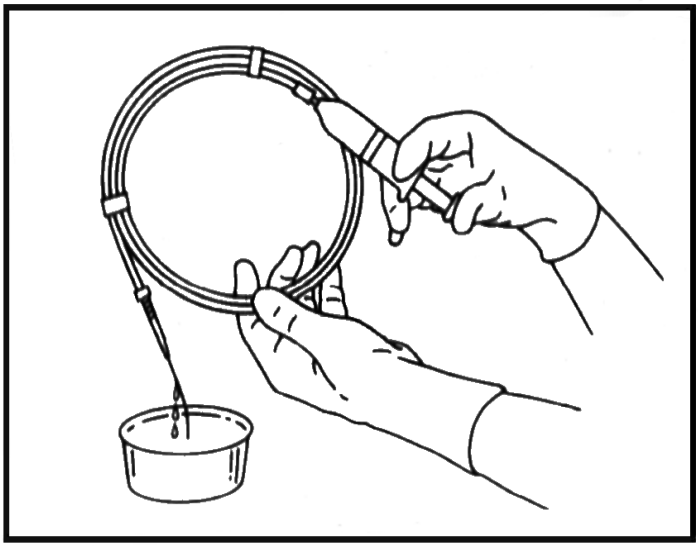
COOK MEDICAL

UroStream™ Hydrophilic Wire Guide

Instructions for Use

T_UROS_DEVO



1

UROSTREAM™ HYDROPHILIC WIRE GUIDE

Read all instructions carefully. Failure to properly follow the information provided may lead to the device not performing as intended or injury to the patient.

CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician (or a properly licensed practitioner).

DEVICE DESCRIPTION

UroStream™ Hydrophilic Wire Guide is a flexible, polyurethane jacketed, hydrophilic coated 150 cm wire that is offered in diameters of 0.025", 0.035", or 0.038", with a straight or angled tip.

Performance Characteristics

- Radiopaque polymer jacket aids visualization under fluoroscopy
- Flexible tip facilitates insertion into patient anatomy
- Nitinol core offers resistance to kinking
- Hydrophilic coating enhances lubricity of the device

Device Compatibility

This device can be used with a variety of urological devices compatible with diameters from 0.025 inches to 0.038 inches (0.635 mm to 0.965 mm) and a length of 150 cm (59.056 inches). Length, diameter, tip, and core configurations are indicated on the product label and should be considered when selecting the wire guide for use with procedural devices.

Patient Population

The wire guide is applicable for any patient undergoing a urological procedure.

Contact with Body Tissue

The device will be placed through the urinary tract via transurethral access, percutaneous nephrostomy by puncturing through the flank of the patient to access the kidney, or open surgical techniques.

Operating Principle

The polyurethane jacket is filled with a radiopacifier to aid visualization under fluoroscopy. The distal (furthest from the user) tip of the wire guide is flexible to reduce the risk of causing undue trauma as it navigates through the urinary tract. The wire guide is designed to navigate through impacted stones, ureteral obstructions, and tortuous anatomy. The nitinol core of the wire guide offers a kink-resistant shaft. The wire guide will establish a tract for device placement and exchange and will be in use up to the duration of the procedure (<24 hrs).

Intended Users

The wire guide is intended for use only by a person trained and experienced in diagnostic and interventional urological procedures and techniques.

INTENDED USE

This device is used to gain access, to establish a tract, and to assist in the placement, replacement, and exchange of medical devices during urological procedures.

INDICATIONS FOR USE

This device is used to facilitate the placement, replacement, and exchange of endourological instruments and medical devices during diagnostic or interventional urological procedures by establishing and maintaining a tract to target anatomy.

CLINICAL BENEFITS

Facilitates urinary tract access for placement, replacement, exchange, or removal of medical devices during urological procedures, thus enabling minimally invasive diagnostic or interventional procedures.

CONTRAINDICATIONS

None

WARNINGS

- Do not use the device if the sterile packaging is damaged or unintentionally opened before use.
- This single use device is not designed for re-use. Attempts to reprocess (re-sterilize) and/or to re-use may lead to device failure and/or transmission of disease.
- To prevent the hydrophilic wire guide from slipping into the procedural device, always keep at least 5 cm of the wire guide protruding from the procedural device fitting.
- The hydrophilic coating on the wire guide is activated by immersion in sterile water or sterile saline solution. Failure to cover the wire guide with solution may lead to difficulty and patient injury when the wire guide is advanced.
- To prevent possible tissue damage, care should be taken when manipulating a procedural device over a wire guide during the device's placement and withdrawal. If resistance is felt during device placement, discontinue the procedure and determine the cause of resistance before proceeding. If the cause of the resistance cannot be determined, remove the wire guide and device as a unit to prevent possible damage and/or complications.

