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# HYBRID DEVICES WITH DIMENSIONS THAT CAN BE ADJUSTED IN VIVO AND METHODS OF MANUFACTURING THEREOF


## 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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## Background/Summary

CROSS-REFERENCE TO RELATED APPLICATIONS [0001] This application is a continuation of U.S. patent application Ser. No. 18/917,388, filed Oct. 16, 2024, now U.S. Pat. No. 12,296,122, which claims priority to U.S. Patent Provisional Application No. 63/591,428, filed Oct. 18, 2023, the entire contents of each of which are incorporated herein by reference.

TECHNICAL FIELD
[0002] This technology 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. Pat. 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. Pat. 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

[0017] The present disclosure 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. In particular, the present disclosure 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.

[0018] In accordance with one aspect, a hybrid shunt comprising shape-memory material for placement at an atrial septum of a patient's heart is provided. The hybrid shunt may comprise a

neck region configured to be malleable at body temperature, a first end region configured to be superelastic at body temperature, a distal end of the first end region configured to be permanently fixed to a proximal end of the neck region at a first connection, a second end region configured to be superelastic at body temperature, a proximal end of the second end region configured to be permanently fixed to with a distal end of the neck region at a second connection, and a passageway extending through the first end region, the neck region, and the second end region for blood to flow across the atrial septum. The flow area of the passageway through the neck region may be configured to be adjustable in vivo. Preferably, the first and second end regions are not formed integrally with the neck region.

[0019] The proximal and distal ends of the neck region may comprise a shape configured to interlock with a complementary shape of the distal end of the first end region and the proximal end of the second end region, respectively. For example, the complementary shapes of the proximal and distal ends of the neck region and the distal end of the first end region and the proximal end of the second end region may comprise a tab element and a socket element. The tab element may be configured to be thermally contracted or the socket element may be configured to be thermally expanded such that the tab element fits within the socket element, and when the tab and socket elements are brought to a same temperature while the tab element is received within the socket element, the tab element and the socket element may form a rigid connection. For example, the tab element may be configured to be thermally contracted from a first size to a second size, such that the second size may be configured to fit within the socket element, and when the tab and socket elements are brought to a same temperature while the tab element is fitted within the socket element, the tab element and the socket element may form a rigid connection. Alternatively, the socket element may be configured to be thermally expanded from a first size to a second size, such that the second size may be configured to receive the tab element therein, and when the tab and socket elements are brought to a same temperature while the tab element is received within the socket element, the tab element and the socket element may form a rigid connection.

[0020] The hybrid shunt further may comprise a retaining ring configured to be disposed over the tab and socket elements when the tab element is fitted within the socket element to maintain a rigid connection between the tab and socket elements. Moreover, an outer surface of the socket element may comprise one or more protrusions, such that the retaining ring maintains the rigid connection between the tab and socket elements via interference fit between the one or more protrusions and an inner surface of the retaining ring. In addition, the hybrid shunt further may comprise a physiological sensor disposed on the tab element, such that the physiological sensor is enclosed within the retaining ring when the retaining ring is disposed over the tab and socket elements. In some embodiments, the shape of the proximal and distal ends of the neck region may comprise the tab element, and the shape of the distal end of the first end region and the shape of the proximal end of the second end region may comprise the socket element. Alternatively, the shape of the proximal and distal ends of the neck region may comprise the socket element, and wherein the shape of the distal end of the first end region and the shape of the proximal end of the second end region may comprise the tab element.

[0021] The first and second end regions may be configured to self-expand from a collapsed delivery state to an expanded deployed state at body temperature. Accordingly, in the expanded deployed state, a proximal end of the first end region may flare outwardly from the distal end of the first end region at the first connection, and a distal end of the second end region may flare outwardly from the proximal end of the second end region at the second connection. In addition, in the expanded deployed state, the first connection may comprise a smooth, continuous transition from the neck region to the first end region, and the second connection may comprise a smooth, continuous transition from the neck region to the second end region.

[0022] In some embodiments, the distal end of the first end region may comprise a plurality of circumferentially spaced apart connectors configured to be permanently fixed to a corresponding

plurality of circumferentially spaced apart connectors of the proximal end of the neck region at the first connection, and the proximal end of the second end region may comprise a plurality of circumferentially spaced apart connectors configured to be permanently fixed to a corresponding plurality of circumferentially spaced apart connectors of the distal end of the neck region at the second connection. For example, the plurality of circumferentially spaced apart connectors of the distal end of the first end region and the proximal end of the neck region may be permanently fixed along a single plane at the first connection, or alternatively, the plurality of circumferentially spaced apart connectors of the distal end of the first end region and the proximal end of the neck region may be permanently fixed in a staggered manner at the first connection, such that the connections do not all lie in a single plane. Additionally, the plurality of circumferentially spaced apart connectors of the proximal end of the second end region and the distal end of the neck region may be permanently fixed along a single plane at the second connection, or alternatively, the plurality of circumferentially spaced apart connectors of the proximal end of the second end region and the distal end of the neck region are permanently fixed in a staggered manner at the second connection, such that the connections do not all lie in a single plane.

[0023] The neck region may comprise NITINOL having an austenitic finish temperature (Af) between 45-60° C. In addition, the neck region may be configured to be mechanically expandable in vivo such that the passageway expands from a first cross-sectional area to a second cross-sectional area larger than the first cross-sectional area. Further, the neck region may be configured to be thermally contractible in vivo. Moreover, the first and second end regions may comprise NITINOL having an austenitic finish temperature (Af) between 5-20° C. Additionally, the first and second end regions and the neck region may comprise a diabolo-shaped shunt. The first and second end regions and the neck region may be at least partially encapsulated with a biocompatible material. In addition, the hybrid shunt further may comprise one or more physiological sensors disposed at the first and/or second connections. For example, the one or more physiological sensors may be configured to measure at least one of pressure, flow, velocity, temperature, or pH.

[0024] The hybrid shunt further may comprise a bridge extending from a first outer surface of the first end region to a second outer surface of the second end region. The bridge may be formed of biocompatible material and may be configured to engage the patient's atrial septum. For example, the first and second end regions and the neck region may be at least partially encapsulated with a biocompatible material integrally formed with the bridge. Alternatively, the first and second end regions and the neck region may be at least partially encapsulated with a biocompatible material different from the biocompatible material of the bridge. For example, the biocompatible material of the bridge may be configured to permit tissue ingrowth and the biocompatible material of the encapsulation may be configured to inhibit tissue ingrowth. Moreover, the biocompatible material of the bridge may have an internodal distance greater than the internodal distance of the biocompatible material of the encapsulation. For example, the internodal distance of the bridge material may be selected to permit tissue ingrowth while the internodal distance of the encapsulation material may be selected to inhibit tissue ingrowth. The biocompatible material of the bridge and the biocompatible material of the encapsulation may be expanded polytetrafluoroethylene (ePTFE). Moreover, the biocompatible material of the bridge may comprise a porosity selected to permit tissue ingrowth. Additionally, the bridge may be configured to remain engaged with the patient's atrial septum when the neck region is contracted.

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## Description

BRIEF DESCRIPTION OF THE DRAWINGS

[0025] FIGS. **1**A-**1**E schematically illustrate an example device with an internal dimension that can be reduced and increased in vivo.

[0026] FIGS. **2**A-**2**E schematically illustrate another example device with an internal dimension that can be reduced and increased in vivo.
[0027] FIGS. **3**A-**3**D schematically illustrate an example device with multiple internal dimensions that can be reduced and increased in vivo.
[0028] FIGS. **4**A-**4**B schematically illustrate example encapsulants that may be provided in a device with an internal dimension that can be reduced and increased in vivo.
[0029] FIGS. **5**A-**5**B schematically illustrate example arrangements of components in a device with an internal dimension that can be reduced and increased in vivo.
[0030] FIG. **6** schematically illustrates another example device with an internal dimension that can be reduced and increased in vivo.
[0031] FIG. **7** schematically illustrates another example device with an internal dimension that can be reduced and increased in vivo.
[0032] FIGS. **8**A-**8**D schematically illustrate example steps for using the device of FIG. **7** in the human body.
[0033] FIGS. **9**A-**9**B schematically illustrate example configurations of the device of FIG. **7**.
[0034] FIGS. **10**A-**10**C schematically illustrate example uses of tooling for preparing the device of FIG. **7**.
[0035] FIG. **11** illustrates a flow of operations in an example method for reducing and increasing an internal dimension of a device in vivo.
[0036] FIG. **12** illustrates a flow of operations in an example method for fixating a device in a body lumen.
[0037] FIGS. **13**A-**13**D schematically illustrate an example dilator device with an external dimension that can be reduced and increased in vivo.
[0038] FIGS. **14**A-**14**I schematically illustrate use of the delivery device of FIGS. **13**A-**13**D in the human body.
[0039] FIGS. **15**A-**15**E 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.
[0040] FIGS. **16**A-**16**H are images of a device prepared and used in accordance with examples provided herein.
[0041] FIG. **17**A is a side view of the device of FIG. **7** with a bridge constructed in accordance with the principles of the present disclosure.
[0042] FIGS. **17**B-**17**E are side, cross-sectional, and perspective views of the device of FIG. **17**A.
[0043] FIGS. **18**A and **18**B are cross-sectional side views of the device of FIG. **17**A.
[0044] FIGS. **19**A-**19**E illustrate example steps for using the device of FIG. **17**A in the human body.
[0045] FIGS. **20**A and **20**B illustrate another example device with an internal dimension that can be reduced and increased in vivo having interlocking components in an unassembled configuration.
[0046] FIGS. **20**C and **20**D illustrate the device of FIGS. **20**A and **20**B in an assembled configuration in a collapsed delivery state.
[0047] FIGS. **20**E and **20**F illustrate the device of FIGS. **20**A and **20**B in an assembled configuration in an expanded deployed state.
[0048] FIGS. **21**A and **21**B illustrate another example device with an internal dimension that can be reduced and increased in vivo having interlocking components and a retaining ring in an assembled configuration.
[0049] FIGS. **21**C and **21**D illustrate the device of FIGS. **21**A and **21**B in an unassembled configuration.
[0050] FIGS. **22**A-**22**I illustrate an example method of assembling the device of FIGS. **21**A and **21**B.
[0051] FIGS. **23**A-**23**E illustrate alternative exemplary interlocking components of a hybrid shunt constructed in accordance with the principles of the present disclosure.

DETAILED DESCRIPTION

[0052] The present disclosure provides devices with dimensions that can be reduced and increased in vivo, and methods of making and using the same. Described herein are apparatus and methods for making and using improved interatrial shunts to improve treatment and outcomes for patients with cardiovascular and cardiopulmonary disorders, such as pulmonary artery hypertension (PAH) or heart failure (HF). In some aspects, the devices have dimensions that can be reduced and increased in vivo.

