CLAIMS

~~1. A sheath for delivery of a catheter device through an arteriotomy of a patient, the sheath comprising:~~

~~a tubular sheath body having a longitudinal axis, an open proximal end, an open distal end, an outer surface and an inner surface, the inner surface defining a lumen between the proximal and distal ends for passage of a catheter device; and~~

~~an inflatable balloon disposed within the lumen and configured to:~~

~~occupy a longitudinal space in the lumen between the inner surface of the sheath body and the catheter device when the catheter device is disposed within the sheath and the balloon is inflated, and~~

~~fluidically seal the lumen.~~

~~2. The sheath according to any of the preceding claims, wherein the balloon forms an interference fit between the catheter device and the inner surface of the sheath body when inflated.~~

~~3. The sheath according to any of the preceding claims, wherein the balloon is positioned at least at the distal end of the sheath body.~~

~~4. The sheath according to any of the preceding claims, wherein the balloon is positioned along the entire length of the sheath body.~~

~~5. The sheath according to any of the preceding claims, wherein the balloon is attached to the inner surface of the sheath body.~~

~~6. The sheath according to claim 5, wherein the balloon is attached at least at the distal end of the inner surface of the sheath body.~~

~~7. The sheath according to claim 4, wherein the balloon is attached along the entire length of the inner surface of the sheath body.~~

~~8. The sheath according to any of claims 5-7, wherein the balloon is attached along at least a portion of the circumference of the sheath body.~~

~~9. The sheath according to any of claims 5-8, wherein the balloon is attached along at least any of the following portions of the sheath body: about 25%, about 50%, about 75%, about 100% of the inner circumference of the sheath body.~~

~~10. The sheath according to any of claims 5-9, wherein the inner surface of the sheath body is pretreated to improve attachment of the balloon to the inner surface of the sheath body.~~

~~11. The sheath according to any of claims 5-10, wherein the balloon is attached to the inner surface of the sheath body via heat or solvent bond.~~

~~12. The sheath according to claim 10, wherein the inner surface of the sheath body is pretreated via any one of: plasma activation and coronary treatment.~~

~~13. The sheath according to any of the preceding claims, wherein the balloon is inflated via an inflation opening located on the inner surface of the distal end of the sheath body.~~

~~14. The sheath according to claim 13, wherein the sheath body comprises an inflation lumen that extends from the proximal end of the sheath body to the inflation opening.~~

~~15. The sheath according to claim 14, wherein the inflation lumen is in fluid communication with the inflation opening.~~

~~16. The sheath according to any of claims 14-22, wherein the inflation lumen extends along the length of the sheath body linearly or curvilinearly.~~

~~17. The sheath according to any of claims 1-4, further comprising:~~

~~a balloon sleeve on which the inflatable balloon is attached, the sleeve aligned in-line with the catheter device and configured to traverse the lumen of the sheath body.~~

~~18. The sheath according to claim 17, wherein the proximal end of the balloon sleeve comprises a hemostasis valve that seals with the catheter device.~~

~~19. The sheath according to any of claims 17-18, wherein the balloon sleeve comprises an inflation lumen in fluid communication with the balloon for inflation.~~

~~20. The sheath according to claim 19, wherein the proximal end of the balloon sleeve comprises an inflation port in fluid communication with the inflation lumen for inflation.~~

~~21. The sheath according to any of claims 1-16, wherein the proximal end of the sheath body is coupled to an inflation port that is in fluid communication with the balloon for inflation.~~

~~22. The sheath according to any of claims 19-21, wherein the inflation lumen is in communication with a fixed volume syringe for inflation of the balloon at the proximal end of the sheath body.~~

~~23. The sheath according to any of claims 21-22, wherein the balloon is inflated via the inflation port with any one of: water, saline and air.~~

~~24. The sheath according to any of the preceding claims, wherein the balloon is positioned in-line with the catheter device.~~

~~25. The sheath according to any of the preceding claims, wherein the balloon is radially symmetric with respect to the longitudinal axis of the sheath body.~~

~~26. The sheath according to any of the preceding claims, wherein the balloon is ring-shaped through which the catheter device traverses.~~

~~27. The sheath according to any of the preceding claims, wherein the balloon applies a radial force on the catheter device when inflated, thereby locking the catheter device in position.~~

28. The sheath according to any of claims 1-18, wherein the balloon is asymmetric with respect to the longitudinal axis of the sheath body.

29. The sheath according to claim 28, wherein the balloon exerts a force on the catheter device so as to push the catheter device towards a portion of the inner surface of the sheath body when inflated, thereby locking the catheter device in position.

30. The sheath according to any of the preceding claims, wherein the sheath body comprises a lamination of a plurality of polymer layers arranged coaxially with each other about the longitudinal axis.

31. The sheath according to any of claims 1-29, wherein the sheath body comprises a combination of a plurality of tubular polymer layer portions arranged sequentially from the proximal to the distal end of the sheath body.

