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Abstract:

BIDIRECTIONAL INTRAVASCULAR ACCESS SHEATH FOR INTERVENTIONAL PROCEDURES ON BLOOD VESSELS, AND ASSOCIATED SYSTEMS AND METHODS

FIG. 1

The disclosed apparatus, systems and methods relate to an intravascular access sheath for use in various medical procedures. The sheath can be introduced into a blood vessel or arteriovenous fistula in both upstream and downstream directions from a single puncture site without removing the device from the blood vessel or arteriovenous fistula. This device is useful in intervention radiology techniques, particularly in accessing an arteriovenous fistula or graft used in hemodialysis patients and various liver interventions and in other intravascular and intraluminal diagnostic and therapeutic interventions where isolation of blood flow or other body fluids is required. It also relates to methods for using such a device on a patient. The device is capable of inflating a balloon to occlude bloodflow and introduce drugs or devices into the access site.
BIDIRECTIONAL INTRAVASCULAR ACCESS SHEATH FOR INTERVENTIONAL PROCEDURES ON BLOOD VESSELS, AND ASSOCIATED SYSTEMS AND METHODS

CROSS-REFERENCE TO RELATED APPLICATIONS


TECHNICAL FIELD

The disclosed devices, systems, and methods relate generally to performing intravascular procedures, and more particularly, to devices, systems and methods including a vascular access device.

BACKGROUND

The disclosure relates to a vascular access device, or "sheath" that is capable of accessing a blood vessel in both upstream and downstream directions from a single puncture site without removing the device from the blood vessel. This device is useful in interventional radiology techniques, particularly in accessing an arteriovenous fistula or graft used in hemodialysis patients. It also relates to methods for using such a device on a patient.

More than 800,000 Americans suffer from end stage renal disease (ESRD). This condition results in permanent kidney failure. In the last thirty years alone, the prevalence has increased nearly 600%. The aging population, increased rates of diabetes and hypertension, and the increase in average life span of patients with ESRD are all positive demographic factors that contribute to this increase. Despite this, the current state of the art for accessing the bloodstream for hemodialysis treatment of ESRD relies on either an arteriovenous fistula (AVF) or a grafted connection between a vein and artery in the patient's arm. This technique results in several problems, particularly clotting of the access sites. Current methods to alleviate blockages near the access site require two puncture wounds to be created in the AVF or graft in order to access...
the blood vessels. This is problematic because clots tend to occur near puncture sites, so the solution actually contributes to the problem and reduces the lifespan of the AVF or graft.

[005] Patients with end stage renal disease are treated by three primary options: kidney transplant, peritoneal dialysis, and hemodialysis. Kidney transplants are the optimal treatment options; however, the donor waitlist is large resulting in nearly decade wait periods for ESRD patients. Therefore, hemodialysis is by and large the most common treatment method used on patients waiting for kidney transplants. Patients receiving dialysis treatments visit dialysis centers 3-4 times a week; typical visits last two hours to greater than four and half hours. In dialysis centers, patients are connected to dialysis machines which perform the actions of the kidney. It is estimated that globally 2.78 million people are being treated for ESRD, of which 1.92 million are being treated with hemodialysis (HD) with 20% of HD taking place in the USA. The number of HD treatments is expected to grow by 6-7% annually. Researchers at the University of Iowa Hospitals and Clinics indicate that a typical hemodialysis patient has their fistula or graft "cleaned" anywhere from two to six times annually in order to reduce the likelihood of thrombosis or stenosis. Taking an average of four "cleanings" per year yields a total procedure rate of 6.4 million procedures globally.

[006] In order to connect a patient to a dialysis machine, an access point is created, typically in the forearm. The preferred access point is a fistula, a direct connection of a native vein to a native artery. In cases when a fistula cannot be made, a graft—a synthetic connection between a vein and artery—is created.

[007] Fistulas and grafts suffer from two main complications: thrombosis (clotting) and stenosis (narrowing of the vessel). Typically, these complications commence in the earlier years of usage, with recurrences 3-4 times a year until the fistula or graft fails. Interventional radiologists are required to surgically deliver clot-busting drugs, implant stents, mechanically remove the complications, and/or several other procedures. This is achieved by inserting two sets of catheters and guide wires through the fistula or graft in an attempt to "flush" out the complications. Punctures are made both on the venous side and the arterial side of the fistula or graft in order to feed two sets of catheters and guide wires through the vessel in a crisscrossing fashion.

[008] FIG. 1 is an X-ray of a graft 102 showing stenosis in the venous side 104 and inadequate imaging in the arterial side 106. This is problematic as it is unknown what problems
may occur in the arterial side. Further occlusion and imaging would be necessary for this patient. Such issues are typical with interventions in the current state of the art. In these known procedures, interventional radiologists must first fluoroscopically image the fistula/graft. In order to accomplish this, a puncture is made in the venous side (since complications most frequently occur on that side), and a sheath is introduced into the fistula/graft. Fluoroscopic dye is injected into the venous side in order to get an image of any complications that may be present. After imaging the venous side, the arterial side must also be imaged. This is challenging due to the natural flow of blood from the arterial side to the venous side. In order to send fluoroscopic dye against the flow of blood, the interventional radiologist must occlude the flow of blood. Three methods are typically used to achieve this, all with major drawbacks. Manual occlusion by pressing a thumb against the fistula/graft from outside the body may be used. This process takes a longer time, thus causing an increase in the radiation dosage to the patient. By manual occlusion, the interventional radiologist's radiation exposure is also prolonged with each procedure requiring this method of occlusion. Occlusion may be obtained by placing a blood pressure cuff on the venous side of the patient's arm. Furthermore, this is largely ineffective in achieving proper occlusion, especially if the patient is overweight, which is common in ESRD patients. A foreign device, such as a balloon, may also be introduced to the fistula/graft in order to achieve occlusion. This option is both invasive and costly to the patient due to the increased time and number of devices used.

