

Claims

1. A peel-away sheath assembly for insertion of a blood pump, the peel-away sheath assembly comprising:

a peel-away sheath hub; and

a peel-away sheath body comprising:

a proximal end connected to the peel-away sheath hub,

a distal end,

an outer layer defining an outer radius of the peel-away sheath body,

an inner layer defining a first lumen of the peel-away sheath body with

an inner radius, and

a reinforcing layer located between the inner radius and the outer radius,

wherein the reinforcing layer has a rigidity that is greater than at least one of a rigidity of the inner layer and a rigidity of the outer layer.

2. The peel-away sheath assembly of claim 1, wherein the reinforcing layer is a hypotube.

3. The peel-away sheath assembly of any of claims 1-2, wherein the reinforcing layer comprises at least two circumferential discontinuities.

4. The peel-away sheath assembly of any of claims 1-3, wherein the at least two circumferential discontinuities each comprise slits formed in a surface of the hypotube.

5. The peel-away sheath assembly of any of claims 1-4, wherein the slits on the surface of the hypotube are parallel to one another and are uniformly spaced along a length of the hypotube.

6. The peel-away sheath assembly of any of claims 1-5, wherein the slits on the surface of the hypotube have a length in a circumferential direction, wherein the length of the slits is substantially identical for all slits.

7. The peel-away sheath assembly of any of claims 1-6, the slits comprising:

a set of first slits, each slit of the set of first slits having a center, wherein centers of each slit in the set of first slits form a first slit axis along the length of the hypotube, and

a set of second slits, each slit of the set of second slits having a center, wherein centers of each slit in the set of second slits form a second slit axis along the length of the hypotube, and

wherein the second slit axis is offset by an angle from the first axis.

8. The peel-away sheath assembly of any of claims 1-7, further comprising first and second peel-away lines on a surface of the peel-away sheath body, wherein at any longitudinal location

along the peel-away sheath body, the first slit axis is at a same circumferential location as the first peel-away line and the second slit axis is at a same circumferential location as the second peel-away line.

9. The peel-away sheath assembly of any of claims 1-8 wherein at least one of the peel-away lines is located on an inner surface of the peel-away sheath body.

10. The peel-away sheath assembly of any of claims 1-8 wherein at least one of the peel-away lines is located on an outer surface of the peel-away sheath body.

11. The peel-away sheath assembly of any of claims 1-10, wherein the first and second peel-away lines are diametrically opposed from one another.

12. The peel-away sheath assembly of any of claims 1-11, the peel-away sheath hub further comprising:

a proximal conical portion, and

a distal cylindrical portion.

13. The peel-away sheath assembly of any of claims 1-12, wherein the proximal conical portion comprises a proximal circumferential discontinuity, and wherein the distal cylindrical portion comprises a distal circumferential discontinuity.

14. The peel-away sheath assembly of any of claims 1-13, wherein the proximal circumferential discontinuity and distal circumferential discontinuity are aligned in a longitudinal direction.

15. The peel-away sheath assembly of any of claims 1-14 wherein a distal end of the distal circumferential discontinuity abuts a proximal end of the at least one peel-away line along the surface of the peel-away sheath body.

16. The peel-away sheath assembly of any of claims 1-15, wherein the inner layer and the outer layer comprise a thermoplastic.

17. The peel-away sheath assembly of any of claims 1-16, wherein the thermoplastic is at least one of PEBAX or TPU.

18. The peel-away sheath assembly of any of claims 1-17, wherein the reinforcing layer is at least one of LCP, PEBAX, stainless steel, Nitinol, or Kevlar.

19. The peel-away sheath assembly of any of claims 1-18, wherein the reinforcing layer is present only in the distal portion of the peel-away sheath body.

20. The peel-away sheath assembly of any of claims 1-18, wherein the reinforcing layer is present only in the proximal portion of the peel-away sheath body.

21. The peel-away sheath assembly of any of claims 1-18, wherein the reinforcing layer is present only in a middle portion of the peel-away sheath body.

