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FRONTLINE MEDICAL PRODUCTS℠
SafetyNET®
Guidewire Introducer

THINLINE®Access Kit Directions for Use

DESCRIPTION

The THINLINE® Access Kit is comprised of a .018" (Stainless Steel or Nitinol) Probe™ guidewire with a radiopaque tip, 21GA SafetyNET® Guidewire Introducer needle with an iECHO® echogenic tip, and radiopaque coaxial introducer. Additionally, a hemostasis valve adapter with a stopcock is included (Radial and Pedal kits only).

INTENDED USE

The THINLINE® Access Kit is indicated for percutaneous introduction of up to a 0.021" guidewire or catheter into the vascular system following a small 21 gauge needle stick. The THINLINE®Access Kit is not intended for use in the coronary or cerebral vasculature. The additional valve adapter is intended to minimize blood loss and facilitate aspiration or infusion (radial and pedal kits only).

POTENTIAL COMPLICATIONS

Potential risks exist for serious complications to include:

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

WARNINGS AND PRECAUTIONS

- Read instructions prior to use.
- Product is sterile in unopened, undamaged package.
- Single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may lead to device failure or contamination. Reuse, reprocessing or resterilization may lead to patient injury, infection, cross-infection, illness or death.
- 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.
- Federal (USA) law restricts this device to sale by or on the order of a physician.

DIRECTIONS 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. For clarification, see DFU on reverse side.
4. Advance the Micro 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 0.021" guidewire or catheter through the sheath.
7. Remove the sheath, leaving the guidewire or catheter positioned in the vasculature.

DIRECTIONS FOR HEMOSTASIS VALVE ADAPTER USE

Radial and Pedal Kits only

1. Flush hemostasis valve adapter, side arm and stopcock prior to use.
2. The hemostasis valve adapter may be attached to Micro Introducer prior to insertion into vessel (step 4 above) or after catheter is in place.
3. Do not over-tighten the luer fitting of the hemostasis valve adapter.
4. Upon removal of hemostasis valve adapter proper precautions should be taken to prevent bleeding.

CAUTIONS:

- The closing force of the hemostasis valve adaptor may alter or impair the function of some catheters.
- Damage to the valve may occur if inner catheter is withdrawn rapidly.

WARRANTY

FRONTLINE MEDICAL PRODUCTS 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.

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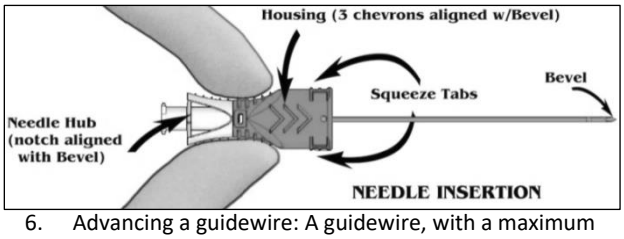
DIRECTIONS FOR SafetyNET® GUIDEWIRE INTRODUCER USE

SafetyNET®Guidewire introducers are intended to introduce a guidewire into a patient for general surgery or into the vascular system, and to provide a means of protecting the needle point after use to reduce the risk of accidental needle stick injury.

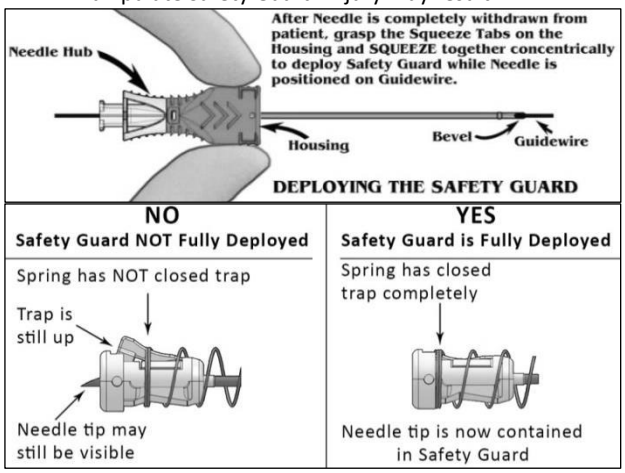
1. Remove guidewire introducer needle, taking care to not remove needle cover until you are ready to use needle.
2. Using aseptic technique, prepare the patient for the procedure. Select the desired vessel entry site.
3. Grasp clear needle hub or the base (proximal end) of the colored housing. With other hand, grasp middle of needle cover on the annular rings and pull cover straight off needle.
4. A syringe may be attached to needle's clear luer hub at discretion of user.
   NOTE: Do not grasp distal end of colored housing to manipulate needle during procedure. Doing so may inadvertently deploy the spring-loaded needle Safety Guard and disrupt the procedure.
   CAUTION: Never attempt to disable, manipulate, or re-set the spring-loaded Safety Guard once it has been deployed. Injury may result.
5. Needle insertion: While gripping clear needle hub, or base (proximal end) of colored housing, needle may be inserted into tissue to desired location. The iECHO® needle includes an echogenic feature at the distal tip allowing pinpoint placement of the needle into the vessel under ultrasound guidance. The clear hub has a "bevel up" notch, and the colored housing has three raised chevrons aligned with top of needle bevel to allow proper bevel orientation during the procedure. Clear needle hub allows visualization of blood flashback. See Figure below for product features and proper gripping position during needle insertion.



6. Advancing a guidewire: A guidewire, with a maximum diameter as specified on the package label, may be threaded through needle to the desired location.
   CAUTION: To avoid guidewire damage, do not withdraw guidewire through needle.
7. Removing the needle: While gripping clear needle hub or proximal portion of colored housing with the dominant hand, pull needle back until it has exited tissue a short distance but is still on guidewire. Use non-dominant hand to stabilize guidewire and control bleeding.

CAUTION: To ensure proper operation of Safety Guard, do not deploy Safety Guard until needle point has fully exited patient.

8. Deploying the Safety Guard: While keeping needle on guidewire, grasp the Squeeze Tabs at distal end of colored housing with thumb and forefinger. Squeeze the tabs together (concentrically) to release the spring-loaded Safety Guard. Safety Guard should move forward to cover end of needle point, but trap will not close and Guard will not lock into place until needle has been pulled off guidewire completely.
   CAUTION: If Safety Guard does not release and/or move forward to end of needle, do not attempt to manipulate Safety Guard. Injury may result.



9. Needle disposal: Withdraw needle completely off guidewire. Safety Guard's trap should close, and spring should move forward to end of Safety Guard to lock Guard into place. Handle and dispose of used needle according to institutional policies and procedures for contaminated sharps.
   CAUTION: Always treat used needle as a contaminated sharp, even if the Safety Guard has been deployed. The presence of a safety feature is not a substitute for good technique. If Safety Guard does not fully deploy or appear to lock into place, do not try to manipulate Safety Guard, but dispose of used needle immediately per institutional policies and procedures