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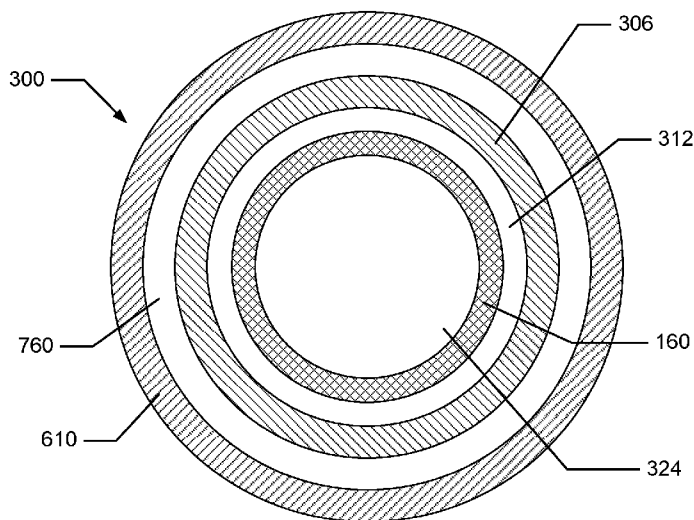


FIG. 20D

(57) Abstract: Disclosed herein are devices, designs, methods of manufacturing and using medical devices comprising expandable bodies for treating saccular vascular aneurysms and occluding segments of blood vessels and other biological conduits. Exemplary expandable bodies include hollow gold structures that can be folded, wrapped, and compressed, joined to a delivery device, advanced to location in the body of patient in need of treatment, expanded by injection of a fluid into the central void, and separated from the delivery device, remaining in place in an open, expanded form without the addition of support structures to the central void. Other expandable bodies include coiled wires that can be loaded into delivery catheters and expelled from the delivery catheters using pusher devices. Also disclosed herein, are methods of using multiple medical devices and expandable bodies where the expandable bodies are placed adjacent to each other to occlude a saccular aneurysm.



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## AMENDED CLAIMS

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What is claimed is:

1. A medical device comprising:

a metallic expandable body configured for permanent implantation in an artery or vein, the expandable body comprising:

a distal region, a proximal region generally opposite the distal region, an intermediate region transitioning from the distal region to the proximal region, a center axis extending proximal-distal between the proximal region and distal region;

a wall extending generally continuously through the intermediate region from the distal region to the proximal region to define an exterior surface of the expandable body and an interior surface of the expandable body, the interior surface defining a central void of the expandable body; and

a proximal neck, a distal neck, a proximal nosecone, a distal nosecone, and one or more elastomeric valves;

a triple lumen delivery catheter assembly comprising:

a longitudinally extending body further comprising a proximal end and a distal end generally opposite the proximal end, wherein the distal end of the delivery catheter is operably coupled to the proximal region of the expandable body;

a first hollow member shaft that defines a first lumen that is continuous from the proximal end to the distal end and is configured to accept a guide wire;

a second hollow member shaft that defines a second lumen to allow for passage of a fluid medium from the proximal end to

the distal end and into the central void of the expandable body; and

a third hollow member shaft that defines a third lumen to allow for passage of a fluid medium from the proximal end to the distal end and into the blood vessel lumen near the location of the expandable body; wherein the third hollow member shaft can be separated from the remainder of the delivery catheter, wherein the expanded expandable body can be separated from the delivery catheter by pulling the third hollow member shaft and the remainder of the delivery catheter assembly components apart;

wherein, the one or more elastomeric valves are configured to close a proximal neck or a distal neck when separated from the delivery catheter such that the pressure inside the central void of the expanded expandable body, after separation from the delivery catheter, is less than or equal to the pressure outside the expanded expandable body,

wherein the expandable body is configured to expand from a deliverable configuration to an expanded configuration, the expandable body is attached to the delivery catheter by a friction fit, without glue, adhesive, or a weld; and

wherein, when the expandable body is in the deliverable configuration, the wall assumes a pleated configuration comprising a plurality of pleats folded over in a clockwise direction relative to the center axis or a counter-clockwise direction relative to the center axis to form a folded-over region of the expandable body.

