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DUAL LUMEN SHEATH FOR ARTERIAL ACCESS

Abstract

A sheath assembly for the insertion of a percutaneous pump includes a tubular sheath body dimensioned for insertion into a blood vessel through a vessel aperture. The tubular sheath body includes a wall having a proximal end portion, a distal end portion, a longitudinal axis, an outer surface, an inner surface defining a first lumen substantially parallel to the longitudinal axis, and a second lumen disposed within the wall between the inner surface and the outer surface and extending from the proximal end portion to the distal end portion. The first lumen is dimensioned to allow passage of a portion of the percutaneous pump, and the second lumen is dimensioned for passage of a guidewire. A stylet is removably positioned to substantially occlude the second lumen. The stylet has a proximal end releasably secured to the sheath assembly.

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Background/Summary

CROSS-REFERENCE TO RELATED APPLICATION [0001] This application is a continuation of U.S. patent application Ser. No. 18/381,219, filed Oct. 18, 2023, now allowed, which application is a continuation of U.S. patent application Ser. No. 17/351,671, filed Jun. 18, 2021, now U.S. Pat. No. 11,833,314, which application is a continuation of U.S. patent application Ser. No. 16/907,533, filed Jun. 22, 2020, now abandoned, which is a divisional of U.S. patent application Ser. No. 14/827,741, filed Aug. 17, 2015, now U.S. Pat. No. 10,737,008, the disclosures of all of which are incorporated herein by reference in their entirety.

BACKGROUND

[0002] A blood pump, such as a percutaneous intracardiac blood pump assembly, is introduced in the heart to deliver blood from the heart into an artery. When deployed in the heart, a blood pump assembly pulls blood from the left ventricle of the heart and expels blood into the aorta, or pulls blood from the right ventricle and expels blood into the pulmonary artery. Blood pump assemblies are introduced surgically or percutaneously during a cardiac procedure through the vascular system. In one common approach, pump assemblies are inserted by a catheterization procedure through the femoral artery using a peel-away introducer sheath.

[0003] The peel-away introducer sheath is inserted into the femoral artery through an arteriotomy to create an insertion path for the pump assembly. A portion of the pump assembly is then advanced through an inner lumen of the introducer and into the artery. Once the pump assembly has been inserted, the peel-away introducer sheath can be peeled away. A repositioning sheath can then be advanced over the pump assembly and into the arteriotomy. Replacing the introducer sheath with the repositioning sheath can prevent blood clot formation in the introducer sheath, prevent or reduce bleeding from the arteriotomy, and allow blood to flow through the femoral artery to the leg. But after the introducer sheath is removed, wire access to the artery is lost. Loss of the guidewire access makes it more difficult to close the vessel after the procedure or to exchange devices in the arteriotomy.

[0004] To maintain guidewire access, some physicians leave the peel-away introducer sheath in the arteriotomy for extended durations of time. The extended presence of the peel-away sheath in the arteriotomy can reduce recoil of the arteriotomy and thus increase the final diameter of the arteriotomy. This increase in diameter can increase the risk of bleeding through the arteriotomy once the peel-away introducer sheath is finally removed. Furthermore, the extended presence of the peel-away sheath in the artery can reduce perfusion through the femoral artery, thereby increasing the risk of ischemia.

[0005] Additionally, clinicians sometimes choose to monitor a patient's arterial pressure during the catheterization procedure. Measurement of the patient's arterial pressure often requires the placement of an additional catheter. The presence of the additional catheter can add bulk to the operating area and requires entry into the arterial system via another access point.

SUMMARY

[0006] Systems, methods, and devices for an improved dual lumen repositioning sheath are presented. The dual lumen sheath can be inserted into an arteriotomy after an introducer sheath is removed to maintain guidewire access to the arteriotomy. The dual lumen sheath includes a first lumen sized for passage of a portion of a percutaneous pump and a second lumen sized for the insertion of a guidewire. The second lumen receives a guidewire to be inserted into the arteriotomy alongside a percutaneous pump to maintain guidewire access to the insertion path of the percutaneous pump. By maintaining guidewire access using the second lumen of the dual lumen sheath, the introducer sheath can be removed from a patient without losing the guidewire access. This allows the physician to remove the introducer sheath earlier in a procedure (e.g., 1 hour, 30 minutes, 10 minutes, 5 minutes, or immediately after successful insertion of the percutaneous pump), which allows the blood vessel aperture to recoil to a smaller diameter compared to the diameter it would assume if the introducer sheath were left in the patient for longer. For example, a recoil of **2** to **3** French (0.667 mm to 1 mm) may be achieved if the introducer sheath is removed before the blood vessel aperture permanently relaxes to the larger diameter of the introducer sheath.

[0007] The dual lumen sheath also includes a removable stylet that is inserted into the second lumen to reduce the risk of blood clot formation in the second lumen during the medical procedure. Maintaining the patency of the second lumen is particularly helpful in procedures having a longer duration (e.g., six hours or longer). The removable stylet may be reversibly coupled to the dual lumen sheath during insertion of the dual lumen sheath into the arteriotomy and during the medical procedure. Before the percutaneous pump is removed, the stylet is removed from the second lumen to allow insertion of the guidewire through the second lumen. In some implementations, the patency of the guidewire port is maintained using a drug or nondrug coating applied to the second lumen. In certain implementations, the second lumen is flushed with a liquid at a controlled rate to maintain patency.

