SpeediCath®Flex Set



Urinary intermittent drainage catheter with integrated urine bag

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

If a person needs help emptying the bladder, catheterisation can be performed by a caregiver who has been taught the technique or by a healthcare professional.

Catheterisation should take place as quickly as possible after opening the package. The catheter should always be removed when the bladder has been emptied.

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

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.

Special storage conditions

Keep away from sunlight.

How to use

General preparation



Wash your hands and the area around the urethral opening with soap and water. 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.

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

Opening method 1:

Peel open the packaging. Take out the product.



Opening method 2:

Stick the packaging to a horizontal surface using the upper part of the adhesive label on the backside. Peel open the packaging. Take out the product.

Catheter preparation



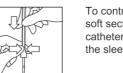
The turquoise symbols printed on the bag indicate action points.

Break off the tab inside the bag to drain the waterbased solution from the sleeve into the bag.

Hold the catheter straight up and glide your fingers down the sleeve to drain the last drops of water-based solution into the bag.



Unscrew the turquoise cap to expose the catheter tip. The catheter is now ready to use.



To control the catheter during insertion, pinch the soft section of the turquoise handle. To advance the catheter, release pressure on the handle while pulling the sleeve.



Instructions for use

23324124 Version 1

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Intended purpose

Sterile urinary intermittent catheter for bladder drainage of urine through the urethra with integrated urine bag for urine collection.

Indications

Intermittent catheters are indicated for male patients suffering from urinary retention and/or experiencing post-micturition residual volume of any aetiology.

Warnings

Re-use of the single use product may create a potential harm to the user. Reprocessing, washing, disinfection and/or sterilisation may compromise product characteristics, causing additional risk of physical harm or infection to the user.

Cautions

Contact your health care professional before you perform selfcatheterisation for the first time.

If you experience a suspected allergic reaction or any other side effects, please contact your health care professional.

Contact your health care professional if you:

- experience that the catheter does not drain the bladder the way you are used to
- experience symptoms such as fever, discomfort when emptying the bladder, a frequent urge to urinate or blood in the urine.

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

Information

For single use only.

Sterilised using irradiation (R).

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.

Insertion



Self-catheterisation

Lift your penis with one hand to straighten out your urethra. While supporting your penis, guide the tip of the catheter into the opening of the urethra.

Once the tip is inserted in the urethra, make sure you hold your penis and the turquoise handle in the same hand.

With your other hand, start pulling the sleeve to insert the catheter towards the bladder. Once urine starts to flow into the bag stop inserting the catheter. Support the bag while it fills with urine.

Catheterisation by a caregiver or healthcare professional

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

Gently press on the sides of the head of the penis to open the urethra and gently slide the catheter into the urethra.

Once the tip is inserted in the urethra, make sure you hold the penis and the turquoise handle in the same hand.

With the other hand, start pulling the sleeve to insert the catheter until it reaches the bladder and urine starts to flow into the bag.

Removal



When urine stops flowing, pull the catheter out about 1-2 cm. If urine starts flowing again, wait until it stops. Then pull the catheter out 1-2 cm again. When your bladder is empty, remove the catheter.



After use, the product can be re-closed with the turquoise cap.

Emptying/Drainage



Open the bag by pulling horizontally on the pull tab.



Empty the bag using the top and bottom handles for support.

Disposal



Return the catheter to the packaging.



Use the sticker on the backside to re-close the packaging.



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



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 barcode as containing Unique Device Identification



Global Trade Item Number



Keep away from sunlight



This way up



Recyclable packaging



Ready to use hydrophilic coated catheter with integrated urine bag