[009] Once the graft is fully imaged, the interventional radiologist must then clean or fix the complications that exist. If complications exist only in the venous side, the interventional radiologist can introduce a single set of catheters, guidewires, and any other devices necessary for the intervention (clot-busting drugs, stents, balloon catheters, etc.) through the sheath that was initially used to image the graft. The arterial side is still checked to ensure no complications have developed on the arterial side, which requires a second puncture. If, however, a complication exists in the arterial side, it is not possible to redirect the same sheath to the arterial side of the fistula/graft. This is due largely to the geometry of the fistula/graft. In order to perform the necessary intervention, a second puncture is made, and a new sheath is introduced toward the arterial side. The necessary intervention can then be performed. The procedure is finished by removing both sets of sheaths from the fistula/graft. While this is the standard of care, it frequently results in damage to the fistula or graft. The puncture sites are typically sites of
further thrombosis and/or stenosis. Upon multiple reinsertions for subsequent cleanings, permanent damage to the vessel is typically found. This decreases the functional lifespan of the fistula or graft and causes the eventual need for the creation of a new fistula or graft on a patient’s arm(s). Preserving the lifespan of the fistula and/or graft is extremely important since there are only limited opportunities (or "real estate") for the creations of fistulas and grafts. The increased prevalence of ESRD in children and patients under the age of 40 makes it increasingly more important to preserve fistulas and grafts for as long as possible in a patient to avoid numerous additional surgeries, complications, and eventually emergency kidney transplant (when available).

Additionally, accessing both upstream and downstream sections of a blood vessel graft currently requires multiple punctures. This is problematic because additional trauma may occur at the puncture sites, rendering fistula/graft material vulnerable to further complications such as reduced life span, clotting, and aneurysm formation. Furthermore, the procedure takes requires more surgical time, thereby increasing the patient's radiation exposure.

There is a need in the art for a device to aid in interventional radiology techniques for clearing clotted AVFs and grafts in hemodialysis patients that requires fewer punctures.

BRIEF SUMMARY

Discussed herein are various embodiments directed to a vascular access device.

In Example 1, a intravascular access device for use on a patient undergoing a medical procedure comprises an elongate shaft further comprising a distal end and a proximal end and further comprising at least one side port disposed near the distal end, a toolhead hub fixedly attached to the proximal end of the elongate shaft, wherein the toolhead hub further comprises at least one infusion port, a retractable sheath disposed over the elongate shaft and configured to be retracted to expose the at least one side opening, and a balloon configured to be deployed and inflated within the vessel of the patient so as to create a barrier in the vessel.

In Example 2, the device of Example 1, further comprising at least one lumen disposed through the elongate shaft.

In Example 3, the device of Example 1, wherein the at least one infusion port comprises a central infusion port in fluid communication with an inner lumen defined in the elongate shaft.
In Example 4, the device of Example 1, further comprising an inner lumen disposed through the elongate shaft and a balloon lumen disposed through the elongate shaft, wherein the balloon lumen is in fluid communication with the balloon.

In Example 5, the device of Example 4, wherein the at least one infusion port comprises a side infusion port in fluid communication with a lumen defined in the elongate shaft.

In Example 6, the device of Example 5, wherein the side infusion port is in fluid communication with the balloon lumen.

In Example 7, an intravascular access sheath system comprises an elongate shaft comprising at least one side port defined in a distal portion of the elongate shaft, a hub operably coupled to a proximal end of the elongate shaft, wherein the hub comprises at least one infusion port, a retractable sheath disposed over the elongate shaft, wherein the retractable sheath comprises a closed configuration in which the retractable sheath is positioned over the at least one side port, and an open configuration in which the at least one side port is exposed, and a balloon operably coupled to the distal portion of the elongate shaft, wherein the balloon is configured to be deployed and inflated within a vessel of a patient so as to create a barrier in the vessel.

In Example 8, the sheath of Example 7, further comprising at least one lumen disposed through the elongate shaft.

In Example 9, the sheath of Example 8, further comprising an inner lumen disposed through the elongate shaft and a balloon lumen disposed through the elongate shaft, wherein the balloon lumen is in fluid communication with the balloon.

In Example 10, the sheath of Example 9, wherein the at least one infusion port comprises a central port in fluid communication with an inner lumen defined in the elongate shaft.

In Example 11, the sheath of Example 7, wherein the at least one infusion port comprises a side port in fluid communication with a lumen defined in the elongate shaft.

