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CURVED OUTER SHEATH FOR A SHUNT DEVICE DELIVERY DEVICE

Abstract

An outer sheath for surrounding and covering components of a delivery device includes a straight section including an aperture extending fully through the straight section. The outer sheath further includes a pre-curved section extending distally from an end of the straight section and including an aperture extending fully through the pre-curved section. The straight section and the pre-curved section include a varying stiffness along a length of the straight section and the pre-curved section.

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Background/Summary

CROSS-REFERENCE TO RELATED APPLICATION(S) [0001] This application is a continuation of International Application No. PCT/US2023/034388, filed Oct. 3, 2023, which claims the benefit of U.S. Provisional Application No. 63/378,174, filed Oct. 3, 2022, the disclosures of which are hereby incorporated by reference in their entireties.

BACKGROUND

[0002] The present disclosure relates generally to implantable devices for a human body, and more particularly to an outer sheath for a delivery device used to aid in delivering and placing a shunt device within a human body.

[0003] Shunt devices can be positioned in the heart to shunt blood between the left atrium and the right atrium to reduce pressure in the left atrium. The left atrium can experience elevated pressure due to abnormal heart conditions caused by age and/or disease. For example, shunt devices can be used to treat patients with heart failure (also known as congestive heart failure). Shunt device can be positioned in the septal wall between the left atrium and the right atrium to shunt blood from the left atrium into the right atrium, thus reducing the pressure in the left atrium.

SUMMARY

[0004] An outer sheath for surrounding and covering components of a delivery device includes a straight section including an aperture extending fully through the straight section. The outer sheath further includes a pre-curved section extending distally from an end of the straight section and including an aperture extending fully through the pre-curved section. The straight section and the pre-curved section include a varying stiffness along a length of the straight section and the pre-curved section.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

Anatomy of Heart H and Vasculature V

[0005] FIG. **1** is a schematic diagram of a heart and vasculature.

[0006] FIG. **2** is a schematic cross-sectional view of the heart.

Shunt Devices **100** and **100′**

[0007] FIG. **3**A is a perspective view of a shunt device.

[0008] FIG. **3**B is a side view of the shunt device.

[0009] FIG. **4** is a perspective view of the shunt device in a collapsed configuration.

[0010] FIG. **5** is a perspective view of a shunt device including a sensor.

Delivery Catheter **200**

[0011] FIG. **6** is a side view of a delivery catheter.

[0012] FIG. **7**A is a side view of a distal portion of the delivery catheter in a sheathed state.

[0013] FIG. **7**B is a side view of the distal portion of the delivery catheter in an unsheathed state.

Delivery Method **300**

[0014] FIG. **8**A is a flow chart showing steps for creating a puncture in a tissue wall between a coronary sinus and a left atrium.

[0015] FIG. **8**B is a flow chart showing steps for implanting a shunt device in the tissue wall between the coronary sinus and the left atrium.
[0016] FIGS. **9**A-**9**R are schematic views showing the steps for implanting a shunt device in the tissue wall between the coronary sinus and the left atrium.
Delivery Device **1000**
[0017] FIG. **10**A is a perspective view of a delivery device including an outer sheath.
[0018] FIG. **10**B is a perspective view of the delivery device with the outer sheath pulled back to expose a shunt device.
[0019] FIG. **11** is a side view of the outer sheath used in the delivery device.
[0020] FIG. **12** is a side view of the outer sheath in a straight configuration.
DETAILED DESCRIPTION
Anatomy of Heart H and Vasculature V (FIGS. **1**-**2**)
[0021] FIG. **1** is a schematic diagram of heart H and vasculature V. FIG. **2** is a cross-sectional view of heart H. FIGS. **1**-**2** will be described together. FIGS. **1**-**2** show heart H, vasculature V, right atrium RA, right ventricle RV, left atrium LA, left ventricle LV, superior vena cava SVC, inferior vena cava IVC, tricuspid valve TV (shown in FIG. **1**), pulmonary valve PV (shown in FIG. **1**), pulmonary artery PA (shown in FIG. **1**), pulmonary veins PVS, mitral valve MV, aortic valve AV (shown in FIG. **1**), aorta AT (shown in FIG. **1**), coronary sinus CS (shown in FIG. **2**), thebesian valve BV (shown in FIG. **2**), inter-atrial septum IS (shown in FIG. **2**), and fossa ovalis FO (shown in FIG. **2**).
[0022] Heart H is a human heart that receives blood from and delivers blood to vasculature V. Heart H includes four chambers: right atrium RA, right ventricle RV, left atrium LA, and left ventricle LV.
[0023] The right side of heart H, including right atrium RA and right ventricle RV, receives deoxygenated blood from vasculature V and pumps the blood to the lungs. Blood flows into right atrium RA from superior vena cava SVC and inferior vena cava IVC. Right atrium RA pumps the blood through tricuspid valve TV into right ventricle RV. The blood is then pumped by right ventricle RV through pulmonary valve PV into pulmonary artery PA. The blood flows from pulmonary artery PA into arteries that delivery the deoxygenated blood to the lungs via the pulmonary circulatory system. The lungs can then oxygenate the blood.
[0024] The left side of heart H, including left atrium LA and left ventricle LV, receives the oxygenated blood from the lungs and pumps the blood to the body. Blood flows into left atrium LA from pulmonary veins PVS. Left atrium LA pumps the blood through mitral valve MV into left ventricle LV. The blood is then pumped by left ventricle LV through aortic valve AV into aorta AT. The blood flows from aorta AT into arteries that deliver the oxygenated blood to the body via the systemic circulatory system.
[0025] Blood is additionally received in right atrium RA from coronary sinus CS. Coronary sinus CS collects deoxygenated blood from the heart muscle and delivers it to right atrium RA. Thebesian valve BV is a semicircular fold of tissue at the opening of coronary sinus CS in right atrium RA. Coronary sinus CS is wrapped around heart H and runs in part along and beneath the floor of left atrium LA right above mitral valve MV, as shown in FIG. **2**. Coronary sinus CS has an increasing diameter as it connects to right atrium RA.
[0026] Inter-atrial septum IS and fossa ovalis FS are also shown in FIG. **2**. Inter-atrial septum IS is the wall that separates right atrium RA from left atrium LA. Fossa ovalis FS is a depression in inter-atrial septum IS in right atrium RA. At birth, a congenital structure called a foramen ovale is positioned in inter-atrial septum IS. The foramen ovale is an opening in inter-atrial septum IS that closes shortly after birth to form fossa ovalis FS. The foramen ovale serves as a functional shunt in utero, allowing blood to move from right atrium RA to left atrium LA to then be circulated through the body. This is necessary in utero, as the lungs are in a sack of fluid and do not oxygenate the blood. Rather, oxygenated blood is received from the mother. The oxygenated blood from the

mother flows from the placenta into inferior vena cava IVC through the umbilical vein and the ductus venosus. The oxygenated blood moves through inferior vena cava IVC to right atrium RA. The opening of inferior vena cava IVC in right atrium RA is positioned to direct the oxygenated blood through right atrium RA and the foramen ovale into left atrium LA. Left atrium LA can then pump the oxygenated blood into left ventricle LV, which pumps the oxygenated blood to aorta AT and the systemic circulatory system. This allows the pulmonary circulatory system to be bypassed in utero. Upon birth, respiration expands the lungs, blood begins to circulate through the lungs to be oxygenated, and the foramen ovale closes to form fossa ovalis FS.

[0027] Shunt devices can be positioned in heart H to shunt blood between left atrium LA and right atrium RA. Left atrium LA can experience elevated pressure due to abnormal heart conditions. It has been hypothesized that patients with elevated pressure in left atrium LA may benefit from a reduction of pressure in left atrium LA. Shunt devices can be used in these patients to shunt blood from left atrium LA to right atrium RA to reduce the pressure of blood in left atrium LA, which reduces the systolic preload on left ventricle LV. Reducing pressure in left atrium LA further relieves back-pressure on the pulmonary circulation to reduce the risk of pulmonary edema.

[0028] For example, shunt devices can be used to treat patients with heart failure (also known as congestive heart failure). The hearts of patients with heart failure do not pump blood as well as they should. Heart failure can affect the right side and/or the left side of the heart. Diastolic heart failure (also known as heart failure with preserved ejection fraction) refers to heart failure occurring when the left ventricle is stiff (having less compliance), which makes it hard to relax appropriately and fill with blood. This leads to increased end-diastolic pressure, which causes an elevation of pressure in left atrium LA. There are very few, if any, effective treatments available for diastolic heart failure. Other examples of abnormal heart conditions that cause elevated pressure in left atrium LA are systolic dysfunction of the left ventricle and valve disease.

[0029] Septal shunt devices (also called inter-atrial shunt devices) are positioned in inter-atrial septum IS to shunt blood directly from left atrium LA to right atrium RA. Typically, septal shunt devices are positioned in fossa ovalis FS, as fossa ovalis FS is a thinner area of tissue in inter-atrial septum IS where the two atria share a common wall. If the pressure in right atrium RA exceeds the pressure in left atrium LA, septal shunt devices can allow blood to flow from right atrium RA to left atrium LA. This causes a risk of paradoxical stroke (also known as paradoxical embolism), as emboli can move from right atrium RA to left atrium LA and then into aorta AT and the systemic circulation.