2. The medical device of claim 1, wherein the expanded expandable body possesses sufficient strength to maintain itself in the expanded configuration within a biological space after separation from the delivery catheter; and wherein no solid or semi-solid material or member, not derived

from the patient, is required in the interior volume of the expandable body to at least assist in causing the expandable body to assume or maintain the expanded configuration after separation of the expanded expandable body and the delivery catheter.

3. The medical device of claim 1 wherein:

the first hollow member shaft and the second hollow member shaft form a first catheter assembly with a first proximal hub, wherein the first catheter assembly is engaged to the metallic expandable body and the third hollow member shaft is a second catheter assembly with a second proximal hub;

wherein the first proximal hub and the second proximal hub are engaged in a deployment configuration; and

wherein the first proximal hub and the second proximal hub are disengaged in a detachment configuration wherein the first catheter assembly and the second catheter assembly are pulled apart, resulting in separation of the expandable body from the first catheter assembly.

4. The medical device of claim 1, wherein the first lumen is located centrally in the delivery catheter and is continuous from the proximal end to the distal end.

5. The medical device of claim 1, wherein the second lumen is defined by an annular gap between an inner wall of the second hollow member shaft and an outer wall of the first hollow member shaft and enables a fluid communication between the proximal hub of the delivery catheter and a central void or space of the expandable body.

6. The medical device of claim 1, wherein the third lumen is defined by an annular gap between an inner wall of the third hollow member shaft and an outer wall of the second hollow member shaft and enables a fluid

communication between a proximal hub of the delivery device and a blood vessel segment lumen near the location of the metallic expandable body.

7. The medical device of claim 1, wherein the first hollow member shaft comprises:
  - an outer layer comprising a polymer, such as polyimide;
  - a middle layer comprising a braided metal; wherein the middle layer is disposed between the outer layer and an inner layer; and,
  - the inner layer comprising a lubricious coating, a lubricious polymer such as PTFE, or a polyimide/PTFE composite.
8. The medical device of claim 1, wherein the second hollow member shaft comprises:
  - one layer comprising a polymer, such as polyimide; and
  - a second layer comprising a braided metal; wherein the middle layer is disposed between the outer layer and an inner layer;
9. The medical device of claim 1, wherein the third hollow member shaft comprises:
  - a lubricious outer surface coating;
  - an outer layer comprising a polymer, such as polyimide or Pebax,
  - a middle layer comprising a coiled metal wire, wherein the middle layer is disposed between the outer layer and an inner layer; and
  - an inner layer comprising a lubricious coating, a lubricious polymer such as PTFE, or a polyimide/PTFE composite.
10. The medical device of claim 9, wherein the wall of the third hollow member shaft comprises a material with a Shore durometer hardness equal to or greater than 55 Shore D.

11. The medical device of any one of claims 1-3, wherein the one or more elastomeric valves close when the expanded expandable body is separated from the delivery device.
12. The medical device of any one of claims 1-3, wherein an opening in one or both necks of the expandable body is sealed by the one or more elastomeric valves after separating the expandable body and the delivery catheter.
13. The medical device of any one of claims 1-3, wherein the one or more elastomeric valves close when the expanded expandable body is separated from the delivery device and wherein an opening in one or both necks of the expandable body is sealed by the one or more elastomeric valves after separating the expandable body and the delivery catheter
14. The medical device of any one of claims 1-3, wherein the one or more elastomeric valves comprise polymer discs.
15. The medical device of any one of claims 1-3, wherein the one or more elastomeric valves comprise liquid polymer material injected into a nose cone.
16. The medical device of any one of claims 1-3, wherein the one or more elastomeric valves comprise silicone rubber.
17. The medical device of claim 1, wherein the one or more elastomeric valves valve comprises a central orifice, such central orifice comprising a round puncture, a slit along a diameter, or orthogonal slits across two diameters.
18. (Cancelled)
19. The medical device of any one of claims 1-3, wherein, prior to separation of the expandable body and the delivery catheter, the first hollow member shaft or second hollow member shaft is inserted into an elastomeric distal valve that is bonded to the expandable body, wherein the elastomeric proximal valve seals against the first hollow member shaft or second hollow member shaft.