In Example 12, a method of performing an intravascular surgical procedure comprising providing an intravascular device comprising an elongate shaft comprising at least one side port defined in a distal portion of the elongate shaft, a hub operably coupled to a proximal end of the elongate shaft, wherein the hub comprises at least one infusion port, a retractable sheath disposed over the elongate shaft, wherein the retractable sheath comprises a
closed configuration in which the retractable sheath is positioned over the at least one side port, and an open configuration in which the at least one side port is exposed, and a balloon operably coupled to the distal portion of the elongate shaft, wherein the balloon is configured to be deployed and inflated within a vessel of a patient so as to create a barrier in the vessel, inserting the device into the fistula or graft of a patient such that the distal end is disposed within a graft or fistula at a puncture site, and performing an intravascular procedure.

[025] In Example 13, the method of Example 12, wherein the intravascular device further comprises at least one lumen disposed through the elongate shaft.

[026] In Example 14, the method of Example 12, wherein the intravascular device further comprises an inner lumen disposed through the elongate shaft and a balloon lumen disposed through the elongate shaft, wherein the balloon lumen is in fluid communication with the balloon.

[027] In Example 15, the method of Example 12, wherein the at least one infusion port comprises a central port in fluid communication with an inner lumen defined in the elongate shaft.

[028] In Example 16, the method of Example 12, wherein the at least one infusion port comprises a side infusion port in fluid communication with a lumen defined in the elongate shaft.

[029] In Example 17, the method of Example 12, wherein the intravascular procedure is an imaging procedure performed on both an arterial and a venous side of the graft or fistula using a single puncture site.

[030] In Example 18, the method of Example 17, wherein the imaging procedure comprises directing the elongate shaft into a venous side of the fistula or graft, delivering imaging contrast liquid through an inner lumen to a port at the distal end of the elongate shaft, taking an x-ray of the venous side of the fistula or graft, pulling back the retractable sheath to expose the balloon and the at least one side port, inflating the balloon to occlude the graft or fistula, delivering imaging contrast liquid through the inner lumen to the at least one side port, and taking an x-ray of the arterial side of the fistula or graft.

[031] In Example 19, the method of Example 18, further comprising partially deflating the balloon, retracting the elongate shaft from the venous side without leaving the graft or fistula, wherein the balloon prevents the elongate shaft from exiting the puncture site, redirecting the elongate shaft into the arterial side of the graft or fistula, inflating the balloon to occlude the graft
or fistula, performing an interventional procedure to eliminate thrombosis or stenosis, deflating the balloon, closing the retractable sheath, and withdrawing the elongate shaft from the graft or fistula.

In Example 20, the method of Example 19, wherein the interventional procedure is one or more of delivering thrombolytic drugs, implanting stents, expanding a vessel with a balloon catheter, or removing clots by aspiration.

While multiple embodiments are disclosed, still other embodiments of the disclosure will become apparent to those skilled in the art from the following detailed description, which shows and describes illustrative embodiments of the disclosed apparatus, systems and methods. As will be realized, the disclosed apparatus, systems and methods are capable of modifications in various obvious aspects, all without departing from the spirit and scope of the disclosure. Accordingly, the drawings and detailed description are to be regarded as illustrative in nature and not restrictive.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an X-ray of a graft showing stenosis in the venous side and inadequate imaging in the arterial side.

FIG. 2A is a cutaway side view of an exemplary embodiment of the vascular access device.

FIG. 2B is a cutaway perspective view of an exemplary embodiment of the vascular access device.

FIG. 3A is a cutaway side view of an exemplary embodiment of the vascular access device with the sheath in the open position.

FIG. 3B is a cutaway side view of an exemplary embodiment of the vascular access device with the sheath in the closed position.

FIG. 4A is a top view of the inner sheath of the embodiment of FIG. 3A.

FIG. 4B is a top view of the inner sheath of the embodiment of FIG. 3A, showing the deployment of the balloon.

FIG. 4C is a close-up view of the distal end of the device according to the embodiment of FIG. 4B.
[042] FIG. 6A is a schematic side internal view of an embodiment of the device comprising an obturator.

[043] FIG. 6B is a schematic side internal view of an embodiment of the device comprising an obturator, wherein the obturator is being used to occlude the distal opening.

[044] FIG. 6C is a schematic side internal view of an embodiment of the device comprising an obturator, wherein the obturator is being used to occlude a side opening.

[045] FIG. 6D is a cross-sectional view of the lumens of the sheath, according to an exemplary embodiment.

[046] FIG. 7A is a side schematic view of a toolhead hub, according to an exemplary embodiment.

[047] FIG. 7B is a side schematic view of the device detailing the balloon lumen, according to an exemplary embodiment.

[048] FIG. 7C is a side schematic view of a toolhead hub, according to an exemplary embodiment.

[049] FIG. 8 is a side schematic view of the device detailing the fluidic communication of the inner lumen, according to an exemplary embodiment.

[050] FIG. 9A is a cartoon schematic of the introduction of an exemplary embodiment of the device into the body of a patient.

[051] FIG. 9B is a cartoon schematic of the introduction of an exemplary embodiment of the device into the body of a patient.

[052] FIG. 9C is a cartoon schematic of the introduction and placement of an exemplary embodiment of the device into the body of a patient.

[053] FIG. 10 is a cartoon schematic of the introduction of an exemplary embodiment of the device into the body of a patient.