[0030] Shunt devices can also be left atrium to coronary sinus shunt devices that are positioned in a tissue wall between left atrium LA and coronary sinus CS where the two structures are in close approximation. Left atrium to coronary sinus shunt devices move blood from left atrium LA into coronary sinus CS, which then delivers the blood to right atrium RA via thebesian valve BV, the natural orifice of coronary sinus CS. Coronary sinus CS acts as an additional compliance chamber when using a left atrium to coronary sinus shunt device. Left atrium to coronary sinus shunt devices further provide increased protections against paradoxical strokes, as the blood would have to flow retrograde from right atrium RA through coronary sinus CS before entering left atrium LA. Further, left atrium to coronary sinus shunt devices also provide protection against significant right atrium RA to left atrium LA shunting, as again the blood would have to flow retrograde from right atrium RA through coronary sinus CS before entering left atrium LA.

Shunt Devices **100** and **100′** (FIGS. **3**A-**5**)

[0031] FIG. **3**A is a perspective view of shunt device **100**. FIG. **3**B is a side view of shunt device **100**. FIG. **4** is a perspective view of shunt device **100** in a collapsed configuration. FIGS. **3**A, **3**B, and **4** will be described together. Shunt device **100** includes body **102**, which is formed of struts **104** and openings **106**. Body **102** includes central flow tube **110**, flow path **112**, and arms **114**. Shunt device **100** also includes tissue capture features **116**. Central flow tube **110** has side portions **120** (including side portion **120**A and side portion **120**B), end portions **122** (including end portion

122A and end portion **122**B), first axial end **124**, and second axial end **126**. Arms **114** include distal arms **130** (including distal arm **130**A and distal arm **130**B) and proximal arms **132** (including proximal arm **132**A and proximal arm **132**B). Distal arms **130** have terminal ends **134** (including terminal end **134**A and terminal end **134**B). Proximal arms **132** have terminal ends **136** (including terminal end **136**A and terminal end **136**B). FIG. **3**B further shows gap G, horizontal reference plane HP, perpendicular reference axis RA, central axis CA, tilt angle θ, first angle α, and second angle β.

[0032] Shunt device **100** is a cardiovascular shunt. Shunt device **100** is shown in an expanded configuration in FIGS. **3**A-**3**B. Shunt device **100** is formed of a super-elastic material that is capable of being compressed into a catheter for delivery into the body that can then retain its relaxed, or expanded, shape when it is released from the catheter. For example, shunt device **100** can be formed of a shape-memory material, such as nitinol (a nickel titanium alloy). Shunt device **100** is shown in a compressed configuration in FIG. **4**. Upon delivery into the body, shunt device **100** will expand back to its relaxed, or expanded, shape. Shunt device **100** can be sterilized before being delivered into the body. Shunt device **100** has body **102** that is formed of interconnected struts **104**. Openings **106** in body **102** are defined by struts **104**. Body **102** of shunt device **100** is formed of struts **104** to increase the flexibility of shunt device **100** to enable it to be compressed and expanded.

[0033] Body **102** includes central flow tube **110** that forms a center portion of shunt device **100**. Central flow tube **110** is tubular in cross-section but is formed of struts **104** and openings **106**. Central flow tube **110** can be positioned in a puncture or opening in a tissue wall and hold the puncture open. Flow path **112** is an opening extending through central flow tube **110**. Flow path **112** is the path through which blood flows through shunt device **100** when shunt device **100** is implanted in the body. Arms **114** extend from central flow tube **110**. Arms **114** extend outward from central flow tube **110** when shunt device **100** is in an expanded configuration. Arms **114** hold shunt device **100** in position in the tissue wall when shunt device **100** is implanted in the body.

[0034] When shunt device **100** is implanted in the tissue wall between the left atrium and the coronary sinus of the heart, central flow tube **110** holds the puncture open so blood can flow from the left atrium to the coronary sinus through flow path **112**. Struts **104** of central flow tube **110** form a lattice or cage of sorts that is sufficient to hold the puncture in the tissue wall open around central flow tube **110**. Central flow tube **110** extends from first axial end **124** to second axial end **126**. Central flow tube **110** is designed to have an axial length, as measured from first axial end **124** to second axial end **126**, that approximates the thickness of the tissue wall between the left atrium and the coronary sinus. When shunt device **100** is implanted in the tissue wall between the left atrium and the coronary sinus, first axial end **124** can be facing the left atrium (i.e., a left atrial side of shunt device **100**) and second axial end **126** can be facing the coronary sinus (i.e., a coronary sinus side of shunt device **100**). In other examples, the orientation of first axial end **124** and second axial end **126** can be reversed.

[0035] Central flow tube **110** has side portions **120** and end portions **122**. Side portion **120**A and side portion **120**B form opposing sides of central flow tube **110**. End portion **122**A and end portion **122**B form opposing ends of central flow tube **110**. End portion **122**A and end portion **122**B each extend between and connect to side portion **120**A and side portion **120**B to form a generally circular or oval opening that defines flow path **112**. Side portions **120** and end portions **122** form a tubular lattice for central flow tube **110**. Struts **104** of central flow tube **110** define openings **106** in central flow tube **110**. In some examples, openings **106** can be generally parallelogram-shaped. In other examples, openings **106** can be any regular or irregular shape as desired. For example, struts **104** of side portions **120** can form an array of parallelogram-shaped openings **106** in side portions **120**. Struts **104** of end portions **122** can form openings **106** in end portions **122**. Struts **104** of arms **114** can form openings **106** in arms **114**.

[0036] As shown in FIG. **3**B, central flow tube **110** is angled with respect to horizontal reference

plane HP extending through shunt device **100**. Horizontal reference plane HP lies generally in the plane of the tissue wall immediately adjacent to shunt device **100** when shunt device **100** is implanted in the tissue wall. End portions **122** are similarly angled with respect to horizontal reference plane HP. Perpendicular reference axis RA, as shown in FIG. **3**B, is perpendicular to horizontal reference plane HP. As shown in FIG. **3**B, central axis CA is an axis through the center of central flow tube **110** and flow path **112**. Central axis CA extends through central flow tube **110** at tilt angle θ with respect to perpendicular reference axis RA. Accordingly, central axis CA defines the angle or tilt of central flow tube **110** with respect to perpendicular reference axis RA (and horizontal reference plane HP). End portions **122** of central flow tube **110** extend parallel to central axis CA.

[0037] Arms **114** of shunt device **100** include two distal arms **130** and two proximal arms **132**. In some examples, individual ones of distal arms **130** and/or proximal arms **132** can be formed of multiple split arm portions. Arms **114** extend outward from end portions **122** of central flow tube **110** when shunt device **100** is in an expanded configuration. Distal arm **130**A is connected to and extends away from end portion **122**A, and distal arm **130**B is connected to and extends away from end portion **122**B. Proximal arm **132**A is connected to and extends away from end portion **122**A, and proximal arm **132**B is connected to and extends away from end portion **122**B. When shunt device **100** is implanted in the tissue wall between the left atrium and the coronary sinus, distal arms **130** will be positioned in the left atrium and proximal arms **132** will be positioned in the coronary sinus. Distal arms **130** each have terminal ends **134**. Specifically, distal arm **130**A has terminal end **134**A, and distal arm **130**B has terminal end **134**B. Proximal arms **132** each have terminal ends **136**. Specifically, proximal arm **132**A has terminal end **136**A, and proximal arm **132**B has terminal end **136**B.

[0038] Distal arms **130** and proximal arms **132** curl outward from end walls **122**. As shown in FIG. **3**B, each of distal arms **130** and proximal arms **132** has a proximal portion adjacent to central flow tube **110** that forms a shallow curve or arc in a direction away from end walls **122** of central flow tube **110**. Each of distal arms **130** and proximal arms **132** flattens out towards respective terminal ends **134** and **136** such that a portion of each of distal arms **130** and proximal arms **132** at or adjacent to the respective terminal end **134** or **136** is generally parallel to horizontal reference plane HP. Accordingly, an axis drawn through terminal end **134**A and an axis drawn through terminal end **136**B, which are approximated in FIG. **3**B as axes in the plane of horizontal reference plane HP for simplicity, can each form first angle α with central axis CA through central flow tube **110**. Similarly, an axis drawn through terminal end **134**B, and an axis drawn through terminal end **136**A, which are approximated in FIG. **3**B as axes in the plane of horizontal reference plane HP for simplicity, can each form second angle β with central axis CA through central flow tube **110**. Alternatively, distal arms **130** and proximal arms **132** do not flatten out and become parallel to horizontal reference plane HP but instead approach horizontal reference plane HP at an angle and/or have respective terminal ends **134** and **136** that angle away from horizontal reference plane HP. In such examples, first angle α and second angle β are approximations of the central angle for the arcs from end walls **122** to the tissue wall that each respective arm encompasses when shunt device **100** is implanted in the tissue wall. Put more simply, first angle α is the angle between central axis CA and horizontal reference plane HP, and second angle β is the supplementary angle to first angle α. In some examples, first angle α can be less than ninety degrees (<90°) and second angle β can be greater than ninety degrees (>90°). In other examples, first angle α and second angle β can be any suitable combination of angles that add to one hundred eighty degrees (180°). The difference between first angle α and second angle β (and the corresponding curvature of ones of distal arms **130** and proximal arms **132**) accommodates for the tilt of central flow tube **110**.

