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### **METHODS FOR ROUTING A GUIDEWIRE FROM A FIRST VESSEL AND THROUGH A SECOND VESSEL IN LOWER EXTREMITY VASCULATURE**

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#### **Abstract**

A catheter system can include a tubular body, and at least one of a targeting system coupled to the tubular body, an expandable member, or a fluid injection port. A method of identifying a bifurcation can include inserting a catheter system into a first vessel, positioning the catheter system at a first location, expanding an expandable member to occlude the first vessel, delivering contrast material so the contrast material pooling proximate to the expandable member, and reviewing a shape of the contrast material in the first vessel under fluoroscopy.

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## Background/Summary

CROSS-REFERENCE TO RELATED APPLICATION(S) [0001] This application is a continuation of U.S. patent application Ser. No. 18/465,450, filed on Sep. 12, 2023, which is a continuation of U.S. patent application Ser. No. 16/747,825, filed on Jan. 21, 2020, which is a divisional of U.S. patent application Ser. No. 16/426,375, filed on May 30, 2019 and issued as U.S. Pat. No. 10,543,308 on Jan. 28, 2019, which is a continuation of International Application No. PCT/IB2018/000549 designating the United States, with an international filing date of Apr. 9, 2018, which claims priority benefit of U.S. Provisional Patent Application No. 62/483,567, filed on Apr. 10, 2017, which are incorporated herein by reference in their entirety for all purposes. Any and all applications for which a foreign or domestic priority claim is identified in the Application Data Sheet as filed with the present application are hereby incorporated by reference in their entirety for all purposes, including but not limited to incorporation by reference under 37 C.F.R. § 1.57.

## TECHNICAL FIELD

[0002] The present application relates to methods and systems for use in percutaneous interventional surgery. In particular, the present application relates to methods and systems for providing or maintaining fluid flow through body passages such as heart cavities and blood vessels.

## BACKGROUND

[0003] Minimally invasive percutaneous surgery, or “key-hole” surgery, is a surgical technique in which surgical devices are inserted into a patient's body cavity through a small aperture cut in the skin. This form of surgery has become increasingly popular as it allows patients to endure less surgical discomfort while retaining the benefits of conventional surgery. Patients treated by such techniques are exposed to lower levels of discomfort, need for general anesthesia, trauma, and risk of infection, and their recovery times can be significantly reduced compared to conventional surgical procedures.

[0004] Key-hole surgery can be used, for example, for laparoscopic surgery and to treat cardiovascular diseases. In treating cardiovascular diseases, balloon angioplasty, in which a balloon catheter is inserted into an artery usually near the patient's groin and guided to the patient's heart where a balloon at a distal portion of the catheter is inflated to widen or dilate an occluded vessel to help restore blood flow to the cardiac tissue, may be used to treat a partially occluded coronary artery as an alternative to open heart surgery. A tubular supporting device (e.g., stent) may be deployed at the site of the blockage to prevent future occlusion (restenosis) or collapse of the blood vessel. The stent may, for example, be an expandable metal mesh tube carried on the balloon of the balloon catheter, or be self-expanding. The balloon-expandable stent expands when the balloon is inflated, so that the stent pushes against the wall of the blood vessel. The stent is arranged to retain its expanded shape when it reaches its expanded position, for example by plastic deformation or by means of a mechanical locking mechanism, so as to form a resilient scaffold or support in the blood vessel. The support structure (e.g., stent) supports and dilates the wall of the blood vessel to maintain a pathway for blood to flow through the vessel. Self-expanding stents are also available, which are held in a collapsed state by a suitably adapted catheter for transport through the artery and which adopt an expanded state when deployed at the site of the blockage. The catheter may, for example, include a retaining sleeve which retains the stent in a compressed or unexpanded state. Upon removal or withdrawal of the sleeve from the stent, the stent expands to support and dilate the wall of the blood vessel.

[0005] Balloon angioplasty is not always a suitable measure, for example in acute cases and in cases where a coronary artery is completely occluded. In these instances, the typical treatment is to employ coronary bypass. Coronary bypass surgery is an open-chest or open-heart procedure, and typically involves grafting a piece of healthy blood vessel onto the coronary artery so as to bypass the blockage and restore blood flow to the coronary tissue. The healthy blood vessel is usually a vein harvested from the patient's leg or arm during the course of the bypass operation. To perform the procedure, the patient's heart must be exposed by opening the chest, separating the breastbone, and cutting the pericardium surrounding the heart, resulting in significant surgical trauma.

[0006] Conventional coronary bypass surgery is not always an option. Certain patients are unsuitable as candidates for conventional coronary bypass surgery due to low expectation of recovery or high risk from the significant trauma due to surgery, high risk of infection, absence of healthy vessels to use as bypass grafts, significant co-morbidities, and expected long and complicated recovery time associated with open-chest surgery. For example, factors such as diabetes, age, obesity, and smoking may exclude a proportion of candidate patients who are in genuine need of such treatment.

## SUMMARY

[0007] The present application provides methods and systems for overcoming certain deficiencies and/or improving percutaneous methods and systems. For example, according to several

embodiments, the methods and systems described herein can improve targeting and localization of therapy administration, which may advantageously provide treatment via percutaneous techniques to patients unsuitable for more invasive surgery. Certain embodiments described herein can provide fluid flow in passages such as coronary and/or peripheral blood vessels by creating a bypass using minimally invasive percutaneous surgical techniques.

[0008] A catheter system can include a tubular body, and at least one of a targeting system coupled to the tubular body, an expandable member, or a fluid injection port.

[0009] In some embodiments, a catheter system for identifying a bifurcation in a vessel comprises, or alternatively consists essentially of, a tubular body, a targeting system coupled to the tubular body, an expandable member configured to appose sidewalls of a vessel to occlude the vessel in an expanded state, and a fluid injection port configured to inject radiopaque fluid into a vessel proximal to the expandable member in the expanded state such that the radiopaque fluid pools proximate to the expandable member and provides visualization of the vessel and branch vessels.

[0010] The expandable member may be coupled to the tubular body. The tubular body may comprise the fluid injection port. The catheter system may further comprise a second tubular body. The expandable member may be coupled to the second tubular body. The second tubular body may comprise the fluid injection port. The targeting system may comprise an ultrasound transducer. The targeting system may comprise an omnidirectional ultrasound transducer.

[0011] In some embodiments, a catheter system comprises, or alternatively consists essentially of, a tubular body, a targeting system coupled to the tubular body, and an expandable member.

[0012] The expandable member may be coupled to the tubular body. The catheter system may further comprise a second tubular body. The expandable member may be coupled to the second tubular body. The expandable member may be configured to appose sidewalls of a vessel to occlude the vessel. The catheter system may further comprise a fluid injection port. The tubular body may comprise the fluid injection port. The catheter system may further comprise a second tubular body comprising the fluid injection port. The targeting system may comprise an ultrasound transducer. The targeting system may comprise an omnidirectional ultrasound transducer.

[0013] In some embodiments, a catheter system comprises, or alternatively consists essentially of, a tubular body, a targeting system coupled to the tubular body, and a fluid injection port.

[0014] The tubular body may comprise the fluid injection port. The catheter system may further comprise a second tubular body comprising the fluid injection port. The catheter system may further comprise an expandable member. The expandable member may be coupled to the tubular body. The catheter system may further comprise a second tubular body. The expandable member may be coupled to the second tubular body. The expandable member may be configured to appose sidewalls of a vessel to occlude the vessel. The targeting system may comprise an ultrasound transducer. The targeting system may comprise an omnidirectional ultrasound transducer.

[0015] In some embodiments, a catheter system comprises, or alternatively consists essentially of, a tubular body, a fluid injection port, and an expandable member.

[0016] The tubular body may comprise the fluid injection port. The catheter system may further comprise a second tubular body comprising the fluid injection port. The expandable member may be coupled to the tubular body. The catheter system may further comprise a second tubular body. The expandable member may be coupled to the second tubular body. The expandable member may be configured to appose sidewalls of a vessel to occlude the vessel. The catheter system may further comprise a targeting system. The targeting system may comprise an ultrasound transducer. The targeting system may comprise an omnidirectional ultrasound transducer. A method of identifying a bifurcation may comprise inserting the catheter system into a first vessel, positioning the catheter system at a first location, expanding the expandable member to occlude the first vessel, and delivering contrast material into the first vessel. The contrast material may pool proximate to the expandable member. The method may further comprise reviewing a shape of the contrast material in the first vessel under fluoroscopy.

[0017] In some embodiments, a method of identifying a bifurcation comprises, or alternatively consists essentially of, inserting a catheter system into a first vessel and positioning the catheter system at a first location. The catheter system comprises an expandable member and a fluid injection port. The method further comprises expanding the expandable member to occlude the first vessel and delivering contrast material out of the fluid injection port. The contrast material pools proximate to the expandable member. The method further comprises reviewing a shape of the contrast material in the first vessel under fluoroscopy.

[0018] A single catheter may comprise the expandable member and the fluid injection port. A first catheter may comprise the expandable member and a second catheter may comprise the fluid injection port. Expanding the expandable member may comprise providing fluid flow through an inflation lumen in fluid communication with the expandable member. Expanding the expandable member may comprise expanding the first vessel. The contrast material may comprise at least one of iodine-based contrast and barium sulfate-based contrast. Delivering the contrast material may comprise expanding the first vessel. Reviewing the shape of the contrast material may comprise identifying the presence of at least one of a bifurcation and a branch vessel. The method may further comprise repositioning the catheter system if at least one of the bifurcation and the branch vessel is present. The method may further comprise extending a needle from another catheter in a second vessel if at least one of the bifurcation and the branch vessel is not present. Extending the needle may comprise exiting the second vessel, traversing interstitial tissue between the second vessel and the first vessel, and entering the first vessel. The method may further comprise advancing a guidewire through the needle. The catheter system may comprise a capture element configured to guide the guidewire into a guidewire lumen.

[0019] The catheter system may comprise a targeting system. Positioning the catheter system at the first location may comprise targeting the targeting system from a complementary targeting system on another catheter in a second vessel. The targeting system may comprise an ultrasound receiver. The complementary targeting system may comprise an ultrasound emitter. The ultrasound receiver may comprise an omnidirectional ultrasound transducer. The ultrasound emitter may comprise a directional ultrasound transducer. The method may further comprise dilating the fistula.

[0020] The method may further comprise deploying a prosthesis at least partially in a fistula between the second vessel and the first vessel. After deploying the prosthesis, blood may be diverted from the first vessel to the second vessel through the prosthesis. The method may further comprise, after deploying the prosthesis, lining the first vessel with a stent-graft including covering the collateral vessels of the first vessel. Lining the first vessel with the stent-graft may comprise lining the first vessel with a plurality of stent grafts. Lining the first vessel with the plurality of stent-grafts may comprise first deploying a distal-most stent-graft of the plurality of stent-grafts and last deploying a proximal-most stent-graft of the plurality of stent-grafts. After lining the first vessel with the plurality of stent-grafts, a proximal edge of a distal-most stent-graft of the plurality of stent-grafts may overlap a distal edge of a next distal-most stent-graft of the plurality of stent-grafts. After lining the first vessel with the plurality of stent-grafts, a proximal edge of a proximal-most stent-graft of the plurality of stent-grafts may overlap a distal edge of the prosthesis.

[0021] The method may further comprise making a valve in the first vessel incompetent. Making the valve in the first vessel incompetent may be after lining the vessel with a stent-graft. Making the valve in first the vessel incompetent may comprise advancing a reverse valvulotome through the prosthesis and distally advancing the reverse valvulotome in the first vessel to disable the valve. Making the valve in the first vessel incompetent may comprise advancing a two-way valvulotome proximate to the valve in a radially compressed state, radially expanding the two-way valvulotome to a radially expanded state, and in the radially expanded state, at least one of distally advancing the two-way valvulotome and proximally retracting the two-way valvulotome in the first vessel to disable the valve. Radially expanding the two-way valvulotome may comprise at least one of proximally retracting a sheath and distally advancing the two-way valvulotome. A method of

making a valve in a vessel incompetent may comprise advancing the two-way valvulotome proximate to the valve in the radially compressed state, radially expanding the two-way valvulotome to the radially expanded state, and in the radially expanded state, at least one of distally advancing the two-way valvulotome and proximally retracting the two-way valvulotome in the vessel to disable the valve.

[0022] In some embodiments, a method of modifying a vessel including making valves in the vessel incompetent and covering collateral vessels of the vessel comprises, or alternatively consists essentially of, lining the vessel with a stent-graft including covering the collateral vessels of the vessel and after lining the vessel with the stent-graft, making a valve in the vessel incompetent.

[0023] The method may further comprise deploying a prosthesis at least partially in a fistula between a second vessel and the vessel. After deploying the prosthesis, blood may be diverted from the second vessel to the vessel through the prosthesis. Lining the vessel with the stent-graft may be after deploying the prosthesis. The method may further comprise dilating the fistula. The method may further comprise advancing a needle from the second vessel to the vessel to form the fistula. Advancing the needle may comprise targeting a first catheter in the vessel with a second catheter in the second vessel. The second catheter may comprise an ultrasound emitter. The first catheter may comprise an ultrasound receiver. Targeting the catheter in the vessel with the catheter in the second vessel may comprise targeting the ultrasound receiver with the ultrasound emitter. The method may further comprise advancing a guidewire through the needle. A catheter system in the vessel may comprise a capture element configured to guide the guidewire into a guidewire lumen. Lining the vessel with the stent-graft may comprise lining the vessel with a plurality of stent grafts. Lining the vessel with the plurality of stent-grafts may comprise first deploying a distal-most stent-graft of the plurality of stent-grafts and last deploying a proximal-most stent-graft of the plurality of stent-grafts. After lining the vessel with the plurality of stent-grafts, a proximal edge of a distal-most stent-graft of the plurality of stent-grafts may overlap a distal edge of a next distal-most stent-graft of the plurality of stent-grafts. After lining the vessel with the plurality of stent-grafts, a proximal edge of a proximal-most stent-graft of the plurality of stent-grafts may overlap a distal edge of a prosthesis in the fistula. Making the valve in the vessel incompetent may comprise distally advancing a reverse valvulotome in the vessel to disable the valve. Making the valve in the vessel incompetent may comprise advancing a two-way valvulotome proximate to the valve in a radially compressed state, radially expanding the two-way valvulotome to a radially expanded state and in the radially expanded state, at least one of distally advancing the two-way valvulotome and proximally retracting the two-way valvulotome in the vessel to disable the valve. Radially expanding the two-way valvulotome may comprise at least one of proximally retracting a sheath and distally advancing the two-way valvulotome. The method may further comprise promoting retroperfusion of blood into toes. Promoting retroperfusion of blood into toes may comprise inflating a first expandable member in a medial plantar vein to occlude the medial plantar vein. Promoting retroperfusion of blood into toes may comprise inflating a second expandable member in a lateral plantar vein to occlude the lateral plantar vein. Promoting retroperfusion of blood into toes may comprise increasing hydrostatic pressure in a deep plantar venous arch. Increasing the hydrostatic pressure in the deep plantar venous arch may comprise disabling venous valves and enabling reversal of blood flow into metatarsal veins.

[0024] In some embodiments, a method of promoting retroperfusion of blood into toes comprises, or alternatively consists essentially of, inflating a first expandable member in a medial plantar vein to occlude the medial plantar vein and increasing hydrostatic pressure in a deep plantar venous arch. Increasing the hydrostatic pressure in the deep plantar venous arch may comprise disabling venous valves and enabling reversal of blood flow into metatarsal veins. The method may further comprise inflating a second expandable member in a lateral plantar vein to occlude the lateral plantar vein.

[0025] In some embodiments, a catheter system for promoting retroperfusion of blood into toes

comprises, or alternatively consists essentially of, a first catheter comprising a first expandable member configured to be expanded in a medial plantar vein to occlude the medial plantar vein and a second catheter comprising a second expandable member configured to be expanded in a lateral plantar vein to occlude the lateral plantar vein.

[0026] The first catheter may be longitudinally movable through the second catheter and the second expandable member. The first catheter may comprise an inflation lumen in fluid communication with the first expandable member. The second catheter may comprise an inflation lumen in fluid communication with the second expandable member. The first catheter may be configured to curve around a lateral plantar vein into a medial plantar vein.

[0027] In some embodiments, a two-way valvulotome comprises, or alternatively consists essentially of, a proximal portion, a distal portion, and an intermediate portion longitudinally between the proximal portion and the distal portion. The intermediate portion comprises a distally facing blade and a proximally facing blade.

[0028] The intermediate portion may comprise a strut comprising the distally facing blade and the proximally facing blade. The intermediate portion may comprise a plurality of struts. One strut of the plurality of struts may comprise the distally facing blade and the proximally facing blade. Each strut of the plurality of struts may comprise a distally facing blade and a proximally facing blade. At least one strut of the plurality of struts may comprise a distally facing blade. At least one strut of the plurality of struts may comprise a proximally facing blade. The intermediate portion may comprise three struts. The three struts may be evenly circumferentially spaced. The intermediate portion may be radially expandable. The intermediate portion may be self-expanding upon release from a sheath. The proximal portion may be coupled to a pusher element. The intermediate portion may be laser cut (e.g., from a hypotube or a sheet). At least one of the distally facing blade and the proximally facing blade may be rotated relative to a circumference of the intermediate portion.

[0029] In some embodiments, a method of making a valve in a vessel incompetent comprises, or alternatively consists essentially of, advancing a two-way valvulotome proximate to the valve in a radially compressed state, radially expanding the two-way valvulotome to a radially expanded state, and in the radially expanded state, at least one of distally advancing the two-way valvulotome and proximally retracting the two-way valvulotome in the vessel to disable the valve.

[0030] Advancing the two-way valvulotome proximate to the valve may comprise advancing the two-way valvulotome in a direction opposite native fluid flow. Advancing the two-way valvulotome proximate to the valve may comprise advancing the two-way valvulotome in a direction of native fluid flow. Advancing the two-way valvulotome proximate to the valve may comprise advancing the two-way valvulotome proximal to the valve. Advancing the two-way valvulotome proximate to the valve may comprise advancing the two-way valvulotome distal to the valve.

[0031] In some embodiments, a catheter for capturing a guidewire comprises, or alternatively consists essentially of, a catheter body, a capture element, and a guidewire lumen in communication with the capture element.

[0032] The capture element may be configured to deploy from a distal end of the catheter body. The capture element may be configured to deploy from a side of the catheter body. The capture element may have a collapsed state and an expanded state. The capture element may comprise shape memory material configured to change to the expanded state at body temperature. The capture element may have an angle between 110° and 150° in the expanded state. The guidewire lumen may comprise an expanded portion proximate to the capture element. The catheter may further comprise an expandable element configured to expand the capture element. The expandable element may comprise an inflatable member. The catheter body may comprise an inflation lumen in fluid communication with the inflatable member. The expandable element may be movable relative to the catheter body.

[0033] In some embodiments, a method of making valves incompetent comprises, or alternatively

consists essentially of, forming a fistula between a first vessel and a second vessel. The first vessel may be an artery. The second vessel may be a vein. Forming the fistula comprises inserting a first catheter into the first vessel. The first catheter comprises an ultrasound emitting transducer and a needle configured to radially extend from the first catheter. Forming the fistula further comprises inserting a second catheter into the second vessel. The second catheter comprises an ultrasound receiving transducer. Forming the fistula further comprises emitting an ultrasound signal from the ultrasound emitting transducer and after the ultrasound signal is received by the ultrasound receiving transducer, extending the needle from the first catheter. Extending the needle comprises exiting the first vessel, traversing interstitial tissue between the first vessel and the second vessel, and entering the second vessel. The method further comprises deploying a prosthesis at least partially in the fistula. After deploying the implantable prosthesis, blood is diverted from the first vessel to the second vessel through the prosthesis. The method further comprises making valves in the second vessel incompetent. Making the valves in the second vessel incompetent comprises using a reverse valvulotome to cut the valves and lining the second vessel with a stent.

[0034] The stent may comprise a covering or a graft. Lining the second vessel may comprise covering collateral vessels of the second vessel. The stent may be separate from the prosthesis. The stent may be spaced from the prosthesis along a length of the second vessel. The stent may be integral with the prosthesis.

[0035] In some embodiments, a method of making valves incompetent comprises, or alternatively consists essentially of, forming a fistula between a first vessel and a second vessel. Forming the fistula comprises inserting a catheter into the first vessel. The catheter comprises a needle configured to radially extend from the first catheter. Forming the fistula further comprises extending the needle from the first catheter. Extending the needle comprises exiting the first vessel, traversing interstitial tissue between the first vessel and the second vessel, and entering the second vessel. The method further comprises deploying a prosthesis at least partially in a fistula between a first vessel and a second vessel. After deploying the implantable prosthesis, blood is diverted from the first vessel to the second vessel through the prosthesis. The method further comprises making valves in the second vessel incompetent. Making the valves in the second vessel incompetent comprises at least one of using a reverse valvulotome to cut the valves, inflating a balloon, expanding a temporary stent, and lining the second vessel with an implantable stent.

[0036] The implantable stent may comprise a covering or a graft. Lining the second vessel may comprise covering collateral vessels of the second vessel. The implantable stent may be separate from the prosthesis. The implantable stent may be integral with the prosthesis. The first catheter may comprise an ultrasound emitting transducer. Forming the fistula may comprise inserting a second catheter into the second vessel, the second catheter comprising an ultrasound receiving transducer, emitting an ultrasound signal from the ultrasound emitting transducer, and extending the needle from the first catheter after the ultrasound signal is received by the ultrasound receiving transducer.

[0037] In some embodiments, a method of making valves incompetent comprises, or alternatively consists essentially of, deploying a prosthesis at least partially in a fistula between a first vessel and a second vessel. After deploying the implantable prosthesis, blood is diverted from the first vessel to the second vessel through the prosthesis. The method further comprises making valves in the second vessel incompetent.

[0038] Making the valves in the second vessel incompetent may comprise using a reverse valvulotome to cut the valves. Making the valves in the second vessel incompetent may comprise lining the second vessel with a stent. The stent may comprise a covering or a graft. Lining the second vessel may comprise covering collateral vessels of the second vessel. The stent may be separate from the prosthesis. The stent may be spaced from the prosthesis along a length of the second vessel. A proximal segment of the stent may longitudinally overlap a distal segment of the prosthesis. The stent may be integral with the prosthesis. Making the valves in the second vessel



incompetent may comprise using a reverse valvulotome to cut the valves and lining the second vessel with a stent. Making the valves in the second vessel incompetent may comprise at least one of inflating a balloon and expanding a temporary stent. Making the valves in the second vessel incompetent may comprise inflating a balloon. Making the valves in the second vessel incompetent may comprise expanding a temporary stent.

[0039] In some embodiments, an implantable prosthesis for treating an occlusion in a first vessel comprises, or alternatively consists essentially of, a plurality of filaments woven together into a woven structure, a proximal end, a distal end, sidewalls between the proximal end and the distal end, a lumen defined by the sidewalls, and a porosity sufficient to direct fluid flow through the lumen substantially without perfusing through the sidewalls.

[0040] The porosity may be between about 0% and about 50%. The porosity may be between about 5% and about 50%. The prosthesis may be substantially free of graft material. The prosthesis may comprise a first longitudinal segment having the porosity and a second longitudinal segment having a second porosity different than the porosity. The second longitudinal segment may have a parameter different than the first longitudinal segment. The parameter may comprise at least one of braid angle, filament diameter, filament material, woven structure diameter, woven structure shape, and supplemental support structure. The prosthesis may further comprise a third longitudinal segment between the first longitudinal segment and the second longitudinal segment. The third longitudinal segment may have a parameter different than at least one of the first longitudinal segment and the second longitudinal segment. The parameter may comprise at least one of braid angle, filament diameter, filament material, woven structure diameter, woven structure shape, and supplemental support structure. The prosthesis may further comprise a supplemental support structure. The supplemental support structure may comprise a second plurality of filaments woven together into a second woven structure, the second plurality of filaments having a parameter different than the plurality of filaments. The parameter may comprise at least one of braid angle, filament diameter, woven structure diameter, and filament material. The supplemental support structure may comprise a cut hypotube. The plurality of filaments may comprise a filament comprising a shape memory material (e.g., nitinol) and a prosthesis comprising a biocompatible polymer (e.g., Dacron®, Kevlar®).

[0041] In some embodiments, an implantable prosthesis for treating an occlusion in a first vessel comprises, or alternatively consists essentially of, a proximal end, a distal end, sidewalls between the proximal end and the distal end, a lumen defined by the sidewalls, a first longitudinal section configured to anchor in a first cavity, a second longitudinal section configured to anchor in a second cavity, and a third longitudinal section between the first longitudinal section and the second longitudinal section. At least one of the first longitudinal section and the third longitudinal section comprises a porosity sufficient to direct fluid flow through the lumen substantially without perfusing through the sidewalls.

[0042] The porosity may be between about 0% and about 50%. The porosity may be between about 5% and about 50%. The prosthesis may be substantially free of graft material. The second longitudinal segment may have a parameter different than the first longitudinal segment. The parameter may comprise at least one of braid angle, filament diameter, filament material, diameter, shape, and supplemental support structure. The third longitudinal segment may comprise a second porosity different than the porosity. The first longitudinal segment may be balloon expandable. The second longitudinal segment may be self expanding. The prosthesis may comprise a plurality of filaments woven together into a woven structure. The plurality filaments may comprise a filament comprising a shape memory material (e.g., nitinol) and a prosthesis comprising a biocompatible polymer (e.g., Dacron®, Kevlar®). The third longitudinal section may have a parameter different than at least one of the first longitudinal section and the second longitudinal section. The parameter may comprise at least one of braid angle, filament diameter, filament material, diameter, shape, and supplemental support structure. The prosthesis may further comprise a supplemental support

structure. The first longitudinal section may be substantially cylindrical and may have a first diameter, the second longitudinal section may be substantially cylindrical and may have a second diameter larger than the first diameter, and the third longitudinal section may be frustoconical and may taper from the first diameter to the second diameter. The first longitudinal section may be substantially cylindrical and may have a first diameter and the second longitudinal section and the third longitudinal section may be frustoconical and taper from the first diameter to a second diameter larger than the first diameter.

[0043] In some embodiments, an implantable prosthesis for treating an occlusion in a first vessel comprises a plurality of filaments woven together into a woven structure, a proximal end, a distal end, sidewalls between the proximal end and the distal end, a lumen defined by the sidewalls, and a porosity between about 5% and about 50%.

[0044] The porosity may be configured to direct fluid flow substantially through the lumen. The prosthesis may comprise a first longitudinal segment having the porosity and a second longitudinal segment having a second porosity different than the porosity.

[0045] In some embodiments, a kit comprises the prosthesis and a fistula formation system. The kit may further comprise a valve disabling device. In some embodiments, a kit comprises the prosthesis and a valve disabling device. The kit may comprising a prosthesis delivery system including the prosthesis. In some embodiments, a method comprises deploying the prosthesis in a fistula between the first vessel and a second vessel. The valve disabling device may comprise a reverse valvulotome. The valve disabling device may comprise a balloon. The valve disabling device may comprise a venous stent. The venous stent may comprise a covering or graft. The venous stent may be integral with the prosthesis.

[0046] In some embodiments, a method of diverting fluid flow from a first vessel to a second vessel in which the first vessel comprises an occlusion comprises deploying a prosthesis at least partially in a fistula between the first vessel and the second vessel. The prosthesis comprises a plurality of filaments woven together into a woven structure comprising a porosity less than about 50%. After deploying the implantable prosthesis, blood may be diverted from the first vessel to the second vessel through the prosthesis.

[0047] The first vessel may be an artery. The vessel passage may be a vein. The method may comprise dilating the fistula. The first vessel may be substantially parallel to the second vessel. Deploying the prosthesis may comprise allowing the prosthesis to self-expand. Deploying the prosthesis may comprise balloon expanding the prosthesis. Deploying the prosthesis may comprise deploying the woven structure and deploying a supplemental support structure. Deploying the supplemental support structure may be before deploying the woven structure. Deploying the supplemental support structure may be after deploying the woven structure. The supplemental support structure may comprise a second plurality of filaments woven into a second woven structure. The supplemental support structure may comprise cut hypotube. The method may further comprise forming the fistula. Forming the fistula may comprise inserting a launching catheter into the first vessel and inserting a target catheter into the second vessel. The launching catheter may comprise an ultrasound emitting transducer and a needle configured to radially extend from the launching catheter. The target catheter may comprise an ultrasound receiving transducer. Forming the fistula may comprise emitting an ultrasound signal from the ultrasound emitting transducer, during emitting the ultrasound signal and until the ultrasound signal may be received by the ultrasound receiving transducer, at least one of rotating the launching catheter and longitudinally moving the launching catheter, and after the ultrasound signal is received by the ultrasound receiving transducer, extending the needle from the launching catheter, wherein extending the needle comprises exiting the first vessel, traversing interstitial tissue between the first vessel and the second vessel, and entering the second vessel. The method may further comprise making valves in the second vessel incompetent. Making valves in the second vessel incompetent may comprise using a reverse valvulotome to cut the valves. Making valves in the second vessel incompetent may

comprise inflating a balloon. Making valves in the second vessel incompetent may comprise expanding a stent. Making valves in the second vessel incompetent may comprise lining the second vessel with a stent. The stent may comprise a covering or a graft. Lining the second vessel may comprise covering collateral vessels of the second vessel. The stent may be separate from the prosthesis. The stent may be spaced from the prosthesis along a length of the second vessel. An end of the stent may abut an end of the prosthesis. A portion of the stent may longitudinally overlap a portion of the prosthesis. The portion of the stent may be radially inward of the portion of the prosthesis. The method may comprise expanding the stent after deploying the prosthesis. The portion of the prosthesis may be radially inward of the portion of the stent. The method may comprise expanding the stent before deploying the prosthesis. The stent may be integral with the prosthesis.

[0048] In some embodiments, an implantable prosthesis for maintaining patency of an anastomosis between an artery and a vein in a lower extremity comprises a first section configured to reside in a lower extremity artery, a second section configured to reside in a lower extremity vein, and a third section longitudinally between the first section and the second section. The third section is configured to maintain patency of an anastomosis between the artery and the vein.

[0049] The first section may be configured to appose the walls of the lower extremity artery. The first section may comprise barbs. The second section may be configured to appose the walls of the lower extremity vein. The second section may comprise barbs. At least one of the first section, the second section, and the third section may be self-expanding. At least one of the first section, the second section, and the third section may be balloon expandable. A length of the second section may be greater than a length of the first section. The second section may be configured to disable valves the lower extremity vein. The second section may be configured to cover collateral vessels of the lower extremity vein.

[0050] In some embodiments, a method of diverting fluid flow from a first vessel to a second vessel in a lower extremity comprises forming an aperture between the first vessel and the second vessel, and expanding the aperture to form an anastomosis.