[054] FIG. 11A is a cartoon schematic of the introduction of an exemplary embodiment of the device into the body of a patient.

[055] FIG. 11B is a cartoon schematic of the withdrawal of the outer sheath according to an exemplary embodiment of the device.

[056] FIG. 11C is a cartoon schematic of the inflation of a balloon according to an exemplary embodiment of the device.
[057] FIG. 11D is a cartoon schematic of the insertion of an obturator, according to the embodiment of FIGS. 11A-1 IC.

[058] FIG. 1E is a cartoon schematic of the introduction of a dye into the arterial side of the vessel, according to the embodiment of FIGS. 11A-1 ID.

[059] FIG. 12A is a cartoon schematic an exemplary embodiment of the device placed into the venous branch, wherein the balloon is deployed.

[060] FIG. 12B is a cartoon schematic of the retraction of the balloon and repositioning of the device of FIG. 12A.

[061] FIG. 12C is a cartoon schematic of the device being returned to the graft entry point following the movement of FIG. 12B.

[062] FIG. 12D is a cartoon schematic of the introduction of the device of FIGS. 12-C into the arterial branch of the fistula or graft.

[063] FIG. 13A is a cartoon schematic an exemplary embodiment of the device placed into the arterial graft or fistula branch, wherein the patient is undergoing angioplasty.

[064] FIG. 13B is a cartoon schematic an exemplary embodiment of the device placed into the arterial graft or fistula branch, wherein the patient is undergoing stenting.

[065] FIG. 13C is a cartoon schematic an exemplary embodiment of the device placed into the arterial graft or fistula branch, wherein the patient is undergoing thrombectomy or thrombolysis.

[066] FIG. 14A is a cartoon schematic an exemplary embodiment of the device placed into the arterial branch, wherein the balloon is deployed.

[067] FIG. 14B is a cartoon schematic of the extension of the outer sheath, the retraction of the balloon and withdrawal of the device of FIG. 14A.

[068] FIG. 14C is a cartoon schematic of the device being returned to the graft entry point and removed from the graft or fistula.

[069] FIG. 15A is a side view schematic of an alternative embodiment of the device comprising a twisting mechanism for extension and retraction of the outer sheath.

[070] FIG. 15B is a further side view schematic of an alternative embodiment of the device comprising a twisting mechanism for extension and retraction of the outer sheath.
DETAILED DESCRIPTION

[071] The various systems and devices disclosed herein relate to devices for use in medical procedures and systems. More specifically, various embodiments relate to various medical devices, including vascular access devices and related methods and systems. It is understood that the various embodiments of the disclosed devices and related methods and systems disclosed herein can be incorporated into or used with any other known medical devices, systems, and methods.

[072] FIGS. 2A-16B depict exemplary embodiments of the present devices, systems and methods in detail. Each of the device embodiments disclosed herein will hereinafter be referred to variously as a "vascular access device" or "sheath" for brevity. This in no way reduces the contemplated scope of the various embodiments of the instant disclosure to a singular modality.

[073] Exemplary embodiments of the sheath 10 can be used when cleaning out the thrombosis, or stenosis, in the graft or fistula via only one puncture and access site. As is shown in FIGS. 2-3B, exemplary embodiments of the disclosed sheath 10 generally comprise an elongate inner shaft 12 having proximal 14 and distal 16 ends. Various embodiments are configured for directional and sealing capabilities. Exemplary embodiments of the distal end 16 comprise a plurality of side openings 18 (best shown in FIGS. 4A-5C and discussed in detail below) and a terminal opening 19. In various embodiments, the proximal end 14 is in operational communication with a central toolhead hub 20, and may further comprise an outer sheath 22 and hand-actuated sheath actuation and retraction grip 24, a central infusion port 25, and at least one side infusion port 26. In exemplary embodiments, at least one of the infusion ports 25, 26 is in fluidic communication with a plurality of lumens contained within the shaft 12. In exemplary embodiments, the shaft comprises an inner lumen 34 and a balloon lumen 36, as is shown in FIG 6D. In further embodiments, the device further comprises an intake lumen 21 and a stop-cock 23 connected to the inner lumen 34 (as best shown in FIGS. 6A-6B) of the inner shaft 12. As would be apparent to one of skill in the art, a variety of fluidic devices can be used for the intake lumen 21, such as a syringe. The intake lumen 21 allows for the introduction of various fluids, such as imaging contrasts, blood-clot busting medications, saline, embolization products and a number of other fluids and pharmaceuticals to be injected into the vessels through the device, the flow of which can be regulated by way of the stopcock 23 or other control mechanism.
In exemplary implementations, the central infusion port 25 is in fluidic communication with the inner lumen 36, as is described further herein in relation to FIGS. 2A-2B and 8, and may further comprise a needleless injection site 25A. In certain exemplary embodiments, the side infusion port 26 can comprise a needleless injection site 26A, which may be used to inflate the balloon 30, as is shown in FIGS. 5A-5C, 7A-C. In alternative embodiments, the infusion port 26 can be substituted with tubing and a stopcock or alternative fluid or gas introduction mechanisms to be used to inflate the balloon 30.

