CLAIMS

WHAT IS CLAIMED IS:

1. A bi-directional stent delivery system, said system comprising:

an inner elongate shaft having a proximal portion and a distal portion;

a radially expandable prosthesis disposed over the inner elongate shaft, the prosthesis having a radially collapsed configuration and a radially expanded configuration, wherein in the collapsed configuration the prosthesis is adapted to be delivered through a patient's vasculature, and in the expanded configuration the prosthesis engages a vessel wall;

an outer elongate shaft having a proximal portion and a distal portion; and

a shuttle sheath having a proximal portion and a distal portion, the shuttle sheath disposed over the radially expandable prosthesis,

wherein the distal portion of the inner shaft is releasably coupled to the distal portion of the shuttle sheath, and the distal portion of the outer shaft is releasably coupled the proximal portion of the shuttle sheath, and

wherein distal advancement of the inner shaft advances the shuttle sheath distally when the outer shaft is uncoupled from the shuttle sheath, thereby allowing the prosthesis to radially expand from a proximal end thereof to a distal end thereof, and

wherein proximal retraction of the outer shaft retracts the shuttle sheath proximally when the inner shaft is uncoupled from the shuttle sheath, thereby allowing the prosthesis to radially expand from a distal end thereof to a proximal end thereof.

2. The system of claim 1, wherein the inner shaft comprises a lumen extending between the proximal and distal portions, the lumen configured to slidably receive a guidewire.

3. The system of claim 1, wherein the prosthesis comprises a first stent.

4. The system of claim 3, further comprising a second stent unattached and axially separated from the first stent by a gap.

5. The system of claim 3, wherein the first stent comprises a self-expanding stent.

6. The system of claim 3, wherein the first stent comprises a nickel titanium alloy.

7. The system of claim 1, wherein the outer shaft comprises a lumen extending between the proximal and distal portions thereof.

8. The system of claim 1, wherein the shuttle sheath has a length greater than or equal to the length of the radially expandable stent.

9. The system of claim 1, wherein the shuttle sheath constrains the prosthesis along substantially the entire length thereof.

10. The system of claim 1, wherein the shuttle sheath has a proximal end, a distal end, and a lumen extending therebetween.

11. The system of claim 1, wherein the shuttle sheath comprises a substantially cylindrical sheath.

12. The system of claim 1, further comprising a distal coupling mechanism, the distal coupling mechanism releasably coupling the distal portion of the inner shaft to the distal portion of the shuttle sheath.

13. The system of claim 12, wherein the distal coupling mechanism comprises a bayonet coupling.

14. The system of claim 12, wherein the distal coupling mechanism comprises a threaded region on the distal portion of the inner shaft and a corresponding threaded region on the distal portion of the shuttle sheath.

15. The system of claim 12, wherein the distal coupling mechanism comprises a helical region on the distal portion of the inner shaft and a corresponding helical region on the distal portion of the shuttle sheath.

16. The system of claim 12, wherein the distal coupling mechanism comprises one or more of a snap fit, an interference fit, a barbed connector, a locking mechanism, a rotatable key lock, a linear key lock, a threaded bushing, a twist lock, a magnetic coupling, or a frangible connector.

17. The system of claim 1, further comprising a proximal coupling mechanism, the proximal coupling mechanism releasably coupling the distal portion of the outer shaft to the proximal portion of the shuttle sheath.

18. The system of claim 17, wherein the proximal coupling mechanism comprises a bayonet coupling.

19. The system of claim 17, wherein the proximal coupling mechanism comprises a threaded region on the distal portion of the outer shaft and a corresponding threaded region on the proximal portion of the shuttle sheath.

20. The system of claim 17, wherein the proximal coupling mechanism comprises a helical region on the distal portion of the outer shaft and a corresponding helical region on the proximal portion of the shuttle sheath.

21. The system of claim 17, wherein the proximal coupling mechanism comprises one or more of a snap fit, an interference fit, a barbed connector, a locking mechanism, a rotatable key lock, a linear key lock, a threaded bushing, a twist lock, a magnetic coupling, or a frangible connector.