[0053] 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.

[0054] 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 sequalae 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.

[0055] 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.

[0056] 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 some examples, the devices provided herein may incorporate technology with adjustable cross-sectional flow areas that may be easily reduced in vivo and/or expanded in vivo, in any order, as clinically necessary. Examples of interatrial shunts with adjustable cross-sectional flow areas are described in U.S. Pat. No.

9,724,499 to Rottenberg, U.S. Pat. No. 10,898,698 to Eigler, WO 2021/224736, and U.S. Pat. No. 11,744,589 to Ben-David, each assigned to the assignee of the present application, the entire contents of each of which are incorporated herein by reference. 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.

[0057] 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 in the above-incorporated PCT application WO 2021/224736, 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.

[0058] FIGS. **1**A-**1**E schematically illustrate an example device with an internal dimension that can be reduced and increased in vivo. Device **100** illustrated in FIGS. **1**A-**1**E 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**.

[0059] For example, FIG. **1**A 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 D**1** (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. **1**B, 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, D**1**, 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. **1**C, to dimension D**2** (corresponding to a second cross sectional area). Second component **120** may be reduced by any suitable amount, for example such as shown in FIGS. **1**D and **1**E, by first using the shape-memory property to contract component **120** to its annealed configuration dimension DO, then expanding (e.g., by balloon dilation) to dimension D**3**

(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.

[0060] In some examples, reducing the dimension of a shape memory material-based component herein always returns that component to its heat-set (annealed) dimension, DO, 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 DO and D**1** may be approximately the same as one another, in other examples DO may be smaller than D**1**, while in still other examples DO may be larger than D**1**. Although FIGS. **1**A-**1**E illustrate only four exemplary dimensions DO, D**1**, D**2**, D**3** of second component **120**, it should be appreciated that any suitable dimension above a minimum set by the annealed configuration, DO, may be obtained by balloon expanding as desired. For example, D**2** may be smaller than D**3**. Alternatively, D**2** may be larger than D**3**, and D**3** may be achieved by reducing second component **120** to its heat-set dimension, DO, as shown in FIG. **1**D, and then expanding second component **120** to dimension D**3** as shown in FIG. **1**E. 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.

[0061] 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. **1**A-**1**E. 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. **1**A-**1**E. 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. **1**A-**1**E 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. **1**A-**1**E. 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. **1**A-**1**E. The present devices may have any suitable cross sectional shape and may include, but are not limited to, circular, or uniform, cross sections.

[0062] In the nonlimiting examples shown in FIGS. **1**B and **1**D, 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.

[0063] 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 (Af) 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 Af of less than 37° C. For example, the Af 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. **10**A-**10**C.

[0064] Second component **120** may include a NITINOL alloy having an austenitic phase transition temperature Af 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 Af, 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 (Af) of greater than 37° C. For example, the Af of the NITINOL of the malleable shape-memory material of second component **120** may be between 40-60° C., e.g., from 45-60° or 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 Af, 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.

[0065] 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.

[0066] Optionally, first component **110** may be configured to engage a lumen in the body, for example in a manner such as described in U.S. Pat. No. 10,898,698 to Eigler, entitled “Devices with dimensions that can be reduced and increased in vivo, and methods of making and using the same,” the entire contents of which are incorporated by reference herein. For example, the lumen may include a blood vessel, and the first component may be configured to engage the blood vessel.

[0067] 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. **2**A-**2**E schematically illustrate another example device with an internal dimension that can be reduced and increased in vivo. Device **200** illustrated in FIGS. **2**A-**2**E 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.

[0068] For example, FIG. **2**A 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 D**1** (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. **2**B, 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. **2**C, to dimension D**2** (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. **2**E, to dimension D**3** (corresponding to a third cross sectional area), by first heating the shape-memory component **220** above its Af temperature, returning it so its annealed configuration, DO, as shown in FIG. **2**D, then expanding it (e.g. by balloon dilation) to a third dimension D**3** (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**.

[0069] Although FIGS. **2**A-**2**E illustrate only three exemplary dimensions D**1**, D**2**, D**3** 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 DO and D**1** may be approximately the same as one another, in other examples DO may be smaller than D**1**, while in still other examples DO may be larger than D**1**. 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 Af 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.

[0070] In the nonlimiting examples shown in FIGS. **2**B and **2**D, 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.

[0071] 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 Af 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. **1**A-**1**E. Second component **220** may include a NITINOL alloy having an austenitic phase transition temperature Af 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 Af, 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. **1**A-**1**E. Alternatively, device **200** may include a single NITINOL alloy that has been heat treated to produce a lower Af in regions respectively corresponding to first component **210** and third component **211**, and that has been heat treated to produce a higher Af 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. **1**A-**1**E. 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. **1**A-**1**E.

[0072] In a manner such as described in greater detail with reference to FIGS. **7**-**10**C, 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**-**10**C. 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**-**10**C. As described in U.S. Pat. No. 10,898,698 to Eigler, 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, first component **210** and/or third component **211** may be configured to engage a lumen in the body, e.g., a blood vessel, and/or the neck, if present, optionally may be configured to be disposed adjacent to an ostium of the blood vessel.

[0073] FIGS. **3**A-**3**D schematically illustrate an example device with multiple internal dimensions that can be reduced and increased in vivo. Device **300** illustrated in FIGS. **3**A-**3**D 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**.

[0074] In addition to defining the rate of fluid flow through device **300**, examples such as described with reference to FIGS. **3**A-**3**D 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. **14**A-**14**C, 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. **3**A-**3**D 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 in U.S. Pat. No. 10,898,698 to Eigler, 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.

[0075] FIG. **3**A 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 D**1** (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. **3**B, 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. **3**C, to respective dimensions D**2** (corresponding to a second cross sectional area) and D**3**. 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. **3**D, to respective dimensions D**4** (corresponding to a third cross sectional area) and D**5**.

[0076] 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. **3**A-**3**D illustrate exemplary dimensions D**1**, D**2**, D**3**, D**4**, and D**5** 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 DO that may be the same as, or different than, one another, and may be crimped to dimension D**1** which is smaller than DO. Second component **320** and third component **321** respectively may be expanded to any suitable dimension(s), reset to DO, and subsequently re-expanded to any suitable dimension(s) any suitable number of times.

[0077] In the nonlimiting examples shown in FIGS. **3**B and **3**D, 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.

[0078] 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 Af 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. **1**A-**1**E. Second component **320** and third component **321** each may include a NITINOL alloy having an austenitic phase transition temperature Af 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 Af, 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. **1**A-**1**E. Alternatively, device **300** may include a single NITINOL alloy that has been heat treated to produce a lower Af in a region corresponding to first component **310**, and that has been heat treated to produce a higher Af 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 Af 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. **1**A-**1**E, 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. **1**A-**1**E.

[0079] In a manner such as described in U.S. Pat. No. 10,898,698 to Eigler, 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. Moreover, 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**. Additionally, 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. A fourth component may be fluidically coupled to first component **310** and configured to extend into another ostium of the blood vessel. 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).

[0080] In the present devices, such as exemplified by devices **100**, **200**, **300** respectively described with reference to FIGS. **1**A-**1**E, **2**A-**2**E, and **3**A-**3**D, 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.

[0081] For example, FIGS. **4**A-**4**B 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. **4**A, 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. **1**A-**1**E, **2**A-**2**E, or **3**A-**3**D. 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. **4**B, 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. **1**A-**1**E, **2**A-**2**E, or **3**A-**3**D. 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.

[0082] 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. Pat. Nos. 11,304,831 and 10,835,394 to Nae, U.S. Pat. No. 11,109,988 to Rosen, U.S. Pat. Nos. 9,034,034 and 9,980,815 to Nitzan, and U.S. Pat. No. 10,076,403 to Eigler, the entire contents of each 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.

[0083] 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.

[0084] 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. **5**A-**5**B 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. **5**A, 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. **1**A-**1**E, **2**A-**2**E, or **3**A-**3**D. 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.

[0085] In example device **501** illustrated in FIG. **5**B, 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. **1**A-**1**E, **2**A-**2**E, or **3**A-**3**D. 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.

[0086] Mechanical interference between components, e.g., such as described with reference to FIGS. **5**A-**5**B, 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. **5**A-**5**B, may reduce or inhibit such recoil. For example, in the configuration described with reference to FIG. **5**B, 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.

[0087] It will be appreciated that devices such as described with reference to FIGS. **1**A-**1**E, **2**A-**2**E, **3**A-**3**D, and options thereof such as described with reference to FIGS. **4**A-**4**B and **5**A-**5**B, 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.

[0088] 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. **2**A-**2**E 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. **3**A-**3**D 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.

[0089] 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**-**10**C.

[0090] 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**-**10**C, 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.

[0091] 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. **2**A-**2**E. 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.

[0092] 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.

[0093] In the nonlimiting example shown in FIG. **7**, first flared end region **702** has first end region dimension D**1**, second flared end region **706** has second end region dimension D**2**, and neck region **704** has neck dimension D**3** which may be increased or reduced in a manner such as described with reference to second component **220** illustrated in FIGS. **2**A-**2**E. 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 D**1** being equal to the second end region dimension D**2**. 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.

[0094] 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. **5**A-**5**B and as further exemplified with reference to FIGS. **20**A-**22**I, described below.

[0095] FIGS. **8**A-**8**D 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 **14**F 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. **2**A. 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. **8**A 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.

[0096] 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. **8**B, 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. **8**C, the neck region may be contracted by injecting, via catheter **803**, a bolus of hot saline having a temperature above the Af of the malleable shape-memory material (e.g., at 40-60° 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. **8**D.

[0097] 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. **8**A. 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, DO, at a third time. Dimension DO is determined by the size of the jig used in a heat-setting step during manufacture. DO 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. **1**A-**1**E.

[0098] The particular configuration of shunt **700** may be selected so as to provide desired flow dynamics therethrough. For example, FIGS. **9**A-**9**B schematically illustrate example configurations of the device of FIG. **7**. In FIGS. **9**A-**9**B, 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.

[0099] Shunt **700** (or any other device provided herein) may be made using any suitable combination of techniques. FIGS. **10**A-**10**C schematically illustrate example uses of tooling for preparing the device of FIG. **7**. As shown in FIGS. **10**A-**10**C, 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-sinked 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. **10**C. 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. In addition, the transition zone may provide a smooth, continuous transition between the neck region and flared end regions during dilatation or contraction of the neck region. 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.

[0100] It will be appreciated that tooling **1000** is optional, and that any of the devices herein (illustratively, device **200** described with reference to FIGS. **2**A-**2**E; device **700** described with reference to FIGS. **7**, **8**A-**8**D, **9**A-**9**B, and **10**A-**10**C; or device **28** described with reference to FIGS. **15**A-**15**E) 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.

