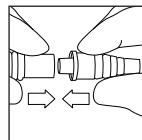


The leg bag has an inlet tube which may be pre-attached to the bag or may be separate from the bag. The length of the tube determines where the bag can be placed on the leg.

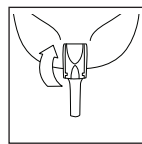


If the tube does not have a pre-attached inlet connector or if the tube itself is not pre-attached to the bag you can shorten the tube to your preferred length. Simply cut the tube with scissors.

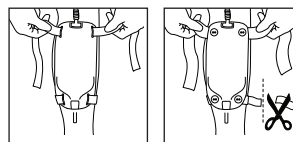
When cutting a corrugated tube, leave as much of the straight section as possible in place. This will ensure a secure connection between tube and connector when mounting the connector.



Attach the connector to the tube by pushing the thin end of the connector into the tube as far as possible.



Make sure the outlet tap is closed.

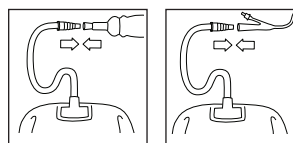


Attach the straps to the bag. Fit the bag to your leg. Any surplus strap may be trimmed off.

Conveen® siliconized strap

Use the longer strap at the top of the bag. If fitting the bag to the calf, wrap the top strap in a figure-of-eight behind and over the knee.

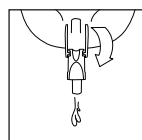
Application



If the connector has a protective cap, remove it.

Attach the connector to the urisheath or catheter.

The urinary collection system is now functional.

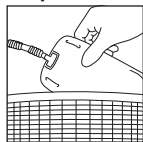


We recommend emptying the bag when it is a little over half full to ensure optimal drainage.

Removal

Disconnect the bag from the urisheath or catheter. Unfasten the straps and remove the bag from your leg.

Disposal



Change the bag according to local guidelines and recommendations.

The straps may be reused.

Empty the bag before discarding it.

The product is intended for single use only and should be disposed of in accordance with local guidelines, e.g. with normal household waste.

Do not flush the product down the toilet.

Reporting of incidents

If, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority.

Explanation of symbols



Medical device



Indicates that the product is in compliance with European legislation for medical devices



Catalogue number



Use-by date (YYYY-MM-DD)



Batch code



Date of manufacture (YYYY-MM-DD)



Manufacturer



Consult instructions for use



Do not re-use



Non-sterile



Indicates a barcode as containing Unique Device Identification



Global Trade Item Number



Keep away from sunlight



Recyclable packaging