

We Claim:

1. An expandable medical sheath comprising

a sheath body having an inner surface and an outer surface, the inner surface defining a lumen that extends along a longitudinal axis between proximal and distal ends of the sheath body, the sheath body comprised of:

at least one first member extending between the proximal end and the distal end of the sheath body, each first member comprising a first material having a first elastic modulus;

a plurality of second members, each second member extending between the proximal end and the distal end of the sheath body, and each second member comprising a second material having a second elastic modulus that is higher than the first elastic modulus; and

a plurality of third members, each third member extending between the proximal end and the distal end of the sheath body without overlapping any other third member of the plurality of third members, and each third member being at least partially encapsulated within one of the plurality of second members and comprising a third material having a third elastic modulus that is higher than the second elastic modulus.

wherein the sheath body is configured to be radially expandable from an unexpanded state to an expanded state to allow the passage of a portion of a medical device through the lumen, the portion of the medical device having a transverse cross-sectional area larger than a transverse cross-sectional area of the lumen when the sheath is in the unexpanded state.

2. The expandable sheath of claim 1, wherein the sheath body comprises only one first member, and each second member is at least partially encapsulated within the first member .

3. The expandable sheath of claim 1, wherein the first material comprises at least one of: polyether ether ketone (PEEK), a polyether block amide (such as PEBAX), a polyethylene material, a high-density polyethylene (HDPE) material, a medium-density polyethylene (MDPE) material, a low-density polyethylene (LDPE) material, a crack-resistant material, a material with a low coefficient of friction, and a material with an elastic modulus of about 40ksi.

4. The expandable sheath of claim 1, wherein the second material comprises at least one of: ethylene-vinyl acetate (EVA), styrene-butadiene copolymer (SBC), synthetic rubber, an elastomer, an elastic material, a material with an elastic modulus of about 1.6ksi, and a material with a yield strain in excess of 200%.
5. The expandable sheath of claim 1, wherein the sheath automatically returns to the unexpanded state after passage of the portion of the medical device.
6. The expandable sheath of claim 1, comprising a plurality of first members and a plurality of second members, the plurality of first members being equal in number to the plurality of second members.
7. The expandable sheath of claim 6, wherein the first and second members are arranged symmetrically in alternating sections about a longitudinal axis of the sheath.
8. The expandable sheath of claim 6, wherein the plurality of first members and the plurality of second members are arranged non-symmetrically in alternating sections about a longitudinal axis of the sheath.
9. The expandable sheath of claim 1, wherein a diameter of the outer surface at the proximal end of the sheath body is larger than a diameter of the outer surface at the distal end of the sheath body, when the sheath is in the unexpanded state.
10. The expandable sheath of claim 1, wherein the third material comprises at least one of: steel, stainless steel, or nitinol.
11. The expandable sheath of claim 1, further comprising a hub coupled to the proximal end of the sheath body, the hub having at least one hemostatic valve in communication with the lumen of the sheath body.

12. The expandable sheath of claim 1, wherein the inner surface has an irregular geometry to minimize contact between the sheath body and the medical device.

13. The expandable sheath of claim 1, wherein the inner surface comprises at least one rib extending between proximal and distal ends of the sheath body.

14. The expandable sheath of claim 1, further comprising a tapered tip attached to the distal end of the expandable sheath body, the tapered tip comprising an outer surface that is continuous with the outer surface of the sheath body, and which reduces in diameter as it approaches a distal end of the tapered tip.

15. The expandable sheath of claim 14, wherein the tip comprises at least one of: ethylene-vinyl acetate (EVA), styrene-butadiene copolymer (SBC), synthetic rubber, an elastomer, an elastic material, a material with an elastic modulus of about 1.6ksi, and a material with a yield strain in excess of 200%.

16. The expandable sheath of claim 15, wherein the tapered tip further comprises an inner surface that is continuous with the inner surface of the sheath body, and which reduces in diameter as it approaches a distal end of the tapered tip.