[0039] As shown in FIG. **3**B, distal arm **130**A and distal arm **130**B extend outwards from central flow tube **110** in opposite directions parallel to horizontal reference plane HP. Distal arm **130**A and distal arm **130**B can be aligned with each other (i.e., oriented at 180° to each other across central

flow tube **110**). In some examples, distal arm **130**A has a longer length than distal arm **130**B. In other examples, distal arm **130**A has a shorter length than distal arm **130**B. In yet other examples, distal arms **130** can have similar lengths. Proximal arm **132**A and proximal arm **132**B extend outwards from central flow tube **110** in opposite directions parallel to horizontal reference plane HP. Proximal arm **132**A and proximal arm **132**B can be aligned with each other (i.e., oriented at 180° to each other across central flow tube **110**). In some examples, proximal arm **132**A has a shorter length than proximal arm **132**B. In other examples, proximal arm **132**A has a longer length than proximal arm **132**B. In yet other examples, proximal arms **132** can have similar lengths. In some examples, distal arm **130**A has generally the same length and shape as proximal arm **132**B, and distal arm **130**B has generally the same length and shape as proximal arm **132**A. In other examples, each of distal arms **130** and proximal arms **132** can have different lengths and shapes, though the overall shape of each arm is similar. As such, shunt device **100** has some degree of inverse symmetry across horizontal reference plane HP, as shown in FIG. **3**B.

[0040] Shunt device **100** is generally elongated longitudinally but is relatively narrow laterally. Stated another way, distal arms **130** and proximal arms **132** are not annular or circular, but rather extend outward generally in only one plane. As shown in FIG. **3**B, shunt device **100** has a generally H-shape when viewing a side of shunt device **100**. The elongated shape of shunt device **100** means that when compressed it elongates along a line, as shown in FIG. **4**, so as to better fit within a catheter.

[0041] Terminal ends **134** of distal arms **130** and terminal ends **136** of proximal arms **132** converge towards one another. Distal arms **130** and proximal arms **132** form two pairs of arms. That is, each of distal arms **130** forms a clamping pair with a corresponding one of proximal arms **132**. Distal arm **130**A and proximal arm **132**A form a first pair of arms extending outward from a first side of central flow tube **110**, and terminal end **134**A of distal arm **130**A converges towards terminal end **136**A of proximal arm **132**A. Distal arm **130**B and proximal arm **132**B form a second pair of arms extending outward from a second side of central flow tube **110**, and terminal end **134**B of distal arm **130**B converges towards terminal end **136**B of proximal arm **132**B. Gap G between terminal ends **134** and terminal ends **136** is sized to be slightly smaller than an approximate thickness of the tissue wall between the left atrium and the coronary sinus, or another tissue wall of interest. This allows distal arms **130** and proximal arms **132** to flex outwards and grip the tissue wall when implanted to help hold shunt device **100** in place against the tissue wall. Thus, a distance corresponding to gap G, as measured once shunt device **100** is implanted, may be slightly different between different clamping pairs of distal arms **130** and proximal arms **132** depending on anatomical variations along the particular tissue wall. Terminal ends **134** of distal arms **130** and terminal ends **136** of proximal arms **132** can also have openings or indentations that are configured to engage a delivery tool to facilitate implantation of shunt device **100**, for example actuating rods of a delivery tool. Additionally, terminal ends **134** of distal arms **130** and terminal ends of proximal arms **132** can include locations for radiopaque markers to permit visualization of the positioning of shunt device **100**.

[0042] When implanted in the tissue wall, distal arms **130** and proximal arms **132** are designed such that the projection of distal arms **130** and proximal arms **132** into the left atrium and the coronary sinus, respectively, is minimized. This minimizes the disruption of the natural flow patterns in the left atrium and the coronary sinus. Shunt device **100** can also be designed so that the profile of proximal arms **132** projecting into the coronary sinus is lower than the profile of distal arms **130** projecting into the left atrium to minimize disruption of the natural blood flow through the coronary sinus and to reduce the potential for proximal arms **132** to block the narrower passage of the coronary sinus.

[0043] Tissue capture features **116** can take several different forms. For example, tissue capture features **116** connected to central flow tube **110** at first axial end **124** and/or second axial end **126** can be tabs that extend outward from side portions **120**. Tissue capture features **116** connected to

arms **114** can be deflectable projections that extend between respective ones of arms **114** and the tissue wall to be compressed back toward the respective arm **114** when shunt device **100** is implanted in the tissue wall. Tissue capture features **116** connected to end portions **122** of central flow tube **110** can be secondary arms associated with one of arms **114**. Tissue capture features **116** that are a part of arms **114** themselves can be, e.g., a lengthened portion of one of arms **114**, separate split arm portions of one of arms **114**, and/or interlacing arms **114**. Any one or more of tissue capture features **116** can be incorporated alone or in combination on shunt device **100** to aid in anchoring shunt device **100** to the tissue wall and to prevent displacement of shunt device **100**.
[0044] FIG. **5** is a perspective view of shunt device **100′** including sensor **150′**. Shunt device **100′** includes body **102′**, which is formed of struts **104′** and openings **106′**. Body **102′** includes central flow tube **110′**, flow path **112′**, arms **114′**. Shunt device **100′** also includes and tissue capture features **116′**. Central flow tube **110′** has side portions **120′** (including side portion **120**A′ and side portion **120**B′), end portions **122′** (including end portion **122**A′ and end portion **122**B′), first axial end **124′**, and second axial end **126′**. Arms **114′** include distal arms **130′** (including distal arm **130**A′ and distal arm **130**B′) and proximal arms **132′** (including proximal arm **132**A′ and proximal arm **132**B′). Distal arms **130′** have terminal ends **134′**(including terminal end **134**A′ and terminal end **134**B′). Proximal arms **132′** have terminal ends **136′** (including terminal end **136**A′ and terminal end **136**B′). Shunt device **100′** further includes sensor **150′** and sensor attachment portion **152′**.
[0045] Shunt device **100′** includes a similar structure and design to shunt device **100** described above, except shunt device **100′** additionally includes sensor **150′** connected to sensor attachment portion **152′**.
[0046] As shown in FIG. **5**, sensor **150′** can be attached to shunt device **100′** so that sensor **150′** is positioned in the left atrium when shunt device **100′** is implanted in the tissue wall between the left atrium and the coronary sinus of the heart. Accordingly, sensor **150′** can be attached to one of distal arms **130′**. Alternatively, sensor **150′** can be attached to shunt device **100′** so that sensor **150′** is positioned in the coronary sinus when shunt device **100′** is implanted in the tissue wall. In such examples, sensor **150′** can be attached to one of proximal arms **132′**. In further examples, an additional sensor can be included on shunt device **100′** to position sensors in both the left atrium and the coronary sinus.
[0047] Sensor **150′** is attached to shunt device **100′** at sensor attachment portion **152′**. Sensor **150′** can be connected to sensor attachment portion **152′** using any suitable attachment mechanism. For example, sensor **150′** and sensor attachment portion **152′** can include complimentary mating features. Sensor attachment portion **152′** can be an extension of one of arms **114′** of shunt device **100′**. In some examples, sensor attachment portion **152′** is an extension of distal arm **130**A′. In other examples, sensor attachment portion **152′** is an extension of distal arm **130**B′ or one of proximal arms **132′**. Alternatively, as shown in FIG. **5**, sensor attachment portion **152′** can be a separate split arm portion of one of arms **114′**. Sensor attachment portion **152′** can be angled away from a horizontal reference plane (not shown) that is in the plane of the tissue wall adjacent to shunt device **100′** when shunt device **100′** is implanted in the tissue wall. That is, sensor attachment portion **152′** can be angled away from the tissue wall.
[0048] Sensor **150′** can be a pressure sensor to sense a pressure in the left atrium. In other examples, sensor **150′** can be any sensor to measure a parameter in the left atrium. In yet other examples, sensor **150′** can be any sensor to measure a parameter in the coronary sinus. Sensor **150′** can include a transducer, control circuitry, and an antenna in one example. The transducer, for example a pressure transducer, is configured to sense a signal from the left atrium. The transducer can communicate the signal to the control circuitry. The control circuitry can process the signal from the transducer or communicate the signal from the transducer to a remote device outside of the body using the antenna. Sensor **150′** can include alternate or additional components in other examples. Further, the components of sensor **150′** can be held in a sensor housing that is hermetically sealed.

