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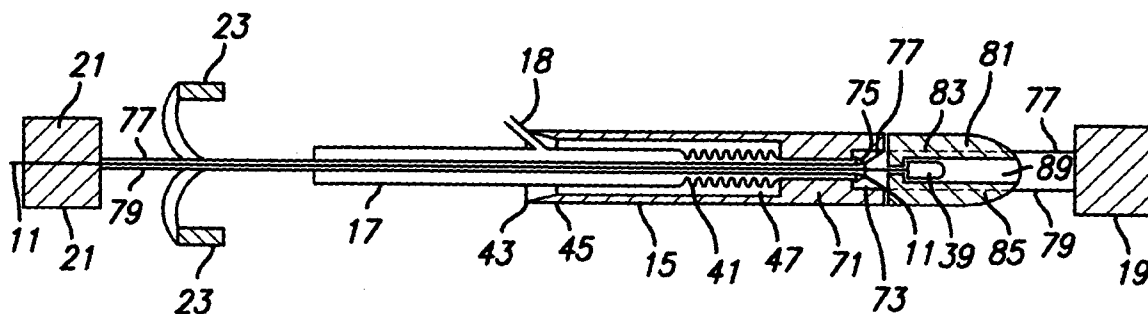
(19) **United States**(12) **Patent Application Publication****Suval**(10) **Pub. No.: US 2005/0004586 A1**(43) **Pub. Date: Jan. 6, 2005**(54) **METHOD AND APPARATUS FOR VESSEL HARVESTING****Publication Classification**(76) Inventor: **William D. Suval**, Apple Valley, CA (US)(51) **Int. Cl.⁷** **A61D 1/02; A61B 17/22**(52) **U.S. Cl.** **606/159**

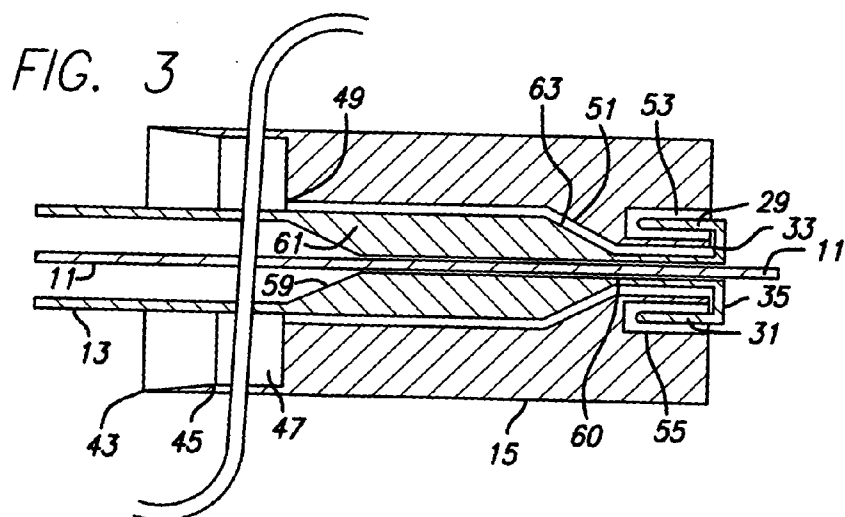
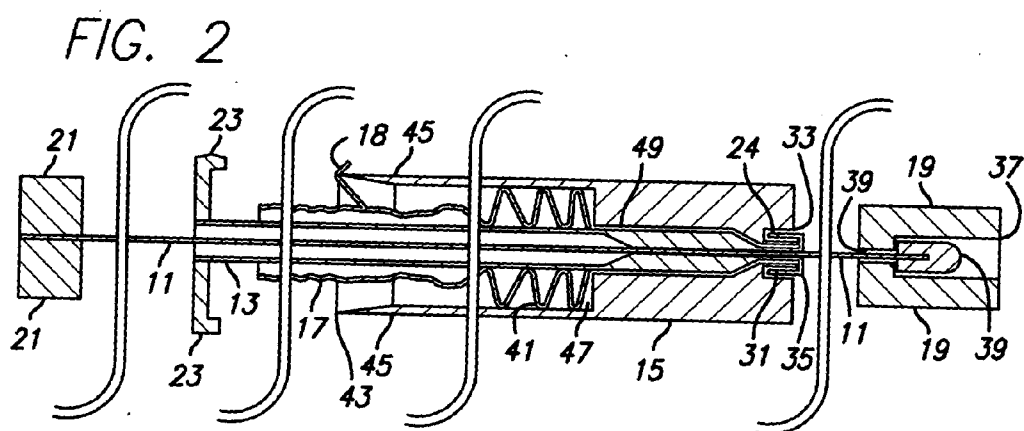
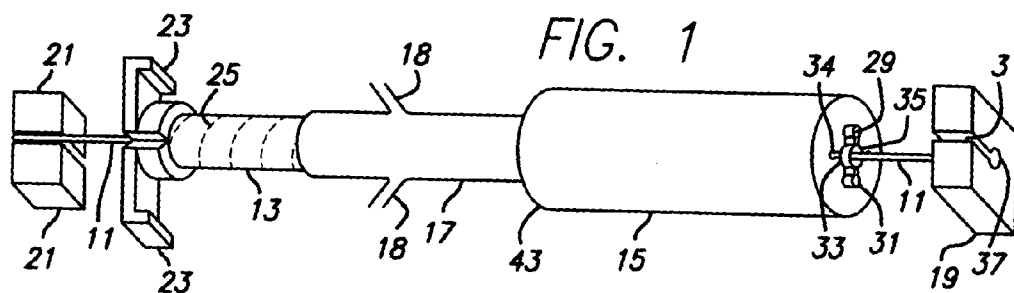
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LOS ANGELES, CA 90071-2899 (US)**(57) **ABSTRACT**(21) Appl. No.: **10/886,072**(22) Filed: **Jul. 6, 2004****Related U.S. Application Data**

