Percutaneous Access Needle 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 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 for Use
None known.

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

- Renal perforation
- Ureteral perforation
- Hemorrhage
- Edema

Precaution: If urine cannot be confirmed, **STOP**, determine fluoroscopic position and reintroduce assembled access needle if needed.

Precaution: If resistance is encountered during advancement or withdrawal, **STOP. DO NOT** continue without first determining cause of resistance and taking remedial action.

Warning: If the guidewire must be withdrawn while the cannula is inserted, remove both cannula and wire as a unit to prevent the cannula from damaging the guidewire.

Warning: 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.