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**HEMOSTASIS VALVE WITH LOCKING
 SEAL**

BACKGROUND OF THE INVENTION

1. The Field of the Invention

The present invention relates to valves and, more specifically, to hemostasis valves.

2. The Relevant Technology

Several modern surgical procedures require temporary and often repeated introduction and removal of catheters and/or guidewires within the cardiovascular system of a patient. For example, using only a relatively small incision, a catheter can be introduced into the body of a patient and used to deliver fluid, such as medication, directly to a predetermined location within the cardiovascular system. Catheters can also be used for exploratory surgery and for removing tissue samples within a body. One increasingly common use for catheters is in the placement of small balloons which can be selectively inflated within a blood vessel. The balloons are used for opening blood vessels that have been blocked or partially blocked by fat build-up. This opening or altering of the vein is referred to as angioplasty.

A common catheter design used in performing many of the procedures mentioned above includes an elongated, flexible, cylindrical catheter body having a fluid flow passageway or a lumen extending along the interior of that catheter body. During one type of use, an end of the catheter referred to as the distal end is inserted into the body of the patient through an incision in a blood vessel in the cardiovascular system. The distal end of the catheter is advanced along the internal passageway of the vessel until the distal end is located at a desired predetermined location for conducting an intended activity.

A guidewire is a long, cylindrical, flexible wire that is commonly used for directing the catheter to the desired location within the body. A guidewire is typically smaller in diameter and more rigid than a catheter. It is, therefore, easier for a surgeon to first direct and advance the guidewire within the cardiovascular system to the desired location within the body of the patient. The opposing end of the guidewire, positioned outside the body of the patient, is then received within the lumen of the catheter. Using the guidewire as a guide, the catheter is advanced along the length of the guidewire so as to properly position the catheter within the body of the patient. If desired, the guidewire can then be removed from within the catheter to open the lumen of the catheter. In an alternative process for inserting the catheter, the guidewire is initially received within the lumen of the catheter, and the catheter and guidewire are simultaneously advanced within the cardiovascular system of the patient.

Operations using catheters can often require the insertion and removal of several different types of catheters and guidewires. One of the problems encountered with the insertion and removal of catheters and guidewires is controlling bleeding at the point where the catheters and guidewires are first introduced into the cardiovascular system.

In one approach to controlling bleeding and insuring easy insertion and removal of a catheter and/or guidewire within the cardiovascular system, a distal end of an introducer is first secured within a large vein of a patient. An introducer is a relatively large, hollow tube. The opposite end of the

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introducer is positioned outside the body of the patient and is attached to an adapter.

An adapter typically comprises a short, rigid tube having a passageway extending therethrough. Attached at one end of the adapter tube, referred to as the distal end, is a connector. The connector is used to connect the passageway of the adapter to the exposed end of the introducer. This enables fluids and/or medical instruments, such as catheters and guidewires, to pass between the adapter and the introducer.

Positioned at the opposite end of the adapter tube, referred to as the proximal end, is a valve commonly referred to as a hemostasis valve. The hemostasis valve includes an enlarged chamber positioned at the proximal end of the adapter tube. The chamber is aligned with and is connected to the passageway extending through the adapter tube.

Positioned within the chamber is a soft, compressible seal. The seal has the appearance of a short piece of cylindrical tubing with a passage extending therethrough. The seal is oriented within the chamber so that the passage in the seal is aligned with and connected to the passageway in the adapter tube.

Finally, a rigid, hollow shaft is also positioned within the chamber. The hollow shaft has an entryway extending therethrough. The shaft is positioned so that the entryway in the shaft is aligned with and connected to the passage in the seal.

The shaft and seal are thus shaped and oriented so that an access is formed through the valve and into the passageway into the adapter tube. In this configuration, a catheter or guidewire can be inserted in the access in the valve and then advanced through the adapter, through the introducer, and into the cardiovascular system of the patient for desired positioning therein.

By advancing the shaft within the chamber, the seal compresses within the chamber. Compression of the seal causes the passage in the seal to constrict. If the shaft is advanced sufficiently far within the chamber, the passage in the seal constricts so as to compress and seal around the exterior surface of a catheter or guidewire positioned therein. Alternatively, if the catheter or guidewire is removed from within the seal, the passage in the seal can constrict so that the seal completely closes off the access through the valve.

During use of the adapter, the pressure on the patient's blood, caused by the beating of the patient's heart, causes the patient's blood to flow up through the introducer and into the passageway of the adapter tube. The seal, which is either independently closed or compressed around a catheter or guidewire, prevents the blood from spilling out of the adapter through the access in the valve.

Although such adapters have been useful in introducing catheters and/or guidewires with minimal blood loss, several shortcomings have been found. For example, compressing the seal within the chamber by the shaft, especially when the catheter is removed, can cause the seal to flow or move out of its proper orientation. For example, a portion of the seal can flow out of the chamber and into the passageway in the adapter tube. This displacement of the seal can cause blood to leak past the seal and out of the valve. A leaking valve not only results in needless blood loss, but also increases the risk of contamination of the patient's blood. Furthermore, leaking blood can produce both a messy and slippery working environment for the surgeons. In addition, with the increasing number of blood disorders, such as AIDS, blood leakage from the adapter increases the risk to the surgeons.