In certain embodiments, the proximal portion of the central hub 20 comprises a hemostasis valve 31 and a Y-connector 33 contained within the central infusion port 25 which is in fluidic/gaseous communication with the side infusion port 26 such that the balloon lumen is supplied with fluid/gas as presently described (and in further detail in relation to FIGS. 8-9B). In certain of these embodiments, the inner lumen 34 is in communication with an intake lumen 21, the central infusion port 25 thereby providing intake access for guidewires, catheters, obturators, needles, and other solid devices, as well as the introduction of drugs or other fluids through the distal openings 18A, 18B by way of the inner lumen 34. Various intake lumens 21 can be used with the various infusion ports 25, 26, 28 to introduce fluids, gases or objects into the body by way of the various lumens.

For example, in certain embodiments the central port 25 and intake lumen 21 are in fluidic communication with the inner lumen 34 (best shown in FIG. 6A-6C) such that fluids can be introduced by way of the intake lumen 21 and an obturator 32 and/or guidewire can be introduced by way of the central port 25, while the infusion port is in fluidic communication with the balloon lumen 36 (as best depicted in FIG. 6A-6D) to introduce air or fluid into the balloon lumen 36 (as described herein in relation to FIGS. 10A-14C) and then travel into the vessel (such as those used for angioplasty and mechanical clot busting).

As mentioned above, in certain embodiments, and as shown in FIGS. 2A-2B, the outer sheath 22 further comprises a hand-actuated sheath actuation and retraction grip 24. In certain embodiments, this can further comprise a hemostasis valve 31. In certain implementations, the grip 24 can be manually actuated. In certain implementations a locking mechanism, such as a Luer-lock, in accordance with industry standard BS EN 1707:1997, may also be utilized 24A, as would be understood by one of skill in the art.
As is further shown in FIGS. 3A-3B, in exemplary embodiments of the sheath 10, the outer sheath 22 is capable of moving between "open" (FIG. 3A) and "closed" (FIG. 3B) positions. That is, the outer sheath 22 is disposed so as to be slidable relative to the shaft 12 in conjunction with the user's operation, as shown by reference arrows P and D.

Another example of the outer sheath 22 moving between the open and closed configurations is shown in FIGS. 4A and 4B. According to the embodiment of FIG. 4A, the outer sheath 22 is positioned in a closed configuration for entry into the blood vessel or conduit (not shown) so as to substantially surround the distal end of the inner shaft 16, thereby covering the plurality of shaft side openings, or ports which are shown at 17, 18A, 18B in FIG. 4B. FIG. 4B depicts an embodiment of the vascular access system 10 wherein the outer sheath 22 has been retracted into an open configuration so as to expose the side openings, or side ports 17, 18A, 18B within the vessel. In these embodiments, the sheath 22 is configured to be anchored in a single location and can be capable of accessing the arterial and venous sides of the vessel.

Certain embodiments of the sheath address portal vein embolization. The liver is the only human organ that can regenerate itself. This capability can be taken advantage of to treat diseased portions of the liver, for example if a tumor is growing on one part of the liver. The diseased portion of the liver can be removed, and the remaining portion of the liver will regenerate. One manner by which the diseased portion of the liver can be targeted is by eliminating blood flow to one of the branches of the portal vein, which supplies 75% of blood flow to the liver. As such, by blocking flow to a portion of the liver, that portion will eventually become necrotic and as this diseased portion of the liver dies, a healthy portion will replace that which was previously occupied by the diseased liver. In certain embodiments, dead tissue can be removed surgically.

The system can be utilized to access the chosen branch of the portal vein. Inflation of the balloon at the distal end of the sheath prevents the embolitic material being dispensed from the distal end of the sheath from traveling to inappropriate branches of the portal vein. This method of occluding branches of the vein is superior to previous methods in that it controls the location of the emboli, producing a more effective blockage of the blood vessels and preventing the embolic agents from traveling through the blood vessels and clogging undesired locations of the portal vein. Overall this system would obviate the need for using different catheters and sheaths to target different branches of portal vein, resulting in reduced procedure time. Therefore
the radiation and contrast dose administered to the patient is lessened and the overall procedure is less invasive.

[081] The intake hub design shown in FIGS 4A-4B depicts a manually guided locking mechanism for the two sheaths, wherein the twisting of the grip 24 allows the free movement of the sheath, while twisting in the opposite direction locks it in place, as would be apparent to one of skill in the art.

[082] As shown in FIGS. 5A-6B, in various embodiments, the inner shaft 16 can contain multiple sets of side openings, or side ports, 17A, 17B defined variously along the shaft. In certain embodiments, a first side port or set of side ports can be defined generally so as to be configured to open arterially and a second set of side ports on the venous aspect of the shaft, so as to allow the introduction of fluids by way of the inner lumen 34 to the region of interest. These embodiments allow for convenient drug delivery in both directions: arterial and venous.