20. The medical device of any one of claims 1-3, wherein the one or more elastomeric valves are configured to seal only the proximal neck, only the distal neck, or both the proximal and distal necks.
21. The medical device of any one of claims 1-3, wherein the one or more elastomeric valves are integrated into a nosecone.
22. The medical device of any one of claims 1-3, wherein the distal end of the second hollow member shaft is inserted into the proximal neck of the expandable body, the proximal end of an elastomeric sleeve is attached to the second hollow member shaft, and the distal end of the elastomeric sleeve is stretched over the proximal neck of the expandable body forming a friction fit between the elastomeric sleeve and the proximal neck of the expandable body and a friction fit between the proximal neck of the expandable body and the distal end of the second hollow member shaft.
23. The medical device of claim 1-3, wherein the one or more elastomeric valves are integrated into a nosecone, wherein the first hollow member shaft, the second hollow member shaft, of the first and second hollow member shafts are inserted into at least one of the one or more elastomeric valves bonded to the expandable body or to a nose cone.
24. The medical device of any one of claims 1-3, wherein the distal end of the second hollow member shaft is inserted into the proximal neck of the expandable body, the distal end of an elastomeric sleeve is attached to the proximal neck of the expandable body or the proximal nosecone, and the distal end of the elastomeric sleeve is stretched over the proximal neck of the expandable body and the distal end of the second hollow member shaft forming a friction fit between the elastomeric sleeve and the proximal neck of the expandable body and a friction fit between the proximal neck of the expandable body and the distal end of the second hollow member shaft.
25. The medical device of any one of claims 1-3, wherein the distal end of the second hollow member shaft is inserted into the proximal neck of the



expandable body, the proximal end of an elastomeric sleeve is attached to the second hollow member shaft, and the distal end of the elastomeric sleeve is stretched over the proximal neck of the expandable body forming a friction fit between the elastomeric sleeve and the proximal neck of the expandable body and a friction fit between the proximal neck of the expandable body and the distal end of the second hollow member shaft, wherein the elastomeric sleeve comprises thermoplastic polyurethane.

26. The medical device of any one of claims 1-3, wherein the distal end of the second hollow member shaft is inserted into the proximal neck of the expandable body, the proximal end of an elastomeric sleeve is attached to the second hollow member shaft, and the distal end of the elastomeric sleeve is stretched over the proximal neck of the expandable body forming a friction fit between the elastomeric sleeve and the proximal neck of the expandable body and a friction fit between the proximal neck of the expandable body and the distal end of the second hollow member shaft, wherein the one or more elastomeric valves are configured to seal only the proximal neck, only the distal neck, or both the proximal and distal necks, wherein the elastomeric sleeve comprises thermoplastic polyurethane.
27. The medical device of any one of claims 1-3, wherein the distal end of the second hollow member shaft is inserted into the proximal neck of the expandable body, the proximal end of an elastomeric sleeve is attached to the second hollow member shaft, and the distal end of the elastomeric sleeve is stretched over the proximal neck of the expandable body forming a friction fit between the elastomeric sleeve and the proximal neck of the expandable body and a friction fit between the proximal neck of the expandable body and the distal end of the second hollow member shaft, wherein the one or more elastomeric valves are integrated into a nosecone and, wherein the elastomeric sleeve comprises thermoplastic polyurethane.
28. The medical device of any one of claims 1-3, wherein the distal end of the second hollow member shaft is inserted into the proximal neck of the

expandable body, the proximal end of an elastomeric sleeve is attached to the second hollow member shaft, and the distal end of the elastomeric sleeve is stretched over the proximal neck of the expandable body forming a friction fit between the elastomeric sleeve and the proximal neck of the expandable body and a friction fit between the proximal neck of the expandable body and the distal end of the second hollow member shaft, wherein the elastomeric sleeve comprises thermoplastic polyurethane.