[0101] 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 in U.S. Pat. No. 10,898,698 to Eigler, 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.

[0102] It will further be appreciated that any suitable combination of superelastic and shape memory NITINOL components may be used within the present devices.

[0103] 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.

[0104] 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. **11** illustrates a flow of operations in an example method **1100** for reducing and increasing dimension of a device in vivo. Method **1100** may include inserting into a fluid path first and second components coupled to one another (**1101**). 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. **1**A-**1**E, **2**A-**2**E, **3**A-**3**D, **4**A-**4**B, **5**A-**5**B, **6**, **7**, **8**A-**8**D, **9**A-**9**B, **15**A-**15**E, **17**A-**17**E, **20**A-**20**F, and **21**A-**22**I.

[0105] Method **1100** illustrated in FIG. **11** also may include expanding the malleable shape-memory material to a second cross sectional area (operation **1102**). For example, as described elsewhere herein, the malleable shape-memory material may be expanded using balloon dilatation.

[0106] Method **1100** illustrated in FIG. **11** contracting the malleable shape-memory material to a third cross sectional area (operation **1103**). 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 Af of the shape-memory material, or using another suitable energy source such as radio frequency electrical current (RF).

[0107] 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.

[0108] 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. **1**A-**1**E, **2**A-**2**E, **3**A-**3**D, **4**A-**4**B, **5**A-**5**B, **6**, **7**, **8**A-**8**D, **9**A-**9**B, **11**A-**11**B, **15**A-**15**E, **17**A-**17**E, **20**A-**20**F, and **21**A-**22**I. 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).

[0109] 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. **12** illustrates a flow of operations in an example method **1200** for repositioning a device. Method **1200** includes inserting into a body lumen a device comprising first and second components coupled to one another (operation **1201**). 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. **1**A-**1**E, **2**A-**2**E, **3**A-**3**D, **4**A-**4**B, **5**A-**5**B, **6**, **7**, **8**A-**8**D, **9**A-**9**B, **11**A-**11**B, **15**A-**15**E, **17**A-**17**E, **20**A-**20**F, and **21**A-**22**I.

[0110] Method **1200** also includes expanding the malleable shape-memory material to a second dimension to fixate the device within a body lumen (operation **1202**), for example via balloon dilatation. Method **1200** also includes thermally contracting the malleable shape-memory material (operation **1203**), for example via application of heat. Method **1200** also includes repositioning the device within the body lumen while the malleable shape-memory material is thermally contracted (operation **1204**), for example by moving the device along a guidewire. Method **1200** also includes mechanically re-expanding the malleable shape-memory material to a third dimension to fixate the device within the body lumen (operation **1205**), for example via balloon dilatation.

[0111] 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. **13**A-**13**D schematically illustrate an example dilator device **1300** with an external dimension that can be reduced and increased in vivo. Device **1300** 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. **14**A-**14**I.

[0112] In the example shown in FIG. **13**A, device **1300** may include dilator **1310** disposed at the distal end of sheath **1320**. As shown in greater detail in FIG. **13**B, dilator **1310** may include tip **1311**, enlarged region **1312**, and reduced region **1313**. Reduced region **1313** may be sized so as to securably engage with the distal end of sheath **1320**, and enlarged region **1312** may be sized so as to provide device **1300** with a smooth profile between sheath **1320** and tip **1311**. Tip **1310** may have an outer dimension d where tip **1311** meets enlarged region **1312**, and its distal end may taper to approximately a point. In the example configuration shown in FIG. **13**B, dilator **1310** includes a martensitic shape-memory material defining enlarged region **1312** and reduced region **1313** (together, denoted region B), and a self-expanding superelastic material defining tip **1311** (denoted region A). The austenitic finish temperature (Af) 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 5-20° C., or 5-15° C. The Af of the martensitic shape memory material may be substantially greater than 37° C., e.g., may be about 40-60° C., e.g., 45-60° C. or about 50° C. Tip **1310**, reduced region **1313**, and enlarged region **1312** optionally are integrally formed from a common frame with one another.

[0113] As shown in FIG. **13**C, 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 **1312** and reduced region **1313**) may return to a smaller, heat-set outer dimension that optionally may be approximately equal to d so that the dilator **1310** has a substantially smooth, reduced size profile. In the alternative configuration shown in FIG. **13**D, dilator **1310′** includes a martensitic shape-memory material defining tip **1311**, enlarged region **1312**, and reduced region **1313**, which may be configured to return to a smaller, heat-set dimension that optionally may be approximately equal to d so that the dilator **1310** has a substantially smooth, reduced size profile.

[0114] FIGS. **14**A-**14**I schematically illustrate use of the delivery device **1300** of FIGS. **13**A-**13**D in the human body. In the nonlimiting example shown in FIG. **14**A, guidewire **1420** is percutaneously placed across a region of the body to be dilated, for example, fossa ovalis **1410** of interatrial septum **1400**, creating a small opening having approximately the dimension of guidewire **1420**. Device **1300** then is advanced over guidewire **1420** to a position adjacent to fossa ovalis **1410** in a manner such as illustrated in FIG. **14**B. As shown in FIG. **14**C, pushing on the proximal end of sheath **1320** forces dilator **1310** through fossa ovalis **1410**, enlarging the opening to approximately the outer dimension of enlarged region **1312**. As shown in FIG. **14**D, sheath **1320** may be retracted relative to dilator **1310**, leaving dilator **1310** in place on the distal side of fossa ovalis **1410**. So as to inhibit harming the tissue of interatrial septum **1400** when retracting dilator **1310**, e.g., by catching tissue with enlarged region **1312** when retracting dilator **1310**, and so as to inhibit dilator **1310** 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 **1310** on the distal side of fossa ovalis **1410** as shown in FIG. **14**E, 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 Af of the shape memory material of the dilator. Such heat causes the outer dimension of the enlarged region **1312** to return to its heat-set size. As shown in FIG. **14**G and its inset **14**H, the reduced-size dilator **1310** may be safely withdrawn through the enlarged opening, and then may be stowed inside of sheath **1320** in a manner such as illustrated in FIG. **14**I 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 **1300**. For example, the adjustable device may be disposed within sheath **1320** and advanced to partially cross the atrial septum together with delivery device **1300** in a manner such as shown in FIG. **14**C. Retracting sheath **1320** in a manner such as shown in FIG. **14**D 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 **1310** 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.

[0115] 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. **15**A-**15**E 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. **15**A is a schematic illustration of a temporary apparatus **28** inside a subject **20**, FIG. **15**B is a schematic illustration of temporary apparatus **28**, in accordance with some examples provided herein, and FIGS. **15**C-**15**E collectively show a technique for removing temporary apparatus **28** from a subject, in accordance with some examples provided herein.

[0116] Apparatus **28** includes device **21**, which may be configured similarly as device **200** described with reference to FIGS. **2**A-**2**B 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. **15**B, 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. **2**A-**2**B 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. **15**A-**15**B) 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. **15**A. 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.

[0117] To facilitate removal of device **21** from the subject in a manner such as described further below with reference to FIGS. **15**C-**15**E, 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. **15**A-**15**B, 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. **15**A, 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. **15**C-**15**E. FIG. **15**B 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.

[0118] 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.

[0119] 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.

[0120] 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. **15**A. The cross sectional area of intermediate portion **42** may be adjusted in response to such measurements. 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.

[0121] 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. **13**A-**14**I. 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. **15**A. 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.

[0122] 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. **15**A 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**.

[0123] 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. **15**C-**15**E, 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.

[0124] 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. **15**C-**15**E, and a permanent shunt of the indicated size is implanted.

[0125] Reference is now made to FIGS. **15**C-**15**E, 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. **15**C-**15**E are provided by way of example only, and that many variations of the illustrated technique are included within the scope of the present disclosure. In FIG. **15**C, 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. **15**C, 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. **15**D. Following the collapse of the proximal portion of device **21**, as shown in FIG. **15**E, 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. **15**E, 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.

[0126] 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. **15**D 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.

[0127] FIGS. **15**C-**15**E 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. **15**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.

[0128] 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. **15**D, and deployed in a manner similar to that described with reference to FIGS. **15**A-**15**B. 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**.
[0129] It is noted that the apparatus and methods such as described with reference to FIGS. **15**A-**15**E 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.
WORKING EXAMPLE
[0130] The following example is intended to be purely illustrative, and not limiting of the present disclosure.
[0131] FIGS. **16**A-**16**H 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. **16**A, within a tank of 37° C. water, a transparent membrane **1601** is suspended in tooling **1602** to simulate an atrial septum, and shunt frame device **700** is deployed from behind the opening in membrane **1601** via sheath **1600** 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 **1600**, 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. **8**A. At the time of FIG. **16**B, 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. **16**C, commercially available angioplasty balloon **1603** is inserted through the neck of device **700**. At the time of FIG. **16**D, balloon **1603** 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. **16**E, the balloon **1603** is deflated. At the time of FIG. **16**F, it may be seen that neck **720** of device **700** remains at a diameter of approximately 7 mm after balloon **1603** is withdrawn, in accordance with the example set forth in FIG. **8**B. At the time of FIG. **16**G, neck **720** is bathed in heated saline via rapid injection through a catheter **1604**, in accordance with the example set forth in FIG. **8**C. At the time of FIG. **16**H, after the heating shown in FIG. **16**G, neck **720** has been returned to its approximately 4 mm heat set diameter, in accordance with the example set forth in FIG. **8**D, demonstrating that the neck region **720** of device **700** exhibits the desired martensitic shape-memory properties. Operations such as described with reference to FIGS. **16**C-**16**G 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 **1601** 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.
[0132] One complication that can arise when adjusting the dimension of the shunt over time is tissue trauma to the atrial septum. The encapsulated shunt may be designed to promote tissue ingrowth and endothelialization and therefore expanding or reducing the encapsulated shunt after tissue has adhered to the encapsulated shunt over time can result in trauma to the atrial septum. Provided herein are devices for adjusting the dimensions of the shunt without disturbing the septal

tissue surrounding the device. In particular, the device may include a bridge as described in U.S. Pat. No. 11,813,386 to Nae, the entire contents of which are incorporated herein by reference. For example, the bridge may be formed of biocompatible material that extends between the outer surfaces of first and second flared end regions, creating a gap between the bridge and a neck region of the encapsulated shunt. The bridge may be configured to engage the patient's atrial septum, rather than the encapsulated shunt itself such that, when the device is adjusted in vivo, the bridge may be configured to remain the same outer diameter while only the inner diameter of the shunt is modified. Accordingly, the bridge prevents dehiscence that may result when the device is adjusted in vivo. Further, the bridge may mitigate any bypass flow that may flow around the outside of the device after the diameter of the neck region is reduced in vivo. In addition, the bridge may be formed of a material having properties selected to encourage tissue ingrowth to thereby facilitate anchoring of the bridge, and accordingly the shunt, to the surrounding tissue.