[083] As is depicted in FIG 5A-C, and as mentioned above, unlike intravascular access sheaths known in the art, the inner shaft 12 disclosed herein further comprises a balloon 30 which can be deployed near the distal end 16 and be in operational communication with one or more of the side openings 17A, 17B, 18A, 18B so as to be deployed and inflated. In certain embodiments, one or more of the openings 17A, 17B are in fluidic or gaseous communication with the balloon 30, while others 18A, 18B are disposed either proximally or distally of the balloon openings 17A, 17B so as to allow the delivery of a substance either upstream or downstream of the balloon 30, and in certain embodiments a distal end port 19 is also present. In certain embodiments, the openings can be oriented in parallel, or otherwise disposed in alternate radial orientations from one another. In certain embodiments, the balloon 30 may take the shape of a disc, though other forms are possible. In various embodiments, the balloon 30 is capable of inflation within a vessel or conduit so as to create a barrier or otherwise restrict the flow of liquid through that vessel.

[084] In these embodiments, the balloon 30 provides the user with various functions for imaging and accessing the arterial or venous side, including occlusion and anchoring. In certain embodiments, the shaft 12 is held within the blood vessel by a balloon while changing directions. This is useful in the field of interventional radiology, particularly for the purpose of cleaning out blockages in grafted vessels utilized in kidney dialysis. In various alternative embodiments, a
mechanism similar to that used in embolic protection devices can be substituted for the balloon 30.  

[085] In certain embodiments of the sheath 10, by retracting the outer sheath 22 and inflating the balloon 30 (as shown in FIGS. 5A-C), the plurality of side openings 18A, 18B, are exposed (as shown in FIG. 5B). In certain embodiments, the terminal opening or end port 19 can be occluded with an obturator or guidewire 32.  

[086] As is shown in FIGS. 6A-6B, the obturator, stylet, or guidewire 32 is capable of occluding the terminal opening 19 such that fluid 40 is forced to exit the lumen 34 by way of one of the side openings 18A, 18B. The balloon 30 in turn prevents liquid from flowing distally. By way of example, if the outer sheath 22 is inserted into the venous side of a vessel, inflation of the balloon 30 in the absence of the obturator 32 will result in the passage of any liquid sent through the inner lumen 34 (discussed in relation to FIG. 6A) to flow to the venous aspect. However, as shown in FIG. 6B, in embodiments wherein the obturator or guidewire 32 is occluding the terminal opening 19, liquid flowing through the inner lumen 34 will be diverted to the arterial (proximal) side. Accordingly, in certain embodiments, the balloon 30 is configured to establish a partition between the various limbs of a vessel, such as the venous and arterial branches.  

[087] In FIG. 6C, in certain alternative embodiments, an obturator 32 can be used to occlude a distal side 18A opening such that the fluid can flow out of the more proximal side openings 18B, 18C, and because the blood flow is occluded, this fluid travels to the arterial side, thereby providing a clear image of any complications on the arterial side, as is described in relation to FIG. HE. In further embodiments, various alternative configurations are possible.  

[088] FIG. 6D, which is mentioned above, depicts a transverse cross-section of an exemplary embodiment of the inner shaft 12 showing a plurality of lumens in the inner shaft 12. By way of example, in certain embodiments, the inner shaft 12 comprises at least an inner lumen 34 and a balloon lumen 36. Other configurations are possible, including a plurality of inner lumens. Any fluid which is injected through an infusion port 25, 26, 28 (as depicted in FIGS. 2A and 2B and discussed above) will be passed by way of the corresponding lumen 34, 36 to a specific branch of the conduit. By way of example, in certain embodiments, the arterial segment can be imaged without moving the outer sheath 22.  

[089] FIGS. 7A-7B are coronal cross-sections of various embodiments of the sheath depicting the separation of fluids to the balloon 30 and inner lumen 34. As shown in FIG. 7B-C,
in this embodiment, the infusion port 26 is in fluidic communication with the balloon lumen 36 (also shown in FIG. 6A-B). As fluid is transferred down the balloon lumen 36, it travels through side port(s) 18A to fill and expand balloon 30. As is shown in FIG. 8, in this embodiment, the central infusion port 25 is in fluidic communication with the inner lumen 34 (also shown in FIG. 6A-B) so as to allow the transfer of fluids to the shaft's distal end 16. Insertion and operation of the sheath is described in further detail in FIGS. 9A-14C.

[090] FIGS. 9A-9C depict the insertion of the sheath 10 into the body 100 and graft 102. In the embodiments depicted in FIGS 9C and 10, the device 10 is set into the venous side for further actuation of the sheath and inflation of the balloon, as is shown in FIGS. 3A-3B. In these embodiments, the sheath 10 can be introduced at approximately a 30° angle (designated by reference arrow C in FIG. 9C). Other angles are of course possible, as would be apparent to one of skill in the art. As is further shown in FIG. 10, after placement of the device 10, various infusion ports (here designated with 28) are configured to deliver fluids 40 from an intake lumen, such as a syringe 21, to the vein 104 or artery 106 or in alternative embodiments be able to inflate the balloon by way of an opening, or as desired. As is shown in FIGS. 9A-14C, the venous and arterial blood flows are designated by the reference arrows V and A, respectively. Certain embodiments further comprise the use of a stopcock connection or a needleless inflation portion. The intake lumen 21 (depicted in FIGS. 2A and 2B) or other introduction device can be used to perform the actuation and/or delivery, as was previously discussed. According to various embodiments, the device 10 is configured to be used in certain venous-side procedures such as angioplasty, stenting, and thrombectomy/thrombolysis.