PRECAUTIONS

- Cook does not recommend a particular technique for use of this wire guide. The steps in the following directions are for information purposes only. Each physician should evaluate the information's appropriateness according to individual patient condition and the physician's own medical training and experience.
- End hole size and length of device must be taken into consideration to ensure a proper fit between the wire guide and the procedural device.
- Manipulation of the wire guide requires appropriate imaging control. Use caution not to force or overmanipulate the wire guide when gaining access.
- When using the wire guide through a metal cannula or needle, use caution, or damage may occur to the outer coating of the wire guide.
- When exchanging or withdrawing an instrument over the wire guide, secure and maintain the wire guide in place under fluoroscopy to avoid wire guide displacement.
- Use caution when using a laser. Direct contact with the laser may cause damage to the wire guide.
- This wire guide is not intended for use in percutaneous transluminal coronary angioplasty (PTCA).
- In all patients undergoing endourologic treatment, perioperative antibiotic prophylaxis is recommended.

POTENTIAL ADVERSE EVENTS

- Acute Bleeding / hematoma
- Acute pyelonephritis
- Hematuria
- Infection / UTI / urosepsis
- Injury to adjacent organs
- Mucosal tear / laceration / abrasion
- Pain

- Ureteral laceration / avulsion / tear / lesion
- Ureteral perforation / false passage / urinoma
- Ureteral stenosis
- Ureteral stricture
- Urinary tract injury
- Vascular injury

HOW SUPPLIED

Supplied sterilized by ethylene oxide gas in peel-open packages. Intended for one-time use. Keep dry and away from sunlight. Upon removal from package, inspect the product to ensure no damage has occurred.

INSPECTION OF DEVICE

Visually inspect the device, paying attention to kinks, bends, and breaks. If an abnormality is detected that would prohibit proper device performance, do not use.

DEVICE PREPARATION

1. Using aseptic technique, remove the wire guide dispenser with the wire guide from its outer packaging and place the wire guide dispenser with the wire guide in the sterile field.
2. Prior to removing the hydrophilic wire guide from its dispenser, fill a syringe with sterile water or sterile saline solution and inject the solution into the Luer lock hub at the end of the dispenser.
3. Inject enough solution to fill the dispenser coil. The solution will completely cover the wire guide surface and activate the hydrophilic coating. (see **Fig 1**.)
4. Remove the hydrophilic wire guide from its dispenser by gently withdrawing the wire guide via its tip.
   NOTE: If the hydrophilic wire guide cannot be easily be removed from its dispenser, then inject more solution into the dispenser and attempt withdrawal again.

INSTRUCTIONS FOR USE

1. Flush the procedural device with saline solution before and during use to ensure smooth movement of the hydrophilic wire guide within the device.
2. Advance the flexible end of the wire guide into the procedural device and position the wire guide in the desired anatomical location.
   NOTE: For optimal performance, rehydrate the hydrophilic-coated wire guide after exposure to ambient environments or if the lubricity of the wire guide is diminished. Replace the wire guide with a new hydrophilic-coated wire guide if wire guide lubricity remains diminished.
3. After wire guide use is complete, remove the wire guide from the patient and discard the wire guide in an appropriate waste receptacle.

DISPOSAL OF DEVICES

After the procedure, this device may be contaminated with potentially infectious substances of human origin and should be disposed of in accordance with institutional guidelines.

REFERENCES

These instructions for use are based on physicians' experiences and/or published literature. Refer to your local Cook Medical sales representative for information on available literature.

PATIENT COUNSELING

Please inform the patient as necessary of the relevant warnings, precautions, contraindications, measures to be taken, and limitations of use that the patient should be aware of.

SERIOUS INCIDENT REPORTING

If any serious incident has occurred in relation to the device, it should be reported to Cook Medical and also the competent authority of the country or region in which the device was used.

Medical Device
EN Medical Device

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

Single Sterile Barrier System with Protective Packaging Outside
EN Single Sterile Barrier System with Protective Packaging Outside

Packaging unit
EN Packaging unit

cookmedical.com/symbol-glossary

Cook Incorporated
750 Daniels Way
Bloomington, IN 47404 U.S.A.

cookmedical.com

2022-10
T_UROS_DEV0