sheathing, removal, visualization during aortography, deployment, positioning, repositioning, retrieval, stability, visibility in place, ease to deploy, and ease to sheath.

**[00205]** Pre-to-post procedure aortic gradient measurements averaged 86.4% reduction in all eleven (11) subjects confirming success of TAVR treatments.

**[00206]** All subjects underwent DW-MRI pre-and-post-procedure, and evaluation of images were consistent with identification of some ischemic lesions. MRI was performed at the Baseline and Pre-Discharge (Day 2-5) visits in the eleven (11) subjects that underwent a Transcatheter Aortic Valve Replacement (TAVR) procedure at each of the two clinical sites. The MRI protocol consisted of the following sequences: Axial DWI, Axial FLAIR and 3D T1-weighted IR-GRE. DWI contrast is sensitive to water molecules and helps locate and quantify fresh lesions. Total lesions were counted, lesion location, size and volume was assessed, and total lesion volume were analyzed. FIGS. 15A – 15J show the DW-MRI images of the brains for three (3) representative human subjects (001-05, 001-06 and 002-01).

**[00207]** A median lesion count of 6 and a median lesion volume of 193.9 $mm^3$ were observed among the eleven (11) subjects. A breakdown of lesions by location is detailed in Table 1. These results indicate a lower lesion count and volume when compared to both historical controls and clinical trials involving cleared and investigational embolic protection devices.

**[00208]** Table 1: Brain lesions by location for all patients (clinical sites 1 and 2) from the clinical study.

| **Vascular Territory** | **Lesion Count** |
|---|---|
| Anterior Choroidal Artery | 2 |
| Anterior Cerebral Artery | 3 |
| Middle Cerebral Artery | 40 |
| Posterior Cerebral Artery | 22 |
| Vertebrobasilar Artery | 1 |
| Anterior Inferior Cerebellar Artery | 0 |
| Posterior Inferior Cerebellar Artery | 12 |
| **Total Lesion Count (Entire Brain)** | **80** |

**[00209]** Table 2 provides a detailed comparison of lesion count and volume between the clinical study of this Example 2 and clinical studies for comparable devices. These results demonstrate that protection using the EPD-1 could reduce the number of ischemic lesions or their volume, thus supporting the utility of the procedure.



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[00210] Table 2: Comparison of EPD-1 performance to that of cleared and investigational devices.

| Study | Device | # of Subjects | Median Lesion Count | Median Lesion Volume ($mm^3$) | Time Range of Imaging |
|---|---|---|---|---|---|
| CLEAN-TAVI | None (control) | 45 | 16 | 800 | 2 D |
| **EXAMPLE 2** | **EPD-1** | **11*** | **6** | **193.9** | **<48 hours** |
| SENTINEL | Claret Medical Sentinel | 91 | 3 Protected areas only | 294 | 2 – 7D |
| PROTAVI-C | Edwards Lifesciences Embrella Embolic Deflector System (investigational) | 42 | 8 | 305 | 7D |
| DEFLECT-III | TriGuard™ HDH Embolic Deflection Device (investigational) | 46 | N/A | 46% > 150 | 2 – 6D |

[00211] The time point at which MRI was taken differs between these studies. Whereas DW-MRI was performed within 48 hours post-procedure for all patients in Example 2; for other referenced studies, imaging was performed at a longer time point. Because the appearance of hyper-intensity during DW-MRI imaging is known to evolve over time, these other referenced studies would have likely observed a higher lesion volume, had DW-MRI been taken within 48 hours post-procedure. Nonetheless, the EPD-1 outperformed the referenced, comparable devices with respect to acute cerebral embolic burden reduction. Three patients had elevated lesion counts; however, they were considered outliers as the filter was recaptured and the TAVR device post dilated. During these outlier procedures, the operators were concerned about interaction of the balloon catheter with the filter frame due to the small anatomy of the aorta. This typically results in liberation of debris.

[00212] The EPD-1 captured thrombi in all procedures. Two examples of captured thrombi are shown in the photographs of FIGS. 16A and 16B. The photograph of FIG. 16A shows a thrombi captured by the EPD-1 of Example 2. The photograph of FIG. 16B shows an actual pathologic finding of a 4.6 mm collagenous fragment captured within the EPD-1 filter during a TAVR procedure. Neurological evaluation of all patients using NIHSS at discharge and 30 days post-procedure showed that scores for all patients remained at baseline levels, except for one patient developing limb ataxia. No serious adverse events were

recorded. Debris captured by the embolic filter of the EPD-1 included collagen, fibrin, thrombi, and calcium.

**[00213]** A summary of endpoints is shown in Table 3.

**[00214]** Table 3: Summary of endpoints from the clinical studies of Example 2.

| **Endpoints** | **Result** | |
|---|---|---|
| | Success | Failure |
| Primary Endpoints | | |
| Device performance successful deployment and retrieval | 100% | 0% |
| Acute cerebral embolic burden reduction after TAVR | The EPD-1 device showed reduction in acute cerebral embolic burden when compared to both historical controls and other marketed and investigational devices. | |
| Secondary Endpoints | | |
| MACCE, 30-days post-procedure (No Events) | 100% | 0% |
| NIH stroke scale pre-and-post-procedure | 100% (Scores=0) | 0% |
| Gross histologic evaluation of embolic debris captured | 100% | 0% |

OTHER EMBODIMENTS

**[00215]** It is to be understood that while the invention has been described in conjunction with the detailed description thereof, the foregoing description is intended to illustrate and not limit the scope of the invention, which is defined by the scope of the appended claims. Other aspects, advantages, and modifications are within the scope of the following claims.

**[00216]** It is to be understood by one having ordinary skill in the art that the specific devices and processes illustrated in the attached drawings and described in this specification are simply example embodiments of the inventive concepts defined in the appended claims. Hence, specific dimensions and other physical characteristics relating to the embodiments disclosed herein are not to be considered as limiting, unless the claims expressly state otherwise. It is also to be understood that construction of the described invention and other components is not limited to any specific material. Other example embodiments of the invention disclosed herein may be formed from a wide variety of materials, unless described otherwise herein.

**[00217]** Changes and modifications in the specifically-described embodiments may be carried out without departing from the principles of the present invention, which is intended to be limited only by the scope of the appended claims as interpreted according to the principles of patent law including the doctrine of equivalents.

What is claimed is:

1. An embolic protection device comprising:

a catheter having a proximal end, a distal end, and a lumen extending from the proximal end to the distal end along a longitudinal axis of the catheter, wherein the lumen is configured to house a guidewire, and a distal portion of the catheter that assumes a generally arcuate shape being at least a semi-circle when the guidewire is at least partially longitudinally retracted;

a self-expanding embolic filter that is disposed around the catheter, proximal to the distal portion, wherein the embolic filter comprises a frame and the frame defines an opening of the embolic filter;

a deployment mechanism that is disposed around at least a portion of the catheter, wherein the deployment mechanism is longitudinally movable with respect to the catheter, the deployment mechanism is configured to contain the embolic filter in a collapsed configuration, and the embolic filter is configured to self-expand upon longitudinal retraction of the deployment mechanism; and

a wire coupled to the frame of the embolic filter, wherein the wire is longitudinally movable, and when longitudinally retracted, is configured to bend the frame longitudinally toward the proximal end of the catheter and laterally outward from the catheter, such that the opening of the embolic filter generally faces the distal end of the catheter.

2. The embolic protection device of claim 1, wherein the wire is coupled to the frame at a distal coupling.

3. The embolic protection device of either of claims 1 or 2, wherein the wire, when longitudinally retracted to a proximal position, is configured to bend the frame so that the opening of the embolic filter defined by the frame is substantially perpendicular to the longitudinal axis of the catheter.

4. The embolic protection device of any one of claims 1-3, wherein the wire, when longitudinally advanced to a distal position, is configured to position the frame so that the opening of the embolic filter defined by the frame is substantially parallel or angled less than 45 degrees with respect to longitudinal axis of the catheter.

5. The embolic protection device of any one of claims 1-4, wherein embolic protection device has a handle, wherein the handle comprises a mechanism configured to advance or retract the wire.

6. The embolic protection device of any one of claims 1-5, wherein embolic protection device has a handle, wherein the handle comprises a mechanism configured to advance or retract the deployment mechanism.

7. The embolic protection device of any one of claims 1-6, wherein the opening of the embolic filter defined by the frame is substantially in the shape of an ellipse.

8. The embolic protection device of any one of claims 1-7, wherein the catheter extends through the opening of the embolic filter.

9. The embolic protection device of any one of claims 1-8, wherein the distal portion of the catheter comprises a radiopaque marker.

10. The embolic protection device of claim 9, wherein the radiopaque marker comprises one or more circumferential bands.

11. The embolic protection device of any one of claims 1-10, wherein the frame comprises a shape memory material.

12. The embolic protection device of any one of claims 1-11, wherein the embolic filter comprises a filter medium, which comprises a semi-permeable polyurethane material having a pore size of from about 100 microns to about 150 microns.

13. The embolic protection device of any one of claims 1-12, wherein the embolic protection device comprises a longitudinal groove along an outer surface of the embolic protection device.

14. The embolic protection device of any one of claims 1-13, further comprising a self-expanding deflector coupled to the catheter, proximal to the distal portion, wherein the deflector has a longitudinal axis parallel to the longitudinal axis of the catheter.

15. The embolic protection device of any one of claims 1-14, wherein the deployment mechanism comprises a sheath that is circumferentially disposed around at least a portion of the catheter, wherein the sheath deploys the self-expanding embolic filter when the sheath is at least partially longitudinally retracted.

16. The embolic protection device of any one of claims 1-15, wherein the distal portion of the catheter comprises one or more apertures that communicates with the lumen of the catheter.

17. A method of capturing embolic debris during a closed-heart procedure, the method comprising:

inserting a distal end of a embolic protection device into a body lumen, the embolic protection device comprising:

a catheter having a proximal end, a distal end, and a lumen extending from the proximal end to the distal end along a longitudinal axis of the catheter, wherein the lumen is configured to house a guidewire, and a distal portion of the catheter that assumes a generally arcuate shape being at least a semi-circle when the guidewire is at least partially longitudinally retracted;

a self-expanding embolic filter that is disposed around the catheter, proximal to the distal portion, wherein the embolic filter comprises a frame, and the frame defines an opening of the embolic filter;

a deployment mechanism that is disposed around at least a portion of the catheter, wherein the deployment mechanism is longitudinally movable with respect to the catheter, the deployment mechanism is configured to contain the embolic filter in a collapsed configuration, and the embolic filter is configured to self-expand upon longitudinal retraction of the deployment mechanism; and

a wire coupled to the frame of the embolic filter, wherein the wire is longitudinally movable, and when longitudinally retracted, bends the frame longitudinally toward the proximal end of the catheter and laterally outward from the catheter, such that the opening of the embolic filter generally faces the distal end of the catheter; and

tracking the lumen of the catheter over the guidewire that is percutaneously inserted into the body lumen.

18. The method of claim 17, further comprising at least partially longitudinally retracting the guidewire from the lumen of the catheter so that the distal portion of the catheter assumes a generally arcuate shape being at least a semi-circle.

19. The method of either of claims 17 or 18, wherein the distal portion of the catheter comprises a radiopaque marker; the method further comprising positioning the catheter by visualizing the radiopaque marker using an imaging technique.

20. The method of any one of claims 17-19, further comprising at least partially longitudinally retracting the deployment mechanism and allowing the self-expanding embolic filter to assume an expanded, deployed configuration.

21. The method of any one of claims 17-20, further comprising longitudinally retracting the wire, thereby bending the frame longitudinally toward the proximal end of the catheter and laterally outward from the catheter, wherein the opening defined by the frame substantially spans the body lumen.

22. The method of any one of claims 17-20, further comprising longitudinally retracting the wire to a proximal position, thereby bending the frame so that the opening of the embolic filter defined by the frame is substantially perpendicular to the longitudinal axis of the catheter, wherein the opening defined by the frame substantially spans the body lumen.

23. The method of any one of claims 17-22, wherein the embolic filter is movably coupled to the catheter and is longitudinally moveable with respect to the catheter; the method further comprising longitudinally moving the embolic filter with respect to the catheter.

24. The method of any one of claims 17-23, wherein the embolic protection device further comprises a self-expanding deflector coupled to the catheter, proximal to the distal portion; the method further comprising deploying the self-expanding deflector to direct embolic debris toward the embolic filter.

25. The method of any one of claims 17-24, wherein the deployment mechanism is a sheath that is circumferentially disposed around at least a portion of the catheter.

26. The method of any one of claims 17-25, wherein the distal portion of the catheter comprises one or more apertures that communicate with the lumen of the catheter; the method further comprising perfusing a fluid into the body lumen through the one or more apertures.

27. The method of any one of claims 17-26, wherein the embolic protection device comprises a longitudinal groove along an outer surface of the embolic protection device; the method further comprising inserting a second catheter device alongside the embolic protection device by tracking the second catheter device along the groove.

28. The method of claim 27, wherein the second catheter device is advanced past the embolic filter of the embolic protection device while the embolic filter is in a deployed configuration.

29. A method of capturing embolic debris during a closed-heart procedure, the method comprising:

inserting a distal end of a embolic protection device into a body lumen, the embolic protection device comprising:

a catheter having a proximal end, a distal end, and a lumen extending from the proximal end of the catheter to the distal end of the catheter, wherein the lumen is configured to house a guidewire, and a distal portion of the catheter assumes a generally arcuate shape being at least a semi-circle when the guidewire is at least partially longitudinally retracted;

a self-expanding embolic filter that is disposed around the catheter, proximal to the distal portion, wherein the embolic filter comprises a frame, and the frame defines an opening of the embolic filter;

a deployment mechanism that is disposed around at least a portion of the catheter, wherein the deployment mechanism is longitudinally movable with respect to the catheter, the deployment mechanism is configured to contain the embolic filter in a collapsed configuration, and the embolic filter is configured to self-expand upon longitudinal retraction of the deployment mechanism;

a wire coupled to the frame of the embolic filter, wherein the wire is longitudinally movable, and when longitudinally retracted, bends the frame longitudinally toward the proximal end of the catheter and laterally outward from the catheter, such that the opening of the embolic filter generally faces the distal end of the catheter; and

tracking the lumen of the catheter over the guidewire that is percutaneously inserted into the body lumen;

at least partially longitudinally retracting the guidewire from the lumen of the catheter, so that the distal portion of the catheter assumes a generally arcuate shape being at least a semi-circle upon retracting the guidewire from the distal portion of the catheter;

longitudinally retracting the deployment mechanism and deploying the self-expanding embolic filter; and

longitudinally retracting the wire and bending the frame of the embolic filter longitudinally toward the proximal end of the catheter and laterally outward from the catheter.

30. A method for capturing embolic debris during a closed-heart procedure comprising:

(i) providing an embolic protection device, wherein the embolic protection device comprises:

a catheter having a proximal end, a distal end, and a lumen extending from the proximal end of the catheter to the distal end of the catheter, wherein the lumen is configured to house a guidewire, and a distal portion of the catheter that assumes a generally arcuate shape being at least a semi-circle when the guidewire is at least partially longitudinally retracted;

a self-expanding embolic filter that is disposed around the catheter, proximal to the distal portion, wherein the embolic filter comprises a frame and the frame defines an opening of the embolic filter;

a deployment mechanism that is disposed around at least a portion of the catheter, wherein the deployment mechanism is longitudinally movable with respect to the catheter, the deployment mechanism is configured to contain the embolic filter in a collapsed configuration, and the embolic filter is configured to self-expand upon longitudinal retraction of the deployment mechanism; and

a wire coupled to the frame of the embolic filter, wherein the wire is longitudinally movable, and when longitudinally retracted, is configured to bend the frame longitudinally toward the proximal end of the catheter and laterally outward from the catheter, such that the opening of the embolic filter generally faces the distal end of the catheter; and

(ii) inserting a distal end of the embolic protection device into a body lumen by tracking the lumen of the catheter over a guidewire that is percutaneously inserted into the body lumen; and

(iii) longitudinally retracting the deployment mechanism and deploying the a self-expanding embolic filter.

31. An embolic protection device comprising:

a catheter having a proximal end, a distal end, and a lumen extending from the proximal end to the distal end along a longitudinal axis of the catheter, wherein the lumen is configured to house a guidewire, and a distal portion of the catheter that assumes a generally arcuate shape being at least a semi-circle when the guidewire is at least partially longitudinally retracted;

a self-expanding embolic filter that is disposed around the catheter, proximal to the distal portion, wherein the embolic filter comprises a frame and the frame defines an opening of the embolic filter;

a deployment mechanism that is disposed around at least a portion of the catheter, wherein the deployment mechanism is longitudinally movable with respect to the catheter, the deployment mechanism is configured to contain the embolic filter in a collapsed configuration, and the embolic filter is configured to self-expand upon longitudinal retraction of the deployment mechanism;

a wire coupled to the frame of the embolic filter, wherein the wire is longitudinally movable with respect to the catheter;

when the wire is longitudinally advanced, in a distal direction, to a first position, the wire is configured to bend the frame longitudinally towards the distal end of the catheter and laterally outward from the catheter, such that the opening of the embolic filter generally faces the distal end of the catheter and expands to a first diameter; and

when the wire is longitudinally advanced, in a distal direction, to a second position distally farther than the first position, the wire is configured to extend the frame radially outward from the catheter, such that the opening of the embolic filter expands to a second diameter larger than the first diameter.

32. The embolic protection device of claim 31, wherein the wire, when longitudinally advanced to the first position, is configured to bend the frame so that the opening of the embolic filter defined by the frame is substantially perpendicular to the longitudinal axis of the catheter.

33. The embolic protection device of any one of claims 31 or 32, wherein the wire, when longitudinally retracted to a proximal position, is configured to position the frame so that the

opening of the embolic filter defined by the frame is substantially parallel or angled less than 45 degrees with respect to the longitudinal axis of the catheter.

34. The embolic protection device of claim 31, wherein the frame includes two sides; and

each side of the frame extending generally in a first lateral direction away from the catheter and then looping back on an opposite side around the catheter, and extend generally in the opposite lateral direction before converging and meeting to form the opening of the embolic filter having a substantially elliptical, ovular or circular shape.

35. The embolic protection device of claim 31, wherein the frame includes

a fixed portion coupled to the catheter, proximal to the distal portion, wherein the fixed portion does not move in a longitudinal direction; and

a movable portion continuous with the fixed portion of the frame, wherein the movable portion is coupled to the wire and is urged by the wire;

when the wire is advanced to the first position, the wire urges the movable portion of the frame, in a longitudinal direction, towards the distal end of the catheter and bends the frame to expand the opening of the embolic filter to the first diameter; and

when the wire is advanced to the second position, the wire urges the movable portion of the frame, in a radial direction, away from the catheter and extends the frame to expand the opening of the embolic filter to the second diameter.

36. The embolic protection device of claim 35, further comprising an outer catheter disposed around at least a portion of the catheter and coaxial with the lumen of the catheter, wherein the outer catheter is longitudinally slidable over the catheter; and

wherein the wire is coupled to a distal portion of the outer catheter such that the wire is moved by the outer catheter sliding over the catheter.

37. The embolic protection device of claim 36, further comprising an inner catheter disposed between the outer catheter and the catheter, wherein the inner catheter is longitudinally slidable over the catheter; and

a guide attached at one end to a distal portion of the inner catheter so that the guide is moved by the inner catheter sliding over the catheter, wherein the guide slidably receives the movable portion of the frame causing the guide to flex outwardly away from the catheter.

38. The embolic protection device of claim 37, wherein the guide is a top guide and the embolic protection device further comprising a bottom guide attached at one end to the catheter, wherein the bottom guide and the top guide are arranged on opposite sides of the catheter, and wherein the bottom guide receives the fixed portion of the frame causing the bottom guide to flex outwardly away from the catheter.

39. The embolic protection device of any one of claims 31-35, wherein embolic protection device has a handle, wherein the handle comprises a mechanism configured to advance or retract the wire.

40. The embolic protection device of claim 37, further comprising:

a handle coupled to the proximal end of the catheter;

a top pull coupled to a proximal portion of the outer catheter and is longitudinally movable within the handle;

a bottom pull coupled to a proximal portion of the inner catheter and is longitudinally movable within the handle, wherein the bottom pull is in temporary engagement with the top pull;

when the top pull and the bottom pull are engaged, the top pull and the bottom pull are moved in unison by movement of a slider, which, in turn, urges the guide together with the movable portion of the frame in the longitudinal direction and expands the opening of the embolic filter to the first diameter; and

when the top pull and the bottom pull are disengaged, the top pull is moved without the bottom pull by movement of the slider, which, in turn, urges the movable portion of the frame in the radial direction and expands the opening of the embolic filter to the second diameter.

41. The embolic protection device of any one of claims 31-40, wherein the catheter extends through the opening of the embolic filter.

42. The embolic protection device of any one of claims 31-41, wherein the distal portion of the catheter comprises a radiopaque marker.

43. The embolic protection device of claim 42, wherein the radiopaque marker comprises one or more circumferential bands.

44. The embolic protection device of any one of claims 31-43, wherein the frame comprises a shape memory material.

45. The embolic protection device of any one of claims 31-44, wherein the embolic filter comprises a filter medium, which comprises a semi-permeable polyurethane material having a pore size of from about 100 microns to about 150 microns.

46. The embolic protection device of any one of claims 21-45, wherein the embolic protection device comprises a longitudinal groove along an outer surface of the embolic protection device.

47. The embolic protection device of any one of claims 31-46, wherein the deployment mechanism comprises a sheath that is circumferentially disposed around at least a portion of the catheter, wherein the sheath deploys the self-expanding embolic filter when the sheath is at least partially longitudinally retracted.

48. The embolic protection device of any one of claims 31-47, wherein the distal portion of the catheter comprises one or more apertures that communicates with the lumen of the catheter.

49. A method of capturing embolic debris during a closed-heart procedure, the method comprising:

inserting a distal end of a embolic protection device into a body lumen, the embolic protection device comprising:

a catheter having a proximal end, a distal end, and a lumen extending from the proximal end to the distal end along a longitudinal axis of the catheter, wherein the lumen is configured to house a guidewire, and a distal portion of the catheter that assumes a generally arcuate shape being at least a semi-circle when the guidewire is at least partially longitudinally retracted;

a self-expanding embolic filter that is disposed around the catheter, proximal to the distal portion, wherein the embolic filter comprises a frame and the frame defines an opening of the embolic filter;

a deployment mechanism that is disposed around at least a portion of the catheter, wherein the deployment mechanism is longitudinally movable with respect to the catheter, the deployment mechanism is configured to contain the embolic filter in a collapsed

configuration, and the embolic filter is configured to self-expand upon longitudinal retraction of the deployment mechanism;

a wire coupled to the frame of the embolic filter, wherein the wire is longitudinally movable with respect to the catheter;

when the wire is longitudinally advanced, in a distal direction, to a first position, the wire is configured to bend the frame longitudinally towards the distal end of the catheter and laterally outward from the catheter, such that the opening of the embolic filter generally faces the distal end of the catheter and expands to a first diameter; and

when the wire is longitudinally advanced, in the distal direction, to a second position distally farther than the first position, the wire is configured to extend the frame radially outward from the catheter, such that the opening of the embolic filter expands to a second diameter larger than the first diameter; and

tracking the lumen of the catheter over the guidewire that is percutaneously inserted into the body lumen.

50. The method of claim 49, further comprising at least partially longitudinally retracting the guidewire from the lumen of the catheter so that the distal portion of the catheter assumes a generally arcuate shape being at least a semi-circle.

51. The method of either of claims 49 or 50, wherein the distal portion of the catheter comprises a radiopaque marker; the method further comprising positioning the catheter by visualizing the radiopaque marker using an imaging technique.

52. The method of any one of claims 49-51, further comprising at least partially longitudinally retracting the deployment mechanism and allowing the self-expanding embolic filter to assume an expanded, deployed configuration.

53. The method of claim 49-52, further comprising longitudinally advancing the wire to the first position, thereby bending the frame longitudinally towards the distal end of the catheter and laterally outward from the catheter, and expanding the opening of the embolic filter to the first diameter, which substantially spans the body lumen.

54. The method of claim 53, further comprising longitudinally advancing the wire to the second position distally farther than the first position, thereby extending the frame radially

outward from the catheter and expanding the opening of the embolic filter to the second diameter larger than the first diameter, which substantially spans the body lumen.

55. The method of any one of claims 49-52, further comprising longitudinally advancing the wire to the first position, thereby bending the frame so that the opening of the embolic filter defined by the frame is substantially perpendicular to the longitudinal axis of the catheter, wherein the opening defined by the frame, substantially spans the body lumen.

56. The method of any one of claims 49-55, wherein the deployment mechanism is a sheath that is circumferentially disposed around at least a portion of the catheter.

57. The method of any one of claims 49-56, wherein the distal portion of the catheter comprises one or more apertures that communicate with the lumen of the catheter; the method further comprising perfusing a fluid into the body lumen through the one or more apertures.

58. The method of any one of claims 49-57, wherein the embolic protection device comprises a longitudinal groove along an outer surface of the embolic protection device; the method further comprising inserting a second catheter device alongside the embolic protection device by tracking the second catheter device along the groove.

59. The method of claim 58, wherein the second catheter device is advanced past the embolic filter of the embolic protection device while the embolic filter is in a deployed configuration.

60. A method of capturing embolic debris during a closed-heart procedure, the method comprising:

inserting a distal end of a embolic protection device into a body lumen, the embolic protection device comprising:

a catheter having a proximal end, a distal end, and a lumen extending from the proximal end of the catheter to the distal end of the catheter, wherein the lumen is configured to house a guidewire, and a distal portion of the catheter that assumes a generally arcuate shape being at least a semi-circle when the guidewire is at least partially longitudinally retracted;

a self-expanding embolic filter that is disposed around the catheter, proximal to the distal portion, wherein the embolic filter comprises a frame and the frame defines an opening of the embolic filter;

a deployment mechanism that is disposed around at least a portion of the catheter, wherein the deployment mechanism is longitudinally movable with respect to the catheter, the deployment mechanism is configured to contain the embolic filter in a collapsed configuration, and the embolic filter is configured to self-expand upon longitudinal retraction of the deployment mechanism; and

a wire coupled to the frame of the embolic filter, wherein the wire is longitudinally movable with respect to the catheter;

tracking the lumen of the catheter over the guidewire that is percutaneously inserted into the body lumen;

at least partially longitudinally retracting the guidewire from the lumen of the catheter, so that the distal portion of the catheter assumes a generally arcuate shape being at least a semi-circle upon retracting the guidewire from the distal portion of the catheter;

longitudinally retracting the deployment mechanism and deploying the self-expanding embolic filter;

longitudinally advancing the wire, in a distal direction, to a first position, thereby bending the frame longitudinally towards the distal end of the catheter and laterally outward from the catheter, and expanding the opening of the embolic filter to a first diameter.

61. The method of claim 60, further comprising longitudinally advancing the wire, in the distal direction, to a second position distally farther than the first position, thereby extending the frame radially outward from the catheter and expanding the opening of the embolic filter to a second diameter larger than the first diameter.

62. A method for capturing embolic debris during a closed-heart procedure comprising:

(i) providing an embolic protection device, wherein the embolic protection device comprises:

a catheter having a proximal end, a distal end, and a lumen extending from the proximal end of the catheter to the distal end of the catheter, wherein the lumen is configured to house a guidewire, and a distal portion of the catheter that assumes a generally arcuate shape being at least a semi-circle when the guidewire is at least partially longitudinally retracted;

a self-expanding embolic filter that is disposed around the catheter, proximal to the distal portion, wherein the embolic filter comprises a frame and the frame defines an opening of the embolic filter;

a deployment mechanism that is disposed around at least a portion of the catheter, wherein the deployment mechanism is longitudinally movable with respect to the catheter, the deployment mechanism is configured to contain the embolic filter in a collapsed configuration, and the embolic filter is configured to self-expand upon longitudinal retraction of the deployment mechanism; and

a wire coupled to the frame of the embolic filter, wherein the wire is longitudinally movable with respect to the catheter; and

(ii) inserting a distal end of the embolic protection device into a body lumen by tracking the lumen of the catheter over a guidewire that is percutaneously inserted into the body lumen;

(iii) longitudinally retracting the deployment mechanism and deploying the a self-expanding embolic filter; and

(iv) longitudinally advancing the wire, in a distal direction, to a first position, thereby bending the frame longitudinally towards the distal end of the catheter and laterally outward from the catheter, and expanding the opening of the embolic filter to a first diameter.

63. The method of claim 62, further comprising longitudinally advancing the wire, in the distal direction, to a second position distally farther than the first position, thereby extending the frame radially outward from the catheter and expanding the opening of the embolic filter to a second diameter larger than the first diameter.

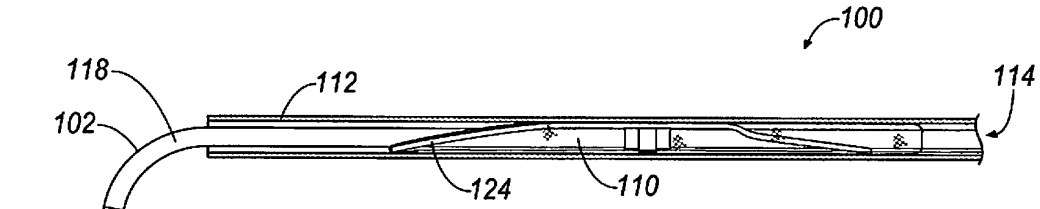

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FIG. 1A

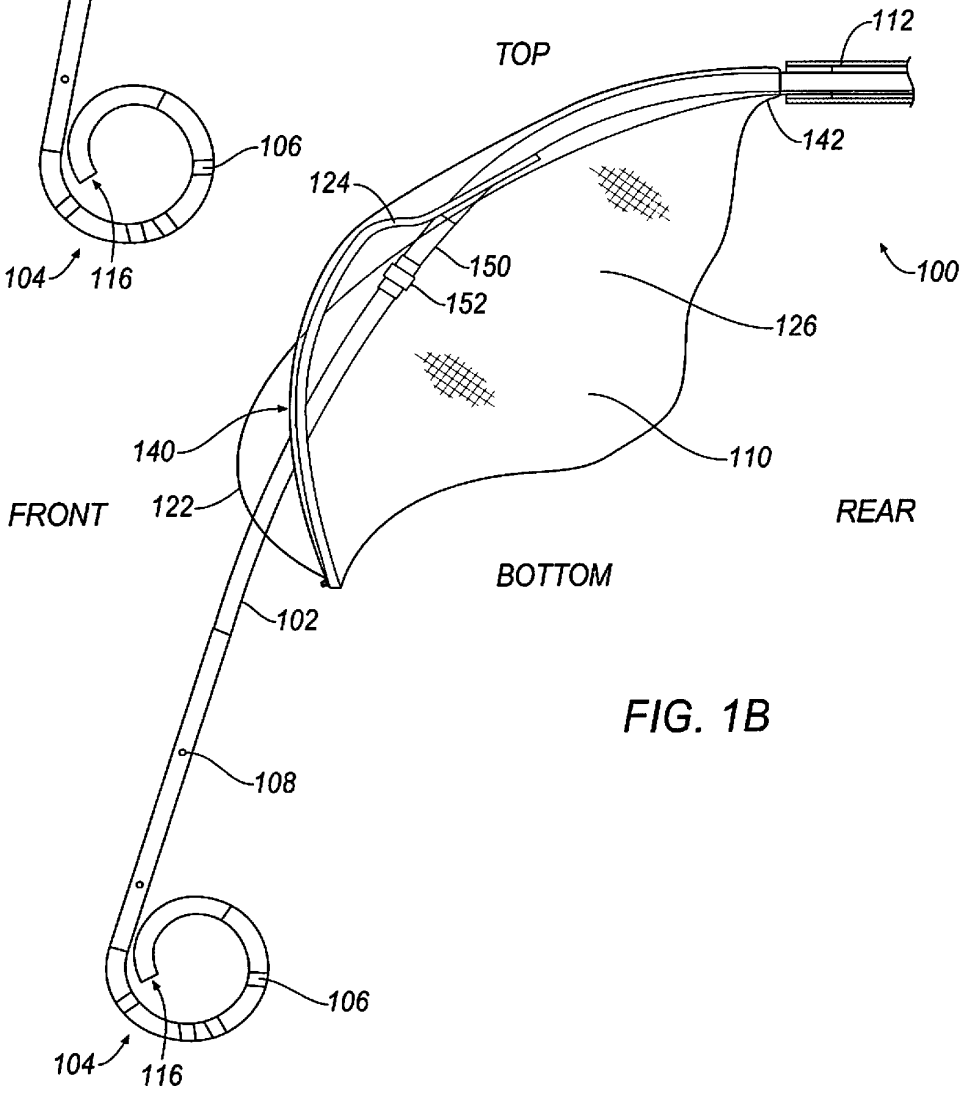

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108
106
104
116

FIG. 1B

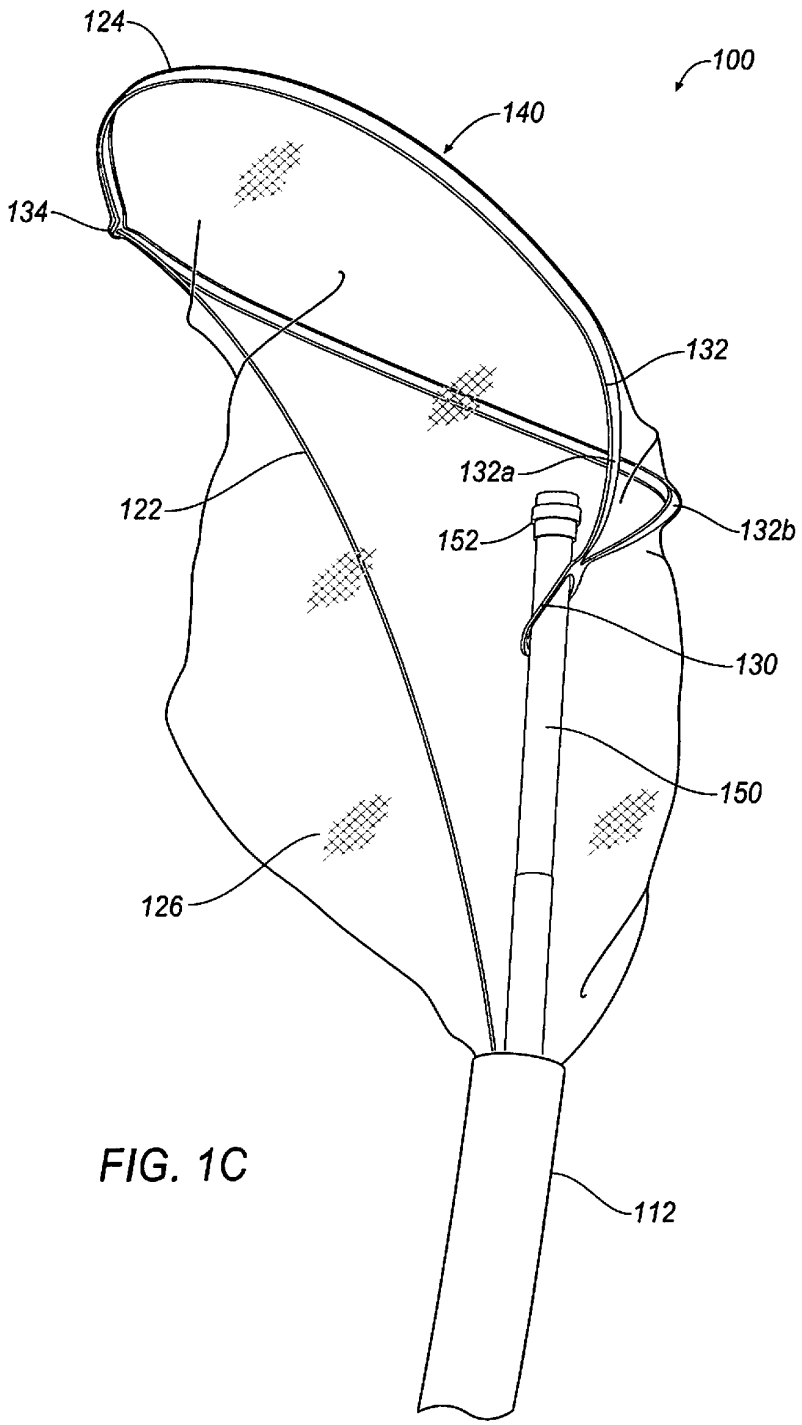



FIG. 1C

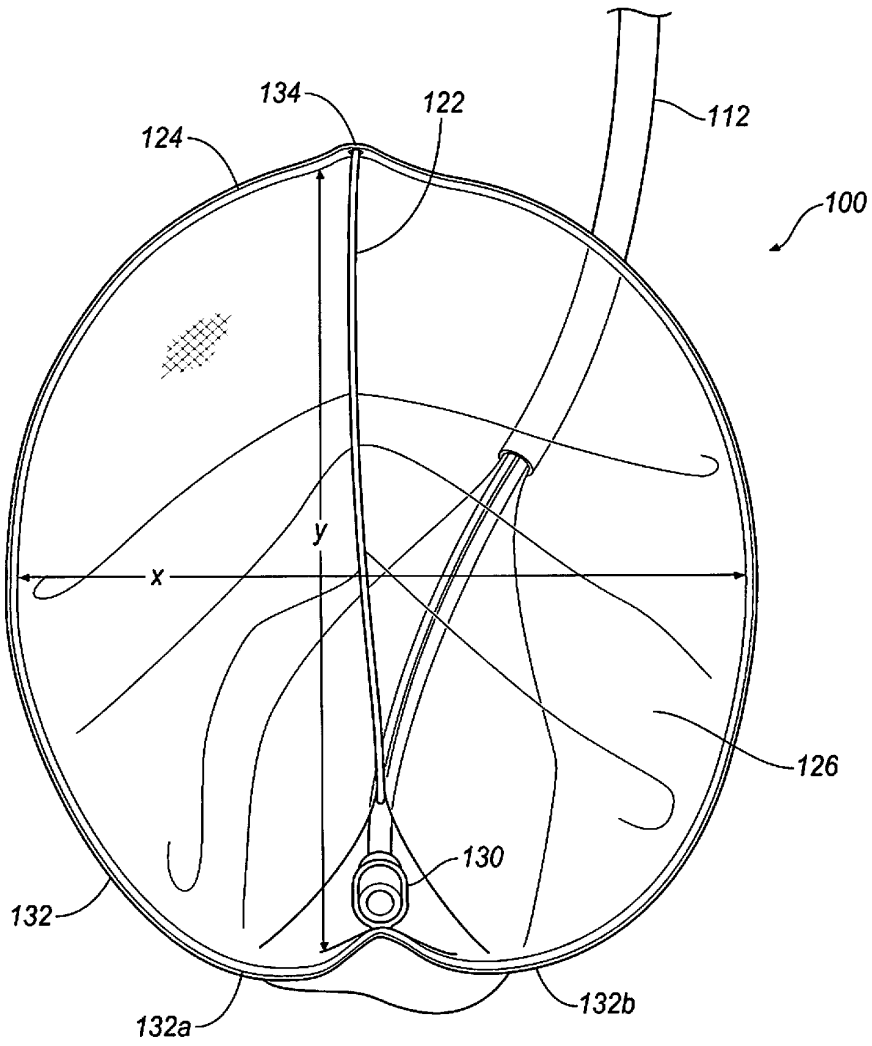



FIG. 1D

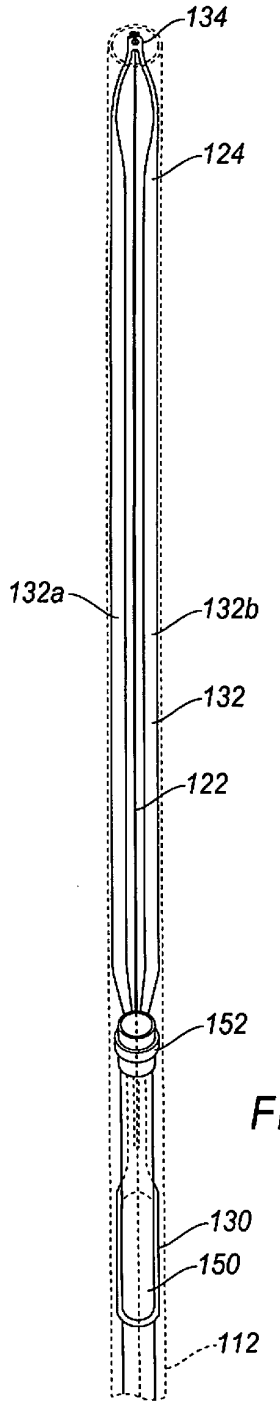

134
124
132a
132b
132
122
152
130
150
112

FIG. 1E

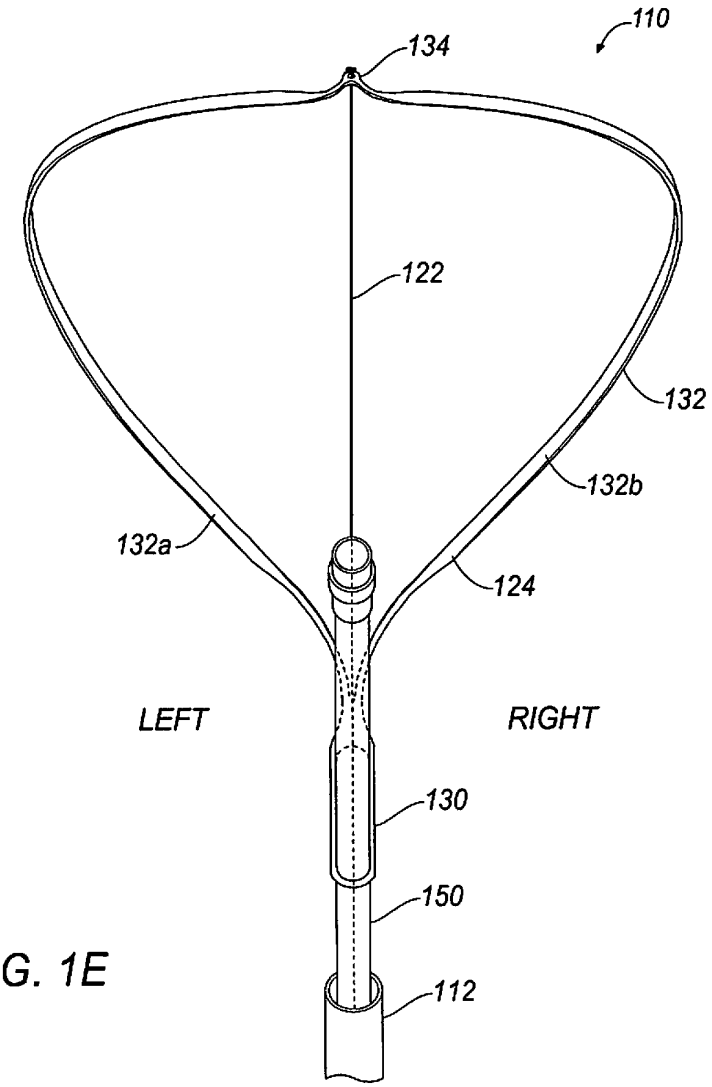

110
134
122
132
132b
132a
124
LEFT
RIGHT
130
150
112

FIG. 1F

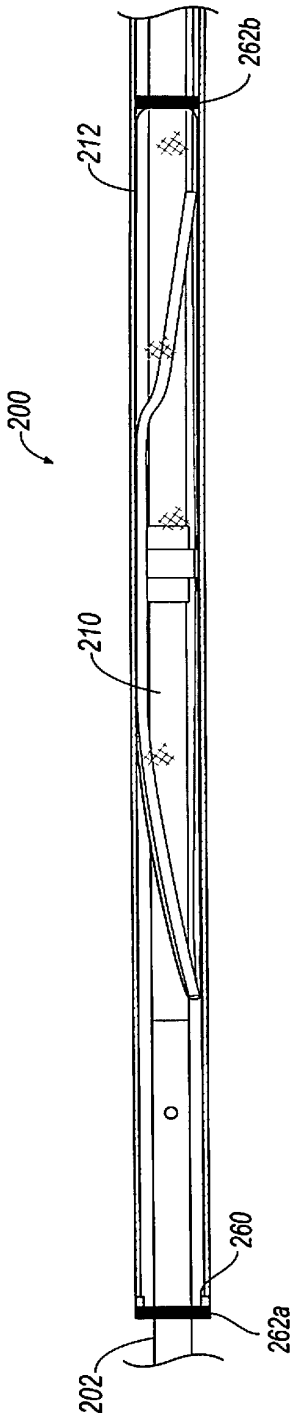

200
212
262b
210
260
262a
202

FIG. 2A

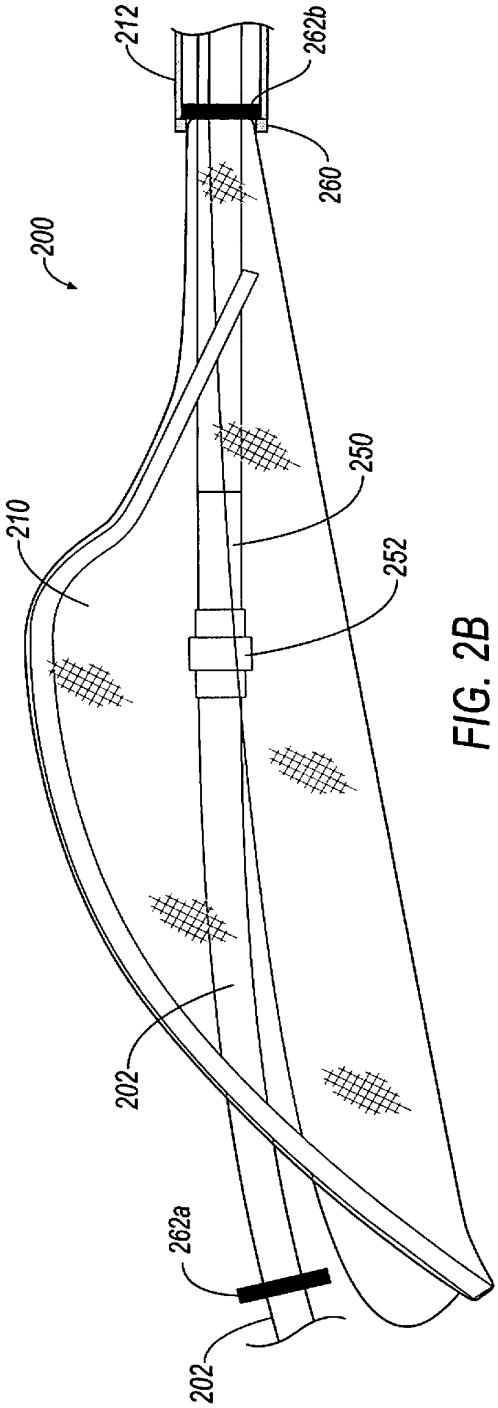

212
262b
260
200
250
210
252
202
262a
202

FIG. 2B

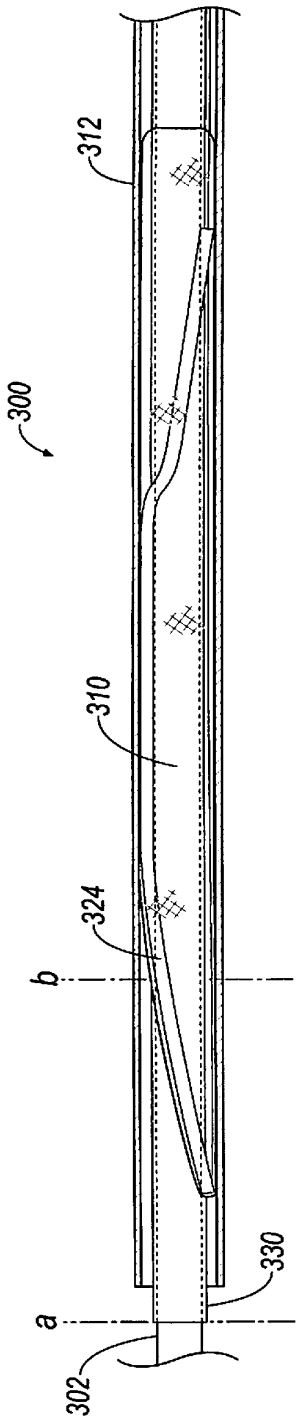



FIG. 3A

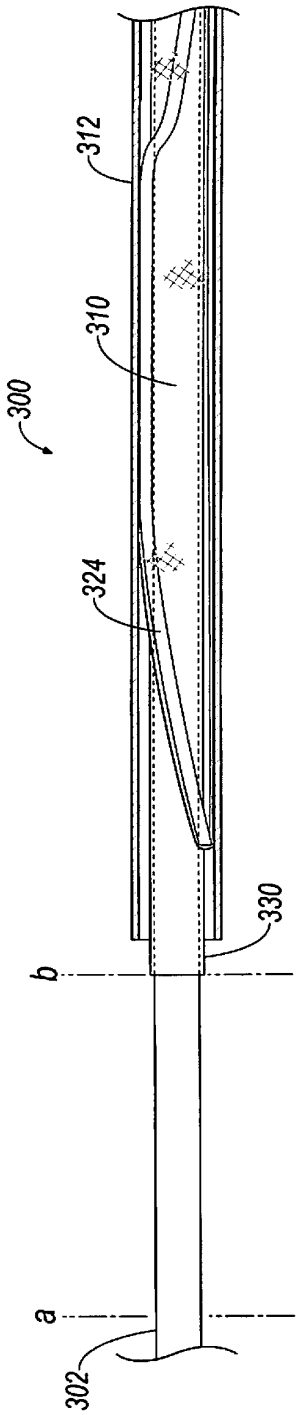



FIG. 3B

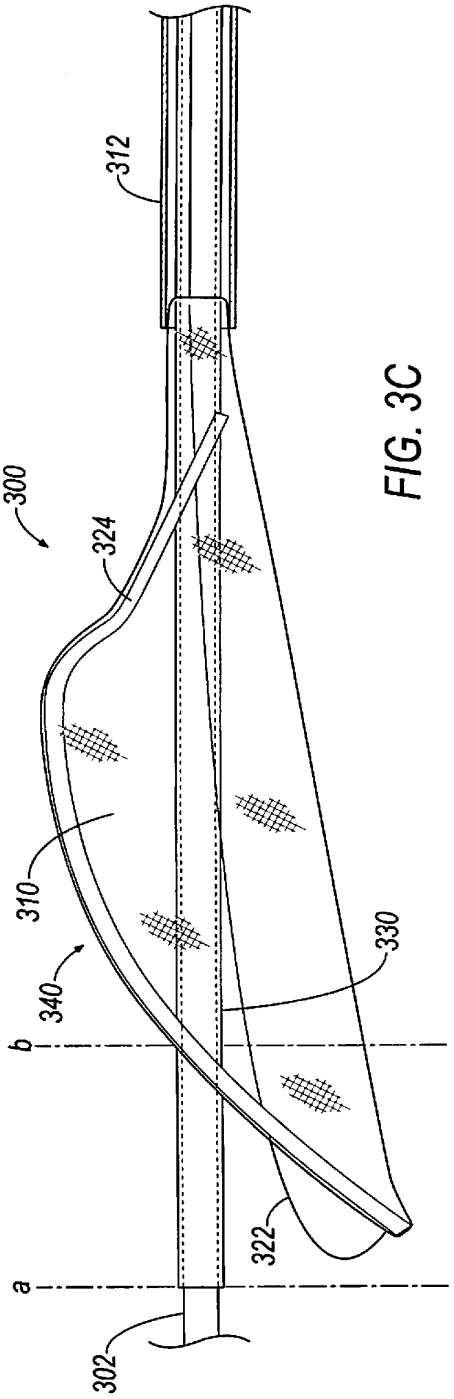



FIG. 3C

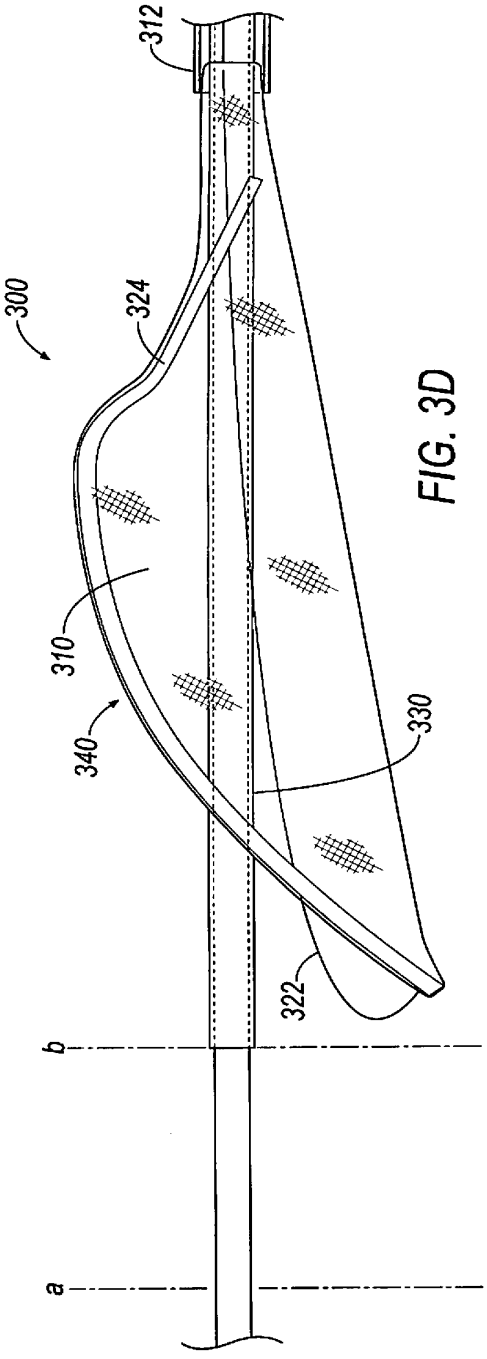



FIG. 3D

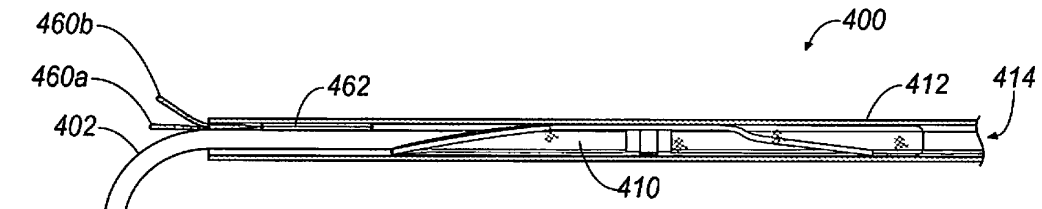

460b
460a
402
462
400
412
414
410

FIG. 4A

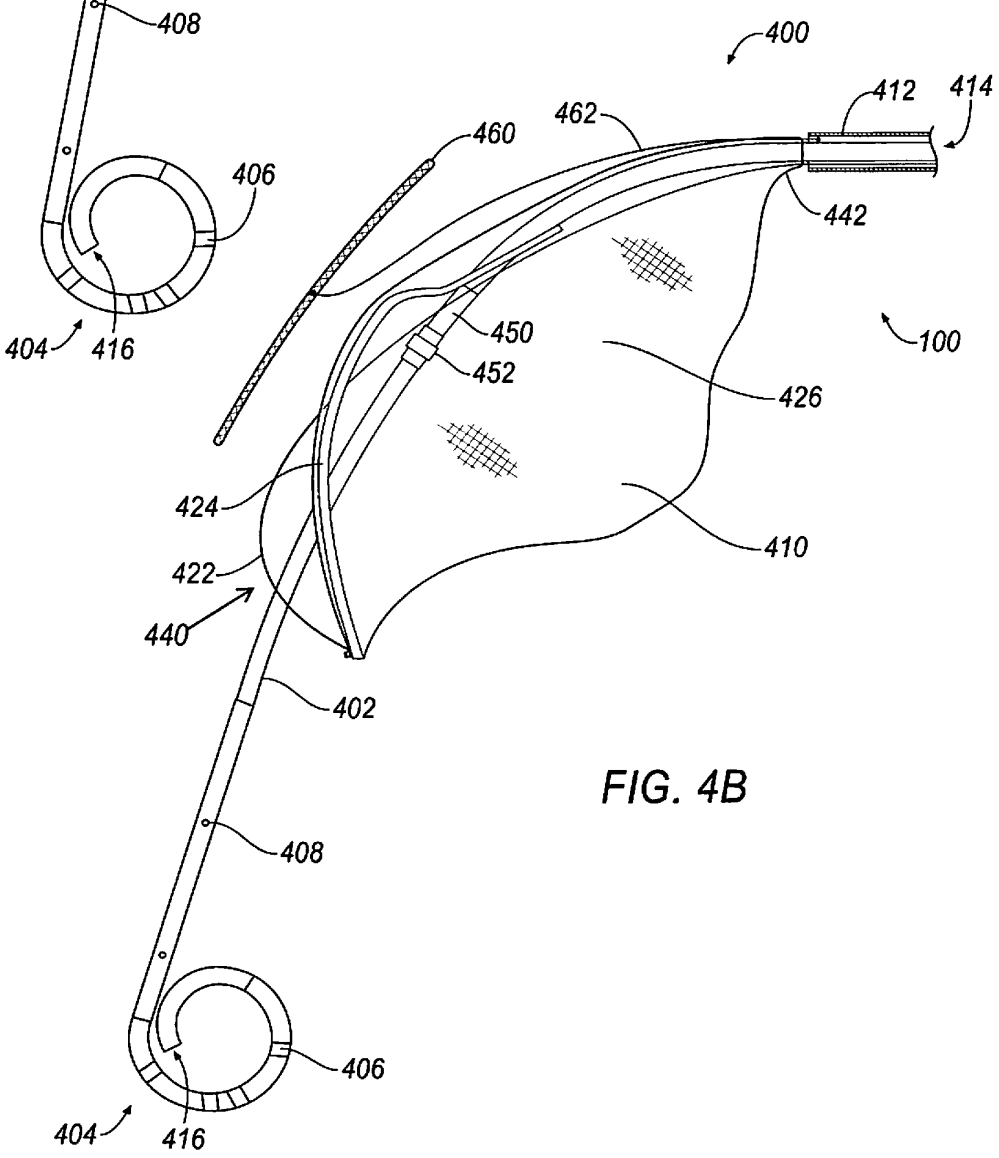

408
406
404
416
400
412
414
462
460
442
450
452
426
100
424
422
440
410
402
408
406
404
416

