

# SpeediCath® Standard

**en** Sterile ready to use coated catheter



## Instructions for use

Please read the following instructions carefully.

23327958 Version 2

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## Intended purpose

The product is intended for intermittent catheterisation through the urethra or a continent urinary stoma.

The product may also be used for intermittent dilation of the urethra.

## Indications

The product is indicated for:

- urinary retention and/or post-void residual volume due to bladder dysfunction.
- urethral strictures.

The product can be used by male and female adults and children.

Choice of model and size of the catheter for the individual patient is made upon recommendation by the local health care professional.

## Warnings

Do not re-use the single use product as cross contamination may occur, potentially leading to infection.

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

## Cautions

For appropriate use, consult your health care professional before you perform self-catheterisation for the first time.

Contact your health care professional if you experience that the catheter does not drain the bladder properly, as it may indicate that you should use another size or type of catheter.

Contact your health care professional if you experience fever, discomfort when emptying the bladder, a frequent urge to urinate or blood in the urine as it may be a symptom of urinary tract infection. Other side-effects related to intermittent catheterisation may include pain, controlled bleeding, false passage, and development of urethral stricture.

Do not use if package is damaged, as sterility of the product may be compromised, potentially leading to infection.

The product is not made with natural rubber latex, however rare contamination with trace amounts of natural rubber latex during manufacturing or packaging may occur, potentially leading to allergic reactions in patients with known or suspected allergies to natural rubber latex.

## Information

Self-catheterisation can be performed by users who have been taught the technique by a health care professional.

If a child or an adult user needs help, the catheterisation can be performed by a caregiver who has been taught the technique or by a health care professional.

The term Continent Urinary Stoma refers to a cutaneous catheterisable continent conduit.

The catheter may be kept rolled up for up to 3 hours without being damaged.

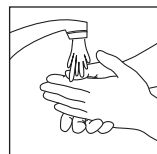
Single use.

Sterilised using irradiation (R).

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.

## How to use

### Preparation

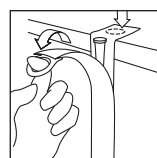


Wash your hands with soap and water and gently clean the area around the urethral/continent stomal opening. It is important to avoid transferring bacteria from your hands to the catheter.

If a caregiver is assisting you, they must wash and dry their hands, then apply a clean pair of gloves.

The packaging contains a coated catheter in a water-based solution. If the catheter has been stored vertically, turn it to a horizontal position to make sure the water-based solution is distributed evenly, ensuring the coating is fully saturated and optimally lubricated.

Before you open the catheter packaging, ensure you are completely ready to proceed with the catheterisation.

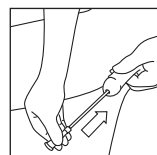


Use the sticker on the back to attach the packaging to a smooth, dry horizontal surface. Open the packaging by pulling the ring towards you and then down. Take out the catheter, which is ready to use.

If there is no toilet nearby, you can connect the catheter to a urine bag or use another receptacle for urine collection.

### Application

#### OPTION 1: Catheterisation through the urethra Men / Boys



##### Self-catheterisation

Lift your penis with one hand to straighten your urethra. Gently press the sides of the head of the penis to open the urethra.

Use your other hand to insert the catheter into the urethra approximately 2 cm at a time. Just before the catheter reaches the bladder, you may feel a slight resistance from the sphincter. Do not squeeze the penis, as this may make inserting the catheter more difficult. Continue inserting the catheter until urine starts to flow, and then a bit further.

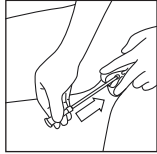
##### Catheterisation by a caregiver or health care professional

Hold their penis up towards their stomach. This position will make it easier to guide the catheter into their urethra.

Gently press on the sides of the head of the penis to open the urethra and gently slide the catheter into the urethra. Continue inserting the catheter until urine starts to flow, and then a bit further.

**Tiemann/Coude catheter (curved tip) only:** Before you begin insertion, make sure the curved tip of the catheter is pointing upwards. The Tiemann indicator (raised ridge) on the connector is designed to help you orient the catheter correctly. When holding the catheter horizontally with the indicator facing upwards, the tip of the catheter will also be pointing upwards.

## Women / Girls



### Self-catheterisation

Part your labia with one hand to expose the urethral opening.

Use your other hand to insert the catheter gently into the urethra approximately 2 cm at a time. Just before the catheter reaches the bladder, you may feel a slight resistance from the sphincter. Continue inserting the catheter until urine starts to flow, and then a bit further.

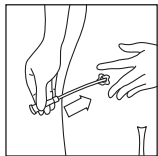
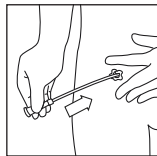
### Catheterisation by a caregiver or health care professional

Part their labia with one hand to expose the urethral opening.

Gently slide the catheter into the urethra. Continue inserting the catheter until urine starts to flow, and then a bit further. You can now let go of the labia to free up the other hand.

## OPTION 2: Catheterisation through a continent urinary stoma

### Men / Boys / Women / Girls



Catheterise in the same way as described for catheterisation through the urethra (Option 1) but insert the catheter into the continent urinary stoma, instead of the urethra.

### Removal (OPTION 1 and OPTION 2)

When the urine stops flowing, gently rotate the catheter to drain any remaining urine in the bladder. Then ease out the catheter 1 to 2 cm. If the flow of urine restarts, wait a few seconds before easing out the catheter another 1 to 2 cm. When the urine stops flowing, slowly remove the catheter.

**Tiemann/Coude catheter (curved tip) only:** Do not rotate the catheter in the bladder.

## OPTION 3: Catheterisation to dilate the urethra

### Men / Boys / Women / Girls

Catheterise in the same way as described for catheterisation through the urethra (Option 1) but with the primary purpose of dilating the urethral passage. The catheter should be inserted as far as advised by your health care professional. Immediately remove the catheter once the stricture has been passed.

### Disposal

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

If you have connected a urine bag, discard it together with the catheter, or disconnect and empty the bag in accordance with the user instructions for the bag.

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



Sterilised using irradiation



Single sterile barrier system



Not made with natural rubber latex



Do not use if package is damaged and consult instructions for use



Indicates a carrier that contains Unique Device Identifier information



Global Trade Item Number



Keep away from sunlight



Recyclable packaging