

MEDICAL INSERTION DEVICE WITH HEMOSTATIC VALVE

BACKGROUND OF THE INVENTION

This invention relates to medical insertion devices generally and in particular to devices that are designed to facilitate introduction of elongated members such as catheters into a vascular system, improve maneuverability throughout the vascular system and provide hemostasis.

Typically, catheter introducers that are presently available have a sheath tube attached to a distal end which is inserted into an artery of a patient, thus providing a user such as a physician with access to the vascular system. The proximal end of such introducers provides an opening for insertion of a catheter through the device into a patient's vascular system. The sheath tube is in fluid communication with an interior passageway of the introducer and the proximal end of the introducer, so that a catheter may be inserted through the device and into the artery. Once the distal end of the tube is inserted into the vasculature, blood can flow into the catheter introducer because the sheath tube is in fluid communication with the patient's bloodstream. Thus, blood also can flow through the catheter introducer and out of the proximal end of the device.

Controlling the blood loss is extremely important since blood loss endangers and traumatizes the patient and risks exposing the attendant user to blood-borne pathogens and diseases. The flow of blood from a catheter introducer also hinders a user's ability to manipulate the catheter. Thus, catheter introducers have been equipped with normally-closed elastomeric valves designed to maintain hemostasis after the distal end of the introducer is inserted into the vascular system of a patient.

Elastomeric valves that have been used in catheter introducers typically have a slit that normally is closed, so that when there is no catheter or guide wire present in the device the valve presents a sealed face to the blood flow from the patient. The slit permits the insertion of a catheter or guide wire therethrough and thus permits access to the patient's vascular system. The valve is designed typically so that the valve engages the periphery of the catheter or guide wire to seal the system and maintain hemostasis.

In order to maintain hemostasis, these slit valve designs must be biased such that they are closed when no catheter is present and must also be biased such that they seal around a catheter when present. A consequence of such designs is that the user must overcome the frictional force that results from the valve being biased closed in order to insert a catheter through the valve. Since catheters have very small diameters, particularly when compared to their length, kinking of the catheter can occur if the frictional forces that must be overcome are too great. Moreover, advancing a catheter through the vascular system of a patient, including advancement through the aortic arch of a patient, frequently requires subtle manipulations so that the catheter is advanced to the proper destination without damaging vascular tissue. Where advancement of a catheter through a catheter introducer requires overcoming large frictional forces, the difficulty of manipulating the catheter in a subtle manner can be greatly increased, thereby increasing the risk of injury to the patient.

Thus, there exists a need to provide a catheter introducer that maintains hemostasis after inserting a catheter into the vascular system of a patient while reducing the frictional forces on catheters inserted into the introducer.

This need also exists with respect to other types of medical insertion devices, such as Y-adapters and tri-

adapters. These devices typically are used with elongated members of various sizes, such as are used in interventional procedures, such as angioplasty and stent implantation. In such procedures, members of various sizes, such as balloon catheters and stents, are inserted through the device and into the vasculature.

SUMMARY OF THE INVENTION

The present invention comprises a medical insertion device that introduces an elongated member such as a catheter into a vascular system and facilitates maneuverability of the elongated member through the vascular system while providing hemostasis. The medical insertion device according to this invention comprises a housing, an elastomeric valve, a shuttle tube, and a means for maintaining hemostasis. The housing has proximal and distal ends and an interior lumen extending through the housing. The elastomeric valve is secured within the interior lumen of the housing and preferably is constructed with an openable slit extending through the valve. The shuttle tube has proximal and distal ends and an interior passageway extending through it, is movable, and is constructed to bias the elastomeric valve open when moved to a forward position. The shuttle tube is located within the interior lumen of the housing, and the interior passageway is in fluid communication with the interior lumen of the housing.

The means for maintaining hemostasis may comprise structures such as a fluid bearing or washer valve. In general, any means which can form a fluid-tight seal around the periphery of a member to be inserted in the housing may be employed.

BRIEF DESCRIPTION OF DRAWINGS

FIG. 1 is a longitudinal cross-sectional view of a catheter introducer of the invention, with the sheath valve in a closed position.

FIG. 2 is a longitudinal cross-sectional view of the sheath housing of the catheter introducer of FIG. 1.

FIG. 3 is a longitudinal cross-sectional view of the shuttle housing of the catheter introducer of FIG. 1.

FIG. 4 is a longitudinal cross-sectional view of the catheter introducer of FIG. 1, with the sheath valve in an open position.

FIG. 5 is a longitudinal cross-sectional view of a Y-adapter of the invention in the unbiased position.

FIG. 6 is a longitudinal cross-sectional view of a catheter introducer of the invention having a dilator attached to its proximal end.

FIG. 7 is a longitudinal cross-sectional view of a catheter introducer of the invention having a catheter inserted therethrough.

FIG. 8 is a longitudinal cross-sectional view of another embodiment of a shuttle housing of the invention.

FIG. 9 is a longitudinal cross-sectional view of a catheter introducer of the invention, applying a fluid bearing seal to a catheter inserted therethrough.

FIG. 10 is a longitudinal cross-sectional view of another embodiment of a shuttle housing of the invention having a catheter inserted therethrough.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The invention utilizes a valve and a separate means for maintaining hemostasis in order to provide hemostasis while