Delivery Catheter **200** (FIGS. **6**-**7**B)

[0049] FIG. **6** is a side view of delivery catheter **200**. FIG. **7**A is a side view of distal portion **214** of delivery catheter **200** in a sheathed state. FIG. **7**B is a side view of distal portion **214** of delivery catheter **200** in an unsheathed state. FIGS. **6**, **7**A, and **7**B will be discussed together. FIGS. **6**-**7**B show delivery catheter **200**. FIG. **7**B shows shunt device **202**. Delivery catheter **200** includes proximal end **200**A, distal end **200**B, proximal portion **210**, intermediate portion **212**, distal portion **214**, handle **216**, outer sheath **218**, inner sheath **220**, bridge **222**, nosecone **224**, actuation rod **226**, side opening **228**, and notch **229**.

[0050] Delivery catheter **200** is one example of a delivery catheter that can be used to implant a shunt device into a patient. Delivery catheter **200** as shown in FIGS. **6**-**7**B is used to implant shunt device **202** (shown in FIG. **7**B). Delivery catheter **200** can take other forms in alternate examples. Shunt device **202** can have the structure and design of any suitable shunt device, for example shunt device **100** or **100**′ as shown in FIGS. **3**A-**5**. Delivery catheter **200** is shown as being configured to implant shunt device **202** without a sensor in the example shown in FIGS. **6**-**7**B. In alternate examples, delivery catheter **200** can be used to implant a shunt device with a sensor, including any needed modifications to accommodate the sensor.

[0051] Delivery catheter **200** includes proximal portion **210** adjacent proximal end **200**A of delivery catheter **200**, intermediate portion **212** extending from proximal portion **210**, and distal portion **214** extending from intermediate portion **212** to distal end **200**B of delivery catheter **200**. Proximal portion **210** includes handle **216**, which can be grasped by a physician to control movement of delivery catheter **200**. Handle **216** includes a number of ports through which guide wires, tubes, fluids, or other components or elements may be passed.

[0052] Intermediate portion **212** extends outward from handle **216** and is a length of catheter that can be moved through a patient. Outer sheath **218** and inner sheath **220** extend outward from handle **216** and form a portion of intermediate portion **212**. Outer sheath **218** covers inner sheath **220**.

[0053] Distal portion **214** extends from intermediate portion **212**. Distal portion **214** includes bridge **222** and nosecone **224**. Bridge **222** extends from inner sheath **220** towards nosecone **224**. Nosecone **224** extends from bridge **222** to distal end **200**B of delivery catheter **200**. Bridge **222** is configured to hold shunt device **202**. As shown in FIG. **7**A, when delivery catheter **200** is in a sheathed state, outer sheath **218** will extend over and cover shunt device **202** on bridge **222**. As shown in FIG. **7**B, when delivery catheter **200** is in an unsheathed state, outer sheath **218** will be pulled back to expose bridge **222** and shunt device **202** on bridge **222**. Nosecone **224** extends outward from bridge **222** and helps guide delivery catheter **200** through a patient's vasculature. Actuation rod **226**, also called an actuation arm, extends through a lumen in inner sheath **220** and bridge **222**. Actuation rod **226** emerges from side opening **228** in bridge **222** and connects to a first proximal arm of shunt device **202**. Side opening **228** extends into a body of bridge **222**. Notch **229** extends into the body of bridge **222** opposite side opening **228**. Notch **229** is configured to seat a second proximal arm of shunt device **202**. The second proximal arm can be retained on bridge **222** prior to deployment by a release wire (not shown) extending through a lumen of bridge **222** and through notch **229**.

[0054] Delivery catheter **200** will be discussed below in more detail with respect to FIGS. **8**A-**9**R.

Delivery Method **300** (FIGS. **8**A-**9**R)

[0055] FIG. **8**A is a flow chart showing steps for creating a puncture in tissue wall TW between coronary sinus CS and left atrium LA. FIG. **8**B is a flow chart showing steps for implanting shunt device **202** in tissue wall TW between coronary sinus CS and left atrium LA. FIGS. **9**A-**9**R are schematic views showing the steps for implanting shunt device **202** in tissue wall TW between coronary sinus CS and left atrium LA. FIGS. **8**A-**9**R will be discussed together. FIGS. **8**A-**8**B show method **300**. FIG. **8**A shows steps **302**-**316** of method **300**. FIG. **8**B shows steps **318**-**334** of method **300**.

[0056] Step **302** includes advancing guidewire **230** into coronary sinus CS, as shown in FIG. **9**A. Guidewire **230** can be inserted using traditional methods. Guidewire **230** is inserted into right atrium RA, through an ostium of coronary sinus CS, and then into coronary sinus CS. Optionally, a catheter having radiopaque markers can be inserted over guidewire **230** and imaging can be done to confirm placement of guidewire **230** in coronary sinus CS. Additionally, contrast can be injected into coronary sinus CS through the catheter to further confirm placement of guidewire **230** in coronary sinus CS. The catheter can then be removed once placement of guidewire **230** in coronary sinus CS is confirmed.

[0057] Step **304** includes advancing puncture catheter **232** over guidewire **230** to coronary sinus CS, as shown in FIG. **9**B. Puncture catheter **232** is used to puncture tissue wall TW between coronary sinus CS and left atrium LA. Puncture catheter **232** includes catheter body **234** having opening **236** on a first side and balloon **238** on a second side opposite opening **236**. Puncture catheter **232** can also include radiopaque markers **239** proximal and distal to opening **236** to confirm placement of puncture catheter **232** in coronary sinus CS. Puncture catheter **232** is advanced into coronary sinus CS so that opening **236** is facing tissue wall TW between coronary sinus CS and left atrium LA. Puncture catheter **232** shown in FIG. **9**B is one example of a puncture catheter. In alternate examples, tissue wall TW can be punctured using other puncture catheters or other suitable mechanisms.

[0058] Step **306** includes inflating balloon **238** of puncture catheter **232**, as shown in FIG. **9**C. As balloon **238** is inflated, it will press against coronary sinus CS opposite of tissue wall TW. The inflation of balloon **238** will press puncture catheter **232** against tissue wall TW. Specifically, opening **236** will be pressed against tissue wall TW. Balloon **238** will anchor puncture catheter **232** in position in coronary sinus CS while a puncture is made in tissue wall TW. In alternate examples, any other suitable anchoring mechanism can be used instead of balloon **238**. In further examples, step **306** is not needed.

[0059] Step **308** includes puncturing tissue wall TW between coronary sinus CS and left atrium LA, as shown in FIG. **9**D. Puncture catheter **232** includes puncture arm **240** extending through a lumen in puncture catheter **232**. Puncture arm **240** includes sheath **242** and needle **244** positioned in sheath **242** so that it extends out a distal end of puncture sheath **242**. Puncture arm **240** can be advanced through puncture catheter **232** and out of opening **236** to puncture through tissue wall TW between coronary sinus CS and left atrium LA.

[0060] Puncture catheter **232** should be positioned in coronary sinus CS so that opening **236** of puncture catheter **232** is positioned 2-4 centimeters from the ostium of coronary sinus CS. This will position the puncture through tissue wall TW at the same location. The puncture, and ultimately the placement of shunt device **202** in the puncture, is positioned over the posterior leaflet of mitral valve MV.

[0061] Step **310** includes removing needle **244** from puncture catheter **232**, as shown in FIG. **9**E. Needle **244** can be removed by pulling it proximally through a lumen extending through needle sheath **242** of puncture arm **240**. Needle **244** is fully removed from puncture catheter **232**, leaving a lumen extending from a proximal end of puncture catheter **232** through a distal end of needle sheath **242**.

[0062] Step **312** includes advancing guidewire **246** through puncture catheter **232** into left atrium LA, as shown in FIG. **9**F. Specifically, guidewire **246** is advanced through a lumen extending through a proximal end of puncture catheter **232** and needle sheath **242** of puncture arm **240**. Guidewire **246** is advanced into left atrium LA until it coils in left atrium LA, as shown in FIG. **9**F. Once guidewire **246** is fully positioned in left atrium LA, puncture catheter **232** and guidewire **230** can be removed from left atrium LA and coronary sinus CS.

[0063] Step **314** includes advancing balloon catheter **248** over guidewire **246** and through the puncture in tissue wall TW, as shown in FIG. **9**G. Balloon catheter **248** is advanced through the puncture in tissue wall TW so balloon **250** of balloon catheter **248** is positioned in the puncture in

tissue wall TW. Balloon catheter **248** is shown as being a separate device from puncture catheter **232** in the example shown in FIG. **9**G. However, in alternate examples, balloon catheter **248** can be inserted through puncture catheter **232** and through the puncture in tissue wall TW.

[0064] Step **316** includes inflating balloon **250** of balloon catheter **248** extending through the puncture in tissue wall TW, as shown in FIG. **9**H. Balloon **250** extends along a distal portion of balloon catheter **248**. As balloon **250** is inflated, it will expand and push open the tissue surrounding the puncture in tissue wall TW. The inflation of balloon **250** will cause the puncture in tissue wall TW to become a wider opening in which a shunt device can be positioned. Balloon **250** can then be deflated and balloon catheter **248** can be removed from left atrium LA and coronary sinus CS.