(63) Continuation of application No. 09/905,735, filed on Jul. 12, 2001.

The present invention is a method and device for harvesting a vessel. The vessel harvester comprises an internal stenting catheter with proximal and distal ends, a sheath catheter with proximal and distal ends, and a cylindrical cutting tube that is attachable to the distal end of the sheath catheter. The vessel harvester is used to harvest vesseal such as the greater and lesser saphenous veins, the basilic vein, the cephalic vein, and the radial artery.





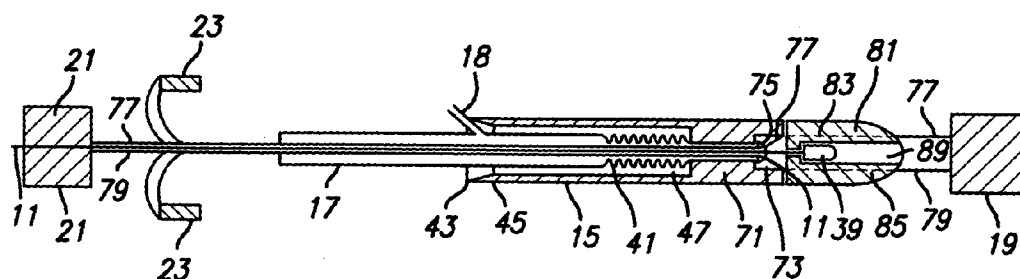


FIG. 4

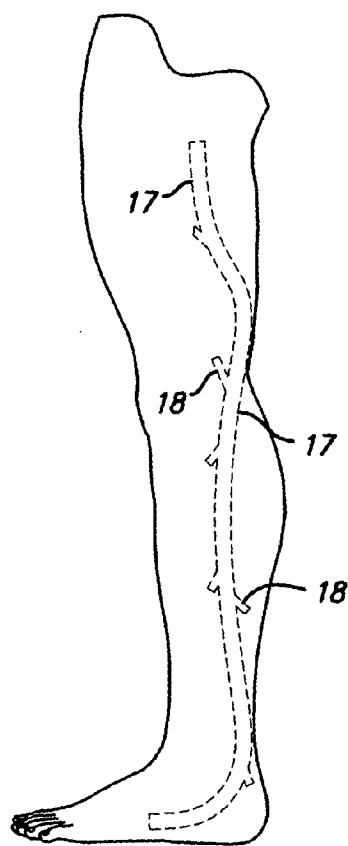


FIG. 5

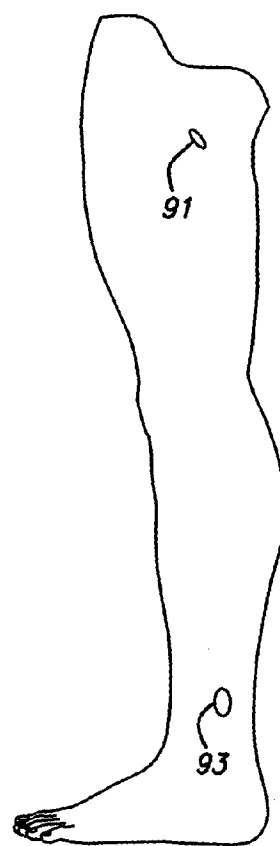
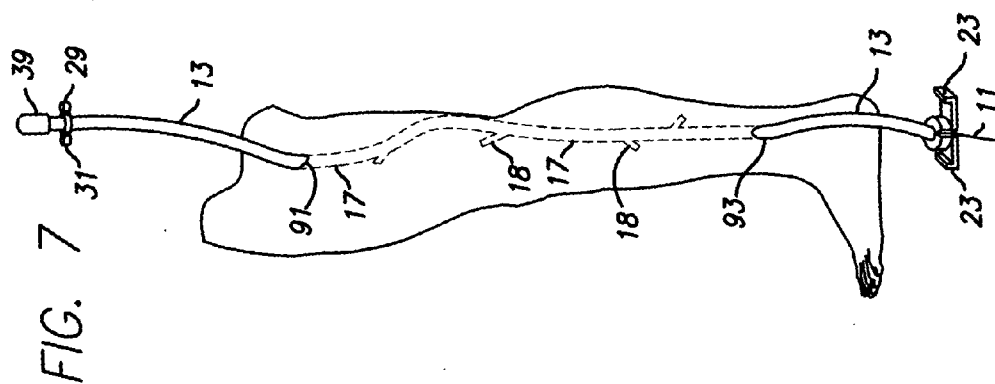
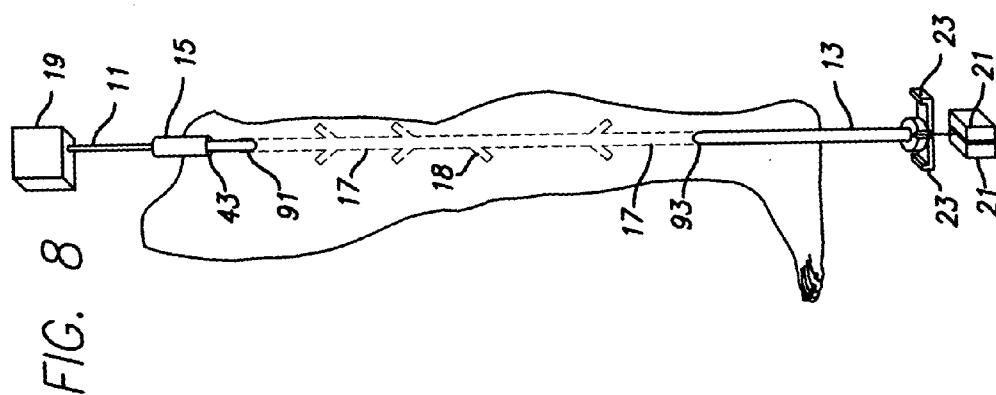
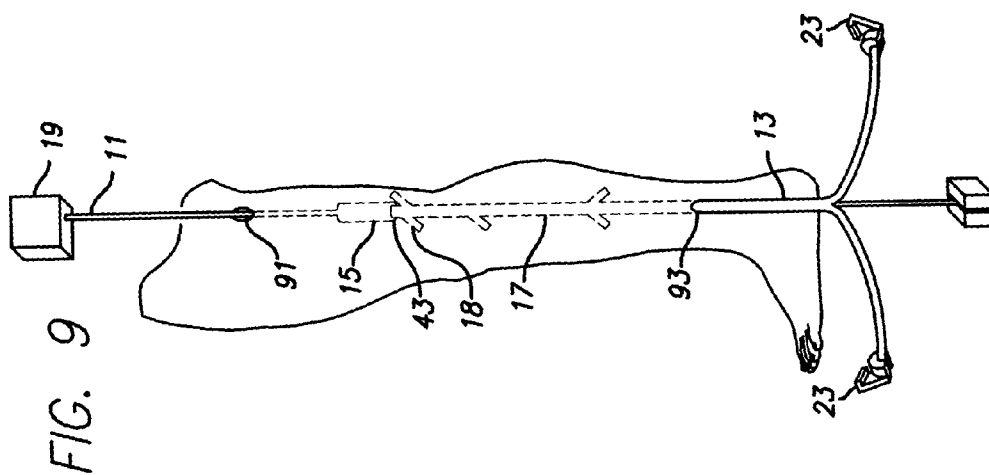


FIG. 6



METHOD AND APPARATUS FOR VESSEL HARVESTING

FIELD OF THE INVENTION

[0001] The present invention relates to an apparatus and method for harvesting vessels, especially veins, for use in bypass grafting surgical procedures.