[0051] Forming the aperture may comprise forcing a wire from the first blood vessel into the second blood vessel. Forming the aperture may comprise traversing a needle from the first blood vessel into the second blood vessel. Expanding the aperture may comprise dilating the aperture using at least one balloon. Dilating the aperture may comprise using a plurality of balloons having progressively higher diameters. A first balloon of the plurality of balloons may have a diameter of about 1.5 mm and wherein a last balloon of the plurality of balloons may have a diameter of about 3 mm. The plurality of balloons may comprise a first balloon having a diameter of about 1.5 mm, a second balloon having a diameter of about 2.0 mm, a third balloon having a diameter of about 2.5 mm, and a third balloon having a diameter of about 3.0 mm. Dilating the aperture using the plurality of balloons may comprise using progressively higher balloon inflation pressures. The method may not include (e.g., be devoid of or free from) placing a prosthesis (e.g., without use of a stent, graft, scaffolding, or other prosthesis). Positions of the first vessel and the second vessel may be substantially maintained by anatomy surrounding the first vessel and the second vessel. The method may further comprise placing a prosthesis in the anastomosis. Placing the prosthesis in the anastomosis may comprise anchoring the prosthesis in at least one of the first vessel and the second vessel. The first vessel may comprise a lateral plantar artery. The second vessel may comprise a lateral plantar vein.

[0052] In some embodiments, a catheter for capturing a guidewire comprises, or alternatively consists essentially of, a sheath and an expandable element. The expandable element has a collapsed state when in the sheath and an expanded state when out of the sheath. The expandable element comprises a plurality of cells configured to snare a guidewire.

[0053] The catheter may further comprise a guidewire sheath extending through the sheath and the expandable element. A proximal end of the expandable element may be coupled to the guidewire

sheath. The expandable element may be configured to expand a vessel upon deployment. The expandable element may be visible under fluoroscopy. The expandable element may comprise struts defining the plurality of cells. The struts may be deflectable if contacted by a needle. The catheter may further comprise an ultrasound receiving transducer. The ultrasound receiving transducer may be distal to the expandable element. The ultrasound receiving transducer may be longitudinally between a proximal end of the expandable element and a distal end of the expandable element. The ultrasound receiving transducer may be proximal to the expandable element. A method of capturing a guidewire may comprise inserting the catheter into a first vessel, expanding the expandable element to the expanded state in the first vessel, and extending a needle from a second vessel, through interstitial tissue, and into the first vessel between the proximal end of the expandable element and the distal end of the expandable element. Extending the needle may comprise extending through a cell of the plurality of cells. The method may further comprise extending a guidewire through the needle and into the expandable element and collapsing the expandable element towards the collapsed state. Collapsing the expandable element may comprise snaring the guidewire.

[0054] In some embodiments, a method of capturing a guidewire comprises, or alternatively consists essentially of, expanding an expandable element to an expanded state in a first vessel, and extending a needle from a second vessel, through interstitial tissue, and into the first vessel between a proximal end of the expandable element and a distal end of the expandable element. The expandable element comprises a plurality of cells. Extending the needle comprises extending through a cell of the plurality of cells. The method further comprises extending a guidewire through the needle and into the expandable element and collapsing the expandable element towards a collapsed state. Collapsing the expandable element comprises snaring the guidewire.

[0055] Collapsing the expandable element may comprise twisting the expandable element. Expanding the expandable element may comprise expanding the first vessel. Extending the needle may comprise targeting the expandable element under fluoroscopy. The method may further comprise proximally retracting the expandable element. Proximally retracting the expandable element may comprise routing the guidewire through the first vessel.

[0056] In some embodiments, a device for deploying a tubular structure comprises, or alternatively consists essentially of, a handle body, a knob, and a slider. The handle body comprises a first segment comprising threads, a second segment longitudinally adjacent and proximal to the first segment, and a longitudinal slot. The second segment is free of threads. The knob comprises threads. The knob is at a distal end of the first segment in a starting position. The slider is operably connected to the knob. The slider is coupled to a sheath. The knob is configured to rotate proximally about the handle body for the first segment and is configured to proximally slide along the handle body for the second segment. The slider is configured to proximally retract the sheath a first amount during rotating the knob and is configured to proximally retract the sheath a second amount during sliding the knob. The device is configured to fully deploy the tubular structure after the sheath is retracted the second amount.

[0057] The first amount may be less than the second amount. The first amount may be between 10% and 50% of the second amount. The tubular structure may comprise a stent. The tubular structure may comprise a stent-graft.

[0058] In some embodiments, a method of deploying a tubular structure comprises, or alternatively consists essentially of, rotating a knob about a handle body. Rotating the knob about the handle body comprises proximally retracting a sheath and deploying a first amount of the tubular structure. The method further comprises, after rotating the knob about the handle body, proximally sliding the knob along the handle body. Proximally sliding the knob along the handle body comprises proximally retracting the sheath deploying a second amount of the tubular structure. The first amount and the second amount are the full amount of the tubular structure.

[0059] The first amount may be less than the second amount. The first amount may be between

10% and 50% of the second amount. The tubular structure may comprise a stent. The tubular structure may comprise a stent-graft.

[0060] In some embodiments, a device for deploying a tubular structure comprises, or alternatively consists essentially of, a sheath, a handle body, a knob comprising a worm gear comprising teeth, and a slider coupled to the sheath. The slider comprises a first portion in the handle body, a second portion outside the handle body; and a worm screw comprising teeth configured to interact with the teeth of the worm gear. The slider is configured to proximally retract the sheath a first amount during rotating the knob and is configured to proximally retract the sheath a second amount during sliding the slider. The device is configured to fully deploy the tubular structure after the sheath is retracted the second amount.

[0061] The first amount may be less than the second amount. The first amount may be between 10% and 50% of the second amount. The tubular structure may comprise a stent. The tubular structure may comprise a stent-graft. The handle body may comprise a longitudinal slot. The slider may comprise a third portion extending through the longitudinal slot. The handle body may comprise a second longitudinal slot. The slider may comprise a fourth portion outside the handle body and a fifth portion extending through the second longitudinal slot. The fourth portion may be on an opposite side of the handle body than the second portion. The handle body may comprise a shell at least partially covering the second portion of the slider until the sheath may be proximally retracted the first amount.

[0062] In some embodiments, a method of deploying a tubular structure comprises, or alternatively consists essentially of, rotating a knob. Rotating the knob comprises proximally retracting a sheath and deploying a first amount of the tubular structure. The method further comprises, after rotating the knob, proximally sliding a slider along a handle body. Proximally sliding the slider along the handle body comprises proximally retracting the sheath a second distance and deploying a second amount of the tubular structure. The first amount and the second amount are the full amount of the tubular structure.

[0063] The first amount may be less than the second amount. The first amount may be between 10% and 50% of the second amount. The tubular structure may comprise a stent. The tubular structure may comprise a stent-graft. The knob may comprise a worm gear comprising teeth. The slider may comprise a worm screw comprising teeth configured to interact with the teeth of the worm gear. The handle body may comprise a longitudinal slot. The slider may comprise a first portion in the handle body, a second portion outside the handle body, and a third portion extending through the longitudinal slot. The handle body may comprise a second longitudinal slot. The slider may comprise a fourth portion outside the handle body and a fifth portion extending through the second longitudinal slot. The fourth portion may be on an opposite side of the handle body than the second portion. Proximally retracting the slider may comprise gripping the second portion and the fourth portion. The handle body may comprise a shell at least partially covering the second portion of the slider until the sheath may be proximally retracted the first amount. An axis of rotation of the knob may be transverse to a longitudinal axis of the handle body.

[0064] The methods summarized above and set forth in further detail below describe certain actions taken by a practitioner; however, it should be understood that they can also include the instruction of those actions by another party. Thus, actions such as “making valves in the first vessel incompetent” include “instructing making valves in the first vessel incompetent.”

[0065] For purposes of summarizing the invention and the advantages that may be achieved, certain objects and advantages are described herein. Not necessarily all such objects or advantages need to be achieved in accordance with any particular embodiment. In some embodiments, the invention may be embodied or carried out in a manner that can achieve or optimize one advantage or a group of advantages without necessarily achieving other objects or advantages.

[0066] All of these embodiments are intended to be within the scope of the invention herein disclosed. These and other embodiments will be apparent from the following detailed description

having reference to the attached figures, the invention not being limited to any particular disclosed embodiment(s). Optional and/or preferred features described with reference to some embodiments may be combined with and incorporated into other embodiments. All references cited herein, including patents and patent applications, are incorporated by reference in their entirety.

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## Description

### BRIEF DESCRIPTION OF THE DRAWINGS

[0067] These and other features, aspects, and advantages of the present disclosure are described with reference to the drawings of certain embodiments, which are intended to illustrate certain embodiments and not to limit the invention, in which like reference numerals are used for like features, and in which:

[0068] FIG. 1 schematically illustrates an example embodiment of a launching device directing a signal from a first body cavity to a target device in a second body cavity.

[0069] FIG. 2 is a cross-sectional representation along the dotted line B-B of FIG. 1.

[0070] FIG. 3 schematically illustrates an example embodiment of a launching device.

[0071] FIG. 4 schematically illustrates an example embodiment of a target device.

[0072] FIG. 5 schematically illustrates another example embodiment of a launching device.

[0073] FIG. 6 schematically illustrates an example embodiment of centering devices for launching and/or target devices.

[0074] FIG. 7 schematically illustrates a prosthesis in place following a procedure such as arterial-venous arterialization.

[0075] FIG. 8 is a side perspective view of an example embodiment of a device for providing fluid flow.

[0076] FIG. 9 shows the device of FIG. 8 in use as a shunt between two blood vessels.

[0077] FIG. 10 is a side perspective view of another example embodiment of a device for providing fluid flow.

[0078] FIG. 11 is a side perspective view of still another example embodiment of a device for providing fluid flow.

[0079] FIG. 12 is a side perspective view of yet another example embodiment of a device for providing fluid flow.

[0080] FIG. 13 is a side perspective view of yet still another example embodiment of a device for providing fluid flow.

[0081] FIG. 14A is a schematic side cross-sectional view of an example embodiment of an ultrasound launching catheter.

[0082] FIG. 14B is an expanded schematic side cross-sectional view of a distal portion of the ultrasound launching catheter of FIG. 14A within the circle 14B.

[0083] FIG. 15A is a schematic side elevational view of an example embodiment of an ultrasound target catheter.

[0084] FIG. 15B is an expanded schematic side cross-sectional view of the ultrasound target catheter of FIG. 15A within the circle 15B.

[0085] FIG. 15C is an expanded schematic side cross-sectional view of the ultrasound target catheter of FIG. 15A within the circle 15C.

[0086] FIG. 16 is an example embodiment of a graph for detecting catheter alignment.

[0087] FIG. 17 is a schematic side elevational view of an example embodiment of a prosthesis delivery system.

[0088] FIG. 18 is a schematic side elevational view of an example embodiment of a prosthesis.

[0089] FIG. 19 is a schematic side elevational view of another example embodiment of a prosthesis.

[0090] FIGS. **20A-20H** schematically illustrate an example embodiment of a method for effecting retroperfusion.

[0091] FIG. **21** is a schematic perspective view of an example embodiment of an ultrasound receiving transducer.

[0092] FIG. **22** is a schematic cross-sectional view of another example embodiment of an ultrasound receiving transducer.

[0093] FIG. **23A** is a schematic perspective view of an example embodiment of a valvulotome.

[0094] FIG. **23B** is a schematic perspective view of an example embodiment of a reverse valvulotome.

[0095] FIG. **24** is a schematic perspective view of an example embodiment of a LeMaitre device.

[0096] FIG. **25A** is a schematic side elevational view of yet another example embodiment of a prosthesis.

[0097] FIG. **25B** is a schematic side elevational view of still another example embodiment of a prosthesis.

[0098] FIG. **25C** is a schematic side elevational view of still yet another example embodiment of a prosthesis.

[0099] FIGS. **26A** and **26B** schematically illustrate another example embodiment of a method for effecting retroperfusion.

[0100] FIG. **27** schematically illustrates another example embodiment of a prosthesis and a method for effecting retroperfusion.

[0101] FIGS. **28A** and **28B** schematically illustrate arteries and veins of the foot, respectively.

[0102] FIG. **29** schematically illustrates an example embodiment of an anastomosis device.

[0103] FIG. **30** schematically illustrates an example embodiment of two blood vessels coupled by an anastomosis device.

[0104] FIG. **31A** schematically illustrates an example embodiment of an arteriovenous fistula stent separate from an example embodiment of a venous stent.

[0105] FIG. **31B** schematically illustrates an example embodiment of an arteriovenous fistula stent comprising an integrated venous stent.

[0106] FIG. **31C** schematically illustrates an example embodiment of a fistula stent comprising an integrated venous stent.

[0107] FIGS. **32A** through **32D** illustrate an example method and device for identifying and avoiding a bifurcation **1104** in a percutaneous bypass procedure.

[0108] FIGS. **33A** and **33B** schematically illustrate an example procedure that can be performed the following connection of a first vessel and a second vessel with a needle traversing interstitial tissue.

[0109] FIGS. **34A** through **35F** illustrate example procedures that can be performed when a guidewire is in a vessel.

[0110] FIGS. **36A** through **36D** illustrate an example method of promoting retroperfusion of blood through a vein into toes.

[0111] FIG. **37A** illustrates an example of a valve disabling device in a radially expanded state.

[0112] FIG. **37B** is a flattened side view of the valve disabling device of FIG. **37A**.

[0113] FIG. **37C** is an expanded view of the flattened side view of the valve disabling device of FIG. **37A** in the area identified by the circle **37C** in FIG. **37B**.

[0114] FIG. **37D** is an end view of the valve disabling device of FIG. **37A** flattened as shown in FIG. **37B**.

[0115] FIG. **37E** is an end view of the valve disabling device of FIG. **37A** in a radially contracted state.

[0116] FIG. **37F** is a side view of the valve disabling device of FIG. **37A** in a radially contracted state.

[0117] FIG. **37G** is another side view of the valve disabling device of FIG. **37A** in a radially contracted state and circumferentially rotated compared to FIG. **37F**.

[0118] FIG. 37H is a side view of the valve disabling device of FIG. 37A in a radially expanded state.

[0119] FIG. 37I is another side view of the valve disabling device of FIG. 37A in a radially expanded state and circumferentially rotated compared to FIG. 37H.

[0120] FIG. 37J is a cross-sectional end view of the valve disabling device of FIG. 37A in a radially expanded state taken along the line 37J-37J of FIG. 37H.

[0121] FIGS. 37Ki through 37Nii illustrate example procedures that can be performed using the valve disabling device of FIG. 37A.

[0122] FIG. 38A schematically illustrates an example of a distal end of a catheter.

[0123] FIGS. 38B through 38D illustrate an example procedure that can be performed using the distal end of the catheter of FIG. 38A.

[0124] FIG. 38Ei and 38Eii illustrates an example of a distal end of a catheter.

[0125] FIG. 38F illustrates an example of a portion of a catheter.

[0126] FIG. 38G illustrates another example of a portion of a catheter.

[0127] FIG. 39A is a perspective view of an example of a portion of a target catheter.

[0128] FIG. 39B is a side view of the target catheter of FIG. 39A in a first state.

[0129] FIG. 39C is a side view of the target catheter of FIG. 39A in a second state.

[0130] FIGS. 39D-39I schematically illustrate an example method of using the target catheter of FIG. 39A.

[0131] FIG. 40A is a perspective view of an example handle for deploying a tubular structure.

[0132] FIG. 40B is an expanded perspective cross-sectional view of a portion of the handle of FIG. 40A.

[0133] FIG. 40C is a perspective view of the handle of FIG. 40A in a deployed state.

[0134] FIG. 40D is an expanded perspective cross-sectional view of a portion of the handle of FIG. 40A in a deployed state.

[0135] FIG. 41A is a perspective view of an example handle for deploying a tubular structure.

[0136] FIG. 41B is an expanded perspective partially transparent view of a portion of the handle of FIG. 41A.

[0137] FIGS. 41C to 41Eiii show an example method of operating the handle of FIG. 41A.

#### DETAILED DESCRIPTION

[0138] Although certain embodiments and examples are described below, the invention extends beyond the specifically disclosed embodiments and/or uses and obvious modifications and equivalents thereof. The scope of the invention herein disclosed should not be limited by any particular embodiment(s) described below.

[0139] Minimally invasive surgery could provide a means for treating a broader range of patients, including those currently excluded from standard surgical techniques. One such procedure is percutaneous in situ coronary venous arterialization (PICVA), which is a catheter-based coronary bypass procedure in which the occlusion in the diseased artery is “bypassed” by creation of a channel between the coronary artery and the adjacent coronary vein. In this way, the arterial blood is diverted into the venous system and can perfuse the cardiac tissue in a retrograde manner (retroperfusion) and restores blood supply to ischemic tissue. Some example devices and methods for performing procedures like PICVA are described in PCT Pub. No. WO 99/049793 and U.S. Patent Pub. No. 2004/0133225, which are hereby incorporated by reference in their entirety.

[0140] Successfully performing a minimally invasive procedure of diverting blood flow from the coronary artery to the adjacent vein heretofore has had a low success rate, most often due to inability to properly target the vein from the artery. Without the proper systems and methods, such procedures (e.g., attempting to target the vein by combination of X-ray fluoroscopy and an imaging ultrasound probe located on the distal tip of the catheter e.g., as described in U.S. Patent Pub. No. 2004/0133225) are often doomed to failure before even starting. Indeed, such an arrangement can be difficult to navigate, and localization of the adjacent vein can require considerable skill on the



part of the clinician. Improvements in the systems and methods for targeting, such as those using the catheters described herein, can enable procedures such as PICVA and transvascular surgery in general. Without such improvements, such percutaneous techniques will remain peripheral to conventional surgical open-heart and other types of bypass operations.

[0141] The present application, according to several embodiments, describes methods and systems usable in minimally invasive surgical procedures, which can reduce performance of conventional surgery to treat conditions such as coronary heart disease and critical limb ischemia. For example, patients who might otherwise be unable to receive surgery such as coronary bypass surgery or peripheral arterial bypass surgery can be treated, and the amount of surgical trauma, the risk of infection, and/or the time to recovery may be reduced or significantly reduced in comparison to conventional surgery.

[0142] FIG. 1 schematically illustrates an example embodiment of a launching device **10** directing a signal from a first body cavity **30** to a target device **20** in a second body cavity **35**. The launching device **10** comprises a signal transmitter **12**. The launching device **10** may comprise, for example, a catheter including an elongate flexible rod-like portion and a tip portion, and may provide a conduit for administering therapy within the body of a patient. The launching device **10** may be suitable for location and movement through a first cavity or vessel **30** (e.g., heart chamber, coronary artery, coronary vein, peripheral artery, peripheral vein) within a patient's body. The elongate portion of the launching device **10** comprises an outer sheath **11** that encloses a space, defining a lumen **13**. The space within the lumen **13** may be suitably partitioned or subdivided as necessary so as to define channels for administering therapy, controlling the positioning of the launching device **10**, etc. Such subdivision may, for example, be achieved either longitudinally or concentrically in an axial fashion.

[0143] The launching device **10** comprises a signal transducer **12**. The signal transducer **12** is configured to provide or emit a signal **40** that is directed outwards from the launching device **10**. In the embodiment shown in FIG. 1, the signal **40** is directed radially outward from the launching device **10** in a direction that is perpendicular to the longitudinal axis of the launching device **10**. As mentioned in greater detail below, in some embodiments, the direction of the signal **40** need not be perpendicular and can be directed at an angle to the longitudinal axis of the launching device **10**. The signal transducer **12** may thereby form at least a portion of a signal generating means.

[0144] The signal transducer **12** is connected to signal transmitter **50**. The signal transmitter **50** can be suitably selected from ultrasound or appropriate electromagnetic sources such as a laser, microwave radiation, radio waves, etc. In some embodiments, as described in further detail below, the signal transmitter **50** is configured to generate an ultrasound signal, which is relayed to the signal transducer **12**, which in turn directs the signal **40** out of the first body cavity **30** into the surrounding tissue.

[0145] A target device **20** is located within an adjacent second body cavity or vessel **32** (e.g., heart chamber, coronary artery, coronary vein, peripheral artery, peripheral vein) within a patient's body. The first and second body cavities **30**, **32** are separated by intervening tissue **34**, sometimes referred to as interstitial tissue or a septum. The first and second body cavities **30**, **32** are located next to each other in a parallel fashion for at least a portion of their respective lengths. For example, many of the veins and arteries of the body are known to run in parallel with each other for at least a portion of their overall length.

[0146] The target device **20** can assume a similar arrangement to that of the launching device **10**. For example, the target device **20** can comprise a catheter including an elongate flexible rod-like portion and a tip portion. For another example, fine movement and positioning of the target device **20** within the body cavity **32** can be achieved. For yet another example, the target device **20** may comprise an outer sheath **21** that encloses a space, defining a lumen **23**. The lumen **23** can be suitably partitioned, for example as with the launching device **10**.

[0147] The target device **20** comprises a receiving transducer **22** configured to receive the signal **40**

from the transducer **12** of the launching device **10**. The receiving transducer **22** makes up at least a portion of a signal detection means. In use, when the receiving transducer **22** receives the signal **40** transmitted from the signal transducer **12**, the receiving transducer **22** transmits the received signal to a signal detector **60**. The signal detector **60** is configured to provide an output reading to the user of the system, for example via an output display **61**. The output display **61** may be a visual display, an audio display (e.g., beeping or emitting some other sound upon receipt of a signal), etc.

[0148] In this way, the transmission and detection of the directed signal **40** can allow for the navigation and positioning of the launching device **10** relative to the target device **20**. In use, the launching device **10** and the target device **20** can be maneuvered by the user of the system until the output display **61** indicates that signal **40** is being received by the target device **40**.

[0149] In some embodiments, the signal **40** comprises or is an ultrasound signal. The signal **40** is directional and is emitted by the signal transducer **12** in the shape of a narrow cone or arc (e.g., with the width of the signal band increasing as the distance from the signal transducer **12** increases). As such, the precision of alignment between the launching device **10** and the target device **20** depends not only upon signal detection, but also upon the distance between the two devices, as the signal beam width is greater at greater distances. This level of error is referred to as “positional uncertainty.” A certain level of tolerance can exist for positional uncertainty; however, if therapy is to be directed with precision, the amount of uncertainty should be reduced or minimized. For example, if the diameter  $d$  of the signal transducer **12** is 1 mm and the frequency of the ultrasound signal is 30 MHz, then the positional uncertainty  $x$  (e.g., the margin of error on either side of a center line) is 1 mm at a perpendicular separation of 5 mm between the launching device **10** and the target device **20**. For clinical applications, the positional uncertainty generally should not exceed around  $\pm 5$  mm (for a total signal beam width of 10 mm at the point of reception). In some embodiments, the positional uncertainty is between about  $\pm 0.01$  mm and about  $\pm 4.50$  mm or between about  $\pm 0.1$  mm and about  $\pm 2$  mm. In some embodiments, the positional uncertainty does not exceed about  $\pm 1$  mm.

[0150] The strength of the signal **40** can be a factor in detection, and signal strength generally diminishes as the distance between the launching device **10** and the target device **20** increases. This distance is in part determined by the amount of intervening tissue **34** between the devices **10**, **20**. By way of example, if the signal **40** is an ultrasound signal, significant deterioration of signal can be expected when the launching device **10** and the target device **20** are separated by more than about 20 mm of solid tissue (e.g., the intervening tissue **34**). The density of the intervening tissue **34** may also have an effect upon the deterioration of signal **40** over distance (e.g., denser tissue deteriorating the signal more than less dense tissue).

[0151] The frequency of the ultrasound signal may also affect the thickness of the signal transducer, which for a standard ultrasound ceramic transducer (e.g., a piezoelectric transducer (PZT)) is 0.075 mm at 30 MHz.

[0152] FIG. **2** is a cross-sectional representation along the dotted line B-B of FIG. **1**. The correct orientation of the launching device relative to the target device can be a factor in detection, as the line of orientation **41** can determine where the therapy is to be applied. The clinical need for precisional placing of therapy in a patient may function better if the directional signal **40** is linked to the means for delivering therapy (e.g., being parallel and longitudinally offset). For example, in this way the user of the system can administer therapy to the correct location by ensuring that the launching device **10** and the target device **20** are correctly positioned via transmission and reception of the signal **40**. The orientation line **41** in FIG. **2** denotes not only the direction of signal travel but also the path along which therapy can be administered to the patient.

[0153] FIG. **3** schematically illustrates an example embodiment of a launching device **10**. The launching device **10** comprises a signal transducer **120** that is oriented at an oblique angle relative to the longitudinal axis of the launching device **10**. The signal **40** is transmitted at an angle that is in the direction of travel (e.g., forward travel, transverse travel) of the launching device **10** as the

launching device enters a body cavity **30** (FIGS. **1** and **2**). In some embodiments, the beam angle is about perpendicular to the longitudinal axis of the launching device **10**. In some embodiments, the beam angle is between about 20° and about 60° to the perpendicular, between about 30° and about 50° to the perpendicular, or about 45° to the perpendicular, when 0° corresponds to the longitudinal axis of the launching device **10** in the direction of travel.

[0154] The launching device **10** comprises a hollow needle or cannula **17**, which is an example means for administering therapy. During travel of the launching device **10**, the hollow needle **17** is located in an undeployed or retracted state within the lumen **13** of launching device **10**. The hollow needle **17** may be deployed/extended from the launching device **10** via an aperture **16** in the outer sheath **11** at a time deemed appropriate by the user (e.g., upon detection of the signal **40** by the target device **20**). The aperture **16** can allow fluid communication between the lumen **13** and the body cavity **30** (FIG. **1**). As illustrated by the example embodiment of FIG. **3**, the hollow needle **17** may travel along a path that is parallel to the direction of the signal **40**. The hollow needle **17** may be used to pierce the intervening tissue **34** (FIG. **1**). In some embodiments, the hollow needle **17** makes a transit across the entirety of the intervening tissue **34**, and in doing so allows the launching device **10** to access the second body cavity **32** (FIG. **2**). If desired, the pathway made by the hollow needle **17** through the intervening tissue **34** can be subsequently widened to allow fluid communication between the first body cavity **30** and the second body cavity **32**.

[0155] Therapeutic means suitable for use in several embodiments can comprise, for example, devices and/or instruments selected from the group consisting of a cannula, a laser, a radiation-emitting device, a probe, a drill, a blade, a wire, a needle, appropriate combinations thereof, and the like.

[0156] In some embodiments, the hollow needle **17** comprises a sensor **19**, which may assist in further determining positional information of the tip of the hollow needle **17** relative to the launching device **10**. In some embodiments, the sensor **19** is configured to detect changes in hydrostatic pressure. Other sensors that are suitable for use in the systems and methods described herein can include temperature sensors, oxygenation sensors, and/or color sensors.

[0157] Optionally, the hollow needle **17** can comprise an additional signal transducer **122**. In the embodiment shown in FIG. **3**, the signal transducer **122** is located near the tip of the hollow needle **17** on the end of a guidewire **14**. The signal transducer **122** can also or alternatively be located on the hollow needle **17** if desired. In use, the signal transducer **122** is driven with a short transmit pulse that produces a directional signal or a non-directional signal pulse. The signal pulse can be detected by the receiving transducer **22** mounted on the target device **20**. The distance from the guidewire **14** or hollow needle **17** to the receiving transducer **22** and hence the target device **20** can be at least partially determined time based on the delay between the transmission of the signal pulse from the signal transducer **122** and receipt of the signal pulse on the receiving transducer **22**.

[0158] FIG. **4** schematically illustrates an example embodiment of a target device **20**. In the embodiment shown in FIG. **4**, the target device **20** is located within a body cavity **32**. As mentioned above, the target device **20** comprises a receiving transducer **22** for receiving the signal **40**. The receiving transducer **22** can be unidirectional (e.g., capable of receiving a signal from one direction only) or omnidirectional (e.g., capable of receiving a signal from any direction). Arrow A shows the reversed direction of blood flow after an arterial-venous arterIALIZATION (also called PICVA) has been effected. The target device **20** comprises an omnidirectional ultrasound signal receiving transducer **60**. An optional reflecting cone **601** can direct the signal **40** onto a disc-shaped receiving transducer **60**. An acoustically transparent window **602** can separate the reflecting cone **601** from the receiving transducer **60**. In some embodiments, an omnidirectional ultrasound signal receiving transducer can be obtained by locating a cylinder of a flexible piezoelectric material such as polyvinylidene difluoride (PVDF) around the outer sheath of the target device **20**. In such a way, the cylinder can act in a similar or equivalent manner to the receiving transducer **60**.

[0159] In the embodiment illustrated in FIG. **4**, the target device **20** comprises an optional channel

25 for administering an agent, such as a therapeutic agent, to a patient. In some embodiments, the channel 25 functions as a conduit to allow application of a blocking material 251 that serves to at least partially obstruct or occlude the body cavity 32. The blocking material 251 can be suitably selected from a gel-based substance. The blocking material 251 can also or alternatively include embolization members (e.g., balloons, self-expanding stents, etc.). The placement of the blocking material 251 can be directed by movement of the target device 20. The presence of a guide member 24 within the lumen 23 of the target device 20 can allow the user to precisely manipulate the position of the target device 20 as desired.

[0160] Referring again to FIG. 2, the launching device 10 comprises a signal transducer 12 that may optionally be oriented so that the signal 40 is transmitted at an angle other than perpendicular to the signal transducer 12. FIG. 5 schematically illustrates another example embodiment of a launching device 10. In some embodiments, for example the launching device 10 shown in FIG. 5, the signal transducer is in the form of a signal transducer array 123. The signal transducer array 123 comprises a plurality of signal transducer elements 124, which can be oriented collectively to at least partially define a signal beam width and angle relative to the launching device 10. Smaller size of the elements 124 can allow the signal transducer 123 to not occupy a significant proportion the lumen 13 of the launching device 10.

[0161] The embodiment shown in FIG. 5 may be useful for ultrasound beam-forming signaling. FIG. 5 shows an array of signal transducer elements 124 that are separately connected to a transmitter 50 via delays 51, which allows the signals to each element 124 to be delayed relative to each other. The delays can provide or ensure that the ultrasound wavefronts from each element 124 are aligned to produce a beam of ultrasound 40 at the desired angle. In some embodiments, for example in which the signal 40 comprises visible light, an array of LEDs can also or alternatively be used.

[0162] FIG. 6 schematically illustrates an example embodiment of centering devices for launching and/or target devices 10, 20. To assist in the process of alignment between the launching device 10 in the first body cavity 30 and the target device 20 in the second body cavity 32, one or both of the devices 10, 20 may comprise means for centering the respective devices within their body cavities.