[0008] In some embodiments, the dual lumen sheath also includes a rotatable connection to a stabilizing structure (e.g., suture pads). The rotatable connection allows the outlet of the second lumen at the distal end of the sheath to be rotated away from an arterial wall. This can facilitate the insertion of the guidewire by allowing the guidewire to be inserted in a direction not directly against the arterial wall, thereby reducing the friction associated with insertion of the guidewire. Additionally, the rotation allows the port for the second lumen to lie flat against the patient when the second lumen is not in use.

[0009] The second lumen provides a number of possible other advantages. For example, it also allows arterial pressure to be transduced without the need for an additional catheter. Transducing the pressure can allow a physician to determine when the dual lumen sheath has been inserted to a sufficient depth. If the second lumen is used to transduce pressure, the rotation of the guidewire outlet enabled by the rotatable connection to the stabilizing structure can improve the reliability of the pressure measurement by keeping the outlet of the second lumen off of the arterial wall. Additionally, the second lumen can be used to determine the depth of insertion without a pressure transducer. For example, the depth of insertion can be determined by observing the onset of blood flow through the second lumen (“bleedback”), which is indicative of penetration into the arteriotomy. Regardless of whether a pressure transducer or a bleedback indicator is used, depth markings can be disposed on an outer surface of the sheath to facilitate measurement of the depth of insertion. The depth markings may be radio-opaque. The measurement of the depth of the arteriotomy relative to the patient's skin can facilitate the subsequent use of certain vessel closure tools which may require such a measurement.

[0010] In one aspect, a sheath assembly for the insertion of a percutaneous pump includes a tubular

sheath body dimensioned for insertion into a blood vessel through a vessel aperture. The tubular sheath body includes a wall having a proximal end portion, a distal end portion, a longitudinal axis, an outer surface, an inner surface defining a first lumen substantially parallel to the longitudinal axis, and a second lumen disposed within the wall between the inner surface and the outer surface and extending from the proximal end portion to the distal end portion. The first lumen is dimensioned to allow passage of a portion of the percutaneous pump, and the second lumen is dimensioned for passage of a guidewire. A stylet is removably positioned to substantially occlude the second lumen.

[0011] In certain implementations, the stylet has a proximal end configured to be releasably secured to the sheath assembly. In some implementations, the length of the stylet is substantially equal to the length of the second lumen. In certain implementations, the stylet is radio-opaque or includes radio-opaque marker bands to show the distance of the sheath in the blood vessel. In certain implementations, the sheath assembly also includes a hub coupled to the proximal end portion of the sheath body and including a first port in fluid communication with the first lumen, and a second port in fluid communication with the second lumen, wherein the second port is configured to secure the proximal end of the stylet. The sheath body may be dimensioned to be introduced through a percutaneous access site of about 20 Fr (6.67 mm) or less (e.g., 19 Fr, 18 Fr, 17 Fr, 16 Fr, 15 Fr, 14 Fr, 13 Fr, 12 Fr, 10 Fr, 9 Fr, 8 Fr, 6 Fr, or less).

[0012] In some implementations, the distal end portion of the sheath body is tapered and includes a tapered surface extending to a distal end face, the distal end face being substantially orthogonal to the longitudinal axis of the sheath body. In certain implementations, the second lumen has an outlet extending through the tapered surface of the distal end portion of the sheath body. The second lumen may be coated with an antithrombogenic agent. In some implementations, the outer surface of the wall of the tubular sheath body includes a hydrophilic coating or any other suitable coating to prevent tissue adhesion. In certain implementations, the outer surface of the wall includes markings for determining a depth of insertion, for example with evenly spaced markings on the outer surface of the wall.

[0013] In certain implementations, the sheath assembly of claim also includes a stabilizing structure rotatably coupled to the tubular sheath body. The stabilizing structure may be rotatable about the longitudinal axis. In some implementations, the stabilizing structure includes a feature configured for suturing to a patient. The stabilizing structure may include a pair of suture wings, each wing having a plurality of ribs for securing sutures.

[0014] In another aspect, a method for maintaining guidewire access includes inserting a sheath into a blood vessel through a percutaneous insertion path and along a portion of a percutaneous pump, wherein the sheath has a first lumen and a second lumen, maintaining the sheath in the vessel for more than 6 hours while preventing blood clot formation from occluding the second lumen, and inserting a guidewire through the second lumen into the percutaneous insertion path after the more than 6 hours.

[0015] In some implementations, maintaining the patency includes inserting a stylet into the second lumen for more than 6 hours, and removing the stylet before inserting the guidewire. In certain implementations, maintaining the patency includes flushing the second lumen with purge fluid. In some implementations, the method the method also includes removing the sheath while maintaining the guidewire in the percutaneous insertion path. In certain implementations, the method also includes inserting a percutaneous tool over the guidewire into the percutaneous insertion path after the sheath is removed. In some implementations, the method also includes coupling a sensor to the proximal inlet of the second lumen and transducing arterial pressure at the distal outlet of the second lumen using the sensor. In certain implementations, the method also includes rotating the sheath relative to a support structure when the pressure measurement indicates that the distal outlet is occluded by an arterial wall. In some implementations, the method also includes determining a depth of insertion from the pressure measurement. The depth of insertion

may be determined using depth markers disposed on an outer surface of the sheath.
[0016] Variations and modifications will occur to those of skill in the art after reviewing this disclosure. The disclosed features may be implemented, in any combination and subcombination (including multiple dependent combinations and subcombinations), with one or more other features described herein. The various features described or illustrated above, including any components thereof, may be combined or integrated in other systems. Moreover, certain features may be omitted or not implemented.