32. The sheath according to any of claims 30-31, wherein each polymer layer comprises a different polymer material type.

33. The sheath according to claim 32, wherein the polymer material type comprises any one of: PEBAX® 7233SA, PEBAX® 7033SA, PEBAX® 6333SA, PEBAX® 5533SA, PEBAX® 3533SA, and PEBAX® 2533SA.

34. The sheath according to any of the preceding claims, wherein the sheath body comprises reinforced structures to prevent kinking.

35. The sheath according claim 34, wherein the reinforced structures comprise any one of: braids, coils and laser cut features.

36. The sheath according to any of the preceding claims, wherein the balloon is fabricated from any one of: urethane, polyurethane, polyethylene, polypropylene, polyethylene terephthalate (PET), polyvinyl chloride (PVC), polyethylene, cross-linked polyethylene, a polyether block amide (PEBA), and nylon.

37. The sheath according to any of the preceding claims, wherein the sheath body is fabricated from any one of: a polyether block amide (such as PEBAX® or PebaSlix®), a polyethylene material, a polytetrafluoroethylene (PTFE) material, a high-density polyethylene (HDPE) material, a medium-density polyethylene (MDPE) material, and a low-density polyethylene (LDPE) material.

38. The sheath according to any of the preceding claims, wherein the distal end of the sheath body is fabricated from a softer elastic material than that used for the rest of the sheath body.

39. The sheath according to claim 38, wherein the distal end of the sheath body comprises a smaller diameter so as to seal onto the catheter device.

40. The sheath according to any claims 17-19, wherein the balloon sleeve is fabricated from any one of: urethane, polyurethane, polyethylene, polypropylene, polyethylene terephthalate (PET), polyvinyl chloride (PVC), polyethylene, cross-linked polyethylene, a polyether block amide (PEBA), and nylon.

~~41. The sheath according to any of the preceding claims, wherein the balloon is compliant and held flush against the inner surface of the sheath body when deflated.~~

~~42. The sheath according to claim 1, wherein the balloon is non-compliant and not held flush against the inner surface of the sheath body when deflated.~~

~~43. The sheath according to any of the preceding claims, wherein the balloon is coated with a hydrophilic coating.~~

~~44. The sheath according to any of claims 1-42, wherein the balloon is coated with a hydrophobic coating.~~

~~45. The sheath according to any of the preceding claims, wherein the coating is of a thickness that ensures appropriate balloon inflation characteristics.~~

~~46. The sheath according to any of the preceding claims, wherein the sheath body deforms when the balloon is inflated, thereby fixing the position of the sheath in the arteriotomy of the patient.~~

~~47. The sheath according to any of the preceding claims, wherein the proximal end of the sheath is coupled to a hub for manipulating the sheath as it is positioned within the arteriotomy of the patient.~~

48. The sheath according to any of claims 14-16 and 19-22, wherein the hub comprises an inflation sideport that is in fluid communication with the fluid lumen, thereby enabling the attachment of a source of balloon inflation fluid.

49. The sheath according to any of claims 47-48, wherein the hub comprises an irrigation port that is in fluid communication with the space between the catheter device and the inner surface of the sheath body, thereby enabling the space to be flushed with fluid prior to inflation of the balloon.

50. A sheath kit for delivery of a catheter device to an arteriotomy of a patient, the sheath kit comprising:

a sheath according to any of 1-49; and

a fixed volume syringe filled with fluid and coupled to the sheath for inflating the balloon with the fluid.

51. A method of fabricating a sheath with an internal balloon, the method comprising the steps of:

providing a tubular sheath body, the sheath body having a longitudinal axis, an open proximal end, an open distal end, an outer surface and an inner surface, the inner surface defining a lumen between the proximal and distal ends for passage of a catheter device; and

providing an inflatable balloon positioned in the lumen, the balloon configured to occupy a space in the lumen between the inner surface of the sheath body and the catheter device when the balloon is inflated thereby sealing the space from the arteriotomy.

52. The method of claim 51, further comprising:

attaching the inflatable balloon to at least a portion of the inner surface of the sheath body.

53. The method of any of claims 51-52, further comprising the step of:

pretreating the inner surface of the sheath body to improve adhesion between the balloon and the inner surface of the sheath body.

54. The method of claim 53, wherein the pretreatment comprises any one of: plasma activation and coronary treatment.

55. The method of claim 51, further comprising:

providing a balloon sleeve for insertion into the lumen of the sheath body, the sleeve aligned in-line with the catheter device; and

attaching the inflatable balloon to at least a portion of the sleeve.

56. The method of any of claims 52-55, wherein attachment of the balloon is carried out via heat or solvent bond.

57. The method of any of claims 51-56, further comprising the step of:

coating the surface of the balloon with either a hydrophilic coating or a hydrophobic coating.

58. The method of claim 57, further comprising:

coating the surface of the balloon up to a predetermined coating thickness to achieve particular inflation characteristics of the balloon.

