Navigator™ HD Ureteral Access Sheath Set with Hydrophilic Coating Prescriptive Information

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.
Caution: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Information for use only in countries with applicable health authority registrations. Material not intended for use in France.

Warning
Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

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 transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

Intended Use/Indications for Use
The Navigator HD Ureteral Access Sheath is indicated for use in endoscopic procedures to facilitate the passage of endoscopes, urological instruments and for the injection of fluids into the urinary tract.

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 use of the device.
- Patients who have the presence of large obstructing distal ureteral calculi.

Precautions
The recommendations given are meant to serve only as a basic guide to the utilization of this access sheath set. The ureteral sheath set 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 bend or kink the dilator or sheath prior to placement; to do so could damage the integrity of the device and result in patient injury.

Precaution
In the event of a dilator tip detachment, remove the tip using standard surgical technique, taking into consideration the patient's medical status and anatomy.

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
- Uretheral strictures
- Acute bleeding or hemorrhage
- Urethral, bladder, or ureteral perforation/avulsion
- Other injury to the urinary tract