

force. In a preferred embodiment, the annular collar **50** is sized so that once the rim **70** has snap-fittingly engaged the sheath cap **30**, the shuttle housing **22** may not be readily removed from the sheath housing **20** without causing destructive effects on the device.

In an alternative embodiment, the shuttle housing **22** may be removably attached to the sheath housing **20**. Here, the annular collar **50** is sized so that the rim **70** of the shuttle body **64** may extend over the annular collar **50** so as to snap-fittingly engage the sheath housing **20**, but is small enough to allow the rim **70** to be taken off the collar **50** by application of external force.

Optionally, devices of the invention may be provided with a locking mechanism that secures the shuttle housing in either the biased or unbiased position, or both. The locking mechanism preferably comprises one or more snap-rings located on the sheath cap body. As illustrated in FIG. **6**, the locking mechanism may comprise a pair of snap-rings **53** located near the proximal and distal ends of the sheath cap body **40** of the sheath cap **30**. The distance between the proximal end of outer shoulder **47** and distal side of snap ring **53** is sized such that when the rim **70** is adjacent to the distal side of the snap ring **53**, the most distal end of the shuttle body **64** abuts the proximal end of shoulder **47**. Thus, when the rim **70** of the shuttle housing **22** engages the distal snap-ring **53**, the rim **70** is secured in place. Proximal snap-ring **53** is located near the proximal end of sheath cap body **40**, such that the rim **70** can engage between the snap-ring **53** and the sheath collar **50**. Instead of a snap-ring arrangement, the locking mechanism may comprise a threaded lock, interference-fit lock, or any other suitable means for preventing undesired movement of the shuttle mechanism.

In a typical procedure utilizing the catheter introducer system of the invention, a user first accesses an artery by inserting a needle therein. A guide wire is then inserted inside the needle until it is inside the artery. The user then removes the needle, which leaves only the guide wire in the artery. Next, the physician inserts a dilator through the introducer device until the dilator is in the sheath tube **24**, and then the physician slides the sheath tube **24** and dilator over the guide wire until the distal ends of the sheath tube **24** and dilator are inside the artery. The sheath hub **26** is located just outside the body. The dilator is then removed followed by the guide wire.

At this point, blood can flow into the catheter introducer system. The sheath valve **28** is closed and maintains hemostasis. Although the guide wire extends through the sheath valve **28** prior to its removal, the valve **28** seals around the guide wire, which does not create an opening in valve **28** large enough to permit blood to pass into the shuttle lumen **94**.

After the sheath tube **24** is in place, the user places a catheter over a second guide wire and inserts the catheter and guide wire into the entrance port **74** of the shuttle cap **68** and guides them through the shuttle valve **66** and shuttle tube **44**, until they reach the sheath valve **28**. The user then advances the catheter and guide wire through the sheath valve **28**. The sheath valve **28** provides hemostasis at this point by engaging the periphery of the catheter. Alternatively, if desired, prior to advancing the catheter through the sheath valve **28** the user could bias the shuttle tube **44** forward until it opens the sheath valve **28** and then push the catheter and guide wire through the opened sheath valve, as is discussed in more detail below.

When the user desires increased maneuverability of the catheter, the user may bias the shuttle housing **22** towards

the sheath housing **20**. The user may slide the shuttle housing **22** along the outer surface **92** of the sheath cap **30**, such as by gripping the sheath ribs **89** on the sheath housing **20** (see FIG. **4**) and the shuttle ribs **65** on the shuttle housing **22**. Because the shuttle tube **44** is connected to the shuttle housing **22**, the shuttle tube **44** also moves forward and biases the sheath valve **28** open so that the sheath valve no longer engages the periphery of the catheter. Consequently, the maneuverability of the catheter is increased. As shown in FIG. **4**, the shuttle lumen **94** of the shuttle housing **22** is axially aligned with the sheath lumen **46** of the sheath housing **20**. The shuttle lumen **94** is thus in fluid communication with sheath lumen **46** when the sheath valve **28** is open. When the shuttle housing **22** is biased forward fully, the rim **70** of the shuttle body **64** abuts outer shoulder **47** of sheath cap **30**.

When the sheath valve **28** is opened, as shown in FIG. **4**, blood can flow through the sheath housing **20** into the shuttle housing **22**. The sheath valve **28** provides hemostasis around the shuttle tube **44**, and the shuttle valve **66** provides hemostasis around the catheter to prevent the loss of blood. Since the diameter of the shuttle valve **66** is only slightly smaller than the outer diameter of the catheter, the shuttle valve **66** is able to provide hemostasis without sacrificing maneuverability. FIG. **7** depicts a device similar to that shown in FIG. **4**, having a catheter **43b** inserted there-through. The device of FIG. **7** also contains snap-rings **53** as a locking mechanism for rim **70**.

A similar procedure can be used with interventional devices such as Y- or tri-adapters. However, a catheter or other elongated member does not necessarily have to be inserted through the device before the shuttle valve can provide hemostasis. In these types of devices, the shuttle valve may comprise a Tuohy-Borst valve, duckbill valve or slit valve. The opening in a Tuohy-Borst valve may be manually changed such that the opening is completely shut and thus provide hemostasis, even without a catheter. A duckbill valve or slit valve usually comprises a slit that remains closed until something is inserted through it and thus can provide hemostasis even when a catheter is not present. In addition, if the user withdraws an elongated member such as a balloon catheter out of the device, the user may withdraw the elongated member even if the sheath valve **28** is biased open and hemostasis will still be maintained. In such an instance, if the shuttle valve **66** is a Tuohy-Borst valve, the opening may be manually closed upon withdrawal of the catheter to maintain hemostasis. If the shuttle valve is a duckbill valve, the opening automatically closes upon withdrawal of the elongated member and hemostasis is maintained.

It should be appreciated that the foregoing is by way of example only, and that alterations or modifications may be made within the scope of the invention.

What is claimed is:

1. A medical insertion device for introducing an elongated member into a vascular system and facilitating maneuverability of the elongated member through the vascular system while providing hemostasis, the device comprising:

- a housing having an interior lumen extending there-through;
- a sheath tube attached to a distal end of the housing, the sheath tube having a distal end adapted for insertion into the vascular system;
- a first elastomeric valve secured within the interior lumen of the housing and having an openable slit therein;
- a shuttle tube having proximal and distal ends and an interior passageway, the interior passageway being in