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WAVY RELEASE WIRE FOR A DELIVERY DEVICE

Abstract

A delivery device for implanting a shunt device in a tissue wall includes an actuation arm extending through the delivery device, the actuation arm configured to seat an arm of the shunt device on the tissue wall, and a wavy release wire extending through the actuation arm, wherein the wavy release wire includes a wavy portion that forms a friction fit with the actuation arm.

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Background/Summary

CROSS-REFERENCE TO RELATED APPLICATION(S) [0001] This application is a continuation of International Application No. PCT/US2023/034390, filed Oct. 3, 2023, which claims the benefit of U.S. Provisional Application No. 63/378,177, filed Oct. 3, 2022, the disclosures of which are hereby incorporated by reference in their entireties.

BACKGROUND
[0002] The present disclosure relates generally to delivery devices for implanting shunt devices, and, more particularly, to a release wire for a delivery device.
[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 devices 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] A delivery device for implanting a shunt device in a tissue wall includes an actuation arm extending through the delivery device, the actuation arm configured to seat an arm of the shunt device on the tissue wall, and a wavy release wire extending through the actuation arm, wherein the wavy release wire includes a wavy portion that forms a friction fit with the actuation arm.

Description

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DETAILED DESCRIPTION

Anatomy of Heart H and Vasculature V (FIGS. **1-2**)

[0020] 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**).

[0021] 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.

[0022] 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.

[0023] 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.

[0024] 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.

[0025] 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.

[0026] 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.

[0027] 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.

[0028] 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.

[0029] 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**)

[0030] 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 **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). 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.

[0031] 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.

[0032] 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.

[0033] 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.

[0034] 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**.

[0035] 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.

[0036] 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.

[0037] 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**.

[0038] 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.

[0039] 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.

[0040] 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**.

[0041] 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.

[0042] 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**.

[0043] 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**′.

[0044] 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**′.

[0045] 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.

[0046] 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.

[0047] 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)

[0048] 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**.

[0049] 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.

[0050] 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.

[0051] 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**.

[0052] 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**.

[0053] 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)

[0054] 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**.

[0055] 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.

[0056] 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.

[0057] 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.

[0058] 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.

[0059] 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.

[0060] 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**.

[0061] 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.

[0062] 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.

[0063] 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.

[0064] 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.

[0065] 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.

[0066] 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.

[0067] 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.

[0068] 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.

[0069] 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.

[0070] 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.