FIG. 4B

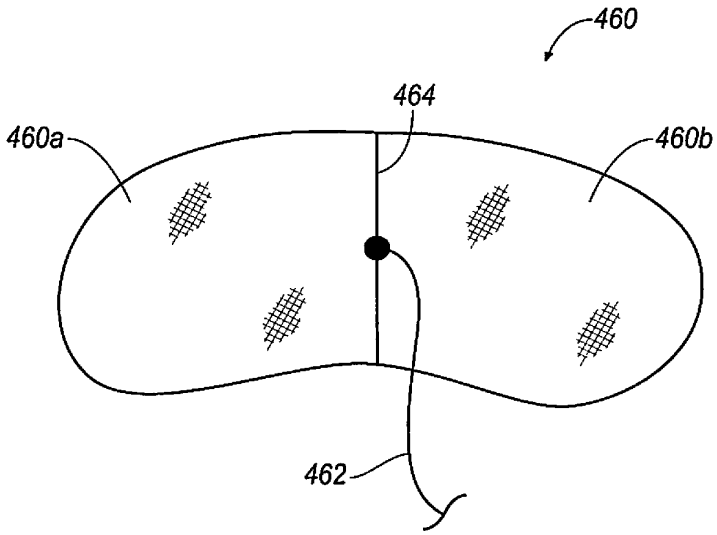



FIG. 4C

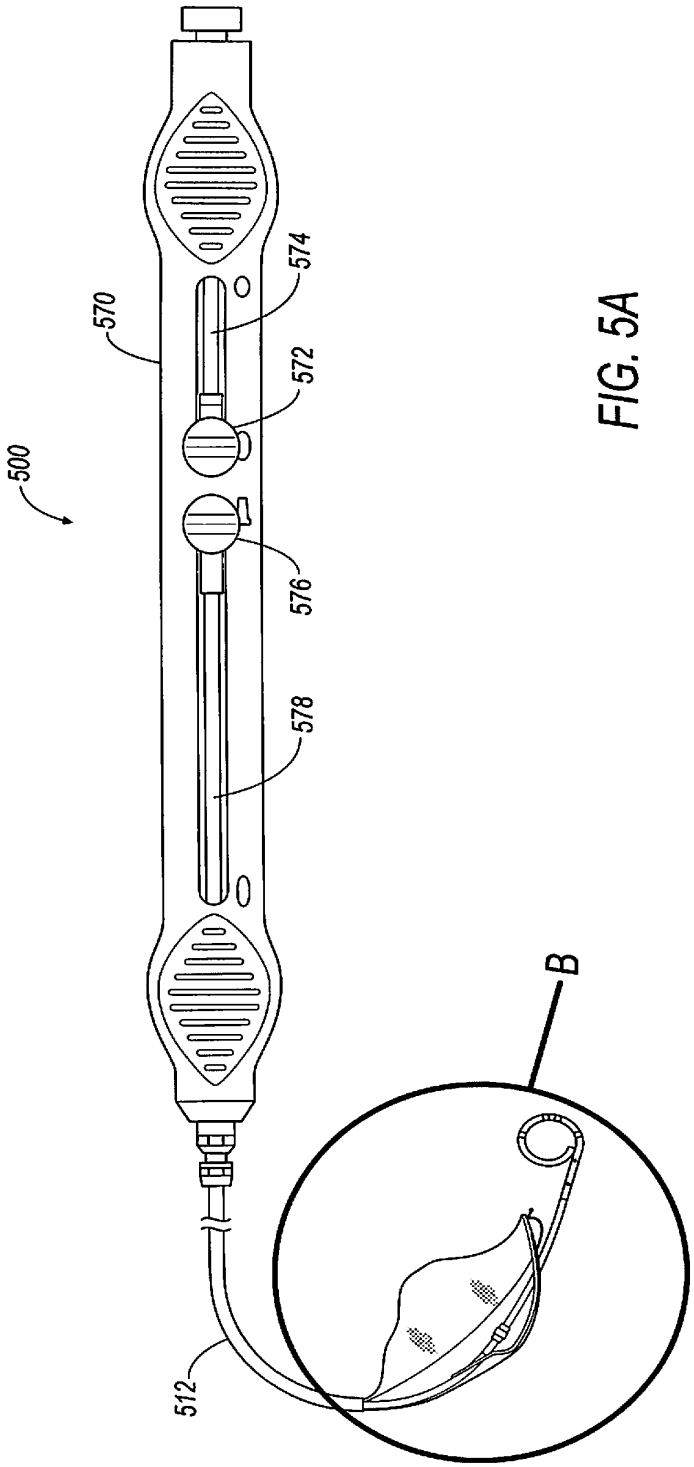



FIG. 5A

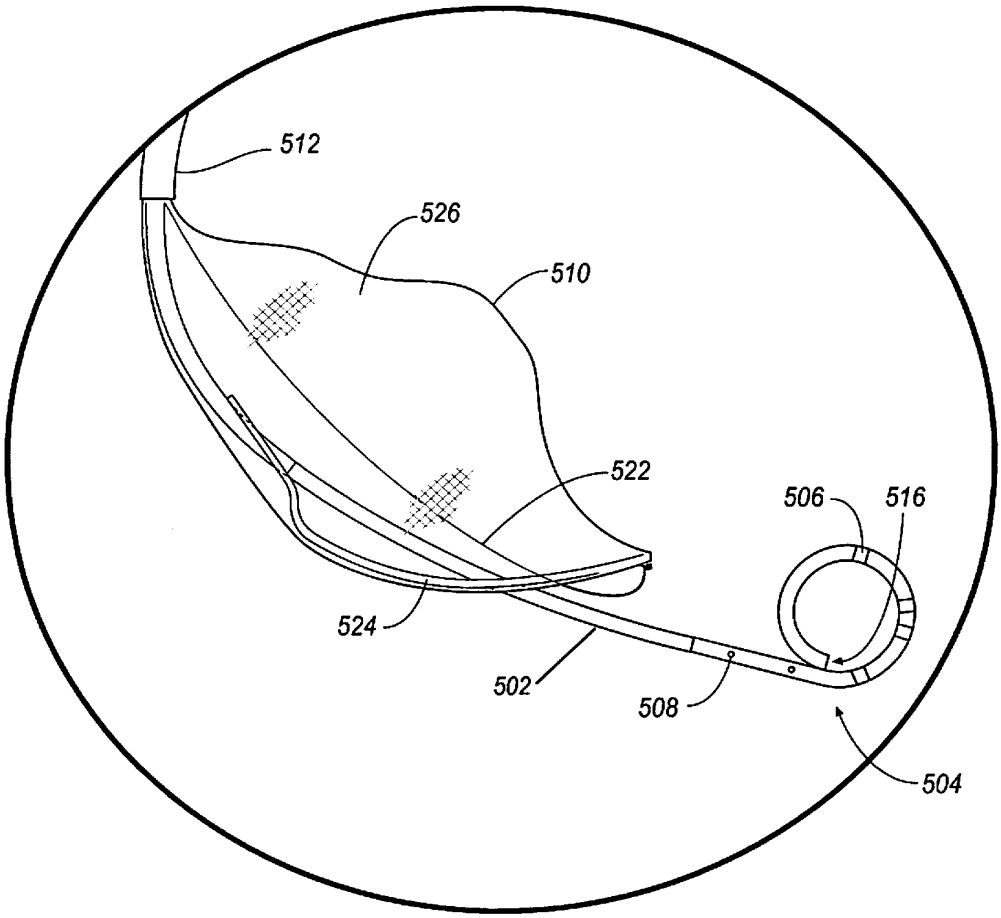



FIG. 5B

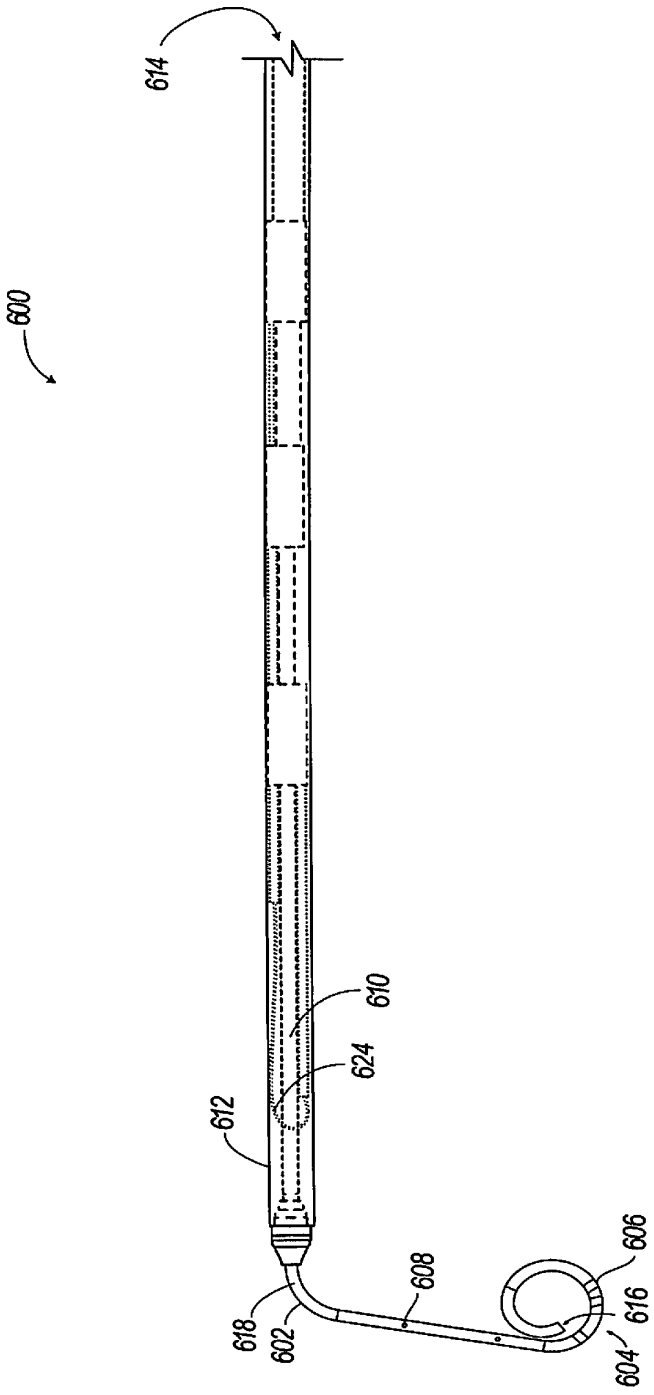



FIG. 6A

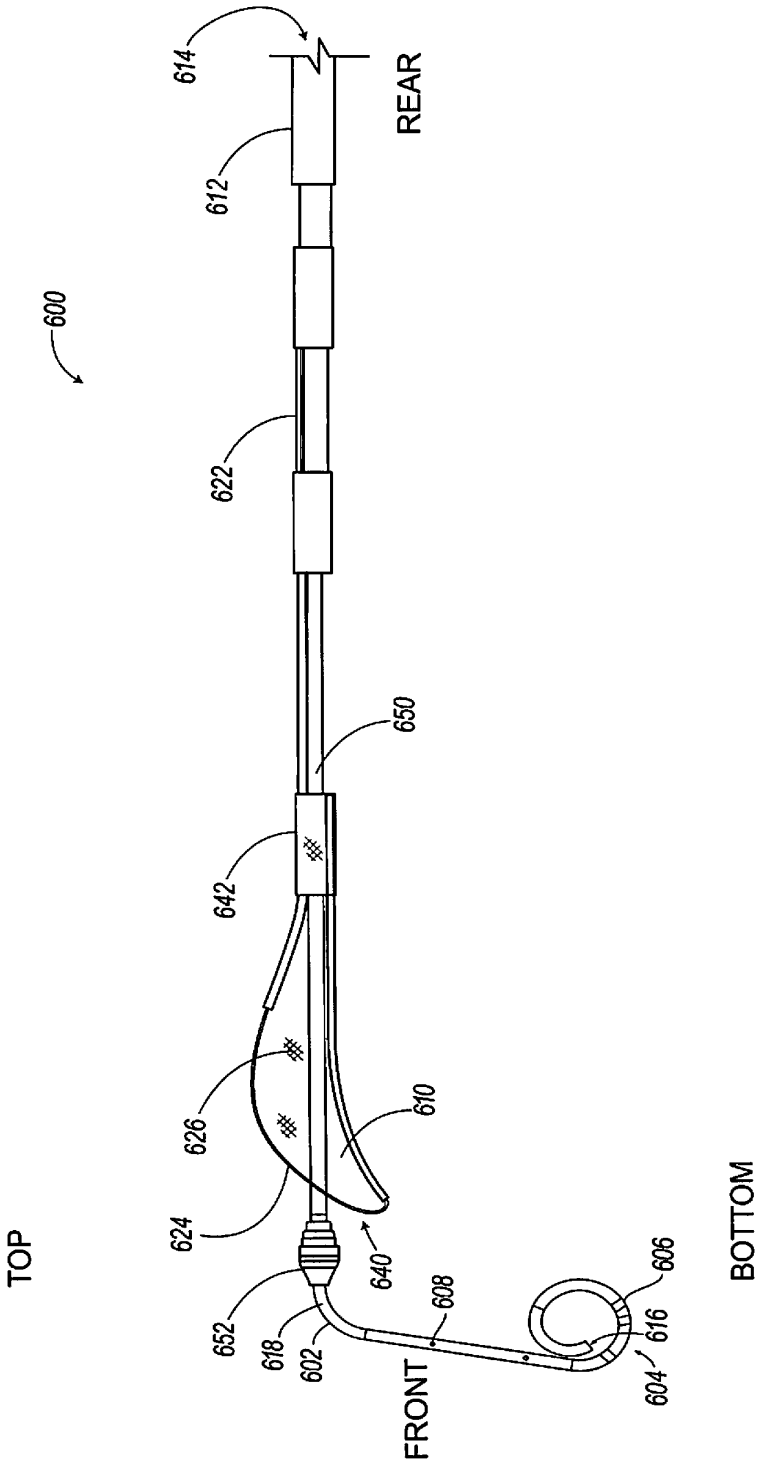

600
614
612
622
650
642
626
624
610
640
652
618
602
608
606
616
604
REAR
TOP
FRONT
BOTTOM

FIG. 6B

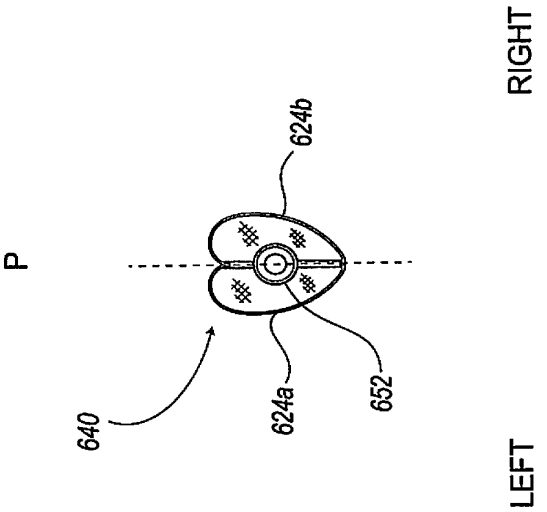



FIG. 6C

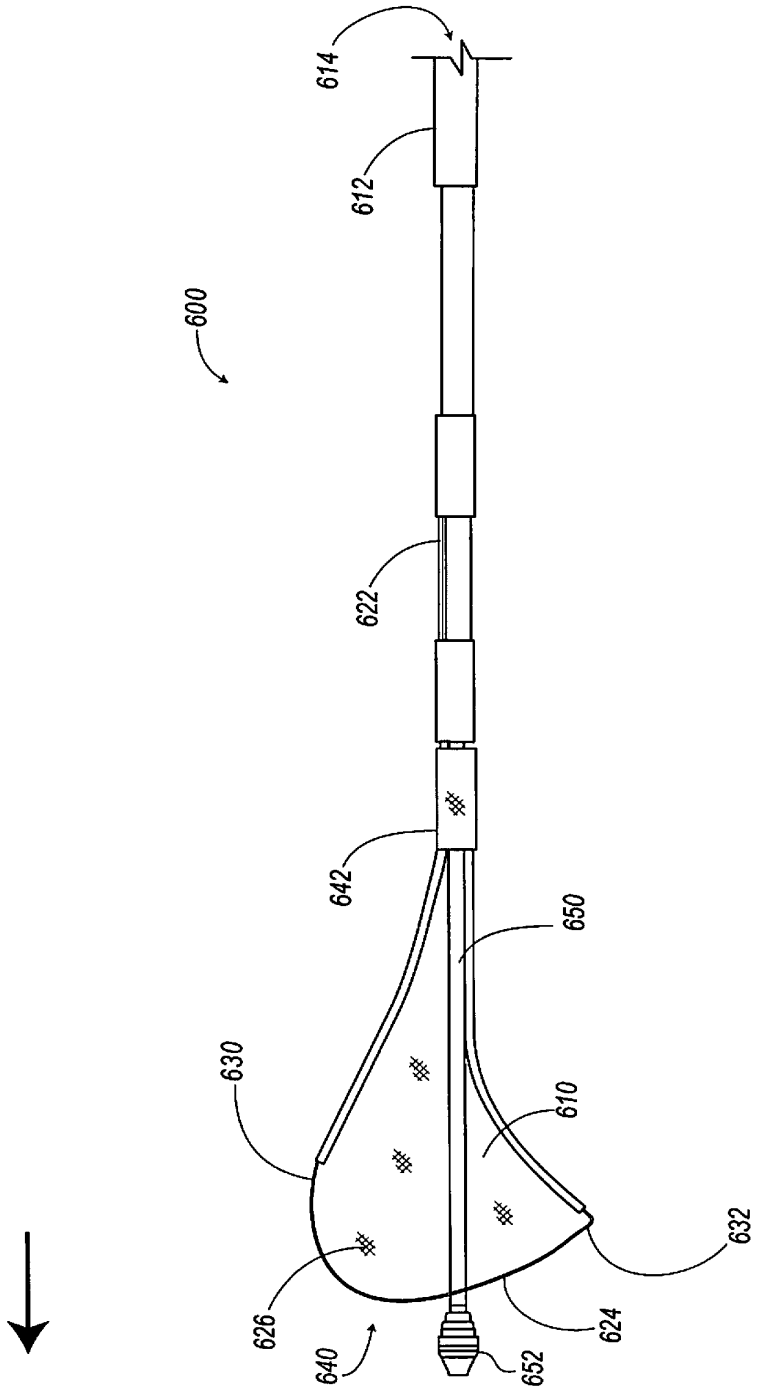



FIG. 6D

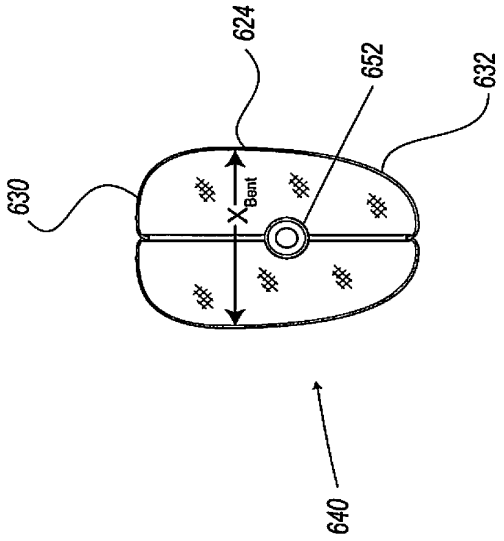



FIG. 6E

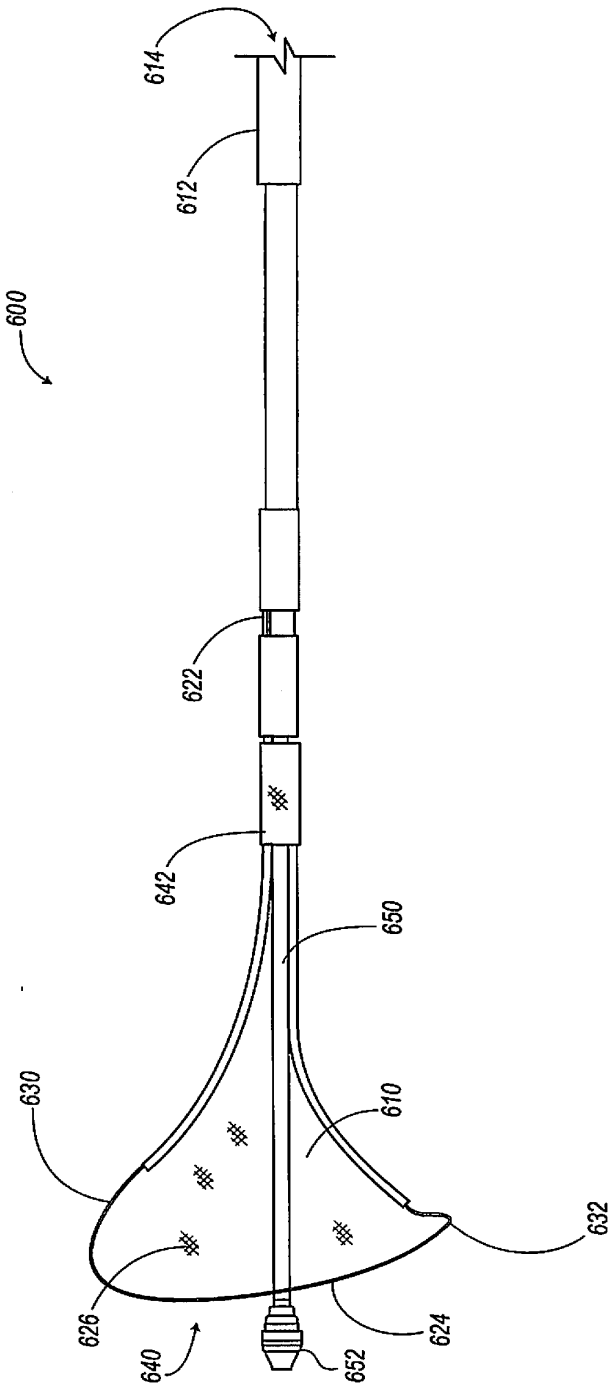



FIG. 6F

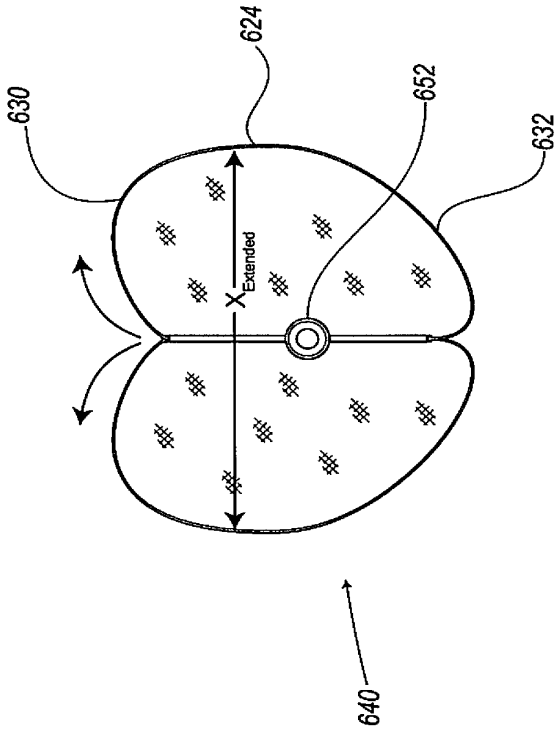



FIG. 6G

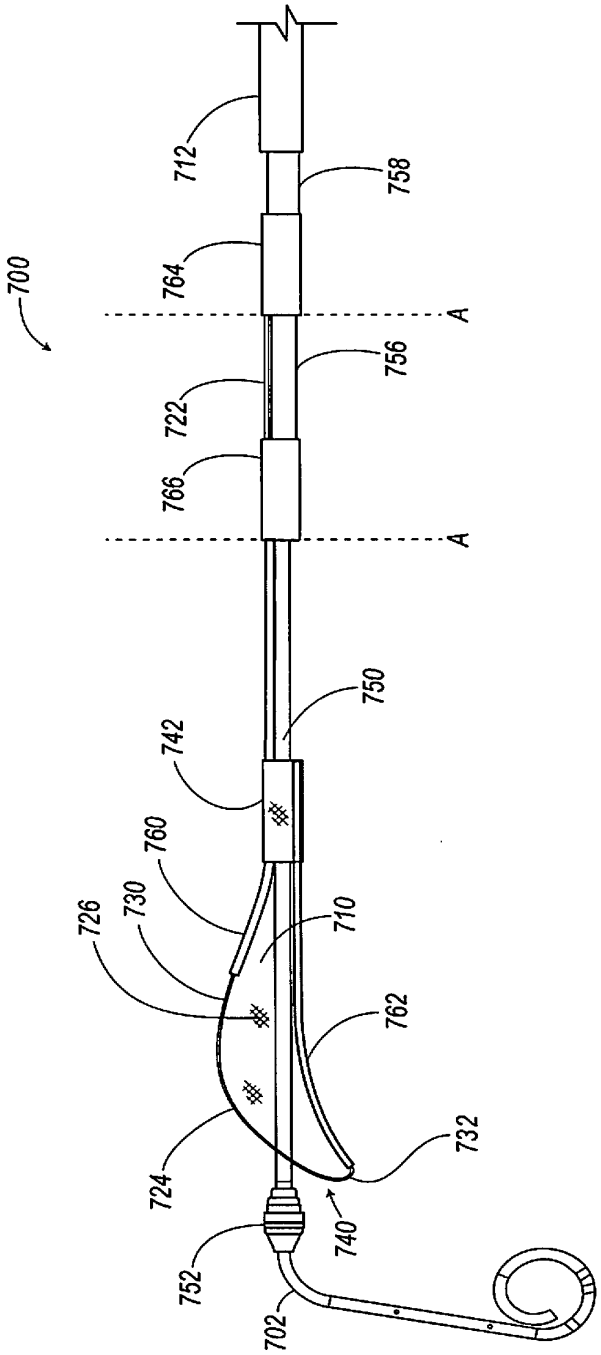

700
712
758
764
A
756
722
766
A
750
742
760
726
730
710
762
724
732
740
752
702

FIG. 7A

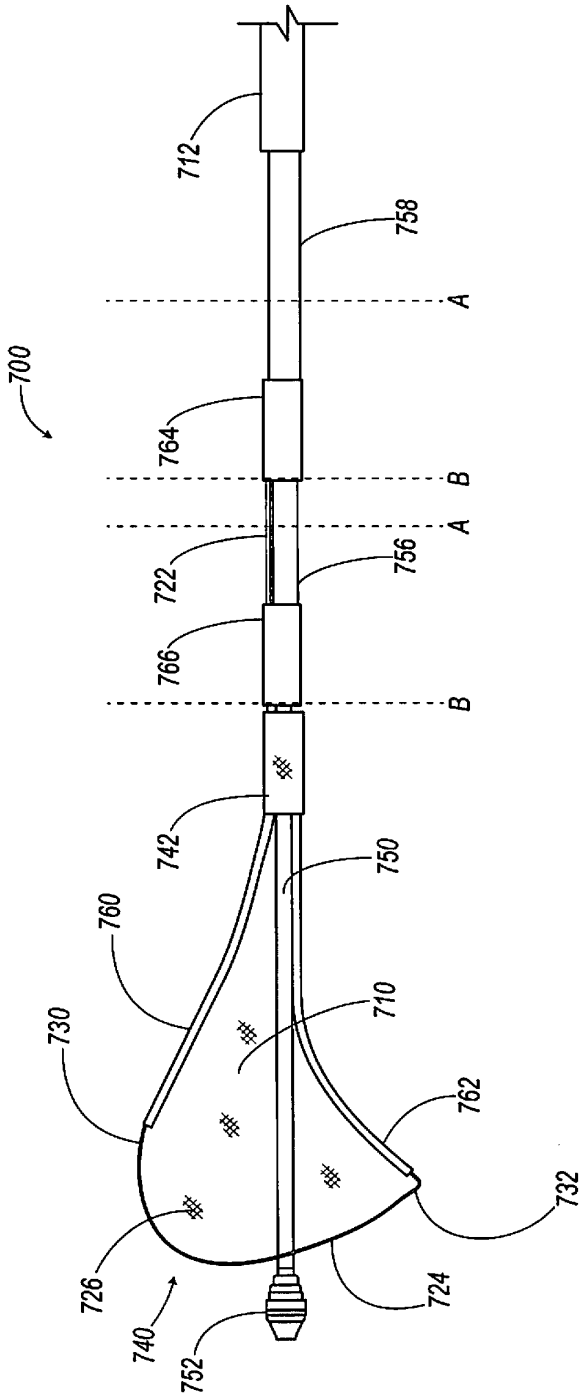

712
758
A
700
764
B
A
722
756
766
B
742
750
760
710
730
762
732
726
740
752
724

FIG. 7B

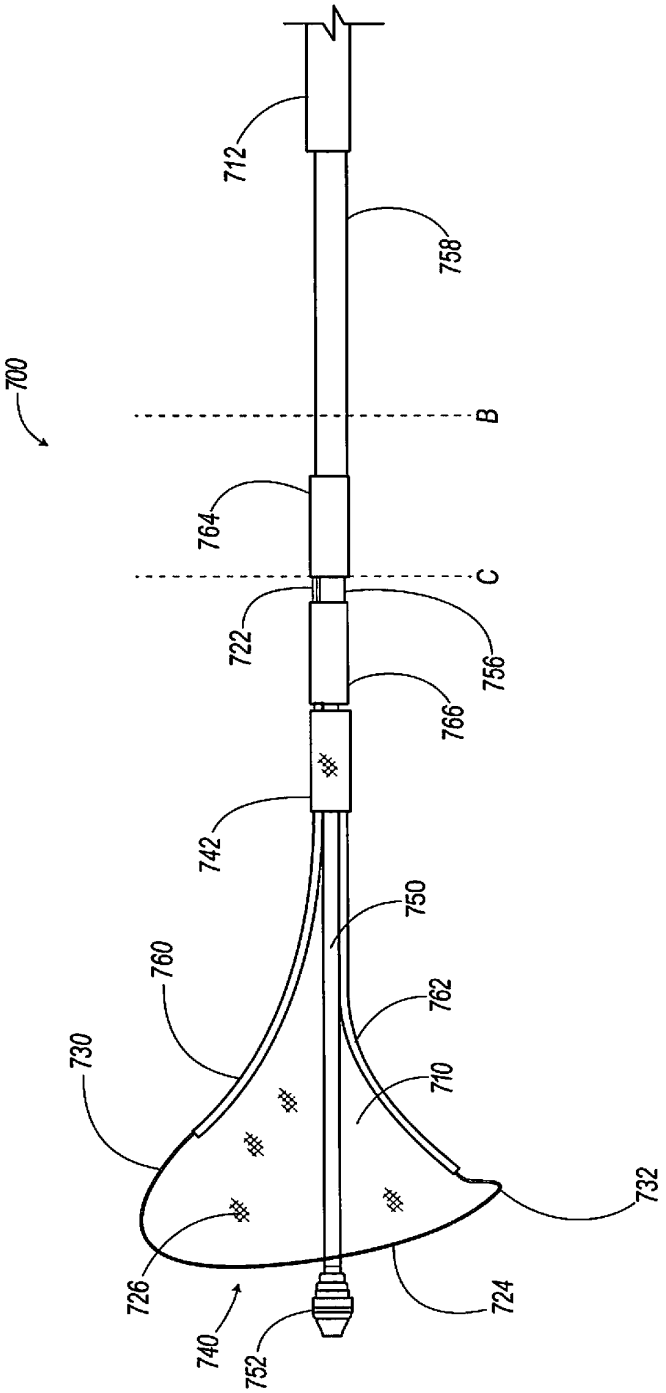

700
712
758
B
764
C
722
756
766
742
750
760
762
730
710
732
726
724
740
752

FIG. 7C

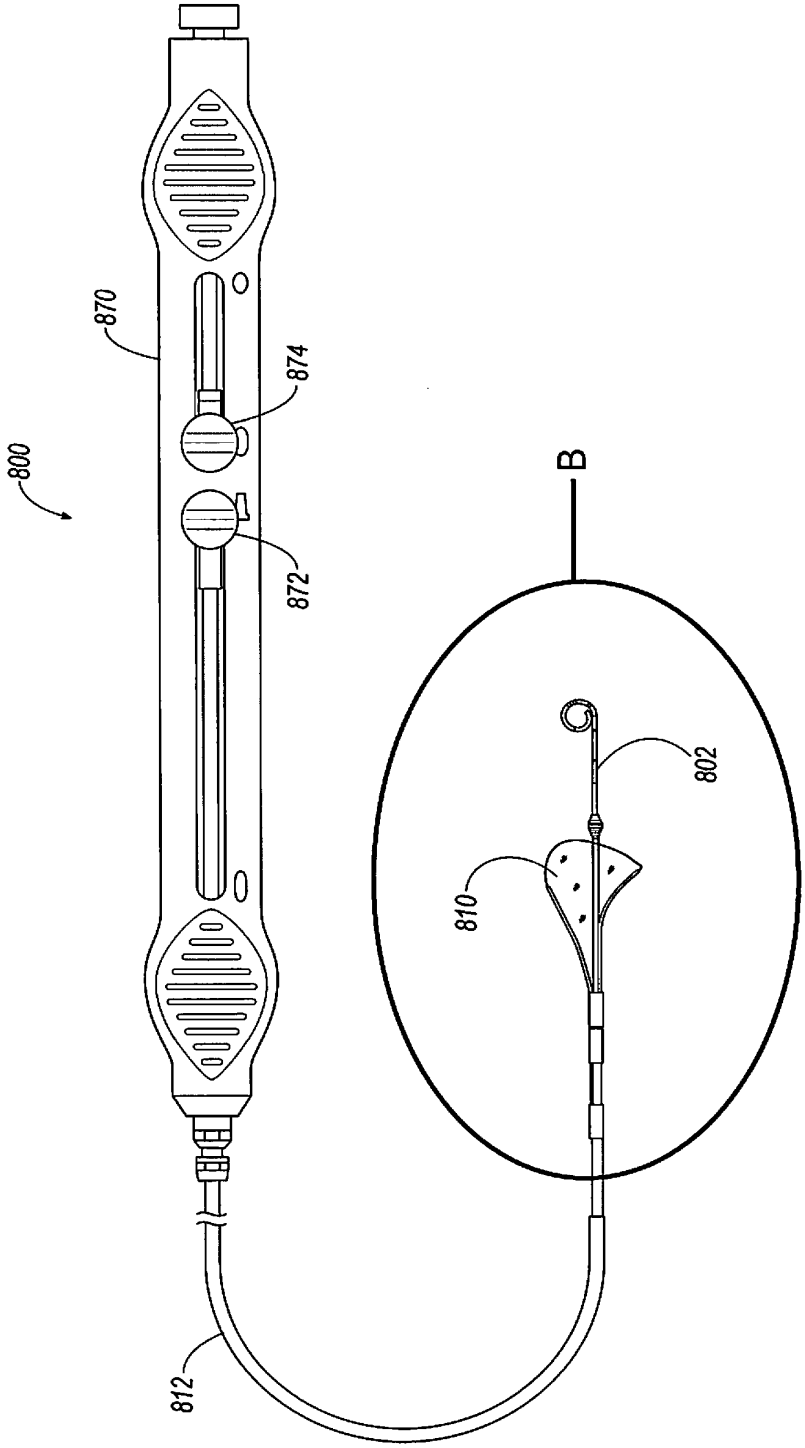



FIG. 8A

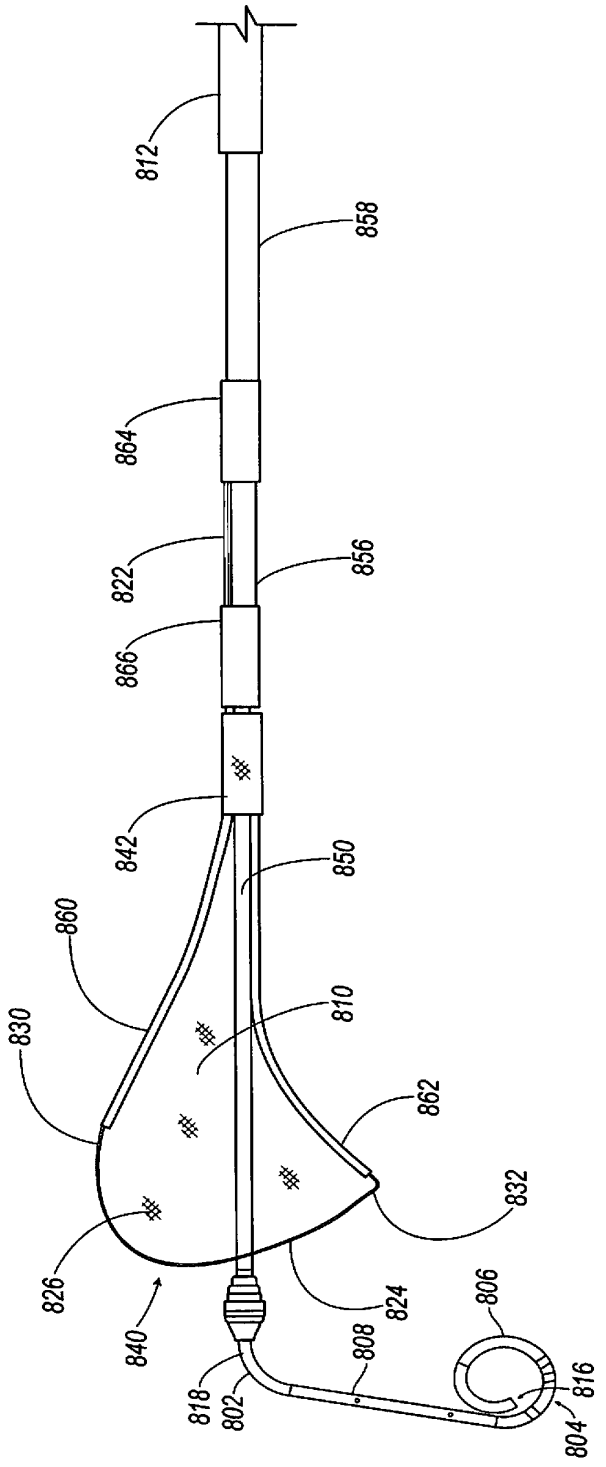

812
858
864
822
856
866
842
850
860
810
830
862
832
826
824
806
840
808
816
818
802
804

FIG. 8B

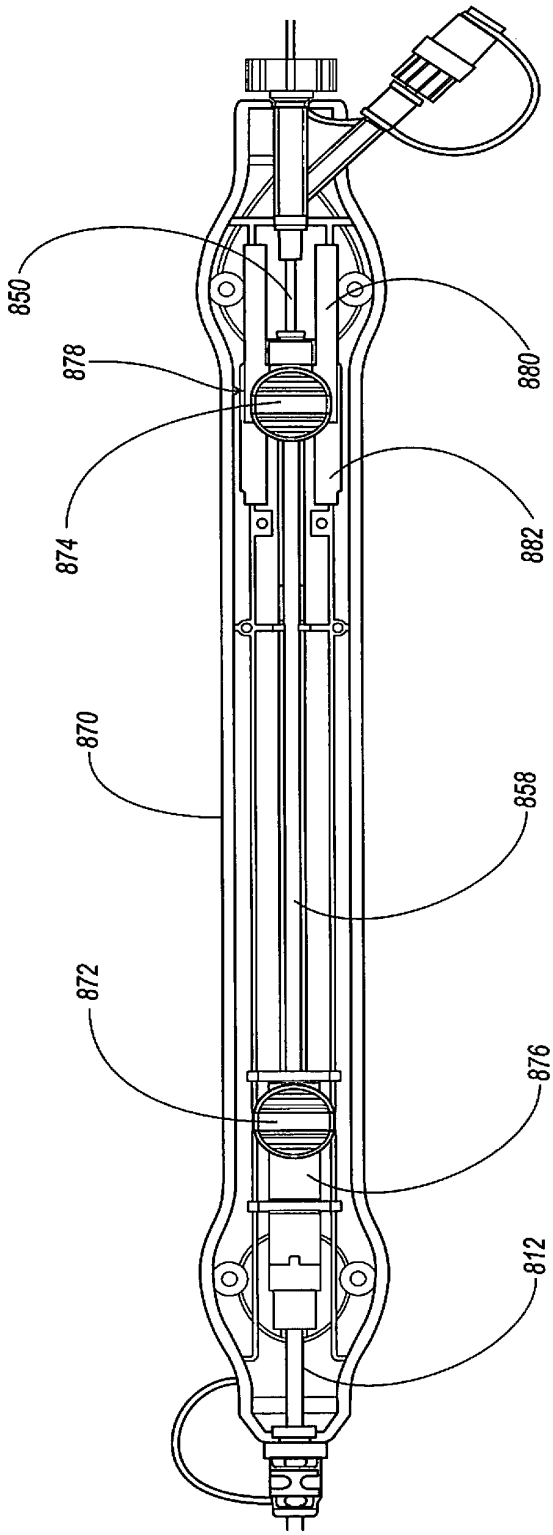



FIG. 8C

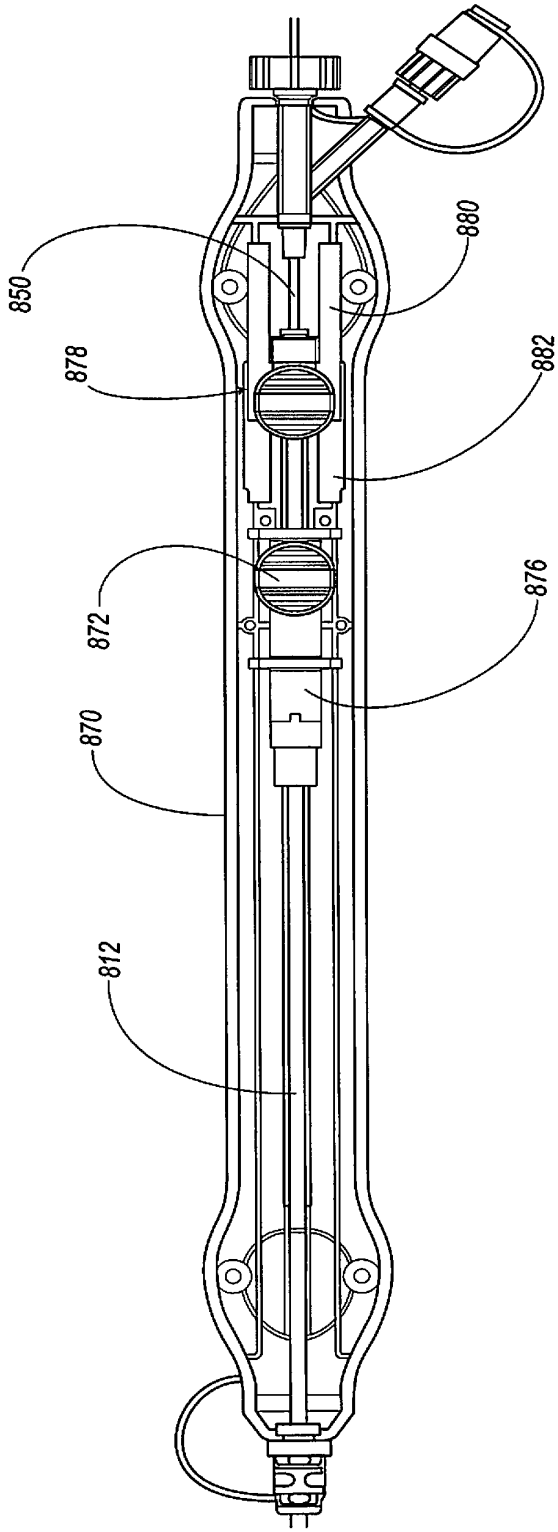



FIG. 8D

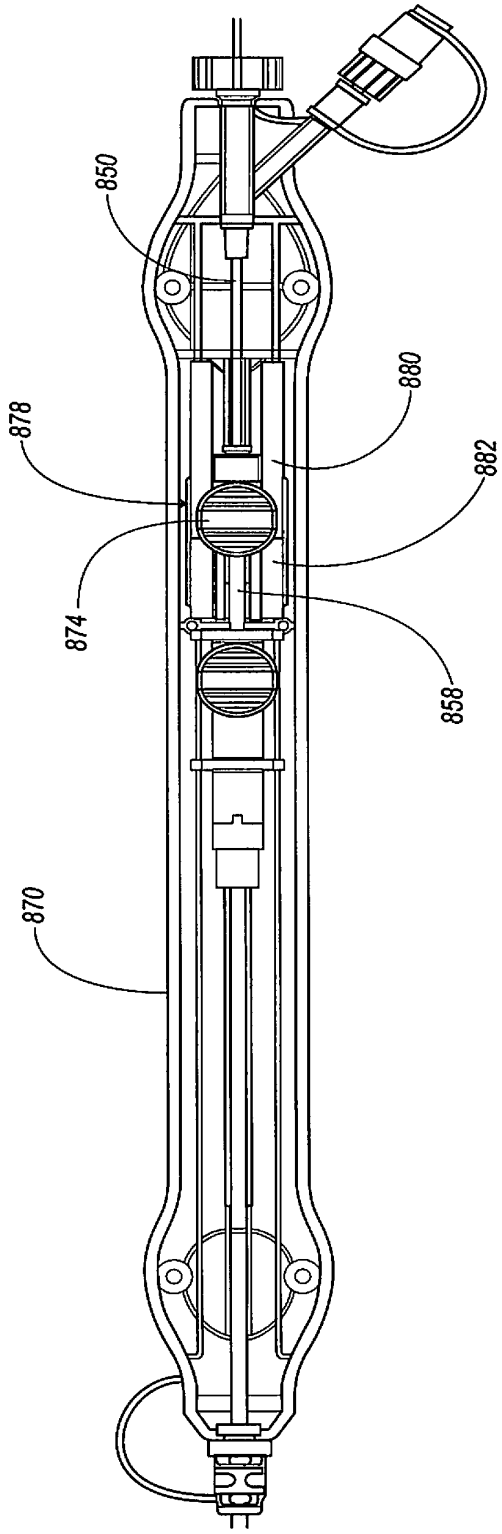



FIG. 8E

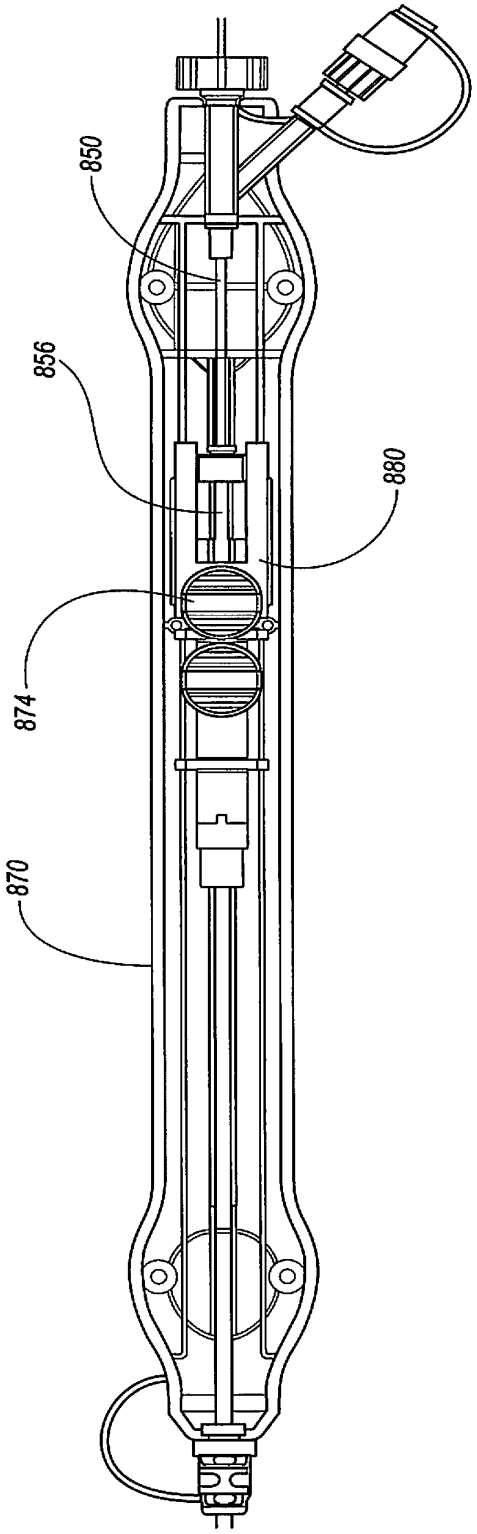



FIG. 8F

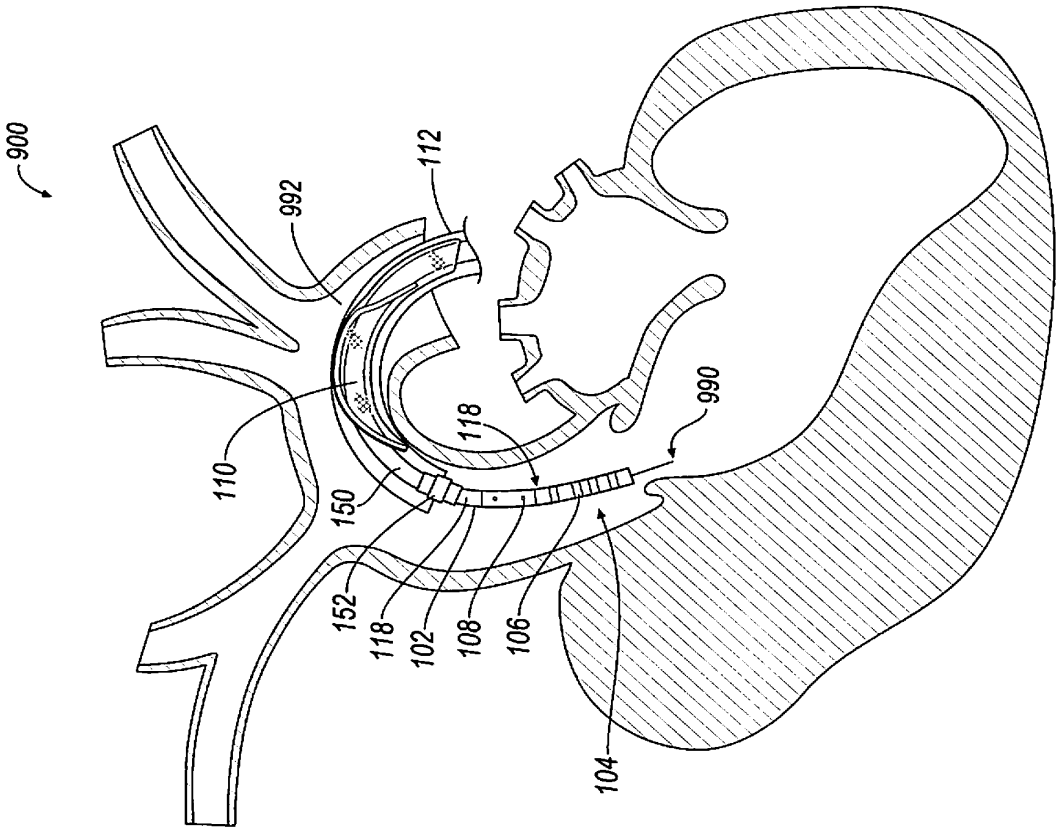



FIG. 9A

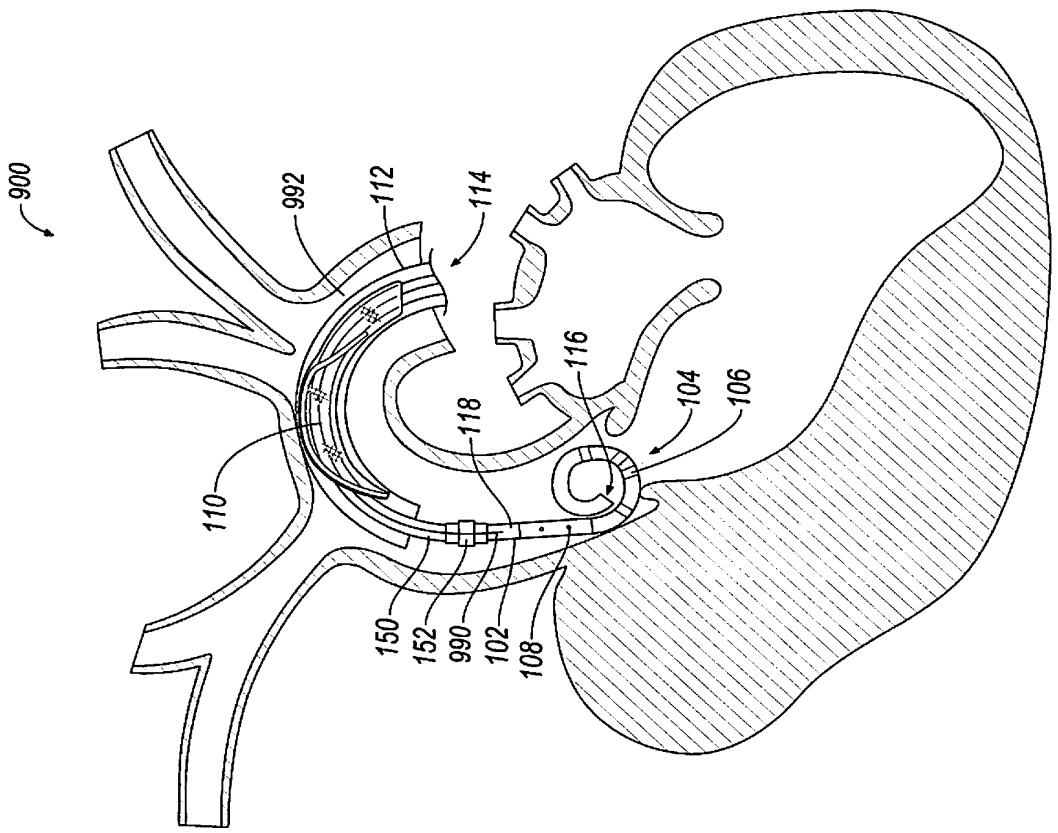



FIG. 9B

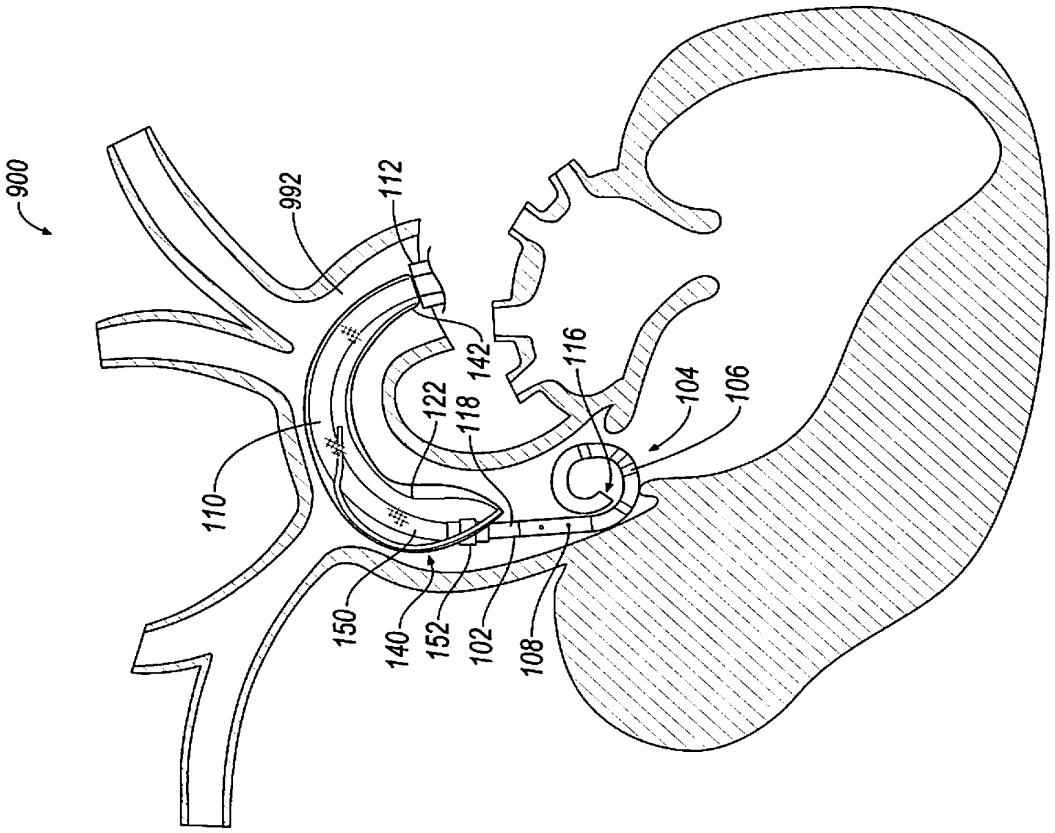



FIG. 9C

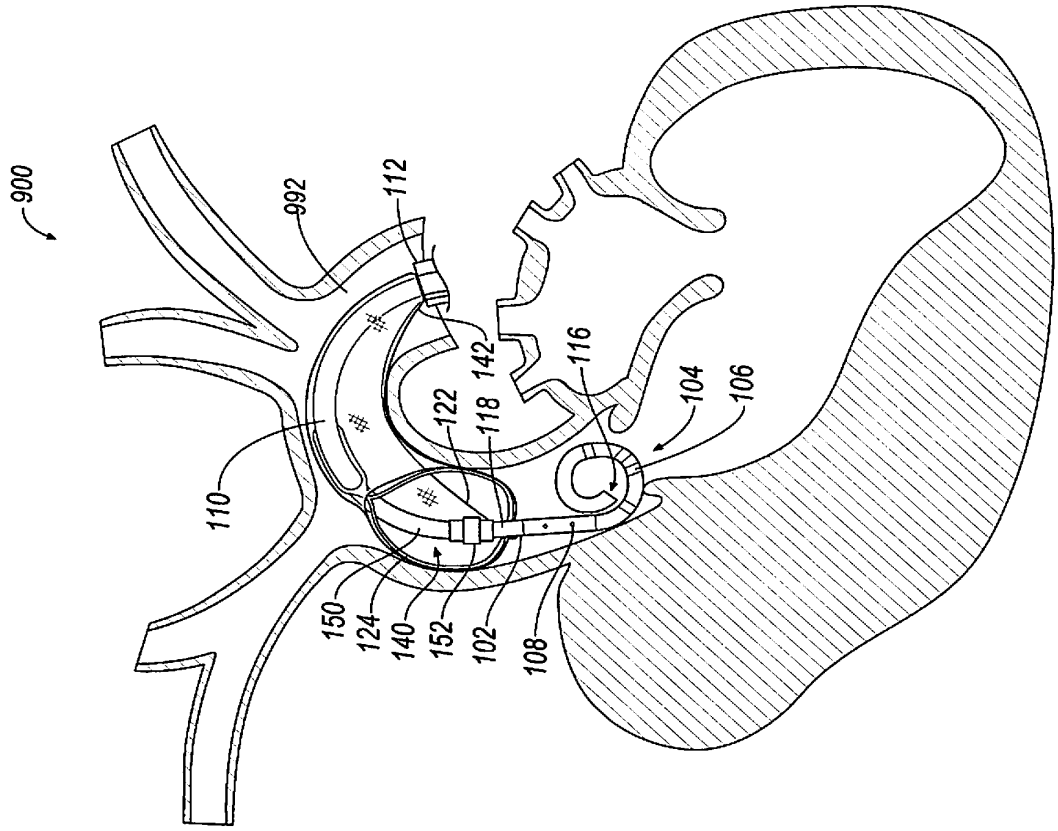



FIG. 9D

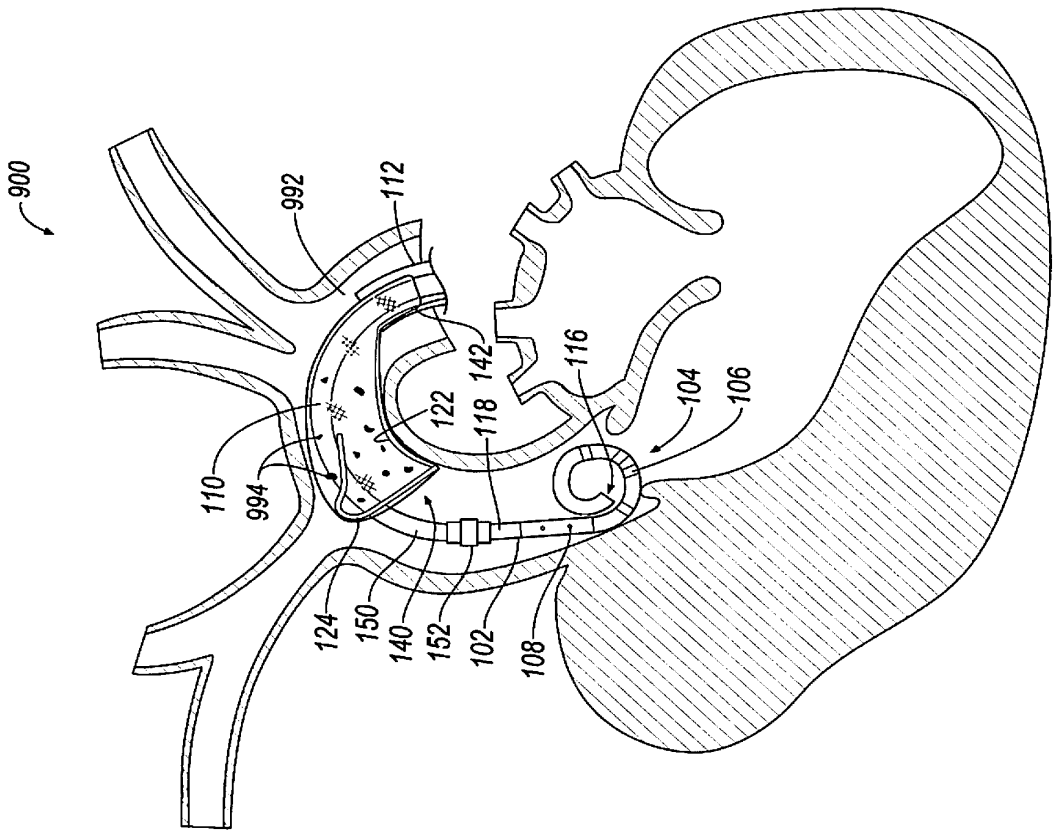

900
992
112
142
116
104
106
122
118
110
994
124
150
140
152
102
108

FIG. 9E

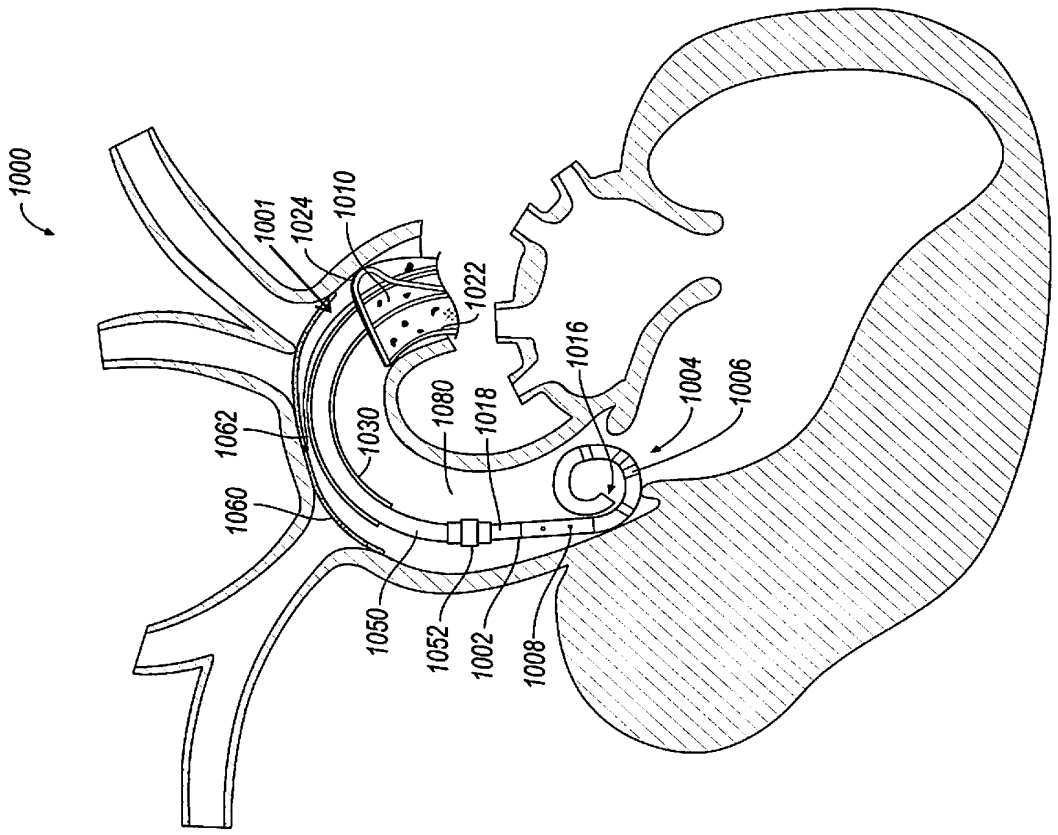

1000
1001
1024
1010
1022
1016
1004
1006
1062
1030
1080
1018
1060
1050
1052
1002
1008

FIG. 10

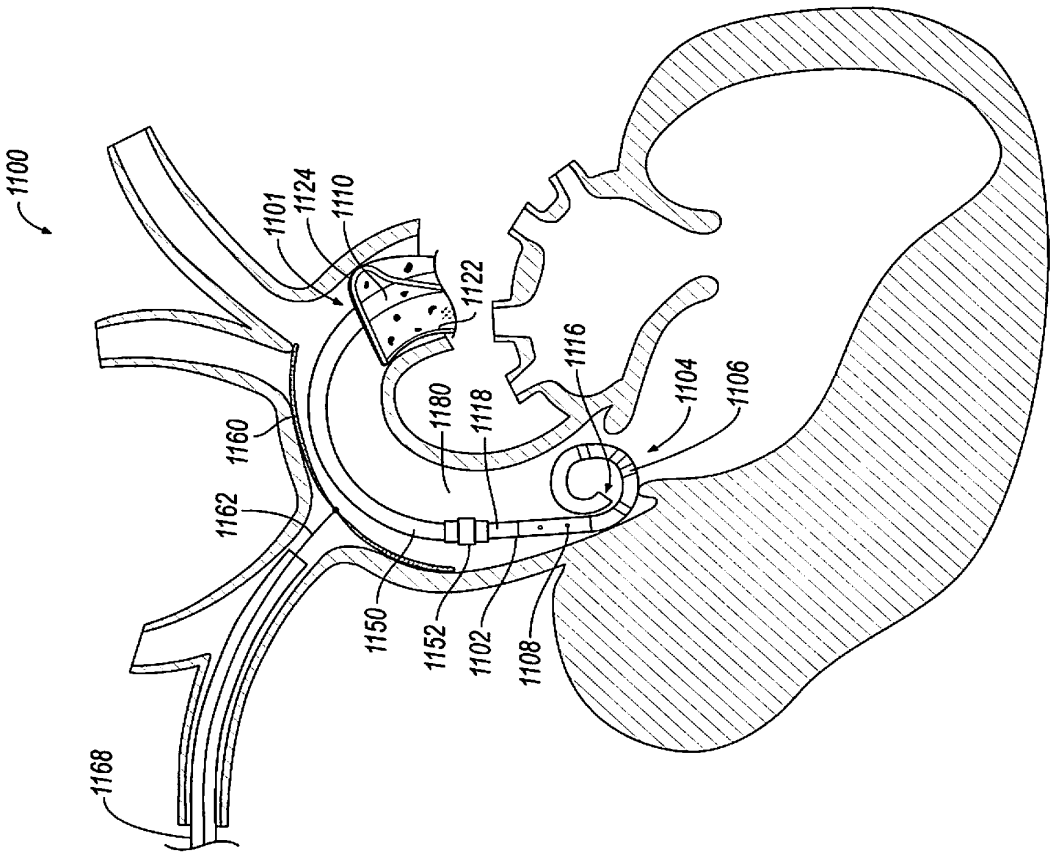

1100
1101
1124
1110
1122
1116
1104
1106
1180
1118
1160
1162
1150
1152
1102
1108
1168