17. The expandable sheath of claim 16, wherein the diameter of the inner surface at the distal end of the tapered tip is configured to seal against a second portion of the medical device, the second portion of the medical device having a transverse cross-sectional area smaller than a transverse cross-sectional area of the lumen when the sheath is in the unexpanded state.

18. The expandable sheath of claim 14, wherein the tapered tip comprises at least one of: ethylene-vinyl acetate (EVA), styrene-butadiene copolymer (SBC), synthetic rubber, an elastomer, a material with an elastic modulus of about 1.6ksi, or a material with a yield strain in excess of 200%.

19. The expandable sheath of claim 14, wherein the tapered tip comprises the second material.

20. The expandable sheath of claim 1, wherein the second elastic modulus is substantially higher than the first elastic modulus.

21. The expandable sheath of claim 14, wherein the outer surface of the tapered tip terminates in a rounded edge at the distal end of the tapered tip.

22. An expandable medical sheath comprising:

a sheath body having an inner surface and an outer surface, the inner surface defining a lumen that extends along a longitudinal axis between a proximal end and a distal end of the sheath body, the sheath body being comprised of:

a plurality of first members and a plurality of second members, each first member and each second member extending between the proximal end and the distal end of the sheath body, each of the first members and the second members being alternately arranged around the lumen, each first member comprising a first material having a first elastic modulus, and each second member comprising a second material having a second elastic modulus that is higher than the first elastic modulus; and

a plurality of third members, each third member extending between the proximal end and the distal end of the sheath body without overlapping any other third member of the plurality of third members, and each third member being at least partially encapsulated within one of the plurality of second members and comprising a third material having a third elastic modulus that is higher than the second elastic modulus; and

wherein the sheath body is configured to be radially expandable from an unexpanded state to an expanded state to allow the passage of a portion of a medical device through the lumen, the portion of the medical device having a transverse cross-sectional area larger than a transverse cross-sectional area of the lumen when the sheath is in the unexpanded state.

~~1. — An expandable medical sheath comprising~~

~~a sheath body having an inner surface and an outer surface, the inner surface defining a lumen that extends between proximal and distal ends of the sheath body, the sheath body comprised of:~~

~~at least one first member extending between the proximal end and the distal end of the sheath body, each first member comprising a first material having a first elastic modulus;~~

~~a plurality of second members, each second member extending between the proximal end and the distal end of the sheath body, and each second member comprising a second material having a second elastic modulus that is higher than the first elastic modulus; and~~

~~a plurality of third members, each third member extending between the proximal end and the distal end of the sheath body without overlapping any other third member of the plurality of third members, and each third member being at least partially encapsulated within one of the plurality of second members and comprising a third material having a third elastic modulus that is higher than the second elastic modulus;~~

~~wherein the sheath body is configured to be radially expandable from an unexpanded state to an expanded state to allow the passage of a portion of a medical device through the lumen, the portion of the medical device having a transverse cross-sectional area larger than a transverse cross-sectional area of the lumen when the sheath is in the unexpanded state.~~

~~2. —The expandable sheath of claim 0, wherein the sheath body comprises only one first member, and each second member is at least partially encapsulated within the first member.~~

~~3. —The expandable sheath of claim 0, wherein the first material comprises at least one of: polyether ether ketone (PEEK), a polyether block amide (such as PEBAX), a polyethylene material, a high-density polyethylene (HDPE) material, a medium-density polyethylene (MDPE) material, a low-density polyethylene (LDPE) material, a crack-resistant material, a material with a low coefficient of friction, and a material with an elastic modulus of about 40ksi.~~

~~4. —The expandable sheath of claim 0, wherein the second material comprises at least one of: ethylene vinyl acetate (EVA), styrene-butadiene copolymer (SBC), synthetic rubber, an elastomer, an elastic material, a material with an elastic modulus of about 1.6ksi, and a material with a yield strain in excess of 200%.~~

~~5. —The expandable sheath of claim 0, wherein the sheath automatically returns to the unexpanded state after passage of the portion of the medical device.~~

6. — The expandable sheath of claim 0, comprising a plurality of first members and a plurality of second members, the plurality of first members being equal in number to the plurality of second members.

