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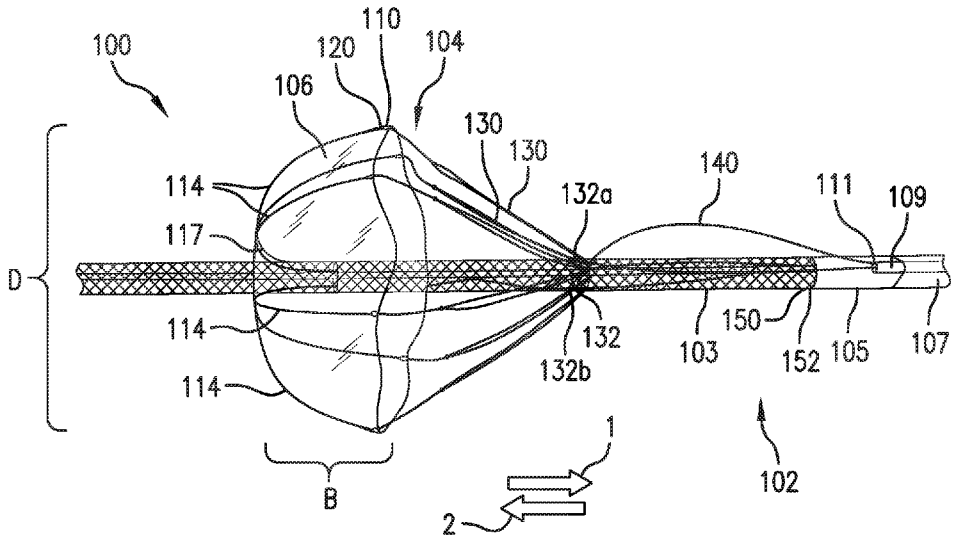

FIG. 1

(57) Abstract: A percutaneous device including a temporary valve (104) attached to a sheath (101), the sheath (101) having an inverting section for delivery and removal thereof from a blood vessel. The sheath (101) is inverted for delivery, housing the valve between inverted layers thereof. To deploy said valve, the sheath (101) is everted to position the temporary valve (104) on an outer surface (117) thereof. The temporary valve (104) and sheath (101) are reversibly movable between inverted and deployed configurations. Upon eversion, the temporary valve (104) assumes a radially expanded canopy (106) shape having an outer diameter selected to contact the vessel wall and allow blood flow in only one direction (1, 2). The temporary valve (104) may be removed by releasing one end of the valve from the sheath (101), flattening the temporary valve (104) along the longitudinal axis of the sheath (101). Also provided is a temporary valve (104) system comprising a dilator (160) for inverting and everting the sheath (101), said dilator (160) being removably connected to the sheath (101).

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1. A temporary valve device, comprising:

a catheter sheath having a first section and a second section, said first section attached to a distal end of said second section;

a temporary valve attached to an outer surface of said first section, said temporary valve extending from a first valve end to a second valve end; and

an attachment mechanism removeably attaching a first end of said temporary valve to said first section;

said temporary valve comprising a canopy permanently attached to said catheter sheath at a second end of said temporary valve.

2. The device of claim 1, wherein said first section is formed of a braided member.

3. The device of claim 1, wherein said temporary valve is formed with an umbrella shape.

4. The device of claim 3, wherein said temporary valve has an opening extending therethrough.

5. The device of claim 1, wherein said attachment mechanism comprises a plurality of lines connecting said second valve end to said first section.

6. The device of claim 5, wherein first ends of said lines are attached to a rim of said temporary valve.

7. The device of claim 5, wherein first ends of said lines are attached to a position separated from a rim of said temporary valve by a predetermined gap.

8. The device of claim 5, further comprising a plurality of reinforcing ribs coupled to said temporary valve, said ribs being disposed about the temporary valve.

9. The device of claim 8, wherein said ribs are one of embedded in the temporary valve, attached to an inner surface of the temporary valve and attached to an outer surface of the temporary valve.

10. The device of claim 8, wherein said ribs extend from respective first rib ends to respective second rib ends, said first rib ends being separated from said first valve end.

11. The device of claim 10, wherein said second rib ends are one of separated from said second valve end and aligned with said second valve end.

