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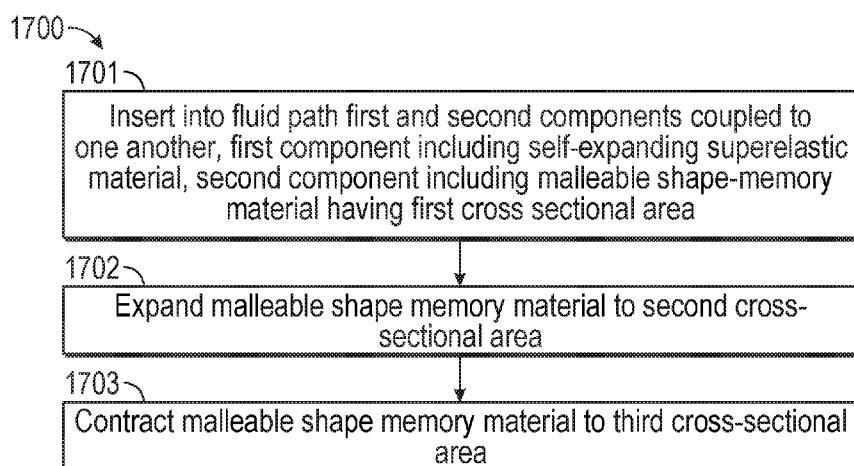


FIG. 17

(57) Abstract: Devices are provided with an internal dimension that can be reduced and increased in vivo. In one example, an interatrial shunt for placement at an atrial septum of a patient's heart includes a body. The body includes first and second regions coupled in fluid communication by a neck region. The body includes a shape-memory material. The body defines a passageway through the neck region for blood to flow between a first atrium and a second atrium. The first and second regions are superelastic at body temperature, and the neck region is malleable at body temperature. A flow area of the passageway through the neck region may be adjusted in vivo.



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DEVICES WITH DIMENSIONS THAT CAN BE REDUCED AND INCREASED IN VIVO

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of, and is a continuation-in-part of, U.S. Patent application No. 17/092,081, filed November 6, 2020 and entitled “Devices With Dimensions That Can Be Reduced And Increased *In Vivo*, And Methods Of Making And Using The Same,” which claims the benefit of, and is a continuation of, U.S. Patent Application No. 16/875,652, filed May 15, 2020 and entitled “Devices With Dimensions That Can Be Reduced And Increased *In Vivo*, And Methods Of Making And Using The Same,” which claims the benefit of U.S. Provisional Patent Application No. 63/019,777, filed May 4, 2020 and entitled “Devices With Dimensions That Can Be Reduced And Increased *In Vivo*, And Methods Of Making And Using The Same,” the entire contents of each of which are incorporated by reference herein.

FIELD OF THE INVENTION

[0002] This application generally relates to devices for use in the human body, such as percutaneously implanted devices and methods for adjusting the flow of fluid, such as blood, within the human body.

BACKGROUND

[0003] For a number of medical conditions, there is benefit in adjusting the flow of fluid within the human body, for example, through a passage between two body cavities. Such a passage is typically used in catheterization procedures where the catheter is delivered through a patient’s vasculature. In some catheterization procedures, there is a benefit in moving from one cavity to another cavity by creating a passage. For example, such a passage may be formed between the right side of the heart and the left side of the heart, e.g., between the right atrium toward the left atrium, where clinical procedures are done on the left side of the heart using an entry from the

right side of the heart. Such clinical procedures include, e.g., arrhythmia ablation procedures in the left atrium and mitral valve repair activities.

[0004] In addition, a passage may be created and maintained in a heart wall between two heart chambers for housing a shunt for redistributing blood from one heart chamber to another to address pathologies such as heart failure (HF), myocardial infarction (MI), and pulmonary arterial hypertension (PAH). HF is the physiological state in which cardiac output is insufficient to meet the needs of the body or to do so only at a higher filling pressure. There are many underlying causes of HF, including MI, coronary artery disease, valvular disease, hypertension (such as PAH), and myocarditis. Chronic heart failure is associated with neurohormonal activation and alterations in autonomic control. Although these compensatory neurohormonal mechanisms provide valuable support for the heart under normal physiological circumstances, they also play a fundamental role in the development and subsequent progression of HF.

[0005] HF is generally classified as either systolic heart failure (“SHF”) or diastolic heart failure (“DHF”). In SHF, the pumping action of the heart is reduced or weakened. A common clinical measurement is the ejection fraction, which is a function of the blood ejected out of the left ventricle (stroke volume) divided by the maximum volume in the left ventricle at the end of diastole or relaxation phase. A normal ejection fraction is greater than 50%. Systolic heart failure generally causes a decreased ejection fraction of less than 40%. Such patients have heart failure with reduced ejection fraction (“HFrEF”). A patient with HFrEF may usually have a larger left ventricle because of a phenomenon called “cardiac remodeling” that occurs secondarily to the higher ventricular pressures.

[0006] In DHF, the heart generally contracts well, with a normal ejection fraction, but is stiffer, or less compliant, than a healthy heart would be when relaxing and filling with blood. Such patients are said to have heart failure with preserved ejection fraction (“HFpEF”). This stiffness may impede blood from filling the heart and produce backup into the lungs, which may result in pulmonary venous hypertension and lung edema. HFpEF is more common in patients older than 75 years, especially in women with high blood pressure.

[0007] Both variants of HF have been treated using pharmacological approaches, which typically involve the use of vasodilators for reducing the workload of the heart by reducing systemic vascular resistance, as well as diuretics, which inhibit fluid accumulation and edema formation, and reduce cardiac filling pressure. No pharmacological therapies have been shown to improve morbidity or mortality in HFpEF whereas several classes of drugs have made an important impact on the management of patients with HFrEF, including renin-angiotensin antagonists, neprilysin inhibitors, beta blockers, mineralocorticoid antagonists and sodium-glucose co-transporter-2 (SGLT2) inhibitors. Nonetheless, in general, HF remains a progressive disease and most patients have deteriorating cardiac function and symptoms over time. In the U.S., there are over 1 million hospitalizations annually for acutely worsening HF and mortality is higher than for most forms of cancer.

[0008] In more severe cases of HFrEF, mechanical circulatory support (MCS) devices such as mechanical pumps are used to reduce the load on the heart by performing all or part of the pumping function normally done by the heart. Chronic left ventricular assist devices (“LVAD”), the total artificial heart, and cardiac transplantation are used as measures of last resort. However, such assist devices typically are intended to improve the pumping capacity of the heart, to increase cardiac output to levels compatible with normal life, and to sustain the patient until a donor heart for transplantation becomes available. This usage of MCS is also known as “bridge to transplant” therapy”. As the supply of donor hearts for transplantation is insufficient for the demand, more often MCS is the only therapeutic option – also known as “destination therapy.” Such mechanical devices enable propulsion of significant volumes of blood (liters/min) but are limited by a need for a power supply, relatively large pumps, and pose a risk of hemolysis, thrombus formation, and infection. Temporary assist devices, intra-aortic balloons, and pacing devices have also been used.

[0009] Various devices have been developed using stents to modify blood pressure and flow within a given vessel, or between chambers of the heart. For example, U.S. Patent No. 6,120,534 to Ruiz is directed to an endoluminal stent for regulating the flow of fluids through a body vessel or organ, for example, for regulating blood flow through the pulmonary artery to treat congenital heart defects. The stent may include an expandable mesh having balloon-expandable lobed or

conical portions joined by a shape-memory constricted region, which limits flow through the stent. The constricted region may be adjusted *in vivo*, and in addition may be heated to recover a maximum degree of constriction. Ruiz is silent on the treatment of HF or the reduction of left atrial pressure.

[0010] U.S. Patent Publication No. 2013/0178784 to McNamara describes an adjustable pressure relief shunt that may be expanded, e.g., via an inflation balloon. A tubular body of the shunt may be plastically deformed *in vivo*, such that the size of the shunt may be repeatedly adjusted by a variety of mechanisms, for example, elastically wound springs or a series of pawls and one-way mechanical ramps, responsive to measurements of the patient's physiological parameters. A key drawback to the approach described in that patent is the hysteresis effect, i.e., non-reversible changes in the underlying crystalline structure that occur when the shunt is permanently deformed. Importantly, such plastic deformation may lead to stress and fatigue-related fracture of the device.

[0011] U.S. Patent No. 6,468,303 to Amplatz et al. describes a collapsible medical device and associated method for shunting selected organs and vessels. Amplatz describes that the device may be suitable to shunt a septal defect of a patient's heart, for example, by creating a shunt in the atrial septum of a neonate with hypoplastic left heart syndrome ("HLHS"). That patent also describes that increasing mixing of pulmonary and systemic venous blood improves oxygen saturation, and that the shunt may later be closed with an occluding device. Amplatz is silent on the treatment of HF or the reduction of left atrial pressure, as well as on means for regulating the rate of blood flow through the device.

[0012] Implantable interatrial shunt devices have been successfully used in patients with severe symptomatic heart failure. By diverting or shunting blood from the left atrium ("LA") to the right atrium ("RA"), the pressure in the left atrium is lowered or prevented from elevating as high as it would otherwise (left atrial decompression). Such an accomplishment would be expected to prevent, relieve, or limit the symptoms, signs, and syndromes associated of pulmonary congestion. These include severe shortness of breath, pulmonary edema, hypoxia, the need for acute hospitalization, mechanical ventilation, and death.

[0013] Shunt flow is generally governed by the pressure gradient between the atria and the fluid mechanical properties of the shunt device. The latter are typically affected by the shunt's geometry and material composition. For example, the general flow properties of similar shunt designs have been shown to be related to the mean interatrial pressure gradient and the effective orifice diameter.

[0014] Percutaneous implantation of interatrial shunts generally requires transseptal catheterization immediately preceding shunt device insertion. The transseptal catheterization system is generally placed from an entrance site in the femoral vein, across the interatrial septum in the region of fossa ovalis ("FO"), which is the central and thinnest region of the interatrial septum. The FO in adults is typically 15-20 mm in its major axis dimension and <3 mm in thickness, but in certain circumstances may be up to 10 mm thick. LA chamber access may be achieved using a host of different techniques familiar to those skilled in the art, including but not limited to: needle puncture, stylet puncture, screw needle puncture, and radiofrequency ablation. The passageway between the two atria is dilated to facilitate passage of a shunt device having a desired orifice size. Dilation generally is accomplished by advancing a tapered sheath/dilator catheter system or inflation of an angioplasty type balloon across the FO. This is the same general location where a congenital secundum atrial septal defect ("ASD") would be located.

[0015] U.S. Patent Publication No. 2005/0165344 to Dobak, III describes apparatus for treating heart failure that includes a tubular conduit having an emboli filter or valve, the device configured to be positioned in an opening in the atrial septum of the heart to allow flow from the left atrium into the right atrium. Dobak discloses that shunting of blood may reduce left atrial pressures, thereby preventing pulmonary edema and progressive left ventricular dysfunction, and reducing LVEDP. Dobak describes that the device may include deployable retention struts, such as metallic arms that exert a slight force on the atrial septum on both sides and pinch or clamp the device to the septum.

[0016] In addition, following implantation of a shunt device within a heart wall, tissue ingrowth including an endothelial layer or neointima layer typically forms on the device, thereby

inhibiting thrombogenicity of the shunt device, and narrowing the size of the passage through the device.

SUMMARY OF THE INVENTION

[0017] The present invention overcomes the drawbacks of previously-known systems and methods by providing devices with dimensions that not only may be increased, but also may be reduced *in vivo*, and methods of making and using the same.

[0018] In particular, the present invention overcomes the limitations of previously known devices and methods by providing an implantable device with a composite structure exhibiting both superelastic and shape-memory properties at body temperature. Dimensions that may affect blood flow or other intended interactions between the implanted device and its biological host can be repeatedly altered in either direction by mechanical deformation of one crystalline phase of the shape-memory component in one direction and reversing the direction by temperature induction of a crystalline phase change of the shape-memory component material to its original dimension, greatly simplifying catheter related manipulations.

[0019] Under one aspect, an interatrial shunt for placement at an atrial septum of a patient's heart. The interatrial shunt may include a body comprising first and second regions coupled in fluid communication by a neck region. The body may include a shape-memory material. The body may define a passageway through the neck region for blood to flow between a first atrium and a second atrium. The first and second regions may be superelastic at body temperature, and the neck region may be malleable at body temperature and may include NITINOL having an austenitic finish temperature (A_f) between 45-60°C. A flow area of the passageway through the neck region may be adjusted *in vivo*.

[0020] In some examples, the first and second regions that are superelastic comprise NITINOL having an austenitic finish temperature (A_f) between 5-20°C. In some examples, the neck region is mechanically expandable. In some examples, the neck region is thermally contractible.

[0021] Under another aspect, an interatrial shunt is provided for placement at an atrial septum of a patient's heart for adjustably regulating fluid flow therethrough. The interatrial shunt may

include a first expandable end region configured to be placed in a first atrium of the heart. The interatrial shunt may include a second expandable end region configured to be placed in a second atrium of the heart. The first and second expandable end regions may include self-expanding superelastic material. The interatrial shunt may include a neck region between the first and second expandable end regions configured for placement at the atrial septum. The neck region may include malleable shape-memory material. The interatrial shunt may define a passageway through the neck region for blood to flow between the first atrium and the second atrium. The neck region may be heat treated to exhibit different shape memory properties than the first and second expandable end regions such that a cross-sectional area of the passageway is adjustable *in vivo*.

[0022] In some examples, the malleable shape-memory material is configured to be expanded *in vivo* such that the passageway expands from the cross-sectional area to a second cross-sectional area larger than the cross-sectional area. In some examples, the malleable shape-memory material is configured to be contracted *in vivo* such that the passageway contracts from the second cross-sectional area to a third cross-sectional area smaller than the second cross-sectional area. In some examples, the cross-sectional area is between 4.9 to 28.3 mm² and the second cross-sectional area and the third cross-sectional area are between 15.9 to 78.6 mm². In some examples, the malleable shape-memory material comprises NITINOL having an austenitic finish temperature (Af) between 45-60°C. In some examples, the self-expanding superelastic material comprises NITINOL having an austenitic finish temperature (Af) between 5-20°C. In some examples, the malleable shape-memory material is mechanically expandable. In some examples, the malleable shape-memory material is thermally contractible. In some examples, the cross-sectional area of the neck region is smaller than respective cross-sectional areas of at least one of the first and second expandable end regions. In some examples, the first and second expandable end regions extend into the first and second atria, respectively, such that respective ends of the first and second expandable end regions do not contact the atrial septum.

[0023] In some examples, the first and second expandable end regions and the neck region comprise a diabolo-shaped shunt. In some examples, the neck region comprises a cylindrical shunt. In some examples, the cylindrical shunt is outside of the diabolo-shaped shunt. In some

examples, the cylindrical shunt is formed of the malleable shape-memory material such that the cylindrical shunt radially constrains a dimension of the diabolo-shaped shunt at the neck region, and the diabolo-shaped shunt self-expands at the neck region responsive to the malleable shape memory material expanding to a second cross-sectional area. In some examples, the cylindrical shunt is inside of the diabolo-shaped shunt. In some examples, the cylindrical shunt is not directly coupled to the diabolo-shaped shunt and the neck region, and the interatrial shunt further includes an encapsulant indirectly and elastically coupling the cylindrical shunt to the diabolo-shaped shunt. In some examples, contraction of the cylindrical shunt does not cause contraction of the diabolo-shaped shunt at the neck region. In some examples, the diabolo-shaped shunt and the cylindrical shunt are integrally formed from a common frame.

[0024] In some examples, the first and second expandable end regions and the neck region are integrally formed from a common frame. In some examples, the first and second expandable end regions and the neck region are at least partially encapsulated with a biocompatible material.

[0025] Under another aspect, an interatrial shunt is provided for adjustably regulating fluid flow in a heart having a first atrium, a second atrium, and an atrial septum. The interatrial shunt may include a first region comprising a self-expanding superelastic material configured to be placed in the first atrium, the first region being superelastic at body temperature. The interatrial shunt may include a second region comprising a malleable shape-memory material configured to be placed through an opening in the atrial septum so as to provide fluid flow from the first atrium to the second atrium. The second region may be malleable at body temperature. The malleable shape-memory material may have a first cross-sectional area. The malleable shape-memory material may be expandable from the first cross-sectional area to a second cross-sectional area. The malleable shape-memory material may be contractible from the second cross-sectional area to a third cross-sectional area.

[0026] In some examples, the self-expanding superelastic material comprises NITINOL having an austenitic finish temperature (A_f) between 5-20°C and the malleable shape-memory material comprises NITINOL having an austenitic finish temperature (A_f) between 45-60°C. In some examples, the malleable shape-memory material is mechanically expandable and thermally

contractible. In some examples, the interatrial shunt further includes a third region comprising a second self-expanding superelastic material, configured to be placed in the second atrium, and coupled to the second region.

[0027] Under another aspect, a device is provided for adjustably regulating fluid flow therethrough *in vivo*. The device may include a first component comprising a first self-expanding superelastic material. The device may include a second component coupled to the first component and comprising a first malleable shape-memory material. The first malleable shape-memory material may have a first cross sectional area. The first malleable shape-memory material may be expandable *in vivo* to a second cross sectional area. The first malleable shape-memory material may be contractible *in vivo* to a third cross sectional area.

[0028] In some examples, the first self-expanding superelastic material comprises NITINOL having an austenitic finish temperature (A_f) of less than 37°C. In some examples, the A_f of the NITINOL of the first self-expanding superelastic material is between 5-20°C. In some examples, the first malleable shape-memory material comprises NITINOL having an austenitic finish temperature (A_f) of greater than 37°C. In some examples, the A_f of the NITINOL of the malleable shape-memory material is between 45-60°C. In some examples, the first malleable shape-memory material is mechanically expandable. In some examples, the first malleable shape-memory material is thermally contractible. In some examples, the first malleable shape-memory material is joined to the first self-expanding superelastic material by welding.

[0029] In some examples, the device includes a plurality of shaped wires, at least one of the wires comprising the first malleable shape-memory material, at least one of the wires comprising the first self-expanding superelastic material. In some examples, at least one of the wires comprises both the first malleable shape-memory material and the first self-expanding superelastic material. In some examples, each of the wires comprises both the first malleable shape-memory material and the first self-expanding superelastic material. In some examples, each of the shaped wires comprises a first end and a second end, wherein the first and second ends are coupled to each other using overlapping, welding, or a swaged tube. In some examples,

the wires are coupled to one another using winding or sleeves. In some examples, at least one of the sleeves is radiopaque. In some examples, each of the sleeves is radiopaque. In some examples, at least one of the wires comprises a radiopaque material. In some examples, an inner core of the wire comprises the radiopaque material. In some examples, an overlay of the wire comprises the first malleable shape-memory material or the first self-expanding superelastic material. In some examples, strands of the wire comprise the first malleable shape-memory material or the first self-expanding superelastic material. In some examples, an overlay of the wire comprises the radiopaque material. In some examples, an inner core of the wire comprises the first malleable shape-memory material or the first self-expanding superelastic material. In some examples, the device further includes an encapsulant covering at least a portion of at least one of the first component and the second component. In some examples, the encapsulant joins the first malleable shape-memory material to the first self-expanding superelastic material.

[0030] In some examples, in the first cross sectional area is smaller than the third cross sectional area. In some examples, the first cross sectional area is larger than the third cross sectional area. In some examples, the device further includes a third component comprising a second self-expanding superelastic material and coupled to the first component and the second component. In some examples, the first component comprises an inlet, the second component comprises a neck, and the third component comprises an outlet fluidically coupled to the inlet via the neck. In some examples, the cross sectional area of the neck is smaller than respective cross sectional areas of at least one of the inlet and the outlet. In some examples, the inlet and outlet anchor the device within an opening through a septum between two chambers within the body, and the neck provides a channel for flow between these chambers. In some examples, the cross sectional area of the neck is larger than respective cross sectional areas of at least one of the inlet and the outlet. In some examples, the second component is configured to engage an opening in the human body. In some examples, the opening is created through a fossa ovalis of an interatrial septum between a right atrium and a left atrium. The neck may be configured to engage the opening. The inlet may be configured to extend into the right atrium. The outlet may be configured to extend into the left atrium. In some examples, the inlet and outlet comprise flanges; the neck comprises flexible longitudinal bars and a sinusoidal ring; the flexible longitudinal bars allow the flanges to

fully expand upon deployment; and the sinusoidal ring has sufficient strength to maintain its diameter when balloon dilated or heat contracted.

[0031] In some examples, the first component is configured to engage a lumen in the human body. In some examples, the lumen comprises a blood vessel, and the first and third components are configured to engage the blood vessel. In some examples, the neck is configured to be disposed adjacent to an ostium of the blood vessel.

[0032] In some examples, the device further includes a third component comprising a second malleable shape-memory material and coupled to the first component and the second component. The second malleable shape-memory material may have a fourth cross sectional area permitting a fourth rate of fluid flow therethrough. The second malleable shape-memory material may be expandable *in vivo* to a fifth cross sectional area permitting a fifth rate of fluid flow therethrough. The second malleable shape-memory material may be contractible *in vivo* to a sixth cross sectional area permitting a sixth rate of fluid flow therethrough. In some examples, the second component comprises an inlet and the third component comprises an outlet fluidically coupled to the inlet via the first component. In some examples, the inlet is configured to engage a blood vessel in the human body, the first component is configured to engage the blood vessel, the outlet is configured to extend into an ostium of the blood vessel. In some examples, the device includes a valve disposed in the second component. The first component may be configured to engage a blood vessel in the human body, and the second component may extend into the blood vessel. In some examples, the second component is located inside of the first component.

[0033] In some examples, the first component comprises a diabolo-shaped shunt having a neck, and the second component comprises a structural member surrounding the neck. In some examples, the structural member comprises a cylindrical shunt. In some examples, the structural member comprises a compression coil. In some examples, a number of times by which the compression coil wraps around the neck varies based on cross sectional area of the neck. In some examples, the compression coil is substantially cylindrical. In some examples, the structural member comprises a compression spring. In some examples, a number of times by which the compression spring wraps around the neck varies based on cross sectional area of the

neck. In some examples, the compression spring is diabolo-shaped. In some examples, the device further includes hooks coupling the compression spring to the shunt. In some examples, the structural member is outside of the diabolo-shaped shunt. In some examples, the first malleable shape-memory material radially constrains a dimension of the neck. In some examples, the first malleable shape-memory material radially contacts an outer surface of the neck so as to constrain the neck from self-expanding to a larger dimension. In some examples, the neck self-expands responsive to the first malleable shape memory material expanding to the second cross sectional area. In some examples, the structural member exerts a force on the neck that varies based on cross-sectional area of the neck. In some examples, the device includes an encapsulant forming an inner lumen through the first component. In some examples, the encapsulant further forms an outer covering of the first component. In some examples, the encapsulant further forms an outer covering of the second component. In some examples, the cylindrical shunt is inside of the diabolo-shaped shunt. In some examples, the cylindrical shunt is not directly coupled to the neck of the diabolo-shaped shunt, and the device includes an encapsulant indirectly and elastically coupling the cylindrical shunt to the diabolo-shaped shunt. In some examples, contraction of the cylindrical shunt does not cause contraction of the neck of the diabolo-shaped shunt. In some examples, the neck of the diabolo-shaped shunt is self-expandable to a fourth cross sectional area. In some examples, contraction of the cylindrical shunt to the third cross sectional area does not change the cross sectional area of the neck.

[0034] In some examples, the second component is located inside of the first component. In some examples, the first malleable shape-memory material radially constrains a dimension of the first component. In some examples, the first malleable shape-memory material radially contacts an inner surface of the first component so as to constrain the first component from contracting to a smaller dimension. In some examples, the first component self-contracts responsive to the first malleable shape memory material contracting to the third cross sectional area. In some examples, the device includes an encapsulant forming an outer covering of the first component and the second component. In some examples, the first component and the second component are integrally formed from a common frame with one another. In some examples, the common frame is substantially cylindrical. In some examples, the common frame

further comprises a third component comprising the first self-expanding superelastic material. The second component may form a central portion of the common frame. The first and third components may form portions of the common frame configured to extend into respective atria of the heart. In some examples, the second component comprises a groove configured to engage an aperture through the atrial septum. In some examples, the first and third components are flared.

[0035] In some examples, the fluid is blood.

[0036] Under another aspect, a method of retrieving a device from an atrial septum of a heart is provided. The method may include disposing a retrieval catheter through the device, the retrieval catheter having disposed therein a tip and a cup. The method may include, while the tip remains in the left atrium of the heart, retracting the cup to the right atrium of the heart, leaving a space between the tip and the cup that coincides with the position of the device. The method may include heating the device to cause the device to contract to a heat set configuration. The method may include retracting the tip to pull the contracted device into the cup. The method may include retrieving the retrieval catheter, with the contracted device at least partially within each of the tip and the cup, from the heart.

[0037] Under another aspect, a method of preparing a device is provided. The method may include using localized heat-treating of one or more portions of each such device to produce a different austenitic finish (Af) temperature from un-heated portion(s) of the device. In some examples, the localized heating of the one or more portions of the device is performed using induction heating, optionally with active cooling of adjacent areas. In some examples, the localized heating of the one or more portions of the device is performed using localized laser heating, optionally with active cooling of adjacent areas.

[0038] Under another aspect, a method of preparing a device is provided. The method may include providing wires having different austenitic finish (Af) temperatures than one another and/or wires having different Af temperatures along the length of the wire. The method may include using the wires to manufacture the device such that the device has multiple Af temperatures.

[0039] In some examples, the different Af temperatures correspond to different phases of NITINOL. In some examples, using the wires to manufacture the device comprises using wire-wrap techniques, wire-mesh techniques, or any suitable combination thereof.

[0040] Under another aspect, an interatrial shunt for placement at an atrial septum of a patient's heart is provided herein. The interatrial shunt includes a body that includes first and second regions coupled in fluid communication by a neck region. The body includes a shape-memory material. The body defines a passageway through the neck region for blood to flow between a first atrium and a second atrium. The first and second regions are superelastic at body temperature, and the neck region is malleable at body temperature. A flow area of the passageway through the neck region may be adjusted *in vivo*.

[0041] The first and second regions that are superelastic may include NITINOL having an austenitic finish temperature (Af) between 5-20°C. The neck region that is malleable may include NITINOL having an austenitic finish temperature (Af) between 45-60°C. The neck region may be mechanically expandable. The neck region may be thermally contractible.

[0042] Under another aspect, an interatrial shunt is provided for placement at an atrial septum of a patient's heart for adjustably regulating fluid flow therethrough. The interatrial shunt may include a first expandable end region configured to be placed in a first atrium of the heart, and a second expandable end region configured to be placed in a second atrium of the heart. The first and second expandable end regions may include self-expanding superelastic material. The interatrial shunt may include a neck region between the first and second expandable end regions. The neck region may be configured for placement at the atrial septum. The neck region may include malleable shape-memory material. The interatrial shunt may define a passageway through the neck region for blood to flow between the first atrium and the second atrium. The neck region may be heat treated to exhibit different shape memory properties than the first and second expandable end regions such that a cross-sectional area of the passageway is adjustable *in vivo*.

[0043] The malleable shape-memory material may be configured to be expanded *in vivo* such that the passageway expands from the cross-sectional area to a second cross-sectional area larger

than the cross-sectional area. The malleable shape-memory material may be configured to be contracted *in vivo* such that the passageway contracts from the second cross-sectional area to a third cross-sectional area smaller than the second cross-sectional area. The cross-sectional area may be between 4.9 to 28.3 mm² and the second cross-sectional area and the third cross-sectional area may be between 15.9 to 78.6 mm². The malleable shape-memory material may include NITINOL having an austenitic finish temperature (Af) between 45-60°C. The self-expanding superelastic material may include NITINOL having an austenitic finish temperature (Af) between 5-20°C. The malleable shape-memory material may be mechanically expandable. The malleable shape-memory material may be thermally contractible. The cross-sectional area of the neck region may be smaller than respective cross-sectional areas of at least one of the first and second expandable end regions. The first and second expandable end regions may extend into the first and second atria, respectively, such that respective ends of the first and second expandable end regions may not contact the atrial septum. The first and second expandable end regions and the neck region may comprise a diabolo-shaped shunt. The neck region may include a cylindrical shunt. The cylindrical shunt may be outside of the diabolo-shaped shunt. The cylindrical shunt may be formed of the malleable shape-memory material such that the cylindrical shunt radially constrains a dimension of the diabolo-shaped shunt at the neck region, and the diabolo-shaped shunt may self-expand at the neck region responsive to the malleable shape memory material expanding to a second cross-sectional area. The cylindrical shunt may be inside of the diabolo-shaped shunt. The cylindrical shunt may not be directly coupled to the diabolo-shaped shunt and the neck region. The device may further include an encapsulant indirectly and elastically coupling the cylindrical shunt to the diabolo-shaped shunt. Contraction of the cylindrical shunt may not cause contraction of the diabolo-shaped shunt at the neck region. The diabolo-shaped shunt and the cylindrical shunt may be integrally formed from a common frame. The first and second expandable end regions and the neck region may be integrally formed from a common frame. The first and second expandable end regions and the neck region may be at least partially encapsulated with a biocompatible material.

[0044] Under another aspect, an interatrial shunt for adjustably regulating fluid flow in a heart having a first atrium, a second atrium, and an atrial septum is provided. The interatrial shunt

may include a first region that includes a self-expanding superelastic material configured to be placed in the first atrium. The first region may be superelastic at body temperature. The interatrial shunt may include a second region that includes a malleable shape-memory material configured to be placed through an opening in the atrial septum so as to provide fluid flow from the first atrium to the second atrium. The second region may be malleable at body temperature. The malleable shape-memory material may have a first cross-sectional area. The malleable shape-memory material may be expandable from the first cross-sectional area to a second cross-sectional area. The malleable shape-memory material may be contractible from the second cross-sectional area to a third cross-sectional area.

[0045] The self-expanding superelastic material may include NITINOL having an austenitic finish temperature (A_f) between 5-20°C, and the malleable shape-memory material may include NITINOL having an austenitic finish temperature (A_f) between 45-60°C. The malleable shape-memory material may be mechanically expandable and thermally contractible. The interatrial shunt may include a third region that includes a second self-expanding superelastic material, is configured to be placed in the second atrium, and is coupled to the second region.

[0046] In accordance with another aspect, a device is provided for adjustably regulating fluid flow therethrough. The device may include a first component including a first self-expanding superelastic material, and a second component coupled to the first component and including a first malleable shape-memory material. The first malleable shape-memory material may have a first cross sectional area. The first malleable shape-memory material may be expandable to a second cross sectional area. The first malleable shape-memory material may be contractible to a third cross sectional area.

[0047] In some examples, the first self-expanding superelastic material includes NITINOL having an austenitic finish temperature (A_f) of less than body temperature (normally ~37°C). Illustratively, the A_f of the NITINOL of the first self-expanding superelastic material may be between 5-20°C.

[0048] In some examples, the first malleable shape-memory material includes NITINOL having an austenitic finish temperature (A_f) of greater than body temperature or 37°C. Illustratively, the

Af of the NITINOL of the malleable shape-memory material may be between 45-60°C. This is higher than body temperature when febrile but not high enough to cause permanent injury such as protein denaturation from brief exposure.

[0049] In some examples, the first malleable shape-memory material is mechanically expandable. In some examples, the first malleable shape-memory material is thermally contractible. In some examples, the first malleable shape-memory material is joined to the first self-expanding superelastic material by welding.

[0050] In some examples, the device includes an encapsulant covering at least a portion of at least one of the first component and the second component. Optionally, the encapsulant joins the first malleable shape-memory material to the first self-expanding superelastic material.

[0051] In some examples, the first cross sectional area is smaller than the third cross sectional area. In some examples, the first cross sectional area is larger than the third cross sectional area.

[0052] In some examples, the device further includes a third component including a second self-expanding superelastic material and coupled to the first component and the second component. Optionally, the first component includes an inlet, the second component includes a neck, and the third component includes an outlet fluidically coupled to the inlet via the neck. As a further option, the cross sectional area of the neck is smaller than respective cross sectional areas of at least one of the inlet and the outlet. As a still further option, the inlet and outlet anchor the device within an opening through a septum between two chambers within the body, and the neck provides a channel for flow between these chambers. In other options, the cross sectional area of the neck is larger than respective cross sectional areas of at least one of the inlet (ingress of blood flow) and the outlet (egress of blood flow). Optionally, the second component is configured to engage an opening in the human body. As a further option, the opening may be created through a fossa ovalis of an interatrial septum between a right atrium and a left atrium. The neck may be configured to engage the opening, the inlet may be configured to extend into the right atrium, and the outlet may be configured to extend into the left atrium.

[0053] In some examples, the first component is configured to engage a lumen in the human body. Optionally, the lumen includes a blood vessel, and the first and third components are configured to engage the blood vessel. The neck may be configured to be disposed adjacent to an ostium of the blood vessel.

[0054] In some examples, the device includes a third component including a second malleable shape-memory material and coupled to the first component and the second component. Optionally, the second malleable shape-memory material has a fourth cross sectional area permitting a fourth rate of fluid flow therethrough. The second malleable shape-memory material may be expandable to a fifth cross sectional area permitting a fifth rate of fluid flow therethrough. The second malleable shape-memory material may be contractible to a sixth cross sectional area permitting a sixth rate of fluid flow therethrough. Optionally, the second component includes an inlet and the third component includes an outlet fluidically coupled to the inlet via the first component. As a further option, the inlet is configured to engage a blood vessel in the human body, the first component is configured to engage the blood vessel, and the outlet is configured to extend into an ostium of the blood vessel.

[0055] In some examples, the device further includes a valve disposed in the second component. The first component may be configured to engage a blood vessel in the human body, and the second component may extend into the blood vessel.

[0056] In some examples, the second component is located inside of the first component.

[0057] In some examples, the first component includes a diabolo-shaped shunt having a neck, and the second component includes a cylindrical shunt. Optionally, the cylindrical shunt is outside of the diabolo-shaped shunt. As a further option, the first malleable shape-memory material may radially constrain a dimension of the neck. The first malleable shape-memory material optionally radially contacts an outer surface of the neck so as to constrain the neck from self-expanding to a larger dimension. Optionally, the neck self-expands responsive to the first malleable shape memory material expanding to the second cross sectional area. The device optionally further includes an encapsulant forming an inner lumen through the first component and an outer covering of the first component and the second component.

[0058] In other examples, the cylindrical shunt is inside of the diabolo-shaped shunt. Optionally, the cylindrical shunt is inside of, and not directly coupled to, the neck of the diabolo-shaped shunt. The device optionally further includes an encapsulant indirectly and elastically coupling the cylindrical shunt to the diabolo-shaped shunt such that the encapsulant forms a lumen through the inner cylindrical shunt. Optionally, contraction of the cylindrical shunt does not cause contraction of neck of the outer diabolo-shaped shunt. Optionally, the neck of the diabolo-shaped shunt is self-expandable to a fourth cross sectional area.

[0059] In some examples, the second component is located inside of the first component. Optionally, the first malleable shape-memory material radially constrains a dimension of the first component. Optionally, the first malleable shape-memory material radially contacts an inner surface of the first component so as to constrain the first component from contracting to a smaller dimension. Optionally, the first component self-contracts responsive to the first malleable shape memory material contracting to the third cross sectional area. Optionally, the device further includes an encapsulant forming an outer covering of the first component and the second component.

[0060] Under another aspect, a method for reducing and increasing an internal dimension of a device *in vivo* is provided. The method may include inserting into a fluid path first and second components coupled to one another. The first component may include a self-expanding superelastic material, and the second component may include a malleable shape-memory material having a first cross sectional area. The method may include expanding the malleable shape-memory material to a second cross sectional area; and contracting the malleable shape-memory material to a third cross sectional area.

[0061] In some examples, contracting the malleable shape-memory material includes heating the malleable shape-memory material. In some examples, the heating includes flowing heated saline through the device via a catheter. In some examples, the heating includes applying radio frequency (RF) energy to the device. In some examples, expanding the malleable shape-memory material includes expanding a balloon within the malleable shape-memory material.

[0062] Under another aspect, a method for adjustably regulating fluid flow is provided. The method may include inserting into a fluid path first and second components coupled to one another. The first component may include a self-expanding superelastic material, and the second component may include a malleable shape-memory material having a first cross sectional area permitting a first rate of fluid flow therethrough. The method may include expanding the malleable shape-memory material to a second cross sectional area permitting a second rate of fluid flow therethrough; and contracting the malleable shape-memory material to a third cross sectional area permitting a third rate of fluid flow therethrough.

[0063] In some examples, contracting the malleable shape-memory material includes heating the malleable shape-memory material. In some examples, the heating includes flowing heated saline through the device via a catheter. In some examples, the heating includes applying radio frequency (RF) energy to the device. In some examples, expanding the malleable shape-memory material includes expanding a balloon within the malleable shape-memory material.

[0064] Under another aspect, a repositionable device for fixation within a body lumen is provided. The device may include a first component including a self-expanding superelastic material; and a second component coupled to the first component and including a malleable shape-memory material. The self-expanding superelastic material may have a predetermined fully expanded dimension. The second component may have a first dimension suitable for deployment through a catheter. The malleable shape-memory material may be expandable to a second dimension for fixation within a body lumen. The malleable shape-memory material may be thermally transitionable to a third dimension. The malleable shape-memory material may be mechanically re-expandable to a fourth dimension.

[0065] Under another aspect, a method for adjustably fixating a device within a body lumen is provided. The method may include inserting into a body lumen a device including first and second components coupled to one another. The first component may include a self-expanding superelastic material. The second component may include a malleable shape-memory material having a first dimension. The method may include expanding the malleable shape-memory material to a second dimension to fixate the device within a body lumen. The method may

include thermally contracting the malleable shape-memory material. The method may include repositioning the device within the body lumen while the malleable shape-memory material is thermally contracted. The method may include mechanically re-expanding the malleable shape-memory material to a third dimension to fixate the device within the body lumen.

[0066] In some examples, thermally contracting the malleable shape-memory material includes heating the malleable shape-memory material. In some examples, the heating includes flowing heated saline through the device via a catheter. In some examples, the heating includes applying radio frequency (RF) energy to the device. In some examples, the mechanically expanding the malleable shape-memory material includes expanding a balloon within the malleable shape-memory material.

[0067] In any of the aforementioned devices and methods, the first component and the second component optionally are integrally formed from a common frame with one another.

[0068] Under another aspect, a dilator for enlarging an opening through a region of the human body is provided. The dilator may include a sheath having a proximal end and a distal end; and a dilator disposed at the distal end of the sheath and including a tip, an enlarged region, and a reduced region. The reduced region may be sized so as to securably engage with the distal end of the sheath. The enlarged region may be sized so as to provide a smooth profile between the sheath and the tip. A distal end of the tip may taper to approximately a point. At least the enlarged region and the reduced region may include a martensitic shape-memory material having an austenitic finish temperature (A_f) substantially greater than 37°C such that, upon application of heat within the body, the shape memory material returns to a smaller, heat-set outer dimension such that the dilator has a substantially smooth, reduced size profile.

[0069] In some examples, the tip also includes the martensitic shape-memory material. In some examples, the tip includes a self-expanding superelastic material. The tip, the reduced region, and the enlarged region optionally are integrally formed from a common frame with one another.

[0070] Under another aspect, a system is provided that includes such a dilator, and a device to deploy in the opening.

[0071] Under another aspect, a method for forming an enlarged opening through a region of the human body is provided. The method may include disposing a guidewire through the region of the human body to form an opening. The method may include pushing a dilator over the guidewire and through the opening to form an enlarged opening. The method may include heating the dilator to reduce the size of the dilator. The method may include, while the dilator has the reduced size, withdrawing the dilator through the enlarged opening.

[0072] In some examples, the heating includes flowing heated saline through the dilator via a catheter. In some examples, the heating includes applying radio frequency (RF) energy to the dilator. In some examples, the method includes deploying a device within the opening, and withdrawing the dilator through the device.

[0073] Under another aspect, a transatrial gate is provided. The transatrial gate may include a left atrial disc including a first self-expanding superelastic material, and a right atrial disc including a second self-expanding superelastic material. The transatrial gate also may include a martensitic shape-memory material that is heat set to completely occlude passage between the left and right atrial discs that is expandable to allow passage between the left and right atrial discs.

[0074] In some examples, the martensitic shape-memory material is provided as a mesh. In some examples, the martensitic shape-memory material is balloon expandable. In some examples, the martensitic shape-memory material is configured to be closeable by application of heat after being expanded to allow passage between the left and right atrial discs. The left atrial disc, the right atrial disc, and the martensitic shape memory material optionally are integrally formed from a common frame with one another.

[0075] Under another aspect, a method of performing a procedure is provided. The method may include implanting a transatrial gate through an opening in an atrial septum of a heart. The transatrial gate may include a left atrial disc including a first self-expanding superelastic material, and a right atrial disc including a second self-expanding superelastic material. The transatrial gate also may include a martensitic shape-memory material that is heat set to completely occlude passage between the left and right atrial discs. The method may include

expanding the martensitic shape-memory material to allow passage between the left and right atrial discs.

[0076] In some examples, the material includes blood. In some examples, the material includes an instrument. In some examples, the method includes using the instrument to perform an additional procedure in a left atrium of the heart. In some examples, the additional procedure includes RF ablation, left atrial appendage closure, MitraClip implantation, mitral valve replacement, or mitral valve repair. In some examples, the martensitic shape-memory material is provided as a mesh. In some examples, the martensitic shape-memory material is expanded using a balloon. In some examples, the method further includes, after the expanding, closing the martensitic shape-memory material by application of heat. The left atrial disc, the right atrial disc, and the martensitic shape memory material optionally are integrally formed from a common frame with one another.

[0077] Under yet another aspect, an apparatus is provided. The apparatus includes a device that includes a proximal portion configured to be disposed in a first atrium of a heart, and a distal portion configured to be disposed in a second atrium of a heart and including a first self-expanding superelastic material. The device further includes an intermediate portion disposed between the proximal portion and the distal portion and configured to be disposed in an atrial septum between the first atrium and the second atrium. The intermediate portion includes a malleable shape-memory material. The apparatus further includes a catheter and at least one constricting flexible longitudinal element. The first self-expanding superelastic material may have a predetermined fully expanded dimension. The intermediate portion may have a first dimension suitable for deployment through the catheter, may be expandable to a second dimension for fixation within the septum, may be thermally transitionable to a third dimension, and may be mechanically re-expandable to a fourth dimension. The device may be removable by drawing the device into the catheter using the at least one constricting flexible longitudinal element.

[0078] In some examples, the proximal portion is flared. In some examples, the distal portion is flared. In some examples, the proximal portion includes a second self-expanding superelastic

material. The proximal portion, the distal portion, and the intermediate portion optionally are integrally formed from a common frame with one another.

[0079] Under another aspect, a method is provided that includes through a catheter, deploying a device through an atrial septum of a heart. The device may include a proximal portion disposed in a first atrium of the heart, and a distal portion disposed in a second atrium of the heart and comprising a first self-expanding superelastic material. The device may include an intermediate portion disposed between the proximal portion and the distal portion and disposed in the atrial septum between the first atrium and the second atrium. The intermediate portion may include a malleable shape-memory material. The first self-expanding superelastic material may have a predetermined fully expanded dimension. The intermediate portion may have a first dimension when deployed through the catheter. The method may include expanding the intermediate portion to a second dimension for fixation within the septum. The method may include thermally transitioning the intermediate portion to a third dimension. The method may include mechanically re-expanding the intermediate portion to a fourth dimension. The method may include removing the device by drawing the device into the catheter using the at least one constricting flexible longitudinal element.

[0080] In some examples, the proximal portion is flared. In some examples, the distal portion is flared. In some examples, the proximal portion includes a second self-expanding superelastic material. The proximal portion, the distal portion, and the intermediate portion optionally are integrally formed from a common frame with one another.

BRIEF DESCRIPTION OF THE DRAWINGS

[0081] FIGS. 1A-1E schematically illustrate an example device with an internal dimension that can be reduced and increased *in vivo*.

[0082] FIGS. 2A-2E schematically illustrate another example device with an internal dimension that can be reduced and increased *in vivo*.

[0083] FIGS. 3A-3D schematically illustrate an example device with multiple internal dimensions that can be reduced and increased *in vivo*.

[0084] FIGS. 4A-4B schematically illustrate example encapsulants that may be provided in a device with an internal dimension that can be reduced and increased *in vivo*.

[0085] FIGS. 5A-5B schematically illustrate example arrangements of components in a device with an internal dimension that can be reduced and increased *in vivo*.

[0086] FIG. 6 schematically illustrates another example device with an internal dimension that can be reduced and increased *in vivo*.

[0087] FIG. 7 schematically illustrates another example device with an internal dimension that can be reduced and increased *in vivo*.

[0088] FIGS. 8A-8D schematically illustrate example steps for using the device of FIG. 7 in the human body.

[0089] FIGS. 9A-9B schematically illustrate example configurations of the device of FIG. 7.

[0090] FIGS. 10A-10C schematically illustrate example uses of tooling for preparing the device of FIG. 7.

[0091] FIGS. 11A-11B schematically illustrate an example modification of the device of FIG. 7.

[0092] FIGS. 12A-12B schematically illustrate another example modification of the device of FIG. 7.

[0093] FIGS. 13A-13B schematically illustrate another example modification of the device of FIG. 7.

[0094] FIGS. 14A-14C schematically illustrate another example device with multiple internal dimensions that can be reduced and increased *in vivo*, and an example of its use in the human body.

[0095] FIGS. 15A-15D schematically illustrate another example device with an internal dimension that can be reduced and increased *in vivo*, and an example of its use in the human body.

[0096] FIGS. 16A-16B schematically illustrate another example device with an internal dimension that can be reduced and increased *in vivo*, and an example of its use in the human body.

[0097] FIG. 17 illustrates a flow of operations in an example method for reducing and increasing an internal dimension of a device *in vivo*.

[0098] FIG. 18 illustrates a flow of operations in an example method for fixating a device in a body lumen.

[0099] FIGS. 19A-19D schematically illustrate an example dilator device with an external dimension that can be reduced and increased *in vivo*.

[0100] FIGS. 20A-20I schematically illustrate use of the delivery device of FIGS. 19A-19D in the human body.

[0101] FIGS. 21A-21D schematically illustrate an example transatrial gate with an internal dimension that can be reduced and increased *in vivo*.

[0102] FIGS. 22A-22H schematically illustrate use of the transatrial gate of FIGS. 21A-21D in the human body.

[0103] FIGS. 23A-23E schematically illustrate another example device with an internal dimension that can be reduced and increased *in vivo*, and an example of its temporary use in the human body.

[0104] FIGS. 24A-24H are images of a device prepared and used in accordance with examples provided herein.

[0105] FIGS. 25A-25D schematically illustrate an example modification of the device of FIG. 7.

[0106] FIGS. 26A-26H schematically illustrate another example modification of the device of FIG. 7.

[0107] FIGS. 27A-27K schematically illustrate another example modification of the device of FIG. 7.

[0108] FIGS. 28A-28D schematically illustrate another example device with an internal dimension that can be reduced and increased *in vivo*.

[0109] FIGS. 29A-29D schematically illustrate an example of the use of the device of FIGS. 28A-28B in the human body.

[0110] FIGS. 30A-30C schematically illustrate an example of the use of the device of FIG. 28C in the human body.

[0111] FIGS. 31A-31E schematically illustrate an example device with a configuration that can be reversibly modified *in vivo*.

[0112] FIGS. 32A-32G schematically illustrate another example device with an internal dimension that can be reduced and increased *in vivo*, and an example of its use in the human body.

DETAILED DESCRIPTION

[0113] The present disclosure provides devices with dimensions that can be reduced and increased *in vivo*, and methods of making and using the same.

[0114] For example, the present devices may be permanently or temporarily implantable in a human body and include one or more components which can be adjusted for size, larger or smaller, after implantation. The need for such adjustable devices may arise, for example, in the treatment of pulmonary artery hypertension (PAH) or heart failure (HF). In PAH, placing a shunt in the interatrial septum allows excessive blood pressure in the right atrium to be relieved by allowing some blood to flow from the right atrium to the left atrium through an orifice. In HF, placing a shunt in the interatrial septum allows excessive blood pressure in the left atrium to be relieved by allowing some blood to flow from the left atrium into the right atrium through an orifice. In both PAH and HF, interatrial shunting has been shown to effectively reduce

symptoms and increase exercise tolerance. Interatrial shunting also may reduce the need for hospitalization and even improve life expectancy.

[0115] However, if the orifice of the interatrial shunt is too small, too little blood may be transferred and the shunt may be relatively ineffective and provide little or no clinical benefit. In contradistinction, shunting too much blood (“over-shunting”) through too large of an orifice may lead to severe or even fatal complications over time. For example, in PAH patients, over-shunting may result in systemic oxygen desaturation and its sequelae including cyanosis, polycythemia with increased blood viscosity, end organ ischemia, and potentially death. In HF patients, over-shunting may result in pulmonary hypertension, right ventricular failure, and potentially death.

[0116] At present, there is no known way to predict the response of a given patient to a particular shunt orifice size. As is previously known, a shunt orifice may be increased *in vivo*, for example by dilating a suitably designed shunt by expanding an inflatable balloon catheter or other similar mechanically expansive means within the shunt, providing however, that the shunt is made from a malleable material and will remain expanded due to plastic deformation or some other physical property, whereby when the balloon or other expansive means is removed, the amount of elastic spring back or recoil will be low enough so that the desired increment in orifice size is achieved. One drawback of this approach is that the orifice size can only be increased. If the shunt starts out too large or if is made too large by balloon dilatation but the patient needs a smaller shunt, there is no way to go back to a smaller size orifice except by providing another, smaller shunt or placing a smaller shunt within the lumen of original shunt. This technique is known as “shunt-in-shunt.” As such, finding a suitable shunt orifice size for a given patient has been a trial and error process in which the shunt orifice size is selected according to the patient’s response, which may be observed for a period of time which may be as short as a few minutes or as long as many months, and the shunt orifice size increased (e.g., by balloon dilatation) or reduced (by providing a new, smaller shunt) depending on the patient’s response. As such, opportunities to increase or reduce the size of the shunt are very limited and may not be repeatable. Furthermore, the extent to which an inflatable balloon catheter can expand a shunt orifice may be limited by the maximum size of the balloon. Thus, what is needed is a means to repeatedly and non-

traumatically adjust the orifice size of shunts, and other implantable devices, *in vivo*, and in both directions, bigger or smaller.

[0117] Provided herein are devices with cross sectional areas that may be easily reduced *in vivo*, and expanded *in vivo*, in any order, as clinically necessary. In particular, some examples of the present devices include a self-expanding superelastic (austenitic phase) material as well as a malleable shape-memory (martensitic phase) material. When the device is implanted in the human body, e.g., by transporting the device in a compressed state within a sheath to a desired location and then removing the sheath, the self-expanding superelastic material may automatically deploy to its desired size, while the malleable shape-memory material initially may remain in a reduced size state. The cross sectional area of the malleable shape-memory material then may be expanded and reduced *in vivo* as desired so as to obtain a cross sectional area that is suitable for treating the patient, e.g., by providing a suitable fluid flow rate therethrough, or so as to appropriately fixate the device within the patient while allowing for repositioning to improve effectiveness of the treatment. A wide variety of devices may be prepared using components respectively including self-expanding superelastic materials and malleable shape-memory materials, such as exemplified herein.

[0118] For example, FIGS. 1A-1E schematically illustrate an example device with an internal dimension that can be reduced and increased *in vivo*. Device 100 illustrated in FIGS. 1A-1E includes first component 110 and second component 120 coupled, e.g., fluidically coupled, to first component 110. First component 110 may include a self-expanding superelastic material, and second component 120 may include a malleable shape-memory material. The malleable shape-memory material of second component 120 may have a first cross sectional area permitting a first rate of fluid flow through the second component, may be expandable to a second cross sectional area permitting a second rate of fluid flow through the second component, and may be contractible to a third cross sectional area permitting a third rate of fluid flow through the second component. Note that the overall rate of fluid flow through device 100 also may depend on the cross sectional area of first component 110.

[0119] For example, FIG. 1A schematically illustrates device 100 in a compressed or crimped state and loaded into sheath 130 for percutaneous implantation within the human body. In the crimped state, both first component 110 and second component 120 may have a dimension D1 (corresponding to a first cross sectional area). Once device 100 is delivered to the desired location, sheath 130 may be retracted so as to percutaneously implant the device. As illustrated in FIG. 1B, following removal of sheath 130 the self-expanding superelastic material of first component 110 may automatically expand to its heat-set superelastic configuration, in this example with dimension Ds, while the malleable shape-memory material of second component 120 may remain in the crimped state (e.g., at the first dimension, D1, corresponding to a first cross sectional area) until it is further adjusted. Second component 120 may be expanded by any suitable amount, for example such as shown in FIG. 1C, to dimension D2 (corresponding to a second cross sectional area). Second component 120 may be reduced by any suitable amount, for example such as shown in FIGS. 1D and 1E, by first using the shape-memory property to contract component 120 to its annealed configuration dimension D0, then expanding (e.g., by balloon dilation) to dimension D3 (corresponding to a third cross sectional area). Based on the particular dimension (and cross sectional areas) to which second component 120 is adjusted by expansion or contraction, different rates of fluid flow may be permitted through that component, thus providing an adjustable orifice for controlling the flow of fluid within the location of the human body in which device 100 is deployed.

[0120] In some examples, reducing the dimension of a shape memory material-based component herein always returns that component to its heat-set (annealed) dimension, D0, determined at the time of manufacture by heat setting within a jig. Once the dimension is thus reduced it may be then expanded, for example by balloon dilation, to an intermediate dimension. Additionally, note that although in some examples D0 and D1 may be approximately the same as one another, in other examples D0 may be smaller than D1, while in still other examples D0 may be larger than D1. Although FIGS. 1A-1E illustrate only four exemplary dimensions D0, D1, D2, D3 of second component 120, it should be appreciated that any suitable dimension above a minimum set by the annealed configuration, D0, may be obtained by balloon expanding as desired. For example, D2 may be smaller than D3. Alternatively, D2 may be larger than D3, and D3 may be achieved by

reducing second component 120 to its heat-set dimension, D0, as shown in FIG. 1D, and then expanding second component 120 to dimension D3 as shown in FIG. 1E. In some examples, the second component may be heated with a hot balloon and the balloon then deflated to a desired dimension, followed by cooling of the second component. As heating creates a crystalline phase change, the dimension of the second component is never plastically deformed by balloon inflation and therefore, the shunt can be repeatedly cycled from one dimension to another, bigger or smaller through any number of cycles the patient requires to optimize shunt size.

[0121] Note that as used herein, “inner dimension” refers to the transverse dimension between inner walls of a device component, e.g., along line A-A indicated in FIGS. 1A-1E. As used herein, “outer dimension” refers to the transverse dimension between outer walls of a device component, e.g., along line A-A indicated in FIGS. 1A-1E. As used herein, “cross sectional area” refers to the area of the transected plane within the walls of the device in a plane running through that dimension, e.g., in a plane parallel to line A-A indicated in FIGS. 1A-1E and crossing through second component 120. The expansion or contraction of a dimension may be with reference to the distance between walls of the device component at a particular location within that component, e.g., along line A-A indicated in FIGS. 1A-1E. The expansion or contraction of a cross sectional area may be with reference to area within the walls of the device in a plane running through the corresponding dimension of the device component at a particular location within that component, e.g., along line A-A indicated in FIGS. 1A-1E. The present devices may have any suitable cross sectional shape and may include, but are not limited to, circular, or uniform, cross sections.

[0122] In the nonlimiting examples shown in FIGS. 1B and 1D, the interface between the crimped state of second component 120 and expanded first component 110 may apply a force that inhibits first component 110 from fully expanding; it should be appreciated that such interface instead may apply a force that causes second component 120 to partially expand. As described in greater detail below, the particular manner in which first component 110 and second component 120 are joined to one another may be selected so as to control the force(s) applied to such components and thus the shapes and dimensions of such components.

[0123] In some examples, the self-expanding superelastic material of first component 110 and the malleable shape-memory material of second component 120 may include different materials than one another, or may include the same material as one another but having different phases than one another. For example, first component 110 and second component 120 independently may include one or more materials selected from the group consisting of nickel titanium (NiTi), also known as NITINOL, other shape memory alloys, self-expanding materials, superelastic materials, polymers, and the like. For example, first component 110 may include a NITINOL alloy having an austenitic finish temperature (A_f) that is sufficiently below body temperature that the material is in an austenitic, superelastic phase while in the human body. In one nonlimiting example, the self-expanding superelastic material of first component 110 includes NITINOL having an A_f of less than 37°C. For example, the A_f of the NITINOL of the self-expanding superelastic material may be between 5-20°C. First component 110 and second component 120 optionally may be integrally formed from a common frame with one another. For example, first component 110 and second component 120 may be initially cut and processed as a single unit from the same tubing, sheet, or other suitable configuration of frame as one another. Portions of that common frame may be heat treated differently than one another so as to define first component 110 and second component 120, e.g., in a manner similar to that described with reference to FIGS. 10A-10C.

[0124] Second component 120 may include a NITINOL alloy having an austenitic phase transition temperature A_f that is slightly above body temperature such that the material remains in its martensitic, shape-memory phase while in the body unless and until it is heated to or above its A_f , for example by the injection of warm or hot saline (or other fluid) into the fluid within or flowing through second component 120, or by applying heat through electrical energy such as with an RF energy source. In one nonlimiting example, the malleable shape-memory material of second component 120 includes NITINOL having an austenitic finish temperature (A_f) of greater than 37°C. For example, the A_f of the NITINOL of the malleable shape-memory material of second component 120 may be between 45-60°C, e.g., from 50-55 °C. In some examples, the warm or hot saline (or other fluid) may be injected sufficiently close to second component 120 to heat that component to or above its A_f , using a side-hole catheter positioned through device 100.

In other examples, a pair of RF electrodes may be brought into contact with device 100, e.g., via a catheter, and actuated at a sufficient voltage and frequency to heat component 120 to or above its Af. In still other examples, any other suitable means of locally applying heat to device 100, such as a laser, magnetic inductance, electrical resistance, or the like, may be used. Heating device 100 using electrical resistance may include contacting the device with a pair of electrodes, e.g., via a catheter, and passing a current through the device that causes heating of the device. Heating device 100 using a laser may include irradiating the device with light from a laser that may be introduced by a catheter. Heating device 100 using magnetic inductance may include passing an alternating magnetic field through the device that induces eddy currents inside the device which heat the device. Note that in blood vessels having a particularly high rate of blood flow (e.g., 2-5 L/min), such as the aorta or internal iliac artery, it may be useful to heat device 100 using direct heating methods, such as using RF energy, a laser, magnetic inductance, or electrical resistance, instead of saline which may be washed away by the high blood flow rate before sufficiently heating the device.

[0125] Alternatively, device 100 may include a single NITINOL alloy (common frame) that has been heat treated to produce a lower Af in a region corresponding to first component 110, and that has been heat treated to produce a higher Af in a region corresponding to second component 120, such that first component 110 and second component 120 are integrally formed with one another. The malleable shape-memory material of second component 120 may be expandable and contractible using any suitable technique. For example, the malleable shape-memory material of second component 120 may be mechanically expanded, e.g., using balloon dilatation such as known in the art. Additionally, or alternatively, malleable shape-memory material of second component 120 may be thermally contracted, e.g., using saline at a temperature at or above the Af of that material, or otherwise heated such as with RF energy or the use of a laser, magnetic inductance, electrical resistance, or the like in a manner such as described above.

[0126] Optionally, first component 110 may be configured to engage a lumen in the body, for example in a manner such as described with reference to FIGS. 14A-14C, 15A-15D, or 16A-16B. Illustratively, the lumen may include a blood vessel, and the first component may be configured to engage the blood vessel.

[0127] It will be appreciated that the present devices may include any suitable number of components including a self-expanding superelastic material, and any suitable number of components including a malleable shape-memory material. For example, FIGS. 2A-2E schematically illustrate another example device with an internal dimension that can be reduced and increased *in vivo*. Device 200 illustrated in FIGS. 2A-2E includes first component 210, second component 220, and third component 211 which is coupled, e.g., fluidically coupled, to first component 210 and second component 220. First component 210 may include a first self-expanding superelastic material, second component 220 may include a malleable shape-memory material, and third component 211 may include a second self-expanding superelastic material. The malleable shape-memory material of second component 220 may have a first cross sectional area permitting a first rate of fluid flow through the second component, may be expandable to a second cross sectional area permitting a second rate of fluid flow through the second component, and may be contractible to a third cross sectional area permitting a third rate of fluid flow through the second component.

[0128] For example, FIG. 2A schematically illustrates device 200 in a crimped state and loaded into sheath 230 for percutaneous implantation within the human body. In the crimped state, first component 210, second component 220, and third component 211 may have a dimension D1 (corresponding to a first cross sectional area). Once device 200 is delivered to the desired location, sheath 230 may be retracted so as to percutaneously implant the device. As illustrated in FIG. 2B, following removal of sheath 230 the respective self-expanding superelastic materials of first component 210 and third component 211 may automatically expand to a heat-set dimension Ds, while the malleable shape-memory material of second component 220 may remain in the crimped state (e.g., at the first cross sectional area) until it is further adjusted. Second component 220 may be expanded by any suitable amount, for example such as shown in FIG. 2C, to dimension D2 (corresponding to a second cross sectional area). Second component 220 may be reduced by any suitable amount in the same manner as described above in relation to FIG. 1, for example such as shown in FIG. 2E, to dimension D3 (corresponding to a third cross sectional area), by first heating the shape-memory component 220 above its Af temperature, returning it to its annealed configuration, D0, as shown in FIG. 2D, then expanding it (e.g. by

balloon dilation) to a third dimension D3 (corresponding to a third cross sectional area). Based on the particular dimension (and cross sectional areas) to which second component 220 is adjusted by expansion or contraction, different rates of fluid flow may be permitted through that component, thus providing an adjustable orifice for controlling the flow of fluid within the location of the human body in which device 200 is deployed. Note that the overall rate of fluid flow through device 200 also may depend on the cross sectional areas of first component 210 and second component 211.

[0129] Although FIGS. 2A-2E illustrate only three exemplary dimensions D1, D2, D3 of second component 220, it should be appreciated that any suitable dimension may be obtained by expanding or contracting the second component as desired. Note that although in some examples D0 and D1 may be approximately the same as one another, in other examples D0 may be smaller than D1, while in still other examples D0 may be larger than D1. Furthermore, it should be appreciated that a shape-memory component may be formed and heat set into other geometries besides the circular cylindrical shape illustrated here, and that its shape may be modified in other ways besides the radial expansion illustrated here, and that the shape-memory component may be returned to its original, heat-set, geometry by heating it above its A_f temperature. Additionally, with regards to each of the examples described herein, it should be appreciated that the components need not necessarily have circular cross sections, but may have any suitable shape of cross section.

[0130] In the nonlimiting examples shown in FIGS. 2B and 2D, the respective interfaces between the crimped state of second component 220 and expanded first component 210 and expanded third component 211 may apply a force that inhibits first component 210 and third component 211 from fully expanding; it should be appreciated that such interface(s) instead may apply a force that causes second component 220 to partially expand. As described in greater detail below, the particular manner in which first component 210, second component 220, and third component 211 respectively are joined to one another may be selected so as to control the force(s) applied to such components and thus the shapes and dimensions of such components. First component 210 and third component 211 may be, but need not necessarily be, the same dimension, shape, and size as one another.

[0131] In some examples, the first self-expanding superelastic material of first component 210, the malleable shape-memory material of second component 220, and the second self-expanding superelastic material of third component 211 may include different materials than one another, or may include the same material as one another but having different phases than one another. For example, first component 210, second component 220, and third component 211 independently may include one or more materials selected from the group consisting of nickel titanium (NiTi), also known as NITINOL, other shape memory alloys, self-expanding materials, superelastic materials, polymers, and the like. In one nonlimiting example, first component 210 and third component 211 each may include a NITINOL alloy having an A_f that is sufficiently below body temperature that the material is in an austenitic, superelastic phase while in the human body in a manner such as described with reference to FIGS. 1A-1E. Second component 220 may include a NITINOL alloy having an austenitic phase transition temperature A_f that is slightly above body temperature such that the material remains in its martensitic, shape-memory phase while in the body unless and until it is heated to its A_f , for example by the injection of warm or hot saline into the fluid within or flowing through second component 220 or the application of RF energy, or the use of a laser, magnetic inductance, electrical resistance, or the like in a manner such as described with reference to FIGS. 1A-1E. Alternatively, device 200 may include a single NITINOL alloy that has been heat treated to produce a lower A_f in regions respectively corresponding to first component 210 and third component 211, and that has been heat treated to produce a higher A_f in a region corresponding to second component 220. The malleable shape-memory material of second component 220 may be expandable and contractible using any suitable technique, e.g., such as described with reference to FIGS. 1A-1E. First component 210, second component 220, and third component 211 optionally may be integrally formed from a common frame with one another in a manner such as described with reference to FIGS. 1A-1E.

[0132] In a manner such as described in greater detail with reference to FIGS. 7-12B and 15A-15D, first component 210 may provide an inlet, second component 220 may provide a neck, and third component 211 may provide an outlet coupled, e.g., fluidically coupled, to the inlet via the neck. As used herein, “inlet” means component with ingress of blood flow, and “outlet” means component with outgress (egress) of blood flow. The particular components that respectively

may be used to provide ingress and outgress (egress) of blood flow may be selected based on the condition being treated. For example, in HF, the inlet may be on the left atrial (LA) side, where blood flow from LA to right atrium (RA), and LA decompression, are desirable. In contradistinction, in PAH, the interatrial pressure gradient is reversed causing R to L flow and RA decompression, and the inlet is on the RA side. The cross sectional area of the neck may be smaller than the cross sectional areas of at least one of the inlet and the outlet, for example as described in greater detail with reference to FIGS. 7-12B. Or, for example, the cross sectional area of the neck may be larger than respective cross sectional areas of at least one of the inlet and the outlet, for example as described in greater detail with reference to FIGS. 15A-15B. Third component 211 may be configured to engage an opening in the human body, for example in a manner such as described with reference to FIGS. 7-12B. Additionally, or alternatively, first component 210 may be configured to engage a lumen in the body, for example in a manner such as described with reference to FIGS. 15A-15D. Optionally, third component 211 may be configured to engage a lumen in the body, for example in a manner such as described with reference to FIGS. 15A-15D. Illustratively, the lumen may include a blood vessel, and the first and third components may be configured to engage the blood vessel. The neck, if present, optionally may be configured to be disposed adjacent to an ostium of the blood vessel, e.g., in a manner such as described with reference to FIGS. 15A-15D.

[0133] FIGS. 3A-3D schematically illustrate an example device with multiple internal dimensions that can be reduced and increased *in vivo*. Device 300 illustrated in FIGS. 3A-3D includes first component 310, second component 320, and third component 321 which is coupled, e.g., fluidically coupled, to first component 310 and second component 320. First component 310 may include a self-expanding superelastic material, second component 320 may include a first malleable shape-memory material, and third component 321 may include a second malleable shape-memory material. The respective malleable shape-memory materials of second component 320 and third component 321 may have a first cross sectional area permitting a first rate of fluid flow through the second component, may be expandable to a second cross sectional area permitting a second rate of fluid flow through the second component, and may be contractible to a third cross sectional area permitting a third rate of fluid flow through the second

component. Note that the cross sectional areas, sizes, and shapes of second component 320 and third component 321 may be, but need not necessarily be, the same as one another. Note that the overall rate of fluid flow through device 200 also may depend on the cross sectional areas of first component 210 and second component 211. Illustratively, in examples where the cross sectional area of second component 320 is smaller than that of third component 321, or where the cross sectional area of second component 320 is larger than that of third component 321, the smaller of the cross sectional areas may define the rate of fluid flow through device 300.

[0134] In addition to defining the rate of fluid flow through device 300, examples such as described with reference to FIGS. 3A-3D may allow for controllably adjusting apposition for anchoring or fixating the device to the wall of a body space by balloon expansion of apposing components 320, 321, e.g., in a manner such as described with reference to FIGS. 14A-14C, while allowing these apposing components to be contracted so that the device may be repositioned after deployment. Additionally, or alternatively, examples such as described with reference to FIGS. 3A-3D may provide for a relatively safe method of implantation as compared, for example, to expanding the first, second, and third components 310, 320, 321 all together with one another. For example, in an implementation such as described with reference to FIGS. 14A-14C, expanding the first, second, and third components 310, 320, 321 all together with one another may cause blockage of the branch arteries. Allowing for selective expansion of specific segments in a more gradual manner can be safer.

[0135] FIG. 3A schematically illustrates device 300 in a crimped state and loaded into sheath 330 for percutaneous implantation within the human body. In the crimped state, first component 310, second component 320, and third component 321 may have a dimension D1 (corresponding to a first cross sectional area). Once device 300 is delivered to the desired location, sheath 330 may be retracted so as to percutaneously implant the device. As illustrated in FIG. 3B, following removal of sheath 330 the self-expanding superelastic material of first component 310 may automatically expand, while the first malleable shape-memory material of second component 320 and the second malleable shape-memory material of third component 321 may remain in the crimped state (e.g., at the first cross sectional area) until they are further adjusted. Second component 320 and third component 321 independently may be expanded by any suitable

amount, for example such as shown in FIG. 3C, to respective dimensions D2 (corresponding to a second cross sectional area) and D3. Second component 320 and third component 321 independently may be reduced to their respective heat-set dimensions and then expanded by any suitable amount, for example such as shown in FIG. 3D, to respective dimensions D4 (corresponding to a third cross sectional area) and D5.

[0136] Based on the particular dimensions (and cross sectional areas) to which second component 320 and third component 321 independently are adjusted by expansion or contraction, different rates of fluid flow may be permitted through such components, thus providing an adjustable orifice for controlling the flow of fluid within the location of the human body in which device 300 is deployed. Although FIGS. 3A-3D illustrate exemplary dimensions D1, D2, D3, D4, and D5 to which second component 320 and third component 321 independently may be set, it should be appreciated that any suitable dimension(s) may be obtained by independently expanding or contracting the second component and third components as desired. For example, second component 320 and third component 321 may have respective heat-set dimensions D0 that may be the same as, or different than, one another, and may be crimped to dimension D1 which is smaller than D0. Second component 320 and third component 321 respectively may be expanded to any suitable dimension(s), reset to D0, and subsequently re-expanded to any suitable dimension(s) any suitable number of times.

[0137] In the nonlimiting examples shown in FIGS. 3B and 3D, the respective interfaces between the crimped state of second component 320 and third component 321 and expanded first component 310 may apply forces that inhibit first component 310 from fully expanding; it should be appreciated that such interfaces instead may apply respective forces that cause second component 320 or third component 321 to partially expand. As described in greater detail below, the particular manner in which first component 310, second component 320, and third component 321 respectively are joined to one another may be selected so as to control the force(s) applied to such components and thus the shapes and dimensions of such components.

[0138] In some examples, the self-expanding superelastic material of first component 310, the first malleable shape-memory material of second component 320, and the second malleable

shape-memory material of third component 321 may include different materials than one another, or may include the same material as one another but having different phases than one another. For example, first component 310, second component 320, and third component 321 independently may include one or more materials selected from the group consisting of nickel titanium (NiTi), also known as NITINOL, other shape memory alloys, self-expanding materials, superelastic materials, polymers, and the like. In one nonlimiting example, first component 310 may include a NITINOL alloy having an A_f that is sufficiently below body temperature that the material is in an austenitic, superelastic phase while in the human body in a manner such as described with reference to FIGS. 1A-1E. Second component 320 and third component 321 each may include a NITINOL alloy having an austenitic phase transition temperature A_f that is slightly above body temperature such that the material remains in its martensitic, shape-memory phase while in the body unless and until it is heated to its A_f , for example by the respective injection of warm or hot saline into the fluid within or flowing through second component 320 or third component 321 or the application of RF energy, or the use of a laser, magnetic inductance, electrical resistance, or the like in a manner such as described with reference to FIGS. 1A-1E. Alternatively, device 300 may include a single NITINOL alloy that has been heat treated to produce a lower A_f in a region corresponding to first component 310, and that has been heat treated to produce a higher A_f in regions respectively corresponding to second component 320 and third component 321. Second component 320 and third component 321 may, but need not necessarily, have the same material or the same A_f as one another. The respective malleable shape-memory materials of second component 320 and third component 321 may be independently expandable relative to one another using any suitable technique, e.g., such as described with reference to FIGS. 1A-1E, may be reset to their respective heat-set dimensions, and then independently re-expanded to respective dimensions. First component 310, second component 320, and third component 321 optionally may be integrally formed from a common frame with one another in a manner such as described with reference to FIGS. 1A-1E.

[0139] In a manner such as described in greater detail with reference to FIGS. 14A-14C, the cross sectional areas of second component 320 and third component 321 may be expanded independently from one another so as to fixate the device within the lumen while allowing for

repositioning. In examples such as described in greater detail with reference to FIGS. 14A-14C, second component 320 may be configured as an inlet, and third component 321 may be configured as an outlet fluidically coupled to the inlet via first component 310. The inlet 320 may be configured to engage a blood vessel in the human body, and the outlet 321 may be configured to extend into an ostium of the blood vessel in a manner such as described with reference to FIGS. 14A-14C. A fourth component may be fluidically coupled to first component 310 and configured to extend into another ostium of the blood vessel, for example in a manner such as described with reference to FIGS. 14A-14C. In some example, first component 310 may be configured to provide a fluidic pathway for blood flow, for example, to channel blood flow past the weak segment of an aneurism, such as an aortic aneurism. In order to effectively protect the aneurism from the stress of aortic pressure, the inlet 320, outlet 321, and fourth component may be expanded so as to form sufficiently tight seals with their respective blood vessel(s).

[0140] In the present devices, such as exemplified by devices 100, 200, 300 respectively described with reference to FIGS. 1A-1E, 2A-2E, and 3A-3D, the first, second, and (if present) third components may be coupled, e.g., fluidically coupled, to one another using any suitable manner(s) of joining. For example, any malleable shape-memory material (such as in component 120, 220, 320, or 321) optionally and independently may be joined to any self-expanding superelastic material (such as in component 110, 210, 211, or 310) by welding. Additionally, or alternatively, any malleable shape-memory material (such as in component 120, 220, 320, or 321) optionally and independently may be joined to any self-expanding superelastic material (such as in component 110, 210, 211, or 310) using an encapsulant which may cover at least a portion of at least one of the components, and which may join such components to one another. Additionally, or alternatively, any shape-memory material and any self-expanding superelastic material may be integrally formed from a common frame with one another.

[0141] For example, FIGS. 4A-4B schematically illustrate example encapsulants that may be provided in a device with an internal dimension that can be reduced and increased *in vivo*. In example device 400 illustrated in FIG. 4A, which may include any suitable number of components (only two components illustrated for simplicity), encapsulant 440 covers a portion

of each of first component 410 and second component 420, which components may be configured similarly as described with reference to FIGS. 1A-1E, 2A-2E, or 3A-3D. Encapsulant 440 may fluidically join the malleable shape-memory material (e.g., of component 420) to the self-expanding superelastic material (e.g., of component 410). Optionally, encapsulant 440 indirectly and elastically joins the malleable shape-memory material to the self-expanding superelastic material. In example device 401 illustrated in FIG. 4B, which may include any suitable number of components (only two components illustrated for simplicity), encapsulant 441 covers the entirety of each of first component 410 and second component 420, which components may be configured similarly as described with reference to FIGS. 1A-1E, 2A-2E, or 3A-3D. Encapsulants 440 or 441 may fluidically join the malleable shape-memory material (e.g., of component 420) to the self-expanding superelastic material (e.g., of component 410). It will be appreciated that in other examples (not specifically illustrated), an encapsulant may entirely cover one or more components, and may only partially cover one or more other components. The encapsulant may indirectly couple one or more components to one another. A combination of encapsulation and mechanically engaging, e.g., welding or mechanical interference, may be used to both directly and indirectly couple the present components to one another.

[0142] Encapsulants 440, 441 may include any suitable biocompatible material, such as a polymer or a natural material. Examples of polymers suitable for use as an encapsulant include expanded polytetrafluoroethylene (ePTFE), silicone, polycarbonate urethane, DACRON (polyethylene terephthalate), Ultra High Molecular Weight Polyethylene (UHMWPE), and polyurethane. Examples of natural materials suitable for use as an encapsulant include pericardial tissue, e.g., from an equine, bovine, or porcine source, or human tissue such as human placenta or other human tissues. The biocompatible material is preferably smooth so as to inhibit thrombus formation, and optionally may be impregnated with carbon so as to promote tissue ingrowth. Alternatively, to promote tissue ingrowth and endothelization, the biocompatible material may form a mesh-like structure. The present devices may be encapsulated with a biocompatible material in a manner similar to that described in U.S. Patent Publication No. 2019/0110911 to Nae et al., entitled "Systems and Methods for Making Encapsulated Hourglass

Shaped Stents,” the entire contents of which are incorporated by reference herein. For example, an inner surface of one of the present devices may be covered with a first graft layer, and an outer surface of the device may be covered with a second graft layer. The graft layers may be securely bonded together to form a monolithic layer of biocompatible material, e.g., may be sintered together to form a strong, smooth, substantially continuous coating that covers the inner and outer surfaces of the device. Portions of the coating then may be removed as desired from selected portions of the device using laser-cutting or mechanical cutting, for example.

[0143] In one example, the device is encapsulated with ePTFE. It will be understood by those skilled in the art that ePTFE materials have a characteristic microstructure consisting of nodes and fibrils, with the fibrils orientation being substantially parallel to the axis of longitudinal expansion. Expanded polytetrafluoroethylene materials may be made by ram extruding a compressed billet of particulate polytetrafluoroethylene and extrusion lubricant through an extrusion die to form sheet or tubular extrudates. The extrudate is then longitudinally expanded to form the node-fibril microstructure and heated to a temperature at or above the crystalline melt point of polytetrafluoroethylene, i.e., 327° C, for a period of time sufficient to sinter the ePTFE material. Heating may take place in a vacuum chamber to prevent or inhibit oxidation of the device. Alternatively, heating may take place in a nitrogen rich environment. A furnace may be used to heat the encapsulated device. Alternatively, or additionally, a mandrel upon which the encapsulated device rests may be used to heat the encapsulated device.

[0144] In addition to, or as an alternative to, any other method of joining components of the present device to one another, one or more of the components may be fully or partially inserted into another one or more of the components. For example, FIGS. 5A-5B schematically illustrate example arrangements of components in a device with an internal dimension that can be reduced and increased *in vivo*. In example device 500 illustrated in FIG. 5A, which may include any suitable number of components (only two components illustrated for simplicity), second component 520 is at least partially located inside of first component 510, which components may be configured similarly as described with reference to FIGS. 1A-1E, 2A-2E, or 3A-3D. Overlap region 550 between first component 510 and second component 520, which region optionally may extend for the entire length of one or both of first component 510 and second component

520, may join the malleable shape-memory material (e.g., of component 520) to the self-expanding superelastic material (e.g., of component 510). For example, the outer surface of second component 520 may engage with (e.g., mechanically interfere with) the inner surface of first component 510 in such a manner as to inhibit lateral motion of the two components relative to one another. Additionally, the dimension of first component 510 may constrain expansion of second component 520 beyond that dimension within overlap region 550, e.g., may apply a force that inhibits second component 520 from fully expanding. As such, even if second component 520 is expanded (e.g., mechanically), the dimension of first component 510 may inhibit the second component from entirely expanding to a larger dimension.

[0145] In example device 501 illustrated in FIG. 5B, which may include any suitable number of components (only two components illustrated for simplicity), first component 511 is at least partially located inside of second component 521, which components may be configured similarly as described with reference to FIGS. 1A-1E, 2A-2E, or 3A-3D. Overlap region 551 between first component 511 and second component 521, which region optionally may extend for the entire length of one or both of first component 511 and second component 521, may join the malleable shape-memory material (e.g., of component 521) to the self-expanding superelastic material (e.g., of component 511). For example, the inner surface of second component 521 may engage with (e.g., mechanically interfere with) the outer surface of first component 511 in such a manner as to inhibit lateral motion of the two components relative to one another. Additionally, the dimension of second component 521 may constrain expansion of first component 511 beyond that dimension within overlap region 551, e.g., may apply a force that inhibits first component 511 from fully expanding. As such, even if first component 511 is expanded (e.g., self-expands), the dimension of second component 521 may inhibit the first component from entirely expanding to a larger dimension.

[0146] Mechanical interference between components, e.g., such as described with reference to FIGS. 5A-5B, may inhibit recoil of the shape memory component. For example, a known problem with martensitic NITINOL stents is recoil, in which about 10-15% diameter shrinkage may make apposition to a vascular wall challenging. Mechanical interference between device components, e.g., concentric coupling such as illustrated in FIGS. 5A-5B, may reduce or inhibit

such recoil. For example, in the configuration described with reference to FIG. 5B, first component 511 may physically inhibit second component 521 from recoiling. In some configurations, the respective hoop strengths of the first and second components may be approximately balanced with one another, optionally with the shape-memory martensitic component being slightly stronger, so as to reduce or minimize recoil.

[0147] It will be appreciated that devices such as described with reference to FIGS. 1A-1E, 2A-2E, 3A-3D, and options thereof such as described with reference to FIGS. 4A-4B and 5A-5B, may have any suitable configuration. For example, FIG. 6 schematically illustrates another example device 600 with an internal dimension that can be reduced and increased *in vivo*. Device 600 includes first component 610 (also designated “A”), second component 620 (also designated “B”), and third component 611 (also designated “C”). Device 600 optionally may include a tube of material that is laser-cut to define a plurality of struts and connecting members, e.g., a plurality of sinusoidal rings connected by longitudinally extending struts (struts not specifically illustrated). The sinusoidal rings illustrated in FIG. 6 may be laser cut to form an integral piece of unitary construction, and different regions of the piece may be heat treated differently than one another to produce components having different Afs than one another in a manner such as described elsewhere herein. Alternatively, the sinusoidal rings of first component 610, second component 620, and third component 611 may be separately defined to form different pieces of material with suitable Afs that are subsequently coupled together to form device 600. Device 600 may also be electropolished to reduce thrombogenicity.

[0148] Optionally, the Af of first component 610 and the Af of third component 611 each may be greater than the Af of second component 620. For example, first component 610 may correspond to first component 210 described with reference to FIGS. 2A-2E and may include a first self-expanding superelastic material, second component 620 may correspond to second component 220 and may include a malleable shape-memory material, and third component 611 may correspond to third component 211 and may include a second self-expanding superelastic material. As another option, the Af of first component 610 and the Af of third component 611 may be less than the Af of second component 620. For example, first component 610 may correspond to first component 310 described with reference to FIGS. 3A-3D and may include a

self-expanding superelastic material, second component 620 may correspond to second component 320 and may include a first malleable shape-memory material, and third component 611 may correspond to third component 321 and may include a second malleable shape-memory material. Optionally, the Af of first component 610 and the Af of third component 611 may be the same as one another.

[0149] It will be appreciated that the present devices may be percutaneously implanted within any suitable portion of the human body, such as a body lumen (e.g., a blood vessel) or the heart. Similarly, it will be appreciated that the present devices suitably may be adjusted *in vivo*, after implantation, in such a manner as to adjust the flow of fluid in such a manner as to treat or ameliorate any suitable condition such as HF, PAH, aneurism, aortic valve stenosis, mitral valve stenosis, or to improve outcomes following cardiac valve repair (e.g., mitral valve repair) or following cardiac ablation (e.g., for treating atrial fibrillation). Some nonlimiting examples of devices for implantation at selected locations are described with reference to FIGS. 7-16B.

[0150] In some examples, the present devices may be or include hourglass or “diabolo” shaped shunts, which optionally are encapsulated with biocompatible material, and which may be used for treating subjects suffering from disorders for which regulating fluid flow may be useful, such as CHF or PAH. In some examples, the hourglass shaped shunts may be specifically configured to be lodged securely in the atrial septum, for example in an opening through the fossa ovalis, to allow blood flow from the left atrium to the right when blood pressure in the left atrium exceeds that of the right atrium, or blood flow from the right atrium to the left when blood pressure in the right atrium exceeds that of the left atrium. As provided herein and described in greater detail with reference to FIGS. 7-10C, the internal dimension of the hourglass shaped shunt suitably may be adjusted *in vivo*, for example, so as to adjust the flow of fluid therethrough, e.g., so as to adjust the flow of fluid between the left atrium and the right atrium through the atrial septum.

[0151] Referring now to FIG. 7, shunt 700 is illustrated that has an internal dimension that can be reduced and increased *in vivo*. Shunt 700 is hourglass or “diabolo” shaped and may include first component 710, second component 720, and third component 730 which are fluidically coupled to one another. First component 710 may include a first self-expanding superelastic

material, second component 720 may include a malleable shape-memory material, and third component 730 may include a second self-expanding superelastic material, in a manner similar to that described with reference to FIGS. 2A-2E. First component 710 may include any suitable number of rings, e.g., rings 712, 713, which are formed of or include the first self-expanding material, and which optionally may be sinusoidal. Second component 720 may include any suitable number of rings, e.g., ring 714, which is formed of or includes the malleable shape-memory material, and which optionally may be sinusoidal. Third component 730 may include any suitable number of rings, e.g., rings 715, 716, which are formed of or include the third self-expanding material, and which optionally may be sinusoidal. Struts 711, 708 may join the rings of first component 710, second component 720, and third component 730 to one another.

[0152] First component 710 may provide a first flared end region 702, third component 730 may provide a second end flared region 706, and second component 720 may provide a neck region 704 disposed between the first and second flared end regions. The inlet and outlet of device 700 may include flanges 702, 706, and the neck 704 may include flexible longitudinal bars 711, 708 and a sinusoidal ring 714. The flexible longitudinal bars 711, 708 may allow the flanges to fully expand upon deployment; and the sinusoidal ring may have sufficient strength to maintain its diameter when balloon dilated or heat contracted.

[0153] In the nonlimiting example shown in FIG. 7, first flared end region 702 has first end region dimension D1, second flared end region 706 has second end region dimension D2, and neck region 704 has neck dimension D3 which may be increased or reduced in a manner such as described with reference to second component 220 illustrated in FIGS. 2A-2E. As shown in FIG. 7, neck region 704 of shunt 700 may be significantly narrower than flared end regions 702 and 706, e.g., may have a smaller cross sectional area and a smaller dimension than do flared end regions 702 and 706. Also shown in FIG. 7, shunt 700 may be asymmetric. For example, shunt 700 may be asymmetric to take advantage of the natural features of the atrial septum of the heart as well as the left and right atrium cavities. Alternatively, hourglass shaped shunt 700 may be symmetric with the first end region dimension D1 being equal to the second end region dimension D2. First flared end region 702 and second flared end region 706 also may have either straight or curved profiles or both. For example, strut 711 has a straight profile and strut

708 has a curved profile. Additionally, first flared end region 702 and second flared end region 706 may assume any angular position consistent with the hour-glass configuration.

[0154] Shunt 700 suitably may be formed in a manner such as described elsewhere herein. For example, in some configurations, shunt 700 is laser-cut from a single tube of NITINOL in a manner such as described with reference to device 600 illustrated in FIG. 6, and different regions of the NITINOL are heat treated differently than one another so as respectively to define self-expanding superelastic material(s) and malleable shape-memory materials. As such, the first, second, and third components 710, 720, 730 of device 700 optionally may be unitary with one another. The first and third self-expanding materials optionally may be the same material as one another. In other configurations, the first, second, and third components 710, 720, 730 of device 700 may be formed independently of one another and assembled together, e.g., in a manner such as described with reference to FIGS. 5A-5B and as further exemplified with reference to FIGS. 11A-12B, described below. Additional optional modifications of shunt 700 are described with reference to FIGS. 13A-13B, 25A-25D, 26A-26H, and 27A-27K, described below.

[0155] FIGS. 8A-8D schematically illustrate example steps for using the device of FIG. 7 in the human body. Shunt 700 may be crimped to a cylindrical shape, for example by pushing it through a conical loading device. In one nonlimiting example, shunt 700 may be crimped to an outer dimension of about 4.6 mm, the inside dimension of a 14F Cook sheath. The sheath may be percutaneously placed through a blood vessel to a desired location in the human body, and the crimped shunt may be placed in the sheath in a manner similar to that illustrated in FIG. 2A. As the crimped shunt is pushed out of the sheath, the self-expanding superelastic flared end regions spring open to their set configuration, while the malleable shape-memory central neck region remains constrained at or near its crimped dimension, e.g., in a manner such as illustrated in FIG. 8A in which the neck region (designated “B” and corresponding to second component 220) engages an opening in the human body. Depending on the desired direction of blood flow through device 700, one of the flared ends (designated “A” or “C” and corresponding to first component 210 or third component 211) provides an inlet and the other of the flared ends (designated “C” or “A” and corresponding to third component 211 or first component 210) provides an outlet. For example, the neck region may engage an opening created through a fossa

ovalis of an interatrial septum between a right atrium and a left atrium, one of the flared ends extends into the right atrium, and the other flared end extends into the left atrium. In some configurations, the flared end in the right atrium is an inlet and the flared end in the left atrium is an outlet, whereas in other configurations, the flared end in the left atrium is an inlet and the flared end in the right atrium is an outlet.

[0156] The cross sectional area (and dimension) of the orifice provided by the malleable shape-memory central neck region may be increased or reduced so as to adjust the flow of fluid through shunt 700. For example, in a manner such as illustrated in FIG. 8B, the neck region may be expanded by balloon dilatation using a balloon 801, which may be fed through the orifice using a wire 802. Additionally, in a manner such as illustrated in FIG. 8C, the neck region may be contracted by injecting, via catheter 803, a bolus of hot saline having a temperature above the A_f of the malleable shape-memory material (e.g., at 45-60°C), which may cause the neck region to return to its heat-set dimension, which may be different from its crimped dimension, in a manner such as illustrated in FIG. 8D.

[0157] For example, heat from the saline may cause the malleable shape-memory material to transition to an austenitic phase, compressing the neck region back to its crimped (or otherwise heat set) dimension, following which the neck region cools to body temperature and transitions back to its martensitic phase. The saline may be delivered in any suitable manner, for example by a flexible catheter having one or more apertures (e.g., one side hole or multiple side-holes) through which hot saline may flow and that may be placed within the neck region, for example, over a guidewire through the neck region. In one nonlimiting example, the neck region may have its crimped inner dimension, typically 1-2 mm, at a first time, such as when initially deployed in a manner such as illustrated in FIG. 8A. The neck region then may be expanded using balloon dilatation to any desired larger dimension between the crimped dimension and 7 mm at a second time. The neck region then may be contracted using hot saline to its heat-set dimension, D0, at a third time. Dimension D0 is determined by the size of the jig used in a heat-setting step during manufacture. D0 may be greater than the dimension of the catheter used to deliver hot saline, and greater than the deflated dimension of the dilation balloon, but smaller than or equal to the smallest anticipated desired final shunt dimension, for example 4 mm. The

neck region then again may be expanded using balloon dilatation to any desired larger dimension between 4 mm and 7 mm at a second time. Any suitable number of expansions and contractions may be applied to the neck region, at any desired time or at separate times than one another, so as to provide a suitable, and customized, flow of fluid through the device for each given patient. It will be appreciated that what constitutes a suitable flow of fluid for a given patient also may change over time, and that the present devices suitably may be adjusted--so as to provide that flow of fluid as appropriate, or so as to suitably fixate the devices within a lumen. It will also be appreciated that the self-expanding superelastic components are not affected by the injection of hot saline, and so will retain their initial full expanded dimension while the shape-memory component (in this example the neck region) is being adjusted. Furthermore, any suitable method for heating the shape memory materials may be used besides or in addition to hot saline, e.g., RF heating or the use of a laser, magnetic inductance, electrical resistance, or the like in a manner such as described with reference to FIGS. 1A-1E.

[0158] The particular configuration of shunt 700 may be selected so as to provide desired flow dynamics therethrough. For example, FIGS. 9A-9B schematically illustrate example configurations of the device of FIG. 7. In FIGS. 9A-9B, the geometry of the inlet and outlet inner dimensions (e.g., the inlet and outlet angles α and β) may be selected so as to adjust the flow dynamics through shunt 700. Apart from adjusting the flow dynamics so as to treat a specific clinical condition, the capability to narrow the inlet or outlet, or both, may reduce the risk of passage of thrombus into or through the device lumen.

[0159] Shunt 700 (or any other device provided herein) may be made using any suitable combination of techniques. FIGS. 10A-10C schematically illustrate example uses of tooling for preparing the device of FIG. 7. As shown in FIGS. 10A-10C, the shunt 700 (or any other device provided herein) may be heat treated within tooling 1000 which allows for the component(s) which are to be substantially self-expanding superelastic material to be maintained at a cooler temperature (e.g., individually insulated or heat-sunked by dies 1001, 1002 within the tooling) than the component(s) which are to be substantially malleable shape-memory material, e.g., which may be exposed such as at region 1003 illustrated in FIG. 10C. As such, the exposed component(s) may receive a greater heat flux during the heat treatment which may result in a

predetermined higher Af temperature as compared to component(s) that are insulated or kept cooler by contact with a heat sink. The temperature gradient between the heated and cooled regions may result in a transition zone between a region that is substantially martensitic at body temperature (37 °C) and a region that is substantially austenitic at body temperature. The heat treatment may be implemented by a furnace, induction heating, an electrical current, or any other suitable and controllable energy source. The difference in heat flux (which may result in a higher Af for the component(s) which are to be substantially malleable shape-memory material) also may be achieved by providing that component with a different (lower) wall thickness, e.g., as may be achieved by material removal from a NITINOL tube prior to laser cutting or using an additive manufacturing process to manufacture the device.

[0160] It will be appreciated that tooling 1000 is optional, and that any of the devices herein (illustratively, device 200 described with reference to FIGS. 2A-2E; device 700 described with reference to FIGS. 7, 8A-8D, 9A-9B, and 10A-10C; device 1110 described with reference to FIGS. 11A-11B; device 1210 described with reference to FIGS. 12A-12B; device 1300 described with reference to FIGS. 13A-13B; device 28 described with reference to FIGS. 23A-23E; device 2500 described with reference to FIGS. 25A-25D; device 2600 described with reference to FIGS. 26A-26H; device 2700 described with reference to FIGS. 27A-27K; or any of devices 2800, 2800', 2800'' described with reference to FIGS. 28A-28D, 29A-29D, and 30A-30C) suitably may be formed using localized heat-treating of one or more portions of each such device to produce a different Af from un-heated portion(s) of the device. Such localized heating of portion(s) of the device may be performed, for example, using induction heating, optionally with active cooling of adjacent areas. Additionally, or alternatively, such localized heating of portion(s) of the device may be performed using localized laser heating, optionally with active cooling of adjacent areas. Furthermore, it is known that the effect of heat treatment on NITINOL Af is cumulative, such that the same effect can be produced by a plurality of short duration heat treatments to a given temperature as by a single longer duration treatment at that temperature. Thus it is contemplated that a series short, intense, localized laser heating pulses, the intensity and duration of each pulse chosen to raise to the area in the laser beam to the desired heat treatment temperature, combined

with active cooling, such as by a flow of cold Argon or other suitable gas, may allow highly localized increase of Af while maintaining a lower Af at adjacent areas.

[0161] It will further be appreciated that wires of different Af temperatures may be used to prepare the present devices. For example, in a manner such as described with reference to FIGS. 27A-27K, wires having different Af temperatures than one another, and/or wires having different Af temperatures along the length of the wire, may be used to prepare the present devices. Such wires may be used to manufacture devices having multiple Af temperatures (e.g., multiple phases of NITINOL), illustratively using wire-wrap techniques, wire-mesh techniques, or any suitable combination thereof.

[0162] It will further be appreciated that any suitable combination of superelastic and shape memory NITINOL components may be used within the present devices.

[0163] Additionally, or alternatively, shunt 700 (or any other device provided herein) may be made using a multi-material additive manufacturing process. For example, the higher Af component(s) which are to be malleable shape-memory material may be provided by using selective laser melting or an electron beam melting powder bed machine which has two or more powder-bins between which the machine could switch during the print process. The Af of a given component may be manipulated by the powder's chemical composition, e.g., different fractions of nickel titanium or of any other element(s) that may be present. For example, the higher the nickel percentage, the higher the Af. The Af of a given component also or alternatively may be manipulated by the powder's physical composition, e.g., particle sizes. For example, the smaller the powder dimension, the lower the Af. For further details of manipulating the Af of materials during a multi-material additive manufacturing process, see Horvay and Schade, "Development of nitinol alloys for additive manufacturing," the entire contents of which are incorporated by reference herein. As another option, the multi-material may be achieved by liquid dispersion methodology (material jetting). For example, a 3-D printer may include two or more cartridges with different powder-liquid compositions in each, in a manner similar to that described for the powder-based example.

[0164] FIGS. 11A-11B schematically illustrate another example modification of the device of FIG. 7. In one specific, nonlimiting example, modified shunt 1100 includes an austenite phase (self-expanding superelastic) NITINOL inner frame and a martensite phase (malleable shape-memory) NITINOL outer frame (structural member). The inner frame may include first component 1110 (corresponding to first flared end region 702) and third component 1111 (corresponding to second flared end region 706). The outer frame may include second component 1120 (corresponding to neck region 704). The A_f of the martensite outer frame may be in the range of 45-60°C, e.g., about 50-55°C. The outer frame may be localized to the shunt neck region (which may be, for example, approximately 5 mm in length) and may not extend to the atrial cones 1110, 1111. The inner and outer frames may be designed so that when placed together their respective geometries mechanically interfere so that they remain co-registered. The martensite outer frame may be heat set for a smaller inner dimension (e.g., 4 mm), while the austenite inner frame may be heat set for a larger orifice dimension (e.g., 7 mm). The inner and outer frames may be constructed such that the force required to expand the outer martensite frame is greater than that produced by the superelasticity of the inner frame, so that at any expanded dimension the martensitic outer frame is strong enough to contain the austenitic inner frame dimension, in a manner similar to that described with reference to FIG. 5B. At room temperature and at body temperature, the martensitic outer frame may be malleable and may be plastically deformed, e.g., by incremental balloon dilatation which may expand its inner dimension by any desired amount, illustratively in the range of 4-7 mm, depending on the balloon dimension and the expanding pressure, e.g., up to 12 atm. The martensitic outer frame may radially contact an outer surface of the neck of the austenitic inner frame so as to constrain the neck from self-expanding to a larger dimension. Responsive to the martensitic outer frame expanding to the larger dimension, the neck self-expands. The two co-registered frames may be encapsulated with ePTFE or other suitable biocompatible material so as to create a smooth path for blood flow and to block proliferating tissue ingress during healing after implantation. For example, the martensite outer frame, which may or may not be encapsulated, may be applied over an encapsulated inner frame, or the martensite outer frame may be applied to a bare inner frame and the two frames together then encapsulated. The encapsulant may form an inner lumen

through a portion of the inner frame (e.g., through component 1110) and an outer covering of the device (e.g., of components 1110 and component 1120).

[0165] In an alternative configuration (not specifically illustrated), the martensitic frame including second component 1120 (corresponding to neck region 704) may be placed inside of the outer austenitic frame including first component 1110 (corresponding to first flared end region 702) and third component 1111 (corresponding to second flared end region 706). With proper mechanical interference, such as by laser spot welding interlocking shapes, the shorter martensitic frame may pull the center of the outer austenitic frame inward when heated above A_f . For example, the martensitic inner frame may radially contact an inner surface of the neck so as to constrain the neck from contracting to a smaller dimension. The neck may self-contract responsive to the martensitic inner frame contracting to a smaller cross sectional area. An encapsulant may form an outer covering of first component 1110 and second component 1120.

[0166] However, the martensitic frame need not necessarily be welded or otherwise directly coupled to the austenitic frame. For example, FIGS. 12A-12B schematically illustrate another example modification 1210 of the device of FIG. 7 in which the shorter martensitic frame 1120 (corresponding to neck region 704) is placed inside of the outer austenitic frame including first component 1110 (corresponding to first flared end region 702) and third component 1111 (corresponding to second flared end region 706) but is not directly coupled thereto. Instead, encapsulant 1140 encapsulates both inner martensitic frame 1120 and outer austenitic frame 1110, 1111 and indirectly and elastically couples the martensitic and austenitic frames to one another. In this example, the heat treatment for the neck of the superelastic outer frame may be heat set to the maximum dimension contemplated for treatment, e.g., 7 mm, rather than to the smallest such dimension as in the above two examples, e.g., 4 mm. Because there is no direct mechanical coupling between the superelastic outer austenitic frame and the shape-memory inner martensitic frame, when implanted in the body the outer frame may expand to the maximum dimension, e.g., 7 mm, or to a smaller dimension if constrained by the body (e.g., by opening 1280 through which the device is lodged). The hoop strength of the outer austenitic frame may be engineered so as to be slightly less than the constrictive force of the body opening 1280, such that the outer frame may maintain contact with opening 1280 without causing enough force to

dilate the opening. The hoop strength of the outer austenitic frame may be adjusted, for example, by choosing a suitable frame tubing thickness and laser-cut frame pattern. The inner malleable shape-memory frame may be stronger than the outer frame and stronger than the compressive force of body opening 1280, so even if the inner frame is expanded to a dimension larger than the opening 1280 dimension of the outer frame as described above (e.g., to a dimension of 4-7 mm), it will maintain that dimension after the dilating balloon is deflated and removed.

[0167] Furthermore, because there is no direct attachment between the inner and outer frames in device 1210, the inner martensitic frame 1120 may returned to its original predilated dimension by application of heat in a manner such as described above, while leaving the outer frame constrained only by contact with opening 1280, as shown in FIG. 12B. Such a configuration may inhibit or prevent loss of contact of the device with opening 1280 (such as an opening through the septal wall), which otherwise may result in a peri-shunt leak that may allow a greater flow of blood from one atrium to another than desired. Additionally, because the inner dimension of the device may be changed independently of the outer dimension (for example, reducing the dimension of the inner martensitic frame device does not change the dimension of the outer austenitic frame), leaving the outer dimension in contact with the opening, there may be reduced, minimal, no disruption or injury to the healing or healed puncture site, and reduced, minimal, or no risk of dislodgment of any thrombus, vegetation, or other tissue that may have grown around the outside of the device during the healing process following formation of opening 1280, e.g., following septal wall puncture and device implantation.

[0168] It will be appreciated that the martensitic outer frame of modified shunt 1110 may include any suitable structure that is plastically deformable at body temperature and also is thermally contractible. For example, FIGS. 25A-25D schematically illustrate an example modification of the device of FIG. 7. In one specific, nonlimiting example, modified shunt 2500 illustrated in FIGS. 25A-25D includes an austenite phase (self-expanding superelastic) NITINOL inner frame 2510 and a martensite phase (malleable shape-memory) NITINOL outer frame 2520 (structural member). The inner frame 2510 may include first component 2511 (corresponding to first flared end region 702) and third component 2512 (corresponding to second flared end region

706). The outer frame 2520 may include a second component 2513 (corresponding to neck region 704). The A_f of the martensite outer frame 2520 may be in the range of 45-60°C, e.g., about 50-55°C. The A_f of the austenite inner frame 2510 may be below body temperature, e.g., may be about 5-20°C. The outer frame 2520 may be localized to the shunt neck region 2513 (which may be, for example, approximately 5 mm in length) and may not extend to the atrial cones 2511, 2512. The inner and outer frames may be designed so that when placed together their respective geometries mechanically interfere so that they remain co-registered. For example, in a manner such as illustrated in FIGS. 25A-25B, outer frame 2520 may include a compression coil that has a fixed length, and thus wraps around neck region 2513 by a number of turns that differs in the collapsed state (FIG. 25A and FIG. 25C) as compared to the expanded state (FIG. 25B and FIG. 25D), and as such may provide a varying amount of compressive force depending on its expansion. The compression coil of outer frame 2520 may be substantially cylindrical, as illustrated in FIGS. 25A-25D.

[0169] For example, in a manner similar to that described with reference to FIGS. 11A-11B, the martensite outer frame 2520 may be coiled up and heat set for a smaller inner dimension (e.g., 4 mm), while the austenite inner frame 2510 may be heat set for a larger orifice dimension (e.g., 7 mm) and the outer frame 2520 later physically attached to inner frame 2510. In an environment below the A_f of outer frame 2520, the coil of the outer frame may be straightened and then one end of it may be physically attached to inner frame 2510, e.g., via an interlock or the like. The attached inner and outer frames 2510, 2520 then may be constrained in a fixture, and the fixture subjected to an elevated temperature (e.g., placed in an oven) so as to cause the previously straightened coil of outer frame 2520 to return to its coiled shape and wrap around inner frame 2510.

[0170] The inner and outer frames 2510, 2520 may be constructed such that the force required to expand the outer martensite frame is greater than that produced by the superelasticity of the inner frame, so that at any expanded dimension the martensitic outer frame is strong enough to contain the austenitic inner frame dimension, in a manner similar to that described with reference to FIG. 5B. In the collapsed state illustrated in FIG. 25A, the compression coil of outer frame 2520 may wrap around neck region 2513 by a first number of turns that exert a relatively large compressive

force on inner frame 2510. At room temperature and at body temperature, the martensitic outer frame 2520 may be malleable and may be plastically deformed, e.g., by incremental balloon dilatation which may expand its inner dimension by any desired amount, illustratively in the range of 4-7 mm, depending on the balloon dimension and the expanding pressure, e.g., up to 12 atm. The martensitic outer frame 2520 may radially contact an outer surface of the neck of the austenitic inner frame 2510 so as to constrain the neck from self-expanding to a larger dimension. Responsive to the martensitic outer frame 2520 expanding to the larger dimension, the neck 2513 of inner frame 2510 self-expands. In the expanded state illustrated in FIG. 25B, the number of coil wraps of outer frame 2520 about the inner frame 2510 is reduced, which in turn reduces the compressive force that the outer frame exerts on inner frame 2510. The variable compressive force exerted by outer frame 2520 may be engineered so as to balance the outward force of inner frame 2510, which is greatest when the inner frame is compressed to a small diameter, and may become negligible when the inner frame reaches its heat-set diameter. Increased compression of the shunt (e.g., such as illustrated in FIG. 25A) may be compensated using increased force, e.g., an increased number of overlapping coils to maintain the shunt in the compressed state (e.g., such as illustrated in FIG. 25C), while decreased compression of the shunt (e.g., such as illustrated in FIG. 25B) may be compensated using reduced force, e.g., a reduced number of overlapping coils to maintain the shunt in the compressed state (e.g., such as illustrated in FIG. 25D).

[0171] In a manner similar to that described with reference to FIGS. 11A-11B, inner frame 2510 may be encapsulated with ePTFE or other suitable biocompatible material so as to create a smooth path for blood flow and to block proliferating tissue ingress during healing after implantation. The martensite outer frame 2520, which may or may not be encapsulated, may be applied over an encapsulated inner frame 2510. In one nonlimiting example, the outer frame 2520 may be independently coated in a relatively thin film (e.g., about 0.005") of PTFE, e.g., while the outer frame is in a straightened state prior to coiling. Such coating may inhibit tissue adhesion, while allowing outer frame 2520 to coil and uncoil relative to the encapsulated inner frame 2510.

[0172] FIGS. 26A-26H schematically illustrate another example modification of the device of FIG. 7. In one specific, nonlimiting example, modified shunt 2600 illustrated in FIGS. 26A-26H includes an austenite phase (self-expanding superelastic) NITINOL inner frame 2610 and a martensite phase (malleable shape-memory) NITINOL outer frame 2620 (structural member). The inner frame 2610 may include first component 2611 (corresponding to first flared end region 702) and third component 2612 (corresponding to second flared end region 706). The outer frame 2620 may include a second component 2613 (corresponding to neck region 704). The A_f of the martensite outer frame 2620 may be in the range of 45-60°C, e.g., about 50-55°C. The A_f of the austenite inner frame 2610 may be below body temperature, e.g., may be about 5-20°C. The outer frame 2620 may be localized to the shunt neck region 2613 (which may be, for example, approximately 5 mm in length) and may not extend to the atrial cones 2611, 2612. The inner and outer frames may be designed so that when placed together their respective geometries mechanically interfere so that they remain co-registered. For example, in a manner such as illustrated in FIGS. 26A-26D, outer frame 2620 may include a compression spring that has a fixed length, and thus wraps around neck region 2613 by a number of turns that differs in the collapsed state (FIGS. 26A-26D) as compared to the expanded state (FIGS. 26E-26H), and as such may provide a varying amount of compressive force depending on its expansion. The compression spring of outer frame 2620 may include hooks 2621 that retain the spring in position relative to inner frame 2610. The compression spring of outer frame 2620 may be non-cylindrical, e.g., may be diabolo-shaped as illustrated in FIGS. 26A-26H.

[0173] In a manner similar to that described with reference to FIGS. 11A-11B, the martensite outer frame 2620 may be heat set for a smaller inner dimension (e.g., 4 mm), while the austenite inner frame 2610 may be heat set for a larger orifice dimension (e.g., 7 mm). The inner and outer frames 2610, 2620 may be constructed such that the force required to expand the outer martensite frame is greater than that produced by the superelasticity of the inner frame, so that at any expanded dimension the martensitic outer frame is strong enough to contain the austenitic inner frame dimension, in a manner similar to that described with reference to FIG. 5B. In the collapsed state illustrated in FIG. 26A, the compression spring of outer frame 2620 may wrap around neck region 2613 by a first number of turns that exert a relatively large compressive force

on inner frame 2610. At room temperature and at body temperature, the martensitic outer frame 2620 may be malleable and may be plastically deformed, e.g., by incremental balloon dilatation which may expand its inner dimension by any desired amount, illustratively in the range of 4-7 mm, depending on the balloon dimension and the expanding pressure, e.g., up to 12 atm. The martensitic outer frame 2620 may radially contact an outer surface of the neck of the austenitic inner frame 2610 so as to constrain the neck from self-expanding to a larger dimension.

Responsive to the martensitic outer frame 2620 expanding to the larger dimension, the neck 2613 of inner frame 2610 self-expands. In the expanded state illustrated in FIGS. 26D-26H, the number of spring coils of outer frame 2620 about the inner frame 2610 is reduced, which in turn reduces the compressive force that the outer frame exerts on inner frame 2610. The variable compressive force exerted by outer frame 2620 may be engineered so as to balance the outward force of inner frame 2610, which is greatest when the inner frame is compressed to a small diameter, and may become negligible when the inner frame reaches its heat-set diameter. Increased compression of the shunt (e.g., such as illustrated in FIGS. 26A-26D) may be compensated using increased force, e.g., an increased number of spring coils to maintain the shunt in the compressed state (e.g., such as illustrated in FIG. 26D), while decreased compression of the shunt (e.g., such as illustrated in FIGS. 26E-26H) may be compensated using reduced force, e.g., a reduced number of spring coils to maintain the shunt in the compressed state (e.g., such as illustrated in FIG. 26H).

[0174] In a manner similar to that described with reference to FIGS. 11A-11B, inner frame 2610 may be encapsulated with ePTFE or other suitable biocompatible material so as to create a smooth path for blood flow and to block proliferating tissue ingress during healing after implantation. The martensite outer frame 2620, which may or may not be encapsulated in a manner similar to that described with reference to outer frame 2520, may be applied over an encapsulated inner frame 2610.

[0175] FIGS. 27A-27K schematically illustrate another example modification of the device of FIG. 7. Turning first to FIGS. 27A-27E, showing device 2700 in the expanded state, the device may include a diabolo-shaped shunt 2700 manufactured from multiple lengths of wire 2730, e.g., between about 3 and about 12 pieces of wire, e.g., 6 pieces of wire in the nonlimiting example

shown in FIGS. 27A-27D. In some examples, one or more portions of one or more wires 2730 of device 2700 may include or may be formed of austenite phase (self-expanding superelastic) NITINOL, while one or more other portions of that wire may include or may be formed of martensite phase (malleable shape-memory) NITINOL. Additionally, or alternatively, one or more individual wires 2730 of device 2700 may include or may be formed entirely of austenite phase (self-expanding superelastic) NITINOL, while one or more other individual wires 2730 may include or may be formed entirely of martensite phase (malleable shape-memory) NITINOL. The wires 2730 may be wound or welded together in such a manner that shunt 2710 includes first component 2711 (corresponding to first flared end region 702), second component 2713 (corresponding to neck region 704), and third component 2712 (corresponding to second flared end region 706). The A_f of the martensite second component 2713 may be in the range of 45-60°C, e.g., about 50-55°C. The A_f of the austenite first and second components 2711, 2712 may be below body temperature, e.g., may be about 5-20°C. The wires 2730 may be configured so as to localize the martensite phase to the shunt neck region 2713 (which may be, for example, approximately 5 mm in length), and to localize the austenite phase to the atrial cones 2711, 2712.

[0176] In a manner similar to that described with reference to FIG. 7, the martensite region 2713 may be heat set for a smaller inner dimension (e.g., 4 mm), and may be plastically deformed to a larger inner dimension (e.g., 7 mm), depending on the balloon dimension and the expanding pressure, e.g., up to 12 atm. In a manner similar to that described elsewhere herein, shunt 2710 may be encapsulated with ePTFE or other suitable biocompatible material so as to create a smooth path for blood flow and to block proliferating tissue ingress during healing after implantation.

[0177] Each of wires 2730 may have any suitable configuration. For example, in a manner such as illustrated in FIG. 27E, each individual wire 2730 may have first and second ends that are suitably coupled one another in region 2731, e.g., via overlap, welding, or an over swaged tube such as illustrated in FIG. 27F. As also illustrated in FIG. 27F, one or more of wires 2730 may be coupled to one another, and/or one or more portions of a given wire may be coupled to one or more other portions of the same wire, using windings 2733. As also illustrated in FIG. 27F, one or more of wires 2730 may be coupled to one another, and/or one or more portions of a given

wire may be coupled to one or more other portions of the same wire, using sleeves 2732. Illustratively, sleeves 2732 may include or may be made from a radiopaque material which would be visible under x-ray, such as platinum or tantalum. It will be appreciated that the such radiopaque sleeves 2732 may render the features of device 2700 readily visible using x-ray imaging, and thus may facilitate the positioning of device 2700 in vivo as well as the appropriate expansion/contraction of the inner diameter of neck region 2713.

[0178] Additionally, or alternatively, one or more of wires 2730 may include a radiopaque material, such as platinum or tantalum. Illustratively, in the example shown in FIG. 27G, wire 2730 may include inner core 2740 formed of or including the radiopaque material, and a plurality of strands 2741 surrounding the inner core and formed of or including NITINOL in a martensite or austenite phase, depending on the location within device 2700 of a given portion of the wire. Alternatively, in the example shown in FIG. 27H, wire 2730 may include inner core 2743 formed of or including the radiopaque material, and overlay 2742 surrounding the inner core and formed of or including NITINOL in a martensite or austenite phase, depending on the location within device 2700 of a given portion of the wire. Alternatively, in the example shown in FIG. 27I, wire 2730 may include inner core 2744 formed of or including NITINOL in a martensite or austenite phase, depending on the location within device 2700 of that portion of the wire, and overlay 2745 formed of or including the radiopaque material and surrounding the inner core. It will be appreciated that each wire 2730 may be made from a variety of raw materials and having any suitable configuration, including stranded constructions (e.g., FIG. 27G) or drawn filled tube (DFT) constructions (e.g., FIGS. 27H-27I) so as to impart any suitable combination of features, such as super elasticity, plasticity, and/or radiopacity.

[0179] Additionally, or alternatively, each given portion of each wire 2730 may be suitably heat treated before being used to construct device 2700, and/or after being used to construct device 2700. For example, FIG. 27J illustrates wire 2730 including first end 2751 and second end 2752, and having a plurality of martensite phase sections (high Af) and a plurality of austenite phase sections (low Af) along its length. Illustratively, the martensite phase sections and austenite phase sections may alternate, such that when wire 2730 is shaped in a manner such as illustrated in FIG. 27K to form a portion of device 2700, different zones of the shaped wire have either the

martensite phase (Af above body temperature) or the austenite phase (Af below body temperature).

[0180] Another way to provide a device for which the inner dimension may be reduced in-vivo is to place a shunt inside of another shunt. This “shunt-in-shunt” approach may be useful, for example, in the circumstance where it would be desired to change the inner shunt anytime after implanting the outer shunt. For example, FIGS. 13A-13B schematically illustrate another example modification of the device of FIG. 7 including a “shunt-in-shunt” arrangement. FIG. 13A illustrates an example cylindrical shunt 1360 that may be used as an inner shunt, e.g., an Advanta V12 balloon expandable covered stent, which is encapsulated in PTFE and commercially available from Getinge AB (Gothenburg, Sweden). In a manner such as illustrated in FIG. 13B, device 1300 may include shunt 1360 placed within shunt 700 described with reference to FIG. 7. In some examples, inner shunt 1360 and outer shunt 700 may be encapsulated independently from one another, may be separable from one another, and optionally may be implanted independently from one another. Inner shunt 1360 may include a malleable shape-memory material, and outer shunt 700 may include a self-expanding superelastic material.

[0181] Illustratively, outer shunt 700 may be implanted in a patient at a first time, and may have a neck dimension that is initially expected to be suitable for the patient. If, at a later time, it may be determined that a different neck dimension would be more suitable for the patient, inner shunt 1360 may be implanted within outer shunt 700 so as to provide that neck dimension, which may be smaller or larger than the neck dimension of outer shunt 700. Inner shunt 1360 may be expanded and optionally contracted in a manner such as to define the rate of fluid flow through device 1300. For example, if it is desired to increase the rate of fluid flow through device 1300, inner shunt 1360 may be selected so as to have a larger dimension than device 700 and a hoop strength sufficient to suitably expand the dimension of device 700 and of any opening through which device 700 may be lodged. In such an example, inner shunt 1360 need not necessarily include a malleable shape-memory material, but instead may include a self-expanding superelastic material that may be heat-set so as to have a maximum neck dimension of suitable size and flared ends that respectively contact the flared ends for outer shunt 700 so as to inhibit

the flow of blood between the two shunts. In another example, inner shunt 1360 may include a neck with a malleable shape-memory material with a heat-set minimum neck dimension of suitable size, and self-expanding superelastic flared ends that respectively contact the flared ends for outer shunt 700 so as to inhibit the flow of blood between the two shunts. The size of the neck of inner shunt 1360 may be increased and reduced in a manner such as described elsewhere herein. Optionally, inner shunt 1360 may be implanted at the same time as outer shunt 700, e.g., may be disposed within outer shunt 700, the two shunts crimped together and delivered through a sheath, and both deployed simultaneously with one another through the sheath.

[0182] It will be appreciated that the present devices may be used in any suitable part(s) of the human body, and are not limited to transatrial shunts. For example, FIGS. 14A-14C schematically illustrate another example device with multiple internal dimensions that can be reduced and increased *in vivo*, and an example of its use in the human body. Device 1400 illustrated in FIGS. 14A-14C may be used, for example, for treating an abdominal aortic aneurism 140 (AAA). Device 1400 includes a component including a self-expanding superelastic material (designated “B”) which may be positioned within AAA 140, and one or more components respectively including malleable shape-memory materials (designated “A” and “C”). Components A and C may have smaller dimensions than component B when initially implanted. Device 1400 may be percutaneously delivered by crimping the device to a cylindrical shape using a crimper, placed within a sheath, and delivered over guidewire 1401 through the external iliac artery to the desired location (abdominal aortic – pararenal). The crimped device 1400 may be implanted such that the distal end (component A) is below the renal ostium and component B is within AAA 140, as illustrated in FIG. 14A. Following implantation, component A may be expanded (e.g., using balloon 1402 dilatation) in a manner such as illustrated in FIG. 14B so as to inhibit the leakage of blood between the device and the blood vessel, and to fixate the device in the desired position.

[0183] In some cases, following implantation the inner dimension of the blood vessel may increase which may result in an endoleak. To seal such endoleak, or for any other desired purpose, component C may be expanded (e.g., using balloon 1403 dilatation). As such, fluid flow through AAA 140 may be shunted through device 1400 in such a manner as to reduce the

risk of rupture of the AAA. If it is desired to move device 1400, then the dimensions of components A and C may be reduced by applying heat in a manner such as described elsewhere herein. Device 1400 then may be removed, or may be moved to a new location as desired and the dimensions of one or both of components A and C again may be expanded so as to fixate the device in the blood vessel. It should be appreciated that the shape-memory material of component C (corresponding to third component 321) may have a first cross sectional area, which may be expanded, contracted (e.g., to a heat-set dimension), and then re-expanded. The cross sectional areas of component A (corresponding to second component 320) and C may be, but need not necessarily be, the same as one another. Component A (corresponding to second component 320) may be configured as an inlet, and component C (corresponding to third component 321) may be configured as an outlet fluidically coupled to the inlet via component B (corresponding to first component 310). Component A may be configured to engage a blood vessel in the human body, and component C may be configured to extend into an ostium of the blood vessel in a manner such illustrated in FIGS. 14A-14C. A fourth component C may extend into a different ostium of the blood vessel in a manner such as illustrated in FIGS. 14A-14C. In one example, when device 1400 is first positioned in the blood vessel, component B is fully expanded, and components A and C are compressed (crimped); after orientation confirmation of component B and ensuring that the side-branch arteries are not occluded, components A and C may be opened in a controlled manner.

[0184] FIGS. 15A-15D schematically illustrate another example device with an internal dimension that can be reduced and increased *in vivo*, and an example of its use in the human body. Device 1500 illustrated in FIGS. 15A-15C may be used, for example, for treating a fenestrated AAA 150. Device 1500 includes one or more components respectively including self-expanding superelastic materials (designated “A” and “C”), one of which may be positioned within AAA 150, and a component including a malleable shape-memory material (designated “B”). Components A and C may have larger dimensions than component B when initially implanted. Device 1500 may be percutaneously delivered by crimping the device to a cylindrical shape using a crimper, placed within a sheath, and delivered over guidewire 1501 through the external iliac artery to the desired location (abdominal aortic – suprarenal). The crimped device

1500 may be implanted such that the distal end (component A) is above the renal ostium 150, component B is adjacent the renal ostium, and component C is within AAA 150, as illustrated in FIG. 15A. The smaller initial outer dimension of component B may facilitate the positioning of a guidewire into the renal artery. Following the positioning of the guidewire, renal stents 1550, 1560 respectively may be inserted into the renal arteries via introducers, as illustrated in FIG. 15B. While the sheaths are in place, component B may be balloon expanded, as illustrated in FIG. 15C. If at this stage the position of the guidewire is lost, the dimension of component B may be reduced by application of heat. Following dilatation of component B, covered stents may be deployed in the renal arteries. Stents 1550, 1560, together with device 1500 following removal of the sheaths, may provide a fenestrated endovascular graft to repair AAA 150, such as illustrated in FIG. 15D. As such, fluid flow through AAA 150 may be shunted through device 1500, which is supported by stents 1550, 1560, in such a manner as to reduce the risk of rupture of the AAA. Additionally, as compared to previously known devices, device 1500 may provide an expandable middle section B which beneficially may reduce blood flow velocity and turbulent flow.

[0185] FIGS. 16A-16B schematically illustrate another example device with an internal dimension that can be reduced and increased *in vivo*, and an example of its use in the human body. Device 1600 illustrated in FIGS. 16A-16B may be used, for example, for providing aortic or mitral valve replacement devices or for closing the left atrial appendage (LAA). Device 1600 includes a component including a self-expanding superelastic material (designated “A”) which may be positioned within a desired portion of a blood vessel, such as the aortic artery, and a component including a malleable shape-memory material (designated “B”). Component B may have a smaller dimension than component A when initially implanted. Device 1600 may be percutaneously delivered by crimping the device to a cylindrical shape using a crimper, placed within a sheath, and delivered over guidewire 1601 through blood vessels to the desired location, as illustrated in FIG. 16A. Following implantation, component B may be expanded (e.g., using balloon 1602 dilatation) in a manner such as illustrated in FIG. 16B so as to inhibit the leakage of blood between the device and the blood vessel, and to fixate the device in the desired position. As such, fluid flow through the blood vessel may be shunted through device 1600 in such a

manner as to treat the patient, e.g., so as to replace the aortic or mitral valve, or so as to close the LAA. If it is desired to move device 1600, then the dimensions of component B may be reduced by applying heat in a manner such as described elsewhere herein. Device 1600 then may be removed, or may be moved to a new location as desired and the dimension of component B again may be expanded so as to fixate the device in the blood vessel. In configurations in which it is desired to replace a valve, such as the aortic or mitral valve, device 1600 may include a valve disposed either in component A or in component B. For example, component A may be configured to engage a blood vessel in a manner such as illustrated in FIGS. 16A-16B, and component B may extend into the blood vessel and may include a valve disposed therein.

[0186] It will be appreciated that any of the devices provided herein, not necessarily limited to the particularly illustrated examples, may be used in a method for adjustably regulating fluid flow. For example, FIG. 17 illustrates a flow of operations in an example method 1700 for reducing and increasing dimension of a device *in vivo*. Method 1700 may include inserting into a fluid path first and second components coupled to one another (1701). The first component may include a self-expanding superelastic material, and the second component may include a malleable shape-memory material having a first cross sectional area. Nonlimiting examples of such first components and second components, and optional configurations thereof, are described with reference to FIGS. 1A-1E, 2A-2E, 3A-3D, 4A-4B, 5A-5B, 6, 7, 8A-8D, 9A-9B, 11A-11B, 12A-12B, 13A-13B, 14A-14C, 15A-15D, 16A-16B, 23A-23E, 25A-25D, 26A-26H, 27A-27K, 28A-28D, 29A-29D, and 30A-30C.

[0187] Method 1700 illustrated in FIG. 17 also may include expanding the malleable shape-memory material to a second cross sectional area (operation 1702). For example, as described elsewhere herein, the malleable shape-memory material may be expanded using balloon dilatation.

[0188] Method 1700 illustrated in FIG. 17 contracting the malleable shape-memory material to a third cross sectional area (operation 1703). For example, as described elsewhere herein, the malleable shape-memory material may be contracted using heat, for example as applied using

saline heated to above A_f of the shape-memory material, or using another suitable energy source such as radio frequency electrical current (RF).

[0189] Accordingly, in examples provided herein, a fluid flow path through an implantable device may be both increased and reduced following implantation, allowing for repositioning of the device or a customized fluid flow that is appropriate to the particular patient's needs. In comparison, for previously known devices repositioning may not be possible, and the size of the fluid flow path either is selected prior to implantation or may be increased using balloon dilatation, providing limited options for achieving a desired hemodynamic result in a patient. In examples such as provided herein, the component(s) including self-expanding superelastic material(s) may assume their shape immediately upon implantation within the body, which may inhibit device migration and ensure accurate positioning. The component(s) including malleable shape-memory material(s) may be plastically deformable (e.g., expandable) at body temperature and may be returned to a heat-set dimension upon application of heat. The heat-set dimension of a malleable shape-memory component optionally may be larger than a crimped dimension of the component. Accordingly, in some examples a malleable shape-memory component may be expanded by suitably applying heat, e.g., as an alternative to an initial balloon dilatation after delivery of the crimped device. The malleable shape-memory component(s) repeatedly may be expanded and contracted, which may allow for adjustment of fluid flow through the device, or for the device to be repositioned, or a combination of such features.

[0190] For example, certain of the devices provided herein may be repositionable for fixation within a body lumen. As described above, the devices may include a first component including a self-expanding superelastic material, and a second component coupled to the first component and comprising a malleable shape-memory material, in a manner such as described with reference to FIGS. 1A-1E, 2A-2E, 3A-3D, 4A-4B, 5A-5B, 6, 7, 8A-8D, 9A-9B, 11A-11B, 12A-12B, 13A-13B, 14A-14C, 15A-15D, 16A-16B, 23A-23E, 25A-25D, 26A-26H, 27A-27K, 28A-28D, 29A-29D, and 30A-30C. The self-expanding superelastic material may have a predetermined fully expanded dimension (e.g., that may be heat set during manufacture). The second component may have a first dimension suitable for deployment through a catheter (e.g., may be crimped to that dimension). The malleable shape-memory material may be expandable to a second

dimension for fixation within a body lumen (e.g., via balloon dilatation), and may be thermally transitionable to a third dimension (e.g., via application of heat within the body as described elsewhere herein). The malleable shape-memory material may be mechanically re-expandable to a fourth dimension (e.g., via balloon dilatation).

[0191] Accordingly, it will be appreciated that certain of the devices provided herein, not necessarily limited to the particularly illustrated examples, may be used in a method for adjustably fixating a device within a body lumen. For example, FIG. 18 illustrates a flow of operations in an example method 1800 for repositioning a device. Method 1800 includes inserting into a body lumen a device comprising first and second components coupled to one another (operation 1801). The first component may include a self-expanding superelastic material, and the second component may include a malleable shape-memory material having a first dimension, in a manner such as described with reference to FIGS. 1A-1E, 2A-2E, 3A-3D, 4A-4B, 5A-5B, 6, 7, 8A-8D, 9A-9B, 11A-11B, 12A-12B, 13A-13B, 14A-14C, 15A-15D, 16A-16B, 23A-23E, 25A-25D, 26A-26H, 27A-27K, 28A-28D, 29A-29D, and 30A-30C.

[0192] Method 1800 also includes expanding the malleable shape-memory material to a second dimension to fixate the device within a body lumen (operation 1802), for example via balloon dilatation. Method 1800 also includes thermally contracting the malleable shape-memory material (operation 1803), for example via application of heat. Method 1800 also includes repositioning the device within the body lumen while the malleable shape-memory material is thermally contracted (operation 1804), for example by moving the device along a guidewire. Method 1800 also includes mechanically re-expanding the malleable shape-memory material to a third dimension to fixate the device within the body lumen (operation 1805), for example via balloon dilatation.

[0193] Although certain examples provided herein relate to permanently implantable devices for use in the human body, it should be appreciated that other examples relate to devices that are used only temporarily in the human body. Additionally, although certain examples herein primarily relate to changing the internal dimension of a device, it should be appreciated that other examples primarily relate to changing the external dimension of a device. For example,

FIGS. 19A-19D schematically illustrate an example dilator device 1900 with an external dimension that can be reduced and increased *in vivo*. Device 1900 may be used, for example, in a “sheathless” method for delivering a permanently implantable device to a suitable location in the human body using an over-the-wire (OTW) approach, e.g., in a manner such as described with reference to FIGS. 20A-20I.

[0194] In the example shown in FIG. 19A, device 1900 may include dilator 1910 disposed at the distal end of sheath 1920. As shown in greater detail in FIG. 19B, dilator 1910 may include tip 1911, enlarged region 1912, and reduced region 1913. Reduced region 1913 may be sized so as to securably engage with the distal end of sheath 1920, and enlarged region 1912 may be sized so as to provide device 1900 with a smooth profile between sheath 1920 and tip 1911. Tip 1910 may have an outer dimension d where tip 1911 meets enlarged region 1912, and its distal end may taper to approximately a point. In the example configuration shown in FIG. 19B, dilator 1910 includes a martensitic shape-memory material defining enlarged region 1912 and reduced region 1913 (together, denoted region B), and a self-expanding superelastic material defining tip 1911 (denoted region A). The austenitic finish temperature (A_f) of the self-expanding superelastic material may be less than body temperature (which is about 37°C), e.g., may be in the range of 5-15°C. The A_f of the martensitic shape memory material may be substantially greater than 37°C, e.g., may be about 45-60°C, e.g., may be about 50°C. Tip 1910, reduced region 1913, and enlarged region 1912 optionally are integrally formed from a common frame with one another.

[0195] As shown in FIG. 19C, upon application of heat (e.g., using hot saline or RF energy or the use of a laser, magnetic inductance, electrical resistance, or the like) the shape memory material of region B (corresponding to enlarged region 1912 and reduced region 1913) may return to a smaller, heat-set outer dimension that optionally may be approximately equal to d so that the dilator 1910 has a substantially smooth, reduced size profile. In the alternative configuration shown in FIG. 19D, dilator 1910' includes a martensitic shape-memory material defining tip 1911, enlarged region 1912, and reduced region 1913, which may be configured to return to a smaller, heat-set dimension that optionally may be approximately equal to d so that the dilator 1910 has a substantially smooth, reduced size profile.

[0196] FIGS. 20A-20I schematically illustrate use of the delivery device 1900 of FIGS. 19A-19D in the human body. In the nonlimiting example shown in FIG. 20A, guidewire 2020 is percutaneously placed across a region of the body to be dilated, for example, fossa ovalis 2010 of interatrial septum 2000, creating a small opening having approximately the dimension of guidewire 2020. Device 1900 then is advanced over guidewire 2020 to a position adjacent to fossa ovalis 2010 in a manner such as illustrated in FIG. 20B. As shown in FIG. 20C, pushing on the proximal end of sheath 1920 forces dilator 1910 through fossa ovalis 2010, enlarging the opening to approximately the outer dimension of enlarged region 1912. As shown in FIG. 20D, sheath 1920 may be retracted relative to dilator 1910, leaving dilator 1910 in place on the distal side of fossa ovalis 2010. So as to inhibit harming the tissue of interatrial septum 2000 when retracting dilator 1910, e.g., by catching tissue with enlarged region 1912 when retracting dilator 1910, and so as to inhibit dilator 1910 from catching or becoming entangled with an expandable device that may be delivered across the septum in a manner such as described below, heat may be applied to dilator 1910 on the distal side of fossa ovalis 2010 as shown in FIG. 20E, for example by applying hot saline or RF energy or the use of a laser, magnetic inductance, electrical resistance, or the like at a temperature above the T_g of the shape memory material of the dilator. Such heat causes the outer dimension of the enlarged region 1912 to return to its heat-set size. As shown in FIG. 20G and its inset 20H, the reduced-size dilator 1910 may be safely withdrawn through the enlarged opening, and then may be stowed inside of sheath 1920 in a manner such as illustrated in FIG. 20I and subsequently withdrawn from the body. Note that any suitable one of the adjustable devices described elsewhere herein, such as device 700, 1100, 1300, or 2100 may be delivered using delivery device 1900. For example, the adjustable device may be disposed within sheath 1920 and advanced to partially cross the atrial septum together with delivery device 1900 in a manner such as shown in FIG. 20C. Retracting sheath 1920 in a manner such as shown in FIG. 20D deploys the distal shunt flange of the adjustable device in the left atrium, followed by pulling the sheath back to the septal wall, releasing the retention hooks, and pulling the sheath further back such that the septum drags the remainder of the shunt out of the sheath, allowing the proximal flange of the shunt to self-expand in the right atrium. The dimension of dilator 1910 then may be adjusted *in vivo* and withdrawn through the adjustable device, thus

providing a “sheathless” implantation procedure with a relatively low crossing profile and a relatively short procedure time.

[0197] FIGS. 21A-21D schematically illustrate an example transatrial gate 2100 with an internal dimension that can be reduced and increased *in vivo*. As illustrated in cross sectional area in FIG. 21A, transatrial gate 2100 may be disposed across an opening through interatrial septum 2000, e.g., through fossa ovalis 2010. Transatrial gate 2100 includes left and right atrial discs (denoted “A” in FIGS. 21A-21D) each including a self-expanding superelastic material, and a martensitic shape-memory material (denoted “B” in FIGS. 21A-21D) which has an A_f that is substantially higher than body temperature, e.g., 45-60°C, e.g., from 50-55°C. Left atrial disc A, right atrial disc A, and martensitic shape-memory material optionally are integrally formed from a common frame with one another. In one example, the martensitic shape-memory material B may be provided as a mesh that forms an internal dimension that may be reduced and expanded *in vivo*. For example, as shown in FIG. 21B, the martensitic shape-memory material B may be heat set to completely occlude passage between the left and right atrial discs A, corresponding to an internal dimension of approximately zero. As shown in FIG. 21C, the martensitic shape-memory material B may be mechanically expanded to provide any suitable expanded internal dimension allowing passage between the left and right atrial discs A. As shown in FIG. 21D, upon heating above A_f , the martensitic shape-memory material may return to its heat set configuration.

[0198] FIGS. 22A-22H schematically illustrate use of the transatrial gate of FIGS. 21A-21D in the human body. In an example use of transatrial gate 2100 as a standalone adjustable transatrial shunt, a guidewire 2220 is used to perform a transseptal puncture in a manner such as shown in FIG. 22A, optionally through fossa ovalis 2210. The opening through atrial septum 2200 optionally may be expanded using an introducer sheath and dilator (not illustrated), or by advancing a noncompliant balloon 2201 over guidewire 2220 and then expanding the balloon in a manner such as illustrated in FIGS. 22B-22D. In one nonlimiting example, the balloon has a maximum outer dimension of 15 mm, although any suitable dimension may be used. The balloon or dilator then is removed, keeping guidewire 2220 in place as shown in FIG 22E. Adjustable transatrial gate 2100 is implanted, for example by advancing gate 2100 crimped into

sheath 2230 over the guidewire in a manner such as shown in FIG. 22F and partially through the atrial septum, and then retracting sheath 2230 allowing the distal end (left side in the illustrated configuration) of gate 2100 to deploy via self-expansion of left atrial disk A in a manner such as shown in FIG. 22G. The sheath is then further retracted, allowing the proximal end (right side in the illustrated configuration) of gate 2100 to deploy via self-expansion of right atrial disk A in a manner such as shown in FIG. 22H. Guidewire 2220 may be left through gate 2100. The gate then is crossed with a dilator having a suitable outer dimension, e.g., of 5 mm, which mechanically expands the inner dimension of martensitic shape-memory material B to the outer dimension of the dilator, e.g., to 5 mm. The inner dimension of martensitic shape-memory material B then may be further increased as appropriate, e.g., using similar mechanical expansion using a larger dilator. If it is determined that the inner dimension of the martensitic shape-memory material B is too large, then it may be heated above its Af to reset that material to its heat set configuration. The inner dimension of the material then may be expanded to another suitable size.

[0199] In an example use of transatrial gate 2100 as transatrial channel that may be opened and closed, a guidewire is used to perform a transseptal puncture. The opening through atrial septum, which optionally is through the fossa ovalis, may be expanded using an introducer sheath and dilator. The dilator then is removed, keeping the sheath in place. A procedure then may be performed in the left atrium via the expanded opening, such as RF ablation, left atrial appendage (LAA) closure, MitraClip implantation, mitral valve replacement, mitral valve repair, or the like. The adjustable transatrial gate is implanted in a manner such as described with reference to FIGS. 21A-21H, e.g., with martensitic shape-memory material in its heat-set state with minimal or zero inner aperture. Optionally, a guidewire is left through the gate and the gate then is crossed with a dilator having a suitable outer dimension, e.g., of 5 mm, which mechanically expands the inner dimension of martensitic shape-memory material B to the outer dimension of the dilator, e.g., to 5 mm. The inner dimension of martensitic shape-memory material B then may be further increased as appropriate, e.g., using similar mechanical expansion using a larger dilator. If it is determined that the inner dimension of the martensitic shape-memory material B is too large, then it may be heated above its Af to reset that material to its

heat set configuration. The inner dimension of the material then may be expanded to another suitable size. The gate may be left open and used to provide a transatrial shunt in a manner such as described above, or may be left closed but reopened as needed so as to perform a separate procedure later on in the left atrium.

[0200] As noted above, the present devices may be permanently or temporarily implanted in the body. In a temporary implantation, the device may be configured for easy removal and may have a dimension that is adjustable in a manner such as described elsewhere herein, or may be permanently connected to the end of a catheter. For example, FIGS. 23A-23E schematically illustrate an example device with an internal dimension that can be reduced and increased *in vivo*, and an example of its temporary use in the human body. More specifically, FIG. 23A is a schematic illustration of a temporary apparatus 28 inside a subject 20, FIG. 23B is a schematic illustration of temporary apparatus 28, in accordance with some examples provided herein, and FIGS. 23C-23E collectively show a technique for removing temporary apparatus 28 from a subject, in accordance with some examples provided herein.

[0201] Apparatus 28 includes device 21, which may be configured similarly as device 200 described with reference to FIGS. 2A-2B or device 700 described with reference to FIG. 7, and which may be placed between two chambers of the heart 22 of subject 20, such as within the interatrial septum 24 of heart 22, between the right atrium 30 and the left atrium 32.

Alternatively, the device 21 may be placed between the two ventricles of the heart, or between any other two body cavities. In the example illustrated in FIG. 23B, device 21 includes a flared distal portion 40, a flared proximal portion 44, and an intermediate portion 42, which is disposed between distal portion 40 and proximal portion 44. Distal portion 40 and proximal portion 44 anchor the device 21 to septum 24 (i.e., prevent migration of the device from within the septum), while intermediate portion 42 provides a passageway across the septum, through which blood may flow. In a manner similar to that described with reference to FIGS. 2A-2B and FIG. 7, flared distal portion 40 (first component) may include a first self-expanding material, intermediate portion 42 (second component) may include a malleable shape-memory material, and proximal portion 44 (third component) may include a second self-expanding material. Proximal portion 44, distal portion 40, and intermediate 42 portion optionally are integrally

formed from a common frame with one another. The flared distal and proximal portions 40, 44 (first and third components) of device 21 expand to their natural shapes (the shapes shown in FIGS. 23A-23B) upon being released from a delivery sheath 46, while the intermediate portion 42 (second component) provides a cross sectional area that may be increased and reduced in vivo in a manner such as further described below. It is noted that, for clarity, apparatus 28 is drawn disproportionately large, relative to heart 22, in FIG. 23A. The proximal and distal portions 40, 44 of device 21 may be “flared,” in that these portions extend radially outward at an acute angle from the axis of the intermediate portion of the stent. In some examples, as shown, each of the proximal and distal portions of the device 40, 44 includes a plurality of leaves 25, such as, for example, six leaves 25, as shown. In other examples, the proximal portion and/or the distal portion does not include a plurality of leaves, but rather, is shaped to define a flared ring, or has some other suitable form.

[0202] To facilitate removal of device 21 from the subject in a manner such as described further below with reference to FIGS. 23C-23E, some examples include one or more device-collapsing flexible longitudinal elements 36, which extend from proximal portion 44 to the exterior of the subject. For example, as shown in FIGS. 23A-23B, the device-collapsing flexible longitudinal elements may include control wires 36. In some examples, while inside the subject, wires 36 are contained within control wire lumens 37 of a delivery catheter 31 passing between proximal portion 44 and the exterior of the subject. For example, delivery catheter 31 may exit the subject via a femoral vein of the subject. As shown in FIG. 23A, the proximal ends of control wires 36 may be coupled to control handle 34, via which wires 36 may be pulled (or alternatively, released, such as to allow the proximal portion of the device to expand). Wires 36 may remain coupled to the device 21 throughout the time that the device is in place inside the subject. Due to wires 36 remaining coupled to device 21, the device may be easily removed at any desired time (e.g., immediately) upon receiving indication that further shunting is no longer required through the device, e.g., in a manner such as described with reference to FIGS. 23C-23E. FIG. 23B shows a particular example in which proximal portion 44 is shaped to define a plurality of orifices 48, and each of control wires 36 passes through at least two of orifices 48. For example, as shown, the end of each leaf 25 may be shaped to define an orifice 48, and each wire may pass

through the respective orifices of two adjacent leaves, such that the wire forms a loop that passes through the orifices. (Thus, in the illustrated example, device having six proximal leaves is coupled to three wires 36, each wire separately controlling the collapse of a respective pair of adjacent leaves.) To collapse the proximal portion of device 21, the two proximal ends of each of the wires may be pulled.

[0203] Alternatively to the example shown, a single wire 36 may form a loop that passes through all of the orifices 48, this single wire controlling the collapse of the entire proximal portion 44. In other words, by pulling on the two ends of this single wire, the entire proximal portion may be collapsed. In yet other examples, wires 36 do not form loops; rather, a separate wire is coupled to each leaf. For example, each leaf may be coupled to the distal end of a respective wire. Thus, for example, a device having six proximal leaves is coupled to six wires, one wire per leaf. Similarly, wires 36 may be formed as extensions of the leaves, such that each leaf has a wire extension that extends to the exterior of the subject. In such examples, the proximal portion of the device may be collapsed by pulling on the single proximal end of each of the wires.

[0204] In some cases, it may be beneficial to increase or reduce the cross sectional area of intermediate portion 42 while device 21 is inside the subject, e.g., in a manner such as described elsewhere herein. To allow the cross sectional area of intermediate portion 42 to be increased, delivery catheter 31 may include an enlarged central multipurpose lumen 39 through which an angioplasty balloon or other suitable balloon may be passed over a guidewire and inflated in a manner such as described elsewhere herein. To reduce the cross sectional area of intermediate portion 42, a catheter with one or more holes may be used to inject hot saline within device 21, in a manner such as described elsewhere herein, to heat intermediate portion 42. In some examples, the catheter with one or more holes is passed over a guidewire within delivery catheter 31. In other examples, the catheter with one or more holes is not passed over the guidewire but is introduced to device 21 separately from the guidewire through multipurpose lumen 39 of delivery catheter 31. It will be appreciated that to increase and reduce the cross sectional area of intermediate portion 42, e.g., to provide an appropriate flow rate through device 21 or to reposition device 21, processes of balloon expansion and heating may be repeated any suitable number of times.

[0205] In some examples, the adjustment of the cross sectional area of intermediate portion 42 of device 21 is based on pressure monitoring. For example, pressure sensors disposed on the device 21 may be used to acquire intra-atrial pressure measurements. A signal indicative of such pressure measurements may be transmitted outside the body via conductors 38 (also referred to as signal wires), shown schematically in FIG. 23A. The cross sectional area of intermediate portion 42 may be adjusted in response to such measurements.

[0206] Alternatively or additionally, the cross sectional area of intermediate portion 42 may be adjusted in response to hemodynamic monitoring, such as by the application of flow imaging techniques such as pulsed wave (PW) or continuous wave (CW) Doppler echocardiography.

[0207] In some examples, to place the device 21 within the septum, the device is first collapsed and placed inside a delivery sheath 46 that has been inserted percutaneously into the vasculature of the subject, such as via a femoral vein of the subject, and is then passed through the vasculature into right atrium 30, e.g., via the inferior vena cava. (Alternatively, sheath 46 may be passed into the right atrium via the jugular vein and superior vena cava.) Subsequently, the distal end of the sheath is passed through the septum and into left atrium 32. Prior to passing the distal end of the sheath through the septum, a puncturing element may be used to create an opening in the septum, and, optionally, a dilator may be used to enlarge the opening, such that the distal end of the sheath may easily pass through the septum; in some examples, the dilator is configured and used in a manner such as described with reference to FIGS. 19A-20I. Once the sheath is across the septum, the dilator is removed and the device 21, connected to catheter 31, is collapsed and placed into the proximal end of the delivery sheath 46, and the catheter 31 is used to push the device 21 through the delivery sheath until the distal flared portion 40 of the device is pushed from the distal end of the sheath and allowed to expand to its deployed shape. Sheath 46 is then slowly withdrawn from the septum until the distal flared portion of device 21 engages the left atrial side of the septum. Continued withdrawal of the sheath causes the device 21 to be dragged out of the sheath by the septum, until the proximal flared portion 44 is released, allowing it to expand to its deployed shape on the right atrial side of the septum, as shown in FIG. 23A. The expanded distal and proximal flared portions, 40 and 44, thereby securely anchor the device 21 across the interatrial septum. Intermediate portion 42 (second component) initially

may remain in its crimped or compressed configuration having a first cross sectional area, and may be suitably expanded to a second cross sectional area using a balloon which is passed over a guidewire through lumen 39 of catheter 31. The cross sectional area of intermediate portion 42 subsequently may be increased and reduced *in vivo* in a manner such as described elsewhere herein.

[0208] Following the deployment of device 21, sheath 46 and catheter 31 may remain within the subject while device 21 is in place. For example, sheath 46 and catheter 31 may remain within the subject such that the distal end of the catheter is near the proximal portion of the device. The catheter may thus be used to deliver medication to the device site, pressure sensors in the catheter may be used to monitor the intra-atrial pressure, balloons may be introduced within device 21 to increase the cross sectional area of intermediate portion 42, or catheters with one or more holes may be introduced within device 21 to reduce the cross sectional area of intermediate portion 42. By way of example, FIG. 23A shows catheter 31 coupled to a control handle 34, such that control handle 34 may be used to advance and withdraw the catheter through sheath 46.

[0209] Device 21 helps relieve excess intra-atrial pressure, by allowing blood to flow from the higher-pressure atrium to the lower-pressure atrium, with a flow rate that may be increased or reduced based on the needs of the particular patient. Device 21 may thus be used as a temporary acute treatment of any relevant condition (e.g., pulmonary hypertension or congestive heart failure) for which the relief of excess pressure is beneficial, or, for example, to help prevent left ventricular dilation and remodeling following an acute myocardial insult. When device 21 is used as an acute treatment, the subject remains hospitalized until the subject's physician decides that sufficient treatment has been provided, at which point device 21 is removed from the subject in a manner such as described with reference to FIGS. 23C-23E, and the subject is released from hospital as appropriate. In some examples, device apparatus 28 includes one or more pressure sensors, disposed, for example, on device 21, on any of the longitudinal elements, or in catheter 31. Such pressure sensors may be used to measure (e.g., continuously) the pressure in the subject's right atrium and/or left atrium, in order to monitor progression of the treatment, to determine whether and by how much the cross sectional area of intermediate portion 42 should be adjusted, and ascertain the point in time at which the device may be removed from the

subject. For example, one pressure sensor may be disposed on the proximal portion 40 of device 21, and another pressure sensor on the distal portion 44 of the device, such that the pressure in both the left atrium and the right atrium is measured.

[0210] In another embodiment, device 21 is used as temporary measurement device to determine the optimal size for a permanently implanted shunt to be subsequently implanted. In this embodiment, the cross sectional area of intermediate portion 42 of device 21 is adjusted while monitoring pressures and/or other physiological parameters as described for the acute treatment embodiment described above. Once the optimum cross sectional area has been determined, device 21 is removed from the subject in a manner such as described with reference to FIGS. 23C-23E, and a permanent shunt of the indicated size is implanted.

[0211] Reference is now made to FIGS. 23C-23E, which collectively show a technique for removing device 21 from subject 20, in accordance with some examples provided herein. It is noted that many of the details shown in FIGS. 23C-23E are provided by way of example only, and that many variations of the illustrated technique are included within the scope of the present disclosure.

[0212] In FIG. 23C, sheath 46 is advanced until the distal end of the sheath is close to proximal portion 44 of device 21. Subsequently, control wires 36 attached to device 21 are pulled, as indicated by the arrow 54 shown in FIG. 23C, such that an inward radial force is exerted on proximal portion 44. The inward radial force causes proximal portion 44 to at least partially collapse, as shown in FIG. 23D. Following the collapse of the proximal portion of device 21, as shown in FIG. 23E, sheath 46 is advanced distally over device 21 while catheter 31 is held in place, drawing the proximal portion of device 21 into the distal end of the sheath. (In passing over device 21, the sheath may at least partly pass through the interatrial septum.) As sheath 46 continues to pass over device 21 from the position shown in FIG. 23E, the catheter may be pulled proximally while holding the sheath in place, pulling device 21 further into the sheath until the sheath collapses distal portion 40 of device 21, such that device 21 becomes entirely collapsed within the sheath. Subsequently, the sheath, containing catheter 31 and device 21, may be removed from the subject.

[0213] In some examples, sheath 46 is advanced while proximal portion 44 is collapsing, such that, as proximal portion 44 continues to collapse, the catheter passes over device 21, until the distal end of the catheter crosses through the septum and reaches the distal portion of device 21. (In such examples, the state shown in FIG. 23D may not actually come to transpire, because sheath 46 covers the proximal portion of device 21 before the proximal portion 44 of device 21 is fully collapsed.) Then, as the pulling of device 21 by catheter 31 via wires 36 continues while sheath 46 is held in place or is pushed forward, the distal end of the catheter exerts a force on the distal portion 40 of device 21, such that the distal portion of device 21 collapses, and device 21 is drawn into the catheter. In such examples, due to the sheath being advanced over device 21 while wires 36 are pulled, device 21 may be relatively unlikely to be pulled into the right atrium before collapsing into the sheath.

[0214] FIGS. 23C-23E show a nonlimiting example in which catheter 31 extends to a stopper 52 contained inside of control handle 34, wires 36 passing through stopper 52. As the wires are pulled, stopper 52 inhibits or prevents catheter 31 from moving proximally, such that most of the pulling force acts on proximal portion 44, rather than on catheter 31. Although flexible, catheter 31 is resistant to buckling, such that the pulling force is effectively transferred to proximal portion 44. In some examples, two separate tubes run through a single lumen, or two separate lumens, of catheter 31, one of these tubes holding control wires 36, and the other of these tubes holding signal wires 38. In another embodiment, control wires 36 as well as the signal wires 38, when present, run through a separate individual lumens disposed in the wall of catheter 31, leaving an enlarged central multipurpose lumen 39, as shown in FIG. 23 A. Such tubes may provide additional resistance to buckling, such that the pulling force exerted on the wires is effectively transmitted to device 21. In such embodiments, stopper 52 may be used to inhibit or prevent the wire-holding tubes from moving proximally as the wires are pulled.

[0215] In some examples, proximal portion 44 may be provided in a malleable shape-memory phase at body temperature, heat set to a collapsed configuration similar to that shown in FIG. 23D, and deployed in a manner similar to that described with reference to FIGS. 23A-23B. However, instead of self-expanding, proximal portion 44 may be deployed by positioning an hourglass-shaped balloon through device 21, and inflating the balloon to expand the proximal

portion. Such balloon expansion of proximal portion 44 may be performed after self-expansion of distal portion 40.

[0216] It is noted that the apparatus and methods such as described with reference to FIGS. 23A-23E may also be used for applications in which device 21 is to be permanently implanted. In such applications, during the implantation procedure, wires 36 may be used to facilitate the retrieval or repositioning of device 21, in the event that the device was not placed at the proper location. Subsequently, upon confirmation that device 21 is properly situated, wires 36 may be detached from device 21, and removed from the subject.

[0217] Other methods of deploying and/or retrieving the present devices suitably may be used. For example, FIGS. 32A-32G schematically illustrate another example device with an internal dimension that can be reduced and increased *in vivo*, and an example of its use in the human body. In a manner such as illustrated in FIG. 32A and described elsewhere herein, device 3300 may be disposed within an aperture through the fossa ovalis. Device 3300 may correspond, for example, device 200 described with reference to FIGS. 2A-2E; device 700 described with reference to FIGS. 7, 8A-8D, 9A-9B, and 10A-10C; device 1110 described with reference to FIGS. 11A-11B; device 1210 described with reference to FIGS. 12A-12B; device 1300 described with reference to FIGS. 13A-13B; device 28 described with reference to FIGS. 23A-23E; device 2500 described with reference to FIGS. 25A-25D; device 2600 described with reference to FIGS. 26A-26H; device 2700 described with reference to FIGS. 27A-27K; or any of devices 2800, 2800', 2800'' described with reference to FIGS. 28A-28D, 29A-29D, and 30A-30C. Device 3300 may be formed predominantly or substantially entirely of shape memory (martensitic) material, preset to its collapsed configuration. Device 3300 may be deployed by balloon expansion.

[0218] As illustrated in FIG. 32A, a retrieval procedure for device 3300 may include disposing a guidewire through device 3300. In a manner such as illustrated in FIG. 32B, a designated retrieval catheter 3320 may cross over wire 3310 and through device 3300, such that the distal end 3323 of catheter 3320 is disposed within the left atrium. Tip 3321 may be partially disposed within catheter 3320. For example, a portion of tip 3321 may extend past distal end 3323 of

catheter 3320, and the outer surface of tip 3321 may provide a relatively smooth profile so as to facilitate guidance of distal end 3323 substantially without damage to tissue. Cup 3322 may be disposed entirely within catheter 3320. Tip 3321 and cup 3322 may be movable independently of one another and independently of catheter 3320. For example, tip 3321 may be coupled to shaft 3331 including a lumen through which guidewire 3310 passes; shaft 3331 may be extended or retracted, from outside the body, relative to guidewire 3310, relative to catheter 3320, and relative to cup 3322, so as to extend the entirety of tip 3321 past distal end 3323. Cup 3322 may be coupled to shaft 3332 including a lumen through which shaft 3331 (having guidewire 3310 therein) passes; shaft 3332 may be extended or retracted, from outside the body, relative to guidewire 3310, relative to catheter 3320, and relative to tip 3321, so as to extend at least a portion of cup 3322 past distal end 3323. Tip 3321 and cup 3322 respectively may include generally rounded conical or bowl-shaped structures, e.g., including any suitable material such as a superelastic material. Tip 3321 and cup 3322 each may receive a portion of device 3300 when device 3300 is in the collapsed configuration, and may cooperate to substantially enclose device 3300 and at least partially pull device 3300 into catheter 3320 for retrieval.

[0219] For example, in a manner such as illustrated in FIG. 32C, after distal end 3323 of catheter 3320 and tip 3321 are disposed in the left atrium (LA), shaft 3331 may be held in place so as to keep tip 3321 in place while retrieval catheter 3320 and shaft 3332 are retracted such that distal end 3323 and cup 3322 are retracted to the right atrium (RA), leaving a space between tip 3321 and cup 3322 that coincides with the position of device 3300. Optionally, at least a portion of cup 3322 may be extended past distal end 3323, e.g., by retracting catheter 3320 relative to shaft 3332 or by extending shaft 3332 relative to catheter 3320. In examples in which cup 3322 includes a shape memory material, cup 3322 may at least partially spring open so as to provide an increased volume for retrieving device 3300. As also illustrated in FIG. 32C, shaft 3331 may heat device 3300 in a manner such as described elsewhere herein, e.g., may include apertures via which hot saline 3324 may be injected toward device 3300, causing device 3300 to contract to its heat set (contracted, e.g., substantially cylindrical) configuration such as illustrated in FIG. 32D. Tip 3321 then may be retracted, e.g., by retracting shaft 3331 relative to shaft 3332 and catheter 3320, so as to pull the contracted device 3300 into the rounded conical or bowl-shaped structure

of tip 3321 in a manner such as illustrated in FIG. 32E. Tip 3321 then may be further retracted, e.g., by further retracting shaft 3331 relative to shaft 3332 and catheter 3320, so as to pull the contracted device 3300 into the rounded conical or bowl-shaped structure of cup 3322, thus at least partially enclosing contracted device 3300 in a manner such as illustrated in FIG. 32F. Cup 3322 and tip 3321 then may be retracted together, e.g., by retracting shafts 3331 and 3332 together relative to catheter 3320, so as to at least partially dispose device 3300 within catheter 3200. For example, as shown in FIG. 32F, a portion of tip 3321 may extend past distal end 3323 of catheter 3320 and cup 3322 may be disposed entirely within catheter 3320, and a portion of device 3300 is within catheter 3320 and a portion of device 3300 extends past distal end 3323. In a manner such as illustrated in FIG. 32G, the retrieval catheter 3320, tip 3321, cup 3322, and device 3300 may be retrieved by retracting catheter 3320, shaft 3331, and shaft 3332 together. Guidewire 3310 may be fully retrieved, and the septal hole may be closed with a closure device such as known in the art. Still other embodiments may be envisioned based on the teachings herein. For example, FIGS. 28A-28D schematically illustrate another example device with an internal dimension that can be reduced and increased *in vivo*. Device 2800 illustrated in FIG. 28A includes a braided shunt having a substantially cylindrical configuration, which may be formed using wires such as described above with reference to FIGS. 27A-27K. The wire portions forming outer portions 2811, 2812 of device 2800, e.g., that may extend into respective atria of the heart, may have an austenite phase (Af below body temperature, e.g., in the range of about 5-20°C), corresponding to regions A and C of FIG. 28B; while the wire portions forming an inner portion 2813 of device 2800, e.g., that may be lodged within the atrial septum, may have a martensite phase (Af above body temperature, e.g., in the range of about 50°C), corresponding to region B of FIG. 28B. Regions A, B, and C of FIG. 28B may be obtained by heat treating suitable portions of wires that are braided together to form device 2800, in a manner similar to that described above with reference to FIGS. 27A-27K. Device 2800 also may include crimp/holder mechanism 2850 for use in delivering the device within the human body. As illustrated in cross-section in FIG. 28B, device 2800 may include a wire mesh tube of NITINOL that has been heat treated differently in section B than in sections A and C such that the example Af temperatures shown in the figure are obtained. The ends of the tube then may be everted,

e.g., pulled back over the middle section B in a manner similar to turning a sock inside-out, until the ends of sections A and C meet and are crimped together along crimp 2850, shown in FIG. 28A in cross section. Note that crimp 2850 may be off-center because section A is shorter than section C. The end result is a double-walled cylindrical shunt in which the outer wall (in contact with the opening in the septum) has a low A_f and is superelastic at body temperature while the inner wall (forming the orifice for blood flow) has an A_f higher than body temperature and thus is in the malleable martensitic phase at body temperature. In some examples, the martensitic mesh extends all the way through the center of the shunt and at least part way around each end. The device may have a fixed outer diameter set by the heat-set size of the superelastic outer wall, while the inner diameter may be increased by balloon expansion. If after expanding the inner diameter it is desired to reduce the inner diameter to its heat set configuration, heat may be applied, e.g., by injecting hot saline in a manner such as described elsewhere herein.

[0220] FIGS. 29A-29D schematically illustrate an example of the use of the device of FIGS. 28A-28B in the human body. For example, device 2800 may be delivered across the atrial septum in a manner such as described elsewhere herein. As illustrated in FIG. 29A, device 2800 may have an initial, heat-set inner diameter when disposed across the atrial septum, e.g., of about 4 mm, and an initial outer diameter as well, e.g., of about 7 mm. As illustrated in FIG. 29B, balloon 2900 may be disposed through device 2800 and expanded so as to expand the inner diameter of the device, e.g., to about 5 to about 7 mm, while the outer diameter of the device is substantially unaffected. As illustrated in FIG. 29C, heat source 2910, e.g., a tube supplying a flow of heated saline, may cause the inner diameter of device 2800 to contract to its initial, heat-set inner diameter such as illustrated in FIG. 29D.

[0221] FIG. 28C illustrates an alternative device 2800' that is configured similarly to device 2800 but also includes groove 2860 which is sized to engage the aperture through the atrial septum. FIGS. 30A-30C schematically illustrate an example of the use of the device of FIG. 28C in the human body. As illustrated in FIG. 30A, alternative device 2800' may have an initial, heat-set inner diameter when disposed across the atrial septum, e.g., of about 4 mm, and an initial outer diameter as well, e.g., of about 7 mm, while groove 2860 engages the aperture through the atrial septum. In a manner similar to that described with reference to FIG. 29B, a

balloon may be disposed through device 2800' and expanded so as to expand the inner diameter of the device in a manner such as illustrated in FIG. 30B, e.g., to about 5 to about 7 mm, while the outer diameter of the device is substantially unaffected. In a manner similar to that described with reference to FIG. 29C, a heat source e.g., a tube supplying a flow of heated saline, may cause the inner diameter of device 2800' to contract to its initial, heat-set inner diameter such as illustrated in FIG. 30C. FIG. 28D illustrates another example alternative device 2800'' that is configured similarly to device 2800' but also is diabolo-shaped so as to include flared ends 2811', 2812' that extend into respective atria of the heart, and neck 2813' that engages the aperture through the atrial septum. Device 2800'' may be formed of braided, heat treated wires in a manner similar to that described with reference to FIGS. 27A-27K, and may be deployed and the inner dimension expanded and contracted in a manner such as described elsewhere herein.

[0222] Accordingly, provided herein is an interatrial shunt for placement at an atrial septum of a patient's heart. The interatrial shunt may be configured similarly as one or more of device 200 described with reference to FIGS. 2A-2E; device 700 described with reference to FIGS. 7, 8A-8D, 9A-9B, and 10A-10C; device 1110 described with reference to FIGS. 11A-11B; device 1210 described with reference to FIGS. 12A-12B; device 1300 described with reference to FIGS. 13A-13B; device 28 described with reference to FIGS. 23A-23E; device 2500 described with reference to FIGS. 25A-25D; device 2600 described with reference to FIGS. 26A-26H; device 2700 described with reference to FIGS. 27A-27K; or any of devices 2800, 2800', 2800'' described with reference to FIGS. 28A-28D, 29A-29D, and 30A-30C. For example, the interatrial shunt may include a body that includes first and second regions coupled in fluid communication by a neck region, e.g., such as included in device 200 described with reference to FIGS. 2A-2E; device 700 described with reference to FIGS. 7, 8A-8D, 9A-9B, and 10A-10C; device 1110 described with reference to FIGS. 11A-11B; device 1210 described with reference to FIGS. 12A-12B; device 1300 described with reference to FIGS. 13A-13B; device 28 described with reference to FIGS. 23A-23E; device 2500 described with reference to FIGS. 25A-25D; device 2600 described with reference to FIGS. 26A-26H; device 2700 described with reference to FIGS. 27A-27K; or any of devices 2800, 2800', 2800'' described with reference to

FIGS. 28A-28D, 29A-29D, and 30A-30C. The body may include a shape-memory material, e.g., in a manner such as described elsewhere herein. The body may define a passageway through the neck region for blood to flow between a first atrium and a second atrium, e.g., in a manner such as device 700 described with reference to FIGS. 7, 8A-8D, 9A-9B, and 10A-10C; device 1110 described with reference to FIGS. 11A-11B; device 1210 described with reference to FIGS. 12A-12B; device 1300 described with reference to FIGS. 13A-13B; or device 28 described with reference to FIGS. 23A-23E. The first and second regions may be superelastic at body temperature, and the neck region may be malleable at body temperature, e.g., in a manner such as described elsewhere herein. A flow area of the passageway through the neck region may be adjusted *in vivo*, e.g., in a manner such as described elsewhere herein.

[0223] The first and second regions that are superelastic may include NITINOL having an austenitic finish temperature (A_f) between 5-20°C, e.g., in a manner such as described elsewhere herein. The neck region that is malleable may include NITINOL having an austenitic finish temperature (A_f) between 45-60°C, e.g., in a manner such as described elsewhere herein. The neck region may be mechanically expandable, e.g., in a manner such as described elsewhere herein. The neck region may be thermally contractible, e.g., in a manner such as described elsewhere herein.

[0224] Also provided herein is an interatrial shunt for placement at an atrial septum of a patient's heart for adjustably regulating fluid flow therethrough. The interatrial shunt may be configured similarly as one or more of device 200 described with reference to FIGS. 2A-2E; device 700 described with reference to FIGS. 7, 8A-8D, 9A-9B, and 10A-10C; device 1110 described with reference to FIGS. 11A-11B; device 1210 described with reference to FIGS. 12A-12B; device 1300 described with reference to FIGS. 13A-13B; device 28 described with reference to FIGS. 23A-23E; device 2500 described with reference to FIGS. 25A-25D; device 2600 described with reference to FIGS. 26A-26H; device 2700 described with reference to FIGS. 27A-27K; or any of devices 2800, 2800', 2800'' described with reference to FIGS. 28A-28D, 29A-29D, and 30A-30C. For example, the interatrial shunt may include a first expandable end region configured to be placed in a first atrium of the heart, and a second expandable end region configured to be placed in a second atrium of the heart, e.g., such as included in device 700 described with

reference to FIGS. 7, 8A-8D, 9A-9B, and 10A-10C; device 1110 described with reference to FIGS. 11A-11B; device 1210 described with reference to FIGS. 12A-12B; device 1300 described with reference to FIGS. 13A-13B; device 28 described with reference to FIGS. 23A-23E; device 2500 described with reference to FIGS. 25A-25D; device 2600 described with reference to FIGS. 26A-26H; device 2700 described with reference to FIGS. 27A-27K; or any of devices 2800, 2800', 2800'' described with reference to FIGS. 28A-28D, 29A-29D, and 30A-30C. The first and second expandable end regions may include self-expanding superelastic material, e.g., in a manner such as described elsewhere herein. The interatrial shunt may include a neck region between the first and second expandable end regions, e.g., such as included in device 200 described with reference to FIGS. 2A-2E; device 700 described with reference to FIGS. 7, 8A-8D, 9A-9B, and 10A-10C; device 1110 described with reference to FIGS. 11A-11B; device 1210 described with reference to FIGS. 12A-12B; device 1300 described with reference to FIGS. 13A-13B; device 28 described with reference to FIGS. 23A-23E; ; device 2500 described with reference to FIGS. 25A-25D; device 2600 described with reference to FIGS. 26A-26H; device 2700 described with reference to FIGS. 27A-27K; or any of devices 2800, 2800', 2800'' described with reference to FIGS. 28A-28D, 29A-29D, and 30A-30C. The neck region may be configured for placement at the atrial septum, e.g., in a manner such as device 700 described with reference to FIGS. 7, 8A-8D, 9A-9B, and 10A-10C; device 1110 described with reference to FIGS. 11A-11B; device 1210 described with reference to FIGS. 12A-12B; device 1300 described with reference to FIGS. 13A-13B; device 28 described with reference to FIGS. 23A-23E; device 2500 described with reference to FIGS. 25A-25D; device 2600 described with reference to FIGS. 26A-26H; device 2700 described with reference to FIGS. 27A-27K; or any of devices 2800, 2800', 2800'' described with reference to FIGS. 28A-28D, 29A-29D, and 30A-30C. The neck region may include malleable shape-memory material, e.g., in a manner such as described elsewhere herein. The interatrial shunt may define a passageway through the neck region for blood to flow between the first atrium and the second atrium, e.g., in a manner such as device 700 described with reference to FIGS. 7, 8A-8D, 9A-9B, and 10A-10C; device 1110 described with reference to FIGS. 11A-11B; device 1210 described with reference to FIGS. 12A-12B; device 1300 described with reference to FIGS. 13A-13B; device 28 described with reference to FIGS. 23A-23E; device 2500 described with reference to FIGS. 25A-25D; device

2600 described with reference to FIGS. 26A-26H; device 2700 described with reference to FIGS. 27A-27K; or any of devices 2800, 2800', 2800'' described with reference to FIGS. 28A-28D, 29A-29D, and 30A-30C. The neck region may be heat treated to exhibit different shape memory properties than the first and second expandable end regions such that a cross-sectional area of the passageway is adjustable *in vivo*, e.g., in a manner such as described elsewhere herein, for example but not limited to a manner such as described with reference to FIGS. 10A-10C, FIGS. 27A-27K, FIGS. 29A-29D, or 30A-30C.

[0225] The malleable shape-memory material may be configured to be expanded *in vivo* such that the passageway expands from the cross-sectional area to a second cross-sectional area larger than the cross-sectional area, e.g., in a manner such as described elsewhere herein. The malleable shape-memory material may be configured to be contracted *in vivo* such that the passageway contracts from the second cross-sectional area to a third cross-sectional area smaller than the second cross-sectional area, e.g., in a manner such as described elsewhere herein. The cross-sectional area may be between 4.9 to 28.3 mm² and the second cross-sectional area and the third cross-sectional area may be between 15.9 to 78.6 mm². For example, for any of device 200 described with reference to FIGS. 2A-2E; device 700 described with reference to FIGS. 7, 8A-8D, 9A-9B, and 10A-10C; device 1110 described with reference to FIGS. 11A-11B; device 1210 described with reference to FIGS. 12A-12B; device 1300 described with reference to FIGS. 13A-13B; device 28 described with reference to FIGS. 23A-23E; device 2500 described with reference to FIGS. 25A-25D; device 2600 described with reference to FIGS. 26A-26H; device 2700 described with reference to FIGS. 27A-27K; or any of devices 2800, 2800', 2800'' described with reference to FIGS. 28A-28D, 29A-29D, and 30A-30C, the cross-sectional area may be between 4.9 to 28.3 mm² and the second cross-sectional area and the third cross-sectional area may be between 15.9 to 78.6 mm².

[0226] The malleable shape-memory material may include NITINOL having an austenitic finish temperature (Af) between 45-60°C, e.g., in a manner such as described elsewhere herein. The self-expanding superelastic material may include NITINOL having an austenitic finish temperature (Af) between 5-20°C, e.g., in a manner such as described elsewhere herein. The malleable shape-memory material may be mechanically expandable, e.g., in a manner such as

described elsewhere herein. The malleable shape-memory material may be thermally contractible, e.g., in a manner such as described elsewhere herein. The cross-sectional area of the neck region may be smaller than respective cross-sectional areas of at least one of the first and second expandable end regions, e.g., in a manner such as described for device 200 described with reference to FIGS. 2A-2E; device 700 described with reference to FIGS. 7, 8A-8D, 9A-9B, and 10A-10C; device 1110 described with reference to FIGS. 11A-11B; device 1210 described with reference to FIGS. 12A-12B; device 1300 described with reference to FIGS. 13A-13B; device 28 described with reference to FIGS. 23A-23E; device 2500 described with reference to FIGS. 25A-25D; device 2600 described with reference to FIGS. 26A-26H; device 2700 described with reference to FIGS. 27A-27K; or any of devices 2800', 2800'' described with reference to FIGS. 28C-28D and 30A-30C. The first and second expandable end regions may extend into the first and second atria, respectively, such that respective ends of the first and second expandable end regions may not contact the atrial septum, e.g., in a manner such as device 700 described with reference to FIGS. 7, 8A-8D, 9A-9B, and 10A-10C; device 1110 described with reference to FIGS. 11A-11B; device 1210 described with reference to FIGS. 12A-12B; device 1300 described with reference to FIGS. 13A-13B; device 28 described with reference to FIGS. 23A-23E; device 2500 described with reference to FIGS. 25A-25D; device 2600 described with reference to FIGS. 26A-26H; device 2700 described with reference to FIGS. 27A-27K; or any of devices 2800, 2800', 2800'' described with reference to FIGS. 28A-28D, 29A-29D, and 30A-30C.

[0227] The first and second expandable end regions and the neck region may comprise a diabolo-shaped shunt, e.g., in a manner such as device 700 described with reference to FIGS. 7, 8A-8D, 9A-9B, and 10A-10C; device 1110 described with reference to FIGS. 11A-11B; device 1210 described with reference to FIGS. 12A-12B; device 1300 described with reference to FIGS. 13A-13B; device 28 described with reference to FIGS. 23A-23E; device 2500 described with reference to FIGS. 25A-25D; device 2600 described with reference to FIGS. 26A-26H; device 2700 described with reference to FIGS. 27A-27K; or device 2800'' described with reference to FIG. 28D. The neck region may include a structural member, such as a cylindrical shunt, e.g., in a manner such as device 1110 described with reference to FIGS. 11A-11B; device 1210

described with reference to FIGS. 12A-12B; device 1300 described with reference to FIGS. 13A-13B; a compression coil in a manner such as device 2500 described with reference to FIGS. 25A-25D; or a compression spring in a manner such as device 2600 described with reference to FIGS. 26A-26H. The structural member (e.g., cylindrical shunt, compression coil, or compression spring) may be outside of the diabolo-shaped shunt, e.g., in a manner such as device 1110 described with reference to FIGS. 11A-11B, device 2500 described with reference to FIGS. 25A-25D or device 2600 described with reference to FIGS. 26A-26H. The structural member (e.g., cylindrical shunt, compression coil, or compression spring) may be formed of the malleable shape-memory material such that the structural member (e.g., cylindrical shunt, compression coil, or compression spring) radially constrains a dimension of the diabolo-shaped shunt at the neck region, and the diabolo-shaped shunt may self-expand at the neck region responsive to the malleable shape memory material expanding to a second cross-sectional area, e.g., in a manner such as device 1110 described with reference to FIGS. 11A-11B, device 2500 described with reference to FIGS. 25A-25D or device 2600 described with reference to FIGS. 26A-26H. The cylindrical shunt may be inside of the diabolo-shaped shunt, e.g., in a manner such as device 1210 described with reference to FIGS. 12A-12B, or device 1300 described with reference to FIGS. 13A-13B. The cylindrical shunt may not be directly coupled to the diabolo-shaped shunt and the neck region, e.g., in a manner such as device 1210 described with reference to FIGS. 12A-12B, or device 1300 described with reference to FIGS. 13A-13B. The device may further include an encapsulant indirectly and elastically coupling the cylindrical shunt to the diabolo-shaped shunt, e.g., in a manner such as device 1210 described with reference to FIGS. 12A-12B. Contraction of the cylindrical shunt may not cause contraction of the diabolo-shaped shunt at the neck region, e.g., in a manner such as device 1210 described with reference to FIGS. 12A-12B, or device 1300 described with reference to FIGS. 13A-13B. The diabolo-shaped shunt and the cylindrical shunt may be integrally formed from a common frame, e.g., in a manner such as described elsewhere herein. The first and second expandable end regions and the neck region may be integrally formed from a common frame, e.g., in a manner such as described elsewhere herein. The first and second expandable end regions and the neck region may be at least partially encapsulated with a biocompatible material, e.g., in a manner such as described elsewhere herein.

[0228] Also provided herein is an interatrial shunt for adjustably regulating fluid flow in a heart having a first atrium, a second atrium, and an atrial septum. The interatrial shunt may be configured similarly as one or more of device 200 described with reference to FIGS. 2A-2E; device 700 described with reference to FIGS. 7, 8A-8D, 9A-9B, and 10A-10C; device 1110 described with reference to FIGS. 11A-11B; device 1210 described with reference to FIGS. 12A-12B; device 1300 described with reference to FIGS. 13A-13B; device 28 described with reference to FIGS. 23A-23E; device 2500 described with reference to FIGS. 25A-25D; or device 2600 described with reference to FIGS. 26A-26H; device 2700 described with reference to FIGS. 27A-27K; or any of devices 2800, 2800', 2800'' described with reference to FIGS. 28A-28D, 29A-29D, and 30A-30C. For example, the interatrial shunt may include a first region that includes a self-expanding superelastic material configured to be placed in the first atrium, e.g., such as included in device 700 described with reference to FIGS. 7, 8A-8D, 9A-9B, and 10A-10C; device 1110 described with reference to FIGS. 11A-11B; device 1210 described with reference to FIGS. 12A-12B; device 1300 described with reference to FIGS. 13A-13B; device 28 described with reference to FIGS. 23A-23E; device 2500 described with reference to FIGS. 25A-25D; device 2600 described with reference to FIGS. 26A-26H; device 2700 described with reference to FIGS. 27A-27K; or any of devices 2800, 2800', 2800'' described with reference to FIGS. 28A-28D, 29A-29D, and 30A-30C. The first region may be superelastic at body temperature, e.g., in a manner such as described elsewhere herein. The interatrial shunt may include a second region that includes a malleable shape-memory material configured to be placed through an opening in the atrial septum so as to provide fluid flow from the first atrium to the second atrium, e.g., such as included in device 700 described with reference to FIGS. 7, 8A-8D, 9A-9B, and 10A-10C; device 1110 described with reference to FIGS. 11A-11B; device 1210 described with reference to FIGS. 12A-12B; device 1300 described with reference to FIGS. 13A-13B; device 28 described with reference to FIGS. 23A-23E; device 2500 described with reference to FIGS. 25A-25D; device 2600 described with reference to FIGS. 26A-26H; device 2700 described with reference to FIGS. 27A-27K; or any of devices 2800, 2800', 2800'' described with reference to FIGS. 28A-28D, 29A-29D, and 30A-30C. The second region may be malleable at body temperature, e.g., in a manner such as described elsewhere herein. The malleable shape-memory material may have a first cross-sectional area, e.g., in a manner such as

described elsewhere herein. The malleable shape-memory material may be expandable from the first cross-sectional area to a second cross-sectional area, e.g., in a manner such as described elsewhere herein. The malleable shape-memory material may be contractible from the second cross-sectional area to a third cross-sectional area, e.g., in a manner such as described elsewhere herein.

[0229] The self-expanding superelastic material may include NITINOL having an austenitic finish temperature (A_f) between 5-20°C, and the malleable shape-memory material may include NITINOL having an austenitic finish temperature (A_f) between 45-60°C, e.g., in a manner such as described elsewhere herein. The malleable shape-memory material may be mechanically expandable and thermally contractible, e.g., in a manner such as described elsewhere herein. The interatrial shunt may include a third region that includes a second self-expanding superelastic material, is configured to be placed in the second atrium, and is coupled to the second region, e.g., such as included in device 700 described with reference to FIGS. 7, 8A-8D, 9A-9B, and 10A-10C; device 1110 described with reference to FIGS. 11A-11B; device 1210 described with reference to FIGS. 12A-12B; device 1300 described with reference to FIGS. 13A-13B; device 28 described with reference to FIGS. 23A-23E; device 2500 described with reference to FIGS. 25A-25D; device 2600 described with reference to FIGS. 26A-26H; device 2700 described with reference to FIGS. 27A-27K; or any of devices 2800, 2800', 2800'' described with reference to FIGS. 28A-28D, 29A-29D, and 30A-30C.

[0230] It will be appreciated that in any of the present examples, device configurations may be reversibly modified *in vivo*. In many examples, the configuration change includes increasing or decreasing a dimension of a device, such as an internal dimension of the device or an external dimension of the device. However, other configuration changes suitably may be implemented. For example, FIGS. 31A-31E schematically illustrate an example device with a configuration that can be reversibly modified *in vivo*. Device 3100 illustrated in FIGS. 31A-31E may be configured similarly, in some respects, as described in U.S. Patent No. 6,964,680 to Shanley, entitled "Expandable medical device with tapered hinge," the entire contents of which are incorporated by reference herein. FIGS. 31A-31B show a planar view of a representative portion

of an unexpanded tissue-supporting medical device 3100, while FIGS. 31C-31E are detail views of the expandable medical device of FIGS. 31A-31B undergoing sequential expansion.

[0231] In a manner similar to that described in U.S. Patent No. 6,964,680, device 3100 illustrated in FIGS. 31A-31B may include a series of axial slots 3210 formed in a cylindrical tube (not shown). Each axial slot 3210 may be displaced radially from the slots in the adjacent rows of slots by approximately 0.010 inches. The plurality of axial slots 3210 may define a plurality of elongated beams 3220. The plurality of elongated beams 3220 may be interconnected by a hinge 3250 disposed at one end and a locking area disposed at the other end. A U-shaped link 3270 may interconnect adjacent rows of beams 3220. The elongated beam 3220 further may include a pawl 3230 having a distal end 3235 disposed at one end of the elongated beam 3220 and a plurality of teeth 3240 disposed at the other end opposite the pawl 3230. The distal end 3235 of the pawl 3230 may be adjacent to the teeth 3240 of the adjacent elongated member 3220. The elongated beam 3220 further may include a hinge 3250 adjacent the pawl 3230. The hinge 3250 further may include a first end 3252 and a second end 3254 defining a section 3265, wherein the section 3265 between the first end 3252 and the second end 3254 may be designed where it will act as a stress/strain concentration area. Specifically, the hinge 3250 may include a first portion extending along about 1/3 of the length of the hinge 3250 and a second section gradually tapering, extending about 2/3 of the length of the hinge 3250. It is contemplated that other ratios may be utilized as well as other geometries in order to confine the maximum stress/strain to the hinge section 3265. Furthermore, the length and width of the hinge can be adjusted to confine the maximum strain in the hinge 3250, to some desired value at the maximum required bend radius of the hinge 3250. For example, if the maximum desired bend angle of the hinge 3250 was set at ninety (90) degrees, and the minimum hinge width was fixed at about 0.002 inches, a hinge length could be determined for which the maximum strain in the hinge 3250 may be well below the elastic limit of the hinge material.

[0232] Referring now to FIGS. 31C through 31E, there is shown a plan view of a section of the expandable medical device 3100 as the device is deployed. In a manner similar to that described in U.S. Patent No. 6,964,680, the expandable device 3100 may be expanded radially by placing an appropriate device, such as a balloon catheter, within the inner diameter of the expandable

device 3100 and expanding the balloon catheter until the expandable device has been expanded to a desired diameter. As shown in FIG. 31C, a partial section of the expandable device 3100 is shown. As described in detail with reference to FIGS. 31A-31B, the expandable device 3100 may include a plurality of elongated members 3220, spaced apart by radial slots 3210. The elongated members may have a pawl 3230 disposed on one end thereof and a plurality of teeth 3240 disposed on the other, and a hinge 3250 adjacent to the pawl 3230. The plurality of elongated members 3220 may be joined together by the hinge 3250 and the locking configuration. In an unexpanded state, as shown in FIG. 31C, the pawl 3230 disposed at one end of an elongated member 3220 may be substantially parallel to hinge 3250. Further still the distal end 3235 of the pawl 3230 may be designed having a `chisel` shape adapted for being received by at least one of the plurality of teeth 3240 on the adjacent substantially parallel elongated member 3220.

[0233] Referring now to FIG. 31D, there is shown the partial section of the expandable device 3100 having been expanded to a second partially expanded diameter. As indicated by arrow 3300 a general rotational motion may be achieved by pawl 3230 as the diameter of the expandable device 3100 is increased and hinge 3250 bends, in a manner similar to that described in U.S. Patent No. 6,964,680. As shown, the locus of points drawn out by distal tip 3235 of the pawl 3230 as it rotates may describe a non-circular arc. The hinge 3250 may bend initially about a predetermined point within the region 3265 as shown in FIG. 31D. The predetermined bending point may be determined by narrowing the width of the hinge 3250 within the section 3265 as defined by the first end 3252 and the second end 3254 of the hinge 3250. As shown FIG. 31D, as the pawl rotates during expansion of the device from an unexpanded state as shown in FIG. 31A to a partially expanded state as shown in FIG. 31D the pawl 3230 no longer may be substantially parallel to the hinge 3250 due to the bending of the hinge 3250.

[0234] Referring now to FIG. 31E, there is shown the section of the expandable medical device 3100 in an expanded state during engagement of the locking mechanism. As shown, a significant curvature develops in the hinge 3250, specifically in the section 3265. As this curvature occurs, the pawl 3230 and the distal end 3235 of the pawl 3230 become capable of both continued angular deflection, as indicated by arrow 3300, and also a linear motion along the axis of the

pawl 3230, as indicated by arrow 3320. The angular motion 3300 and the linear motion 3320 are both possible in this region because the axis of the pawl 3230 is no longer directly aligned with the now-curved, centroidal axis of the hinge 3250. Rather, the motion of the pawl 3230 along its own axis requires only additional bending of the hinge 3250 near second end 3254 of the hinge 3250. This ability of the hinge 3250 to provide both the rotational motion 3300 and the axial motion 3320 allows the distal tip 3235 of the pawl 3230 to follow the contour of the teeth 3240 without local plastic yielding of either feature. Additionally, the elastic energy stored in the hinge 3250 provides a means for creating a spring return force (not shown) that can be resolved at the distal tip 3235 of the pawl into components parallel and perpendicular to the axis of the pawl. When the expansion device has positioned the distal tip 3235 of the pawl 3230 beyond one of the locking teeth 3240, and the expansion device is then withdrawn, these spring return forces force the distal tip 3235 to contact the locking tooth 3240, thereby locking the expandable device 3100 into an expanded state in a manner such as described in U.S. Patent No. 6,964,680. The mating faces of the distal tip 3235 and the locking tooth 3240 are contoured according to well-known techniques to insure that forces that are externally applied to the tissue-supporting device 3100 act to further lock the features in position. Furthermore, the teeth 3240 may include many different geometrical shapes, which are adapted to receive the distal end 3235 of the pawl 3230. For example, the teeth 3240 may include depressions adapted to receive the distal end 3235 of the pawl 3230. Thus, the teeth 3240 as shown and described are not to be considered limiting and are exemplary only; it is contemplated that the teeth 3240 as well as the distal end 3235 of the pawl 3230 may include many different shapes as shall be apparent to one skilled in the art.

[0235] Additionally, in a manner such as described in U.S. Patent No. 6,964,680, the hinge 3250 may be contoured as described above in order to control the bending pattern of the hinge 3250 and thus the motion of the pawl during the bend sequence. For example, when the width of the hinge is narrowest near the pawl proximal end 3232 of the pawl 3230, the hinge may tend to bend in this area first. As a result, the instant center of rotation of the pawl may be initially closer to the proximal end 3232 of the pawl 3230, and the arc traced by the distal tip 3235 of the pawl 3230 may quickly pass through the region 3238 as indicated in FIGS. 31C-31E. This may be visualized by imagining the limiting case of a simple pivot point located at end 3252 of hinge

3250 the arc traced by distal tip 3235 would in this case be circular, and the initial motion of the tip 3235 would be orthogonal to the axis of pawl 3230 (i.e., downward, or directly toward the adjacent strut 3220). The second limiting case would correspond to a pivot point at the other end 3254 of hinge 3250. The arc traced by distal tip 3235 would again be circular, but in this case, the initial motion of the tip 3235 would be parallel to the axis of pawl 3230, the tip of the pawl would move away from contact with adjacent strut 3220 from the outset, and no locking may be possible with teeth 3240 of the adjacent strut 3220. By contouring the shape of hinge 3250 between these extremes, the relative motion of pawl 3230 with respect to adjacent strut 3220 containing teeth 3240 may be optimized.

[0236] While U.S. Patent No. 6,964,680 discloses the use of certain materials within device 3100, the present disclosure provides that any suitable combination of superelastic and shape memory NITINOL components may be used within device 3100. For example, ductile hinges 3250 may be formed of NITINOL in the martensitic phase at body temperature while the remainder of device 3100 may be superelastic. It is contemplated to manufacture device 3100 by laser cutting it from a single tube of superelastic NITINOL, followed by localized heat treatment of ductile hinges 3250 using multiple high intensity laser pulses as described previously to raise A_f above body temperature, or about 50 °C, so that device 3100 may perform in the manner described with reference to FIGS. 31C-31E, and when heated (e.g., using hot saline in a manner such as described elsewhere herein) may return to a pre-set configuration such that the locking mechanism is released. For example, responsive to such heating, hinge segment 3265 illustrated in FIG. 31E may return to its straight configuration as shown in FIG. 31C, forcing pawl 3230 to disengage from teeth 3240, allowing device 3100 to return to its uncompressed configuration as shown in FIGS. 31A-31C. Accordingly, device 3100 may be used as a resizable shunt that may repeatedly be returned to a heat-set configuration.

WORKING EXAMPLE

[0237] The following example is intended to be purely illustrative, and not limiting of the present invention.

[0238] FIGS. 24A-24H are sequential images of a device prepared and used in accordance with examples provided herein. More specifically, the diabolo-shaped shunt frame device 700 described with reference to FIG. 7 was formed from NITINOL with an initial austenitic finish temperature below 20 °C, so that it would be in austenitic superelastic phase at body temperature of 37 °C. The superelastic device 700 was heat-set to the shape shown in FIG. 7, within a jig that formed a neck diameter of 4 mm. Subsequently, the shunt was changed from a purely self-expanding, superelastic austenitic phase to a configuration where at least some elements of the frame exhibited malleable shape-memory martensitic phase physical properties, with all dimensions, including the neck diameter, remaining the same, by re-heating the device to above 500°C in an oven for a suitable duration. At the time of FIG. 24A, within a tank of 37 °C water, a transparent membrane 2401 is suspended in tooling 2402 to simulate an atrial septum, and shunt frame device 700 is deployed from behind the opening in membrane 2401 via sheath 2400 in a manner such as described elsewhere herein. It should be noted that the distal flange 702 (toward the viewer) has self-expanded from its crimped configuration in the delivery sheath 2400, indicating that this component is at least in part in an austenitic superelastic phase at the 37 °C temperature of the water bath, in accordance with the example set forth in FIG. 8A. At the time of FIG. 24B, following deployment across the transparent membrane, the neck 720 of device 700 has an initial cross-sectional area corresponding to its heat set minimum diameter of approximately 4 mm. At the time of FIG. 24C, commercially available angioplasty balloon 2403 is inserted through the neck of device 700. At the time of FIG. 24D, balloon 2403 is inflated to a diameter of approximately 7 mm at a pressure and for a duration sufficient to deform the neck of device 700. At the time of FIG. 24E, the balloon 2403 is deflated. At the time of FIG. 24F, it may be seen that neck 720 of device 700 remains at a diameter of approximately 7 mm after balloon 2403 is withdrawn, in accordance with the example set forth in FIG. 8B. At the time of FIG. 24G, neck 720 is bathed in heated saline via rapid injection through a catheter 2404, in accordance with the example set forth in FIG. 8C. At the time of FIG. 24H, after the heating shown in FIG. 24G, neck 720 has been returned to its approximately 4 mm heat set diameter, in accordance with the example set forth in FIG. 8D, demonstrating that the neck region 720 of device 700 exhibits the desired martensitic shape-memory properties. Operations such as described with reference to FIGS. 24C-24G may be repeated any suitable number of times so as

to increase and reduce the dimensions of neck 720 as desired, while first and third portions 710, 730 securely retain device 700 in the opening through membrane 2401 simulating the atrial septum. Similar operations may be performed on other devices provided herein, e.g., so as to adjust the flow rate of such devices or to permit repositioning of the devices. Accordingly, it may be understood that one or more dimensions of the present devices suitably may be increased and decreased *in vivo*.

Additional comments

[0239] While various illustrative embodiments of the invention are described above, it will be apparent to one skilled in the art that various changes and modifications may be made therein without departing from the invention. For example, although examples of the present devices are described as having two or three components, it should be understood that the present devices may include any suitable number of components that respectively include a self-expanding superelastic material or a malleable shape-memory material. The appended claims are intended to cover all such changes and modifications that fall within the true spirit and scope of the invention.

WHAT IS CLAIMED IS:

1. An interatrial shunt for placement at an atrial septum of a patient's heart, the interatrial shunt comprising:

a body comprising first and second regions coupled in fluid communication by a neck region, the body comprising a shape-memory material, the body defining a passageway through the neck region for blood to flow between a first atrium and a second atrium,

wherein the first and second regions are superelastic at body temperature, and the neck region is malleable at body temperature and comprises NITINOL having an austenitic finish temperature (A_f) between 45-60°C, and

wherein a flow area of the passageway through the neck region may be adjusted *in vivo*.

2. The interatrial shunt of claim 1, wherein the first and second regions that are superelastic comprise NITINOL having an austenitic finish temperature (A_f) between 5-20°C.

3. The interatrial shunt of claim 1 or claim 2, wherein the neck region is mechanically expandable.

4. The interatrial shunt of any one of claims 1 to 3, wherein the neck region is thermally contractible.

5. An interatrial shunt for placement at an atrial septum of a patient's heart for adjustably regulating fluid flow therethrough, the interatrial shunt comprising:

a first expandable end region configured to be placed in a first atrium of the heart;

a second expandable end region configured to be placed in a second atrium of the heart,

the first and second expandable end regions comprising self-expanding superelastic material; and

a neck region between the first and second expandable end regions configured for placement at the atrial septum, the neck region comprising malleable shape-memory material, the

interatrial shunt defining a passageway through the neck region for blood to flow between the first atrium and the second atrium,

wherein the neck region is heat treated to exhibit different shape memory properties than the first and second expandable

end regions such that a cross-sectional area of the passageway is adjustable *in vivo*.

6. The interatrial shunt of claim 5, wherein the malleable shape-memory material is configured to be expanded *in vivo* such that the passageway expands from the cross-sectional area to a second cross-sectional area larger than the cross-sectional area.

7. The interatrial shunt of claim 6, wherein the malleable shape-memory material is configured to be contracted *in vivo* such that the passageway contracts from the second cross-sectional area to a third cross-sectional area smaller than the second cross-sectional area.

8. The interatrial shunt of claim 7, wherein the cross-sectional area is between 4.9 to 28.3 mm² and the second cross-sectional area and the third cross-sectional area are between 15.9 to 78.6 mm².

9. The interatrial shunt of any one of claims 5 to 8, wherein the malleable shape-memory material comprises NITINOL having an austenitic finish temperature (Af) between 45-60°C.

10. The interatrial shunt of any one of claims 5 to 9, wherein the self-expanding superelastic material comprises NITINOL having an austenitic finish temperature (Af) between 5-20°C.

11. The interatrial shunt of any one of claims 5 to 10, wherein the malleable shape-memory material is mechanically expandable.

12. The interatrial shunt of any one of claims 5 to 11, wherein the malleable shape-memory material is thermally contractible.

13. The interatrial shunt of any one of claims 5 to 12, wherein the cross-sectional area of the neck region is smaller than respective cross-sectional areas of at least one of the first and second expandable end regions.
14. The interatrial shunt of any one of claims 5 to 13, wherein the first and second expandable end regions extend into the first and second atria, respectively, such that respective ends of the first and second expandable end regions do not contact the atrial septum.
15. The interatrial shunt of any one of claims 5 to 14, wherein the first and second expandable end regions and the neck region comprise a diabolo-shaped shunt.
16. The interatrial shunt of claim 15, wherein the neck region comprises a cylindrical shunt.
17. The interatrial shunt of claim 16, wherein the cylindrical shunt is outside of the diabolo-shaped shunt.
18. The interatrial shunt of claim 17, wherein the cylindrical shunt is formed of the malleable shape-memory material such that the cylindrical shunt radially constrains a dimension of the diabolo-shaped shunt at the neck region, and wherein the diabolo-shaped shunt self-expands at the neck region responsive to the malleable shape memory material expanding to a second cross-sectional area.
19. The interatrial shunt of claim 16, wherein the cylindrical shunt is inside of the diabolo-shaped shunt.
20. The interatrial shunt of claim 16, wherein the cylindrical shunt is not directly coupled to the diabolo-shaped shunt and the neck region,

further comprising an encapsulant indirectly and elastically coupling the cylindrical shunt to the diabolo-shaped shunt.

21. The interatrial shunt of claim 16, wherein contraction of the cylindrical shunt does not cause contraction of the diabolo-shaped shunt at the neck region.

22. The interatrial shunt of claim 16, wherein the diabolo-shaped shunt and the cylindrical shunt are integrally formed from a common frame.

23. The interatrial shunt of any one of claims 5 to 15, wherein the first and second expandable end regions and the neck region are integrally formed from a common frame.

24. The interatrial shunt of any one of claims 5 to 15, wherein the first and second expandable end regions and the neck region are at least partially encapsulated with a biocompatible material.

25. An interatrial shunt for adjustably regulating fluid flow in a heart having a first atrium, a second atrium, and an atrial septum, the interatrial shunt comprising:

a first region comprising a self-expanding superelastic material configured to be placed in the first atrium, the first region being superelastic at body temperature; and

a second region comprising a malleable shape-memory material configured to be placed through an opening in the atrial septum so as to provide fluid flow from the first atrium to the second atrium, the second region being malleable at body temperature,

the malleable shape-memory material having a first cross-sectional area,

the malleable shape-memory material being expandable from the first cross-sectional area to a second cross-sectional area, and

the malleable shape-memory material being contractible from the second cross-sectional area to a third cross-sectional area.

26. The interatrial shunt of claim 25, wherein the self-expanding superelastic material comprises NITINOL having an austenitic finish temperature (A_f) between 5-20°C and the malleable shape-memory material comprises NITINOL having an austenitic finish temperature (A_f) between 45-60°C.
27. The interatrial shunt of claim 25 or claim 26, wherein the malleable shape-memory material is mechanically expandable and thermally contractible.
28. The interatrial shunt of any one of claims 25 to 27, further comprising a third region comprising a second self-expanding superelastic material, configured to be placed in the second atrium, and coupled to the second region.
29. A device for adjustably regulating fluid flow therethrough *in vivo*, the device comprising:
a first component comprising a first self-expanding superelastic material; and
a second component coupled to the first component and comprising a first malleable shape-memory material,
the first malleable shape-memory material having a first cross sectional area,
the first malleable shape-memory material being expandable *in vivo* to a second cross sectional area, and
the first malleable shape-memory material being contractible *in vivo* to a third cross sectional area.
30. The device of claim 29, wherein the first self-expanding superelastic material comprises NITINOL having an austenitic finish temperature (A_f) of less than 37°C.
31. The device of claim 30, wherein the A_f of the NITINOL of the first self-expanding superelastic material is between 5-20°C.

32. The device of any one of claims 29 to 31, wherein the first malleable shape-memory material comprises NITINOL having an austenitic finish temperature (A_f) of greater than 37°C.
33. The device of claim 32, wherein the A_f of the NITINOL of the malleable shape-memory material is between 45-60°C.
34. The device of any one of claims 29 to 33, wherein the first malleable shape-memory material is mechanically expandable.
35. The device of any one of claims 29 to 34, wherein the first malleable shape-memory material is thermally contractible.
36. The device of any one of claims 29 to 35, wherein the first malleable shape-memory material is joined to the first self-expanding superelastic material by welding.
37. The device of any one of claims 29 to 36, comprising a plurality of shaped wires, at least one of the wires comprising the first malleable shape-memory material, at least one of the wires comprising the first self-expanding superelastic material.
38. The device of claim 37, wherein at least one of the wires comprises both the first malleable shape-memory material and the first self-expanding superelastic material.
39. The device of claim 37, wherein each of the wires comprises both the first malleable shape-memory material and the first self-expanding superelastic material.
40. The device of any one of claims 37 to 39, wherein each of the shaped wires comprises a first end and a second end, wherein the first and second ends are coupled to each other using overlapping, welding, or a swaged tube.

41. The device of any one of claims 37 to 40, wherein the wires are coupled to one another using winding or sleeves.
42. The device of claim 41, wherein at least one of the sleeves is radiopaque.
43. The device of claim 41, wherein each of the sleeves is radiopaque.
44. The device of any one of claims 37 to 43, wherein at least one of the wires comprises a radiopaque material.
45. The device of claim 44, wherein an inner core of the wire comprises the radiopaque material.
46. The device of claim 45, wherein an overlay of the wire comprises the first malleable shape-memory material or the first self-expanding superelastic material.
47. The device of claim 45, wherein strands of the wire comprise the first malleable shape-memory material or the first self-expanding superelastic material.
48. The device of claim 45, wherein an overlay of the wire comprises the radiopaque material.
49. The device of claim 48, wherein an inner core of the wire comprises the first malleable shape-memory material or the first self-expanding superelastic material.
50. The device of any one of claims 29 to 49, further comprising an encapsulant covering at least a portion of at least one of the first component and the second component.

51. The device of claim 50, wherein the encapsulant joins the first malleable shape-memory material to the first self-expanding superelastic material.
52. The device of any one of claims 29 to 51, wherein the first cross sectional area is smaller than the third cross sectional area.
53. The device of any one of claims 29 to 51, wherein the first cross sectional area is larger than the third cross sectional area.
54. The device of any one of claims 29 to 53, further comprising a third component comprising a second self-expanding superelastic material and coupled to the first component and the second component.
55. The device of claim 54, wherein the first component comprises an inlet, the second component comprises a neck, and the third component comprises an outlet fluidically coupled to the inlet via the neck.
56. The device of claim 55, wherein the cross sectional area of the neck is smaller than respective cross sectional areas of at least one of the inlet and the outlet.
57. The device of claim 56, wherein the inlet and outlet anchor the device within an opening through a septum between two chambers within the body, and the neck provides a channel for flow between these chambers.
58. The device of claim 55, wherein the cross sectional area of the neck is larger than respective cross sectional areas of at least one of the inlet and the outlet.
59. The device of claim 55, wherein the second component is configured to engage an opening in the human body.

60. The device of claim 59, wherein:
the opening is created through a fossa ovalis of an interatrial septum between a right atrium and a left atrium,
the neck is configured to engage the opening,
the inlet is configured to extend into the right atrium, and
the outlet is configured to extend into the left atrium.
61. The device of claim 60, wherein:
the inlet and outlet comprise flanges;
the neck comprises flexible longitudinal bars and a sinusoidal ring;
the flexible longitudinal bars allow the flanges to fully expand upon deployment; and
the sinusoidal ring has sufficient strength to maintain its diameter when balloon dilated or heat contracted.
62. The device of claim 55, wherein the first component is configured to engage a lumen in the human body.
63. The device of claim 62, wherein:
the lumen comprises a blood vessel, and
the first and third components are configured to engage the blood vessel.
64. The device of claim 63, wherein the neck is configured to be disposed adjacent to an ostium of the blood vessel.
65. The device of any one of claims 29 to 53, further comprising a third component comprising a second malleable shape-memory material and coupled to the first component and the second component.

66. The device of claim 65, wherein:
the second malleable shape-memory material has a fourth cross sectional area permitting a fourth rate of fluid flow therethrough,
the second malleable shape-memory material is expandable *in vivo* to a fifth cross sectional area permitting a fifth rate of fluid flow therethrough, and
the second malleable shape-memory material is contractible *in vivo* to a sixth cross sectional area permitting a sixth rate of fluid flow therethrough.
67. The device of claim 65 or claim 66, wherein the second component comprises an inlet and the third component comprises an outlet fluidically coupled to the inlet via the first component.
68. The device of claim 67, wherein:
the inlet is configured to engage a blood vessel in the human body,
the first component is configured to engage the blood vessel,
the outlet is configured to extend into an ostium of the blood vessel.
69. The device of any one of claims 29 to 53, further comprising a valve disposed in the second component, wherein:
the first component is configured to engage a blood vessel in the human body, and
the second component extends into the blood vessel.
70. The device of any one of claims 29 to 53, wherein the second component is located inside of the first component.
71. The device of any one of claims 29 to 53, wherein the first component comprises a diabolo-shaped shunt having a neck, and the second component comprises a structural member surrounding the neck.

72. The device of claim 71, wherein the structural member comprises a cylindrical shunt.
73. The device of claim 71, wherein the structural member comprises a compression coil.
74. The device of claim 73, wherein a number of times by which the compression coil wraps around the neck varies based on cross sectional area of the neck.
75. The device of claim 74, wherein the compression coil is substantially cylindrical.
76. The device of claim 71, wherein the structural member comprises a compression spring.
77. The device of claim 76, wherein a number of times by which the compression spring wraps around the neck varies based on cross sectional area of the neck.
78. The device of claim 77, wherein the compression spring is diabolo-shaped.
79. The device of any one of claims 76 to 78, further comprising hooks coupling the compression spring to the shunt.
80. The device of claim 71, wherein the structural member is outside of the diabolo-shaped shunt.
81. The device of claim 71, wherein the first malleable shape-memory material radially constrains a dimension of the neck.
82. The device of claim 81, wherein the first malleable shape-memory material radially contacts an outer surface of the neck so as to constrain the neck from self-expanding to a larger dimension.

83. The device of claim 82, wherein the neck self-expands responsive to the first malleable shape memory material expanding to the second cross sectional area.
84. The device of claim 71, wherein the structural member exerts a force on the neck that varies based on cross-sectional area of the neck.
85. The device of claim 71, further comprising an encapsulant forming an inner lumen through the first component.
86. The device of claim 85, wherein the encapsulant further forms an outer covering of the first component.
87. The device of claim 86, wherein the encapsulant further forms an outer covering of the second component.
88. The device of claim 71, wherein the cylindrical shunt is inside of the diabolo-shaped shunt.
89. The device of claim 88, wherein the cylindrical shunt is not directly coupled to the neck of the diabolo-shaped shunt,
the device further comprising an encapsulant indirectly and elastically coupling the cylindrical shunt to the diabolo-shaped shunt.
90. The device of claim 89, wherein contraction of the cylindrical shunt does not cause causes contraction of the neck of the diabolo-shaped shunt.
91. The device of claim 89, wherein the neck of the diabolo-shaped shunt is self-expandable to a fourth cross sectional area.

92. The device of claim 91, wherein contraction of the cylindrical shunt to the third cross sectional area does not change the cross sectional area of the neck.

93. The device of any one of claims 29 to 53, wherein the second component is located inside of the first component.

94. The device of claim 93, wherein the first malleable shape-memory material radially constrains a dimension of the first component.

95. The device of claim 94, wherein the first malleable shape-memory material radially contacts an inner surface of the first component so as to constrain the first component from contracting to a smaller dimension.

96. The device of claim 93, wherein the first component self-contracts responsive to the first malleable shape memory material contracting to the third cross sectional area.

97. The device of claim 93, further comprising an encapsulant forming an outer covering of the first component and the second component.

98. The device of claim 29, wherein the first component and the second component are integrally formed from a common frame with one another.

99. The device of claim 98, wherein the common frame is substantially cylindrical.

100. The device of claim 98 or claim 99, wherein:
the common frame further comprises a third component comprising the first self-expanding superelastic material;
the second component forms a central portion of the common frame; and

the first and third components form portions of the common frame configured to extend into respective atria of the heart.

101. The device of claim 100, wherein the second component comprises a groove configured to engage an aperture through the atrial septum.

102. The device of claim 100 or claim 101, wherein the first and third components are flared.

103. The device of any one of claims 29 to 102, wherein the fluid is blood.

104. A method of retrieving a device from an atrial septum of a heart, the method comprising:
disposing a retrieval catheter through the device, the retrieval catheter having disposed therein a tip and a cup;

while the tip remains in the left atrium of the heart, retracting the cup to the right atrium of the heart, leaving a space between the tip and the cup that coincides with the position of the device;

heating the device to cause the device to contract to a heat set configuration;

retracting the tip to pull the contracted device into the cup; and

retrieving the retrieval catheter, with the contracted device at least partially within each of the tip and the cup, from the heart.

105. A method of preparing a device, the method comprising using localized heat-treating of one or more portions of each such device to produce a different Af from un-heated portion(s) of the device.

106. The method of claim 105, wherein the localized heating of the one or more portions of the device is performed using induction heating, optionally with active cooling of adjacent areas.

107. The method of claim 105, wherein the localized heating of the one or more portions of the device is performed using localized laser heating, optionally with active cooling of adjacent areas.

108. A method of preparing a device, the method comprising:
providing wires having different austenitic finish (Af) temperatures than one another
and/or wires having different Af temperatures along the length of the wire; and
using the wires to manufacture the device such that the device has multiple Af temperatures.

109. The method of claim 108, wherein the different Af temperatures correspond to different phases of NITINOL.

110. The method of claim 108, wherein using the wires to manufacture the device comprises using wire-wrap techniques, wire-mesh techniques, or any suitable combination thereof.

111. A device for adjustably regulating fluid flow therethrough, the device comprising:
a first component comprising a first self-expanding superelastic material; and
a second component coupled to the first component and comprising a first malleable shape-memory material,
the first malleable shape-memory material having a first cross sectional area,
the first malleable shape-memory material being expandable to a second cross sectional area, and
the first malleable shape-memory material being contractible to a third cross sectional area.

112. The device of claim 111, wherein the first self-expanding superelastic material comprises NITINOL having an austenitic finish temperature (Af) of less than 37°C.

113. The device of claim 112, wherein the Af of the NITINOL of the first self-expanding superelastic material is between 5-20°C.

114. The device of any one of claims 111 to 113, wherein the first malleable shape-memory material comprises NITINOL having an austenitic finish temperature (Af) of greater than 37°C.

115. The device of claim 114, wherein the Af of the NITINOL of the malleable shape-memory material is between 45-60°C.

116. The device of any one of claims 111 to 115, wherein the first malleable shape-memory material is mechanically expandable.

117. The device of any one of claims 111 to 116, wherein the first malleable shape-memory material is thermally contractible.

118. The device of any one of claims 111 to 117, wherein the first malleable shape-memory material is joined to the first self-expanding superelastic material by welding.

119. The device of any one of claims 111 to 118, further comprising an encapsulant covering at least a portion of at least one of the first component and the second component.

120. The device of claim 119, wherein the encapsulant joins the first malleable shape-memory material to the first self-expanding superelastic material.

121. The device of any one of claims 111 to 120, wherein the first cross sectional area is smaller than the third cross sectional area.

122. The device of any one of claims 111 to 121, wherein the first cross sectional area is larger than the third cross sectional area.

123. The device of any one of claims 111 to 122, further comprising a third component comprising a second self-expanding superelastic material and coupled to the first component and the second component.

124. The device of claim 123, wherein the first component comprises an inlet, the second component comprises a neck, and the third component comprises an outlet fluidically coupled to the inlet via the neck.

125. The device of claim 124, wherein the cross sectional area of the neck is smaller than respective cross sectional areas of at least one of the inlet and the outlet.

126. The device of claim 125, wherein the inlet and outlet anchor the device within an opening through a septum between two chambers within the body, and the neck provides a channel for flow between these chambers.

127. The device of claim 124, wherein the cross sectional area of the neck is larger than respective cross sectional areas of at least one of the inlet and the outlet.

128. The device of any one of claims 123 to 127, wherein the second component is configured to engage an opening in the human body.

129. The device of claim 128 as depends from claim 124, wherein:
the opening is created through a fossa ovalis of an interatrial septum between a right atrium and a left atrium,
the neck is configured to engage the opening,
the inlet is configured to extend into the right atrium, and
the outlet is configured to extend into the left atrium.

130. The device of any one of claims 111 to 126, wherein the first component is configured to engage a lumen in the human body.

131. The device of any one of claims 111 to 126 or 129 or 130, wherein:
the lumen comprises a blood vessel, and
the first and third components are configured to engage the blood vessel.

132. The device of claim 131 as depends from claim 124, wherein the neck is configured to be disposed adjacent to an ostium of the blood vessel.

133. The device of any one of claims 111 to 122, further comprising a third component comprising a second malleable shape-memory material and coupled to the first component and the second component.

134. The device of claim 133, wherein:
the second malleable shape-memory material has a fourth cross sectional area permitting a fourth rate of fluid flow therethrough,
the second malleable shape-memory material is expandable to a fifth cross sectional area permitting a fifth rate of fluid flow therethrough, and
the second malleable shape-memory material is contractible to a sixth cross sectional area permitting a sixth rate of fluid flow therethrough.

135. The device of claim 133 or claim 134, wherein the second component comprises an inlet and the third component comprises an outlet fluidically coupled to the inlet via the first component.

136. The device of claim 135, wherein:
the inlet is configured to engage a blood vessel in the human body,
the first component is configured to engage the blood vessel,

the outlet is configured to extend into an ostium of the blood vessel.

137. The device of any one of claims 111 to 122, further comprising a valve disposed in the second component, wherein:

the first component is configured to engage a blood vessel in the human body, and
the second component extends into the blood vessel.

138. The device of any one of claims 111 to 122, wherein the second component is located inside of the first component.

139. The device of any one of claims 111 to 122, wherein the first component comprises a diabolo-shaped shunt having a neck, and the second component comprises a cylindrical shunt.

140. The device of claim 139, wherein the cylindrical shunt is outside of the diabolo-shaped shunt.

141. The device of claim 140, wherein the first malleable shape-memory material radially constrains a dimension of the neck.

142. The device of claim 141, wherein the first malleable shape-memory material radially contacts an outer surface of the neck so as to constrain the neck from self-expanding to a larger dimension.

143. The device of claim 141 or claim 142, wherein the neck self-expands responsive to the first malleable shape memory material expanding to the second cross sectional area.

144. The device of any one of claims 140 to 143, further comprising an encapsulant forming an inner lumen through the first component and an outer covering of the first component and the second component.

145. The device of claim 139, wherein the cylindrical shunt is inside of the diabolo-shaped shunt.

146. The device of claim 145, wherein the cylindrical shunt is not directly coupled to the neck of the diabolo-shaped shunt,

the device further comprising an encapsulant indirectly and elastically coupling the cylindrical shunt to the diabolo-shaped shunt.

147. The device of claim 146, wherein contraction of the cylindrical shunt does not cause causes contraction of the neck.

148. The device of claim 146, wherein the neck of the diabolo-shaped shunt is self-expandable to a fourth cross sectional area.

149. The device of claim 148, wherein contraction of the cylindrical shunt to the third cross sectional area does not change the cross sectional area of the neck.

150. The device of any one of claims 111 to 122, wherein the second component is located inside of the first component.

151. The device of claim 150, wherein the first malleable shape-memory material radially constrains a dimension of the first component.

152. The device of claim 151, wherein the first malleable shape-memory material radially contacts an inner surface of the first component so as to constrain the first component from contracting to a smaller dimension.

153. The device of any one of claims 150 to 152, wherein the first component self-contracts responsive to the first malleable shape memory material contracting to the third cross sectional area.
154. The device of any one of claims 150 to 153, further comprising an encapsulant forming an outer covering of the first component and the second component.
155. A method for reducing and increasing an internal dimension of a device *in vivo*, the method comprising:
- inserting into a fluid path first and second components coupled to one another,
 - the first component comprising a self-expanding superelastic material,
 - the second component comprising a malleable shape-memory material having a first cross sectional area;
 - expanding the malleable shape-memory material to a second cross sectional area; and
 - contracting the malleable shape-memory material to a third cross sectional area.
156. The method of claim 155, wherein contracting the malleable shape-memory material comprises heating the malleable shape-memory material.
157. The method of claim 156, wherein the heating comprises flowing heated saline through the device via a catheter.
158. The method of claim 156, wherein the heating comprises applying radio frequency (RF) energy to the device.
159. The method of any one of claims 155 to 158, wherein expanding the malleable shape-memory material comprises expanding a balloon within the malleable shape-memory material.
160. A method for adjustably regulating fluid flow, the method comprising:

inserting into a fluid path first and second components coupled to one another,
the first component comprising a self-expanding superelastic material,
the second component comprising a malleable shape-memory material having a first cross sectional area permitting a first rate of fluid flow therethrough;
expanding the malleable shape-memory material to a second cross sectional area permitting a second rate of fluid flow therethrough; and
contracting the malleable shape-memory material to a third cross sectional area permitting a third rate of fluid flow therethrough.

161. The method of claim 160, wherein contracting the malleable shape-memory material comprises heating the malleable shape-memory material.

162. The method of claim 161, wherein the heating comprises flowing heated saline through the device via a catheter.

163. The method of claim 161, wherein the heating comprises applying radio frequency (RF) energy to the device.

164. The method of any one of claims 160 to 163, wherein expanding the malleable shape-memory material comprises expanding a balloon within the malleable shape-memory material.

165. A repositionable device for fixation within a body lumen, the device comprising:
a first component comprising a self-expanding superelastic material; and
a second component coupled to the first component and comprising a malleable shape-memory material,
the self-expanding superelastic material having a predetermined fully expanded dimension,
the second component having a first dimension suitable for deployment through a catheter,

the malleable shape-memory material being expandable to a second dimension for fixation within a body lumen,

the malleable shape-memory material being thermally transitionable to a third dimension, and

the malleable shape-memory material being mechanically re-expandable to a fourth dimension.

166. A method for adjustably fixating a device within a body lumen, the method comprising: inserting into a body lumen a device comprising first and second components coupled to one another,

the first component comprising a self-expanding superelastic material,

the second component comprising a malleable shape-memory material having a first dimension;

expanding the malleable shape-memory material to a second dimension to fixate the device within a body lumen;

thermally contracting the malleable shape-memory material;

repositioning the device within the body lumen while the malleable shape-memory material is thermally contracted; and

mechanically re-expanding the malleable shape-memory material to a third dimension to fixate the device within the body lumen.

167. The method of claim 166, wherein thermally contracting the malleable shape-memory material comprises heating the malleable shape-memory material.

168. The method of claim 167, wherein the heating comprises flowing heated saline through the device via a catheter.

169. The method of claim 167, wherein the heating comprises applying radio frequency (RF) energy to the device.

170. The method of any one of claims 166 to 169, wherein the mechanically expanding the malleable shape-memory material comprises expanding a balloon within the malleable shape-memory material.

171. A dilator for enlarging an opening through a region of the human body, the dilator comprising:

- a sheath having a proximal end and a distal end; and

- a dilator disposed at the distal end of the sheath and comprising a tip, an enlarged region, and a reduced region, wherein:

- the reduced region is sized so as to securably engage with the distal end of the sheath,

- the enlarged region is sized so as to provide a smooth profile between the sheath and the tip,

- a distal end of the tip tapers to approximately a point, and

- at least the enlarged region and the reduced region comprise a martensitic shape-memory material having an austenitic finish temperature (A_f) substantially greater than 37°C such that, upon application of heat within the body, the shape memory material returns to a smaller, heat-set outer dimension such that the dilator has a substantially smooth, reduced size profile.

172. The dilator of claim 171, wherein the tip also includes the martensitic shape-memory material.

173. The dilator of claim 171, wherein the tip includes a self-expanding superelastic material.

174. A system including the dilator of any one of claims 171 to 173 and a device to deploy in the opening.

175. A method for forming an enlarged opening through a region of the human body, the method comprising:

- disposing a guidewire through the region of the human body to form an opening;
- pushing a dilator over the guidewire and through the opening to form an enlarged opening;
- heating the dilator to reduce the size of the dilator; and
- while the dilator has the reduced size, withdrawing the dilator through the enlarged opening.

176. The method of claim 175, wherein the heating comprises flowing heated saline through the dilator via a catheter.

177. The method of claim 175, wherein the heating comprises applying radio frequency (RF) energy to the dilator.

178. The method of any one of claims 175 to 178, further comprising deploying a device within the opening, and withdrawing the dilator through the device.

179. A transatrial gate, comprising:

- a left atrial disc comprising a first self-expanding superelastic material;
- a right atrial disc comprising a second self-expanding superelastic material; and
- a martensitic shape-memory material that is heat set to completely occlude passage between the left and right atrial discs that is expandable to allow passage between the left and right atrial discs.

180. The transatrial gate of claim 179, wherein the martensitic shape-memory material is provided as a mesh.

181. The transatrial gate of claim 179 or claim 180, wherein the martensitic shape-memory material is balloon expandable.

182. The transatrial gate of any one of claims 179 to 181, wherein the martensitic shape-memory material is configured to be closeable by application of heat after being expanded to allow passage between the left and right atrial discs.

183. A method of performing a procedure, the method comprising:
implanting a transatrial gate through an opening in an atrial septum of a heart, the transatrial gate comprising:
a left atrial disc comprising a first self-expanding superelastic material;
a right atrial disc comprising a second self-expanding superelastic material; and
a martensitic shape-memory material that is heat set to completely occlude passage between the left and right atrial discs; and
expanding the martensitic shape-memory material to allow passage between the left and right atrial discs.

184. The method of claim 183, wherein the material comprises blood.

185. The method of claim 183 or claim 184, wherein the material comprises an instrument.

186. The method of claim 185, wherein the method comprises using the instrument to perform an additional procedure in a left atrium of the heart.

187. The method of claim 186, wherein the additional procedure comprises RF ablation, left atrial appendage closure, MitraClip implantation, mitral valve replacement, or mitral valve repair.

188. The method of any one of claims 183 to 187, wherein the martensitic shape-memory material is provided as a mesh.

189. The method of any one of claims 183 to 188, wherein the martensitic shape-memory material is expanded using a balloon.

190. The method of any one of claims 183 to 189, further comprising, after the expanding, closing the martensitic shape-memory material by application of heat.

191. An apparatus, comprising:

a device comprising:

a proximal portion configured to be disposed in a first atrium of a heart;

a distal portion configured to be disposed in a second atrium of a heart and comprising a first self-expanding superelastic material;

an intermediate portion disposed between the proximal portion and the distal portion and configured to be disposed in an atrial septum between the first atrium and the second atrium, the intermediate portion comprising a malleable shape-memory material;

a catheter; and

at least one constricting flexible longitudinal element,

the first self-expanding superelastic material having a predetermined fully expanded dimension,

the intermediate portion having a first dimension suitable for deployment through the catheter,

the intermediate portion being expandable to a second dimension for fixation within the septum,

the intermediate portion being thermally transitionable to a third dimension,

the intermediate portion being mechanically re-expandable to a fourth dimension,

and

the device being removable by drawing the device into the catheter using the at least one constricting flexible longitudinal element.

192. The device of claim 191, wherein the proximal portion is flared.

193. The device of claim 191 or claim 192, wherein the distal portion is flared.

194. The device of any one of claims 191 to 193, wherein the proximal portion comprises a second self-expanding superelastic material.

195. A method, comprising:

through a catheter, deploying a device through an atrial septum of a heart, the device comprising:

a proximal portion disposed in a first atrium of the heart;

a distal portion disposed in a second atrium of the heart and comprising a first self-expanding superelastic material;

an intermediate portion disposed between the proximal portion and the distal portion and disposed in the atrial septum between the first atrium and the second atrium, the intermediate portion comprising a malleable shape-memory material;

the first self-expanding superelastic material having a predetermined fully expanded dimension,

the intermediate portion having a first dimension when deployed through the catheter;

expanding the intermediate portion to a second dimension for fixation within the septum;

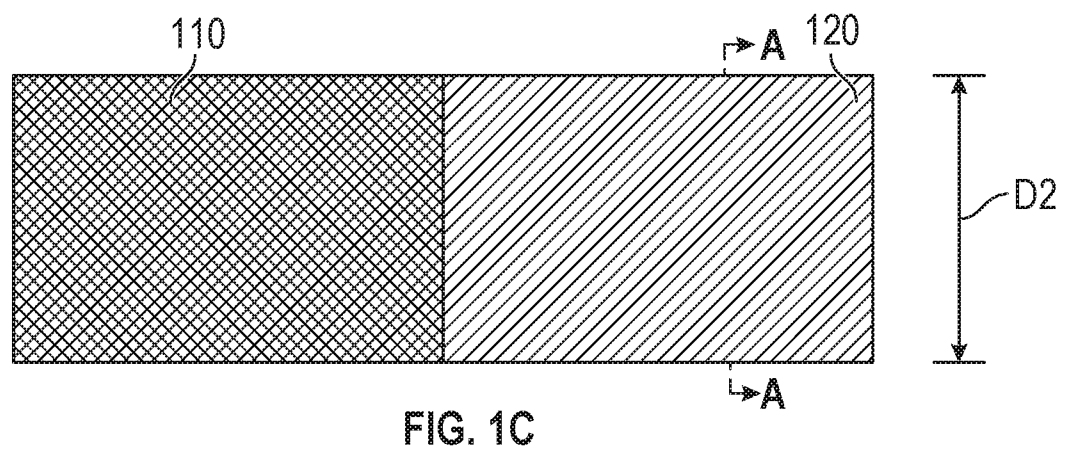
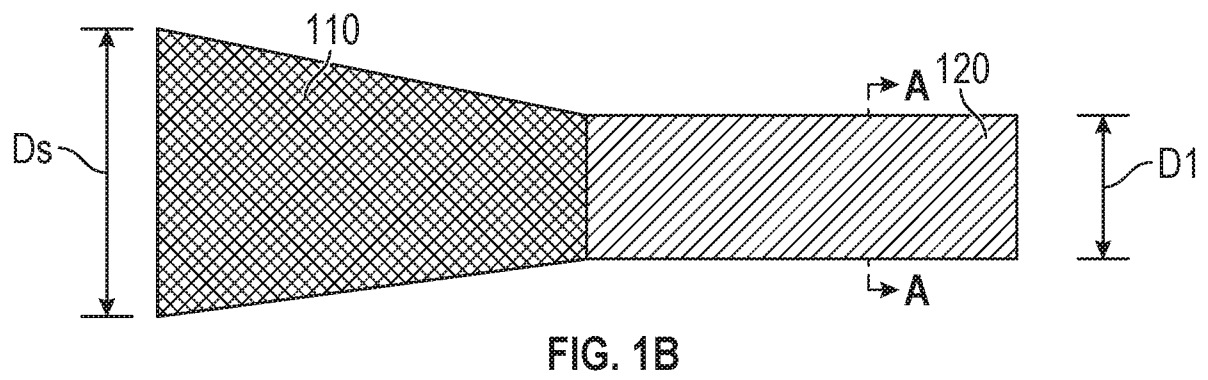
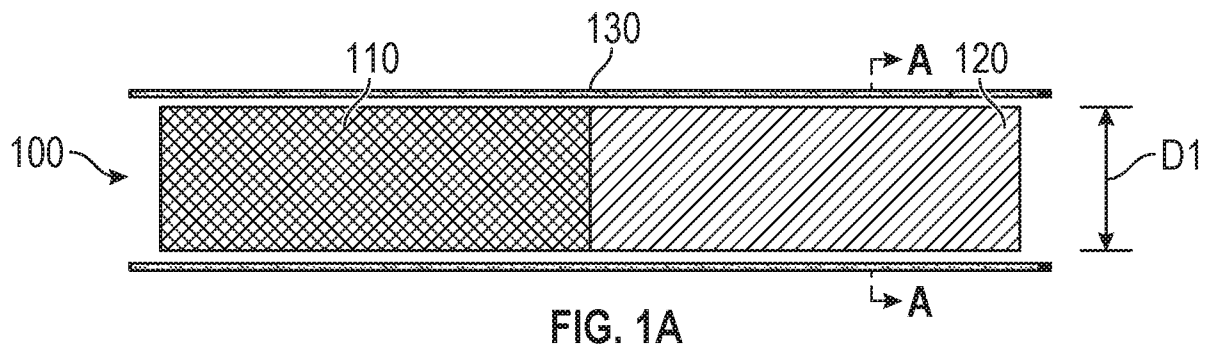
thermally transitioning the intermediate portion to a third dimension;

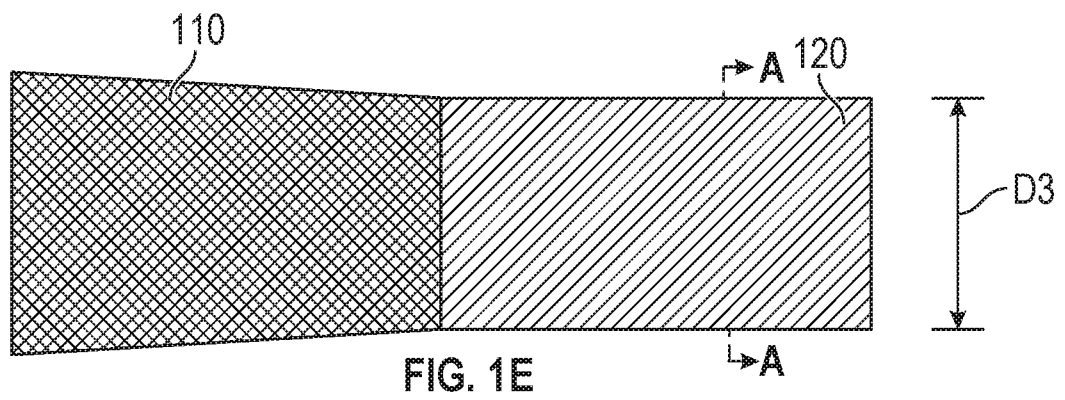
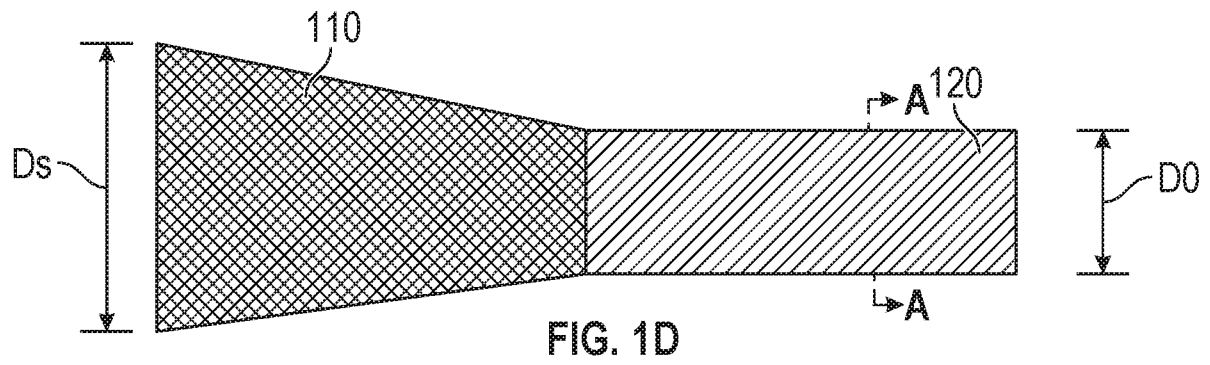
mechanically re-expanding the intermediate portion to a fourth dimension; and

removing the device by drawing the device into the catheter using the at least one constricting flexible longitudinal element.

196. The method of claim 195, wherein the proximal portion is flared.
197. The method of claim 195 or claim 196, wherein the distal portion is flared.
198. The method of any one of claims 195 to 197, wherein the proximal portion comprises a second self-expanding superelastic material.
199. The device of any one of claims 111 to 137 or 165, wherein the first component and the second component are integrally formed from a common frame with one another.
200. The method of any one of claims 155-159, 160-164, or 166-170, wherein the first component and the second component are integrally formed from a common frame with one another.
201. The dilator of any one of claims 171-174, wherein the tip, the reduced region, and the enlarged region are integrally formed from a common frame with one another.
202. The gate of any one of claims 179-182, wherein the left atrial disc, the right atrial disc, and the martensitic shape memory material are integrally formed from a common frame with one another.
203. The method of any one of claims 183-190, wherein the left atrial disc, the right atrial disc, and the martensitic shape memory material are integrally formed from a common frame with one another.
204. The apparatus of any one of claims 191-194, wherein the proximal portion, the distal portion, and the intermediate portion are integrally formed from a common frame with one another.

205. The method of any one of claims 195-198, wherein the proximal portion, the distal portion, and the intermediate portion are integrally formed from a common frame with one another.





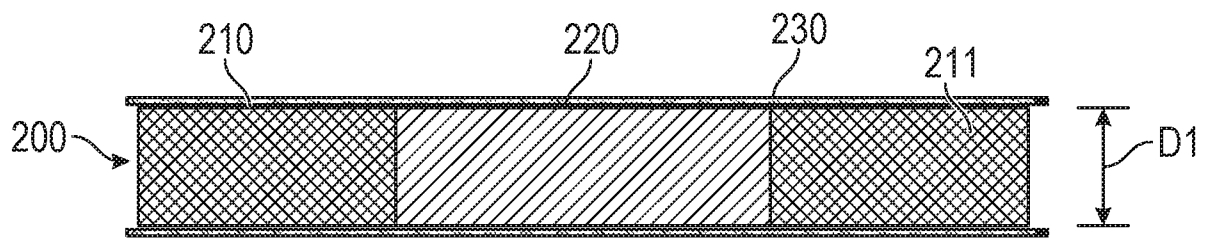


FIG. 2A

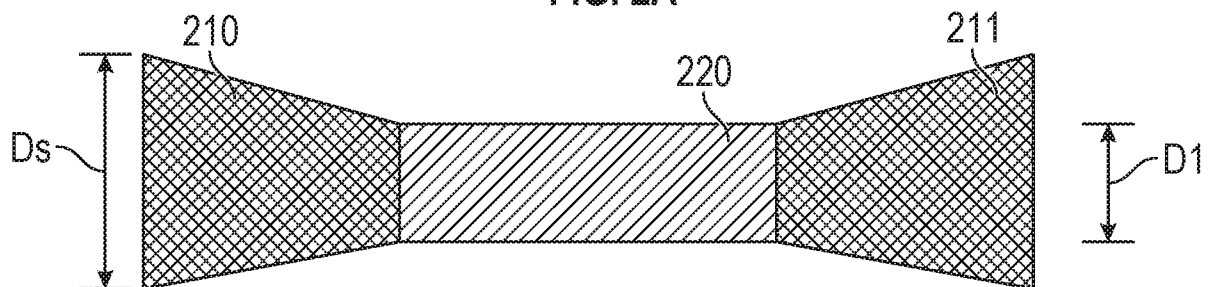


FIG. 2B

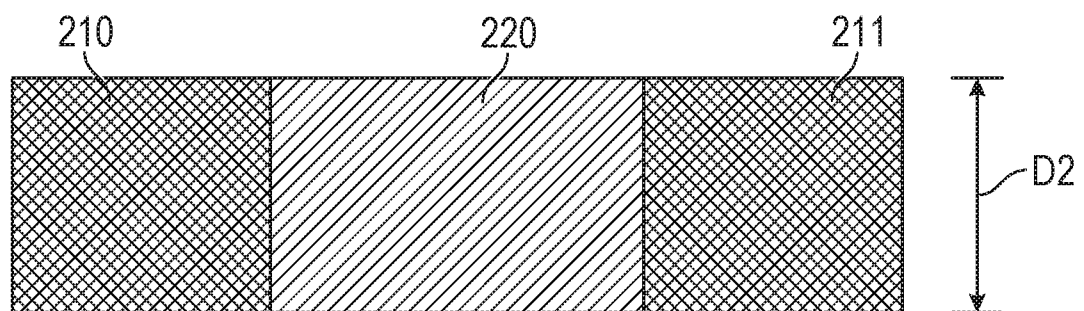


FIG. 2C

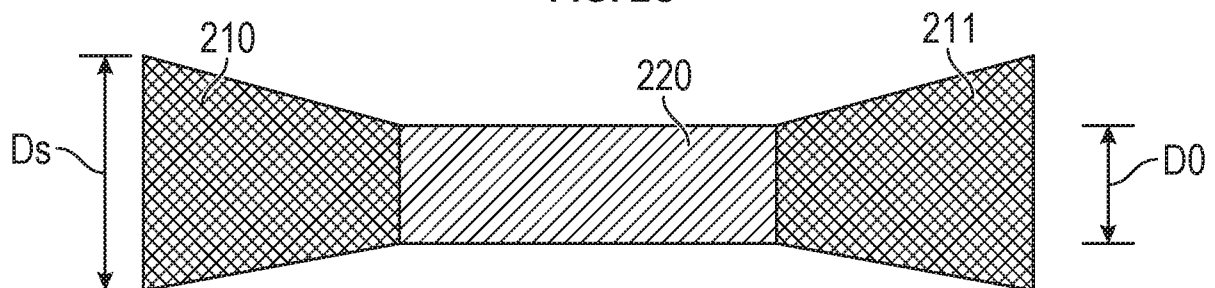


FIG. 2D

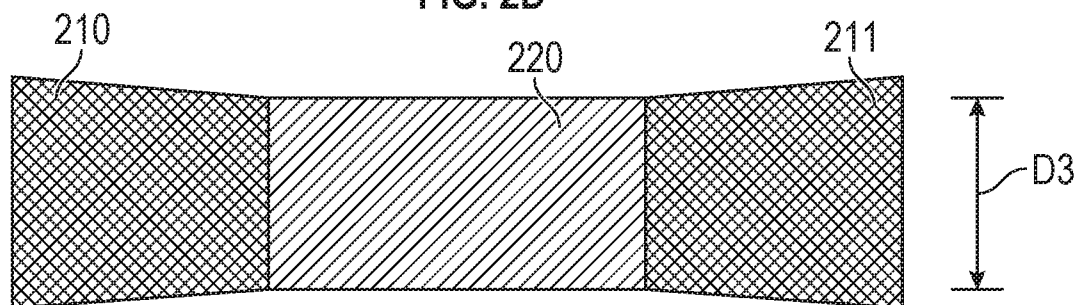


FIG. 2E

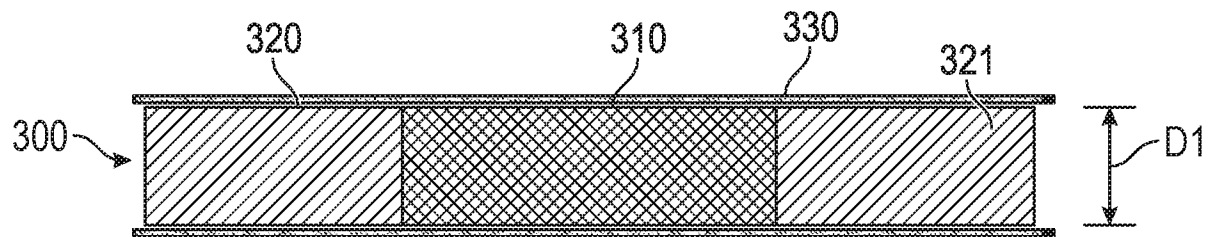


FIG. 3A

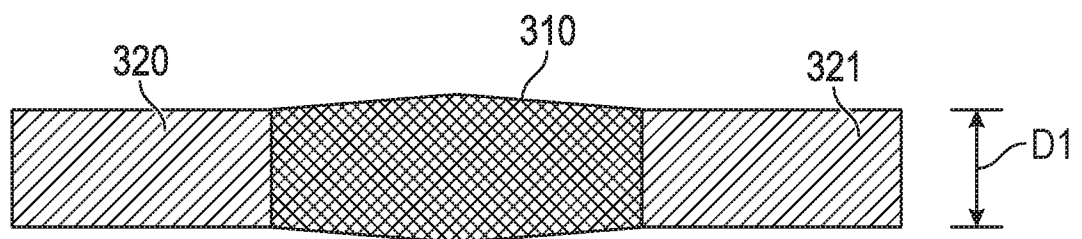


FIG. 3B

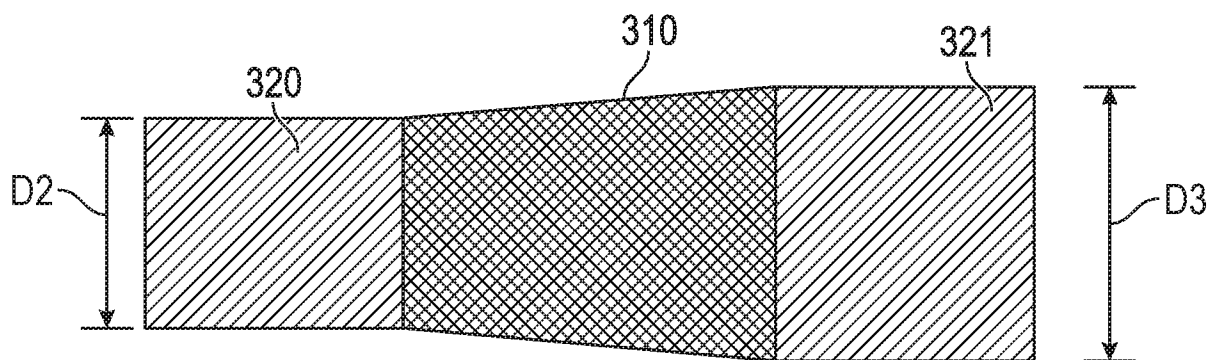


FIG. 3C

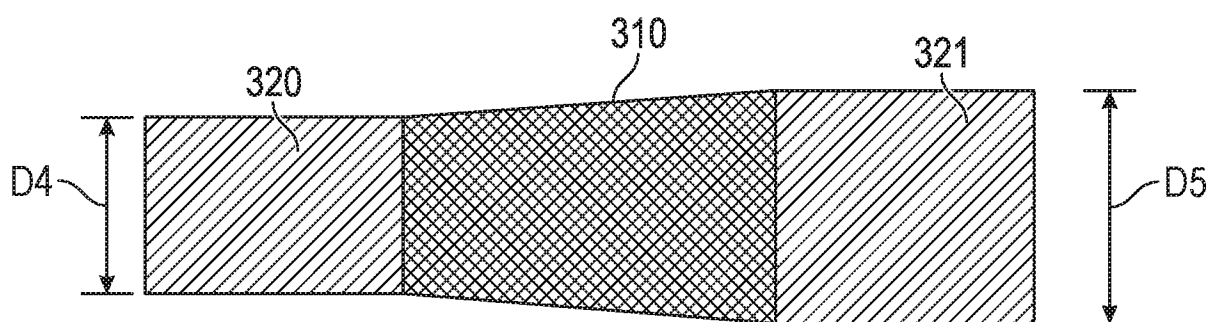


FIG. 3D

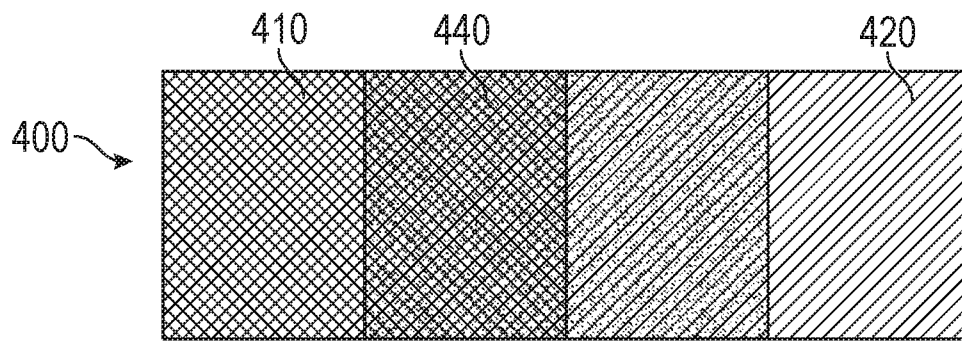


FIG. 4A

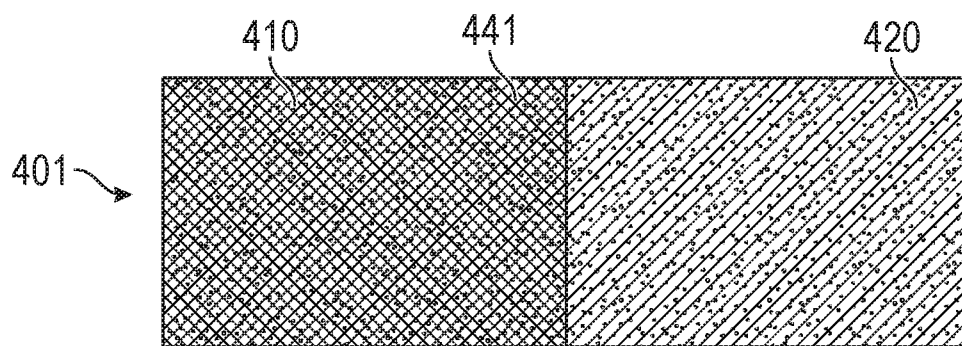


FIG. 4B

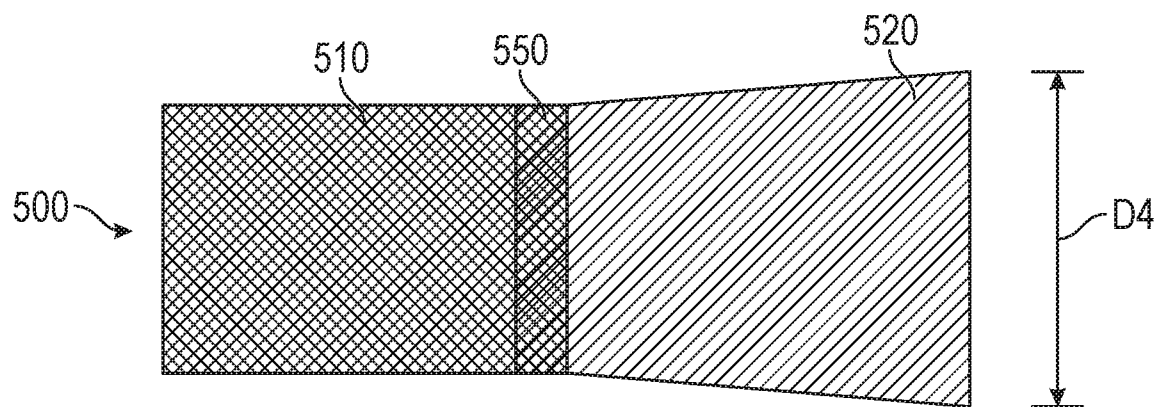


FIG. 5A

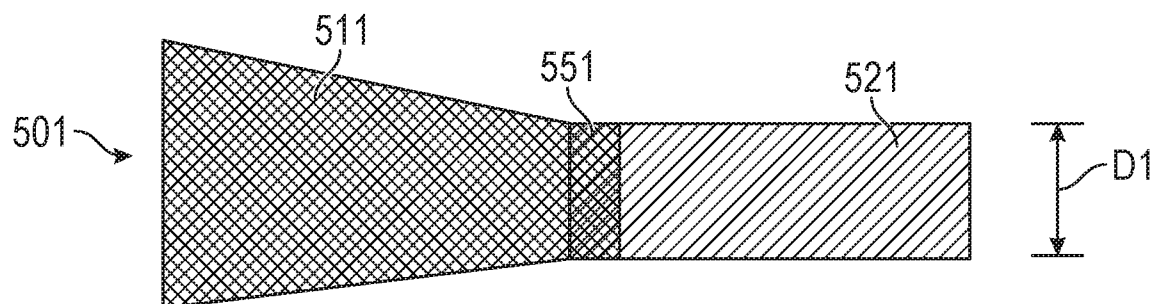


FIG. 5B

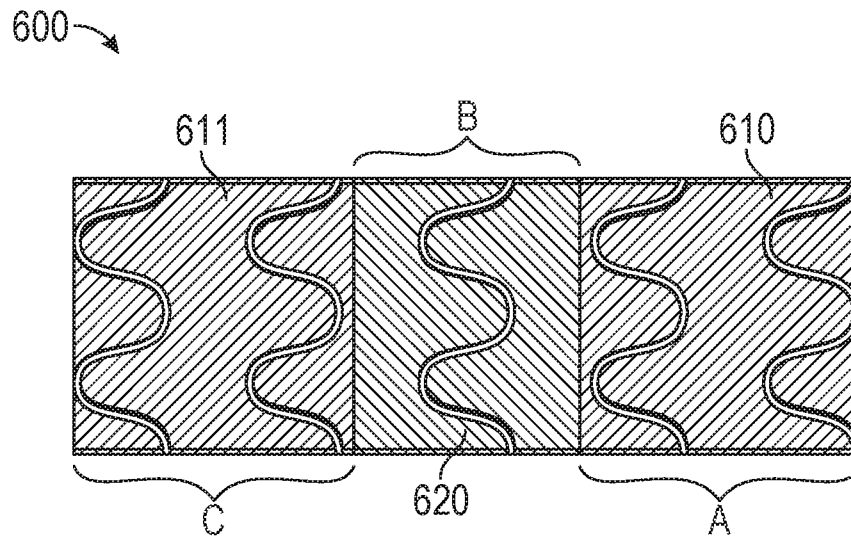


FIG. 6

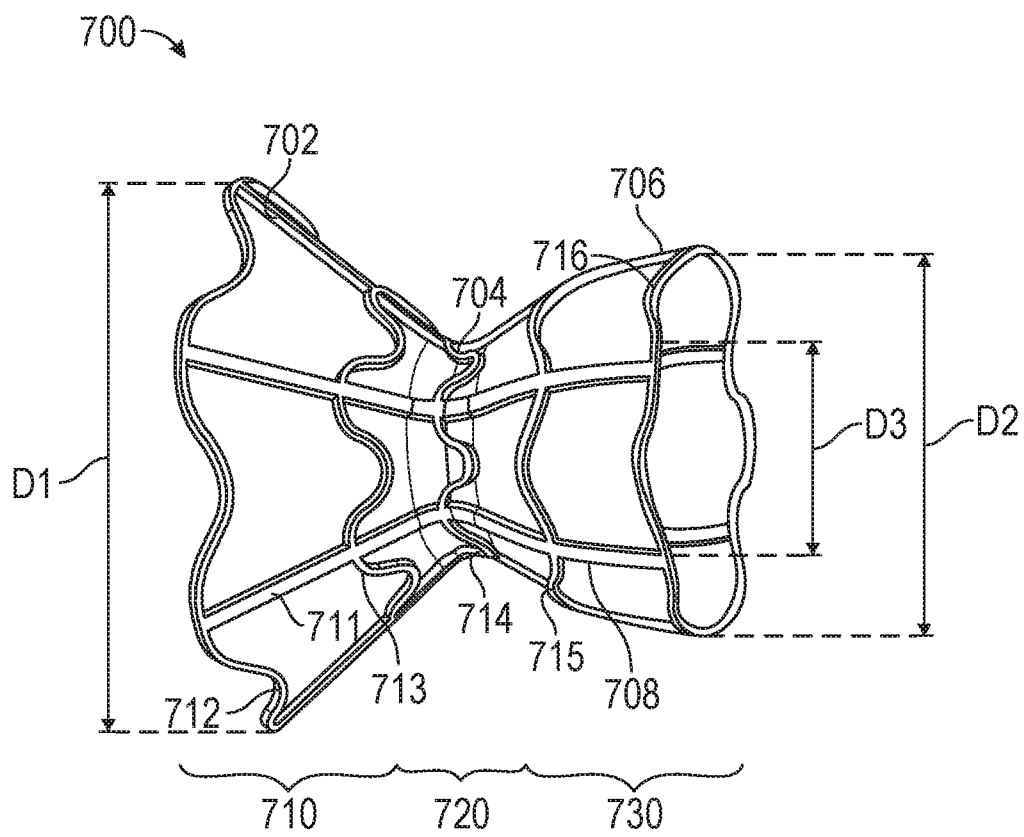


FIG. 7

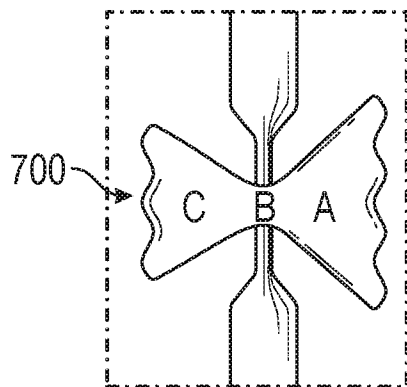


FIG. 8A

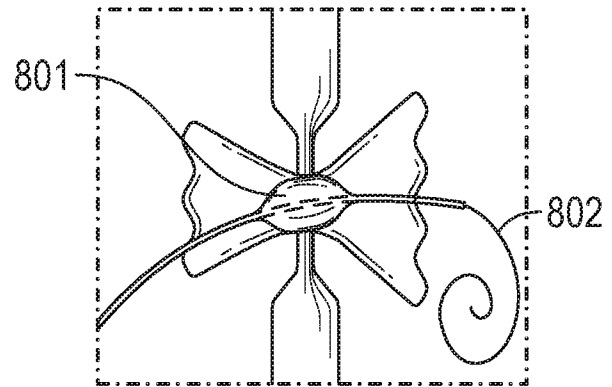


FIG. 8B

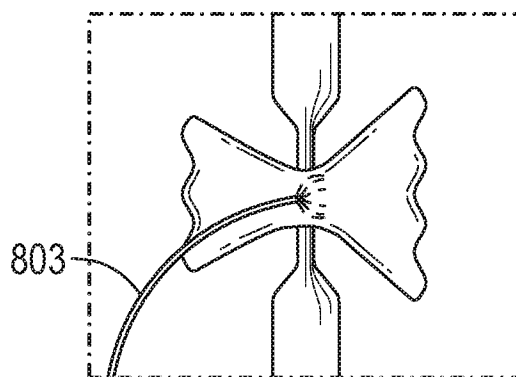


FIG. 8C

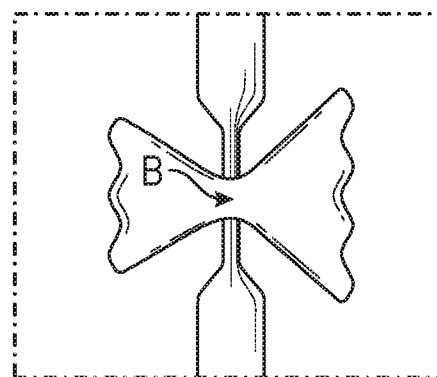
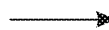