FIG. 11

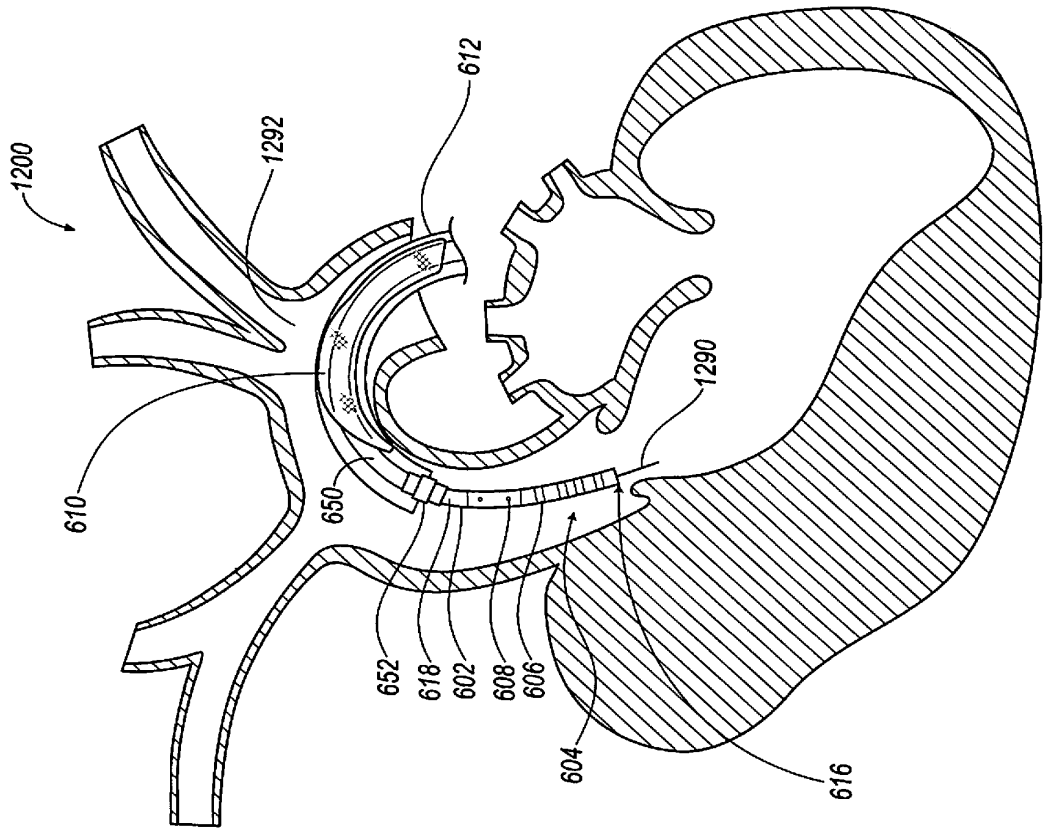



FIG. 12A

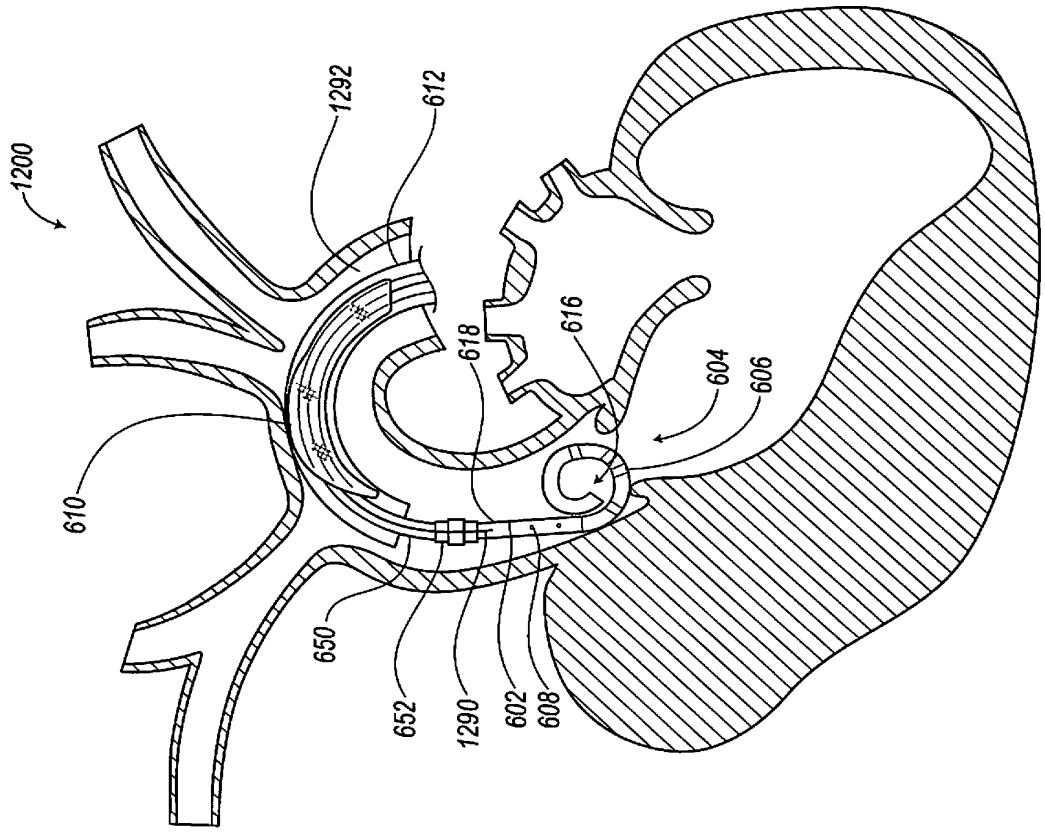



FIG. 12B

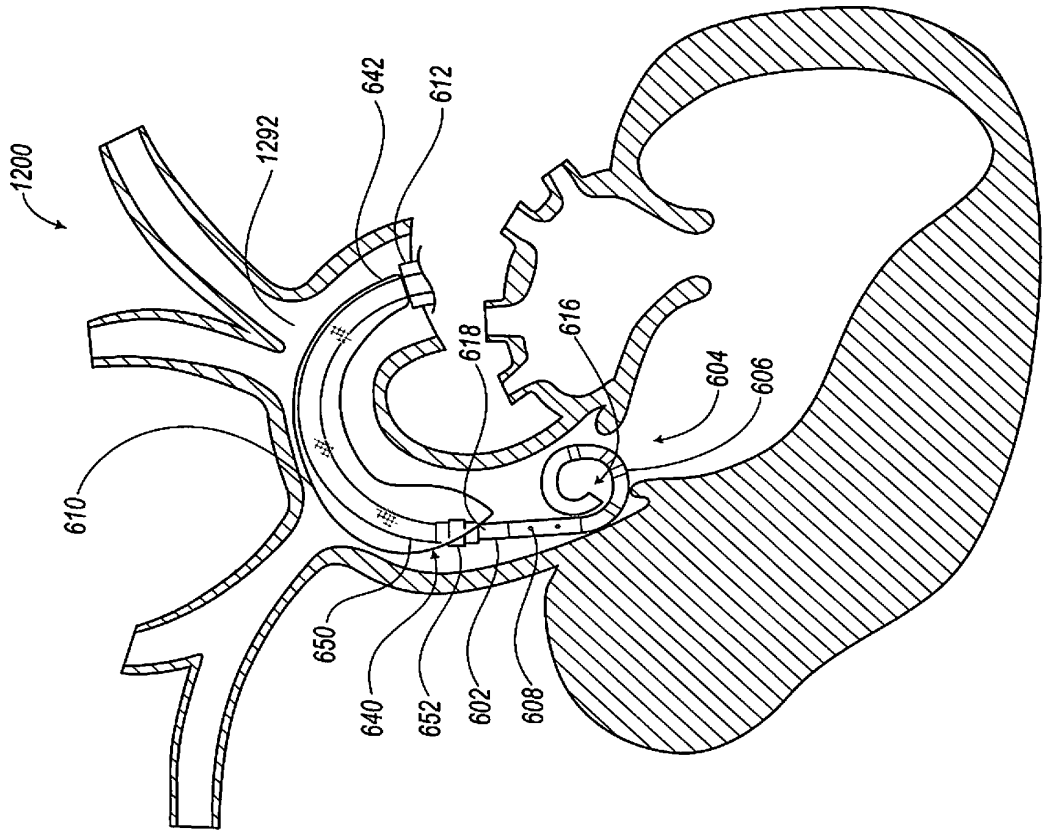



FIG. 12C

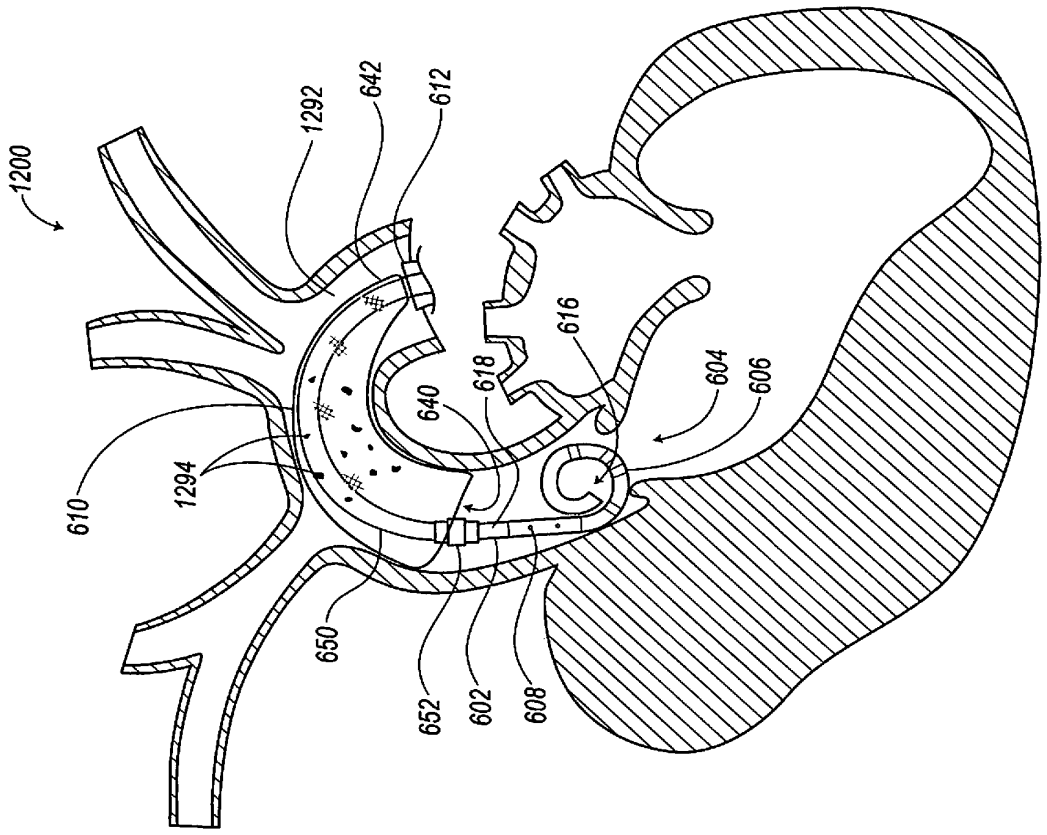



FIG. 12D

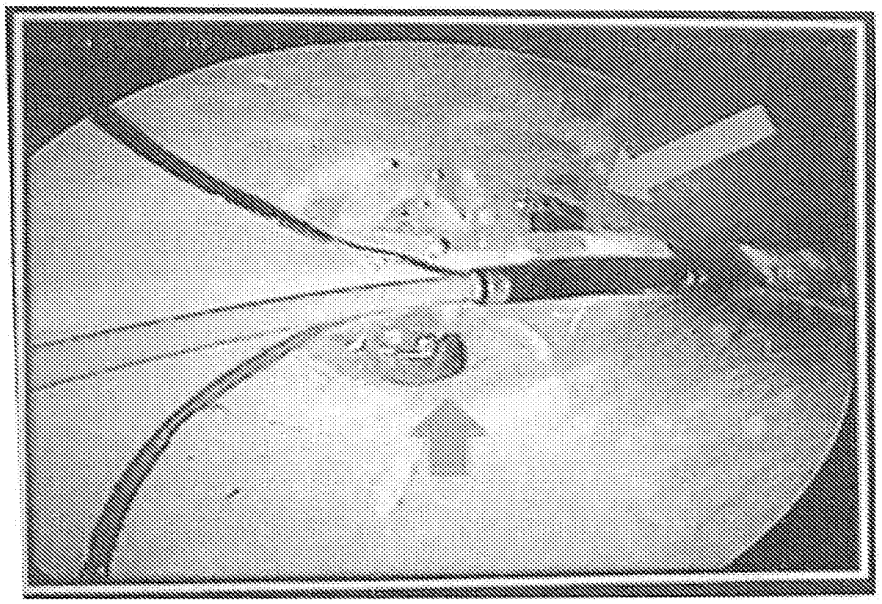


FIG. 13A

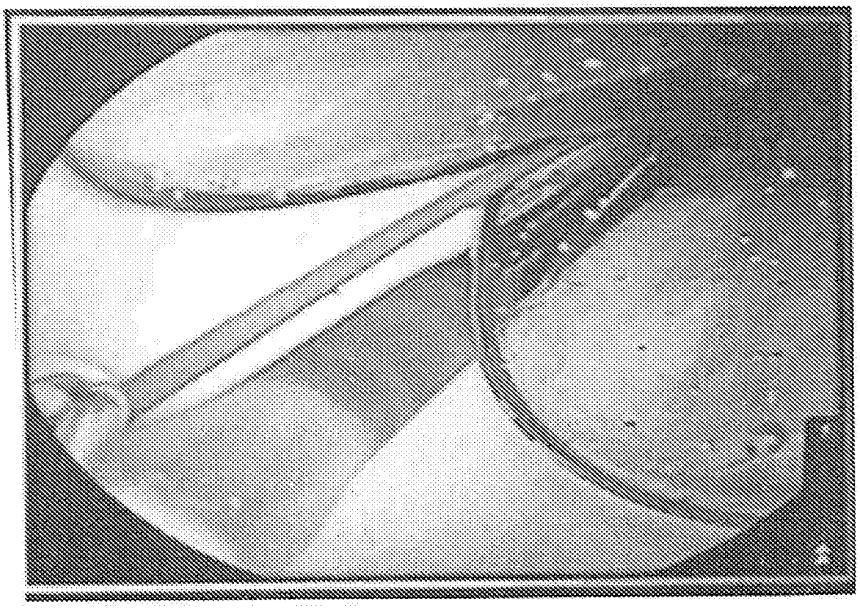


FIG. 13B

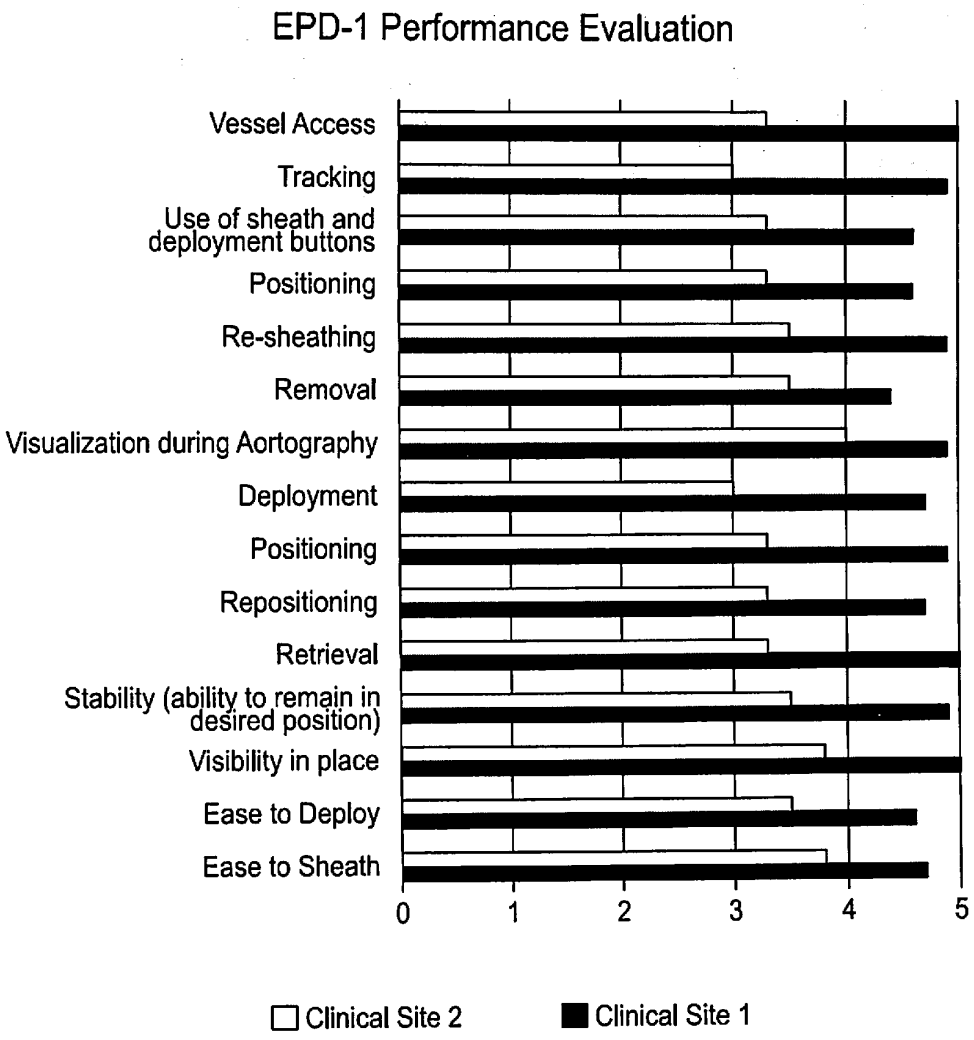

EPD-1 Performance Evaluation
Vessel Access
Tracking
Use of sheath and deployment buttons
Positioning
Re-sheathing
Removal
Visualization during Aortography
Deployment
Positioning
Repositioning
Retrieval
Stability (ability to remain in desired position)
Visibility in place
Ease to Deploy
Ease to Sheath
0
1
2
3
4
5
Clinical Site 2
Clinical Site 1

*FIG. 14*

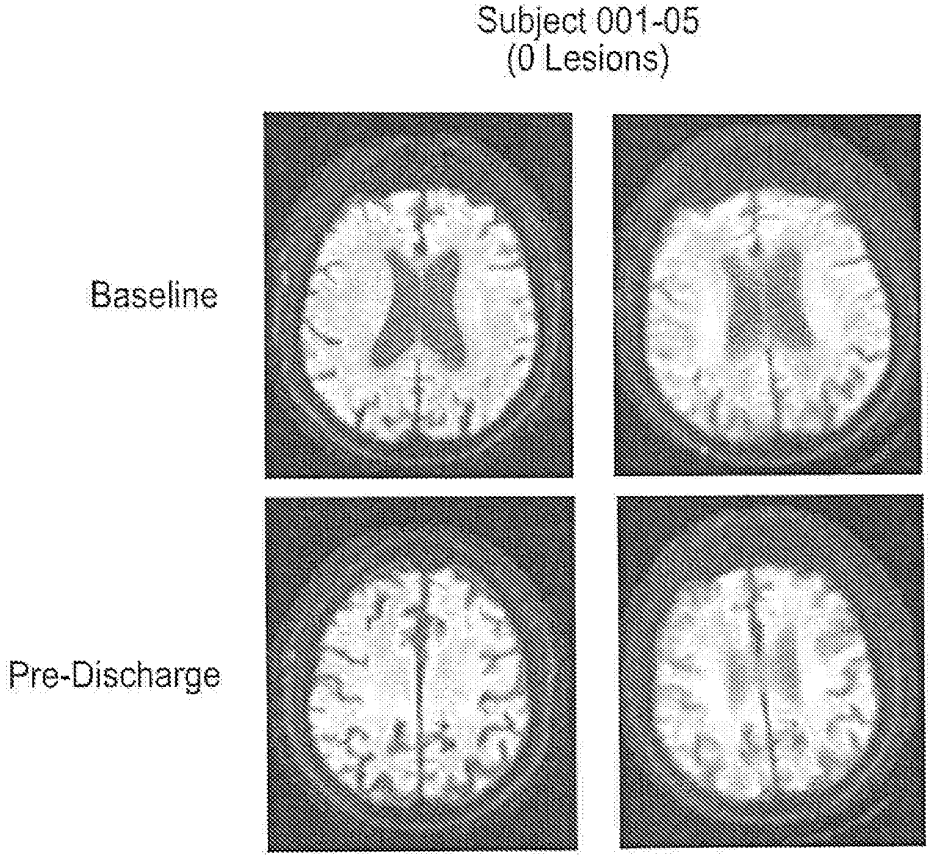



FIG.15A

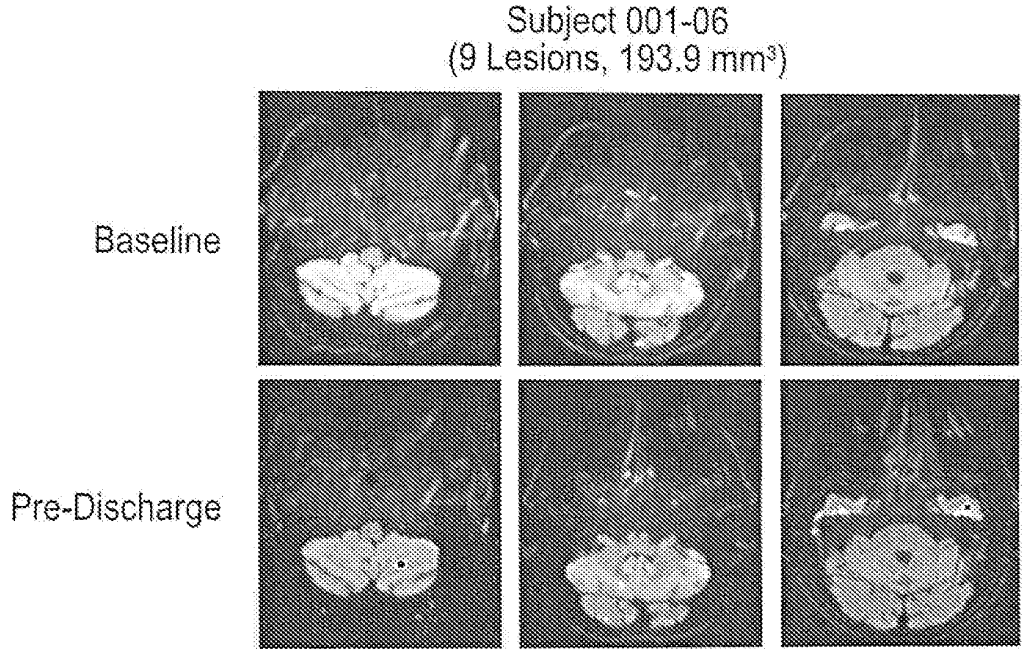



FIG. 15B

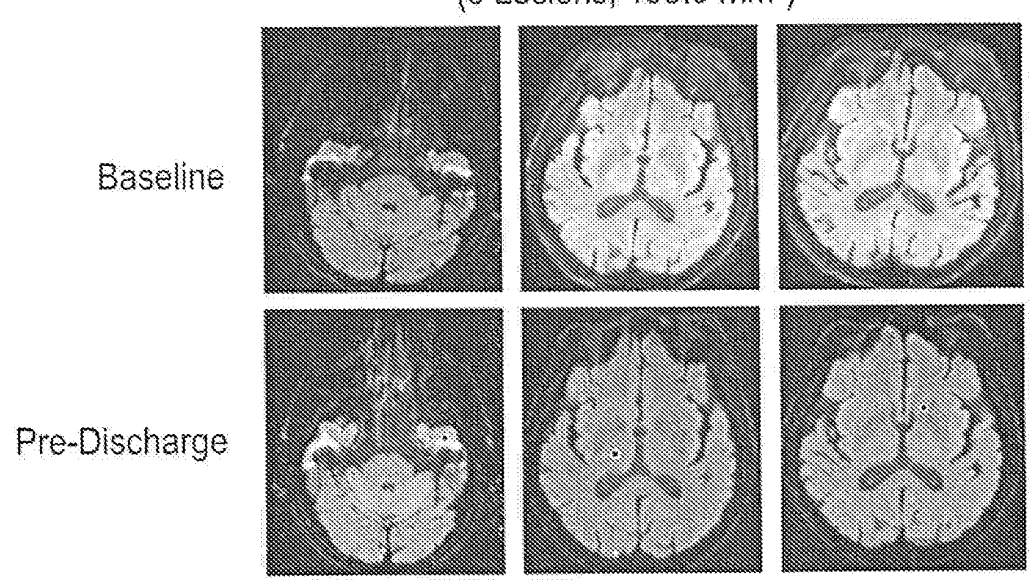



FIG. 15C

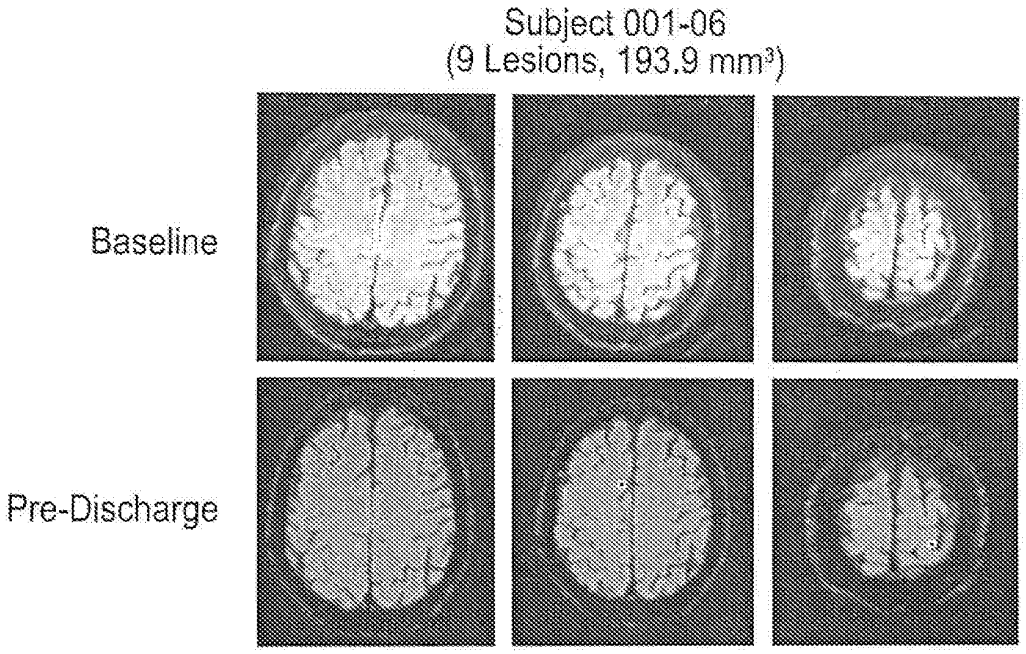



FIG. 15D

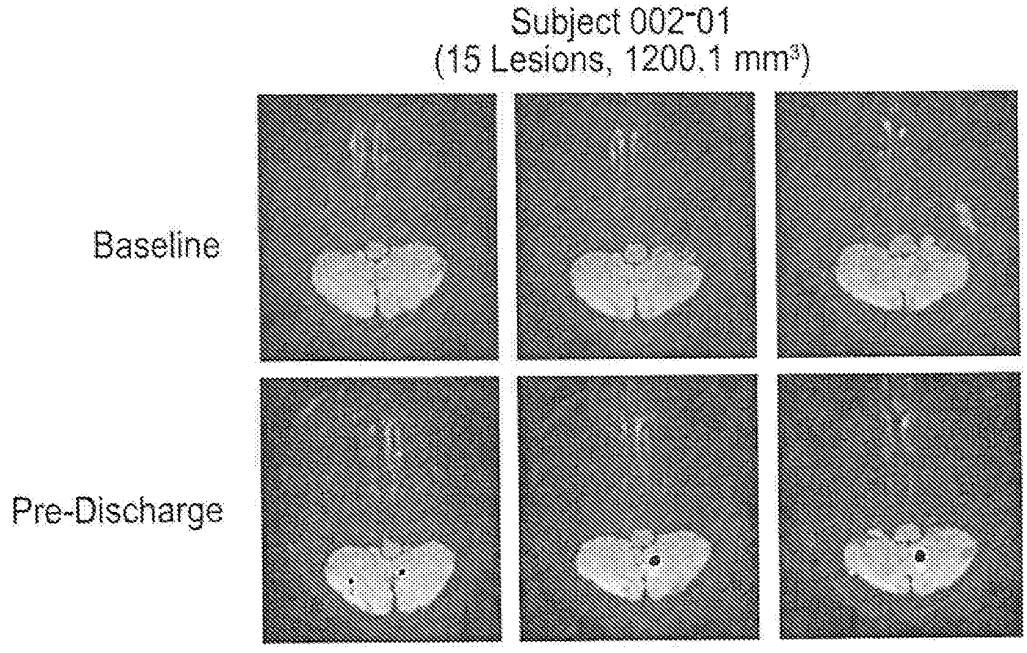



FIG. 15E

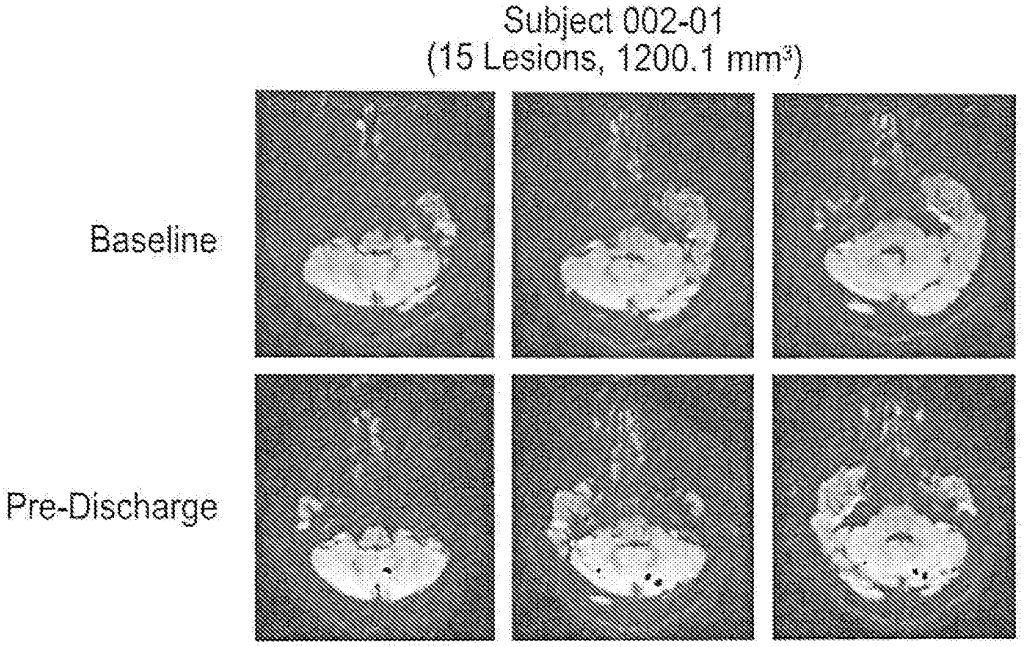



FIG. 15F

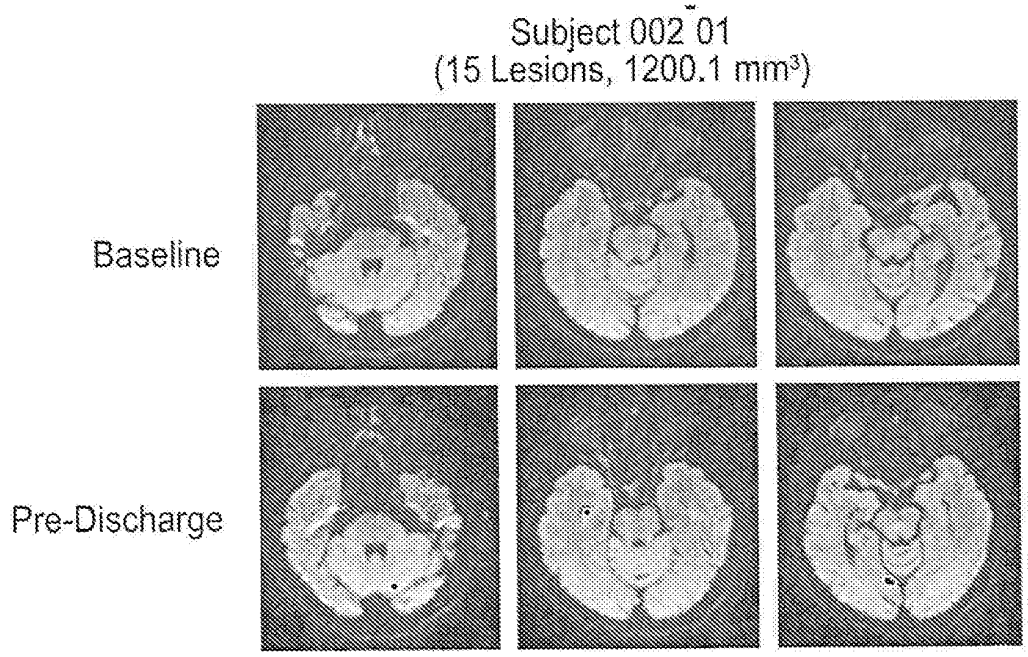



FIG. 15G

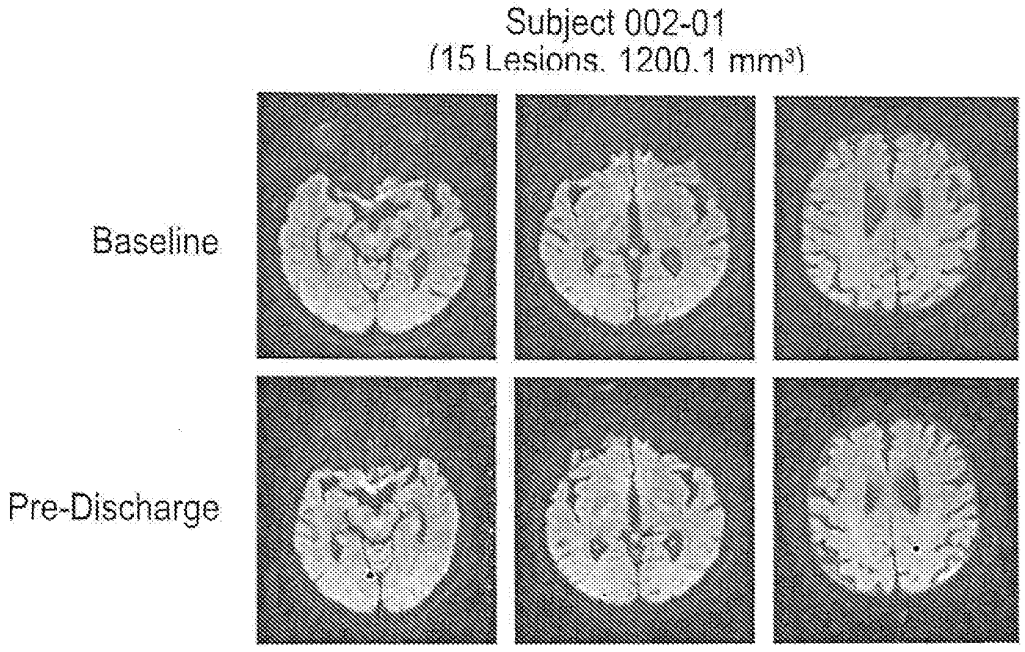



FIG. 15H

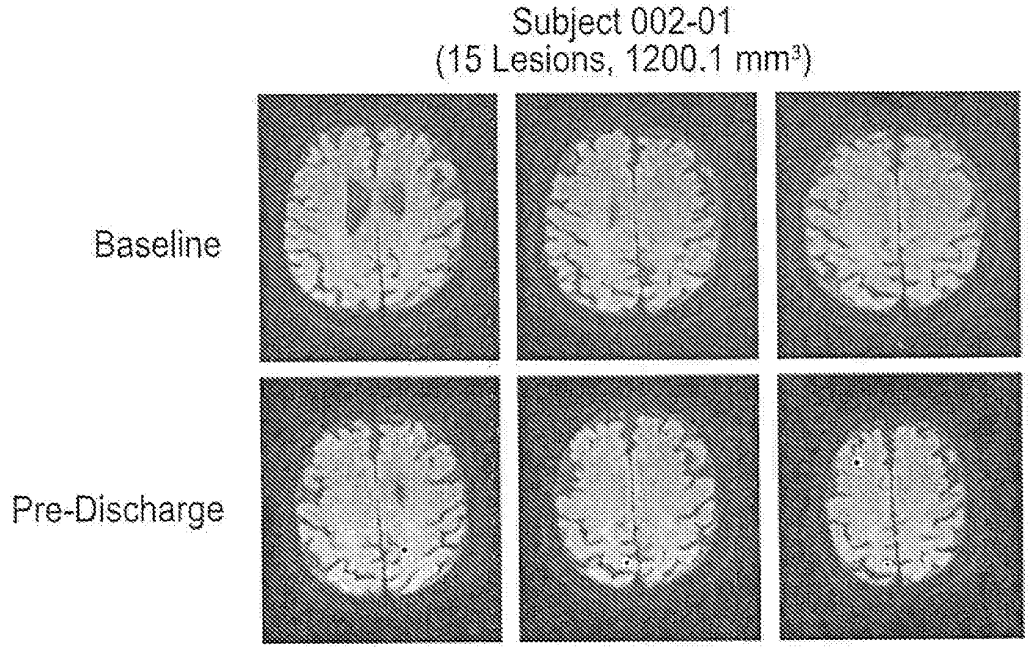



FIG. 15I

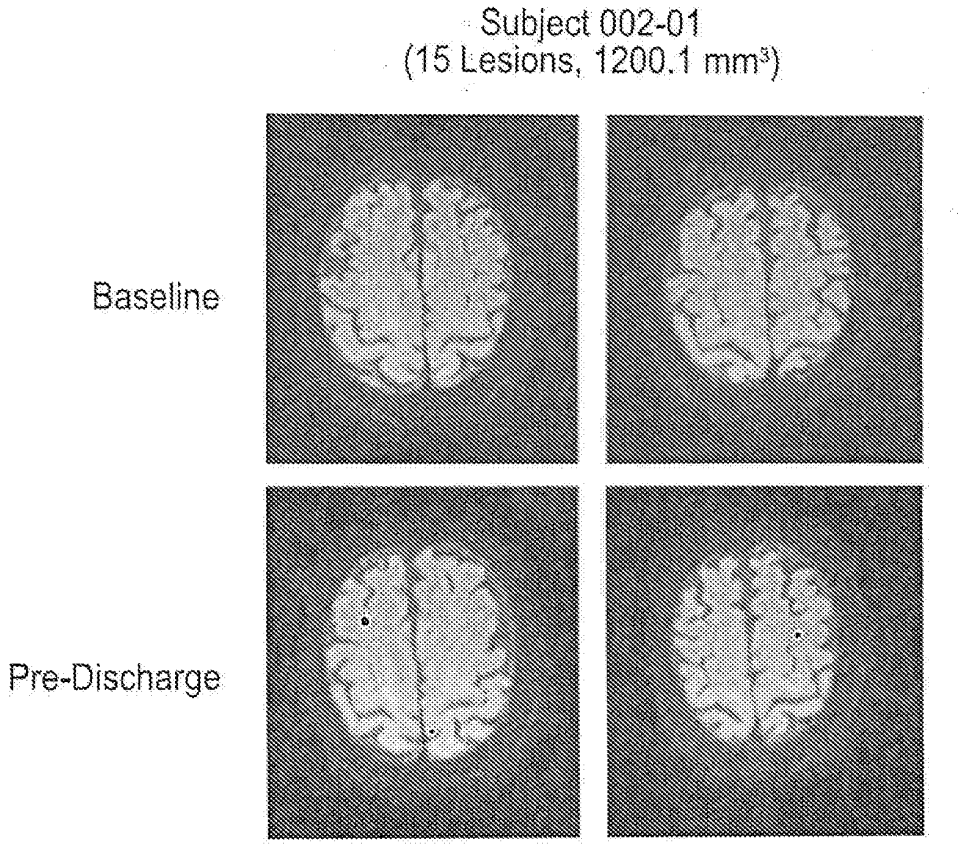



FIG. 15J

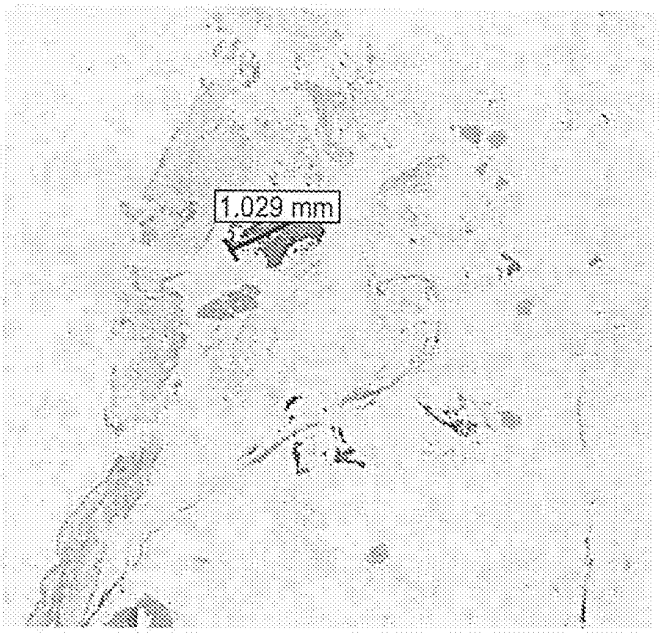



FIG. 16A

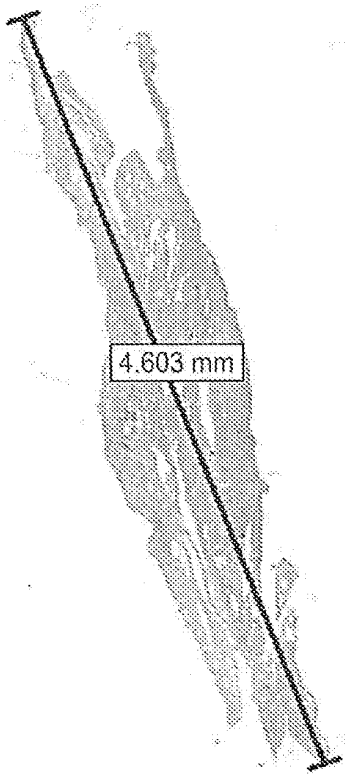



FIG. 16B

# INTERNATIONAL SEARCH REPORT

International application No
PCT/US2019/020952

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/01
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X<br>Y<br><br><br>A | US 2013/245669 A1 (BASU SHUBHAYU [US] ET AL) 19 September 2013 (2013-09-19)<br>paragraphs [0100], [0101], [0105], [0093], [0094]; claims; figures<br>-----<br>US 2012/179033 A1 (MERHI WILLIAM M [US]) 12 July 2012 (2012-07-12)<br>paragraph [0094]; figure 12<br>----- | 1-13,15,<br>16<br>14,<br>31-34,<br>39,41-48<br>35-38,40<br><br>14 |
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[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 10 May 2019 | 21/05/2019 |

| Name and mailing address of the ISA/ | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040,<br>Fax: (+31-70) 340-3016 | Douskas, K |

1

Form PCT/ISA/210 (second sheet) (April 2005)

## INTERNATIONAL SEARCH REPORT

International application No
PCT/US2019/020952

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
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| A | US 2012/172915 A1 (FIFER DANIEL W [US] ET AL) 5 July 2012 (2012-07-05) paragraphs [0165] - [0182]; figure 36 ----- | 1-7 |
| Y | US 2014/180329 A1 (KRAHBICHLER ERIK [SE]) 26 June 2014 (2014-06-26) paragraph [0129]; claims; figures ----- | 31-34, 39,41-48 |

1

Form PCT/ISA/210 (continuation of second sheet) (April 2005)

## INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2019/020952

**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 17-30, 49-63
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (2)) (April 2005)

## INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2019/020952

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
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| 63/397,649 | 12 August 2022 (12.08.2022) | US |


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(74) Agent: **CASHDOLLAR, Benjamin D.** et al.; PERKINS COIE LLP, P.O. Box 1247, Seattle, Washington 98111-1247 (US).


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(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, CV, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SC, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, ME, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).


(54) Title: DILATOR FOR VASCULAR ACCESS SYSTEMS, AND ASSOCIATED DEVICES AND METHODS

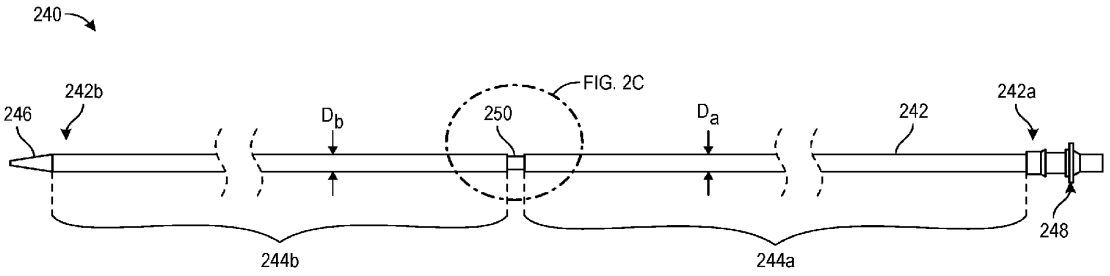



*FIG. 2A*

(57) Abstract: Disclosed herein are dilators for vascular access systems, and associated devices and methods. In some embodiments, a dilator includes an elongate body having a diameter that is generally constant or uniform along the length of the body. The diameter can be sized to correspond with a catheter of a vascular access system, such that the dilator can be positioned within the catheter with little or no gaps or spacing between the dilator and an interior of the catheter. Additionally, or alternatively, the body of the dilator can include multiple body regions, each having one or more respective mechanical properties. In these and other embodiments, the dilator can be configured to interface with at least a portion of the vascular access system. For example, the dilator can include one or more notches configured to couple the dilator to the vascular access system via a valve of the vascular access system.

WO 2023/215779 A2

*[Continued on next page]*

**Published:**

— *without international search report and to be republished upon receipt of that report (Rule 48.2(g))*

# DILATOR FOR VASCULAR ACCESS SYSTEMS, AND ASSOCIATED DEVICES AND METHODS

## CROSS-REFERENCE TO RELATED APPLICATION(S)

**[0001]** This application claims benefit of U.S. Patent Application No. 63/338,266, filed May 4, 2022 and U.S. Patent Application No. 63/397,649, filed August 12, 2022, each of which is herein incorporated by reference in its entirety.

## TECHNICAL FIELD

**[0002]** The present technology generally relates to dilators for vascular access systems, and associated devices and methods.

## BACKGROUND

**[0003]** Thrombosis is the local coagulation or clotting of the blood in a part of the circulatory system, and a thrombus is a blood clot formed in situ within the vascular system. A venous thrombus is a blood clot that forms within a vein. A common type of venous thrombosis is a deep vein thrombosis (DVT), which is the formation of a blood clot within a deep vein (e.g., predominantly in the legs). Nonspecific signs of a thrombosis may include pain, swelling, redness, warmness, and engorged superficial veins.

**[0004]** If the thrombus breaks off (embolizes) and flows towards the lungs, it can become a life-threatening pulmonary embolism (PE) (e.g., a blood clot in the lungs). In addition to the loss of life that can arise from PE, DVT can cause significant health issues such as post thrombotic syndrome, which can cause chronic swelling, pressure, pain, and ulcers due to valve and vessel damage. Further, DVT can result in significant health-care costs either directly or indirectly through the treatment of related complications and inability of patients to work.

**[0005]** Existing methods for treating DVT and PE often involve treating the DVT or PE with a catheter system that is advanced through the patient's vasculature, such as along a venous access path. Such catheter systems—especially those having a large size (e.g., greater than 16 French)—often include a navigation component, such as a smaller catheter or a dilator, that may be used to dilate the patient's vasculature and guide a large catheter to a target treatment site. For example, the larger catheter may be inserted over the navigation component, using the navigation component as a "rail" to guide the larger catheter to the target treatment site.

**[0006]** However, during advancement of a catheter through the vasculature, the navigation component and/or the catheter can experience considerable force or resistance from the patient's vasculature. In some instances, this may result in practitioners unintentionally injuring patients by over-advancing large catheters along navigation components. Furthermore, the force against the navigation component can cause the navigation component to move or backslide relative to the catheter. If the navigation component bends or flexes relative to the catheter, it can hinder a practitioner's ability to advance the navigation component and catheter together through the patient's vasculature. If the navigation component backslides far enough through the catheter, the edge of the catheter can be exposed and may cause damage to a percutaneous access site or the vasculature of the patient.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0007]** Many aspects of the present technology can be better understood with reference to the following drawings. The components in the drawings are not necessarily to scale. Instead, emphasis is placed on illustrating clearly the principles of the present disclosure.

**[0008]** Figure 1 is a partially schematic side view of a vascular access system configured in accordance with the present technology.

**[0009]** Figures 2A and 2B are a side view and a side cross-sectional view, respectively, of a dilator configured in accordance with embodiments of the present technology.

**[0010]** Figure 2C is an enlarged perspective view of region 2C of the dilator shown in Figure 2A in accordance with embodiments of the present technology.

**[0011]** Figures 3A and 3B are side cross-sectional views of the dilator of Figures 2A-2C positioned within a valve of the vascular access system of Figure 1 in accordance with embodiments of the present technology.

**[0012]** Figures 4A and 4B are perspective views of the dilator of Figures 2A–2C positioned within the vascular access system of Figure 1 in accordance with embodiments of the present technology.

## DETAILED DESCRIPTION

**[0013]** The present technology is generally directed to navigation components ("dilators") for vascular access systems, and associated devices and methods. In some embodiments, a dilator includes an elongate body having a diameter that is generally constant or uniform along

the length of the body. The diameter can be sized to correspond with a catheter of a vascular access system, such that the dilator can be positioned within the catheter with little or no gaps or spacing between the dilator and the interior of the catheter. In these and other embodiments, the body of the dilator can include multiple body regions, each having one or more respective mechanical properties. In at least some embodiments, for example, the dilator includes a first body region having a first flexibility profile and a second body region having a second flexibility profile greater than the first flexibility profile, such that the second body region is more flexible than the first body region. The second body region can be distal from the first body region, such that the less flexible/stiffer first body region can provide a portion of the dilator against which force can be applied to advance the dilator through the patient's vasculature, and the less stiff/more flexible second body region can provide improved navigation response and/or control while advancing the dilator through the patient's vasculature.

**[0014]** Currently existing dilators may be tapered or sloped to provide flexibility. For example, the diameter of a tapered dilator can decrease toward the tapered dilator's distal tip, with the decreased diameter providing increased flexibility toward the distal tip. However, these tapered dilators can be difficult to secure relative to vascular access devices such as catheters. For example, the tapered shape of these dilators can lead to gaps or spacing between the tapered dilator and the catheter when the tapered dilator is positioned within the catheter, which can allow the tapered dilators to bend or flex within the catheter during use. This bending or flexing can reduce control and/or navigational precision during a procedure. In contrast to the current sloped dilators, the dilators of the present technology can have generally constant or uniform diameters that improve these dilators' fit within vascular access devices, and/or may reduce or prevent unwanted flexing or bending of these dilators during a procedure. Additionally, or alternatively, the respective mechanical properties of the body regions of the dilators can be selected to improve these dilators' flexibility.

**[0015]** Additionally or alternatively, the dilator can be configured to interface with at least a portion of the vascular access system. In some embodiments, the dilator includes one or more notches. Each of the notches can extend at least partially or fully around a longitudinal axis of the body of the dilator, and can be configured to couple the dilator to the vascular access system via a valve of the vascular access system. For example, the valve can include one or more internal components or tethers configured to open and/or close a path through the valve. When the dilator is positioned within the valve with one of the notches aligned with the tether, the tether can be inserted at least partially into the notch to thereby create a resistive force or

interference fit that inhibits or prevents further movement of the dilator relative to the valve (and/or movement of the valve relative to the dilator). Each of the notches can be spaced along the length of the dilator such that, when coupled via the valve, each notch can be associated with a different position of the dilator relative to the vascular access system and/or a different length of the dilator that extends beyond the vascular access system. Because each notch can inhibit further movement of the dilator and/or the vascular access system relative to one another, the positions of the one or more notches can be configured to inhibit or prevent over-insertion of the dilator, and/or can provide a user with increased control over an amount of the dilator that extends beyond the vascular access system.

**[0016]** Certain details are set forth in the following description and in Figures 1–4B to provide a thorough understanding of various embodiments of the present technology. In other instances, well-known structures, materials, operations, and/or systems often associated with intravascular procedures, clot removal procedures, catheters, and the like are not shown or described in detail in the following disclosure to avoid unnecessarily obscuring the description of the various embodiments of the technology. Those of ordinary skill in the art will recognize, however, that the present technology can be practiced without one or more of the details set forth herein, and/or with other structures, methods, components, and so forth.

**[0017]** The terminology used below is to be interpreted in its broadest reasonable manner, even though it is being used in conjunction with a detailed description of certain examples of embodiments of the technology. Indeed, certain terms may even be emphasized below; however, any terminology intended to be interpreted in any restricted manner will be overtly and specifically defined as such in this Detailed Description section.

**[0018]** The accompanying Figures depict embodiments of the present technology and are not intended to be limiting of its scope unless expressly indicated. The sizes of various depicted elements are not necessarily drawn to scale, and these various elements may be enlarged to improve legibility. Component details may be abstracted in the Figures to exclude details such as position of components and certain precise connections between such components when such details are unnecessary for a complete understanding of how to make and use the present technology. Many of the details, dimensions, angles and other features shown in the Figures are merely illustrative of particular embodiments of the disclosure. Accordingly, other embodiments can have other details, dimensions, angles and features without departing from the present technology. In addition, those of ordinary skill in the art will appreciate that further

embodiments of the present technology can be practiced without several of the details described below.

**[0019]** With regard to the terms "distal" and "proximal" within this description, unless otherwise specified, the terms can reference a relative position of the portions of a catheter subsystem with reference to an operator and/or a location in the vasculature. Also, as used herein, the designations "rearward," "forward," "upward," "downward," and the like are not meant to limit the referenced component to a specific orientation. It will be appreciated that such designations refer to the orientation of the referenced component as illustrated in the Figures; the systems of the present technology can be used in any orientation suitable to the user.

**[0020]** Figure 1 is a partially schematic side view of a vascular access system 100 ("the system 100") configured in accordance with embodiments of the present technology. The system 100 can also be referred to as an aspiration assembly, a clot treatment system, a clot removal system, a thrombectomy system, an introducer sheath assembly, and/or the like. In the illustrated embodiment, the system 100 includes a tubing assembly 110 fluidly coupled to a catheter 120 via a valve 130. In some embodiments, the catheter 120 is an elongate member configured to be inserted into and through a patient's vasculature and used to, for example, treat clot material therein. In other embodiments, the catheter 120 can be an introducer sheath configured to be inserted through the skin and tissue tract of the patient to provide an access site through which other components (e.g., other catheters used to treat clot material) can traverse to easily access the vasculature. Accordingly, while referred to as "catheter 120," the catheter 120 can comprise an introducer sheath, an access sheath, and/or another type of elongate member configured to be inserted through the skin and tissue tract and/or to traverse the vasculature of a patient. In general, the system 100 (i) can include features generally similar or identical to those of the clot treatment systems described in detail in U.S. Patent Application No. 16/536,185, filed August 8, 2019, and titled "SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS," which is incorporated herein by reference in its entirety, and/or (ii) can be used to treat/remove clot material from a patient (e.g., a human patient) using any of the methods described in detail therein.

**[0021]** In the illustrated embodiment, the catheter 120 includes a proximal region or portion 122a and a distal tip region or portion 122b opposite the proximal region 122a. The proximal region 122a can include a proximal terminus 126a of the catheter 120, and the distal tip region 122b can include a distal terminus 126b of the catheter 120. The catheter 120 further

defines a lumen 124 (shown using dashed-line in Figure 1) extending entirely therethrough from the proximal region 122a to the distal tip region 122b. The lumen 124 and/or the catheter 120 can at least partially define a longitudinal axis X of the system 100.

**[0022]** The valve 130 is fluidly coupled to the lumen 124 of the catheter 120 and can be integral with or coupled to the proximal region 122a of the catheter 120 such that these components move together. In some embodiments, the valve 130 is a hemostasis valve that is configured to maintain hemostasis during a clot removal procedure by preventing fluid flow in a proximal direction P through the valve 130 as various components such as dilators, delivery sheaths, pull members, guidewires, interventional devices, other aspiration catheters, and so on are inserted through the valve 130 to be delivered through the catheter 120 to a treatment site in a blood vessel. The valve 130 can include a branch or side port 102 configured to fluidly couple the lumen 124 of the catheter 120 to the tubing assembly 110. In some embodiments, the valve 130 can be a valve of the type disclosed in U.S. Patent Application No. 16/117,519, filed August 30, 2018, and titled "HEMOSTASIS VALVES AND METHODS OF USE," which is incorporated herein by reference in its entirety.

**[0023]** In the illustrated embodiment, the tubing assembly 110 fluidly couples the catheter 120 to a pressure source 104, such as a syringe. The pressure source 104 can be configured to generate (e.g., form, create, charge, build-up) a vacuum (e.g., negative relative pressure) and store the vacuum for subsequent application to the catheter 120. The tubing assembly 110 can include one or more tubing sections 112 (individually labeled as a first tubing section 112a and a second tubing section 112b), at least one fluid control device 114 (e.g., a valve), and at least one connector 116 (e.g., a Toomey tip connector) for fluidly coupling the tubing assembly 110 to the pressure source 104 and/or other suitable components. In some embodiments, the fluid control device 114 is a stopcock that is fluidly coupled to (i) the side port 102 of the valve 130 via the first tubing section 112a and (ii) the connector 116 via the second tubing section 112b. The fluid control device 114 is externally operable by a user to regulate the flow of fluid therethrough and, specifically, from the lumen 124 of the catheter 120 to the pressure source 104. In some embodiments, the connector 116 is a quick-release connector (e.g., a quick disconnect fitting) that enables rapid coupling/decoupling of the catheter 120 and the fluid control device 114 to/from the pressure source 104.

**[0024]** During a clot treatment procedure, at least a portion of the system 100, such as the distal terminus 126b and/or distal tip region 122b of the catheter 120, can be inserted through

the vasculature of a patient. In some embodiments, the system 100 is inserted through an introducer sheath that traverses the skin and tissue of the patient to provide an access site. When the catheter 120 is positioned at a desired position relative to clot material (e.g., a pulmonary embolism, deep vein thrombosis) within the patient, a user can first close the fluid control device 114 before generating a vacuum in the pressure source 104 by, for example, withdrawing the plunger of a syringe coupled to the connector 116. In this manner, a vacuum is charged within the pressure source 104 (e.g., a negative pressure is maintained) before the pressure source 104 is fluidly connected to the lumen 124 of the catheter 120. To aspirate the lumen 124 of the catheter 120, the user can open the fluid control device 114 to fluidly connect the pressure source 104 to the catheter 120 and thereby apply or release the vacuum stored in the pressure source 104 to the lumen 124 of the catheter 120. Opening the fluid control device 114 instantaneously or nearly instantaneously applies the stored vacuum pressure to the tubing assembly 110 and the catheter 120, thereby generating a suction pulse throughout the catheter 120 that can aspirate the clot material into the catheter 120. In particular, the suction is applied at the distal tip region 122b of the catheter 120 to suck/aspirate at least a portion of the clot material proximate the distal tip region 122b into the lumen 124 of the catheter 120. Additionally, or alternatively, the catheter 120 can act as an introducer sheath and can be inserted through the skin and tissue of a patient and partially into a vessel to provide an access point through which other medical instruments can be delivered and/or otherwise used to treat the patient.

**[0025]** Figures 2A and 2B are a side view and a side cross-sectional view, respectively, of a navigation component or dilator 240 configured in accordance with embodiments of the present technology. The dilator 240 is configured to be inserted into and advanced together with the catheter 120 of Figure 1. The dilator 240 includes a generally elongate body 242 having a proximal region or portion 242a, a distal tip region or portion 242b opposite the proximal region 242a, and one or more body segments or regions 244 (individually identified as a first body region 244a and a second body region 244b) extending at least partially between the proximal region 242a and the distal tip region 242b. The dilator 240 can further include a tip 246 (e.g., an atraumatic tip) in or near the distal tip region 242b, a coupling component 248 in or near the proximal region 242a, and one or more notches 250 (e.g., insertion positioning features). The coupling component 248 can include a twist-lock connector, a luer connector, and/or another suitable coupling component, and can be configured to couple or lock the dilator 240 to a valve of a vascular access system, such as the valve 130 of the system 100 of Figure 1. In the illustrated embodiment, the tip 246 is distal from the second body region 244b and the coupling component

248 is proximal from the first body region 244a. In other embodiments, the second body region 244b can include all or part of the tip 246, and/or the first body region 244a can include and/or be positioned within all or part of the coupling component 248. The notch 250 is described in further detail below with reference to Figure 2C.

**[0026]** In some embodiments, the body 242, the tip 246, and/or the coupling component 248 can be hollow, as shown in Figure 2B, such that a guide wire (not shown) can be positioned within the dilator 240 and used to aid the navigation thereof. In such embodiments, each of the body regions 244 can have a respective thickness T, individually labeled in Figure 2B as a first thickness $T_a$ and a second thickness $T_b$. The first and second thicknesses $T_{a-b}$ can be the same or different, and/or each thickness $T_{a-b}$ may be constant or variable along all or part of the length of the respective body region 244a-b.

**[0027]** The first body region 244a, the second body region 244b, the tip 246, and/or the coupling component 248 can each be formed from one or more polymers, and/or other suitable materials. For example, the first and second body regions 244a-b can be formed from the same or different materials.

**[0028]** Each of the body regions 244a-b can have a respective outer dimension or diameter D, individually labeled as a first diameter $D_a$ and a second diameter $D_b$. In some embodiments, the diameters $D_{a-b}$ of the body regions 244a-b can be different from each other and/or vary along their respective lengths, such that the first and second body regions 244a-b, and/or one or more portions thereof, can have different diameters. In the illustrated embodiment, the first and second diameters $D_{a-b}$ are generally similar or identical such that the body 242 of the dilator 240 has a substantially uniform diameter. In these and other embodiments, one or more of the diameters $D_{a-b}$ can correspond to and/or be less than an inner dimension of a catheter, such as an inner diameter of the lumen 124 of the catheter 120 (Figure 1). Accordingly, the dilator 240 can be positioned within the catheter 120 (e.g., via the valve 130) with at least a portion of the tip 246 extending distally beyond the distal terminus 126b of the catheter 120 (Figure 1).

**[0029]** Each of the body regions 244 can have one or more respective mechanical properties, such as a hardness, stiffness, durometer, flexibility, rigidity, Young's modulus, density, and/or the like. The mechanical properties (e.g., varying durometer) can give the body regions 244 different flexibility profiles. In some embodiments, individual ones of the body regions 244 can include one or more coils, braids, and/or other structures configured to increase or decrease the flexibility profile, e.g., relative to one or more other body regions 244. In at least

some embodiments, the first body region 244a has a first flexibility profile and the second body region 244b has a second flexibility profile greater than the first flexibility profile such that the second body region 244b is less stiff/more flexible than the first body region 244a. For example, in the illustrated embodiment the first body region 244a has a first durometer and the second body region 244b has a second durometer less (e.g., less stiff/more flexible) than the first durometer. In some aspects of the present technology, the less-stiff second body region 244b can improve the navigability of the dilator 240 while traveling through vasculature, while the more-stiff first body region 244a can improve control of and/or force transfer to (e.g., the "pushability" and/or column strength of) the dilator 240 while navigating through the vasculature. Although the dilator 240 shown in Figures 2A and 2B includes two body regions 244a-b, in other embodiments the dilator 240 can include more body regions 244, and each of the body regions 244 can have one or more respective mechanical properties greater than, equal to, or less than one or more of the other body regions 244. Accordingly, in some embodiments the dilator 240 includes two or more body regions 244 having the same diameter but different stiffnesses, durometers, flexibilities, etc.

**[0030]** Figure 2C is an enlarged perspective view of region 2C of Figure 2A in accordance with embodiments of the present technology. In the illustrated embodiment, the notch 250 defines/comprises a recessed area extending at least partially or fully around the body 242 of the dilator 240, such as circumferentially around a longitudinal axis Y of the body 242. Accordingly, the notch 250 can define a third diameter $D_c$ of the dilator 240 that can be less than the first diameter $D_a$ and/or the second diameter $D_b$. In the illustrated embodiment, the notch 250 is positioned between the first body region 244a and the second body region 244b. In other embodiments, the notch 250 can be positioned at least partially within one or both of the body regions 244a-b. In these and other embodiments, the dilator 240 can include a plurality of notches 250, individual ones of which can be positioned at least partially between the first and second body regions 244a-b, at least partially within the first body region 244a, at least partially within the second body region 244b, or at another suitable position along the dilator 240.

**[0031]** Figures 3A and 3B are side cross-sectional views of the dilator 240 positioned within the valve 130 in accordance with embodiments of the present technology. More specifically, in Figure 3A the dilator 240 is at a first position within the valve 130, and in Figure 3B the dilator 240 has been moved (e.g., distally) to a second position within the valve 130, as shown by arrow A. In Figures 3A and 3B, the dilator 240 includes the notch 250 ("first notch 250") and an additional second notch 350 positioned proximally from the first notch 250. The

second notch 350 can be at least generally similar or identical in structure and/or function to the first notch 250.

**[0032]** Referring to Figures 3A and 3B together, the valve 130 includes a first or distal aperture 332a, a second or proximal aperture 332b, and a central lumen 334 extending therebetween. The distal aperture 332a can be fluidly coupled to a catheter, such as the catheter 120 of Figure 1. The valve 130 further includes a filament or tether 336 operably coupled to one or more actuators or buttons 338 (individually identified as a first button 338a and a second button 338b in Figures 3A and 3B). The tether 336 can be configured to open and/or close the central lumen 334 of the valve 130, e.g., to form a substantially fluid-impermeable seal that inhibits or prevents fluid communication between the distal and proximal apertures 332a-b. In the illustrated embodiment, for example, the buttons 338 are biased outwardly by springs 339 (individually identified as a first spring 339a and a second spring 339b in Figures 3A and 3B) to a first position shown in Figure 3A. When the buttons 338a-b are in the first position, the buttons 338a-b draw the tether 336 taught to constrict and seals the central lumen 334. A user can depress the buttons 338 to a second position shown in Figure 3B against the biasing force of the springs 339 to relax the tether 336 and thereby unconstrict and unseal the central lumen 334. In general, the valve 130 (i) can include at least some features that are generally similar or identical to those of the hemostasis valves described in detail in U.S. Patent No. 11,000,682, filed August 30, 2018, and titled "HEMOSTASIS VALVES AND METHODS OF USE," which is incorporated herein by reference in its entirety, and/or (ii) can be used to treat/remove clot material from a patient (e.g., a human patient) using any of the methods described in detail therein.