22. The system of claim 1, wherein the inner shaft is threadably engaged with the shuttle sheath, and the outer shaft is also threadably engaged with the shuttle sheath, and wherein the threads engaging the inner shaft with the shuttle sheath have a first orientation, and the threads engaging the outer shaft with the shuttle sheath have a second orientation opposite of the first orientation such that rotation of the inner shaft in a first direction couples the inner shaft with the shuttle sheath and rotation of the inner shaft in a second direction opposite the first direction disengages the inner shaft from the shuttle sheath, and wherein rotation of the outer shaft in the first direction disengages the outer shaft from the shuttle sheath and rotation of the outer shaft in the second direction engages the outer shaft with the shuttle sheath.

23. The system of claim 1, wherein the inner shaft is helically engaged with the shuttle sheath, and the outer shaft is also helically engaged with the shuttle sheath, and wherein the helix engaging the inner shaft with the shuttle sheath have a first orientation, and the helix engaging the outer shaft with the shuttle sheath have a second orientation opposite of the first orientation such that rotation of the inner shaft in a first direction couples the inner shaft with the shuttle sheath and rotation of the inner shaft in a second direction opposite the first direction disengages the inner shaft from the shuttle sheath, and wherein rotation of the outer shaft in the first direction disengages the outer shaft from the shuttle sheath and rotation of the outer shaft in the second direction engages the outer shaft with the shuttle sheath.

24. The system of claim 1, wherein the inner shaft is coupled with the shuttle sheath with a first bayonet coupling mechanism having a slot in a first orientation, and the outer shaft is coupled with the shuttle sheath with a second bayonet coupling mechanism having a slot in a second orientation opposite the first slot, and wherein rotation of the inner shaft in a first direction couples the inner shaft with the shuttle sheath and rotation of the inner shaft in a second direction opposite the first direction disengages the inner shaft from the shuttle sheath, and wherein rotation of the outer shaft in the first direction disengages the outer shaft from the shuttle sheath and rotation of the outer shaft in the second direction engages the outer shaft with the shuttle sheath.

25. The system of claim 1, further comprising a middle shaft concentric with the inner and the outer shafts, and disposed therebetween.

26. The system of claim 25, wherein the prosthesis is disposed over the middle shaft and in direct engagement therewith.

27. The system of claim 26, wherein the middle shaft comprises an outer surface that is substantially smooth.

28. The system of claim 25, wherein the middle shaft comprises a proximal stent stop and a distal stent stop, the proximal stopping element disposed proximally of a proximal end of the prosthesis, and the distal stopping element disposed distally of a distal end of the prosthesis, wherein the proximal stopping element prevents proximal movement of the prosthesis, and the distal stopping element prevents distal movement of the prosthesis.

29. The system of claim 28, wherein the proximal stopping element comprises one or more of a ring, a band, a step, a bushing, or a sleeve, that prevent proximal movement of the prosthesis.

30. The system of claim 28, wherein the distal stopping element comprises one or more of ring, a band, a step, a bushing, or a sleeve, that prevents distal movement of the prosthesis.

31. The system of claim 1, further comprising an actuator mechanism disposed near a proximal end of the delivery system, the actuator mechanism operably coupled with the inner and outer shafts, thereby allowing an operator to couple and uncouple the inner and outer shafts with the shuttle sheath, and wherein the actuator mechanism is also configured to slidably move the inner and the outer shafts both proximally and distally.

32. The system of claim 1, further comprising an intravascular ultrasound device configured to allow visualization of the prosthesis and surrounding tissue.