12. The device of claim 10, wherein said second rib ends include attachment rings for attachment to said lines.

13. The device of claim 8, wherein said device includes one of 4 ribs, 8 ribs and 16 ribs.

14. The device of claim 8, wherein said ribs are biased to a radially expanded configuration.

15. The device of claim 5, wherein said lines include loops for attachment to an attachment wire.

16. The device of claim 15, wherein said attachment wire is interwoven through said line loops and said first section, said interwoven portion extending 180 degrees about a circumference of said first section.

17. The device of claim 15, wherein said first section includes a plurality of sheath loops to which the line loops are attached via the attachment wire.

18. The device of claim 1, further comprising a first control wire extending through said valve device and having first and second free ends located outside of said valve device, wherein a proximal retraction of said first and second free ends moves said first section and temporary valve to an inverted delivery configuration.

19. The device of claim 1, wherein the temporary valve is invertible.

20. The device of claim 1, wherein said attachment mechanism is one of an attachment wire, string and pin.

21. The device of claim 1, wherein said attachment mechanism couples the temporary valve directly to said first section.

22. A percutaneous temporary valve system, comprising:

an invertible catheter sheath having a first section and a second section, said first section attached to a distal end of said second section; and

a temporary valve attached to an outer surface of said first section, said temporary valve extending from a first valve end to a second valve end; and

a dilator for insertion through said valve device, said dilator having a nosecone at a distal end thereof; and

an attachment mechanism removeably attaching a first end of said temporary valve to said first section;

said temporary valve comprising a canopy permanently attached to said catheter sheath at a second end of said temporary valve.

23. The system of claim 22, further comprising a first wire having first and second free ends located outside of said valve device, wherein a proximal retraction of said first and second free ends moves said first section and temporary valve to an inverted delivery configuration.

24. The system of claim 23, wherein said first wire is woven through said dilator, out of a distal dilator opening thereof and through said first section at an attachment point.

25. The system of claim 24, further comprising a second wire connected to said dilator, said second wire including wire loops for receiving said first wire.

26. The system of claim 25, wherein said temporary valve comprises a plurality of lines connecting said second valve end to said first section.

27. The system of claim 26, further comprising an attachment wire, wherein said lines include looped free ends for attachment to said first section via said attachment wire.

28. The system of claim 24, wherein the dilator comprises a reduced diameter waist distally of said distal opening.

29. The system of claim 25, further comprising a third wire coupled to said first section, said third wire controlling inversion and eversion of the first section independently of a position of said dilator.

30. The system of claim 22, wherein said first section is formed of a braided member.

31. The system of claim 22, wherein said temporary valve is invertible.

32. A temporary valve device, comprising:

a catheter sheath having a first section and a second section, said first section attached to a distal end of said second section; and

an invertible temporary valve attached to an outer surface of said first section, said temporary valve extending from a first valve end to a second valve end; and

an attachment mechanism removeably attaching said first valve end to said first section;

wherein said temporary valve is reversibly movable between an inverted delivery configuration and a deployed configuration, wherein, in said delivery configuration, said first section is inverted into said second section and wherein in said deployed configuration, said first section is moved distally out of said second section to permit radial expansion of said temporary valve.

33. The device of claim 32, wherein said first section is formed of a braided member.

34. The device of claim 32, wherein said temporary valve is formed with an umbrella shape having an opening extending therethrough to house a delivery device.

35. The device of claim 32, wherein a diameter of said temporary valve increases from said proximal end to said distal end.

36. The device of claim 32, wherein said temporary valve comprising a plurality of lines connecting said second valve end to said first section.

37. The device of claim 36, wherein first ends of said lines are attached to a rim of said temporary valve.

38. The device of claim 36, wherein first ends of said lines are attached to a position separated from a rim of said temporary valve by a predetermined gap.

39. The device of claim 32, further comprising a plurality of reinforcing ribs coupled to said temporary valve, said ribs being symmetrically disposed about the temporary valve.

40. The device of claim 39, wherein said ribs are one of embedded in the temporary valve, attached to an inner surface of the temporary valve and attached to an outer surface of the temporary valve.