Description

BRIEF DESCRIPTION OF THE DRAWINGS
[0017] The foregoing and other objects and advantages will be apparent upon consideration of the following detailed description, taken in conjunction with the accompanying drawings, in which like reference characters refer to like parts throughout, and in which:
[0018] FIG. **1** shows a top view of an illustrative dual lumen sheath for arterial access;
[0019] FIG. **2** shows a lateral section view of the dual lumen sheath of FIG. **1**;
[0020] FIG. **3** shows a transverse cross section of the distal portion of the dual lumen sheath of FIG. **1**;
[0021] FIG. **4** shows a detailed section view of a distal portion of the dual lumen sheath of FIG. **1**;
[0022] FIG. **5** shows the dual lumen sheath of FIG. **1** inserted into a blood vessel of a patient over a percutaneous pump; and
[0023] FIG. **6** shows an illustrative process for maintaining guidewire access.
DETAILED DESCRIPTION
[0024] To provide an overall understanding of the systems, method, and devices described herein, certain illustrative embodiments will be described. Although the embodiments and features described herein are specifically described for use in connection with a percutaneous blood pump system, it will be understood that all the components and other features outlined below may be combined with one another in any suitable manner and may be adapted and applied to other types of cardiac therapy and cardiac assist devices, including balloon pumps, cardiac assist devices implanted using a surgical incision, and the like.
[0025] The systems, methods, and devices described herein provide a dual lumen sheath having a first lumen sized for passage of a portion of a percutaneous pump and a second lumen sized for insertion of a guidewire. The second lumen is positioned to allow the guidewire to be inserted into the insertion path of the percutaneous pump. This allows guidewire access to the insertion path to be maintained even after the percutaneous pump and dual lumen sheath are retracted. The guidewire access allows one or more other tools (e.g., a vessel closure tool) to be subsequently inserted into the same insertion path to facilitate vessel closure or any other medical procedures involving guidewire access. Because the second lumen enables a physician to maintain the guidewire access after the introducer sheath is removed, the physician can remove the introducer sheath earlier in a medical procedure. Earlier removal of the introducer sheath allows the insertion path to recoil to a smaller diameter, thereby reducing the risk of bleeding through the access site.
[0026] The systems, methods, and devices described herein also include a stylet that maintains the patency of the second lumen. The stylet is used to occlude the second lumen when the second lumen is not being used for insertion of a guidewire or for pressure measurement. For example, the removable stylet may be positioned within the second lumen during insertion of the dual lumen sheath into the arteriotomy and during the operation of the percutaneous pump. Before the percutaneous pump is removed, the stylet is removed from the second lumen to allow insertion of the guidewire through the second lumen. The occlusion of the second lumen with the stylet can impede blood clot formation in the second lumen during medical procedures having a long duration

(e.g., six hours or greater). This allows the second lumen to remain accessible during and after the medical procedure, for example to provide a path for insertion of the guidewire before removing the percutaneous pump. In some implementations, blood clot formation is prevented using a drug or nondrug coating applied to the second lumen. In certain implementations, blood clot formation is impeded by flushing the second lumen with a liquid at a controlled rate.

[0027] The dual lumen sheath may also include a rotatable connection to a stabilizing structure (e.g., suture wings). The rotatable connection allows the outlet of the second lumen at the distal end of the sheath to be rotated away from an arterial wall. This can facilitate the insertion of the guidewire by allowing the guidewire to be inserted in a direction not directly against the arterial wall, thereby reducing the friction associated with insertion of the guidewire. Additionally, the rotation allows the port for the second lumen to lie substantially flat against the patient when the second lumen is not in use.

[0028] The second lumen can also establish fluid communication between a guidewire port and the interior of the blood vessel. This can allow arterial pressure measurement (e.g., by a pressure transducer) during a procedure without the use of a separate catheter. Measuring the arterial pressure can allow a physician to detect when the dual lumen sheath has been inserted to a sufficient depth into the vessel. The rotation of the guidewire outlet enabled by the rotatable connection to the stabilizing structure can improve the reliability of the pressure measurement by keeping the outlet of the second lumen off of the arterial wall.

[0029] FIG. **1** shows an illustrative dual lumen sheath assembly **100** for maintaining arterial access, according to certain implementations. FIG. **2** shows a lateral section view of the sheath assembly **100** taken along section line **2-2**, and FIG. **3** shows a transverse cross-section of a distal portion of the sheath assembly **100** taken along section line **3-3**. The sheath assembly **100** includes a tubular sheath body **102**, a stylet **120**, a hub **126**, and a stabilizing structure **150**. The tubular sheath body **102** is dimensioned for insertion into a blood vessel through a vessel aperture. In some implementations, the tubular sheath body **102** is dimensioned for insertion into a femoral artery through an arteriotomy. The majority of the tubular sheath body **102** may have a substantially uniform outer diameter **101** of about 10 Fr, 11 Fr, 12 Fr, 13, Fr, 14 Fr, 15Fr, 16 Fr, 17 Fr, 20 Fr, or any other suitable diameter. The tubular sheath body may be dimensioned to be introduced through a percutaneous access site of about 20 Fr (6.67 mm) or smaller (e.g., 19 Fr, 18 Fr, 17 Fr, 16 Fr, 15 Fr, 14 Fr, 13 Fr, 12 Fr, 10 Fr, 9 Fr, 8 Fr, 6 Fr, or less). The tubular sheath body may have a length of about 80 mm, 100 mm, 120 mm, 140 mm, 160 mm, or any other suitable length. Additionally, the tubular sheath body **102** may be made of a flexible material, such as polyether block amides or any other suitable polymer, to reduce the stress on the blood vessel aperture.