33. A bi-directional method for deploying a prosthesis at a treatment site in a patient, said method comprising:

providing a delivery catheter comprising a prosthesis having a proximal end and a distal end, the prosthesis in a collapsed configuration and disposed on the delivery catheter;

delivering the prosthesis to the target treatment site;

selecting a deployment direction for the prosthesis, wherein the deployment direction comprises radially expanding the prosthesis from the proximal end thereof to the distal end thereof, and radially expanding the prosthesis from the distal end thereof to the proximal end thereof;

removing a constraint from the prosthesis thereby permitting the prosthesis to radially expand in the selected deployment direction;

radially expanding the prosthesis from the collapsed configuration to an expanded configuration in the selected deployment direction so that the expanded prosthesis engages tissue at the target treatment site; and

withdrawing the delivery catheter from the patient and leaving the prosthesis deployed at the target treatment site.

34. The method of claim 33, wherein the prosthesis comprises a first stent.

35. The method of claim 33, wherein the prosthesis comprises a second stent unattached and axially separated from the first stent by a gap.

36. The method of claim 33, wherein delivering the prosthesis comprises advancing the delivery catheter through vasculature of the patient to the target treatment site.

37. The method of claim 33, wherein the delivery catheter has a proximal end, a distal end, and a lumen therebetween, and delivering the prosthesis comprises slidably advancing the delivery catheter over a guidewire disposed in the lumen.

38. The method of claim 33, wherein delivering the prosthesis comprises positioning the prosthesis in a vein.

39. The method of claim 38, wherein the vein comprises the iliac vein.

40. The method of claim 33, wherein the delivery catheter comprises an inner elongate shaft and a shuttle sheath disposed over the prosthesis, and selecting the deployment direction for the prosthesis comprises:

coupling the inner elongate shaft with the shuttle sheath;

distally advancing the inner elongate shaft distally thereby advancing the shuttle sheath distally away from the prosthesis; and

radially expanding the prosthesis from the proximal end thereof to the distal end thereof.

41. The method of claim 40, wherein coupling the inner elongate shaft with the shuttle sheath comprises threadably engaging the inner elongate shaft with the shuttle sheath.

42. The method of claim 40, wherein coupling the inner elongate shaft with the shuttle sheath comprises helically engaging the inner elongate shaft with the shuttle sheath.

43. The method of claim 40, wherein coupling comprises coupling the inner elongate shaft and the shuttle sheath with a bayonet coupling.

44. The method of claim 40, wherein the delivery catheter further comprises an outer elongate shaft, and selecting the deployment direction further comprises:

decoupling the outer elongate shaft from the shuttle sheath.

45. The method of claim 44, wherein decoupling the outer elongate shaft from the shuttle sheath comprise threadably disengaging the outer elongate shaft from the shuttle sheath.

46. The method of claim 44, wherein decoupling the outer elongate shaft from the shuttle sheath comprise helically disengaging the outer elongate shaft from the shuttle sheath.

47. The method of claim 44, wherein decoupling comprises releasing a bayonet coupling between the outer elongate shaft and the shuttle sheath.

48. The method of claim 33, wherein the delivery catheter comprises an outer elongate shaft and a shuttle sheath disposed over the prosthesis, and selecting the deployment direction for the prosthesis comprises:

coupling the outer elongate shaft with the shuttle sheath;

proximally retracting the outer elongate shaft thereby retracting the shuttle sheath proximally away from the prosthesis; and

radially expanding the prosthesis from the distal end thereof to the proximal end thereof.

49. The method of claim 48, wherein coupling the outer elongate shaft with the shuttle sheath comprises threadably engaging the outer elongate shaft with the shuttle sheath.

50. The method of claim 48, wherein coupling the outer elongate shaft with the shuttle sheath comprises helically engaging the outer elongate shaft with the shuttle sheath.

51. The method of claim 48, wherein coupling comprises coupling the outer elongate shaft and the shuttle sheath with a bayonet coupling.

52. The method of claim 48, wherein the delivery catheter further comprises an inner elongate shaft, and selecting the deployment direction further comprises:

decoupling the inner elongate shaft from the shuttle sheath.

53. The method of claim 52, wherein decoupling the inner elongate shaft from the shuttle sheath comprises threadably decoupling the inner elongate shaft from the shuttle sheath.

54. The method of claim 52, wherein decoupling the inner elongate shaft from the shuttle sheath comprises helically decoupling the inner elongate shaft from the shuttle sheath.

