MICRO-STICK® INTRODUCER SET
INSTRUCTIONS FOR USE

DESCRIPTION:
The Micro-Stick® Set is comprised of a .018" guidewire with radiopaque tip, 21GA introducer needle, and radiopaque coaxial introducer.

INTENDED USE:
The Micro-Stick® Set is indicated for percutaneous introduction of up to a 0.038 inch guidewire or catheter into the vascular system following a small 21 gauge needle stick. The Micro-Stick® Set is not intended for use in the coronary or cerebral vasculature.

POTENTIAL COMPLICATIONS:
Potential risks exist for serious complications to include:

- Air Embolus
- Bleeding
- Brachial plexus injury
- Cardiac arrhythmia
- Cardiac tampanade
- Extravasation
- Edema
- Hematoma
- Hydrothorax
- Inflammation, necrosis or scarring
- Laceration of a vessel or viscus
- Trauma/Perforation of a vessel or viscus
- Pain in region
- Skin infection
- Hemothorax
- Wire or catheter embolism

WARNINGS AND PRECAUTIONS:

- Federal (USA) law restricts this device to sale by or on the order of a physician.
- Product is sterile in unopened, undamaged package. Sterlized by ethylene oxide. STERILE EO
- Single use only. DO NOT RE-USE. Re-Use may lead to infection or illness/injury.
- Do not use if package is damaged.
- Do not resterilize.
- Do not advance the guidewire against resistance until the cause of the resistance has been determined.
- Do not insert or withdraw the guidewire forcibly from any component. The wire may break or unravel. If the guidewire becomes damaged, the introducer needle or sheath dilator and guidewire must be removed together.
- Caution when using this device. Be aware of sharps.
- Do not use if components are damaged, deformed or missing.
- Do not overtighten. Do not proceed if resistance is felt or interaction between components is failing.
- Discard biohazard according to facility protocol.

INSTRUCTIONS FOR USE:

1. Gain percutaneous access with the 21GA 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" guidewire through the 21GA needle. **CAUTION:** The guidewire should not be withdrawn through the 21GA needle.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 If the guidewire tip must be withdrawn while the needle is inserted, remove both the needle and the wire as a unit.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 21GA needle.
4. Advance the Micro-Stick® Introducer over the 0.018" guidewire.
5. Remove the dilator and the 0.018" guidewire, leaving the sheath in 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" guidewire or catheter through the sheath.
7. Remove the sheath, leaving the guidewire or catheter positioned in the vasculature.
8. Examine the device after it is removed from the patient to ensure no foreign material remains inside the patient.

Caution: If unable to tear sheath, stop the procedure.

Medcomp® does not recommend a particular technique for the use of this device. The physician should evaluate the appropriateness of the device according to individual patient conditions and his or her medical training and experience.

WARRANTY

Medcomp® WARRANTS THAT THIS PRODUCT WAS MANUFACTURED ACCORDING TO APPLICABLE STANDARDS AND SPECIFICATIONS. PATIENT CONDITION, CLINICAL TREATMENT, AND PRODUCT MAINTENANCE MAY AFFECT THE PERFORMANCE OF THIS PRODUCT. USE OF THIS PRODUCT SHOULD BE IN ACCORDANCE WITH THE INSTRUCTIONS PROVIDED AND AS DIRECTED BY THE PRESCRIBING PHYSICIAN.

Because of continuing product improvement, prices, specifications, and model availability are subject to change without notice. Medcomp® reserves the right to modify its products or contents without notice.

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SYMBOL TABLE

5.1.1	Manufacturer*	5.6.3	Non-pyrogenic*
5.1.4	Use-by Date*	5.3.2	Keep Away from Sunlight*
5.4.2	Do Not Re-use*	5.2.6	Do Not Resterilize*
5.3.4	Keep Dry*	Rx Only	Prescription Use Only***
5.1.5 LOT	Batch/Lot Number*	5.1.6 REF	Catalogue Number*
5.2.8	Do Not Use if Package is Damaged*		
5.1.2 EC REP	Authorized Representative in the European Community*		
5.3.7	Upper and Lower Temperature Limits*		
5.2.3 STERILE EO	Sterilized Using Ethylene Oxide*		
5.4.4	Caution, consult Accompanying Documents		

*** This symbol is in accordance with ISO 15223-1.**

***** FDA guidance Use of Symbols in Labeling.**

Note: Temperature symbols : "This symbol only applies to kits with drugs".

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