[0030] The tubular sheath body **102** includes a wall **104**, a proximal end portion **106**, a distal end portion **108**, a longitudinal axis **110**, an outer surface **112**, a first inner surface **114**, a second inner surface **115**, a first lumen **116**, and a second lumen **118**. The distal end portion **108** of the tubular sheath body **102** includes a tapered surface **103**, a first outlet **105** in fluid communication with the first lumen **116**, and a second outlet **107** in fluid communication with the second lumen **118**. The tapered surface **103** has an outer diameter graduated from 11 Fr to 15 Fr (3.667 mm to 5 mm). The graduation in the tapered surface **103** may permit the sheath to be inserted to a variable depth as necessary to plug the gap between the percutaneous pump and the insertion site.

[0031] The outer surface **112** of the tubular sheath body **102** may be coated with a hydrophilic coating to case insertion of the tubular sheath body **102** into the arteriotomy. A hydrophilic coating can also prevent adhesions to the blood vessel wall. Such adhesions could damage the vessel if the sheath is removed after having been in the blood vessel for an extended period of time (e.g., many days). The risk of adhesion to the blood vessel wall can increase as the duration of a procedure increases. In some embodiments, the outer surface **112** of the tubular sheath body **102** includes depth markings. The depth markings may be pad printed or laser etched onto the outer surface **112**. In certain implementations, the depth markings are radio-opaque. The depth markings may be in centimeters, inches, millimeters, or any other suitable unit of measurement or combination thereof.

[0032] The first inner surface **114** of the tubular sheath body defines the first lumen **116**. The first lumen **116** is dimensioned to allow passage of a portion of the percutaneous pump. The first lumen **116** extends from the proximal end portion **106** of the tubular sheath body **102** to the distal end portion **108**, substantially parallel to the longitudinal axis **110**. The second lumen **118** is disposed within the wall **104** between the inner surface **114** and the outer surface **112**. The second lumen **118** extends from the proximal end portion **106** of the tubular sheath body **102** to the distal end portion **108**, offset from and substantially parallel to the longitudinal axis **110**. The second lumen **118** is dimensioned for the passage of a guidewire and is defined by the second inner surface **115** (as shown in FIG. **3**). The second inner surface **115** may include a drug or non-drug coating to prevent blood clot formation in the second lumen **118**. In some implementations, the second inner surface is coated with heparin. The second lumen **118** terminates at the second outlet **107** formed in the tapered surface **103**. The second outlet **107** is adjacent to the first outlet **105** of the first lumen **116**. As a result, if a guidewire is inserted through the second lumen **118**, the guidewire enters the insertion path of the percutaneous pump (not shown) passing through the first lumen **116**. Thus, the second lumen **118** may be used to maintain or regain guidewire access to the insertion path of a percutaneous pump inserted through the first lumen **116**. This allows guidewire access to the insertion path to be maintained even after an introducer sheath is removed. The guidewire access allows one or more other tools to be subsequently inserted into the same insertion path to facilitate vessel closure or any other medical procedures involving guidewire access. For example, the guidewire access may permit the subsequent insertion of a vessel closure tool or a micro pressure measurement catheter (e.g., MILLAR Mikro-Tip.RTM. pressure catheter). A micro pressure measurement catheter may allow measurement of pressure in the left ventricle or any other suitable pressure. Furthermore, since the second lumen enables a physician to maintain guidewire access after the introducer sheath is removed, the physician can remove the introducer sheath earlier. Earlier removal of the introducer sheath allows the vessel aperture to recoil to a smaller diameter, thereby reducing the risk of bleeding through the access site. Additionally, since the second outlet **107** is offset from the longitudinal axis **110**, rotating the tubular sheath body **102** allows the position of the second outlet **107** to be adjusted. This can allow a user to keep the second outlet **107** off of a blood vessel wall to case insertion of a guidewire or to increase the accuracy of an arterial pressure measurement.

