COOK®
MEDICAL

Seidmon Antegrade AQ® Stent Set

Instructions for Use

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SEIDMON ANTEGRADE AQ® STENT SET

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

DEVICE DESCRIPTION

This device consists of an Antegrade AQ® stent and a Peel-Away® Introducer.

INTENDED USE

The Seidmon Antegrade AQ Stent Set is intended for internal drainage from the ureteropelvic junction to the bladder while maintaining external access to the stent as well as providing external drainage in patients age 18 years and older when treated as adults.

CONTRAINDICATIONS

The device is contraindicated where percutaneous drainage catheterization is unacceptable.

WARNINGS

Do not use the stent for feeding tube/gastrostomy procedures. Exposure to gastric fluids may damage the stent.

PRECAUTIONS

- The maximum indwelling time for this device is four weeks. Periodic evaluation of the stent is advised.
- This device is intended for use by physicians trained and experienced in percutaneous access and ureteral stenting techniques. Standard techniques should be employed.
- Improper handling can seriously weaken the stent. Acute bending or overstressing during placement may result in subsequent separation of the stent at the point of stress after a prolonged indwelling period.
- Ureteral stents should be checked periodically for signs of encrustation and proper function. Periodic checks of the stent by cystoscopic and/or radiographic procedures are recommended at intervals deemed appropriate by the physician in consideration of the individual patient's condition and other patient-specific factors.
- Do not forcefully advance any component during placement or removal of the stent. Carefully remove the components if any resistance is encountered.

POTENTIAL ADVERSE EVENTS

Complications that may result from the use of this device include:

- Stent occlusion
- Dysuria and frequency/urgency
- Encrustation
- Fistula
- Hemorrhage/Hematoma
- Infection/Sepsis
- Pain
- Perforation
- Peritonitis
- Pneumothorax
- Loss of renal function
- Migration and/or dislodgement

MRI SAFETY INFORMATION

Nonclinical testing has demonstrated that the Seidmon Antegrade AQ Stent is **MR Conditional**. A patient with this device may be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 3.0 Tesla or 1.5 Tesla only
- Maximum magnetic field spatial gradient of 1900 gauss/cm (19 T/m) or less
- Maximum MR system reported, whole-body-averaged specific absorption rate (SAR) of ≤ 2.0 W/kg (Normal Operating Mode)

Nonclinical testing demonstrated that the Seidmon Antegrade AQ Stent is not expected to induce RF heating greater than that of biological tissue.

The image artifact extends approximately 2.0 mm from the Seidmon Antegrade AQ Stent as found during nonclinical testing when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

INSTRUCTIONS FOR USE

1. Perform standard techniques for establishing a nephrostomy tract under fluoroscopic guidance, leaving a wire guide in the bladder. Ensure fluoroscopically that the wire guide travels the length of the ureter and is well into the bladder. **NOTE**: The stent will accept a wire guide up to .038 inch in diameter.
2. Introduce the Peel-Away introducer over the wire guide and remove the inner dilator.
3. Prior to placing the stent, immerse the stent in sterile water or isotonic saline to allow the hydrophilic surface to absorb water and become lubricious. This will ease placement under standard conditions.
4. Gradually advance the stent over the external end of the wire guide and down into the bladder. Under direct vision and/or fluoroscopically, confirm the distal end of the stent is in the bladder and the proximal radiopaque band of the stent is in the renal pelvis.
5. Using each side of the Peel-Away Introducer, gently pull back and split the introducer into two parts while leaving the stent in situ. **NOTE**: Maintain stent/wire guide position while peeling the introducer away.
6. While holding the shaft of the stent securely in position with one hand use the other hand to slightly withdraw the wire guide enough to allow the retentive coil to form in the bladder. When you have confirmed appropriate position of the stent via fluoroscopy and/or direct visualization, fully remove the wire guide. **NOTE**: To reposition the stent, advance the wire guide back through the stent and into the bladder to straighten the stent. The stent can then be repositioned to the appropriate location.
7. Slide the adapter to the proximal end of the stent and gently tighten it.
8. Suture the stent to the skin. **NOTE**: You may also tape or suture a retention disc to aid in securing the stent. A dressing may be applied.
9. Use a connecting tube to connect the stent to a drainage bag.

Stent Removal

1. Maintain access by passing a wire guide through stent and down into the bladder.
2. While maintaining wire guide access with one hand, remove the stent with the other hand.

HOW SUPPLIED

Supplied sterilized by ethylene oxide gas in peel-open packages. Intended for one-time use. Sterile if package is unopened and undamaged. Do not use the product if there is doubt as to whether the product is sterile. Store in a dark, dry, cool place. Avoid extended exposure to light. Upon removal from the package, inspect the product to ensure no damage has occurred.

REFERENCES

These instructions for use are based on experience from physicians and (or) their published literature. Refer to your local Cook sales representative for information on available literature.

A symbol glossary can be found at https://cookmedical.com/symbol-glossary

MR Conditional

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