[0163] In some embodiments, the centering means comprises an inflatable bladder or balloon 111 that is located in the lumen 13, 23 when in an undeployed state and, when the device 10, 20 reaches the desired location within the patient, can be inflated. The balloon 111 can be disposed on an outer surface of the outer sheath 11, 21. The balloon 111 can be annular in shape such that it at least partially surrounds the device 10, 20 in a toroidal or doughnut-like fashion. The balloon 111 can be arranged such that it inflates on only one side or only on two opposite sides of the device 10, 20. As illustrated in FIG. 6, the balloon 111 is deployed on one side of the launching device 10.

[0164] In some embodiments, the centering means comprises one or more loop structures 112 located either in the lumen 13, 23 or within recesses made in the outer sheath 11, 21 when in an undeployed or retracted state. When the device 10, 20 reaches the desired location within the patient, the one or more loop structures 112 can be expanded radially outwardly from the device 10, 20, thereby centering the device 10, 20 within the body cavity 30, 32. Outward expansion of the loop structures 112 can be suitably effected by compression of a length of wire, for example, such that it bows outwardly from the outer sheath 11, 21. A centering device that adopts this conformation may comprise a plurality of compressible lengths of wire or other suitable flexible material arranged in parallel at radially spaced intervals around the periphery of the outer sheath 11, 21. Compression of the plurality of wires can be induced by way of a sliding member (not shown) located proximally and/or distally near to the ends of the plurality of wires. The sliding member is capable of translational movement along the longitudinal axis of the device 10, 20. As illustrated in FIG. 6, the target device 20 comprises fully deployed centering means 112 that has allowed the target device 20 to be centered within the body cavity 32.

[0165] Other possible means for centering the devices 10, 20 within the body cavities 30, 32

include, but are not limited to, expandable Chinese-lantern type devices, reversibly expandable stents, coils, helices, retractable probes or legs, combinations thereof, and the like.

[0166] In some embodiments, the centering means or other means (e.g., balloons, metal stand-offs having differing lengths, etc.) can be used to orient the devices **10**, **20** within the body cavities **30**, **32** other than in the center or substantially the center of the body cavities. For example, the device **10** may be oriented proximate to the wall of the body cavity **30** where the needle **17** will exit the body cavity **30**, which can, for example, provide a shorter ultrasound signal path and/or reduce error due to the needle **17** traversing intraluminal space. For another example, the device **10** may be oriented proximate to the wall of the body cavity **30** opposite the wall of the body cavity **30** where the needle **17** will exit the body cavity **30**, which can, for example, provide a firm surface for the needle **17** to push against. For yet another example, the device **20** may be oriented proximate to the wall of the body cavity **32** where the needle **17** will enter the body cavity **32**, which can, for example, provide a shorter ultrasound signal path. Other device orientations that are neither centered nor proximate to a vessel wall are also possible (e.g., some fraction of the diameter away from the wall and/or the center of the lumen, such as  $\frac{1}{2}$ ,  $\frac{1}{3}$ ,  $\frac{1}{4}$ , etc.).

#### EXAMPLE

[0167] The methods and systems described herein demonstrate particular utility in cardiovascular surgery according to several embodiments. Certain aspects are further illustrated by the following non-limiting example, in which the system is used by a clinician to perform the procedure of arterial-venous connection (PICVA) so as to enable retroperfusion of cardiac tissue following occlusion of a coronary artery.

[0168] The launching catheter **10** is inserted into the occluded coronary artery by standard keyhole surgical techniques (e.g., tracking over a guidewire, tracking through a guide catheter). The target catheter **20** is inserted into the coronary vein that runs parallel to the coronary artery by standard keyhole surgical techniques (e.g., tracking over a guidewire, tracking through a guide catheter). The coronary vein is not occluded and, therefore, provides an alternative channel for blood flow to the cardiac muscle, effectively allowing the occlusion in the coronary artery to be bypassed.

[0169] The launching catheter **10** comprises a PZT ultrasound transducer **12** (e.g., available from CTS Piezoelectric Products of Albuquerque, New Mexico) that is oriented such that a directional ultrasound beam is transmitted in this example at a  $45^\circ$  angle (relative to the longitudinal axis of the launching device), preferably in the direction of blood flow in the artery **30**, although other angles including about  $90^\circ$  are also possible. The ultrasound transducer **12** is activated, and in this example a 30 MHz directional ultrasound signal **40** is transmitted from the launching catheter **10**, although other frequencies are also possible. The target catheter **20** comprises an omnidirectional ultrasound receiving transducer **60**. To assist with localization of both the launching catheter **10** and the target catheter **20**, both catheters **10**, **20** comprise centering or orienting means, in this example in the form of an annular inflatable balloon **111**, although other or absence of centering or orienting means are also possible. The centering means **111** on the launching catheter **10** is deployed by the clinician when the launching catheter **10** is deemed to be in an appropriate location close to the site of the occlusion within the coronary artery **30**. This may be determined via standard fluoroscopic imaging techniques and/or upon physical resistance. The target catheter **20** is then moved within the adjacent coronary vein **32** until the directed ultrasound signal **40** is detected by the signal receiving transducer **60**. To enable more precise alignment between the launching catheter **10** and the target catheter **20**, the centering means **111** on the target catheter **20** can be deployed either before or after the signal **40** is detected.

[0170] Upon reception of the transmitted signal **40**, the clinician can be certain that the launching catheter **10** and the target catheter **20** are correctly located, both rotationally and longitudinally, within their respective blood vessels **30**, **32** to allow for the arterial-venous connection procedure to commence. The target catheter **20** may be used to block blood flow within the coronary vein **32** via administration of a gel blocking material **251** through a channel **25** in the target catheter **20**. The

blocking material **251** may be administered at a position in the coronary vein **32** that is downstream in terms of the venous blood flow relative to the location of the receiving signal transducer **60**. [0171] The clinician may then initiate arterial-venous connection by deploying a hollow needle **17** from the launching catheter **10** substantially along a path that is parallel and close to the path taken by the ultrasound signal **40** though the intervening tissue **34** between the coronary artery **30** and the coronary vein **32**, or the hollow needle **17** may traverse a path that intercepts the path of the ultrasound signal at a point within the coronary vein **32**. The hollow needle **17** optionally comprises a sensor **19** near its tip that is configured to detect changes in hydrostatic pressure or Doppler flow such that the user can monitor the transition from arterial pressure to venous pressure as the hollow needle **17** passes between the two vessels **30**, **32**. The hollow needle **17** optionally comprises a guidewire **14** in a bore or lumen of the hollow needle **17** during deployment. Once the hollow needle **17** and guidewire **14** have traversed the intervening tissue **34**, the hollow needle **17** may be retracted back into the lumen **13** of the launching catheter **10**, leaving the guidewire **14** in place. In some embodiments, once the hollow needle **17** has traversed the intervening tissue **34**, the user can separately pass the guidewire **14** through the bore or lumen of the hollow needle **17** and then retract the needle **17** into the launching catheter **10**.

[0172] The clinician withdraws the launching catheter **10** from the patient, leaving the guidewire **14** in place. A further catheter device is then slid along the guidewire **14**. FIG. 7 schematically illustrates a prosthesis **26** such as an expandable stent **26** in place following a procedure such as arterial-venous arterialization. Further detail about possible prostheses including stents and stent-grafts are provided below. The stent **26** may be deployed to widen the perforation in the intervening tissue **34** between the coronary artery **30** and the coronary vein **32**, in which the interrupted arrow A shows the direction of blood flow through the stent **26** between the first and second body cavities **30**, **32** (e.g., arterial blood is thereby diverted into the venous system and is enabled to retroperfuse the cardiac muscle tissue). The stent **26** can block flow upwards in the cavity **32**, forcing blood flow in the cavity **32** to be in the same direction as blood flow in the cavity **30**. Graft material of the stent **26** can form a fluid-tight lumen between the cavity **30** and the cavity **32**. The target catheter **20** is withdrawn from the patient, leaving the blocking material **251** in position. Optionally, a further block or suture may be inserted into the coronary vein to inhibit or prevent reversal of arterial blood flow, as described in further detail herein.

[0173] Whilst the specific example described above is with respect to cardiovascular surgery, the methods and systems described herein could have far reaching applications in other forms of surgery. For example, any surgery involving the need to direct therapy from one body cavity (e.g., for treatment of peripheral artery disease) towards another adjacent body cavity could be considered. As such, applications in the fields of neurosurgery, urology, and general vascular surgery are also possible. The type of therapy need not be restricted to formation of channels between body cavities. For instance, the methods and systems described herein may also be used in directing techniques such as catheter ablation, non-contact mapping of heart chambers, the delivery of medicaments to precise areas of the body, and the like.

[0174] Certain techniques for effectively bypassing an occlusion in an artery by percutaneous surgery are described above. These techniques include creating a channel or passage between a first passage, such as an artery upstream of an occlusion, a vein, or a heart chamber, and a second passage, such as an artery, vein, or heart chamber, proximate to the first passage to interconnect the first and second passages by a third passage. Fluid such as blood may be diverted from the first passage into the second passage by way of the interconnecting third passage. In embodiments in which the first passage includes an artery and the second passage includes a vein, the arterial blood can perfuse into tissue in a retrograde manner (retroperfusion).

[0175] As described above, an interconnecting passage between first and second body passages can be created by, for example, deploying a needle outwards from a first catheter located within the first passage, so that the needle traverses the interstitial tissue or septum between the first and

second passages. A second catheter may be located in the second passage, so as to provide a target device which receives a signal, for example an ultrasound signal, transmitted from the first catheter. By monitoring the received signal, the position of the first catheter with respect to the second catheter can be determined so as to ensure that the needle is deployed in the correct position and orientation to create a passage for fluid flow between the first and second passages.

[0176] In order to provide or maintain the flow of blood thorough the interconnecting passage or channel, a structure including a lumen may be inserted in the passage to support the interstitial tissue and/or to inhibit or prevent the passage from closing. The tube may, for example, include a stent expanded in the channel using a balloon catheter or self-expansion, as described herein. A catheter to deliver the structure, for example a balloon catheter or catheter that allows self-expansion, may be guided to the channel by a guidewire deployed in the passage by the first catheter.

[0177] Passages such as arteries, veins, and heart chambers can pulsate as the heart beats, for example due to movement of heart walls, peripheral limbs, and/or fluctuations in pressure within the passages themselves. This pulsation can cause movement of the passages relative to each another, which can impose stress on a structure within an interconnecting passage therebetween. This stress may be large in comparison to stress experienced by a structure within a single passage. Stress can lead to premature failure of the structure, for example by fatigue failure of the stent struts. Failure of the structure may result in injury to the interstitial tissue and/or occlusion of the interconnecting passage, which could lead to significant complications or complete failure of the therapy.

[0178] FIG. 8 illustrates a device or implant or prosthetic **100** for providing or maintaining fluid flow through at least one passage. The device **100** includes a first or proximal end portion **102**, a second or distal end portion **104**, and an intermediate portion **106** between the proximal end portion **102** and the distal end portion **104**. The device includes a bore or lumen **110** for passage of fluid through the device **100**. The device **100**, for example at least the intermediate portion **106** of the device **100**, includes a flexible polymer tube **108**. The flexible polymer tube **108** may at least partially define the lumen **110**.

[0179] The device **100** includes a support structure (e.g., at least one stent) including a mesh **112** and a mesh **114**. In some embodiments, at least a portion of the mesh **112** is embedded in the outside wall of the tube **108** proximate to the proximal end portion **102** of the device **100**. In some embodiments, at least a portion of the mesh **114**, for example a wire or a strut, is embedded in the outside wall of the tube **108** proximate to the distal end portion **104** of the device **100**. The meshes **112**, **114** may include biocompatible metal such as stainless steel and/or shape memory material such as nitinol or chromium cobalt.

[0180] The wire meshes **112**, **114** can stiffen the end portions **102**, **104**, respectively. In some embodiments in which the intermediate portion **106** does not include a mesh, the intermediate portion **106** may be relatively flexible in comparison to the end portions **102**, **104**, and/or the end portions **102**, **104** may have a relatively high radial stiffness.

[0181] In some embodiments, the end portions **102**, **104** of the device **100** are diametrically expandable. For example, the wire meshes **112**, **114** may have a smaller diameter after formation or manufacture than the passages, for example blood vessels, into which the device **100** will be deployed. When the device **100** is in position in the passages, the end portions **102**, **104** can be expanded or deformed outwardly so that the respective diameters of the end portions **102**, **104** increase, for example to abut the interior sidewalls of the passages. The end portions **102**, **104** are configured to maintain the expanded diameter indefinitely, for example by plastic deformation of the material (e.g., wires, struts) of the meshes **112**, **114** and/or by provision of a locking mechanism arranged to mechanically lock the meshes **112**, **114** in the expanded position. The intermediate portion **106** of the device **100** may be diametrically expandable, for example by way of plastic deformation of the tube **108**.

[0182] FIG. 9 shows the device 100 of FIG. 8 deployed to provide a fluid flow path between a first passage 116 and a second passage 118. The passages 116, 118 may include coronary blood vessels, for example a coronary artery 116 and a coronary vein 118, or vice versa. The passages 116, 118 may include peripheral blood vessels (e.g., blood vessels in limbs), for example a femoral or other peripheral artery 116 and a femoral or other peripheral vein 118, or vice versa. The end portions 102, 104 and the intermediate portion 106 of the device 100 have been expanded to meet with and push against the inner walls of the passages 116, 118. The distal end portion 104 of the device 100 is located within the second passage 118, and the proximal end portion 102 of the device 100 is located within the first passage 116. The intermediate portion 106 extends through an opening or interconnecting passage 130 surgically formed between the passages 116, 118.

[0183] The expanded end portions 102, 104 of the device 100 are resilient, and impart an outward radial force on the inner walls of the passages 116, 118. By virtue of the radial stiffness of the end portions 102, 104 of the device 100, the end portions 102, 104 are held or anchored in place within the respective passages 116, 118. Slippage of the device 100 within the passages 116, 118 is thereby prevented or reduced. In this way, the end portions 102, 104 of the device 100 can anchor or fix the device 100 in position, in use, while providing or maintaining fluid flow through the lumen 110 of the tube 108 (FIG. 8). In this way, the device 100 can act as a shunt between the first passage 116 and the second passage 118.

[0184] The intermediate portion 106 of the device 100 may be flexible, for example allowing the intermediate portion 106 to form an 'S' shape formed by the combination of the first passage 116, the second passage 118, and the interconnecting passage 130 (FIG. 9). The flexible intermediate portion 106 can allow the end portions 102, 104 of the device 100 to move with respect to one another in response to relative movement of the passages 116, 118.

[0185] In embodiments in which the intermediate portion 106 does not include a wire mesh but includes the flexible polymer material of the tube 108, the intermediate portion 106 may not be susceptible to damage due to mesh fatigue, for example upon cyclic or other stress imparted by relative movement of the passages 116, 118.

[0186] The intermediate portion 106 of the device 100 has sufficient resilience to maintain dilatation of the interconnecting passage 130, so that the interconnecting passage 130 remains open to provide or maintain a path for blood flow from the artery 116 to the vein 118 by way of the lumen 110 of the tube 108 (FIG. 8). Blood flow from the artery 116 to the vein 118, by way of the interconnecting passage 130, may thereby be provided or maintained through the lumen 110 of the tube 108. The device 100 at least partially supports the artery 116, the vein 118, and the interconnecting passage 130 to provide a pathway for fluid communication through the device 100.

[0187] The proximal end portion 102 and the distal end portion 104 of the device 100 are arranged so that, when the device 100 is deployed with the distal end portion 104 in a vein 118 and the proximal end portion 102 in an artery 116, for example as shown in FIG. 9, the diameter of the expanded distal end portion 104 is sufficient to hold the distal end portion 104 within the vein 118, and the diameter of the expanded proximal end portion 102 is sufficient to hold the proximal end portion 102 within the artery 116. The diameter of the proximal end portion 102 may therefore differ from the diameter of the distal end portion 104. By selecting appropriate diameters for the end portions 102, 104 and the intermediate portion 106, the device 100 can be tailored to a certain anatomy and/or the anatomy of an individual patient.

[0188] An example procedure for positioning the device 100 of FIG. 8 to provide a shunt between an occluded artery 116 and a vein 118 (e.g., a coronary artery 116 and a coronary vein 118, or a peripheral artery 116 and a peripheral vein 118) to achieve retroperfusion of arterial blood, for example as shown in FIG. 9, will now be described.

[0189] A catheter may be inserted into the patient's arterial system by way of a small aperture cut, usually in the patient's groin area. The catheter is fed to the artery 116 and guided to a position upstream of the site of the occlusion, for example at a site proximate and parallel or substantially



parallel to a vein **118**. A hollow needle is deployed from the catheter, through the wall of the artery **116**, through the interstitial tissue **132** that separates the artery **116** and vein **118**, and through the wall of the vein **118**. The path of the needle creates an interconnecting passage or opening **130**, which allows blood to flow between the artery **116** and the vein **118**. Deployment of the needle may be guided by a transmitter (e.g., a directional ultrasound transmitter) coupled to a catheter in the artery **116** and a receiver (e.g., an omnidirectional ultrasound receiver) coupled to a catheter in the vein **118**, or vice versa, for example as described herein and in U.S. patent application Ser. No. 11/662,128. Other methods of forming the opening **130** are also possible (e.g., with or without directional ultrasound guidance, with other types of guidance such as described herein, from vein to artery, etc.).

[0190] Before the needle is withdrawn from the passage **130**, a guidewire (e.g., as described with respect to the guidewire **14** of FIG. 3) is inserted through the hollow needle and into the vein **118**. The needle is then retracted, leaving the guidewire in place in the artery **116**, the passage **130**, and the vein **118**. The catheter carrying the needle can then be withdrawn from the patient's body. The guidewire can be used to guide further catheters to the interconnecting passage **130** between the artery **116** and the vein **118**.

[0191] A catheter carrying the device **100** in a non-expanded state is advanced towards the interconnecting passage **130**, guided by the guidewire, for example by a rapid exchange lumen or through the lumen **110**. The catheter may include, for example, a balloon catheter configured to expand at least a portion of the device **100** and/or a catheter configured to allow self-expansion of at least a portion of the device **100**. The distal end portion **104** of the device **100** is passed through the interconnecting passage **130** and into the vein **118**, leaving the proximal end portion **102** in the artery **116**. The intermediate portion **106** of the device **100** is at least partially in the passage **130**, and is at least partially within the artery **116** and the vein **118**. The intermediate portion **106** flexes to adopt a curved or "S"-shaped formation, depending on the anatomy of the site. Adoption of such curvature may conform the shape of an intermediate portion **106** extending through the interconnecting passage **130**, and optionally into at least one of the passages **116**, **118**, to the shape of at least the interconnecting passage **130**.

[0192] The distal end portion **104** of the device **100** is expanded, for example upon inflation of a balloon or by self-expansion, so as to increase the diameter of the distal end portion **104** and anchor the distal end portion **104** against the inner wall of the vein **118**. The catheter may be adapted to expand the intermediate portion **106** of the device **100**, for example by inflation of a balloon, so that the interconnecting passage **130** can be widened or dilated to obtain blood flow (e.g., sufficient blood flow) from the artery **116** to the vein **118**. The proximal end portion **102** of the device **100** is expanded, for example upon inflation of a balloon or by self-expansion, so as to increase the diameter of the proximal end portion **102** and anchor the proximal end portion **102** against the inner wall of the artery **116**.

[0193] After the end portions **102**, **104** of the device **100** are expanded, for example due to self-expansion and/or balloon expansion, and with or without improving expansion after deployment, the catheter and the guidewire are withdrawn from the patient's body. In this way, the device **100** is anchored or fixed in position within the vein **118**, the artery **116**, and the interconnecting passage **130** as shown in FIG. 9. In embodiments in which the device **100** comprises a stent-graft, the graft, which can form a fluid-tight passage between the artery **116** and the vein **118**, can inhibit or prevent blood from flowing antegrade in the vein **118** because such passageway is blocked, which can be in addition to or instead of a blocking agent in the vein **118**.

[0194] The catheter may be adapted to selectively expand the proximal end portion **102**, the distal end portion **104**, and/or the intermediate portion **106** of the device **100** individually or in combination, for example by the provision of two or more separately inflatable balloons or balloon portions, a single balloon configured to expand all of the portions of the device **100** simultaneously, or a single balloon configured to expand one or more selected portions of the device **100**. For

example, the end portions **102**, **104** may be self-expanding, and the intermediate portion **106** may be expanded by a balloon to dilate the passage **130**. In some embodiments including balloon expansion, all or selected parts of the device **100** may be expanded, for example, simultaneously by a balloon across the entire length of the device **100** or by a plurality of balloons longitudinally spaced to selectively inflate selected parts of the device **100**, and/or sequentially by a balloon or plurality of balloons. In some embodiments including at least partial self-expansion, all or selected parts of the device **100** may be expanded, for example, by proximal retraction of a sheath over or around the device **100**, which can lead to deployment of the device **100** from distal to proximal as the sheath is proximally retracted. Deployment of the device **100** proximal to distal and deployment of the device **100** intermediate first then the ends are also possible. In some embodiments, for example embodiments in which the device **100** is at least partially conical or tapered, a conical or tapered balloon may be used to at least partially expand the device **100**. In certain such embodiments, a portion of the balloon proximate to the vein **118** may have a larger diameter than a portion of the balloon proximate to the artery **116**, for example such that the device **100** can adapt to changing vein diameters due to any increase in pressure or blood flow in the vein **118**.

[0195] Other steps may be included in the procedure. For example, before the device **100** is deployed, a balloon catheter may be guided to the interconnecting passage **130** and positioned so that an inflatable balloon portion of the catheter lies in the interconnecting passage **130**. Upon inflation of the balloon, the balloon pushes against the walls of the interconnecting passage **130** to widen or dilate the interconnecting passage **130** to ease subsequent insertion of the device **100**.

[0196] FIG. **10** illustrates another device **134** for providing fluid flow through at least one passage. The device **134** includes a mesh **136** and a polymer tube **108**. The mesh **136** is shown as being on the outside of the polymer tube **108**, but as described herein could also or alternatively be on an inside of the polymer tube and/or within the polymer tube **108**. As described with respect to the device **100**, the device **134** includes a proximal end portion **102**, a distal end portion **104**, and an intermediate portion **106**. In the embodiment illustrated in FIG. **10**, the mesh **136** extends along the entire length of the device **134**, including along the intermediate portion **106**.

[0197] In some embodiments, the spacing of filaments or struts of the mesh **136** varies along the length of the device **134**. For example, winding density of a woven or layered filamentary mesh may be varied and/or a window size pattern of a cut mesh may be varied.

[0198] In some embodiments, the spacing may be relatively small in the proximal end portion **102** and the distal end portions **104**, and the spacing may be relatively large in the intermediate portion **106**. In other words, the density or window size of the mesh **136** may be relatively low in the intermediate portion **106**, and the density or window size of the mesh **136** may be relatively high in the end portions **102**, **104**. In certain such embodiments, the intermediate portion **106** may be flexible in comparison to the end portions **102**, **104**. The relatively rigid end portions **102**, **104** may engage and anchor in passages. Although the mesh **136** in the intermediate portion **106** may be subject to stress such as cyclic stress, in use, the relatively high flexibility of the intermediate portion **106** due to the low density or window size allows the impact of the stress to be low because the intermediate portion **106** can flex in response to the stress. The risk of fatigue failure of the device **134**, and particularly the filaments or struts **138** of the mesh **136**, may therefore be reduced in comparison to a device having uniform flexibility along its entire length.

[0199] In some embodiments, the spacing may be relatively large in the proximal end portion **102** and the distal end portions **104**, and the spacing may be relatively small in the intermediate portion **106**. In other words, the density of the mesh **136** may be relatively high (or the window size of the mesh **136** may be relatively low) in the intermediate portion **106**, and the density of the mesh **136** may be relatively low (or the window size of the mesh **136** may be relatively high) in the end portions **102**, **104**. In certain such embodiments, the intermediate portion **106** may have radial strength sufficient to inhibit or prevent collapse of the passage **130**, yet still, flexible enough to flex in response to stress such as cyclic stress. The end portions **102**, **104** may engage and anchor in

passages.

[0200] FIG. 11 illustrates another device or implant or prosthetic **140** for providing fluid flow through at least one passage. As described with respect to the device **100**, the device **140** includes a proximal end portion **102**, a distal end portion **104**, and an intermediate portion **106**. The device **140** includes a polymer tube **108** and a support structure including a first mesh **142** and a second mesh **144**. The first mesh **142** extends from the proximal end portion **102** toward (e.g., into) the intermediate portion **106** and optionally into the distal end portion **104**. The second mesh **144** extends from the distal end portion **104** toward (e.g., into) the intermediate portion **106** and optionally into the proximal end portion **102**. The meshes **142**, **144** thereby overlap each other at least in the intermediate portion **106**. Both meshes **142**, **144** may be on the outside of the tube **108**, on the inside of the tube **108**, or embedded within the tube **108**, or one mesh may be on the outside of the tube **108**, on the inside of the tube **108**, or embedded within the tube **108** while the other mesh is differently on the outside of the tube **108**, on the inside of the tube **108**, or embedded within the tube **108** (e.g., one mesh inside the tube **108** and one mesh outside the tube **108**). The meshes **142**, **144** may be formed, for example, by winding wire in a lattice configuration around or inside the polymer tube **108**, by placing a cut tube around or inside the polymer tube **108**, by being embedded in the polymer tube **108**, combinations thereof, and the like.

[0201] In some embodiments, the density of the meshes **142**, **144** is relatively high (or the window size of the meshes **142**, **144** is relatively low) in their respective end portions **102**, **104** and decreases in density (or increases in window size) towards the intermediate portion **106**. The total winding density (e.g., the winding density of both meshes **142**, **144**, taken together) may be lower in the intermediate portion **106** than in the end portions **102**, **104**, or the total window size (e.g., the window size of both meshes **142**, **144**, taken together) may be higher in the intermediate portion **106** than in the end portions **102**, **104**. In certain such embodiments, the intermediate portion **106** is relatively flexible in comparison to the end portions **102**, **104**. In some embodiments, the meshes **142**, **144** do not extend into the intermediate portion, and absence of a mesh could cause the intermediate portion **106** to be relatively flexible in comparison to the end portions **102**, **104**. In some embodiments, as window size increases (e.g., longitudinally along a tapered portion of the device **140**), the density decreases, the mesh coverage decreases, and/or the porosity increases because the width of the struts and/or filaments remains substantially constant or constant or does not increase in the same proportion as the window size, which could provide a change in flexibility along a longitudinal length.

[0202] The first and second meshes **142**, **144** may include different materials, which can allow optimization of the properties of each of the respective distal and proximal end portions **102**, **104** of the device **140** for a particular application of the device **140**. For example, the second mesh **144** at the distal end portion **104** of the device **140** may include a relatively flexible metallic alloy for ease of insertion through an interconnecting passage between two blood vessels, while the first mesh **142** at the proximal end portion **102** of the device **140** may include a relatively inelastic metallic alloy to provide a high degree of resilience at the proximal end portion **104** to anchor the device **140** firmly in position. The first and second meshes **142**, **144** could include the same material composition (e.g., both including nitinol) but different wire diameters (gauge) or strut thicknesses.

[0203] FIG. 12 illustrates another device or implant or prosthetic **150** for providing fluid flow through at least one passage. The device **150** includes a support structure (e.g., stent) **152** and a graft **154**. As described with respect to the device **100**, the device **150** includes a proximal end portion **102**, a distal end portion **104**, and an intermediate portion **106**. The proximal end portion **102** includes a cylindrical or substantially cylindrical portion and the distal end portion **104** includes a cylindrical or substantially cylindrical portion. The diameter of the proximal end portion **102** is smaller than the diameter of the distal end portion **104**. In some embodiments, the diameter of the proximal end portion **102** is larger than the diameter of the distal end portion **104**. The intermediate portion **106** has a tapered or frustoconical shape between the proximal end portion **102**

and the distal end portion **104**. The stent **152** may include filaments (e.g., woven, layered), a cut tube or sheet, and/or combinations thereof.

[0204] Parameters of the stent **152** may be uniform or substantially uniform across a portion and/or across multiple portions, or may vary within a portion and/or across multiple portions. For example, the stent **152** at the proximal end portion **102** may include a cut tube or sheet, the stent **152** at the distal end portion **104** may include a cut tube or sheet, and the stent **152** at the intermediate portion **106** may include filaments (e.g., woven or layered). Certain such embodiments may provide good anchoring by the proximal end portion **102** and the distal end portion **104** and good flexibility (e.g., adaptability to third passage sizes and dynamic stresses) of the intermediate portion **106**.

[0205] The stent **152** may include different materials in different portions. For example, the stent **152** at the proximal end portion **102** may include chromium cobalt and/or tantalum, the stent **152** at the distal end portion **104** may include nitinol, and the stent **152** at the intermediate portion **106** may include nitinol. Certain such embodiments may provide good anchoring and/or wall apposition by the device **150** in each deployment areas (e.g., the proximal end portion **102** engaging sidewalls of an artery, the distal end portion **104** engaging sidewalls of a vein, and the intermediate portion **106** engaging sidewalls of the passage between the artery and the vein). In some embodiments in which the distal end portion **104** is self-expanding, the distal end portion **104** can adapt due to changing vessel diameter (e.g., if vein diameter increases due to an increase in pressure or blood flow), for example by further self-expanding.

[0206] Combinations of support structure materials and types are also possible. For example, the stent **152** at the proximal portion may include a cut tube or sheet including chromium cobalt and/or tantalum, the stent **152** at the distal end portion **104** may include a cut tube or sheet including nitinol, and the stent **152** at the intermediate portion **106** may include filaments including nitinol.

[0207] In embodiments in which the stent **152** includes at least one portion including a cut tube or sheet, the cut pattern may be the same. For example, the cut pattern may be the same in the proximal end portion **102** and the distal end portion **104**, but proportional to the change in diameter. In some embodiments, the window size or strut density is uniform or substantially uniform within a portion **102**, **104**, **106**, within two or more of the portions **102**, **104**, **106**, and/or from one end of the stent **152** to the other end of the stent **152**. In embodiments in which the stent **152** includes at least one portion including filaments, the winding may be the same. For example, the winding may be the same in the proximal end portion **102** and the distal end portion **104**, but changed due to the change in diameter. In some embodiments, the winding density or porosity is uniform or substantially uniform within a portion **102**, **104**, **106**, within two or more of the portions **102**, **104**, **106**, and/or from one end of the stent **152** to the other end of the stent **152**. In embodiments in which the stent **152** includes at least one portion including a cut tube or sheet and at least one portion including filaments, the cut pattern and winding may be configured to result in a uniform or substantially uniform density. Non-uniformity is also possible, for example as described herein.

