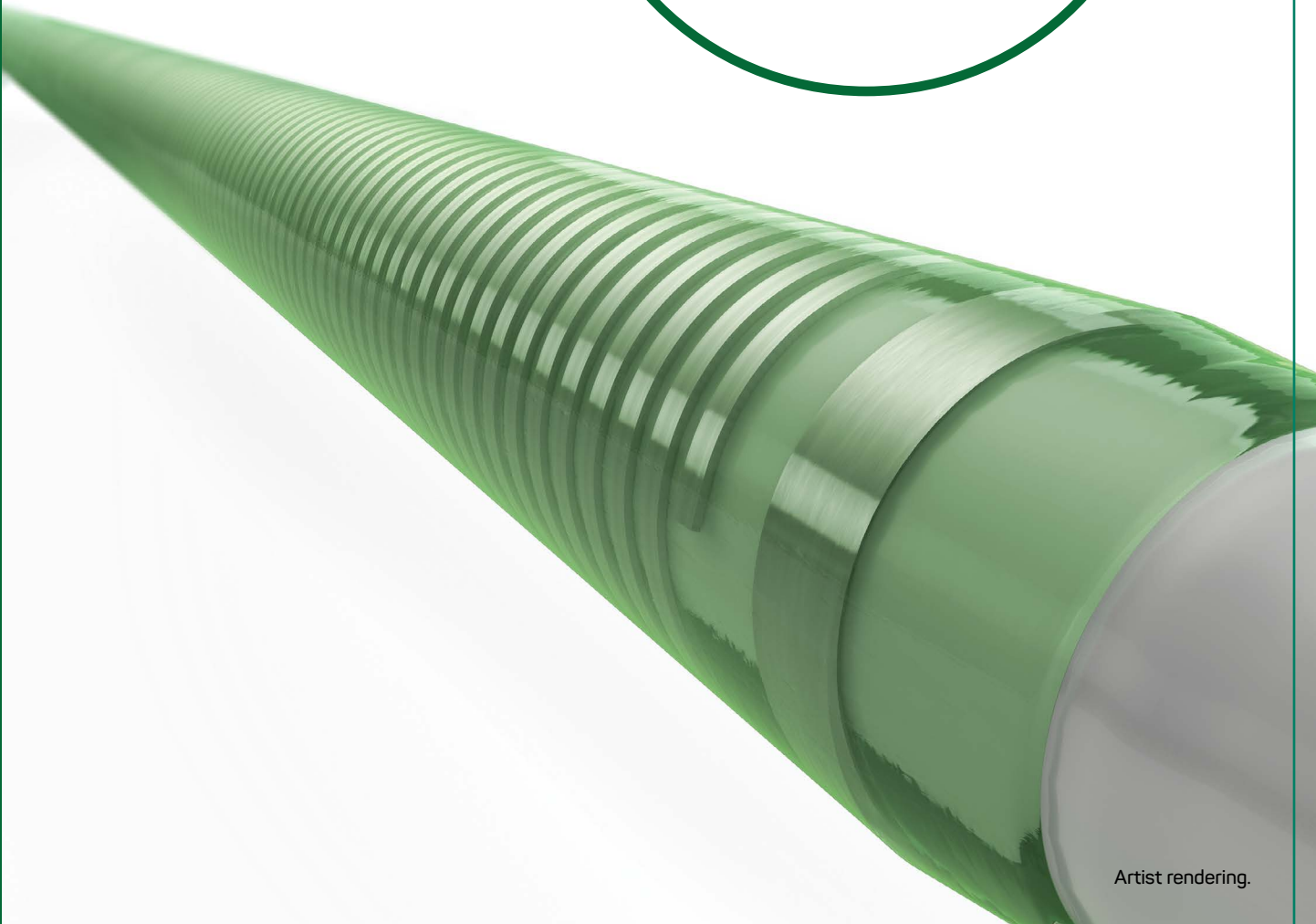


# Proxis™

URETERAL ACCESS SHEATH

Get closer.



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ACCESS SHEATH

Hydrophilic coating designed to help ease insertion\*

A smooth dilator-sheath transition is achieved by increasing the diameter of the dilator near the end of the sheath to help minimize the space between components\*

The intuitive locking mechanism snaps together to help ensure the sheath and dilator components are secured together before advancing into the urinary tract\*



**Indications for Use:**

The Proxis™ ureteral access sheath is indicated for use in endoscopic urology procedures where ureteral dilation and ureteral access is desired for injection of fluids and insertion and removal of endoscopes and related instruments.

**Contraindications:**

- Patients who are contraindicated for retrograde urological procedures
- Patients who are contraindicated for antegrade urologic procedures, including but not limited to patients with blood clotting anomalies due to coagulopathies or pharmacological anticoagulations
- Patients who have the presence of tight strictures which would limit the use of the device
- Patients who have the presence of large obstructing distal ureteral calculi

**Warning:**

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure, which in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transition of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. Do not use if barrier is damaged. After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practices and with applicable laws and regulations.

**CAUTION:** Federal (U.S.A.) Law restricts this device sales by or on the order of a physician.

**Precautions:**

The recommendations given are meant to serve only as a basic guide to the utilization of this access sheath. The ureteral access sheath should not be used without comprehensive knowledge of the indications, techniques, and risks of the procedure.

To minimize resistance during advancement, ensure the hydrophilic coating on the dilator and sheath is activated with saline or sterile water prior to placement. Do not advance sheath without the dilator in place as this could lead to trauma or injury to patient. Do not bend the device prior to placement as this could damage the integrity of the device and result in patient injury. Do not advance or withdraw device if any resistance is encountered during placement or removal without determining cause and taking action.

**Adverse Events**

Potential adverse events associated with the use of the transurethral access device include, but are not limited to:

- Mucosal irritation, inflammation and edema
- Urethral strictures
- Acute bleeding or hemorrhage
- Urethral, bladder, or ureteral perforation
- Other injury to the urinary tract

Item Number	Outer Dilator/Sheath Diameter (Fr)	Length (cm)
231025	10 / 12	25
231035	10 / 12	35
231045	10 / 12	45
231225	12 / 14	25
231235	12 / 14	35
231245	12 / 14	45

\*Data on file; preclinical testing may not correlate to outcomes in humans.

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Davol Rubber Company, Providence, Rhode Island, begins to manufacture the Foley catheter. Bard becomes the exclusive distributor for the Foley catheter and other Davol latex products.