

CLAIMS:

1. An expandable sheath for deploying a medical device, comprising:
a first polymeric layer;
a braided layer radially outward of the first polymeric layer, the braided layer comprising a plurality of filaments braided together;
a resilient elastic layer radially outward of the braided layer, the elastic layer being configured to apply radial force to the braided layer and the first polymeric layer; and
a second polymeric layer radially outward of the elastic layer and bonded to the first polymeric layer such that the braided layer and the elastic layer are encapsulated between the first and second polymeric layers;
wherein when a medical device is passed through the sheath, the diameter of the sheath expands from a first diameter to a second diameter around the medical device while the first and second polymeric layers resist axial elongation of the sheath such that a length of the sheath remains substantially constant; and
wherein the sheath resiliently returns to the first diameter by radial force applied by the elastic layer upon passage of the medical device.
2. The expandable sheath of claim 1, wherein:
the first and second polymeric layers comprise a plurality of longitudinally-extending folds when the sheath is at the first diameter.
3. The expandable sheath of claim 2, wherein the longitudinally extending folds create a plurality of circumferentially spaced ridges and a plurality of circumferentially spaced valleys.
4. The expandable sheath of claim 3, wherein, as a medical device is passed through the sheath, the ridges and valleys level out to allow the sheath to radially expand.
5. The expandable sheath of any one of claims 1-4, wherein the elastic layer comprises one or more elastic bands helically wound over the braided layer.
6. The expandable sheath of claim 5, wherein the elastic layer comprises two elastic bands wound with opposite helicity.

7. The expandable sheath of any one of claims 1-6, wherein the filaments of the braided layer are movable between the first and second polymeric layers such that the braided layer is configured to radially expand as a medical device is passed through the sheath while the length of the sheath remains substantially constant.

8. The expandable sheath of claim 7, wherein the filaments of the braided layer are not engaged or adhered to the first or second polymeric layers.

9. The expandable sheath of any one of claims 1-8, wherein the filaments of the braided layer are resiliently buckled when the sheath is at the first diameter.

10. The expandable sheath of claim 9, wherein the first and second polymeric layers are attached to each other at a plurality of open spaces between the filaments of the braided layer.

11. The expandable sheath of any one of claims 1-10, further comprising one or more longitudinally extending cords attached to the braided layer.

12. The expandable sheath of any one of claims 1-11, further comprising an outer cover extending longitudinally beyond distal ends of the first polymeric layer, the braided layer, the elastic layer, and the second polymeric layer to form an overhang.

13. The expandable sheath of claim 12, wherein the outer cover comprises one or more longitudinally extending slits, weakened portions, or scorelines.

14. The expandable sheath of either of claims 12, wherein the outer cover is formed of a heat-shrink material.

15. The expandable sheath of claim 12, wherein the outer cover is elastomeric.

16. A method of making an expandable sheath, the method comprising:
placing a braided layer radially outward of a first polymeric layer situated on a mandrel, the braided layer comprising a plurality of filaments braided together, the mandrel having a first diameter;
applying an elastic layer radially outward of the braided layer, the elastic layer being configured to apply radial force to the first polymeric layer and the braided layer;
applying a second polymeric layer radially outward of the elastic layer;
applying heat and pressure to the first polymeric layer, the braided layer, the elastic layer, and the second polymeric layer such that the first and second polymeric layers bond to each other and encapsulate the braided layer and the elastic layer to form an expandable sheath; and
removing the expandable sheath from the mandrel to allow the expandable sheath to at least partially radially collapse to a second diameter that is less than the first diameter under radial force applied by the elastic layer.
17. The method of claim 16, wherein applying the elastic layer further comprises wrapping one or more elastic bands around the braided layer.
18. The method of claim 17, wherein applying an elastic layer further comprises applying the one or more elastic bands in a stretched configuration.
19. The method of claim 17, wherein after application of the braided layer, the method further comprises removing the first polymeric layer and the braided layer from the mandrel, applying the elastic layer in a relaxed or a moderately stretched state, and placing the first polymeric layer, the braided layer, and the elastic layer back on the mandrel to stretch the elastic layer prior to application of the second polymeric layer.
20. The method of any one of claims 16-19, wherein applying heat and pressure further comprises placing the mandrel in a vessel containing a thermally-expandable material, and heating the thermally-expandable material in the vessel.

21. The method of claim 20, wherein applying heat and pressure further comprises applying a radial pressure of 100 MPa or more to the mandrel via the thermally-expandable material.

22. The method any one of claims 16-21, wherein applying heat and pressure further comprises applying a heat shrink tubing layer over the second polymeric layer and applying heat to the heat shrink tubing layer.

23. The method any one of claims 16-22, further comprising resiliently buckling the filaments of the braided layer as the sheath is radially collapsed to the second diameter.