**[0033]** In some embodiments, the tether 336 is configured to releasably couple the dilator 240 to the valve 130 by interfacing with one of the notches 250, 350. For example, in the illustrated embodiment the tether 336 constricts around the central lumen 334 when the buttons 338a-b are in the first position, as shown in Figure 3A. Accordingly, when the dilator 240 is inserted through the proximal aperture 332b, the first notch 250 can be positioned in alignment with the tether 336 to thereby allow at least part of the tether 336 to be driven toward and/or into the first notch 250 and create a resistive force/interference fit that couples the dilator 240 to the valve 130. The resistive force/interference fit inhibits or prevents further movement (e.g., proximal and/or distal movement) of the dilator 240 relative to the valve 130.

**[0034]** The dilator 240 can be uncoupled from the valve 130 by actuating/pressing one or more of the buttons 338, as shown in Figure 3B, to move the tether 336 radially outward away from the longitudinal axis of the central lumen 334 and radially outwardly from/out of the first notch 250. Pressing/actuating one or more of the buttons 338 can thereby allow further movement (e.g., proximal and/or distal movement) of the dilator 240 relative to the valve 130. In some embodiments, the resistive force/interference fit can be overcome by applying increased force to the dilator 240 and/or the valve 130, e.g., to displace the tether 336 from the first notch 250 and allow further movement of the dilator 240 and/or the valve 130 relative to each other without pressing/actuating one or more of the buttons 338. In Figure 3B, the dilator 240 has been moved further distally through the valve 130 from a proximal position (Figure 3A) to a more distal position. In some embodiments, the dilator 240 can be advanced further distally until the second notch 350 is positioned in alignment with the tether 336. When the second notch 350 is aligned with the tether 336, the tether 336 can be driven radially into the second notch 350, as described previously with reference to the first notch 250, and thereby again couple the dilator 240 to the valve 130.

**[0035]** Referring to Figures 1–3B together, the dilator 240 can be inserted distally through the valve 130 (e.g., via the proximal aperture 332b) and extend fully through the lumen 124 past the distal terminus 126b of the catheter 120, such that the tip 246 of the dilator 240 is positioned beyond the distal terminus 126b of the catheter 120. The notch 250 can be configured to control the position of the dilator 240 relative to the catheter 120, e.g., during insertion. For example, when the dilator 240 is inserted (e.g., distally) through the valve 130 into the catheter 120, the notch 250 can interface with (e.g., releasably couple to) the tether 336 to thereby create a resistive force or interference fit that at least inhibits or prevents further movement (e.g., proximal and/or distal movement) of the dilator 240 relative to the catheter 120. A magnitude of the resistive force/interference fit between the notch 250 and the valve 130 (e.g., the tether 336) can correspond to the difference in size between the third diameter $D_c$ and another diameter of a body region of the dilator 240, such as the first diameter $D_a$ of the first body region 244a and/or the second diameter $D_b$ of the second body region 244b.

**[0036]** Generally, a difference in size between the third diameter $D_c$ and a diameter of a body region positioned proximal and adjacent to the notch 250 (e.g., the first diameter $D_a$ of the first body region 244a) can be associated with a resistive force/interference fit that inhibits or prevents further distal movement of the dilator 240 through the system 100 (e.g., through the catheter 120) and/or further proximal movement of the system 100 over the dilator 240.

Additionally, a difference in size between the third diameter $D_c$ and a diameter of a body region positioned distal and adjacent to the notch 250 (e.g., the second diameter $D_b$ of the second body region 244b) can be associated with a resistive force/interference fit that at inhibits or prevents further proximal movement of the dilator 240 through the system 100 and/or further distal movement of the system 100 over the dilator 240. For example, if the difference between third diameter $D_c$ and the first diameter $D_a$ is between about 0.1mm and about 0.5mm, the resistive force/interference fit can be relatively slight and partially prevent further (distal) movement of the dilator 240 and/or further (proximal) movement of the system 100. In such embodiments, the resistive force/interference fit may provide a tactile indication or sensation (e.g., a "clicking" sound or sensation perceptible to a user) associated with the relative positions of the dilator 240 and the system 100, and any resistance/interference to further movement may be overcome by applying increased force to the dilator 240 and/or the system 100 to decouple the notch 250 and the valve 130 (e.g., the tether 336). As another example, if the difference between the third diameter $D_c$ and the first diameter $D_a$ is greater than 0.5mm, the resistive force/interference fit can be relatively substantial and fully prevent further (distal) movement of the dilator 240 and/or further (proximal) movement of the system 100. In such embodiments, the resistive force/interference fit may be overcome by actuating one or more of the buttons 338 of the valve 130 to release the dilator 240. Dilators with greater diameters can include notches having a greater depth (e.g., corresponding to a greater difference between the third diameter $D_c$ and the first and/or second diameters $D_a$, $D_b$) than dilators with a comparatively lesser depth, and greater notch depths are expected to provide increased resistive forces/interference fits than lesser notch depths.

**[0037]** In some embodiments, the magnitude of the resistive force/interference fit is based at least partially on a spring force applied by the valve 130 (e.g., via the springs 339a-b) to the dilator 240. For example, springs with a relatively high spring constant are expected to provide a greater resistive force than springs with a comparatively lower spring constant.

**[0038]** With the dilator 240 positioned within the catheter 120, the dilator 240 and the catheter 120 can together be inserted into a patient (e.g., a human patient) during a clot treatment procedure. For example, the dilator 240 and the catheter 120 can be inserted into and advanced together through a blood vessel of the patient to a target location in the blood vessel. In some embodiments, after the dilator 240 has been inserted through the catheter 120, because the dilator 240 and the catheter 120 can move relative to one another, the catheter 120 can be advanced (e.g., distally, telescopically, etc.) over the dilator 240, e.g., using the dilator 240 as a guide or

"rail" to position the catheter 120 at or near the target location. With the catheter 120 positioned at or near the target location, the dilator 240 can then be retracted (e.g., proximally) through the catheter 120 to allow for other intravascular medical devices to be introduced into the patient via the catheter 120 and/or for aspiration of the catheter 120.

**[0039]** In some aspects of the present technology, the uniform diameter and varying stiffness of the dilator 240 is expected to improve the control and advancement characteristics of the dilator 240 and the catheter 120. For example, the uniform diameter of the dilator 240 is expected to better match the inner dimension of the lumen 124 of the catheter 120 which, in turn, can reduce or eliminate gaps or spacing between the dilator 240 and the catheter 120. Reducing/eliminating these gaps can at least partially inhibit or prevent the dilator 240 from flexing or buckling within the catheter 120 when navigating through a patient's vasculature, which can improve control of the dilator's movement during a procedure. Additionally, or alternatively, the uniform diameter of the dilator 240 is expected to improve the durability (e.g., crush resistance) of the catheter 120 when the dilator 240 is positioned within the catheter 120. For example, reducing/eliminating the gaps can also reduce the size of, or eliminate entirely, one or more crush zones associated with the gaps or spacing between the dilator 240 and the catheter 120 and in which the catheter 120 can be crushed or buckled during use. Furthermore, the variable mechanical properties of the dilator's body regions 244a-b can improve the dilator's flexibility and/or response to forces exerted on the dilator 240 (e.g., by a practitioner and/or from the catheter 120) during a procedure. In these and other embodiments, the notch 250 is expected to further improve the control and advancement characteristics of the dilator 240 and/or the system 100. For example, the magnitude of the resistive force/interference fit between the notch 250 and the valve 130 (e.g., the tether 336) can be configured to inhibit or prevent over-insertion of the dilator 240, which may damage a patient's vasculature. Additionally, or alternatively, the tactile feedback or sensation provided by the interference fit between the notch 250 and the valve 130 can provide (e.g., to a user) an indication of the relative position of the dilator 240 within the system 100.

**[0040]** Figures 4A and 4B are perspective views of the dilator 240 positioned within the system 100, in accordance with embodiments of the present technology. More specifically, Figure 4A shows the dilator 240 in a first position or state 401a, and Figure 4B shows the dilator 240 in a second position or state 401b. In Figures 4A and 4B, the coupling component 248 of the dilator 240 includes one or more luer-coupling features 452 (individually identified as a first luer-coupling feature 452a and a second luer-coupling feature 452b in Figures 4A and 4B) and/or

one or more stopping features 454 (individually identified as a first stopping feature 454a and a second stopping feature 454b). Individual ones of the stopping features 454 can be spaced apart and/or positioned proximally from one or more of the luer-coupling features 452.

**[0041]** Referring to Figure 4A, the dilator 240 can be inserted through the system 100 until the dilator 240 is coupled to the valve 130 via the notch 250 (Figures 2A-3B), as described previously herein with reference to Figures 3A and 3B. With the dilator 240 and the system 100 in the first state 401a, a first length L1 of the dilator 240 can extend distally beyond the distal terminus 126b of the catheter 120. In the illustrated embodiment, the first length L1 includes the tip 246 and a portion of the body 242. Additionally, or alternatively, the first length L1 can extend from about 1 cm to about 5 cm beyond the distal terminus 126b. In the first state 401a, the dilator 240 and the catheter 120 can be in a "standard" or "vascular access" mode or configuration in which the catheter 120 and the dilator 240 can be inserted into and/or used to navigate through a patient's vasculature, e.g., to a target location, as described previously herein. The dilator 240 may then be removed from the catheter 120 so that the system 100 can be used to treat and/or remove clot material from within the patient.

**[0042]** Referring to Figure 4B, the dilator 240 can be advanced from the first state 401a to the second state 401b by advancing the dilator 240 distally through the system 100 and/or retracting the system 100 proximally over the dilator 240. In the second state 401b, a second length L2 of the dilator 240 can extend distally beyond the distal terminus 126b. The second length L2 can be greater than the first length L1. In at least some embodiments, for example, the second length L2 is between about 5cm and about 20cm, such as at least 15cm, or another suitable length therebetween. In the second state 401b, the dilator 240 and the catheter 120 can be in a "rail" or "telescoping delivery" mode or configuration in which the catheter 120 can be advanced into and/or through the patient's vasculature while sliding along and/or otherwise moving over (e.g., telescopically over) the dilator 240. In at least some embodiments, telescopically inserting the catheter 120 over the dilator 240 can include moving from the second state 401b to and/or toward the first state 401a (Figure 4A). In these and other embodiments, once the dilator 240 and/or the catheter 120 are position at or near a target location, the dilator 240 may then be removed from the catheter 120 the so that the system 100 can be used to treat and/or remove clot material from within the patient.

**[0043]** In some embodiments, one or more of the luer-coupling features 452 (Figure 4A) can be coupled to the valve 130 in the second state 401b, for example, to at least partially or

fully prevent further movement (e.g., unintended movement) of the catheter 120 and/or the dilator 240 relative to each other. Additionally, or alternatively, one or more of the stopping features 454 can contact or abut the valve 130 in the second state 401b, to thereby inhibit or prevent (i) further distal movement of the dilator 240 relative to the system 100 and/or (ii) further proximal movement of the system 100 relative to the dilator 240.

**[0044]** As described in detail above, the dilator 240 can include more than one notch (e.g., including the second notch 350 shown in Figures 3A and 3B). Each of the notches can be spaced along the length of the dilator 240 such that, when coupled via the valve 130, each notch can be associated with a different position of the dilator 240 relative to the system 100 and/or a different length of the dilator 240 (e.g., between the first and second lengths L1, L2) that extends beyond the distal terminus 126b. For example, referring to Figures 3A–4B together, the second notch 350 is positioned proximal of the first notch 250 such that the dilator extends farther past the distal terminus 126b of the catheter 120 when the valve 130 is coupled to (e.g., locked to) the dilator 240 at the second notch 350.

**[0045]** Because each notch can inhibit further movement of the dilator 240 and/or the system 100 relative to each other, the positions of one or more of the notches can be configured to inhibit or prevent over-insertion of the dilator 240, and/or can provide a user with increased control over the amount of the dilator 240 that extends beyond the distal terminus 126b. Additionally, when the dilator 240 includes multiple notches, the dilator 240 can be configured to be transitioned between more than the two states 401a-b shown in the illustrated embodiment. For example, the dilator 240 can be configured to be transitioned between at least three, four, five, or more different states.

Examples

**[0046]** Several aspects of the present technology are set forth in the following examples:

1. A dilator, comprising:

a tip;

a coupling component;

a first body region between the tip and the coupling component, wherein the first body region has a first flexibility profile; and

a second body region between the first body region and the tip, wherein the second body region has a second flexibility profile greater than the first flexibility profile,

wherein the first body region and the second body region have a same diameter.

2. The dilator of example 1 wherein the first body region has a first stiffness, wherein the second body region has a second stiffness, and wherein the first stiffness is greater than the second stiffness.

3. The dilator of example 1 or example 2 wherein the first body region has a first durometer, wherein the second body region has a second durometer, and wherein the second durometer is less than the first durometer.

4. The dilator of any of examples 1-3 wherein the first body region comprises a first material, and wherein the second body region comprises a second material different than the first material.

5. The dilator of any of examples 1-4, further comprising a third body region between the tip and the coupling component, wherein the third body region has a third flexibility profile different than the first flexibility profile or the second flexibility profile.

6. The dilator of any of examples 1-5, further comprising a notch positioned between the tip and the coupling component.

7. The dilator of example 6 wherein the notch is positioned between the first body region and the second body region.

8. The dilator of example 6 or example 7 wherein the notch is a first notch, the dilator further comprising a second notch positioned on a proximal or a distal side of the first notch.

9. A vascular access system, comprising:

a valve having a proximal end and a distal end;

a catheter defining a lumen and coupled to the valve; and

a dilator configured to be positioned within the lumen through the valve, wherein the dilator includes—

a first body region having a first flexibility profile; and

a second body region having a second flexibility profile less than the first flexibility profile,

wherein the first body region and the second body region have a same diameter.

10. The vascular access system of example 8 wherein the first body region has a first stiffness, wherein the second body region has a second stiffness, and wherein the first stiffness is greater than the second stiffness.

11. The dilator of example 9 or example 10 wherein the first body region has a first durometer, wherein the second body region has a second durometer, and wherein the second durometer is less than the first durometer.

12. The vascular access system of any of examples 9-11 wherein the first body region comprises a first material, and wherein the second body region comprises a second material different than the first material.

13. The vascular access system of any of examples 9-12, wherein the dilator further includes a notch configured to extend at least partially around a longitudinal axis of the dilator, wherein the valve is configured to be releasably coupled to the dilator via the notch.

14. The vascular access system of example 13 wherein the notch defines a recessed region of the dilator having a notch diameter less than the diameter of the first body region and the second body region.

15. The vascular access system of example 13 or example 14 wherein the valve includes a tether, and wherein the tether is configured to be positioned at least partially within the notch to releasably couple the dilator to the valve.

16. The vascular access system of example 15 wherein the tether is biased in a first direction to releasably couple the dilator to the valve, the valve further comprising a button operably coupled to the tether and configured to move the tether in a second direction, opposite the first direction, to cause the tether to uncouple the dilator from the valve.

17. The vascular access system of any of examples 13–16 wherein the notch is a first notch, and wherein the dilator further includes a second notch positioned on a proximal side or a distal side of the notch.

18. The vascular access system of example 17 wherein the catheter includes a distal terminus, wherein a first length of the dilator extends beyond the distal terminus when the first notch is coupled to the valve, and wherein a second length of the dilator extends beyond the distal terminus when the second notch is coupled to the valve.

19. The vascular access system of example 18 wherein the second length is greater than the first length.

20. A method of treating clot material within a patient, the method comprising:

positioning a dilator within a vascular access system such that a valve of the vascular access system releasably engages a notch of the dilator to inhibit further movement of the dilator relative to the vascular access system;

actuating a button of the valve to release the notch from the valve to allow further movement of the dilator relative to the vascular access system; and

moving the dilator relative to the vascular access system and/or the vascular access system relative to the dilator.

21. The method of example 20 wherein moving the dilator relative to the vascular access system includes advancing the dilator through the vascular access system to increase a length of the dilator that extends beyond a distal terminus of the vascular access system.

22. The method of example 20 wherein moving the vascular access system relative to the dilator includes advancing the vascular access system over the dilator to decrease a length of the dilator that extends beyond a distal terminus of the vascular access system.

23. The method of any of examples 20-22 wherein the notch is a first notch, the method further comprising:

positioning the dilator within the vascular access system such that the valve releasably engages a second notch of the dilator; and

applying a force to the dilator and/or the vascular access system to release the second notch from the valve.

24. The method of example 23 wherein applying the force to release the second notch from the valve includes applying the force to release the second notch from the valve without actuating the button.

25. A vascular access system, comprising:

a dilator extending along a longitudinal axis, wherein the dilator has a varying flexibility profile at least partially along the longitudinal axis, and wherein the dilator defines a notch extending at least partially circumferentially about the longitudinal axis;

a valve having a proximal end and a distal end; and

a catheter coupled to the valve and defining a lumen;

wherein the valve is configured to be releasably coupled to the dilator via the notch to inhibit movement of the dilator relative to the catheter when at least a portion of the dilator is inserted through the valve into the lumen of the catheter.

26. The vascular access system of example 25 wherein the dilator includes a body region having a diameter, and wherein the notch includes a recessed region of the dilator having a notch diameter less than the diameter of the body region.

27. The vascular access system of example 25 or example 26 wherein the valve includes a tether, and wherein the tether is configured to be positioned at least partially within the notch to releasably couple the dilator to the valve.

28. The vascular access system of example 27 wherein the tether is biased in a first direction to releasably couple the dilator to the valve, the valve further comprising a button operably coupled to the tether and configured to move the tether in a second direction, opposite the first direction, to move the tether at least partially out of the notch to uncouple the dilator from the valve.

29. The vascular access system of any of examples 25-28 wherein the notch is a first notch, wherein the portion of the dilator is a first portion, wherein the dilator further defines a second notch extending at least partially circumferentially about the longitudinal axis, and wherein the valve is configured to be releasably coupled to the dilator via the second notch to inhibit movement of the dilator relative to the catheter when at least a second portion of the dilator is inserted through the valve into the lumen of the catheter.

30. The vascular access system of example 29 wherein the catheter includes a distal terminus, wherein a first length of the dilator extends beyond the distal terminus when the first notch is coupled to the valve, and wherein a second length of the dilator extends beyond the distal terminus when the second notch is coupled to the valve.

31. The vascular access system of example 30 wherein the second length is greater than the first length.

32. The vascular access system of any of examples 25-31 wherein the dilator includes a proximal body region having a first flexibility profile and a distal body region having a second flexibility profile greater than the first flexibility profile, wherein the notch is positioned at least partially between the proximal body region and the distal body region.

33. The vascular access system of claim 25 wherein the dilator has a varying durometer at least partially along the longitudinal axis.

**[0047]** The above detailed descriptions of embodiments of the technology are not intended to be exhaustive or to limit the technology to the precise form disclosed above. Although specific embodiments of, and examples for, the technology are described above for illustrative purposes, various equivalent modifications are possible within the scope of the technology as those skilled in the relevant art will recognize. For example, although steps are presented in a given order, alternative embodiments may perform steps in a different order. The various embodiments described herein may also be combined to provide further embodiments.

**[0048]** From the foregoing, it will be appreciated that specific embodiments of the technology have been described herein for purposes of illustration, but well-known structures

and functions have not been shown or described in detail to avoid unnecessarily obscuring the description of the embodiments of the technology. Where the context permits, singular or plural terms may also include the plural or singular term, respectively.

**[0049]** Moreover, unless the word "or" is expressly limited to mean only a single item exclusive from the other items in reference to a list of two or more items, then the use of "or" in such a list is to be interpreted as including (a) any single item in the list, (b) all of the items in the list, or (c) any combination of the items in the list. Additionally, the term "comprising" is used throughout to mean including at least the recited feature(s) such that any greater number of the same feature and/or additional types of other features are not precluded. It will also be appreciated that specific embodiments have been described herein for purposes of illustration, but that various modifications may be made without deviating from the technology. Further, while advantages associated with some embodiments of the technology have been described in the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the technology. Accordingly, the disclosure and associated technology can encompass other embodiments not expressly shown or described herein.

CLAIMS

I/We claim:

1. A dilator, comprising:

a tip;

a coupling component;

a first body region between the tip and the coupling component, wherein the first body region has a first flexibility profile; and

a second body region between the first body region and the tip, wherein the second body region has a second flexibility profile greater than the first flexibility profile,

wherein the first body region and the second body region have a same diameter.

2. The dilator of claim 1 wherein the first body region has a first stiffness, wherein the second body region has a second stiffness, and wherein the first stiffness is greater than the second stiffness.

3. The dilator of claim 1 wherein the first body region has a first durometer, wherein the second body region has a second durometer, and wherein the second durometer is less than the first durometer.

4. The dilator of claim 1 wherein the first body region comprises a first material, and wherein the second body region comprises a second material different than the first material.

5. The dilator of claim 1, further comprising a third body region between the tip and the coupling component, wherein the third body region has a third flexibility profile different than the first flexibility profile or the second flexibility profile.

6. The dilator of claim 1, further comprising a notch positioned between the tip and the coupling component.

7. The dilator of claim 6 wherein the notch is positioned between the first body region and the second body region.

8. The dilator of claim 6 wherein the notch is a first notch, the dilator further comprising a second notch positioned on a proximal or a distal side of the first notch.

9. A vascular access system, comprising:

a valve having a proximal end and a distal end;

a catheter defining a lumen and coupled to the valve; and

a dilator configured to be positioned within the lumen through the valve, wherein the dilator includes—

a first body region having a first flexibility profile; and

a second body region having a second flexibility profile less than the first flexibility profile,

wherein the first body region and the second body region have a same diameter.

10. The vascular access system of claim 9 wherein the first body region has a first stiffness, wherein the second body region has a second stiffness, and wherein the first stiffness is greater than the second stiffness.

11. The vascular access system of claim 9 wherein the first body region has a first durometer, wherein the second body region has a second durometer, and wherein the second durometer is less than the first durometer.

12. The vascular access system of claim 9 wherein the first body region comprises a first material, and wherein the second body region comprises a second material different than the first material.

13. The vascular access system of claim 9, wherein the dilator further includes a notch configured to extend at least partially around a longitudinal axis of the dilator, wherein the valve is configured to be releasably coupled to the dilator via the notch.

14. The vascular access system of claim 13 wherein the notch defines a recessed region of the dilator having a notch diameter less than the diameter of the first body region and the second body region.

15. The vascular access system of claim 13 wherein the valve includes a tether, and wherein the tether is configured to be positioned at least partially within the notch to releasably couple the dilator to the valve.

16. The vascular access system of claim 15 wherein the tether is biased in a first direction to releasably couple the dilator to the valve, the valve further comprising a button operably coupled to the tether and configured to move the tether in a second direction, opposite the first direction, to cause the tether to uncouple the dilator from the valve.

17. The vascular access system of claim 13 wherein the notch is a first notch, and wherein the dilator further includes a second notch positioned on a proximal side or a distal side of the notch.

18. The vascular access system of claim 17 wherein the catheter includes a distal terminus, wherein a first length of the dilator extends beyond the distal terminus when the first notch is coupled to the valve, and wherein a second length of the dilator extends beyond the distal terminus when the second notch is coupled to the valve.

19. The vascular access system of claim 18 wherein the second length is greater than the first length.

20. A method of treating clot material within a patient, the method comprising:

positioning a dilator within a vascular access system such that a valve of the vascular access system releasably engages a notch of the dilator to inhibit further movement of the dilator relative to the vascular access system;

actuating a button of the valve to release the notch from the valve to allow further movement of the dilator relative to the vascular access system; and

moving the dilator relative to the vascular access system and/or the vascular access system relative to the dilator.

21. The method of claim 20 wherein moving the dilator relative to the vascular access system includes advancing the dilator through the vascular access system to increase a length of the dilator that extends beyond a distal terminus of the vascular access system.

22. The method of claim 20 wherein moving the vascular access system relative to the dilator includes advancing the vascular access system over the dilator to decrease a length of the dilator that extends beyond a distal terminus of the vascular access system.

23. The method of claim 20 wherein the notch is a first notch, the method further comprising:

positioning the dilator within the vascular access system such that the valve releasably engages a second notch of the dilator; and

applying a force to the dilator and/or the vascular access system to release the second notch from the valve.

24. The method of claim 23 wherein applying the force to release the second notch from the valve includes applying the force to release the second notch from the valve without actuating the button.

25. A vascular access system, comprising:

a dilator extending along a longitudinal axis, wherein the dilator has a varying flexibility profile at least partially along the longitudinal axis, and wherein the dilator defines a notch extending at least partially circumferentially about the longitudinal axis;

a valve having a proximal end and a distal end; and

a catheter coupled to the valve and defining a lumen;

wherein the valve is configured to be releasably coupled to the dilator via the notch to inhibit movement of the dilator relative to the catheter when at least a portion of the dilator is inserted through the valve into the lumen of the catheter.

26. The vascular access system of claim 25 wherein the dilator includes a body region having a diameter, and wherein the notch includes a recessed region of the dilator having a notch diameter less than the diameter of the body region.

27. The vascular access system of claim 25 wherein the valve includes a tether, and wherein the tether is configured to be positioned at least partially within the notch to releasably couple the dilator to the valve.

28. The vascular access system of claim 27 wherein the tether is biased in a first direction to releasably couple the dilator to the valve, the valve further comprising a button operably coupled to the tether and configured to move the tether in a second direction, opposite the first direction, to move the tether at least partially out of the notch to uncouple the dilator from the valve.

29. The vascular access system of claim 25 wherein the notch is a first notch, wherein the portion of the dilator is a first portion, wherein the dilator further defines a second notch extending at least partially circumferentially about the longitudinal axis, and wherein the valve is configured to be releasably coupled to the dilator via the second notch to inhibit movement of the dilator relative to the catheter when at least a second portion of the dilator is inserted through the valve into the lumen of the catheter.

30. The vascular access system of claim 29 wherein the catheter includes a distal terminus, wherein a first length of the dilator extends beyond the distal terminus when the first notch is coupled to the valve, and wherein a second length of the dilator extends beyond the distal terminus when the second notch is coupled to the valve.

31. The vascular access system of claim 30 wherein the second length is greater than the first length.

32. The vascular access system of claim 25 wherein the dilator includes a proximal body region having a first flexibility profile and a distal body region having a second flexibility profile greater than the first flexibility profile, wherein the notch is positioned at least partially between the proximal body region and the distal body region.

33. The vascular access system of claim 25 wherein the dilator has a varying durometer at least partially along the longitudinal axis.

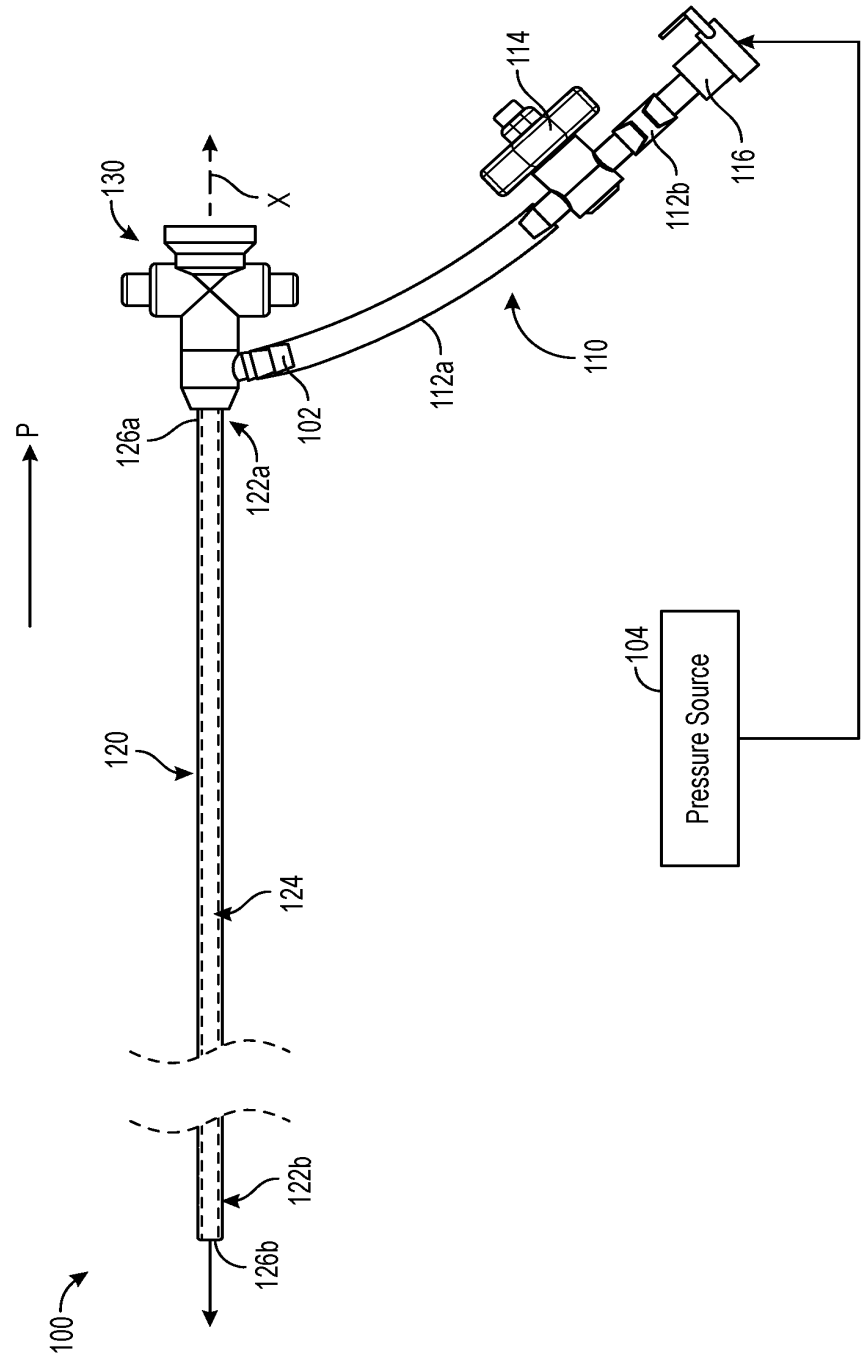

130
X
114
116
112b
110
112a
102
126a
122a
P
120
124
122b
126b
100
104
Pressure Source

*FIG. 1*

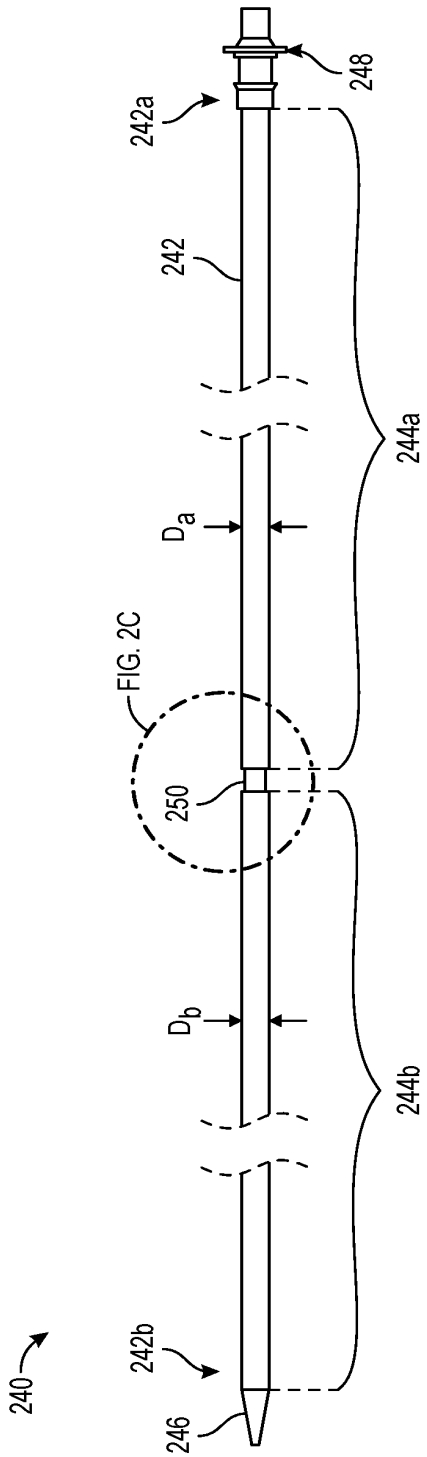

240
242b
246
244b
$D_b$
FIG. 2C
250
$D_a$
244a
242
242a
248

*FIG. 2A*

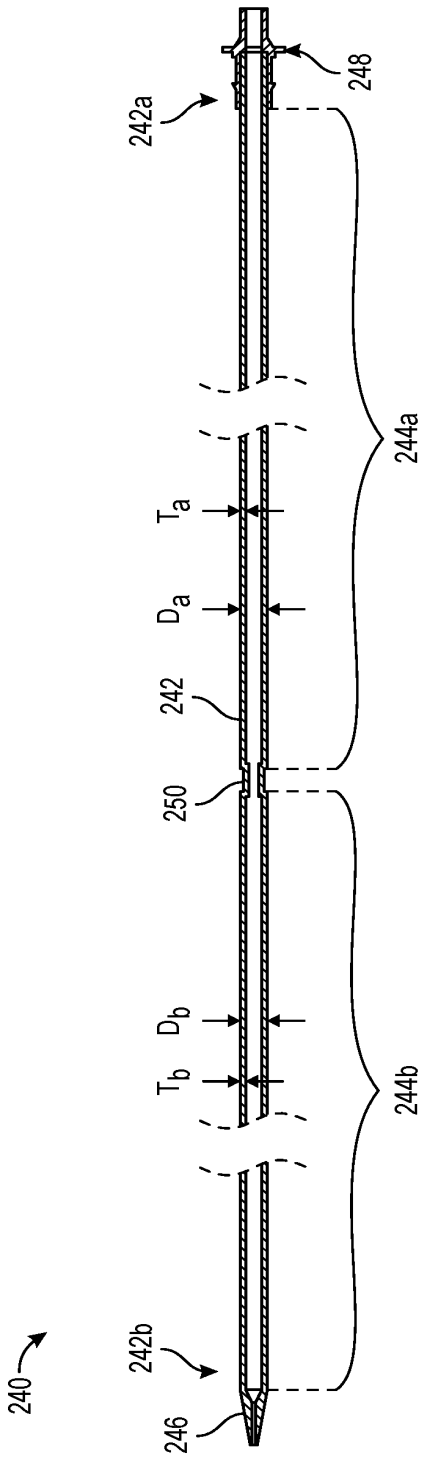

240
242b
246
244b
$T_b$
$D_b$
250
242
$D_a$
$T_a$
244a
242a
248

*FIG. 2B*

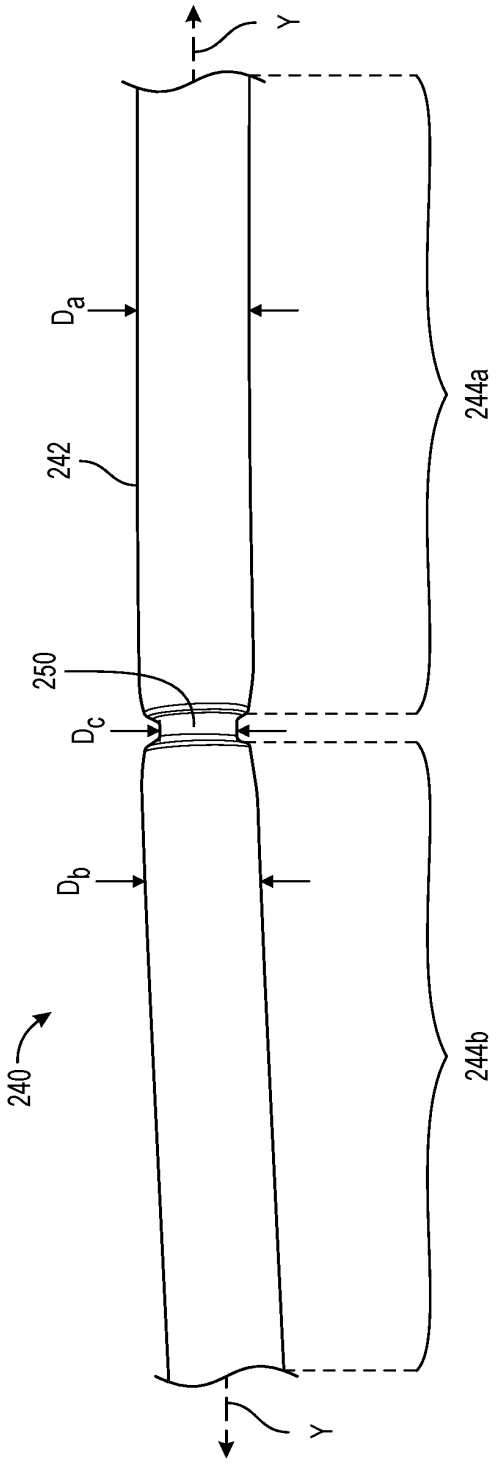



*FIG. 2C*

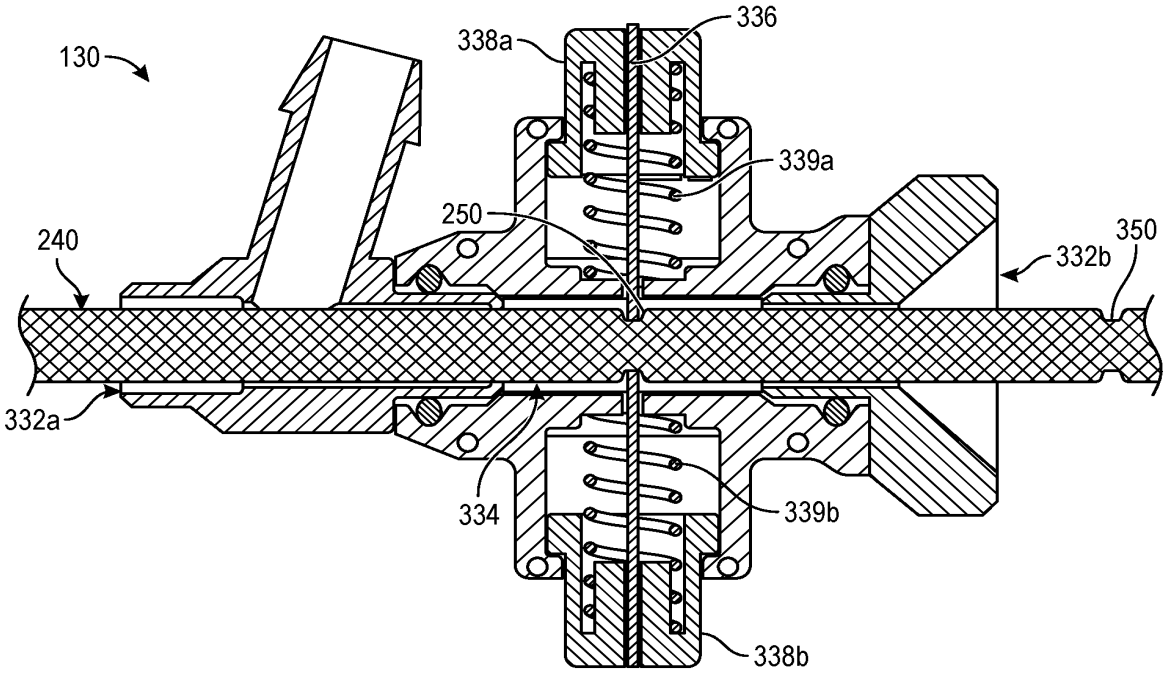

130
338a
336
339a
250
240
350
332b
332a
334
339b
338b

*FIG. 3A*

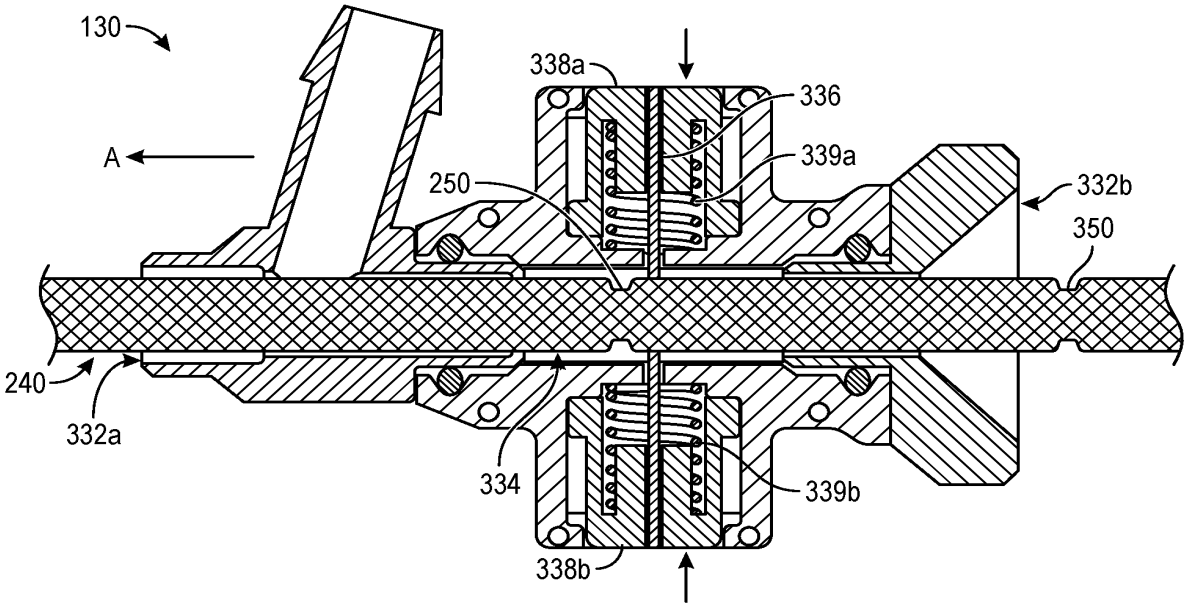

130
338a
336
A
339a
250
332b
350
240
332a
334
339b
338b

*FIG. 3B*

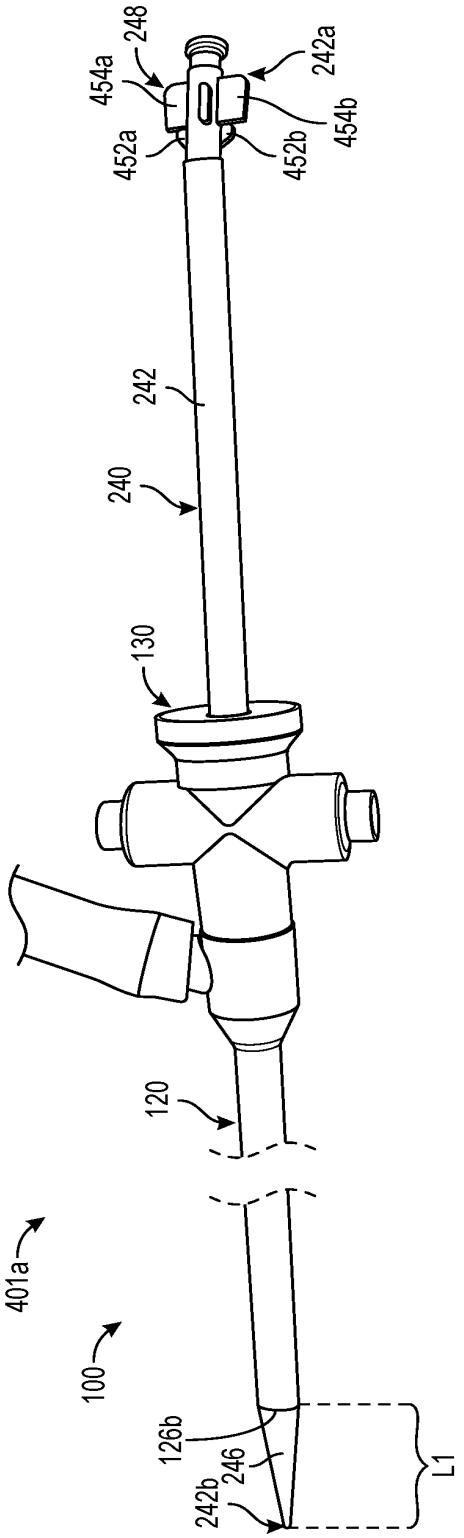

248
454a
242a
452a
452b
454b
242
240
130
120
401a
100
126b
246
242b
L1

FIG. 4A

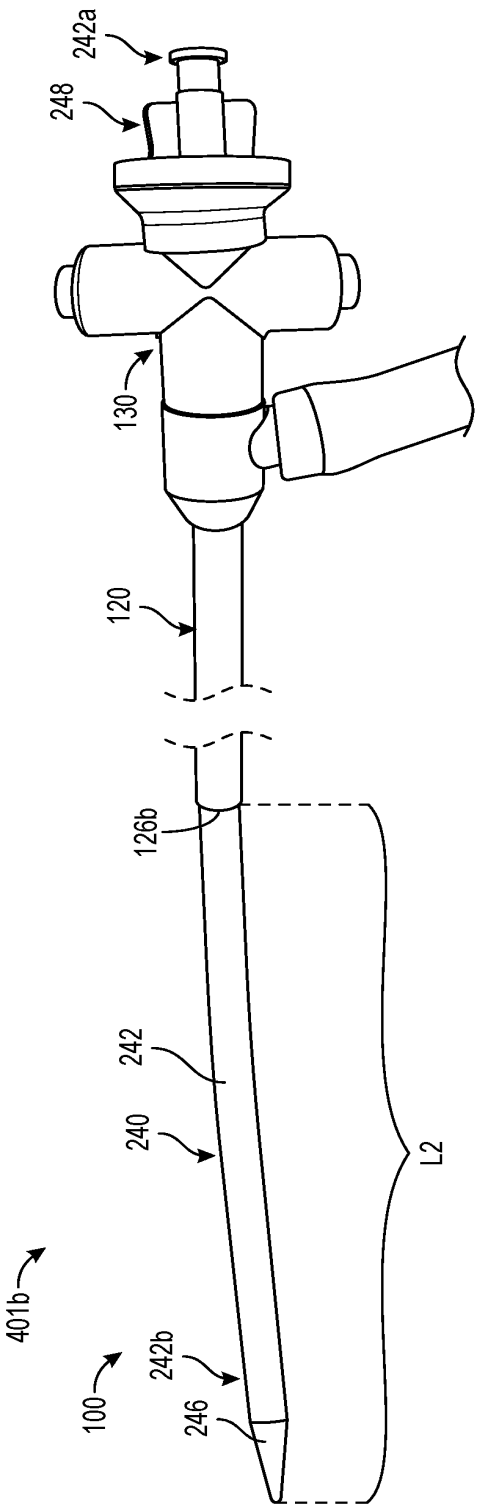

242a
248
130
120
126b
242
240
L2
401b
100
242b
246

FIG. 4B

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

| **PATENT APPLICATION FEE DETERMINATION RECORD**<br>Substitute for Form PTO-875 | Application or Docket Number<br>18/342,553 | Filing Date<br>06/27/2023 | ☐ To be Mailed |
|---|---|---|---|

**ENTITY:** ☑ LARGE ☐ SMALL ☐ MICRO

## APPLICATION AS FILED - PART I

| | (Column 1) | (Column 2) | | | |
|---|---|---|---|---|---|
| FOR | NUMBER FILED | NUMBER EXTRA | | RATE ($) | FEE ($) |
| ☐ BASIC FEE (37 CFR 1.16(a), (b), or (c)) | N/A | N/A | | N/A | |
| ☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m)) | N/A | N/A | | N/A | |
| ☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q)) | N/A | N/A | | N/A | |
| TOTAL CLAIMS (37 CFR 1.16(i)) | minus 20 = | * | | x $100 = | |
| INDEPENDENT CLAIMS (37 CFR 1.16(h)) | minus 3 = | * | | x $480 = | |
| ☐ APPLICATION SIZE FEE (37 CFR 1.16(s)) | If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s). | | | | |
| ☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j)) | | | | | |
| * If the difference in column 1 is less than zero, enter "0" in column 2. | | | | TOTAL | |

## APPLICATION AS AMENDED - PART II

| | | (Column 1) | | (Column 2) | (Column 3) | | | |
|---|---|---|---|---|---|---|---|---|
| AMENDMENT | 02/06/2024 | CLAIMS REMAINING AFTER AMENDMENT | | HIGHEST NUMBER PREVIOUSLY PAID FOR | PRESENT EXTRA | | RATE ($) | ADDITIONAL FEE ($) |
| | Total (37 CFR 1.16(i)) | * 20 | Minus | ** 20 | = 0 | | x $100 = | 0 |
| | Independent (37 CFR 1.16(h)) | * 2 | Minus | *** 3 | = 0 | | x $480 = | 0 |
| | ☐ Application Size Fee (37 CFR 1.16(s)) | | | | | | | |
| | ☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j)) | | | | | | | |
| | | | | | | | TOTAL ADD'L FEE | 0 |

| | | (Column 1) | | (Column 2) | (Column 3) | | | |
|---|---|---|---|---|---|---|---|---|
| AMENDMENT | | CLAIMS REMAINING AFTER AMENDMENT | | HIGHEST NUMBER PREVIOUSLY PAID FOR | PRESENT EXTRA | | RATE ($) | ADDITIONAL FEE ($) |
| | Total (37 CFR 1.16(i)) | * | Minus | ** | = | | x $0 = | |
| | Independent (37 CFR 1.16(h)) | * | Minus | *** | = | | x $0 = | |
| | ☐ Application Size Fee (37 CFR 1.16(s)) | | | | | | | |
| | ☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j)) | | | | | | | |
| | | | | | | | TOTAL ADD'L FEE | |

| | |
|---|---|
| * If the entry in column 1 is less than the entry in column 2, write "0" in column 3. | LIE |
| ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20". | /TAMARA D HARRELL/ |
| *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3". | |
| The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1. | |

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

*If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.*

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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 18/342,553 | 06/27/2023 | Ben Merritt | 111552.8018.US11 | 6799 |

25096 7590 11/06/2023

PERKINS COIE LLP - SEA General
PATENT-SEA
P.O. BOX 1247
SEATTLE, WA 98111-1247

| EXAMINER | |
|---|---|
| RASSAVONG, ERIC | |
| **ART UNIT** | **PAPER NUMBER** |
| 3781 | |
| **NOTIFICATION DATE** | **DELIVERY MODE** |
| 11/06/2023 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentprocurement@perkinscoie.com

| *Office Action Summary* | Application No. 18/342,553 | Applicant(s) Merritt et al. | |
|---|---|---|---|
| | Examiner ERIC RASSAVONG | Art Unit 3781 | AIA (FITF) Status Yes |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☑ Responsive to communication(s) filed on 06/27/2023.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims***

5) ☑ Claim(s) 1-20 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☑ Claim(s) 1-17 and 19-20 is/are allowed.

7) ☑ Claim(s) 18 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

**Application Papers**

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 06/27/2023 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

**Certified copies:**

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

**DETAILED ACTION**

***Notice of Pre-AIA or AIA Status***

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

***Claim Rejections - 35 USC § 102***

2. In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis (i.e., changing from AIA to pre-AIA) for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

4. **Claim 18** is rejected under 35 U.S.C. 102(a)(1) as being anticipated by Garrison et al. (US 20150173782 A1), hereinafter referred to as "Garrison".

Regarding **Claim 18**, Garrison teaches a clot treatment system (see Figure 33 and 34), comprising:

a first clot aspiration assembly (first aspiration assembly connected to line (2025), see Figure 33), including:

a first catheter (flow line (2025)); a first pressure source (source of aspiration (3125));

a fluid control device (valve (3325) which may be stopcock valve, see Figure 34) (a single embodiment can also be implemented in multiple embodiments separately or in any suitable sub-combination, see Paragraph [0175]) between the first catheter (2025) and the first pressure source (source of aspiration (3125), see Figure 33 and 34),

wherein the fluid control device (valve (3325) may be a stopcock valve or a flow controller with a simple actuation which selects the open or closed configuration, see Paragraph [0132]) is movable between (a) an open position in which the first pressure source is fluidly connected to the first catheter (open position of stopcock (3325)) and (b) a closed positioned in which the first pressure source is fluidly disconnected from the first catheter (closed position of stopcock valve (3325)),

wherein the first pressure source is configured to generate vacuum pressure while the fluid control device is in the closed position (the source of aspiration may be a locking syringe that is pulled back into a locked position by the user while the connection to the flow line is closed prior to the thrombectomy step of the procedure, see Paragraph [0134]]), and

wherein, upon movement of the fluid control device from the open position to the closed position, the vacuum pressure is applied to the first catheter to generate suction at a distal portion of the first catheter (the user may open the connection to the aspiration syringe to enable the maximum level of aspiration in a rapid fashion with one use, see Paragraph [0134]); and a second clot aspiration assembly (second aspiration assembly connected to line (2045), see Figure 33), including: a second catheter (flow line (2045)); and a second pressure source (3425) configured to be fluidly coupled to the second catheter (see Figure 33) and to

generate suction at a distal portion of the second catheter (aspiration source (3425) provides suction to the distal portion of the flow line (2045), see Figure 33).

***Allowable Subject Matter***

5. **Claims 1-17 and 19-20** are allowed.

6. The following is an examiner's statement of reasons for allowance:

**Claims 1 and 11** are allowable for reciting, *inter alia,* "a second catheter advanceable through the first catheter; a second pressure source; and a fluid control device between the second catheter and the second pressure source".

Garrison (US 20150173782 A1) teaches all of the limitations as discussed above and Garrison further teaches a second clot aspiration assembly (second aspiration assembly connected to line (2045), see Figure 33), including: a second catheter (flow line (2045)); and a second pressure source (3425) configured to be fluidly coupled to the second catheter (see Figure 33) and to generate suction at a distal portion of the second catheter (aspiration source (3425) provides suction to the distal portion of the flow line (2045), see Figure 33). However, Garrison fails to teach a second catheter advanceable through the first catheter. The second catheter (2045) does not advance through first catheter (2025), as shown in Figure 33. There is no reason to advance the second catheter through the first catheter of Garrison. Also Garrison does not explicitly disclose the flow lines (2025 and 2045) advancing through arterial access device (2010). It would be unreasonable to modify the flow lines to advance through the arterial access device (2010) because it would interfere with the thrombectomy device. Therefore, the limitations of claims 1 and 11 are considered allowable. **Claims 1-10** are

allowable for depending on claim 1. **Claims 12-17 and 19-20** are allowable for depending on claim 11.

Prior art like Johnson et al. (US 6719717 B1) teaches a thrombectomy treatment system and method comprising a catheter for insertion into the vascular system of the patient (see Abstract) (see Figure 1); wherein there is first source of suction (110) connected to the proximal end of the catheter (20) and a second source of suction (190) which also provides suction to catheter (20). However, Johnson fails to teach coupling a second pressure source to the second catheter; and activating the second pressure source to generate suction at the distal portion of the second catheter. There second pressure source (190) is connected to same catheter as the first suction source. It would be unreasonable to combine any suction source to the device of Shiber unless the sources of suction are connected to a first and second catheter in the same configuration as Shiber. Therefore, the limitations of claims 1 and 11 are considered allowable. **Claims 2-10** are allowable for depending on claim 1. **Claims 12-17 and 19-20** are allowable for depending on claim 11.

Devices like Garrison et al. (US 20180064453 A1) teaches a clot treatment system, comprising: a first clot aspiration assembly (see Figure 1 and 11), including:

a first catheter (222);

a first pressure source (600); and

a first fluid control device (242) between the first catheter and the first pressure source (see Figure 11), wherein the first fluid control device is movable between (a) an open position in which the first pressure source is fluidly connected to the first catheter (see Paragraph [0067]) and (b) a closed positioned in which the first pressure source is fluidly disconnected from the

first catheter, wherein the first pressure source is configured to generate vacuum pressure while the first fluid control device is in the closed position (see Paragraph [0067]), and wherein, upon movement of the first fluid control device from the open position to the closed position, the vacuum pressure is applied to the first catheter to generate suction at a distal portion of the first catheter (suction can be provided to sheath (222) when valve (242 is open).

However, Garrison et al. (US 20180064453 A1) fails to teach a second clot aspiration assembly, including: a second catheter advanceable through the first catheter; a second pressure source; and a second fluid control device between the second catheter and the second pressure source, wherein the second fluid control device is movable between (a) an open position in which the second pressure source is fluidly connected to the second catheter and (b) a closed positioned in which the second pressure source is fluidly disconnected from the second catheter, wherein the second pressure source is configured to generate vacuum pressure while the second fluid control device is in the closed position, and wherein, upon movement of the second fluid control device from the open position to the closed position, the vacuum pressure is applied to the second catheter to generate suction at a distal portion of the second catheter.

7. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Conclusion***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC RASSAVONG whose telephone number is (408)918-7549. The examiner can normally be reached Monday - Friday 9:00am-5:30pm PT.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas J. Weiss can be reached on (571)270-1775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E.R./ (10/27/2023)
Examiner, Art Unit 3781

/SUSAN S SU/
Primary Examiner, Art Unit 3781
1 November 2023

| Notice of References Cited | Application/Control No. 18/342,553 | Applicant(s)/Patent Under Reexamination Merritt et al. | |
|---|---|---|---|
| | Examiner ERIC RASSAVONG | Art Unit 3781 | Page 1 of 1 |

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| Index of Claims | Application/Control No. | Applicant(s)/Patent Under Reexamination |
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| | **Examiner** | **Art Unit** |
| | ERIC RASSAVONG | 3781 |

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| ✓ | Rejected | - | Cancelled | N | Non-Elected | A | Appeal |
| = | Allowed | ÷ | Restricted | I | Interference | O | Objected |

**CLAIMS**

☑ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

| CLAIM | | DATE | | | | | | | | |
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| Final | Original | 10/27/2023 | | | | | | | | |
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| Search Notes | Application/Control No. | Applicant(s)/Patent Under Reexamination |
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| | Examiner | Art Unit |
| | ERIC RASSAVONG | 3781 |

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| **Symbol** | **Date** | **Examiner** |
| A61F2/01 | 10/25/2023 | /E.R./ |
| A61B17/12109, 17/221, 2017/22034, 2017/22079, 17/005 | 10/25/2023 | /E.R./ |
| A61M1/815, 1/84, 1/79, 25/10 | 10/25/2023 | /E.R./ |

| CPC Combination Sets - Searched* | | |
|---|---|---|
| **Symbol** | **Date** | **Examiner** |
| | | |

| US Classification - Searched* | | | |
|---|---|---|---|
| **Class** | **Subclass** | **Date** | **Examiner** |
| | | | |

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

| Search Notes | | |
|---|---|---|
| **Search Notes** | **Date** | **Examiner** |
| Inventor Name Search PALM | 10/25/2023 | /E.R./ |
| CPC and text searching completed. | 10/27/2023 | /E.R./ |

| Interference Search | | | |
|---|---|---|---|
| **US Class/CPC Symbol** | **US Subclass/CPC Group** | **Date** | **Examiner** |
| | Keyword search in USPAT | 10/27/2023 | /E.R./ |

| /E.R./<br>Examiner, Art Unit 3781 | |
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# Bibliographic Data

Application No: 18/342,553

Foreign Priority claimed: ○ Yes ◉ No

35 USC 119 (a-d) conditions met: ☐ Yes ☐ No ☐ Met After Allowance

Verified and Acknowledged: /ERIC RASSAVONG/ Examiner's Signature | Initials

Title: SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

| FILING or 371(c) DATE | CLASS | GROUP ART UNIT | ATTORNEY DOCKET NO. |
|---|---|---|---|
| 06/27/2023 | 606 | 3781 | 111552.8018.US11 |
| RULE | | | |

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Jacqueline Macias, Fullerton, CA, UNITED STATES

Brian Michael Strauss, San Clemente, CA, UNITED STATES

Thomas Tu, Louisville, KY, UNITED STATES

**CONTINUING DATA**

This application is a CON of 18167757 02/10/2023

18167757 is a CON of 17976711 10/28/2022

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**FOREIGN APPLICATIONS**

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07/17/2023

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UNITED STATES

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UNITED STATES

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| | **First Named Inventor** | Ben Merritt |
| | **Art Unit** | ~~Not Yet Assigned~~ 3781 |
| | **Examiner Name** | ~~Not Yet Assigned~~ Eric Rassavong |
| | **Attorney Docket Number** | 111552-8018.US11 |

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## EXAMINER SIGNATURE

| Examiner Signature/ERIC RASSAVONG/ (10/25/2023 | Date Considered | 10/25/2023 |
|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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| | **Art Unit** | Not Yet Assigned |
| | **Examiner Name** | Not Yet Assigned |
| | **Attorney Docket Number** | 111552-8018.US11 |

## CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).

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☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

It is submitted that the Information Disclosure Statement is in compliance with 37 C.F.R. § 1.98 and the Examiner is respectfully requested to consider the listed references. This Information Disclosure Statement is not to be construed as a representation that: (i) a search has been made; (ii) additional information that may be material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the cited information is, or is considered to be, material to patentability. In addition, Applicant does not admit that any enclosed item of information constitutes prior art to the subject invention and specifically reserves the right to demonstrate that any such reference is not prior art.

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

| | | | |
|---|---|---|---|
| Signature | /Matthew S. Williams/ | Date (YYYY-MM-DD) | 2023-7-24 |
| Name/Print | Matthew S. Williams | Registration Number | 77,516 |

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| | **Examiner Name** | ~~Not Yet Assigned~~ Eric Rassavong |
| | **Attorney Docket Number** | 111552.8018.US11 |

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| | **Art Unit** | Not Yet Assigned |
| | **Examiner Name** | Not Yet Assigned |
| | **Attorney Docket Number** | 111552.8018.US11 |

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Doc description: Information Disclosure Statement (IDS) Filed
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| | **Examiner Name** | Not Yet Assigned |
| | **Attorney Docket Number** | 111552.8018.US11 |

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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
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| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | | |
|---|---|---|
| | **Application Number** | 18/342,553 - Conf # 6799 |
| | **Filing Date** | June 27, 2023 |
| | **First Named Inventor** | Ben Merritt |
| | **Art Unit** | Not Yet Assigned |
| | **Examiner Name** | Not Yet Assigned |
| | **Attorney Docket Number** | 111552.8018.US11 |

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| | 49. ** | YOUTUBE; Merci Retrieval System X Series Animation; uploaded March 16,2009 (product information); posted on May 7, 2009 by SSMDePAUL, time 1:09, retrieved from the internet: https://www.youtube.com/watch?v=MGX7deuFkhc; 3 pgs.; retrieved/printed: 3/24/2016 | |
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| | 56. | International Search Report and Written Opinion for International App. No. PCT/US23/60502; Date of Filing: January 11, 2023, Applicant: Inari Medical, Inc., Date of Mailing: May 25, 2023, 9 pages. | |
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| EXAMINER SIGNATURE | | | |
|---|---|---|---|
| Examiner Signature | /ERIC RASSAVONG/ (10/23/2023) | Date Considered | 10/23/2023 |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed
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| | **Application Number** | 18/342,553 - Conf # 6799 |
| | **Filing Date** | June 27, 2023 |
| | **First Named Inventor** | Ben Merritt |
| | **Art Unit** | Not Yet Assigned |
| | **Examiner Name** | Not Yet Assigned |
| | **Attorney Docket Number** | 111552.8018.US11 |

## CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).

**OR**

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

It is submitted that the Information Disclosure Statement is in compliance with 37 C.F.R. § 1.98 and the Examiner is respectfully requested to consider the listed references. This Information Disclosure Statement is not to be construed as a representation that: (i) a search has been made; (ii) additional information that may be material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the cited information is, or is considered to be, material to patentability. In addition, Applicant does not admit that any enclosed item of information constitutes prior art to the subject invention and specifically reserves the right to demonstrate that any such reference is not prior art.

### COPIES OF REFERENCES

In accordance with 37 C.F.R. § 1.98(a)(2)(ii), Applicant has not submitted copies of U.S. patents and U.S. patent applications. Applicant submits herewith copies of foreign patents and non-patent literature in accordance with 37 C.F.R. § 1.98(a)(2). Those documents which are marked with a double asterisk (**) next to the Cite No. in the attached form PTO/SB/08 are not supplied because they were previously cited by or submitted to the Office in prior application number **16/536,185** and filed on **August 8, 2019** and relied upon in this application for an earlier filing date under 35 U.S.C. § 120.

## SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

| | | | |
|---|---|---|---|
| Signature | /Matthew S. Williams/ | Date (YYYY-MM-DD) | 2023-07-13 |
| Name/Print | Matthew S. Williams | Registration Number | 77,516 |

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

## PE2E SEARCH - Search History (Prior Art)

| Ref # | Hits | Search Query | DBs | Default Operator | Plurals | British Equivalents | Time Stamp |
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| | | "5954737" OR<br>"5971938" OR<br>"5972019" OR<br>"5974938" OR<br>"5989233" OR<br>"5993483" OR<br>"6030397" OR<br>"6059814" OR<br>"6066158" OR<br>"6068645" OR<br>"6126635" OR<br>"6142987" OR<br>"6146396" OR<br>"6146403" OR<br>"6152144" OR<br>"6152946" OR<br>"6156055" OR<br>"6159230" OR<br>"6165196" OR<br>"6168579" OR<br>"6179859" OR<br>"6221006" OR<br>"6228060" OR<br>"6238412" OR<br>"6245078" OR<br>"6245089" OR<br>"6254571" OR<br>"6258115" OR<br>"6264663" OR<br>"6306163" OR<br>"6322572" OR<br>"6350271" OR<br>"6361545" OR<br>"6364895" OR<br>"6368339" OR<br>"6383205" OR<br>"6402771" OR<br>"6413235" OR<br>"6423032" OR<br>"6432122" OR<br>"6451036" OR<br>"6458103" OR<br>"6475236" OR<br>"6485502" OR<br>"6508782" OR<br>"6511492" OR<br>"6514273" OR<br>"6530923" OR<br>"6530935" OR<br>"6540722" OR<br>"6544276" OR<br>"6544278" OR<br>"6544279" OR<br>"6551342" OR<br>"6564828" OR<br>"6569181" OR<br>"6575995" OR<br>"6589263" OR | | | | | |

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| | | "6596011" OR<br>"6602271" OR<br>"6605074" OR<br>"6605102" OR<br>"6610077" OR<br>"6620148" OR<br>"6620179" OR<br>"6620182" OR<br>"6623460" OR<br>"6635068" OR<br>"6645222" OR<br>"6660013" OR<br>"6660014" OR<br>"6663650" OR<br>"6692504" OR<br>"6699260" OR<br>"6702830" OR<br>"6719717" OR<br>"6755847" OR<br>"6767353" OR<br>"6790204" OR<br>"6800080" OR<br>"6818006" OR<br>"6824545" OR<br>"6824550" OR<br>"6824553" OR<br>"6830561" OR<br>"6846029" OR<br>"6902540" OR<br>"6939361" OR<br>"6942682" OR<br>"6945977" OR<br>"6960189" OR<br>"6960222" OR<br>"7004931" OR<br>"7004954" OR<br>"7036707" OR<br>"7041084" OR<br>"7052500" OR<br>"7056328" OR<br>"7063707" OR<br>"7069835" OR<br>"7094249" OR<br>"7128073" OR<br>"7152605" OR<br>"7179273" OR<br>"7223253" OR<br>"7232432" OR<br>"7244243" OR<br>"7285126" OR<br>"7300458" OR<br>"7306618" OR<br>"7320698" OR<br>"7323002" OR<br>"7331980" OR<br>"7534234" OR<br>"7578830" OR<br>"7621870" OR | | | | | |

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| | | "7674247" OR<br>"7678131" OR<br>"7691121" OR<br>"7695458" OR<br>"7713282" OR<br>"7722641" OR<br>"7763010" OR<br>"7766934" OR<br>"7775501" OR<br>"7780696" OR<br>"7905877" OR<br>"7905896" OR<br>"7938809" OR<br>"7938820" OR<br>"7967790" OR<br>"7976511" OR<br>"7993302" OR<br>"7993363" OR<br>"8043313" OR<br>"8052640" OR<br>"8057496" OR<br>"8057497" OR<br>"8066757" OR<br>"8070769" OR<br>"8070791" OR<br>"8075510" OR<br>"8080032" OR<br>"8088140" OR<br>"8092486" OR<br>"8100935" OR<br>"8109962" OR<br>"8118829" OR<br>"8197493" OR<br>"8246641" OR<br>"8261648" OR<br>"8267897" OR<br>"8298257" OR<br>"8317748" OR<br>"8337450" OR<br>"8357178" OR<br>"8361104" OR<br>"8409215" OR<br>"8480708" OR<br>"8486105" OR<br>"8491539" OR<br>"8512352" OR<br>"8523897" OR<br>"8535283" OR<br>"8535334" OR<br>"8535343" OR<br>"8545526" OR<br>"8568432" OR<br>"8574262" OR<br>"8579915" OR<br>"8585713" OR<br>"8608754" OR<br>"8647367" OR<br>"8657867" OR | | | | | |

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| | | "8696622" OR<br>"8715314" OR<br>"8721714" OR<br>"8753322" OR<br>"8771289" OR<br>"8777893" OR<br>"8784441" OR<br>"8784442" OR<br>"8784469" OR<br>"8795305" OR<br>"8795345" OR<br>"8801748" OR<br>"8808259" OR<br>"8814927" OR<br>"8820207" OR<br>"8826791" OR<br>"8828044" OR<br>"8833224" OR<br>"8834519" OR<br>"8845621" OR<br>"8852205" OR<br>"8852226" OR<br>"8939991" OR<br>"8945143" OR<br>"8945172" OR<br>"8956384" OR<br>"8992504" OR<br>"9005172" OR<br>"9011551" OR<br>"9028401" OR<br>"9078682" OR<br>"9101382" OR<br>"9125683" OR<br>"9126016" OR<br>"9149609" OR<br>"9155552" OR<br>"9161766" OR<br>"9168043" OR<br>"9173668" OR<br>"9186487" OR<br>"9204887" OR<br>"9216277" OR<br>"9259237" OR<br>"9283066" OR<br>"9301769" OR<br>"9351747" OR<br>"9358037" OR<br>"9439664" OR<br>"9439751" OR<br>"9456834" OR<br>"9463035" OR<br>"9463036" OR<br>"9526864" OR<br>"9526865" OR<br>"9566073" OR<br>"9566424" OR<br>"9579116" OR<br>"9581942" OR | | | | | |

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| | | "9616213").pn. | | | | | |
| L4 | 17 | ("9636206" OR "9643035" OR "9700332" OR "9717488" OR "9717514" OR "9717519" OR "9744024" OR "9757137" OR "9827084" OR "9844386" OR "9844387" OR "9848975" OR "9849014" OR "9962178" OR "9980813" OR "9999493" OR "RE43902").pn. | (US-PGPUB; USPAT) | OR | ON | ON | 2023/10/23 05:11 PM |
| L5 | 4 | "20160030708".pn. | (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/23 05:14 PM |
| L6 | 4 | "20160135829".pn. | (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/23 05:14 PM |
| L7 | 4 | ("20230200970" OR "20230218310" OR "20230218313" OR "20230218383").pn. | (US-PGPUB; USPAT) | OR | ON | ON | 2023/10/25 06:42 PM |
| L8 | 6 | "2015179329".pn. | (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 06:43 PM |
| L9 | 8 | ("10183159" OR "20070233043" OR "20230233311" OR "20230240705" OR "20230240706" OR "20230241302" OR "8343167" OR "8568465").pn. | (US-PGPUB; USPAT) | OR | ON | ON | 2023/10/25 06:56 PM |
| L10 | 55 | ("10058339" OR "10384034" OR | (US-PGPUB; USPAT) | OR | ON | ON | 2023/10/25 06:59 PM |

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| | | "10456555" OR<br>"10485952" OR<br>"10926060" OR<br>"10953195" OR<br>"1101890" OR<br>"11065019" OR<br>"11185664" OR<br>"11224450" OR<br>"11224721" OR<br>"11305094" OR<br>"11383064" OR<br>"11395903" OR<br>"11576691" OR<br>"11596768" OR<br>"11744691" OR<br>"20040019310" OR<br>"20080312681" OR<br>"20110071503" OR<br>"20120109109" OR<br>"20130150793" OR<br>"20170143359" OR<br>"20170143938" OR<br>"20170281204" OR<br>"20180055999" OR<br>"20180250498" OR<br>"20190015298" OR<br>"20190366036" OR<br>"20200046940" OR<br>"20200121334" OR<br>"20210138194" OR<br>"20210205577" OR<br>"20210404464" OR<br>"20220033888" OR<br>"20220370761" OR<br>"20230059721" OR<br>"20230122587" OR<br>"20230248380" OR<br>"20230270991" OR<br>"3416531" OR<br>"3860006" OR<br>"4981478" OR<br>"5391152" OR<br>"5639276" OR<br>"5971958" OR<br>"7122034" OR<br>"7481805" OR<br>"7815608" OR<br>"8021351" OR<br>"8070694" OR<br>"9241669" OR<br>"9265512" OR<br>"9532792" OR<br>"9662129").pn. | | | | | |
| L11 | 5 | "106178227" | (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, | OR | ON | ON | 2023/10/25 07:21 PM |

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| | | | SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | | | | |
| L12 | 7801 | A61F2/01.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:22 PM |
| L13 | 17515 | A61B17/12109.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:22 PM |
| L14 | 1279 | A61M1/815.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:22 PM |
| L15 | 12292 | A61M1/84.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:22 PM |
| L16 | 22696 | A61B17/221.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:23 PM |
| L17 | 5168 | A61B2017/22034.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:39 PM |
| L18 | 8040 | A61B2017/22079.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, | OR | ON | ON | 2023/10/25 07:39 PM |

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| | | | SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | | | | |
| L19 | 29726 | A61B2217/005.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:39 PM |
| L20 | 4679 | A61M1/79.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:39 PM |
| L21 | 34676 | A61M25/10.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:39 PM |
| L22 | 1137 | A61B17/12109.cpc. AND A61F2/01.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:40 PM |
| L23 | 37 | A61M1/815.cpc. AND A61F2/01.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:40 PM |
| L24 | 34 | A61M1/84.cpc. AND A61F2/01.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:40 PM |
| L25 | 732 | A61B17/221.cpc. AND A61F2/01.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, | OR | ON | ON | 2023/10/25 07:40 PM |

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| | | | SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | | | | |
| L26 | 231 | A61B2017/22034.cpc. AND A61F2/01.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:40 PM |
| L27 | 113 | A61B2017/22079.cpc. AND A61F2/01.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:40 PM |
| L28 | 114 | A61B2217/005.cpc. AND A61F2/01.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:40 PM |
| L29 | 35 | A61M1/79.cpc. AND A61F2/01.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:40 PM |
| L30 | 129 | A61M25/10.cpc. AND A61F2/01.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:40 PM |
| L31 | 17515 | A61B17/12109.cpc. AND A61B17/12109.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:40 PM |
| L32 | 33 | A61M1/815.cpc. AND A61B17/12109.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, | OR | ON | ON | 2023/10/25 07:41 PM |

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| | | | SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | | | | |
| L33 | 170 | A61M1/84.cpc. AND A61B17/12109.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:41 PM |
| L34 | 1076 | A61B17/221.cpc. AND A61B17/12109.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:41 PM |
| L35 | 544 | A61B2017/22034.cpc. AND A61B17/12109.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:41 PM |
| L36 | 441 | A61B2017/22079.cpc. AND A61B17/12109.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:41 PM |
| L37 | 476 | A61B2217/005.cpc. AND A61B17/12109.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:41 PM |
| L38 | 30 | A61M1/79.cpc. AND A61B17/12109.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:41 PM |
| L39 | 1330 | A61M25/10.cpc. AND A61B17/12109.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, | OR | ON | ON | 2023/10/25 07:41 PM |

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| | | | SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | | | | |
| L40 | 209 | A61M1/84.cpc. AND A61M1/815.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:42 PM |
| L41 | 30 | A61B17/221.cpc. AND A61M1/815.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:42 PM |
| L42 | 32 | A61B2017/22034.cpc. AND A61M1/815.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:42 PM |
| L43 | 64 | A61B2017/22079.cpc. AND A61M1/815.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:42 PM |
| L44 | 69 | A61B2217/005.cpc. AND A61M1/815.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:42 PM |
| L45 | 100 | A61M1/79.cpc. AND A61M1/815.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:42 PM |
| L46 | 30 | A61M25/10.cpc. AND A61M1/815.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, | OR | ON | ON | 2023/10/25 07:42 PM |

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| | | | SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | | | | |
| L47 | 426 | A61B17/221.cpc. AND A61M1/84.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:43 PM |
| L48 | 231 | A61B2017/22034.cpc. AND A61M1/84.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:43 PM |
| L49 | 673 | A61B2017/22079.cpc. AND A61M1/84.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:43 PM |
| L50 | 2007 | A61B2217/005.cpc. AND A61M1/84.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:43 PM |
| L51 | 641 | A61M1/79.cpc. AND A61M1/84.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:43 PM |
| L52 | 738 | A61M25/10.cpc. AND A61M1/84.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:43 PM |
| L53 | 3952 | A61B2017/22034.cpc. AND A61B17/221.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, | OR | ON | ON | 2023/10/25 07:44 PM |

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| | | | SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | | | | |
| L54 | 2586 | A61B2017/22079.cpc. AND A61B17/221.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:44 PM |
| L55 | 2026 | A61B2217/005.cpc. AND A61B17/221.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:44 PM |
| L56 | 115 | A61M1/79.cpc. AND A61B17/221.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:44 PM |
| L57 | 975 | A61M25/10.cpc. AND A61B17/221.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:44 PM |
| L58 | 1026 | A61B2017/22079.cpc. AND A61B2017/22034.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:45 PM |
| L59 | 648 | A61B2217/005.cpc. AND A61B2017/22034.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:46 PM |
| L60 | 71 | A61M1/79.cpc. AND A61B2017/22034.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, | OR | ON | ON | 2023/10/25 07:46 PM |

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| | | | SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | | | | |
| L61 | 557 | A61M25/10.cpc. AND A61B2017/22034.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:46 PM |
| L62 | 3178 | A61B2217/005.cpc. AND A61B2017/22079.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:47 PM |
| L63 | 265 | A61M1/79.cpc. AND A61B2017/22079.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:47 PM |
| L64 | 520 | A61M25/10.cpc. AND A61B2017/22079.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:47 PM |
| L65 | 1004 | A61M1/79.cpc. AND A61B2217/005.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:47 PM |
| L66 | 908 | A61M25/10.cpc. AND A61B2217/005.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:47 PM |
| L67 | 59 | A61M25/10.cpc. AND A61M1/79.cpc. | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, | OR | ON | ON | 2023/10/25 07:48 PM |

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| | | | SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | | | | |
| L68 | 72 | ((WO-2015179329-A1 OR WO-2017024258-A1 OR WO-2015061365-A1 OR WO-2014081892-A1 OR JP-2005323702-A OR WO-0053120-A1 OR WO-9744082-A2).did. AND FTDB.dbnm.) OR ((US-8343167-B2 OR US-10226263-B2 OR US-9999493-B2 OR US-9757137-B2 OR US-9744024-B2 OR US-9700332-B2 OR US-9616213-B2 OR US-9566424-B2 OR US-9526865-B2 OR US-9463036-B2 OR US-9456834-B2 OR US-9439751-B2 OR US-9439664-B2 OR US-9149609-B2 OR US-9161766-B2 OR US-8777893-B2 OR US-8585713-B2 OR US-8512352-B2 OR US-8409215-B2 OR US-7938820-B2 OR US-7905896-B2 OR US-7763010-B2 OR US-7220269-B1 OR US-7041084-B2 OR US-6767353-B1 OR US-6719717-B1 OR US-6454775-B1 OR US-6238412-B1 OR US-6217548-B1 OR US-6066149-A OR US-5971958-A).did. AND USPT.dbnm.) OR ((US-20200046368-A1 OR US-20190231373-A1 OR US-20190070401-A1 OR US-20180193043-A1 OR US-20180064453-A1 OR US-20170049942-A1 OR US-20160220741-A1 OR US-20150265423-A1 OR US-20150133990-A1 OR US-20150025555-A1 OR | (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:51 PM |

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|---|---|---|---|---|---|---|---|
| | | US-20150018860-A1 OR US-20140228869-A1 OR US-20140155830-A1 OR US-20140025048-A1 OR US-20130261638-A1 OR US-20120310166-A1 OR US-20110264133-A1 OR US-20110054405-A1 OR US-20100249753-A1 OR US-20100204712-A1 OR US-20100030256-A1 OR US-20090163846-A1 OR US-20080269798-A1 OR US-20080157017-A1 OR US-20070208361-A1 OR US-20050113762-A1 OR US-20030135230-A1 OR US-20020120277-A1).did. AND PGPB.dbnm.) OR ((WO-2018206747-A1 OR US-20170105743-A1 OR US-6589264-B1 OR US-20020151922-A1).did. AND DWPI.dbnm.) OR ((WO-2014186413-A2 OR WO-2013158342-A1).did. AND FPRS.dbnm.) | | | | | |
| L69 | 75 | ((US-9259237-B2 OR US-9439751-B2 OR US-9463036-B2 OR US-9566424-B2 OR US-9579116-B1 OR US-9408620-B2 OR US-9757137-B2 OR US-9439664-B2 OR US-9999493-B2 OR US-9700332-B2 OR US-9456834-B2 OR US-9161766-B2 OR US-9526865-B2 OR US-9149609-B2 OR US-9744024-B2 OR US-6238412-B1 OR US-7938820-B2 OR US-8585713-B2 OR US-6066149-A OR US-6767353-B1 OR US-7905896-B2 OR US-8409215-B2 OR US-10098651-B2 OR US- | (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:51 PM |

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| | | 7220269-B1 OR US-7763010-B2 OR US-8512352-B2 OR US-6217548-B1 OR US-10226263-B2 OR US-9616213-B2 OR US-8777893-B2 OR US-7041084-B2 OR US-6454775-B1 OR US-6719717-B1).did. AND USPT.dbnm.) OR ((US-20150018860-A1 OR US-20100114113-A1 OR US-20080269798-A1 OR US-20110264133-A1 OR US-20140025048-A1 OR US-20090163846-A1 OR US-20020120277-A1 OR US-20120310166-A1 OR US-20100204712-A1 OR US-20180125512-A1 OR US-20150133990-A1 OR US-20070208361-A1 OR US-20190070401-A1 OR US-20100030256-A1 OR US-20180193043-A1 OR US-20130261638-A1 OR US-20190231373-A1 OR US-20150025555-A1 OR US-20150265423-A1 OR US-20100249753-A1 OR US-20050113762-A1 OR US-20080157017-A1 OR US-20110054405-A1 OR US-20030135230-A1 OR US-20200046368-A1 OR US-20140155830-A1 OR US-20140228869-A1 OR US-20160220741-A1 OR US-20180064453-A1 OR US-20170049942-A1).did. AND PGPB.dbnm.) OR ((WO-2014186413-A2 OR WO-2013158342-A1).did. AND FPRS.dbnm.) OR ((US-6589264-B1 OR US-20020151922-A1 OR | | | | | |

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| | | WO-2018206747-A1 OR US-20170105743-A1).did. AND DWPI.dbnm.) OR ((WO-9744082-A2 OR JP-2005323702-A OR WO-2014081892-A1 OR WO-2015061365-A1 OR WO-2017024258-A1 OR WO-0053120-A1).did. AND FTDB.dbnm.) | | | | | |
| L70 | 26 | ((US-20050054995-A1 OR US-20180064453-A1 OR US-20160262774-A1 OR US-20190000492-A1 OR US-20140276288-A1 OR US-20170143938-A1 OR US-20170143359-A1 OR US-20080312681-A1 OR US-20170281204-A1 OR US-20180184912-A1 OR US-20120172918-A1 OR US-20140371779-A1 OR US-20180064454-A1 OR US-20120310166-A1 OR US-20030116731-A1).did. AND PGPB.dbnm.) OR ((WO-2016182977-A1 OR WO-2006124307-A2 OR JP-2001321364-A).did. AND FTDB.dbnm.) OR ((US-5421824-A OR US-8808259-B2 OR US-8753322-B2 OR US-10531883-B1 OR US-9345499-B2 OR US-4880408-A OR US-8535283-B2 OR US-9028401-B1).did. AND USPT.dbnm.) | (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:52 PM |
| L71 | 18 | (Artificial Intelligence) More like doc: US-20160135829-A1<br>Text: (US-8075510-B2 OR US-2009163846-A1 OR US-10383983-B2 OR US-2011213392-A1 OR US-2011301634-A1 OR EP-2231256-B1 OR | (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, | OR | ON | ON | 2023/10/25 07:58 PM |

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| | | US-2016151079-A1 OR US-2019321525-A1 OR US-8506512-B2 OR WO-2012148645-A2 OR US-8613717-B2 OR US-2011213393-A1 OR US-2013304082-A1 OR WO-2012151025-A1 OR US-8734374-B2 OR US-2020121333-A1 OR US-2020164117-A1 OR US-2017136158-A1 OR WO-2012141969-A2 OR US-2011213297-A1).did. | NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB) | | | | |
| L72 | 24 | (Artificial Intelligence)<br>More like doc:<br>US-20190239910-A1<br>Text:<br>(US-11464528-B2 OR US-2023000510-A1 OR WO-2018019829-A1 OR JP-2019527110-A OR KR-20220150422-A OR CN-109788964-B OR KR-20190035792-A OR JP-7010925-B2 OR KR-102460052-B1 OR JP-20190527110-A5 OR BR-112019001481-A2 OR CN-109788964-A OR US-2021128182-A1 OR US-11337712-B2 OR US-2023026412-A1 OR EP-3806757-A1 OR WO-2020023541-A1 OR US-11197683-B1 OR US-2021361314-A1 OR US-2020397957-A1).did. | (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:58 PM |
| L73 | 34 | (Artificial Intelligence)<br>More like doc:<br>US-20150164666-A1<br>Text:<br>(US-9782186-B2 OR WO-2016141025-A1 OR EP-3265001-A1 OR CN-107405160-B OR EP-3265001-B1 OR EP-3364890-B1 OR WO-2017070316-A1 OR EP-3364890-A1 OR WO-2020260632-A1 OR EP-3990083-A1 OR US-2022265962-A1 OR US-9827126-B2 OR | (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:59 PM |

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| | | EP-3990083-B1 OR CA-3000119-C OR US-9474639-B2 OR WO-2019236597-A1 OR EP-3813740-A1 OR CA-3102299-A1 OR US-2019374358-A1 OR CN-112218601-A).did. | | | | | |
| L74 | 22 | (Artificial Intelligence) More like doc: US-20180064453-A1 Text: (US-10485952-B2 OR US-9681882-B2 OR US-2016367272-A1 OR US-2020215306-A1 OR AU-2016215229-B2 OR US-9820761-B2 OR AU-2022204503-A1 OR CN-112155656-A OR US-2020016369-A1 OR US-2019366043-A1 OR US-11305094-B2 OR US-10456555-B2 OR US-11224721-B2 OR US-11185664-B2 OR US-2019366042-A1 OR US-2021138193-A1 OR US-2021138194-A1 OR US-2020046940-A1 OR US-11383064-B2 OR US-2020164178-A1).did. | (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 07:59 PM |
| L75 | 24 | (Artificial Intelligence) More like doc: US-20110034986-A1 Text: (US-9655755-B2 OR US-2015141760-A1 OR US-2017354523-A1 OR US-10085864-B2 OR US-8858490-B2 OR US-9259215-B2 OR US-2016158044-A1 OR US-2019269538-A1 OR US-2021307945-A1 OR US-10952882-B2 OR US-2017312491-A1 OR WO-2012021406-A2 OR US-9623228-B2 OR US-10369346-B2 OR US-2013197621-A1 OR EP-2249750-B1 OR US-2020054871-A1 OR WO-2014025930-A1 OR WO-2010099437-A1 OR US- | (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 08:00 PM |

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| | | 2013281788-A1).did. | | | | | |
| L76 | 23 | (Artificial Intelligence)<br>More like doc:<br>US-20120143239-A1<br>Text:<br>(EP-2646102-A1 OR WO-2012075415-A1 OR CA-2819670-A1 OR US-8956383-B2 OR CA-2819670-C OR JP-2014503254-A OR US-8506512-B2 OR WO-2012151025-A1 OR US-2011213290-A1 OR WO-2012158269-A1 OR US-2011213393-A1 OR US-2009163846-A1 OR US-8075510-B2 OR US-2011213392-A1 OR US-2013304082-A1 OR EP-2231256-B1 OR US-2020121333-A1 OR US-2019321525-A1 OR US-10517617-B2 OR US-2016151079-A1).did. | (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 08:01 PM |
| L77 | 28 | (Artificial Intelligence)<br>More like doc:<br>US-20090163846-A1<br>Text:<br>(EP-2231256-A1 OR WO-2009082513-A1 OR US-8075510-B2 OR EP-2231256-B1 OR EP-3311875-A1 OR US-2011213392-A1 OR JP-2015154985-A OR JP-2016190050-A OR JP-2011507602-A OR US-8506512-B2 OR US-8613717-B2 OR US-2016303297-A1 OR WO-2012148645-A2 OR US-2014221949-A1 OR US-9402938-B2 OR WO-2012151025-A1 OR US-2011301634-A1 OR US-10383983-B2 OR US-8734374-B2 OR US-2020121333-A1).did. | (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 08:01 PM |
| L78 | 35 | (Artificial Intelligence)<br>More like doc:<br>US-20180042623-A1<br>Text:<br>(JP-2020519405-A OR EP-3952967-A1 OR | (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, | OR | ON | ON | 2023/10/25 08:02 PM |

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|---|---|---|---|---|---|---|---|
| | | CN-113660970-A OR WO-2020167276-A1 OR US-11452841-B2 OR CN-113365687-A OR US-2020324079-A1 OR CN-113951980-A OR WO-2021167614-A1 OR WO-2023192925-A2 OR US-2023310751-A1 OR WO-2012151025-A1 OR US-11266825-B2 OR CN-113425369-A OR US-2005085769-A1 OR WO-2020145928-A1 OR TR-201900192-A2 OR WO-2005074520-A2 OR US-2021260262-A1 OR TR-201902349-A2).did. | HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB) | | | | |
| L79 | 31 | (Artificial Intelligence) More like doc: US-20100204712-A1 Text: (EP-2395929-A2 OR WO-2010093836-A2 OR WO-2010093836-A3 OR EP-2395929-A4 OR CN-112057133-A OR CN-112057133-B OR WO-2023057179-A1 OR US-7645290-B2 OR US-2006253145-A1 OR US-2021361305-A1 OR US-2018338770-A1 OR AU-2007200632-B2 OR AU-2007200632-A1 OR US-6719718-B2 OR US-6805684-B2 OR US-6676627-B1 OR US-6945951-B1 OR WO-2016146640-A1 OR US-6764483-B1 OR AU-2010202027-A1).did. | (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 08:02 PM |
| L80 | 20 | (Artificial Intelligence) More like doc: US-20150173782-A1 Text: (WO-2015100178-A1 OR EP-3086835-A1 OR US-9561345-B2 OR EP-3086835-B1 OR US-10569049-B2 OR EP-4137191-A1 OR US-10864351-B2 OR US-10213582-B2 OR | (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, | OR | ON | ON | 2023/10/25 08:03 PM |

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| | | US-2022370767-A1 OR US-2022280753-A1 OR US-10471233-B2 OR US-2017274180-A1 OR US-2023241348-A1 OR US-2020345981-A1 OR US-2018133436-A1 OR US-2021069467-A1 OR US-2017281204-A1 OR US-11534575-B2 OR US-2017368309-A1 OR US-11318282-B2).did. | TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB) | | | | |
| L81 | 30 | (Artificial Intelligence) More like doc: US-20170319221-A1<br>Text: (WO-2017192351-A1 OR EP-3451947-A1 OR US-10588650-B2 OR EP-3451947-B1 OR CN-109069169-B OR US-11534190-B2 OR EP-3692933-A1 OR EP-3692933-B1 OR CN-113425224-A OR US-2020178990-A1 OR CN-109069169-A OR US-2018125516-A1 OR US-10828053-B2 OR CN-110996752-A OR WO-2017180727-A1 OR CN-110996752-B OR US-2016089127-A1 OR US-10194893-B2 OR US-2019133564-A1 OR US-10918365-B2).did. | (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 08:03 PM |
| L82 | 23 | (Artificial Intelligence) More like doc: US-6767353-B1<br>Text: (WO-03074104-A2 OR WO-03074104-A3 OR US-2005113853-A1 OR US-8747332-B2 OR US-2012010640-A1 OR US-8353922-B2 OR US-6824550-B1 OR US-9113955-B2 OR US-2014171988-A1 OR US-2013296906-A1 OR US-2005228418-A1 OR US-2013110143-A1 OR US-8496680-B2 OR US-8043312-B2 OR US-2010049169-A1 OR US-8043314-B2 OR | (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 08:03 PM |

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|---|---|---|---|---|---|---|---|
| | | US-5120323-A OR US-2004230213-A1 OR US-6482215-B1 OR EP-4034182-B1).did. | | | | | |
| L83 | 26 | (Artificial Intelligence) More like doc: US-8939991-B2 Text: (US-2010036312-A1 OR US-2015119896-A1 OR US-9855067-B2 OR WO-2010002549-A2 OR EP-2299916-A2 OR CA-2726851-A1 OR EP-2299916-B1 OR US-2018092653-A1 OR US-10716586-B2 OR CA-2726851-C OR JP-5584204-B2 OR JP-2011522635-A OR US-2011264133-A1 OR US-11648021-B2 OR CN-113423451-A OR US-8574170-B2 OR CN-113423451-B OR US-2013267934-A1 OR EP-2647404-B1 OR US-11266434-B2).did. | (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 08:04 PM |
| L84 | 33 | (Artificial Intelligence) More like doc: US-5476450-A Text: (WO-9512421-A1 OR WO-9512421-B1 OR JP-H11514541-A OR WO-9716215-A1 OR JP-2009172390-A OR CA-2231153-A1 OR US-5624396-A OR US-2021338255-A1 OR JP-2021164670-A OR WO-2022251678-A1 OR US-6569146-B1 OR WO-0215802-A1 OR US-5782797-A OR AU-1172795-A OR WO-2008060396-A2 OR US-2007287956-A1 OR US-2007060882-A1 OR US-2010204712-A1 OR WO-2010093836-A2 OR EP-2395929-A2).did. | (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 08:04 PM |
| L85 | 26 | (Artificial Intelligence) More like doc: US-9351747-B2 Text: | (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, | OR | ON | ON | 2023/10/25 08:05 PM |

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| | | (US-2016066931-A1 OR EP-3125789-A1 OR WO-2016040550-A1 OR US-2016242798-A1 OR CA-2955841-C OR US-10390849-B2 OR EP-3125789-B1 OR CA-2955841-A1 OR ES-2644543-T3 OR AU-2009266808-A1 OR AU-2009266808-B2 OR US-9855067-B2 OR US-8939991-B2 OR US-2010036312-A1 OR US-2015119896-A1 OR US-2018092653-A1 OR US-10716586-B2 OR EP-2299916-B1 OR CA-2726851-A1 OR CA-2726851-C).did. | CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB) | | | | |
| L86 | 29 | (Artificial Intelligence) More like doc: US-6719717-B1<br>Text: (EP-2231256-A1 OR WO-2009082513-A1 OR WO-2009154441-A1 OR EP-2309934-A1 OR US-2011190806-A1 OR EP-2309934-B1 OR US-2011301634-A1 OR US-2011213297-A1 OR US-8613717-B2 OR EP-3311875-A1 OR US-8734374-B2 OR JP-H0833716-A OR EP-2231256-B1 OR WO-2012148645-A2 OR CN-202724337-U OR US-2014221949-A1 OR US-2016303297-A1 OR US-9402938-B2 OR US-2019175210-A1 OR US-10383983-B2).did. | (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/25 08:05 PM |
| L87 | 4 | "20170143359".pn. | (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/27 07:38 PM |
| L88 | 482 | (embolism clot).clm. AND (tube catheter).clm. AND (suction "neagtive pressure").clm. AND | (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, | OR | ON | ON | 2023/10/27 07:49 PM |

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|---|---|---|---|---|---|---|---|
| | | (two second).clm. AND first.clm. | SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | | | | |
| L89 | 316 | A61F2/01.cpc. AND (embolism clot) AND (tube catheter) AND (suction "neagtive pressure") AND (two second) AND first | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/27 07:57 PM |
| L90 | 139 | A61M1/815.cpc. AND (embolism clot) AND (tube catheter) AND (suction "neagtive pressure") AND (two second) AND first | (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) | OR | ON | ON | 2023/10/27 07:57 PM |

## PE2E SEARCH - Search History (Interference)

| Ref # | Hits | Search Query | DBs | Default Operator | Plurals | British Equivalents | Time Stamp |
|---|---|---|---|---|---|---|---|
| N1 | 747 | (embolism clot).clm. AND (tube catheter).clm. AND (suction "neagtive pressure").clm AND (two).clm. | (US-PGPUB; USPAT) | OR | ON | ON | 2023/10/27 07:49 PM |
| N2 | 154 | (embolism clot).clm. AND (tube catheter).clm. AND (suction "neagtive pressure").clm. AND (two second).clm. AND first.clm. | (US-PGPUB; USPAT) | OR | ON | ON | 2023/10/27 07:49 PM |
| N3 | 175 | (embolism clot).clm. AND (tube catheter).clm. AND (suction "neagtive pressure").clm. AND (two second).clm. | (US-PGPUB; USPAT) | OR | ON | ON | 2023/10/27 07:50 PM |
| N4 | 10244525 | (embolism clot).clm. AND (tube catheter).clm. (two second).clm. | (US-PGPUB; USPAT) | OR | ON | ON | 2023/10/27 07:50 PM |
| N5 | 1460 | (embolism clot).clm. AND (tube catheter).clm. AND (two second).clm. | (US-PGPUB; USPAT) | OR | ON | ON | 2023/10/27 07:50 PM |

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | | |
|---|---|---|
| | **Application Number** | 18/342,553- Conf # 6799 |
| | **Filing Date** | June 27, 2023 |
| | **First Named Inventor** | Ben Merritt |
| | **Art Unit** | 3781 |
| | **Examiner Name** | ~~Not Yet Assigned~~ Eric Rassavong |
| | **Attorney Docket Number** | 111552.8018.US11 |

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| Examiner Initial* | Cite No | Patent Number | Issue Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
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| Examiner Initial* | Cite No | Foreign Document Number[3] | Publication Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T[5] |
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## NON-PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Cite No | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T[5] |
|---|---|---|---|
| | | | |

## EXAMINER SIGNATURE

| Examiner Signature | /ERIC RASSAVONG/ (10/25/2023) | Date Considered | 10/25/2023 |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.



163380412.1

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /E.R./

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed
PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | | |
|---|---|---|
| | **Application Number** | 18/342,553- Conf # 6799 |
| | **Filing Date** | June 27, 2023 |
| | **First Named Inventor** | Ben Merritt |
| | **Art Unit** | 3781 |
| | **Examiner Name** | Not Yet Assigned |
| | **Attorney Docket Number** | 111552.8018.US11 |

## CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).

**OR**

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

It is submitted that the Information Disclosure Statement is in compliance with 37 C.F.R. § 1.98 and the Examiner is respectfully requested to consider the listed references. This Information Disclosure Statement is not to be construed as a representation that: (i) a search has been made; (ii) additional information that may be material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the cited information is, or is considered to be, material to patentability. In addition, Applicant does not admit that any enclosed item of information constitutes prior art to the subject invention and specifically reserves the right to demonstrate that any such reference is not prior art.

### COPIES OF REFERENCES

In accordance with 37 C.F.R. § 1.98(a)(2)(ii), Applicant has not submitted copies of U.S. patents and U.S. patent applications. Applicant submits herewith copies of foreign patents and non-patent literature in accordance with 37 C.F.R. § 1.98(a)(2).

## SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

| | | | |
|---|---|---|---|
| Signature | /Matthew S. Williams/ | Date (YYYY-MM-DD) | 2023-08-14 |
| Name/Print | Matthew S. Williams | Registration Number | 77,516 |

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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| | **Filing Date** | June 27, 2023 |
| | **First Named Inventor** | Ben Merritt |
| | **Art Unit** | 3781 |
| | **Examiner Name** | ~~Not Yet Assigned~~ Eric Rassavong |
| | **Attorney Docket Number** | 111552.8018.US11 |

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| Examiner Initial* | Cite No | Patent Number | Issue Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /E.R./

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
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| | **Application Number** | 18/342,553- Conf # 6799 |
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| | **First Named Inventor** | Ben Merritt |
| | **Art Unit** | 3781 |
| | **Examiner Name** | Not Yet Assigned |
| | **Attorney Docket Number** | 111552.8018.US11 |

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| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | | |
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| | **First Named Inventor** | Ben Merritt |
| | **Art Unit** | 3781 |
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| | **Attorney Docket Number** | 111552.8018.US11 |

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| Examiner Initial* | Cite No | Foreign Document Number[3] | Publication Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T[5] |
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## EXAMINER SIGNATURE

| Examiner Signature | /ERIC RASSAVONG/ (10/25/2023) | Date Considered | 10/25/2023 |
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☐ See attached certification statement.

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| | | | |
|---|---|---|---|
| Signature | /Matthew S. Williams/ | Date (YYYY-MM-DD) | 2023-09-21 |
| Name/Print | Matthew S. Williams | Registration Number | 77,516 |

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The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

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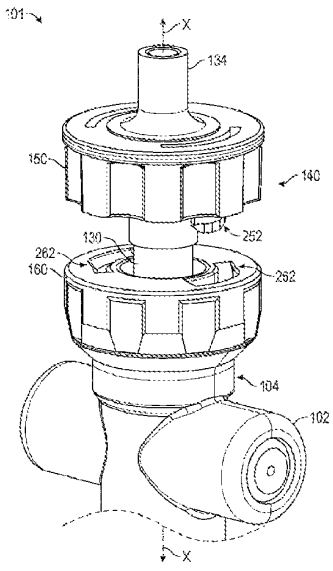



*FIG. 2A*

(57) Abstract: Disclosed herein are vascular access systems with dilator locking mechanisms, and associated devices and methods. In some embodiments, the dilator locking mechanisms include a first cap coupled to a dilator component and a second cap coupled to the vascular access system. The first cap can include one or more locking members. The second cap can include one or more locking features, each configured to be releasably coupled to one of the locking members. In operation, the dilator component can be inserted into the vascular access system, and at least a portion of one or more of the locking members can be aligned with and inserted into the corresponding locking feature to, e.g., couple the first cap and the second cap. The interaction between first and second caps when coupled can at least partially prevent the dilator from moving relative to the vascular access system.

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# CLOT TREATMENT SYSTEMS WITH DILATOR LOCKING MECHANISMS, AND ASSOCIATED DEVICES AND METHODS

## CROSS-REFERENCE TO RELATED APPLICATION

**[0001]** This application claims the benefit of U.S. Provisional Patent Application No. 63/307,766 filed February 8, 2022, and titled "CLOT TREATMENT SYSTEMS WITH DILATOR LOCKING MECHANISMS, AND ASSOCIATED DEVICES AND METHODS," which is incorporated herein by reference in its entirety.

## TECHNICAL FIELD

**[0002]** The present technology generally relates to vascular access systems, such as clot treatment systems, including locking mechanisms for releasably locking a dilator to a catheter to facilitate their joint navigation through a patient's skin, tissue, and vasculature.

## BACKGROUND

**[0003]** Thrombosis is the local coagulation or clotting of the blood in a part of the circulatory system, and a thrombus is a blood clot formed in situ within the vascular system. A venous thrombus is a blood clot that forms within a vein. A common type of venous thrombosis is a deep vein thrombosis (DVT), which is the formation of a blood clot within a deep vein (e.g., predominantly in the legs). Nonspecific signs of a thrombosis may include pain, swelling, redness, warmness, and engorged superficial veins.

**[0004]** If the thrombus breaks off (embolizes) and flows towards the lungs, it can become a life-threatening pulmonary embolism (PE) (e.g., a blood clot in the lungs). In addition to the loss of life that can arise from PE, DVT can cause significant health issues such as post thrombotic syndrome, which can cause chronic swelling, pressure, pain, and ulcers due to valve and vessel damage. Further, DVT can result in significant health-care costs either directly or indirectly through the treatment of related complications and inability of patients to work.

**[0005]** Existing methods for treating DVT and PE often involve treating the DVT or PE with a catheter system that is advanced through the patient's vasculature, such as along a venous access path. Such catheter systems—especially those having a large size (e.g., greater than 16 French)—often include a dilator component that is inserted through a catheter and used to

dilate the vasculature while the catheter is navigated to a target treatment site. Similarly, such systems are often used in conjunction with an introducer sheath that acts as a resealable access point through which the DVT and PE catheter systems can traverse to easily access the vasculature. The introducer sheath provides a stable tract and prevents excessive manipulation of devices with the access site, and can be inserted through the skin and tissue tract with a dilator component interested therein.

**[0006]** However, during advancement of a catheter through the vasculature, the dilator component and/or the catheter can experience considerable force or resistance from the patient's vasculature. Similarly, during insertion of an introducer sheath, the dilator component and/or the introducer sheath can experience considerable force or resistance from the patient's skin and tissue. In some instances, the force against the dilator component can cause the dilator component to retract or backslide within the catheter/introducer sheath. If the dilator retracts far enough, the edge of the catheter/introducer sheath can be exposed and may cause damage to a percutaneous access site or the vasculature of the patient.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0007]** Many aspects of the present technology can be better understood with reference to the following drawings. The components in the drawings are not necessarily to scale. Instead, emphasis is placed on illustrating clearly the principles of the present disclosure.

**[0008]** Figure 1 is a partially schematic side view of a vascular access system including a cap assembly and configured in accordance with the present technology.

**[0009]** Figure 2A–2C are a partially-exploded isometric view, a side cross-sectional view, and an enlarged view, respectively, of the cap assembly of Figure 1 in accordance with embodiments of the present technology.

**[0010]** Figures 3A–3C are a perspective view, a cross-sectional view, and a bottom view, respectively, of a first cap of the cap assembly of Figure 1 in accordance with embodiments of the present technology.

**[0011]** Figures 4A–4C are a perspective view, a cross-sectional view, and a bottom view, respectively, of a second cap of the cap assembly of Figure 1 in accordance with embodiments of the present technology.

**[0012]** Figures 5A and 5B are respective bottom views of the cap assembly of Figure 1 in accordance with embodiments of the present technology.

**[0013]** Figures 6A–6C are top views of respective second caps in accordance with additional embodiments of the present technology.

**[0014]** Figure 7 is a top view of a second cap in accordance with additional embodiments of the present technology.

**[0015]** Figure 8 is a perspective view of a cap-locking valve in accordance with embodiments of the present technology.

## DETAILED DESCRIPTION

**[0016]** The present technology is generally directed to vascular access systems with dilator locking mechanisms, and associated devices and methods. In some of the embodiments described in detail below, a dilator locking mechanism includes a first cap coupled to a dilator and a second cap coupled to a catheter (e.g., an aspiration catheter, an introducer/access sheath) of, for example, a clot treatment system. The first cap can include one or more locking members, and the second cap can include one or more locking features corresponding to one or more of the locking members. Each of the locking members (first cap) can be aligned with and inserted at least partially into the corresponding locking feature (second cap) to, for example, couple the first cap to the second cap. Because the first cap is coupled to the dilator, the interaction between the first and second caps when coupled can secure the dilator relative to the catheter to inhibit or even prevent the dilator from moving proximally and/or distally relative to the catheter.

**[0017]** In some embodiments, the locking features are configured to deflect the locking members into a locked position when the locking members are inserted therein. In these and other embodiments, the first cap can be rotated relative to the second cap (and/or the second cap rotated relative to the first cap) to move the locking members from the locked position to an unlocked position to uncouple the dilator locking mechanism and allow the dilator to move relative to the catheter of the vascular access system.

**[0018]** Current dilator locking mechanisms may involve a direct connection between the associated dilator and vascular access system. For example, such locking mechanisms may require that the dilator be fully advanced through the clot treatment system and then rotated to secure the dilator. With this style of mechanism, it may be difficult for an operator to distinguish (e.g., visually) between situations where the dilator is (i) fully inserted into and secured to the clot treatment system and (ii) fully inserted into but not secured to the clot

treatment system. In contrast to these current mechanisms, the dilator locking mechanisms of the present technology can be located at or near a proximal end of the clot treatment system, such that a user of the clot treatment system (e.g., a physician) can easily observe the first and second caps to determine whether the dilator is secured to the clot treatment system by observing the relative positions and/or alignment of the first and second caps.

**[0019]** Certain details are set forth in the following description and in Figures 1–8 to provide a thorough understanding of various embodiments of the present technology. In other instances, well-known structures, materials, operations, and/or systems often associated with intravascular procedures, clot removal procedures, catheters, and the like are not shown or described in detail in the following disclosure to avoid unnecessarily obscuring the description of the various embodiments of the technology. Those of ordinary skill in the art will recognize, however, that the present technology can be practiced without one or more of the details set forth herein, and/or with other structures, methods, components, and so forth.

**[0020]** The terminology used below is to be interpreted in its broadest reasonable manner, even though it is being used in conjunction with a detailed description of certain examples of embodiments of the technology. Indeed, certain terms may even be emphasized below; however, any terminology intended to be interpreted in any restricted manner will be overtly and specifically defined as such in this Detailed Description section.

**[0021]** The accompanying Figures depict embodiments of the present technology and are not intended to be limiting of its scope unless expressly indicated. The sizes of various depicted elements are not necessarily drawn to scale, and these various elements may be enlarged to improve legibility. Component details may be abstracted in the Figures to exclude details such as position of components and certain precise connections between such components when such details are unnecessary for a complete understanding of how to make and use the present technology. Many of the details, dimensions, angles and other features shown in the Figures are merely illustrative of particular embodiments of the disclosure. Accordingly, other embodiments can have other details, dimensions, angles and features without departing from the present technology. In addition, those of ordinary skill in the art will appreciate that further embodiments of the present technology can be practiced without several of the details described below.

**[0022]** With regard to the terms "distal" and "proximal" within this description, unless otherwise specified, the terms can reference a relative position of the portions of a catheter

subsystem with reference to an operator and/or a location in the vasculature. Also, as used herein, the designations "rearward," "forward," "upward," "downward," and the like are not meant to limit the referenced component to a specific orientation. It will be appreciated that such designations refer to the orientation of the referenced component as illustrated in the Figures; the systems of the present technology can be used in any orientation suitable to the user.

**[0023]** Figure 1 is a partially schematic side view of a vascular access system 100 ("the system 100") configured in accordance with embodiments of the present technology. The system 100 can also be referred to as an aspiration assembly, a clot treatment system, a clot removal system, a thrombectomy system, an introducer sheath assembly, and/or the like. In the illustrated embodiment, the system 100 includes a tubing assembly 110 fluidly coupled to a catheter 120 via a valve 102. In some embodiments, the catheter 120 is an elongate member configured to be inserted into and through a patient's vasculature and used to, for example, treat clot material therein. In other embodiments, the catheter 120 can be an introducer sheath configured to be inserted through the skin and tissue tract of the patient to provide an access site through which other components (e.g., other catheters used to treat clot material) can traverse to easily access the vasculature. Accordingly, while referred to as "catheter 120," the catheter 120 can comprise an introducer sheath, an access sheath, and/or another type of elongate member configured to be inserted through the skin and tissue tract and/or to traverse the vasculature of a patient. In general, the system 100 (i) can include features generally similar or identical to those of the clot treatment systems described in detail in U.S. Patent Application No. 16/536,185, filed August 8, 2019, and titled "SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS," which is incorporated herein by reference in its entirety, and/or (ii) can be used to treat/remove clot material from a patient (e.g., a human patient) using any of the methods described in detail therein.

**[0024]** In the illustrated embodiment, the catheter 120 includes a proximal region or portion 122 and a distal tip region or portion 124 opposite the proximal region 122. The catheter 120 further defines a lumen 121 (shown in dashed-line in Figure 1) extending entirely therethrough from the proximal region 122 to the distal tip region 124. The lumen 121 and/or the catheter 120 can at least partially define a longitudinal axis X of the system 100. The proximal region 122 can include a proximal terminus 126 of the catheter 120, and the distal tip region 124 can include a distal terminus 128 of the catheter 120.

**[0025]** The valve 102 is fluidly coupled to the lumen 121 of the catheter 120 and can be integral with or coupled to the proximal region 122 of the catheter 120 such that these components move together. In some embodiments, the valve 102 is a hemostasis valve that is configured to maintain hemostasis during a clot removal procedure by preventing fluid flow in a proximal direction P through the valve 102 as various components such as dilators, delivery sheaths, pull members, guidewires, interventional devices, other aspiration catheters, and so on are inserted through the valve 102 to be delivered through the catheter 120 to a treatment site in a blood vessel. In the illustrated embodiment, for example, a dilator 130 is inserted through the valve 102 and positioned within the catheter 120. The valve 102 includes a branch or side port 106 configured to fluidly couple the lumen 121 of the catheter 120 to the tubing assembly 110. In some embodiments, the valve 102 can be a valve of the type disclosed in U.S. Patent Application No. 16/117,519, filed August 30, 2018, and titled "HEMOSTASIS VALVES AND METHODS OF USE," which is incorporated herein by reference in its entirety.

**[0026]** In the illustrated embodiment, the tubing assembly 110 fluidly couples the catheter 120 to a pressure source 108, such as a syringe. The pressure source 108 can be configured to generate (e.g., form, create, charge, build-up) a vacuum (e.g., negative relative pressure) and store the vacuum for subsequent application to the catheter 120 (e.g., after the dilator 130 has been removed from the catheter 120). The tubing assembly 110 can include one or more tubing sections 112 (individually labeled as a first tubing section 112a and a second tubing section 112b), at least one fluid control device 114 (e.g., a valve), and at least one connector 116 (e.g., a Toomey tip connector) for fluidly coupling the tubing assembly 110 to the pressure source 108 and/or other suitable components. In some embodiments, the fluid control device 114 is a stopcock that is fluidly coupled to (i) the side port 106 of the valve 102 via the first tubing section 112a and (ii) the connector 116 via the second tubing section 112b. The fluid control device 114 is externally operable by a user to regulate the flow of fluid therethrough and, specifically, from the lumen 121 of the catheter 120 to the pressure source 108. In some embodiments, the connector 116 is a quick-release connector (e.g., a quick disconnect fitting) that enables rapid coupling/decoupling of the catheter 120 and the fluid control device 114 to/from the pressure source 108.

**[0027]** In the illustrated embodiment, the dilator 130 is inserted through the valve 102 in a distal direction D and extends fully through the lumen 121 and past the distal terminus 128 of the catheter 120, such that a distal tip 132 (e.g., an atraumatic tip) of the dilator 130 is positioned beyond the distal terminus 128 of the catheter 120. The dilator 130 and the system

100 can together define a catheter or introducer assembly 101 that can be inserted into a patient (e.g., a human patient) during a clot treatment procedure. For example, the dilator 130 and the system 100 can be inserted into and advanced together through a blood vessel of the patient to a target location in the blood vessel. The dilator 130 can then be retracted proximally (e.g., in the proximal direction P) through the system 100 to allow for other intravascular medical devices to be introduced into the patient via the system 100 and/or for aspiration of the catheter 120. For example, in some embodiments the system 100 and/or the catheter assembly 101 can be used in any of the clot removal procedures disclosed in U.S. Patent Application No. 16/536,185, filed August 8, 2019, and titled "SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS," which is incorporated herein by reference in its entirety.

**[0028]** The catheter assembly 101 can include a locking mechanism or cap assembly 140 (which can also be referred to as a locking cap assembly, a dilator locking mechanism, a dilator coupling mechanism, and/or the like) configured to releasably couple and secure the dilator 130 to the system 100. The cap assembly 140 can lock the dilator 130 to the valve 102 and the catheter 120 to inhibit or even prevent the dilator 130 from moving within the catheter 120 in the proximal direction P and/or the distal direction D when the catheter assembly 101 is advanced through the vasculature of a patient. More specifically, for example, the cap assembly 140 can inhibit or even prevent the distal tip 132 of the dilator 130 from moving proximally toward the distal terminus 128 of the catheter 120 when the catheter assembly 101 is advanced through the vasculature of the patient.

**[0029]** In the illustrated embodiment, the cap assembly 140 includes (i) a first or proximal cap 150 coupled to or integrally formed with the dilator 130 (via, e.g., a coupling element or luer connector 134) opposite the distal tip 132 and (ii) a second or distal cap 160 coupled to a proximal portion 104 of the valve 102. The first cap 150 can be releasably coupled/locked to the second cap 160. Accordingly, inserting the dilator 130 into the catheter 120 can include moving the first cap 150 toward the second cap 160. In some embodiments, the first cap 150 can mate with the second cap 160 to lock the dilator 130 to the valve 102 when the dilator 130 is fully seated within the system 100. In some aspects of the present technology, a user can easily determine the state of the dilator 130 (e.g., how far the dilator 130 is inserted into the catheter 120 and/or whether the dilator 130 is secured to the system 100) by viewing the cap assembly 140. Additional details regarding the cap assemblies of the present technology, including the cap assembly 140, are discussed in detail below with reference to Figures 2A–8.

**[0030]** During a clot treatment procedure, the catheter assembly 101 can be inserted through the vasculature of a patient (e.g., through an introducer sheath that traverses the skin and tissue of the patient to provide an access site) with the cap assembly 140 locking the dilator 130 to the valve 102 and the catheter 120. When the catheter 120 is positioned at a desired position relative to clot material (e.g., a pulmonary embolism, deep vein thrombosis) within the patient, the cap assembly 140 can be unlocked and the dilator 130 withdrawn from the catheter 120. Then, a user can first close the fluid control device 114 before generating a vacuum in the pressure source 108 by, for example, withdrawing the plunger of a syringe coupled to the connector 116. In this manner, a vacuum is charged within the pressure source 108 (e.g., a negative pressure is maintained) before the pressure source 108 is fluidly connected to the lumen 121 of the catheter 120. To aspirate the lumen 121 of the catheter 120, the user can open the fluid control device 114 to fluidly connect the pressure source 108 to the catheter 120 and thereby apply or release the vacuum stored in the pressure source 108 to the lumen 121 of the catheter 120. Opening of the fluid control device 114 instantaneously or nearly instantaneously applies the stored vacuum pressure to the tubing assembly 110 and the catheter 120, thereby generating a suction pulse throughout the catheter 120 that can aspirate the clot material into the catheter 120. In particular, the suction is applied at the distal tip region 124 of the catheter 120 to suck/aspirate at least a portion of the clot material proximate the distal tip region 124 into the lumen 121 of the catheter 120. In other embodiments, where the catheter 120 is an introducer sheath, the introducer assembly 101 can be inserted through the skin and tissue of a patient and partially into a vessel to provide an access point for other medical instruments.

**[0031]** Figure 2A is a partially-exploded isometric view of cap assembly 140 of Figure 1 in accordance with embodiments of the present technology. In the illustrated embodiment, the cap assembly 140 is in an unlocked position in which the first cap 150 is not secured to the second cap 160 such that the dilator 130 is free to move relative to the valve 102 and the catheter 120 (Figure 1). The first cap 150 can include one or more coupling or locking members 252 extending (e.g., downwardly, distally, and/or toward the second cap 160) in a direction parallel or generally parallel to the longitudinal axis X. In the illustrated embodiment, the first cap 150 includes two of the locking members 252 (one of the locking members 252 is obscured in Figure 2A) positioned on opposite sides of the first cap 150 (e.g., 180-degrees apart). The second cap 160 can include one or more coupling or locking features 262 that extend through the second cap 160 at least partially about the longitudinal axis X. In the illustrated embodiment, the locking members 252 are projections and the locking features 262

are corresponding grooves or openings. In other embodiments, the first cap 150 can include more or fewer of the locking members 252 and/or the second cap 160 can include more or fewer of the locking features 262. For example, the first cap 150 can include one or more than two of the locking members 252, and the second cap 160 can include the same number of the locking features 262. In the illustrated embodiment, the first cap 150 and the second cap 160 have circular shapes. In other embodiments, the first cap 150 and/or the second cap 160 can have a triangular, square, rectangular, rectilinear, curvilinear, or any other suitable shape. In at least some embodiments, the first cap 150 and the second cap 160 can have a same shape. In other embodiments, the first cap and the second cap can have different shapes.

**[0032]** Each of the locking members 252 can be relatively flexible and configured to undergo elastic or generally elastic deformations. Additionally, each of the locking features 262 can be configured (e.g., shaped and sized) to bend or deflect the corresponding locking members 252 inwardly (toward the longitudinal axis X) to facilitate locking/coupling of the first cap 150 to the second cap 160. In the illustrated embodiment, individual ones of the locking features 262 are configured (e.g., shaped, sized, positioned) to releasably receive a corresponding one of the locking members 252. In general, to secure (e.g., couple, lock) the first cap 150 to the second cap 160, the locking members 252 can be at least partially aligned with and inserted into the corresponding locking features 262. Once inserted, the outward bias of the locking members 252 can cause the locking members 252 to engage the corresponding locking features 262 (and/or another portion of the valve 102) to secure the first cap 150 to the second cap 160. In some embodiments, aligning the locking members 252 with the corresponding locking features 262 can include rotating the first cap 150 (e.g., about the longitudinal axis X) relative to the second cap 160.

**[0033]** In operation, inserting the dilator 130 into the valve 102 and the catheter 120 includes moving the first cap 150 toward the second cap 160. While moving the dilator 130 through the valve 102, the user can rotate the first cap 150 such that individual ones of the locking members 252 are at least partially aligned with the corresponding ones of the locking features 262. With the locking members 252 and the corresponding locking features 262 in this orientation, the user can bring the first cap 150 into contact with the second cap 160 to insert the locking members 252 into the corresponding locking features 262 and secure the first cap 150 to the second cap 160.

**[0034]** More specifically, Figure 2B is a side cross-sectional view of the cap assembly 140 of Figure 2A in accordance with embodiments of the present technology. Figure 2C is an enlarged view of a region 2C of Figure 2B in accordance with embodiments of the present technology. The cap assembly 140 is in a locked position in Figures 2B and 2C in which the first cap 150 is secured to the second cap 160 such that the dilator 130 is locked in position relative to the valve 102 and the catheter 120 (Figure 1). Referring to Figures 2B and 2C together, each of the locking features 262 of the second cap 160 can include a channel or slot 264 defined at least partially by a first or inner wall 263 and a second or outer wall 265 spaced radially apart from the inner wall 263. In the locked position shown in Figures 2B and 2C, the locking members 252 are inserted into the corresponding locking features 262 such that at least a portion of the locking members 252 are positioned in the slots 264 of the corresponding locking features 262 between the inner wall 263 and the outer wall 265.

**[0035]** Referring to Figure 2B, in some embodiments the second cap 160 includes an opening 261 sized, positioned, and/or otherwise configured to allow the dilator 130 to pass through the second cap 160. The first cap 150 is secured to the dilator 130 and can include an opening 251 configured to receive the dilator 130 and a connected or integral luer connector 134. In the illustrated embodiment, for example, the opening 251 is at least partially defined by one or more luer coupling members 253. Each of the luer coupling members 253 can be positioned radially inward relative to one or more of the locking members 252. Additionally, each of the luer coupling members 253 can be generally flexible and configured to undergo elastic or generally elastic deformations. The luer connector 134 can include a first or distal flange 236 and a second or proximal flange 238 opposite and spaced apart from the distal flange 236. The dilator 130 and the luer connector 134 can be inserted through the opening 251 such that the distal flange 236 contacts individual ones of the luer coupling members 253 to cause the luer coupling members 253 to bend or deflect radially outward away from the luer connector 134. Once the distal flange 236 has moved distally past the luer coupling members 253, the luer coupling members 253 can return to their original (e.g., unbent) configuration, as shown in Figure 2B. With the luer connector 134 and the luer coupling members 253 in the respective positions shown in Figure 2B, at least a portion of the first cap 150 (e.g., the luer coupling members 253) can be positioned between the distal flange 236 and the proximal flange 238 to secure the dilator 130 to the first cap 150. In other embodiments, the dilator 130 can be secured to the first cap 150 in other manners.

**[0036]** Referring to Figure 2C, each of the locking features 262 in the second cap 160 can further include a first surface 266 (which can also be referred to as a proximal, deflecting, angled, and/or insertion surface) and a second surface 268 (which can also be referred to as a distal, retaining, and/or locking surface). The second surface 268 can extend from the outer wall 265 toward the inner wall 263 in an inward direction perpendicular or generally perpendicular to the inner and/or outer walls 263, 265. The first surface 266 can extend upwardly at an incline from the second surface 268 and away from the inner wall 263, to, for example, form an acute interior angle with the second surface 268. In other embodiments, the first and second surfaces 266, 268 can be positioned on the inner wall 263 opposite the outer wall 265, or have any other suitable configuration.

**[0037]** Each of the locking members 252 can include a tab 254. Each tab 254 can be positioned at or near a distal end of the associated locking members 252. In the illustrated embodiment, the tab 254 extends outward and/or perpendicularly from the associated locking member 252 (e.g., toward the outer wall 265). In other embodiments, one or more of the tabs 254 can extend inward from the associated locking member 252 (e.g., toward the inner wall 263), or in any other suitable direction. The tab 254 can define a stopping or retaining surface 256. When the first cap 150 is coupled to the second cap 160, as shown in Figure 2C, the retaining surface 256 is at least partially aligned with and/or parallel to the second surface 268. The alignment of the retaining surface 256 with the second surface 268 can prevent, or at least partially prevent, the first cap 150 from moving (e.g., upwardly and/or proximally) relative to the second cap 160 which, in turn, can couple or "lock" the first cap 150 and the second cap 160 to one another. In Figure 2C, the retaining surface 256 and the second surface 268 are shown as being spaced apart for the sake of illustration; those of ordinary skill in the art will understand that, in other embodiments, at least part of the retaining surface 256 can contact at least part of the second surface 268 to prevent, or at least partially prevent, the first cap 150 from moving relative to the second cap 160.

**[0038]** Referring to Figures 2A–2C together, to couple the dilator 130 to the valve 102, a user can position the locking members 252 of the first cap 150 such that the tabs 254 are at least partially aligned with the slots 264 of the second cap 160 and/or contacting the first surfaces 266 of the corresponding locking features 262. The user can then move the first cap 150 toward the second cap 160 to cause the tabs 254 to translate along the corresponding first surfaces 266 inwardly in a first direction D1 (Figure 2C; e.g., toward the longitudinal axis X in Figure 2A). The movement of the tabs 254 in the first direction D1 can cause a corresponding

bend or deflection in the locking members 252. Continued movement of the first cap 150 toward the second cap 160 can move the tabs 254 past the corresponding first surfaces 266; once past the first surfaces 266, the locking members 252 can move in a second direction D2 (Figure 2C; e.g., away from the longitudinal axis X in Figure 2A) opposite the first direction D1. The movement of the locking members 252 in the second direction D2 can be due at least partially to the elastic or generally elastic deformation properties of the locking members 252. As the locking members 252 move in the second direction D2, each of the retaining surfaces 256 can be at least partially aligned with the second surface 268 of the corresponding locking features 262 to secure the first cap 150 and the second cap 160. That is, the tabs 254 can be advanced past and snap inward behind the corresponding second surfaces 268, which retain the tabs 254 and the first cap 150 in the locked position, e.g., as described previously herein.

**[0039]** Figures 3A–3C are a perspective view, a cross-sectional view, and a bottom view, respectively, of the first cap 150 in accordance with embodiments of the present technology. Referring to Figures 3A–3C together, the first cap 150 can have a longitudinal axis Y and, when the first cap 150 is coupled to the valve 102 and the catheter 120 (Figure 1), the longitudinal axis Y can be the same as (e.g., colinear with) the longitudinal axis X (Figures 1 and 2A). In the illustrated embodiment, the first cap 150 is bilaterally and/or radially symmetric relative to the longitudinal axis Y. In other embodiments, the first cap 150 can be configured to have any other symmetry and/or be asymmetrical. Referring to Figure 3B, each of the locking members 252 can be deflectable at least in the first direction D1 (e.g., outwardly and/or away from the longitudinal axis Y). Each of the luer coupling members 253 can be oppositely deflectable compared to the locking members 252 (e.g., at least in the second direction D2). Each of the locking members 252 and/or the luer coupling members 253 can extend away from an upper surface 357 of the first cap 150 (e.g., downwardly and/or in a direction parallel or generally parallel to the longitudinal axis Y). Referring to Figure 3C, each of the locking members 252 and/or the luer coupling members 253 can be curved or arcuate and extend at least partially around the longitudinal axis Y. In at least some embodiments, the curvature of one or more of the locking members 252 and/or the luer coupling members 253 is concentric with the opening 251.

**[0040]** Figures 4A–4C are a perspective view, a cross-sectional view, and a bottom view, respectively, of the second cap 160 of the cap assembly 140 of Figure 1 in accordance with embodiments of the present technology. Referring to Figures 4A–4C together, the second cap 160 can have a longitudinal axis Z and when the second cap 160 is coupled to the valve 102

and the catheter 120 (Figure 1), the longitudinal axis Z can be the same as (e.g., colinear with) the longitudinal axis X (Figures 1 and 2A). Additionally, when the first cap 150 (Figures 1–3C) is coupled to the second cap 160, the longitudinal axis Z can be the same as (e.g., colinear with) the longitudinal axis Y (Figures 3A–3C). Each of the locking features 262 and/or one or more of the elements thereof (e.g., the slot 264, the first surface 266, etc.) can be curved or arcuate and extend at least partially around the longitudinal axis Z.

