Brief Summary Document

Overview

Product	Navigator™ HD & Navigator™ Ureteral Access Sheath Set– IFU 51605158-01

Rx Statement

CAUTION: *Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.*

This product is intended for use only by clinicians with adequate training and experience in endourological procedures.

Prior to use, please refer to all applicable "Instructions for Use" for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator's Instructions.

Content

INTENDED USE/INDICATIONS FOR USE

The Navigator & 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 anticoagulants.
- Patients who have the presence of tight ureteral 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.
- 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.
- If resistance is encountered during advancement or withdrawal of the device, STOP. DO NOT continue without first determining the cause of the resistance and taking remedial action.
- DO NOT advance the sheath without the dilator in place; to do so could cause injury to the patient.

POTENTIAL ADVERSE EVENTS

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

- Tissue damage, inflammation, and edema
- Post-operative urethral/ureteral strictures
- Bleeding or hemorrhage
- Urethral, bladder, or ureteral perforation/ laceration or avulsion
- Infection
- Pain
- Urinary symptoms, such as urgency and retention
- Other injury to the urinary tract
- Adverse events may require additional medical or surgical intervention

There are currently no known WARNINGS associated with the use of this device.