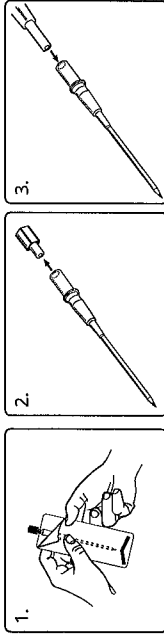




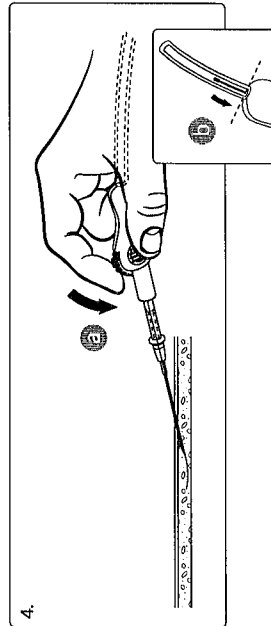
How to hold SonoStik®



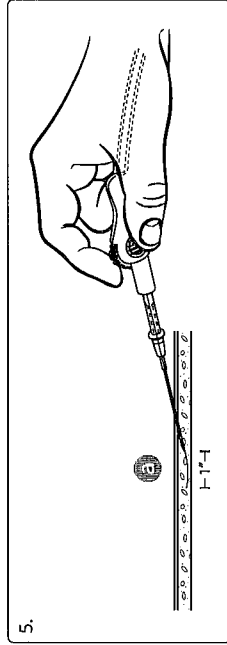
How to use SonoStik®



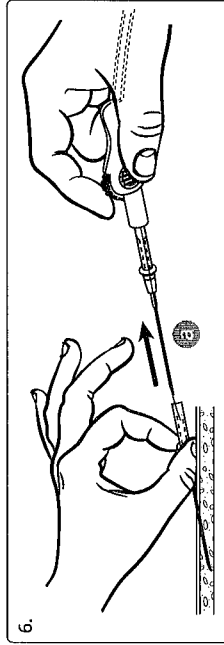
1. Remove one of the recommended catheter and needle sets from the packaging.
2. Remove the flash cap from the end of the needle.
3. Insert the proximal slip tip connector into the distal end of the needle until there is a snug fit and the tip of the male lure connector is contacting the needle.



4. Once you get a flash, you can begin to introduce the guide wire. Begin moving the wheel forward to advance the wire into the vessel (a). The wire has to travel from the device through the length of the needle. There is a plastic stop on the proximal end of the guide wire which can be used for further confirmation of guide wire movement (b).



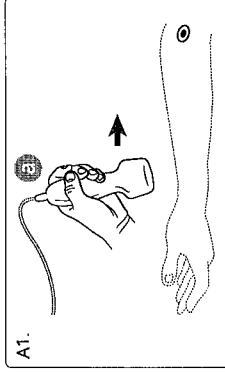
5. Advance the guide wire into the vessel approximately 1", depending on the catheter length (a).



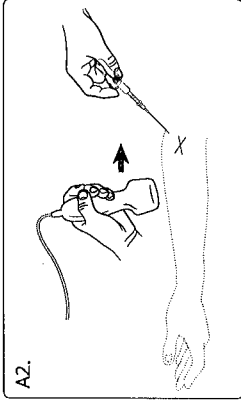
6. Using your index finger, advance the catheter over the needle and guide wire into the vessel. Remove the SonoStik® introducer guide wire and needle as a single unit (a). The wire does not need to be retracted nor does the SonoStik® device need to be removed from the needle. The entire assembly can be removed in one step and disposed of in a sharps container.

WARNING: DO NOT EXTEND THE GUIDE WIRE BEYOND THE TIP OF THE NEEDLE BEFORE INSERTION. DOING SO COULD DAMAGE THE GUIDE WIRE AND DISRUPT EVIDENCE OF A FLASH.

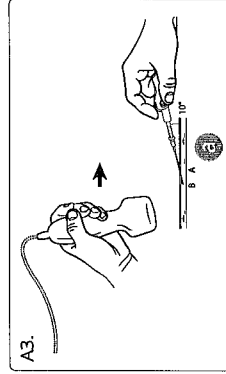
Appendix: Ultrasound and Catheter Placement



- A1. Using a desired ultrasound system (a), place the wand on the patient's arm to locate the vessel in the transverse plane.



- A2. Once an appropriate vessel is located, use the mated device and needle to begin puncture. This may be done while holding the SonoStik® device in one hand, and the ultrasound wand in the other.



- A3. Push the needle through the tissue at an appropriate angle of approach at approximately 10°. The needle should travel through subcutaneous tissue until it reaches the vessel. While advancing the needle, you should also move the ultrasound wand forward simultaneously in order to fully visualize penetration. Once you are in the vessel, you should observe a blood flash. The needle punctures the tissue at point A, travels through the tissue, and punctures the vein at point B (a).

Instructions For Use

Cat. # SON-PVI-01

SonoStik Guide Wire Introducer

Safety and Efficacy Considerations:

Do not use if package has been previously opened or damaged.

Warning: Prior to use read all package insert warning, precautions, and instructions. Failure to do so may result in severe patient injury or death.

The product is designed for single use only. Do not re-sterilize or reuse. Do not alter introducer or catheter components during insertion, use or removal.