[0133] The bridge described above could also be used with encapsulated shunts that are not adjustable in vivo, as well as encapsulated shunts that are disposed in another portion of the human body, such as a body lumen (e.g., a blood vessel). Patients who may benefit from an interatrial shunt also may have required or will require a prior transeptal procedure resulting in a hole in the septal wall. Alternatively, the patient may have septal defect that is predilated larger than the delivery system required to implant the device described here. Incorporating the bridge of biocompatible material to the encapsulated shunt increases the outer diameter of the device, thus permitting implantation of the device in the enlarged septal hole, without affecting the inner diameter of the device and fluid flow rate throughout the device.

[0134] For example, referring now to FIGS. **17**A and **17**E, a shunt, e.g., shunt **700**, with a bridge is provided. As described above, first flared end region **702** has first end region dimension D**1**, second flared end region **706** has second end region dimension D**2**, and neck region **704** has neck dimension D**3** which may be increased or reduced in a manner such as described with reference to second component **720** illustrated in FIGS. **19**A-**19**D. As shown in FIG. **17**A, shunt **700** may be modified to add bridge **1740** at neck region **704**, which is configured to engage a patient's atrial septum. As described above, shunt **700** is preferably encapsulated with graft material to create a shunt-graft assembly and a passageway to permit blood to flow; this graft material has been omitted from FIG. **17**A to better illustrate the location of bridge **1740**. Bridge **1740** may be made of a biocompatible material, such as a polymer or a natural material as described above, and may be the same material as the material used to encapsulate the frame or may be a different material. Preferably, the biocompatible material of the bridge is one that encourages tissue adherence such that contact with the septal wall is maintained if the inner diameter of the shunt is decreased. Maintaining contact with the septal wall helps prevent any fluid bypass around the outside of the device. The biocompatible material may be configured to promote tissue ingrowth over the entire bridge or over only a portion of the bridge. For example, holes may be placed at the location of bridge **1740** that is configured to engage the atrial septum while the remainder of bridge **1740** remains whole such that tissue ingrowth is not encouraged on the flared end regions. Such addition of holes or other processing to promote tissue ingrowth or encourage adhesion may be performed on the biocompatible material prior to or after the shunt is assembled.

[0135] In addition, or alternatively, bridge **1740** may be made of a different biocompatible material than the biocompatible material used to encapsulate the shunt. For example, the shunt may be encapsulated with a biocompatible material, such as ePTFE, having a sufficiently small pore size such that tissue ingrowth is mitigated and the bridge may be made of a biocompatible material having a larger pore size that is designed to encourage tissue ingrowth. Generally, the larger the pore size of the biocompatible material, the greater the adherence of tissue to the biocompatible material. In addition to encouraging tissue growth, greater porosity permits the exchange of fluids in and out of the gap between the outer surface of neck region **704** and bridge **1740**. For example, bridge **1740** may be made of ePTFE that has a larger intermodal distance (e.g., approximately 60-

200 μm) than the ePTFE that encapsulates the shunt.
[0136] Alternatively, bridge **1740** may be made of woven Dacron to further encourage tissue ingrowth. The Dacron may be securely attached to the encapsulated shunt using stitches. Because Dacron is bulkier than ePTFE, the cross-section of the device in the collapsed or crimped configuration may be increased, which may mean that a larger diameter sheath may be required for delivery of the device. Additional materials that may be used to promote tissue ingrowth include using a mesh-like structure, electrospun fabrics, or silicone.
[0137] In some embodiments, the shunt may be encapsulated with ePTFE having a thickness of 0.002″ and an internodal distance of ≤30 microns. Clowes et al., Rapid Transmural Capillary Ingrowth Provides a Source of Intimal Endothelium and Smooth Muscle in Porous PTFE Prostheses, Arterial Graft Failure, Vol. 123, No. 2, pages 220-230 (May 1986) describes that ePTFE with IND≤30 microns exhibits low porosity and Applicant's studies have shown that tissue ingrowth is inhibited within shunts encapsulated with ePTFE with IND=30 microns. On the other hand, bridge **1740** may have a thickness of 0.002″ or 0.005″ and a pore size to augment cellular and collagen transmural infiltration into the potential space between bridge **1740** and other layers of ePTFE. This can be done using a larger pore size ePTFE (for example with an ePTFE material having IND ranging from 60 to 200 microns). Alternatively, transmural infiltration may be encouraged by creating a pattern or plurality of perforations of similar dimension into bridge **1740** fabricated from conventional low-porosity (IND≤30 microns), either before or after its application to the shunt. Such dedicated perforation process may be performed using, e.g., an energy source such as laser, RF, etc., or a mechanical source e.g. punch, or any other technique known to those skilled in the art of thin materials processing.
[0138] In some embodiments, the frame encapsulation material is intended to block tissue ingrowth, whereas the bridge encapsulation material would be more elastic to support the significant expansion/contraction in diameter, without damaging the Fossa Ovalis or the frame encapsulation material. In some embodiments, the gap **1743** between the bridge **1740** and the neck region **704** increases as the shunt neck region **704** is contracted. Bridge **1740** may be configured to remain engaged with the patient's atrial septum when the neck region is contracted. In some embodiments, the biocompatible material of bridge **1740** has a porosity (as measured by, e.g., its internodal distance) greater than the porosity of the biocompatible material of the encapsulation of the shunt frame. As such, the internodal distance of the bridge material may be selected to permit tissue ingrowth while the internodal distance of the encapsulation material is selected to inhibit tissue ingrowth. In some embodiments, the internodal distance of the bridge is greater than 30 microns (e.g., in a range of 45-200 microns) while the internodal distance of the encapsulation is less than or equal to 30 microns. In one embodiment, the internodal distance of the bridge is 60 microns while the internodal distance of the encapsulation is 30 microns. The biocompatible material of the bridge and the biocompatible material of the encapsulation may be expanded polytetrafluoroethylene (ePTFE).
[0139] Bridge **1740** may have a length shorter than shunt-graft assembly **1710** and a diameter greater than the diameter of neck region **704**. Bridge **1740** may have first end **1741** and second end **1742** and may be shaped and sized such that first end **1741** is disposed approximately half way up first flared end region **702** and second end **1742** is disposed approximately half way up second flared end region **706**. Alternatively, first end **1741** and second end **1742** may extend further up first flared end region **702** and second flared end region **706** or may be attached nearer neck region **704**. Bridge **1740** may be stretched such that a gap is created between the outer surface of neck region **704** and the inner surface of bridge **1740**. The gap may be widest at the narrowest point of the outer surface of neck region **704**.
[0140] As described above, the encapsulated shunt may be adjusted in vivo to increase or decrease the neck dimension and thereby adjust the fluid flow rate through the shunt. Because the encapsulated shunt may be designed to promote tissue ingrowth and endothelialization, tissue may

adhere to the shunt over time. Adjustments of the encapsulated shunt to increase or decrease the dimensions can therefore result in trauma to the atrial septum. Bridge **1740** is designed to prevent dehiscence and to mitigate the tissue trauma that can result from such adjustments. Bridge **1740** is configured to engage with the atrial septum and defines outer diameter D**4**. Preferably, outer diameter D**4** is larger than neck dimension D**3**. In one embodiment, outer diameter D**4** may be 7-9 mm and neck dimension D**3** may be 4.5-5.5 mm. When the device is adjusted in vivo, bridge **1740** may be configured to remain the same outer diameter D**4** while only the neck dimension D**3** of the shunt and the size of the gap is modified. Due to the creation of a gap between neck region **704** and bridge **1740**, neck dimension D**3** may be decreased or increased up to outer diameter D**4** causing an increase or decrease in the size of the gap, without disturbing the septal tissue contacting and surrounding bridge **1740** and while maintaining contact with the septal tissue such that leakage or bypass flow around the outer surface of the shunt is minimized.

[0141] Bridge **1740** could also be used with encapsulated shunts that are not adjustable in vivo. In particular, incorporating bridge **1740** into an encapsulated shunt may be beneficial for patients who have an enlarged hole prior to implantation of the device, for example, from a prior transseptal procedure, or have a septal defect that is predilated larger than the delivery system required to implant the device described herein. For example, for a patient with severe mitral regurgitation and poor left ventricular function, it may be clinically desirable to first perform a repair procedure on the mitral valve, e.g. MitraClip® of mitral annuloplasty by the percutaneous transseptal approach, followed by interatrial shunt placement. These mitral valve procedures currently use a 23Fr I.D. (˜8 mm outer diameter) guiding catheter to cross the foramen ovalis. After mitral repair, a shunt with an outer minimal diameter matching the larger aperture defect caused by the prior procedure may be implanted, wherein the conduit as a smaller diameter desirable for shunting (e.g. 5.0 to 6.5 mm). Likewise, such shunts advantageously may be used where, during the transseptal procedure, the fossa ovalis has been torn, thus creating a larger aperture defect than required.

[0142] Incorporating the bridge of biocompatible material to the encapsulated shunt increases the outer diameter of the device, thus permitting implantation of the device in the enlarged septal hole, without affecting the inner diameter and fluid flow rate throughout the device. Further, bridge **1740** permits the inner diameter of the encapsulated shunt to be temporarily increased, for example, during a separate transseptal procedure after implantation of the device, without disturbing the outer diameter of the neck region, thus minimizing the risk of tears to the septal tissue. As will be understood by a person having ordinary skill in the art, the present devices described herein, e.g., with reference to FIGS. **1**A-**1**E, **2**A-**2**E, **3**A-**3**D, **4**A-**4**B, **5**A-**5**B, **6**, **7**, **8**A-**8**D, **9**A-**9**B, **15**A-**15**E, **20**A-**20**F, and **21**A-**22**I, may similarly incorporate a bridge.

[0143] Referring now to FIGS. **17**B to **17**E, additional side, front, side cross-sectional, and perspective views are shown, respectively. FIG. **17**B shows shunt **700** encapsulated with biocompatible material **717** to create shunt-graft assembly **1710** and to define a flow path through shunt-graft assembly **1710**. As shown in FIG. **17**D, neck region **704** defines the inner diameter, neck dimension D**3**, of the passageway through which blood flows. Bridge **1740** surrounds the entire neck region **704** to define outer diameter D**4**.

[0144] Referring now to FIGS. **18**A and **18**B, cross-sectional side views of the device of FIG. **17**A showing an unfilled and a filled gap between the bridge and the encapsulated shunt. Bridge **1740** is attached at first end **1741** to first flared end region **702** and is attached at second end **1742** at second flared end region **706**. Preferably, bridge **1740** is stretched such that a gap is created between neck region **704** and bridge **1740**. Gap **1743** may be filled with a flexible biocompatible material or a liquid biocompatible material, such as a hydrogel. Alternatively, gap **1743** may be filled with bodily fluids upon delivery and implantation of shunt-graft **1710**. This embodiment is advantageous where the dimensions of the shunt are configured to be adjusted in vivo. Specifically, gap **1743** may be increased or decreased during such adjustments while the outer diameter of the neck region that contacts the atrial septum (e.g., the bridge) remains the same, thus minimizing any

tissue trauma. For example, bridge **1740** may be made of ePTFE having holes such that when shunt-graft assembly **1710** expands, the biocompatible material disposed within gap **1743** is configured to permeate through bridge **1740**.

[0145] As shown in FIG. **18**B, the gap between bridge **1740** and the encapsulated shunt may be filled with a biocompatible material, such as a polymer or a natural material that is not flexible such that the gap remains the same size even if the dimensions of shunt-graft assembly **1710** are adjusted. This embodiment may be beneficial where the device is designed to be implanted into an enlarged septal hole and the device is not configured to be adjusted in vivo. In particular, because the inner diameter of the device may not be adjusted, the dimensions of gap **1744** do not need to be adjustable. Accordingly, gap **1744** may be filled with a solid material or a low durometer material such as a hydrogel, which may increase the stability of the device and make the bridge more robust.

[0146] FIGS. **19**A-**19**E schematically illustrate example steps for using the device of FIG. **17**A in the human body. Shunt-graft assembly **1710** may be crimped to a cylindrical shape, for example by pushing it through a conical loading device. In one non-limiting example, shunt-graft assembly **1710** may be crimped to an outer dimension of about 4.6 mm, the inside dimension of a **14**F Cook sheath. For example, FIG. **19**A illustrates shunt-graft assembly **1710** disposed within sheath **1900**. As will be understood by one of skill in the art, shunt-graft assembly **1710** may be crimped to a smaller or larger outer dimension if a different size Cook sheath is used. In addition, a layer of hydrogel may be placed with gap **1744** between bridge **1740** and shunt-graft assembly **1710**, which may affect the crimped dimension. The delivery catheter and sheath **1900** may be designed as described in U.S. Pat. No. 9,713,696 to Yacoby, U.S. Pat. No. 11,612,385 to Nae, entitled “Systems and Methods for Delivering Implantable Devices across an Atrial Septum,” U.S. Patent App. Pub. No. 2022/0184356 to Nae, and/or WO 2023/079498, each assigned to the assignee of the present application, the entire contents of each of which are incorporated by reference herein. The sheath may be percutaneously placed through a blood vessel to a desired location in the human body. As the crimped shunt is pushed out of sheath **1900**, 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. **19**B in which bridge **1740**, disposed over neck region **704** (designated “B” and corresponding to second component **720**), engages an opening in the human body.

[0147] Depending on the desired direction of blood flow through shunt-graft assembly **1710**, first flared end region **702** and second flared end region **706** (designated “A” or “C” and corresponding to first component **710** or third component **730**) provides an inlet and the other of the flared ends (designated “C” or “A” and corresponding to third component **730** or first component **710**) provides an outlet. For example, bridge **1740** 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. 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.

[0148] 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-graft assembly **1710**. For example, in a manner such as illustrated in FIG. **19**C, the neck region may be expanded by balloon dilatation using balloon **1901** (e.g., a 12 mm diameter balloon),

which may be fed through the orifice using a wire **1902**. Preferably, balloon **1901** expands the neck region only to a threshold outer diameter, defined by bridge **1740**, such that expansion of the neck region does not affect the outer diameter of the device or disturb the septal tissue surrounding bridge **1740**. For example, bridge **1740** may be sized and shaped to define an outer diameter of 7-14 mm and balloon **1901** may be configured to expand the neck region up to 9 mm.

[0149] Additionally, in a manner such as illustrated in FIG. **19**D and as described above, the neck region may be contracted by injecting, via a distal end of catheter **1903**, a bolus of hot saline having a temperature above the Af of the malleable shape-memory material (e.g., at 40-65° C. or 45-65° C.), which may cause the neck region to return to its heat-set dimension, which may be different from its crimped dimension and preferably is 4.5-5.5 mm. FIG. **19**D illustrates one method of heating the neck region, but other methods may be used. For example, the saline may be injected via side-holes in catheter **1903**. Further, a second balloon catheter may be inserted through shunt-graft assembly **1710** such that the balloon is distal to the location the saline is delivered and the balloon may be expanded to block blood flow through shunt-graft assembly **1710** during delivery of the saline. In other examples, a pair of electrodes may be positioned to contact shunt-graft assembly, e.g., via catheter **1903**, and actuated at an appropriate voltage and frequency to heat the neck region to or above its Af. In still other examples, other suitable means of locally applying heat to shunt **700**, such as a laser, magnetic inductance, electrical resistance, or the like, may be used. Preferably, the return of the neck region to its heat-set dimension does not affect the outer diameter of bridge **1740**, as illustrated in FIG. **19**E.

[0150] For example, heat from the saline may cause the malleable shape-memory material to transition to an austenitic phase, contracting 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 end hole, 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 non-limiting 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. **19**B. The neck region then may be expanded using balloon dilatation to any desired larger dimension between the crimped dimension and the outer diameter of bridge **1740** at a second time. The neck region then may be contracted using hot saline to its heat-set dimension at a third time. The heat-set dimension is determined by the size of the jig used in a heat-setting step during manufacture and may be approximately the same as, may be smaller than, or may be larger than the dimension of the neck region in the crimped state. The heat-set dimension 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 the outer diameter of bridge **1740** 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.

[0151] 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.

[0152] As described above, the present devices may comprise individual components that are

formed separately and assembled together. For example, the first and second expandable end regions may be formed and heat treated to achieve the superelastic properties described herein, separate from the neck region, which may be formed and heat treated to achieve the martensitic, shape-memory properties described herein. By treating the shape-memory components separate from the superelastic components, the components may be treated in large batches without a complex treatment apparatus as may be required for manufacturing hybrid shunts from a unitary nitinol frame, which may significantly reduce manufacturing time. As described in further detail below with regard to FIGS. **20**A to **22**I, the components of the various devices described herein may be assembled together via interlocking shapes that retain the advantages of unitary construction, particularly, a smooth, continuous transition between the components throughout the range of device dimensions, e.g., neck diameters, as discontinuous changes in lumen diameter may introduce undesirable eddies and/or turbulence in flow. Such flow disturbances can lower the discharge coefficient or even produce platelet activation and thrombus formation, or conceivably even damage to red blood cells (hemolysis).

[0153] Referring now to FIGS. **20**A-**20**F, a hybrid shunt device having interlocking components with different shape-memory properties that are treated separately and assembled together is provided. FIGS. **20**A and **20**B illustrate hybrid shunt **2000** in an unassembled configuration, e.g., after the separate components have been treated to achieve the desired material properties. For example, shunt **2000** may be formed of first end region **2002**, neck region **2004**, and second end region **2006**. As described above, neck region **2004** may be treated such that it is malleable at body temperature, e.g., having an Af temperature between about 40-60° C., and first end region **2002** and second end region **2006** may be treated such that they are superelastic at body temperature, e.g., having an Af temperature between about 5-20° C.

[0154] As shown in FIG. **20**A, first end region **2002** may include proximal end **2008** and distal end **2010** having a plurality of first end region connectors **2011**, neck region **2004** may include proximal end **2012** having a plurality of proximal neck region connectors **2013** and distal end **2014** having a plurality of distal neck region connectors **2015**, and second end region **2006** may include proximal end **2016** having a plurality of second end region connectors **2017** and distal end **2018**. Like device **700** of FIG. **7**, each of first end region **2002**, neck region **2004**, and second end region **2006** may be formed of a plurality of longitudinal extending struts interconnected via one or more circumferentially extending sinusoidal rings. For example, as shown in FIG. **20**A, first end region **2002** may include a plurality of longitudinal struts **2020***a* interconnected via sinusoidal ring **2022***a*, such that the plurality of first end region connectors **2011** are disposed at distal end **2010** of each of longitudinal struts **2020***a*. Neck region **2004** may include a plurality of longitudinal struts **2020***b* interconnected via sinusoidal rings **2022***b*, such that the plurality of proximal neck region connectors **2013** are disposed at proximal end **2012** of each of longitudinal struts **2020***b* and the plurality of distal neck region connectors **2015** are disposed at distal end **2014** of each of longitudinal struts **2020***b*. Second end region **2006** may include a plurality of longitudinal struts **2020***c* interconnected via sinusoidal ring **2022***c*, such that the plurality of second end region connectors **2017** are disposed at proximal end **2016** of each of longitudinal struts **2020***c*. As will be understood by a person having ordinary skill in the art, although FIG. **20**A illustrates first end region **2002** and second end region **2006** having a single sinusoidal ring, first end region **2002** and second end region **2006** may each include more than one sinusoidal ring interconnecting plurality of longitudinal struts **2020***a*, **2020***c*. Similarly, although FIG. **20**A illustrates neck region **2004** having two sinusoidal rings, neck region **2004** may have less or more than two sinusoidal rings interconnecting plurality of longitudinal struts **2020***b*. Moreover, shunt **2000** may include less or more longitudinal struts than is illustrated in FIG. **20**A.

[0155] Each connector of the plurality of first end region connectors **2011** of first end region **2002** may have a shape configured to interlock with a complementary shape of each connector of the plurality of proximal neck region connectors **2013** of neck region **2004**, and each connector of the

plurality of second end region connectors **2017** of second end region **2006** may have a shape configured to interlock with a complementary shape of each connector of the plurality of distal neck region connectors **2015** of neck region **2004**. For example, the complementary shapes of first end region connectors **2011** and proximal neck region connectors **2013**, and second end region connectors **2017** and distal neck region connectors **2015** may include tab and socket elements. As will be understood by a person having ordinary skill in the art, other complementary shapes may be used that provide an interlocking puzzle-like connection.

[0156] For example, as shown in FIG. **20**B, first end region connectors **2011** may include a socket element and proximal neck region connectors **2013** may include a tab element. Similarly, distal neck region connectors **2015** may include a tab element and second end region connectors **2017** may include a socket element. As will be understood by a person having ordinary skill in the art, first end region connectors **2011** and second end region connectors **2017** alternatively may include a tab element, whereas proximal neck region connectors **2013** and distal neck region connectors **2015** include a socket element. In some embodiments, distal end **2010** of first end region **2002** (and similarly proximal end **2016** of second end region **2006**) may include eyelet **2009** adjacent to socket element **2011** to improve structurally integrity of socket element **2011** while also providing flexibility to first end region **2002** as first end region **2002** transitions between a collapsed delivery state and an expanded deployed state, as well as during adjustment of the lumen diameter of neck region **2004**. Moreover, a radiopaque marker may be disposed within eyelet **2009** to facilitate visualization of shunt **2000**, e.g., under fluoroscopy.

[0157] As shown in FIG. **20**B, socket element **2011** includes an opening sized and shaped to fixedly receive tab element **2013**. Preferably, when socket element **2011** and tab element **2013** are at the same temperature, tab element **2013** is slightly larger than the opening of socket element **2011** such that tab element **2013** may be permanently fixed to socket element **2011** when tab element **2013** is disposed within the opening of socket element **2011**. Accordingly, tab element **2013** may be thermally contractible, e.g., via cooling, such that tab element **2013** transitions from a first size to a second size smaller than the first size, and smaller than the opening of socket element **2011**. While in the thermally contracted state having the second size, tab element **2013** may be fitted within the opening of socket element **2013**, such that when tab element **2013** and socket element **2011** are brought to the same temperature while tab element **2013** is disposed within the opening of socket element **2011**, tab element **2013** may be permanently fixed to socket element **2011**. For example, tab element **2013** may thermally expand to its first size, such that tab element **2013** is fixed within the opening of socket element **2011**, e.g., via an interference fit. When tab element **2013** is fixed within the opening of socket element **2011**, tab element **2013** and socket element **2011** form a rigid connection that provides a smooth, continuous transition between first end region **2002** and neck region **2004**, such that first end region **2002** may bend uniformly relative to neck region **2004** as a single element would. Tab elements **2015** at distal end **2014** of neck region **2004** may be fixed to socket elements **2017** at proximal end **2016** of second end region **2006** in the same manner as tab elements **2013** and socket elements **2011** described herein.

[0158] Additionally, or alternatively, socket element **2011** may be thermally expandable, e.g., via heating, such that the opening of socket element **2011** transitions from a first size to a second size larger than the first size, and larger than tab element **2013**. While in the thermally expanded state having the second size, tab element **2013** may be fitted within the opening of socket element **2011**, such that when tab element **2013** and socket element **2011** are brought to the same temperature while tab element **2013** is disposed within the opening of socket element **2011**, tab element **2013** may be permanently fixed to socket element **2011**. For example, socket element **2011** may thermally contract to its first size, such that tab element **2013** is fixed within the opening of socket element **2011**, e.g., via an interference fit. Accordingly, tab element **2013** and socket element **2011** may form a rigid connection that provides a smooth, continuous transition between first end region **2002** and neck region **2004**, such that first end region **2002** may bend uniformly relative to neck

region **2004** as a single element would. In some embodiments, tab element **2013** and socket element **2011** may be welded together to permanently fix first end region **2002** to neck region **2004**, and similarly tab element **2015** and socket element **2017** may be welded together to permanently fix second end region **2006** to neck region **2004**. Moreover, in some embodiments, the plurality of first end region connectors **2011** also may be configured to interlock with the plurality of distal neck region connectors **2015**, and the plurality of second end region connectors **2017** also may be configured to interlock with the plurality of proximal neck region connectors **2013**.

[0159] FIGS. **20**C and **20**D illustrate the components of shunt **2000** permanently fixed together in an assembled configuration where first end region **2002** is permanently fixed to neck region **2004** via first end region connectors **2011** and proximal neck region connectors **2013** at first connection **2003**, and second end region **2006** is permanently fixed to neck region **2004** via second end region connectors **2017** and distal neck region connectors **2015** at second connection **2005**. As shown in FIG. **20**C, each of first end region connectors **2011** may be permanently fixed to proximal neck region connectors **2013** along a single plane at first connection **2003**, and each of second end region connectors **2017** may be permanently fixed to each of distal neck region connectors **2015** along a single plane at second connection **2005**. For example, the planes may be parallel to each other and may be perpendicular to a longitudinal axis of neck region **2004**.

[0160] Alternatively, each of first end region connectors **2011** may be permanently fixed to each of proximal neck region connectors **2013** in a staggered manner along the circumference of shunt **2000**, such that stress is distributed to alternate sides of the connections, thus distributing the strain and producing a smoother transition between components. For example, every other connection of first end region connectors **2011** and proximal neck region connectors **2013** may be offset from the adjacent connections of first end region connectors **2011** and proximal neck region connectors **2013** therebetween. Accordingly, every other longitudinal strut of first end region **2002** may longer (or shorter) than the adjacent longitudinal struts therebetween of first end region **2002**, and for every longer (or shorter) longitudinal strut of first end region **2002**, the corresponding longitudinal strut of neck region **2004** may be shorter (or longer) than the adjacent longitudinal struts therebetween of neck region **2004**. Each of second end region connectors **2017** may similarly be permanently fixed to each of distal neck region connectors **2015** in a staggered manner along the circumference of shunt **2000**.

[0161] FIGS. **20**E and **20**F illustrate assembled shunt **2000** with first end region **2002** and second end region **2006** in their expanded deployed states. As shown in FIG. **20**E, in the expanded state, proximal end **2008** of first end region **2002** flares radially outward from distal end **2010** at first connection **2003**, and distal end **2018** of second end region **2006** flares radially outward from proximal end **2016** at second connection **2005**. Moreover, as described above, the components of shunt **2000** are constructed such that first connection **2003** provides a smooth, continuous transition from neck region **2004** to first end region **2002**, as shown in FIG. **20**F, and second connection **2005** provides a smooth, continuous transition from neck region **2004** to second end region **2006** throughout the range of lumen diameters of neck region **2004**. Accordingly, first connection **2003** and second connection **2005** provides smooth, continuous transitions between the respective components as first end region **2002** and second end region **2006** transitions between their collapsed delivery states and expanded deployed states, for any given lumen diameter of neck region **2004**.

[0162] In some embodiments, neck region **2004** may be treated in a non-uniform manner. For example, a center portion of neck region **2004** may be treated to produce a martensitic phase at body temperature and an Af temperature of, e.g., around 40-50° C. or 42° C., while the end portions of neck region **2004** that are to be fixedly coupled to the superelastic first and second end regions **2002**, **2006** may be treated to produce an intermediate phase between martensite and austenite, e.g., an R-phase, at body temperature. In this embodiment, there may be a more gradual change in response to manipulation of the device, such as by mechanical expansion or thermal

contraction of the shape-memory neck region, resulting in a smooth, continuous transition between the connected components.

[0163] Referring now to FIGS. **21**A-**21**D, another hybrid shunt device having interlocking components with different shape-memory properties that are treated separately and assembled together is provided. FIGS. **21**A and **21**B illustrate hybrid shunt **2100** in an assembled configuration, and FIGS. **21**C and **21**D illustrate hybrid shunt **2100** in an unassembled configuration, e.g., after the separate components have been treated to achieve the desired material properties. For example, shunt **2100** may be formed of first end region **2102**, neck region **2104**, and second end region **2106**. As described above, neck region **2104** may be treated such that it is malleable at body temperature, e.g., having an Af temperature between about 40-60° C., and first end region **2102** and second end region **2106** may be treated such that they are superelastic at body temperature, e.g., having an Af temperature between about 5-20° C. In some embodiments, like neck region **2004**, neck region **2104** may be treated in a non-uniform manner.

[0164] As shown in FIG. **21**C, first end region **2102** may include proximal end **2108** and distal end **2110** having a plurality of first end region connectors **2111**, neck region **2104** may include proximal end **2112** having a plurality of proximal neck region connectors **2113** and distal end **2114** having a plurality of distal neck region connectors **2115**, and second end region **2106** may include proximal end **2116** having a plurality of second end region connectors **2117** and distal end **2118**. Like device **2000** of FIGS. **20**A-**20**F, each of first end region **2102**, neck region **2104**, and second end region **2106** may be formed of a plurality of longitudinal extending struts interconnected via one or more circumferentially extending sinusoidal rings. For example, as shown in FIGS. **21**A and **21**C, first end region **2102** may include a plurality of longitudinal struts **2120***a* interconnected via sinusoidal rings **2122***a*, such that the plurality of first end region connectors **2111** are disposed at distal end **2110** of each of longitudinal struts **2120***a*.

[0165] Neck region **2104** may include a plurality of longitudinal struts **2120***b* interconnected via sinusoidal rings **2122***b*, such that the plurality of proximal neck region connectors **2113** are disposed at proximal end **2112** of each of longitudinal struts **2120***b* and the plurality of distal neck region connectors **2115** are disposed at distal end **2114** of each of longitudinal struts **2120***b*. Second end region **2106** may include a plurality of longitudinal struts **2120***c* interconnected via sinusoidal ring **2122***c*, such that the plurality of second end region connectors **2117** are disposed at proximal end **2116** of each of longitudinal struts **2120***c*. As will be understood by a person having ordinary skill in the art, although FIGS. **21**A and **21**B illustrate first end region **2102** having two sinusoidal rings and second end region **2106** having three sinusoidal rings, first end region **2102** may include less or more than two sinusoidal rings interconnecting plurality of longitudinal struts **2120***a*, and second end region **2106** may each include less or more than three sinusoidal rings interconnecting plurality of longitudinal struts **2120***c*. Similarly, although FIGS. **21**A and **21**B illustrate neck region **2104** having two sinusoidal rings, neck region **2104** may have less or more than two sinusoidal rings interconnecting plurality of longitudinal struts **2120***b*. Moreover, shunt **2100** may include less or more longitudinal struts than is illustrated in FIGS. **21**A and **21**C.

[0166] Like the connectors of shunt **2000**, each connector of the plurality of first end region connectors **2111** of first end region **2102** may have a shape configured to interlock with a complementary shape of each connector of the plurality of proximal neck region connectors **2113** of neck region **2104**, and each connector of the plurality of second end region connectors **2117** of second end region **2106** may have a shape configured to interlock with a complementary shape of each connector of the plurality of distal neck region connectors **2115** of neck region **2104**. For example, the complementary shapes of first end region connectors **2111** and proximal neck region connectors **2113**, and second end region connectors **2117** and distal neck region connectors **2115** may include tab and socket elements. As shown in FIG. **21**D, second end region connectors **2117** may include a socket element and distal neck region connectors **2115** may include a tab element. Similarly, proximal neck region connectors **2113** may include a tab element and first end region

connectors **2111** may include a socket element. As will be understood by a person having ordinary skill in the art, first end region connectors **2111** and second end region connectors **2117** alternatively may include a tab element, whereas proximal neck region connectors **2113** and distal neck region connectors **2115** include a socket element.

[0167] As shown in FIG. **21**D, socket element **2117** includes an opening sized and shaped to receive tab element **2115**. Unlike the tab and socket elements of shunt **2000**, tab element **2115** may be fitted within the opening of socket element **2117** without thermally contracting tab element **2115** or thermally expanding socket element **2117**. Instead, when tab element **2115** is disposed within the opening of socket element **2117**, retaining ring **2124** may be disposed over both tab element **2115** and socket element **2117** to thereby maintain the rigid connection between neck region **2104** and second end region **2106** at second connection **2105**, as shown in FIG. **21**B, while providing a smooth, continuous transition from neck region **2104** to second end region **2106** throughout the range of lumen diameters of neck region **2104**. Similarly, when tab element **2113** at proximal end **2112** of neck region **2104** is disposed within the opening of socket element **2111** at distal end **2110** of first end region **2102**, retaining ring **2124** may be disposed over both tab element **2113** and socket element **2111** to thereby maintain the rigid connection between neck region **2104** and first end region **2102** at first connection **2103**, while providing a smooth, continuous transition from neck region **2104** to first end region **2102** throughout the range of lumen diameters of neck region **2104**. Accordingly, first end region **2102** and second end region **2106** may bend uniformly relative to neck region **2104** as a single element would. In some embodiments, retaining rings **2124** may be made from radiopaque materials such that they are visible under fluoroscopy.

[0168] Moreover, the shunt devices described herein further may include one or more physiologic sensors, e.g., pressure sensors configured to acquire intra-atrial pressure measurements. For example, shunt **2100** may include one or more pressure sensors disposed at first connections **2103**, e.g., for measuring pressure in a first atrium of the patient's heart, and/or at second connection **2105**, e.g., for measuring pressure in a second atrium of the patient's heart, such that the progression of the treatment may be continuously monitored. As shown in FIG. **21**D, sensor **2126**, e.g., a pressure sensor, may be disposed on, e.g., embedded within, one or more of tab elements **2115**, such that sensor **2126** is enclosed within retaining ring **2124** when retaining ring **2124** is disposed over tab element **2115** and socket element **2117** at second connection **2105**, as described above. Accordingly, retaining ring **2124** may form a hermetic biocompatible packaging that resists ingress of corrosive body fluids on the electronic components of sensor **2126**, while minimizing residual internal stress on sensor **2126**.

[0169] Sensor **2126** similarly may be disposed on one or more of tab elements **2113**, such that sensor **2126** may be enclosed within retaining ring **2124** when retaining ring **2124** is disposed over tab element **2113** and socket element **2111** at first connection **2103**. Accordingly, pressure measurements obtained by the sensor at first connections **2103**, e.g., atrial pressure within a first atrium of the patient's heart, and pressure measurements obtained by the sensor at second connections **2105**, e.g., atrial pressure within a second atrium of the patient's heart, may be used to calculate a pressure gradient across shunt **2100**, between the first and second atria. For example, the sensors may be configured for telemetry and include circuitry for transmitting data between each other and/or to a receiver external to the patient's body for processing. Sensors **2126** may be configured to acquire other physiological measurements including, for example, flow, velocity, temperature, pH, or the concentration of certain chemical species, within one or both atria, e.g., for comparing the measurements across the shunt, as described above. For example, sensors **2126** may be constructed similar to the sensors described in U.S. Patent App. Pub. No. 2022/0151784 to Eigler, assigned to the assignee of the present application, the entire contents of which are incorporated by reference herein. Additionally, or alternatively, sensor **2126** may be disposed on, e.g., embedded within, retaining ring **2124** itself.

[0170] Like shunt **2000**, each of first end region connectors **2111** may be permanently fixed to each

of proximal neck region connectors **2113** along a single plane at first connection **2103**, and each of second end region connectors **2117** may be permanently fixed to each of distal neck region connectors **2115** along a single plane at second connection **2105**. Alternatively, each of first end region connectors **2111** and each of second end region connectors **2117** may be permanently fixed to each of proximal neck region connectors **2113** and each of distal neck region connectors **2115**, respectively, in a staggered manner along the circumference of shunt **2100**, such that stress is distributed to alternate sides of the connections, thus distributing the strain and producing a smoother transition between components.

[0171] Referring now to FIGS. **22**A-**22**I, an exemplary method for assembling the components of shunt **2100** is provided. First, retaining rings **2124** may be disposed over and beyond each connector of first end region **2102** and second end region **2106**, e.g., first end region connectors **2111** and second end region connectors **2117**, such that each retaining ring **2124** is temporarily disposed over longitudinal struts **2120***a* of first end region **2102** and longitudinal struts **2120***c* of second end region **2106** and the opening of the respective socket elements is exposed. For example, as shown in FIGS. **22**A and **22**B, retaining ring alignment tool **2202** may be used to slide each retaining ring **2124** over each second end region connector **2117**. An end of retaining ring alignment tool **2202** may include one or more fingers **2204**, each having an extended portion extending therefrom, sized and shaped to receive retaining ring **2124** thereon, and configured to align with a connector of the plurality of second end region connectors **2117**, such that when aligned, retaining ring **2124** may easily be transferred from finger **2204** over connector **2117** and onto longitudinal strut **2120***c*, as shown in FIG. **22**D.

[0172] In some embodiments, retaining ring alignment tool **2202** may have a number of fingers **2204** corresponding to the number of connectors of the plurality of second end region connectors **2117**, as shown in FIG. **22**A, such that each retaining ring **2124** may be deposited over each connector of second end region **2106** simultaneously as a group, or individually. Retaining ring alignment tool **2202** may similarly be used to slide each retaining ring **2124** over each first end region connector **2111**. In addition, as shown in FIG. **22**B, the outer surface of each socket element **2117**, e.g., the lateral sides of the fingers of socket element **2117** defining the opening of socket **2117**, may include one or more protrusions **2119** extending outwardly therefrom to facilitate securement of retaining ring **2124** to tab element **2115** and socket element **2117** when tab element **2115** is disposed within the opening of socket element **2117**, e.g. via interference fit. When tab element **2115** is not disposed within socket element **2117**, the fingers of socket element **2117** may be pushed inward towards each other, e.g., as retaining ring **2124** is moved over socket element **2117**, via engagement between protrusions **2119** and the inner surface of retaining ring **2124**.

[0173] As shown in FIGS. **22**C and **22**D, the components of shunt **2100** may then be assembled together over alignment pin **2206**. Alignment pin **2206** may include a plurality of ridges **2208** extending longitudinally along the outer surface of alignment pin **2206**, each ridge **2208** spaced apart circumferentially about the outer surface of alignment pin **2206** and separated by a plurality of grooves **2210**. The position of ridges **2208** on alignment pin **2206** may correspond with the longitudinal struts of shunt **2100**, as shown in FIG. **22**C, to thereby provide support to the points of connection between the components of shunt **2100**. As shown in FIG. **22**C, tab elements **2113** of neck region **2104** may be fitted within the opening of socket elements **2111** of first end region **2102** when retaining rings **2124** are disposed over the longitudinal struts of first end region **2102**, and tab elements **2115** of neck region **2104** may be fitted within the opening of socket elements **2117** of second end region **2106** when retaining rings **2124** are disposed over the longitudinal struts of second end region **2106**. FIG. **22**D illustrates tab element **2113** of neck region **2104** disposed within the opening of socket element **2111** having protrusions **2121** while retaining ring **2124** is disposed over longitudinal strut **2120***a* of first end region **2102**.

[0174] Next, each retaining ring **2124** may be moved such that they are disposed over the socket/tab connections. As shown in FIGS. **22**E, **22**F, and **22**H, support ring **2216** having a lumen

extending therethrough may be slid over shunt **2100** over alignment pin **2206** until support ring **2216** is positioned over the middle portion of neck region **2104**. The inner surface of support ring **2216** may have a plurality of ridges and grooves, such that the position of the ridges correspond with the longitudinal struts of shunt **2100**, as shown in FIG. **22**E, to thereby provide additional support to the points of connection between the components of shunt **2100** along with ridges **2208** of alignment pin **2206** and prevent buckling of the frame of shunt **2100** as retaining rings **2124** are moved to their final position over the socket/tab connections.

[0175] Moreover, as shown in FIGS. **22**E, **22**F, and **22**H, one or more seating rings **2212***a*, **2212***b* may be used to slide each retaining ring **2124** over each socket/tab connection between neck region **2104** and first and second end regions **2102**, **2106**. Accordingly, seating rings **2212***a*, **2212***b* may have a lumen extending therethrough sized and shaped such that seating rings **2212***a*, **2212***b* may be advanced over first and second end regions **2102**, **2106** over alignment pin **2206**. An end of each seating ring **2212***a*, **2212***b* may include one or more fingers **2214***a*, **2214***b*, respectively, each sized and shaped to be aligned with and engage with retaining ring **2124** as seating rings **2212***a*, **2212***b* are moved over first and second end regions **2102**, **2106**, respectively, towards neck region **2104** over alignment pin **2206**.

[0176] For example, as shown in FIGS. **22**G and **22**I, seating ring **2212***b* may be moved proximally over second end region **2106** over alignment pin **2206** in the direction of the arrow until finger **2214***b* contacts and engages with retaining ring **2124**, such that further proximal movement of seating ring **2212***b* causes finger **2214***b* to push retaining ring **2124** over socket element **2217** and tab element **2115**. As tab element **2115** is fitted within the opening of socket element **2117**, the fingers of socket element **2217** defining the opening cannot move inward, and thus, protrusions **2119** exert a force against the inner surface of retaining ring **2124** when retaining ring **2124** is disposed thereon to facilitate securement of retaining ring **2124** over the socket/tab connection. As shown in FIG. **22**I, retaining ring **2124** may have a very thin wall thickness to thereby provide a smooth, continuous transition from neck region **2104** to second end region **2106** as described above.

[0177] In some embodiments, seating ring **2212***b* may have a number of fingers **2214***b* corresponding to the number of connectors of the plurality of second end region connectors **2117**, as shown in FIG. **22**E, such that each retaining ring **2124** may be moved to its final position over the socket/tab connection simultaneously as a group, or individually. Seating ring **2212***a* may similarly be used to slide each retaining ring **2124** to its final position over each socket/tab connection between neck region **2104** and first end region **2102**. Preferably, both seating rings **2212***a*, **2212***b* are pushed simultaneously to move the retaining rings to their final position over the respective socket/tab connections between neck region **2104** and first region **2102** and between neck region **2104** and second end region **2106**. Alternatively, a single seating ring may be used to push the retaining rings over the first set of socket/tab connections at, e.g., at first connection **2103**, and subsequently to push the remaining retaining rings over the second set of socket/tab connections at, e.g., at second connection **2105**, or vice versa. As described above, an encapsulant may be disposed over shunt **2100**, e.g., when retaining rings **2124** are in their final positions over the respective socket/tab connections, thereby further securing the retaining rings to shunt **2100**. As will be understood by a person having ordinary skill in the art, hybrid shunts **2000**, **2100** may be used in conjunction with the other features described herein, e.g., for acute treatment as described above with regard to FIGS. **15**A-**15**E and/or bridge **1740** of FIGS. **17**A-**17**E.

