

# TOTAL VEIN SYSTEMS™ INTRODUCER PRODUCTS

## APPLICATION

The Total Vein Systems™ Introducers are indicated for use in arterial and venous procedures requiring percutaneous introduction of intravascular devices. Curved tip Introducer allows for contralateral access to the iliac artery and selected vasculature.

Radiopaque banded introducers identify location of Introducer distal tip for positioning.

## CAUTIONS

- For single use only. Do not reuse or resterilize.
- Federal (USA) Law restricts this device to sale by or on the order of a physician.
- Physician should be familiar with insertion techniques of introducers using a guide wire (Seldinger/Modified Seldinger.)
- Do not withdraw the guide wire back through the needle as this may shear the guide wire.
- Percutaneous introducer sheaths should not remain indwelling without internal support of the sheath wall.
- Care should be exercised during insertion, manipulation and withdrawal of the catheter through the hemostasis valve. The integrity of the hemostasis valve may be compromised with the use of excessive force or rapid withdrawal. If resistance is encountered; **DO NOT FORCE.** Remove the catheter and introducer as a unit.
- If using the Touhy-Borst Introducer, **DO NOT** tighten the adapter without internal support.
- If repositioning of the sheath suture tab is necessary, insure that internal support is provided by a vessel dilator prior to insertion to avoid twisting the sheath.
- Upon removal of a catheter or other medical device, it is recommended that a Total Vein Systems™ Obturator be immediately placed in the sheath.
- Upon withdrawal of a device. The sideport should be aspirated in order to remove any clotted material that may have accumulated. This should be accomplished before the insertion of another medical device.
- Depth markings on outside diameter of Introducer tubing are reference only for visual confirmation of introducer insertion distance. NOTE: Depth markings are not intended for use as a finite measurement.

## WARNINGS

- **CARE SHOULD BE EXERCISED DURING INSERTION, USE OR REMOVAL OF THE DEVICE TO PREVENT ASPIRATION OF AIR INTO THE VASCULATURE.**
- Rapid withdrawal of the catheter or dilator through the hemostasis valve may cause misalignment of the valve gasket assembly, causing bleedback through the valve. **IN THIS SCENARIO, THE SLOW REINSERTION OF A VESSEL DILATOR TIP OR CATHETER SHOULD REALIGN THE VALVE STOPPING BLEEDBACK.**
- Inspect the packaging and product for damage prior to use. Do not use if the package is damaged as sterility may be compromised.
- Care should be taken that acetone solutions or isopropyl alcohol do not come in contact with introducer hub. Such substances could weaken the hub and cause possible leakage.
- Tighten all connections prior to use. **WITHOUT OVERTIGHTENING.** Overtightening can cause damage to the components.
- Periodically check all connections for tightness.

## SUGGESTED DIRECTIONS FOR USE OF TOTAL VEIN SYSTEMS™ I INTRODUCER PRODUCTS

The following instructions are supplied for information about the techniques of percutaneous catheter introduction. Procedural details may be altered at the discretion of the physician.

1. Prepare and drape the skin at the intended puncture site, achieve local anesthesia as necessary.
2. Locate vessel with an appropriate sized needle and syringe.
3. Enter vessel using thin walled needle or O-T-N catheter. Remove locator needle. If O-T-N catheter is used, advance catheter over needle into vessel and remove needle when good flow verifies placement of catheter tip within the vessel. **IF INSERTION IS UNSUCCESSFUL, WITHDRAW COMPLETE ASSEMBLY AS A UNIT. DO NOT ADVANCE NEEDLE INTO CATHETER OR ATTEMPT TO WITHDRAW CATHETER BACKWARDS OVER THE NEEDLE WHILE CATHETER IS IN THE PATIENT.**
4. Straighten "J" tip of guide wire with plastic insertion sleeve.
5. Insert guide wire into the O-T-N catheter or thin walled needle and gently advance it to the desired length. It may be necessary to gently rotate the "J" tip for successful advance of the guide wire. Avoid vigorous manipulation to prevent damage to vessel or shearing of the guide wire tip. **MAINTAIN A FIRM GRIP ON GUIDE WIRE AT ALL TIMES.**
6. If an obstruction is met that cannot be passed, remove needle and guide wire together and select another introduction site. **DO NOT ATTEMPT TO WITHDRAW GUIDE WIRE BACKWARDS THROUGH NEEDLE OR CATHETER AS THIS MAY RESULT IN SHEARING GUIDE WIRE OR DAMAGING CATHETER.**
7. When guide wire is advanced to desired location remove O-T-N catheter or needle proximally.
8. Thread assembled sheath/dilator until over guide wire and advance to puncture site. Enlarging puncture site with a small nick if needed, insert sheath/dilator unit into vessel with a slight rotary motion.
9. Remove the dilator and guide wire together leaving sheath in vessel.
10. Suture sheath in place using suture tab or hub. **DO NOT PLACE SUTURE ON SHEATH TUBING AS THIS MAY RESTRICT FLOW OR DAMAGE TUBING.**
11. Connect hemostasis valve securely to sheath when utilizing an introducer with removable valve.
12. A catheter one-half to one French size smaller than introducer sheath is recommended to allow adequate flow through introducer side-port.
13. Touhy-Borst adapters should be gently hand-tightened to prevent blood reflux and/or catheter migration. Overtightening may compromise indwelling catheter lumen.
14. Follow hospital protocol for puncture site dressing and maintenance.
15. Care should be exercised not to pull the guide wire or catheter to extreme angles while the device is through the hemostasis valve as it will distort the valve leaflets and promote leakage.