[0065] Step **318** includes advancing delivery catheter **200** over guidewire **246**, as shown in FIG. **9**I. Delivery catheter **200** has the general structure and design as discussed with reference to FIGS. **6-7**B above. Delivery catheter **200** is inserted through coronary sinus CS, through the opening in tissue wall TW, and into left atrium LA. When delivery catheter **200** is properly positioned in tissue wall TW, nosecone **224** will be positioned in left atrium LA, and bridge **222** will extend through tissue wall TW between left atrium LA and coronary sinus CS. Nosecone **224** tapers from a smaller diameter at a distal end to a larger diameter at a proximal end. The taper of nosecone **224** helps to advance nosecone **224** through the opening in tissue wall TW and widens the opening as needed. Bridge **222** holds shunt device **202** (not shown in FIG. **9**I) in a collapsed position on bridge **222**. Bridge **222** is positioned in tissue wall TW so that shunt device **202** is generally positioned in the opening in tissue wall TW for deployment into the opening.

[0066] Step **320** includes withdrawing outer sheath **218** of delivery catheter **200** to release distal arms **252** of shunt device **202**, as shown in FIG. **9**J. Outer sheath **218** can be withdrawn to expose part of shunt device **202** held on bridge **222** of delivery catheter **200**. As outer sheath **218** is withdrawn, distal arms **252** of shunt device **202** will be released and assume their preset shape. Delivery catheter **200** should be positioned in left atrium LA such that when outer sheath **218** is withdrawn to release distal arms **252** of shunts device **202**, distal arms **252** of shunt device **202** are positioned in left atrium LA.

[0067] Step **322** includes pulling delivery catheter **200** proximally to seat distal arms **252** of shunt device **202** on tissue wall TW, as shown in FIG. **9**K. Delivery catheter **200** can be gently pulled proximally to seat distal arms **252** of shunt device **202** on tissue wall TW in left atrium LA. A physician should stop gently pulling on delivery catheter **200** when resistance is sensed, indicating that distal arms **252** have come into contact with tissue wall TW. This will also position a central flow tube of shunt device **202** in the opening in tissue wall TW.

[0068] Step **324** includes withdrawing outer sheath **218** of delivery catheter **200** to expose proximal arms **254** of shunt device **202**, as shown in FIG. **9**L. Outer sheath **218** is withdrawn a set distance to fully expose shunt device **202**, including proximal arms **254** of shunt device **202**. Delivery catheter **200** should be positioned in left atrium LA, tissue wall TW, and coronary sinus CS so that proximal arms **254** will be positioned in coronary sinus CS when outer sheath **218** is withdrawn. Proximal arms **254** are constrained on bridge **222** of delivery catheter **200** and will not automatically assume their preset shape when outer sheath **218** is withdrawn.

[0069] Step **326** includes moving first proximal arm **254**A of shunt device **202** towards tissue wall TW using actuation rod **226** of delivery catheter **200**, as shown in FIG. **9**M. Actuation rod **226** extends through a lumen in delivery catheter **200** and can be actuated forward to move first proximal arm **254**A towards tissue wall TW.

[0070] Step **328** includes seating first proximal arm **254**A on tissue wall TW, as shown in FIG. **9**N. Actuation rod **226** of delivery catheter **200** is actuated fully outward to seat first proximal arm **254**A on tissue wall TW. When first proximal arm **256**A is seated on tissue wall TW, it will be positioned in coronary sinus CS.

[0071] Step **330** includes injecting contrast into coronary sinus CS and left atrium LA to confirm

placement of shunt device **202** in tissue wall TW, as shown in FIG. **9**O. Contrast can be injected through a lumen extending through delivery catheter **200**. The contrast can move through coronary sinus CS and left atrium LA. The contrast will highlight shunt device **202** under fluoroscopy to confirm proper placement of distal arms **252** and first proximal arm **254**A of shunt device **202** on tissue wall TW.

[0072] Step **332** includes removing actuation rod **226** from first proximal arm **254**A of shunt device **202**, as shown in FIG. **9**P. Actuation rod **226** can be held on and removed from first proximal arm **254**A using any suitable mechanism. In the example shown in FIG. **9**P, a release wire holds actuation rod **226** on first proximal arm **254**A. The release wire can be withdrawn proximally to disconnect release wire from first proximal arm **254**A. Actuation rod **226** can then be pulled proximally through a lumen of delivery catheter **200** to remove actuation rod **226** from coronary sinus CS.

[0073] Step **334** includes withdrawing delivery catheter **200** from coronary sinus CS and left atrium LA to release second proximal arm **254**B of shunt device **202**, as shown in FIG. **9**Q. Second proximal arm **254**B is held in place on bridge **222** in notch **229** formed in bridge **222**. As delivery catheter **200** is withdrawn, second proximal arm **254**B will be released from notch **229** in bridge **222** and take its preset shape. Specifically, second proximal arm **254**B will seat upon tissue wall TW as it takes its preset shape. Second proximal arm **245**B will be positioned in coronary sinus CS. After second proximal arm **254**B is seated on tissue wall TW, shunt device **202** will be fully deployed in tissue wall TW, as shown in FIG. **9**R. Delivery catheter **200** and guidewire **246** can then be removed from left atrium LA and coronary sinus CS.

[0074] Method **300** is one example of a method that can be used to implant shunt device **202** in tissue wall TW between left atrium LA and coronary sinus CS. Method **300** can include fewer, more, or different steps in alternate examples. Further, puncture catheter **232** and delivery catheter **200** are shown as being separate catheters in the example shown in FIGS. **9**A-**9**R, but can be a single catheter in alternate examples.

Delivery Device **1000** (FIGS. **10**A-**12**)

[0075] FIG. **10**A is a perspective view of delivery device **1000** including outer sheath **1002**. FIG. **10**B is a perspective view of delivery device **1000** with outer sheath **1002** pulled back to expose shunt device **100**′. FIGS. **10**A-**10**B will be discussed together. Delivery device **1000** includes outer sheath **1002** (including proximal end **1002**A (not shown in FIGS. **10**A-**10**B) and distal end **1002**B), straight section **1004**, pre-curved section **1006**, distal portion **1101**, nosecone **1102**, molded bridge **1104** (including proximal end **1104**A and distal end **1104**B), straight portion **1106**, and tapered portion **1108**. FIG. **10**B further shows shunt device **100**′, central flow tube **110**′, sensor **150**′.

[0076] Delivery device **1000** is a catheter device that is configured to be transported into and out of a human body. More specifically, delivery device **1000** is configured to transport shunt device **100**′ into a human body and then delivery device **1000** is configured to deploy shunt device **100**′ within the human body. In some examples, shunt device **100**′ is coupled to delivery device **1000**, shunt device **100**′ is positioned at least partially within outer sheath **1002**, and then delivery device **1000** is translated along a guidewire into a human body to properly position shunt device **100**′ within the human body. The various examples, features, and methods of using delivery device **1000** will be described in detail below. Although the following discussion specifically describes shunt device **100**′ with sensor **150**′ coupled to delivery device **1000** and positioned within delivery device **1000**, it is to be understood that the following discussion equally applies to shunt device **100** without a sensor.

[0077] Delivery device **1000** includes outer sheath **1002**, distal portion **1101**, and shunt device **100**′ including sensor **150**′ coupled to delivery device **1000**. Outer sheath **1002** can include proximal end **1002**A, distal end **1002**B, straight section **1004**, and pre-curved section **1006**. As shown in FIG. **10**B, distal portion **1101** can include nosecone **1102** and molded bridge **1104**. Nosecone **1102** includes straight portion **1106** and tapered portion **1108**. Molded bridge **1104** includes proximal end

