English

MICRO ACE™

Advanced Micro Access System

INSTRUCTIONS FOR USE

PRODUCT DESCRIPTION
The Merit® Micro ACE™ Advanced Micro Access System utilizes a small coaxial introducer with .introducer with reinforced coil, marker band, dilator, and guide wire for placement of larger diameter guide wires into the vasculature system when a small needle stick is preferred.

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

INDICATIONS FOR USE
The Merit Micro ACE is indicated for patients requiring percutaneous placement of a 0.035" (0.89 mm) or 0.038" (0.97 mm) guide wire into the vascular system per physician assessment.

CLINICAL BENEFITS
The Merit Micro Ace device has indirect clinical benefits as it facilitates introduction and placement of guidewires into the vascular system for the treatment of various medical conditions.

CONTRAINDICATIONS
None known

INTENDED USERS AND PATIENTS
The Merit Micro ACE is intended to be used by trained physicians or healthcare professionals familiar with the indications, limitations, and potential complications of percutaneous vascular access.

The Merit Micro Ace is intended for patients who require vascular access for percutaneous introduction of guidewires for treatment of various medical conditions

WARNINGS
- This product contains Cobalt. Please consider the risk and impact of using this device, especially in children, pregnant or breastfeeding women, or other vulnerable patient groups.
- In the EU, any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the applicable Member State.
- Do not advance guide wire if resistance is met.
- Withdrawal, pull back, or manipulation of the guide wire distal tip through the needle tip may result in breakage or embolization
- Store in a cool dry place

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 AND RESIDUAL RISKS
Potential complications include risks normally associated with percutaneous diagnostic and/or interventional procedures. Other complications include, but are not limited to:
- Air embolism
- Thrombus formation
- Infection
- Pseudo aneurysm formation
- Hematoma
- Guide wire embolization
- Bleeding
- Perforation or laceration of the vessel wall
- Additional Procedure
- Inflammation

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. Optionally confirm the tip position using fluoroscopy to image the marker band.
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.

WARNINGS
- After use, dispose of device in a manner consistent with standard protocols for biohazard waste disposal.
- For single patient 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.

	Caution
	Do not use if package is damaged and consult instruction for use
REF	Catalog number
LOT	Batch code
MD	Medical Device
UDI	Unique Device Identifier
	Single use
	Do not resterilize
	Consult Instructions for Use For electronic copy scan QR Code, or go to www.merit.com/ifu and enter IFU ID Number. For printed copy available within seven calendar days, call U.S.A. or EU Customer Service.
STERILE EO	Sterilized using ethylene oxide
℞ ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Single sterile barrier system
	Use by date: YYYY-MM-DD
	Date of manufacture: YYYY-MM-DD
	Manufacturer
EC REP	Authorized Representative in European Community
	Keep away from sunlight
	Keep dry

Basic UDI-DI:0884450BUDI407PR

MERIT MEDICAL®

CE 2797

www.merit.com

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EC REP
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