[0033] The tubular sheath body **102** is connected at its proximal end portion **106** to the hub **126**. The hub **126** includes a first port **128**, a second port **130**, second port threads **131**, and a bearing **136**. The second port **130** is connected to the second lumen **118** so that a guidewire can be inserted through the second port **130** into the second lumen **118** and out of the second outlet **107**. When a guidewire is not in the second lumen **118**, the stylet **120** can be inserted into the second port **130** to seal the second lumen **118** (as shown in FIGS. **1**, **2**, and **3**). The stylet **120** includes a head **121**, a stylet body **122**, a rounded end **123**, and threads **126**. The stylet body **122** is sized to substantially occlude the second lumen **118** when the stylet **120** is inserted into the second lumen **118**. In some implementations, the stylet body **122** is made of a formable or ductile material, such as a metal. This may allow the stylet to be formed, either during the medical procedure or before, into a shape that reduces stress on the vessel aperture. In certain implementations, the stylet **120** is radio-opaque or includes radio-opaque marker bands to show the depth of the tubular sheath body **102** in a blood vessel. The threads **124** of the stylet head **121** reversibly couple with the second port threads **131** to hold the stylet **120** within the second lumen **118**. When the stylet head **121** is reversibly coupled to the second port **130**, the stylet head **121** forms a liquid tight seal across the second port **130**, which prevents the leakage of blood out of the blood vessel. In certain implementations, in place of the stylet **120**, a pressure bag is connected to the second port **130** using the threads **131**. The pressure bag can be used to flush the second lumen **118** with a fluid to maintain the patency of the second lumen **118**. An infusion pump may be used in combination with the pressure bag to regulate the flow rate of liquid into the patient. For example, the flow rate may be limited to 1 mL/hr, 2 mL/hr, 5 mL/hr, 10 mL/hr, or any other suitable flow rate. In some implementations, a pressure measuring device is connected to the second port **130** to measure pressure within the vessel **10**. This pressure measurement can be used to determine when the second port **130** has been inserted sufficiently deep into the blood vessel aperture. For example, when a pressure about equal to arterial pressure is measured at the second port **130**, the second outlet **107** may be in fluid communication with the blood vessel. The pressure measurement can also be used to monitor arterial pressure in the patient's blood vessel during a medical procedure. This may allow an arterial pressure measurement to be taken without the use of an additional catheter, which may reduce the amount of equipment necessary in the potentially crowded operating area.

[0034] The first port **128** of the hub **126** allows the passage of the percutaneous pump (not shown). The first port **128** includes a cap **132** and a seal **134**. The cap **132** snaps into the first port **128** to hold the seal **134** against the first port **128**. The cap **132** and seal **134** together act as a hemostatic valve and form a liquid tight seal between the percutaneous pump and the first port **128**. The seal **134** is formed of an elastomer, such as silicone, so that it can flex to seal around a portion of the percutaneous pump.

[0035] The hub **126** is coupled to the stabilizing structure **150** by the bearing **136**. The stabilizing structure **150** includes wings **152** and **154**, suture holes **156-159**, ribs **160-162**, and a bearing surface **164** that mates with the bearing **136**. The mating of the bearing surface **164** of the stabilizing structure **150** with the bearing **136** of the hub **126** allows rotation of the hub **126** relative to the stabilizing structure **150**. As discussed above, this rotation allows the tubular sheath body **102** to be rotated such that the second outlet **107** is oriented away from a vessel wall. Additionally, this rotation allows the second port **130** to lie flat against a patient when the second port **130** is not in use. The suture holes **156-159** allow the wings **152** and **154** to be sutured to a patient to stabilize the sheath assembly **100**. While only four suture holes **156-159** are shown, any suitable number of suture holes may be used. The stabilizing structure **150** is also designed to be easily attached to a vascular graft with umbilical tape or sutures. This feature is beneficial during axillary insertions or any other insertions which require pump placement through a vascular graft. Additionally, in some implementations, the stabilizing structure **150** is coupled to a patient using ribs **160-162**. For example, sutures may be wrapped around the outer surface **165** of the stabilizing structure between the ribs **160-162**. When sutures are wrapped around the outer surface **165** in such a manner, the ribs **160-162** prevent the sutures from sliding off of the outer surface **165** along the longitudinal axis **110**. In certain implementations, other stabilizations devices, such as surgical tape, a STATLOCK.RTM. stabilization device (Bard Access Systems, Inc., Salt Lake City, Utah), or any other suitable adhesive stabilization device, may be coupled to the stabilizing structure **150** around the ribs **160-162**.

[0036] FIG. **4** shows a detailed section view of the distal portion **108** of the dual lumen sheath assembly **100** of FIGS. **1**, **2**, and **3**. The distal portion **108** includes the tapered surface **103**, the first outlet **105**, the second outlet **107**, and distal portions of the stylet body **122**, the first lumen **116**, and the second lumen **118**. The first lumen **116** includes a proximal section **116***a* having an inner diameter **117**, a distal section **116***b* having an inner diameter **217** which is less than the inner diameter **117**, and a restriction **216** therebetween. The inner diameter **117** is about 13 Fr (4.333 mm), and the inner diameter **217** is about 9 Fr (3 mm). The restriction **216** allows the distal section **116***b* of the first lumen **116** to form a tighter fit with the percutaneous pump to prevent or reduce blood leakage without causing unacceptably high friction in the proximal section **116***a*. Similar to the first lumen **116**, the second lumen **118** includes a proximal section **118***a* having a diameter **119**, a distal section **118***b* having a diameter **219** that is less than the diameter **119**, and a restriction **218** therebetween. The diameter **119** is about 1.1 mm and the diameter **219** is about 1 mm. The restriction **218** allows a tighter fit between the stylet body **122** and the second lumen **118** at the distal section **118***a* to reduce blood ingress, while allowing a clearance in the proximal section **118***b* to reduce friction. The friction between the second lumen **118** and the stylet body **122** is further reduced by the rounding of the end **123** of the stylet body **122**. The rounded end **123** is located adjacent to the second outlet **107** when the stylet **120** is fully inserted into the second lumen **118**, thereby preventing or reducing blood ingress into the second lumen **118**.

