Luja™

en Sterile ready to use coated catheter

Coloplast

Coloplast A/S
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Instructions for use
Please read all the instructions before using this device.

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

Indications
Luja female is indicated for use by patients with urine retention and patients with a post void residual volume (PVR) due to neurogenic and non-neurogenic voiding dysfunction. The catheter is inserted into the urethra to reach the bladder allowing urine to drain.

The product is indicated for female patients only (adults and children of and above the age of 2 years).

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
Caution specific for health care professionals: Apply with caution if the patient produces urine with many particles clearly distinguishable by the naked eye, as it may lead to transient urine retention.

For appropriate use, consult your healthcare professional before you perform self-catheterization for the first time.

Contact your healthcare 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 healthcare 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 user needs help, catheterization can be performed by a caregiver who has been taught the technique or by a healthcare professional.

This product features micro-holes that enable emptying of the bladder with minimal mucosal suction without repositioning the catheter. Incomplete emptying of the bladder can be a risk factor for the development of urinary tract infections.

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

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

Single use.

Sterilized 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 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.

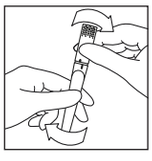
The packaging contains a hydrophilic coated catheter in a water-based solution.

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

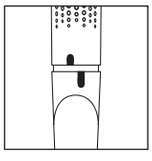
If there is no toilet nearby, you can connect the catheter to a urine bag* or use another receptacle for urine collection.



Hold the product upright so that the handle (wide end) points upwards.

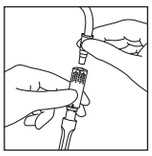


Open the product by turning the handle in either direction to break the packaging.



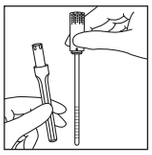
You will know the packaging is open when the blue lines on the handle and the container (narrow end) are no longer aligned.

Pull the handle upwards approximately 3/4 inch (2 cm) until a resistance is felt.



In this position, a urine bag* can be connected to the end of the handle, if required. Insert the urine bag connector into the opening in the top of the handle. Make sure the connector is firmly attached.

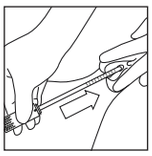
**The product can be used with urine bags with a connector size of max 8.5 mm diameter at the tip.*



To fully open the product, continue to pull the handle straight up until the sterile catheter is completely revealed. It is important that the catheter is not bent during the opening process.

The container may be discarded as recyclable waste or emptied and retained for discreet disposal of the catheter later.

Application



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

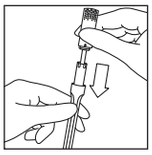
Use your other hand to insert the catheter gently into the urethra approximately 3/4 inches (2 cm) at a time. Just before the catheter reaches the bladder, you may feel a slight resistance from the sphincter. Continue inserting the catheter until urine starts to flow, and then a bit further to ensure a steady and continuous flow.

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 to ensure a steady and continuous flow. You can now let go of the labia to free up the other hand.

Removal
When the urine begins to drip slowly, remove the catheter.

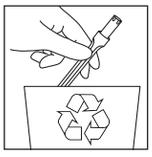
Disposal



The product can be re-closed for transportation and convenient disposal by re-inserting the catheter into the container.

If a urine bag is connected, it must be removed before the product can be correctly closed.

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



The container material is recyclable and may be disposed of in accordance with local guidelines for recyclable waste.

If the product has been re-closed, do not recycle the container.

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

MD	Medical device
REF	Catalog number
	Use-by date (YYYY-MM-DD)
LOT	Batch code
	Date of manufacture (YYYY-MM-DD)
	Manufacturer
	Consult instructions for use
	Do not re-use
STERILE R	Sterilized using irradiation
STERILE R	Single sterile barrier system
LATEX	Not made with natural rubber latex
	Do not use if package is damaged and consult instructions for use
UDI	Indicates a carrier that contains Unique Device Identifier information
	Keep away from sunlight and heat
	Recyclable packaging
	Catheter microholes
	Sterile ready to use coated catheter, nelaton
5 PP	Container is made of polypropylene
Rx ONLY	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner