MERIT S-MAK XL™ Stiffened Mini Access Kit

INSTRUCTIONS FOR USE

PRODUCT DESCRIPTION

The Merit® S-MAK XL™ (Stiffened Mini Access Kit) utilizes a coaxial introducer with dilator and guide wire for placement of larger diameter guide wires, laser fibers, or catheters into the vasculature system when a small needle stick is preferred.

The Merit S-MAK XL consists of the following components. These components are packaged in a single pouch.

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

INTENDED USE

The Merit S-MAK XL is intended for percutaneous placement of up to a 0.038" (0.97mm) guide wire, laser fiber, or catheter into the vascular system.

Clinical Benefits

The S-MAK XL devices provide access and allow percutaneous introduction of guidewires, laser fibers or catheters into the vascular system for the treatment of various medical conditions.

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, laser fiber, or catheter if resistance is met. Do not activate the laser fiber when the tip of the laser fiber is inside of the access sheath.

CAUTIONS

- Read instructions prior to use
- **℞ 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

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.

WARNING: After use, dispose of device in a manner consistent with standary protocols for biohazard waste disposal.

SYMBOL	DESIGNATION
℞ ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Caution
	Single use
	Do Not Use If Package is Damaged and Consult Instruction for Use
STERILE EO	Sterilized using ethylene oxide.
REF	Catalog Number
LOT	Lot Number
	Use By: YYYY-MM-DD
	Do Not Re-sterilize
	Date of Manufacture: YYYY-MM-DD
MD	Medical Device
	Single sterile barrier system
UDI	Unique Device Identifier
	Consult Instructions for Use For electronic copy scan QR code, or go to www.merit.com/ IFU and enter IFU ID. For printed copy, call U.S.A. or EU Customer Service
EC REP	Authorized Representative in European Community
	Manufacturer

MERIT MEDICAL®

CE 2797

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