

NaviGuide™ Percutaneous Access Needle

Prescriptive Information

Caution: US Federal law restricts this device to sale by or on the order of a physician.

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 Percutaneous Access Needle is intended to facilitate access into the renal pelvis, and to advance guidewires into the collecting system in an antegrade manner.

Contraindications

None known.

Warnings

- If the guidewire must be withdrawn while the cannula is inserted, remove both cannula and wire as a unit to prevent the cannula from damaging the guidewire.
- Use of this device should be restricted to use by or under the supervision of physicians trained in urologic and percutaneous access procedures. Care should be exercised to prevent accidental advancement into other non-intended puncture areas.

Potential Adverse Events

The following are some of the complications which can result from the use of access needles:

- Renal perforation
- Ureteral perforation
- Hemorrhage
- Edema
- Tissue Damage
- Infection

Precautions

- Before removing the inner stylet, confirm the stylet hub is fully unlocked by turning the hub a ¼ counterclockwise turn (as denoted by the visual cue on the top of the stylet hub) to ensure needle access is not inadvertently compromised.
- If urine cannot be confirmed, STOP, determine fluoroscopic position and reintroduce assembled access needle if needed.
- If resistance is encountered during advancement or withdrawal, STOP. DO NOT continue without first determining cause of resistance and taking remedial action.