

CLAIMS

We claim:

1. A sheath for delivering a medical device, wherein the sheath has a proximal end and a distal end and comprises:
 - a variable diameter inner liner comprising:
 - a sheet having a first edge and a second edge and is defined by an inner surface and an outer surface,
 - wherein the sheet is wound in a spiral configuration such that at least a portion of the inner surface of the sheet overlays at least a portion of the outer surface of the sheet,
 - wherein the first edge of the sheet is slidable along at least a portion of the inner surface of the sheet and the second edge is slidable along at least a portion of the outer surface of the sheet, and
 - wherein the inner surface of the sheet defines a lumen of the sheath having a longitudinal axis; and
 - an outer layer having an inner surface and an outer surface and extending about at least a portion of the variable diameter inner liner such that the inner surface of the outer layer is positioned adjacent to the outer surface of the inner liner,
 - wherein the outer layer comprises:
 - at least one layer of a first elastomeric polymer having a predetermined thickness and having an inner surface and outer surface,
 - and
 - wherein the variable diameter inner liner is configured to expand from a first rest diameter d_r to a second expanded diameter d_e by sliding the first edge of the sheet along at least a portion of the inner surface and sliding the second edge of the sheet along at least a portion of the outer surface, during application of a radial outward force by passage of a medical device through the lumen of the inner liner; and

a lubricant disposed along at least a portion of the outer surface of the inner liner.

2. The sheath of claim 1, wherein when the sheath is in an unexpanded rest state, the first and the second edges of the sheath are substantially aligned in a spaced relationship along a vertical axis passing through a thickness of the sheath.
3. The sheath of claim 1 or 2, wherein when the sheet is in an unexpanded rest state, the inner liner comprises at least two layers of the sheet overlaying each other at at least a portion of a circumference of the sheath.
4. The sheath of claim 1, wherein when the sheath is in an unexpanded rest state, the first edge of the sheet is substantially aligned with a vertical axis passing through a thickness of the sheath and the second edge circumferentially offset from the vertical axis.
5. The sheath of claim 4, wherein when the sheath is in an expanded state, at at least a portion of a circumference of the sheath, the inner liner comprises one layer of the sheet without any overlaying portion.
6. The sheath of any one of claims 1-5, wherein an amount of the lubricant is disposed between at least a portion of an overlying portion of the sheet and at least a portion of the sliding portions of the sheet, wherein the overlying portion of the sheet refers to the at least the portion of the inner surface of the sheet that overlays the at least a portion of the outer surface of the sheet.
7. The sheath of any one of claims 1-6 wherein the disposed lubricant has a predetermined pattern.
8. The sheath of any one of claims 1-7, wherein the polymer layer of the sheet comprises a compound material comprising a polyolefin and a lubricious filler.
9. The sheath of claim 8, wherein the lubricious filler is present in an amount from between 5 wt % to 20 wt % of a total weight of the compound material.

10. The sheath of any one of claims 1-9, further comprising at least one tie layer.
11. The sheath of claim 10, wherein the tie layer is disposed at the outer surface of the sheet such that when the sheet is in the spiral configuration, the tie layer is disposed between an overlapping portion of the sheet and at an outermost surface of the inner liner, wherein the overlying portion of the sheet refers to the at least the portion of the inner surface of the sheet that overlays the at least a portion of the outer surface of the sheet.
12. The sheath of any one of claims 10-11, wherein the tie layer is coextruded with the sheet.
13. The sheath of any one of claims 1-12 further comprising at least one lubricious liner.
14. The sheath of claim 13, wherein the at least one lubricious liner is disposed on the tie layer.
15. The sheath of any one of claims 1-14, wherein the outer layer comprises a polyether block amide, a styrene-based elastomer, polyurethane, latex, copolymers thereof, blends thereof or extrudates thereof.
16. The sheath of claim 15, wherein the outer layer comprises one or more layers.
17. The sheath of claim 16, wherein at least one layer comprises the styrene-based elastomer.
18. The sheath of claim 16 or 17, wherein at least one layer comprises polyurethane.
19. The sheath of claim 16, wherein at least one layer comprises a blend of the styrene-based elastomer and polyurethane.
20. The sheath of any one of claims 17-19, wherein the styrene-based elastomer has a Shore A durometer between 20A to 50A.

21. The sheath of any one of claims 1-16, wherein the outer layer further comprises a first polymer layer comprising a first compound composition comprising:

from greater than 0 wt% to less than 100 wt% of a polymer comprising a polyether block amide, a polyurethane, or a combination thereof based on a total weight of the first compound composition;

less than 65% of an inorganic filler based on a total weight of the first compound composition; and

up to 20 % of a solid lubricant filler based on a total weight of the first compound composition.

22. The sheath of claim 21, wherein the polymer in the first polymer layer composition has a Shore D from 20D to 35D.

23. The sheath of any one of claims 21-22, wherein the inorganic filler comprises bismuth oxychloride, barium sulfate, bismuth subcarbonate, calcium carbonate, aluminum trihydrate, barite, kaolin clay, limestone, or any combination thereof.

24. The sheath of any one of claims 21-23, wherein the inorganic filler is present in an amount of at least 10 % based on a total weight of the first compound composition.

25. The sheath of any one of claims 21-24, wherein the first compound composition further comprises at least one tackiness reducing compound.

26. The sheath of claim 25, wherein the at least one tackiness reducing compound is present in an amount from 1 % to 20 % based on a total weight of the first compound composition.

27. The sheath of any one of claims 21-26, wherein the outer layer comprises a second polymer layer comprising a second compound composition comprising from greater than 0 wt% to 100 wt% of a second polymer comprising polyether block amide, a polyurethane, or a composition thereof.

28. The sheath of claim 27, wherein the second polymer has a Shore D Durometer from 20D to 35D.
29. The sheath of any one of claims 27-28, wherein the second compound composition is free of an inorganic filler.
30. The sheath of any one of claims 27-29, wherein the second compound composition is free of a solid lubricant filler.
31. The sheath of any one of claims 27-30, wherein one or more additional polymer layers are disposed between the first polymer layer and the second polymer layer.
32. The sheath of any one of claims 1-31, further comprising a hydrophilic coating disposed at an outermost surface of the sheath.