59. The method of any of claims 51-58, further comprising the step of:

coupling a proximal end of the sheath body to a hub.

60. A method of fabricating a sheath with an internal balloon according to any of claims 1-49.

61. A method of using a sheath with an internal balloon for treating a patient with a catheter device, the method comprising the steps of:

positioning a sheath according to any one of claims 1-49 in an arteriotomy of the patient;

inserting the catheter device into the lumen to position a distal end of the catheter device in the arteriotomy of the patient;

flushing the space with an irrigation fluid; and

inflating the balloon with an inflation fluid so as to seal the space from the arteriotomy.

62. A method of using a sheath according to claim 61, further comprising the step of:

inserting a balloon sleeve on which the inflatable balloon is attached into the lumen, the sleeve aligned in-line with the catheter device.

63. A method of inserting a catheter based device through an arteriotomy of a patient, the method comprising the steps of:

inserting a sheath having a lumen running therethrough into the arteriotomy of the patient;

~~inserting the catheter based device into the lumen; and~~

~~inflating a balloon within the lumen between the sheath and the catheter based device so as to fluidically seal the lumen.~~

~~64. The method of claim 63, further comprising flushing the lumen prior to inflating the balloon.~~

~~65. The method of any of claims 63-64, wherein inserting the sheath comprises inserting a dilator into the lumen of the sheath for positioning the sheath into the arteriotomy of the patient.~~

~~66. The method of any of claims 63-65, wherein the balloon is attached to the sheath.~~

~~67. The method of any of claims 63-65, further comprising inserting a balloon sleeve, onto which the balloon is attached, into the lumen of the sheath between the sheath and the catheter based device, before inflating the balloon.~~

~~68. The method of claim 67, wherein the balloon sleeve is tightly coaxially arranged around the catheter based device.~~

1. An introducer sheath assembly comprising:

a tubular sheath body having a longitudinal axis, a proximal end, a distal end, an outer surface and an inner surface, the inner surface defining a lumen between the proximal and distal ends for passage of a catheter device,

a balloon sleeve on which an inflatable balloon is attached, the balloon sleeve configured to surround and slide over a portion of the catheter device for insertion into the lumen of the sheath body such that a distal end of the inflatable balloon is aligned with the distal end of the sheath body and the inflatable balloon forms a fluidic seal between the distal end of the sheath body and the catheter device when the balloon is inflated, the fluidic seal being configured to prevent fluid from entering the distal end of the sheath body between the sheath body and the catheter device.

2. The introducer sheath assembly according to claim 1, wherein the balloon is configured to form an interference fit between the catheter device and the inner surface of the sheath body when inflated, thereby preventing any axial movement of the catheter device relative to the sheath body.

3. The introducer sheath assembly according to claim 1, wherein a length of the inflatable balloon is configured such that a proximal end of the inflatable balloon will be aligned with the proximal end of the sheath body when the balloon sleeve is inserted into the lumen of the sheath body such that the distal end of the inflatable balloon is aligned with the distal end of the sheath body.

4. The introducer sheath assembly according to claim 1, wherein a proximal end of the balloon sleeve is configured to remain proximal of the proximal end of the sheath body when the balloon sleeve is inserted into the lumen of the sheath body such that the distal end of the inflatable balloon is aligned with the distal end of the sheath body.

5. The introducer sheath assembly according to claim 1, wherein the balloon sleeve comprises an inflation lumen that extends linearly or curvilinearly from a proximal end of the balloon sleeve to an inflation opening located within the inflatable balloon, wherein the inflation lumen is in fluid communication with the inflation opening.

6. The introducer sheath assembly according to claim 1, wherein the balloon is radially symmetric with respect to a longitudinal axis of the balloon sleeve when inflated.

7. The introducer sheath assembly according to claim 1, wherein the balloon is ring-shaped when inflated.

8. The introducer sheath assembly according to claim 1, wherein the balloon is configured to apply a radial force on the catheter device when inflated, thereby locking the catheter device in a position relative to the sheath body.

9. The introducer sheath assembly according to claim 1, wherein the balloon is asymmetric with respect to a longitudinal axis of the balloon sleeve when inflated.

10. The introducer sheath assembly according to claim 9, wherein the balloon is configured to exert a force on the catheter device so as to push the catheter device towards a portion of the inner surface of the sheath body when inflated, thereby locking the catheter device in a position relative to the sheath body.

11. The introducer sheath assembly according to claim 1, wherein the distal end of the sheath body comprises an elastic material that is softer than a material of a rest of the sheath body.

12. The introducer sheath assembly according to claim 1, wherein the balloon sleeve comprises a hub at a proximal end of the balloon sleeve.

13. The introducer sheath assembly according to claim 12, wherein the hub comprises a hemostasis valve.

14. The introducer sheath assembly according to claim 12, wherein the hub comprises an irrigation port that is configured to be in fluid communication with a space between the catheter device and an inner surface of the balloon sleeve, thereby enabling the space to be flushed with fluid prior to inflation of the balloon.