[0037] FIG. **5** shows the dual lumen sheath assembly **100** of FIG. **1** inserted into a blood vessel **10** of a patient over a percutaneous pump **60**. The percutaneous pump **60** includes a pump head **66** and a catheter body **62**. The percutaneous pump **60** may be an intravascular blood pump, a blood pump driven by flexible drive shaft, a blood pump including an implantable motor, a blood pump having an expandable pump rotor, or any other suitable pump. The dual lumen sheath assembly **100** is advanced into the blood vessel **10** over the catheter body **62** of the percutaneous pump **60** through the blood vessel aperture **12** in the direction indicated by arrow **70**. The first lumen **116** of the dual lumen sheath assembly **100** may be threaded on the catheter body **62** when the percutaneous pump **60** is initially inserted into the blood vessel **10**. The blood vessel **10** may be a femoral artery, and the blood vessel aperture **12** may be an arteriotomy. The blood vessel aperture **12** may have an opening slightly larger than the diameter **64** of the catheter body **62**. Thus, the tubular body **102** of the dual lumen sheath assembly **100** may effectively plug the gap between the blood vessel aperture **12** and the catheter by **64** when the sheath assembly **100** is advanced into the blood vessel **10** over the catheter body **62**. The outer diameter **101** of the tubular sheath body **102** may be graduated as discussed above to so that the diameter **101** of the tubular sheath body **102** increases from its distal end portion **108** to its proximal end portion **106**. This can allow the tubular sheath body **102** to be inserted farther into the blood vessel **10** to plug a larger gap between the blood vessel aperture **12** and the catheter body **62**. The plugging effect of the tubular sheath body **102** can reduce or prevent bleeding out of the blood vessel aperture **12**. The tubular sheath body **102** is flexible so that the tubular sheath body **102** can form a bend **80** which allows the tubular sheath body **102** to follow the contours of the vessel **10**. This flexibility can reduce the stress placed on the blood vessel aperture **12** by reducing the force required to deform the tubular sheath body **102**.

[0038] Once the tubular sheath body **102** has been advanced over the catheter body **62** of the percutaneous pump **60** to a sufficient depth to plug the gap between the vessel aperture **12** and the catheter body **62**, the dual lumen sheath assembly **100** may be fixed relative to the catheter body **62**. This fixation may be achieved by fixing the stabilizing structure **150** to the patient's tissue **14**. In some implementations, this is achieved by suturing wings (not shown) of the stabilizing structure **150** to the patient tissue **14**. In certain implementations, the stabilizing structure **150** is attached to a vascular graft with umbilical tape or sutures. This may be performed during axillary insertions or any other insertions which require pump placement through a vascular graft. In some implementations, fixing the placement of the dual lumen sheath assembly **100** may be achieved by tightening the seal **134** around the catheter body **62** or by means of a separate anchoring ring. The second port **130** may be rotated relative to the stabilizing structure **150** so that the second port **130** lies flat against the patient tissue **14**. After the dual lumen sheath assembly **100** has been fixed in the appropriate position, a physician may begin operation of the percutaneous pump **60**. The percutaneous pump **60** may be operated during a percutaneous coronary intervention (PCI), open-heart surgery, heart valve replacement surgery, or during treatment of acute myocardial infarction (AMI), cardiogenic shock, or ST segment elevation myocardial infarction (STEMI), as well as any other suitable medical procedure. In certain implementations, the percutaneous pump **60** is operated for an extended period of time, such as greater than six hours, greater than 12 hours, greater than 24 hours, greater than 48 hours, greater than 72 hours, greater than one week, or any other suitable duration of time. In such cases, a stylet (not shown in FIG. **5**), such as the stylet **120** from FIGS. **1-4**, may be positioned within the second lumen **118** during insertion of the dual lumen sheath assembly **100** to prevent blood ingress into the second lumen **118**, which could lead to clotting that could obstruct the second lumen **118** or to bleeding out of the second port **130**.

[0039] In certain implementations, a pressure bag is connected to the second port **130** in place of the stylet to maintain the patency of the second lumen **118**. An infusion pump may be used in combination with the pressure bag to regulate the flow rate of liquid into the patient. For example, the flow rate may be limited to 1 mL/hr, 2 mL/hr, 5 mL/hr, 10 mL/hr, or any other suitable flow rate. In some implementations, a pressure measuring device is connected to the second port **130** to measure the pressure within the vessel **10**. This pressure measurement can be used to determine when the second port **130** has been inserted sufficiently deep into the blood vessel aperture **12**. For example, when a pressure about equal to arterial pressure is measured at the second port **130**, the second outlet **107** may be in fluid communication with the blood vessel **10**. After penetration into the blood vessel aperture **12** has been detected, the depth of the blood vessel aperture **12** relative to the patient's skin can be measured using depth markings disposed on an outer surface of the sheath. The measurement of this depth can facilitate the subsequent use of certain vessel closure tools which may require such a measurement. The pressure measurement can also be used to monitor arterial pressure in the blood vessel **10** during a medical procedure. This may allow an arterial pressure measurement to be taken without the use of an additional catheter, which may reduce the amount of equipment necessary in the potentially crowded operating area. Additionally, the second lumen **118** can allow a determination of the depth of insertion without a pressure transducer by allowing observation of the onset of blood flow through the second lumen **118** (“bleedback”), which is indicative of penetration into the blood vessel aperture **12**.