[0208] The graft **154** may include materials and attachment to the stent **152** as described with respect to the tube **108**. The graft **154** generally forms a fluid-tight passage for at least a portion of the device **150**. Although illustrated as only being around the intermediate portion **106**, the graft **154** may extend the entire length of the device **150**, or may partially overlap into at least one of the cylindrical end portions **102**, **104**.

[0209] FIG. **13** illustrates another device **160** for providing fluid flow through at least one passage. The device **160** includes a support structure (e.g., stent) and a graft **164**. As described with respect to the device **100**, the device **160** includes a proximal end portion **102**, a distal end portion **104**, and an intermediate portion **106**. The proximal end portion **102** includes a tapered or frustoconical portion and the distal end portion **104** includes a tapered or frustoconical portion. The diameter of the proximal end of the proximal end portion **102** is smaller than the diameter of the distal end of the distal end portion **104**. In some embodiments, the diameter of the proximal end of the proximal

end portion **102** is larger than the diameter of the distal end of the distal end portion **104**. The intermediate portion **106** has a tapered or frustoconical shape between the proximal end portion **102** and the distal end portion **104**. In some embodiments, the angle of inclination of the portions **102**, **104**, **106** is the same or substantially the same (e.g., as illustrated in FIG. **13**). In some embodiments, the angle of inclination of at least one portion is sharper or narrower than at least one other portion. The frustoconical proximal end portion **102** and distal end portion **104** may allow better anchoring in a body passage, for example because arteries tend to taper with distance from the heart and veins tend to taper with distance towards the heart, and the end portions **102**, **104** can be configured to at least partially correspond to such anatomical taper.

[0210] FIG. **12** illustrates a device **150** comprising a first cylindrical or straight portion, a conical or tapered portion, and second cylindrical or straight portion. FIG. **13** illustrates a device **160** comprising one or more conical or tapered sections (e.g., the entire device **160** being conical or tapered or comprising a plurality of conical or tapered sections). In some embodiments, combinations of the devices **150**, **160** are possible. For example, a device may comprise a cylindrical or straight portion and a conical or tapered portion for the remainder of the device. In certain such embodiments, the device may have a length between about 1 cm and about 10 cm (e.g., about 5 cm), which includes a cylindrical or straight portion having a diameter between about 1 mm and about 5 mm (e.g., about 3 mm) and a length between about 0.5 cm and about 4 cm (e.g., about 2 cm) and a conical or tapered portion having a diameter that increases from the diameter of the cylindrical or straight portion to a diameter between about 3 mm and about 10 mm (e.g., about 5 mm) and a length between about 1 cm and about 6 cm (e.g., about 3 cm). Such a device may be devoid of another cylindrical or conical portion thereafter.

[0211] As described above with respect to the support structure **152**, the support structure **162** may include filaments (e.g., woven, layered), a cut tube or sheet, the same materials, different materials, and combinations thereof.

[0212] The graft **164** may include materials and attachment to the stent **162** as described with respect to the tube **108**. The graft **164** generally forms a fluid-tight passage for at least a portion of the device **160**. Although illustrated as only being around the intermediate portion **106**, the graft **164** may extend the entire length of the device **160**, or may partially overlap into at least one of the frustoconical end portions **102**, **104**.

[0213] In some embodiments, a combination of the device **150** and the device **160** are possible. For example, the proximal end portion **102** can be cylindrical or substantially cylindrical (e.g., as in the device **150**), the distal end portion **104** can be tapered or frustoconical (e.g., as in the device **160**), with the proximal end portion **102** having a larger diameter than the distal end of the distal end portion **104**. For another example, the proximal end portion **102** can be tapered or frustoconical (e.g., as in the device **160**), the distal end portion **104** can be cylindrical or substantially cylindrical (e.g., as in the device **150**), with the proximal end of the proximal end portion **102** having a larger diameter than the distal end portion **104**. In each example, the intermediate portion **106** can have a tapered or frustoconical shape between the proximal end portion **102** and the distal end portion **104**.

[0214] An example deployment device for the implantable devices described herein is described in U.S. patent application Ser. No. 12/545,982, filed Aug. 24, 2009, and U.S. patent application Ser. No. 13/486,249, filed Jun. 1, 2012, the entire contents of each of which is hereby incorporated by reference. The device generally includes a handle at the proximal end with a trigger actuable by a user and a combination of tubular member at the distal end configured to be pushed and/or pulled upon actuation of the trigger to release the device. Other delivery devices are also possible. The delivery device may include a portion slidable over a guidewire (e.g., a guidewire that has been navigated between the artery and the vein via a tissue traversing needle) and/or may be trackable through a lumen of a catheter.

[0215] Although certain embodiments and examples are shown or described herein in detail,

various combinations, sub-combinations, modifications, variations, substitutions, and omissions of the specific features and aspects of those embodiments are possible, some of which will now be described by way of example only.

[0216] The device, for example a stent of the device, a mesh of the device, a support structure of the device, etc., may be self-expanding. For example, a mesh may include a shape-memory material, such as nitinol, which is capable of returning to a pre-set shape after undergoing deformation. In some embodiments, the stent may be manufactured to a shape that is desired in the expanded configuration, and is compressible to fit inside a sleeve for transport on a catheter to a vascular site. To deploy and expand the stent, the sleeve is drawn back from the stent to allow the shape memory material to return to the pre-set shape, which can anchor the stent in the passages, and which may dilate the passages if the stent has sufficient radial strength. The use of a balloon catheter is not required to expand a fully self-expanding stent, but may be used, for example, to improve or optimize the deployment.

[0217] A device may include one or more self-expanding portions, and one or more portions which are expandable by deformation, for example using a balloon catheter. For example, in the embodiment shown in FIG. 11, the first mesh 142 may include stainless steel expandable by a balloon catheter, and the second mesh 144 may include nitinol for self-expansion upon deployment.

[0218] With respect to any of the embodiments described herein, the polymer tube 108, including the grafts 154, 164, may include any suitable compliant or flexible polymer, such as PTFE, silicone, polyethylene terephthalate (PET), polyurethane such as polycarbonate aromatic biodegradable thermoplastic polyurethane elastomer (e.g., ChronoFlex C® 80A and 55D medical grade, available from AdvanSource Biomaterials of Wilmington, Massachusetts), combinations thereof, and the like. The polymer tube 108 may include biodegradable, bioabsorbable, or biocompatible polymer (e.g., polylactic acid (PLA), polyglycolic acid (PGA), polyglycolic-lactic acid (PLGA), polycaprolactone (PCL), polyorthoesters, polyanhydrides, combinations thereof, etc.). The polymer may be in tube form before interaction with a support structure (e.g., stent), or may be formed on, in, and/or around a support structure (e.g., stent). For example, the polymer may include spun fibers, a dip-coating, combinations thereof, and the like. In some embodiments, for example when the device is to be deployed within a single blood vessel, the device may omit the tube. In certain such embodiments, the intermediate portion of the stent may include a mesh with a low winding density or high window size, while the end portions of the stent include a mesh with a higher winding density or lower window size, the mesh being generally tubular to define a pathway for fluid flow through the center of the mesh. In some embodiments, the polymer tube 108 includes a lip (e.g., comprising the same or different material), which can help form a fluid-tight seal between the polymer tube 108 and the body passages. The seal may be angled, for example to account for angled positioning of the polymer tube 108 between body passages. In some embodiments, the polymer tube 108 may extend longitudinally beyond the support structure in at least one direction, and the part extending beyond is not supported by the support structure.

[0219] The mesh may include any suitable material, such as nickel, titanium, chromium, cobalt, tantalum, platinum, tungsten, iron, manganese, molybdenum, combinations thereof (e.g., nitinol, chromium cobalt, stainless steel), and the like. The mesh may include biodegradable, bioabsorbable, or biocompatible polymer (e.g., polylactic acid (PLA), polyglycolic acid (PGA), polyglycolic-lactic acid (PLGA), polycaprolactone (PCL), polyorthoesters, polyanhydrides, combinations thereof, etc.) and/or glass, and may lack metal. Different materials may be used for portions of the mesh or within the same mesh, for example as previously described with reference to FIG. 11. For example, the mesh 114 at the distal end portion 104 and the mesh 112 at the proximal end portion 102 of the device 100 may include different materials. For another example, the mesh 112, and/or the mesh 114, may include a metallic alloy (e.g., comprising cobalt, chromium, nickel, titanium, combinations thereof, and the like) in combination with a different type of metallic alloy (e.g., a shape memory alloy in combination with a non-shape memory alloy, a

first shape memory alloy in combination with a second shape memory alloy different than the first shape memory alloy, a clad material (e.g., comprising a core including a radiopaque material such as titanium, tantalum, rhenium, bismuth, silver, gold, platinum, iridium, tungsten, etc.)) and/or a non-metallic material such as a polymer (e.g., polyester fiber), carbon, and/or bioabsorbable glass fiber. In some embodiments, at least one mesh **112**, **114** comprises nitinol and stainless steel. The nitinol may allow some self-expansion (e.g., partial and/or full self-expansion), and the mesh could then be further expanded, for example using a balloon.

[0220] Although generally illustrated in FIGS. **8**, **10**, and **11** as a woven filament mesh, any other structure that can provide the desired degree of resilience may be used. For example, layers of filaments wound in opposite directions may be fused at the filament ends to provide an expandable structure. For another example, a metal sheet may be cut (e.g., laser cut, chemically etched, plasma cut, etc.) to form perforations and then heat set in a tubular formation or a metal tube (e.g., hypotube) may be cut (e.g., laser cut, chemically etched, plasma cut, etc.) to form perforations. A cut tube (including a cut sheet rolled into a tube) may be heat set to impart an expanded configuration.

[0221] Filaments or wires or ribbons that may be woven or braided, or layered or otherwise arranged, are generally elongate and have a circular, oval, square, rectangular, etc. transverse cross-section. Example non-woven filaments can include a first layer of filaments wound in a first direction and a second layer of filaments wound in a second direction, at least some of the filament ends being coupled together (e.g., by being coupled to an expandable ring). Example braid patterns include one-over-one-under-one, a one-over-two-under-two, a two-over-two-under-two, and/or combinations thereof, although other braid patterns are also possible. At filament crossings, filaments may be helically wrapped, cross in sliding relation, and/or combinations thereof. Filaments may be loose (e.g., held together by the weave) and/or include welds, coupling elements such as sleeves, and/or combinations thereof. Ends of filaments can be bent back, crimped (e.g., end crimp with a radiopaque material such as titanium, tantalum, rhenium, bismuth, silver, gold, platinum, iridium, tungsten, etc. that can also act as a radiopaque marker), twisted, ball welded, coupled to a ring, combinations thereof, and the like. Weave ends may include filament ends and/or bent-back filaments, and may include open cells, fixed or unfixed filaments, welds, adhesives, or other means of fusion, radiopaque markers, combinations thereof, and the like. Parameters of the filaments may be uniform or substantially uniform across a portion and/or across multiple portions, or may vary within a portion and/or across multiple portions. For example, the proximal end portion **102** may include a first parameter and the distal end portion **104** may include a second parameter different than the first braid pattern. For another example, the proximal end portion **102** and the distal end portion **104** may each include a first parameter and the intermediate portion **106** may include a second parameter different than the parameter. For yet another example, at least one of the proximal end portion **102**, the distal end portion **104**, and the intermediate portion **106** may include both a first parameter and a second parameter different than the first parameter. Filament parameters may include, for example, filament type, filament thickness, filament material, quantity of filaments, weave pattern, layering, wind direction, pitch, angle, crossing type, filament coupling or lack thereof, filament end treatment, weave end treatment, layering end treatment, quantity of layers, presence or absence of welds, radiopacity, braid pattern, density, porosity, filament angle, braid diameter, winding diameter, and shape setting.

[0222] Tubes or sheets may be cut to form strut or cell patterns, struts being the parts of the tube or sheet left after cutting and cells or perforations or windows being the parts cut away. A tube (e.g., hypotube) may be cut directly, or a sheet may be cut and then rolled into a tube. The tube or sheet may be shape set before or after cutting. The tube or sheet may be welded or otherwise coupled to itself, to another tube or sheet, to filaments, to a graft material, etc. Cutting may be by laser, chemical etchant, plasma, combinations thereof, and the like. Example cut patterns include helical spiral, weave-like, coil, individual rings, sequential rings, open cell, closed cell, combinations

thereof, and the like. In embodiments including sequential rings, the rings may be coupled using flex connectors, non-flex connectors, and/or combinations thereof. In embodiments including sequential rings, the rings connectors (e.g., flex, non-flex, and/or combinations thereof) may intersect ring peaks, ring valleys, intermediate portions of struts, and/or combinations thereof (e.g., peak-peak, valley-valley, mid-mid, peak-valley, peak-mid, valley-mid, valley-peak, mid-peak, mid-valley). The tube or sheet or sections thereof may be ground and/or polished before or after cutting. Interior ridges may be formed, for example to assist with fluid flow. Parameters of the cut tube or sheet may be uniform or substantially uniform across a portion and/or across multiple portions, or may vary within a portion and/or across multiple portions. For example, the proximal end portion **102** may include a first parameter and the distal end portion **104** may include a second parameter different than the first parameter. For another example, the proximal end portion **102** and the distal end portion **104** may each include a first parameter and the intermediate portion **106** may include a second parameter different than the parameter. For yet another example, at least one of the proximal end portion **102**, the distal end portion **104**, and the intermediate portion **106** may include both a first parameter and a second parameter different than the first parameter. Cut tube or sheet parameters may include, for example, radial strut thickness, circumferential strut width, strut shape, cell shape, cut pattern, cut type, material, density, porosity, tube diameter, and shape setting.

[0223] In some embodiments, the perforations may provide the mesh with a relatively flexible intermediate portion and relatively stiff end portions. The supporting structure may instead be an open-cell foam disposed within the tube.

[0224] Filaments of a stent, stent-graft, or a portion thereof, and/or struts of a cut stent, stent-graft, or a portion thereof, may be surface modified, for example to carry medications such as thrombosis modifiers, fluid flow modifiers, antibiotics, etc. Filaments of a stent, stent-graft, or a portion thereof, and/or struts of a cut stent, stent-graft, or a portion thereof, may be at least partially covered with a coating including medications such as thrombosis modifiers, fluid flow modifiers, antibiotics, etc., for example embedded within a polymer layer or a series of polymer layers, which may be the same as or different than the polymer tube **108**.

[0225] Thickness (e.g., diameter) of filaments of a stent, stent-graft, or a portion thereof, and/or struts of a cut stent, stent-graft, or a portion thereof, may be between about 0.0005 inches and about 0.02 inches, between about 0.0005 inches and about 0.015 inches, between about 0.0005 inches and about 0.01 inches, between about 0.0005 inches and about 0.008 inches, between about 0.0005 inches and about 0.007 inches, between about 0.0005 inches and about 0.006 inches, between about 0.0005 inches and about 0.005 inches, between about 0.0005 inches and about 0.004 inches, between about 0.0005 inches and about 0.003 inches, between about 0.0005 inches and about 0.002 inches, between about 0.0005 inches and about 0.001 inches, between about 0.001 inches and about 0.02 inches, between about 0.001 inches and about 0.015 inches, between about 0.001 inches and about 0.01 inches, between about 0.001 inches and about 0.008 inches, between about 0.001 inches and about 0.007 inches, between about 0.001 inches and about 0.006 inches, between about 0.001 inches and about 0.005 inches, between about 0.001 inches and about 0.004 inches, between about 0.001 inches and about 0.003 inches, between about 0.001 inches and about 0.002 inches, between about 0.002 inches and about 0.02 inches, between about 0.002 inches and about 0.015 inches, between about 0.002 inches and about 0.01 inches, between about 0.002 inches and about 0.008 inches, between about 0.002 inches and about 0.007 inches, between about 0.002 inches and about 0.006 inches, between about 0.002 inches and about 0.005 inches, between about 0.002 inches and about 0.004 inches, between about 0.002 inches and about 0.003 inches, between about 0.003 inches and about 0.02 inches, between about 0.003 inches and about 0.015 inches, between about 0.003 inches and about 0.01 inches, between about 0.003 inches and about 0.008 inches, between about 0.003 inches and about 0.007 inches, between about 0.003 inches and about 0.006 inches, between about 0.003 inches and about 0.005 inches, between about 0.003 inches and about 0.004 inches, between about 0.004 inches and about 0.02 inches, between about 0.004 inches and about



0.015 inches, between about 0.004 inches and about 0.01 inches, between about 0.004 inches and about 0.008 inches, between about 0.004 inches and about 0.007 inches, between about 0.004 inches and about 0.006 inches, between about 0.004 inches and about 0.005 inches, between about 0.005 inches and about 0.02 inches, between about 0.005 inches and about 0.015 inches, between about 0.005 inches and about 0.01 inches, between about 0.005 inches and about 0.008 inches, between about 0.005 inches and about 0.007 inches, between about 0.005 inches and about 0.006 inches, between about 0.006 inches and about 0.02 inches, between about 0.006 inches and about 0.015 inches, between about 0.006 inches and about 0.01 inches, between about 0.006 inches and about 0.008 inches, between about 0.006 inches and about 0.007 inches, between about 0.007 inches and about 0.02 inches, between about 0.007 inches and about 0.015 inches, between about 0.007 inches and about 0.01 inches, between about 0.007 inches and about 0.008 inches, between about 0.008 inches and about 0.02 inches, between about 0.008 inches and about 0.015 inches, between about 0.008 inches and about 0.01 inches, between about 0.01 inches and about 0.02 inches, between about 0.01 inches and about 0.015 inches, or between about 0.015 inches and about 0.02 inches. Other thicknesses are also possible, including thicknesses greater than or less than the identified thicknesses. Filaments and/or struts comprising certain materials (e.g., biodegradable material, materials with less restoring force, etc.) may be thicker than the identified thicknesses.

[0226] Thicknesses of filaments and/or struts may be based, for example, on at least one of device or device portion size (e.g., diameter and/or length), porosity, radial strength, material, quantity of filaments and/or struts, cut pattern, weave pattern, layering pattern, and the like. For example, larger filament and/or strut thicknesses (e.g., greater than about 0.006 inches) may be useful for large devices or device portions used to treat large vessels such as coronary vessels, mid-sized filament and/or strut thicknesses (e.g., between about 0.003 inches and about 0.006 inches) may be useful for mid-sized used to treat mid-sized vessels such as peripheral vessels, and small filament and/or strut thicknesses (e.g., less than about 0.003 inches) may be useful for small devices or device portions used to treat small vessels such as veins and neurological vessels.

[0227] The internal or external diameter of a stent, a stent-graft, or a first end portion, second end portion, intermediate portion, or subportion thereof, for example taking into account filament or strut thickness, may be between about 1 mm and about 12 mm, between about 1 mm and about 10 mm, between about 1 mm and about 8 mm, between about 1 mm and about 6 mm, between about 1 mm and about 4 mm, between about 1 mm and about 2 mm, between about 2 mm and about 12 mm, between about 2 mm and about 10 mm, between about 2 mm and about 8 mm, between about 2 mm and about 6 mm, between about 2 mm and about 4 mm, between about 4 mm and about 12 mm, between about 4 mm and about 10 mm, between about 4 mm and about 8 mm, between about 4 mm and about 6 mm, between about 6 mm and about 12 mm, between about 6 mm and about 10 mm, between about 6 mm and about 8 mm, between about 8 mm and about 12 mm, between about 8 mm and about 10 mm, or between about 10 mm and about 12 mm. Certain such diameters may be suitable for treating, for example, coronary vessels. The internal or external diameter of a stent, a stent-graft, or a portion thereof, for example taking into account filament or strut thickness, may be between about 1 mm and about 10 mm, between about 1 mm and about 8 mm, between about 1 mm and about 6 mm, between about 1 mm and about 4 mm, between about 1 mm and about 2 mm, between about 2 mm and about 10 mm, between about 2 mm and about 8 mm, between about 2 mm and about 6 mm, between about 2 mm and about 4 mm, between about 4 mm and about 10 mm, between about 4 mm and about 8 mm, between about 4 mm and about 6 mm, between about 6 mm and about 10 mm, between about 6 mm and about 8 mm, or between about 8 mm and about 10 mm. Certain such diameters may be suitable for treating, for example, veins. The internal or external diameter of a stent, a stent-graft, or a portion thereof, for example taking into account filament or strut thickness, may be between about 6 mm and about 25 mm, between about 6 mm and about 20 mm, between about 6 mm and about 15 mm, between about 6 mm and about 12 mm,

between about 6 mm and about 9 mm, between about 9 mm and about 25 mm, between about 9 mm and about 20 mm, between about 9 mm and about 15 mm, between about 9 mm and about 12 mm, between about 12 mm and about 25 mm, between about 12 mm and about 20 mm, between about 12 mm and about 15 mm, between about 15 mm and about 25 mm, between about 15 mm and about 20 mm, or between about 20 mm and about 25 mm. Certain such diameters may be suitable for treating, for example, peripheral vessels. The internal or external diameter of a stent, a stent-graft, or a portion thereof, for example taking into account filament or strut thickness, may be between about 20 mm and about 50 mm, between about 20 mm and about 40 mm, between about 20 mm and about 35 mm, between about 20 mm and about 30 mm, between about 30 mm and about 50 mm, between about 30 mm and about 40 mm, between about 30 mm and about 35 mm, between about 35 mm and about 50 mm, between about 35 mm and about 40 mm, or between about 40 mm and about 50 mm. Certain such diameters may be suitable for treating, for example, aortic vessels. Other diameters are also possible, including diameters greater than or less than the identified diameters. The diameter of the device may refer to the diameter of the first end portion, the second end portion, or the intermediate portion, each of which may be in expanded or unexpanded form. The diameter of the device may refer to the average diameter of the device when all of the portions of the device are in either expanded or unexpanded form.

[0228] The length of a stent, a stent-graft, or a first end portion, second end portion, intermediate portion, or subportion thereof may be between about 5 mm and about 150 mm, between about 5 mm and about 110 mm, between about 5 mm and about 70 mm, between about 5 mm and about 50 mm, between about 5 mm and about 25 mm, between about 5 mm and about 20 mm, between about 5 mm and about 10 mm, between about 10 mm and about 150 mm, between about 10 mm and about 110 mm, between about 10 mm and about 70 mm, between about 10 mm and about 50 mm, between about 10 mm and about 25 mm, between about 10 mm and about 20 mm, between about 20 mm and about 150 mm, between about 20 mm and about 110 mm, between about 20 mm and about 70 mm, between about 20 mm and about 50 mm, between about 20 mm and about 25 mm, between about 25 mm and about 150 mm, between about 25 mm and about 110 mm, between about 25 mm and about 70 mm, between about 25 mm and about 50 mm, between about 50 mm and about 150 mm, between about 50 mm and about 110 mm, between about 50 mm and about 70 mm, between about 70 mm and about 150 mm, between about 70 mm and about 110 mm, or between about 110 mm and about 150 mm. Other lengths are also possible, including lengths greater than or less than the identified lengths.

[0229] The porosity of a stent, a stent-graft, or a first end portion, second end portion, intermediate portion, or subportion thereof may be between about 5% and about 95%, between about 5% and about 50%, between about 5% and about 25%, between about 5% and about 10%, between about 10% and about 50%, between about 10% and about 25%, between about 25% and about 50%, between about 50% and about 95%, between about 50% and about 75%, between about 50% and about 60%, between about 60% and about 95%, between about 75% and about 90%, between about 60% and about 75%, and combinations thereof. The density of a stent may be inverse to the porosity of that stent. The porosity of a portion of a stent covered by a graft may be about 0%. The porosity may vary by objectives for certain portions of the stent. For example, the intermediate portion may have a low porosity to increase fluid flow through the device, while end portions may have lower porosity to increase flexibility and wall apposition.

[0230] FIG. 25A is a schematic side elevational view of yet another example embodiment of a prosthesis **500**. The prosthesis or stent or device **500** includes and/or consist essentially of a plurality of filaments **502** woven together into a woven structure. The stent **500** may be devoid of graft material, as described in further detail below.

[0231] The filaments **502**, which may also be described as wires, ribbons, strands, and the like, may be woven, braided, layered, or otherwise arranged in a crossing fashion. The filaments **502** are generally elongate and have a circular, oval, square, rectangular, etc. transverse cross-section.

Example non-woven filaments can include a first layer of filaments wound in a first direction and a second layer of filaments wound in a second direction, at least some of the filament ends being coupled together (e.g., by being coupled to an expandable ring). Example weave patterns include one-over-one-under-one (e.g., as shown in FIG. 25A), a one-over-two-under-two, a two-over-two-under-two, and/or combinations thereof, although other weave patterns are also possible. At crossings of the filaments **502**, the filaments **502** may be helically wrapped, cross in sliding relation, and/or combinations thereof. The filaments **502** may be loose (e.g., held together by the weave) and/or include welds, coupling elements such as sleeves, and/or combinations thereof. Ends of filaments **502** can be bent back, crimped (e.g., end crimp with a radiopaque material such as titanium, tantalum, rhenium, bismuth, silver, gold, platinum, iridium, tungsten, etc. that can also act as a radiopaque marker), twisted, ball welded, coupled to a ring, combinations thereof, and the like. Weave ends may include filament **502** ends and/or bent-back filaments **502**, and may include open cells, fixed or unfixed filaments **502**, welds, adhesives, or other means of fusion, radiopaque markers, combinations thereof, and the like.

[0232] The stent **500** includes pores **504** or open, non-covered areas between the filaments **502**. The porosity of the stent **500** may be computed as the outer surface area of the pores **504** divided by the total outer surface area of the stent **500**. The porosity may be affected by parameters such as, for example, the number of filaments **502**, the braid angle **506**, the size (e.g., diameter) of the filaments **502**, and combinations thereof.

[0233] The porosity of the stent **500** may be less than about 50% (e.g., slightly more covered than open), between about 0% (e.g., almost no open area) and about 50%, between about 0% and about 45%, between about 0% and about 40%, between about 0% and about 35%, between about 0% and about 30%, between about 0% and about 25%, between about 0% and about 20%, between about 0% and about 15%, between about 0% and about 10%, between about 0% and about 5%, between about 5% and about 50%, between about 5% and about 45%, between about 5% and about 40%, between about 5% and about 35%, between about 5% and about 30%, between about 5% and about 25%, between about 5% and about 20%, between about 5% and about 15%, between about 5% and about 10%, between about 10% and about 50%, between about 10% and about 45%, between about 10% and about 40%, between about 10% and about 35%, between about 10% and about 30%, between about 10% and about 25%, between about 10% and about 20%, between about 10% and about 15%, between about 15% and about 50%, between about 15% and about 45%, between about 15% and about 40%, between about 15% and about 35%, between about 15% and about 30%, between about 15% and about 25%, between about 15% and about 20%, between about 20% and about 50%, between about 20% and about 45%, between about 20% and about 40%, between about 20% and about 35%, between about 20% and about 30%, between about 20% and about 25%, between about 20% and about 15%, between about 20% and about 10%, between about 25% and about 50%, between about 25% and about 45%, between about 25% and about 40%, between about 25% and about 35%, between about 25% and about 30%, between about 25% and about 15%, between about 25% and about 10%, between about 30% and about 50%, between about 30% and about 45%, between about 30% and about 40%, between about 30% and about 35%, between about 30% and about 25%, between about 30% and about 20%, between about 30% and about 15%, between about 30% and about 10%, between about 35% and about 50%, between about 35% and about 45%, between about 35% and about 40%, between about 35% and about 30%, between about 35% and about 25%, between about 35% and about 20%, between about 35% and about 15%, between about 35% and about 10%, between about 40% and about 50%, between about 40% and about 45%, between about 40% and about 30%, between about 40% and about 25%, between about 40% and about 20%, between about 40% and about 15%, between about 40% and about 10%, between about 45% and about 50%, between about 45% and about 40%, between about 45% and about 30%, between about 45% and about 25%, between about 45% and about 20%, between about 45% and about 15%, between about 45% and about 10%, and combinations thereof.

[0234] In some embodiments in which the porosity is less than about 50%, blood may be unable to perfuse through the sidewalls of the stent **500** under normal vascular pressures (e.g., a pressure drop across a vessel, a pressure drop from an afferent vessel to an efferent vessel). In certain such embodiments, blood flowing into a proximal end of the stent **500** can be directed through a lumen of the stent **500** to a distal end of the stent **500** without (e.g., substantially without, free of, substantially free of) graft material, but still without loss or substantial loss of blood through the sidewalls of the stent **500**. By contrast, in certain so-called “flow diverting stents,” the porosity is specifically designed to be greater than about 50% in order to ensure perfusion to efferent vessels.

[0235] The density of the stent **500** may be inverse to the porosity (e.g., the outer surface area of

the filaments **502** divided by the total outer surface area of the stent **500**). The density of the stent **500** may be 100% minus the porosity values provided above.

[0236] The filaments **502** are at a braid angle **506** relative to an axis perpendicular to the longitudinal axis of the stent **500** (e.g., as illustrated by the example dashed line in FIG. 25A). The braid angle **506** can range from just more than 90° to just under 180°. The braid angle **506** can be acute or obtuse. In some embodiments, the braid angle **506** is between about 90° and about 180°, between about 120° and about 180°, between about 150° and about 180°, between about 160° and about 180°, between about 170° and about 180°, between about 160° and about 170°, between about 165° and about 175°, combinations thereof, and the like. In some embodiments, the closer the braid angle **506** is to 180°, the greater the radial strength of the stent **500**. Devices **500** with greater radial strength may aid in keeping a fistula (e.g., formed as described herein) open or patent. Other factors can also influence radial strength such as filament **502** diameter, filament **502** material, number of filaments **502**, etc.

[0237] The filaments **502** may all be the same or some of the filaments **502** may have a different parameter (e.g., material, dimensions, combinations thereof, and the like). In some embodiments, some of the filaments **502** comprise shape memory material (e.g., comprising nitinol) and others of the filaments **502** comprise another material (e.g., comprising aramid fiber (e.g., Kevlar®), Dacron®, biocompatible polymer, etc.). The shape memory material may provide the mechanical structure and the other material may provide low porosity (e.g., by being thick in the dimension of the sidewalls).