1104A and distal end **1104**B.
[0078] Straight portion **1106** of nosecone **1102** is positioned adjacent and closest to a distal end of delivery device **1000**, compared to any other feature/component of delivery device **1000**. Straight portion **1106** includes a generally constant diameter extending a length of straight portion **1106**, and straight portion **1106** includes an aperture extending fully through straight portion **1106**. In some examples, a proximal end of straight portion **1106** can be coupled to a distal end of tapered portion **1108**. In alternate examples, straight portion **1106** and tapered portion **1108** can be formed as a unitary, single-piece component. In some examples, straight portion **1106** and tapered portion **1108** can each be constructed from one or more of a thermoplastic polymer, a nylon, or other polymer based material. Tapered portion **1108** is positioned between and coupled to both straight portion **1106** and molded bridge **1104**. Tapered portion **1108** of nosecone **1102** also includes an aperture extending fully through tapered portion **1108**. The aperture extending through tapered portion **1108** is axially aligned with the aperture extending through straight portion **1106** of nosecone **1102**. Further, the apertures extending through straight portion **1106** and tapered portion **1108** are configured to accept a guidewire, discussed with respect to FIGS. **11-12** below.
[0079] Molded bridge **1104** includes proximal end **1104**A and distal end **1104**B. Distal end **1104**B of molded bridge **1104** is coupled to an end of tapered portion **1108** of nosecone **1102**. In some examples, distal end **1104**B of molded bridge **1104** coupled to an end of tapered portion **1108** includes an outer diameter equal to an outer diameter of the end of tapered portion **1108** coupled to distal end **1104**B of molded bridge **1104**. In other examples, distal end **1104**B of molded bridge **1104** may not have the same outer diameter as then end of tapered portion **1108** coupled to molded bridge **1104**. As shown, shunt device **100**′ surrounds at least a portion of delivery device **1000** and shunt device **100**′ is configured to be coupled to delivery device **1000** for delivery into a human body. Further, the features and components of delivery device **1000** are configured to release shunt device **100**′ from delivery device **1000** and allow shunt device **100**′ to couple to tissue within the human body. To avoid any adverse effects of inserting delivery device **1000** and shunt device **100**′ into a human body, delivery device **1000** and shunt device **100**′ can each be sterilized before entering the human body.
[0080] In the example shown, central flow tube **110**′ of shunt device **100**′ surrounds a portion of molded bridge **1104**, such that a portion of molded bridge **1104** extends through central flow tube **110**′. Further, a portion of central flow tube **110**′ is positioned adjacent and abutting a portion of molded bridge **1104**. The portion of central flow tube **110**′ abutting molded bridge **1104** and an arm of shunt device **100**′ are coupled to molded bridge **1104** for delivery into the human body. Sensor **150**′ is also positioned adjacent and abutting a portion of molded bridge **1104**. More specifically, sensor **150**′ extends from an arm of shunt device **100**′ in a direction towards nosecone **1102** of delivery device **1000**. Sensor **150**′ is positioned at least partially within a pocket of molded bridge **1104**. Shunt device **100**′ including sensor **150**′ is coupled to delivery device **1000** for translation and placement of shunt device **100**′ and sensor **150**′ within the human body. Shunt device **100**′ can be uncoupled from molded bridge **1104** of delivery device **1000** to allow shunt device **100**′ to release from delivery device **1000** and couple to tissue within the human body. After shunt device **100**′ and sensor **150**′ have been properly placed and coupled to tissue within the human body, delivery device **1000** can be translated out of the human body to remove delivery device **1000** from the human body.
[0081] Referring to FIG. **10**A, outer sheath **1002** of delivery device **1000** is configured to surround and cover at least a portion of delivery device **1000**, such that nosecone **1102** and distal end **1104**B of molded bridge **1104** are positioned outside of outer sheath **1002**. Further, outer sheath **1002** is configured to fully surround and cover shunt device **100**′. As such, outer sheath **1002** is configured to surround and cover shunt device **100**′ and a portion of molded bridge **1104** during the insertion of delivery device **1000** into the human body. Further, distal end **1002**B of outer sheath **1002** abuts molded bridge **1104** adjacent distal end **1104**B of molded bridge **1104** to ensure shunt device **100**′

and a portion of molded bridge **1104** remain covered during the insertion and translation into the human body. Covering shunt device **100**′ and a portion of molded bridge **1104** with outer sheath **1002** facilitates a smooth insertion of delivery device **1000** into the human body by providing a smooth outer surface for translation into the human body. In some examples, distal end **1002**B of outer sheath **1002** can be coupled to distal end **1104**B of molded bridge **1104** through a friction fit (otherwise known as an interference fit), such that the frictional force between outer sheath **1002** and molded bridge **1104** holds the components together. In other examples, distal end **1002**B of outer sheath **1002** can be coupled to distal end **1104**B of molded bridge **1104** through a non-permanent coupling mechanism.

[0082] As shown in FIG. **10**B, after delivery device **1000** has been translated into the human body and positioned in the correct location, outer sheath **1002** can be pulled in a direction away from nosecone **1102** and molded bridge **1104** to reveal shunt device **100**′ and the portion of molded bridge **1104** previously covered by outer sheath **1002**. More specifically, outer sheath **1002** is pulled in a direction away from distal end **1104**B of molded bridge **1104** and towards proximal end **1104**A of molded bridge **1104** to uncouple distal end **1002**B of outer sheath **1002** from distal end **1104**B of molded bridge **1104**. Uncoupling outer sheath **1002** from molded bridge **1104** and pulling outer sheath **1002** in a direction towards proximal end **1002**A (not shown in FIGS. **4**A-**4**B) of outer sheath **1002** is the beginning of the process to couple shunt device **100**′ to tissue within the human body. Specifically, after outer sheath **1002** is pulled far enough towards proximal end **1002**A of outer sheath **1002**, at least one arm of shunt device **100**′ is allowed to unfold and clamp onto tissue within the human body. Delivery device **1000** proceeds to release the other arms of shunt device **100**′ to allow shunt device **100**′ and sensor **150**′ to fixedly couple to tissue within the human, the steps of which are generally discussed above with respect to FIGS. **8**A-**9**R. An issue with previous sheaths is that the sheaths can kink during insertion and/or induce excess forces and stresses to the tissue of the human body during the insertion process, which is undesirable during a medical procedure. Outer sheath **1002** of the present application includes many advantages over previous sheaths, as will be realized by those skilled in the art.

[0083] FIG. **11** is a side view of outer sheath **1002** used in delivery device **1000**. FIG. **12** is a side view of outer sheath **1002** in a straight configuration. FIGS. **11**-**12** will be discussed together. Delivery device **1000** includes outer sheath **1002** (including proximal end **1002**A and distal end **1002**B), straight section **1004**, pre-curved section **1006**, first length **1008**, second length **1010**, third length **1012**, fourth length **1014**, and inner surface **1016**.

[0084] Outer sheath **1002** can include proximal end **1002**A, distal end **1002**B, straight section **1004**, and pre-curved section **1006**. As shown in FIG. **12**, outer sheath **1002** can include first length **1008**, second length **1010**, third length **1012**, and fourth length **1014**. As discussed, outer sheath **1002** is a component of delivery device **1000** that is configured to aid in transporting and placing shunt device **100**′ in a human body. Further, outer sheath **1002** is kink resistant. That is, outer sheath **1002** is configured to prevent or minimize kinking and undesirable forces and stresses during the insertion of delivery device **1000** into the human body.

[0085] Outer sheath **1002** includes proximal end **1002**A and distal end **1002**B positioned at an opposite end of outer sheath **1002**. Proximal end **1002**A is the end of outer sheath **1002** positioned closest to a doctor or user's hand during the insertion of delivery device **1000** into the human body. Distal end **1002**B is the end of outer sheath **1002** positioned furthest from a doctor or user's hand during the insertion of delivery device **1000** into the human body. In addition, distal end **1002**B is the end of outer sheath **1002** that is configured to cover and surround shunt device **100**′ and a portion of molded bridge **1004** (shown in FIGS. **10**A-**10**B) during the insertion of delivery device **1000** into the human body. Outer sheath **1002** includes straight section **1004** and pre-curved section **1006** extending from an end of straight section **1004**. In the example shown, straight section **1004** extends from proximal end **1002**A of outer sheath **1002** in a straight configuration in a direction generally towards distal end **1002**B of outer sheath **1002**. Further, in the example shown, pre-

curved section **1006** extends from a distal end of straight section **1004** in a curved or arched configuration such that together straight section **1004** and pre-curved section **1006** form a hook-shaped outer sheath **1002** in a relaxed configuration.

[0086] Straight section **1004** includes an aperture extending fully through straight section **1004**. Likewise, pre-curved section **1006** includes an aperture extending fully through pre-curved section **1006**. More specifically, outer sheath **1002** has a circular or oval outer cross-section with an aperture extending fully through straight section **1004** and pre-curved section **1006**. Therefore, outer sheath **1002** has a generally tubular or cylindrical shape with straight section **1004** having a generally straight hollow cylindrical shape and pre-curved section **1006** having a generally curved hollow cylindrical shape. Outer sheath **1002** fully surrounds and covers components of delivery device **1000** such that the components of delivery device **1000** are positioned within the aperture extending through outer sheath **1002**. More specifically, the interior of outer sheath **1002** is hollow to allow shunt device **100′** and a portion of delivery device **1000** to be inserted within the hollow center of outer sheath **1002** for delivery into the human body.

[0087] As shown best in FIG. **11**, pre-curved section **1006** is a portion of outer sheath **1002** that remains in a curved configuration when in the relaxed position. The curved configuration of pre-curved section **1006** aids in preventing or minimizing kinking and undesirable forces and stresses during the insertion of delivery device **1000** into the human body, discussed further below. In some examples, pre-curved section **1006** can include an inner diameter ranging between 2.40 inches (6.096 centimeters) and 3.20 inches (8.128 centimeters), measuring from axis AA of pre-curved section **1006** to inner surface **1016** of pre-curved section **1006**. In some examples, pre-curved section **1006** can include an inner diameter ranging between 2.0 inches (5.08 centimeters) and 4.0 inches (10.16 centimeters), measuring from axis AA of pre-curved section **1006** to inner surface **1016** of pre-curved section **1006**. Further, in one specific example, pre-curved section **1006** can include an inner diameter of 2.8 inches (7.112 centimeters), measuring from axis AA of pre-curved section **1006** to inner surface **1016** of pre-curved section **1006**. In some examples, pre-curved section **1006** extends from an end of straight section **1004** about axis AA of pre-curved section **1006** at least 180 degrees from the connection point of pre-curved section **1006** and straight section **1004**. In another example, pre-curved section **1006** extends from an end of straight section **1004** about axis AA of pre-curved section **1006** between a range of 170 degrees and 210 degrees from the connection point of pre-curved section **1006** and straight section **1004**. In other examples, pre-curved section **1006** extends from an end of straight section **1004** about axis AA of pre-curved section **1006** between a range of 130 degrees and 240 degrees from the connection point of pre-curved section **1006** and straight section **1004**. In yet other examples, pre-curved section **1006** extends from an end of straight section **1004** about axis AA of pre-curved section **1006** 190 degrees from the connection point of pre-curved section **1006** and straight section **1004**.