[0071] 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.
[0072] 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.
[0073] 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.
Actuation Arm **1000** (FIGS. **10-12**)
[0074] FIG. **10** is a side view of actuation arm **1300** and wavy release wire **1302**. FIG. **10** shows actuator arm **1300** and wavy release wire **1302**. Actuation arm **1300** includes proximal end **1300**A, distal end **1300**B, tube **1310**, proximal portion **1312**, distal portion **1314**, collar **1316**, pocket **1318**, and soft tip **1320**.
[0075] Actuation arm **1300** as shown in FIG. **10** is one example of an actuation arm that can form part of a delivery device for implanting a shunt device. The delivery device can, for example, have the general design as delivery device **200** shown in FIGS. **6-7**B. Further, the delivery device can be used to implant, for example, shunt device **100** shown in FIGS. **3**A-**4** or shunt device **100**′ having sensor **150**′ shown in FIG. **5**. Actuation arm **1300** is one example of actuation arm **226**, as discussed above with respect to FIGS. **9**M-**9**N and **9**P. An arm of a shunt device can be held in actuation arm **1300** using wavy release wire **1302**. Actuation arm **1300** can be actuated outwards from the delivery device to seat the arm of the shunt device on a tissue wall when the shunt device is being implanted in the tissue wall. Wavy release wire **1302** can then be pulled proximally to withdraw wavy release wire **1302** from the arm of the shunt device to release the shunt device from actuation arm **1300**. Actuation arm **1300** can then be withdrawn proximally back into the delivery device.
[0076] Actuation arm **1300** includes proximal end **1300**A and distal end **1300**B opposite of proximal end **1300**A. Actuation arm **1300** includes tube **1310** beginning at proximal end **1300**A of actuation arm **1300** and extending towards distal end **1300**B of actuation arm **1300**. Tube **1310** has proximal portion **1312** and distal portion **1314**. Proximal portion **1312** is positioned proximally to distal portion **1314**. Proximal portion **1312** has a first outer diameter, and distal portion **1314** has a second outer diameter that is greater than the first outer diameter. A lumen extends through tube **1310**. In one example, tube **1310** is a hypo tube.
[0077] Actuation arm **1300** further includes collar **1316** coupled to tube **1310**. Collar **1316** is distal to tube **1310**. Collar **1316** can be coupled to tube **1310** using any suitable mechanism. In some examples, collar **1316** and tube **1310** can be integrally formed. Collar **1316** has pocket **1318** extending into a first side of collar **1316**. Pocket **1318** of collar **1316** is configured so that an arm of a shunt device can be positioned in pocket **1318**. A lumen extends through collar **1316** and is axially aligned with the lumen extending through tube **1310**.
[0078] Actuation arm **1300** further includes soft tip **1320** coupled to collar **1316**. Soft tip **1320** is distal to collar **1316** and extends to distal end **1300**B of actuation arm **1300**. Soft tip **1320** can be coupled to collar **1316** using any suitable mechanism. In some examples, soft tip **1320** and collar **1316** can be integrally formed. Soft tip **1320** is configured to be a soft portion of actuation arm **1300** that can contact and slide along vessel walls without puncturing, tearing, or otherwise

damaging the vessel walls.
[0079] Wavy release wire **1302** extends through the lumen extending through tube **1310** and the lumen extending through collar **1316**. A distal end of wavy release wire **1302** is positioned in a trough in soft tip **1320**, as will be discussed in more detail with respect to FIG. **12** below. Wavy release wire **1302** will be discussed in more detail with respect to FIG. **11** below. Wavy release wire **1302** is configured to be retractable from the delivery device to release an arm of the shunt device from actuation arm **1300**.
[0080] FIG. **11** is a side view of wavy release wire **1302**. Wavy release wire **1302** includes proximal end **1302**A, distal end **1302**B, proximal straight portion **1330**, wavy portion **1332**, and distal straight portion **1334**. FIG. **11** further shows diameter D and height H.
[0081] Wavy release wire **1302** is a release wire that can be used with actuation arm **1300** as discussed above with respect to FIG. **10**. Wavy release wire **1302** includes proximal end **1302**A and distal end **1302**B opposite of proximal end **1302**A. Wavy release wire **1302** includes proximal straight portion **1330** beginning at proximal end **1302**A of wavy release wire **1302** and extending distally. Wavy release wire **1302** includes wavy portion **1332** extending distally from proximal straight portion **1330**. Wavy release wire **1302** further includes distal straight portion **1334** extending distally from wavy portion **1332** and ending at distal end **1302**B of wavy release wire **1302**.
[0082] Proximal straight portion **1330** is a proximal section of wavy release wire **1302**. When wavy release wire **1302** is positioned in actuation arm **1300** (as shown in FIG. **10**), proximal straight portion **1330** is positioned in proximal portion **1312** of tube **1310**. Proximal straight portion **1330** has a length of approximately between 56.7 inches (144.018 centimeters) and 57.1 inches (145.034 centimeters) in some examples. Proximal straight portion **1330** has a length of approximately 56.9 inches (144.526 centimeters) in one example.
[0083] Wavy portion **1332** is a middle section of wavy release wire **1302**. When wavy release wire **1302** is positioned in actuation arm **1300**, wavy portion **1332** is positioned in proximal portion **1312** of tube **1310**. Wavy portion **1332** has a length of approximately between 0.4 inches (1.016 centimeters) and 0.8 inches (2.032 centimeters) in some examples. Wavy portion **1332** has a length of approximately 0.6 inches (1.524 centimeters) in one example. Wavy portion **1332** has a number of repeating waves extending along a length of wavy portion **1332**. In the example shown in FIG. **11**, wavy portion **1332** has four waves, each wave having a peak and a valley. In alternate examples, wavy portion **1332** can have any number of suitable waves.
[0084] Distal straight portion **1334** is a distal section of wavy release wire **1302**. When wavy release wire **1302** is positioned in actuation arm **1300**, distal straight portion **1334** is positioned partially in proximal portion **1312** of tube **1310**, in distal portion **1314** of tube **1310**, in collar **1316**, and in soft tip **1320**. Distal straight portion **1334** has a length of approximately between 1.3 inches (3.302 centimeters) and 1.7 inches (4.318 centimeters) in some examples. Distal straight portion **1334** has a length of approximately 1.5 inches (3.81 centimeters) in on example.
[0085] Wavy release wire **1302** is not drawn to scale in FIG. **11**. Proximal straight portion **1330** is the longest section of wavy release wire **1302**, having a greater length than wavy portion **1332** and distal straight portion **1334**. Further, distal straight portion **1334** has a greater length than wavy portion **1332**.
[0086] Wavy release wire **1302** has diameter D between 0.0086 inches (0.0218 centimeters) and 0.0094 inches (0.0239 centimeters). In one example, wavy release wire **1302** has diameter D of 0.0090 inches (0.0229 centimeters). The waves in wavy portion **1332** of wavy release wire **1302** also have height H, which is the distance between the outermost point of the peak and the outmost point of the valley of one wave. Height H is between 0.022 inches (0.0559 centimeters) and 0.028 inches (0.0711 centimeters). In one example, wavy release wire **1302** has height H of 0.025 inches (0.0635 centimeters). Wavy release wire **1302** is made out of nitinol (a nickel titanium alloy) in the example shown in FIGS. **10-11**, but can be made out of any super elastic or shape memory alloy in