55. The method of claim 52, wherein decoupling comprises releasing a bayonet coupling between the inner elongate shaft and the shuttle sheath.

56. The method of claim 33, wherein the delivery catheter comprises a shuttle sheath disposed over the prosthesis, and removing the constraint comprises distally advancing the shuttle sheath away from the prosthesis so that the prosthesis is unconstrained from radial expansion in a direction extending from the proximal end of the prosthesis to the distal end of the prosthesis.

57. The method of claim 33, wherein the delivery catheter comprises a shuttle sheath disposed over the prosthesis, and removing the constraint comprises proximally retracting the shuttle sheath away from the prosthesis so that the prosthesis is unconstrained from radial expansion in a direction extending from the distal end of the prosthesis to the proximal end of the prosthesis.

58. The method of claim 33, wherein radially expanding the prosthesis comprises self-expanding a stent.

59. The method of claim 33, wherein withdrawing the delivery catheter from the patient comprises withdrawing the delivery catheter from the patient's vasculature.

60. The method of claim 33, wherein the prosthesis comprises two prostheses, the method comprising:

selecting a first deployment direction for the first prosthesis;

radially expanding the first prosthesis in the first deployment direction; and

radially expanding the second prosthesis in a second deployment direction opposite of the first deployment direction.

61. The method of claim 33, further comprising visualizing the expanded prosthesis.

62. The method of claim 61, wherein visualizing comprises observing the expanded prosthesis with ultrasound or fluoroscopy.

63. The method of claim 33, further comprising retracting the radially expanded prosthesis into a shuttle sheath;

repositioning the prosthesis; and

radially expanding the prosthesis.

64. The method of claim 33, further comprising dilating the radially expanded prosthesis with an expandable member.

65. A method of releasing a prosthesis from a catheter, comprising:

Providing a delivery catheter comprising a prosthesis having a proximal end and a distal end, the prosthesis in a collapsed configuration and disposed on the delivery catheter;

Rotating a portion of a handle on the proximal end of the catheter to release a part of a coupling adjacent to the prosthesis at the distal end of the catheter; and

Sliding a knob along the handle to move the released part of the coupling so as to release the prosthesis from the collapsed configuration.

66. The method of claim 65 wherein the part is a pin and the rotating the step moves the pin along a slot in the coupling.

67. The method of claim 65 the sliding a knob step further comprising: moving a shuttle sheath to uncover the prosthesis.

68. The method of claim 67 wherein the shuttle sheath uncovers the prosthesis to provide a distal prosthesis deployment.

69. The method of claim 67 wherein the shuttle sheath uncovers the prosthesis to provide a proximal prosthesis deployment.

70. The method of claim 65 wherein the coupling adjacent to the prosthesis is a bayonet coupling positioned distal to the prosthesis.

71. The method of claim 65 wherein the coupling adjacent to the prosthesis is a bayonet coupling positioned proximal to the prosthesis.

72. The method of claim 65 wherein the coupling adjacent to the prosthesis further comprises a first bayonet coupling positioned proximal to the prosthesis and a second bayonet coupling positioned distal to the prosthesis and the sliding a knob step selectively moves a part of the first bayonet coupling or the second bayonet coupling.

73. The method of claim 65 further comprising: before the rotating step, moving a direction selection knob along the handle to control the direction of rotation of the portion of the handle during the rotating step.

74. The system of claim 12, the bayonet coupling further comprising a male connector with at least one pin and a female connector having a slot configured to receive the at least one pin.

75. The system of claim 74 wherein the slot comprises a linear section, a transverse section and a receiver section.

76. The system of claim 75 wherein the transverse section is arranged at about a 90 degree angle from the linear section.

77. The system of claim 74 wherein the width of the slot is narrowed at one portion so as to form a friction fit with the at least one pin.

78. The system of claim 74 wherein the female connector has two or more slots of similar configuration with the two or more slots arranged equidistant from one another around the circumference of the female connector.