**[0041]** Referring to Figures 4A and 4B together, each of the locking features 262 can include an axial removal surface 470. Each of the axial removal surfaces 470 can be adjacent to the slot 264, opposite an end wall 469 of the slot 264 and at least partially between the first surface 266 and the inner wall 263. Additionally, each of the axial removal surfaces 470 can be inclined upwardly (e.g., along the longitudinal axis Z and/or toward an upper surface 467 of the second cap 160). Accordingly, when the locking members 252 are positioned in the slots 264, the axial removal surfaces 470 can drive the locking members 252 axially and/or upwardly there along, as described in detail below with reference to Figures 5A and 5B.

**[0042]** Referring to Figure 4C, each of the locking features 262 can further include a radial removal surface 472. Each of the radial removal surfaces 472 can be positioned at least partially within the associated slot 264 and extend (e.g., downwardly, distally) from the associated second surface 268 (from the perspective shown in Figure 4C, the radial removal surfaces 472 extend away from the page toward the viewer). Additionally, each of the radial removal surfaces 472 can be angled relative to the outer wall 265 and/or the inner wall 263. In the illustrated embodiment, for example, each of the radial removal surfaces 472 extend inward away from the outer wall 265 and toward the inner wall 263 and/or the longitudinal axis Z. Accordingly, when the locking members 252 are positioned in the slots 264 and brought into contact with the radial removal surfaces 472, the radial removal surfaces 472 can drive the locking members 252 inwardly there along, as described in detail below with reference to Figures 5A and 5B.

**[0043]** The slots 264 can have a slot dimension S defined at least partially by the slot end wall 469 and the axial removal surface 470. The slot dimension S can be an angle, an arc length, or any other suitable dimension. Because the locking members 252 can be inserted along the length of the slot 264, an increased slot dimension S can reduce the difficulty of aligning the first cap 150 with the second cap 160. Additionally, or alternatively, the slot dimension S can at least partially define an amount that the first cap 150 can rotate while at least partially

coupled to the second cap 160. For example, a relatively high slot dimension (e.g., a greater arc length) can correspond to a relatively increased degree of rotation of the first cap 150, and a relatively low slot dimension can correspond to a relatively decreased degree of rotation of the first cap 150.

**[0044]** Figures 5A and 5B are respective bottom views of the cap assembly of Figure 1 in accordance with embodiments of the present technology. In Figure 5A, the cap assembly 140 is in the locked position with the locking members 252 of the first cap 150 positioned in the corresponding locking features 262 of the second cap 160 such that the first cap 150 is coupled to the second cap 160. In Figure 5B, the cap assembly 140 is in the unlocked position in which the first cap 150 has been rotated in a direction R relative to the second cap 160 and/or about the longitudinal axes Y and/or Z to uncouple the first cap 150 from the second cap 160. In the illustrated embodiment, the direction R is a clockwise direction when viewed from the bottom of the cap assembly 140 (e.g., a counter-clockwise direction when viewed from the top of the cap assembly 140). In other embodiments, the first cap 150 and/or the second cap 160 can be configured such that the direction R is a counter-clockwise direction when viewed from the bottom of the cap assembly 140 (e.g., a clockwise direction when viewed from the top of the cap assembly 140).

**[0045]** Referring to Figures 5A and 5B together, rotating the first cap 150 in the direction R (Figure 5B) can move the tabs 254 toward the corresponding radial removal surfaces 472 until one or more of the tabs 254 at least partially contact the corresponding radial removal surface 472. In response to the rotation in the direction R, the radial removal surfaces 472 can deflect each of the tabs 254 inward in the direction D1, as shown in Figure 5B. This deflection of the tabs 254 causes a corresponding inward deflection in the associated locking members 252. In some aspects of the present technology, the radial removal surfaces 472 at least partially prevent the first cap 150 from being accidentally or unintentionally disconnected from the second cap 160 until a force (e.g., torque) sufficient to deflect the locking members 252 inward is applied to the first cap 150.

**[0046]** With the tabs 254 in the position shown in Figure 5B, continued rotation of the first cap 150 in the direction R causes the tabs 254 to contact the corresponding axial removal surfaces 470 (Figures 4A and 4B). Each of the locking members 252 can translate upwardly across the corresponding axial removal surface 470 and cause the first cap 150 to move away from the second cap 160 in a direction generally along the longitudinal axis Z (e.g., to the unlocked

position shown in Figure 2A). Continued rotation of the first cap 150 can fully uncouple the first cap 150 and the second cap 160. However, it will be appreciated that, with the tabs 254 deflected inwardly in the position shown in Figure 5B, the first cap 150 can be moved away from the second cap 160 without further rotation to decouple the first cap 150 from the second cap 160.

**[0047]** Accordingly, in some aspects of the present technology the locking features 262 include (i) the insertion surface 266 for deflecting one or more of the tabs 254 inward during insertion and/or in response to axial movement, (ii) the radial removal surface 472 for deflecting the tabs 254 inward (e.g., radially inward) during removal and/or in response to rotary movement, and (iii) the axial removal surface 470 for moving the tabs 254 upward (e.g., axially upward) during removal and/or in response to rotary movement. The insertion surface 266 can be positioned to align with the corresponding tab 254 when the cap assembly 140 is in the unlocked position. During insertion, the tab 254 can move toward, contact, and translate inwardly along the insertion surface 266. The radial removal surface 472 can be positioned proximate the tab 254 when the cap assembly 140 is in the locked position. During removal, the tab 254 can move (e.g., rotate) toward, contact, and translate inwardly along the radial removal surface 472. The cap assembly 140 can transition from the locked position toward the unlocked position as the tab 254 translates along the radial removal surface 472. Additionally, the tab 254 can move toward the axial removal surface 470 as it translates along the radial removal surface 472. The axial removal surface 470 can be angled upwardly, away from the radial removal surface 472. Accordingly, during removal, the tab 254 can move (e.g., rotate) toward, contact, and translate upward along the axial removal surface 470. Translating the tab 254 along the axial removal surface 470 can return the cap assembly 140 to the unlocked position.

**[0048]** Figures 6A–6C are top views of respective second caps in accordance with additional embodiments of the present technology. Each of the second caps 660a-c can be generally similar to the second cap 160 of Figures 1–2C and 4A-5B. However, referring to Figure 6A, the second cap 660a includes a reduced slot dimension S1, such that the second cap 660a does not allow the first cap (not shown) to rotate while remaining coupled to the second cap 660a and/or any rotation of the first cap begins the decoupling process described above. Referring to Figure 6B, the second cap 660b includes an increased slot dimension S2 that allows the first cap (not shown) to rotate up to 60 degrees relative to the second cap 660b while still remaining coupled to the second cap 660b and/or before the rotation of the first cap begins the decoupling

process described above. Referring to Figure 6C, the second cap 660c does not include one or more of inner walls 263 (Figures 2B, 2C, and 4A~4C), such that the opening 661 and one or more of the slots 664 are connected or are otherwise not separated by inner walls.

**[0049]** Figure 7 is a top view of a second cap 760 configured in accordance with additional embodiments of the present technology. At least some aspects of the second cap 760 can be at least generally similar or identical in structure and/or function to one or more of the second caps 160, 660a-c described in detail previously herein. In the illustrated embodiment, the second cap 760 further includes one or more rotationally agnostic locking features 762 ("locking features 762"). In the illustrated embodiment, each of the locking features 762 includes an outer wall 765 and two radial removal surfaces 772 positioned e.g., on left and right sides of the outer wall 765. The second cap 760 can further include axial removal surfaces 770 positioned on the left and right sides of the locking features 762 and/or aligned with the radial removal surfaces 772 thereof. Accordingly, when a locking member of a first cap (e.g., the locking members 252 of the first cap 150 of Figure 2A) is received within one of the locking features 762, the first cap can be rotated in the direction R or opposite the direction R (e.g., counterclockwise or clockwise) to drive the locking member against one of the radial removal surfaces 772 and uncouple the first cap and the second cap 760. Continued rotation of the first cap can translate the locking members of the first cap along the axial removal surfaces 770. This rotationally agnostic configuration of the locking features 762 is expected to allow the first cap to be quickly and easily uncoupled from the second cap 760. The locking features 762 can be aligned with and/or positioned distally of a respective first surface 766, and the locking members of a first cap (e.g., the locking members 252 of the first cap 150 of Figure 2A) can contact and be driven radially inward by the first surfaces 766 to couple with the locking features 762.

**[0050]** In some embodiments, the second cap 760 can include one or more support surfaces 774positioned radially inward of one of the first surfaces 766, e.g., between the axial removal surfaces 770 associated with one of the locking features 762. Each of the support surfaces 774 can be configured to contact at least part of a coupling member of a first cap, e.g., after the first cap is coupled/locked to the second cap 760. In some embodiments, one or more of the support surfaces 774 can be curved or concave. Accordingly, when the first cap is coupled to the second cap 760 and/or the coupling members of the first cap contact the support surfaces 774, the curvature/concavity of the support surfaces 774 can at least partially prevent rotation of the

first cap relative to the second cap 760, e.g., in addition to or in lieu of the resistance to rotation of the first cap provided by the radial removal surfaces 772.

**[0051]** Figure 8 is a perspective view of a cap-locking valve 880 configured in accordance with embodiments of the present technology. The cap-locking valve 880 can include a valve 802 and an integrated locking feature 860. The valve 802 can include at least some aspects that are at least generally similar or identical in structure and/or function to the valve 102 of Figure 1. In at least some embodiments, for example, the valve 802 can be a hemostasis valve that is configured to maintain hemostasis during a clot removal procedure by preventing fluid flow in a proximal direction through the valve 802 as various components such as dilators, delivery sheaths, pull members, guidewires, interventional devices, other aspiration catheters, and so on are inserted through the valve 802.

**[0052]** The integrated locking feature 860 can be formed in the valve at or near a proximal end of the valve 802 or at another suitable position on/in the valve 802. The integrated locking feature 860 can include at least some aspects that are at least generally similar or identical in structure and/or function to one or more of the second caps 160, 660a-c, 760 described herein. In the illustrated embodiment, for example, the integrated locking feature 860 includes at least some features that are at least generally similar in structure and/or function to the second cap 760 of Figure 7. In other embodiments, the integrated locking feature 860 can have another suitable configuration. In these and other embodiments, the integrated locking feature 860 can be directly integrated into the valve 802 rather than being included in a separate cap or other component releasably couplable to the valve 802.

**[0053]** Several aspects of the present technology are set forth in the following examples:

1. A cap assembly for a catheter, the cap assembly comprising:

a first cap including a locking member, wherein the locking member includes an end portion and a tab positioned proximate the end portion; and

a second cap including a locking feature, wherein the locking feature includes a slot extending at least partially through the second cap, and wherein—

the first cap is configured to be secured to the second cap in a locked position,

in the locked position, the locking feature is configured to receive the locking member through the slot such that the tab engages a portion of the

second cap to inhibit movement of the first cap relative to the second cap, and

the first cap is configured to rotate relative to the second cap to move the tab out of engagement with the second cap to move the first cap from the locked position to an unlocked position.

2. The cap assembly of example 1 wherein the first cap includes an upper surface, and wherein the locking member extends from the upper surface in a direction generally perpendicular to the upper surface, and wherein the end portion of the locking member is opposite the upper surface.

3. The cap assembly of example 1 or example 2 wherein the tab extends perpendicularly from the locking member.

4. The cap assembly of any one of examples 1–3 wherein the tab defines a retaining surface positioned to contact at least a portion of the second cap when the first cap is coupled to the second cap.

5. The cap assembly of any one of examples 1–4 wherein the locking member is flexible, and wherein the second cap is configured to bend the locking member when the first cap moves between the unlocked position and the locked position.

6. The cap assembly of any one of examples 1–5 wherein the locking feature includes a locking surface positioned to at least partially contact the tab of the locking member when the first cap is coupled to the second cap.

7. The cap assembly of any one of examples 1–6 wherein the locking feature includes an angled insertion surface positioned to engage and deflect the locking member when the first cap moves from the unlocked position toward the locked position.

8. The cap assembly of example 7 wherein the cap assembly includes a longitudinal axis, and where the insertion surface is angled to bend the locking member inward toward the longitudinal axis.

9. The cap assembly of any one of examples 1–8 wherein the locking feature includes a radial removal surface, and wherein the radial removal surface is angled to deflect the tab inward when the first cap is rotated relative to the second cap.

10. The cap assembly of any one of examples 1–9 wherein the locking feature includes an axial removal surface positioned proximate the slot and angled to move the first cap away from the second cap when the first cap is rotated relative to the second cap.

11. The cap assembly of any one of examples 1–10 wherein:

the first cap includes an upper surface, and the locking member extends from the upper surface in a direction perpendicular to the upper surface;

the locking member is flexible and configured to deflect when the first cap moves between the unlocked position and the locked position;

the tab defines a retaining surface positioned to contact at least a portion of the second cap in the locked position; and

the locking feature includes—

a locking surface positioned to at least partially contact the retaining surface of the tab in the locked position,

an insertion surface positioned to be at least partially aligned with the locking member and angled to deflect the locking member inward when the first cap moves from the unlocked position toward the locked position,

a radial removal surface positioned proximate the tab of the locking member in the locked position, wherein the radial removal surface is angled to move the tab radially inward when the first cap moves from the locked position toward the unlocked position, and

an axial removal surface positioned proximate the slot and angled to move the first cap longitudinally away from the second cap when the first cap moves from the locked positioned toward the unlocked position.

12. The cap assembly of any one of examples 1–11 wherein the locking member is a first locking member, wherein the locking feature is a first locking feature, wherein the first cap includes one or more second locking members, wherein the second cap includes one or more second locking features, and wherein individual ones of the second locking members are

configured to receive and secure corresponding ones of the second locking members in the locked position.

13. The cap assembly of any one of examples 1-12 wherein the locking feature is configured to be rotationally agnostic such that rotation of the first cap relative to the second cap in a first direction and a second direction opposite the first direction moves the tab out of engagement with the second cap to move the first cap from the locked position to an unlocked position.

14. A vascular access system, comprising:

a valve having a proximal end and a distal end;

a catheter defining a lumen and coupled to the distal end of the valve, the catheter defining a longitudinal axis of the vascular access system;

a dilator configured to extend at least partially through the valve and the lumen; and

a cap assembly movable between a locked configuration and an unlocked configuration, wherein the cap assembly includes (i) a valve cap connected to the proximal end of the valve and including a coupling feature, and (ii) a dilator cap coupled to the dilator and including a coupling tab insertable into the coupling feature, wherein—

in the locked configuration, the coupling feature is configured to receive the coupling tab such that the coupling tab engages a portion of the valve cap to inhibit movement of the dilator relative to the valve along the longitudinal axis, and

the dilator cap is configured to rotate relative to the valve cap to move the coupling tab out of engagement with the valve cap to move the cap assembly from the locked configuration toward the unlocked configuration.

15. The vascular access system of example 14 wherein the coupling tab is flexible, wherein the coupling feature is configured to deflect the coupling tab toward the longitudinal axis when the cap assembly moves from the unlocked configuration toward the locked configuration.

16. The vascular access system of example 14 or example 15 wherein the dilator cap includes a coupling member extending in a direction generally parallel to the dilator and having a distal end, and wherein the coupling tab is positioned proximate the distal end of the coupling member.

17. The vascular access system of any one of examples 14–16 wherein valve cap has a valve cap longitudinal axis, and wherein the coupling feature is curved circumferentially at least partially about the valve cap longitudinal axis.

18. The vascular access system of any one of examples 14–17 wherein the coupling feature includes a coupling surface positioned to at least partially contact the coupling tab of the dilator cap when the cap assembly is in the locked configuration.

19. The vascular access system of example 18 wherein the coupling feature includes an insertion surface positioned to engage and deflect the coupling tab toward the longitudinal axis when the cap assembly moves from the unlocked configuration toward the locked configuration.

20. The vascular access system of example 19 wherein the insertion surface is positioned proximally from the coupling surface.

21. The vascular access system of example 19 or example 20 wherein the insertion surface forms an acute interior angle relative to the coupling surface.

22. The vascular access system of any one of examples 14–21 wherein the coupling feature includes a radial removal surface configured to move the coupling tab radially inward toward the longitudinal axis when the cap assembly moves from the locked configuration toward the unlocked configuration.

23. The vascular access system of any one of examples 14–22 wherein the coupling feature includes (i) a slot configured to receive the coupling tab, and (ii) an axial removal surface positioned proximate the slot and angled to move the dilator cap away from the valve cap along the longitudinal axis when the dilator cap is rotated relative to the valve cap.

24. The vascular access system of any of examples 14-22 wherein the coupling feature includes an outer wall and a pair of radial removal surfaces positioned on left and right sides of the outer wall, and wherein—

in the locked configuration, the coupling tab is positioned between the pair of radial removal surfaces, and

rotation of the dilator cap in a left or right direction relative to the valve cap moves the cap assembly from the locked configuration toward the unlocked configuration.

25. The vascular access system of any one of examples 14-24 wherein the valve cap is integrally formed with proximal end of the valve.

26. The vascular access system of any one of examples 14-24 wherein the valve cap is releasably coupled to the proximal end of the valve.

27. A method of using a vascular access system, the method comprising:

aligning a first cap of the vascular access system with a second cap of the vascular access system, wherein the first cap is coupled to a dilator of the vascular access system, wherein the second cap is coupled to a catheter of the vascular access system, and wherein aligning the first cap with the second cap includes aligning at a locking member of the first cap with a locking feature of the second cap; and

coupling the first cap to the second cap to inhibit the dilator from moving relative to the catheter of the vascular access system, wherein coupling the first cap to the second cap includes inserting the locking member into the locking feature such that the locking feature drives the locking member past a locking surface of the locking feature, and wherein the locking surface is configured to engage the locking member to inhibit longitudinal movement of the first cap relative to the second cap.

28. The method of example 27 wherein coupling the first cap to the second cap further includes positioning the dilator at least partially within the catheter.

29. The method of example 27 or example 28 wherein coupling the first cap to the second cap further includes inserting the dilator fully through the catheter.

30. The method of any one of examples 27–29 wherein aligning the locking member of the first cap with the locking feature of the second cap includes aligning a tab of the locking member with an insertion surface of the locking feature.

31. The method of example 30 wherein moving the first cap toward the second cap includes (i) positioning the tab of the locking member to contact the insertion surface of the locking feature and (ii) translating the tab across the insertion surface to deflect the tab.

32. The method of any one of examples 27–31, further comprising rotating the first cap relative to the second cap to uncouple the first cap from the second cap after coupling the first cap to the second cap.

33. The method of example 32 wherein rotating the first cap includes translating at least a portion of the locking member across a radial removal surface of the locking feature, wherein the radial removal surface is angled to deflect the locking member when the first cap is rotated relative to the second cap.

34. The method of example 32 or example 33 wherein rotating the first cap includes moving the first cap longitudinally away from the second cap.

35. The method of example 34 wherein moving the first cap away from the second cap includes translating the locking member across an axial removal surface of the locking feature, wherein the axial removal surface is angled to move the first cap away from the second cap as the locking member translates across the axial removal surface.

36. The method of any one of examples 32-35 wherein rotating the first cap relative to the second cap to uncouple the first cap from the second cap includes rotating the first cap in a first direction or a second direction opposite the first direction to uncouple the first cap from the second cap.

**[0054]** The above detailed descriptions of embodiments of the technology are not intended to be exhaustive or to limit the technology to the precise form disclosed above. Although specific embodiments of, and examples for, the technology are described above for illustrative purposes, various equivalent modifications are possible within the scope of the technology as those skilled in the relevant art will recognize. For example, although steps are presented in a given order, alternative embodiments may perform steps in a different order. The various embodiments described herein may also be combined to provide further embodiments.

**[0055]** From the foregoing, it will be appreciated that specific embodiments of the technology have been described herein for purposes of illustration, but well-known structures and functions have not been shown or described in detail to avoid unnecessarily obscuring the description of the embodiments of the technology. Where the context permits, singular or plural terms may also include the plural or singular term, respectively.

**[0056]** Moreover, unless the word "or" is expressly limited to mean only a single item exclusive from the other items in reference to a list of two or more items, then the use of "or" in such a list is to be interpreted as including (a) any single item in the list, (b) all of the items in the list, or (c) any combination of the items in the list. Additionally, the term "comprising" is used throughout to mean including at least the recited feature(s) such that any greater number of the same feature and/or additional types of other features are not precluded. It will also be appreciated that specific embodiments have been described herein for purposes of illustration, but that various modifications may be made without deviating from the technology. Further, while advantages associated with some embodiments of the technology have been described in the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the technology. Accordingly, the disclosure and associated technology can encompass other embodiments not expressly shown or described herein.

CLAIMS

I/We claim:

1. A cap assembly for a catheter, the cap assembly comprising:

a first cap including a locking member, wherein the locking member includes an end portion and a tab positioned proximate the end portion; and

a second cap including a locking feature, wherein the locking feature includes a slot extending at least partially through the second cap, and wherein—

the first cap is configured to be secured to the second cap in a locked position,

in the locked position, the locking feature is configured to receive the locking member through the slot such that the tab engages a portion of the second cap to inhibit movement of the first cap relative to the second cap, and

the first cap is configured to rotate relative to the second cap to move the tab out of engagement with the second cap to move the first cap from the locked position to an unlocked position.

2. The cap assembly of claim 1 wherein the first cap includes an upper surface, and wherein the locking member extends from the upper surface in a direction generally perpendicular to the upper surface, and wherein the end portion of the locking member is opposite the upper surface.

3. The cap assembly of claim 1 wherein the tab extends perpendicularly from the locking member.

4. The cap assembly of claim 1 wherein the tab defines a retaining surface positioned to contact at least a portion of the second cap when the first cap is coupled to the second cap.

5. The cap assembly of claim 1 wherein the locking member is flexible, and wherein the second cap is configured to bend the locking member when the first cap moves between the unlocked position and the locked position.

6. The cap assembly of claim 1 wherein the locking feature includes a locking surface positioned to at least partially contact the tab of the locking member when the first cap is coupled to the second cap.

7. The cap assembly of claim 1 wherein the locking feature includes an angled insertion surface positioned to engage and deflect the locking member when the first cap moves from the unlocked position toward the locked position.

8. The cap assembly of claim 7 wherein the cap assembly includes a longitudinal axis, and where the insertion surface is angled to bend the locking member inward toward the longitudinal axis.

9. The cap assembly of claim 1 wherein the locking feature includes a radial removal surface, and wherein the radial removal surface is angled to deflect the tab inward when the first cap is rotated relative to the second cap.

10. The cap assembly of claim 1 wherein the locking feature includes an axial removal surface positioned proximate the slot and angled to move the first cap away from the second cap when the first cap is rotated relative to the second cap.

11. The cap assembly of claim 1 wherein:

the first cap includes an upper surface, and the locking member extends from the upper surface in a direction perpendicular to the upper surface;

the locking member is flexible and configured to deflect when the first cap moves between the unlocked position and the locked position;

the tab defines a retaining surface positioned to contact at least a portion of the second cap in the locked position; and

the locking feature includes—

a locking surface positioned to at least partially contact the retaining surface of the tab in the locked position,

an insertion surface positioned to be at least partially aligned with the locking member and angled to deflect the locking member inward when the first cap moves from the unlocked position toward the locked position,

a radial removal surface positioned proximate the tab of the locking member in the locked position, wherein the radial removal surface is angled to move the tab radially inward when the first cap moves from the locked position toward the unlocked position, and

an axial removal surface positioned proximate the slot and angled to move the first cap longitudinally away from the second cap when the first cap moves from the locked positioned toward the unlocked position.

12. The cap assembly of claim 1 wherein the locking member is a first locking member, wherein the locking feature is a first locking feature, wherein the first cap includes one or more second locking members, wherein the second cap includes one or more second locking features, and wherein individual ones of the second locking members are configured to receive and secure corresponding ones of the second locking members in the locked position.

13. The cap assembly of claim 1 wherein the locking feature is configured to be rotationally agnostic such that rotation of the first cap relative to the second cap in a first direction and a second direction opposite the first direction moves the tab out of engagement with the second cap to move the first cap from the locked position to an unlocked position.

14. A vascular access system, comprising:

a valve having a proximal end and a distal end;

a catheter defining a lumen and coupled to the distal end of the valve, the catheter defining a longitudinal axis of the vascular access system;

a dilator configured to extend at least partially through the valve and the lumen; and

a cap assembly movable between a locked configuration and an unlocked configuration, wherein the cap assembly includes (i) a valve cap connected to the proximal end of the valve and including a coupling feature, and (ii) a dilator cap coupled to the dilator and including a coupling tab insertable into the coupling feature, wherein—

in the locked configuration, the coupling feature is configured to receive the coupling tab such that the coupling tab engages a portion of the valve cap to inhibit movement of the dilator relative to the valve along the longitudinal axis, and

the dilator cap is configured to rotate relative to the valve cap to move the coupling tab out of engagement with the valve cap to move the cap assembly from the locked configuration toward the unlocked configuration.

15. The vascular access system of claim 14 wherein the coupling tab is flexible, wherein the coupling feature is configured to deflect the coupling tab toward the longitudinal axis when the cap assembly moves from the unlocked configuration toward the locked configuration.

16. The vascular access system of claim 14 wherein the dilator cap includes a coupling member extending in a direction generally parallel to the dilator and having a distal end, and wherein the coupling tab is positioned proximate the distal end of the coupling member.

17. The vascular access system of claim 14 wherein valve cap has a valve cap longitudinal axis, and wherein the coupling feature is curved circumferentially at least partially about the valve cap longitudinal axis.

18. The vascular access system of claim 14 wherein the coupling feature includes a coupling surface positioned to at least partially contact the coupling tab of the dilator cap when the cap assembly is in the locked configuration.

19. The vascular access system of claim 18 wherein the coupling feature includes an insertion surface positioned to engage and deflect the coupling tab toward the longitudinal axis when the cap assembly moves from the unlocked configuration toward the locked configuration.

20. The vascular access system of claim 19 wherein the insertion surface is positioned proximally from the coupling surface.

21. The vascular access system of claim 19 wherein the insertion surface forms an acute interior angle relative to the coupling surface.

22. The vascular access system of claim 14 wherein the coupling feature includes a radial removal surface configured to move the coupling tab radially inward toward the longitudinal axis when the cap assembly moves from the locked configuration toward the unlocked configuration.

23. The vascular access system of claim 14 wherein the coupling feature includes (i) a slot configured to receive the coupling tab, and (ii) an axial removal surface positioned proximate the slot and angled to move the dilator cap away from the valve cap along the longitudinal axis when the dilator cap is rotated relative to the valve cap.

24. The vascular access system of claim 14 wherein the coupling feature includes an outer wall and a pair of radial removal surfaces positioned on left and right sides of the outer wall, and wherein—

in the locked configuration, the coupling tab is positioned between the pair of radial removal surfaces, and

rotation of the dilator cap in a left or right direction relative to the valve cap moves the cap assembly from the locked configuration toward the unlocked configuration.

25. The vascular access system of claim 14 wherein the valve cap is integrally formed with proximal end of the valve.

26. The vascular access system of claim 14 wherein the valve cap is releasably coupled to the proximal end of the valve.

27. A method of using a vascular access system, the method comprising:

aligning a first cap of the vascular access system with a second cap of the vascular access system, wherein the first cap is coupled to a dilator of the vascular access system, wherein the second cap is coupled to a catheter of the vascular access system, and wherein aligning the first cap with the second cap includes aligning at a locking member of the first cap with a locking feature of the second cap; and

coupling the first cap to the second cap to inhibit the dilator from moving relative to the catheter of the vascular access system, wherein coupling the first cap to the

second cap includes inserting the locking member into the locking feature such that the locking feature drives the locking member past a locking surface of the locking feature, and wherein the locking surface is configured to engage the locking member to inhibit longitudinal movement of the first cap relative to the second cap.

28. The method of claim 27 wherein coupling the first cap to the second cap further includes positioning the dilator at least partially within the catheter.

29. The method of claim 27 wherein coupling the first cap to the second cap further includes inserting the dilator fully through the catheter.

30. The method of claim 27 wherein aligning the locking member of the first cap with the locking feature of the second cap includes aligning a tab of the locking member with an insertion surface of the locking feature.

31. The method of claim 30 wherein moving the first cap toward the second cap includes (i) positioning the tab of the locking member to contact the insertion surface of the locking feature and (ii) translating the tab across the insertion surface to deflect the tab.

32. The method of claim 27, further comprising rotating the first cap relative to the second cap to uncouple the first cap from the second cap after coupling the first cap to the second cap.

33. The method of claim 32 wherein rotating the first cap includes translating at least a portion of the locking member across a radial removal surface of the locking feature, wherein the radial removal surface is angled to deflect the locking member when the first cap is rotated relative to the second cap.

34. The method of claim 32 wherein rotating the first cap includes moving the first cap longitudinally away from the second cap.

35. The method of claim 34 wherein moving the first cap away from the second cap includes translating the locking member across an axial removal surface of the locking feature, wherein the axial removal surface is angled to move the first cap away from the second cap as the locking member translates across the axial removal surface.

36. The method of claim 32 wherein rotating the first cap relative to the second cap to uncouple the first cap from the second cap includes rotating the first cap in a first direction or a second direction opposite the first direction to uncouple the first cap from the second cap.

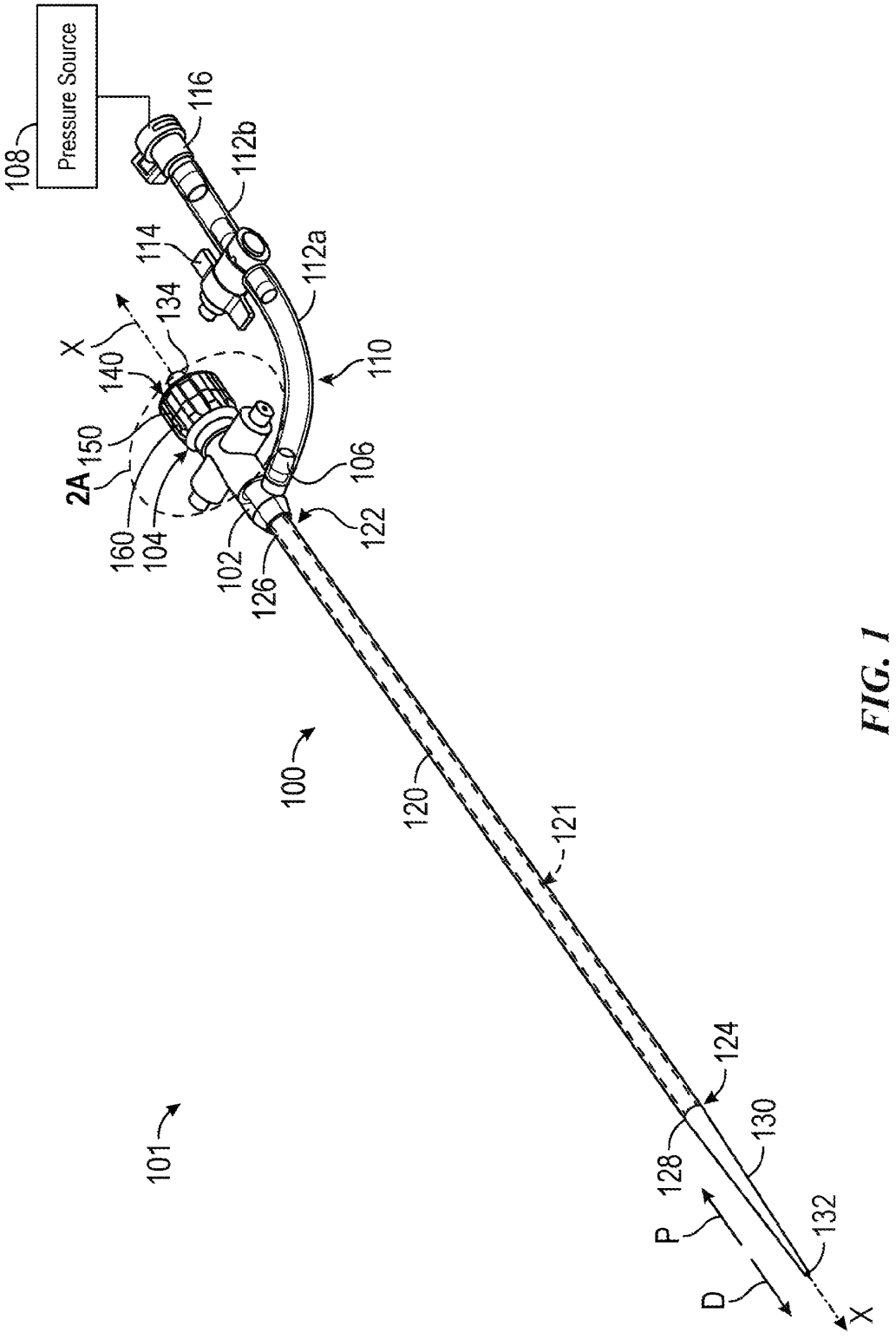

Pressure Source
108
116
112b
114
112a
134
X
140
110
150
2A
106
160
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102
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120
121
124
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101
128
P
132
D
X

*FIG. 1*

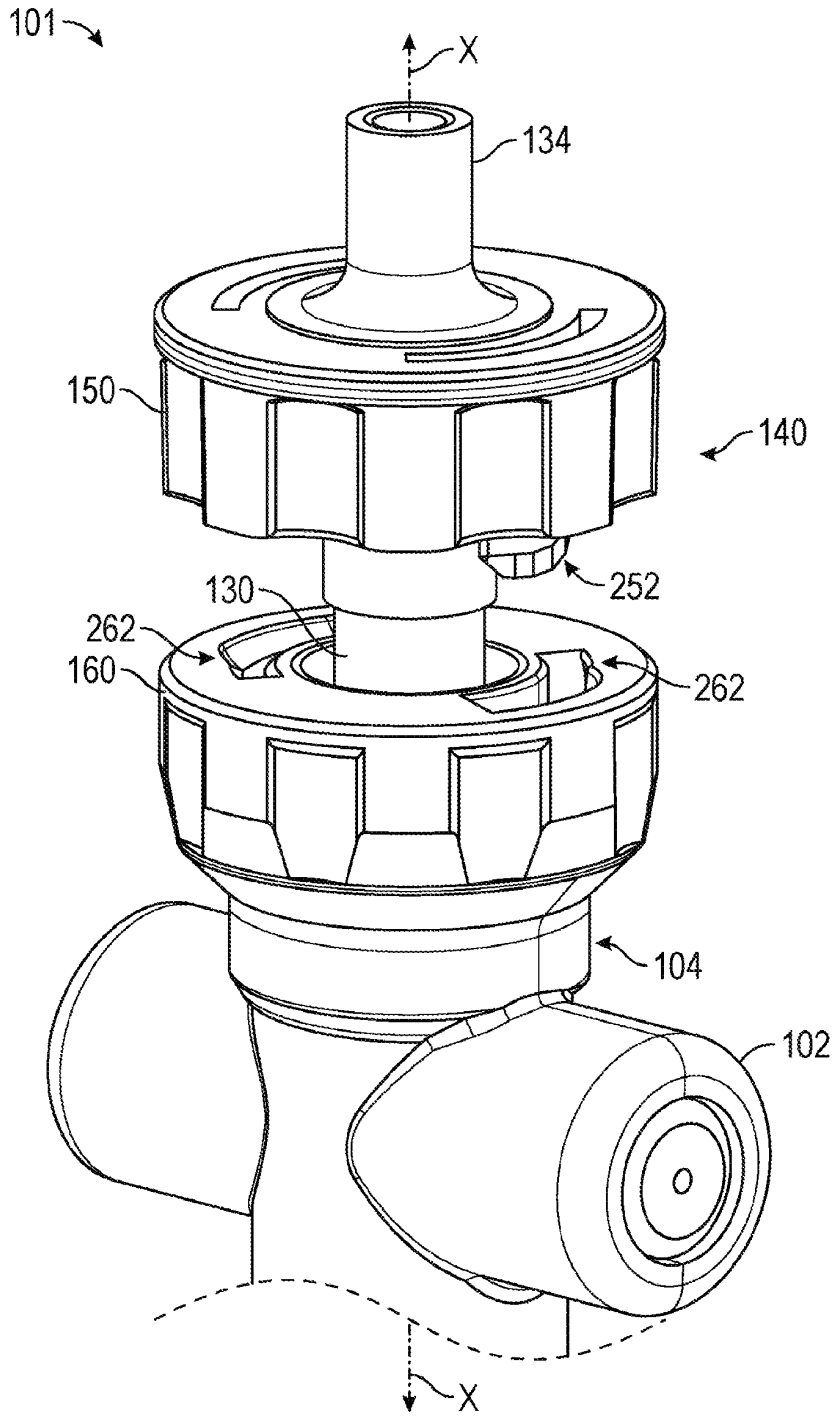



*FIG. 2A*

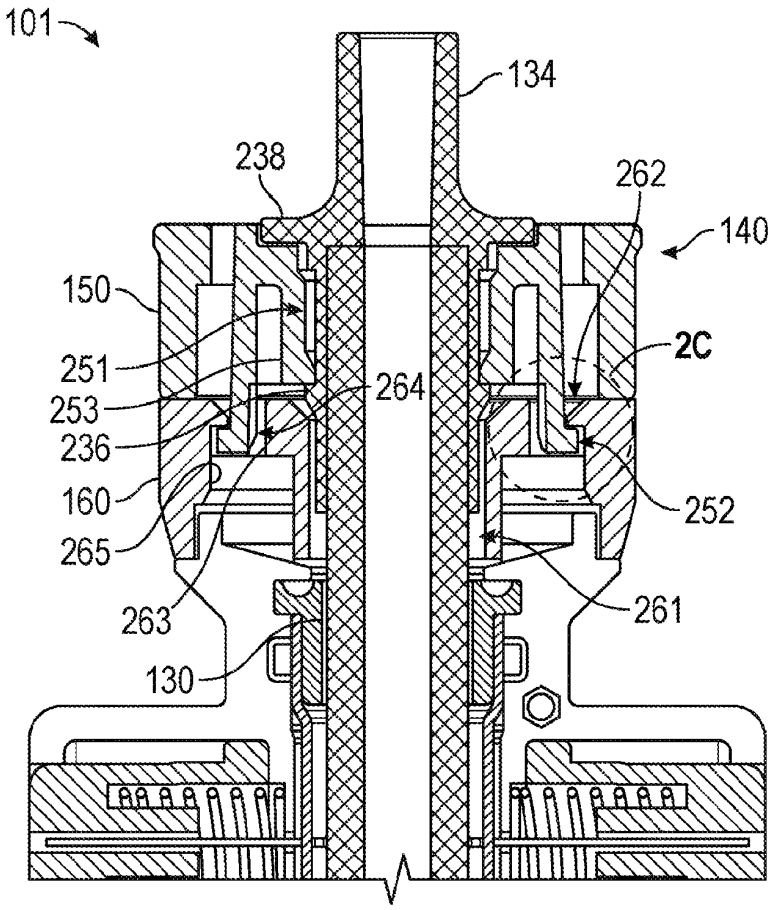

101
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140
150
2C
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264
253
236
160
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252
263
261
130

*FIG. 2B*

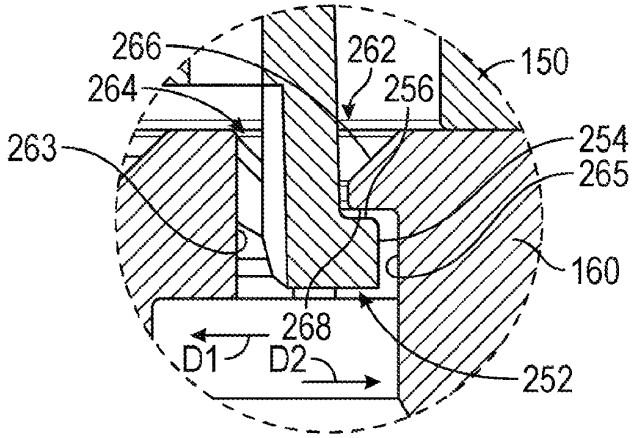

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262
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264
256
263
254
265
160
268
D1
D2
252

*FIG. 2C*

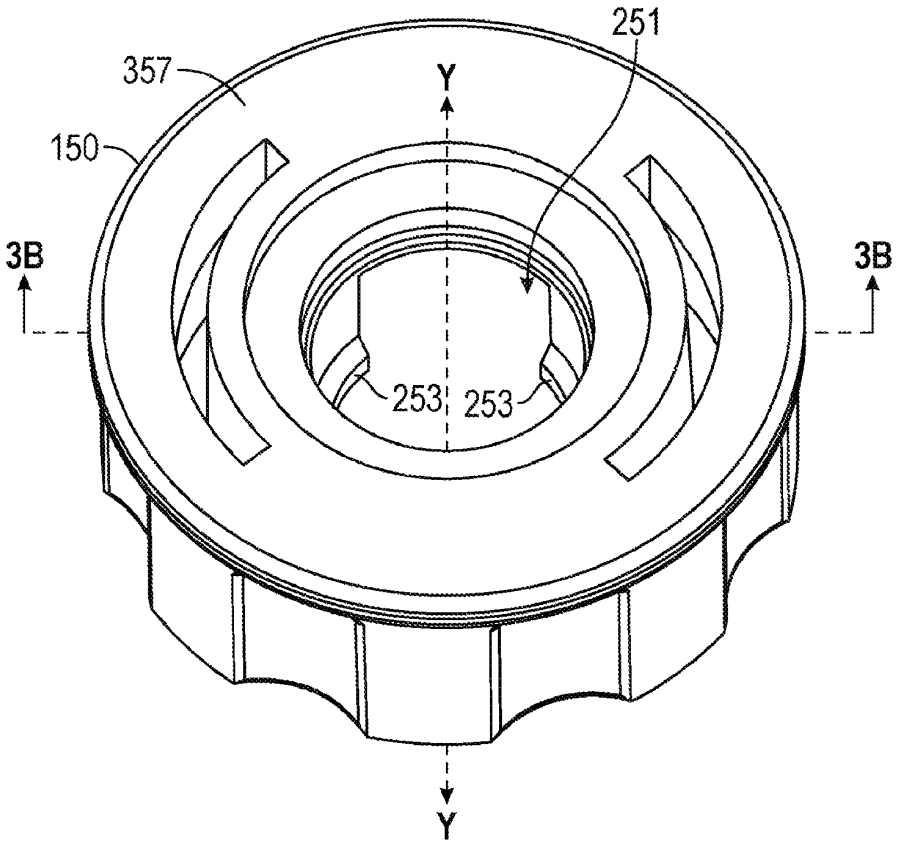

251
357
Y
150
3B
3B
253
253
Y

*FIG. 3A*

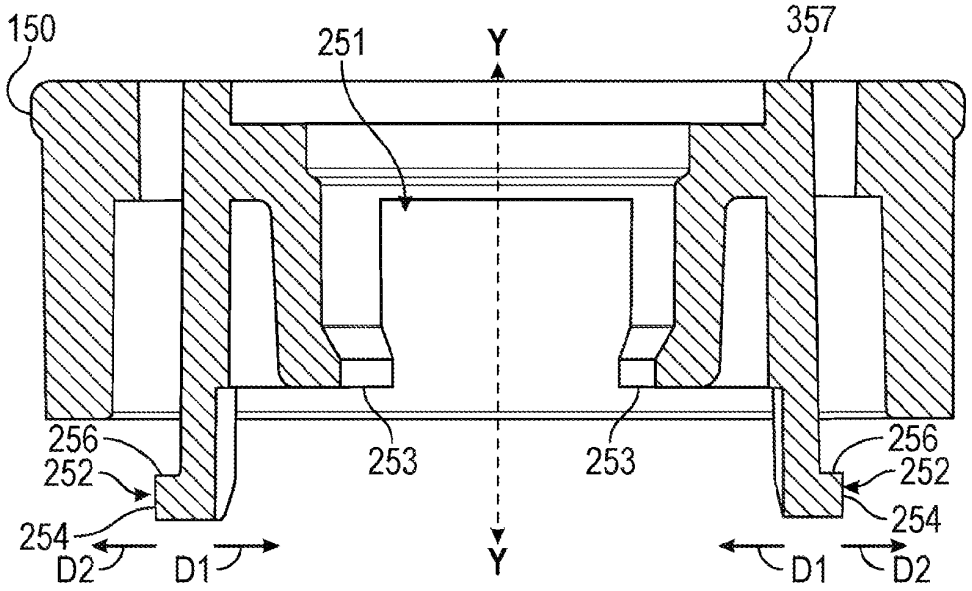

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Y
D1
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*FIG. 3B*

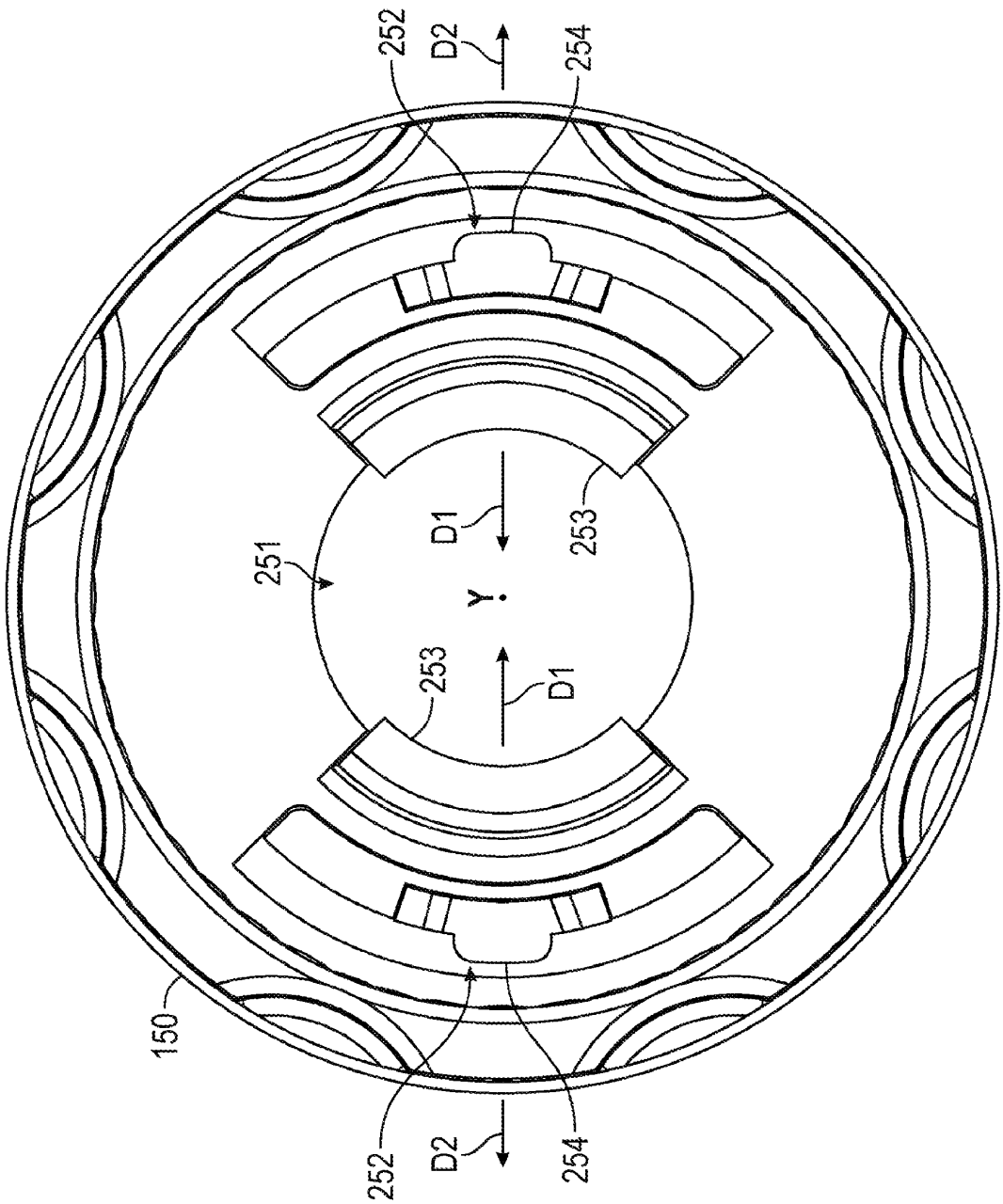



FIG. 3C

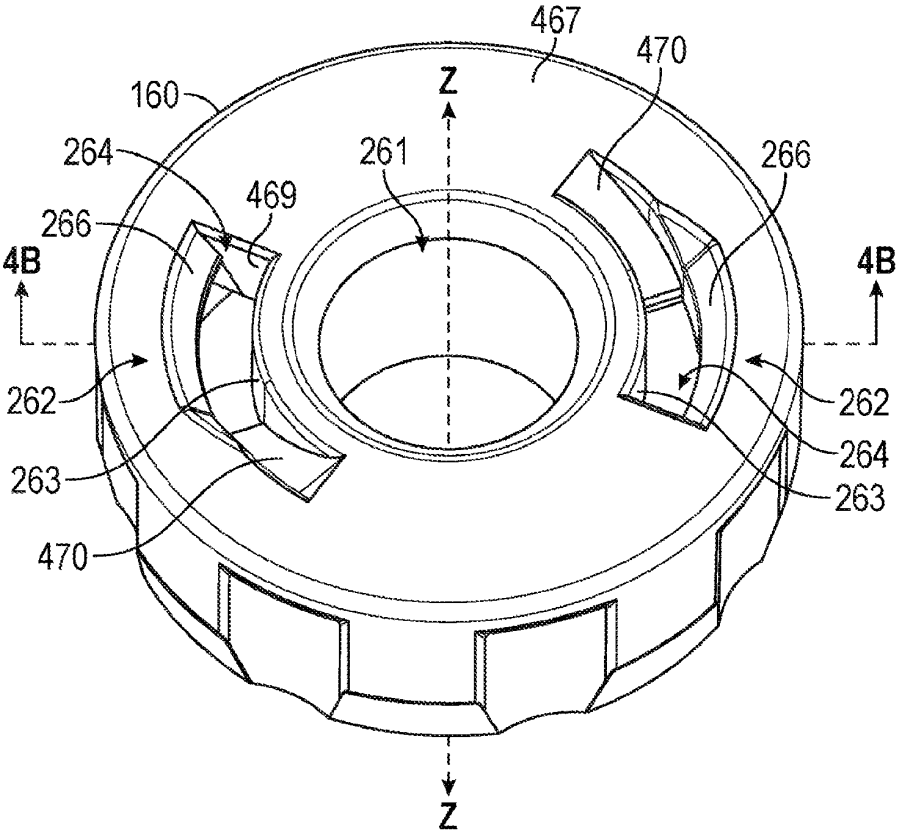

467
470
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264
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4B
4B
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264
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470
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*FIG. 4A*

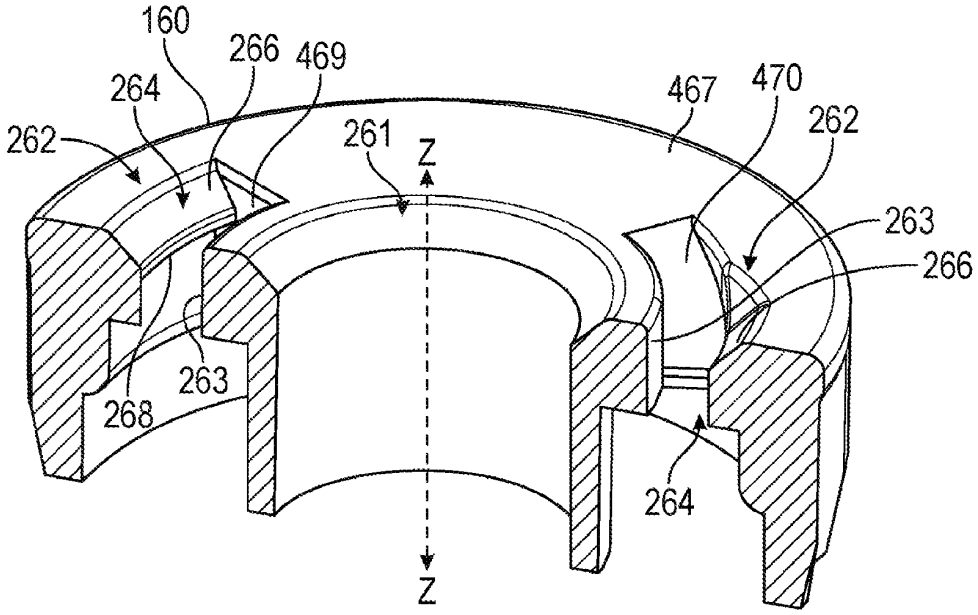

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*FIG. 4B*

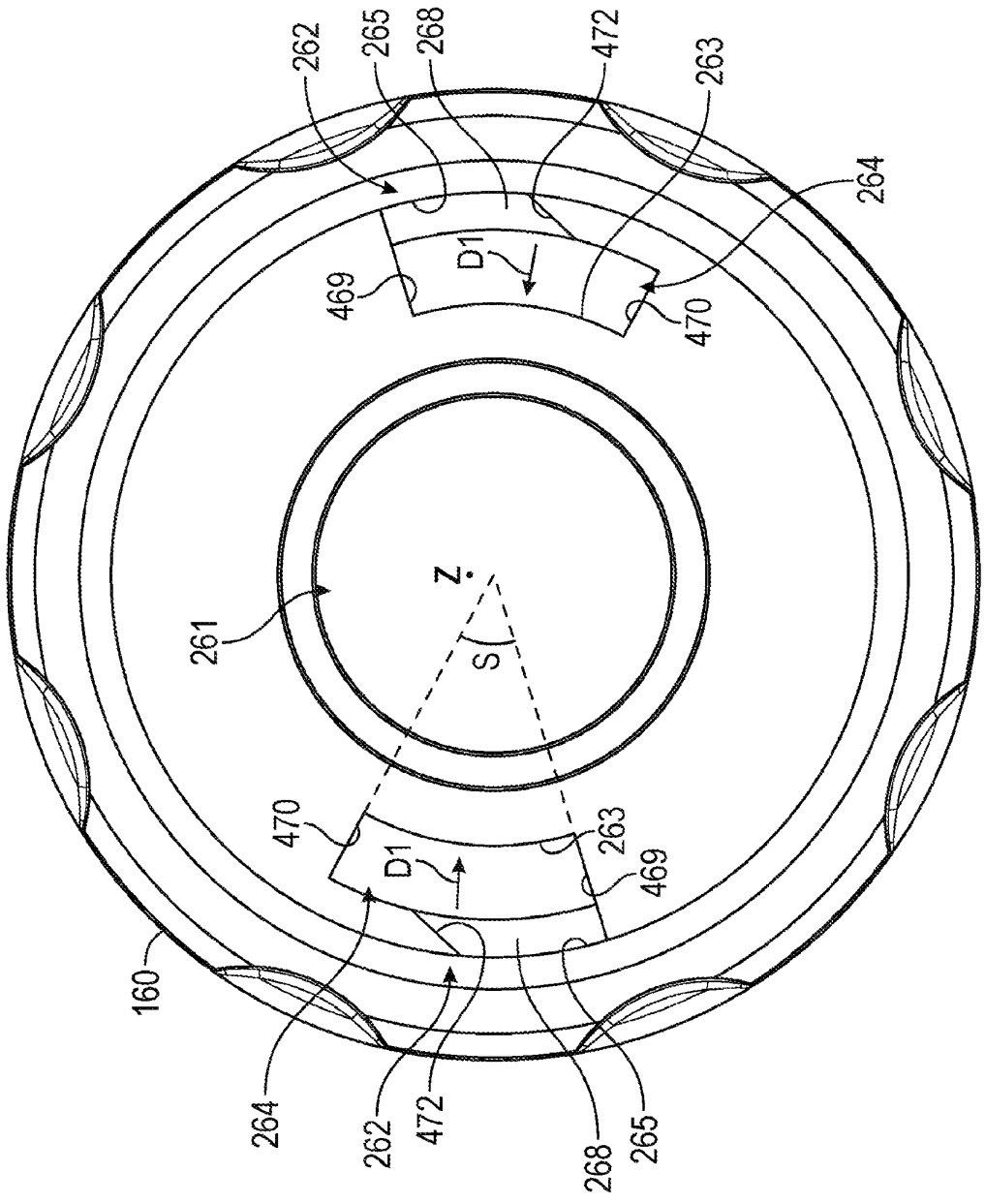

262
265
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472
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FIG. 4C

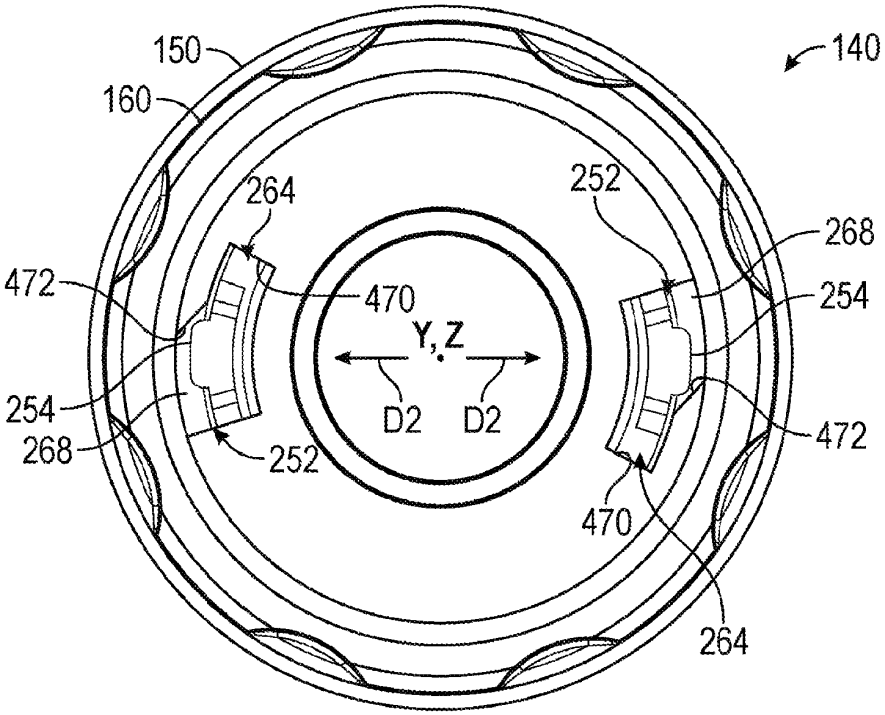

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*FIG. 5A*

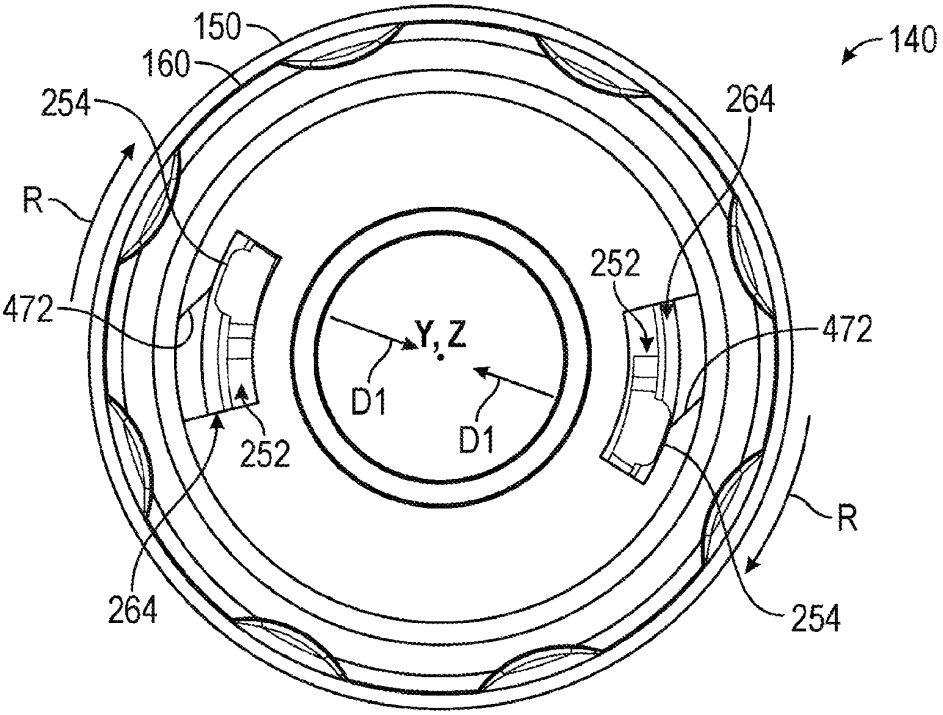

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*FIG. 5B*

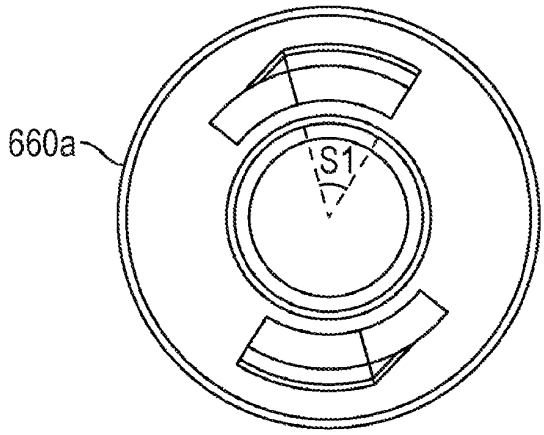



*FIG. 6A*

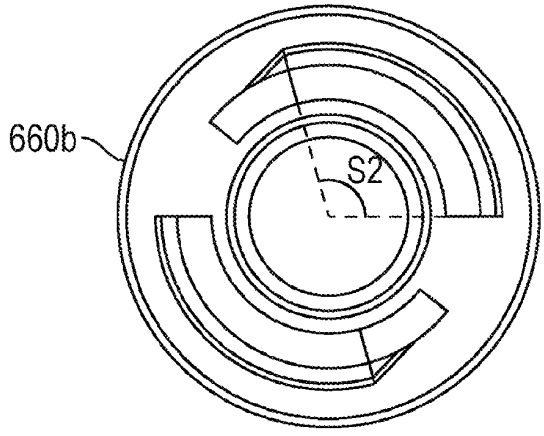



*FIG. 6B*

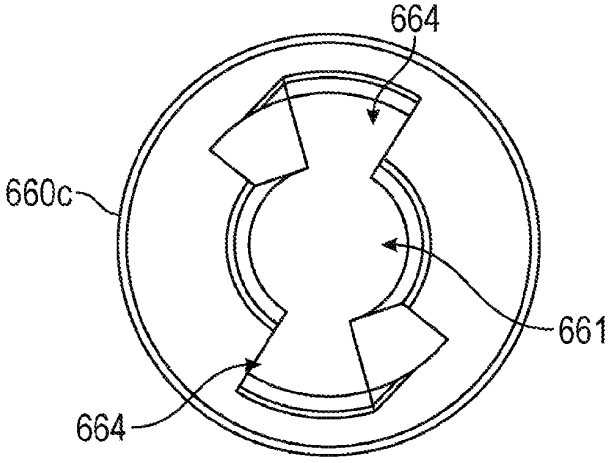



*FIG. 6C*

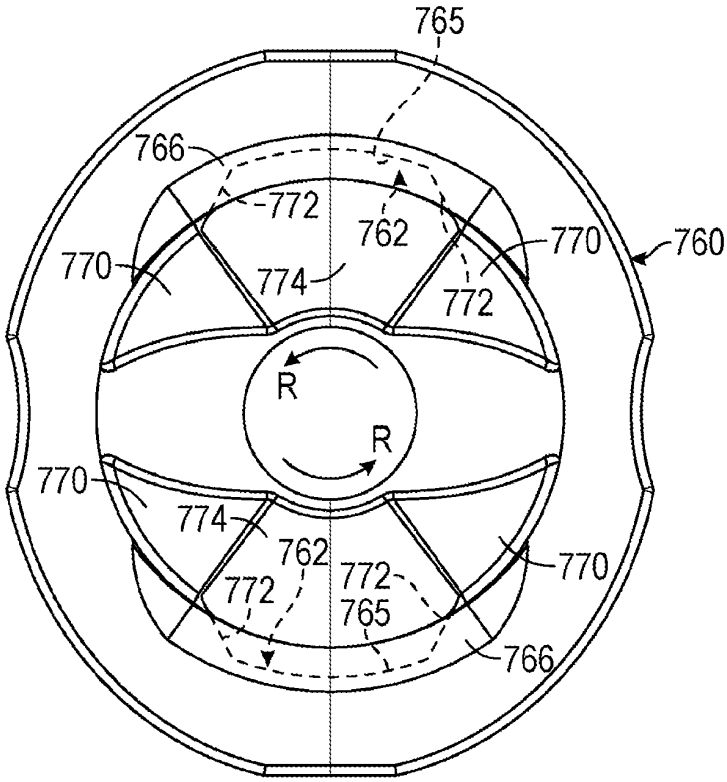

765
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*FIG. 7*

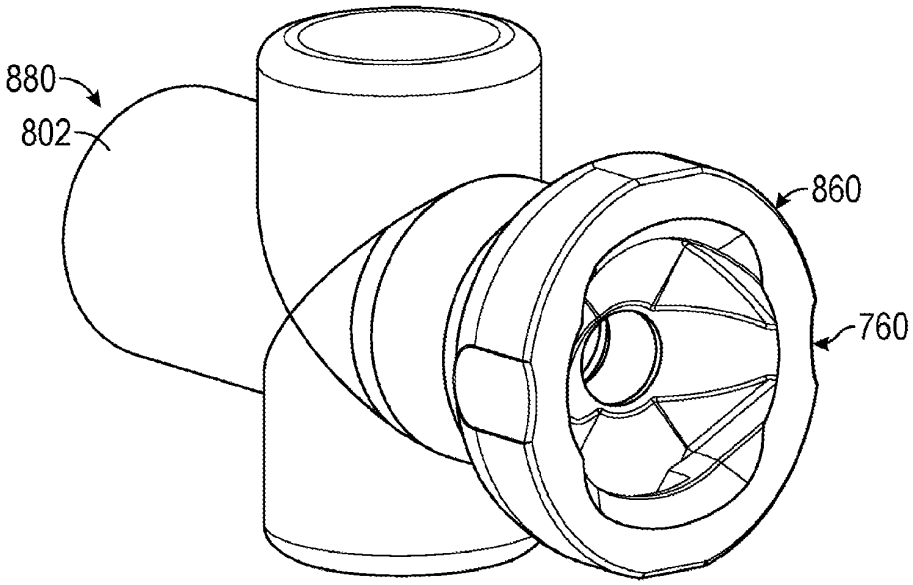

880
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*FIG. 8*

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 3 620 204 A1

# (12) EUROPEAN PATENT APPLICATION

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(51) Int Cl.:
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*A61M 25/06* *(2006.01)*

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(62) Document number(s) of the earlier application(s) in accordance with Art. 76 EPC:
**16708246.0 / 3 253 437**

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Remarks:
This application was filed on 25.10.2019 as a divisional application to the application mentioned under INID code 62.