alternate examples. The waves in wavy portion **1332** are shape set into wavy release wire **1302**.

[0087] When wavy release wire **1302** is fully positioned in actuation arm **1300**, wavy portion **1332** extends through a section of proximal portion **1312** of tube **1310**. Height H of the waves in wavy portion **1332** is greater than an inner diameter of the lumen extending through tube **1310**. When wavy release wire **1302** is positioned in proximal portion **1312** of tube **1310**, the waves in wavy portion **1332** will be compressed by the inner surface of the lumen extending through tube **1310**, which will create a friction fit between wavy release wire **1302** and proximal portion **1312** of tube **1310**. This friction fit between wavy release wire **1302** and tube **1310** will hold wavy release wire **1302** in position in actuation arm **1300**. The friction fit can prevent wavy release wire **1302** from being inadvertently pulled from actuation arm **1300** during manufacturing, shipping, and deployment of the shunt device into the body.

[0088] FIG. **12** is a perspective view of soft tip **1320**. Soft tip **1320** includes proximal end **1320**A, distal end **1320**B, body **1340**, trough **1342**, and curved outer surface **1344**.

[0089] Soft tip **1320** is coupled to actuation arm **1300** at a distal portion of actuation arm **1300**. Soft tip **1320** includes proximal end **1320**A and distal end **1320**B opposite of proximal end **1320**A. Soft tip **1320** includes body **1340** that forms a main portion of soft tip **1320**. Trough **1342** is formed in a first side of body **1340** and is a channel formed in body **1340**. Trough **1342** begins at proximal end **1320**A of soft tip **1320** and extends towards distal end **1320**B of soft tip **1320**. Trough **1342** is configured to receive a portion of wavy release wire (shown in FIGS. **10-11**). Soft tip **1320** also includes curved outer surface **1344** that forms a second side of soft tip **1340**. Curved outer surface **1344** is a smooth surface that is configured to slide along a blood vessel wall without puncturing, tearing, or otherwise damaging the blood vessel wall.

