

## ANGULAR SHEATH INTRODUCER

### FIELD OF THE INVENTION

The present invention relates to a hemostatic sheath introducer, and more particularly to a sheath introducer that can slidably receive catheters or other similar devices after being inserted into a vessel while providing an improved angle for inserting and manipulating a catheter.

### BACKGROUND OF THE ART

Hemostatic sheath introducers are well known in the art as devices for facilitating insertion, removal and manipulation of stents, catheters or like devices into a vein or artery. A procedure has been developed called Transjugular Intrahepatic Portalsystemic Shunts (TIPS), in which a catheter is inserted into the jugular vein via a sheath introducer. A sheath introduced is an access device comprising a cannula with fluid barrier valve and an access port. The cannula portion is inserted into a patient's blood vessel, typically an artery, and a number of different devices are insertable into the sheath introducer and into the vessel with an objective being to cause minimal trauma to the vessel and surrounding area.

Intrahepatic portal-systemic shunts are artificial fistulas between branches of the portal vein and the systemic circulation in the substance of the liver. The insertion and deployment of such shunts are among the most complex procedures in interventional medicine. During the procedure a number of catheters or similar devices must be inserted into a blood vessel via the sheath introducer. Currently available sheath introducers, such as that described in U.S. Pat. No. 4,000,739, issued to Stevens, and its progeny, utilize a straight bodied sheath introducer and are normally used for insertion into certain areas of the body. Insertion of a cannula into the jugular vein involves a less flexible site because the curved jaw and neck area provide awkward placement of a sheath introducer relative to the patient's body.

The sheath introducer of Stevens utilizes a straight body and co-axially aligned cannula, with a tapering body portion integrating with the cannula. Because the cannula is mounted in the center of the bottom of the body, this sheath introducer design has a disadvantage that when it is inserted into the vessel the body of the introducer can lift the cannula away from the surface of skin area, possibly causing stress and trauma to the vessel underneath and kinking the introducer cannula. Additionally, the access port is co-axially aligned with the cannula requiring insertion of catheters to be made substantially horizontal to the skin and a catheter may be difficult to insert where the cannula is inserted near the uneven topography of the jaw and neck region. It would be desirable to have a cannula that would angle away from the skin to permit more facile insertion of a catheter and reduce pulling and trauma to the vessel during insertion. It would also be desirable to have a cannula that extended eccentrically from the body of the introducer to minimize bending of the cannula with respect to the vessel and to prevent or reduce the likelihood of kinking the cannula.

### SUMMARY OF THE INVENTION

The present invention provides a hemostatic sheath introducer suitable for TIPS and other catheterization procedures where an angled access port is useful.

Generally described, the present invention provides a generally cylindrical body with a top, a bottom and a sidewall, a portion of the body being at an angle, the body having a curved channel extending eccentrically there-through tapering from the top to the bottom; a cannula extending from a peripheral portion of the bottom of the body and in fluid communication with the channel, the distal end of the cannula being slightly tapered; a cap fitted onto the top and having a housing within which fits a hemostatic valve; and, a sideport channel in fluid communication with the channel and in communication with a boss extending outward from the sidewall, the boss being connectable to a stopcock or other device by a tube. In one embodiment of the invention the boss is angled slightly downward toward the bottom corner of the body and preferably rotated 90° about the axis of the body. The valve can have an opening extending partially therethrough and a Y-slit which forms a penetrable fluid tight seal.

A dilator designed for use with the present invention is angled at the upper portion of the dilator body to more securely fit within the body of the sheath introducer. Such a dilator design provides an easier insertion and fit within the sheath introducer.

Accordingly, it is a principal object of the present invention to provide a hemostatic sheath introducer that affords increased access to the access port.

It is a further object of the present invention to provide a hemostatic sheath introducer that reduces trauma to the skin and vessel.

It is another object of the present invention to provide a hemostatic sheath introducer that has an eccentrically positioned cannula with respect to the body so as to lie closer to the skin when in an inserted position.

It is still a further object of the present invention to provide a hemostatic sheath introducer that reduces the likelihood of kinking the cannula during catheter manipulation.

Other objects, features, and advantages of the present invention will become apparent upon reading the following detailed description of embodiments of the invention, when taken in conjunction with the accompanying drawings and the appended claims.

### BRIEF DESCRIPTION OF THE DRAWINGS

The invention is illustrated in the drawings in which like reference characters designate the same or similar parts throughout the figures of which:

FIG. 1 is a side cutaway view of a preferred embodiment of the sheath introducer of the present invention.

FIG. 2 is a side cutaway detail view of the top of the body, the valve and the cap.

FIG. 3 is a top view of the hemostatic valve.

FIG. 4 is a side cutaway view of the hemostatic valve.

FIG. 5 is a side perspective view in partial cutaway of the sheath introducer.

FIG. 6 is a front side perspective view.

FIG. 7 is a back side perspective view.

FIG. 8 is a side view in partial cutaway of an adapted angled dilator of the present invention.

FIG. 9 is a side cutaway view of the sheath introducer with a dilator inserted into the cannula.

### DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIGS. 1-7 shows a sheath introducer 10 according to a preferred embodiment in which a generally cylindrical body