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AccuStick™ Needle or Guidewires

Introducer Needle or Guidewire for use with AccuStick™ II Introducer System

Rx ONLY

Caution: Federal Law (USA) 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.

ADVERSE EVENTS

Potential risks exist for serious complications to include:

- Perforation of a vessel or viscus
- Laceration of a vessel or viscus
- Bleeding
- Wire or catheter embolism
- Extravasation
- Hematoma
- Hemothorax
- Hydrothorax
- Inflammation, necrosis or scarring
- Risks normally associated with percutaneous interventional procedures
- Pain in region
- Skin infection
- Edema

These and other complications are well documented in medical literature. Use of the AccuStick II Introducer System with radiopaque marker should be reserved by persons knowledgeable of the risks involved and qualified in the procedures.

PRECAUTIONS

None known.

DEVICE DESCRIPTION

The AccuStick Needle or Guidewires are used with the AccuStick II Introducer System. The AccuStick II Introducer System with radiopaque marker is a coaxial dilator sheath with locking stiffening cannula.

INTENDED USE/INDICATIONS FOR USE

The AccuStick Needle or Guidewires are used with the AccuStick II Introducer System. The AccuStick II Introducer System with radiopaque marker facilitates introduction and placement of a guidewire.

PRIOR TO USE

How Supplied

Do not use if package is opened or damaged. Do not use if labeling is incomplete or illegible.

The AccuStick II Introducer System with radiopaque marker is supplied sterile in a sealed pouch and intended for single-use only. Prior to use, inspect both the sterile seal and the device for any damage. If there is a breach to the seal or if the product is damaged, DO NOT USE. Immediately return defective package/product to Boston Scientific for replacement.

CONTRAINDICATIONS

None known.

WARNINGS

None known.

HANDLING AND STORAGE

Store in a cool, dry, dark place.

INSTRUCTIONS FOR USE

Caution: Device should be used for non-vascular procedures only.

Precaution: Advancement and/or withdrawal of 0.47/0.97 mm (0.018 in/0.038 in) wires should be smooth and without resistance. **DO NOT USE EXCESSIVE FORCE.** If resistance is felt, carefully remove wire(s) and system as a unit.

1. Insert 21 gauge (0.83 mm) x 15 cm needle and opacity and/or sample to verify needle tip location.
2. Carefully advance 0.47 mm (0.018 in) wire through needle. See Figure 1.

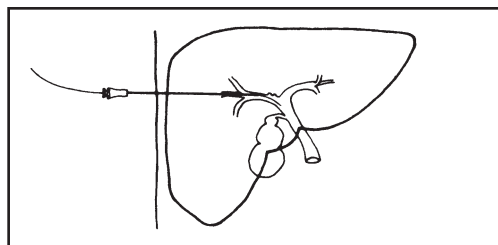


Figure 1.

3. Remove 21 gauge (0.83 mm) x 15 cm needle.
4. Advance Percutaneous Introducer System over 0.47 mm (0.018 in) wire into position.

5. For optimum placement the sheath (blue hub) may be advanced over dilator/cannula until distal tips are aligned. Alignment is indicated when reference mark on dilator is even with proximal hub of sheath. See Figure 2.

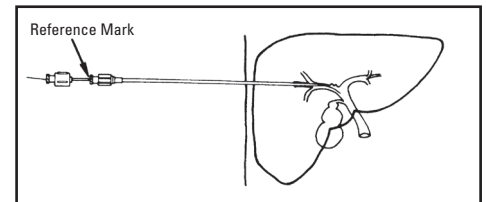


Figure 2.

6. Remove cannula and 4F (≤1.47 mm) dilator.
7. Advance 0.97 mm (0.038 in) wire through sheath out end hole. See Figure 3.

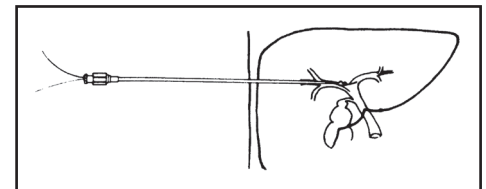


Figure 3.

Note: The 0.47 mm (0.018 in) wire can be left in the sheath while the working wire is placed. Remove 0.47 mm (0.018 in) wire after placement of working wire.

8. Remove sheath.

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

Prices, models and availability are subject to change without notice.

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 **Recyclable
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