BACKGROUND OF THE INVENTION

[0002] Atherosclerosis is a disease that affects hundreds of thousand of people each year. The disease can occur anywhere throughout the body including the lower extremities, the carotid arteries and the heart. When it affects the blood supply to the heart it is called coronary artery disease. Vascular complications produced by atherosclerosis, such as stenosis, aneurysm, rupture or occlusion oftentimes call for surgical intervention. If the disease is extensive, the affected artery or vessel is no longer reliable and is often replaced or bypassed around by a bypass graft, usually referred to as an "autograft." To this end, the involved section of the vessel is bypassed with an autograft surgically attached proximal to the lesion and at a point distal to the lesion to provide a bypass path for blood flow. In a patient who undergoes coronary artery bypass grafting (CABG) surgery, a non-critical vessel (artery or vein) is harvested from elsewhere in the body and is sewn into place in such a manner that reestablishes the flow of blood to the heart region that had lost or diminished its supply of blood because of the atherosclerotic lesion.

[0003] The saphenous vein in the leg is a vessel that is commonly harvested for use as a bypass graft in coronary artery surgery. It is also common to use the saphenous vein for bypass surgery in the lower extremity to bypass lesions in the femoral or popliteal arteries. However, typical procedures for harvesting a saphenous vein autograft are tedious, time consuming, and cause undesirable patient trauma. In one harvesting procedure, an incision is made along the leg for a length corresponding to the length of the autograft required, wherein the vein is transected and is stripped from the leg. The incision then must be sutured or stapled along its length. In some patients, the incision must be made along the entire length of the leg. The surgery required for harvesting a vessel in this manner is traumatic to the patient, increases recovery time, increases the patient's hospital confinement, and adds to the cost of the coronary artery surgery.

[0004] Another method of harvesting a saphenous vein is by use of an endoscope. In this method, a few small incisions are made on the leg over the saphenous vein. The saphenous vein is transected and ligated at its ends and the endoscope is inserted into the small incisions. While visualizing the vein with the endoscope, the entire length of the vein is harvested by slow dissection. The endoscope is advanced under the skin along the saphenous vein's length while transecting and ligating its connecting branches until the entire segment of the saphenous vein is free and is able to be removed. This method is more advantageous to the patient in that only a few small incisions are made and much less scarring occurs. However, the endoscopic harvesting of the vein is a difficult procedure and takes a substantial amount of time. The increased time in the operating room increases the cost of the procedure and increases the risk of infection and complications to the patient.

[0005] Other vessels are often used as well in bypass surgical procedures. For example, the radial arteries are often used as coronary conduits. The lesser saphenous, basilic, and cephalic veins are also used.

[0006] Accordingly, it would be highly desirable to provide a less invasive procedure for harvesting vessels, especially the saphenous vein, which avoids the need for a long incision, is easy to use, and does not require a substantial amount of time to complete.

SUMMARY OF THE INVENTION

[0007] The present invention provides a fast, uniform, and inexpensive way to harvest a vessel for bypass surgery. An embodiment of the present invention comprises an internal stenting catheter with proximal and distal ends, a sheath catheter with proximal and distal ends, and a cylindrical cutting tube that is attachable to the distal end of the sheath catheter. The stenting catheter is located within the sheath catheter and is used as a stent to straighten out the vein and to guide the cylindrical cutting tube around the vein. The sheath catheter is used to pull the cylindrical cutting tube under the skin and around the vein, cutting the side branches as it is pulled along the length of the vein and collecting the vein within the lumen of the cylindrical cutting tube.