22. The peel-away sheath assembly of any of claims 1-18, wherein the reinforcing layer is present in alternating portions along the length of the peel-away sheath body.
23. The peel-away sheath assembly of any of claims 1-22 wherein the hypotube is configured as two c-shaped halves.
24. The peel-away sheath assembly of any of claims 1-23 wherein the peel away line on the inner surface of the peel-away sheath body extends along the entire length of the peel-away sheath body.
25. The peel-away sheath assembly of any of claims 1-24 wherein a hydrophilic coating covers at least a portion of the outer layer of the peel-away sheath body.
26. The peel-away sheath assembly of any of claims 1-25 wherein the portion of the outer layer covered by the hydrophilic coating extends from the distal end of the peel-away sheath body to about 5 centimeters distal of the proximal end of the peel-away sheath body.
27. The peel-away sheath assembly of any of claims 1-26 wherein the portion of the outer layer covered by the hydrophilic coating extends from the distal end of the sheath body to about 2 centimeters distal of the proximal end of the peel-away sheath body.
28. A peel-away sheath assembly for insertion of a blood pump, the peel-away sheath assembly comprising:
- a peel-away sheath hub; and
 - a peel-away sheath body comprising:
 - a proximal end connected to the peel-away sheath hub,
 - a distal end,
 - an outer layer defining an outer radius of the peel-away sheath body,
 - an inner layer defining a first lumen of the peel-away sheath body with an inner radius,
 - a reinforcing layer located between the inner radius and the outer radius,
 - and
 - a pair of diametrically opposed notches, wherein the notches extend radially through at least one of the inner layer or outer layer.
29. The peel-away sheath assembly of any of claims 1-28, wherein the notches are inner diameter notches that extend from an innermost surface of the inner layer and through the reinforcing layer.
30. The peel-away sheath assembly of any of claims 1-29 wherein the notches terminate before the outer layer.

31. The peel-away sheath assembly of any of claims 1-30, wherein the notches terminate within the outer layer.
32. The peel-away sheath assembly of any of claims 1-31, wherein the notches are outer diameter notches that extend from an outermost surface of the outer layer and through the reinforcing layer.
33. The peel-away sheath assembly of any of claims 1-32, wherein the notches terminate before the inner layer.
34. The peel-away sheath assembly of any of claims 1-33, wherein the notches terminate within the inner layer.
35. The peel-away sheath assembly of any of claims 1-34, wherein the pair of diametrically opposed notches defines a pair of diametrically opposed peel-away lines on a surface of the peel-away sheath body, wherein each of the pair of peel-away lines extends along a length of the peel-away sheath body and wherein the peel-away sheath body can be separated along the peel-away lines.
36. The peel-away sheath assembly of any of claims 1-35, wherein the surface of the peel-away sheath body is an inner surface.
37. The peel-away sheath assembly of any of claims 1-36, wherein the surface of the peel-away sheath body is an outer surface.
38. The peel-away sheath assembly of any of claims 1-37, wherein the reinforcing layer is only present in a proximal portion of the peel-away sheath body.
39. The peel-away sheath assembly of any of claims 1-38, wherein at any longitudinal location along the peel-away sheath body having a pair of diametrically opposed notches, each notch in the pair of notches is located at a same circumferential location as the peel-away line that the notch defines.
40. A peel-away sheath assembly for insertion of a blood pump, the peel-away sheath assembly comprising:
- a peel-away sheath hub; and
 - a peel-away sheath body comprising:
 - a proximal end connected to the peel-away sheath hub,
 - a distal end,
 - an outer layer defining an outer radius of the peel-away sheath body,
 - an inner layer defining a first lumen of the peel-away sheath body with an inner radius, and
 - a reinforcing layer located between the inner radius and the outer radius,

at least a pair of diametrically opposed first inner notches extending through the inner layer to a fourth radius between the inner radius and the third radius, and
at least a pair of diametrically opposed second outer notches extending through the outer layer to a fifth radius between the inner radius and the third radius.