## (54) RAPID ASPIRATION THROMBECTOMY SYSTEM

(57) There is provided a dilator (1340) for facilitation of intraluminal medical procedures within the neurovasculature. The dilator (1340) comprises a flexible distal dilator portion (1360) having a proximal end region and a distal end region having a distal tapered tip (1346), a single lumen, and an outer diameter, wherein the single lumen extends longitudinally through the dilator portion to a distal opening at the distal tapered tip (1346). The dilator (1340) further comprises a spine (1362) extending proximally from the proximal end region of the dilator portion (1360), wherein the spine (1362) is made of a different material than the dilator portion (1360) and has a single lumen that communicates with the single lumen of the dilator portion (1360).

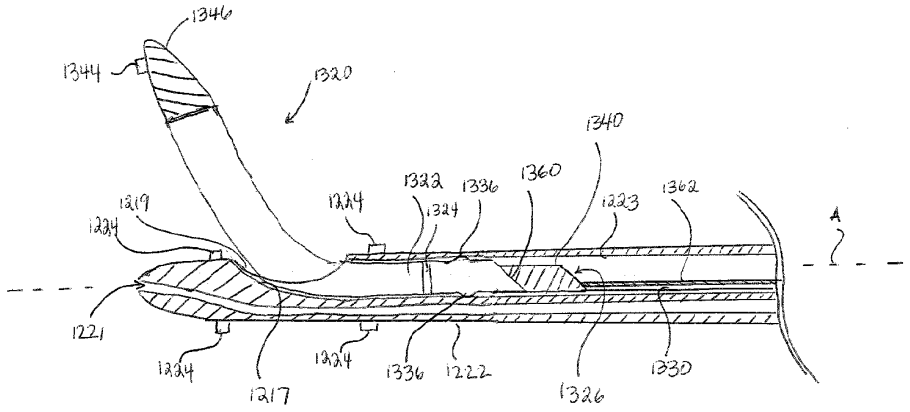



Fig. 12C

EP 3 620 204 A1

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## Description

### CROSS-REFERENCE TO RELATED APPLICATIONS

**[0001]** This application claims priority to U.S. Provisional Application Serial No. 62/111,481, filed February 4, 2015, and U.S. Provisional Application Serial No. 62/142,637, filed April 3, 2015.

**[0002]** This application is also related to the following U.S. Patent Applications: (1) US Patent Application Serial Number 14/576,953, filed December 19, 2014; and (2) US Patent Application Serial Number 14/569,365, filed December 12, 2014; (3) US Patent Application Serial Number 14/537,316, filed November 10, 2014; (4) US Patent Application Serial Number 14/221,917, filed March 21, 2014.

### BACKGROUND

**[0003]** The present disclosure relates generally to medical methods and devices for the treatment of acute ischemic stroke. More particularly, the present disclosure relates to methods and systems for navigating complex anatomy to perform rapid and safe aspiration and removal of cerebral occlusions.

**[0004]** Acute ischemic stroke is the sudden blockage of adequate blood flow to a section of the brain, usually caused by thrombus or other emboli lodging or forming in one of the blood vessels supplying the brain. If this blockage is not quickly resolved, the ischemia may lead to permanent neurologic deficit or death. The timeframe for effective treatment of stroke is within 3 hours for intravenous (IV) thrombolytic therapy and 6 hours for site-directed intra-arterial thrombolytic therapy or up to 8 hours for interventional recanalization of a blocked cerebral artery. Re-perfusing the ischemic brain after this time period has no overall benefit to the patient, and may in fact cause harm due to the increased risk of intracranial hemorrhage from fibrinolytic use. Even within this time period, there is strong evidence that the shorter the time period between onset of symptoms and treatment, the better the results. Unfortunately, the ability to recognize symptoms, deliver patients to stroke treatment sites, and finally to treat these patients within this timeframe is rare. Despite treatment advances, stroke remains the third leading cause of death and the leading cause of serious, long-term disability in the United States.

**[0005]** Endovascular treatment of acute stroke is comprised of either the intra-arterial administration of thrombolytic drugs such as recombinant tissue plasminogen activator (rtPA), mechanical removal of the blockage, or a combination of the two. As mentioned above, these interventional treatments must occur within hours of the onset of symptoms. Both intra-arterial (IA) thrombolytic therapy and interventional thrombectomy involve accessing the blocked cerebral artery via endovascular techniques and devices.

**[0006]** Like IV thrombolytic therapy, IA thrombolytic therapy alone has the limitation in that it may take several hours of infusion to effectively dissolve the clot. Interventional thrombectomy therapies have involved capturing and removing the clot using snares, coils or temporary stents (also known as retrievable stent devices), and suctioning the clot with or without adjunct disruption of the clot. Retrievable stent devices are also utilized to restore flow quickly to the vessel during the intervention. Hybrid procedures are also utilized, combining retrievable stent devices and aspiration via the guide catheter or via intermediate catheters to aid in the removal of the clot and reduce the risk of distal emboli. Finally, balloons or stents have been used to create a patent lumen through the clot when clot removal or dissolution was not possible.

**[0007]** To access the cerebral anatomy, guide catheters or guide sheaths are used to guide interventional devices to the target anatomy from an arterial access site, typically the femoral artery. Balloon guide catheters are often used to enable proximal carotid artery occlusion during periods of the procedure which may potentially liberate a high level of emboli. The proximal occlusion has the effect of arresting forward flow and increasing aspiration efficiency through the lumen of the guide catheter. The length of the guide is determined by the distance between the access site and the desired location of the guide distal tip. Interventional devices such as guidewires, microcatheters, and intermediate catheters used for sub-selective guides and aspiration, are inserted through the guide and advanced to the target site. Often, devices are used in a co-axial fashion, namely, a guidewire inside a microcatheter inside an intermediate catheter is advanced as an assembly to the target site in a stepwise fashion with the inner, most atraumatic elements, advancing distally first and providing support for advancement of the outer elements. The length of each element of the coaxial assemblage takes into account the length of the guide, the length of proximal connectors on the catheters, and the length needed to extend from the distal end. Thus, for example, the working length of an intermediate catheter is typically 20-40 cm longer than the working length of a guide, and the working length of a microcatheter is typically 10-30 cm longer than the working length of the intermediate catheter. The guidewire is typically longer than the microcatheter by another 20-50 cm.

**[0008]** Some exemplary issues with current technology include the time required or even the ability to access the site of the occlusion, the time required to restore flow or the inability to fully, or even partially, restore flow to the vessel, the occurrence of distal emboli during the procedure, which has potentially negative neurologic effect and procedural complications such as perforation and intracerebral hemorrhage. There is a need for a system of devices and methods that enable rapid access, optimized aspiration of the clot, distal protection throughout all stages of the procedure, which potentially liberate emboli, and safe and rapid exchange of devices as needed to fully restore flow to the blocked cerebral vessel.

## SUMMARY

**[0009]** In one aspect, there is disclosed an intravascular access system for facilitation of intraluminal medical procedures within the neurovasculature through an access sheath. The system includes an aspiration or support catheter having a flexible, distal luminal portion having an inner diameter defining a lumen extending between a proximal opening at a proximal end of the luminal portion and a distal opening at a distal end of the luminal portion. The catheter has a rigid spine coupled to at least the proximal end of the luminal portion and extending proximally therefrom. The system includes a dilator having a flexible, distal dilator portion sized to be received within the lumen of the luminal portion; and a rigid, dilator spine extending proximally from the dilator portion.

**[0010]** The dilator spine can align side-by-side with the spine of the catheter. The distal dilator portion can have a tapered distal tip. The dilator can have a length at least as long as a length of the catheter such that a distal tip of the dilator protrudes from the distal opening of the luminal portion. The dilator can be generally tubular along at least a portion of the length. A proximal end of the catheter spine can include a gripping feature configured for a user to grasp in order to move the catheter through an access sheath. A proximal end of the dilator spine can include a tab configured to be locked with the gripping feature on the catheter spine. When the catheter and the dilator are in a locked configuration they can be advanced as a single unit through the access sheath. The gripping feature and the dilator tab can be removably coupled such that in a locked configuration the dilator tab engages the gripping feature and in an unlocked configuration the dilator tab disengages from the gripping feature. The dilator tab can be affixed to the dilator or can be slideable on the dilator to accommodate different relative positions between the dilator and the catheter. The distal dilator portion can include one or more detents on an outer surface configured to lock with correspondingly-shaped surface features on an inner surface of the luminal portion lumen through which the dilator portion extends. The dilator spine and the catheter spine can have a similar stiffness and kink-resistance. The dilator can have a visual marker on a distal end and/or a proximal end of the distal tip. A distal end region of the dilator can be more flexible and increasingly stiffen towards a proximal end region of the dilator. The catheter spine and dilator spine can be configured to cause bi-directional sliding movement of the luminal portion through a lumen of an access sheath and navigate the luminal portion into a cerebral vessel to reach a treatment site.

**[0011]** In an interrelated aspect, disclosed is an intravascular access system for facilitation of intraluminal medical procedures within the neurovasculature having an access sheath and an aspiration or support catheter. The access sheath has a sheath body having an inner diameter defining a lumen between a proximal end and a distal end of the sheath body. The sheath body has at least one opening from the lumen near a distal end region of the sheath body. The aspiration or support catheter includes a flexible, distal luminal portion having an outer diameter sized for insertion through the lumen of the access sheath, an inner diameter defining a lumen extending between a proximal opening at a proximal end of the luminal portion and a distal opening at a distal end of the luminal portion, and a length between the proximal opening and the distal opening. The aspiration or support catheter includes a rigid spine coupled to at least the proximal end of the luminal portion and extending proximally therefrom. The rigid spine is configured to cause bi-directional sliding movement of the luminal portion through the lumen of the access sheath and out the at least one opening to navigate the luminal portion into a cerebral vessel to reach a treatment site. A portion of the outer diameter of the luminal portion fluidly seals with the inner diameter of the access sheath when the distal end of the luminal portion extends into the cerebral vessel to reach the treatment site.

**[0012]** The luminal portion and the sheath body can be concentrically aligned and the lumen of the luminal portion and the lumen of the sheath body form a contiguous aspiration lumen from the distal end of the luminal portion to the proximal end of the sheath body. The contiguous aspiration lumen can be used to aspirate fluid and debris from the distal opening of the luminal portion. The contiguous aspiration lumen can be to deliver materials through the distal opening of the luminal portion. The contiguous aspiration lumen can form a step-up in diameter where the lumen of the luminal portion empties into the lumen of the sheath body. The lumen of the luminal portion can be shorter than the lumen of the sheath body. The luminal portion and the sheath body can form an overlap region when the luminal portion extends distally beyond the at least one opening of the sheath body. The outer diameter of the luminal portion can approach the inner diameter of the lumen of the sheath body such that a seal is formed by the overlap region. The seal can be configured to enable sealing against a vacuum of up to 25 inHg, or up to 28 inHg. The seal within the overlap region can be configured to enable sealing against a pressure of up to 300 mmHg or up to 600 or up to 700 mmHg. The seal can be located distal a proximal end of the luminal portion and proximal to the at least one opening of the sheath body.

**[0013]** The system can further include a sealing element positioned on an external surface of the luminal portion. The sealing element can include a stepped up diameter or protruding feature in the overlap region. The sealing element can include one or more external ridge features. The one or more ridge features can be compressible when the luminal portion is inserted into the lumen of the sheath body. The sealing element can include one or more inclined surfaces biased against an inner surface of the sheath body lumen. The sealing element can include one or more expandable members actuated to seal. The sheath body can have an outer

diameter suitable for insertion into the carotid artery. The outer diameter of the sheath body can be between 5Fr and 7Fr.

**[0014]** The sheath body can have a length between the proximal end and the distal end suitable for locating the distal end of the sheath body at the petrous portion of an internal carotid artery from a transfemoral approach. The length of the sheath body can be between 80 cm and 105 cm. The length of the luminal portion can be between 10 cm and 25 cm. The length of the luminal portion can be less than a length of the sheath body such that as the catheter is retracted into the sheath body a seal remains between an overlap region of the luminal portion and the inner diameter of the sheath body.

**[0015]** The spine can be longer than an entire length of the sheath body. The luminal portion can include three or more layers including an inner lubricious liner, a reinforcement layer, and an outer jacket layer. The outer jacket layer can be composed of discreet sections of polymer with different durometers, compositions, and/or thicknesses to vary the flexibility along the length of the distal luminal portion. The outer diameter of the distal luminal portion can be sized for navigation into cerebral arteries. The inner diameter of the distal luminal portion can be between 0.040" and 0.088". The outer diameter of the luminal portion can approach the inner diameter of the sheath body creating a sealed area at an overlap region while still allowing the catheter to move through the sheath body. The catheter can be tapered towards the distal opening such that a distal-most end of the luminal portion has a smaller outer diameter compared to a more proximal region of the luminal portion near where the luminal portion seals with the sheath body. The distal end region of the sheath body can include an occlusion element. The distal end region of the sheath body can include an expanding distal tip. The at least one opening from the lumen can include a side opening located a distance away from a distal tip of the sheath body. The distal tip of the sheath body further can include a ramp feature configured to direct at an angulation the catheter away from a longitudinal axis of the sheath body lumen out through the at least one opening.

**[0016]** The spine can be longer than an entire length of the sheath body. The spine can be a wire having an outer dimension from 0.014" to 0.018". The spine can be a hypotube having a guide-wire passageway extending therethrough. The spine can be a ribbon having an outer dimension from 0.010" to 0.025" thick. The ribbon can be curved along at least a portion of an arc. The spine can be configured to rotate the luminal portion around a longitudinal axis of the access sheath. The spine can be eccentrically coupled to the luminal portion and the spine extend proximally from the luminal portion to outside the proximal end of the sheath body. The proximal end of the luminal portion can have an angled cut. The angled cut can be generally planar or curved. The sheath body can have one or more visual markers on the distal end region of the sheath body. The distal luminal portion can have one or more visual markers at a distal end region of the luminal portion, a proximal end region of the luminal portion or both. The one or more visual markers on the sheath body and the one or more visual markers on the luminal portion can be visually distinct. The spine can have one or more visual markers. The one or more visual markers of the spine can indicate overlap between the distal luminal portion and the sheath body. The one or more visual markers of the spine can be positioned so that when the visual marker of the spine is aligned with a portion of the access sheath, the catheter is positioned at a distal-most position with minimal overlap length needed to create a seal between the catheter and the sheath body.

**[0017]** The system can further include a dilator having a flexible, distal dilator portion having a distal tip and sized to be received within the luminal portion of the catheter. The dilator can be a tubular element along at least a portion of its length. The dilator can be a solid rod formed of malleable material configured to be shaped by a user. The dilator can further include a rigid, dilator spine extending proximally from the dilator portion. The dilator spine can be coaxial and can have a lumen extending through it. The dilator spine can be eccentric. When in use, the dilator spine can align side-by-side with the spine of the catheter. The distal tip of the dilator can be tapered. The dilator can have a length at least as long as a length of the catheter such that the distal tip protrudes from the distal opening of the luminal portion. A proximal end of the spine can include a gripping feature configured for a user to grasp in order to move the catheter through the access sheath. A proximal end of the dilator spine can include a tab configured to be locked with the gripping feature on the catheter spine. When the catheter and dilator are in a locked configuration they can be advanced as a single unit through the sheath body. The gripping feature and the dilator tab can be removably coupled such that in a locked configuration the dilator tab engages the gripping feature and in an unlocked configuration the dilator tab disengages from the gripping feature. The dilator tab can be affixed to the dilator and/or can be slideable on the dilator to accommodate different relative positions between the dilator and the catheter.

**[0018]** The distal dilator portion can include one or more detents on an outer surface configured to lock with correspondingly-shaped surface features on an inner surface of the luminal portion lumen through which the dilator portion extends. The dilator spine and the catheter spine can have a similar stiffness and kink-resistance. The dilator can have a visual marker on a distal end and/or a proximal end of the distal tip. A distal end region of the dilator can be more flexible and increasingly stiffens towards the proximal end region of the dilator.

**[0019]** The access sheath can further include a connector that connects the proximal end of the sheath body to a proximal hemostasis valve. The proximal hemostasis valve can have an adjustable opening sized large enough to allow removal of the catheter without dislodging any

clots thereon. When in use with the access sheath, the rigid spine of the catheter can extend proximally from the luminal portion through the access sheath lumen and out the proximal hemostasis valve of the access sheath. The connector can provide a connection of the proximal end of the sheath body to an aspiration line. The connector can have a large bore inner lumen and connects to a large-bore aspiration line. The aspiration line can connect to an aspiration source. The aspiration source can be an active aspiration source. The aspiration line can connect to a forward drip or flush line. The access sheath can further include a proximal extension portion such that when the distal luminal portion of the catheter is withdrawn from the sheath body lumen it remains within the proximal extension portion. The inner diameter of the luminal portion can be sized to permit placement of an interventional device through the luminal portion.

**[0020]** Other features and advantages should be apparent from the following description of various implementations, which illustrate, by way of example, the principles of the invention.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0021]**

FIG. 1 is an exploded view of a system of devices for accessing and removing a cerebral occlusion to treat acute ischemic stroke from a femoral artery access site;

FIG. 2A shows components of the system of FIG. 1 in position in a patient from the transfemoral approach to treat the occlusion;

FIG. 2B is a detailed view of a portion of the system of FIG. 2A taken along circle BB;

FIG. 3 shows components of the system of FIG. 1 being used via a transcarotid access site;

FIG. 4 shows an implementation of an access sheath;

FIG. 5 shows an implementation of a proximal portion of the access sheath of FIG. 4 provided as a separate, removable component;

FIG. 6 shows an implementation of a connector to minimize flow resistance through the access sheath of FIG. 4 into the proximal portion;

FIG. 7 shows an implementation of an access sheath having an occlusion balloon;

FIGs. 8A-8B show implementations of sealing elements between the access sheath body and luminal portion of a catheter extending therethrough;

FIG. 9 shows an implementation of a microcatheter and retrievable stent device positioned through a spined catheter;

FIGs. 10A-10C show implementations of expandable portions on retrievable stent devices;

FIG. 11 shows an implementation of an aspiration system for use with the systems described herein;

FIG. 12A shows an implementation of a spined catheter system for use with the systems described herein;

FIG. 12B shows the spined catheter system of FIG. 12A having a spined dilator extending through a lumen of a spined catheter;

FIG. 12C shows the spined catheter system of FIG. 12A extended through a side opening of an implementation of an access sheath;

FIG. 13 is a cross-sectional view taken about line A-A of FIG. 12B;

FIG. 14 is a cross-sectional view taken about line B-B of FIG. 12B;

FIG. 15A shows an implementation of a spined aspiration catheter-dilator system having a spined catheter and a spined dilator in a locked configuration;

FIG. 15B shows the spined aspiration catheter-dilator system having the spined catheter and the spined dilator in an unlocked configuration;

FIG. 16 shows an implementation of a spined catheter system extending distally to an access sheath to treat an embolus in a cerebral vessel.

## DETAILED DESCRIPTION

**[0022]** One of the major drawbacks to current acute stroke intervention procedures is the amount of time required to restore blood perfusion to the brain. This time includes the time it takes to access the occlusive site or sites in the cerebral artery, and the time it takes to completely remove the occlusion in the artery. Because it is often the case that more than one attempt must be made to completely remove the occlusion, reducing the number of attempts as well as reducing the time required to exchange devices for additional attempts is an important factor in minimizing the overall time. Additionally, each attempt is associated with potential procedural risk due to device advancement in the delicate cerebral vasculature.

**[0023]** Disclosed herein are methods and devices that

enable safe and rapid access to the complex neurovascular anatomies of the cerebral and intracranial arteries and removal of the occlusion. The methods and devices include one or more access devices, catheters, and thrombectomy devices to remove the occlusion. Methods and devices are also disclosed to provide active aspiration and/or passive flow reversal for the purpose of facilitating removal of the occlusion as well as minimizing distal emboli. The system offers the user a degree of flow control so as to address the specific hemodynamic requirements of the cerebral vasculature. The systems described herein provide superior ease of use in that a single operator may operate the disclosed systems using single-point continuous aspiration for rapid and safe exchange without switching. The higher efficiency of aspiration force through the systems described herein reduces distal embolic debris and increases the rate of "one-pass" thrombectomy.

**[0024]** It should be appreciated that while some embodiments are described with specific regard to aspirating a neurovascular anatomy, the embodiments are not so limited and may also be applicable to other uses. For example, the spined aspiration catheter and one or more components of the access systems described herein may be used to deliver working devices to a target vessel of a coronary anatomy, or other vasculature anatomy. It should be appreciated that where the phrase "aspiration catheter" is used herein that such a catheter may be used for other purposes besides or in addition to aspiration, such as the delivery of fluids to a treatment site or as a support catheter providing a conduit that facilitates and guides the delivery or exchange of other devices such as a guidewire or interventional devices. Alternatively, the access systems need not be limited only to the vasculature can be useful for access of other parts of the body outside the vasculature. It should also be appreciated that reference throughout this specification to a particular feature, structure, configuration, characteristic or implementation or embodiment may be combined in any suitable manner. The use of relative terms throughout the description may denote a relative position or direction. For example, "distal" may indicate a first direction away from a reference point. Similarly, "proximal" may indicate a location in a second direction opposite to the first direction. However, such terms are provided to establish relative frames of reference, and are not intended to limit the use or orientation of an anchoring delivery system to a specific configuration described in the various embodiments below.

**[0025]** FIG. 1 shows a system of devices for accessing and removing a cerebral occlusion to treat acute ischemic stroke from a femoral artery access site. The system 100 includes an access sheath 220, sheath dilator 250, guidewire 270, one or more spined aspiration or support catheters 320, dilator 340, microcatheter 400, and a retrievable stent device 500, each of which will be described in more detail below. Further, the system 100 can include one or more arterial access sheath system 200 that includes an access sheath 220, one or more sheath dilators 250 and a sheath guidewire 270. The system 100 can include one or more spined catheter systems 300 including a spined aspiration or support catheter 320, a tapered dilator 340, and alternatively a catheter clearing tool 350. The spine catheter system 300 can incorporate nested spined catheters to provide for extended reach into distal sites. The system 100 can include an access sheath system 200, a tapered catheter system 300, a microcatheter 400, and a retrievable stent device 500.

**[0026]** FIG. 2A shows some elements of the system in position in the patient from the transfemoral approach to treat the occlusion. The access sheath 220 can be inserted through a femoral artery insertion site positioned with the distal tip of the access sheath 220 at or near the petrous portion of the internal carotid artery ICA. The spined aspiration catheter 320 can be positioned with the distal tip at the face of the occlusion in the artery. In some implementations, the access sheath 220 can be inserted through a direct puncture in the wall of the common carotid artery and advanced into the internal carotid artery rather than via a transfemoral approach (see FIG. 3).

**[0027]** As seen more clearly in detailed FIG. 2B, the access sheath 220 can have a sheath body 222 and an inner lumen 223 extending between a proximal end and a distal end region of the sheath body 222. The spined aspiration catheter 320 is sized to extend through the inner lumen 223 of the access sheath 220 such that a distal end region of the catheter 320 extends beyond a distal end region of the access sheath 220. The catheter 320 is shown in FIG. 2B exiting the lumen 223 of the sheath body 222 through a distal opening 221. It should be appreciated, however, that the sheath body 222 may have one or more side openings near a distal end region of the body 222 through which the catheter 320 can extend (see FIG. 12C) as will be described in more detail below.

**[0028]** Still with respect to FIG. 2B, the spined aspiration catheter 320 can include a relatively flexible, distal luminal portion 322 coupled to a stiff and kink-resistant proximal spine 330. The distal luminal portion 322 can have an inner lumen 323 extending between a proximal end and a distal end of the luminal portion 322. The lumen 323 of the catheter 320 can have a first inner diameter and the lumen 223 of the access sheath 220 can have a second, larger inner diameter. The lumens 223, 323 are fluidly connected and contiguous such that fluid flow into and/or out of the system is possible, such as by applying suction from an aspiration source coupled to the system via a connector 226 on the access sheath 220. An overlap region 120 between the distal section of the sheath body 222 and the luminal portion 322 of the catheter 320 is sized and configured to create a seal that enables a continuous aspiration lumen from the distal tip region of the spined catheter 320 to the proximal sheath connector 226. If the sheath body 222 has a side opening through which the distal luminal portion 322 of the catheter 320 extends, the seal created at the overlap region 120 be-

tween the sheath body 222 and the luminal portion 322 is located proximal to the side opening.

**[0029]** Key dimensions that affect aspiration force through a tube include radius (r), pressure (P), viscosity (n) and length (L) where Flow = $Q = \pi r^4(\Delta P)/8nL$. Changes in radius increase flow to the $4^{th}$ power and length is inversely proportional to flow. As will be described in more detail below, the aspiration catheter has an over-the-wire portion that is a fraction of the overall distance required to reach the target site. This configuration greatly speeds up the time required to retract and re-advance the catheter. Further, the systems described herein can provide for a markedly increased radius and luminal area for aspiration of the clot and markedly shorter length, particularly compared to prior systems where the aspiration lumen runs along the entire inner diameter of the aspiration catheter. In the systems described herein, the majority of the aspiration lumen has a radius of the procedural sheath. The catheter 320 is smaller in diameter than the guide, but steps up in luminal diameter upon reaching the lumen of the access sheath 220 allowing for a greater aspiration force to be applied to a majority of the length of the luminal system. Further, the overall length of this narrow diameter region of the catheter 320 is much shorter compared to the overall length of the access sheath. The proximal spine 330 of the catheter 320 has a length and structure that extends through the lumen 223 of the access sheath 220 to a proximal end of the system such that it can be used to advance and retract the catheter 320 through the lumen 223 of the sheath 220. The spine 330 of the aspiration catheter 320, however, takes up only a fraction of the luminal space the system resulting in increased luminal area for aspiration. Increased luminal area for aspiration increases the time it takes to aspirate the occlusion and increases the possibility of removing the occlusion in a single aspiration attempt. The stepped up luminal diameter also increases the annular area available for forward flushing of contrast, saline, or other solutions while devices such as microcatheters or tapered dilators are coaxially positioned in the spined catheter 320 and access sheath 220. This can increase the ease and ability to perform angiograms during device navigation.

**[0030]** Current stroke interventions pose a risk of distal emboli being released. During the effort to remove or dissolve clot blockages in the cerebral artery, for example, there is a significant risk of thrombus fragmentation creating embolic particles that can migrate downstream into either the occluded vessel or other vessels and compromise cerebral perfusion. In carotid artery stenting procedures (CAS), embolic protection devices and systems are commonly used to reduce the risk of embolic material from entering the cerebral vasculature. The types of devices include intravascular distal filters, and reverse flow or static flow systems. Unfortunately, because of the delicate anatomy and access challenges as well as the need for rapid intervention, these types of embolic protection systems are not used in interventional treatment of acute ischemic stroke. The period of a stroke intervention when flow is restored is normally considered an important time as the brain is now being perfused by blood. However, it is also a period of embolic risk. While there is blockage in the artery, there is no flow. Therefore any embolic debris created by crossing the occlusion with guidewire and/or microcatheter, or deployment of a retrievable stent device across the occlusion, remains stagnant. However, when flow is restored to the artery, the emboli can now flow antegrade to distal vascular territories.

**[0031]** A second period of embolic risk occurs when the retrievable stent device is being pulled back into the guide or catheter. In prior methods and devices, aspiration is applied to the intermediate catheter during retrievable stent device retraction into the catheter, or the catheter and retrievable stent device are pulled back together into the guide, while simultaneously applying aspiration to the guide catheter. Two points of aspiration, through the catheter and through the guide, may both be utilized to reduce risk of distal emboli during the critical step of drawing the occlusion through the guide and out of the patient. Often, two people are required to enable two points of aspiration, or aspiration is performed sequentially from first the catheter and then the guide, which may lead to interruption in aspiration or sub-optimal aspiration. In the disclosed systems and methods, reverse flow may be applied to the target site during device advancement, at the critical time of flow restoration, and during the entire time that the occlusion is being removed, with a single point of aspiration.

**[0032]** In an aspect of the disclosure, the level of aspiration may be modified from a low level to achieve adequate protection from distal emboli, to a higher level to provide effective aspiration removal of the occlusion. This aspect allows distal protection without high levels of blood loss, yet allows a strong aspiration force as needed to remove the occlusion.

**[0033]** In another aspect, there are disclosed methods and devices for additionally providing active aspiration or passive retrograde flow during the procedure to remove thrombus and to minimize distal emboli. The system offers the user a degree of blood flow control so as to address the specific hemodynamic requirements of the cerebral vasculature. The system may include a flow controller, which allows the user to control the timing and mode of aspiration.

**[0034]** In another aspect, there are disclosed methods and devices for additionally providing flushing steps to minimize emboli entrapment in the system and increased visibility of particulates in the system during use.

**[0035]** The following descriptions provide detailed implementations and benefits of each aspect of the disclosed invention.

**[0036]** Referring again to FIG. 1 illustrating an implementation of an access sheath 220. The sheath 220 can include a sheath body 222 that is the insertable portion of the sheath 220 (i.e. the portion that inserts into the patient), a proximal connector 226, an aspiration line 230,

a proximal hemostasis valve 234 and a flush line 236. The sheath 220 may also include a proximal extension portion 240, and may also include a valve on the connector 226 to fluidly isolate the sheath body 222 from the proximal portion 240 of the access sheath 220. The access sheath 220 may come in a kit with one or more dilators 250, and a sheath guidewire 270.

**[0037]** The diameter of the sheath body 222 is suitable for insertion into the carotid artery, with an inner lumen 223 that is suitably sized for providing a passageway for catheters to treat the occlusion. In an implementation, the sheath body 222 can have an inner diameter of about 0.074" and an outer diameter of about 0.090", corresponding to a 5 French sheath size, an inner diameter of about 0.087" and an outer diameter of about 0.104", corresponding to a 6 French sheath size, or an inner diameter of about 0.100" and an outer diameter of about 0.177", corresponding to a 7 French sheath size. The length of the sheath body 222 is configured to enable the distal tip of the sheath body 222 to be positioned as far distal as the petrous portion of the internal carotid artery. In an implementation, the sheath body 222 length is suitable for a transfemoral approach, in the range 80 to 90 cm or up to about 100 cm or up to about 105 cm. In an implementation, the sheath body 222 length is suitable for a transcarotid approach to the petrous ICA, in the range 20 to 25 cm. In an implementation, the sheath body 222 length is suitable for a transcarotid approach to the CCA or proximal ICA, in the range 10-15 cm. The sheath body 222 is configured to assume and navigate the bends of the vasculature and be subject to high aspiration forces without kinking, collapsing, or causing vascular trauma.

**[0038]** The sheath body 222 can be constructed in two or more layers. An inner liner can be constructed from a low friction polymer such as PTFE (polytetrafluoroethylene) or FEP (fluorinated ethylene propylene) to provide a smooth surface for the advancement of devices through the inner lumen. An outer jacket material can provide mechanical integrity to the inner liner and may be constructed from materials such as PEBAX, thermoplastic polyurethane, polyethylene, nylon, or the like. A third layer can be incorporated that can provide reinforcement between the inner liner and the outer jacket. The reinforcement layer can prevent flattening or kinking of the inner lumen of the sheath body 222 to allow unimpeded device navigation through bends in the vasculature as well as aspiration or reverse flow. The sheath body 222 can be circumferentially reinforced. The reinforcement layer can be made from metal such as stainless steel, Nitinol, Nitinol braid, helical ribbon, helical wire, cut stainless steel, or the like, or stiff polymer such as PEEK. The reinforcement layer can be a structure such as a coil or braid, or tubing that has been laser-cut or machine-cut so as to be flexible. In another implementation, the reinforcement layer can be a cut hypotube such as a Nitinol hypotube or cut rigid polymer, or the like.

**[0039]** The flexibility of the sheath body 222 can vary over its length, with increasing flexibility towards the distal portion of the sheath body 222. The variability in flexibility may be achieved in various ways. For example, the outer jacket may change in durometer and/or material at various sections. A lower durometer outer jacket material can be used in a distal section of the sheath compared to other sections of the sheath. Alternately, the wall thickness of the jacket material may be reduced, and/or the density of the reinforcement layer may be varied to increase the flexibility. For example, the pitch of the coil or braid may be stretched out, or the cut pattern in the tubing may be varied to be more flexible. Alternately, the reinforcement structure or the materials may change over the length of the sheath body 222. In an implementation, the distal-most section has a flexural stiffness (E*I) in the range 50 to 300 N-mm2 and the remaining portion of the sheath body 222 has a flexural stiffness in the range 500 to 1500 N-mm2 , where E is the elastic modulus and I is the area moment of inertia of the device. In another implementation, there is a transition section between the distal-most flexible section and the proximal section, with one or more sections of varying flexibilities between the distal-most section and the remainder of the sheath body 222. In this implementation, the distal-most section is about 2 cm to about 5 cm, the transition section is about 2 cm to about 10 cm and the proximal section takes up the remainder of the sheath length.

**[0040]** The tip of the sheath body 222 may include one or more distal radiopaque markers 224 (see FIG. 1). In an implementation, the radiopaque tip marker 224 is a metal band, for example platinum iridium alloy, embedded near the distal end of the sheath body 222. Alternately, the access sheath tip material may be a separate radiopaque material, for example a barium polymer or tungsten polymer blend. The distal region of the sheath body 222 is also the area of the overlap region 120 that allows a seal between the catheter 320 and the sheath body 222, creating a continuous aspiration lumen. Thus, the outer diameter of the luminal portion 322 of the aspiration catheter 320 approaches the inner diameter of the distal region of the sheath body 222 lumen 223 such that a seal is formed. The relative location of the seal formed may vary depending on where the aspiration catheter 320 exits the lumen 223 of the sheath body 222 and the location of the openings from the sheath body 222, as described in more detail below. For example, if the sheath body 222 has an opening at the distal tip the location of the seal may be closer to the distal end of the sheath body 222 compared to if the sheath body 222 has one or more side openings in the distal end region of the sheath body 222 through which the catheter 320 exits the lumen 223.

**[0041]** Referring again to FIG. 1, the access sheath 220 also can include a connector 226 that connects a proximal end of the sheath body 222 to the proximal hemostasis valve 234, and also provides a connection to the aspiration line 230. This connector 226 can have a large bore inner lumen, and connects to a large-bore aspiration line 230. In an implementation, the inner lumen

of the connector 226 is at least .080". In an implementation, the inner lumen of the aspiration line 230 is at least .080". The aspiration line 230 can terminate in a stopcock, female Luer connector, or other connector 232 that allows connection to an aspiration source. In an implementation, the aspiration source is an active aspiration source such as a syringe or a pump. In another implementation, the aspiration source is a reverse flow shunt line such as that described in US Patent Number 8,157,760 and US Patent Publication Number 2010/0217276, which are both incorporated by reference. The large bore aspiration line 230 can be constructed to be resistant to collapse. For example, the aspiration line 230 can be a thick-walled polymer tubing or a reinforced polymer tubing. The aspiration line valve 232 enables the line 230 to be opened or closed. In one implementation, the valve 232 also allows connection of one or more additional fluid lines, for connecting a forward drip or a flush line for contrast or saline injections. As an example, the valve 232 may be a stopcock manifold commonly used in interventional procedures to allow multiple connections. The connector 226 may also include means to secure the access sheath 220 to the patient to reduce the risk of sheath dislodgement during the case. For example, the connector 226 may include one or more suture eyelets 233.

**[0042]** With reference still to FIG. 1, the proximal end of the access sheath 220 can terminate in a proximal hemostasis valve 234. This valve 234 allows the introduction of devices through the sheath 220 into the vasculature, while preventing or minimizing blood loss and preventing air introduction into the access sheath 220. The hemostasis valve 234 can include a flush line 236 or a connection to a flush line 236 so that the sheath 220 can be flushed with saline or radiopaque contrast during the procedure as desired. The flush line 236 can also be used as a second point of aspiration during portions of the procedure as described more fully below. The hemostasis valve 234 can be a static seal-type passive valve, or an adjustable-opening valve such as a Tuohy-Borst valve or rotating hemostasis valve (RHV). The hemostasis valve 234 can be integral to the access sheath 220, or the access sheath 220 can terminate on the proximal end in a female Luer adaptor to which a separate hemostasis valve 234 component, such as a passive seal valve, a Tuohy-Borst valve or rotating hemostasis valve may be attached. In an implementation, the valve 234 has an adjustable opening that is open large enough to allow removal of devices that have adherent clot on the tip without causing the clot to dislodge at the valve 234 during removal. Alternately, the valve 234 is removable and is removed when the catheter tip is being removed from the sheath 220 to prevent clot dislodgement at the valve 234.

**[0043]** Referring again to FIG. 1, the arterial sheath system 200 can include one or more sheath dilators 250 and a sheath guidewire 270. The sheath guidewire 270 can be inserted first into the artery using standard vascular access techniques such as a micropuncture technique or Modified Seldinger technique. The sheath dilator 250 allows for smooth insertion of the access sheath 220 through a puncture site in the arterial wall. The dilator 250 can be inserted into the access sheath 220 and then the two components can be inserted together over the sheath guidewire 270 into the artery The distal end 256 of the dilator 250 can be generally tapered to allow the dilator 250 to dilate the needle puncture site as it is being inserted through the arterial wall into the artery. The tapered distal end 256 can be generally between 6 and 12 degrees total included angle (relative to a longitudinal axis of the dilator), with a radiused leading edge.

**[0044]** An inner lumen of the dilator 250 can accommodate the sheath guidewire 270, and can have an inner diameter of between .037" to .041" to correspond to a sheath guidewire 270 of between .035" to .038". Alternately, the inner lumen of the dilator 250 can be between .020" to .022" to accommodate a sheath guidewire 270 of between .014" to .018". Alternately, the dilator 250 can be a two part dilator with an inner dilator and an outer dilator. The outer dilator can have an inner diameter of between .037" to .041", and the inner dilator can have an inner diameter of between .020" to .022". In use, the sheath 220 can be inserted into the artery with the outer dilator with a sheath guidewire 270 between .035" and .038". The sheath guidewire 270 may then be removed and replaced with the inner dilator and a smaller guidewire of between .014" and .018", and the access sheath 220 can then be advanced further distally to the desired site in the carotid artery.

**[0045]** To insert the arterial sheath 220 initially over the sheath guidewire 270 into the artery, the dilator taper 256 can have a certain stiffness and taper angle to provide the adequate dilating force on the arterial puncture site. However, to safely reach the petrous portion of the ICA, it may be desirable to have a sheath dilator 250 with a softer and/or longer taper at a distal end than that used for initial arterial access. In an implementation, the access sheath system 200 can include two or more tapered dilators. The first tapered dilator can be used with the arterial access device to gain entry into the artery, and is thus sized and constructed in a manner similar to standard introducer sheath dilators. Example materials that may be used for the tapered dilator include, for example, high density polyethylene, 72D PEBAX, 90D PEBAX, or equivalent stiffness and lubricity material. A second tapered dilator may be supplied with a softer distal section or a distal section that has a lower bending stiffness relative to the distal section of the first tapered dilator, and/or a longer taper length. That is, the second dilator has a distal region that is softer, more flexible, or articulates or bends more easily than a corresponding distal region of the first dilator. The distal region of the second dilator thus bends more easily than the corresponding distal region of the first dilator. In an implementation, the distal section of the first dilator has a bending stiffness in the range of 50 to 100 N-mm2 and the distal section of the

second dilator has a bending stiffness in the range of 5 to 15 N-mm2. The second dilator (which has a distal section with a lower bending stiffness) may be exchanged with the initial, first dilator such that the access sheath 220 may be advanced into the internal carotid artery and around curvature in the artery without undue force or trauma on the vessel due to the softer distal section of the second dilator.

**[0046]** The distal section of the soft, second dilator may be, for example, 35 or 40D PEBAX, with a proximal portion made of, for example 72D PEBAX. An intermediate mid portion or portions may be included on the second dilator to provide a smooth transition between the soft distal section and the stiffer proximal section. In an implementation, both dilators have an inner diameter of between .037" to .041". In an alternate implementation, the first dilator has an inner diameter of between .037" to .041" and the second dilator has an inner diameter of between .020" to .022". In yet another implementation, the second dilator is a two part dilator with an inner dilator and an outer dilator, as described above. In an implementation, one or both dilators may have radiopaque tip markers 224 so that the dilator tip position is visible on fluoroscopy. In one variation, the radiopaque marker 224 is a section of tungsten loaded PEBAX or polyurethane that is heat welded to the distal tip of the dilator. Other radiopaque materials may similarly be used to create a radiopaque marker 224 at the distal tip.

**[0047]** In an implementation, the access sheath 220 includes a proximal extension 240 that extends between the connector 226 and the proximal hemostasis valve 234. In the transcarotid configuration of the system, it may be desirable to move the proximal hemostasis valve 234 away from the distal tip of the access sheath 220, effectively elongating or lengthening the proximal portion of the access sheath that is outside the body while maintaining the length of the insertable sheath body portion 222. This allows the user to insert devices into the proximal hemostasis valve 234 of the access sheath 220 from a point further away from the target site and therefore away from the x-ray source and/or image intensifier used to image the target site fluoroscopically, thereby minimizing radiation exposure of the user's hands and also his or her entire body. In this implementation, the proximal extension 240 can be in the range between 10 and 25 cm, or between 15 and 20 cm. In either the transcarotid or transfemoral configuration, it may also be desirable to provide a section of the access sheath 220 that is fluidly connected to the access sheath aspiration line, but which may extend proximally from the aspiration line connection. This will allow users to pull devices out of the flow of blood from the sheath tip to the aspiration line, without completely removing the device from the access sheath 220.

**[0048]** In an alternate implementation, it may also be desirable to intermittently isolate this proximal portion 240 from the sheath body 222. In an implementation, as shown in FIG. 4, the connector 226 includes a valve 242 that can close off the fluid connection between the sheath body 222 and the proximal portion 240 of the access sheath 220, including the aspiration line 230, proximal extension 240 and proximal hemostasis valve 234. This can allow the distal portion of a catheter, retrievable stent device, or other thrombectomy device to be pulled into this proximal extension portion 240, the valve 242 closed to fluidly isolate the sheath body 222 from the proximal portion of the sheath, and then the proximal hemostasis valve 234 to be widely opened or removed, or the entire proximal extension portion 240 of the sheath 220 removed, without arterial bleeding from the sheath 220. The proximal extension 240 can be at least as long as the distal luminal portion 222 of the spined catheter 320 so that the distal luminal portion 322 may be pulled entirely into the proximal extension 240 and the valve 242 closed off before the proximal hemostasis valve 234 is widely opened to remove the catheter 320 entirely from the sheath 220.

**[0049]** Alternately, after the thrombectomy device or other interventional device is pulled into this proximal extension portion 240 and the sheath body 222 closed off via the valve 242, a portion of the thrombectomy device, such as the distal luminal portion 322 of the aspiration catheter 320, may remain in the proximal extension 240 and be flushed or otherwise cleared by creating flow from the flush line to the aspiration lines to dislodge clot without fully removing the device 320 from the access sheath 220. This ability to flush and clear the thrombectomy device without fully removing the thrombectomy device may reduce bleeding, time, and risk of air emboli during the steps between thrombectomy attempts. Also, withdrawing the thrombectomy device into the proximal extension 240 without fully removing it from the sheath body 222 while flushing and clearing also minimizes operator and staff exposure to blood and debris associated with device cleansing. In any of these implementations, the proximal extension tubing is clear so that the flush solution and presence/absence of embolic debris or air is clearly visible through the tubing.

**[0050]** The proximal extension portion 240 of the access sheath 220 can be provided as a separate, removable component that can be attached to any sheath with a standard connection on the proximal end. As shown in FIG. 5, a proximal component 280 includes a connector 285 that can attach to a proximal hub 15 of a standard sheath 10. The coupled components can create an assembly with the configuration and features of access sheath 220. In this implementation, the user can select from any of several already available sheaths of appropriate length, shape, and mechanical characteristics for the procedure, and perform the steps of the procedure described in this disclosure. The removable proximal component 280 can include the Y-arm connector 226, aspiration line 230, proximal extension 240, proximal hemostasis valve 234 and flush line 236, along with the valve connectors 232 and 238 terminating the aspiration

line 230 and flush line 236 respectively. A connector 285 can couple to the proximal connector 226 on the sheath 220. In an implementation as shown in FIG. 6, the connector 285 is configured to minimize the flow resistance through the sheath 10 and into the proximal portion 280. For example, instead of a standard male-female Luer connection, the connector 285 can include an adaptor 60 with an inner lumen and surface that matches a standard female Luer connector 62 typically found on sheaths, a seal element 64 that seals between the adaptor 60 and the sheath female Luer 62, and a rotating nut 66 that engages the thread elements of the female Luer 62 and couples the adaptor 60 and Luer 62 together such that the seal 64 is compressed and can seal against fluid and air vacuum and pressure. Again with respect to FIG.5, the proximal component 280 may also include a valve 242 on the Y-arm connector 226, so that when the proximal component 280 is attached to a sheath 10, the proximal section may be selectively open or closed to fluid connection with the sheath 10. A similar type of connection can be made for connector 232 connecting the sheath aspiration line 230 to an aspiration source.

**[0051]** In a preferred implementation, the proximal connection has a proximal extension length of about 22 cm, a Y-arm connector of about 7 cm, and a proximal hemostasis valve of length about 5 cm for a total length of about 34 cm.

**[0052]** It may be desirable to transiently occlude the carotid artery during the intervention to arrest antegrade flow of emboli during portions of the procedure. In an implementation, as shown in FIG. 7, the access sheath 220 includes an occlusion balloon 246 on the distal tip of the sheath body 222. An additional lumen in sheath body 222 can be connected to an inflation line 248 and fluidly connects the balloon 246 to the inflation line 248. An inflation device is attached to inflation line 248 to inflate the occlusion balloon 246. In this implementation, the balloon 246 is inflated when carotid artery occlusion is desired.

**[0053]** In some instances it is desirable to keep the sheath tip as small as possible during sheath insertion to minimize the diameter of the arterial puncture, but to expand the opening of the sheath 220 after it has been inserted into the vessel. At least one purpose of this feature is to minimize the effect or creation of distal emboli during pull back of an aspiration catheter 320 or other thrombectomy device into the sheath 220. During a thrombectomy procedure, the thrombus may be "pulled back" into a distal opening 221 of the sheath 220 on a device that has captured the thrombus. If the distal tip of the sheath 220 is enlarged relative to its initial size, or flared into a funnel shape, the chance of pieces of the thrombus breaking off and causing emboli is minimized because the larger size or funnel shape of the sheath tip is more likely to accommodate the emboli being drawn into it without being split into multiple pieces. This creates a better clinical outcome for the patient. In an implementation of the access sheath, the distal portion of the sheath body 222 is a material and/or construction such that the tip can be expanded after the sheath 220 is inserted into the artery and positioned in its desired location. In an implementation, the distal region of the sheath has an ID of about 0.087" can be enlarged to a diameter of about 0.100" to 0.120" although the size may vary and/or be flared.

**[0054]** Examples of expanding distal tip constructions include covered braided tips that can be shortened to expand. Another example of an expanding distal tip construction is an umbrella or similar construction that can open up with mechanical actuation or elastic spring force when unconstrained. Other mechanisms of expandable diameter tubes are well known in the art. One particular implementation is a sheath made of material that is deformable when expanded using a high pressure balloon. Co-pending U. S. Patent Publication number 2015/0173782, filed on December 19, 2014, describes exemplary devices and is incorporated herein by reference in its entirety. Construction of such features are described in co-pending Publication number 2015/0173782.

**[0055]** The distal end region of the sheath body 222 also may vary in the location, size and number of openings. The sheath body 222 may incorporate one or more openings near the distal end region of the sheath 220 that allow for fluid flow between the lumen 223 of the sheath body 222 and the vasculature within which the sheath 220 is positioned. The one or more openings can be sized to allow at least the luminal portion 322 of the aspiration catheter 320 to extend therethrough. The one or more openings may be sized larger than the outer diameter of the luminal portion 322 such that the one or more openings form an elongate mouth, slot or notch in a distal end region of the sheath body 222. The one or more openings may be formed within a region of the side wall of the sheath body 222 just proximal to the distal end, such that the opening is located at least 0.25 mm, 0.5 mm, 1.0 mm, 1.5 mm, 2.0 mm, 2.5 mm, 3.0 mm, 3.5 mm, or 4.0 mm or greater from the distal end of the sheath body 222. The one or more openings may be a plurality of openings forming a porous region near the distal end region of the sheath body 222 wherein at least one of the pluralities of openings is sized large enough to allow one or more components of the system to exit the lumen 223 of the sheath body 222. In some implementations, the one or more openings includes a distal opening 221 from the lumen 223 of the sheath body 222 (see FIGs. 4 and 12C). In some implementations, the one or more openings includes an elongate, distal mouth forming a side opening 1219 on a first side of the sheath body 222 located near a distal end region (see FIG. 12C). The side opening 1219 may be located at least 0.25 mm or more from the distal end of the sheath body 222. The side opening 1219 may having a diameter that is at least as large as the outer diameter of the distal luminal portion 322 of the spined catheter 320. Preferably, the side opening 1219 has a diameter that is at least 1.5x, 2x, 2.5x, or

3x as large as the outer diameter of the distal luminal portion 322. In another implementation, the sheath body 222 includes a pair of side openings 1219 on opposing and/or adjacent sides of the sheath body 222 near the distal end region. In another implementation, the sheath body 222 includes a distal opening 221 from the lumen 223 and one or more elongate side openings 1219 from the lumen 223. It should be appreciated that the sheath body 222 can be rotated around the longitudinal axis A such that the one or more side openings 1219 are positioned to allow for distal extension of the catheter 320 from the side openings 1219 in a desired direction relative to the longitudinal axis A of the sheath 220. Inclusion of a wide-mouthed side opening 1219 can allow for a range of exit angles for the catheter 320 from a position substantially (i.e. very nearly) parallel to the sheath body 222 to a position that is at an angle to the sheath body 222, for example substantially perpendicular or at a right angle to the sheath body 222, as well as greater than 90° angle. This arrangement can be critically important in situations where there is severe angulation within the vessel being traversed or where a bifurcation is present. Often, tortuous segments in vessels and bifurcations have severe angulations to 90° or greater angle up to 180°. Classic severe angulation points in the vasculature can include the aorto-iliac junction, the left subclavian artery takeoff from the aorta, the brachiocephalic (innominate) artery takeoff from the ascending aorta as well as many other peripheral locations.

**[0056]** Referring again to FIG. 1, as mentioned above the catheter system 300 can include a spined aspiration catheter 320 having a flexible, distal luminal portion 322 and a rigid, proximal spine 330. The outer diameter of the distal luminal portion 322 as well as the flexibility and lubricity of the luminal portion 322 paired with the rigid spine 330 allow for the spined aspiration catheter 320 to navigate to the site of occlusions in the cerebral vasculature compared to other systems configured to navigate the cardiac vasculature. The systems described herein can reach occlusions in a region of the anatomy that has a long, tortuous access route. The route may contain stenosis plaque material in the aortic arch and carotid and brachiocephalic vessel origins, presenting a risk of embolic complications. Further, cerebral vessels are usually more delicate and prone to perforation than coronary or other peripheral vasculature. The catheter systems described herein can provide for neurovascular interventional procedures more easily due to its ability to overcome these access challenges. The catheter systems described herein are designed for navigating tortuosity rather than pushing through it. U.S. Patent Publication Number 2015/0174368, filed on December 12, 2014, and U.S. Patent Publication Number 2015/0173782, filed on December 19, 2014, describe features of catheter devices that can navigate the tortuous anatomy of the cerebral arteries.

**[0057]** The length of the distal luminal portion 322 can vary. In some implementations, the length of the distal luminal portion 322 extends from a region near the distal tip of the access sheath body 222 to the site of the occlusion in the carotid artery, forming a proximal overlap region 120 with the distal end of the access sheath 220 (see FIG. 2B). Taking into account the variation in occlusion sites and sites where the access sheath distal tip may be positioned, the length of the distal luminal portion 322 may range from about 10 cm to about 25 cm. The length of the distal luminal portion 322 is less than the length of the sheath body 222 of the access sheath 220, such that as the spined aspiration catheter 320 is retracted into the sheath body 222 there remains a seal between the overlap region 328 of the spined aspiration catheter 320, and the inner diameter of the sheath body 222.

**[0058]** The catheter systems described herein can incorporate multiple spined catheters that are nested inside one another to allow for an extended reach into the tortuous anatomy. For example, a first spined catheter 320 having an outer diameter sized to be received within the lumen of the sheath body 222 may have a second spined catheter 320 extending through the inner lumen of the first spined catheter 320. The second spined catheter 320 can be extended using its proximal spine beyond a distal end of the first spined catheter 320 such that the smaller diameter second spined catheter 320 can reach a more distal region of the vasculature, particularly one having a narrower dimension. In this implementation, the first spined catheter 320 can act as a support catheter for the second spined catheter 320. The second spined catheter 320 can have an inner lumen that fluidly communicates with the inner lumen of the first spined catheter 320 that fluidly communicates with an inner lumen of the sheath body 222 forming a contiguous aspiration lumen.

**[0059]** In an implementation, the distal luminal portion 322 of the catheter 320 is constructed to be flexible and lubricious, so as to be able to be safely navigated to the target site, and kink resistant and collapse resistant when subjected to high aspiration forces, so as to be able to effectively aspirate the clot, with sections of increasing flexibility towards the distal end. In an implementation, the distal luminal portion 322 includes three or more layers, including an inner lubricious liner, a reinforcement layer, and an outer jacket layer. The outer jacket layer may be composed of discreet sections of polymer with different durometers, composition, and/or thickness to vary the flexibility along the length of the distal luminal portion 322. In an implementation the lubricious inner liner is a PTFE liner, with one or more thicknesses along variable sections of flexibility. In an implementation, the reinforcement layer is a generally tubular structure formed of, for example, a wound ribbon or wire coil or braid. The material for the reinforcement structure may be stainless steel, for example 304 stainless steel, nitinol, cobalt chromium alloy, or other metal alloy that provides the desired combination of strengths, flexibility, and resistance to crush. In an implementation, the reinforcement structure includes multiple materials and/or designs, again to vary the flexibility along the length of the

distal luminal portion 322. In an implementation, the outer surface of the catheter 320 is coated with a lubricious coating such as a hydrophilic coating. In some implementations the coating may be on an inner surface and/or an outer surface to reduce friction during tracking. The coating may include a variety of materials as is known in the art. The spine portion 330 may also be coated to improve tracking through the access sheath 220. Suitable lubricious polymers are well known in the art and may include silicone and the like, hydrophilic polymers such as high-density polyethylene (HDPE), polytetrafluoroethylene (PTFE), polyarylene oxides, polyvinylpyrolidones, polyvinylalcohols, hydroxy alkyl cellulosics, algins, saccharides, caprolactones, and the like, and mixtures and combinations thereof. Hydrophilic polymers may be blended among themselves or with formulated amounts of water insoluble compounds (including some polymers) to yield coatings with suitable lubricity, bonding, and solubility.

**[0060]** The outer diameter of the distal luminal portion 322 can be sized for navigation into cerebral arteries. It is desirable to have a catheter having an inner diameter that is as large as possible that can be navigated safely to the site of the occlusion, in order to optimize the aspiration force. A suitable size for the inner diameter may range between .040" and .075" or may range between 0.040" and 0.088", depending on the patient anatomy and the clot size and composition. The outer diameter should be as small as possible while still maintaining the mechanical integrity of the catheter 320. However, at the overlap region 120, the outer diameter (OD) of the catheter 320 approaches the inner diameter (ID) of the access sheath 220, so as to create a sealed area at the overlap region 120 whilst still enabling the catheter 320 to be inserted easily through the sheath 220 and positioned at the desired site. In an implementation, the catheter 320 and access sheath 220 are sized to match at the overlap region 120 with no change in catheter 320 outer diameter (see FIG. 2B). In an implementation, the difference between the catheter OD and the access sheath ID at the overlap region is .002" or less. In another implementation, the difference is .003" or less. In an implementation, the catheter 320 is tapered towards the distal tip of the distal luminal portion 322 such that the distal-most end of the catheter has a smaller outer diameter compared to a more proximal region of the catheter near where it seals with the access sheath. In another implementation, the catheter OD steps up at an overlap portion 328 to more closely match the sheath inner diameter (see FIG. 1). This implementation is especially useful in a system with more than one catheter suitable for use with a single access sheath size. It should be appreciated where the catheter OD of the spined catheter 320 matches the sheath inner diameter or the difference is 0.002" or less, a seal to fluid being injected or aspirated can be achieved by the overlap portion 328 such that no increase in catheter OD is necessary. A seal to fluid being injected or aspirated between the catheter and the sheath can be achieved by the overlap between their substantially similar dimensions without incorporating any separate sealing structure or seal feature.

**[0061]** In another implementation as shown in Figure 8A and 8B, there is a sealing element 336 positioned on the external surface of the proximal end of the distal luminal portion 322. The sealing element 336 can be one or more external ridge features, and can be compressed when the catheter 320 is inserted into the lumen of the access sheath 220. The ridge geometry can be such that the sealing element 336 behaves as an O-ring, quad ring, or other piston seal design. Figure 8B shows a similar configuration, with the sealing element 336 having a wiper seal configuration such as an inclined surface that is biased against an inner surface of access sheath body 222. Alternately, the seal element 336 may be an inflatable or expandable member such as a balloon or covered braid structure that can be inflated or expanded and provide sealing between the two devices at any time, including after the catheter 320 is positioned at the desired site. An advantage to this implementation is that there is no sealing force being exerted on the catheter 320 during catheter positioning, but rather is applied or actuated to seal after the catheter 320 is positioned.

**[0062]** It should be appreciated that the shape of the proximal end region of the distal luminal portion 322 may have an angled cut compared to the straight cut shown in the FIGs. 8A-8B. It should also be appreciated that the spine 330 may be coupled to a proximal end region of the catheter 320 and/or may extend along at least a portion of the distal luminal portion 322 such that the spine 330 couples to the distal luminal portion 322 a distance away from the proximal end. The spine 330 can be coupled to the portion 322 by a variety of mechanisms including bonding, welding, gluing, sandwiching, stringing, tethering, or tying one or more components making up the spine 330 and/or portion 322. In some implementations, the spine 330 and luminal portion 322 are coupled together by sandwiching the spine 330 between layers of the distal luminal portion 322. For example, the spine 330 can be a hypotube or rod having a distal end that is skived, ground or cut such that the distal end can be laminated or otherwise attached to the layers of the catheter portion 322 near a proximal end region. The region of overlap between the distal end of the spine 330 and the portion 322 can be at least about 1 cm. This type of coupling allows for a smooth and even transition from the spine 330 to the luminal portion 322.

**[0063]** In an implementation, the overlap region is configured to enable sealing against a vacuum of up to 25 inHg, or up to 28 inHg. In an implementation, the overlap region 120 is configured to enable sealing against a pressure of up to 300 mmHg or up to 600 mmHg or up to 700 mmHg with minimal to no leakage. In addition, there may be features that prevent excessive advancement of the spined aspiration catheter 320 beyond the distal end of the access sheath 220. In any implementation that involves a stepped up diameter or protruding feature at the overlap region 328 of the spined aspiration catheter 320,

the access sheath body 222 may include an undercut at the tip that prevents the proximal overlap portion of the spined aspiration catheter 320 to exit the sheath body 222.

**[0064]** The distal luminal portion 322 of the catheter 320 can have a radiopaque marker 324 at the distal tip to aid in navigation and proper positioning of the tip under fluoroscopy (see FIG. 1). Additionally, the proximal overlap region 328 of the catheter 320 may have one or more proximal radiopaque markers 1324 (see FIG. 12C) so that the overlap region 120 can be visualized as the relationship between the access sheath distal marker 224 and the catheter proximal marker 1324. In an implementation, the two markers (marker 324 at distal tip and a more proximal marker 1324) are distinct so as to minimize confusion of the fluoroscopic image, for example the catheter proximal marker 1324 may be a single band and the sheath tip marker 224 may be a double band.

**[0065]** The spine 330 of the spined aspiration catheter 320 is coupled to a proximal end region of the distal luminal portion 322. The spine 330 is configured to allow distal advancement and proximal retraction of the catheter 320 through the lumen 223 of the access sheath 220. In an implementation, the length of the spine 330 is longer than the entire length of the access sheath 220 (from distal tip to proximal valve), such as by about 5 cm to 15 cm. As shown in FIG. 1, the spine 330 can include a mark 332 to indicate the overlap between the distal luminal portion 322 of the catheter 320 and the sheath body 222. The mark 332 can be positioned so that when the mark 332 is aligned with the sheath proximal valve 234 during insertion of the catheter 320 through the sheath 220, the spined aspiration catheter 320 is positioned at the distal-most position with the minimal overlap length needed to create the seal between the spined aspiration catheter 320 and the access sheath 220. The spine 330 can include a gripping feature such as a tab 334 on the proximal end to make the spine easy to grasp and advance or retract. The tab 334 can coupled with one or more other components of the system 300, such as a dilator configured to extend through the lumen 323 of the distal luminal portion 322 as will be described in more detail below. The proximal tab 334 can be designed to be easily identifiable amongst the other devices existing in the sheath proximal valve 234, such as guidewires 270 or retrievable stent device wires 500. In an implementation, the spine 330 is colored a bright color, or marked with a bright color, to make it easily distinguishable from guidewire, retrievable stent tethers, or the like.

**[0066]** The spine 330 can be configured with sufficient stiffness to allow advancement and retraction of the distal luminal portion 322 of the spined aspiration catheter 320, yet also be flexible enough to navigate through the cerebral anatomy as needed. Further, the outer diameter of the spine 330 is sized to avoid taking up too much luminal area in the lumen 223 of the access sheath 220 and sheath body 222. In an implementation, the spine 330 is a round wire, with dimensions from .014" to .018". In another implementation, the spine 330 is a ribbon with dimensions ranging from .010" to .015" thick, and .015" thick to .025" thick. The ribbon can have a variety of cross-sectional shapes such as a flat ribbon or curved ribbon forming a c-shape or other shape along an arc. In another implementation, the spine 330 is a hypotube. In an implementation, the spine 330 material is a metal such as a stainless steel or nitinol as well as a plastic such as any of a variety of polymers.