24. The method any one of claims 16-23, further comprising press fitting the removed expandable sheath into an outer cover such that the outer cover extends distally off distal ends of the first polymeric layer, the braided layer, the elastic layer, and the second polymeric layer at an overhang.

25. The method of claim 24, wherein the outer cover is a heat shrink tubing.

26. The method of claim 24, wherein the outer cover is elastomeric.

27. The method any one of claims 16-26, further comprising attaching one or more longitudinally extending cords to the braided layer to prevent axial elongation of the braided layer.

28. The method any one of claims 16-27, further comprising crimping the expandable sheath to a third diameter, the third diameter being smaller than the first diameter and the second diameter.

29. The method of claim 28, wherein crimping the expandable sheath comprises supporting an inner surface of the entire length of the uncrimped sheath on an elongated mandrel having a conical end portion, the conical end portion nested within a narrowing lumen of a crimping mechanism, advancing the expandable sheath over the conical end portion and through the narrowing lumen while the uncrimped portion is supported by the

mandrel, and compressing the sheath to the third, crimped diameter via pressure from an interior surface of the narrowing lumen of the crimping piece.

30. The method of claim 28, wherein crimping the expandable sheath comprises contacting an end of the sheath with a plurality of radially arranged disc-shaped rollers, advancing the sheath through the plurality of disc-shaped rollers, and compressing the sheath to the third, crimped diameter via pressure from a circular edge of each disc-shaped roller as it rolls along an outer surface of the sheath.

31. The method of claim 28, wherein crimping the expandable sheath comprises applying a first heat shrink tube to an outer surface of the sheath, compressing the sheath by shrinking the first heat shrink tube to an intermediate diameter, removing the first heat shrink tube, applying a second heat shrink tube to an outer surface of the sheath, compressing the sheath by shrinking the second heat shrink tube to a diameter smaller than the intermediate diameter, and removing the second heat shrink tube.

32. The method of claim 31, further comprising applying and shrinking additional, consecutively smaller heat shrink tubes until the sheath is compressed to the third diameter.

33. A method of forming a laminate product, comprising:
placing two or more layers of material inside a vessel such that the two or more layers of material are surrounded by a thermally-expandable material; and
heating the thermally-expandable material in the vessel such that the thermally-expandable material expands and applies heat and pressure to the two or more material layers to form a laminate product.

34. The method of claim 33, wherein the two or more layers of material are positioned over a mandrel.

35. An assembly, comprising:
the expandable sheath of any one of claims 1-15 or 64-66, further comprising a distal end portion resiliently expandable between the first diameter and a second diameter;

a vessel dilator disposed within the sheath, the vessel dilator comprising a tapered nose cone and a retaining member that extends at least partially over the distal end portion of the sheath and is configured to retain the distal end portion of the sheath at the first diameter.

36. The assembly of claim 35, wherein the distal end portion is heat-set toward an expanded configuration, and the elastic layer of the sheath terminates proximally of the distal end of the sheath.

37. The assembly of either of claims 35 or 36, wherein a distal end portion of the braided layer is heat-set toward a flared configuration.

38. The assembly of any one of claims 35-37, wherein the retaining member is a polymeric heat-shrink layer.

39. The assembly of any one of claims 35-, wherein the retaining member is elastomeric and configured to compress the distal end portion of the sheath.

40. The assembly of any one of claims 35-39, wherein the retaining member is glued or fused to the sheath.

41. The assembly of any one of claims 35-40, wherein the retaining mechanism comprises a shaft disposed between the dilator and the sheath, the shaft comprising a releasable coupling that mechanically engages both the dilator and the sheath and that can be manually deactivated.

42. The assembly of any one of claims 35-41, wherein the retaining mechanism comprises one or more balloons disposed between the dilator and the sheath.

43. A method of delivering a medical device, the method comprising:
inserting an assembly into a blood vessel, the assembly comprising a vessel dilator disposed within an expandable sheath, the vessel dilator comprising a tapered nose cone, the expandable sheath comprising a first polymeric layer, a braided layer radially outward of the

first polymeric layer, a resilient elastic layer radially outward of the braided layer, and a second polymeric layer radially outward of the elastic layer,
 withdrawing the vessel dilator through the sheath;
 advancing a medical device through the sheath having a maximum diameter that is up to three times larger than the first diameter of the sheath;
 resisting axial elongation of the sheath as the medical device is advanced through the sheath such that the length of the sheath remains substantially constant; and
 returning the sheath to the first diameter via radial force applied by the elastic layer.

44. The method of claim 43, wherein inserting an assembly into a blood vessel further comprises engaging the vessel dilator and the sheath by pressing the retaining member against the sheath.

45. The method of either of claims 43 or 44, wherein advancing the vessel dilator distally of the sheath further comprises breaking an adhesive bond between the retaining member and the sheath.

46. The method of any one of claims 43-45, further comprising manually deactivating a releasable coupling that mechanically engages both the dilator and the sheath prior to advancing the vessel dilator distally of the sheath.