[0238] FIG. 25B is a schematic side elevational view of still yet another example embodiment of a prosthesis **520**. The prosthesis or stent or device **520** includes and/or consist essentially of a first plurality of filaments **522** woven together into a first woven structure and a second plurality of filaments **524** woven together into a second woven structure. The stent **520** may be devoid of graft material, as described in further detail herein. The first plurality of filaments **522** may be similar to the filaments **502** of the stent **500** described with respect to FIG. 25A. In some embodiments, the filaments **522** may lack sufficient radial force to keep a fistula open and/or to appose sidewalls of an artery and/or a vein. In certain such embodiments, the filaments **524** may act as a supplemental support structure to provide the radial force. The filaments **524** may be radially outward of the filaments **522** (e.g., as illustrated in FIG. 25B), radially inward of the filaments **522**, and/or integrated with the filaments **522** (e.g., such that the first and second woven structures are not readily separable). The filaments **524** may be the same or different material as the filaments **522**, the same or different thickness as the filaments **522**, etc., and/or the filaments **524** may be braided with the same or different parameters (e.g., braid angle) than the filaments **522**, resulting in filaments **524** having greater radial force. The filaments **524** may be coupled to the filaments **522** (e.g., in a single deployable stent **520**) or separately deployed. For example, if the filaments **524** are deployed and then the filaments **522** are deployed, the filaments **524** can prop open a fistula and allow the filaments **522** to expand within the lumen created by the filaments **524** without substantial opposing force. For another example, if the filaments **522** are deployed and then the filaments **524** are deployed, the filaments **524** can act as an expansion force on the portions of the filaments **522** in need of an expansive force.

[0239] Although illustrated in FIG. 25B as comprising a second woven structure, the supplemental support structure may additionally or alternatively comprise a helical coil, a cut hypotube, combinations thereof, and the like. Determination of the porosity of the prosthesis **520** may be primarily based on the porosity of the first woven structure such that the supplemental support structure may be designed primarily for providing radial force (e.g., sufficient to keep a fistula open or patent).

[0240] Although illustrated as being uniform or substantially uniform across the length of the stent **500**, parameters of the stent **500** and the filaments **502** may vary across the stent **500**, for example as described with respect to FIG. 25C. Uniformity may reduce manufacturing costs, reduce a

demand for precise placement, and/or have other advantages. Non-uniformity may allow specialization or customization for specific properties and/or functions along different lengths and/or have other advantages.

[0241] FIG. 25C is a schematic side elevational view of still another example embodiment of a prosthesis **540**. The prosthesis or stent or device **540** includes and/or consist essentially of a plurality of filaments **542** woven together into a woven structure. The stent **540** may be devoid of graft material, as described in further detail herein. The stent **540** comprises a first longitudinal section or segment or portion **544** and a second longitudinal section or segment or portion **546**. Parameters such as porosity (e.g., as illustrated in FIG. 25B), braid angle, braid type, filament **542** parameters (e.g., diameter, material, etc.), existence of a supplemental support structure (e.g., the supplemental support structure **544**), stent diameter, stent shape (e.g., cylindrical, frustoconical), combinations thereof, and the like may be different between the first longitudinal section **524** and the second longitudinal section **546**. The porosity may vary by objectives for certain portions of the stent **540**. For example, the first longitudinal section **544**, which may be configured for placement in an artery and a fistula, may have low porosity (e.g., less than about 50% as described with respect to the stent **500** of FIG. 25A) to increase fluid flow through the stent **500**, while the second longitudinal section, which may be configured for placement in a vein, may have higher porosity to increase flexibility and wall apposition.

[0242] In some embodiments, a stent comprises a first longitudinal section comprising and/or consisting essentially of a low porosity weave configured to divert flow from an artery into a fistula and no supplemental support structure, a second longitudinal section comprising and/or consisting essentially of a low porosity weave configured to divert blood flow through a fistula and comprising a supplemental support structure configured to prop open the fistula, and a third longitudinal section comprising and/or consisting essentially of low porosity weave configured to divert flow from a fistula into a vein. In certain such embodiments, the first longitudinal section may be configured as the stent **500** of FIG. 25A and the third longitudinal section may be configured as the stent **500** of FIG. 25A or as the stent **540** of FIG. 25C.

[0243] The difference between the first longitudinal section **544** and the second longitudinal section **546** may be imparted during manufacturing (e.g., due to braid parameters, shape setting, etc.) and/or in situ (e.g., during and/or after deployment (e.g., by stent packing)).

[0244] Other variations between the first longitudinal section **544** and the second longitudinal section **546** (e.g., including laser-cut portions, additional longitudinal sections, etc.), for example as described herein, are also possible. In some embodiments, a stent comprises a first longitudinal section comprising and/or consisting essentially of a low porosity weave configured to divert flow from an artery into a fistula, a second longitudinal section comprising and/or consisting essentially of a low porosity laser cut portion configured to be placed in a fistula, to divert blood through the fistula, and/or to prop open the fistula, and a third longitudinal section comprising and/or consisting essentially of low porosity weave configured to divert flow from a fistula into a vein. In certain such embodiments, the first longitudinal section may be configured as the stent **500** of FIG. 25A and the third longitudinal section may be configured as the stent **500** of FIG. 25A or as the stent **540** of FIG. 25C.

[0245] FIG. 27 schematically illustrates an example embodiment of a prosthesis **720**, which is described with respect to the anatomy in FIG. 27 in further detail below. The prosthesis **720** comprises a first longitudinal section **722**, a second longitudinal section **724**, and a third longitudinal section **726** between the first longitudinal section **722** and the second longitudinal section **724**. The porosity of the prosthesis **720** may allow the fluid to flow substantially through the lumen of the prosthesis **720** substantially without perfusing through the sidewalls, even when substantially lacking graft material, for example due to a low porosity woven structure.

[0246] In embodiments in which the prosthesis **720** is used in peripheral vasculature, the first longitudinal section **722** may be described as an arterial section, the second longitudinal section

**724** may be described as a venous section, and the third longitudinal section **726** may be described as a transition section. The first longitudinal section **722** is configured to appose sidewalls of an artery **700** or another cavity. For example, for some peripheral arteries, the first longitudinal section **722** may have an expanded diameter between about 2 mm and about 4 mm (e.g., about 3 mm). The second longitudinal section **724** is configured to appose sidewalls of a vein **702** or another cavity. For example, for some peripheral veins, the second longitudinal section **724** may have an expanded diameter between about 5 mm and about 7 mm (e.g., about 6 mm). In some embodiments, rather than being substantially cylindrical as illustrated in FIG. 27, the second longitudinal section **724** and the third longitudinal section **726** may have a shape comprising frustoconical, tapering from the smaller diameter of the first longitudinal section **722** to a larger diameter.

[0247] The length of the prosthesis **720** may be configured or sized to anchor the prosthesis **720** in the artery **700** and/or the vein **702** (e.g., enough to inhibit or prevent longitudinal movement or migration of the prosthesis **720**) and to span the interstitial tissue T between the artery **700** and the vein **702**. For example, for some peripheral arteries, the length of the first longitudinal section **722** in the expanded or deployed state may be between about 20 mm and about 40 mm (e.g., about 30 mm). For another example, for some peripheral veins, the length of the second longitudinal section **724** in the expanded or deployed state may be between about 10 mm and about 30 mm (e.g., about 20 mm). For yet another example, for some peripheral vasculature, the length of the third longitudinal section **726** in the expanded or deployed state may be between about 5 mm and about 15 mm (e.g., about 10 mm). The total length of the prosthesis **720** in the expanded or in a deployed state may be between about 30 mm and about 100 mm, between about 45 mm and about 75 mm (e.g., about 60 mm). The interstitial tissue T is illustrated as being about 2 mm thick, although other dimensions are possible depending on the specific anatomy of the deployment site. Other dimensions of the prosthesis **720**, the first longitudinal section **722** and/or the second longitudinal section **724**, for example as described herein, are also possible.

[0248] The third longitudinal section **726** comprises a frustoconical or tapered shape, expanding from the smaller diameter of the first longitudinal section **722** to the second longitudinal section **724**. Transition points between the longitudinal sections **722**, **724**, **726** may be distinct or indistinct. For example, the transition section may be said to include a portion of the first longitudinal section **722** and the third longitudinal section **726**, or the third longitudinal section **726** may be said to include a cylindrical portion having the same diameter as the first longitudinal section **722**. The longitudinal sections **722**, **724**, **726** may differ in shape and dimensions as described above, and/or in other ways (e.g., materials, pattern, etc.). For example, one or more portions may be cylindrical, frustoconical, etc., as illustrated in FIGS. 12, 13, and 27 and described herein.

[0249] The first longitudinal section **722** and/or the third longitudinal section **726** may comprise a relatively high radial force, for example configured to keep a fistula patent, and the second longitudinal section **724** may comprise a relatively low radial force. In some embodiments, the first longitudinal section **722** and/or the third longitudinal section **726** comprise a balloon-expandable stent, a woven stent with a high braid angle, and/or the like. In some embodiments, the second longitudinal section **724** comprises a self-expanding stent, a woven stent with a low braid angle, and/or the like. Combinations of laser-cut stents, woven stents, different cut patterns, different weave patterns, and the like are described in further detail herein. In some embodiments, the longitudinal sections **722**, **724**, **726** may be integral or separate. The second longitudinal section **724** may be relatively flexible, for example comprising relatively low radial force, which may help the second longitudinal section **724** flex with the anatomy during pulses of blood flow.

[0250] In some embodiments, the second longitudinal section **724** and/or the third longitudinal section **726** may comprise some graft material (e.g., comprising silicone). The graft material may inhibit or prevent flow through sidewalls of the prosthesis **720** and/or may be used to carry medicaments. For example, graft material may or may not occlude or substantially occlude the pores of the portions of the prosthesis **720** depending on the purpose of the graft material.

[0251] The proximal and/or distal ends of the prosthesis **720** may be atraumatic, for example comprising an end treatment, low braid angle, small filament diameter, combinations thereof, and the like.

[0252] The radial strength or compression resistance of a stent, a stent-graft, or a first end portion, second end portion, intermediate portion, or subportion thereof may be between about 0.1 N/mm and about 0.5 N/mm, between about 0.2 N/mm and about 0.5 N/mm, between about 0.3 N/mm and about 0.5 N/mm, between about 0.1 N/mm and about 0.3 N/mm, between about 0.1 N/mm and about 0.2 N/mm, between about 0.2 N/mm and about 0.5 N/mm, between about 0.2 N/mm and about 0.3 N/mm, or between about 0.3 N/mm and about 0.5 N/mm.

[0253] The values of certain parameters of a stent, a stent-graft, or a first end portion, second end portion, intermediate portion, or subportion thereof may be linked (e.g., proportional). For example, a ratio of a thickness of a strut or filament to a diameter of a device portion comprising that strut or filament may be between about 1:10 and about 1:250, between about 1:25 and about 1:175, or between about 1:50 and about 1:100. For another example, a ratio of a length of a device or portion thereof to a diameter of a device or a portion thereof may be between about 1:1 and about 50:1, between about 5:1 and about 25:1, or between about 10:1 and about 20:1.

[0254] Portions of the device may include radiopaque material. For example, filaments and/or struts a stent, a stent-graft, or a first end portion, second end portion, intermediate portion, or subportion thereof may comprise (e.g., be at least partially made from) titanium, tantalum, rhenium, bismuth, silver, gold, platinum, iridium, tungsten, combinations thereof, and the like. For another example, filaments and/or struts of a stent, stent-graft, or a portion thereof may comprise (e.g., be at least partially made from) a material having a density greater than about 9 grams per cubic centimeter. Separate radiopaque markers may be attached to certain parts of the device. For example, radiopaque markers can be added to the proximal end of the device or parts thereof (e.g., a proximal part of the intermediate portion, a proximal part of the distal portion), the distal end of the device or parts thereof (e.g., a distal part of the intermediate portion, a distal part of the proximal portion), and/or other parts. A radiopaque marker between ends of a device may be useful, for example, to demarcate transitions between materials, portions, etc. Radiopacity may vary across the length of the device. For example, the proximal portion could have a first radiopacity (e.g., due to distal portion material and/or separate markers) and the distal portion could have a second radiopacity (e.g., due to distal portion material and/or separate markers) different than the first radiopacity.

[0255] In some embodiments, the device includes a polymer tube, and no supporting structure is provided. The intermediate portion of such a device may be relatively more flexible than the end portions by, for example, decreasing the wall thickness of the polymer tube within the intermediate portion.

[0256] When a mesh or other supporting structure is provided in combination with a polymer tube, the supporting structure may be located around the outside of the tube, in the inner bore of the tube, or embedded within a wall of the tube. More than one supporting structure may be provided, in which case each supporting structure may have a different location with respect to the tube.

[0257] One or both of the end portions of the device may include anchoring elements such as hooks, protuberances, or barbs configured to grasp or grip inner sidewalls of a blood vessel. The radial force of the end portions after expansion may be sufficient to grasp or grip inner sidewalls of a blood vessel without anchoring elements.

[0258] There need not be a well-defined transition between the intermediate and end portions. For example, mesh type, material, wall thickness, flexibility, etc. may gradually change from an end portion toward an intermediate portion or from an intermediate portion toward an end portion.

[0259] The flexibility of the device may increase gradually when moving from an end portion towards the intermediate portion, for example as described with respect to the devices **134**, **140**. The change in flexibility may be due to change in mesh density (e.g., winding density, window

size), tube thickness, or other factors. The flexibility of the device may be uniform or substantially uniform along the entire length of the support structure (e.g., stent), or along certain portions of the support structure (e.g., along an entire end portion, along the entire intermediate portion, along one end portion and the intermediate portion but not the other end portion, etc.).

[0260] While the devices described herein may be particularly suitable for use as a transvascular shunt in percutaneous surgery, the devices could be used in many other medical applications. For example, the devices could be used in angioplasty for the treatment of occluded blood vessels with tortuous or kinked paths, or where the vessels may be subject to deflection or deformation at or near the position of the stent. The stent could also be used for the repair of damaged blood vessels, for example in aortic grafting procedures or after perforation during a percutaneous procedure. In certain such cases, the intermediate portion of the device can allow the device to conform to the shape of the blood vessel and to deform in response to movement of the vessel with reduced risk of fatigue failure while remaining fixed or anchored in position by the end portions. For another example, the devices could be used to form a shunt between a healthy artery and a healthy vein for dialysis access and/or access for administration of medications (e.g., intermittent injection of cancer therapy, which can damage vessels).

[0261] Referring again to FIGS. 4 and 7, blocking material 251 may be used to help inhibit or prevent reversal of arterial blood flow. As will now be described in further detail, additional or other methods and systems can be used to inhibit or prevent reversal of arterial blood flow, or, stated another way, to inhibit or prevent flow of arterial blood now flowing into the vein from flowing in the normal, pre-procedure direction of blood flow in the vein such that oxygenated blood bypasses downstream tissue such as the foot.

[0262] In the absence of treatment, Peripheral Vascular Disease (PVD) may progress to critical limb ischemia (CLI), which is characterized by profound chronic pain and extensive tissue loss that restricts revascularization options and frequently leads to amputation. CLI is estimated to have an incidence of approximately 50 to 100 per 100,000 per year, and is associated with mortality rates as high as 20% at 6 months after onset.

[0263] Interventional radiologists have been aggressively trying to treat CLI by attempting to open up chronic total occlusions (CTOs) or bypassing CTOs in the sub-intimal space using such products as the Medtronic Pioneer catheter, which tunnels a wire into the sub-intimal space proximal to the CTO and then attempts to re-enter the vessel distal to the occlusion. Once a wire is in place, a user can optionally create a wider channel and then place a stent to provide a bypass conduit past the occlusion. Conventional approaches such as percutaneous transluminal angioplasty (PTA), stenting, and drug eluting balloons (DEB) to treat PAD can also or alternatively be used in CLI treatment if a wire is able to traverse the occlusion.

[0264] From the amputee-coalition.org website, the following are some statistics regarding the CLI problem: [0265] There are nearly 2 million people living with limb loss in the United States. [0266] Among those living with limb loss, the main causes are: [0267] vascular disease (54%) (including diabetes and peripheral artery disease (PAD)), [0268] trauma (45%), and [0269] cancer (less than 2%). [0270] Approximately 185,000 amputations occur in the United States each year. [0271] Hospital costs associated with having a limb amputated totaled more than \$6.5 billion in 2007. [0272] Survival rates after an amputation vary based on a variety of factors. Those who have amputations due to vascular disease (including PAD and diabetes) face a 30-day mortality rate reported to be between 9% and 15% and a long-term survival rate of 60% at 1 year, 42% at 3 years, and 35%-45% at 5 years. [0273] Nearly half of the people who lose a limb to dysvascular disease will die within 5 years. This is higher than the 5-year mortality rate experienced by people with colorectal, breast, and prostate cancer. [0274] Of people with diabetes who have a lower-limb amputation, up to 55% will require amputation of the second leg within 2 to 3 years.

[0275] CLI has been surgically treated by open-leg venous arterialization since the early 1900's. Numerous small series of clinical trials have been published over the years using such an open-leg



surgical approach, as summarized by a 2006 meta-analysis article by Lu et al. in the European Journal of Vascular and Endovascular Surgery, vol. 31, pp. 493-499, titled “Meta-analysis of the clinical effectiveness of venous arterialization for salvage of critically ischemic limbs.” The article had the following results and conclusions: [0276] Results: [0277] A total of 56 studies were selected for comprehensive review. No randomized control trial (RCT) was identified. Seven patient series, comprising 228 patients, matched the selection criteria. Overall 1-year foot preservation was 71% (95% CI: 64%-77%) and 1-year secondary patency was 46% (95% CI: 39%-53%). The large majority of patients in whom major amputation was avoided experienced successful wound healing, disappearance of rest pain, and absence of serious complications. [0278] Conclusions: [0279] On the basis of limited evidence, venous arterialization may be considered as a viable alternative before major amputation is undertaken in patients with “inoperable” chronic critical leg ischemia.

[0280] Among other maladies as described herein, the methods and systems described herein may be used to create an arterial-venous (AV) fistula in the below-the-knee (BTK) vascular system using an endovascular, minimally invasive approach. Such methods may be appropriate for patients that (i) have a clinical diagnosis of symptomatic critical limb ischemia as defined by Rutherford 5 or 6 (severe ischemic ulcers or frank gangrene); (ii) have been assessed by a vascular surgeon and interventionist and it was determined that no surgical or endovascular treatment is possible; and/or (iii) are clearly indicated for major amputation.

[0281] In some embodiments, a system or kit optionally comprises one or more of the following components: a first ultrasound catheter (e.g., an arterial catheter, a launching catheter including a needle, etc.); a second ultrasound catheter (e.g., a venous catheter, a target catheter, etc.); and a prosthesis (e.g., a covered nitinol stent graft in a delivery system (e.g., a 7 Fr (approx. 2.3 mm) delivery system)). The system or kit optionally further comprises an ultrasound system, a control system (e.g., computer). Some users may already have an appropriate ultrasound system that can be connected to the ultrasound catheter(s). The catheters and prostheses described above may be used in the system or kit, and details of other, additional, and/or modified possible components are described below.

[0282] FIG. 14A is a schematic side cross-sectional view of an example embodiment of an ultrasound launching catheter **170** comprising a needle **172** (e.g., a first ultrasound catheter, an arterial catheter (e.g., if extending a needle from artery into vein), a venous catheter (e.g., if extending a needle from vein into artery)). The catheter **170** is placed into an artery with the needle **172** in a retracted state inside a lumen of the catheter **170**. The catheter **170** can be tracked over a guidewire (e.g., a 0.014 inch (approx. 0.36 mm) guidewire) and/or placed through a sheath in the artery (e.g., a femoral artery), and advanced up to the point of the total occlusion of the artery (in the tibial artery). The catheter **170** includes a handle **174** that includes a pusher ring **176**.

Longitudinal or distal advancement of the pusher ring **176** can advance the needle **172** from out of a lumen of the catheter **170**, out of the artery and into a vein, as described herein. Other advancement mechanisms for the needle **172** are also possible (e.g., rotational, motorized, etc.). Before, after, and/or during after advancing the needle **172**, a guidewire (e.g., a 0.014 inch (approx. 0.36 mm) guidewire) can be placed through the needle **172** (e.g., as described with respect to the guidewire **14** of FIG. 3), and this guidewire can be referred to as a crossing wire.

[0283] FIG. 14B is an expanded schematic side cross-sectional view of a distal portion of the ultrasound launching catheter **170** of FIG. 14A within the circle **14B**. Upon advancing or launching, the needle **172** extends radially outwardly from a lumen **173** of the catheter **170**. In some embodiments, the lumen **173** ends proximal to the ultrasound transmitting device **178**. The needle **172** may extend along a path that is aligned with (e.g., parallel to) the path of the directional ultrasound signal emitted by the ultrasound transmitting device **178**. FIG. 14B also shows the lumen **175**, which can be used to house a guidewire for tracking the catheter **170** to the desired position.

[0284] FIG. 15A is a schematic side elevational view of an example embodiment of an ultrasound target catheter **180** (e.g., a second ultrasound catheter, an arterial catheter (e.g., if extending a needle from vein into artery), a venous catheter (e.g., if extending a needle from artery into vein)). FIG. 15B is an expanded schematic side cross-sectional view of the ultrasound target catheter **180** of FIG. 15A within the circle 15B. FIG. 15C is an expanded schematic side cross-sectional view of the ultrasound target catheter **180** of FIG. 15A within the circle 15C. The catheter **180** can be tracked over a guidewire (e.g., a 0.014 inch (approx. 0.36 mm) guidewire) and/or placed through a sheath in the vein (e.g., a femoral vein), and advanced up to a point (e.g., in the tibial vein) proximate and/or parallel to the distal end of the catheter **170** and/or the occlusion in the artery. The catheter **180** includes an ultrasound receiving transducer **182** (e.g., an omnidirectional ultrasound receiving transducer) that can act as a target in the vein for aligning the needle **172** of the catheter **170**. The catheter **180** may be left in place or remain stationary or substantially stationary while the catheter **170** is rotated and moved longitudinally to obtain a good or optimal ultrasound signal indicating that the needle **172** is aligned with and in the direction of the catheter **180**.

[0285] The catheters **170**, **180** may be connected to an ultrasound transceiver that is connected to and controlled by a computer running transceiver software. As described in further detail herein, the catheter **170** includes a flat or directional ultrasound transmitter **178** configured to transmit an ultrasound signal having a low angular spread or tight beam (e.g., small beam width) in the direction of the path of the needle **172** upon advancement from the lumen **173** of the catheter **170**. The catheter **180** includes an omnidirectional (360 degrees) ultrasound receiver **182** configured to act as a target for the ultrasound signal emitted by the directional transmitter **178** of the catheter **170**. The catheter **170** is rotated until the peak ultrasound signal is displayed, indicating that the needle **172** is aligned to the catheter **180** such that, upon extension of the needle **172** (e.g., by longitudinally advancing the ring **176** of the handle **174**), the needle **172** can pass out of the artery in which the catheter **170** resides, through interstitial tissue, and into the vein in which the catheter **180** resides.

[0286] FIG. 16 is an example embodiment of a graph for detecting catheter alignment, as may be displayed on display device of an ultrasound system (e.g., the screen of a laptop, tablet computer, smartphone, combinations thereof, and the like). The graph in FIG. 16 shows that the signal originating from the transmitting catheter in the artery has been received by the receiving catheter in the vein. The second frequency envelope from the right is the received signal. The distance from the left side of the illustrated screen to the leading edge of the second frequency envelope may indicate the distance between the catheters. The operator can move the catheter in the artery both rotationally and longitudinally, for example until the second envelope is maximal, which indicates the catheters are correctly orientated.

[0287] FIG. 17 is a schematic side elevational view of an example embodiment of a prosthesis (e.g., stent, stent-graft) delivery system **190**. In some embodiments, the delivery system **190** is a 7 Fr (approx. 2.3 mm) delivery system. FIG. 18 is a schematic side elevational view of an example embodiment of a prosthesis (e.g., stent, stent-graft) **200**. In FIG. 17, a prosthesis (e.g., the prosthesis **200**, other prostheses described herein, etc.) is in a compressed or crimped state proximate to the distal end **192** of the delivery system **190**. In some embodiments, the prosthesis **200** comprises a shape-memory stent covered with a graft material, for example as described above. Once the crossing wire extends from the artery to the vein, for example as a result of being advanced through the needle **172** as described herein, the delivery system **190** can be advanced over the crossing wire. The prosthesis **200** may be deployed from the delivery system **190**, for example by squeezing the trigger handle **194** of the delivery system **190**, causing the outer cover sheath to proximally retract and/or distally advance the prosthesis **200**. The prosthesis **200** can create a flow path between the artery and the vein and through the interstitial tissue. Other types of delivery systems and prostheses are also possible.

[0288] Referring again to FIG. 17, some non-limiting example dimensions of the delivery system

**190** are provided. The distance **196** of travel of the trigger handle **194** may be, for example, between about 0.4 inches (approx. 1 cm) and about 12 inches (approx. 30 cm), between about 1 inch (approx. 2.5 cm) and about 8 inches (approx. 20 mm), or between about 2 inches (approx. 5 cm) and about 6 inches (approx. 15 mm) (e.g., about 2 inches (approx. 5 cm)). In some embodiments, the distance **196** of travel of the trigger handle **194** is at least as long as the length of the prosthesis **200** to be deployed (e.g., in the radially expanded state). In some embodiments, gearing or other mechanisms may be employed to reduce the distance **196** of travel of the trigger handle **194** be less than the length of the prosthesis **200** to be deployed (e.g., in the radially expanded state). The distance **196** may be adjusted for example, based on at least one of: the length of the prosthesis **200** to be deployed, the degree of foreshortening of the prosthesis **200** to be deployed, the mechanism of deployment (e.g., whether the outer sheath is proximally retracted, the prosthesis **200** is pushed distally forward, or both, whether the delivery system **190** includes gearing mechanism, etc.), combinations thereof, and the like. The length **197** of the outer sheath or catheter portion may be, for example, between about 40 inches (approx. 1,020 mm) and about 50 inches (approx. 1,270 mm), between about 46 inches (approx. 1,170 mm) and about 47 inches (approx. 1,190 mm), or between about 46.48 inches (approx. 1,180 mm) and about 46.7 inches (approx. 1,186 mm). The total length **198** of the delivery system **190** from proximal tip to distal tip may be, for example, between about 40 inches (approx. 1,000 mm) and about 60 inches (approx. 1,500 mm). The lengths **197**, **198** may be adjusted, for example based on at least one of: length of the prosthesis **200** to be deployed, the degree of foreshortening of the prosthesis **200** to be deployed, the height of the patient, the location of the occlusion being treated, combinations thereof, and the like. In some embodiments, spacing the trigger handle **194** from the vascular access point, for example by between about 10 cm and about 30 cm (e.g., at least about 20 cm) may advantageously provide easier handling or management by the user. In certain such embodiments, the length **197** may be between about 120 cm and about 130 cm (e.g., for an antegrade approach) or between about 150 cm and about 180 cm (e.g., for a contralateral approach).

[0289] Referring again to FIG. **18**, some non-limiting example dimensions of the prosthesis **200** are provided, depending on context at least in the compressed state. The thickness **201** of a structural strut may be, for example, between about 0.05 mm and about 0.5 mm or between about 0.1 mm and about 0.2 mm (e.g., about 0.143 mm). The spacing **202** between struts of a structural strut may be, for example, between about 0.005 mm and about 0.05 mm or between about 0.01 mm and about 0.03 mm (e.g., about 0.025 mm). The thickness **203** of a linking strut may be, for example, between about 0.05 mm and about 0.5 mm or between about 0.1 mm and about 0.2 mm (e.g., about 0.133 mm). The longitudinal length **204** of the structural components may be, for example, between about 1 mm and about 5 mm or between about 2.5 mm and about 3 mm (e.g., about 2.8 mm). The longitudinal length **205** between structural components may be, for example, between about 0.25 mm and about 1 mm or between about 0.5 mm and about 0.6 mm (e.g., about 0.565 mm). The length **206** of a strut within a structural component, including all portions winding back and forth, may be, for example, between about 25 mm and about 100 mm or between about 65 mm and about 70 mm (e.g., about 67.62 mm). The total longitudinal length of the prosthesis **200** may be, for example, between about 25 mm and about 150 mm or between about 50 mm and about 70 mm (e.g., about 62 mm). As described herein, a wide variety of laser-cut stents, woven stents, and combinations thereof, including various dimensions, are possible. The struts described herein may comprise wires or filaments or portions not cut from a hypotube or sheet.

[0290] The proximal and/or distal ends of the prosthesis **200** may optionally comprise rings **210**. The rings **210** may, for example, help to anchor the prosthesis **200** in the artery and/or the vein. The circumferential width **211** of a ring **210** may be, for example, between about 0.25 mm and about 1 mm or between about 0.5 mm and about 0.75 mm (e.g., about 0.63 mm). The longitudinal length **212** of a ring **210** may be, for example, between about 0.25 mm and about 2 mm or between about 0.5 mm and about 1 mm (e.g., about 0.785 mm). In some embodiments, a ratio of the total length

of the prosthesis **200** to the longitudinal length **212** of a ring **210** may be between about 50:1 and about 100:1 (e.g., about 79:1). The dimensions **211**, **212** of the rings **210** may be adjusted, for example based on at least one of: strut thickness, diameter of the prosthesis (e.g., relative to the vessel), total length of the prosthesis, material, shape setting properties, combinations thereof, and the like.

[0291] FIG. **19** is a schematic side elevational view of another example embodiment of a prosthesis **220**. The prosthesis **200** may have the shape of the prosthesis **220**, for example in a radially expanded state (e.g., upon being deployed from the delivery system **190**). FIG. **19** illustrates an example shape of the prosthesis **220** comprising a first portion **221** and a second portion **225**. The first portion **221** has a substantially cylindrical or cylindrical shape having a length **222** between about 15 mm and about 25 mm (e.g., about 21 mm) and a diameter **223** between about 2.5 mm and about 5 mm (e.g., about 3.5 mm). The second portion **225** has a substantially frustoconical or frustoconical shape having a length **226** between about 30 mm and about 50 mm (e.g., about 41 mm) and a widest diameter **227** between about 4 mm and about 10 mm, between about 4 mm and about 7 mm (e.g., about 5.5 mm), etc. The angle of taper of the second portion **225** away from the first portion **221** may be between about 0.02 degrees and about 0.03 degrees (e.g., about 0.024 degrees).

[0292] Further details regarding prostheses that can be used in accordance with the methods and systems described herein are described in U.S. patent application Ser. No. 13/791,185, filed Mar. 8, 2013, which is hereby incorporated by reference in its entirety.

[0293] FIGS. **20A-20H** schematically illustrate an example embodiment of a method for effecting retroperfusion. The procedure will be described with respect to a peripheral vascular system such as the lower leg, but can also be adapted as appropriate for other body lumens (e.g., cardiac, other peripheral, etc.). Certain steps such as anesthesia, incision specifics, suturing, and the like may be omitted for clarity. In some embodiments, the procedure can be performed from vein to artery (e.g., with the venous catheter coming from below).