The SonoStik Guide Wire Introducer is intended to be used with one of two 18 gauge IV catheter and needle sets—the B Braun Intracath Safety IV Catheter or the BD Angiocath IV. The Guide Wire Introducer works best with catheter and needle sets between 1 and 2.5 inches long.

Procedure must be performed by trained personnel versed in anatomical landmarks, safe technique and potential complications.

Indications for Use:

The SonoStik IV Guide Wire Introducer device is used to facilitate placing a catheter through the skin into a vein or artery of the peripheral vasculature. The Entry Needle is an accessory device which is used to gain access to the vein or artery, for placement of the mini Guide Wire. The mini Guide Wire is an accessory device which is used for placement of the sheath into the vein or artery. The SonoStik Guide Wire Introducer is not intended for use in the coronary arteries or neurovasculature.

Warnings and Precautions:

1. **Warning:** Practitioners, when attempting to place the catheter into the artery or vein with a guide wire, must be aware of complications associated with arterial procedures, including bacteremia, septicemia, vessel wall perforation, intravascular clotting and embolization, hematoma, arterial spasm, tissue necrosis, hemorrhage, thrombosis, peripheral ischemia

and infarction, peripheral nerve damage, air embolism, and occlusion.

2. **Warning:** In brachial procedures, collateral flow cannot be guaranteed, and therefore intravascular clotting can result in tissue necrosis.

3. **Warning:** In radial artery procedures, practitioners must ascertain that definite evidence of collateral ulnar flow exists.

4. **Warning:** Care should be exercised that guide wire does not puncture artery or vein, shear off or that the catheter is not inadvertently kinked at hub area when securing catheter to patient. Kinking may weaken wall of catheter and cause a fraying of fatigue or material, leading to possible separation of the catheter.

5. **Warning:** Due to risk of exposure to HIV or other blood borne pathogens, health care workers should routinely use universal blood and body-fluid precautions in the care of all patients.

6. **Precaution:** Alcohol and acetone can weaken the structure of polyurethane materials. Check ingredients of prep sprays and swabs for acetone and alcohol content.

Acetone: Do not use acetone on SonoStik Device or guide wire surface.

Acetone may be applied to the skin but must be allowed to dry completely prior to applying dressing.

Alcohol: Do not use alcohol to soak catheter surface or to restore catheter patency. Care

should be taken when instilling drugs containing high concentrations of alcohol. Always

allow alcohol to dry completely prior to applying dressing

7. **Precaution:** Some disinfectants used at the catheter insertion site contain solvents which can attack the guide wire or catheter material. Assure insertion site is dry before dressing.

8. **Precaution:** Indwelling catheter should be routinely inspected for desired flow rate, security of dressing, and possible migration. Do not use scissors to remove dressing to minimize the risks of cutting catheter.

A Suggested Procedure:

Use sterile technique.

1. Assess for adequate collateral arterial circulation,
2. Prep and drape anticipated puncture site per hospital protocol.
3. Use local anesthetic as required.
4. Remove the flash cap from the back of the cannulated needle catheter set. Insert the spring loaded mating tip of the introducer into the back end of the needle catheter set. Ensure there is a snug fit by holding the set stationary and gently but firmly pressing the introducer into the set so the mating tip is contacting the back end

of the needle, and forms a snug seal with the inside of the flash chamber.

5. Remove protective cover from needle. Trial advance and retract guide wire through needle using advancing wheel to ensure proper function. Move the advancing wheel towards you. **Precaution:** prior to insertion, actuating lever must be retracted proximally as far as possible or blood flashback may be inhibited

6. Puncture vessel using a continuous, controlled, slow, forward motion, avoid transfixing both vessel walls.

7. **Precaution:** If both vessel walls are punctured, subsequent advancement of guide wire could result in inadvertent sub-vessel placement. Blood flashback in clear tip of hub of introducer needle and/or confirmation of the introducer needle tip in the vessel indicates successful entry into vessel

8. Stabilize position of introducer needle and carefully advance guide wire using the advancing wheel.

9. **Precaution:** Do not advance guide wire unless there is blood flashback confirmation of needle tip in the vessel. **WARNING: DO NOT EXTEND THE GUIDE WIRE BEYOND THE TIP OF THE NEEDLE BEFORE INSERTION. DOING SO COULD DAMAGE THE GUIDE WIRE AND DISRUPT EVIDENCE OF A FLASH**

10. **Precaution:** If resistance is encountered while advancing guide wire do not force feed. **Warning:** Do not retract guide wire against edge of needle while in vessel to minimize the risk of guide wire damage. If resistance is encountered during guide wire advancement withdraw entire unit and attempt new puncture.

11. Advance the guide wire a maximum of 1 to 2mm further into vessel

12. Firmly hold introducer needle hub in position and advance catheter forward, with a slight rotating motion over guide wire into vessel.

13. Hold catheter in place and remove needle/guide wire assembly. Blood flow indicates positive placement in the vessel. **Precaution:** Do not reinsert needle into catheter to minimize risk of catheter damage

14. Safely dispose of needle and guide wire assembly in sharps container

15. Attach desired stopcock, injection cap or connecting tubing to catheter hub. Secure catheter to patient in preferred manner. **Warning:** Care should be exercised that indwelling catheter is not inadvertently kinked at hub area when securing catheter to patient. Kinking may weaken wall of catheter and cause a fraying or fatigue of material, leading to possible separation of the catheter.

16. **Precaution:** Dress placed catheter according to hospital protocol.