79. The system of claim 24 wherein the slot comprises a linear section, a transverse section and a receiver section.

80. The system of claim 79 wherein the transverse section is arranged at about a 90 degree angle from the linear section.

81. The system of claim 24 wherein the width of the slot is narrowed at one portion so as to form a friction fit with a portion of the coupling mechanism.

82. The system of claim 81 wherein the portion of the coupling mechanism is a pin.

CLAIMS

WHAT IS CLAIMED IS:

1. A bi-directional stent delivery system, said system comprising:

an elongated inner shaft having a proximal portion and a distal portion;

a radially expandable prosthesis disposed over the inner shaft, the prosthesis having a radially collapsed configuration and a radially expanded configuration, wherein in the collapsed configuration the prosthesis is adapted to be delivered through a vasculature, and in the expanded configuration the prosthesis engages a vessel wall;

an elongated outer shaft having a proximal portion and a distal portion; and

a shuttle sheath having a proximal portion and a distal portion, the shuttle sheath disposed over the radially expandable prosthesis and releasably lockable to the inner shaft and the outer shaft,

wherein the stent delivery system is configured to be selectively actuated between a proximal deployment configuration and a distal deployment configuration, when the stent delivery system is in the proximal deployment configuration, the shuttle sheath is locked with the inner shaft and unlocked from the outer shaft such that distal advancement of the inner shaft advances the shuttle sheath distally relative to the outer shaft, thereby allowing the prosthesis to radially expand from a proximal end thereof to a distal end thereof, and

when the stent delivery system is in the distal deployment configuration, the shuttle sheath is unlocked from the inner shaft and locked with the outer shaft such that proximal retraction of the outer shaft retracts the shuttle sheath proximally relative to the inner shaft, thereby allowing the prosthesis to radially expand from the distal end thereof to the proximal end thereof.

2. The system of claim 1, wherein the inner shaft comprises a lumen extending between the proximal and distal portions, the lumen configured to slidably receive a guidewire.

3. The system of claim 1, wherein the prosthesis comprises a first stent.

4. The system of claim 3, further comprising a second stent unattached and axially separated from the first stent by a gap.

5. The system of claim 3, wherein the first stent comprises a self-expanding stent.

6. The system of claim 3, wherein the first stent comprises a nickel titanium alloy.

7. The system of claim 1, wherein the outer shaft comprises a lumen extending between the proximal and distal portions thereof.

8. The system of claim 1, wherein the shuttle sheath has a length greater than or equal to the length of the radially expandable prosthesis.

9. The system of claim 1, wherein the shuttle sheath constrains the prosthesis along substantially the entire length of the prosthesis.

10. The system of claim 1, wherein the shuttle sheath has a proximal end, a distal end, and a lumen extending therebetween.

11. The system of claim 1, wherein the shuttle sheath comprises a substantially cylindrical sheath.

12. The system of claim 1, further comprising a distal coupling mechanism, the distal coupling mechanism releasably coupling the distal portion of the inner shaft to the distal portion of the shuttle sheath.

13. The system of claim 12, wherein the distal coupling mechanism comprises a bayonet coupling.

14. The system of claim 12, wherein the distal coupling mechanism comprises a threaded region on the distal portion of the inner shaft and a corresponding threaded region on the distal portion of the shuttle sheath.

15. The system of claim 12, wherein the distal coupling mechanism comprises a helical region on the distal portion of the inner shaft and a corresponding helical region on the distal portion of the shuttle sheath.

16. The system of claim 12, wherein the distal coupling mechanism comprises one or more of a snap fit, an interference fit, a barbed connector, a locking mechanism, a rotatable key lock, a linear key lock, a threaded bushing, a twist lock, a magnetic coupling, or a frangible connector.

17. The system of claim 1, further comprising a proximal coupling mechanism, the proximal coupling mechanism releasably coupling the distal portion of the outer shaft to the proximal portion of the shuttle sheath.