FIG. 8D

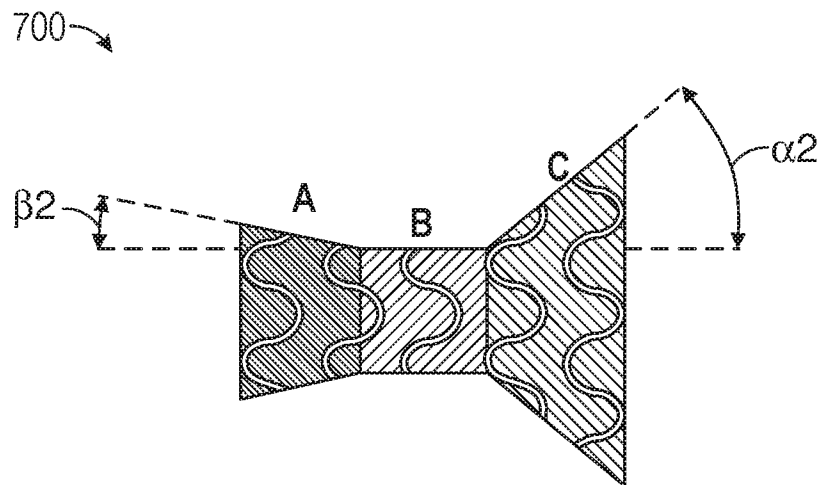


FIG. 9A

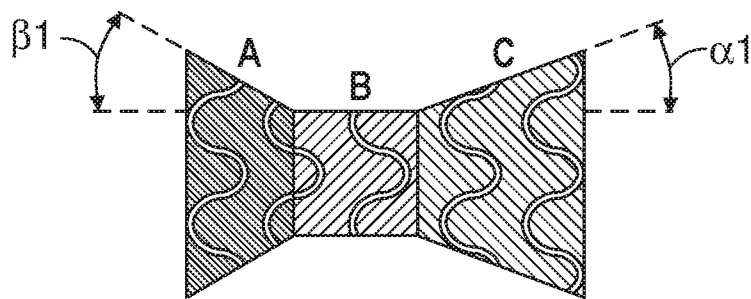


FIG. 9B

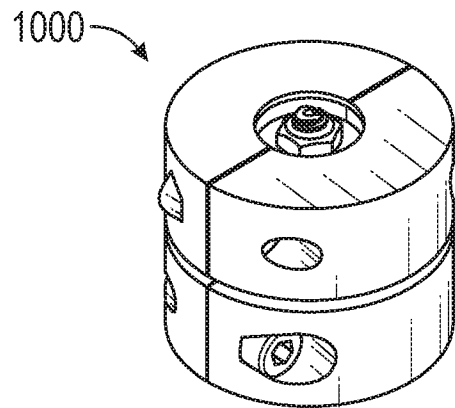


FIG. 10A

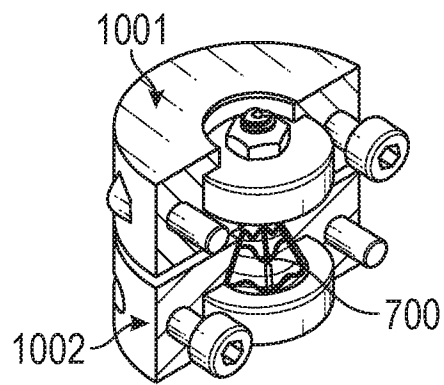


FIG. 10B

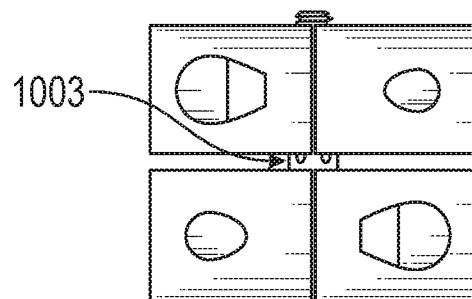


FIG. 10C

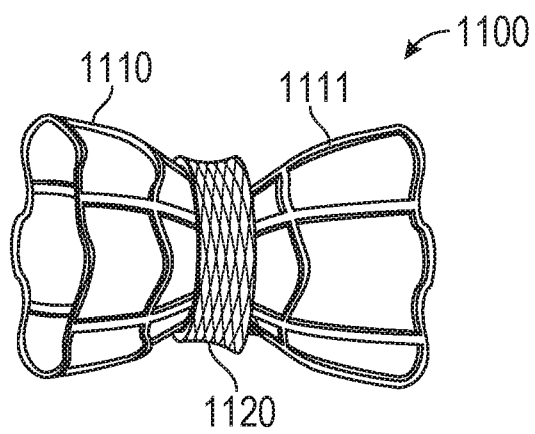


FIG. 11A

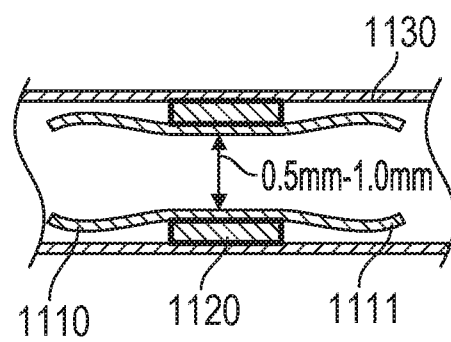


FIG. 11B

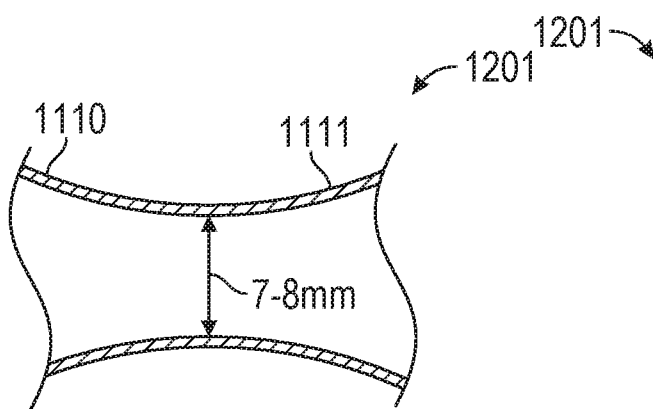


FIG. 12A

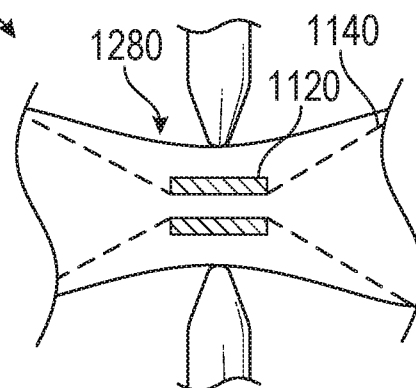


FIG. 12B

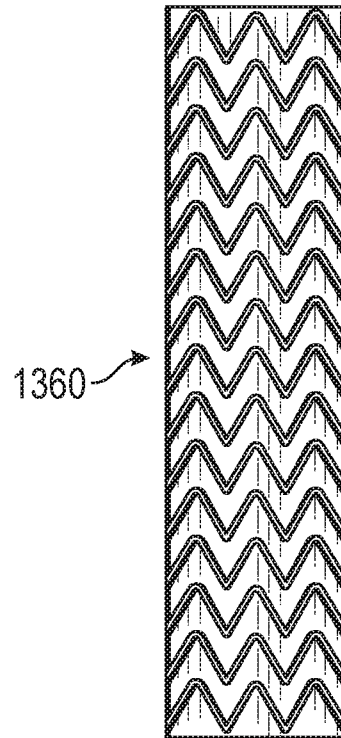


FIG. 13A

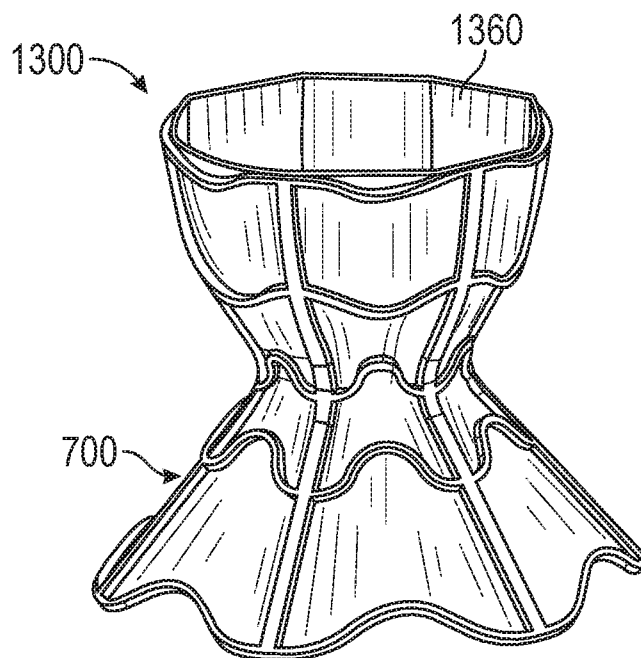


FIG. 13B

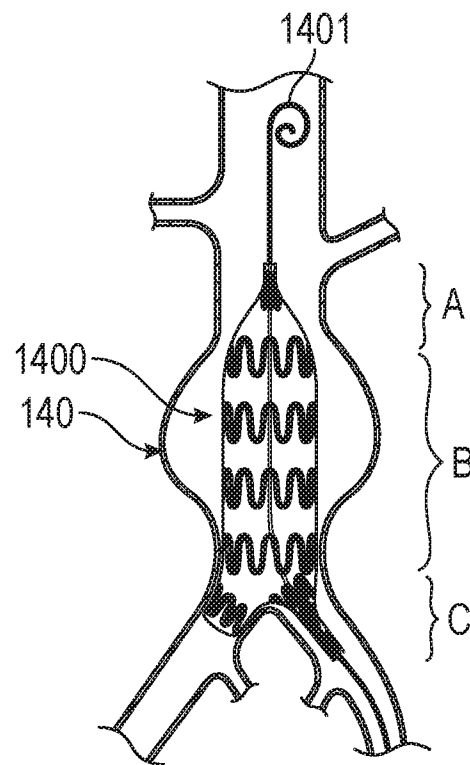


FIG. 14A

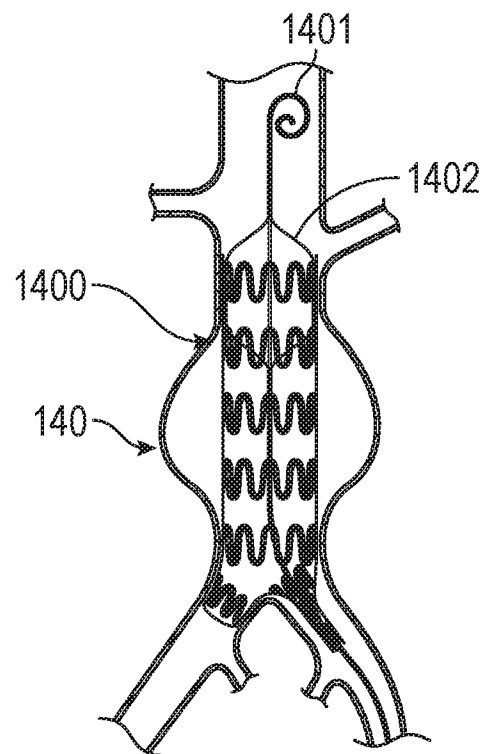


FIG. 14B

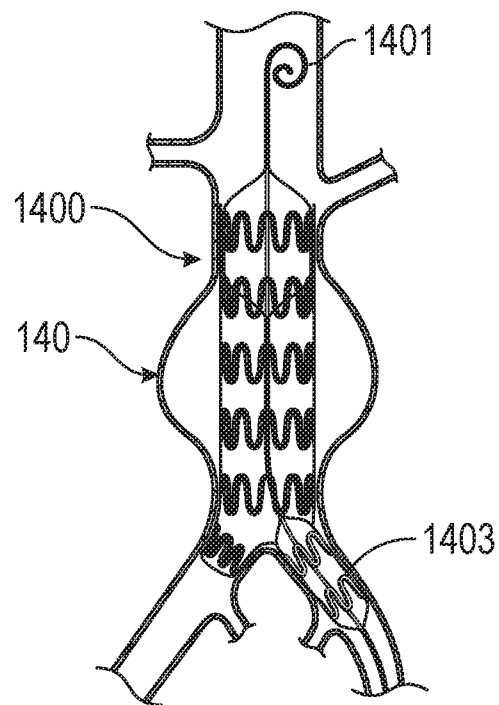


FIG. 14C

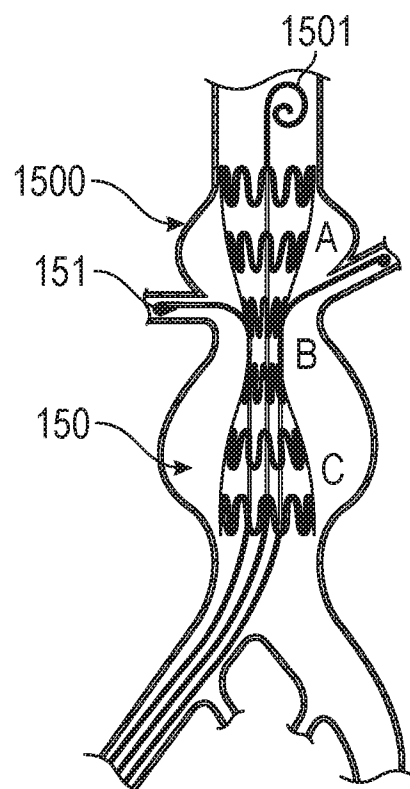


FIG. 15A

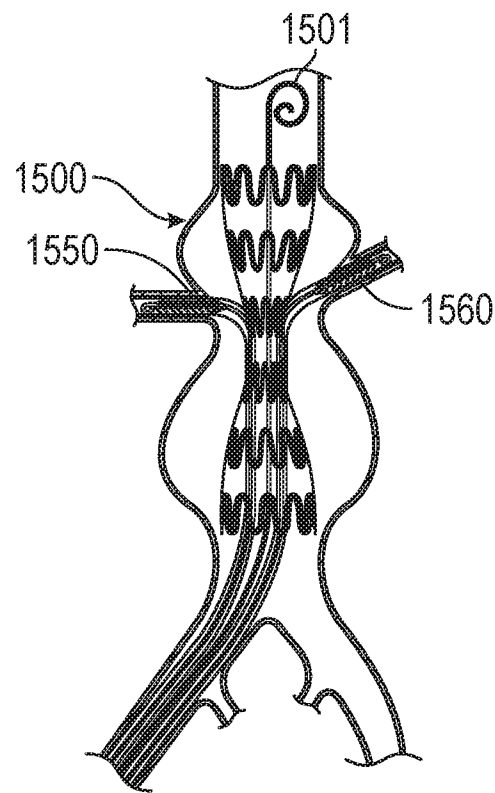


FIG. 15B

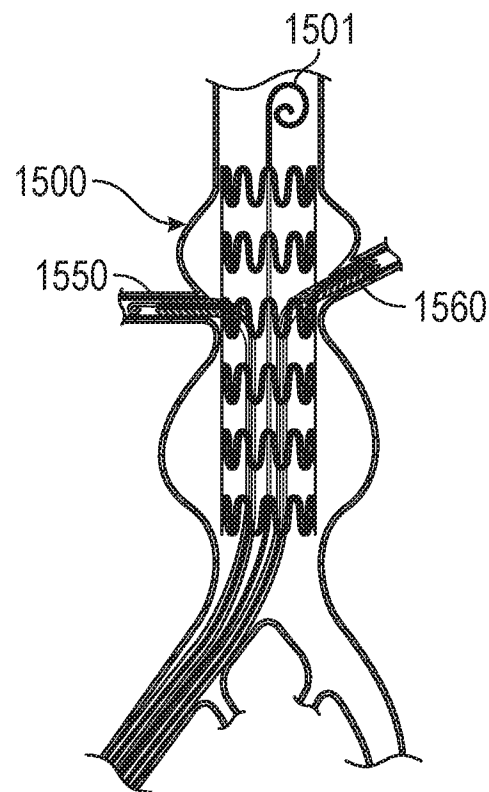


FIG. 15C

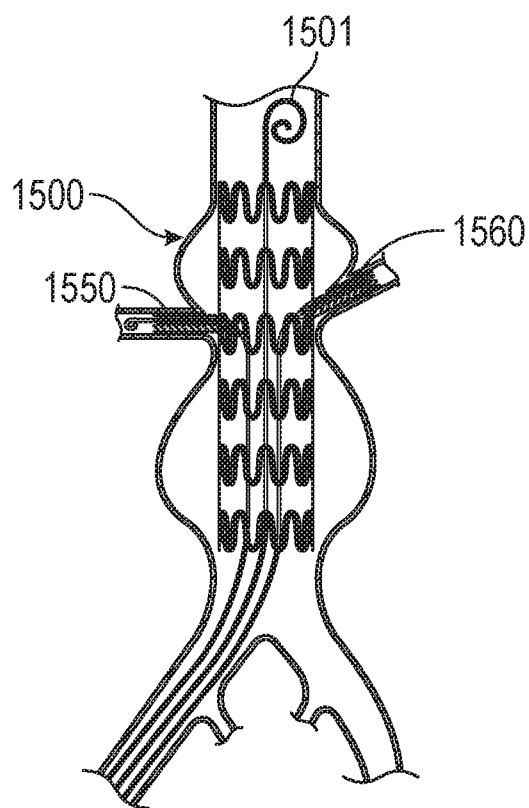


FIG. 15D

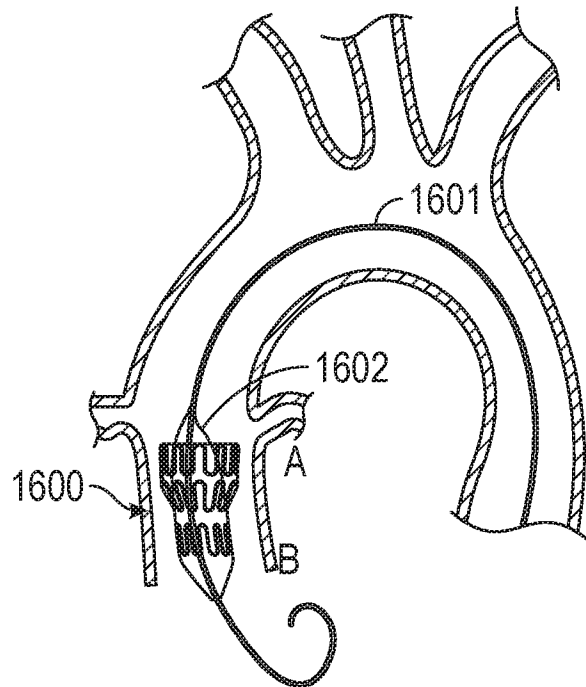


FIG. 16A

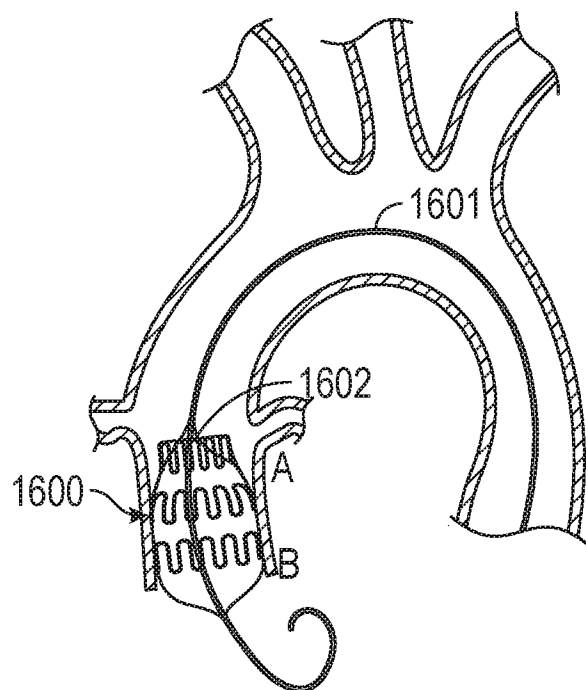


FIG. 16B

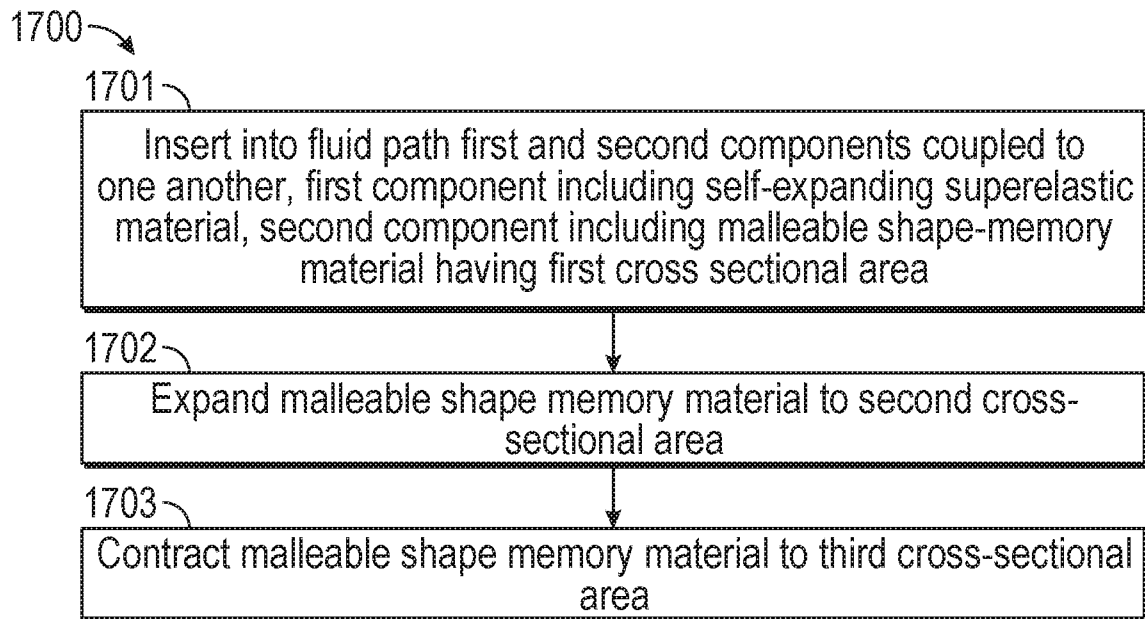


FIG. 17

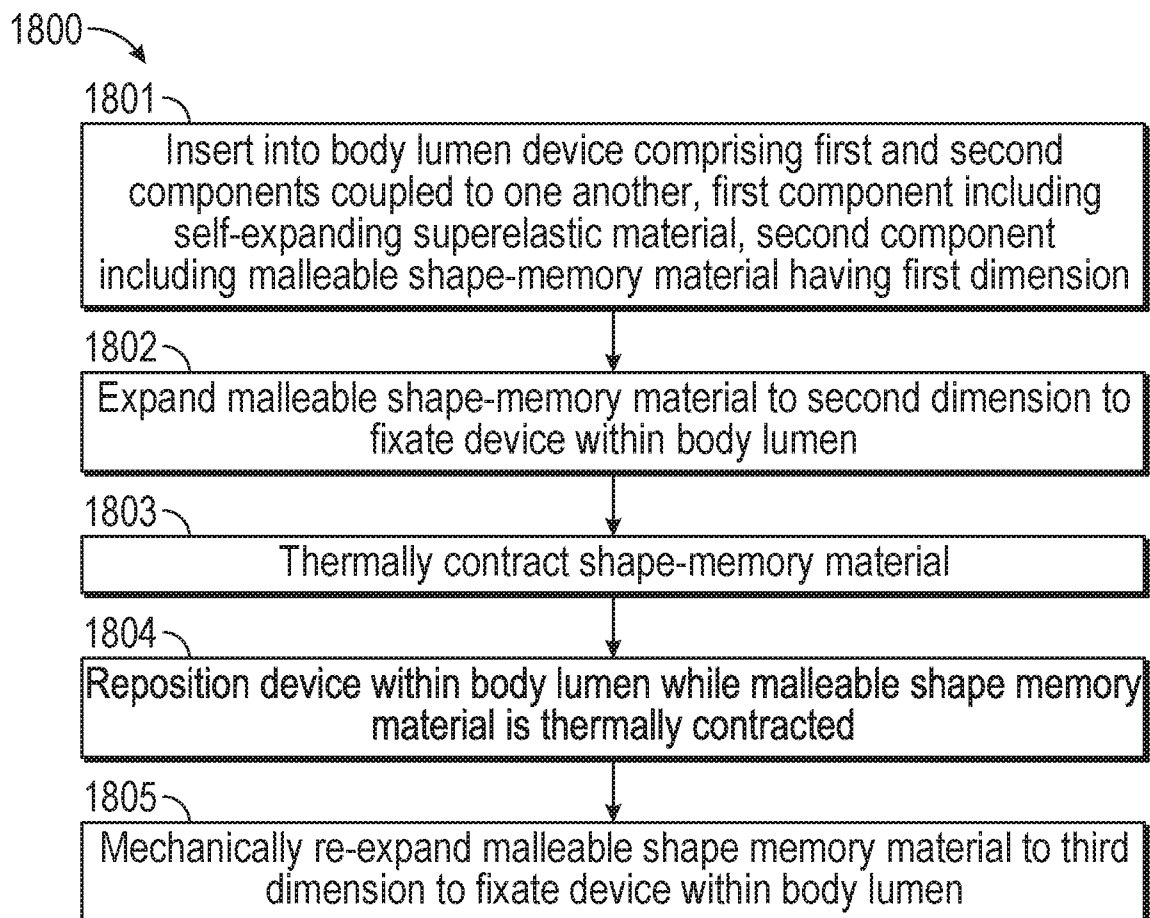


FIG. 18

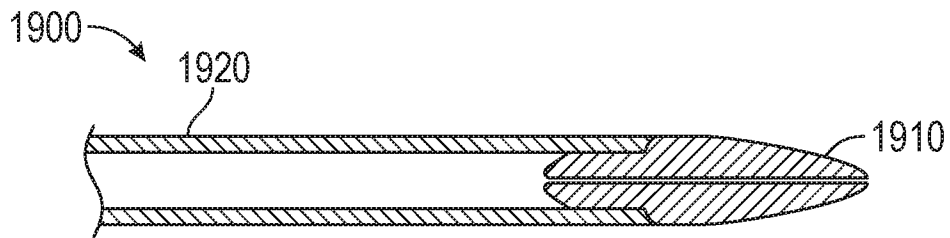


FIG. 19A

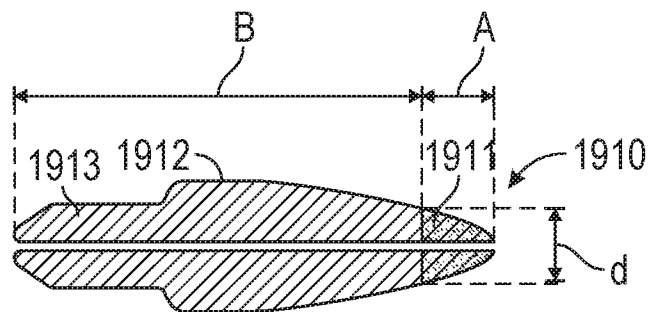


FIG. 19B

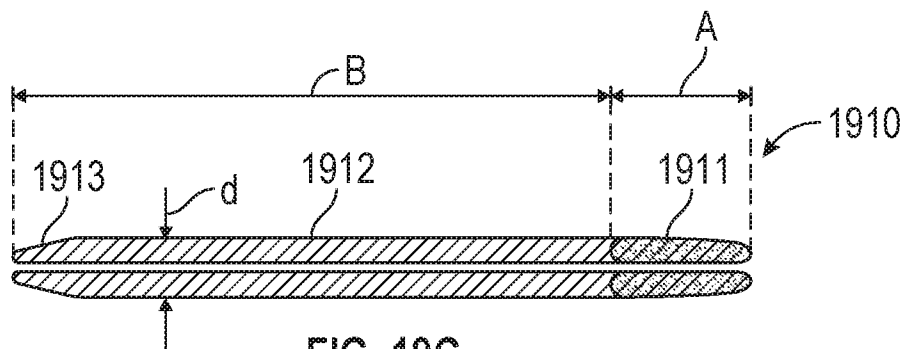


FIG. 19C

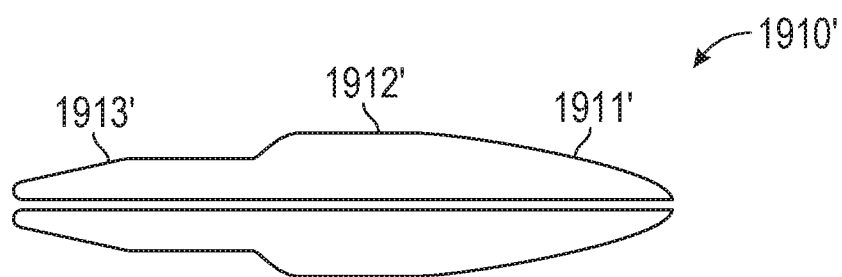


FIG. 19D

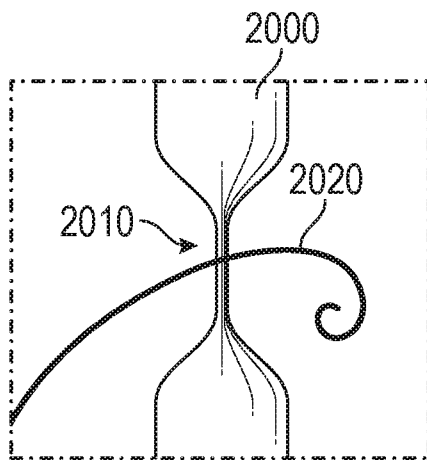


FIG. 20A

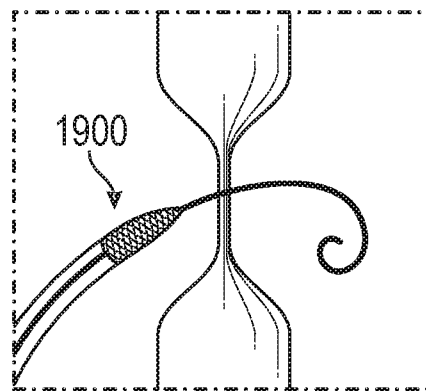


FIG. 20B

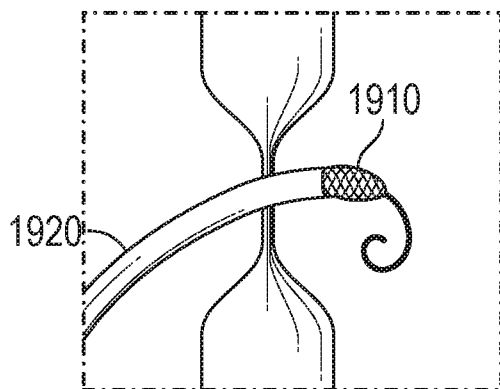


FIG. 20C

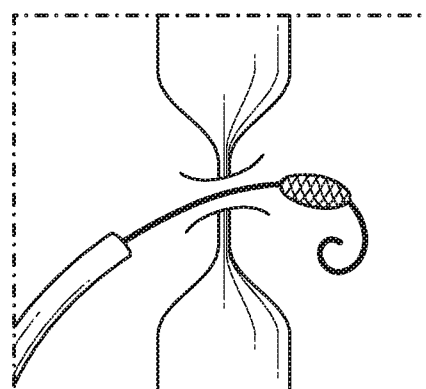


FIG. 20D

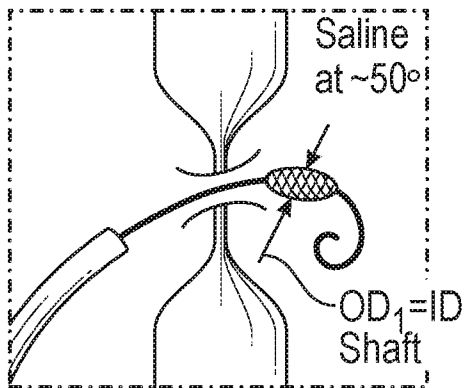


FIG. 20E

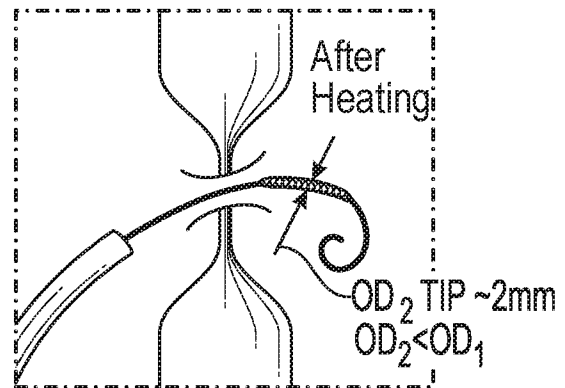


FIG. 20F

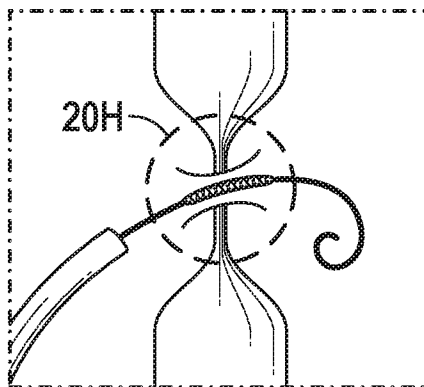


FIG. 20G

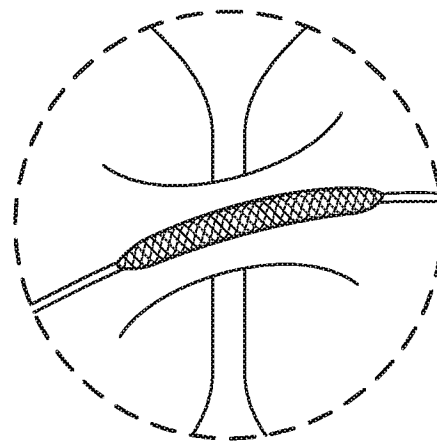


FIG. 20H

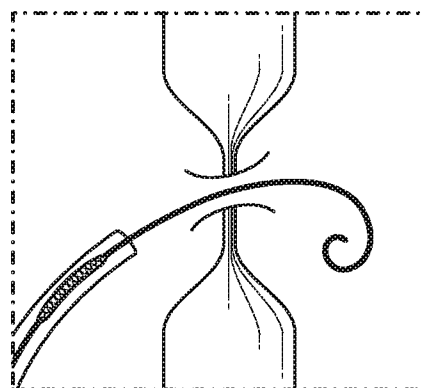


FIG. 20I

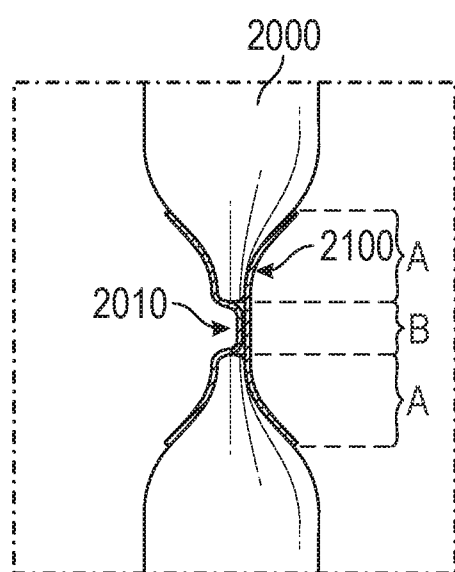