[091] FIGS. 11A-E depict embodiments directed to arterial side imaging. In these embodiments, retracting the outer sheath 22 exposes the side ports on the arterial aspect of the shaft 12. As is shown in FIGS. 11B, following the retraction, the sheath 22 can be retracted, and then in FIG. 11C, the balloon 30 can be inflated by way of introduction of the balloon lumen (accessed by way of an infusion port 26) to occlude blood flow (A and V) through the vessel 100. As shown in FIG. 11D, following this occlusion, the user inserts an obturator 32 or uses an existing guidewire so as to block the distal side opening 18A or end opening 19 so as to introduce dye 40 through the inner lumen 34 in an arterial direction, as designated by reference arrow B in FIG. 11E.
[092] FIGS. 12A-D depict embodiments of the sheath directed to addressing complications which may be found following the imaging procedure of FIGS. 11A-E. If complications exist in the arterial side 106 and intervention is necessary, the user removes the obturator 32 and partially deflates the balloon 30 to allow redirection, as shown in FIG. 12A. In these embodiments, the balloon 30, still partially inflated, can act as anchoring device and does not allow the sheath 10 to exit the vessel 1. As such, and as shown in FIGS. 12B-D, the device 10 can then be redirected to arterial side 106 without being removed, so as to perform various interventions on the arterial side, such as angioplasty 200, stenting 202, and thrombectomy/thrombolysis 204, as is depicted in FIGS. 13A-C, respectively. Following the performance of any arterial procedures, the balloon 30 is retracted back through the side opening 18A, the sheath 22 is closed and the device retracted from the arterial aspect, as is depicted in FIGS. 14A-C.

[093] FIGS. 15A-B depict various embodiments of the sheath 10 configured for a twisting mechanism 50 for moving the outer sheath 22 as opposed to the locking mechanism of the embodiments of FIGS. 4A-5C. In these embodiments, the sheath 10 further comprises a hub 50, which is configured to actuate the sheath 22 retraction by way of a threaded member 52.

[094] Further, exemplary embodiments allow the physician or user access to a blood vessel or conduit in both upstream and downstream directions from one puncture site without reinserting another access sheath. Thus, the sheath enables the physician or user to access clots both upstream and downstream with a single puncture site reducing the amount of time the patient is exposed to radiation and increasing efficiency for the physician. Additionally, because the device is capable of halting blood flow in a vessel, the device can deliver radiopaque or other marker fluid or drugs in the upstream direction of the blood vessel, whereas current devices cannot.

[095] The initial anticipated fields of application of the disclosed system are interventional radiology and interventional cardiology. A hemodialysis patient has a graft or fistula in their arm, which connects the artery to the vein. The problem is that these grafts and fistulas are being punctured about three times a week, causing damage to the vessels and conduit, which often times leads to thrombosis and stenosis. When cleaning out the thrombosis there are two additional punctures to separately access the upstream and downstream directions of the arterial side and venous side, causing additional damage.
Although the disclosure has been described with reference to preferred embodiments, persons skilled in the art will recognize that changes may be made in form and detail without departing from the spirit and scope of the disclosed apparatus, systems and methods. Accordingly, while the sheaths in accordance with the present disclosure have been described as being used in connection with procedures relating to renal disease, it is envisioned that the sheaths, systems and methods disclosed may be used in other procedures. It is understood that various modifications may be made to the embodiments of the presently disclosed device and system. Therefore, the above description should not be construed as limiting, but merely illustrative of the variations described herein.
CLAIMS

What is claimed is:

1. A intravascular access device for use on a patient undergoing a medical procedure comprising:
   a. an elongate shaft further comprising a distal end and a proximal end and further comprising at least one side port disposed near the distal end;
   b. a toolhead hub fixedly attached to the proximal end of the elongate shaft, wherein the toolhead hub further comprises at least one infusion port;
   c. a retractable sheath disposed over the elongate shaft and configured to be retracted to expose the at least one side opening; and
   d. a balloon configured to be deployed and inflated within the vessel of the patient so as to create a barrier in the vessel.

2. The device of claim 1, further comprising at least one lumen disposed through the elongate shaft.

3. The device of claim 1, wherein the at least one infusion port comprises a central infusion port in fluid communication with an inner lumen defined in the elongate shaft.

4. The device of claim 1, further comprising an inner lumen disposed through the elongate shaft and a balloon lumen disposed through the elongate shaft, wherein the balloon lumen is in fluid communication with the balloon.

5. The device of claim 4, wherein the at least one infusion port comprises a side infusion port in fluid communication with a lumen defined in the elongate shaft.

6. The device of claim 5, wherein the side infusion port is in fluid communication with the balloon lumen.

7. A intravascular access sheath system comprising:
a. an elongate shaft comprising at least one side port defined in a distal portion of
   the elongate shaft;
   b. a hub operably coupled to a proximal end of the elongate shaft, wherein the hub
      comprises at least one infusion port;
   c. a retractable sheath disposed over the elongate shaft, wherein the retractable
      sheath comprises:
      i. a closed configuration in which the retractable sheath is positioned over
         the at least one side port; and
      ii. an open configuration in which the at least one side port is exposed; and
   d. a balloon operably coupled to the distal portion of the elongate shaft, wherein the
      balloon is configured to be deployed and inflated within a vessel of a patient so as
      to create a barrier in the vessel.