[0090] Wavy release wire **1302** has a rounded tip at distal end **1302**B of wavy release wire **1302**. The rounded tip at distal end **1302**B of wavy release wire **1302** prevents distal end **1302**B from puncturing, tearing, or otherwise damaging vessel walls or other tissue when actuation arm **1300** is used to deploy an arm of a shunt device onto a tissue wall. Further, distal end **1302**B of wavy release wire **1302** is configured to rest in trough **1342** of soft tip **1320**. Trough **1342** provides a channel in which distal end **1302**B of wavy release wire **1302** can be positioned to further prevent distal end **1302**B of wavy release wire **1302** from puncturing, tearing, or otherwise damaging vessel walls or other tissue. When distal end **1302**B of wavy release wire **1302** is positioned in trough **1342**, it will not come into contact with vessel walls or other tissue. Soft tip **1320** also has a slight curve in a distal portion of body **1340**. If distal end **1302**B of wavy release wire **1302** were to be moved distally, distal end **1302**B would advance into body **1340**. This further prevents distal end **1302**B of wavy release wire **1302** from touching vessel walls or other tissue.

[0091] Referring generally to FIGS. **10-12**, wavy release wire **1302** creates a friction fit within actuation arm **1300**, which prevents wavy release wire **1302** from inadvertently being withdrawn from an arm of a shunt device during manufacturing, shipping, or deployment of a delivery device including actuation arm **1300** and wavy release wire **1302**. Wavy release wire **1302** extends through the delivery device. Proximal end **1302**A of wavy release wire **1302** will extend to or through a proximal end of the delivery device. This allows proximal end **1302**A of wavy release wire **1302** to be grasped by a physician or other user, either directly or through a knob or other suitable mechanism. Distal straight end **1334** of wavy release wire **1302** will extend through an arm of a shunt device to hold the shunt device in position on the delivery device. Actuation arm **1300** can be actuated distally to move and seat the arm of the shunt device on the tissue wall in which the shunt device is being implanted. Once the arm of the shunt device is seated on the tissue wall, wavy release wire **1302** can be withdrawn to release the arm of the shunt device from actuation arm **1300** and the delivery device generally. Wavy release wire **1302** can be withdrawn a preset distance to release the arm of the shunt device but need not be fully withdrawn from the delivery device.

[0092] Previous versions of a release wire included a loop at a distal end of the release wire to prevent accidental release of the shunt device from the delivery device during manufacturing, shipment, and deployment of the shunt device into the body. The loop also formed an atraumatic tip so that the release wire did not puncture or tear through vessel or tissue walls in the body. However, the loop on the end of the release wire can get caught on an outer sheath of the delivery device as the outer sheath is pulled over the shunt device to sheath the shunt device for delivery into the body, which can damage the sheath and/or other components of the delivery device or shunt device. Further, the loop on the end of the release wire can get entangled on the shunt device and/or the delivery device as the release wire is withdrawn during deployment of the shunt device, resulting in high pull forces being needed to withdraw the release wire from the shunt device.

[0093] Wavy release wire **1302** requires a lower pull force to withdraw it from actuation arm **1300**. When a physician or other user pulls on wavy release wire **1302** to withdraw it form the arm of the shunt device, the physician or user will be pulling against the friction force created between the waves in wavy portion **1332** of wavy release wire **1302** and the inner surface of tube **1310** of actuation arm **1300**. The number of waves in wavy release wire **1302** can affect the pull force needed to remove wavy release wire **1302** from actuation arm **1300**.

[0094] 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.).

[0095] 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

[0096] The following are non-exclusive descriptions of possible examples of the present invention.

