

WHAT IS CLAIMED IS:

1. An expandable sheath comprising:
an elongated inner member including at least one foldable axial portion;
an outer elastomeric member extending at least partially over the inner member and configured to exert a compressive force onto the inner member to bias the at least one foldable axial portion into a folded configuration; and
a proximal seal including a middle member extending from an outer surface of the inner member to an inner surface of the outer elastomeric member, the seal configured to guard against proximal migration of fluid from a distal free end of the expandable sheath to a proximal end of the expandable sheath.
2. The expandable sheath of claim 1, wherein the inner member and outer elastomeric member have an unconnected length distal to the proximal seal.
3. The expandable sheath of claim 2, wherein the unconnected length extends distally from the proximal seal to the distal free end of the expandable sheath.
4. The expandable sheath of either claim 2 or claim 3, wherein the proximal seal is configured to block a path starting at the distal free end and extending proximally to the proximal seal.
5. The expandable sheath of any one of claims 1-4, further comprising an outer jacket extending over the outer elastomeric member at the proximal seal.
6. The expandable sheath of any one of claims 1-4, wherein the outer elastomeric member is fused to the inner member at the seal.
7. The expandable sheath of any one of claims 1-6, wherein the outer elastomeric member is foldable at the proximal seal along with the inner member.
8. The expandable sheath of any one of claims 1-7, wherein the inner member is foldable independent of the outer elastomeric member distal to the seal.
9. The expandable sheath of any one of claims 1-8, wherein the elongated inner member is configured to at least partially unfold to an open configuration for passage of an implant.
10. The expandable sheath of any one of claims 1-10, further comprising a strain relief portion extending distally from the proximal end of the expandable sheath and wherein the proximal seal has a proximal end adjacent a distal end of the strain relief portion.

11. The expandable sheath of any one of claims 1-11, wherein the elongated inner member defines a central lumen, a first circumferential portion including first and second longitudinal edges, and a second circumferential portion extending between the first and second longitudinal edges.

12. The expandable sheath of claim 11, wherein the elongated inner member is configured to crease at the first and second longitudinal edges into the folded configuration wherein the second circumferential portion is positioned at least partially between the overlapping longitudinal edges.

13. The expandable sheath of either claim 11 or claim 12, wherein the elongated inner member further includes a distal tip, the distal tip including a flap extending from the first longitudinal edge and at least to the second longitudinal edge in an open configuration of the elongated inner member.

14. A method of making an expandable sheath, the method comprising:
forming a folded configuration in an elongated inner member by forming a crease along a first longitudinal edge and a second longitudinal edge of the elongated inner member so that a first circumferential portion is positioned at least partially between the longitudinal edges in the folded configuration;

covering the elongated member with an elastomeric outer member; and
forming a proximal seal proximal a distal free end of the expandable sheath by extending a middle member from an outer surface of the inner member to an inner surface of the elastomeric outer member.

15. A method of claim 14, further comprising blocking a path extending between the inner and outer members with the proximal seal.

16. A method of either claim 14 or claim 15, further comprising fusing the elastomeric outer member to the inner member at the seal.

17. A method of any one of claims 14-16, further comprising extending an outer jacket over the outer elastomeric member at the proximal seal.

18. A method of either claim 16 or claim 17, further comprising stretching the inner and elastomeric outer members over a mandrel into an open configuration for fusing.

19. A method of delivering a prosthetic device, the method comprising:
positioning an expandable sheath within the vascular system of a patient up to a proximal seal on the expandable sheath;

introducing a prosthetic device into a lumen of the expandable sheath;

at least partially blocking proximal migration of blood between an inner member and outer elastomeric member of the expandable sheath by blocking a path starting at a distal free end of the expandable sheath and extending proximally to the seal;

advancing the prosthetic device through the lumen of the expandable sheath such that the prosthetic device exerts a radially outward localized force on an inner surface of the inner member of the expandable sheath and locally unfolds the inner member into an expanded configuration; and

at least partially collapsing the inner member at the distal tip with the outer elastomeric member after the prosthetic device has passed out of the lumen of the expandable sheath.

20. A method of claim 19, further comprising at least partially blocking the path with the proximal seal using a middle layer extending between the inner member and an outer elastomeric member.