8. The sheath of claim 7, further comprising at least one lumen disposed through the
   elongate shaft.

9. The sheath of claim 8, further comprising an inner lumen disposed through the elongate
   shaft and a balloon lumen disposed through the elongate shaft, wherein the balloon lumen is in
   fluid communication with the balloon.

10. The sheath of claim 9, wherein the at least one infusion port comprises a central port in
    fluid communication with an inner lumen defined in the elongate shaft.

11. The sheath of claim 7, wherein the at least one infusion port comprises a side port in fluid
    communication with a lumen defined in the elongate shaft.

12. A method of performing an intravascular surgical procedure comprising:
    a. providing an intravascular device comprising:
       i. an elongate shaft comprising at least one side port defined in a distal
          portion of the elongate shaft;
ii. a hub operably coupled to a proximal end of the elongate shaft, wherein the hub comprises at least one infusion port;

iii. a retractable sheath disposed over the elongate shaft, wherein the retractable sheath comprises:
   A. a closed configuration in which the retractable sheath is positioned over the at least one side port; and
   B. an open configuration in which the at least one side port is exposed; and

iv. a balloon operably coupled to the distal portion of the elongate shaft, wherein the balloon is configured to be deployed and inflated within a vessel of a patient so as to create a barrier in the vessel.

b. inserting the device into the fistula or graft of a patient such that the distal end is disposed within a graft or fistula at a puncture site; and

c. performing an intravascular procedure.

13. The method of claim 12, wherein the intravascular device further comprises at least one lumen disposed through the elongate shaft.

14. The method of claim 12, wherein the intravascular device further comprises an inner lumen disposed through the elongate shaft and a balloon lumen disposed through the elongate shaft, wherein the balloon lumen is in fluid communication with the balloon.

15. The method of claim 12, wherein the at least one infusion port comprises a central port in fluid communication with an inner lumen defined in the elongate shaft.

16. The method of claim 12, wherein the at least one infusion port comprises a side infusion port in fluid communication with a lumen defined in the elongate shaft.

17. The method of claim 12, wherein the intravascular procedure is an imaging procedure performed on both an arterial and a venous side of the graft or fistula using a single puncture site.
18. The method of claim 17, wherein the imaging procedure comprises:
   a. directing the elongate shaft into a venous side of the fistula or graft;
   b. delivering imaging contrast liquid through an inner lumen to a port at the distal end of the elongate shaft;
   c. taking an x-ray of the venous side of the fistula or graft;
   d. pulling back the retractable sheath to expose the balloon and the at least one side port;
   e. inflating the balloon to occlude the graft or fistula;
   f. delivering imaging contrast liquid through the inner lumen to the at least one side port; and
   g. taking an x-ray of the arterial side of the fistula or graft.

19. The method of claim 18, further comprising:
   a. partially deflating the balloon;
   b. retracting the elongate shaft from the venous side without leaving the graft or fistula, wherein the balloon prevents the elongate shaft from exiting the puncture site;
   c. redirecting the elongate shaft into the arterial side of the graft or fistula;
   d. inflating the balloon to occlude the graft or fistula;
   e. performing an interventional procedure to eliminate thrombosis or stenosis;
   f. deflating the balloon;
   g. closing the retractable sheath; and
   h. withdrawing the elongate shaft from the graft or fistula.

20. The method of claim 19, wherein the interventional procedure is one or more of delivering thrombolytic drugs, implanting stents, expanding a vessel with a balloon catheter, or removing clots by aspiration.
FIG. 10
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION O P SUBJECT MATTER
   IPC(8) - A61M 25/00 (2015.01)
   CPC - A61M 25/007 (2015.07)
   According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED
   Minimum documentation searched (classification system followed by classification symbols)
   IPC(8) - A61B 17/00, 17/22, 17/3205, 17/3207; A61M 25/00, 25/01, 25/10, 31/00 (2015.01)
   Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
   USPC - 604/48, 500, 507, 508, 509, 510 (keyword delimited)
   Electronic database consulted during the international search (name of data base and, where practicable, search terms used)
   PatBase, Google Patents, Google.
   Search terms used: blood vessel, fistula graft, dialysis, retractable sheath, jacket, side port, infusion, imaging, contrast, balloon

C. DOCUMENTS CONSIDERED TO BE RELEVANT
   Category* Citation of document, with indication, where appropriate, of the relevant passages Relevant to claim No.
   X US 2013/0178790 A1 (TEKULVE) 11 July 2013 (11.07.2013) entire document 1-5, 7-16
   Y US 2008/0058758 A1 (RANCHOD et al) 06 March 2008 (06.03.2008) entire document 6, 17, 18
   A US 2012/0109057 A1 (KROLIK et al) 03 May 2012 (03.05.2012) entire document 1-20

Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:
   "A" document defining the general state of the art which is not considered to be of particular relevance
   "E" earlier application or patent but published on or after the international filing date
   "L" document which may doubt on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
   "O" document referring to an oral disclosure, use, exhibition or other means
   "P" document published prior to the international filing date but later than the priority date claimed
   "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
   "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
   "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
   "&" document member of the same patent family

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14 July 2015

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Name and mailing address of the ISA/
Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-8300

Authorized officer Blaine Copenhaver
PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

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