29. The medical device of claim 1-3, wherein the distal end of the second hollow member shaft is inserted into the proximal neck of the expandable body, the proximal end of an elastomeric sleeve is attached to the second hollow member shaft, and the distal end of the elastomeric sleeve is stretched over the proximal neck of the expandable body forming a friction fit between the elastomeric sleeve and the proximal neck of the expandable body and a friction fit between the proximal neck of the expandable body and the distal end of the second hollow member shaft, wherein the first hollow member shaft, the second hollow member shaft, of the first and second hollow member shafts are inserted into at least one of the one or more elastomeric valves bonded to the expandable body or to a nose cone, wherein the elastomeric sleeve comprises thermoplastic polyurethane.
30. The medical device of any one of claims 1-3, wherein the distal end of the second hollow member shaft is inserted into the proximal neck of the expandable body, the proximal end of an elastomeric sleeve is attached to the second hollow member shaft, and the distal end of the elastomeric sleeve is stretched over the proximal neck of the expandable body forming a friction fit between the elastomeric sleeve and the proximal neck of the expandable body and a friction fit between the proximal neck of the expandable body and the distal end of the second hollow member shaft, wherein the distal end of the second hollow member shaft is inserted into the proximal neck of the expandable body, wherein the elastomeric sleeve comprises thermoplastic polyurethane.

31. The medical device of any one of claims 1-3, wherein the distal end of the second hollow member shaft is inserted into the proximal neck of the expandable body, the distal end of an elastomeric sleeve is attached to the proximal neck of the expandable body or the proximal nosecone, and the distal end of the elastomeric sleeve is stretched over the proximal neck of the expandable body and the distal end of the second hollow member shaft forming a friction fit between the elastomeric sleeve and the proximal neck of the expandable body and a friction fit between the proximal neck of the expandable body and the distal end of the second hollow member shaft wherein at least one of the one or more elastomeric valves forms a friction fit with a shaft.
32. The medical device of any one of claims 1-3, wherein the distal end of the second hollow member shaft is inserted into the proximal neck of the expandable body, the proximal end of an elastomeric sleeve is attached to the second hollow member shaft, and the distal end of the elastomeric sleeve is stretched over the proximal neck of the expandable body forming a friction fit between the elastomeric sleeve and the proximal neck of the expandable body and a friction fit between the proximal neck of the expandable body and the distal end of the second hollow member shaft, wherein the one or more elastomeric valves are integrated into a nosecone, wherein the elastomeric sleeve comprises thermoplastic polyurethane and, wherein at least one of the one or more elastomeric valves forms a friction fit with a shaft.
33. The medical device of any one of claims 1-3, wherein the distal end of the second hollow member shaft is inserted into the proximal neck of the expandable body, the proximal end of an elastomeric sleeve is attached to the second hollow member shaft, and the distal end of the elastomeric sleeve is stretched over the proximal neck of the expandable body forming a friction fit between the elastomeric sleeve and the proximal neck of the expandable body and a friction fit between the proximal neck of the expandable body and the distal end of the second hollow member shaft wherein the elastomeric

sleeve comprises thermoplastic polyurethane wherein at least one of the one or more elastomeric valves forms a friction fit with a shaft.

34. The medical device of claim 1-3, wherein the distal end of the second hollow member shaft is inserted into the proximal neck of the expandable body, the proximal end of an elastomeric sleeve is attached to the second hollow member shaft, and the distal end of the elastomeric sleeve is stretched over the proximal neck of the expandable body forming a friction fit between the elastomeric sleeve and the proximal neck of the expandable body and a friction fit between the proximal neck of the expandable body and the distal end of the second hollow member shaft, wherein the first hollow member shaft, the second hollow member shaft, of the first and second hollow member shafts are inserted into at least one of the one or more elastomeric valves bonded to the expandable body or to a nose cone, wherein the elastomeric sleeve comprises thermoplastic polyurethane, wherein at least one of the one or more elastomeric valves forms a friction fit with a shaft.
35. The medical device of any one of claims 1-3, wherein the distal end of the second hollow member shaft is inserted into the proximal neck of the expandable body, the distal end of an elastomeric sleeve is attached to the proximal neck of the expandable body or the proximal nosecone, and the distal end of the elastomeric sleeve is stretched over the proximal neck of the expandable body and the distal end of the second hollow member shaft forming a friction fit between the elastomeric sleeve and the proximal neck of the expandable body and a friction fit between the proximal neck of the expandable body and the distal end of the second hollow member shaft, wherein the elastomeric sleeve comprises thermoplastic polyurethane, wherein at least one of the one or more elastomeric valves forms a friction fit with a shaft.
36. The medical device of claim 1, wherein a telescoping segment is bonded to distal neck of the expandable body and extends into the central void of the expandable body; the distal end of the first hollow member shaft is engaged

with telescoping segment; and the telescoping segment and the distal end of the first hollow member shaft combine to form a two-part bridging segment through the central void of the expandable body.

