

Livia 3,5 Fr Urinary Catheter + Kit

Instructions for Use

Urinary Catheter, Productcode: LK35FR250, REF: JI

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Storage

The product should be stored in its original pouch to avoid the possibility of damage and thus impairment of the sterility of the components.

This product has been sterilised with ethylene oxide (EO) and is sterile packed. Do not use it if the packaging is damaged or shows signs of tampering, as sterility is no longer guaranteed. A damaged or opened product must not be used and must be disposed of in accordance with local regulations. This product is suitable for an ambient temperature between 5°C and 40°C. Do not use this product after the expiry date. If the packaging is damaged, the product may no longer be used sterile.

Indications and Intended Use

The Livia urinary catheter set is a closed urinary drainage system that can be used to accurately measure urine output in newborns and children.

Contents

1. Biocompatible 3.5 Fr silicone urinary drainage catheter (100 % medical grade silicone)
2. Stopcock with latex-free injection site
3. 100 ml collection burette with drain tap
4. 100 ml urine collection bag

Precautions

- Reuse of this sterile device poses a significant risk of cross contamination and sepsis and/or dependence on an unvalidated process. This device is not structurally designed or validated for reuse.
- Never use sharp clamps or instruments on the catheter as a slight nick or cut can cause the catheter to break or perforate.
- When removing the Livia catheter, do not stretch the catheter tubing.
- Clinicians must be familiar with and trained in the use of indwelling urinary catheters according to established institutional protocol, including proper aseptic techniques and skin preparation.
- Do not use alcohol, acetone or alcohol containing antiseptics directly on the catheter. Carefully check solutions for alcohol or acetone. Ensure gloves or other surfaces which have alcohol on them are completely dry before touching or manipulating the catheter.

Cautions

When attaching external components, be careful not to over-tighten.

Disposal

This product is intended for single use. After use, dispose of in accordance with local regulations for medical waste. Products that have come into contact with body fluids must be disposed of in accordance with the institutional guidelines for biohazardous substances. Please check regional regulations for proper disposal.

Suggested Procedure for Catheterization of the Neonate

Male Infant

1. Restrain infant in a supine position with infant's thighs abducted and knees slightly flexed in a frog-like position.
2. Put on sterile gloves. Open Povidone-Iodine swab stick pouch. Open sterile surgical lubricant and squeeze onto sterile field.
3. Drape infant.
4. Hold the shaft of the penis and retract the foreskin to expose the meatus with one hand. This hand is considered contaminated.
5. Cleanse glans several times with the Povidone-Iodine swab sticks in a circular motion from the tip of the penis down the shaft. Discard the swab stick after use and repeat procedure. Allow to dry.
6. Apply small amount of lubricant to the tip of the catheter.
7. Apply caudal traction on the penile shaft and gently insert the catheter through the meatus until urine is seen and then advance the catheter an additional 0,5 centimeters to ensure that the second hole of the catheter is in the bladder.

Caution: Do not insert too far!

8. Secure the catheter. **Caution: Do not suture!**
9. Place the burette so that the open filter on top of the burette remains dry.
10. Urine samples for analysis can be obtained by using a stopcock attached to the urinary catheter to stop urine flow to the drainage system, thus enabling direct urine aspiration from the urinary catheter through the sampling port.

Caution: Use gentle aspiration. Avoid any excessive force when aspirating the urine to prevent damage to the bladder mucosa.

11. The urinary drainage system allows accurate recording of output. The system can be emptied by turning the two-way stopcock on the drainage port, located at the base of the burette, to the "on" position.

Female infant

1. Restrain infant in a supine position with infant's thighs abducted and the knees slightly flexed in a frog-like position.
2. Put on sterile gloves. Open Povidone-Iodine swab stick pouch. Open sterile surgical lubricant and squeeze onto sterile field.
3. Drape infant.
4. Have an assistant retract labia majora and minora gently with cotton tip applicators.
5. Gently cleanse area between the labia minora in a downward motion with Povidone-Iodine swab stick. Discard the swab stick after use and repeat procedure. Allow to dry.
6. Apply a small amount of lubricant to the tip of the catheter.

7. Insert catheter until urine appears in the tube and then advance 0,5 centimeters to ensure that second hole of catheter is in the bladder. **Caution: Do not insert catheter too far.**
8. Secure the catheter. **Caution: Do not suture.**
9. Place the burette so that the open filter on top of the burette remains dry.
10. Urine samples for analysis can be obtained by using a stopcock attached to the urinary catheter to stop urine flow to the drainage system, thus enabling direct urine aspiration from the urinary catheter through the sampling port.
Caution: Use gentle aspiration. Avoid any excessive force when aspirating the urine to prevent damage to the bladder mucosa.
11. The urinary drainage system allows accurate recording of output. The system can be emptied by turning the two-way stopcock on the drainage port, located at the base of the burette, to the "on" position.

Duration of Catheterization

The duration of catheterization of urinary catheters in premature and newborn babies should be kept as short as possible. A duration of up to 7 days is possible, ideally, we recommend no longer than 1 to 3 days. Regular checking of the catheter site is necessary in order to recognize and avoid infections and complications at an early stage.

Troubleshooting

If urine will not drain, the filter on the top of the exhaust port of the burette may be blocked as a result of getting wet. Replace the system.

Validity

Three years. The shelf life is only guaranteed if the product is stored under the recommended storage conditions (5 °C to 40 °C).

Symbols and Illumination

	Medical Device		Do not use if package is damaged
	Federal (USA) law restricts this to sale by or on the order of physician or other licensed practitioner		Product is not manufactured with natural rubber latex
	Do not re-use		Sterilized using ethylene oxide
	Do not resterilize		Manufacturer
	Authorized representative in the European Community		Notified body
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