[0097] A delivery device for implanting a shunt device in a tissue wall includes an actuation arm extending through the delivery device, the actuation arm configured to seat an arm of the shunt device on the tissue wall, and a wavy release wire extending through the actuation arm. The wavy release wire includes a wavy portion that forms a friction fit with the actuation arm, and the wavy portion has a height between a peak and a valley of a wave. The wavy release wire is configured to be retractable from the delivery device to release the arm of the shunt device from the actuation arm.

[0098] The delivery device of the preceding paragraph can optionally include, additionally and/or alternatively, any one or more of the following features, configurations, and/or additional components:

[0099] The wavy portion of the wavy release wire can include four waves.

[0100] The actuation arm can further include a tube with a proximal end at a proximal end of the actuation arm, a collar coupled to the tube, and a soft tip coupled to the collar and having a distal end at a distal end of the actuation arm; and a lumen can extend through the tube and the collar.

[0101] The wavy release wire can extend through the lumen extending through the tube and the collar and into the soft tip.

[0102] A distal end of the wavy release wire can be positioned in the soft tip.

[0103] The soft tip can further include a body and a trough extending into a first side of the body.

[0104] The distal end of the wavy release wire can be positioned in the trough of the soft tip.

[0105] The soft tip can further include a curved outer surface on a second side of the soft tip, and the curved outer surface can be configured to slide along a vessel wall.

[0106] The wavy portion of the wavy release wire can extend through the lumen extending through the tube of the actuation arm and form the friction fit with the tube.

[0107] The height can be greater than an inner diameter of the lumen of the tube.

[0108] The height can be between 0.022 inches (0.0559 centimeters) and 0.028 inches (0.0711 centimeters).

[0109] The height can be 0.025 inches (0.0635 centimeters).
[0110] The wavy release wire can further include a proximal straight portion with a proximal end at a proximal end of the wavy release wire and a distal straight portion with a distal end at a distal end of the wavy release wire, and the wavy portion can extend between the proximal straight portion and the distal straight portion.
[0111] The proximal straight portion and the wavy portion of the wavy release wire can be positioned in the tube of the actuation arm.
[0112] The distal straight portion of the wavy release wire can be positioned partially in the tube, in the collar, and in the soft tip of the actuation arm.
[0113] A length of the proximal straight portion of the wavy release wire can be greater than a length of the wavy portion and a length of the distal straight portion.
[0114] A length of the distal straight portion can be greater than a length of the wavy portion.
[0115] The proximal straight portion can have a length between 56.7 inches (144.018 centimeters) and 57.1 inches (145.034 centimeters).
[0116] The wavy portion can have a length between 0.4 inches (1.016 centimeters) and 0.8 inches (2.032 centimeters).
[0117] The distal straight portion can have a length between 1.3 inches (3.302 centimeters) and 1.7 inches (4.318 centimeters).
[0118] The wavy release wire can be made out of nitinol.
[0119] The wavy release wire can have a diameter between 0.0086 inches (0.0218 centimeters) and 0.0094 inches (0.0239 centimeters).
[0120] The wavy release wire can have a diameter of 0.0090 inches (0.0229 centimeters).
[0121] 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. A delivery device for implanting a shunt device in a tissue wall, the delivery device comprising: an actuation arm extending through the delivery device, the actuation arm configured to seat an arm of the shunt device on the tissue wall; and a wavy release wire extending through the actuation arm, wherein the wavy release wire includes a wavy portion that forms a friction fit with the actuation arm, wherein the wavy portion has a height between a peak and a valley of a wave, and wherein the wavy release wire is configured to be retractable from the delivery device to release the arm of the shunt device from the actuation arm.
2. The delivery device of claim 1, wherein the wavy portion of the wavy release wire includes four waves.
3. The delivery device of claim 1, wherein the actuation arm further comprises: a tube with a proximal end at a proximal end of the actuation arm; a collar coupled to the tube; and a soft tip coupled to the collar and having a distal end at a distal end of the actuation arm; wherein a lumen extends through the tube and the collar; wherein the wavy release wire extends through the lumen extending through the tube and the collar and into the soft tip; and wherein a distal end of the wavy release wire is positioned in the soft tip.
4. The delivery device of claim 3, wherein the soft tip further comprises: a body; and a trough extending into a first side of the body; and wherein the distal end of the wavy release wire is positioned in the trough of the soft tip.