[0294] Access to a femoral artery and a femoral vein is obtained. An introducer sheath (e.g., 7 Fr (approx. 2.3 mm)) is inserted into the femoral artery and an introducer sheath (e.g., 6 Fr (approx. 2 mm)) is inserted into the femoral vein, for example using the Seldinger technique. A guidewire (e.g., 0.014 inch (approx. 0.36 mm), 0.035 inch (approx. 0.89 mm), 0.038 inch (approx. 0.97 mm)) is inserted through the introducer sheath in the femoral artery and guided into the distal portion of the posterior or anterior tibial diseased artery **300**. A second guidewire (e.g., 0.014 inch (approx. 0.36 mm), 0.035 inch (approx. 0.89 mm), 0.038 inch (approx. 0.97 mm)) or a snare is inserted through the introducer sheath in the femoral vein. In embodiments in which a snare is used, the described third guidewire, fourth guidewire, etc. described herein are accurate even though the numbering may not be sequential.

[0295] A venous access needle is percutaneously inserted into a target vein, for example a tibial vein (e.g., the proximal tibial vein (PTV)). In some embodiments, the venous access needle may be guided under ultrasound. In some embodiments, contrast may be injected into the saphenous vein towards the foot (retrograde), and then the contrast will flow into the PTV. This flow path can be captured using fluoroscopy such that the venous access needle can be guided by fluoroscopy rather than or in addition to ultrasound.

[0296] The target vein may be accessed proximate to and distal to (e.g., a few inches or centimeters) below where the launching catheter **310** will likely reside. In some embodiments, the target vein may be in the ankle. Once the venous access needle is in the vein, a third guidewire (or “second” guidewire in the case that a snare is used instead of a second guidewire) is inserted into the venous access needle and advanced antegrade in the target vein up to the femoral vein. This access method can advantageously reduce issues due to advancing wires retrograde across venous valves, which are described in further detail below. The third guidewire is snared, for example using fluoroscopic guidance, and pulled through the femoral vein sheath. The target catheter **320** is

inserted into the femoral vein sheath over the third guidewire, which has been snared. The target catheter **320** is advanced over the third guidewire into the venous system until the target catheter is proximate to and/or parallel with the guidewire in the distal portion of the posterior or anterior tibial diseased artery and/or proximate to the occlusion **304**, as shown in FIG. **20A**.

[0297] In some embodiments, the third guidewire may include an ultrasound receiving transducer (e.g., omnidirectional) mounted to provide the target for the signal emitted by the launching catheter **310** or the target catheter **320** could be tracked over the third guidewire, either of which may allow omission of certain techniques (e.g., femoral vein access, introducing vein introducer sheath, inserting second guidewire, antegrade advancing of the third guidewire up to the femoral vein, snaring the third guidewire, advancing the target catheter **320** over the third guidewire).

[0298] In some embodiments, the PTV may be accessed directly, for example using ultrasound, which can allow placement of the target catheter **320** directly into the PTV, for example using a small sheath, which may allow omission of certain techniques (e.g., femoral vein access, introducing vein introducer sheath, inserting second guidewire, antegrade advancing of the third guidewire up to the femoral vein).

[0299] In some embodiments, the catheter **320** is not an over-the-wire catheter, but comprises a guidewire and an ultrasound receiving transducer (e.g., omnidirectional). The catheter **320** may be inserted as the third guidewire, as discussed above, as the second guidewire, or as a guidewire through a small sheath when directly accessing the PTV.

[0300] Ultrasound transducers generally include two electrodes including surfaces spaced by a ceramic that can vibrate. An incoming or received ultrasound signal wave can couple into a length extensional mode, as shown in FIG. **21**. FIG. **21** is a schematic perspective view of an example embodiment of an ultrasound receiving transducer **350**. If the proximal or top end **352** of the transducer **350** and the distal or bottom end **354** of the transducer are conductive and electrically connected to wires, the transducer can receive ultrasound signals. In some embodiments, the transducer **350** has a length **356** between about 0.1 mm and about 0.4 mm (e.g., about 0.25 mm). In some embodiments, the transducer **350** has an overlap length **358** between about 0.1 mm and about 0.3 mm (e.g., about 0.2 mm). In some embodiments, the transducer **350** has a diameter that is similar to, substantially similar to, or the same as the guidewire on which it is mounted. In some embodiments, an array or series of laminates may enhance the signal-receiving ability of the transducer **350**.

[0301] In some embodiments, a guidewire comprising an ultrasound receiving transducer may comprise a piezoelectric film (e.g., comprising plastic), which could enhance the signal-receiving ability of the transducer. FIG. **22** is a schematic cross-sectional view of another example embodiment of an ultrasound receiving transducer **360**. The ultrasound receiving transducer **360** shown in FIG. **22** includes an optional lumen **368**. The ultrasound receiving transducer **360** includes a series of layers **362**, **364**, **366**. The layer **362** may comprise a polymer (e.g., polyvinylidene fluoride (PVDF)) layer. The layer **364** may comprise an inorganic compound (e.g., tungsten carbide) layer. The layer **366** may comprise a polymer (e.g., polyimide) layer. The layer **366** may have a thickness between about 25 micrometers ( $\mu\text{m}$  or microns) and about 250  $\mu\text{m}$  (e.g., at least about 50  $\mu\text{m}$ ).

[0302] The launching catheter **310** is tracked over the guidewire in the femoral and tibial arteries proximate to and proximal to the occlusion **304**, as shown in FIG. **20B**. The catheter **310** may be more proximal to the occlusion **304** depending on suitability at that portion of the anatomy for the retroperfusion process. In some embodiments, the catheter **310** may be positioned in the distal portion of the posterior or anterior tibial artery, for example proximate to the catheter **320**. In some embodiments, the catheter **310** may be positioned within a few inches or centimeters of the ankle.

[0303] The launching catheter **310** emits a directional ultrasound signal. As shown by the arrow **311**, **312** in FIG. **20C**, the launching catheter **310** is rotated and moved longitudinally until the signal is received by the target catheter **320**. Once the signal is received, which indicates alignment

such that extension of the needle form the launching catheter **310** will result in successful access of the vein, a crossing needle **314** is advance out of the catheter **310**, out of the tibial artery **300** and into the tibial vein **302**, as shown in FIG. **20D**. Accuracy of the placement of the crossing needle **314** to form a fistula between the artery **300** and the vein **302** may be confirmed, for example, using contrast and fluoroscopy.

[0304] In some embodiments, the ultrasound signal can be used to determine the distance between the artery **300** and the vein **302**. Referring again to FIG. **16**, the distance from the left side of the illustrated screen to the leading edge of the second frequency envelope can be used as an indicator of distance between the catheters.

[0305] Referring again to FIG. **16**, a display device may graphically show signal alignment peaks to allow the user to determine the alignment position. In some embodiments, the signal alignment may change color above or below a threshold value, for example from red to green. In some embodiments, an audio signal may be emitted, for example when an alignment signal crosses over a threshold value, which can allow a user to maintain focus on the patient rather than substantially continuously monitoring a screen.

[0306] In some embodiments, a horizontal line on the screen may move up to indicate the maximum signal value or peak achieved to that point during the procedure. This line may be called “peak hold.” If a greater signal value is achieved, the horizontal line moves to match that higher value. If no manipulation is able to raise the peak above the horizontal line, that can indicate maximum alignment. If the signal peak falls a certain amount below the horizontal line, the catheters may have moved and no longer be properly aligned. Since the level of alignment indicated by the horizontal line has previously been achieved during the procedure, the user knows that such a level of alignment can be achieved by further rotational and/or longitudinal manipulation.

[0307] A fourth guidewire **316** (e.g., 0.014 inch (approx. 0.36 mm)) (or “third” guidewire in the case that a snare is used instead of a second guidewire) is placed through the lumen of the crossing needle **314** of the catheter **310** and into the tibial vein **302** in a retrograde direction (of the vein **302**) towards the foot, as shown in FIG. **20E**. External cuff pressure may be applied above the needle crossing point to reduce flow in the artery **300** to inhibit or prevent formation of a hematoma, and/or to engorge the vein to facilitate valve crossing. The catheters **310**, **320** may be removed, leaving the guidewire **316** in place, extending from the introducer sheath in the femoral artery, through the arterial tree, and into the tibial vein **302**.

[0308] Certain techniques for crossing a guidewire **316** from an artery **300** to a vein **302** may be used instead of or in addition to the directional ultrasound techniques described herein.

[0309] In some embodiments, a tourniquet can be applied to the leg, which can increase vein diameters. In some embodiments, a blocking agent (e.g., as discussed with respect to FIGS. **4** and **7**, a blocking balloon, etc.) may be used to increase vein diameter. For example, venous flow could back up, causing dilation of the vein. A larger vein diameter can produce a larger target for the crossing needle **314**, making the vein **300** easier to access with the crossing needle **314**.

[0310] In some embodiments, a PTA balloon can be used in the target vein, and a needle catheter (e.g., Outback, available from Cordis) can target the PTA balloon under fluoroscopy. The crossing needle **314** can puncture the PTA balloon, and the reduction in pressure of the PTA balloon can confirm proper alignment of the crossing needle **314**. The PTA balloon can increase vein diameter, producing a larger target for the crossing needle **314**, making the vein **300** easier to access with the crossing needle **314**. The guidewire **316** may be advanced through the crossing needle **314** and into the PTA balloon.

[0311] In some embodiments, the PTA balloon comprises a mesh (e.g., a woven mesh), for example embedded in the polymer of the balloon. When a balloon without such a mesh is punctured, the balloon material could rupture and cause emboli (e.g., pieces of the balloon floating downstream). The mesh can help to limit tearing of the balloon material, which can inhibit or prevent balloon

material from causing emboli.

[0312] In some embodiments, two PTA balloons spaced longitudinally along the axis of the catheter can be used in the target vein, and a needle catheter can target the one of the PTA balloons. Upon puncturing of one of the PTA balloons by the crossing needle **314**, contrast in a well between the PTA balloons can be released because the punctured balloon no longer acts as a dam for the contrast. The release of contrast can be monitored using fluoroscopy. The PTA balloons can be on the same catheter or on different catheters.

[0313] In some embodiments, two PTA balloons spaced longitudinally along the axis of the catheter can be used in the target vein, and a needle catheter can target the space or well between the PTA balloons. Upon puncturing of the well by the crossing needle **314**, contrast in the well can be disturbed. The disturbance of contrast can be monitored using fluoroscopy. The PTA balloons can be on the same catheter or on different catheters.

[0314] In some embodiments in which a PTA balloon may be used in combination with an ultrasound target in the target vein, a PTA balloon catheter includes a PTA balloon and an ultrasound receiving transducer (e.g., omnidirectional). In certain such embodiments, the launching catheter **310** can target the PTA balloon under fluoroscopy and/or can target the ultrasound receiving transducer as described herein. The crossing needle **314** can puncture the PTA balloon, and the reduction in pressure of the PTA balloon can confirm proper alignment of the crossing needle **314**. The PTA balloon can increase vein diameter, producing a larger target for the crossing needle **314**, making the vein **300** easier to access with the crossing needle **314**. The guidewire **316** may be advanced through the crossing needle **314** and into the PTA balloon.

[0315] In some embodiments, a LeMaitre device (e.g., the UnBalloon™ Non-Occlusive Modeling Catheter, available from LeMaitre Vascular of Burlington, Massachusetts) can be used in the target vein. In some embodiments, a LeMaitre device can increase vein diameters. A larger vein diameter can produce a larger target for the crossing needle **314**, making the vein **300** easier to access with the crossing needle **314**. In some embodiments, the needle **314** can penetrate into the LeMaitre device. In certain such embodiments, the LeMaitre device can act as a mesh target (e.g., comprising radiopaque material visible under fluoroscopy) for the crossing needle **314**. The mesh of the LeMaitre device can be radially expanded by distally advancing a proximal portion of the mesh and/or proximally retracting a distal portion of the mesh (e.g., pushing the ends together like an umbrella) and/or by allowing the mesh to self-expand (e.g., in embodiments in which at least some parts of the mesh comprise shape-memory material). In some embodiments, a LeMaitre device can grip a crossing wire to hold the crossing wire in the target vein as the LeMaitre device closes.

[0316] In some embodiments, the launching catheter **310** may comprise a first magnet having a first polarity and the target catheter **320** may comprise a second magnet having a second polarity. When the magnets are close enough for magnetic forces to move one or both of the catheters **310**, **320**, the crossing needle **314** may be advanced to create the fistula between the artery **300** and the vein **302**. In some embodiments, the first magnet maybe circumferentially aligned with the crossing needle **314** and/or the launching catheter **310** may be magnetically shielded to provide rotational alignment. In some embodiments, the second magnet may be longitudinally relatively thin to provide longitudinal alignment. In some embodiments, the crossing needle **314** and/or the guidewire **316** may be magnetically pulled from the artery **300** to the vein **302**, or vice versa. Some systems may include both ultrasound guidance and magnetic guidance. For example, ultrasound guidance could be used for initial alignment and magnetic guidance could be used for refined alignment.

[0317] Referring again to FIGS. **20A-20H**, a prosthesis delivery system **330** carrying a prosthesis **340** is tracked over the guidewire **316** through the interstitial space between the artery **300** and the vein **300** and then into the vein **302**, as shown in FIG. **20F**. In some embodiments, a separate PTA balloon catheter (e.g., about 2 mm) can be tracked over the guidewire **316** to pre-dilate the fistula between the artery **300** and the vein **302** prior to introduction of the prosthesis delivery system **330**.

Use of a PTA balloon catheter may depend, for example, on the radial strength of the prosthesis **340**.

[0318] The prosthesis **340** is deployed from the prosthesis delivery system **330**, for example by operating a trigger handle **194** (FIG. 17). In some embodiments, for example if the prosthesis **340** is not able to expand and/or advance, the prosthesis delivery system **330** may be removed and a PTA catheter (e.g., about 2 mm) advanced over the guidewire **316** to attempt to dilate or further dilate the fistula the artery **300** and the vein **302**. Deployment of the prosthesis **340** may then be reattempted (e.g., by self-expansion, balloon expansion, etc.). In some embodiments, deployment of the prosthesis **340** may remodel a vessel, for example expanding the diameter of the vessel by at least about 10%, by at least about 20%, by at least about 30%, or more, by between about 0% and about 10%, by between about 0% and about 20%, by between about 0% and about 30%, or more. In embodiments in which the prosthesis **340** is self-expanding, the degree of remodeling may change over time, for example the prosthesis **340** expanding as the vessel expands or contracting when the vessel contracts.

[0319] Once the prosthesis **340** is deployed, as shown in FIG. 20G, the fistula may be dilated with a PTA catheter. The diameter of the PTA catheter (e.g., about 3 mm to about 6 mm) may be selected based at least in part on: the diameter of the artery **300**, the diameter of the vein **302**, the composition of the interstitial tissue, the characteristics of the prosthesis **340**, combinations thereof, and the like. In some embodiments, the prosthesis delivery system **330** may comprise a PTA balloon catheter (e.g., proximal or distal to the prosthesis **340**) usable for one, several, or all of the optional PTA balloon catheter techniques described herein. In embodiments in which the prosthesis comprises a conical portion, the PTA balloon may comprise a conical portion. Once the prosthesis **340** is in place, the prosthesis delivery system **330** may be removed, as shown in FIG. 20H. An AV fistula is thereby formed between the artery **300** and the vein **302**. Confirmation of placement of various catheters **310**, **320**, **330** and the prosthesis **340** may be confirmed throughout parts or the entire procedure under fluoroscopy using contrast injections.

[0320] In some embodiments, a marker (e.g., a clip a lancet, scissors, a pencil, etc.) may be applied (e.g., adhered, placed on top of, etc.) to the skin to approximately mark the location of the fistula formed between the artery **300** and the vein **302** by the crossing needle **314** prior to deployment of the prosthesis **340**. In embodiments in which the user uses a sphygmomanometer inflated above the fistula to avoid bleeding, the lack of blood flow can render visualization or even estimation of the fistula site difficult, and the marker can provide such identification. In embodiments in which the transmitting and receiving catheters are removed after fistula formation, the cross-over point may be difficult for the user to feel or determine, and the marker can provide such identification. If the fistula is to be dilated, a midpoint of the dilation balloon may be preferably aligned with the midpoint of the fistula (e.g., to increase or maximize the hole-through interstitial space). In some embodiments, the marker may be visualized under fluoroscopy (e.g., comprising radiopaque material) to allow the user to see and remember the location of the fistula under fluoroscopy prior to deployment of the prosthesis **340**.

[0321] Once the prosthesis **340** is in place, an obstacle to blood flowing through the vein **302** and into the foot are the valves in the veins. Steering a guidewire across venous valves can be a challenge, for example because pressure from the artery may be insufficient to extend the veins and make the valves incompetent. The Applicant has discovered that venous valves distal to the AV fistula can be disabled or made incompetent using one or more of a variety of techniques such as PTA catheters, stents (e.g., covered stents, stent-grafts, etc.), and a valvulotome, as described in further detail below. Disabling venous valves can allow blood to flow via retroperfusion from the femoral artery, retrograde in the vein **302**, and retrograde in the vein to the venules and capillaries to the distal part of the venous circulation of the foot to provide oxygenated blood to the foot in CLI patients.

[0322] In some embodiments, a high-pressure PTA balloon catheter may be used to make venous



valves incompetent (e.g., when inflated to greater than about 10 atm (approx. 1,013 kilopascals (kPa))).

[0323] In some embodiments, one or more stents can be placed across one or more venous valves to render those valves incompetent. For example, such stents should have sufficient radial force that the valves stay open. The stent may forcefully rupture the valves. In some embodiments, the stent comprises a covering or a graft. Certain such embodiments can cover venous collateral vessels. In some embodiments, the stent is bare or free of a covering or graft. Certain such embodiments can reduce costs. The venous stent may extend along a length (e.g., an entire length) of the vein. For example, in some embodiments, the entire length of the PTV is lined with a covered stent, covering the venous collaterals, disrupting venous valves.

[0324] In some embodiments, the venous stent is separate from the fistula prosthetic. A separate venous stent may allow more flexibility in properties such as dimensions (e.g., length, diameter), materials (e.g., with or without a covering or graft), and other properties. FIG. 31A schematically illustrates an example embodiment of an arteriovenous fistula stent **340** separate from an example embodiment of a venous stent **342**. The venous stent **342** may be spaced from the fistula stent **340** (e.g., as illustrated in FIG. 31A), abutting the fistula stent **340**, or overlapping, telescoping, or coaxial with the fistula stent **340** (e.g., a distal segment of the fistula stent **340** being at least partially inside a proximal segment of the venous stent **342** or a proximal segment of the venous stent **342** being at least partially inside a distal segment of the fistula stent **340**). In embodiments in which the fistula stent **340** and the venous stent **342** overlap, placement of the venous stent **342** first can allow the proximal end of the venous stent **342**, which faces the direction of retrograde blood flow, to be covered by the fistula stent **340** to reduce or eliminate blood flow disruption that may occur due the distal end of the venous stent **342**. In embodiments in which the fistula stent **340** and the venous stent **342** overlap, placement of the venous stent **342** second can be through the fistula stent **340** such that both stents **340**, **342** can share at least one deployment parameter (e.g., tracking stent deployment devices over the same guidewire). The venous stent **342** may be deployed before or after the fistula stent **340**. The venous stent **342** may have a length between about 2 cm and about 30 cm (e.g., about 2 cm, about 3 cm, about 4 cm, about 5 cm, about 6 cm, about 7 cm, about 8 cm, about 9 cm, about 10 cm, about 11 cm, about 12 cm, about 13 cm, about 14 cm, about 15 cm, about 16 cm, about 17 cm, about 18 cm, about 19 cm, about 20 cm, about 21 cm, about 22 cm, about 23 cm, about 24 cm, about 25 cm, about 26 cm, about 27 cm, about 28 cm, about 29 cm, about 30 cm, ranges between such values, etc.).

[0325] In some embodiments, the venous stent is integral with the fistula prosthetic. An integral venous stent may allow more flexibility in properties such as dimensions (e.g., length, diameter), materials (e.g., with or without a covering or graft), and other properties. FIG. 31B schematically illustrates an example embodiment arteriovenous fistula stent **344** comprising an integrated venous stent. FIG. 31C schematically illustrates an example embodiment of fistula stent **344** comprising an integrated venous stent. The stent **344** comprises a first portion **346** configured to anchor in an artery, a second portion **350** configured to anchor in and line a length of a vein, and a third portion **348** longitudinally between the first portion **346** and the second portion **350**. In embodiments in which the first portion **346** and the second portion **350** have different diameters (e.g., as illustrated in FIG. 31C), the third portion **348** may be tapered. In some embodiments, a portion of the second portion **350** that is configured to line a vein has a different property (e.g., diameter, material, radial strength, combinations thereof, and the like) than other portions of the second portion **350**. A length of the second section **350** may be greater than a length of the first section **346**. For example, the second section **350** may have a length configured to line a vessel such as the PTV. The second section **350** may have a length between about between about 2 cm and about 30 cm (e.g., about 2 cm, about 3 cm, about 4 cm, about 5 cm, about 6 cm, about 7 cm, about 8 cm, about 9 cm, about 10 cm, about 11 cm, about 12 cm, about 13 cm, about 14 cm, about 15 cm, about 16 cm, about 17 cm, about 18 cm, about 19 cm, about 20 cm, about 21 cm, about 22 cm, about 23 cm, about 24 cm,

about 25 cm, about 26 cm, about 27 cm, about 28 cm, about 29 cm, about 30 cm, ranges between such values, etc.).

[0326] In some in situ bypass procedures, a saphenous vein is attached to an artery in the upper leg and another artery in the lower leg, bypassing all blockages in the artery. In certain such procedures, the vein is not stripped out of the patient, flipped lengthwise, and used as a prosthesis, but rather is left in place so that blood flow is retrograde (against the valves of the vein). A standard valvulotome may be placed into the saphenous vein from below and advanced to the top in a collapsed state, opened, and then pulled backwards in an open state, cutting venous valves along the way. Cutting surfaces of such valvulotomes face backwards so as to cut during retraction during these procedures. FIG. 23A is a schematic perspective view of an example embodiment of a valvulotome **400** that may be used with such procedures, including blades **402** facing proximally.

[0327] In some embodiments of the methods described herein, access distal to the vein valves is not available such that pulling a valvulotome backwards is not possible, but pushing a reverse valvulotome as described herein forward is possible. FIG. 23B is a schematic perspective view of an example embodiment of a valvulotome **410** that may be used with such procedures. The reverse valvulotome **410** includes one or a plurality of blades **412** (e.g., two to five blades (e.g., three blades)) facing forward or distal such that valves can be cut as the reverse valvulotome **410** is advanced distally. At least because retrograde access to veins to be disabled has not previously been recognized as an issue, there has been no prior motivation to reverse the direction of the blades of a valvulotome to create a reverse valvulotome **410** such as described herein. The reverse valvulotome **410** may be tracked over a guidewire **414**, which can be steered into the veins, for making the venous valves incompetent. After forming a fistula between an artery and a vein as described herein, the flow of fluid in the vein is in the direction opposite the native or normal or pre-procedure direction of fluid flow in the vein such that pushing the reverse valvulotome **410** is in a direction opposite native fluid flow but in the direction of post-fistula fluid flow.

[0328] Other systems and methods are also possible for making the valves in the vein incompetent (e.g., cutting balloons, atherectomy, laser ablation, ultrasonic ablation, heating, radio frequency (RF) ablation, a catheter with a tip that is traumatic or not atraumatic (e.g., an introducer sheath) being advanced and/or retracted, combinations thereof, and the like).

[0329] Crossing vein valves in a retrograde manner before such valves are made incompetent can also be challenging. FIG. 24 is a schematic perspective view of an example embodiment of a LeMaitre device **420** that may be used to radially expand the veins, and thus their valves. The LeMaitre device **420** includes an expandable oval or oblong leaf shape **422**, for example a self-expanding nitinol mesh. In some embodiments, a PTA balloon catheter may be used to radially expand the veins, and thus their valves. In some embodiments, application of a tourniquet to the leg can radially expand the veins, and thus their valves. Upon radial expansion, a guidewire can be advanced through the stretched valve(s) (e.g., through an expansion device such as the LeMaitre device) and catheters (e.g., PTA, stent delivery, atherectomy, etc.) or other over-the-wire devices can be advanced over the guidewire.

[0330] FIGS. 26A and 26B schematically illustrate another example embodiment of a method for effecting retroperfusion. Referring again to FIG. 20E, a fistula may be created between an artery **600** including an occlusion **604** and a vein **602** with a guidewire **606** extending therethrough using one or more of the techniques described herein and/or other techniques. A prosthesis delivery system carrying a prosthesis **620** is tracked over the guidewire **606** through the interstitial space between the artery **600** and the vein **602** and then into the vein **602**, as shown in FIG. 26A. In some embodiments, a separate PTA balloon catheter (e.g., about 2 mm) can be tracked over the guidewire **606** to pre-dilate the fistula between the artery **600** and the vein **602** prior to introduction of the prosthesis delivery system. Use of a PTA balloon catheter may depend, for example, on the radial strength of the prosthesis **620**. The prosthesis **620** may be the stent **500**, **520**, **540** of FIGS. 25A-25C or variations thereof (e.g., as described with respect to FIG. 25C), which include uncovered

and low porosity woven filaments configured to divert blood flow.

[0331] The flow diverting properties of uncovered woven filaments may depend on certain hemodynamic characteristics of the vascular cavities. For example, if the occlusion **604** is not total such that some pressure drop may occur between the lumen of the prosthesis **620** and the portion of the artery **600** between the occlusion **604** and the prosthesis **620**, blood may be able to flow through the sidewalls of the prosthesis **620** rather than into the fistula. Referring again to FIG. 4 and the description of the blocking material **251**, blocking material **608** may optionally be provided in the artery **600** to further occlude the artery **600**, which can inhibit hemodynamic effects that might cause and/or allow blood to flow through the sidewalls of the prosthesis **620**. For another example, a pressure drop between the artery **600** and the vein **602** might cause and/or allow blood to flow through the sidewalls of the prosthesis in the normal direction of venous blood flow rather than through the lumen of the prosthesis to effect retroperfusion. Referring again to FIG. 4 and the description of the blocking material **251**, blocking material **610** may optionally be provided in the vein **602** to occlude the portion of the vein **602** downstream to the fistula under normal venous flow, which can inhibit hemodynamic effects that might cause and/or allow blood to flow through the sidewalls of the prosthesis **620**.

[0332] The prosthesis **620** is deployed from the prosthesis delivery system, for example by operating a trigger handle **194** (FIG. 17). In some embodiments, for example if the prosthesis **620** is not able to expand and/or advance, the prosthesis delivery system may be removed and a PTA catheter (e.g., about 2 mm) advanced over the guidewire **620** to attempt to dilate or further dilate the fistula the artery **600** and the vein **602**. Deployment of the prosthesis **620** may then be reattempted (e.g., by self-expansion, balloon expansion, etc.). In some embodiments, deployment of the prosthesis **620** may remodel a vessel, for example expanding the diameter of the vessel as described herein. In embodiments in which the prosthesis **620** is self-expanding, the degree of remodeling may change over time, for example the prosthesis **620** expanding as the vessel expands or contracting when the vessel contracts. The prosthesis **620** may be conformable to the anatomy in which the prosthesis **620** is deployed. For example, in an expanded state on a table or benchtop, the prosthesis **620** may be substantially cylindrical, but the prosthesis **620** may conform to the diameters of the vessels and fistula in which the prosthesis **620** is deployed such that the prosthesis may have different diameters in different longitudinal segments, tapers, non-cylindrical shapes, combinations thereof, and the like.

[0333] In some embodiments in which the prosthesis **620** comprises a supplemental support structure (e.g., as described with respect to FIG. 25B), deployment of the prosthesis may comprise deploying the first woven structure and, before, during, and/or after deploying the first woven structure, deploying the supplemental support structure.

[0334] The fistula may optionally be dilated with a PTA catheter before, during, and/or after deploying the prosthesis **620**. The diameter of the PTA catheter (e.g., about 3 mm to about 6 mm) may be selected based at least in part on: the diameter of the artery **600**, the diameter of the vein **602**, the composition of the interstitial tissue, the characteristics of the prosthesis **620**, combinations thereof, and the like.

[0335] Once the prosthesis **620** is in place, the prosthesis delivery system may be removed, as shown in FIG. 26B. An AV fistula is thereby formed between the artery **600** and the vein **602**.

[0336] Blood flows through the lumen of the prosthesis **620** even though the prosthesis lacks or is free from graft material due to the hemodynamic effects of the low porosity (e.g., less than about 50% porosity or other values described herein). FIG. 26B shows an implementation in which the blocking material **608**, **610** was not used. Once the prosthesis **620** is in place, valves in the veins may be made incompetent, for example as described herein.

[0337] In embodiments in which the prosthesis **620** comprises two pluralities of filaments that may be deployed separately (e.g., as described with respect to certain embodiments of FIG. 25B), the pluralities of filaments may be deployed at least partially simultaneously, sequentially deployed

without intervening steps, or sequentially with intervening steps such as the PTA steps described herein.

[0338] FIG. 27 schematically illustrates another example embodiment of a prosthesis 720 and a method for effecting retroperfusion. Although some dimensions and even an example scale of “10 mm” are provided, the shapes, dimensions, positional relationships, etc. of the features illustrated therein may vary. The prosthesis 720 is positioned in an artery 700 including an occlusion 704, in a vein 702, and spanning interstitial tissue T between the artery 700 and the vein 702. The prosthesis 720 may be positioned, for example, as described herein and/or using other methods. In some embodiments, the prosthesis 720 is delivered through a delivery system having a 5 Fr (1.67 mm) inner diameter over a guidewire having a 2 Fr (0.67 mm) outer diameter.

[0339] In some embodiments, the porosity of the first longitudinal section 722, the second longitudinal section 724, and/or the third longitudinal section 726, or one or more portions thereof may be between about 0% and about 50% and ranges therebetween, for example as described herein. Blood flow from the artery 700 may be diverted into the vein 702 through the prosthesis 720, for example due to hemodynamic forces such as a pressure difference between the artery 700 and the vein 702. The low porosity of the prosthesis 720 may allow the fluid to flow substantially through the lumen of the prosthesis 720 substantially without perfusing through the sidewalls of the prosthesis 720. In some embodiments, proximal and/or distal portions towards the ends of the prosthesis 720 may be configured to appose vessel sidewalls, for example having a lower porosity, since blood is not likely to flow through those portions.

[0340] The techniques described herein may be useful for forming a fistula between two body cavities near the heart, in the periphery, or even in the lower extremity such as the plantar arch. FIGS. 28A and 28B schematically illustrate arteries and veins of the foot, respectively. A fistula or anastomosis may be formed between two blood vessels in the foot. In one example, a passage from an artery to a vein was formed in the mid-lateral plantar, from the lateral plantar artery to the lateral plantar vein.