[0008] The present invention is used in the following manner. The patient is prepared for surgery in standard manner and placed under proper anesthesia (local or general). A small skin incision is made at the distal end of the vessel. Next, a small skin incision is made at the proximal end of the vessel. Using a cut-down technique, for example the Seldinger Technique, the vessel is isolated and the vessel is ligated. The stenting catheter and the sheath catheter are then introduced within the vessel through the distal incision at the vessel's distal end and advanced to the vessel's proximal end where it exits the vessel and the proximal skin incision. Next, the cylindrical cutting tube is placed over the distal end of the sheath catheter and locked into place. The proximal and distal ends of the stenting catheter which are outside of the vessel and the skin are then placed into clamping devices and tension is placed on the stenting catheter until the catheter is straight. The cylindrical cutting tube is then advanced through the proximal skin incision and around the proximal end of the vessel to be harvested. The sheath catheter is used to pull the cutting tube distally down around the vessel cutting connective tissue and branches along the way. The vessel being harvested is collected within the collection lumen of the cutting tube as it is being cut free from the connective tissue and branches. Once the cutting tube has been pulled completely through the course of the vessel, the cutting tube is then removed from the distal skin incision. The cutting tube is then cut free from the stenting catheter and the remains of peel-away catheter. The harvested vessel is then removed from the lumen of the cutting tube, dilated, and the cut branches are sutured or clipped according to standard bypass grafting techniques. The vessel is now ready for the bypass grafting procedure (CABG or other bypass surgery). The area where the vessel was removed is then wrapped with elastic wraps to seal the cut edges and minimize swelling. At the end of the bypass procedure, the skin incisions are cleaned, any hematomas are expelled, and the wounds are closed.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] For a better understanding of the invention, reference is now made to the drawings where like numerals represent similar objects throughout the figures where:

[0010] **FIG. 1** is a perspective schematic view of an embodiment of the present invention for harvesting a vessel;

[0011] **FIG. 2** is a cross-sectional view of the embodiment of **FIG. 1**;

[0012] **FIG. 3** is a detailed schematic view of the cutting tube of **FIG. 2**;

[0013] **FIG. 4** is a cross-sectional view of an alternate embodiment of the present invention;

[0014] **FIG. 5** is a schematic view of a lower extremity of a patient and the greater saphenous vein;

[0015] **FIG. 6** is a schematic view of incisions made on the lower extremity to harvest the greater saphenous vein;

[0016] **FIG. 7** is a schematic view of the stenting catheter and peel-away catheter passed through the greater saphenous vein;

[0017] **FIG. 8** is a schematic view of the stenting catheter with tension and the cutting tube connected to the distal end of the peel-away catheter; and

[0018] **FIG. 9** is a schematic view of the peel-away catheter being pulled apart and the cutting tube advancing distally along the greater saphenous vein cutting connective tissue and side branches of the vein.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0019] Turning now to **FIGS. 1 and 2**, the vessel harvester of the present invention is illustrated. The vessel harvester comprises a stenting catheter **11** with proximal and distal ends, a sheath catheter **13** with proximal and distal ends, and a cylindrical cutting tube **15** with a proximal cutting edge **43** and a distal connecting port **33**. The stenting catheter is located within the lumen of the sheath catheter. Both the stenting catheter and the sheath catheter are illustrated within the lumen of a vessel **17** with side branches **18**. The cutting tube, on the other hand, is located around the outside of the vessel. The cutting tube is connectably attached to the distal end **35** of the sheath catheter via the connecting port and the connecting prongs **29** and **31** located on the sheath catheter.

[0020] The stenting catheter **11** can be made out of an appropriately strong biocompatible material. The catheter can be made from an extruded biocompatible plastic such as polyurethane or polyethyl terephthalate, a biocompatible metal such as surgical stainless steel wire or wire braids, a combination of wire and plastic, or other readily available materials known in the art. The catheter has to have enough flexibility to navigate the curved path of the vessel to be harvested, but also needs to have enough strength such that when axial tension is applied to straighten out the vessel, the catheter will not break. The size of the stenting catheter can vary depending on the length of the vessel to be harvested. For the greater saphenous vein, the length of the stenting catheter is about 36 to about 48 inches. For smaller veins, such as the lesser saphenous vein, the length of the stenting

catheter is about 12 to about 36 inches. The diameter of the stenting catheter is about 1 to about 3 mm. The diameter has to be small enough to fit within the sheath catheter. Additionally, the catheter has to be fairly lubricious to allow for the sheath catheter to easily travel along its axial length when the vessel is being harvested. To this end the stenting catheter can be coated with a lubricious surface such as Teflon® or the like. The distal end of the stenting tube is provided with a rounded bullet nose member **39** for ease in threading the stenting catheter through the vein to be harvested. Additionally, the bullet nose can be used to fit in a clamping member **19** for placing tension on the stenting catheter once it has been threaded through the vein. The proximal end of the stenting catheter can also be placed in a clamping member **21** for opposing the tension placed by clamping member **19**.