[0088] Pre-curved section **1006** is configured to prevent or minimize kinking and undesirable forces and stresses during the insertion of delivery device **1000** into the human body. Specifically, as outer sheath **1002** and delivery device **1000** are translated along a guidewire into the human body, pre-curved section **1006** of outer sheath **1002** will bend into a straight configuration along straight portions of the guidewire and pre-curved section **1006** will bend back into its original curved shape along curved portions of the guidewire. Pre-curved section **1006** having a curved-bias shape allows pre-curved section **1006**, and outer sheath **1002** as a whole, to more easily follow the curved portions of guidewire, which prevents or minimizes kinking and undesirable forces and stresses during the insertion of outer sheath **1002** into the human body. As such, during insertion of outer sheath **1002** into the human body, the shape of outer sheath **1002** will vary depending on the tracking shape of sections of the guidewire. Specifically, outer sheath **1002** can enter a straight or generally straight configuration along straight portions of the guidewire and outer sheath **1002** can revert back to a curved configuration along curved portions of the guidewire.

[0089] In addition, to prevent or minimize kinking and undesirable forces and stresses during the

insertion of delivery device **1000** into the human body, outer sheath **1002** can have a varying stiffness along a length of outer sheath **1002**. Specifically, straight section **1004** and pre-curved section **1006** can each include a varying stiffness along a length of each of straight section **1004** and pre-curved section, respectively. In some examples, straight section **1004** of outer sheath **1002** can be stiffer than pre-curved section **1006** of outer sheath **1002**. In other examples, a portion near proximal end **1002**A of outer sheath **1002** can be stiffer than a portion near distal end **1002**B of outer sheath **1002**, which can aid in a doctor or user in pushing and pulling on proximal end **1002**A of outer sheath **1002** to insert or remove, respectively, outer sheath **1002** from a human body. Further, if a portion near proximal end **1002**A of outer sheath **1002** were too soft, it would prevent or increase the difficulty of inserting and removing outer sheath **1002** from a human body due to the lack of rigidity and structure of outer sheath **1002**. In further examples, a portion near distal end **1002**B of outer sheath **1002** can be softer than proximal end **1002**A of outer sheath **1002**, allowing distal end **1002**B of outer sheath **1002** to easily bend and track around curved portions of a guidewire positioned within a human body.

[0090] FIG. **12** is a side view of outer sheath **1002** in a straight configuration, illustrating an example outer sheath **1002** including first length **1008**, second length **1010**, third length **1012**, and fourth length **1014** (not shown to scale). Outer sheath **1002** is shown in a straight configuration for illustrative and descriptive purposes only and it is to be understood that outer sheath **1002** includes a generally hook shaped orientation when in a relaxed state. Although the specific example shown in FIG. **12** includes four lengths **1008**, **1010**, **1012**, and **1014**, it is to be understood that other examples of outer sheath **1002** can include more or less than four lengths as described. The different lengths **1008**, **1010**, **1012**, and **1014** of outer sheath **1002** each have varying lengths and stiffnesses to prevent or minimize kinking and undesirable forces and stresses during the insertion of outer sheath **1002** and delivery device **1000** into the human body. The specific lengths and stiffnesses of each of lengths **1008**, **1010**, **1012**, and **1014** can be determined using one or more of mathematical calculations, computational analysis, and experimental testing, among other options.

[0091] First length **1008** is positioned adjacent and closest to distal end **1002**B of outer sheath **1002**, and first length **1008** extends from distal end **1002**B of outer sheath **1002** in a direction towards proximal end **1002**A of outer sheath **1002**. Second length **1010** is positioned adjacent first length **1008**, and second length **1010** extends from a distal end of first length **1008** towards proximal end **1002**A. Third length **1012** is positioned adjacent and closest to proximal end **1002**A of outer sheath **1002**, and third length **1012** extends from proximal end **1002**A of outer sheath **1002** in a direction towards distal end **1002**B of outer sheath **1002**. Fourth length **1014** is positioned and extends between second length **1010** and third length **1012**. In some examples, first length **1008** of outer sheath **1002** can have a stiffness of 35 durometer. Further, in some examples, second length **1010** of outer sheath **1002** can have a stiffness of 45 durometer. In another example, third length **1012** of outer sheath **1002** can have a stiffness of 72 durometer. In yet another example, fourth length **1014** of outer sheath **1002** can have a stiffness of 55 durometer. The specific stiffness of each of lengths **1008**, **1010**, **1012**, and **1014** can be determined using one or more of mathematical calculations, computational analysis, and experimental testing, among other options, to achieve outer sheath **1002** with optimal bending and flexibility characteristics for translating into and out of a human body.

[0092] In some examples, as shown, second length **1010** of outer sheath **1002** can be greater than first length **1008** of outer sheath **1002**. Further, in some examples, third length **1012** of outer sheath **1002** can be greater than first length **1008** of outer sheath **1002**, and third length **1012** of outer sheath **1002** can be greater than second length **1010** of outer sheath **1002**. In some examples, third length **1012** of outer sheath **1002** can be greater than a combined length of first length **1008** and second length **1010** of outer sheath **1002**. In other examples, fourth length **1014** of outer sheath **1002** can be greater than first length **1008** of outer sheath **1002**, and fourth length **1014** of outer sheath **1002** can be greater than second length **1010** of outer sheath **1002**. In yet another example,

fourth length **1014** of outer sheath **1002** can be greater than a combined length of first length **1008** and second length **1010** of outer sheath **1002**. In another examples, fourth length **1014** of outer sheath **1002** can be less than third length **1012** of outer sheath **1002**. The specific lengths of each of lengths **1008**, **1010**, **1012**, and **1014** can be determined using one or more of mathematical calculations, computational analysis, and experimental testing, among other options, to achieve outer sheath **1002** with optimal bending and flexibility characteristics for translating into and out of a human body.

[0093] As discussed, the shape of pre-curved section **1006** and the lengths and stiffness of each of lengths **1008**, **1010**, **1012**, and **1014** of outer sheath **1002** are optimized to prevent or minimize kinking and undesirable forces and stresses during the insertion of delivery device **1000** into the human body. In addition, outer sheath **1002** can be constructed from a braided material such that both straight section **1004** and pre-curved section **1006** are constructed from the same braided material. The braided material can include a constant weave pattern extending from proximal end **1002**A of outer sheath **1002** to distal end **1002**B of outer sheath. The braided material including a constant weave pattern can further reduce or prevent kinking of outer sheath **1002** during the insertion and removal of outer sheath **1002** from a human body. In some examples, the braided material can have a constant weave pattern with between 30 and 40 picks per inch (between about 11.811 and about 15.748 picks per centimeter). In one example, the braided material can have a constant weave pattern with 30 picks per inch (about 11.811 picks per centimeter). In other examples, the braided materials can include less than 30 picks per inch or more than 40 picks per inch (less than about 11.811 picks per centimeter or more than about 15.748 picks per centimeter). In some examples, outer sheath **1002** (i.e., the braided material) can be constructed from a stainless steel covered in a thermoplastic elastomer. The thermoplastic elastomer can be, for example, a Pebax® thermoplastic elastomer. In some examples, outer sheath **1002** can also include a liner or lining material. For example, the liner can be formed of a fluoropolymer material, such as a polytetrafluoroethylene (PTFE).

[0094] As will be realized by a person skilled in the art, outer sheath **1002** provides many advantages over previous outer sheaths. Specifically, outer sheath **1002** is optimized to prevent or minimize kinking and undesirable forces and stresses during the insertion of outer sheath **1002** and delivery device **1000** into the human body. Outer sheath **1002** aids in the delivery and placement of shunt device **100′** within a human body, while preventing undesirable tissue stress and/or damage during the insertion and removal process. As such, outer sheath **1002** is an improved sheath with reduced kinking characteristics and improved trackability into the human body, improving the medical procedure of transporting and placing shunt device **100′** (or other implantable device) within the human body.

[0095] Any of the various systems, devices, apparatuses, etc. in this disclosure can be sterilized (e.g., with heat, radiation, ethylene oxide, hydrogen peroxide, etc.) to ensure they are safe for use with patients, and the methods herein can comprise sterilization of the associated system, device, apparatus, etc. (e.g., with heat, radiation, ethylene oxide, hydrogen peroxide, etc.).

[0096] The treatment techniques, methods, steps, etc. described or suggested herein or in references incorporated herein can be performed on a living animal or on a non-living simulation, such as on a cadaver, cadaver heart, anthropomorphic ghost, simulator (e.g., with the body parts, tissue, etc. being simulated), etc.