5. The delivery device of claim 4, wherein the soft tip further comprises: a curved outer surface on a second side of the soft tip, wherein the curved outer surface is configured to slide along a vessel wall.
6. The delivery device of claim 3, wherein the wavy portion of the wavy release wire extends through the lumen extending through the tube of the actuation arm and forms the friction fit with the tube, and wherein the height is greater than an inner diameter of the lumen of the tube.
7. The delivery device of claim 6, wherein the height is between 0.022 inches (0.0559 centimeters) and 0.028 inches (0.0711 centimeters).
8. The delivery device of claim 6, wherein the height is 0.025 inches (0.0635 centimeters).
9. A delivery device for implanting a shunt device in a tissue wall, the delivery device comprising: an actuation arm extending through the delivery device, the actuation arm configured to seat an arm of the shunt device on the tissue wall; and a wavy release wire extending through the actuation arm, wherein the wavy release wire includes a wavy portion that forms a friction fit with the actuation arm, and wherein the wavy portion includes a number of repeating waves extending along a length of the wavy portion, each wave of the repeating waves having a peak and a valley.
10. The delivery device of claim 9, wherein the wavy release wire further comprises: a proximal straight portion with a proximal end at a proximal end of the wavy release wire; and a distal straight portion with a distal end at a distal end of the wavy release wire; wherein the wavy portion extends between the proximal straight portion and the distal straight portion.
11. The delivery device of claim 10, wherein the actuation arm further comprises: a tube with a proximal end at a proximal end of the actuation arm; a collar coupled to the tube; and a soft tip coupled to the collar and having a distal end at a distal end of the actuation arm; wherein a lumen extends through the tube and the collar; wherein the wavy release wire extends through the lumen extending through the tube and the collar and into the soft tip; and wherein a distal end of the wavy release wire is positioned in the soft tip.
12. The delivery device of claim 11, wherein the proximal straight portion and the wavy portion of the wavy release wire are positioned in the tube of the actuation arm.
13. The delivery device of claim 11, wherein the distal straight portion of the wavy release wire is positioned partially in the tube, in the collar, and in the soft tip of the actuation arm.
14. The delivery device of claim 10, wherein a length of the proximal straight portion of the wavy release wire is greater than a length of the wavy portion and a length of the distal straight portion, and wherein the length of the distal straight portion is greater than the length of the wavy portion.
15. The delivery device of claim 10, wherein the wavy portion has a length between 0.4 inches (1.016 centimeters) and 0.8 inches (2.032 centimeters).
16. The delivery device of claim 10, wherein the distal straight portion has a length between 1.3 inches (3.302 centimeters) and 1.7 inches (4.318 centimeters).
17. A delivery device for implanting a medical device in a patient, the delivery device comprising: an actuation arm adapted to hold a portion of the medical device; and a wavy release wire extending through at least a portion of the actuation arm, wherein the wavy release wire includes a wavy portion that forms a friction fit with the actuation arm, and wherein the wavy portion comprises a number of repeating waves extending along a length of the wavy portion, each wave of the repeating waves having a peak and a valley.
18. The delivery device of claim 17, wherein the wavy release wire is made of nitinol.
19. The delivery device of claim 17, wherein the wavy release wire has a diameter between 0.0086 inches (0.0218 centimeters) and 0.0094 inches (0.0239 centimeters).
20. The delivery device of claim 17, wherein the wavy release wire has a diameter of 0.0090 inches (0.0229 centimeters).