

MICROACE™

Advanced Micro Access System

INSTRUCTIONS FOR USE

PRODUCT DESCRIPTION

The Micro ACE™ Advanced Micro Access System utilizes a small coaxial introducer with dilator and guide wire for placement of larger diameter guide wires into the vasculature system when a small needle stick is preferred.

The Micro ACE consists of the following components. These components may be packaged in a single pouch or may be packaged separately.

- One (1) 4F or 5F coaxial introducer/dilator pair or 4F or 5F coaxial introducer/stiffened dilator pair
- One (1) 21 gauge introducer needle or 21 gauge echo enhanced introducer needle
- One (1) 0.018" (0.46mm) guide wire

INTENDED USE

The Micro ACE is intended for percutaneous placement of a 0.035" (0.89mm) or 0.038" (0.97mm) guide wire into the vascular system.

WARNINGS

Withdrawal, pull back, or manipulation of the guide wire distal tip through the needle tip may result in breakage or embolization.

Do not advance the guide wire if resistance is met.

CAUTIONS

- Read instructions prior to use
- RX Only
- Store in a cool dry place
- This device is intended for single use only. Do not reuse or resterilize.



POTENTIAL COMPLICATIONS

Potential complications include risks normally associated with percutaneous diagnostic and/or interventional procedures. Other complications include, but are not limited to:

- Air embolism
- Infection
- Hematoma
- Bleeding
- Thrombus formation
- Pseudo aneurysm formation
- Guide wire embolization
- Perforation or laceration of the vessel wall

INSTRUCTIONS FOR USE

1. Identify the insertion site and prepare the site using proper aseptic technique and local anesthesia as required.
2. Insert the 21 gauge introducer needle using standard technique.
3. Carefully advance the flexible end of the 0.018" (0.46mm) guide wire through needle. Advance the guide wire as far as appropriate. Verify correct positioning.
WARNING: Do not advance guide wire if resistance is met.
4. Remove needle while maintaining the 0.018" (0.46mm) guide wire in position.
WARNING: Withdrawal, pull back, or manipulation of the guide wire distal tip through the needle tip may result in breakage or embolization. To avoid guide wire damage during manipulation, remove the introducer needle and proceed to step 5.
5. Insert the coaxial introducer/dilator pair over the 0.018" (0.46mm) guide wire and advance to the desired position.
6. Remove dilator and 0.018" (0.46mm) guide wire leaving the introducer in position.
NOTE: Place a finger over the hub of the introducer to minimize blood loss and risk of air aspiration.
7. Insert 0.035" (0.89mm) or 0.038" (0.97mm) guide wire through introducer.
8. Remove introducer, leaving 0.035" (0.89mm) or 0.038" (0.97mm) guide wire in place.

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|  | Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. |
|  | Manufacturer |



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