[0040] When it is time to remove the percutaneous pump **60**, a guidewire **50** is inserted through the second port **130** into the second lumen **118** and out the second outlet **107** into the blood vessel **10**. Thus, the guidewire **50** enters the same insertion path as the percutaneous pump **60**, thereby maintaining access to the insertion path. If a stylet was used during insertion of the dual lumen sheath assembly **100**, the stylet is removed before insertion of the guidewire **50**. The guidewire **50** has an outer diameter that approximately matches the inner diameter of the second outlet **107** to prevent blood from flowing out of the blood vessel **10** through the second port **130**. For example, the guidewire may have an outer diameter of about 1 mm. Additionally, in some implementations, a seal at the second port **130** is included to further ensure that no blood exits the second port **130** while the guidewire **50** is in place.

[0041] After the guidewire **50** has been placed in the blood vessel **10**, the percutaneous pump **60** and the dual lumen sheath assembly **100** may be removed through the blood vessel aperture **12** while the guidewire **50** is left in place. The tubular sheath body **102** may be coated with a hydrophilic coating or any other suitable coating that prevents adhesions to the blood vessel **10**, thereby facilitating removal of the tubular sheath body **102** without damaging the blood vessel **10**. The removal of the dual lumen sheath assembly **100** and percutaneous pump **60** while the guidewire **50** is left in place allows guidewire access to the insertion path **11** to be maintained. The removal of the percutaneous pump **60** requires the concurrent removal of the dual lumen sheath assembly **100** because the diameter **68** of the pump head **66** cannot pass through the first lumen **116**. This is because the inner diameter of the first lumen **116** is sized to fit tightly around the diameter **64** of the catheter body **62**, but cannot accommodate the larger diameter **68** of the pump head **66**. As a result, the first lumen **116** is not available to be used to maintain guidewire access to the insertion path **11**. Thus, the second lumen **118** is necessary to maintain guidewire access to the insertion path **11**.

[0042] After the percutaneous pump **60** and the dual lumen sheath assembly **100** have been removed, the guidewire **50** remains in the blood vessel **10** and the insertion path **11**. Thus, another tool may be inserted over the guidewire **50** into the insertion path **11**. In some implementations, a vascular closure device is inserted into the insertion path **11** using the guidewire **50**. The vascular closure device may be the VASOSEAL vascular sealing device, the ANGIO-SEAL bio-absorbable active closure system, the PERCLOSE vascular sealing device, or any other suitable vascular closure device or combination of vascular closure devices. After a vascular closure device or other device has been successfully inserted through the vessel aperture **12** into the insertion path **11**, the guidewire **50** may be removed from the vessel aperture **12**.

[0043] FIG. **6** shows an illustrative process **600** for maintaining guidewire access. The illustrative process **600** may be performed using the dual lumen sheath assembly **100** or any other suitable sheath tool. In step **602**, a sheath is inserted into a blood vessel through a percutaneous insertion path and along a portion of a percutaneous pump. The sheath has a first lumen and a second lumen. The blood vessel may be an artery, such as the femoral artery. The insertion path passes through a blood vessel aperture (e.g., an arteriotomy). The percutaneous pump is inserted into the insertion path using an introducer prior to step **602**. Therefore, the percutaneous pump guides the sheath into the existing insertion path. The percutaneous pump may be an intravascular blood pump, a blood pump driven by flexible drive shaft, a blood pump including an implantable motor, a blood pump having an expandable pump rotor, or any other suitable pump. The first lumen of the sheath may be sealed against the percutaneous pump by a hemostatic valve to prevent leakage of blood from the blood vessel out of the patient.

[0044] In some implementations, the sheath is only inserted into the vessel as deep as is necessary to close the gap between the percutaneous pump and the vessel aperture to prevent bleeding. To reliably detect whether the sheath has been inserted sufficiently deep into the vessel, the pressure within the vessel can be detected using the second lumen. For example, a detected pressure about equal to arterial pressure may indicate that the outlet of the second lumen has been inserted into the blood vessel. Alternatively, the second lumen can allow a determination of the depth of insertion without a pressure transducer by allowing observation of the onset of blood flow through the second lumen (“bleedback”), which is indicative of penetration into the blood vessel aperture. After penetration into the blood vessel aperture has been detected, the depth of the blood vessel aperture relative to the patient's skin can be measured using depth markings disposed on an outer surface of the sheath. In some implementations, the depth markings are radio-opaque and can be imaged using a tomographic imaging modality (e.g., CT, MRI, X-ray). The measurement of this depth can facilitate the subsequent use of certain vessel closure tools which may require such a measurement. Additionally, once inserted to the appropriate depth, the second lumen can be used to measure arterial pressure during the procedure.

[0045] In step **604**, the sheath is maintained in the vessel for about six hours or more while blood clot formation is prevented from occluding the second lumen. The sheath may be maintained in the vessel for 6 hours, 12 hours, 24 hours, 48 hours, 72 hours, one week, two weeks, or any other suitable duration of time. Blood clot formation in the second lumen may be prevented during this time using a stylet that temporarily occludes the second lumen. For example, the stylet **120** of FIGS. **1-3** may be used to temporarily occlude the second lumen. In certain implementations, blood clot formation in the second lumen is prevented or reduced using a drug or nondrug coating in the second lumen. The coating may include heparin or any other suitable substance. In some implementations, blood clot formation in the second lumen is prevented or reduced by flushing the second lumen with a liquid (e.g., saline solution, glucose solution, or any other suitable solution). Preventing the occlusion of the second lumen by blood clots allows the patency of the second lumen to be preserved for insertion of a guidewire.