[0341] The artery supplying blood to the foot was occluded and the subintimal space was calcific. A wire was urged distally, and traversed into an adjacent vein. The hole between the artery and the vein was dilated with a 1.5 mm balloon, for example because a small arteriovenous fistula should not cause much if any damage for the patient at that position and in that position. After dilatation, blood started to flow from the artery to the vein without leakage. After such flow was confirmed, further dilatation of the space was performed using larger balloons (2.0 mm, 2.5 mm, 3.0 mm) at larger pressures (e.g., 20-30 atm). Leakage was surprisingly minimal or non-existent, even without placement of a stent, graft, scaffolding, or other type of device. Procedures not including a prosthesis may reduce costs, procedure time, complexity, combinations thereof, and/or the like. The lateral plantar vein goes directly into the vein arch of the forefoot, making it an excellent candidate for supplying blood to that portion of the foot. The patient had a lot of pain in the foot prior to the procedure and no pain in the foot after the procedure, indicating that blood was able to be supplied through the vein retrograde, as described herein. Fistula or anastomosis maintaining devices may optionally be omitted for certain situations, such as for hemodialysis in which a distal or lower extremity artery and vein may be described as “glued” in surrounding tissue (e.g., mid-lateral plantar artery and vein).

[0342] In some situations, a fistula or anastomosis maintaining device may be optionally used. Several fistula maintaining devices are described herein. FIG. 29 schematically illustrates an example embodiment of an anastomosis device 800. The anastomosis device includes a first section 802, a second section 804, and optionally a third section 806 longitudinally between the first section 802 and the second section 804. The first section 802 may be configured to anchor in a first body cavity (e.g., blood vessel such as an artery or vein). The first section 802 may include expandable members, barbs, etc. The second section 804 may be configured to anchor in a second body cavity (e.g., blood vessel such as an artery or vein, which may be the opposite type of the first

body cavity). The third section **806** may be configured to span between the lumens of the first body cavity and the second body cavity. In some embodiments, the space between the lumens of the first body cavity and the second body cavity generally comprises the vessel walls such that the dimensions of the third section **806** may be small or even omitted.

[0343] Some anastomosis devices are available and/or have been developed for the treating holes in larger vessels (e.g., Spyder from Medtronic, CorLink from Johnson and Johnson, Symmetry from St. Jude Medical, PAS-Port from Cardica, and ROX Coupler from ROX Medical). Such devices may be appropriate for use in the periphery or the lower extremity, for example if resized and/or reconfigured. Other devices are also possible.

[0344] FIG. **30** schematically illustrates an example embodiment of two blood vessels **902** and **904** coupled together with an anastomosis device **800** spanning the walls of the blood vessels **902**, **904**. The blood vessel **902** is an artery, as schematically shown by having thick walls, and the blood vessel **904** is a vein. Other combinations of blood vessels and other body cavities are also possible. After a passage **906** is formed between the first blood vessel **902** and the second blood vessel **904**, for example as described herein (e.g., using a wire, a deployable needle, one or more balloons, etc.), the anastomosis device **800** is deployed. For example, the distal end of an anastomosis device **800** deployment system may reside in the first blood vessel **902** and extend partially through the passage **906**. The first section **802** of the anastomosis device **800** may be deployed through the passage **906** and in the second blood vessel **904**. Upon deployment, the first section **802** may self-expand, for example to appose the walls of the second vessel **904**. The third section **806** of the anastomosis device **800** may be deployed through the passage **906**. Upon deployment, the third section **806** may self-expand, for example to appose the tissue surrounding the passage **906** and to maintain patency through the passage **906**. The second section **804** of the anastomosis device **800** may be deployed in the first blood vessel **902**. Upon deployment, the second section **804** may self-expand, for example to appose the walls of the first vessel **902**. One or more of the first section **802**, the second section **804**, and the third section **806** may be expanded using a balloon. Different balloons or series of balloons can be used for different of the sections **802**, **804**, **806** of the anastomosis device **800**.

[0345] FIGS. **32A** through **32D** illustrate an example method and device for identifying and avoiding a bifurcation **1104** in a percutaneous bypass procedure. A first vessel **1000** (e.g., an artery) is occluded by an occlusion **1008**. The occlusion **1008** may be partial or complete (e.g., causing critical limb ischemia). A percutaneous procedure, for example as described herein, can use a second vessel **1002** (e.g., a vein) to bypass the occlusion **1008**. A first catheter **1010** resides in the first vessel **1000**. A second catheter **1020** resides in the second vessel **1002**. The second vessel **1002** includes a bifurcation **1004** at a junction with a branch or collateral vessel **1006**. The first catheter **1010** comprises ultrasound transmitter **1012** (e.g., a directional transmitter) configured to send a signal **1014** to an ultrasound receiver **1022** (e.g., an omnidirectional receiver) of the second catheter **1020** in the second vessel **1002**, for example as described herein. A needle **1016** (FIG. **32D**) may extend out of the first catheter **1010** towards the second vessel **1002**. In the configuration shown in FIG. **32A**, if the needle **1016** extends at the same angle as the signal **1014**, for example as described herein (e.g., FIG. **3**), then the needle **1016** may extend into the bifurcation **1004** and into the branch vessel **1006**. Subsequent navigation of a guidewire through a lumen of the needle **1016** may disadvantageously be into the branch vessel **1006** rather than second vessel **1002**. Navigation in the branch vessel **1006** rather than the second vessel **1002** may be difficult to detect by the user.

[0346] FIG. **32B** illustrates a first step in an example method of diagnosing the existence and/or location of the bifurcation **1004**. The expandable member **1024** is expanded, for example by providing fluid flow (e.g., saline, contrast materials, etc.) through an inflation lumen **1026** in fluid communication with the expandable member. In FIGS. **32A-32D**, the second catheter **1020** comprises an integral expandable member **1024** (e.g., comprising a balloon) and an inflation lumen

**1026.** A separate catheter comprising an expandable member may be used in the second vessel **1002**. Expansion of the expandable member **1024** occludes the second vessel **1002**. As shown by the arrows **1027**, blood is still flowing towards the expandable member **1020** from both from a proximal end of the second vessel **1002** and from the branch vessel **1006**. The occlusion of the second vessel **1002** and the blood still flowing into the second vessel **1002** can cause the second vessel **1002** to expand. Expansion of the second vessel **1002** can make the second vessel easier to target and/or puncture with the needle **1016**.

[0347] FIG. **32C** shows the introduction of contrast material **1028** in the second vessel **1002**. The contrast material **1028** maybe delivered through an infusion port integral with the second catheter **1020** and/or using a separate catheter in the second vessel **1002**. The contrast material **1028** may comprise, for example contrast agents or contrast media configured to improve fluoroscopy including iodine-based, barium sulfate-based (e.g., for subjects with impaired kidney function), combinations thereof, and the like. The contrast material **1028** can contribute to expansion of the second vessel **1002**. The contrast material **1028** flows until reaching the expandable member **1024**, then begins to gather proximate to the expandable member **1024**. A portion of the contrast material **1028** may gather in the bifurcation **1004**, making the existence and location of the bifurcation **1004** and/or the branch vessel **1006** visible under fluoroscopy. Without the expandable member **1024**, the contrast material **1028** would flow through the second vessel **1002** without showing the bifurcation **1004** and/or the branch vessel **1006**. With knowledge of the angle of the needle **1016**, and the position of the first catheter **1010**, the user can determine whether the needle **1016** would extend into the bifurcation **1004** and/or the branch vessel **1006**. Since this situation would generally result in ineffective bypass, a different puncture site for forming a fistula may be selected.

[0348] In FIG. **32D**, the first catheter **1010** has been retracted by a distance **1018**. The ultrasound signal **1014** (FIG. **32A**) from the first catheter **1010** may be used to target the second catheter **1020**. The procedure shown in FIGS. **32B** and **32C** may be repeated, for example looking for another bifurcation. Once the user is satisfied with that the needle **1016** will puncture the second vessel **1002** at a position free from a bifurcation to inhibit or prevent advancement into a branch vessel rather than the second vessel **1002**, the needle **1016** may be extended from the first catheter **1010**, out of the first vessel **1000**, through interstitial tissue between the first vessel **1000** and the second vessel **1002**, and into the second vessel **1002** at a position at which the second vessel **1002** does not include a bifurcation or branch vessel. The needle **1016** may be extended with the expandable member **1024** inflated or deflated, or even with the second catheter **1020** removed from the second vessel **1002**. In some embodiments, a permanent occluder may be positioned in the second vessel **1002**, for example as described herein (e.g., FIG. **4**). A guidewire may be tracked through a lumen of the needle **1016**, and other procedures as described herein, for example fistula dilation, deployment of a fistula prosthesis, deployment of a stent graft, use of a reverse valvulotome, etc., can be performed by tracking a catheter over guidewire (e.g., through the first vessel **1000**, through the fistula, and then through the second vessel **1002**). In some embodiments, the devices and methods described herein can be used to guide a needle into a bifurcation and/or a branch vessel if desired by the user.

[0349] FIGS. **33A** and **33B** schematically illustrate an example procedure that can be performed the following connection of a first vessel **1100** (e.g., an artery) and a second vessel **1102** (e.g., a vein) with a needle **1116** traversing interstitial tissue **1101**. The needle **1116** extends from a first catheter **1110** in the first vessel **1100**. The first vessel **1100** is occluded by an occlusion **1108**. In FIG. **33A**, a guidewire **1118** extends through a lumen in the needle **1116**, and can then be navigated through the second vessel **1102**. The needle **1116** may be retracted upon placement of the guidewire **1118**, and the first catheter **1110** may be retracted from the first vessel **1100**. As illustrated in FIG. **33B**, a second catheter **1120** maybe tracked over the guidewire **1118** through the first vessel **1100**, through the interstitial tissue **1101**, and into the second vessel **1102**. In FIG. **33B**, the second catheter **1120** comprises a balloon catheter comprising a balloon **1122** (e.g., a PTA balloon). Inflation of the

balloon **1122** can dilate a fistula formed between the first vessel **1100** and the second vessel **1102**. Dilation of the interstitial tissue **1101** and/or aperture in the vessels **1100**, **1102** can enhance later procedures, such as placement of a prosthesis across the fistula.

[0350] FIGS. **34A** through **35F** illustrate example procedures that can be performed when a guidewire **1118** is in a vessel **1102** (e.g., a vein). In FIG. **34A**, a prosthesis **1124** has been placed across the interstitial tissue **1101** between the first vessel **1100** in the second vessel **1102**. The deployment system for placing the prosthesis **1124** may have been tracked over the guidewire **1118**. A catheter **1130A** is tracked over the guidewire **1118** distal to the prosthesis **1124**. As shown in FIG. **34B**, the catheter **1130A** may be tracked all the way towards a heel **1103** of the subject.

[0351] As shown in FIG. **34C**, the catheter **1130A** is configured to deliver a first stent graft **1132A**, which can line the second vessel **1102**, disabling valves in the second vessel **1102**, occluding branch vessels of the second vessel **1102**, etc., for example as described. In FIG. **34D**, the catheter **1130A** has been retracted and another catheter **1130B** has been tracked over the guide wire **1118**. FIG. **34D** also shows an example of where the occlusion **1108** in the first vessel **1100** may terminate, which may be useful if another fistula was formed between the first vessel **1100** and the second vessel **1102** (e.g., to bypass the occlusion **1108**). Forming a second fistula may be the same or different than forming the first fistula (e.g., using at least one of the ultrasound guidance, extending a needle, and prosthesis deployment described herein). In FIG. **34E**, the catheter **1130B** is delivering a second stent graft **1132B**, which may at least partially overlap the first stent graft **1132A** in an area **1133**. In some embodiments, the distal end of the second stent graft **1132B** may be configured to overlap the proximal end of the first stent graft **1132A**. In some embodiments, the proximal end of the first stent graft **1132A** may be configured to be overlapped by the distal end of the second stent graft **1132B**. In some embodiments, for example if the second stent graft **1132B** is placed first, the proximal end of the first stent graft **1132A** may be configured to be overlapped by the distal end of the second stent graft **1132B**. The second stent graft **1132B** may be longitudinally spaced from the first stent graft **1132A**, for example if the longitudinal spacing is small enough that there is unlikely to be a branch vessel and/or a valve in the location of the spacing.

[0352] In FIG. **34F**, the second stent graft **1132B** at least partially overlaps the prosthesis **1124**. In some embodiments, the proximal end of the second stent graft **1132A** may be configured to overlap the distal end of the prosthesis **1124**. In some embodiments, the distal end of the prosthesis may be configured to be overlapped by the proximal end of the second stent graft **1132B**. The second stent graft **1132B** may be longitudinally spaced from the prosthesis **1124**, for example if the longitudinal spacing is small enough that there is unlikely to be a branch vessel and/or a valve in the location of the spacing. FIG. **34F** also shows the catheter **1132B** retracted out of the vasculature. Although two stent grafts **1132A**, **1132B** are described in this example, one, two, three, or more stent grafts may be used, for example depending on the length of the second vessel **1102** distal to the prosthesis **1124**, the length(s) of the stent graft(s), the likelihood or existence of branch vessels, etc.

[0353] FIG. **35A** shows the second vessel **1102** distal to the first stent graft **1132A**. The second vessel **1102** comprises a first valve **1105A** that inhibits or prevents blood **1111** from flowing distal to the first valve **1105A**. In FIG. **35B**, a catheter **1140** is tracked over the guidewire **1118** towards the first valve **1105A** through the stent graft **1132A**. The catheter **1140** comprises a valve disabling device. In FIG. **35C**, the catheter **1140** is shown as comprising a reverse valvulotome **1142**, for example as described herein, and a sheath **1144**. Referring again FIG. **35B**, when the reverse valvulotome **1142** is in the sheath **1144**, the reverse valvulotome **1142** is in a radially contracted state. As shown in the FIG. **35C**, when the sheath **1144** is proximally retracted and/or the reverse valvulotome **1142** is distally advanced, the reverse valvulotome **1142** radially expands to a state configured to cut valves upon distal advancement. In FIG. **35D**, the blade or blades of the reverse valvulotome **1142** ablate or cut or sever the leaflets of the first valve **1105A**, allowing blood **1111** to flow distal to the first valve **1105A**.

[0354] Referring to FIG. **35E**, after the first valve **1105A** has been disabled, the reverse

valvulotome **1142** may be radially compressed in the outer sheath **1144** for further distal advancement without affecting the second vessel **1102**. As shown in FIG. 35F, when a second valve **1105B** is encountered, the reverse valvulotome **1142** may extend from the sheath **1144** and then distally advanced to disable the second valve **1105B**, allowing the blood **1111** to flow distal to the second valve **1105B**. The use of the reverse valvulotome **1142** may be repeated for as many valves in the second vessel **1102** as desired by the user. In some embodiments, a reverse valvulotome **1142** may be used before placement of stent grafts **1132A**, **1132B**. Valve disabling devices other than a reverse valvulotome, for example but not limited to the two-way valvulotome **1300** as described herein, may also or alternatively be used.

[0355] FIGS. 36A through 36D illustrate method of promoting retroperfusion of blood through a vein into toes. In FIG. 36A, the vasculature illustrated includes a lateral plantar vein **1200**, a deep plantar venous arch **1202**, metatarsal veins **1204**, and a medial plantar vein **1206**. Blood flow through the lateral plantar vein **1200**, as illustrated by the arrow **1201**, is counter to the normal direction of blood flow, for example due to retroperfusion caused by percutaneous bypass from an artery into a vein upstream of the lateral plantar vein **1200**. The blood continues to flow through the vasculature as shown by the arrows **1203**, where the blood is joined by blood flowing away from the toes in the normal direction of blood flow through the metatarsal veins **1204**, as indicated by the arrows **1205**. The medial plantar vein **1206** is configured to return blood towards the heart, so normal blood flow, as indicated by the arrow **1207**, is maintained. Blood may preferentially flow as illustrated in FIG. 36A, which is not desirable when the intended effect of the retroperfusion is to perfuse oxygenated blood to the toes.

[0356] FIG. 36B illustrates an example embodiment of a device that can be used to promote blood flow to the toes through the metatarsal veins **1204**. A first catheter **1210** comprising a first expandable member **1212** (e.g., balloon) may comprise a 6 French occlusion catheter comprising a three-way fitting. The expandable member **1212** is inflated in the lateral plantar vein **1200**. A second catheter **1220** that is coaxial with the first catheter **1210** extends through the expandable member **1212**, through the deep plantar venous arch **1202**, and into the medial plantar vein **1206**. The second catheter **1220** comprises an expandable member **1222** (e.g., balloon), which may be inflated in the medial plantar vein **1206**. At that point, the medial plantar vein **1206** is partially or fully occluded, and blood flow through the medial plantar vein **1206** is inhibited or prevented. Blood may continue to flow from the toes through the metatarsal veins **1204**, as indicated by the persistence of the arrows **1205**. The blood has no exit route, so hydrostatic pressure may build up in the deep plantar venous arch **1202**, which can disable valves and/or other structures configured to promote normal blood flow. Optionally, the first expandable member **1212** may permit retroperfusion blood to flow, which can further build pressure in the deep plantar venous arch **1202**. Blood flow would normally perfuse opposite to the direction of the retroperfusion in the lateral plantar vein **1200**, but the expandable member **1212** can inhibit or prevent such flow.

[0357] In some embodiments, a device comprising a single catheter may be used to promote blood flow to the toes through the metatarsal veins **1204**. The device may comprise a first expandable member and a second expandable member. For example, the device can comprise a double balloon catheter having a first balloon and a second balloon distal to the first balloon.

[0358] The device may allow one of the first and second expandable members to inflate independently of the other expandable member. For example, in some embodiments, the device may comprise at least a first lumen and a second lumen. The first lumen can be configured to inflate the first expandable member independently of the second expandable member. The second lumen can be configured to inflate the second expandable member independently of the first expandable member. The device may comprise a single lumen configured to inflate both the first and second expandable members. The device may include one or more inflation ports configured to inflate at least one of the first and second expandable members.

[0359] The device may be configured to adjust the distance between the expandable members prior



to inflation of at least one of the expandable members. The device may permit the expandable members to isolate a patient-specific treatment area and promote retroperfusion of blood through a vein into toes, as described herein. For example, the device may permit the placement of the first expandable member in the lateral plantar vein **1200** and placement of the second expandable member in the medial plantar vein **1206**, and/or vice versa. The device may comprise one or more handles configured to control the movement of various portions of the device. For example, the device may comprise a first handle to control the movement of both the first and second expandable members. In some embodiments, the device may comprise a second handle configured to control the movement of the first expandable member independently of the second expandable member. The second handle may allow the device to advance the first expandable member in a proximal direction relative to the second expandable member from a first position to a second position. After the first expandable member has been advanced to a second position, the second handle may allow the device to advance the first expandable member in a distal direction to the first position.

[0360] The device may comprise an infusion port configured to inject fluid into a treatment area defined by the first and second expandable members. For example, the treatment area may comprise the deep plantar venous arch **1202**. After the first and second expandable members have been inflated, blood flow through the medial plantar vein **1206** is inhibited or prevented. The infusion port may then allow the device to inject fluid into the treatment area. The injection of fluid can increase hydrostatic pressure within the treatment area. The hydrostatic pressure increases due to the inflated first and second expandable members preventing the injected fluid from flowing outside the treatment area through the medial plantar vein **1206** and/or the lateral plantar vein **1200**. The infusion port can be configured to sufficiently increase in hydrostatic pressure within the treatment area to allow the device to disable valves and/or other structures. For example, the infusion port may be sized to inject an amount of fluid sufficient to increase the hydrostatic pressure to promote blood flow to the toes.

[0361] In FIG. **36C**, blood flow is allowed through the expandable member **1212**, as shown by the arrow **1201**, but the inflatable member **1212** inhibits normal blood flow in the deep plantar venous arch **1202**. Pressure due to the restricted flow builds up in the deep plantar venous arch **1202**. The pressure buildup, optionally in combination with the flow of blood from the lateral plantar vein **1200**, can cause reversal of blood flow into the metatarsal veins **1204**, as shown by the arrows **1209**.

[0362] In FIG. **36D**, the first catheter **1210** and the second catheter **1220** are removed. The disabling of the normal vasculature in the deep plantar venous arch **1202** causes continued retroperfusion of blood through the metatarsal veins **1204**, as shown by the maintenance of the arrows **1209**. A small amount of oxygenated blood may flow through the medial plantar vein **1206**. In some embodiments, the medial plantar vein **1206** may remain occluded using the expandable member **1222** (e.g., detachable from the catheter **1220**) or a different occluder. In some embodiments, blood may flow through the plantar vein **1206** in a direction opposite normal blood flow.

[0363] FIG. **37A** illustrates an example of a valve disabling device **1300** in a radially expanded state. The valve disabling device **1300** is configured to cut or ablate or sever or disable leaflets of a valve (e.g., a venous valve) upon retraction and/or advancement in a radially expanded state. The valve disabling device **1300** comprises a proximal portion **1308**, a distal portion **1306**, and intermediate portion **1302** between the proximal portion **1308** and the distal portion **1306**. The proximal portion **1308** comprises a tubular element. The distal portion **1306** comprises a tubular portion. The device **1300** may be formed by cutting (e.g., laser cutting) a hypotube, cutting a flat sheet and rolling into a hypotube, forming parts of the device **1300** and then coupling the parts together, shape setting, combinations thereof, and the like. The tubular element of the distal portion **1306** and/or the tubular element of the proximal portion **1308** may comprise an uncut portion of a

hypotube or sheet.

[0364] The proximal portion **1308** may be coupled to a pusher element **1320**. The pusher element may comprise a lumen, for example configured to advance across a guidewire. The device **1300** may be in a radially compressed state when confined in a sheath **1304** and in a radially expanded state when not confined in the sheath **1304**. The device **1300** may be radially expanded by proximally retracting the sheath **1304** and/or by distally advancing the pusher element **1320** and thereby the device **1300**. The device **1300** may be radially compressed by distally advancing the sheath **1304** and/or by proximally retracting the pusher element **1320** and thereby the device **1300**. In the radially expanded state, the intermediate portion **1302** may radially expand while the proximal portion **1308** and the distal portion **1306** do not radially expand (e.g., as shown in FIG. 37A).

[0365] The intermediate portion **1302** may comprise cut portions of a hypotube or sheet. The intermediate portion **1302** may comprise one or more struts **1316** extending between the proximal portion **1308** and the distal portion **1306**. The intermediate portion **1302** may comprise between about one strut and about eight struts (e.g., one strut, two struts, three struts (e.g., as shown in FIG. 37A), four struts, five struts, six struts, seven struts, eight struts, ranges between such values, etc.). The struts **1316** may be approximately equally circumferentially spaced, for example to provide uniform cutting in any circumferential orientation. For example, three struts **1316** may be circumferentially spaced by about 120°. The struts **1316** may unequally circumferentially spaced, for example to provide more cutting in a certain circumferential area. For example, a first strut **1316** may be circumferentially spaced from a second strut **1316** by about 135° and spaced from a third strut **1316** by about 135°, and the second strut **1316** may be spaced from the third strut **1316** by about 90°.

[0366] The strut **1316** may comprise between about one and about four blades (e.g., one blade, two blades (e.g., as shown in FIG. 37A), three blades, four blades, ranges between such values, etc.). The strut **1316** shown in FIG. 37A comprises a first blade **1312** and a second blade **1314**. The first blade **1312** faces proximally and is configured to cut as the device **1300** is proximally retracted. The second blade **1314** faces distally and is configured to cut as the device **1300** is distally advanced. The proximally facing blades **1312** and the distally facing blades **1314** allow the device **1300** to disable a valve when proximally retracted and/or when distally advanced, providing flexibility as a two-way valvulotome. Other configurations are also possible. For example, a first strut **1316** may comprise a proximally facing blade **1312** and a second strut **1316** may comprise a distally facing blade **1314**. For another example, a first strut **1316** may comprise a plurality of proximally facing blades **1312** and a second strut **1316** may comprise a plurality of distally facing blades **1314**. For another example, a first strut **1316** may comprise a proximally facing blade **1312** and a distally facing blade **1314** and a second strut **1316** may comprise zero blades or be free of or devoid of blades. For another example, a first strut **1316** may comprise a proximally facing blade **1312** and a distally facing blade **1314** and a second strut **1316** may comprise a distally facing blade **1314**. For another example, a first strut **1316** may comprise two proximally facing blades **1312** and a distally facing blade **1314**.

[0367] FIG. 37B is a flattened side view of the valve disabling device **1300** of FIG. 37A. The device **1300** may be cut from a flat sheet that is rolled into a hypotube. FIG. 37B provides an example cut pattern that may be used to form the device **1300**. The cut pattern shown in FIG. 37B may also be on a round hypotube. FIG. 37B provides some example dimensions of the device **1300**. The length **1340** of the distal portion **1306** may be between about 0.1 mm and about 3 mm (e.g., about 0.1 mm, about 0.5 mm, about 1 mm, about 1.5 mm, about 2 mm, about 3 mm, ranges between such values, etc.). The distal portion **1306** may have a length **1340** configured to provide a stable joint for the distal ends of the struts **1316**. The circumferential length **1342** of the distal portion **1306** may be between about 1.5 mm and about 5 mm (e.g., about 1.5 mm, about 2 mm, about 2.5 mm, about 3 mm, about 3.5 mm, about 4 mm, about 5 mm, ranges between such values,

etc.). The circumferential length **1342** of the distal portion **1306** may correspond to a circumference of a hypotube used to form the disabling device **1300** or an expansion thereof. The length **1344** of the space between struts **1316** may be between about 0.1 mm and about 1 mm (e.g., about 0.1 mm, about 0.2 mm, about 0.3 mm, about 0.4 mm, about 0.5 mm, about 0.7 mm, about 0.8 mm, about 0.9 mm, about 1 mm, ranges between such values, etc.). The length **1344** of the space between struts **1316** may be between about 2% and about 67% of the circumferential length **1340** of the distal portion **1306** (e.g., about 2%, about 5%, about 10%, about 15%, about 20%, about 25%, about 35%, about 50%, about 67%, ranges between such values, etc.). The circumferential thickness **1346** of the struts **1316** may be between about 0.1 mm and about 1 mm (e.g., about 0.1 mm, about 0.2 mm, about 0.3 mm, about 0.4 mm, about 0.5 mm, about 0.7 mm, about 0.8 mm, about 0.9 mm, about 1 mm, ranges between such values, etc.). The circumferential thickness **1346** of the struts **1316** may be between about 2% and about 67% of the circumferential length **1340** of the distal portion **1306** (e.g., about 2%, about 5%, about 10%, about 15%, about 20%, about 25%, about 35%, about 50%, about 67%, ranges between such values, etc.). Thicker struts **1316** and/or less spacing between the struts **1316** may provide more rigidity and cutting than thinner struts **1316**. Thinner struts **1316** and/or more spacing between the struts **1316** may use less force for radial expansion and/or retraction. If the spaces between the struts **1316** have rounded proximal edges, the radius of curvature **1350** at the interface between the proximal portion **1308** and the intermediate portion **1302** may be between about 0.1 mm and about 0.5 mm (e.g., about 0.1 mm, about 0.2 mm, about 0.3 mm, about 0.4 mm, about 0.5 mm, ranges between such values, etc.). If the spaces between the struts **1316** have rounded distal edges, the radius of curvature at the interface between the distal portion **1306** in the intermediate portion may be between about 0.1 mm and about 0.5 mm (e.g., about 0.1 mm, about 0.2 mm, about 0.3 mm, about 0.4 mm, about 0.5 mm, ranges between such values, etc.). The radii of curvature at the proximal and distal interfaces may be the same or different. Rather than a radius of curvature, the struts **1316** could meet the proximal portion **1308** and/or the distal portion **1306** at angle. The length **1348** of the proximal portion **1308** may be between about 0.1 mm and about 8 mm (e.g., about 0.1 mm, about 0.5 mm, about 1 mm, about 2 mm, about 3 mm, about 4 mm, about 5 mm, about 6 mm, about 8 mm, ranges between such values, etc.). The proximal portion **1308** may have a length **1348** configured to provide a stable joint for the proximal ends of the struts **1316**. The proximal portion **1308** may have a length **1348** configured to be coupled to the pusher element **1320**. The circumferential length of the proximal portion **1308** may correspond to a circumference of a hypotube used to form the disabling device **1300** or an expansion thereof. The circumferential length of the proximal portion **1308** may be the same or different than the circumferential length **1342** of the distal portion **1306**. For example, if the device **1300** is cut from a hypotube and the proximal portion **1308** and the distal portion **1306** comprise uncut portions of the hypotube, the proximal portion **1308** and the distal portion **1306** may have the same circumferential length, or one may be expanded relative to the other (e.g., due to a shape setting process, expansion by outward force of a pusher element **1320**, etc.).

[0368] FIG. 37C is an expanded view of the flattened side view of the valve disabling device **1300** of FIG. 37A in the area identified by the circle 37C in FIG. 37B. FIG. 37C shows some example dimensions of the device **1300**. The radius of curvature **1356** of the blade **1314** may be between about 0.1 mm and about 1 mm (e.g., about 0.1 mm, about 0.2 mm, about 0.3 mm, about 0.4 mm, about 0.5 mm, about 0.7 mm, about 0.8 mm, about 0.9 mm, about 1 mm, ranges between such values, etc.). The distance **1358** between an edge of the blade **1314** and a strut **1316** may be between about 0.1 mm and about 2 mm (e.g., about 0.1 mm, about 0.25 mm, about 0.5 mm, about 0.75 mm, about 1 mm, about 1.25 mm, about 1.5 mm, ranges between such values, etc.). The combined thickness **1360** of a strut **1316** and blade may be between about 0.1 mm and about 3 mm (e.g., about 0.1 mm, about 0.5 mm, about 1 mm, about 1.5 mm, about 2 mm, about 3 mm, ranges between such values, etc.). The dimensions of the blade **1312** on the strut **1316** of FIG. 37C may be the same or different than the dimensions of the blade **1314** in FIG. 37C. The dimensions of the

other blades **1314** may be the same or different than the dimensions of the blade **1314** in FIG. **37C**. [0369] FIG. **37D** is an end view of the valve disabling device **1300** of FIG. **37A** flattened as shown in FIG. **37B**. FIG. **37D** shows some example dimensions of the device **1300**. The thickness **1362** may be between about 0.05 mm and about 0.25 mm (e.g., about 0.05 mm, about 0.1 mm, about 0.15 mm, about 0.2 mm, about 0.25 mm, ranges between such values, etc.). A greater thickness **1362** may provide more rigidity and cutting force. A smaller thickness **1362** may use less force for radial expansion and/or retraction. If the device **1300** is formed from a hypotube, the thickness **1362** maybe a difference between an inner diameter of the hypotube and an outer diameter of the hypotube, or the thickness of the hypotube wall. The circumferential distance **1342**, as described above, may be about 1.5 mm and about 5 mm (e.g., about 1.5 mm, about 2 mm, about 2.5 mm, about 3 mm, about 3.5 mm, about 4 mm, about 5 mm, ranges between such values, etc.).