47. The method of any one of claims 43-46, further comprising deflating one or more balloons disposed between the dilator and the sheath prior to advancing the vessel dilator distally of the sheath.

48. The method of any one of claims 43-47, wherein the vessel dilator further comprises a retaining member configured to retain a distal end portion of the sheath at a first diameter and the method further comprises advancing the vessel dilator distally of the sheath such that the retaining member releases the distal end portion of the sheath, and the distal end portion of the sheath expands to a second diameter

49. The method of any one of claims 43-48, wherein inserting an assembly into a blood vessel further comprises engaging the vessel dilator and the sheath by pressing an overhang portion of an outer cover of the sheath onto an outer surface of the vessel dilator.

50. The method of any one of claims 43-49, wherein advancing a medical device through the sheath further comprises leveling out ridges and valleys created by a plurality of longitudinally extending folds.

51. The method of any one of claims 43-50, wherein resisting axial elongation of the sheath further comprises straightening buckled filaments of the braided layer.

52. A crimping mechanism comprising:
a first end surface, a second end surface, and a longitudinal axis extending therethrough;
a plurality of disc-shaped rollers radially arranged about the longitudinal axis, each disc-shaped roller having a circular edge, a first side surface, a second side surface, and a central axis extending between a center point of the first side surface and a center point of the second side surface, the plurality of disc-shaped rollers being oriented such that the central axes of the disc-shaped rollers each extend perpendicularly to the longitudinal axis of the crimping mechanism; and
an axially extending passage extending along the longitudinal axis of the crimping mechanism and at least partially defined by the circular edges of the radially arranged plurality of disc-shaped rollers.

53. The crimping mechanism of claim 52, wherein each of the disc-shaped rollers are arranged at least partially between the first and second end surfaces of the crimping mechanism.

54. The crimping mechanism of either one of claims 52 or 53, wherein each of the disc-shaped rollers is held in the radially arranged configuration by a radially arranged plurality of connectors that are each attached to the crimping mechanism.

55. The crimping mechanism of claim 54, wherein each of the radially arranged connectors comprises a first and second arm extending over a selected disc-shaped roller

from the circular edge to a central portion of the disc-shaped roller, and a bolt attached to and extending between the first and second arms, the rod positioned loosely within a lumen defined between center points of the first and second side surfaces of the disc-shaped roller to allow the disc-shaped roller to rotate about the central axis of the disc-shaped roller.

56. The crimping mechanism of claim 54, wherein each of the radially arranged connectors is attached to the crimping mechanism by one or more fasteners.

57. The crimping mechanism of any one of claims 52-56, wherein each of the disc-shaped rollers is held in the radially arranged configuration by a radially arranged plurality of connectors, the location of each of the plurality of connectors being fixed with respect to the first end surface of the crimping mechanism.

58. A device for crimping an elongated sheath, the device comprising:
an elongated base;
an elongated mandrel positioned above the elongated base, the elongated mandrel comprising a conical end portion; and
a holding mechanism attached to the elongated base and supporting the elongated mandrel in an elevated position, the holding mechanism comprising:
a first end piece including a crimping mechanism, the crimping mechanism including a narrowing lumen that mates with the conical end portion of the mandrel; and
a second end piece that is movable relative to the elongated base such that a distance between the first end piece and the second end piece is adjustable;
wherein the conical end portion of the mandrel is positioned loosely within the narrowing lumen of the first end piece to facilitate passage of an elongated sheath over the conical end portion and through the narrowing lumen.

59. The device of claim 58, wherein the elongated base comprises at least one elongated sliding track, the second end piece being slidably engaged with the at least one elongated sliding track via at least one reversible fastener.

60. The device of claim 59, wherein the reversible fastener comprises a bolt extending through the second end piece, the elongated sliding track, and the elongated base.

61. The device of any one of claims 58-60, wherein the mandrel further comprises a cylindrical end portion extending outwardly from the conical end portion, the cylindrical end portion defining an end of the mandrel.

62. The device of any one of claims 58-61, wherein the narrowing lumen of the crimping mechanism comprises a first tapered portion opening toward the second end piece of the device, the first tapered portion having a narrow end that opens to a cylindrical portion of the narrowing lumen of the crimping mechanism.

63. The device of claim 62, wherein the narrowing lumen of the crimping mechanism further comprises a second tapered portion opening away from the second end piece of the device and the first tapered portion, the second tapered portion having a narrow end that opens to the cylindrical portion of the narrowing lumen of the crimping mechanism.

64. The device of any one of claims 1-15, wherein a distal end portion of the second polymeric layer extends longitudinally beyond distal ends of the first polymeric layer, the braided layer, and the elastic layer.

65. The device of claim 64, wherein the distal end portion comprises multiple circumferential folds when the sheath is in a collapsed configuration.

66. The device of claim 64, wherein the distal end portion comprises multiple layers of polymer material.