18. The system of claim 17, wherein the proximal coupling mechanism comprises a bayonet coupling.

19. The system of claim 17, wherein the proximal coupling mechanism comprises a threaded region on the distal portion of the outer shaft and a corresponding threaded region on the proximal portion of the shuttle sheath.

20. The system of claim 17, wherein the proximal coupling mechanism comprises a helical region on the distal portion of the outer shaft and a corresponding helical region on the proximal portion of the shuttle sheath.

21. The system of claim 17, wherein the proximal coupling mechanism comprises one or more of a snap fit, an interference fit, a barbed connector, a locking mechanism, a rotatable

key lock, a linear key lock, a threaded bushing, a twist lock, a magnetic coupling, or a frangible connector.

22. The system of claim 1, wherein the inner shaft and the outer shaft each have a threaded region and are releasably lockable with the shuttle sheath by the threaded region of the respective inner or outer shaft threadably engaging a threaded region of the shuttle sheath, wherein rotation of the inner shaft in a first direction locks the inner shaft with the shuttle sheath and rotation of the inner shaft in a second direction opposite the first direction unlocks the inner shaft from the shuttle sheath, and wherein rotation of the outer shaft in the first direction unlocks the outer shaft from the shuttle sheath and rotation of the outer shaft in the second direction locks the outer shaft with the shuttle sheath.

23. The system of claim 1, wherein the inner shaft and the outer shaft each have a helix and are releasably lockable with the shuttle sheath by the helix of the respective inner or outer shaft helically engaging a helix of the shuttle sheath, wherein rotation of the inner shaft in a first direction locks the inner shaft with the shuttle sheath and rotation of the inner shaft in a second direction opposite the first direction unlocks the inner shaft from the shuttle sheath, and wherein rotation of the outer shaft in the first direction unlocks the outer shaft from the shuttle sheath and rotation of the outer shaft in the second direction locks the outer shaft with the shuttle sheath.

24. The system of claim 1, wherein the inner shaft is releasably lockable with the shuttle sheath with a first bayonet coupling mechanism having a slot in a first orientation, and the outer shaft is releasably lockable with the shuttle sheath with a second bayonet coupling mechanism having a slot in a second orientation opposite the first orientation of the first slot, and wherein rotation of the inner shaft in a first direction locks the inner shaft with the shuttle sheath and rotation of the inner shaft in a second direction opposite the first direction unlocks the inner shaft from the shuttle sheath, and wherein rotation of the outer shaft in the first direction unlocks

the outer shaft from the shuttle sheath and rotation of the outer shaft in the second direction locks the outer shaft with the shuttle sheath.

25. The system of claim 1, further comprising a middle shaft concentric with the inner and the outer shafts, and disposed therebetween.

26. The system of claim 25, wherein the prosthesis is disposed over the middle shaft and in direct engagement therewith.

27. The system of claim 26, wherein the middle shaft comprises an outer surface that is substantially smooth.

28. The system of claim 25, wherein the middle shaft comprises a proximal stent stop and a distal stent stop, the proximal stent stop disposed proximally of the proximal end of the prosthesis, and the distal stent stop disposed distally of the distal end of the prosthesis, wherein the proximal stent stop prevents proximal movement of the prosthesis beyond the proximal stent stop, and the distal stent stop prevents distal movement of the prosthesis beyond the distal stent stop.

29. The system of claim 28, wherein the proximal stent stop comprises one or more of a ring, a band, a step, a bushing, or a sleeve, that prevent proximal movement of the prosthesis beyond the proximal stent stop.

30. The system of claim 28, wherein the distal stent stop comprises one or more of ring, a band, a step, a bushing, or a sleeve, that prevents distal movement of the prosthesis beyond the distal stent stop.

31. The system of claim 1, further comprising an actuator mechanism operably coupled with the inner and outer shafts to slidably move the inner and outer shafts at least one of proximally or distally relative to each other, the actuator mechanism configured to allow an operator to selectively lock and unlock the inner and outer shafts with the shuttle sheath.

32. The system of claim 1, further comprising an intravascular ultrasound device configured to allow visualization of the prosthesis and surrounding tissue.