FIG. 21A

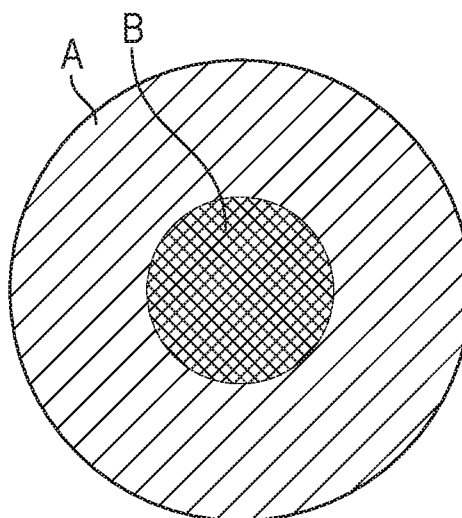


FIG. 21B

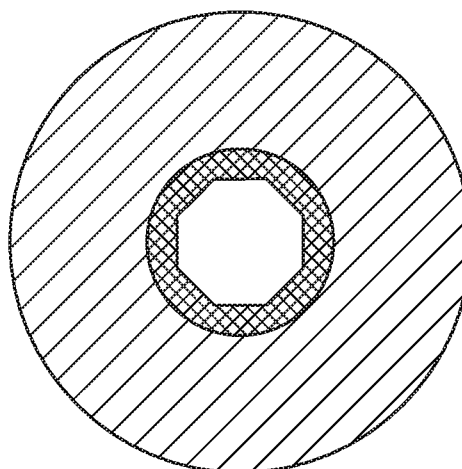


FIG. 21C

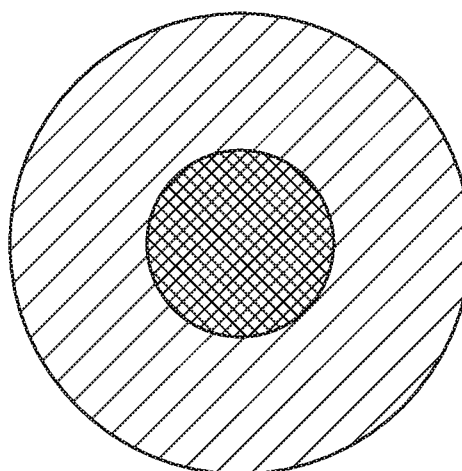


FIG. 21D

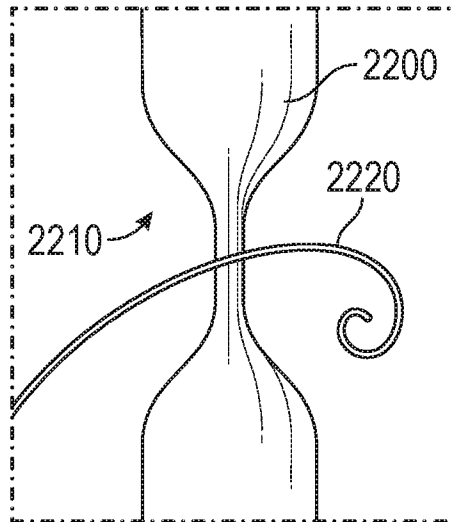


FIG. 22A

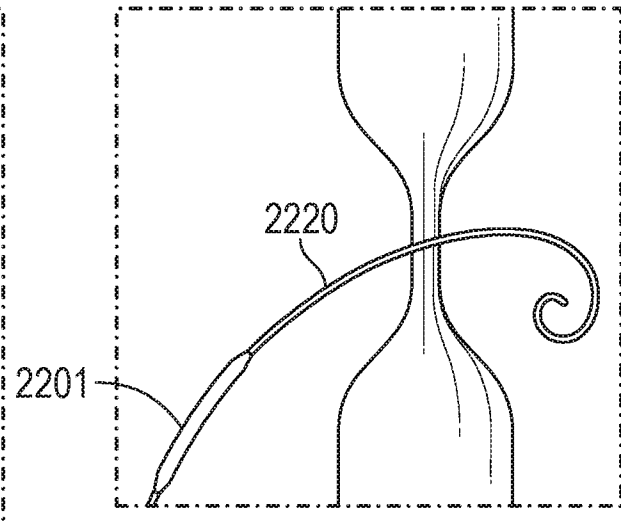


FIG. 22B

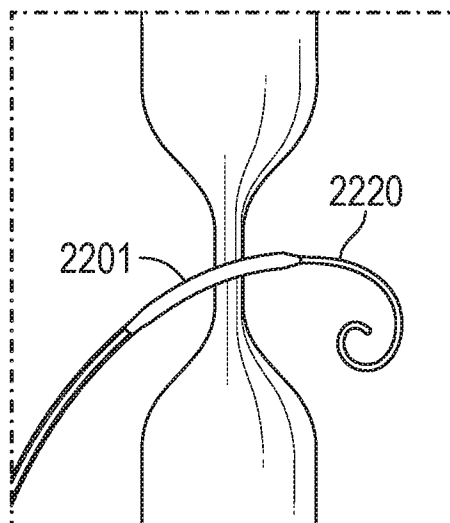


FIG. 22C

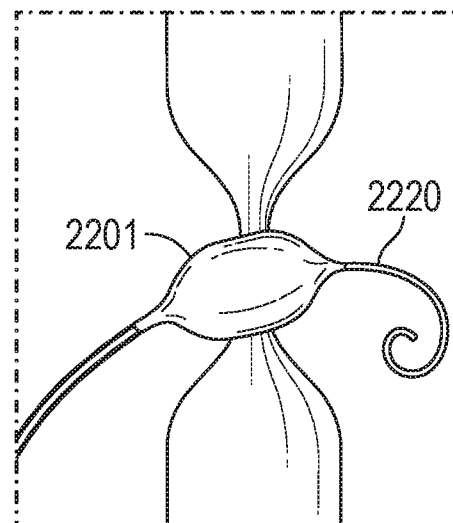


FIG. 22D

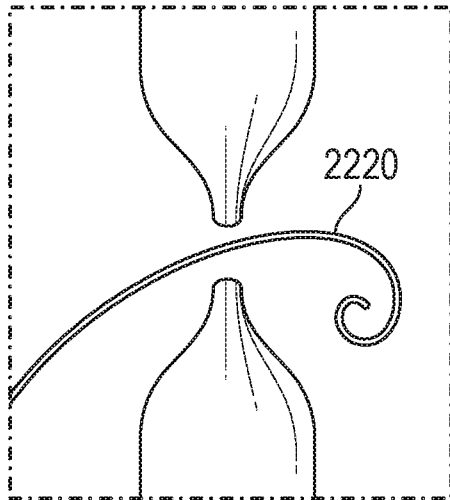


FIG. 22E

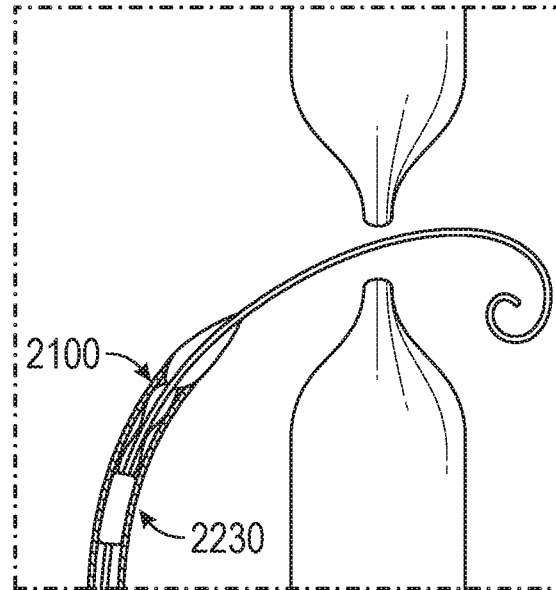


FIG. 22F

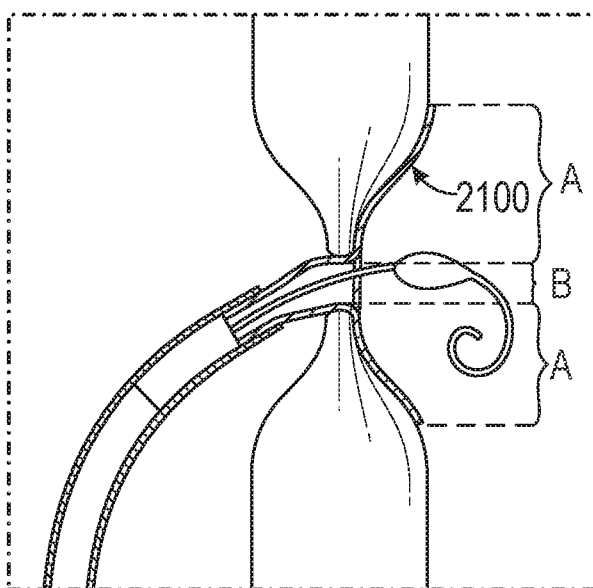


FIG. 22G

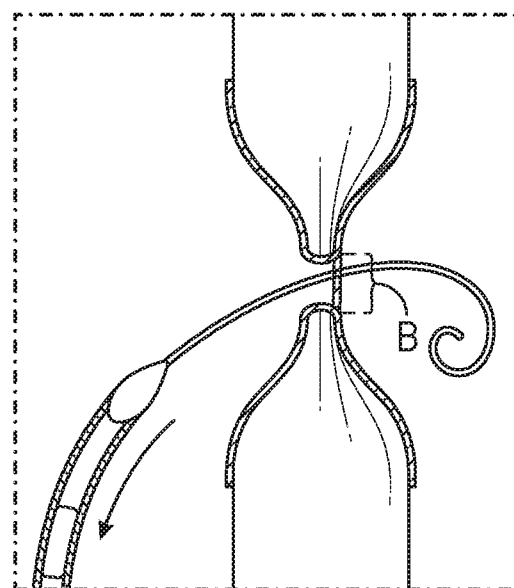


FIG. 22H

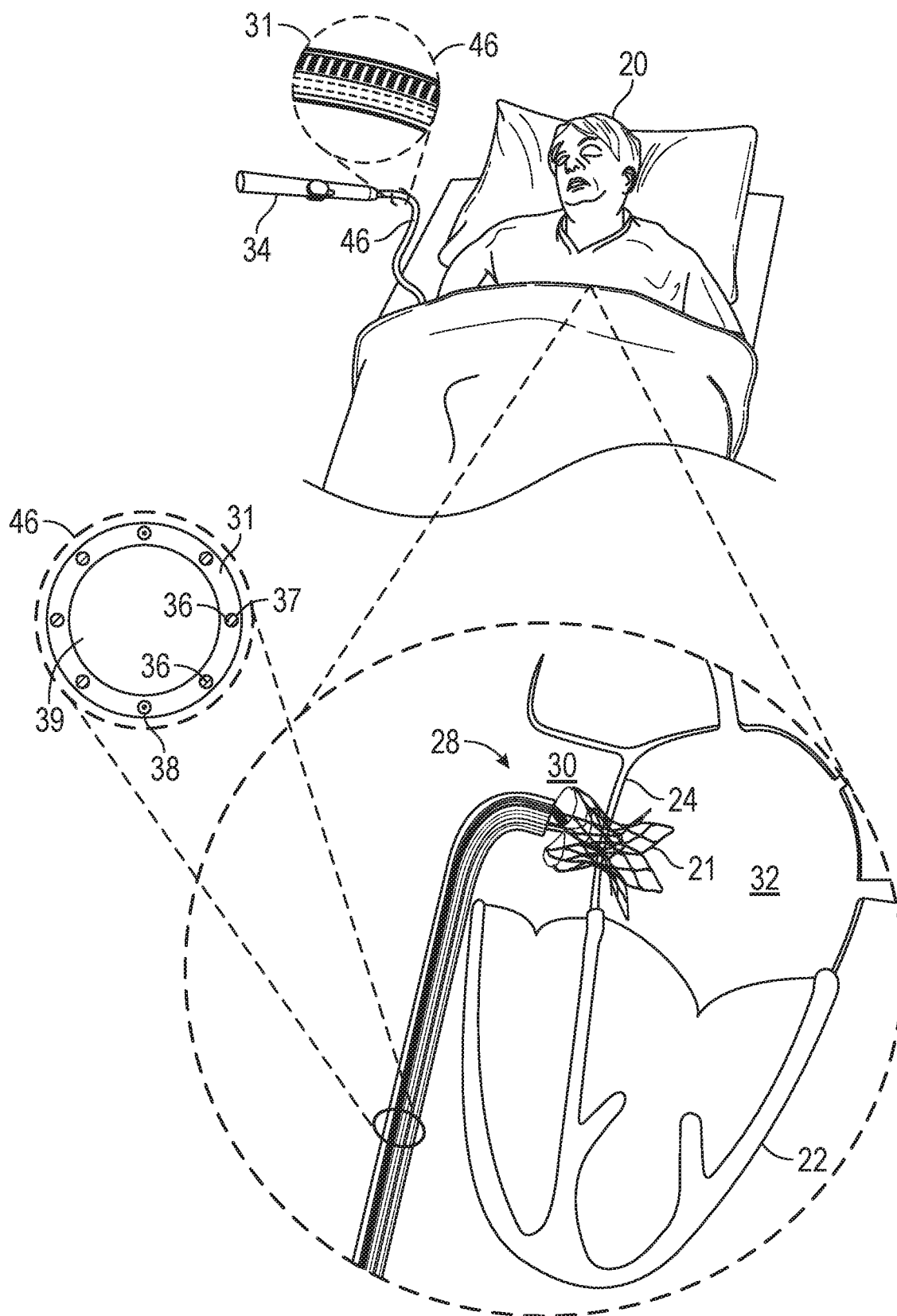


FIG. 23A

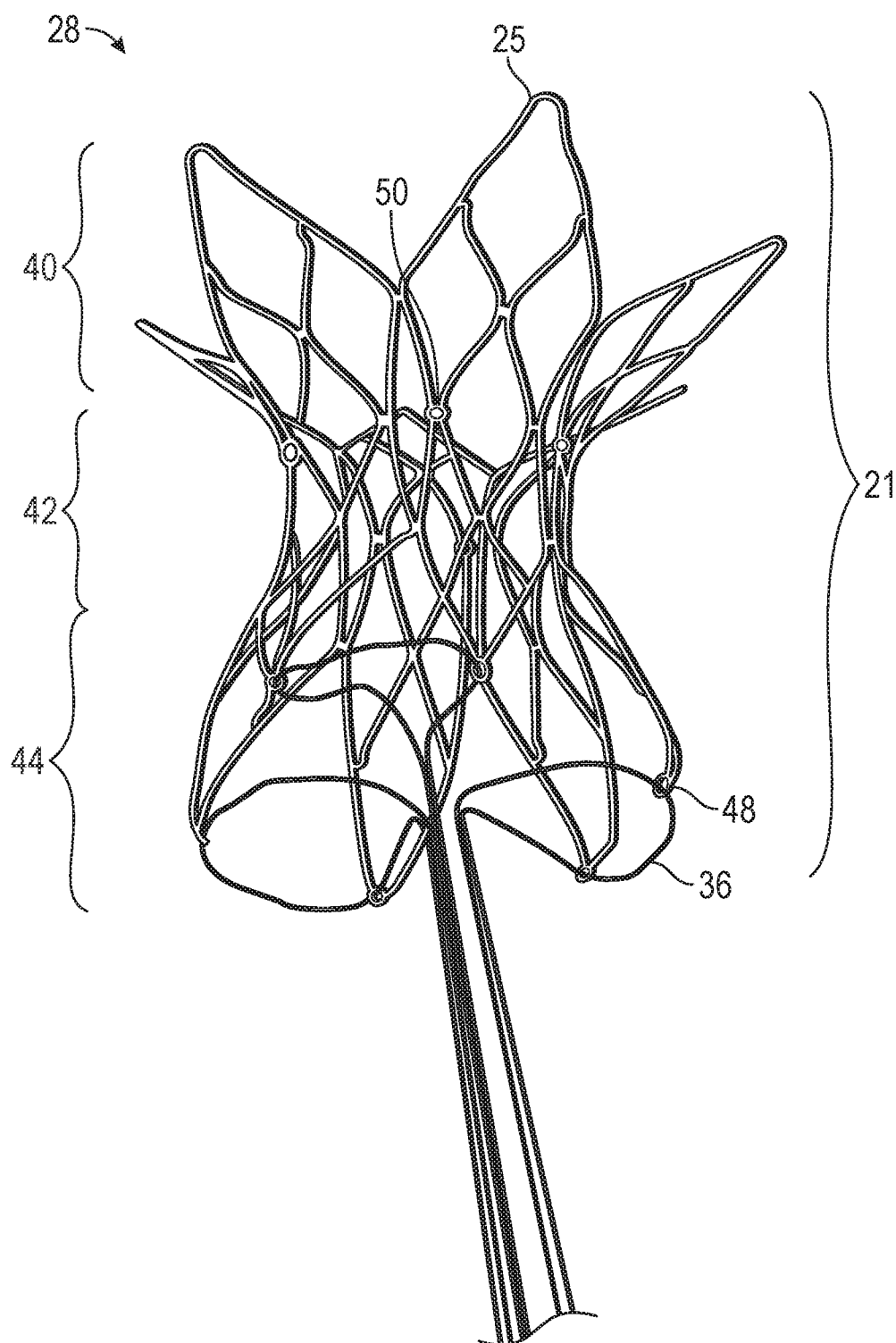


FIG. 23B

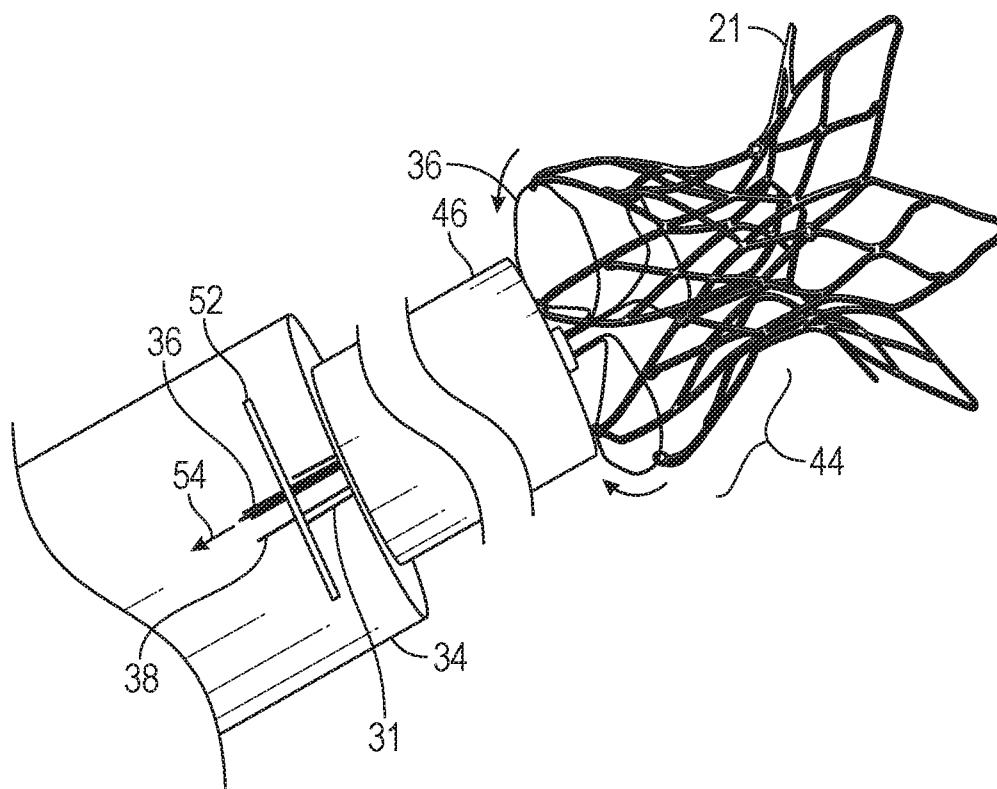


FIG. 23C

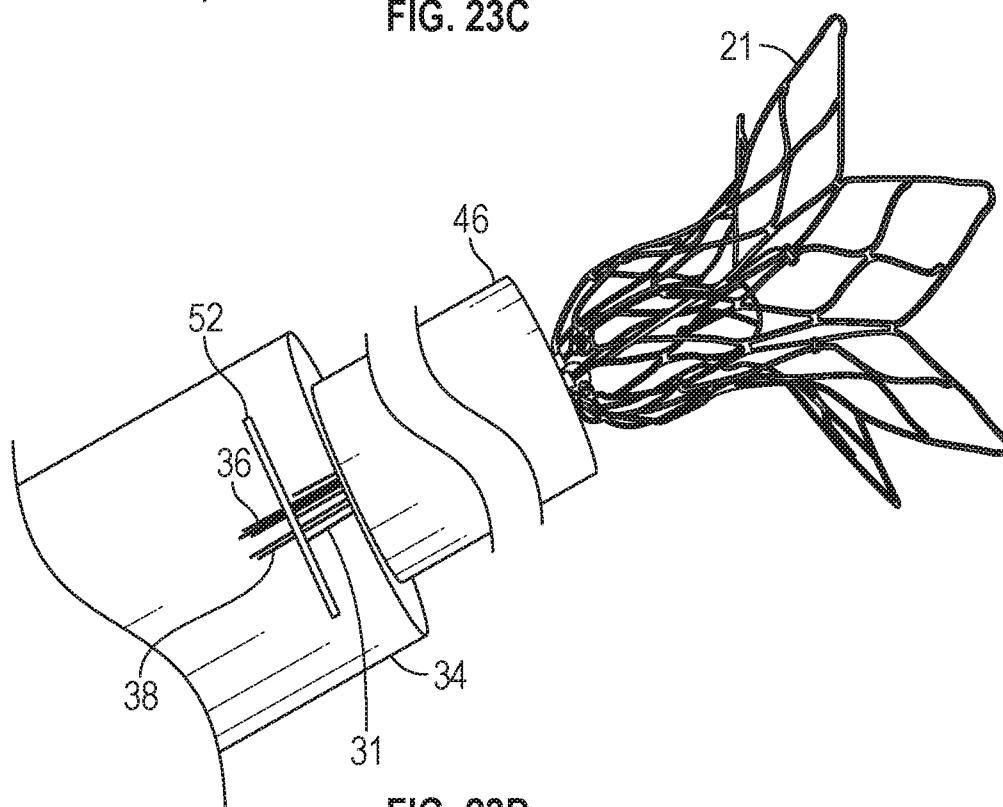


FIG. 23D

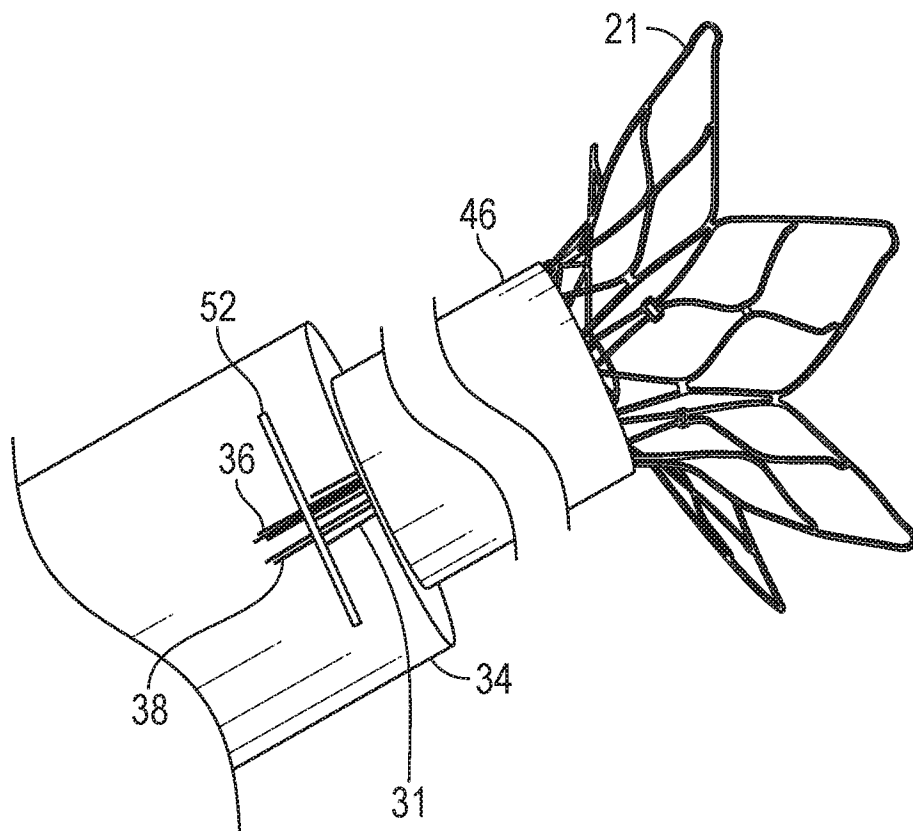


FIG. 23E

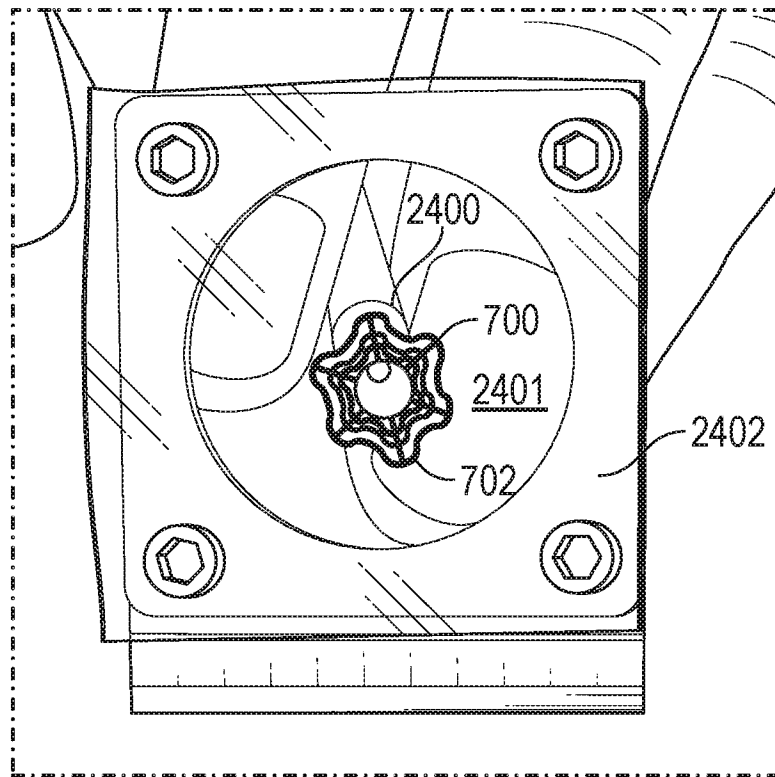


FIG. 24A

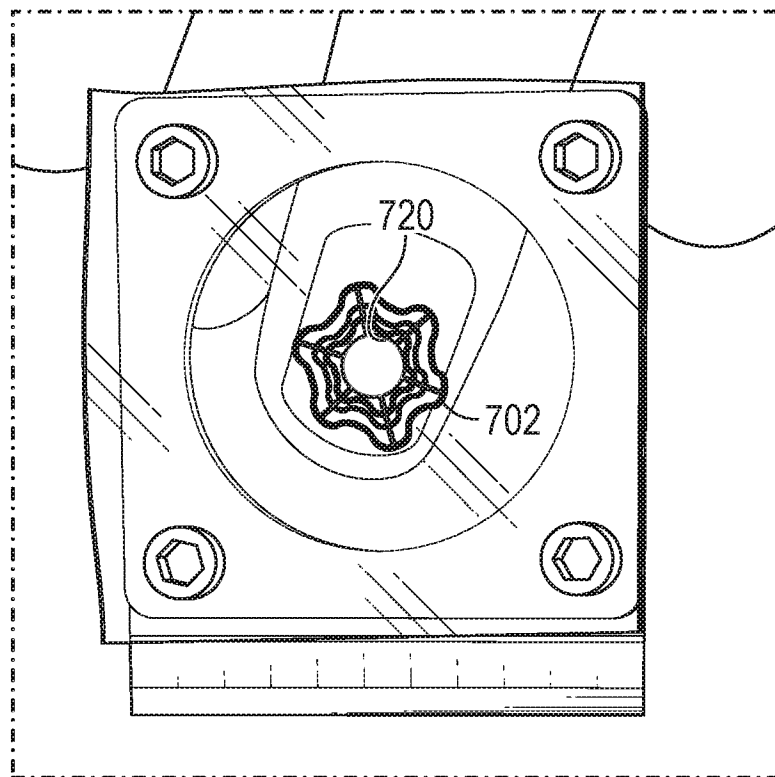


FIG. 24B

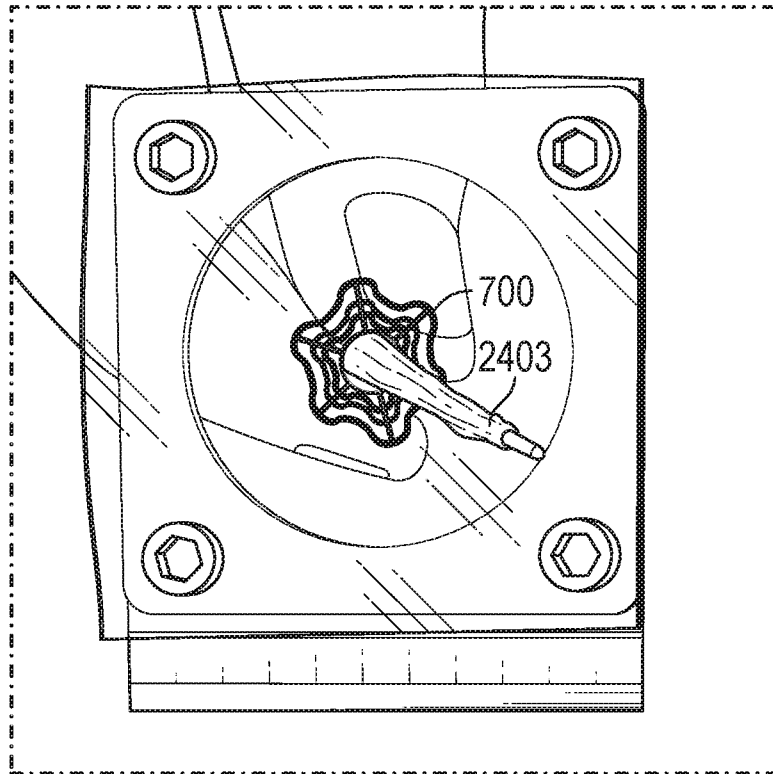


FIG. 24C

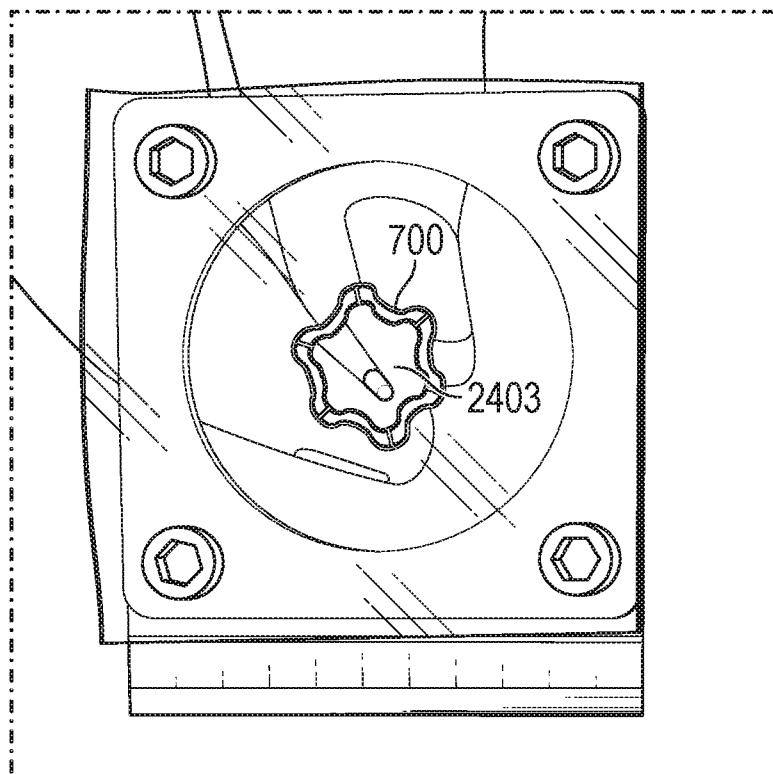


FIG. 24D

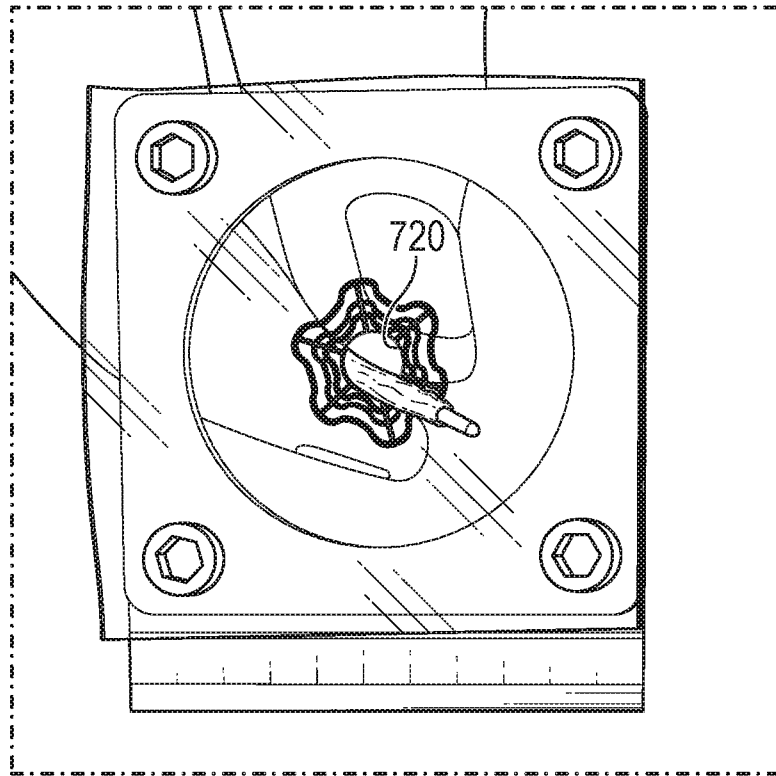


FIG. 24E

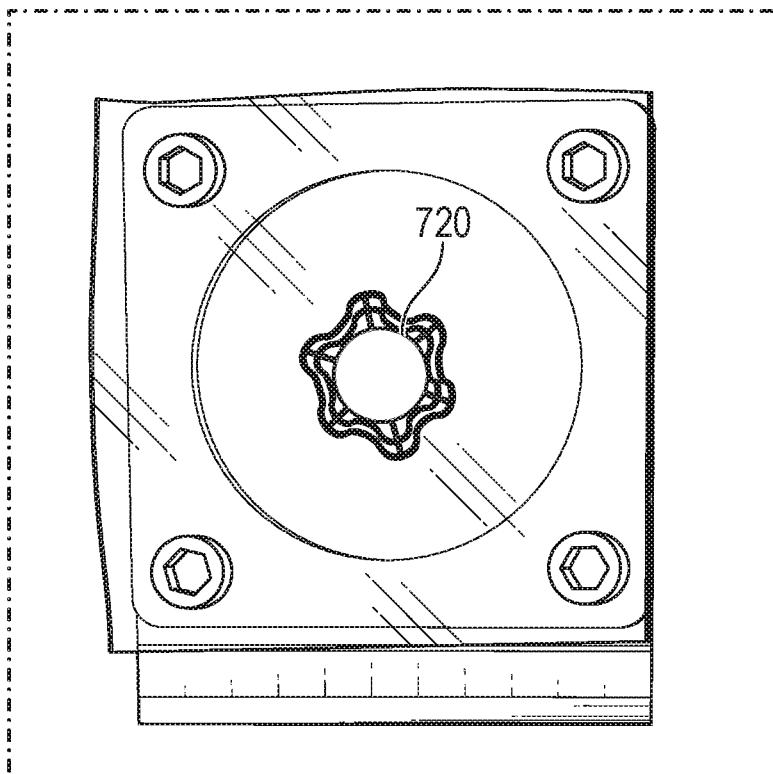


FIG. 24F

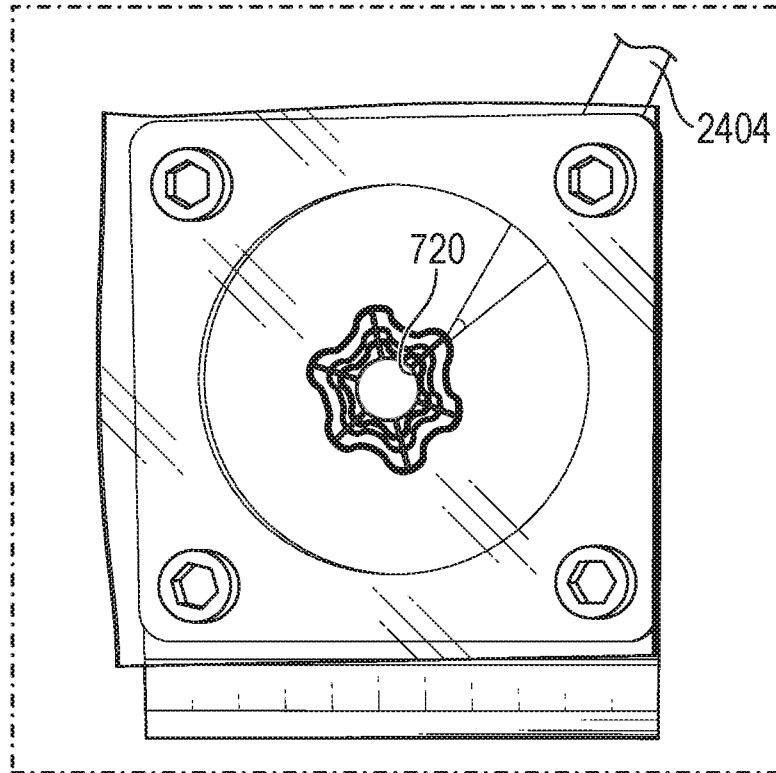


FIG. 24G

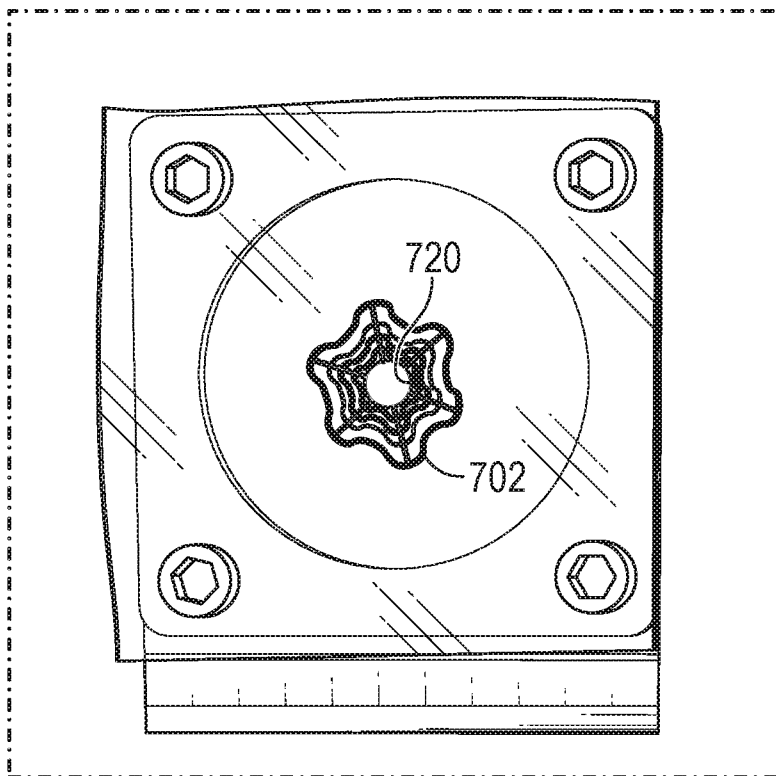


FIG. 24H

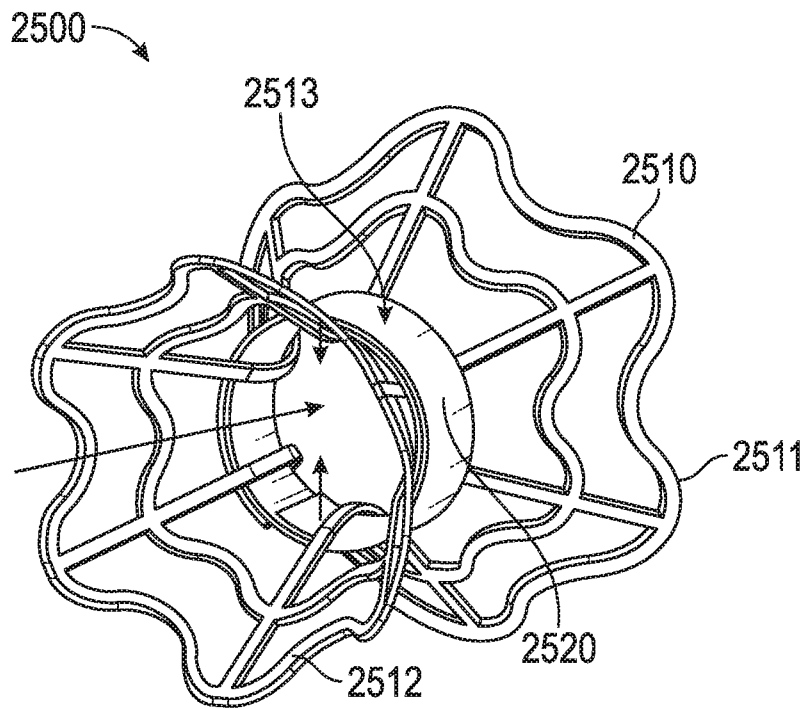


FIG. 25A

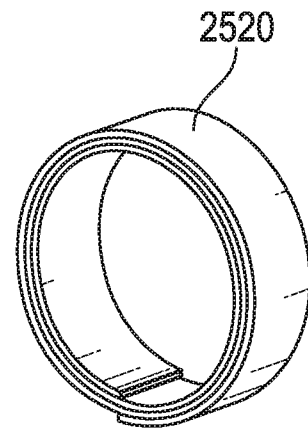


FIG. 25C

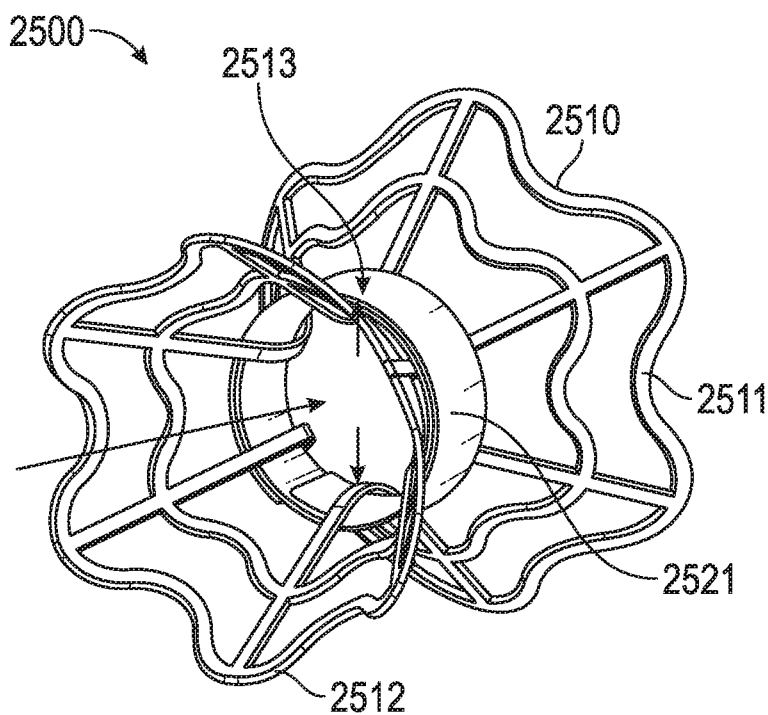


FIG. 25B

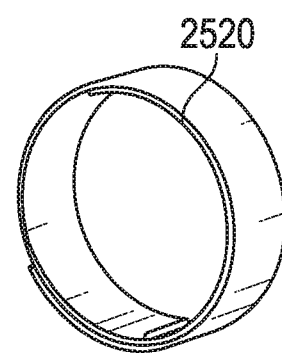


FIG. 25D

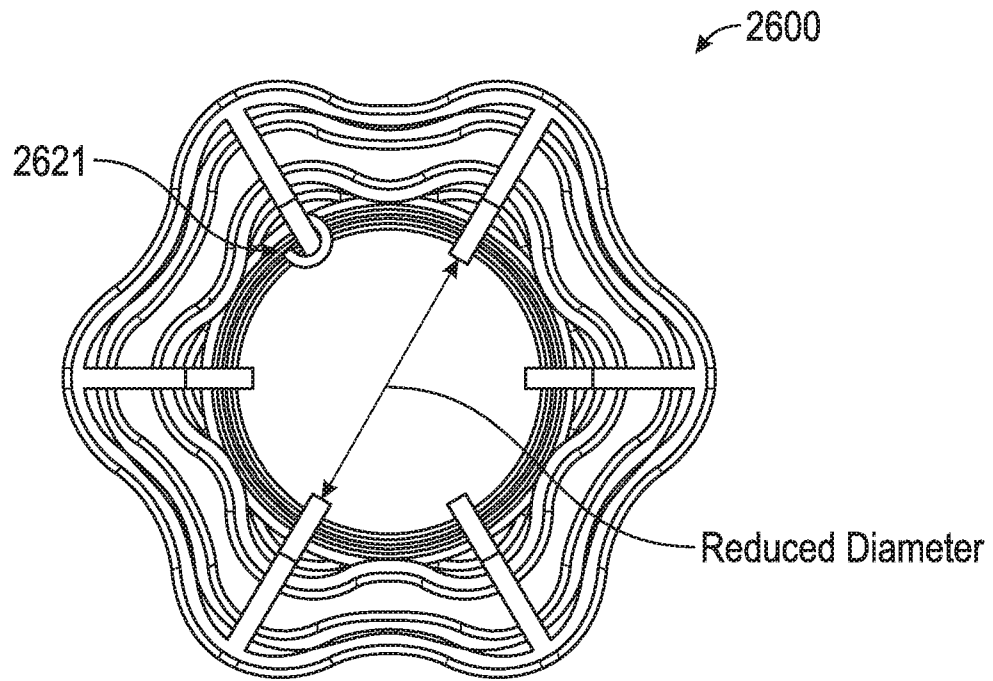


FIG. 26A

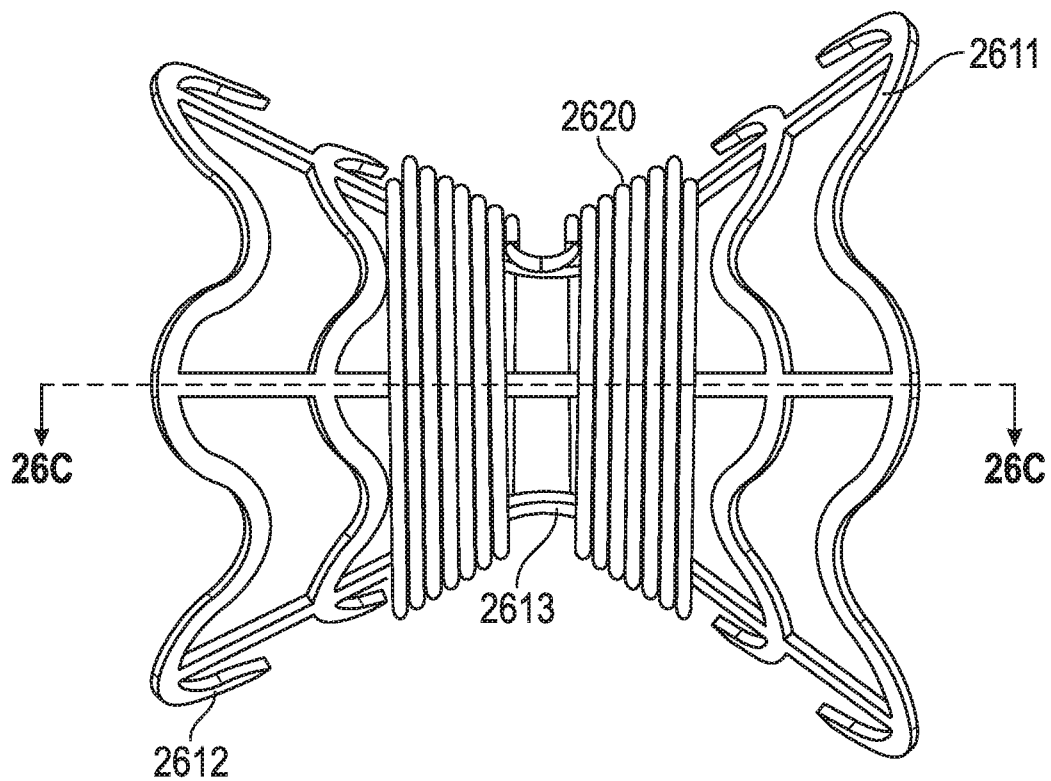
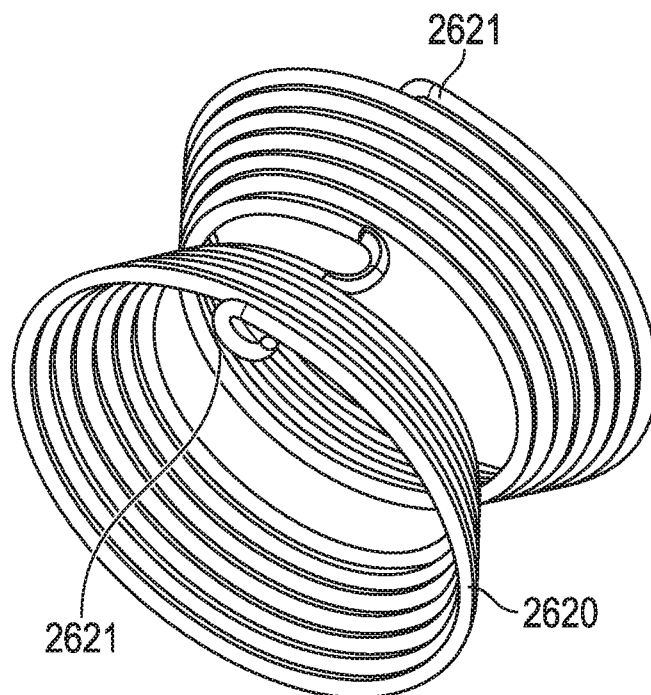
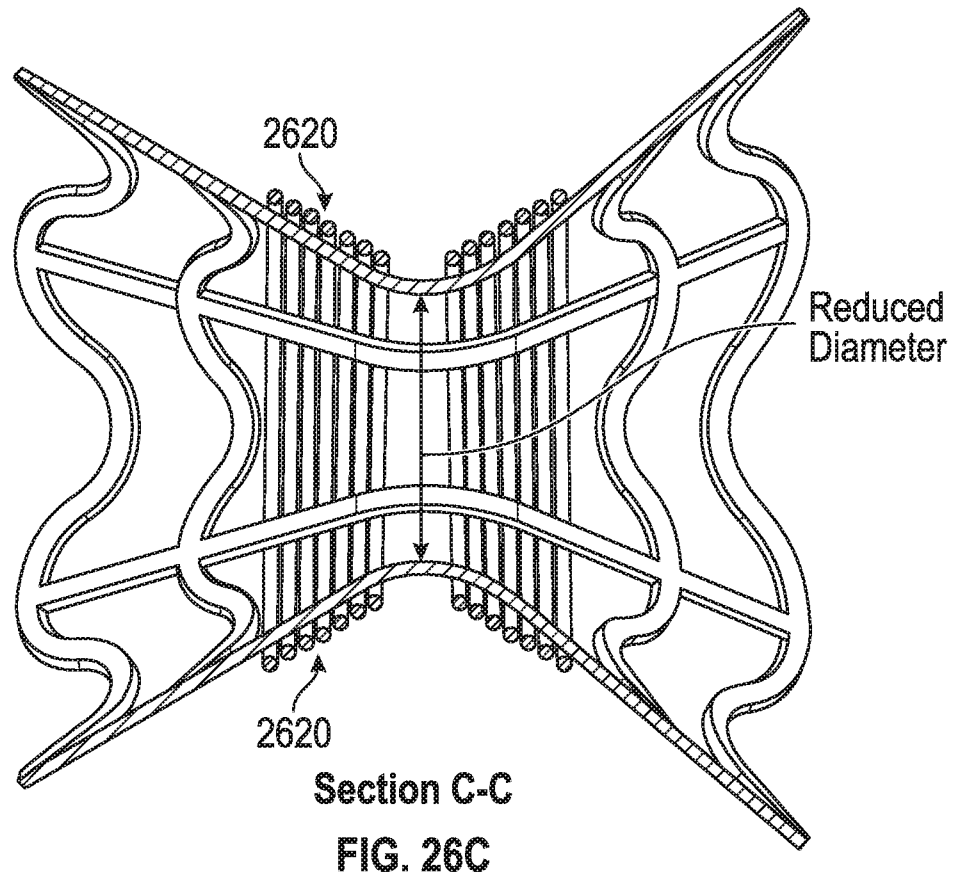


FIG. 26B



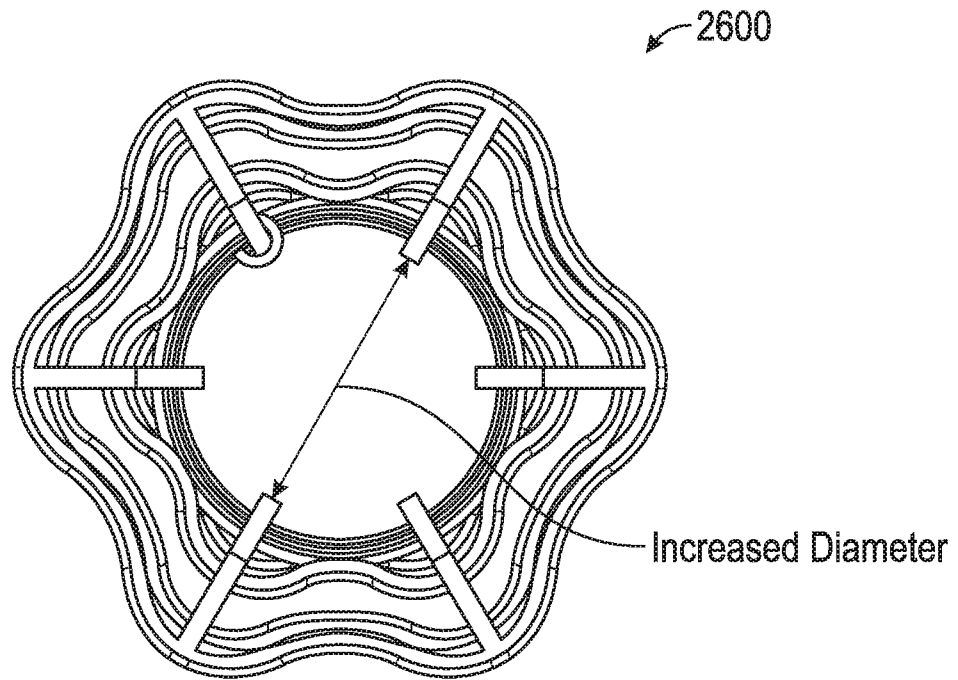


FIG. 26E

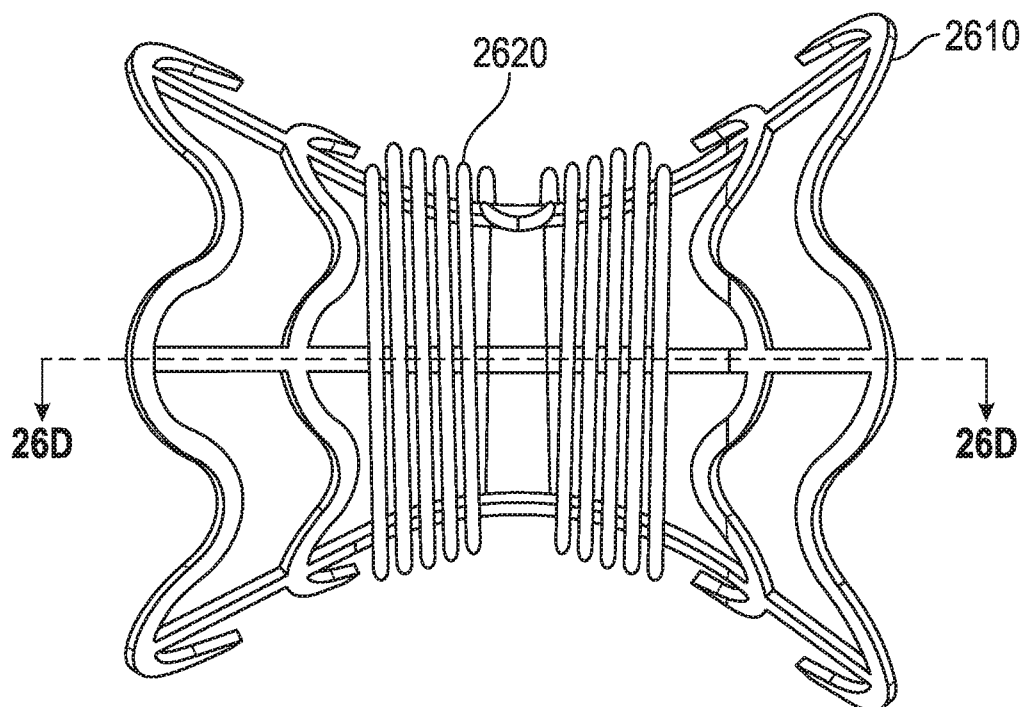


FIG. 26F

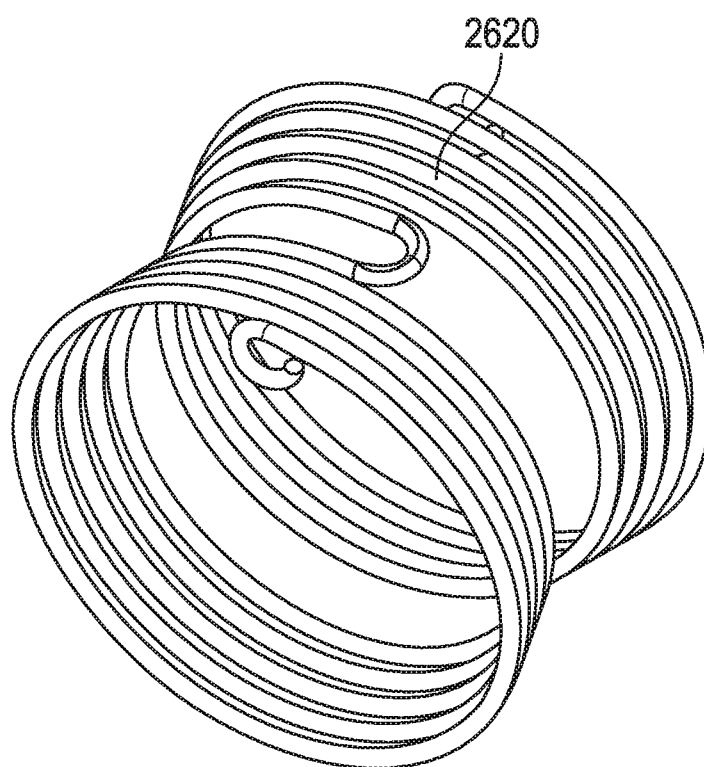
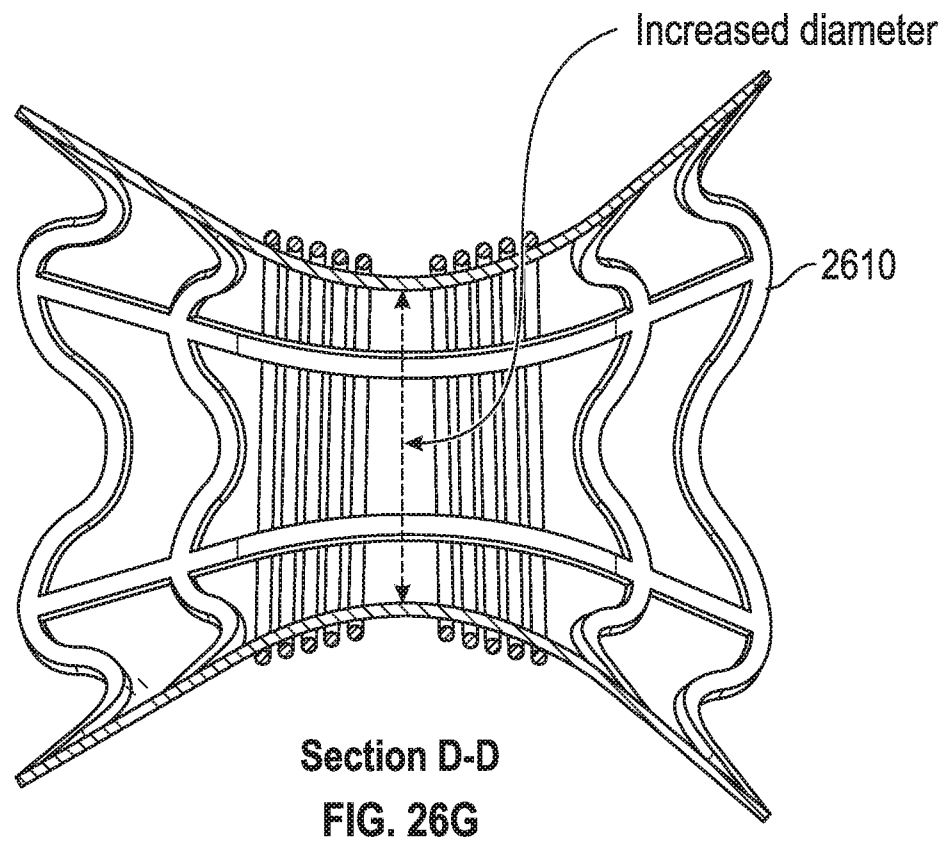