41. The device of claim 39, wherein said ribs extend from respective first rib ends to respective second rib ends, said first rib ends being separated from said first valve end.

42. The device of claim 41, wherein said second rib ends are one of separated from said second valve end and aligned with said second valve end.

43. The device of claim 41, wherein said second rib ends include attachment rings for attachment to said lines.

44. The device of claim 39, wherein said device includes one of 8 ribs and 16 ribs.

45. The device of claim 39, wherein said ribs are biased to a radially expanded configuration.

46. The device of claim 36, further comprising an attachment wire, wherein said lines include line loops are free ends thereof for attachment to said first section via said attachment wire.

47. The device of claim 46, wherein attachment wire is interwoven through said line loops and said first section, said interwoven portion extending 180 degrees about a circumference of said first section.

48. The device of claim 47, wherein said first section includes a plurality of sheath loops to which the line loops are attached via the attachment wire.

49. The device of claim 32, further comprising a first control wire extending through said valve device and having first and second free ends located outside of said valve device, wherein a proximal retraction of said first and second free ends moves said catheter sheath and temporary valve to said inverted delivery configuration.

50. The device of claim 36, wherein said lines are removably attached to said first section.

51. A method of deployment of a temporary valve, comprising:

guiding the temporary valve to a target position in a vessel in an inverted configuration, said temporary valve comprising a sheath having a first section and a second section, said first section attached to a distal end of said second section, wherein said temporary valve is attached to an outer surface of said first section, said temporary valve extending from a first valve end to a second valve end, wherein said temporary valve is housed between two layers of said first section in said inverted configuration; and

advancing a dilator distally through said sheath, said distal advancement moving said temporary valve from an inverted configuration to a radially expanded canopy configuration, wherein said temporary valve is oriented on an outer surface of said first section in said radially expanded canopy configuration.

52. The method of claim 51, further comprising:

moving said temporary valve between said inverted configuration and radially expanded canopy configuration any plurality of times.

53. The method of claim 51, further comprising:

moving said temporary valve to said inverted configuration; and

withdrawing said temporary valve from said vessel in said inverted configuration.

54. The method of claim 51, further comprising:

retracting a wire connecting said valve device to said first section to invert said first section and temporary valve proximally into said second section.

55. The method of any of claims 51-54, wherein said temporary valve comprises a plurality of lines connecting said second valve end to said first section, the method further comprising:

disconnecting said lines from said first section to permit inversion of said temporary valve; and

withdrawing said temporary valve from said vessel.

56. The method of claim 55, wherein said lines are connected to said first section via a control wire, said method comprising the step of retracting said control wire proximally from said temporary valve to disconnect said lines from said first section.

57. A method of removing a temporary valve device from a body vessel, said temporary valve device comprising a sheath having a first section and a second section, said first section attached to a distal end of said second section, a temporary valve attached to an outer surface of said first section, said temporary valve having a first valve end and a second valve end and comprising a plurality of lines connecting said second valve end to said first section, and an attachment wire, wherein said lines are attached to said first section via said attachment wire, said method comprising the steps of:

retracting said attachment wire connecting said lines to said first section, said retraction disengaging said temporary valve from said first section and reducing an outer profile of said temporary valve; and

retracting said temporary valve device from the body.

58. A method of removing a temporary valve device from a body vessel, said temporary valve device comprising a sheath having a first section and a second section, said first section attached to a distal end of said second section; and a temporary valve attached to an outer surface of said first section, said temporary valve having a first valve end and a second valve end and comprising a plurality of lines connecting said second valve end to said first section, said method comprising the step of:

retracting said temporary valve device from the body.

59. A method of removing a temporary valve device from a body vessel, said temporary valve device comprising a sheath having a first section and a second section, said first section attached to a distal end of said second section, a temporary valve attached to an outer surface of said first section, said temporary valve comprising a plurality of lines connecting said second valve end to said first section, and a dilator positioned to traverse said sheath, said dilator having a wire extending therethrough and out of a distal opening in said dilator to couple said temporary valve to said first section, said method comprising the steps of:

pulling said wire, thereby retracting a distal portion of said first section into a luminal portion of the second section to invert the temporary valve; and

retracting said temporary valve device from the body.