37. The medical device of claim 36, wherein the telescoping segment is rigid.
38. The medical device of claim 37, wherein the telescoping segment comprises a metal.
39. (Cancelled)
40. (Cancelled)
41. The medical device of claim 3, wherein the engagement of the first and second proximal hubs prevents leaking during injection of the third lumen, and further wherein, when the first and second proximal hubs are disengaged, the second proximal hub comprises a valve to prevent leaking during injection of the third lumen when the first and second proximal hubs are disengaged.
42. The medical device of claim 3, wherein the engagement of the first and second proximal hubs prevents leaking during injection of the third lumen, and further wherein, when the first and second proximal hubs are disengaged, the second proximal hub does not comprise a valve to prevent leaking during injection of the third lumen when the first and second proximal hubs are disengaged.
43. The medical device of any one of claims 1- 3, wherein the expandable body has a wall thickness in a range from 3 to 50 microns.
44. The medical device of any one of claims 1-3, wherein the wall of the expandable body comprises at least one layer, with the at least one layer being a metal layer.
45. The medical device of claim 1-3, wherein the wall of the expandable body comprises at least one layer, with the at least one layer being a metal layer, wherein the metal layer comprises gold.

46. (Cancelled)
47. (Cancelled)
48. The medical device of claim 46, wherein at least a portion of the wall of the expandable body is formed by electroforming.
49. The medical device of claim 46, wherein at least a portion of the wall of the expandable body is annealed.
50. The medical device claims 1 - 3, wherein, the expandable body is has a single lobe.
51. (Cancelled)
52. (Cancelled)
53. The medical device of any one of claims 1- 3, wherein the expanded expandable body comprises an overall shape that is generally oblong.
54. The medical device of any one of claims 1- 3, wherein the expanded expandable body comprises an overall shape that is generally cylindrical with rounded ends.
55. The medical device of any one of claims 1- 3, wherein the external surface of the expandable body comprises surface structures that have a surface height of approximately 0.01  $\mu\text{m}$  to approximately 1  $\mu\text{m}$ .
56. The medical device of any one of claims 1- 3, wherein the expandable body is configured to be expanded from the deliverable configuration to the expanded configuration by applying a pressure of 3 atmospheres or less to the central void of the expandable body during the passage of a fluid medium from the proximal end of the delivery catheter to the central void of the expandable body.
57. The medical device claims 1 - 3, wherein the expandable body is has a single lobe wherein the expandable body has an expanded diameter ranging from about 2 mm to about 30 mm.

58. (Cancelled)
59. The medical device of any one of claims 1- 3, wherein the expanded expandable body comprises an overall shape that is generally oblong, wherein the expandable body has an expanded diameter ranging from about 2 mm to about 30 mm.
60. The medical device of any one of claims 1- 3, wherein the expanded expandable body comprises an overall shape that is generally cylindrical with rounded ends, wherein the expandable body has an expanded diameter ranging from about 2 mm to about 30 mm.
61. The medical device of any one of claims 1-3, wherein the expandable body has an expanded length of between about 5 mm to about 60 mm.
62. The medical device claims 1 - 3, wherein the expandable body has a single lobe wherein the expandable body has an expanded length of between about 5 mm to about 60 mm.
63. (Cancelled)
64. The medical device of any one of claims 1- 3, wherein the expanded expandable body comprises an overall shape that is generally oblong, wherein the expandable body has an expanded length of between about 5 mm to about 60 mm.
65. The medical device of any one of claims 1- 3, wherein the expanded expandable body comprises an overall shape that is generally cylindrical with rounded ends, wherein the expandable body has an expanded length of between about 5 mm to about 60 mm.
66. The medical device of any one of claims 1-3, wherein the outer diameter of the delivery catheter is 2 - 5 Fr.
67. The medical device of any one of claims 1-3, wherein the outer diameter of the expandable body in a deliverable configuration is 2 - 8 Fr.
- 68-264. (Cancelled)