FIG. 26H

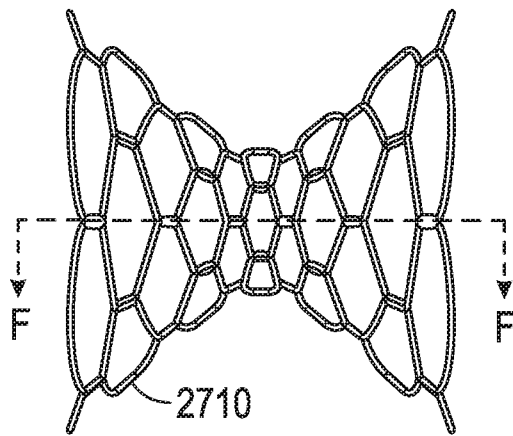


FIG. 27A

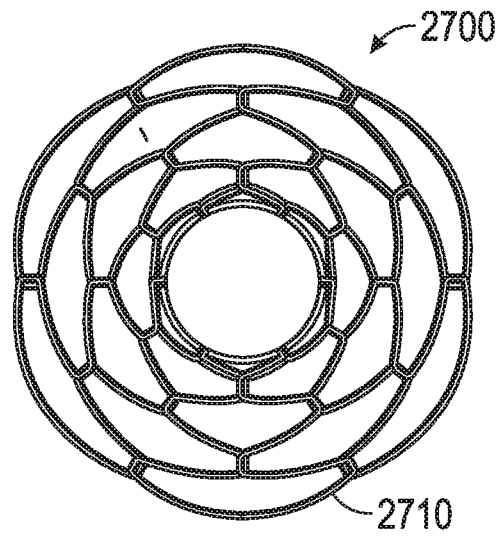


FIG. 27B

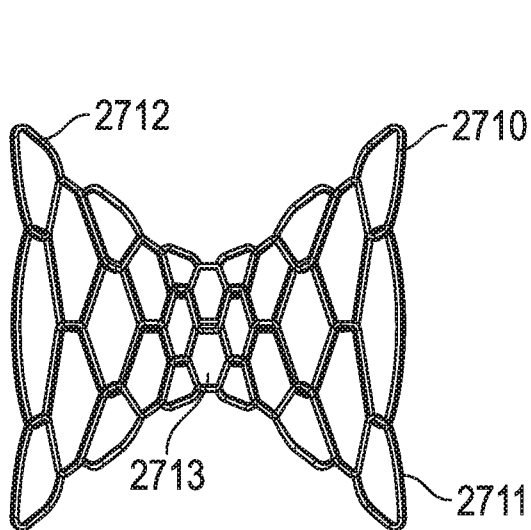


FIG. 27C

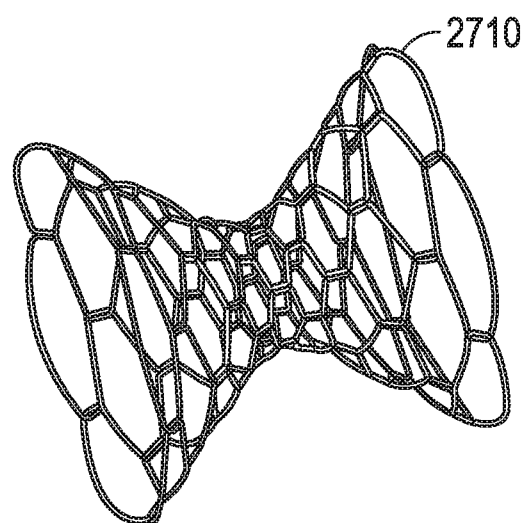


FIG. 27D

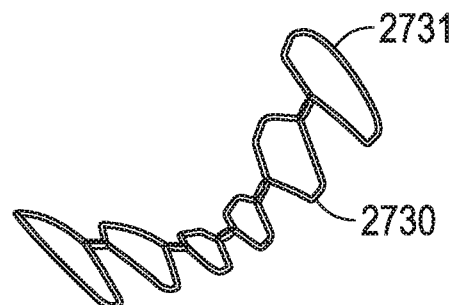


FIG. 27E

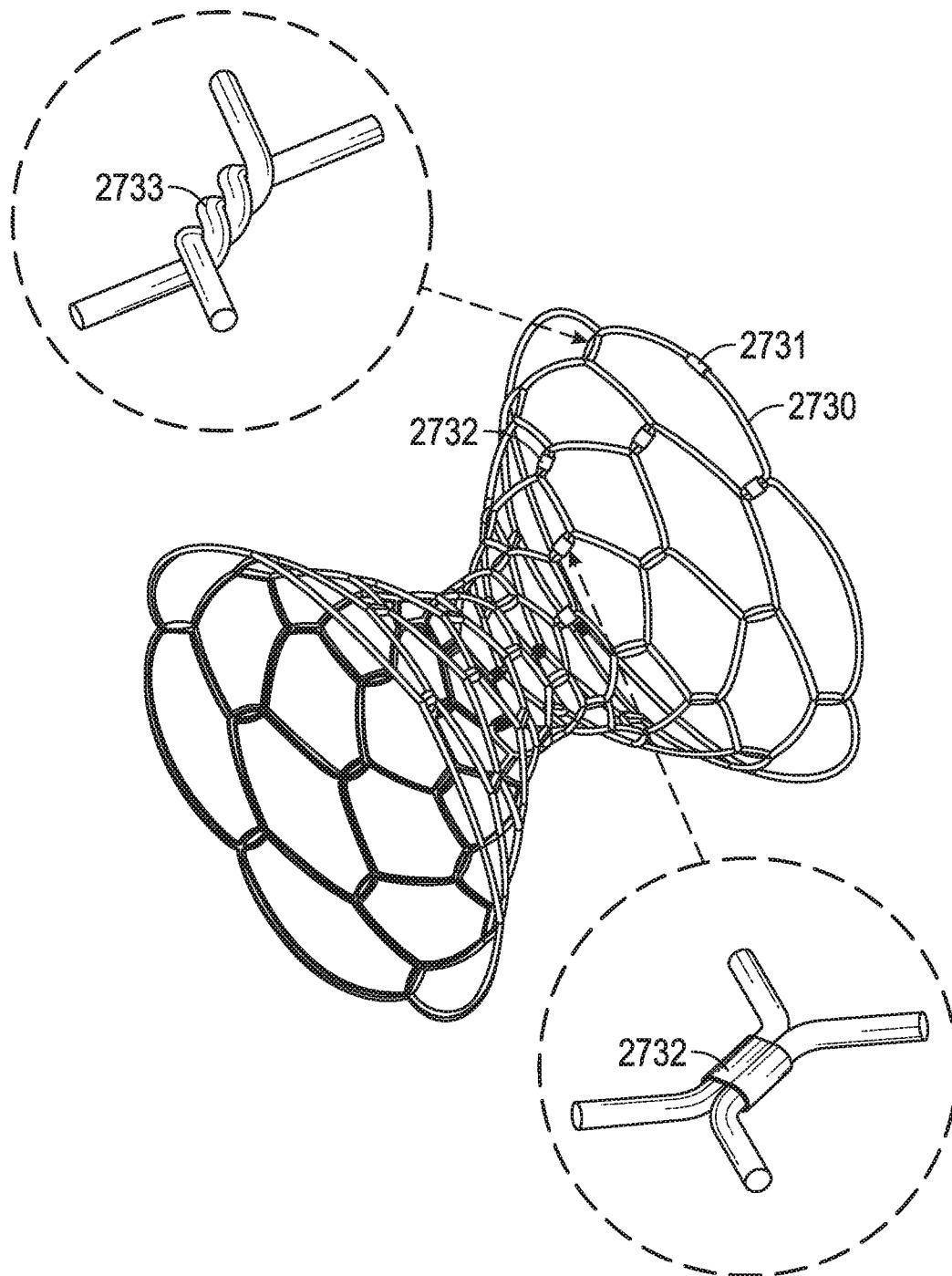
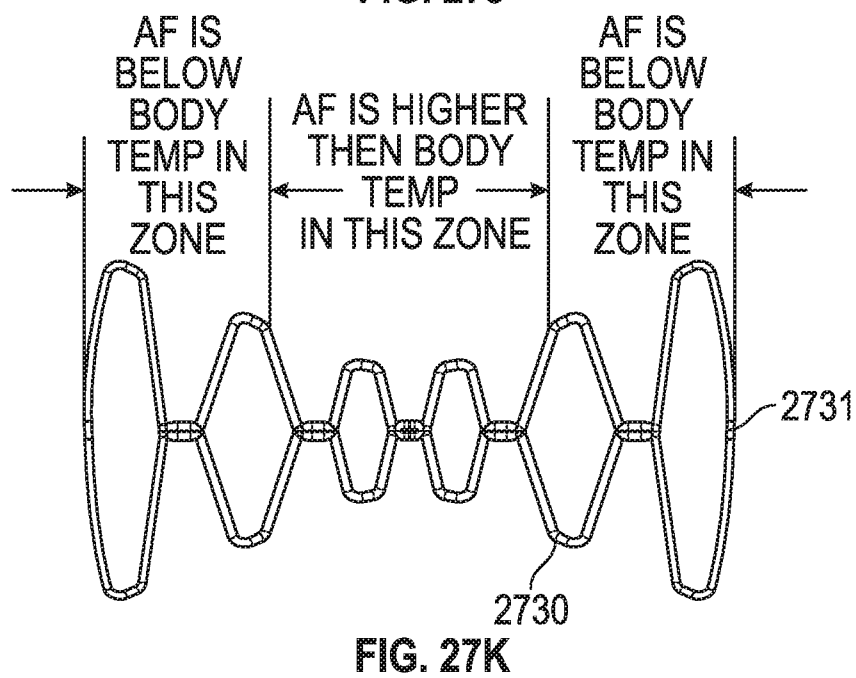
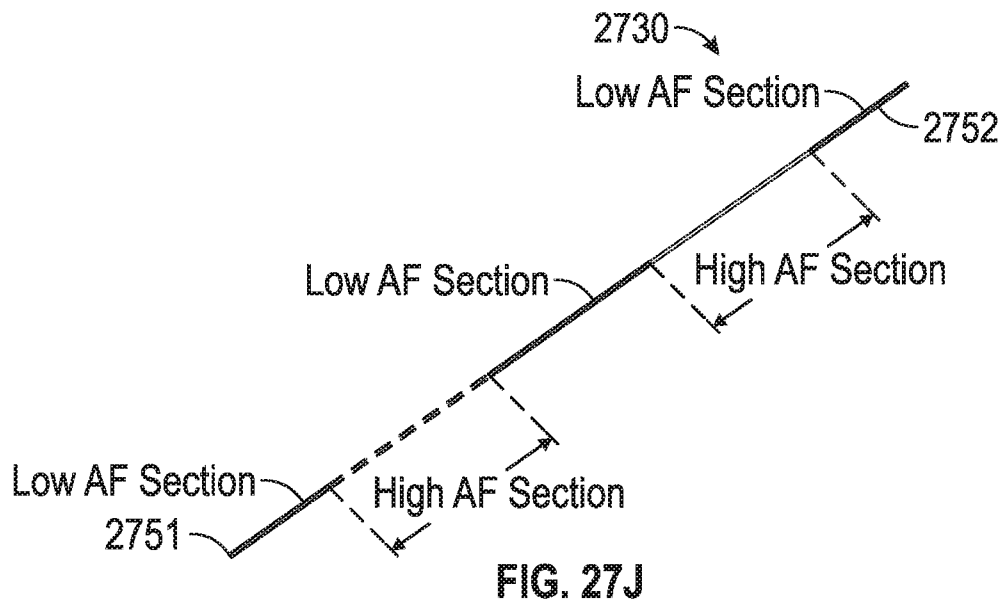
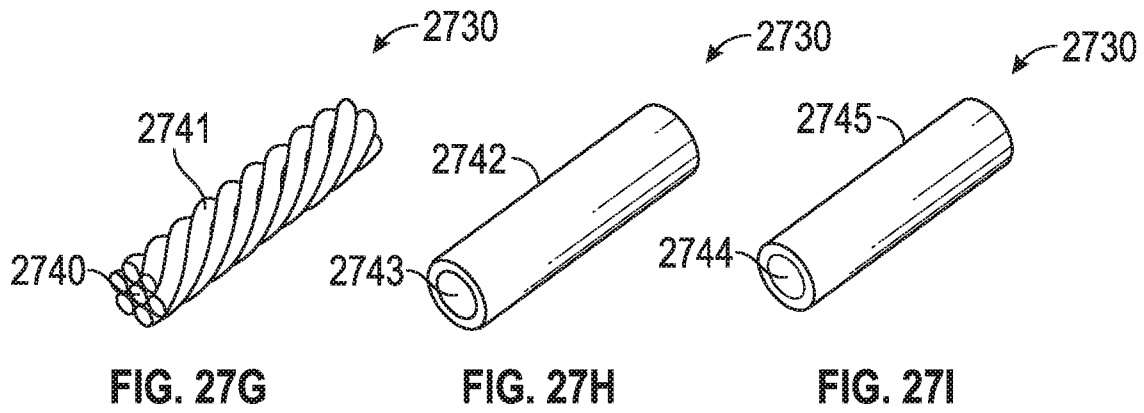


FIG. 27F



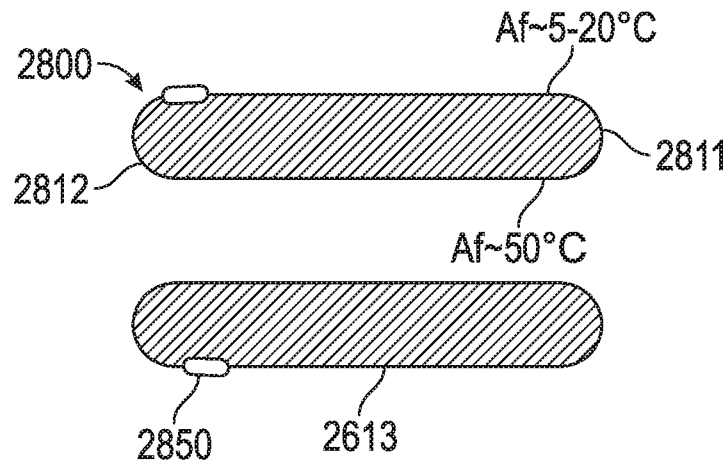


FIG. 28A

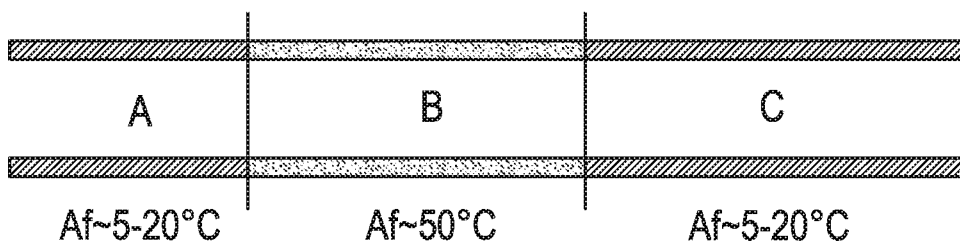


FIG. 28B

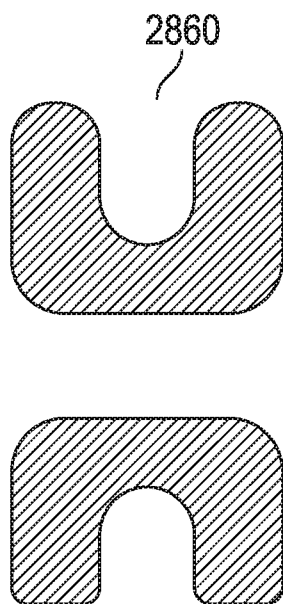


FIG. 28C

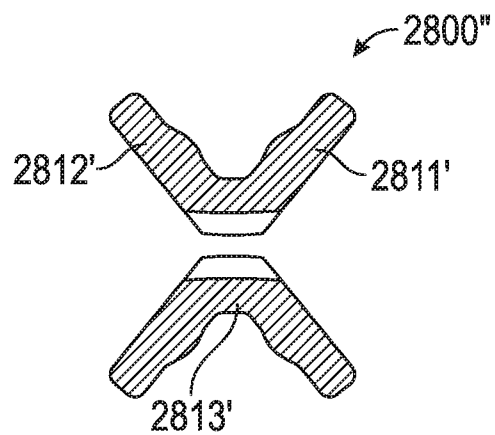


FIG. 28D

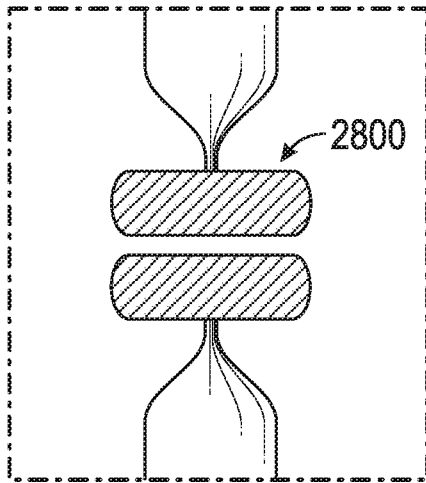


FIG. 29A

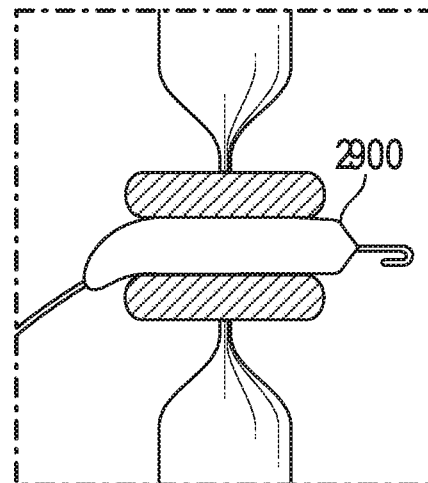


FIG. 29B

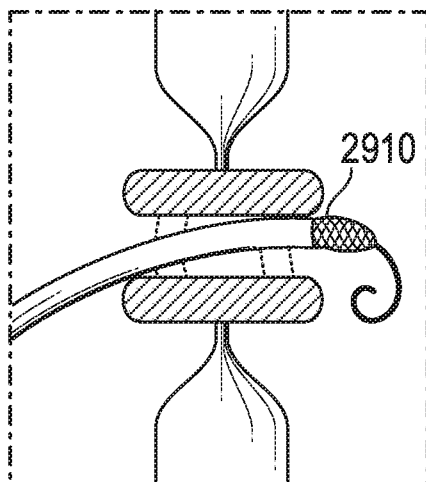


FIG. 29C

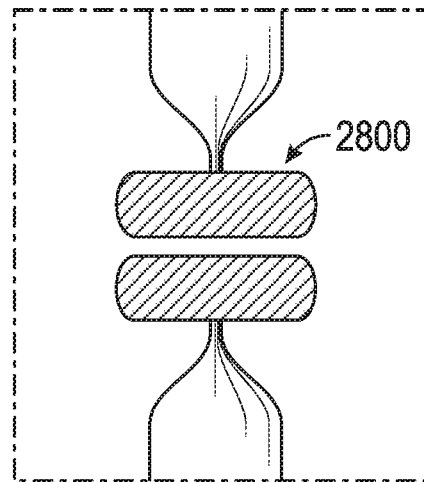


FIG. 29D

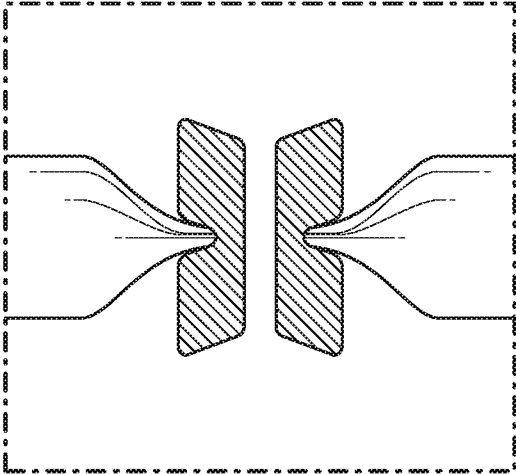


FIG. 30C

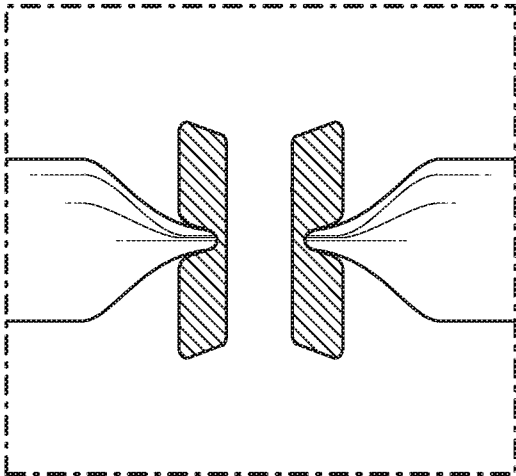


FIG. 30B

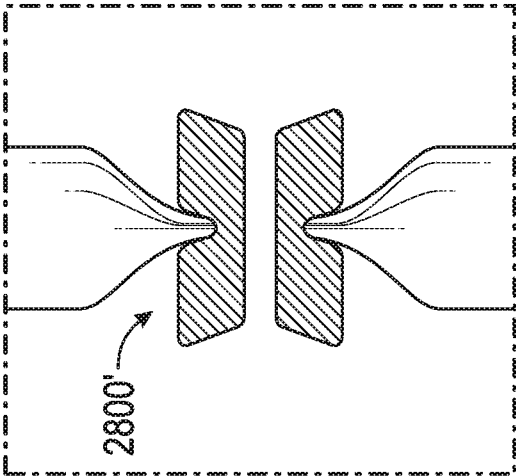


FIG. 30A

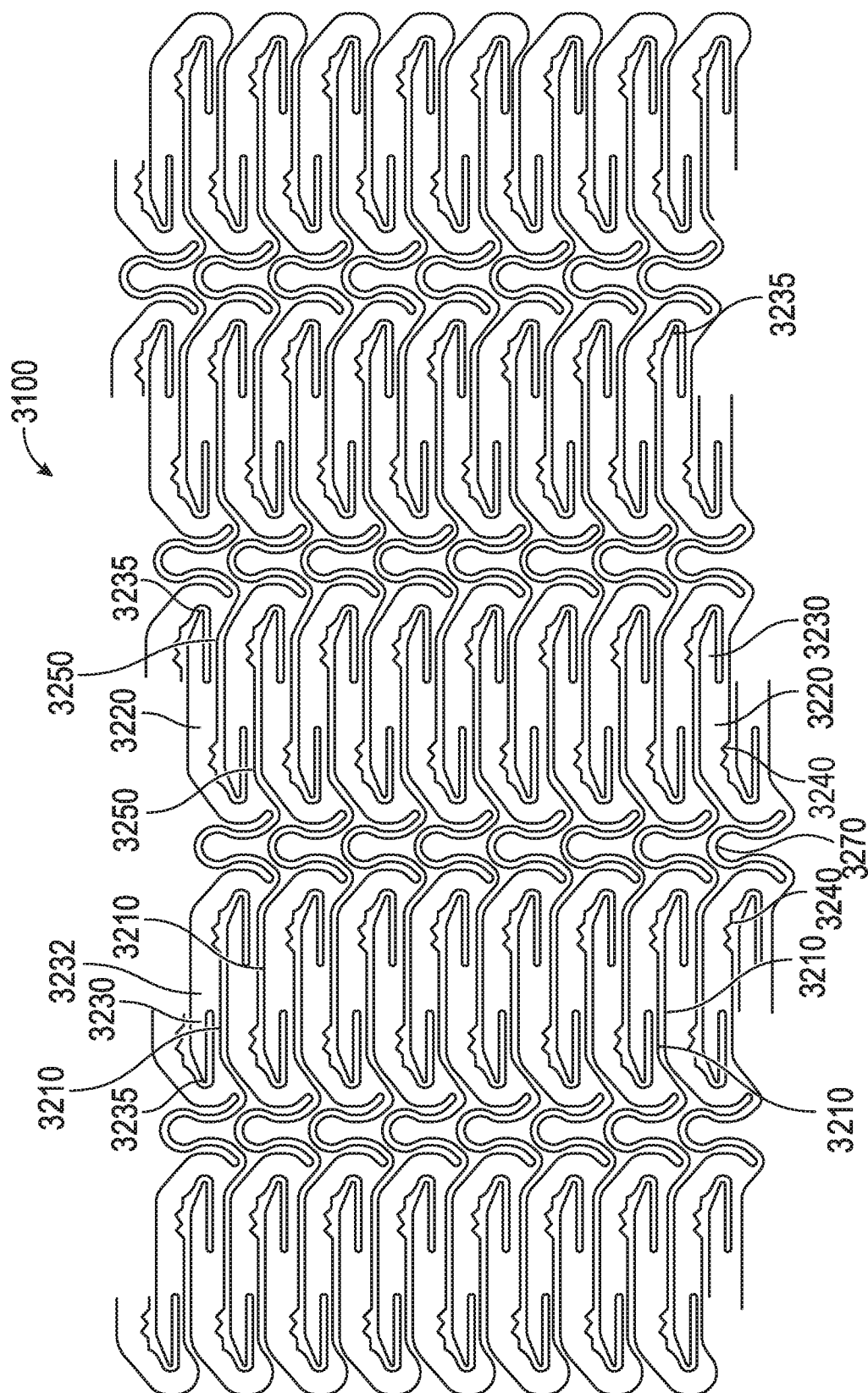


FIG. 31A

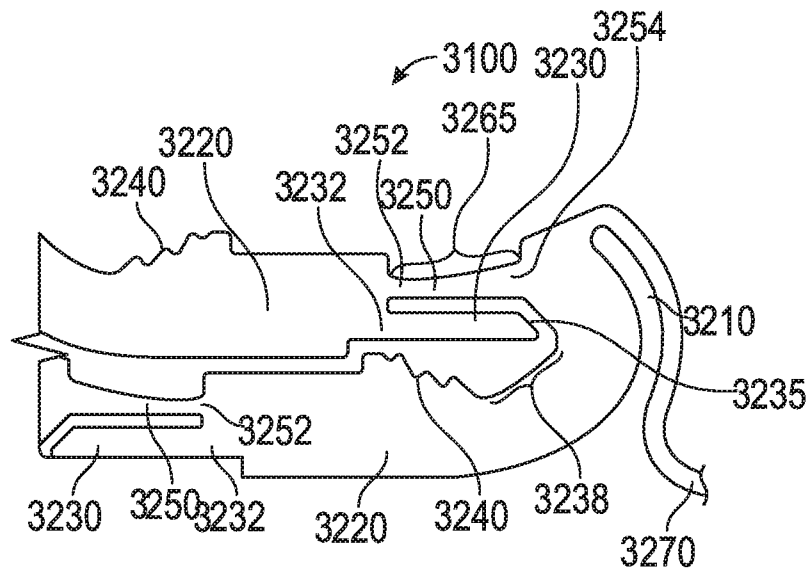


FIG 31B

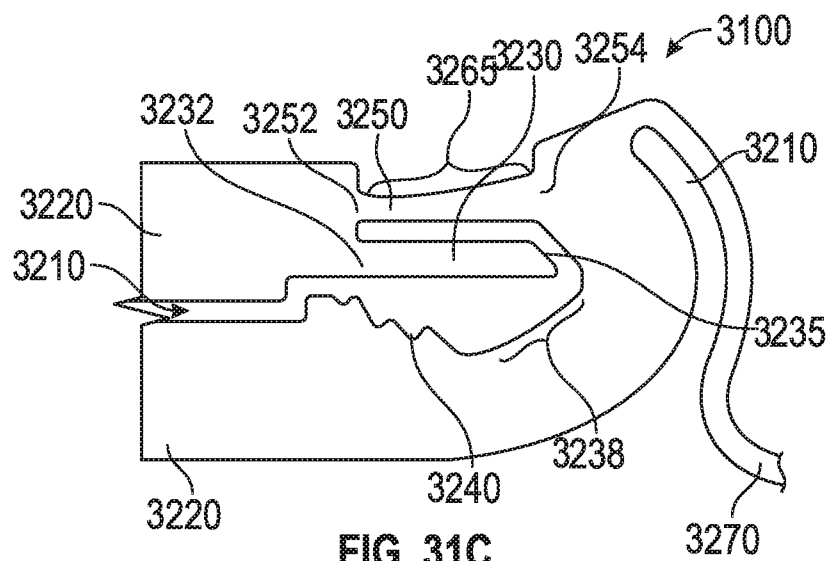


FIG. 31C

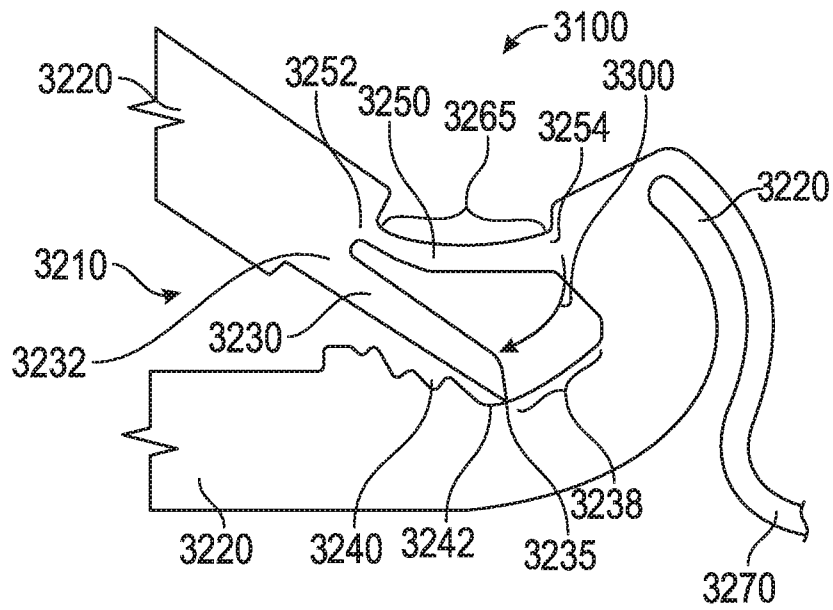


FIG. 31D

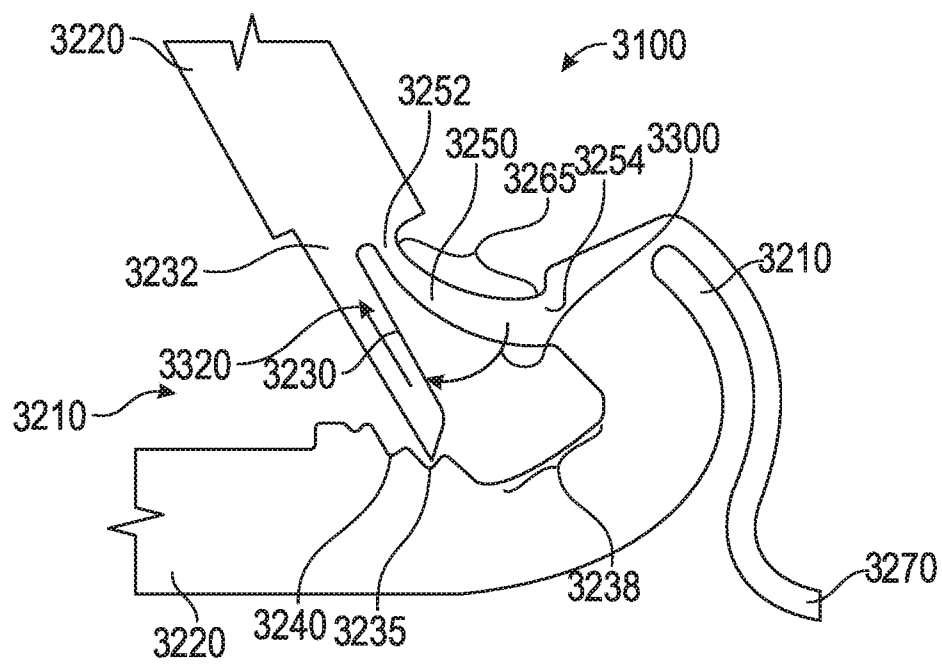


FIG. 31E

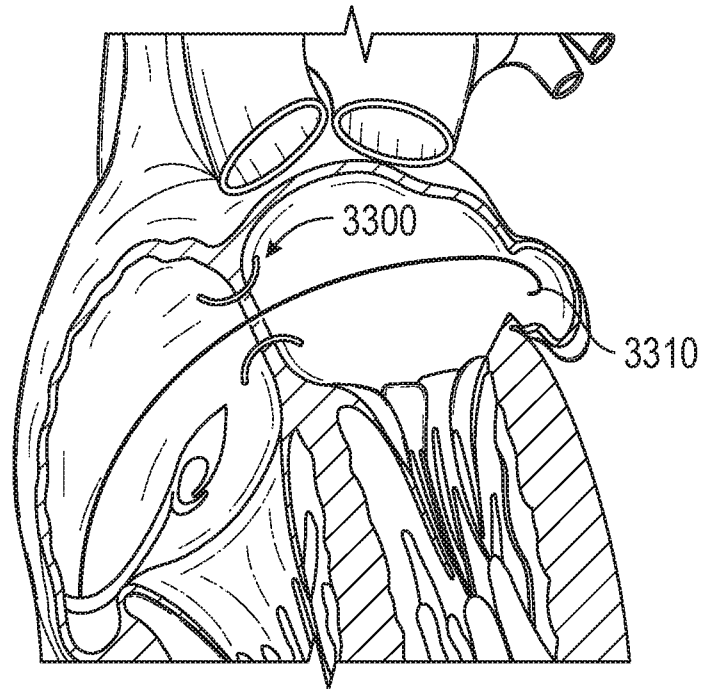


FIG. 32A

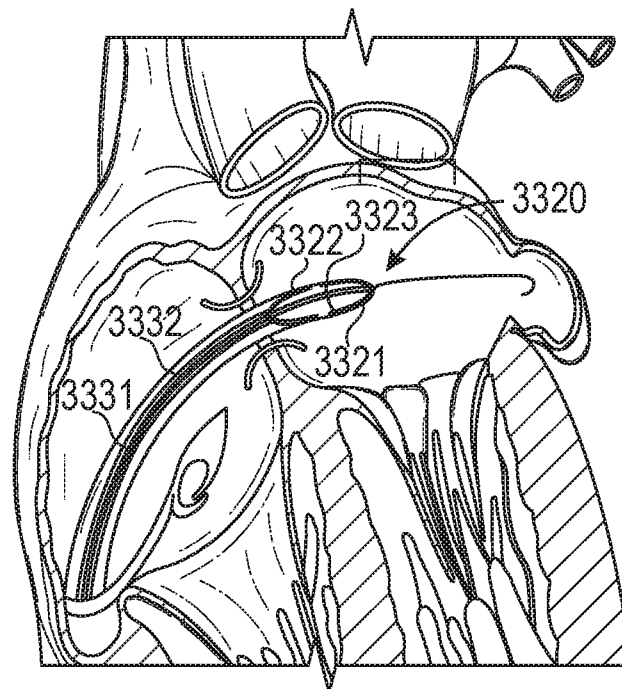


FIG. 32B

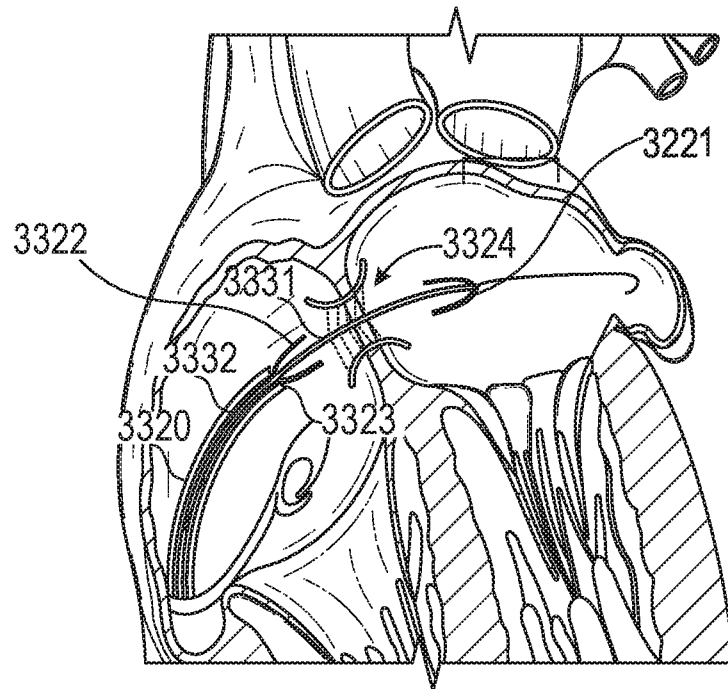


FIG. 32C

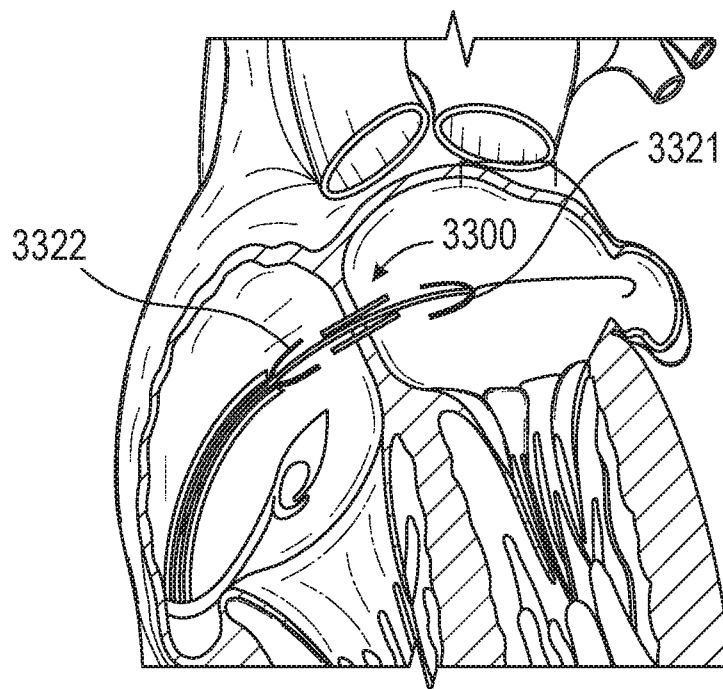


FIG. 32D

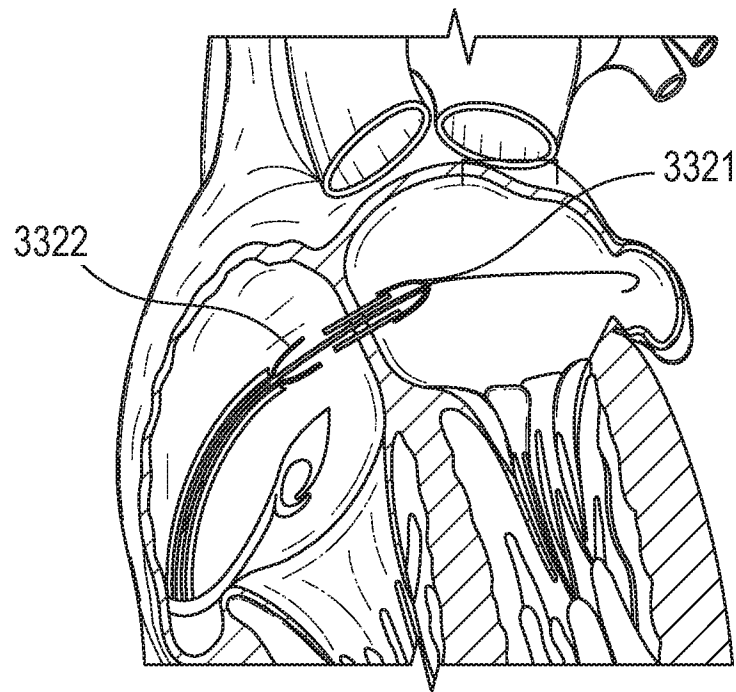


FIG. 32E

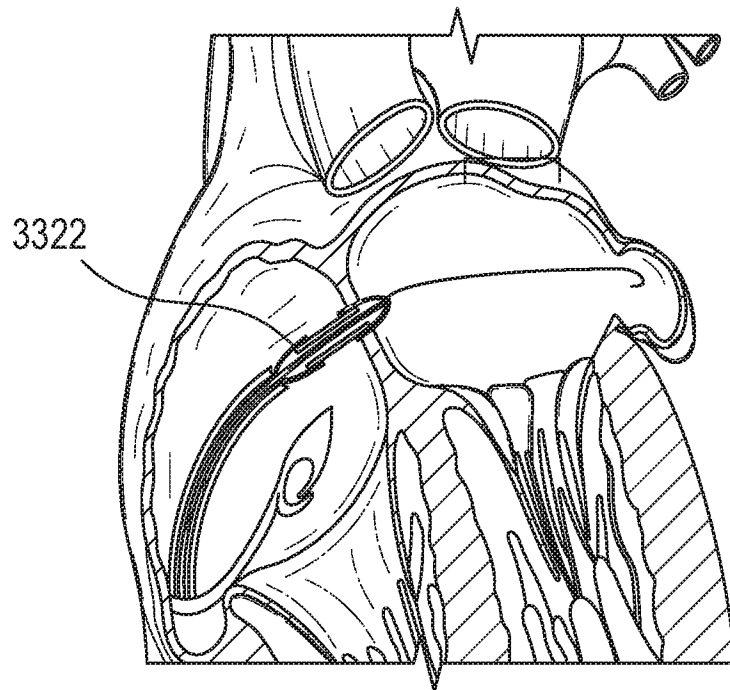


FIG. 32F

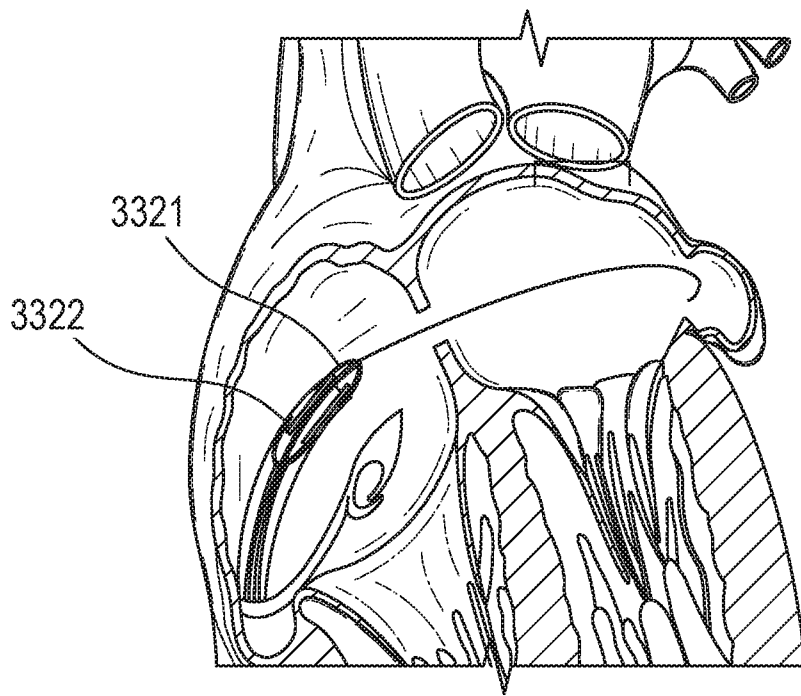


FIG. 32G

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2021/053594

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/00
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EP0-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2015/034217 A1 (VAD SIDDHARTH [US]) 5 February 2015 (2015-02-05) paragraphs [0030] - [0039]; figures 1a,1b,1c	29-103
X	----- AU 2003 291 117 B2 (VACTRONIX SCIENTIFIC LLC [US]) 23 April 2009 (2009-04-23) paragraphs [0033] - [0039]; figures 1,3	29-103
X	----- CA 2 378 920 A1 (BOSTON SCIENT LTD [BB]) 8 February 2001 (2001-02-08) page 8, line 16 - page 9, line 2; claim 1; figure 3 ----- -/--	29-35, 98,99, 103



Further documents are listed in the continuation of Box C.



See patent family annex.

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"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

14 July 2021

Date of mailing of the international search report

23/07/2021

Name and mailing address of the ISA/

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INTERNATIONAL SEARCH REPORT

International application No

PCT/IB2021/053594

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 95/31945 A1 (SCIMED LIFE SYSTEMS INC [US]; BURMEISTER PAUL H [US] ET AL.) 30 November 1995 (1995-11-30) page 4, line 5 - page 5, line 24; claim 9; figures 1-3 -----	29-35, 37-39, 44, 46-48, 50, 52-54, 70, 93-96,98
X	WO 02/087473 A1 (VASCULAR INNOVATION INC [US]) 7 November 2002 (2002-11-07) paragraphs [0019] - [0032] -----	29-41, 52,53, 98,99, 103
X	WO 00/50100 A1 (ADVANCED CARDIOVASCULAR SYSTEM [US]) 31 August 2000 (2000-08-31) page 4, line 12 - page 6, line 10; claim 1; figure 1 -----	29-35, 98,99, 103

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2021/053594

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☒ Claims Nos.: 1-28, 104-205
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 1-28, 104-205

In his submission of 10-07-2021, which follows the issuance of a CLAR, the applicant explained that claims 1 to 28 and 104 to 205 should not be searched.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guidelines C-IV, 7.2), should the problems which led to the Article 17(2) PCT declaration be overcome.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IB2021/053594

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US 2015034217 A1	05-02-2015	EP 2614795 A2 EP 3150176 A1 US 2013166010 A1 US 2015034217 A1	17-07-2013 05-04-2017 27-06-2013 05-02-2015
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