[0021] In the preferred embodiment, the sheath catheter **13** is a peel-away catheter which has two pull tabs **23** that have two notches **24** located on opposite sides for easy separation. Typical peel-away catheters have axial scoring along their length such that the catheter can peel away into two halves. It is contemplated in the present invention that this type of scoring can be used. If this type of scoring is used, then when the peel-away catheter is pulled apart, the cutting tube **15** attached to the distal end of the peel away catheter **35** is pulled straight down the stenting catheter. However, it is also contemplated in the present invention that the cutting tube is more effective when it is rotated while being pulled down. To achieve this rotation, the scoring **25** of the peel-away catheter is in a spiral configuration. Thus, when the peel-away catheter is pulled apart at its proximal end, the distal end of the peel-away catheter rotates, which in turn causes the rotation of the cutting tube. The peel away catheter can be made out of biocompatible plastics such as polyurethane, PET, or the like by extrusion and/or molding techniques or other means well known in the art. The peel-away catheter can also be reinforced with stainless steel wire to provide it strength for the rotational force needed to rotate the cutting tube within the patient. The size of the peel-away catheter can vary depending on the length of the vein to be harvested. For the greater saphenous vein, the length of the peel-away catheter is about 24 to about 48 inches. For smaller veins, such as the lesser saphenous vein, the length of the peel-away catheter is about 6 to about 36 inches. The diameter of the peel-away catheter is about 2 to about 4 mm.

[0022] The cylindrical cutting tube **15** is a hollow tube with a vein collecting lumen **47** in the proximal portion of the tube. The proximal edge of the cutting tube is a sharp circular blade **43** which can cut connective tissue and vessel branches. The blade is created by bevel **45** which is bevelled radially outward instead of inward. This beveling configuration prevents the cutting tube from cutting the vessel to be harvest if the tube axially torques and rubs against the side of the vessel. Instead, the cutting edge acts like a razor blade traveling along the surface of the vessel and cutting the connective tissue and vessel branches. The distal end of the cutting tube has a smaller lumen **49** for closely fitting over the peel-away catheter. Turning now to **FIGS. 2 and 3**, the smaller lumen **49** is provided with a taper **51** near the distal end which then narrows to the distal opening **33**. The distal end of the cutting tube is also provided with two connecting channels **53** and **55** that are located radially outward from the distal lumen **33**. The peel-away sheath catheter **13** is provided with a taper **59** to a smaller lumen **60** for closely

fitting over the stenting catheter 11. Additionally, the peel-away catheter's outer diameter through this section remains the same until the taper 63 nearer the distal end which fits within the taper 51 of the cutting tube. This provides a thick area 61 where the peel-away catheter is thicker and stiffer to support the cutting tube and track over the stenting catheter to help prevent axial torquing of the cutting tube while it is pulled down along the vessel. The peel-away catheter is also provided with connecting prongs 29 and 31 for insertion into the connecting ports 53 and 55 of the cutting tube. The connecting prongs of the sheath catheter are passed through a channel 34 in the cutting tube (see FIG. 1) and then rotated 90 degrees for insertion into the connecting ports. Once the connecting prongs are inserted into the connecting channels, pulling apart the peel-away catheter allows for the pulling of the cutting tube down the vessel and the rotation of the cutting tube if a spiral scoring of the peel-away catheter is used.

[0023] The cutting tube can come in different sizes depending on the size and length of the vessel to be harvested. For the greater saphenous vein, the length of the cutting tube is about 7 to about 20 cm and the length of the vessel collecting lumen is about 5 to about 15 cm. For smaller vessels, such as the lesser saphenous vein or the radial artery, the length of the cutting tube is about 5 to about 15 cm and the length of the vessel collecting lumen is about 3 to about 10 cm. The diameter of the cutting tube can vary from about 3 to about 15 mm depending on the size of the vessel being harvested.