[0370] FIG. **37E** is an end view of the valve disabling device **1300** of FIG. **37A** in a radially contracted state. FIG. **37** shows some example dimensions of the device **1300** in a radially contracted state. The outer diameter **1352** may be between 0.6 mm and about 1.5 mm (e.g., about 0.6 mm, about 0.8 mm, about 1 mm, about 1.2 mm, about 1.5 mm, ranges between such values, etc.). The outer diameter **1352** is greater than the inner diameter **1354**. The inner diameter **1354** may be between about 0.5 mm and about 1.4 mm (e.g., about 0.5 mm, about 0.75 mm, about 1 mm, about 1.25 mm, about 1.4 mm, ranges between such values, etc.). Referring again to FIG. **37D**, the thickness **1362** may correspond to the difference between the outer diameter **1352** and the inner diameter **1354**, divided by two. For example, if the outer diameter **1352** is 1 mm and the inner diameter **1354** is 0.8 mm, the thickness **1362** would be:  $(1\text{ mm}-0.8\text{ mm})/2=0.1\text{ mm}$ .

[0371] FIG. **37F** is a side view of the valve disabling device **1300** of FIG. **37A** in a radially contracted state. FIG. **37G** is another side view of the valve disabling device **1300** of FIG. **37A** in a radially contracted state and circumferentially rotated compared to FIG. **37F**. FIGS. **37F** and **37G** show some example dimensions of the device **1300** in a radially contracted state. The length **1364** between a distal end of the distal portion **1306** and a proximal end of the proximal portion **1308** may be between about 15 mm and about 27 mm (e.g., about 15 mm, about 18 mm, about 21 mm, about 24 mm, about 27 mm, ranges between such values, etc.). Referring again to FIG. **37B**, the length **1340** of the distal portion **1306** and the length **1348** of the proximal portion **1308** may be subtracted from the length **1364** to calculate the length of the intermediate portion **1302**. The length **1366** between an edge of the blade **1314** and a distal end of the proximal portion **1308** may be between about 5 mm and about 10 mm (e.g., about 5 mm, about 6 mm, about 7 mm, about 8 mm, about 9 mm, about 10 mm, ranges between such values, etc.). The length **1366** may affect and/or be based on a diameter of the blade **1314** in a radially expanded state.

[0372] FIG. **37H** is a side view of the valve disabling device **1300** of FIG. **37A** in a radially expanded state. FIG. **37I** is another side view of the valve disabling device **1300** of FIG. **37A** in a radially expanded state and circumferentially rotated compared to FIG. **37H**. FIGS. **37H** and **37G** show some example dimensions of the device **1300** in a radially expanded state. The radially expanded state shown in FIGS. **37H** and **37G** may be fully expanded (e.g., the shape of the device **1300** absent external forces) or a partially radially expanded state. The length or radius **1368** between a longitudinal axis **1367** through a center of the device **1300** and outer circumference of an expanded intermediate portion **1302** may be between about 0.5 mm and about 7 mm (e.g., about 0.5 mm, about 1 mm, about 1.5 mm, about 2 mm, about 2.5 mm, about 3 mm, about 4 mm, about 5 mm, about 6 mm, about 7 mm, ranges between such values, etc.). A length **1370** between a distal end of the distal portion **1306** and a proximal end of the proximal portion **1308** may be between 10 mm and about 25 mm (e.g., about 10 mm, about 15 mm, about 18 mm, about 20 mm, about 22 mm, about 25 mm, ranges between such values, etc.). Referring again to FIG. **37F**, the length **1364** in a radially contracted state may be longer than the length **1370** in the radially expanded state. The difference between the length **1370** and the length **1364** may be between about 0.1 mm and about 1 mm (e.g., about 0.1 mm, about 0.2 mm, about 0.3 mm, about 0.4 mm, about 0.5 mm, about 0.6

mm, about 0.7 mm, about 0.8 mm, about 0.9 mm, ranges between such values, etc.). Referring again to FIG. 37B, the length **1340** of the distal portion **1306** and the length **1348** of the proximal portion **1308** maybe subtracted from the length **1370** to calculate the length of the intermediate portion **1302** in a really expanded state. The length **1372** between a tip of a first blade **1314** and a second blade **1314**, taken transverse to the longitudinal axis **1367** of the device **1300**, may be between about 2 mm and about 4 mm (e.g., about 2 mm, about 2.5 mm, about 3 mm, about 3.5 mm, about 4 mm, ranges between such values, etc.).

[0373] FIG. 37J is a cross-sectional end view of the valve disabling device **1300** of FIG. 37A in a radially expanded state taken along the line 37J-37J of FIG. 37H. FIG. 37J shows that the blades **1314** maybe rotated relative to the struts **1316**, as indicated by the arrows **1321**. Each blade **1314** may be rotated the same amount and in the same direction, or different blades **1314** may be rotated in different amounts and/or in different directions. The blades **1312** may also be rotated the same way and/or in a different way (e.g., opposite) than as shown for the blades **1314** in FIG. 37J.

[0374] FIGS. 37Ki through 37Nii illustrate example procedures that can be performed using the valve disabling device **1300** of FIG. 37A. The procedures are not mutually exclusive and maybe performed based on, for example, user preference, anatomy, vessel access point, other procedure(s) being performed, combinations thereof, and the like.

[0375] FIG. 37Ki shows a device **1300** being tracked through a vessel **1301** having a valve **1305**. The device **1300** may be tracked over a guidewire **1318** that has been navigated through the valve **1305**. The device **1300** may be advanced over the guidewire **1318** in a radially contracted state, with the intermediate portion **1302** collapsed in the sheath **1304**. In FIG. 37Kii, the sheath **1304** is retracted, as indicated by the arrow **1323**, which allows the intermediate portion **1302** to radially expand, as shown by the arrows **1325**. The device **1300** may then be distantly advanced, as shown by the arrow **1327**. The distally facing blades **1314** may interact with the valve **1305** to cut or ablate or disable the leaflets of the valve **1305**. The intermediate portion **1302** may be really compressed by proximally retracting the device **1300** into the sheath **1304** and/or by distally advancing the sheath **1304** over the device **1300**. The device **1300** may then be used to disable another valve or withdrawn as desired.

[0376] FIG. 37Li shows a device **1300** tracked through the cavity a vessel **1301** including a valve **1305**. The device **1300** has been advanced distal to the valve **1305** in a radially contracted state over the guidewire **1318**. In FIG. 37Lii, the sheath **1304** is proximally retracted, as indicated by the arrow **1323**, which allows the intermediate portion **1302** of the device **1300** to radially expand, as shown by the arrows **1325**. The device **1300** may then be proximally retracted, as shown by the arrow **1329**, which allows the proximally facing blade **1312** to disable the valve **1305**. The intermediate portion **1302** may be really compressed by proximally retracting the device **1300** into the sheath **1304** and/or by distally advancing the sheath **1304** over the device **1300**. The device **1300** may then be used to disable another valve or withdrawn as desired.

[0377] FIG. 37Mi shows a device **1300** being tracked through a vessel **1301** having a valve **1305**. The device **1300** may be tracked over a guidewire **1318** that has been navigated through the valve **1305**. The device **1300** may be advanced over the guidewire **1318** in a radially contracted state, with the intermediate portion **1302** collapsed in the sheath **1304**. In FIG. 37Mii, the sheath **1304** is retracted, as indicated by the arrow **1323**, which allows the intermediate portion **1302** to radially expand, as shown by the arrows **1325**. The device **1300** may then be distantly advanced, as shown by the arrow **1327**. The distally facing blades **1314** may interact with the valve **1305** to cut or ablate or disable the leaflets of the valve **1305**. The intermediate portion **1302** may be really compressed by proximally retracting the device **1300** into the sheath **1304** and/or by distally advancing the sheath **1304** over the device **1300**. The device **1300** may then be used to disable another valve or withdrawn as desired. Compared to FIGS. 37Ki and 37Kii, the method shown in FIGS. 37Mi and 37Mii is from an opposite direction. One direction may be upstream and the other direction may be downstream. One direction may be in the direction of normal blood flow and the

other direction may be the direction of blood flow after retroperfusion.

[0378] FIG. 37Ni shows a device **1300** tracked through the cavity a vessel **1301** including a valve **1305**. The device **1300** has been advanced distal to the valve **1305** in a radially contracted state over the guidewire **1318**. In FIG. 37Nii, the sheath **1304** is proximally retracted, as indicated by the arrow **1323**, which allows the intermediate portion **1302** of the device **1300** to radially expand, as shown by the arrows **1325**. The device **1300** may then be proximally retracted, as shown by the arrow **1329**, which allows the proximally facing blade **1312** to disable the valve **1305**. The intermediate portion **1302** may be really compressed by proximally retracting the device **1300** into the sheath **1304** and/or by distally advancing the sheath **1304** over the device **1300**. The device **1300** may then be used to disable another valve or withdrawn as desired. Compared to FIGS. 37Li and 37Lii, the method shown in FIGS. 37Ni and 37Nii is from an opposite direction. One direction may be upstream and the other direction may be downstream. One direction may be in the direction of normal blood flow and the other direction may be the direction of blood flow after retroperfusion.

[0379] FIG. 38A schematically illustrates an example of a distal end of a catheter **1400**. The catheter **1400** may include an ultrasound transducer or other targeting device. The catheter **1400** may be used in a second vessel (e.g. a vein) that can be targeted by another catheter (e.g., comprising an ultrasound transducer) in a first vessel. The distal end of the catheter **1400** comprises a capture element **1404** having a funnel shape extending distal to a tubular element **1402**. The capture element **1404** may extend out the tubular element **1402**, for example due to an actuation mechanism coupled to the handle and the capture element **1404**, by comprising shape memory material configured to assume a predetermined shape upon undergoing a phase change due to temperature (e.g., due to body temperature versus room temperature), due to expansion by an expandable member (e.g., an inflatable balloon), and/or other mechanisms. The capture element **1404** may have an angle between about 90° and about 170° (e.g., about 90°, about 110°, about 130°, about 150°, about 170°, ranges between such values, etc.). The tubular member **1402** may comprise a lumen **1408** extending at least partially therethrough for guiding a guidewire captured by the capture element **1404** through the catheter **1400**. Guiding a guidewire through the catheter **1400** can ensure that the guidewire is advanced through the same vessel(s) as the catheter **1400**, rather than through unintended branch or collateral vessels. The lumen **1408** may comprise an expanded portion **1409** that is internal to the tubular member **1402**.

[0380] FIGS. 38B through 38D illustrate an example procedure that can be performed using the distal end of the catheter **1400** of FIG. 38A. FIG. 38B is similar to FIG. 32D in that a needle **1016** has passed from a first vessel **1000**, through interstitial tissue, and into a second vessel **1002**. The catheter **1400** of FIG. 38A is in the second vessel **1002**. The catheter **1400** may have been proximally retracted, for example as indicated by the arrow **1403**, after being successfully targeted by the catheter **1010** in the first vessel **1000**. The distance of retraction of the catheter **1400** after successful targeting may be predetermined (e.g., based on a distance between the distal end of the catheter **1400** and a transducer of the catheter **1400**) and/or maybe based on user experience, fluoroscopy, combinations thereof, and the like. In FIG. 38C, the capture element **1404** has expanded out of the distal end of the catheter **1400**. The capture element **1404** can act as a funnel to guide a guidewire extending out of the needle **1016** into the catheter **1400**. In FIG. 38D, a guidewire **1406** extends out of the needle **1016**, for example as described herein, is captured by the capture element **1404**, and then is guided by the portion **1409** into the lumen **1408**. The guidewire **1406**, further distally advanced, will extend further into the lumen **1408**, as opposed to any chance of the guidewire **1406** extending through the branch vessel **1006** and/or other branch vessels. Procedures performed by tracking over the guidewire **1406** (e.g., valve disabling, graft placement, balloon expansion, etc.), can ensure that such procedure will be performed in the intended vessels, which can provide better and more predictable retroperfusion.

[0381] FIGS. 38Ei and 38Eii illustrate an example of a distal end of a catheter **1440**. The catheter

**1440** may be similar to the catheter **1400**. The catheter **1440** includes an inflation lumen **1445** and an expandable member **1446** (e.g., comprising a balloon). When the catheter **1440** is in an appropriate position, for example as illustrated in FIG. **38B**, an expandable member **1444** may be expanded, and the capture element **1444** may be expanded by the expandable member **1446**. Compared to FIG. **38Ei**, FIG. **38Eii** shows the expandable member **1446** slightly distally advanced and then in expanded in order to push the capture element **1444** radially outward. The expandable member **1446** may be positioned and/or shaped to expand the capture element **1444** without being distally advanced. As described above, other methods of expanding a capture element **1444** are also possible.

[0382] FIG. **38F** illustrates an example of a portion of a catheter **1420**. The catheter **1420** comprises an ultrasound transducer **1422**. The catheter **1420** comprises a capture element **1424** that extends out a side of the catheter **1420**. The capture element **1424** may comprise a funnel leading to a lumen **1428**, which may optionally comprise an expanded portion **1429**. The capture element **1424** is configured to capture a guidewire **1406** and guide the guidewire **1406** into the lumen **1428**. The capture element **1424** may be located proximate to the transducer **1422**. In accordance with certain targeting systems described herein, the needle **1016** may extend towards the transducer **1422** such that the guidewire **1406** extending out of the needle **1016** would be proximate to the transducer **1422**, and thus proximate to the capture element **1424**. The capture element **1424** may be proximal to the transducer **1422**.

[0383] FIG. **38G** illustrates another example of a portion of a catheter **1430**. The catheter **1430** comprises a transducer **1422**. The catheter **1430** comprises a capture element **1434** that extends out a side of the catheter **1430**. The capture element **1434** may comprise a partial funnel leading to a lumen **1438**, which may optionally comprise an expanded portion **1439**. The capture element **1434** may extend partially or fully around a circumference of the catheter **1430**. The capture element **1434** is configured to guide a guidewire **1406** into a lumen **1438**, which may include an expanded portion **1439**. The capture element **1434** may comprise, for example, a portion of the catheter **1430** that is deformed upon reaching body temperature to open an aperture to lumen **1438** as the capture element **1434** expands. The capture element **1434** may be configured to appose a sidewall of a vessel in which the catheter **1430** resides. The features of the catheters **1400**, **1420**, **1430**, **1440** may be combined with the features of the catheter **1020** or other catheters described herein.

[0384] FIG. **39A** is a perspective view of an example of a portion of a target catheter **1500**. The target catheter **1500** comprises a sheath **1502** and an expandable structure **1504**. The expandable structure **1504** comprises a collapsed state and an expanded state. FIG. **39A** shows the expandable structure **1504** in the expanded state. The expandable structure **1504** comprises a plurality of struts that taper towards the proximal end **1506** in the expanded state. The struts form a plurality of cells. In some examples, a guidewire sheath **1508** extends through the sheath **1502** and the expandable structure **1504**. The target catheter **1500** may be tracked over a first guidewire extending through the guidewire sheath **1508**.

[0385] FIG. **39B** is a side view of the target catheter **1500** of FIG. **39A** in a first state. The first state may be considered a closed state or a delivery state. In the first state, the expandable structure **1504** is in the collapsed state in the sheath **1502**. In some examples, the guidewire sheath **1508** protrudes out of the distal end of the sheath **1502**. A proximal end of the target catheter may include flush ports, guidewire ports, and/or the like. A distal end of the catheter may include a targeting sensor (e.g., an ultrasound receiver), a diagnostic sensor (e.g., a pressure sensor), combinations thereof, and/or the like. In some examples, a targeting sensor is proximal to the expandable structure **1504** in the collapsed state and/or in the expanded state. In some examples, a targeting sensor is distal to the expandable structure **1504** in the collapsed state and/or in the expanded state. In some examples, a targeting sensor is longitudinally between a proximal end of the expandable structure **1504** and a distal end of the expandable structure **1504** in the collapsed state and/or in the expanded state.

[0386] FIG. 39C is a side view of the target catheter **1500** of FIG. 39A in a second state. The second state may be considered an open state or a deployed state. The expandable structure **1504** can be deployed from the sheath **1502** by distally advancing the expandable structure **1504** and/or proximally retracting the sheath **1502**. FIG. 39C shows the relative movement between the sheath **1502** and the expandable structure **1504** by the arrow **1510** and the corresponding radial expansion of the expandable structure **1504** by the arrows **1512**. In some examples, the expandable structure **1504** is self-expanding (e.g., comprising a shape-memory material such as nitinol) and is able to assume the expanded state when not confined by the sheath **1502**. The expandable structure **1504** can be retrieved in the sheath **1502** by distally advancing the sheath **1502** and/or proximally retracting the expandable structure **1504**.

[0387] FIGS. 39D-39I schematically illustrate an example method of using the target catheter **1500** of FIG. 39A. In FIG. 39D, a first catheter **1010** is advanced in a first vessel **1000** comprising an occlusion, for example as described herein. The target catheter **1500** is advanced in a second vessel **1002**. For example, the target catheter may be tracked over a first guidewire that has been advanced through the second vessel **1002**. The distal end of the sheath **1502** may be longitudinally proximate to the occlusion. In FIG. 39E, the expandable structure **1504** is radially expanded, as shown by the arrows **1514**. In some examples, expansion of the expandable structure **1504** radially expands the vessel **1002**, as shown by the arrows **1516**. Expanding the vessel **1002** can increase the target for a needle extending from the first catheter **1010**. In some examples in which the second vessel **1002** is a vein, expanding the vessel **1002** can keep the vein open, which can avoid influence of potential or eventual spasm.

[0388] In FIG. 39F, a needle **1016** extends from the first catheter **1010** out of the first vessel **1000**, through interstitial tissue, and into the second vessel **1002**. In the second vessel **1002**, the needle **1016** extends between the proximal end of the expandable structure **1504** and the distal end of the expandable structure **1504**. The needle **1016** may extend through a cell of the expandable structure **1504**. If the needle **1016** initially contacts a strut of the expandable structure **1504**, the strut may be deflected such that the needle **1016** extends through a cell. The tip of the needle **1016** does not necessarily need to pierce the center of the second vessel **1010** because, even if the second vessel **1002** is pierced at an angle, the needle **1016** can extend into the expandable structure **1504** at an angle, and a subsequently deployed second guidewire **1406** can be snared by the expandable structure **1504**. The extension of the needle **1016** may be guided using a targeting system (e.g., a directional ultrasound targeting system, for example as described herein). In some examples, the needle may be extended towards the expandable structure **1504**, for example using fluoroscopy with or without a targeting system. In certain such examples, the expandable structure **1504** may comprise radiopaque markers and/or the material of the expandable structure **1504** may be radiopaque.

[0389] In FIG. 39G, a second guidewire **1406** is advanced through the first catheter **1010** and the needle **1016** into the second vessel **1002**. Because the needle **1016** extends into the expandable structure **1504**, the second guidewire **1406** extends into the expandable structure **1504**. In FIG. 39H, the expandable structure **1504** is collapsed, for example by at least partially retracting the expandable structure **1504** into the sheath **1502**. Collapsing the expandable structure **1504** grabs or snares the second guidewire **1406**. In some examples, the expandable structure **1504** may optionally be twisted or torqued to help snare the second guidewire **1406**. In FIG. 39I, the target catheter **1500** is proximally retracted. Because the second guidewire **1406** is snared by the expandable structure **1504**, the second guidewire **1406** is advanced through the second vessel **1002**, for example during removing the target catheter **1500** from the second vessel **1002**. Catheters comprising a valvulotome, a stent-graft, and the like may be tracked over the second guidewire **1406** and through the second vessel **1002**, for example as described herein.

[0390] FIG. 40A is a perspective view of an example handle **1600** for deploying a tubular structure. The tubular structure may comprise a stent such as the stent **1122** or a stent-graft such as the stent-



graft **1132**. In some examples, the handle **1600** may be used to deploy a valvulotome such as the valvulotome **1142**, **1300**, an expandable structure such as the expandable structure **1504**, and the like. The handle **1600** comprises a body **1602** and a knob **1604**. The body **1602** comprises a first segment **1606** comprising threads **1607**. The body **1602** comprises a second segment **1608** free of threads. A slot **1609** extends from a proximal part of the body **1602** to a distal part of the body **1602**.

[0391] FIG. **40B** is an expanded perspective cross-sectional view of a portion of the handle **1600** of FIG. **40A**. The knob **1604** comprises threads **1617** configured to interact with the threads **1607**. A slider **1610** extends through the slot **1609**. The slider **1610** comprises a connector **1612** coupled to an external sheath such that proximal movement of the slider **1610** proximally retracts the external sheath. As the knob **1604** is rotated, the slider **1610** is proximally retracted, which proximally retracts the external sheath. The initial deployment of a tubular structure may need a higher quantity of force than later deployment because friction between the tubular structure and the external sheath decreases as the tubular structure is deployed from the external sheath. The threads **1607**, **1617** can help to transmit higher force by converting rotational force into longitudinal force. Once the knob **1604** is retracted proximal to the threads **1607**, the knob **1604** may be proximally pulled, pulling the slider **1610** and thus the external sheath. In some examples, the initial amount of force would be very difficult to effect by proximal pulling but can be accomplished by rotation of the knob **1604**. In some examples, rotating the knob **1604** deploys a first amount of the tubular structure and sliding the knob **1604** deploys a second amount of the tubular structure. The first and second amounts total the entire tubular structure. In some examples, the first amount is less than the second amount. For example, the first amount may be between about 10% and about 60% of the second amount (e.g., about 10%, about 20%, about 30%, about 40%, about 50%, about 60%, ranges between such values, and the like).

[0392] In some examples, the transition between the first amount and the second amount corresponds to approximately a peak deployment force. The peak deployment force can vary based on, for example, tubular structure design (e.g., length, diameter, radial force, material(s)), outer sheath design (e.g., diameter, material(s), coating(s)), combinations thereof, and the like. In some examples, the transition is at least about one third of the length of the tubular structure. In some examples, the transition is at least about one half of the length of the tubular structure. In some examples, a ratio between the first amount and the second amount can be adjusted by adjusting the threads (e.g., length and/or pitch).

[0393] FIG. **40C** is a perspective view of the handle **1600** of FIG. **40A** in a deployed state. FIG. **40D** is an expanded perspective cross-sectional view of a portion of the handle **1600** of FIG. **40A** in a deployed state. The knob **1604** has been rotated and then proximally retracted. Distal to the handle **1600**, a tubular structure is deployed. For example, a stent may be deployed from a first vessel, through interstitial tissue, and into a second vessel.

[0394] FIG. **41A** is a perspective view of an example handle **1700** for deploying a tubular structure. The tubular structure may comprise a stent such as the stent **1122** or a stent-graft such as the stent-graft **1132**. In some examples, the handle **1700** may be used to deploy a valvulotome such as the valvulotome **1142**, **1300**, an expandable structure such as the expandable structure **1504**, and the like. The handle **1700** comprises a body **1702** and a knob **1704**. The body **1702** optionally includes a shell **1716**. A slot **1709** extends from a proximal part of the body **1702** to a distal part of the body **1702**.

[0395] FIG. **41B** is an expanded perspective partially transparent view of a portion of the handle **1700** of FIG. **41A**. FIG. **41B** shows the handle **1700** from an opposite side compared to FIG. **41A**. The knob **1704** is coupled to a gear or worm gear or worm wheel **1706** having teeth **1717** configured to interact with teeth **1707** of a slider member or worm or worm screw **1710**. The body **1702** is fixably coupled to an inner shaft assembly. The slider member **1710** is fixably coupled to an outer sheath. In some examples, the inner shaft assembly has a distal end comprising a plurality of

radiopaque marker bands which can make a tubular structure pocket visible. A proximal radiopaque marker fixed to the inner shaft assembly can act as a pusher to maintain the longitudinal position of the tubular structure while an outer sheath is proximally retracted. Movement of the slider member **1710** relative to the body **1702** causes movement of the outer sheath relative to the inner shaft assembly. The slider **1710** comprises a first portion **1712**, a second portion **1713**, and a third portion **1714**. The first portion **1712** is fixably coupled to an outer sheath. The first portion **1712** is inside the body **1702**. The second portion **1713** protrudes through the slot **1709**. The third portion **1714** is wider than the second portion **1713**. The third portion **1714** is outside the body **1702**, except in examples including a shell **1716**. The user interacts with the third portion **1714** once the slider member **1710** is in position to be proximally pulled. The body **1702** may include two slots **1709**, for example circumferentially opposite each other. In certain such examples, the slider member **1710** may include two second portions **1713** and two third portions **1714** (e.g., as illustrated in FIG. **41B**). Two third portions **1714** may allow a user to grip both sides of the slider member **1710**, providing grip that is better than one side. In some examples, the third portion(s) **1714** may comprise features to enhance grip (e.g., textured surfaces, recesses, flanges, etc.). [0396] FIGS. **41C** to **41Eiii** show an example method of operating the handle **1700** of FIG. **41A**. In FIG. **41C**, rotation of the knob **1704** causes the gear **1706**, including the teeth **1717**, to rotate. The teeth **1717** interact with the teeth **1707** of the slider **1710** to convert the rotational force into longitudinal force, proximally retracting the slider member **1710**, which proximally retracts an external sheath. The initial deployment of a tubular structure may need a higher quantity of force than later deployment because friction between the tubular structure and the external sheath decreases as the tubular structure is deployed from the external sheath. The shell **1716** may inhibit a user from attempting to proximally retract the slider member **1710** until an amount of the tubular structure is deployed that deploying the remaining amount of the tubular structure does not require a high amount of force. The shell **1716** includes a proximal aperture **1718** that the slider can exit upon proximal retraction.

[0397] In FIG. **41Di**, the knob **1704** has been rotated until the slider member **1710** is in a proximal position out of the shell **1716**. The exposed slider member **1710** may be proximally pulled, thereby pulling the outer sheath. In some examples, the initial amount of force would be very difficult to effect by proximal pulling but can be accomplished by rotation of the knob **1704**. FIG. **41Dii** shows an example tubular structure **1720** being deployed from an example outer sheath **1722**. FIG. **41Dii** shows the positions of the tubular structure **1720** and the outer sheath **1722** after the knob **1704** has been rotated until the slider member **1710** is in a position to be proximally retracted (e.g., out of the shell **1716**). A first portion **1724** of the tubular structure **1720** has been deployed from the outer sheath **1722**.

[0398] FIG. **41Ei** is a perspective view the handle **1700** of FIG. **41A** in a retracted position. FIG. **41Eii** is a perspective cross-sectional view the handle **1700** of FIG. **41A** in a retracted position. The slider member **1710** has been proximally retracted to a distal part of the body **1702**, proximally retracting the outer sheath by a quantity sufficient to deploy an entire tubular structure. FIG. **41Eiii** shows the positions of the tubular structure **1720** and the outer sheath **1722** after the slider member **1710** has been proximally retracted to the distal part of the body **1702**. A second portion **1726** of the tubular structure **1720** has been deployed from the outer sheath **1722**. The first portion **1724** and the second portion **1726** may be an entire length of the tubular structure **1720**.

[0399] In some examples, rotating the knob **1704** deploys a first amount of the tubular structure and sliding the slider member **1710** deploys a second amount of the tubular structure. The first and second amounts may total the entire tubular structure. In some embodiments, first and second amounts plus a third amount, a fourth amount, etc. may total the entire tubular structure. The third amount, fourth amount, etc. optionally may be deployed using other features. In some examples, the first amount is less than the second amount. For example, the first amount may be between about 10% and about 70% of the second amount (e.g., about 10%, about 20%, about 30%, about

40%, about 50%, about 60%, about 70%, ranges between such values, and the like). In some examples, a ratio of the first amount to the second amount is between about 1:5 and about 5:3 (e.g., about 1:5, about 2:5, about 3:5, about 4:5, about 5:5, about 5:4, about 5:3, ranges between such values, and the like).

[0400] With the tubular structure deployed, a catheter coupled to the handle **1700** may be removed from the subject. In some examples in which the tubular structure is coupled to a distal end of the inner shaft assembly, the slider member **1710** may be distally advanced to capture a first portion of the tubular structure. In some examples, capturing the first portion of the tubular structure is an amount that is sufficient to safely remove a catheter coupled to the handle **1700** from the subject. In some examples, the knob **1704** may then be rotated to capture a second portion of the tubular structure.

[0401] Although some example embodiments have been disclosed herein in detail, this has been done by way of example and for the purposes of illustration only. The aforementioned embodiments are not intended to be limiting with respect to the scope of the appended claims, which follow. It is contemplated by the inventors that various substitutions, alterations, and modifications may be made to the invention without departing from the spirit and scope of the invention as defined by the claims.

[0402] While the devices described herein may be used in applications in which the fluid that flows through the device is a liquid such as blood, the devices could also or alternatively be used in applications such as tracheal or bronchial surgery where the fluid is a gas, such as air. In some embodiments, the fluid may contain solid matter, for example emboli or, in gastric surgery where the fluid includes food particles.

[0403] While the invention is susceptible to various modifications, and alternative forms, specific examples thereof have been shown in the drawings and are herein described in detail. It should be understood, however, that the invention is not to be limited to the particular forms or methods disclosed, but, to the contrary, the invention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the various embodiments described and the appended claims. Any methods disclosed herein need not be performed in the order recited. The methods disclosed herein include certain actions taken by a practitioner; however, they can also include any third-party instruction of those actions, either expressly or by implication. For example, actions such as “making valves in the first vessel incompetent” include “instructing making valves in the first vessel incompetent.” The ranges disclosed herein also encompass any and all overlap, sub-ranges, and combinations thereof. Language such as “up to,” “at least,” “greater than,” “less than,” “between,” and the like includes the number recited. Numbers preceded by a term such as “about” or “approximately” include the recited numbers. For example, “about 10 mm” includes “10 mm.” Terms or phrases preceded by a term such as “substantially” include the recited term or phrase. For example, “substantially parallel” includes “parallel.”

## Claims

**1.** A catheter system for identifying a bifurcation in a vessel, the catheter system comprising: a tubular body; a targeting system coupled to the tubular body; an expandable member configured to appose sidewalls of a vessel to occlude the vessel in an expanded state; and a fluid injection port configured to inject radiopaque fluid into a vessel proximal to the expandable member in the expanded state such that the radiopaque fluid pools proximate to the expandable member and provides visualization of the vessel and branch vessels.

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