41. The peel-away sheath assembly of any of claims 1-40, wherein
the first inner notches extend along a first longitudinal segment of the peel-away sheath body, and wherein
the second outer notches extend along a second longitudinal segment of the peel-away sheath body.
42. The peel-away sheath assembly of any of claims 1-41, wherein the first segment and the second segment partially overlap in a longitudinal direction.
43. The peel-away sheath assembly of any of claims 1-42, wherein the first segment and the second segment fully overlap.
44. The peel-away sheath assembly of any of claims 1-43, wherein the at least a pair of diametrically opposed first inner notches and the at least a pair of diametrically opposed second outer notches define a pair of diametrically opposed peel-away lines, each of the pair of peel-away lines extending along a length of the peel-away sheath body and along which the peel-away sheath body can be separated.
45. The peel-away sheath assembly of any of claims 1-44, wherein each peel-away line of the pair of peel-away lines is formed by both inner notches and outer notches.
46. The peel-away sheath assembly of any of claims 1-45, wherein the reinforcing layer comprises a first set of discontinuities extending along a length of the sheath, and a second set of discontinuities extending along the length of the peel-away sheath body.
47. The peel-away sheath assembly of any of claims 1-46, wherein at any longitudinal location along the peel-away sheath body, an axis of the first set of discontinuities is at a same circumferential location as the first peel-away line and an axis of the second set of discontinuities is at a same circumferential location as the second peel-away line.
48. A method for manufacturing a peel-away sheath assembly for insertion of a blood pump, the peel-away sheath assembly comprising a peel-away sheath body and a peel-away sheath hub, the method comprising:
coating a mandrel with a first layer of a first material;
heat-shrinking the first layer;

coating the heat-shrunk first layer with a second layer of a second material and an outermost third layer of a third material, wherein the second layer is a reinforcing layer; and

heat-shrinking the first, second, and third layer materials.

49. The method of manufacturing a peel-away sheath assembly for insertion of a blood pump of any of claims 1-48, wherein:

the mandrel possesses a raised protrusion that is configured to leave at least an inner diameter notch in the heat-shrunk sheath body, wherein the at least an inner diameter notches extend from an innermost surface of the first layer, through the second layer, and terminate before or within the third layer.

50. A peel-away sheath assembly for insertion of a blood pump, the peel-away sheath assembly comprising:

a peel-away sheath hub; and

a peel-away sheath body comprising:

a proximal end connected to the peel-away sheath hub, a middle segment, a distal end, a proximal segment between the proximal end and the middle segment, and a distal segment between the middle segment and the distal end,

an outer layer defining an outer radius of the sheath,

an inner layer defining a first lumen of the peel-away sheath body with an inner radius, and

a reinforcing layer located in the middle segment between the inner layer and the outer layer,

wherein the reinforcing layer has a rigidity that is greater than at least one of a rigidity of the inner layer and a rigidity of the outer layer.

51. The peel-away sheath assembly of any of claims 1-50, wherein the reinforcing layer is located in the proximal segment.

52. The peel-away sheath assembly of any of claims 1-51, wherein the reinforcing layer is located in the distal segment.

53. A peel-away sheath assembly for insertion of a blood pump, the peel-away sheath assembly comprising:

a peel-away sheath hub; and

a peel-away sheath body comprising:

a proximal end connected to the peel-away sheath hub, a middle segment, a distal end, a proximal segment between the proximal end and the middle segment, and a distal segment between the middle segment and the distal end,

an outer layer defining an outer radius of the peel-away sheath body and comprising an outer layer material,

an inner layer defining a first lumen of the sheath with an inner radius, and comprising an inner layer material, and

a reinforcing layer located in the middle segment between the inner layer and the outer layer,

wherein the reinforcing layer comprises a material having a stiffness that is greater than at least one of a stiffness of the inner layer material and a stiffness of the outer layer material.

54. The peel-away sheath assembly of any of claims 1-53, wherein the reinforcing layer is located in the proximal segment.

55. The peel-away sheath assembly of any of claims 1-54, wherein the reinforcing layer is located in the distal segment.

56. A peel-away sheath assembly for insertion of a blood pump, the peel-away sheath assembly comprising:

a peel-away sheath hub; and

a peel-away sheath body comprising:

a proximal end connected to the peel-away sheath hub;

a medial longitudinal section,

a distal end;

an outer layer defining an outer radius of the peel-away sheath;

an inner layer defining a peel-away sheath body lumen having an inner radius;

and

a reinforcing hypotube located between the inner layer and the outer layer,

wherein the reinforcing hypotube has a rigidity that is greater than at least one of a rigidity of the inner layer and a rigidity of the outer layer,

wherein the reinforcing hypotube is configured in two longitudinally extending c-shaped halves and wherein the reinforcing hypotube is configured to extend along the medial longitudinal section; and

wherein the inner layer further comprises a peel-away line extending continuously in the longitudinal direction along the sheath body.