[0024] Turning now to FIG. 4 an alternate embodiment is illustrated in cross-section. In this embodiment, the sheath catheter 13 is a peel-away catheter which is longitudinally scored and has the same outer diameter until the very distal end where a beveled flange 75 is provided. The flange is inserted through a small lumen 71 of the cutting tube 15 until it rests within a larger lumen 73 of the cutting tube at its distal end. In the center of the peel away catheter is a stenting catheter 11 with a bullet nose member 39 at its distal end. Additionally, within the center of the peel away catheter are a plurality of guide wires (two being illustrated 77 and 79) for helping to keep the cutting tube aligned when it is being pulled down under the skin of the patient. The guide wires are secured at both ends of the patient in clamping member 19 and 21. The stenting catheter on the other hand is inserted into a lumen 89 in a larger bullet member 81 for actually pulling the cutting tube under the skin. The guide wires travel through the bullet member 81 in small channels 83 and 85 that help to keep the cutting tube aligned while harvesting the vein.

[0025] To harvest the vessel using the embodiment of FIG. 4, the stenting catheter is used to pull the cutting tube while the peel away catheter is used as a sheath for covering the guide wires and stenting catheter during the procedure. The vessel 17 is collected in the large lumen 47 of the cutting tube and the side branches 18 are cut with the cutting edge 43.

[0026] Turning now to FIGS. 5-9, the method of harvesting a vessel is illustrated. FIG. 5 schematically illustrates a greater saphenous vein 17 with side branches 18 in a leg of a patient. As can be seen, the greater saphenous vein is a curved vein located on the medial to anterior parts of the leg. Two skin incisions 91 and 93 are made along the course of

the vein (see FIG. 6). As would be apparent, one skin incision is located at the distal end 93 of the vein and one is at the proximal end 91 of the vein. The location of the skin incisions can vary depending on the length of saphenous vein needed. Using a cut-down procedure such as the Seldinger technique, the saphenous vein is isolated and ligated.

[0027] Turning now to FIG. 7, the stenting catheter 11 is then inserted into the sheath catheter 13 which is then inserted into the proximal end of the vein through incision 93 and then exits the vein at the distal incision 91. As illustrated in FIG. 8, the cutting tube is then inserted over the distal end of the peel-away catheter and locked into place using connecting tabs 29 and 31. The stenting catheter is then pulled taught and inserted into the clamping members 19 and 21. These clamping members are ideally secured to the operating table to allow for the tension to be maintained throughout the cutting process. When the stenting catheter is pulled taught, the saphenous vein 17 becomes straight. The cutting tube 15 is then inserted under the skin through the skin incision 91. The sheath catheter is a peel away catheter which is then broken apart at the tabs 23 on the proximal end and pulled apart at the serrations. While pulling the peel-away catheter apart, the cutting tube is pulled under the skin of the patient around the saphenous vein 17. As the cutting tube is being pulled, side branches 18 are cut by the cutting edge 43 of the cutting tube. If needed, the cutting tube can be manually manipulated from outside the skin of the patient to help keep it straight to prevent axial torquing and continue the harvesting of the vein. Eventually, the cutting tube is pulled all the way to the proximal incision 93 where the tube is removed from the patient. The peel-away catheter and the stenting catheter are then cut and removed from the cutting tube. The vein is then removed from the cutting tube and the cut side branches are sutured or clamped. The vein is then prepared for being a bypass conduit using standard techniques and then is used as a bypass conduit as needed.

[0028] The skin incisions 91 and 93 are then closed using standard surgical closure techniques and the leg of the patient is then wrapped with tight leg wrapping to seal the cut vein branches. The leg is monitored to insure that there is appropriate blood flow and proper recovery. If need be, hematomas are removed.

[0029] Similar methods are used for harvesting other vessels such as the lesser saphenous vein, the basilic vein, the cephalic vein, the radial artery and the like.

[0030] The vein harvesting device and method of the present invention may be embodied in other specific forms without departing from the teachings or essential characteristics of the invention. The described embodiments are therefore to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than by the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore to be embraced therein.

1-22. (Cancelled)

23. A method for harvesting a vessel from a patient, the method comprising:

opening a vessel in the patient, thereby defining a vessel portion extending between an opened proximal end and an opened distal end;

threading a flexible elongate member entirely through the vessel portion until a distal end of the flexible elongate member protrudes from the distal end of the vessel portion while a proximal end of flexible elongate member protrudes from the proximal end of the vessel portion, wherein the flexible elongate member comprises an elongate guide component slidably coupled to an elongate pulling component that is substantially coextensive therewith;

coupling a terminal member to the elongate pulling component of the flexible elongate member distal to the distal end of the vessel portion, wherein the terminal member is configured to sever the vessel portion from surrounding tissue of the patient when drawn along a length of the vessel portion; and

drawing the terminal member through the patient to the proximal end of the vessel portion, by pulling the elongate pulling component out the proximal end of the vessel portion while holding the elongate guide component distal to the distal end of the vessel portion, thereby severing the vessel portion from surrounding tissue of the patient.