[0178] Referring now to FIGS. **23**A to **23**E, alternative exemplary interlocking components for permanently coupling separately treated regions of a hybrid shunt are provided. As shown in FIG. **23**A, first interlocking component **2302**, e.g., a first end region connector of a first end region of the hybrid shunt, may include a first geometry, e.g., one or more tab elements **2306**, and second interlocking component **2304**, e.g., a proximal neck region connector of a neck region of the hybrid shunt, may include a second geometry, e.g., one or more socket elements **2308**, sized and shaped to

complementarily receive one or more tabs **2306**, as shown in FIG. **23**B. As shown in FIG. **23**A, tab elements **2306** may be disposed at the distal ends of a pair of fingers extending from a distal region of first interlocking component **2302** in a circular manner, such that the pair of fingers define a circular shaped opening therebetween. For example, the pair of fingers may initially extend away from each other, and then towards each other to thereby form the circular shaped opening. The inner surface of the circular shaped opening defined by the pair of fingers of first interlocking component **2302** may form at least a portion of eyelet **2310** when tab elements **2306** are disposed within socket elements **2308**, as shown in FIG. **23**B. Accordingly, the inner surface at the proximal end of second interlocking component **2304**, e.g., the end facing towards first interlocking component **2302** when first interlocking component **2302** is coupled to second interlocking component **2304**, may form the remaining portion of eyelet **2310** when tab elements **2306** are disposed within socket elements **2308**, as shown in FIG. **23**B.

[0179] FIG. **23**C illustrates a plug-like component, e.g., radiopaque marker **2312**, sized and shaped to be tightly disposed within eyelet **2310** defined by first interlocking component **2302** and second interlocking component **2304** when tab elements **2306** are disposed within socket elements **2308**. Radiopaque marker **2312** may be formed of, e.g., Tantalum, Platinum, Iridium etc., to thereby facilitate visualization under fluoroscopy. Moreover, radiopaque marker **2312** may have a geometry that is slightly larger than the geometry of eyelet **2310**, such that, when radiopaque marker **2312** is disposed within eyelet **2310**, radiopaque marker **2312** applies a mechanical force to first interlocking component **2302** and second interlocking component **2304** to thereby secure tab elements **2306** within socket elements **2308** and permanently fix first interlocking component **2302** to second interlocking component **2304**, as shown in FIG. **23**D. FIG. **23**E is a side view of first interlocking component **2302** and second interlocking component **2304** when radiopaque marker **2312** is disposed within eyelet **2310**. Thus, when radiopaque marker **2312** is disposed within eyelet **2310**, tab elements **2306** and socket elements **2308** form a rigid connection that provides a smooth, continuous transition between the first end region and the neck region of the hybrid shunt, such that the first end region may bend uniformly relative to the neck region as a single element would. As will be understood by a person having ordinary skill in the art, eyelet **2310** may have a geometry other than a circle shape, such that radiopaque marker **2312** may have a corresponding shape configured to be tightly disposed within the eyelet. Alternatively, instead of a radiopaque marker, one or more of eyelets **2310** may have one or more physiologic sensors disposed therein. For example, as described above, the physiological sensors may be configured to acquire measurements including, for example, intra-atrial pressure measurements, flow, velocity, temperature, pH, or the concentration of certain chemical species.

[0180] As will be understood by a person having ordinary skill in the art, first interlocking component **2302** be may the proximal neck region connector of the neck region of the hybrid shunt, and accordingly, second interlocking component **2304** may be the first end region connector of the first end region of the hybrid shunt, such that the first end region and the neck region of the hybrid shunt may be permanently fixed together to form a rigid connection. Moreover, the second end region connector of the second end region of the hybrid shunt may have a geometry similar to the geometry of first interlocking component **2302** when the distal neck region connector of the neck region of the hybrid shunt may have a geometry similar to the geometry of second interlocking component **2304**, or alternatively, the second end region connector of the second end region of the hybrid shunt may have a geometry similar to the geometry of second interlocking component **2304** when the distal neck region connector of the neck region of the hybrid shunt may have a geometry similar to the geometry of first interlocking component **2302**.

[0181] Accordingly, 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. **2**A-**2**E; device **700** described with reference to FIGS. **7**, **8**A-**8**D, **9**A-**9**B, and **10**A-**10**C; device **28** described with

reference to FIGS. **15**A-**15**E; device **2000** of FIGS. **20**A-**20**F; or device **2100** of FIGS. **21**A-**21**D. For example, the interatrial shunt may include a body that includes first and second expandable end regions coupled in fluid communication by a neck region. The first expandable end region may be configured to be placed in a first atrium of the heart, the second expandable end region may be configured to be placed in a second atrium of the heart, and the neck region may be configured for placement at the atrial septum.

[0182] 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**, **8**A-**8**D, **9**A-**9**B, and **10**A-**10**C; device **28** described with reference to FIGS. **15**A-**15**E; device **2000** of FIGS. **20**A-**20**F; or device **2100** of FIGS. **21**A-**21**D. 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.

[0183] 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. For example, the first and second expandable end regions that are superelastic may include NITINOL having an austenitic finish temperature (Af) 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 (Af) between 40-60° 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.

[0184] For example, 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 mm.sup.2 and the second cross-sectional area and the third cross-sectional area may be between 15.9 to 78.6 mm.sup.2.

[0185] The malleable shape-memory material may include NITINOL having an austenitic finish temperature (Af) between 40-60° 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. 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. As described above, the first and second expandable end regions and the neck region may comprise a diabolo-shaped shunt. 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. Alternatively, the first and second expandable end regions and the neck region may be formed separately and assembled together, 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.

[0186] 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, such as those described in U.S. Pat. No. 6,964,680 to Shanley, entitled “Expandable medical device with tapered hinge,” the entire contents of which are incorporated by reference herein.

[0187] 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.

## Claims

**1**. A method for treating a heart condition using a hybrid shunt comprising shape-memory material at an atrial septum of a patient's heart, the method comprising: advancing the hybrid shunt via a catheter system to the atrial septum, the hybrid shunt comprising a neck region configured to be malleable at body temperature and first and second end regions configured to be superelastic at body temperature, the first end region permanently fixed to the neck region at a first connection site and the second end region permanently fixed to the neck region at a second connection site; and implanting the hybrid shunt using the catheter system such that the first end region is in a first atrium, the neck region is at the atrial septum, and the second end region is in a second atrium, thereby allowing blood to flow across the atrial septum via a passageway extending through the first end region, the neck region, and the second end region, wherein a flow area of the passageway through the neck region is configured to be adjustable in vivo.

**2**. The method of claim 1, wherein the hybrid shunt allows blood to flow from a left atrium across the atrial septum to a right atrium to treat heart failure with reduced ejection fraction (HFrEF).

**3**. The method of claim 1, wherein a distal end of the first end region is permanently fixed to a proximal end of the neck region at the first connection site and a proximal end of the second end region is permanently fixed to a distal end of the neck region at the second connection site.

**4**. The method of claim 1, further comprising, after implanting the hybrid shunt, mechanically expanding the neck region in vivo such that the passageway expands from a first cross-sectional area to a second cross-sectional area larger than the first cross-sectional area.

**5**. The method of claim 1, further comprising, after implanting the hybrid shunt, contracting the neck region in vivo.

**6**. The method of claim 5, wherein the contracting comprises thermally contracting the neck region in vivo.

**7**. The method of claim 1, wherein the first and second end regions are not formed integrally with the neck region.

**8**. The method of claim 1, wherein ends of the neck region comprise a shape configured to interlock with complementary shapes at ends of the first and second end regions.

**9**. The method of claim 8, wherein the complementary shapes of the neck region and the first and second end regions comprise a tab element and a socket element.

**10**. The method of claim 9, further comprising sensing physiological information with a physiological sensor disposed on the tab element.

**11**. The method of claim 1, wherein implanting the hybrid shunt comprises deploying the hybrid shunt from a collapsed delivery state within the catheter system to an expanded deployed state such that the first and second end regions self-expand at body temperature when deployed.

**12**. The method of claim 11, wherein, in the expanded deployed state, a proximal end of the first

end region flares outwardly from a distal end of the first end region at the first connection site, and a distal end of the second end region flares outwardly from a proximal end of the second end region at the second connection site.

**13**. The method of claim 1, wherein a distal end of the first end region comprises a plurality of circumferentially spaced apart connectors configured to be permanently fixed to a corresponding plurality of circumferentially spaced apart connectors of a proximal end of the neck region at the first connection site, and wherein a proximal end of the second end region comprises a plurality of circumferentially spaced apart connectors configured to be permanently fixed to a corresponding plurality of circumferentially spaced apart connectors of a distal end of the neck region at the second connection site.

**14**. The method of claim 13, wherein the plurality of circumferentially spaced apart connectors of the distal end of the first end region and the proximal end of the neck region are permanently fixed along a single plane at the first connection site, and wherein the plurality of circumferentially spaced apart connectors of the proximal end of the second end region and the distal end of the neck region are permanently fixed along a single plane at the second connection site.

**15**. The method of claim 13, wherein the plurality of circumferentially spaced apart connectors of the distal end of the first end region and the proximal end of the neck region are permanently fixed in a staggered manner at the first connection site, such that the connections do not all lie in a single plane, and wherein the plurality of circumferentially spaced apart connectors of the proximal end of the second end region and the distal end of the neck region are permanently fixed in a staggered manner at the second connection site, such that the connections do not all lie in a single plane.

**16**. The method of claim 1, wherein the neck region comprises NITINOL having an austenitic finish temperature (Af) between 45-60° C.

**17**. The method of claim 1, wherein the first and second end regions comprise NITINOL having an austenitic finish temperature (Af) between 5-20° C.

**18**. The method of claim 1, wherein the hybrid shunt is formed from one or more shape memory alloys, self-expanding materials, superelastic materials, or polymers.

**19**. The method of claim 1, wherein the first and second end regions and the neck region comprise a diabolo-shaped shunt when implanted.

**20**. The method of claim 1, wherein the first and second end regions and the neck region are at least partially encapsulated with a biocompatible material.

**21**. The method of claim 20, wherein implanting the hybrid shunt comprises engaging a bridge formed of biocompatible material to the atrial septum, the bridge extending from a first outer surface of the first end region to a second outer surface of the second end region.

**22**. The method of claim 1, further comprising measuring at least one of pressure, flow, velocity, temperature, or pH using one or more physiological sensors disposed at the first and/or second connections sites.

**23**. The method of claim 1, wherein portions of the neck region are treated to produce an intermediate phase between martensite and austenite at body temperature.