[0046] In step **606**, a guidewire is inserted through the second lumen into the percutaneous insertion path after the about six hours or more. If a stylet was used to temporarily occlude the second lumen, the stylet is removed before inserting the guidewire. The percutaneous pump inserted through the first lumen may be removed after insertion of the guidewire. After the guidewire has been inserted, the sheath may be removed from the percutaneous insertion path while the guidewire remains in place. This can allow another tool (e.g., an access closure tool) to be inserted into the insertion path. This frees a physician from depending on an introducer to maintain guidewire access. Thus, the physician is able to remove the introducer earlier in a procedure. This can allow greater recoil of the blood vessel aperture, thereby reducing the risk of bleeding. For example, removing the introducer within an hour of insertion may allow a recoil of

about 2 to 3 Fr (0.667 mm to 1 mm).
[0047] The foregoing is merely illustrative of the principles of the disclosure, and the systems, methods, and devices can be practiced by other than the described embodiments, which are presented for purposes of illustration and not of limitation. It is to be understood that the systems, methods, and devices disclosed herein, while shown for use in a system percutaneous intravascular blood pumps, may be applied to systems, methods, and devices for other implantable blood pumps or implantable cardiac assist devices.
[0048] Variations and modifications will occur to those of skill in the art after reviewing this disclosure. For example, in some implementations, the sheath assembly may be used to provide guidewire access for procedures of a short duration (e.g., less than six hours). Furthermore, the stylet may be omitted in some implementations in which the patency of the second lumen is adequately maintained by other means. For example, in some implementations, the second lumen is flushed with a liquid, either intermittently or continuously. The disclosed features may be implemented, in any combination and subcombination (including multiple dependent combinations and subcombinations), with one or more other features described herein. The various features described or illustrated above, including any components thereof, may be combined or integrated in other systems. Moreover, certain features may be omitted or not implemented.
[0049] Examples of changes, substitutions, and alterations are ascertainable by one skilled in the art and could be made without departing from the scope of the information disclosed herein. All references cited herein are incorporated by reference in their entirety and made part of this application.

Claims

1. A sheath assembly for insertion of a percutaneous pump, the sheath assembly comprising: a tubular sheath body dimensioned for insertion into a blood vessel through a vessel aperture and comprising: a wall having a proximal end portion, a distal end portion, a longitudinal axis, an outer surface, and an inner surface defining a first lumen substantially parallel to the longitudinal axis, wherein the first lumen is dimensioned to allow passage of a portion of the percutaneous pump and the first lumen comprises a proximal section, a distal section, and a restriction between the proximal section and the distal section; and a second lumen disposed within the wall between the inner surface and the outer surface and extending from the proximal end portion of the wall to the distal end portion of the wall, wherein the second lumen is dimensioned for passage of a guidewire and the second lumen comprises a proximal section, a distal section, and a restriction between the proximal section and the distal section.
2. The sheath assembly of claim 1, further comprising a stylet positioned to substantially occlude the second lumen, wherein the stylet has a proximal end releasably secured to the sheath assembly.
3. The sheath assembly of claim 2, wherein the proximal section of the second lumen has a proximal section diameter and the distal section of the second lumen has a distal section diameter, and wherein the proximal section diameter is greater than the distal section diameter.
4. The sheath assembly of claim 3, wherein the distal section diameter is about equal to an outer diameter of the stylet.
5. The sheath assembly of claim 1, wherein the second lumen is coated with an antithrombogenic agent.
6. The sheath assembly of claim 2, further comprising a hub coupled to a proximal end portion of the tubular sheath body, wherein the hub comprises: a first port in fluid communication with the first lumen, and a second port in fluid communication with the second lumen, wherein the second port is configured to secure the proximal end of the stylet.
7. The sheath assembly of claim 1, wherein the outer surface of the wall includes at least one of a hydrophilic coating and a coating to reduce tissue adhesion.

8. The sheath assembly of claim 1, wherein the outer surface of the wall includes markings for determining a depth of insertion.
9. The sheath assembly of claim 1, wherein the distal end portion of the wall is tapered and includes a tapered surface extending to a distal end face, the distal end face being substantially orthogonal to the longitudinal axis of the wall.
10. The sheath assembly of claim 9, wherein the second lumen has an outlet extending through the tapered surface of the distal end portion of the wall.
11. The sheath assembly of claim 1, further comprising a stabilizing structure rotatably coupled to the tubular sheath body.
12. The sheath assembly of claim 11, wherein the stabilizing structure is rotatable about the longitudinal axis.
13. The sheath assembly of claim 12, wherein the stabilizing structure includes a feature configured for suturing to a patient.
14. The sheath assembly of claim 13, wherein the stabilizing structure includes a pair of suture wings, each wing having a plurality of ribs for securing sutures.
15. The sheath assembly of claim 1, wherein the tubular sheath body is dimensioned to be introduced through a percutaneous access site of about 20 Fr (6.67 mm) or less.
16.-**24**. (canceled)
25. The sheath assembly of claim 2, wherein a length of the stylet is substantially equal to a length of the second lumen.