24. The method of claim 23, further comprising maintaining tension in the elongate guide component during the drawing step.

25. The method of claim 23, further comprising splitting the elongate pulling component after it is drawn out the proximal end of the vessel portion during the drawing step.

26. The method of claim 23, further comprising rotating the elongate pulling component and the terminal member coupled thereto, while the pulling component is being drawn out the proximal end of the vessel portion during the drawing step.

27. The method of claim 26, wherein the rotating step further comprises causing rotation of the elongate pulling component by splitting the pulling component along a helical path after it is drawn out the proximal end of the vessel portion.

28. The method of claim 23, further comprising cutting around an outer perimeter of the vessel portion using the terminal member, during drawing step.

29. The method of claim 23, further comprising collecting the vessel portion in a receptacle connected to the terminal member, during the drawing step.

30. The method of claim 23, wherein the threading step further comprises threading the flexible elongate member comprising a sheath catheter disposed around a stenting catheter.

31. An apparatus for harvesting a length of vessel from a patient, the apparatus comprising:

a flexible elongate guide member longer than the length of vessel to be harvested;

a flexible elongate pulling member longer than the length of vessel to be harvested and shorter than the guide member, slidably coupled to the guide member and substantially coextensive therewith; and

a coupling connected to a distal end of the pulling member, and configured to permit the guide member to extend past the coupling, the coupling further configured to couple to a terminal member, wherein the guide

member, the pulling member, and the coupling together comprise an assembly configured for threading through the length of vessel and that, when coupled to the terminal member, is configured to sever the length of vessel from the patient when the terminal member is drawn along the length of vessel by the pulling member, while at least a distal end of the guide member is substantially fixed relative to the patient.

32. The apparatus of claim 31, wherein the pulling member comprises a sheath catheter.

33. The apparatus of claim 31, wherein the guide member comprises a stenting catheter.

34. The apparatus of claim 31, wherein the pulling member comprises a stenting catheter.

35. The apparatus of claim 31, wherein the guide member comprises a wire.

36. The apparatus of claim 31, further comprising the terminal member coupled to the coupling.

37. The apparatus of claim 36, wherein the terminal member comprises a cutter configured to cut around an outer periphery of the length of vessel.

38. The apparatus of claim 37, wherein the cutter comprises a circular blade having an inside diameter greater than an outside diameter of the length of vessel.

39. The apparatus of claim 36, further comprising a receptacle connected to a distal portion of the terminal member, configured for collecting the length of vessel.

40. The apparatus of claim 39, wherein the terminal member and the receptacle together comprise a cylindrical cutting tube.

41. The apparatus of claim 31, wherein the pulling member comprises a peel-away catheter.

42. The apparatus of claim 31, wherein the pulling member comprises a peel-away catheter configured to peel along a helix.

43. A vessel harvesting device comprising a flexible elongate guide member, a pulling member disposed over the guide member and having proximal and distal ends, and a cutter connectable to the distal end of pulling member, wherein the guide member and the pulling member are arranged to be inserted through a length of vessel in an organism, and the cutter is connectable to the pulling member for movement relative to a fixed distal end of the guide member along the outside of the vessel.

44. The apparatus of claim 43, wherein the pulling member comprises a sheath catheter.

45. The apparatus of claim 43, wherein the guide member comprises a stenting catheter.

46. The apparatus of claim 43, wherein the pulling member comprises a stenting catheter.

47. The apparatus of claim 43, wherein the guide member comprises a wire.

48. The apparatus of claim 43, wherein the cutter comprises a circular blade having an inside diameter greater than an outside diameter of the vessel.

49. The apparatus of claim 43, further comprising a receptacle connected to a distal portion of the pulling member and disposed behind the cutter, configured for collecting the length of vessel.

50. The apparatus of claim 49, wherein the cutter and the receptacle together comprise a cylindrical cutting tube.

51. The apparatus of claim 43, wherein the pulling member comprises a peel-away catheter.

52. The apparatus of claim 43, wherein the pulling member comprises a peel-away catheter configured to peel along a helix.