21. An expandable sheath comprising:

an elongated inner member defining a central lumen, a first circumferential portion including a first and second longitudinal edges, and a second circumferential portion extending between the first and second longitudinal edges,

wherein the elongated inner member is configured to crease at the first and second longitudinal edges into a folded configuration wherein the second circumferential portion is positioned at least partially between the overlapping longitudinal edges; and

an outer elastomeric member extending around the elongated inner member and configured to bias the elongated inner member into the folded configuration;

wherein the elongated inner member further includes a distal tip, the distal tip including a flap extending from the first longitudinal edge and at least to the second longitudinal edge in an open configuration of the elongated inner member.

22. The expandable sheath of claim 21, wherein the flap is configured to slide circumferentially over an outer surface of the first circumferential portion when the elongated inner member is biased into the folded configuration by the elastic outer member.

23. The expandable sheath of either claim 21 or claim 22, wherein the second circumferential portion has a distal edge extending longitudinally at least to a proximal edge of the flap.

24. The expandable sheath of claim 23, wherein the proximal edge of the flap extends over the distal edge of the second circumferential portion onto an outer surface of the second circumferential portion.

25. The expandable sheath of any one of claims 21-24, wherein the flap includes a longitudinal section of the second circumferential portion cut along the second longitudinal edge.

26. The expandable sheath of claim 25, wherein the longitudinal section is also cut circumferentially from the distal end of the second circumferential portion.

27. The expandable sheath of either claim 25 or claim 26, wherein the flap further includes an overlap extension that extends circumferentially from the longitudinal section.

28. The expandable sheath of claim 27, wherein the overlap extension extends proximally from the longitudinal section.

29. The expandable sheath of any one of claims 21-28, wherein the distal tip further comprises an elastomeric end extending from a distal end of the elongated inner member.

30. The expandable sheath of claim 29, wherein the elastomeric end has a distally tapering shape.

31. The expandable sheath of any one of claims 21-30, further comprising a marker embedded in the distal tip of the elongate inner member.

32. A method of making an expandable sheath, the method comprising:
forming a folded configuration in an elongated inner member by forming a crease along a first longitudinal edge and a second longitudinal edge of the elongated inner member so that a first circumferential portion is positioned at least partially between the longitudinal edges in the folded configuration;

forming a flap on a distal tip of an inner member so that the flap extends from a first longitudinal edge of the inner member at least to a second longitudinal edge of the inner member; and

covering the elongated inner member with an elastomeric outer member.

33. The method of claim 32, wherein forming the flap includes extending the flap circumferentially over an outer surface of the first circumferential portion.

34. The method of either claim 32 or claim 33, wherein forming the flap includes forming a proximal edge on the flap that extends over a distal edge and onto an outer surface of the second circumferential portion.

35. The method of claim 34, wherein the flap is formed at least partially by cutting a longitudinal section from the second circumferential portion.

36. The method of claim 35, wherein the flap is formed at least partially by attaching an overlap extension to the longitudinal section.

37. The method of any one of claims 32-36, further comprising attaching an elastomeric end to a distal end of the elongated inner member.

38. The method of claim 37, further comprising forming a tapered shape into the elastomeric end.

39. A method of delivering a prosthetic device, the method comprising:
positioning an expandable sheath within the vascular system of a patient;
introducing a prosthetic device into a lumen of the expandable sheath;
advancing the prosthetic device through the lumen of the expandable sheath such that the prosthetic device exerts a radially outward force on an inner surface of an inner member of the expandable sheath and locally unfolds the inner member into an expanded configuration;
advancing the prosthetic device further through the lumen to a distal tip of the expandable sheath and causing a free end of a flap of the distal tip to slide circumferentially over an outer surface of a first circumferential portion of the expandable sheath to locally enlarge the lumen in response to radial pressure exerted by passage of the prosthetic device; and
at least partially collapsing the inner member at the distal tip after the prosthetic device has passed out of the lumen of the expandable sheath.

40. The method of claim 39, further comprising advancing the prosthetic device through an elastomeric end extending around a distal end of the lumen to expand the elastomeric end and at least partially collapsing the elastomeric end after passage of the prosthetic device therethrough.

41. The method of either claim 39 or claim 40, wherein at least partially collapsing the inner member includes sliding the free end of the flap of the distal tip circumferentially over the outer surface of the first circumferential portion to locally reduce the lumen.