7. — The expandable sheath of claim 6, wherein the first and second members are arranged symmetrically in alternating sections about a longitudinal axis of the sheath.

8. — The expandable sheath of claim 6, wherein the plurality of first members and the plurality of second members are arranged non-symmetrically in alternating sections about a longitudinal axis of the sheath.

9. — The expandable sheath of claim 0, wherein a diameter of the outer surface at the proximal end of the sheath body is larger than a diameter of the outer surface at the distal end of the sheath body, when the sheath is in the unexpanded state.

10. — The expandable sheath of claim 0, wherein the third material comprises at least one of: steel, stainless steel, or nitinol.

11. — The expandable sheath of claim 0, further comprising a hub coupled to the proximal end of the sheath body, the hub having at least one hemostatic valve in communication with the lumen of the sheath body.

12. — The expandable sheath of claim 0, wherein the inner surface has an irregular geometry to minimize contact between the sheath body and the medical device.

13. — The expandable sheath of claim 0, wherein the inner surface comprises at least one rib extending between proximal and distal ends of the sheath body.

14. — The expandable sheath of claim 0, further comprising a tapered tip attached to the distal end of the expandable sheath body, the tapered tip comprising an outer surface that is continuous

with the outer surface of the sheath body, and which reduces in diameter as it approaches a distal end of the tapered tip.

15. — The expandable sheath of claim 14, wherein the tip comprises at least one of: ethylene-vinyl acetate (EVA), styrene-butadiene copolymer (SBC), synthetic rubber, an elastomer, an elastic material, a material with an elastic modulus of about 1.6ksi, and a material with a yield strain in excess of 200%.

16. — The expandable sheath of claim 15, wherein the tapered tip further comprises an inner surface that is continuous with the inner surface of the sheath body, and which reduces in diameter as it approaches a distal end of the tapered tip.

17. — The expandable sheath of claim 14, wherein the diameter of the inner surface at the distal end of the tapered tip is configured to seal against a second portion of the medical device, the second portion of the medical device having a transverse cross-sectional area smaller than a transverse cross-sectional area of the lumen when the sheath is in the unexpanded state.

18. — The expandable sheath of claim 14, wherein the tapered tip comprises at least one of: ethylene-vinyl acetate (EVA), styrene-butadiene copolymer (SBC), synthetic rubber, an elastomer, a material with an elastic modulus of about 1.6ksi, or a material with a yield strain in excess of 200%.

19. — The expandable sheath of claim 14, wherein the tapered tip comprises the second material.

20. — The expandable sheath of claim 0, wherein the second elastic modulus is substantially higher than the first elastic modulus.

21. — The expandable sheath of claim 04, wherein the outer surface of the tapered tip terminates in a rounded edge at the distal end of the tapered tip.

22. — An expandable medical sheath comprising:

a sheath body having an inner surface and an outer surface, the inner surface defining a lumen that extends along a longitudinal axis between a proximal end and a distal end of the sheath body, the sheath body being comprised of:

a plurality of first members and a plurality of second members, each first member and each second member extending between the proximal end and the distal end of the sheath body, each of the first members and the second members being alternately arranged around the lumen, each first member comprising a first material having a first elastic modulus, and each second member comprising a second material having a second elastic modulus that is higher than the first elastic modulus; and

a plurality of third members, each third member extending between the proximal end and the distal end of the sheath body without overlapping any other third member of the plurality of third members, and each third member being at least partially encapsulated within one of the plurality of second members and comprising a third material having a third elastic modulus that is higher than the second elastic modulus; and

wherein the sheath body is configured to be radially expandable from an unexpanded state to an expanded state to allow the passage of a portion of a medical device through the lumen, the portion of the medical device having a transverse cross sectional area larger than a transverse cross sectional area of the lumen when the sheath is in the unexpanded state.