BLEED BACK CONTROL ASSEMBLY AND METHOD

BACKGROUND

This invention relates generally to a bleed back control assembly for controlling blood loss during vascular diagnostic or interventional procedures, such as insertion and removal of catheters from a patient's blood vessels.

Treatment of patients with diseases, such as coronary heart disease, can typically involve use of catheters, balloon catheters, stents, and other vascular intervention devices which are introduced transluminally, i.e. to and through the interior of a patient's blood vessels. Typically, catheterization procedures include the use of a hemostatic valve to reduce blood loss.

It is known in the art to provide a large bore rotating hemostasis valve (RHV) which attaches to the end of a guiding catheter and acts as an open/close valve. After a device is introduced into the lumen of an RHV, the RHV serves as a seal around the device to reduce blood loss. An RHV must be opened to allow introduction of an interventional device into the RHV's lumen, and must be closed to control blood loss while allowing device adjustment, such as moving it back and forth. A doctor must adjust a screw cap of a conventional RHV in order to adjust the seal around various devices introduced axially through the RHV's lumen. Conventional RHV's utilize a Touhy-Bourst seal design, which may be opened and closed by the user, but such a seal allows fluid to escape until properly adjusted.

A significant amount of the patient's blood may be lost during these adjustments of the RHV's screw cap which are required in order to move a device, such as a catheter, in and out of the RHV. When the RHV is not adjusted to seal around the device introduced in the RHV's lumen, there is no mechanism for inhibiting substantial bleed back or blood loss.

Accordingly, a conventional RHV allows excessive blood loss when the RHV is not adjusted or whenever the RHV is in the open position. This drawback in an RHV allows for excessive and undesirable blood loss from the patient. The excessive blood loss also creates a more ensanguined operating environment for the user of the RHV, increasing risks associated with unwanted exposure to blood (or other fluids) and making more difficult the manipulation or operation of devices.

For example, U.S. Pat. No. 5,269,764, issued to Vetter et al., discloses a hemostatic gasket and valve assembly, including a terminal plug, which can be rotated and thus tightened to cause radial compression of the hemostatic gasket.

SUMMARY

An advantage of the present invention is to provide a bleed back control assembly which permits diagnostic or interventional vascular procedures, such as insertion of devices like catheters, guide wires, or stent delivery systems in a patient's blood vessels, while controlling and significantly reducing the amount of blood loss, even when the catheter must be adjusted or moved.

Another advantage of the invention is to provide a bleed back control assembly which permits diagnostic or interventional vascular procedures, while allowing a user to clamp an interventional device introduced into the bleed back control assembly, to maintain device position while controlling blood loss.

A bleed back control apparatus in accordance with one aspect of the invention includes a side arm body having proximal and distal ends, and a seal body connected to the proximal end of the side arm body, where the seal mechanism includes a seal assembly and a cap assembly. The seal assembly comprises a bleed back control seal held within an interior chamber of a seal holder.

In another aspect, the cap assembly includes a threaded cap which is rotatably attached to the exterior of the proximal end of the side arm body and a funnel cap attached to the threaded cap.

In another aspect, a bleed back control seal in accordance with one aspect of the invention has a cylindrical body with a lumen, a web area covering a cross-section of the lumen and having a dilatable aperture, and the cylindrical body and web area are formed of an elastomer.

In another related aspect, the seal assembly further comprises a clamp seal with a cylindrical body tapering to a frustum, with a lumen through the cylindrical body and frustum, and the clamp seal is formed of an elastomer.

In another aspect, a side arm body in accordance with another aspect of the invention has a proximal end and means for sealing connected to the proximal end of the side arm body, where the means for sealing comprises means for controlling bleed back during use.

In a related aspect, a method in accordance with another aspect of the invention for controlling blood loss using a bleed back control assembly includes introducing a vascular intervention device (such as, but not limited to, a catheter) transluminally within the assembly, and forming a bleed back control seal around the introduced vascular intervention device.

Accordingly, with these and other apparatus and method aspects of the invention, a bleed back control assembly in accordance with one aspect of the present invention controls blood loss during insertion, movement, and removal of a vascular intervention device (such as catheter) from the assembly. The user can adjust a clamp seal to clamp a vascular intervention device introduced transluminally, such as a catheter, to maintain device position or perform high pressure injections. The user can also close the clamp seal, without a vascular intervention device introduced transluminally, to allow high pressure injections into the side arm body.

These and other aspects of the invention are described further below.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1***a* is a cross-sectional view of a side arm body in accordance with the present invention. FIG. **1***b* is a cross-sectional view of a side arm body and seal assembly in accordance with the present invention.

FIG. **1***c* is a cross-sectional view of a side arm body, a seal assembly, and a cap assembly in accordance with the present invention. FIG. **1***d* is a cross-sectional view of a bleed back control assembly in accordance with the present invention.

FIG. **2** is an exploded view of a seal body and side arm body of a bleed back control assembly in accordance with the present invention.

FIG. **3** is a cross-sectional view of a seal body and a proximal end of a side arm body of a bleed back control assembly in accordance with the present invention.

FIG. **4***a* is an exploded view and FIG. **4***b* is a cross-sectional view of a side arm body and male luer connector in accordance with the present invention.