INSTRUCTIONS FOR USE

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Device Description
An introducer kit consisting of a 0.018 in. guidewire, a radiopaque coaxial micro-introducer and a 21G echogenic introducer needle.

Indications for Use
The Coaxial Micro-Introducer Kit is indicated for percutaneous introduction of up to a 0.038 in. guidewire or catheter into the vascular system through an initial puncture of a 21G introducer.

Contraindications
None known.

Warnings
• Contents supplied STERILE using ethylene oxide (EO). Non-Pyrogenic. Do not use if sterile barrier is opened or damaged. Do not reuse, reprocess or resterilize.
• This device has been designed for single patient use only. Reusing this medical device bears the risk of cross-patient contamination as medical devices – particularly those with long and small lumina, joints and/or crevices between components – are difficult or impossible to clean once body fluids or tissues with potential pyrogenic or microbial contamination have had contact with the medical device for an indeterminable period of time. The residue of biological materials can promote the contamination of the device with pyrogens and microorganisms, which may lead to infectious complications.
• Do not resterilize. After resterilization, the sterility of the product is not guaranteed because of an indeterminable degree of potential pyrogenic or microbial contamination which may lead to infectious complications. Cleaning, reprocessing and/or resterilization of the present medical device increases the probability that the device will malfunction due to potential adverse effects on components that are influenced by thermal and/or mechanical changes.
• After use, this product may be a potential biohazard. Handle and dispose in accordance with accepted medical practice and applicable local, state and federal laws and regulations.
• Place a sterile gloved finger over the hub of the needle to minimize blood loss and risk of air aspiration. The risk of air embolism is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver.
• Place a sterile gloved finger over the orifice of the sheath to minimize blood loss and risk of air aspiration. The risk of air embolism is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver.
• The guidewire should not be withdrawn through the needle. Damage or shearing of the guidewire may occur. If the guidewire tip must be withdrawn while the needle is inserted, remove both the needle and the wire as a unit.

Precautions
• Examine the package carefully before opening to confirm its integrity and that the expiration date has not passed. The product is supplied in a sterile package and is non-pyrogenic. Do not use if the package is damaged, opened or the expiration date has passed.
• Carefully read and follow all instructions prior to use.
• Only qualified healthcare practitioners should insert, manipulate and remove this device.

Potential Adverse Reactions
• Perforation of a vessel or viscus
• Laceration of a vessel or viscus
• Bleeding
• Hematoma formation
• Extravasation
• Inflammation, necrosis or scarring
• Pain in region
• Skin infection
• Edema
• Air embolus
• Brachial plexus injury
• Cardiac arrhythmia
• Cardiac tamponade
• Guidewire embolus
• Hemothorax
• Hydrothorax
• Pneumothorax

Directions for Use

Handling & Storage
Store in a cool, dry, dark place.

1. Gain percutaneous access with the 21G introducer needle.

WARNING: Place a sterile gloved finger over the hub of the needle to minimize blood loss and risk of air aspiration. The risk of air embolism is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver.

2. Advance the 0.018 in. guidewire through the 21G introducer needle.
WARNING: The guidewire should not be withdrawn through the needle. Damage or shearing of the guidewire may occur. If the guidewire tip must be withdrawn while the needle is inserted, remove both the needle and the wire as a unit.

3. Withdraw the 21G introducer needle.
4. Advance the micro-introducer (introducer sheath/dilator) over the 0.018 in. guidewire.
5. Remove the dilator and 0.018 in. guidewire, leaving the sheath positioned in the vasculature.

WARNING: Place a sterile gloved finger over the orifice of the sheath to minimize blood loss and risk of air aspiration. The risk of air embolism is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver.

6. Advance up to a 0.038 in. guidewire or catheter through the sheath.
7. Remove the sheath, leaving the guidewire or catheter positioned in the vasculature.

3. Withdraw the 21G introducer needle.
4. Advance the micro-introducer (introducer sheath/dilator) over the 0.018 in. guidewire.
5. Remove the dilator and 0.018 in. guidewire, leaving the sheath positioned in the vasculature.

WARNING: Place a sterile gloved finger over the orifice of the sheath to minimize blood loss and risk of air aspiration. The risk of air embolism is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver.

6. Advance up to a 0.038 in. guidewire or catheter through the sheath.
7. Remove the sheath, leaving the guidewire or catheter positioned in the vasculature.