

GlideAccess™ System

PERCUTANEOUS SHEATH INTRODUCER KIT

INTENDED USE

The percutaneous sheath introducer kit is intended to be used for percutaneous introduction of 0.035 inch (approx. 0.89mm) or 0.038 inch (approx. 0.97mm) guide wires into the vascular system following a small 21 gauge needle puncture.

The device is intended for single use only. Do not reuse. Do not resterilize. Do not reprocess as reprocessing may compromise the biocompatibility and functional integrity of the product. Do not use if unit package is damaged or open.

POTENTIAL COMPLICATIONS

- Perforation of a vessel or viscus
- Laceration of a vessel or viscus
- Bleeding
- Hematoma
- Extravasation
- Inflammation, necrosis or scarring
- Pain in region
- Skin infection
- Edema

DESCRIPTION

This kit contains the following 3 devices - 1) a coaxial dilator, 2) a 0.018" guide wire and 3) an entry needle. All components that enter blood vessels are radiopaque.

INSTRUCTIONS FOR USE

1. Gain percutaneous access with a 21 Ga. entry needle.
2. Advance a 0.018 inch guide wire through the 21 Ga. needle, according to the enclosed instructions for use.
3. Withdraw the entry needle while leaving the 0.018 inch guide wire in place.
4. Advance the co-axial micro-introducer over the 0.018 inch guide wire.
5. Remove the inner dilator and 0.018 inch guide wire from the coaxial micro-introducer sheath.
6. Advance a 0.035 inch or 0.038 inch guide wire or catheter through the introducer.
7. Dispose of all contaminated articles according to facility protocol observing State and Federal regulations for biohazard disposal.

CAUTION: Rx Only

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

Manufactured by: Terumo Medical Corporation
Elkton, Maryland 21921

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