



Instructions for use

Please read all the instructions before using this device.

23341266 Version 3

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Distributed by:

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Indications

The Self-Cath Plus catheter is intended for use in male, female and pediatric patients (neonates, infants, children, adolescents, and transitional adolescents) requiring bladder drainage as determined by their physician. This device is indicated for those individuals unable to promote a natural urine flow or for those individuals who have a significant volume of residual urine following a natural bladder-voiding episode.

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

Contraindications

This device is contraindicated in the presence of conditions, such as urethral trauma, which create unacceptable risk during catheterization.

Warnings

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

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

Cautions

Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

For appropriate use, consult your health care professional before you perform self-catheterization 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 catheterization 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-catheterization can be performed by users who have been taught the technique by a healthcare professional.

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

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

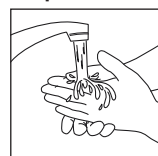
Single use.

Sterilized using ethylene oxide (EO).

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

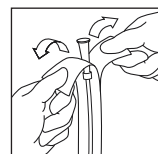


Wash your hands with soap and water and gently clean the area around the urethral opening. It is important to avoid transferring bacteria from your hands to the catheter.

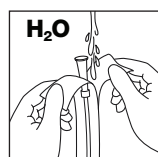
If a caregiver is assisting you, they must wash and dry their hands, then apply a clean pair of gloves.

The packaging contains a coated catheter that requires addition of water for lubrication. Use clean tap water. If you do not have access to clean tap water, use bottled water, or bottled sterile water if recommended by your health care professional. Do not add any additives to the water.

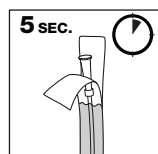
Before you open the catheter packaging, ensure you are completely ready to proceed with the catheterization.



Open the packaging 2-3 cm / 3/4 to 1 1/4 inches.



Pour water into the packaging until it reaches the catheter connector.



No soaking time necessary.

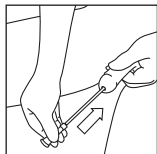
Take out the catheter which is ready to use.

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

Application

Men / Boys

Position yourself in front of the toilet or on a chair opposite the toilet. Many men prefer to stand during the catheterisation procedure. If a caregiver is assisting you, lying on your back with your legs extended is another option.



Self-catheterization

Lift your penis with one hand to straighten your urethra. Gently press on 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/ 3/4 inch in 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.

Catheterization by a caregiver or healthcare professional

Hold his penis up towards his stomach. This position will make it easier to guide the catheter into his 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/Coudé catheter (curved tip) only: Before you begin insertion, make sure the curved tip of the catheter is pointing upwards. On some models, you will find a guide stripe (blue line on the catheter). The guide stripe will help ensure the catheter tip is still oriented correctly when approaching the bladder. When holding the catheter horizontally with the blue line facing upwards, the tip of the catheter will also be pointing upwards.

Women / Girls

Position yourself comfortably with thighs spread apart. Many women prefer to sit on the toilet or on a chair opposite the toilet. If a caregiver is assisting you, lying on your back with your knees bent is another option.



Self-catheterization

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/ 3/4 inch in 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.

Catheterization by a caregiver or healthcare professional

Part her 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.

Removal

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/ 3/8 to 3/4 inch in. If the flow of urine restarts, wait a few seconds before easing out the catheter another 1 to 2 cm/ 3/8 to 3/4 inch in. When the urine stops flowing, slowly remove the catheter.

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

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



Catalog number



Use-by date (YYYY-MM-DD)



Batch code



Date of manufacture (YYYY-MM-DD)



Manufacturer



Consult instructions for use



Do not re-use



Sterilized using ethylene oxide



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



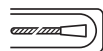
Keep away from sunlight



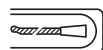
Recyclable packaging

Rx ONLY

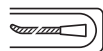
Prescription use only



Sterile coated catheter, straight tip



Sterile coated catheter, olive coudé tip



Sterile coated catheter, tapered coudé tip



Sterile coated catheter, straight tip, luer end, flared