Discussion of Possible Examples

[0097] The following are non-exclusive descriptions of possible examples of the present invention.

[0098] An outer sheath for surrounding and covering components of a delivery device includes a straight section including an aperture extending fully through the straight section. The outer sheath further includes a pre-curved section extending distally from an end of the straight section and including an aperture extending fully through the pre-curved section. The straight section and the pre-curved section include a varying stiffness along a length of the straight section and the pre-

curved section.
[0099] The outer sheath of the preceding paragraph can optionally include, additionally and/or alternatively, any one or more of the following features, configurations, and/or additional components:
[0100] The straight section and the pre-curved section can be constructed from a braided material.
[0101] The braided material can include between 30 and 40 picks per inch (between about 11.811 and about 15.748 picks per centimeter).
[0102] The braided material can include a constant weave pattern extending from a proximal end of the outer sheath to a distal end of the outer sheath.
[0103] The braided material can be a stainless steel covered with a thermoplastic elastomer.
[0104] The straight section of the outer sheath can be stiffer than the pre-curved section of the outer sheath.
[0105] Together the straight section and the pre-curved section can form a hook-shaped outer sheath.
[0106] A diameter of an inner surface of the pre-curved section can range between 2.40 inches (6.096 centimeters) and 3.20 inches (8.128 centimeters).
[0107] A diameter of an inner surface of the pre-curved section can be 2.8 inches (7.112 centimeters).
[0108] The pre-curved section can extend about an axis of the pre-curved section at least 180 degrees from a connection point of the pre-curved section and the straight section.
[0109] The pre-curved section can extend about an axis of the pre-curved section between a range of 170 degrees and 210 degrees from a connection point of the pre-curved section and the straight section.
[0110] The pre-curved section can extend about an axis of the pre-curved section 190 degrees from a connection point of the pre-curved section and the straight section.
[0111] A distal end of the outer sheath can include a first length of the outer sheath having a stiffness of 35 durometer.
[0112] A second length of the outer sheath can be positioned adjacent to the first length of the outer sheath, and the second length of the outer sheath can have a stiffness of 45 durometer.
[0113] The second length of the outer sheath can be greater than the first length of the outer sheath.
[0114] A third length of the outer sheath can be positioned at a proximal end of the outer sheath, and the third length of the outer sheath can have a stiffness of 72 durometer.
[0115] The third length of the outer sheath can be greater than the first length of the outer sheath and the second length of the outer sheath.
[0116] The third length of the outer sheath can be greater than a combined length of the first length of the outer sheath and the second length of the outer sheath.
[0117] A fourth length of the outer sheath can extend between the second length of the outer sheath and the third length of the outer sheath, and the fourth length of the outer sheath can have a stiffness of 55 durometer.
[0118] The fourth length of the outer sheath can be greater than the first length of the outer sheath and the second length of the outer sheath.
[0119] The fourth length of the outer sheath can be greater than a combined length of the first length of the outer sheath and the second length of the outer sheath.
[0120] The fourth length of the outer sheath can be less than the third length of the outer sheath.
[0121] The outer sheath can be kink resistant.
[0122] The outer sheath can be constructed from a stainless steel covered with a thermoplastic elastomer.
[0123] The outer sheath can be sterilized before insertion into a human body.
[0124] The delivery device can be configured to deliver a shunt device within a human body.
[0125] The straight section of the outer sheath can have a straight hollow cylindrical shape.

[0126] The pre-curved section of the outer sheath can have a curved hollow cylindrical shape.
[0127] The outer sheath can fully surround and cover components of the delivery device such that the components of the delivery device are positioned within the aperture extending fully through the pre-curved section.
[0128] A proximal end of the outer sheath can be stiffer than a distal end of the outer sheath, allowing a user to push and pull on the proximal end of the outer sheath.
[0129] A distal end of the outer sheath can be softer than a proximal end of the outer sheath, allowing the distal end of the outer sheath to bend around a curved guidewire.
[0130] While the invention has been described with reference to an exemplary example(s), it will be understood by those skilled in the art that various changes may be made and equivalents may be substituted for elements thereof without departing from the scope of the invention. In addition, many modifications may be made to adapt a particular situation or material to the teachings of the invention without departing from the essential scope thereof. Therefore, it is intended that the invention not be limited to the particular example(s) disclosed, but that the invention will include all examples falling within the scope of the appended claims.

Claims

1. An outer sheath for surrounding and covering components of a delivery device, the outer sheath comprising: a straight section including an aperture extending fully through the straight section; and a pre-curved section extending distally from an end of the straight section, wherein the pre-curved section includes an aperture extending fully through the pre-curved section; wherein the straight section and the pre-curved section include a varying stiffness along a length of the straight section and the pre-curved section; and wherein a distal end of the outer sheath is softer than a proximal end of the outer sheath, allowing the distal end of the outer sheath to bend around a curved guidewire.
2. The outer sheath of claim 1, wherein the straight section and the pre-curved section form a hook-shaped outer sheath in a relaxed state.
3. The outer sheath of claim 1, wherein the outer sheath is kink resistant, and wherein the outer sheath is constructed from a stainless steel covered with a thermoplastic elastomer.
4. The outer sheath of claim 1, wherein the straight section and the pre-curved section are constructed from a braided material having a constant weave pattern extending from a proximal end of the outer sheath to a distal end of the outer sheath.
5. The outer sheath of claim 1, wherein the pre-curved section extends about a central axis with respect to a curvature of the pre-curved section at least 180 degrees from a connection point of the pre-curved section and the straight section.
6. The outer sheath of claim 1, wherein the pre-curved section extends about a central axis with respect to a curvature of the pre-curved section between a range of 170 degrees and 210 degrees from a connection point of the pre-curved section and the straight section.
7. The outer sheath of claim 1, wherein the pre-curved section extends about a central axis with respect to a curvature of the pre-curved section 190 degrees from a connection point of the pre-curved section and the straight section.
8. The outer sheath of claim 1, wherein a diameter of an inner surface of the pre-curved section ranges between 2.40 inches (6.096 centimeters) and 3.20 inches (8.128 centimeters).
9. An outer sheath for surrounding and covering components of a delivery device, the outer sheath comprising: a straight section including an aperture extending fully through the straight section; and a pre-curved section extending distally from an end of the straight section, wherein the pre-curved section includes an aperture extending fully through the pre-curved section; wherein the straight section and the pre-curved section include a varying stiffness along a length of the straight section and the pre-curved section; and wherein the straight section and the pre-curved section are

constructed from a braided material having a constant weave pattern extending from a proximal end of the outer sheath to a distal end of the outer sheath.

10. The outer sheath of claim 9, wherein the braided material includes between 30 and 40 picks per inch (between about 11.811 and about 15.748 picks per centimeter).

11. The outer sheath of claim 9, wherein the braided material is a stainless steel covered with a thermoplastic elastomer.

12. The outer sheath of claim 9, wherein a proximal end of the outer sheath is stiffer than a distal end of the outer sheath, allowing a user to push and pull on the proximal end of the outer sheath, and wherein the distal end of the outer sheath is softer than the proximal end of the outer sheath, allowing the distal end of the outer sheath to bend around a curved guidewire.

13. The outer sheath of claim 9, wherein a distal end of the outer sheath includes a first length of the outer sheath having a stiffness of 35 durometer.

14. The outer sheath of claim 13, wherein a second length of the outer sheath is positioned adjacent to the first length of the outer sheath, wherein the second length of the outer sheath has a stiffness of 45 durometer, and wherein the second length of the outer sheath is greater than the first length of the outer sheath.

15. The outer sheath of claim 14, wherein a third length of the outer sheath is positioned at a proximal end of the outer sheath, wherein the third length of the outer sheath has a stiffness of 72 durometer, and wherein the third length of the outer sheath is greater than the first length of the outer sheath and the second length of the outer sheath.

16. The outer sheath of claim 15, wherein a fourth length of the outer sheath extends between the second length of the outer sheath and the third length of the outer sheath, wherein the fourth length of the outer sheath has a stiffness of 55 durometer, wherein the fourth length of the outer sheath is greater than the first length of the outer sheath and the second length of the outer sheath, and wherein the fourth length of the outer sheath is less than the third length of the outer sheath.

17. A delivery device for transporting and deploying a shunt device within a human body, the delivery device comprising: an outer sheath including: a straight section including an aperture extending fully through the straight section; and a pre-curved section extending distally from an end of the straight section, wherein the pre-curved section includes an aperture extending fully through the pre-curved section; wherein the straight section and the pre-curved section include a varying stiffness along a length of the straight section and the pre-curved section; and a distal portion including a nosecone and a molded bridge.

18. The delivery device of claim 17, wherein the straight section of the outer sheath is stiffer than the pre-curved section of the outer sheath.

19. The delivery device of claim 17, wherein together the straight section and the pre-curved section form a hook-shaped outer sheath.

20. The delivery device of claim 17, wherein the straight section and the pre-curved section are constructed from a braided material having a constant weave pattern extending from a proximal end of the outer sheath to a distal end of the outer sheath.