57. The peel-away sheath assembly of any of claims 1-56, wherein the reinforcing hypotube is configured to extend into the proximal portion of the peel-away sheath body.
58. The peel-away sheath assembly of any of claims 1-57, further comprising a hydrophilic coating extending over a longitudinal portion of the outer layer.
59. A sheath body for the insertion of a blood pump, the sheath body comprising:
a first strip of a first material having a first rigidity; and
a second strip of a second material having a second rigidity, wherein the first rigidity is larger than the second rigidity;
wherein the first strip and the second strip are oriented adjacently in a helix from a distal end to a proximal end of the sheath body.
60. The sheath body of any of claims 1-59, wherein the first material comprises one of a polyether block amide (PEBA) and polyethylene and the second material comprises one of a PEBA and a thermoplastic elastomer.
61. The sheath body of any of claims 1-60, wherein the first strip and the second strip have the same width.
62. The sheath body of any of claims 1-61, wherein a first width of the first strip and a second width of the second width is 1 mm.
63. The sheath body of any of claims 1-62, wherein the first strip and the second strip have different widths.
64. The sheath body of any of claims 1-63, wherein a first width of the first strip is 3 mm and a second width of the second strip is 1 mm.
65. The sheath body of any of claims 1-64, further comprising:
a wall having a thickness; and
a first notch and a second notch in the wall, wherein the first notch and the second notch are axially aligned along a length of the sheath body and are oriented opposite each other.
66. The sheath body of any of claims 1-65, wherein the first notch and the second notch are on an inner surface of the sheath body.
67. The sheath body of any of claims 1-66, wherein the first notch and the second notch are on an outer surface of the sheath body.
68. The sheath body of any of claims 1-67, wherein the sheath body is bisected along the first notch and the second notch during a peel-away of the sheath body.
69. The sheath body of any of claims 1-68, further comprising a tapered tip.

70. The sheath body of any of claims 1-69, wherein the tapered tip comprises the first material and the second material.
71. The sheath body of any of claims 1-70, wherein the tapered tip comprises only the first material.
72. The sheath body of any of claims 1-71, wherein the tapered tip comprises only the second material.
73. An introducer sheath for the insertion of a blood pump, the introducer sheath comprising:
a sheath body having proximal and distal ends, the sheath body comprising:
a first strip of a first material having a first rigidity;
a second strip of a second material having a second rigidity, wherein the first rigidity is larger than the second rigidity;
wherein the first strip and the second strip are oriented adjacently in a helix from the distal end to the proximal end of the sheath body; and
a first lumen defined by the first strip and the second strip; and
a sheath hub having proximal and distal ends defining a second lumen, wherein the distal end of the sheath hub is attached to the proximal end of the sheath body.
74. The introducer sheath of any of claims 1-73, wherein the first lumen and the second lumen are in fluid communication.
75. The introducer sheath of any of claims 1-74, wherein the sheath hub further comprises a hemostasis valve sized for preventing fluid from exiting the proximal end of the hub.
76. The introducer sheath of any of claims 1-75, wherein the sheath hub further comprises:
a first notch and a second notch, wherein the first notch and the second notch are axially aligned along a length of the sheath hub and are oriented opposite each other.
77. The introducer sheath of any of claims 1-76, wherein the first notch and the second notch are on an inner surface of the sheath hub.
78. The introducer sheath of any of claims 1-77, wherein the first notch and the second notch are on an outer surface of the sheath hub.
79. A method of manufacturing a flexible introducer sheath body, the method comprising:
wrapping a first strip of a first material and a second strip of a second material adjacently around a mandrel;
securing a first distal end of the first strip and a second distal end of the second strip;
securing a first proximal end of the first strip and a second proximal end of the second strip;

placing a heat shrink tube over the first strip, the second strip, and the mandrel;
heating the first strip and the second strip;
removing the heat shrink tube; and
removing the first strip and the second strip from the mandrel.

80. A sheath body for the insertion of a blood pump, the sheath body comprising:
a first strip of a first material having a first rigidity;
a second strip of a second material having a second rigidity, wherein the first rigidity is larger than the second rigidity; and
an inner lumen defined by distal and proximal ends of the sheath body;
wherein the first strip and the second strip are oriented adjacently in a helix over the inner lumen from the distal end to the proximal end of the sheath body.
81. The sheath body of any of claims 1-80, wherein the second rigidity is larger than a third rigidity of the inner lumen.
82. The sheath body of any of claims 1-81, further comprising:
an outer wall having a first thickness;
an inner wall having a second thickness; and
a first notch and a second notch in the outer wall, wherein the first notch and the second notch are axially aligned along a length of the sheath body and are oriented opposite each other.