**[0067]** One or more components of the systems described herein may be made from a metal, metal alloy, polymer, a metal-polymer composite, ceramics, combinations thereof, and the like, or other suitable materials. Some examples of suitable metals and metal alloys include stainless steel, such as 304V, 304L, and 316LV stainless steel; mild steel; nickel-titanium alloy such as linear-elastic and/or super-elastic nitinol; other nickel alloys such as nickel-chromium-molybdenum alloys (e.g., UNS: N06625 such as INCONEL® 625, UNS: N06022 such as HASTELLOY® C-22®, UNS: N10276 such as HASTELLOY® C276®, other HASTELLOY® alloys, and the like), nickel-copper alloys (e.g., UNS: N04400 such as MONEL® 400, NICKELVAC® 400, NICORROS® 400, and the like), nickel-cobalt-chromium-molybdenum alloys (e.g., UNS: R30035 such as MP35-N® and the like), nickel-molybdenum alloys (e.g., UNS: N10665 such as HASTELLOY® ALLOY B2®), other nickel-chromium alloys, other nickel-molybdenum alloys, other nickel-cobalt alloys, other nickel-iron alloys, other nickel-copper alloys, other nickel-tungsten or tungsten alloys, and the like; cobalt-chromium alloys; cobalt-chromium-molybdenum alloys (e.g., UNS: R30003 such as ELGILOY®, PHYNOX®, and the like); platinum enriched stainless steel; titanium; combinations thereof; and the like; or any other suitable material.

**[0068]** The junction between the distal luminal portion 322 of the catheter 320 and the proximal spine 330 can be configured to allow a smooth transition of flexibility between the two portions so as not to create a kink or weak point, and also allow smooth passage of devices such as guidewires and microcatheters through the continuous inner lumen created by the lumen 223 of the access sheath 220 and the lumen 323 of the luminal portion 322 of the catheter 320. In an implementation, the distal luminal portion 322 has a transition section 326 (see FIG. 1) near where the portion 322 couples to the spine 330 that has an angled cut such that there is no abrupt step transition from the sheath 220 inner lumen 223 to the catheter 320 inner lumen 323. The angled cut can be generally planer. In an alternate implementation, the angled cut is curved or stepped to provide a more gradual transition zone. The distal luminal portion 322 and the spine 330 may be joined by a weld bond, a mechanical bond, an adhesive bond, or some combination thereof. The distal end of the spine 330 may have features that facilitate a mechanical joint during a weld, such as a textured surface, protruding features, or cut-out features. During a heat weld process, the features would facilitate

a mechanical bond between the polymer distal luminal portion 322 and the spine 330. In another implementation, such as the catheter system 1300 shown in FIGs. 12A-12B having a spined catheter 1320 and a dilator 1340 extending therethrough, a smooth transition of flexibility between the two portions is formed so as not to kink or create a weak point during advancement of the system 1300. Loss of this smooth flexibility transition can occur upon removal of the dilator 1340 from the spined catheter 1320. The spine 1330 can be intended primarily to withdraw the spined catheter 1320 where risk of kink or weak spot formation is markedly lower.

**[0069]** Because the spined aspiration catheter 320 does not have a lumen that runs its entire length 320 due to the presence of the spine 330 on its proximal end region, traditional flushing and preparation steps, either before use or during the procedure should the lumen of the catheter become clogged, are ineffective. In a traditional single lumen catheter, a syringe is attached to the proximal adaptor of the catheter and the inner lumen may be forcefully flushed with solution. The spined catheter 320 can be supplied with an accessory catheter flushing and clearing device 350 (see FIG. 1). This device 350 may be a tube with a rounded or tapered tip on a distal end and a female Luer connection on the proximal end. The Luer connector allows a syringe to be connected to the device 350. The blunt or tapered tip enables the device 350 to be inserted into either the distal or proximal end of the luminal portion 322 of the catheter 320, without risk of damaging the catheter 320, and the syringe actuated to flush the device. The OD of the clearing device 350 is closely matched with the ID of the luminal portion 322 of the spined catheter 320, such that the spined aspiration catheter 320 may be flushed with enough force to clear out the catheter of debris and aspirated occlusive material. The device 350 may also be used to mechanically clear out any entrapped thrombus in a plunger-type action, the working length of the device 350 can be at least as long as the distal luminal portion 322 of the catheter 320, so that it may be inserted through the entire lumen 323 of the distal luminal portion 322. Flushing may occur in conjunction with plunging the device 350, to more effectively clear the catheter 320 of entrapped thrombus or other embolic material.

**[0070]** In an alternate implementation, the aspiration catheter 320 is a single lumen catheter, for example, the type of catheter described in co-pending application U.S. Patent Publication Number 2015/0174368, filed December 12, 2014. In such an implementation, the catheter may be supplied with or coupled with a tapered co-axial dilator 340 that is generally tubular and has a tapered distal portion that provides a smooth transition between the catheter and a guidewire positioned within the catheter.

**[0071]** The spined aspiration catheter 320 can be navigated through the vasculature over an appropriately-sized microcatheter and guidewire. Alternately, the spined catheter 320 can be supplied with a co-axial dilator 340 (see FIG. 1). The dilator 340 is sized and shaped to be inserted through the internal lumen 323 of the distal luminal portion 322 of the catheter 320 in a coaxial fashion, such that a proximal end region of the dilator 340 aligns side-by-side with the spine 330 of the catheter 320 when in use. The dilator 340 can have a tapered distal tip 346. The length of the dilator 340 can be at least as long as the spined aspiration catheter 320 allowing for the distal tapered tip 346 as a minimum to protrude from the distal end of the luminal portion 322 of the spined catheter 320. The dilator 340 can have an outer diameter that forms a smooth transition to the distal tip of the catheter, and the distal tapered tip 346 that provides a smooth transition down to the guidewire that extends out the inner lumen of the dilator 340. The dilator 340 can be generally tubular along at least a portion of its length. In an implementation, the tapered dilator 340 is designed to accommodate a guidewire that may be in the range of 0.014" and 0.018" diameter for example. In this implementation, the inner luminal diameter may be between .020" and .024". The tapered distal tip 346 may be in range from 1.5 cm to 3 cm.

**[0072]** It should be appreciated that the dilators described herein for use with the spined catheters can vary in their configuration. For example, as described above the dilator 340 can be a co-axial dilator 340 that is generally tubular and has a tapered distal portion that provides a smooth transition between the catheter 320 and a guidewire positioned within the catheter 320. The tubular body of the dilator 340 can extend along the entire length of the catheter 320. Alternatively, the dilator 340 can incorporate a proximal spine that aligns side-by-side with the spine of the catheter 320. The proximal spine can be positioned co-axial or eccentric to a distal end region of the dilator 340. The co-axial proximal spine of the dilator 340 can have a lumen extending through it. Alternatively, the dilator 340 can be a solid rod having no lumen. The solid rod dilator can be formed of a malleable material that skives down to have a narrow outer diameter (e.g. 0.010" - 0.014") such that the dilator can be shaped to whatever angle or shape is desired by the user, similar to how a guidewire may be used. In this configuration, the catheter system does not include a guidewire or microcatheter. Such a dilator has a benefit over a microcatheter in that it can have an outer diameter that is 0.003" - 0.010" smaller than the inner diameter of the spined catheter 320.

**[0073]** The dilator 340 may have a proximal female Luer adaptor 348 at a proximal end to allow the dilator 340 to be flushed with a syringe. The dilator 340 may also incorporate a clip feature at a proximal end allowing the dilator 340 to be the material of the dilator 340 can be flexible enough and the taper distal tip 346 can be long enough to create a smooth transition between the flexibility of the guidewire and the flexibility of the catheter. This configuration can facilitate advancement of the catheter 320 through the curved anatomy and into the target cerebral vasculature. In an implementation, the distal end

of the dilator 340 has a radiopaque marker 344 and/or a marker 343 at the proximal end of the taper distal tip 346. The marker material may be a platinum/iridium band, a tungsten, platinum, or tantalum-impregnated polymer, or other radiopaque marker.

**[0074]** The dilator 340 can be constructed to have variable stiffness between the distal and proximal ends of the dilator 340. For example, the distal most section that extends beyond the distal end of the luminal portion 322 of the catheter 320 can be made from a more flexible material, with increasingly stiffer materials towards the more proximal sections. In some implementations, the dilator 340 can be a spined dilator having a proximal spine as will be described in more detail below. The proximal end of the dilator 340 can include a tab 1364 that allows the dilator 340 to lock with the tab 334 on the proximal end of the spine 330 of the catheter 320, such that the two components (the spined catheter 320 and the dilator 340) may be advanced as a single unit over the guidewire (see FIG. 12A). In some implementations, the tab 334 of the catheter 320 can form a ring having a central opening extending therethrough. The tab 1364 of the dilator 340 can have an annular detent with a central post. The central post of the tab 1364 can be sized to insert through the central opening of the tab 334 such that the ring of the tab 334 is received within the annular detent of tab 1364 forming a singular grasping element for a user to advance and/or withdraw the catheter system through the access sheath. The tab 1364 may be affixed to the dilator 340, or may be slideable on the dilator 340 to accommodate different relative positions between the dilator 340 and the spined catheter 320.

**[0075]** FIGs. 12A-16 provide additional views of a spined aspiration catheter and dilator system 1300 as described elsewhere herein. FIGs. 12A-12B show the spined aspiration catheter 1320 having a dilator 1340 extending through an aspiration lumen 1323 of the distal luminal portion 1322. As described elsewhere herein, the catheter 1320 can have a proximal spine 1330 having a tab 1334 and a distal luminal portion 1322 having an aspiration lumen 1323. The spine 1330 can extend between the distal luminal portion 1322 and the tab 1334. The dilator 1340 can be received within the aspiration lumen 1323 of the spined catheter 1320. The dilator 1340 can include a distal dilator portion 1360 and a proximal spine 1362. The dilator portion 1360 can extend between a distal tip 1346 of the dilator 1340 to the start of the proximal spine 1362. When engaged with the catheter 1320, the dilator portion 1360 of the dilator 1340 may extend through an entire length of the distal luminal portion 1322 of the catheter 1320 such that the dilator tip 1346 extends a fixed distance beyond a distal end of the distal luminal portion 1322 of the catheter 1320 providing a smooth transition for improved tracking. The dilator tip 1346 can be tapered as described elsewhere herein and can be soft, atraumatic and flexible to the vessel wall to facilitate endovascular navigation to an embolus in a tortuous anatomy compared to dilators typically used for percutaneous arterial access, which are meant to bluntly dissect through tissue and artery wall.

**[0076]** The dilator 1340 is shown in a locked configuration with the catheter 1320 configured for improved tracking through a tortuous and often diseased vasculature in acute ischemic stroke. The dilator portion 1360 can include one or more detents on an outer surface of the dilator portion 1360. The detents can be located near a proximal end region and/or a distal end region of the dilator portion 1360. The detents are configured to lock with correspondingly-shaped surface features on the inner surface of the lumen 1323 through which the dilator portion 1360 extends. The dilator 1340 can include a dilator tab 1364 on a proximal end of the proximal spine 1362 of the dilator 1340, which as discussed above can be configured to connect and lock with a corresponding feature on the proximal end region of the catheter spine 1330, for example via one or more detents or other surface features. Thus, the dilator 1340 and the catheter 1320 can have more than a single point of locking connection between them. The proximal spine 1362 of the dilator 1340 can extend between the dilator portion 1360 and the tab 1364 of the dilator 1340. The dilator portion 1360 can be a tubular element as described elsewhere herein that forms a guidewire lumen running a length of the dilator portion 1360 (and an entire length of the distal luminal portion 1322 of the spined catheter 1320). It should be appreciated that the entire dilator 1340 can be tubular element configured to receive a guidewire through the spine 1362 as well as the dilator portion 1360. The proximal end of the dilator portion 1360, i.e., the transition section 1326 between the dilator portion 1360 and the proximal spine 1362, may include a "step up" to smooth the transition between the distal luminal portion 1322 of the catheter 1320 and the dilator portion 1360 of the dilator 1340. The transition section 1326 can incorporate an angled cut such that there is no abrupt step transition from the sheath 1220 inner lumen 1223 to the catheter 1320 inner lumen 1323. Accordingly, the spined aspiration catheter-dilator 1300 may be smooth to the vascular wall it interfaces with.

**[0077]** The proximal spine 1362 of the dilator 1340 may have a similar stiffness and character as the spine 1330 of catheter 1320. More particularly, one or both of the spines 1362, 1330 may be stiff and/or kink resistant. Furthermore, one or both of the spines 1362, 1330 may have a stiffness to allow pushing the distal portions, i.e., the combined distal luminal portion 1322 and dilator portion 1360, through an access sheath or a guide-sheath while producing a very low profile. In an embodiment, one or both of the spines 1362, 1330 includes a stiff wire.

**[0078]** The catheter tab 1334 and the dilator tab 1364 can be removably connected with one another. More particularly, the tabs 1334, 1364 may have a locked configuration and an unlocked configuration. In the locked configuration, the dilator tab 1364 can be engaged with the catheter tab 1334. In the unlocked configuration, the dilator tab 1364 may be disengaged from the catheter tab

1334. The dilator tab 1364 may attach, e.g., click or lock into, the catheter tab 1334 in a fashion as to maintain the relationships of corresponding section of the spined dilator 1340 and the spined catheter 1320 in the locked configuration. Such locking may be achieved by, e.g., using a detent on the dilator tab 1364 that snaps into place within a recess formed in the catheter tab 1334, or vice versa. In some implementations, the spine 1330 of the spined catheter 1320 can run alongside or within a specialized channel of the dilator spine 1362. The channel can be located along a length of the dilator spine 1362 and have a cross-sectional shape that matches a cross-sectional shape of the catheter spine 1330 such that the spine 1330 of the catheter 1320 can be received within the channel and slide smoothly along the channel bi-directionally. Once the spined catheter 1320 and spined dilator 1340 are fixed, the combined system, i.e., the spined aspiration catheter-dilator 1300 may be delivered to a target site, for example through the lumen 223 of the access sheath 220 described elsewhere herein.

**[0079]** Referring to FIG. 12B, a spined aspiration catheter-dilator 1300 having a spined catheter 1320 and a spined dilator 1340 in an unlocked configuration is illustrated in accordance with an embodiment. When the spined aspiration catheter-dilator 1300 is positioned at the target site, as discussed herein, the dilator tab 1364 can be unlocked from the catheter tab 1334. The spined dilator 1340 may be withdrawn and the spined catheter 1320 may be used, e.g., for aspiration or for wire or balloon delivery.

**[0080]** Referring to FIG. 13, a cross-sectional view, taken about line A-A of FIG. 12B, of a spined catheter 1320 coaxially aligned with a spined dilator 1340 is illustrated in accordance with an embodiment. The cross-section illustrates a portion of the catheter-dilator having the dilator portion 1360 received within the aspiration lumen 1323 of distal luminal portion 1322. The lumen 1323 may have an inner diameter in a range up to 0.072 inches, although a larger or smaller inner diameter is possible (larger or smaller possible). The wall of the distal luminal portion 1322 may resist kinking or ovalizing to provide maximum diameter for aspiration. The dilator portion 1360 may be received in the distal luminal portion 1322 in a slip fit. Thus, in an embodiment, an outer dimension of the dilator portion 1360 may be less than the inner diameter of the distal luminal portion 1322. For example, the lumen 1323 may have a diameter of 0.072 inches and the dilator portion 1360 may have an outer dimension of 0.070 inches.

**[0081]** Referring to FIG. 14, a cross-sectional view, taken about line B-B of FIG. 12B, of a spined catheter 1320 after removal of a spined dilator 1340 is illustrated in accordance with an embodiment. The cross-section illustrates the distal luminal portion 1322 after the dilator portion 1360 has been retracted and/or removed. The distal luminal portion 1322 has an inner wall 1321 defining the lumen 1323. The lumen 1323 may be circular, as shown, or may have any other shape. In an embodiment, the effective diameter of the lumen 1323 ranges up to 0.072 inches.

**[0082]** Referring to FIG. 15A, a spined aspiration catheter-dilator system 1300 having a spined catheter 1320 and a spined dilator 1340 in a locked configuration is illustrated in accordance with an embodiment. In an embodiment, the spine 1330 and dilator 1340 may have an outer dimension that is substantially similar over an entire length. For example, rather than converging to a smaller dimension between the dilator portion 1360 and the dilator spine 1362, the dilator spine 1362 may have a same dimension as the dilator portion 1360. Thus, a catheter-dilator having a substantially same cross-sectional area over at least a majority of its length may be provided. As discussed above, the spine dilator 1340 and the spine catheter 1320 may have corresponding tabs 1334, 1364 that engage in a locked configuration and disengage in an unlocked configuration.

**[0083]** Referring to FIG. 15B, a spined aspiration catheter-dilator having a spined catheter 1320 and a spined dilator 1340 in an unlocked configuration is illustrated in accordance with an embodiment. The spined dilator 1340 may be removed from the spined catheter 1320 in a manner similar to that described above. In an embodiment, the spined aspiration catheter-dilator may have a similar cross-sectional area over a majority of its length, and thus, the shapes of the spined catheter 1320 and the spined dilator 1340 may be complimentary. For example, the spine 1330 may have a cross-sectional area along an arc, such as a quarter circle, and thus, a cross-sectional area of the dilator spine 1362 may be three quarters of a circle. As such, the spine 1330 may conform to the dilator spine 1362 to provide an overall cross-sectional area of a full circle.

**[0084]** Referring to FIG. 16, a schematic view of a spined catheter 1320 having a distal luminal portion 1322 having an inner lumen 1323 located in a neurovascular anatomy is illustrated in accordance with an embodiment. Used in conjunction with an access sheath 1220 having a sheath body 1222 and an inner lumen 1232, in an embodiment where the spined catheter 1320 reaches the ICA and the distance to embolus E is consistently felt to be less than 20 cm, one would see that the distal luminal portion 1322 having a length of 25 cm would allow for an overlap region 1120 with the access sheath 1220 to create a seal. The overlap region 1120 may have a length of a few centimeters, and the may vary depending on the distance from the embolus E to the distal end of the distal luminal portion 1322, e.g., depending on how far the spined catheter 1320 is advanced relative to the access sheath 1220.

**[0085]** As described elsewhere herein, the luminal area available for aspiration of the embolus is greater using the spined catheter 1320 as compared to an aspiration system having a conventional large bore catheter in an access sheath. More particularly, the combined volume of the luminal area of the spined catheter 1320 and the luminal area of the access sheath 1220 proximal to the

distal luminal portion 1322 is greater than the luminal area of the large bore catheter along the entire length of the system. Thus, the likelihood of removing the embolus in a single aspiration attempt may be increased. More particularly, the stepped up luminal diameter along the spine 1330 may enable a greater aspiration force to be achieved resulting in improved aspiration of the embolus. The stepped up luminal diameter may also increase the annular area available for forward flushing of contrast, saline, or other solutions while devices such as microcatheters or tapered inner members are coaxially positioned in the spined catheter and access sheath. Thus, the ease and ability to perform angiograms during device navigation may be improved.

**[0086]** The disclosed systems may be supplied with ancillary devices that are particularly configured to be used with the system. It should be appreciated that reference to one implementation of an access sheath system or aspiration catheter system is not intended to be limited and that the ancillary devices described herein can be used with any of the systems having any of a variety or combination of features described herein. For example, where an access sheath is described below it should be appreciated that one or more features of any of the access sheaths or access sheath systems described herein can be incorporated. Similarly, where a spined catheter is described below one or more featured of any of the spined catheters or spined catheter systems described herein can be incorporated.

**[0087]** In an implementation, the system includes a microcatheter 400 (see FIG. 1). The microcatheter 400 can be configured to be particularly suited for navigation in the cerebral vasculature. The microcatheter 400 may be used in place of the tapered dilator 340 to help navigate the spined catheter 320 to the desired site. As such, it may include means at the proximal end to lock the spine 330 to the microcatheter 400, so that so that the two components (the spined catheter 320 and the microcatheter 400) may be advanced as a single unit over the guidewire. In some instances the microcatheter 400 is advanced ahead of the catheter 320, to provide support as the catheter 320 is advanced, or to cross the occlusion and perform an angiogram distal to the occlusion. In this case, the length of the microcatheter 400 can be longer than the spined catheter 320 by about 10 to 20 cm. The microcatheter 400 may also be used to deliver a retrievable stent device 500 to the occlusion. In this case, the microcatheter 400 can have an inner diameter suitable for delivery of the retrievable stent device 500, for example, in the range .021" to .027" and with a PTFE inner liner. The microcatheter 400 can be at least about 5-10 cm longer or at least about 5 - 20 cm longer than the overall length of the spined catheter 320 to allow the microcatheter 400 to extend beyond the distal end of the aspiration catheter 320 during navigation.

**[0088]** In an implementation, the system includes a retrievable stent device 500 with a distal expandable section 510, which is sized and configured to be delivered through the microcatheter 400, as shown in FIG. 9. The retrievable stent device 500 may be used in conjunction with the other components of the system to aid in removal of the occlusion. The retrievable stent device 500 may also be used to quickly restore flow to the occluded artery during the thrombectomy procedure. Examples of retrievable stent devices include the Solitaire Revascularization Device (Medtronic) or the Trevo Stentriever (Stryker).

**[0089]** In a method of use, the retrievable stent device 500 is used to assist in bringing thrombus into the catheter 320 during an aspiration step, or clearing the catheter 320 that may become clogged during the aspiration step. In an implementation, the retrievable stent device 500 is configured to be particularly suited for performing these functions. For example, as shown in FIG. 10A, the distal end of the expandable portion 510 of the device 500 has multiple struts or elements 520 that come together at the distal tip to close off the distalmost end, such that the device allows blood flow across the device, but captures the thrombus pieces as the device 500 is pulled into the catheter 320, and subsequently through the catheter 320 and out the distal end. Alternately, the distal end 520 is a filter element or a balloon element.

**[0090]** In another example, in FIG. 10B, the retrievable stent device 500 includes two or more segments with one or more proximal segments 510a configured to be expanded in the catheter distal inner lumen while one or more distal segments 510b are expanded across the occlusion as is done with prior retrievable stent devices. Alternately, as seen in FIG. 10C, the retrievable stent device 500 has a very long expandable portion 510, such that a proximal portion of the expandable portion may be expanded in the catheter distal inner lumen while the distal portion is expanded across the occlusion. In all these implementations, the proximal end of expandable section 510 has minimal structural elements that will allow the expandable section to be pulled easily into the lumen of the catheter 320, and out of the access sheath 320, so as minimize impediment of thrombus aspiration through the device. In these examples, the expandable portion 510 is still engaged with the clot even when the clot is aspirated into the catheter 320, and if the catheter 320 becomes corked, the device 500 is well-positioned to clear the clot when it is pulled back. Once the retrievable stent device 500 has been removed from the luminal portion 322 of the catheter 320, additional aspiration can be applied to the site through the catheter 320 if it is still partially or fully occluded. This step would not be possible if the catheter 320 remained clogged; the catheter would have to be removed and cleared outside the patient before being reinserted for additional aspiration. This configuration of retrievable stent device 500 can be used with either a conventional single lumen aspiration catheter, or a spined aspiration catheter 320.

**[0091]** The implementations of device 500 as shown in FIGs. 10A-10C may be used with known thrombectomy devices and methods to address the issue of cathe-

ters clogging during thrombus aspiration.

**[0092]** In an implementation, the system includes an aspiration source 600, as shown in FIG. 2A or FIG. 3. The aspiration source 600 can be attached to the aspiration line 230 on the access sheath 220. Examples of aspiration source 600 include a syringe or an active aspiration pump. The aspiration source 600 may be connected to a delivery location, such as a receptacle. The receptacle and source of aspiration 600 may be separate, such as a mechanical or electromechanical fluid pump whose outlet is connected to a blood collection reservoir or may be combined into a single device such as a syringe or syringe pump. Alternately, the blood collection reservoir is connected to a source of vacuum such as a hospital vacuum line or an air vacuum pump, and is thus the receptacle as well as the source of aspiration. A filter and/or a check valve may be coupled with the aspiration source. The pump may be a positive displacement pump such as a diaphragm or piston pump, a peristaltic pump, centrifugal pump, or other fluid pump mechanism known in the art.

**[0093]** In an implementation, the aspiration source is a variable state or multi-state aspiration source, and includes a mechanism to control the level of aspiration, for example by modifying the vacuum level in the vacuum pump, by modifying the power to the motor of a positive displacement, peristaltic or centrifugal pump, or modifying the syringe pull back speed in the syringe or syringe pump. Alternately, the aspiration rate may be varied by providing an element with variable resistance to flow, for example parallel flow paths that can switch between a high and low flow resistance path, flow orifices or lumens that can be variably opened, or other means to vary flow resistance. In an example, the aspiration source is configured to have two levels of aspiration: a high level of aspiration to be used when the catheter is in contact with the thrombotic material, to aspirate the thrombotic occlusion, and a low level of aspiration to be used during steps in the procedure that are high risk of causing distal emboli, for example crossing the lesion or when flow is restored to the vessel when a retrievable stent device is expanded.

**[0094]** In another example, as shown in FIG. 11, the aspiration source 600 further includes a flow sensor 275 that senses flow in the aspiration line 230, coupled to a controller that controls the level of aspiration. The aspiration source 600 can increase in aspiration level when the flow rate is slow and decrease when the flow rate is increased. In this manner, the force is greatest when the catheter is clogged or partially clogged, but decreases to a minimal level when there is free flow to ensure protection from distal emboli but limit the volume of aspirated blood. In this manner, the system optimizes the thrombus aspiration while limiting the amount of blood aspirated. Alternately, the aspiration source 600 can include a vacuum gauge. When the flow in the catheter 320 is blocked or restricted the pump creates a higher level of vacuum. In this example the aspiration force may be configured to rise when higher vacuum is detected.

**[0095]** In yet another aspiration source implementation, the aspiration source 600 provides a cyclic level of aspiration force, for example, an aspiration force that cycles between a high level of vacuum to a lower level of vacuum at a set frequency, or from a high level of vacuum to no vacuum, or from a high level of vacuum to a pressure source. A cyclic aspiration mode may provide a jackhammer type force on the thrombus and increase the ability to aspirate the thrombus through the catheter. The cyclic aspiration force may be enabled through solenoid valves, a programmable pump motor, or the like. In an implementation, cyclic aspiration is applied only when clogged or restricted flow is detected in the aspiration line, either through low flow or high vacuum, as discussed above, and at other times, the aspiration source reverts to a low level of flow, or be turned off. This configuration may be controlled by the user, or controlled automatically via a feedback loop to the aspiration source.

**[0096]** In an implementation, the system includes a mechanism for passive reverse flow that is configured to be connected to the aspiration line on the access sheath. For example, the aspiration line is connected to a lower pressure site such as a central vein, or an external receptacle set to zero or negative pressure.

**[0097]** In an implementation as shown in FIG. 11, the flush line 236 may be connected via stopcock 238 to a syringe 286 that may hold saline fluid or radiopaque contrast. Additionally the flush line 236 may be connected to a flush source 288, for example, a pressurized bag of saline. A valve 292 can control flow from the flush source 288 to the flush line 236. When the valve 292 is opened to the flush line 236 a pressurized source of fluid is provided. In an implementation, the valve 292 is coupled via a mechanical or electromechanical coupler 295 to the aspiration source 600 such that the valve 292 is only open when the aspiration source 600 is on. Alternately, the valve 292 is coupled to a flow sensor 275 in the aspiration line 230, such that the valve 292 is only on when there is flow in the direction towards the aspiration source 600. In these implementations, the flow rate of the flush source 288 is configured to flow just enough to keep the proximal extension 240 clear of blood but not so high as to cause flow to work against the aspiration flow and limit aspiration of thrombus. An advantage of this implementation is that the proximal extension 240 remains clear of blood and any emboli or air that is in the proximal extension 240 is clearly visible. This provides a feedback to the user on when and if to flush the catheter with saline or contrast via syringe 286.

**[0098]** In another implementation, the valve 292 is coupled either mechanically or electromechanically to the valve 242 that connects the sheath body 222 to the proximal portion 240 of the sheath 220. The coupling 290 can be configured such that the valve 292 can only be opened when the valve 242 is closed. This feature allows the proximal extension 240 to be cleared of blood via a flush step, without risk of flushing emboli back through the

catheter into the vasculature. The coupling 290 may be configured in one of several ways For example, the coupling 290 may always open the valve 238 when the valve 242 is closed, or the coupling may prevent the valve 238 from opening unless valve 242 is closed but that does not automatically open.

**[0099]** In an implementation, the valve 292 is a variable state valve that allows different levels of flush flow rate. In this example, the valve 292 is configured to allow a slow flush when the aspiration source is on a low setting, a higher level of flush when the aspiration source is on a high setting. In an implementation, the valve allows yet a higher level of flush when the valve 242 is closed. These configurations allow a continuous removal of debris and/or clear visibility of the proximal portion of the access sheath and minimizes the risk of distal emboli or air entering the vasculature during the steps of the procedure. For example, during the step when the distal tip of catheter is being removed from the proximal hemostasis valve 234, any clot that was captured on the tip of the catheter may be liberated when the catheter is pulled through the valve, but with the continuous flush the liberated emboli would be flushed into the aspiration line and not remain in the sheath where it might be re-injected into the vasculature, for example during a contrast injection after the catheter is removed.

**[0100]** Again with respect to FIG. 1, the system 100 may include a kit of multiple devices. In an implementation, the kit includes an access sheath system 200 wherein the access sheath system includes an access sheath, one or more tapered sheath dilators, and one or more sheath guidewires. In another implementation, the system 100 includes an access sheath system 200 and one or more spined catheter systems 300 with one or more inner diameters. In an implementation, the spined catheter system 300 includes a spined aspiration catheter 320 and a tapered dilator 340. In an implementation, the spined catheter system 300 also includes a catheter clearing tool 350. In yet another implementation, the system 100 includes an access sheath system 200, a tapered catheter system 300, a microcatheter 400, and a retrievable stent device 500.

**[0101]** In an implementation configured for transcarotid access, the kit includes an access sheath 220, wherein the insertable sheath body 222 length is about 23 cm, the proximal extension 240 is about 22 cm, the connector 226 is about 7 cm and the proximal hemostasis valve 234 is about 5 cm, for an overall access sheath length of about 57 cm. In an implementation, the kit also includes a spined aspiration catheter 320 wherein the catheter distal luminal portion 322 is about 20 cm, the transition section 326 is about 2-4 cm, and the spine section 330 is about 65 cm, for an overall spined catheter length of about 88 cm. In another implementation, the kit also includes a tapered dilator 340 with a working length of 93 cm. In another implementation, the kit also includes a microcatheter 400 with a working length of about 198 cm and a retrievable stent device 500 with an overall length of 128 cm.

**[0102]** In an implementation configured for transfemoral access, the kit includes an access sheath system 220, wherein the insertable sheath body 222 length is about 90 cm, the proximal extension 240 is about 22 cm, the connector 226 is about 7 cm and the proximal hemostasis valve 234 is about 5 cm, for an overall access sheath length of about 124 cm. The proximal portion of the access sheath may be a removable proximal portion 280. In an implementation, the kit also includes a spined aspiration catheter 320, wherein the catheter distal luminal portion 322 is about 20 cm, the transition section 326 is about 2-4 cm, the spine section 330 is about 132 cm, for an overall spined catheter length of about 155 cm. In another implementation, the kit also includes a tapered dilator 340 with a working length of 160 cm. In another implementation, the kit also includes a microcatheter 400 with a working length of about 165 cm and a retrievable stent device 500 with an overall length of 195 cm.

**[0103]** In another implementation, the kit includes an access sheath 220 with a removable proximal portion 280, and a single lumen aspiration catheter. In another implementation, the kit includes only the proximal portion 280 that can be attached to any introducer sheath suitable for the procedure. In this implementation, the kit may also include a spined aspiration catheter 320 or a single lumen aspiration catheter.

**[0104]** In any of these implementations, the kit may also include an aspiration source, for example a pump, an attachment to a vacuum pump, a syringe, a syringe that is attachable to a syringe pump, or the like. The kit may also include means for automatic flushing, for example coupling means 290 or 292.

**[0105]** As described elsewhere herein, it should be appreciated that reference to one implementation of an access sheath system or catheter system is not intended to be limited and that the kits described herein can incorporate any of the systems and/or ancillary devices described herein as having any of a variety of features. For example, where an access sheath is described as being a part of a kit it should be appreciated that one or more features of any of the access sheaths or access sheath systems described herein can be incorporated. Similarly, where a spined catheter is described as being part of a kit one or more featured of any of the spined catheters or spined catheter systems described herein can be incorporated.

**[0106]** FIGs. 2A and 3 illustrates methods of use. As shown in FIG. 2A, an access sheath 220 is inserted using standard vascular access sheath into the femoral artery, and advanced until the sheath tip is positioned at a site as distal as safely possible in the internal or common carotid artery. In FIG. 3, the access sheath 220 is inserted directly into the common carotid artery, and advanced until the sheath tip is positioned at a site as distal as safely possible in the internal carotid artery. In either scenario, the sheath may be advanced initially to the common carotid artery or proximal internal carotid artery, and

then the dilator and is exchanged for a softer dilator before advancing the sheath more distally into the internal carotid artery. The sheath is then secured to the patient using a suture through the eyelet on the sheath connector. The sheath aspiration line 230 is connected to an aspiration source 600 such as a syringe or aspiration pump. The sheath aspiration line may also be connected via a stopcock or stopcock manifold to a forward flush line (such as a pressurized saline bag).

**[0107]** Once the sheath tip is positioned at the desired location, it is secured to the patient. A spined catheter, tapered dilator, and guidewire are pre-assembled in a co-axial configuration and introduced through the sheath proximal hemostasis valve into the carotid artery. The spined aspiration catheter 320 is advanced through access sheath and positioned until the distal tip is at the treatment site. The devices are advanced using standard interventional techniques until the distal catheter tip is at the proximal face of the occlusion. A mark 332 on the spine 330 ensures that there is still an overlap region 120 between the distal luminal portion 322 of the catheter and the access sheath body 222. At this point, the tapered dilator 340 and guidewire can be removed. In an alternate implementation, a microcatheter 400 is used in place of the tapered dilator 340 to help navigate the catheter 320 to the occlusion. During the procedure, the forward flush is opened to the aspiration lumen to keep the lumen clear before or between periods of aspiration. At any point during device navigation, aspiration may be initiated from the aspiration source 600 at a level suitable for distal embolic protection, for example when the guidewire or microcatheter 400 is crossing the occlusion.

**[0108]** Once the distal tip of the spined aspiration catheter 320 is at the face of the clot, aspiration is initiated at a level suitable for aspiration thrombectomy, which is a higher level than for distal embolic protection. The catheter 320 may remain in aspiration mode against the clot for some period of time, as deemed suitable by the user. Depending on the results of the aspiration thrombectomy maneuver (as observed by flow though the aspiration line and/or resistance to backwards force on the spine of the catheter), the user may determine that the clot has been completely aspirated, or if not, the user may choose to move the catheter 320 back and forth to aspirate the clot in situ, or to slowly retract the catheter 320 into the sheath 220. If flow is restored to the artery via aspiration of the clot through the catheter 320 and sheath 220, a final angiogram may be performed and the catheter 320 can be retracted. If however, thrombus occludes the catheter tip and cannot be removed, the catheter 320 is pulled back, with some or all of the occlusion attached through suction force to the tip of the catheter 320.

**[0109]** In the latter scenario, aspiration is maintained at the tip of the catheter 320 the entire time the catheter 320 is being pulled into the access sheath 220. Once the catheter 320 has been completely retracted into the access sheath 220, the catheter 320 can be quickly removed from the sheath body 222 while aspiration is maintained on the sheath 220. It should be appreciated that the catheter 320 may be withdrawn into the sheath body 222 after extending through the distal opening 219 at the distal tip of the sheath body 222. Alternatively, the catheter 320 may be extending through a side opening 219 near a distal end region of the sheath body 222 such that withdrawal of the catheter 320 into the sheath body 220 occurs through this side opening 219. At some time during catheter retraction, depending on if the catheter 320 is clogged with occlusive material, the aspiration level may be changed from a high level desirable for aspiration thrombectomy to a lower level desirable for distal embolic protection. By providing the ability to maintain aspiration continuously from either the catheter tip or the sheath tip or the sheath distal region, and providing the means to change aspiration levels and maintain asp, the procedure optimizes the ability to aspiration clot while minimizing distal emboli and minimizing blood loss from aspiration. If desired, aspiration may also be initiated at the flush line 236 of the proximal valve 234, to reduce chance of distal embolization during removal of the catheter tip with possibly adhered clot through the proximal valve 234.

**[0110]** The spined aspiration catheter 320 may be removed completely from the proximal hemostasis valve 234 of the sheath 220. Alternately, if the access sheath 220 has a proximal extension 240, the distal luminal portion 322 may be pulled into the proximal extension portion 240. In the latter scenario, once pulled in, the catheter 320 and sheath 220 may be flushed to remove potential embolic material without removing the catheter 320 completely from the sheath 220. A vigorous flush from the proximal valve flush line 236 simultaneous with aspiration from the aspiration line 230 creates a flush environment for the catheter 320 and sheath 220. If desired, a catheter clearing tool 350 may be inserted into the sheath proximal valve 234 and used at this time to clear the inner lumen 323 of the catheter 320. If the access sheath 220 has a connector valve 242, the proximal portion 240 may be closed off from the sheath body 222 during this stage, so that there is no risk of flushing embolic material into the sheath body 222 and thence into the artery.

**[0111]** Alternately, the valve 242 may be closed off and aspiration paused while the proximal valve 242 is opened or removed and the catheter 320 is completely removed from the sheath 220. Closing the valve 242 limits the blood loss from the sheath 220 as the catheter 320 is removed. The catheter 320 may then be flushed onto the table or into a bowl or other receptacle, using the cleaning tool 350. The proximal extension portion 240 may also be flushed by providing a flush source 288 from the proximal valve flush line 236 simultaneous with aspiration from the aspiration line 230, or by opening a side port on the aspiration line 230 to flush to the table or into a bowl or other receptacle. If desired, an angiogram may be performed to assess flow through the treated artery. If the procedure dictates, the catheter 320 or another catheter may be re-advanced as above over a guidewire and tapered dilator 340 or microcatheter 400 to the site of the

occlusion to attempt another aspiration thrombectomy step. The flushing of the catheters and proximal extension portion 240 of the access sheath 220 minimizing the risk of distal emboli during these subsequent steps.

**[0112]** In another exemplary method, a retrievable stent device 500 can be used in conjunction with aspiration to remove the thrombotic occlusion. FIG. 9 illustrates this method of use through either a transcarotid or transfemoral access site. In this scenario, the access sheath 220 can be positioned as above and advanced until the sheath tip is positioned at a site as distal as safely possible in the internal carotid artery. The spined aspiration catheter 320 can be then pre-loaded onto a microcatheter 400 and guidewire, and the co-axial assembly can be introduced via the access sheath 220 into the carotid artery and advanced into the cerebral vasculature. The microcatheter 400 and guidewire can be advanced across occlusion. The tip of the spined aspiration catheter 320 can be advanced as distal as possible but proximal to the clot.

**[0113]** At this point, the guidewire can be removed and the retrievable stent device 500 inserted through the microcatheter 400 until it too is positioned across the occlusion. The microcatheter 400 can be pulled back to deploy the stent. At any point during device navigation, aspiration may be initiated from the aspiration source at a level suitable for distal embolic protection, for example when the guidewire or microcatheter 400 is crossing the occlusion, or prior to stent deployment. By having aspiration initiated before stent deployment, any emboli that was liberated while crossing the lesion is not carried downstream on restoration of flow in the artery, but is rather captured into the catheter tip. While the retrievable stent device 500 is deployed, aspiration may be maintained. It is typically deployed for several minutes before retraction of the stent is attempted, to maximize the engagement of the stent struts to the occlusion. Then, the retrievable stent device 500 can be pulled into the spined catheter 320 and continued to be retracted until it has been completely removed from the proximal valve of the access sheath 220.

**[0114]** Alternately, the stent device 500 can be pulled into the distal portion of the spined catheter 320, and the stent device 500 and spined catheter 320 can be pulled back together out of the access sheath 220. Aspiration may be increased to a higher level during stent and/or catheter retraction steps, to optimize aspiration of clot and minimize distal emboli. If the access sheath 220 has a proximal extension 240 with a valve on the connector, the device 500 can be pulled into the proximal extension 240 and the valve closed, and then the proximal hemostasis valve 234 may be opened widely and the stent device 500 or the stent device/spined catheter combination may be pulled out. The proximal extension section 240 may then be flushed via the valve flush line 236 and the aspiration line 230 before the same or alternate devices are reinserted for another thrombectomy attempt, if the procedure dictates.

**[0115]** Alternately after placement of an aspiration catheter 320, a long or segmented stent retriever 500 can be positioned as above with a microcatheter 400 such that part of the expandable portion 510 is across the thrombus and part is in the distal segment 322 of the catheter 320, and then expanded. After the expandable portion 510 is expanded aspiration can be initiated so that thrombus either is suctioned completely out of the vessel and catheter 320 into the aspiration source 600, or is suctioned into the distal tip and/or distal lumen 323 of the catheter 320. At that point, the long or segmented stent retriever 500 can be carefully pulled into the catheter 320, while maintaining aspiration. During this time clot that has been clogging the catheter 320 and/or debris that is liberated during this step should be aspirated into the catheter 320. Complete removal of the stent retrieval device 500 from the working channel 323 of the catheter 320 should free up the lumen 323 from occlusive material.

**[0116]** In any of these scenarios, the aspiration source may be a variable or multi-state aspiration source that is configured to maximize the aspiration force on the thrombotic occlusion while minimizing blood loss during periods of free flow in the catheter.

**[0117]** In another exemplary method, the access sheath 220 has an occlusion balloon 246. As seen in FIG. 7, the balloon 246 may be inflated during steps of the procedure that are high risk for distal emboli, for example retraction of the stent device 500 or the spined catheter 320 with adhered clot. The balloon 246 has the effect of stopping antegrade flow and increasing the force of aspiration in the carotid artery, thus increasing the aspiration of clot and reducing the risk of distal emboli.

**[0118]** In another exemplary method, the access sheath 220 has an expandable distal tip. In this method, the distal tip may be expanded sometime after the access sheath tip has been positioned at the desired site, but before retraction of the spined catheter 320 into the access sheath 220. This method would reduce the chance of distal emboli caused by the release of clot that was adhered to the distal tip of the spined catheter 320, as the distal tip is pulled into the tip of the sheath 220. Instead, the access sheath tip that is expanded or flared out acts as a funnel to capture the entire clot.

**[0119]** In another exemplary method and as discussed briefly above, the access sheath 1220 has a side opening 1219 (best shown in FIG. 12C). In this method, the spined catheter 1320 having a spined dilator 1340 extending through lumen 1323 of the distal luminal portion 1322 of the catheter 1320 can be advanced distally through the lumen 1223 of the access sheath 1220 towards the distal end region of the sheath body 1222. The distal tip of the distal luminal portion 1322 of the spined catheter 1320 (which may having the spined dilator extending through the distal luminal portion 1322 and forming a distal-most end to the catheter system) may exit the lumen 1223 via the side opening 1219 and then be further advanced distally beyond the distal tip of the access sheath 1220. A ramp feature 1217 or other internal feature can be incor-

porated at a distal end region of the lumen 1223 to provide a surface against which the tip of the dilator can be deflected to guide the catheter 1320 away from a longitudinal axis A of the lumen 1223 of the sheath body 1222 towards the side opening 1219 to achieve a smooth transition or exit from the lumen 1223. The distal tip 1346 of the dilator 1340 can abut against the ramp feature 1217 and be directed at a slight angulation away from the longitudinal axis of the sheath body 1222 towards the side opening 1219. As described elsewhere herein, the sheath body 1222 and thus the side opening 1219 can be rotated around the longitudinal axis A such that the one or more side openings 1219 are positioned to allow for distal extension of the catheter 1320 from the side openings 1219 in a desired direction relative to the longitudinal axis A of the sheath 1220. This will often be dictated by the anatomy encountered by the operator. Also as mentioned elsewhere herein, an overlap region 1120 is formed between the distal luminal portion 1322 of the catheter and the access sheath body 1222. A sealing element 1336 can be positioned on the external surface of the distal luminal portion 1322, for example, near a proximal end region of the distal luminal portion 1322 and may be located within the overlap region 1120. The seal formed can allow for full transmission of aspiration force through the contiguous lumen formed by the lumen 1323 of the luminal portion 1322 and the lumen 1223 of the access sheath body 1222 upon withdrawal of the dilator 1340 from the lumen 1323 of the luminal portion 1322.

**[0120]** In another exemplary method, the aspiration source 600 is connected to a blood collection reservoir that maintains the integrity of the blood in such a way that the blood can be safely returned to the patient at the conclusion of the thrombectomy portion of the procedure, either directly or through subsequent treatment of the blood such as cell washing and/or blood filtration. In another exemplary method, the aspiration source is connected to a blood shunt that is connected in turn to a device such as a venous sheath or a venous return catheter that enables blood to be returned to the patient during the procedure and not requiring a blood reservoir. In another exemplary method, the blood is collected in a reservoir and subsequently discarded at the end of the procedure.

**[0121]** In another exemplary method, the access sheath 1220 is delivered as described elsewhere herein from a femoral insertion site to a right or left subclavian artery or an external carotid artery. The access sheath 1220 may be delivered to a carina of a bifurcation between a target vessel having the embolus, such as the internal carotid artery (ICA), and another vessel, such as the external carotid artery (ECA). Once the access sheath 1220 is in position a working device such as a splined aspiration catheter 1320 can be delivered through the lumen 1223 of the access sheath 1220 into the target vessel. The lumen 1223 of the access sheath 1220 and the lumen 1323 of the catheter 1320 are contiguous and form a stepped up diameter for aspiration as described elsewhere herein. An overlap region 1120 is maintained between the catheter 1320 extending distally from the lumen 1223 of the access sheath 1220. It should be appreciated that the catheter 1320 can extend distally from the lumen 1223 of the access sheath 1220 through an opening 1221 at the distal tip of the access sheath 1220 or a side opening 1119 near the distal region of the access sheath 1220. The body 1222 of the access sheath 1220 may be oriented to provide optimum placement of the side opening 1119 relative to the anatomy. The overlap region 1120 between the distal luminal portion 1322 of the catheter 1320 and the access sheath body 1222 can create a seal and allow for full transmission of aspirating force through the contiguous lumen formed by the lumen 1323 of the luminal portion 1322 and the lumen 1223 of the access sheath body 1222, as well as providing a seal for delivery of fluids to the target vessel such as angiographic contrast injection, saline, one or more drugs or other materials directly into the neurovascular anatomy. The spined aspiration catheter 1320 can create a more powerful aspiration force by allowing for the working lumen 1223 of the access sheath 1220 to provide a majority of the aspiration column. As described elsewhere herein, the dimension of the lumen 1323 of the distal luminal portion 1322 of the aspiration catheter 1320 may be less than the diameter of the lumen 1223 of the access sheath 1220, which is reduced only by a diameter of the spine 1330 extending therethrough. The increased diameter of the lumen can create a larger aspiration column than, e.g., an aspiration column of a large bore catheter having a similar overall length. The spined aspiration catheter 1320 may also be used as a supportive delivery catheter, for example, where the operator wants to reach the petrous carotid or other hard to reach landmarks within the cerebral vasculature. More particularly, after delivering the spined aspiration catheter 1320 into the target vessel through the working lumen 1223 of the access sheath 1220, a secondary working device such as a guidewire, microcatheter, stent retriever, etc. may be delivered through the lumen 1323 into a more distal anatomy to perform other procedural operations as described elsewhere herein.

**[0122]** While this specification contains many specifics, these should be construed as descriptions of features specific to particular implementations. Certain features that are described in this specification in the context of separate implementations can also be implemented in combination in a single implementation. Conversely, various features that are described in the context of a single implementation can also be implemented in multiple implementations separately or in any suitable sub-combination. Moreover, although features may be described above as acting in certain combinations and even initially claimed as such, one or more features from a claimed combination can in some cases be excised from the combination, and the claimed combination may be directed to a sub-combination or a variation of a sub-combination.

Similarly, while operations are depicted in the drawings in a particular order, this should not be understood as requiring that such operations be performed in the particular order shown or in sequential order, or that all illustrated operations be performed, to achieve desirable results.

**STATEMENTS**

**[0123]**

1. An intravascular access system for facilitation of intraluminal medical procedures within the neurovasculature through an access sheath, the system comprising:

an aspiration or support catheter comprising:

a flexible, distal luminal portion having an inner diameter defining a lumen extending between a proximal opening at a proximal end of the luminal portion and a distal opening at a distal end of the luminal portion; and a rigid spine coupled to at least the proximal end of the luminal portion and extending proximally therefrom; and

a dilator comprising:

a flexible, distal dilator portion sized to be received within the lumen of the luminal portion; and
a rigid, dilator spine extending proximally from the dilator portion.

2. The system of statement 1, wherein, when in use, the dilator spine aligns side-by-side with the spine of the catheter.
3. The system of statements 1 or 2, wherein the distal dilator portion has a tapered distal tip.
4. The system of any of statements 1-3, wherein the dilator has a length at least as long as a length of the catheter such that a distal tip of the dilator protrudes from the distal opening of the luminal portion.
5. The system of any of statements 1-4, wherein the dilator is generally tubular along at least a portion of the length.
6. The system of any of statements 1-5, wherein a proximal end of the catheter spine includes a gripping feature configured for a user to grasp in order to move the catheter through an access sheath.
7. The system of statement 6, wherein a proximal end of the dilator spine includes a tab configured to be locked with the gripping feature on the catheter spine.
8. The system of statement 7, wherein when the catheter and the dilator are in a locked configuration they are advanced as a single unit through the access sheath.
9. The system of statements 7 or 8, wherein the gripping feature and the dilator tab are removably coupled such that in a locked configuration the dilator tab engages the gripping feature and in an unlocked configuration the dilator tab disengages from the gripping feature.
10. The system of any of statements 7-9, wherein the dilator tab is affixed to the dilator.
11. The system of any of statements 7-9, wherein the dilator tab is slideable on the dilator to accommodate different relative positions between the dilator and the catheter.
12. The system of any of the preceding statements, wherein the distal dilator portion comprises one or more detents on an outer surface configured to lock with correspondingly-shaped surface features on an inner surface of the luminal portion lumen through which the dilator portion extends.
13. The system of any of the preceding statements, wherein the dilator spine and the catheter spine have a similar stiffness and kink-resistance.
14. The system of any of the preceding statements, wherein the dilator has a visual marker on a distal end and/or a proximal end of the distal tip.
15. The system of any of the preceding statements, wherein a distal end region of the dilator is more flexible and increasingly stiffens towards a proximal end region of the dilator.
16. The system of any of the preceding statements, wherein the catheter spine and dilator spine are configured to cause bi-directional sliding movement of the luminal portion through a lumen of an access sheath and navigate the luminal portion into a cerebral vessel to reach a treatment site.
17. An intravascular access system for facilitation of intraluminal medical procedures within the neurovasculature, the system comprising:

an access sheath having a sheath body comprising an inner diameter defining a lumen between a proximal end and a distal end of the sheath body, and at least one opening from the lumen near a distal end region of the sheath body; and
an aspiration or support catheter comprising:

a flexible, distal luminal portion having an outer diameter sized for insertion through the lumen of the access sheath, an inner diameter defining a lumen extending between a proximal opening at a proximal end of the luminal portion and a distal opening at a distal end of the luminal portion, and a length between the proximal opening and the distal opening; and
a rigid spine coupled to at least the proximal end of the luminal portion and extending

proximally therefrom,

wherein the rigid spine is configured to cause bi-directional sliding movement of the luminal portion through the lumen of the access sheath and out the at least one opening to navigate the luminal portion into a cerebral vessel to reach a treatment site, and

wherein a portion of the outer diameter of the luminal portion fluidly seals with the inner diameter of the access sheath when the distal end of the luminal portion extends into the cerebral vessel to reach the treatment site.

18. The system of statement 17, wherein the luminal portion and the sheath body are concentrically aligned and the lumen of the luminal portion and the lumen of the sheath body form a contiguous aspiration lumen from the distal end of the luminal portion to the proximal end of the sheath body.

19. The system of statement 18, wherein the contiguous aspiration lumen is usable to aspirate fluid and debris from the distal opening of the luminal portion.

20. The system of statements 18 or 19, wherein the contiguous aspiration lumen is usable to deliver materials through the distal opening of the luminal portion.

21. The system of any of statements 17-20, wherein the contiguous aspiration lumen forms a step-up in diameter where the lumen of the luminal portion empties into the lumen of the sheath body.

22. The system of any of statements 17-21, wherein the lumen of the luminal portion is shorter than the lumen of the sheath body.

23. The system of any of statements 17-22, wherein the luminal portion and the sheath body form an overlap region when the luminal portion extends distally beyond the at least one opening of the sheath body.

24. The system of statement 23, wherein the outer diameter of the luminal portion approaches the inner diameter of the lumen of the sheath body such that a seal is formed by the overlap region.

25. The system of statement 24, wherein the seal is configured to enable sealing against a vacuum of up to 25 inHg, or up to 28 inHg.

26. The system of statement 24, wherein the seal within the overlap region is configured to enable sealing against a pressure of up to 300 mmHg.

27. The system of any of statements 24-26, wherein the seal is located distal a proximal end of the luminal portion and proximal to the at least one opening of the sheath body.

28. The system of any of statements 24-27, further comprising a sealing element positioned on an external surface of the luminal portion.

29. The system of statement 28, wherein the sealing element includes a stepped up diameter or protruding feature in the overlap region.

30. The system of statement 28, wherein the sealing element comprises one or more external ridge features.

31. The system of statement 30, wherein the one or more ridge features are compressible when the luminal portion is inserted into the lumen of the sheath body.

32. The system of statement 28, wherein the sealing element comprises one or more inclined surfaces biased against an inner surface of the sheath body lumen.

33. The system of statement 28, wherein the sealing element comprises one or more expandable members actuated to seal.

34. The system of any statements 17-33, wherein the sheath body has an outer diameter suitable for insertion into the carotid artery.

35. The system of statement 34, wherein the outer diameter of the sheath body is between 5Fr and 7Fr.

36. The system of any of statements 17-35, wherein the sheath body has a length between the proximal end and the distal end suitable for locating the distal end of the sheath body at the petrous portion of an internal carotid artery from a transfemoral approach.

37. The system of statement 36, wherein the length of the sheath body is between 80 cm and 105 cm.

38. The system of any of statements 17-37, wherein the length of the luminal portion is between 10 cm and 25 cm.

39. The system of any of statements 17-38, wherein the length of the luminal portion is less than a length of the sheath body such that as the catheter is retracted into the sheath body a seal remains between an overlap region of the luminal portion and the inner diameter of the sheath body.

40. The system of any of statements 17-39, wherein the spine is longer than an entire length of the sheath body.

41. The system of any of statements 17-40, wherein the luminal portion includes three or more layers including an inner lubricious liner, a reinforcement layer, and an outer jacket layer.

42. The system of statement 41, wherein the outer jacket layer is composed of discreet sections of polymer with different durometers, compositions, and/or thicknesses to vary the flexibility along the length of the distal luminal portion.

43. The system of any of statements 17-42, wherein the outer diameter of the distal luminal portion is sized for navigation into cerebral arteries.

44. The system of any of statements 17-43, wherein the inner diameter of the distal luminal portion is between 0.040" and 0.088".

45. The system of any of statements 17-44, wherein the outer diameter of the luminal portion approaches the inner diameter of the sheath body creating a sealed area at an overlap region while still allowing the catheter to move through the sheath body.

46. The system of any of statements 17-45, wherein the catheter is tapered towards the distal opening such that a distal-most end of the luminal portion has a smaller outer diameter compared to a more proximal region of the luminal portion near where the luminal portion seals with the sheath body.
47. The system of any of statements 17-46, wherein the distal end region of the sheath body comprises an occlusion element.
48. The system of any of statements 17-47, wherein the distal end region of the sheath body comprises an expanding distal tip.
49. The system of any of statements 17-48, wherein the at least one opening from the lumen comprises a side opening located a distance away from a distal tip of the sheath body.
50. The system of any of statements 17-49, wherein a distal tip of the sheath body further comprises a ramp feature configured to direct at an angulation the catheter away from a longitudinal axis of the sheath body lumen out through the at least one opening.
51. The system of any of statements 17-50, wherein the spine is longer than an entire length of the sheath body.
52. The system of any of statements 17-51, wherein the spine is a wire having an outer dimension from 0.014" to 0.018".
53. The system of any of statements 17-52, wherein the spine is a hypotube having a guide-wire passageway extending therethrough.
54. The system of any of statements 17-53, wherein the spine is a ribbon having an outer dimension from 0.010" to 0.025" thick.
55. The system of statement 54, wherein the ribbon is curved along at least a portion of an arc.
56. The system of any of statements 17-55, wherein the spine is configured to rotate the luminal portion around a longitudinal axis of the access sheath.
57. The system of any of statements 17-56, wherein the spine is eccentrically coupled to the luminal portion and the spine extends proximally from the luminal portion to outside the proximal end of the sheath body.
58. The system of any of statements 17-57, wherein the proximal end of the luminal portion has an angled cut.
59. The system of statement 58, wherein the angled cut is generally planar or is curved.
60. The system of any of statements 17-59, wherein the sheath body has one or more visual markers on the distal end region of the sheath body.
61. The system of any of statements 17-60, wherein the distal luminal portion has one or more visual markers at a distal end region of the luminal portion, a proximal end region of the luminal portion or both.
62. The system of statements 60 or 61, wherein the one or more visual markers on the sheath body and the one or more visual markers on the luminal portion are visually distinct.
63. The system of any of statements 60-62, wherein the spine has one or more visual markers.
64. The system of statement 63, wherein the one or more visual markers of the spine indicates overlap between the distal luminal portion and the sheath body.
65. The system of statements 63 or 64, wherein the one or more visual markers of the spine is positioned so that when the visual marker of the spine is aligned with a portion of the access sheath, the catheter is positioned at a distal-most position with minimal overlap length needed to create a seal between the catheter and the sheath body.
66. The system of any of statements 17-65, further comprising a dilator comprising a flexible, distal dilator portion having a distal tip and sized to be received within the luminal portion of the catheter.
67. The system of statement 66, wherein the dilator is a tubular element along at least a portion of its length.
68. The system of statement 66, wherein the dilator is a solid rod formed of malleable material configured to be shaped by a user.
69. The system of statement 66, wherein the dilator further comprises a rigid, dilator spine extending proximally from the dilator portion.
70. The system of statement 69, wherein the dilator spine is coaxial.
71. The system of statement 70, wherein the coaxial dilator spine has a lumen extending through it.
72. The system of statement 69, wherein the dilator spine is eccentric.
73. The system of any of statements 69-72, wherein when in use the dilator spine aligns side-by-side with the spine of the catheter.
74. The system of any of statements 66-73, wherein the distal tip is tapered.
75. The system of statement 74, wherein the dilator has a length at least as long as a length of the catheter such that the distal tip protrudes from the distal opening of the luminal portion.
76. The system of any of statements 69-75, wherein a proximal end of the spine includes a gripping feature configured for a user to grasp in order to move the catheter through the access sheath.
77. The system of statement 76, wherein a proximal end of the dilator spine includes a tab configured to be locked with the gripping feature on the catheter spine.
78. The system of statement 77, wherein when the catheter and dilator are in a locked configuration they are advanced as a single unit through the sheath body.
79. The system of statements 77 or 78, wherein the gripping feature and the dilator tab are removably coupled such that in a locked configuration the dilator

tab engages the gripping feature and in an unlocked configuration the dilator tab disengages from the gripping feature.

80. The system of any of statements 77-79, wherein the dilator tab is affixed to the dilator.

81. The system of any of statements 77-79, wherein the dilator tab is slideable on the dilator to accommodate different relative positions between the dilator and the catheter.

82. The system of any of statements 66-81, wherein the distal dilator portion comprises one or more detents on an outer surface configured to lock with correspondingly-shaped surface features on an inner surface of the luminal portion lumen through which the dilator portion extends.

83. The system of any of statements 69-82, wherein the dilator spine and the catheter spine have a similar stiffness and kink-resistance.

84. The system of any of statements 66-83, wherein the dilator has a visual marker on a distal end and/or a proximal end of the distal tip.

85. The system of any of statements 66-84, wherein a distal end region of the dilator is more flexible and increasingly stiffens towards the proximal end region of the dilator.

86. The system of any of statements 17-85, wherein the access sheath further comprises a connector that connects the proximal end of the sheath body to a proximal hemostasis valve.

87. The system of statement 86, wherein the proximal hemostasis valve has an adjustable opening sized large enough to allow removal of the catheter without dislodging any clots thereon.

88. The system of statement 86 or 87, wherein, when in use with the access sheath, the rigid spine of the catheter extends proximally from the luminal portion through the access sheath lumen and out the proximal hemostasis valve of the access sheath.

89. The system of any of statements 86-88, wherein the connector provides a connection of the proximal end of the sheath body to an aspiration line.

90. The system of any of statements 86-89, wherein the connector has a large bore inner lumen and connects to a large-bore aspiration line.

91. The system of statement 89 or 90, wherein the aspiration line connects to an aspiration source.

92. The system of statement 91, wherein the aspiration source is an active aspiration source.

93. The system of any of statements 89-92, wherein the aspiration line connects to a forward drip or flush line.

94. The system of any of statements 17-93, wherein the access sheath further comprises a proximal extension portion such that when the distal luminal portion of the catheter is withdrawn from the sheath body lumen it remains within the proximal extension portion.

95. The system of any of statements 17-94, wherein the inner diameter of the luminal portion is sized to permit placement of an interventional device through the luminal portion.

## Claims

1. A dilator (340, 1340) for facilitation of intraluminal medical procedures within the neurovasculature, the dilator (340, 1340) comprising:

   a flexible distal dilator portion (1360) having a proximal end region and a distal end region (346, 1346) having a distal tapered tip (346, 1346), a single lumen, and an outer diameter, wherein the single lumen extends longitudinally through the dilator portion (1360) to a distal opening at the distal tapered tip (346, 1346); and
   a spine (1362) extending proximally from the proximal end region of the dilator portion (1360), wherein the spine is made of a different material than the dilator portion and has a single lumen that communicates with the single lumen of the dilator portion (1360).

2. The dilator of claim 1, further including a first radiopaque marker (344) at a distal end of the distal tapered tip (346, 1346).

3. The dilator of claim 1 or claim 2, further including a second radiopaque marker (343) at a proximal end of the distal tapered tip (346, 1346).

4. The dilator of claim 2 or 3, wherein the flexible distal dilator portion is made of polymer.

5. The dilator of claim 1 or 4, wherein the spine is made of metal.

6. The dilator of claim 1 or 5, wherein the distal dilator portion has a variable stiffness between the distal end region and the proximal end region, wherein the distal end region of the distal dilator portion is made of a more flexible material than the proximal end region with increasingly stiffer material moving proximally.

7. The dilator of claim 1 or 2, wherein the outer diameter is generally tubular along at least a portion of the flexible distal dilator portion.

8. The dilator of claim 7, wherein the tubular portion extends along the entire length of the dilator.

9. The dilator of claim 7, wherein the outer diameter is sized to be received within a lumen of a catheter, the lumen having an inner diameter sized to receive the dilator in a slip fit, optionally wherein the outer diam-

eter of the dilator is about 1.778 mm and the inner diameter of the catheter is about 1.828 mm

**10.** The dilator of claim 1, 2 or 3 wherein the distal tapered tip (346, 1346) has a length between 1.5 cm and 3 cm.

**11.** The dilator of any of the preceding claims further including a proximal female luer adaptor (348) at a proximal end of the proximal end region of the flexible distal dilator portion.

**12.** The dilator of claim 1, wherein the spine has an outer diameter that is equal to the outer diameter of the flexible distal dilator portion.

**13.** The dilator of claim 1, wherein the spine has an outer diameter that is less than the outer dimeter of the flexible distal dilator portion.

**14.** The dilator of claim 1 or 2, wherein the lumen of the flexible distal dilator portion is sized to accommodate a guidewire having a diameter between 0.356 mm and 0.457 mm, or, wherein the inner luminal diameter of the flexible distal dilator portion is between 0.508 mm and 0.620 mm.

**15.** The dilator of claim 1 or 2, wherein the outer diameter of the flexible distal dilator portion (1360) is sized to be received within a lumen of a catheter (320, 1320) and form a smooth transition between the flexible distal dilator portion and the lumen of the catheter (320, 1320).

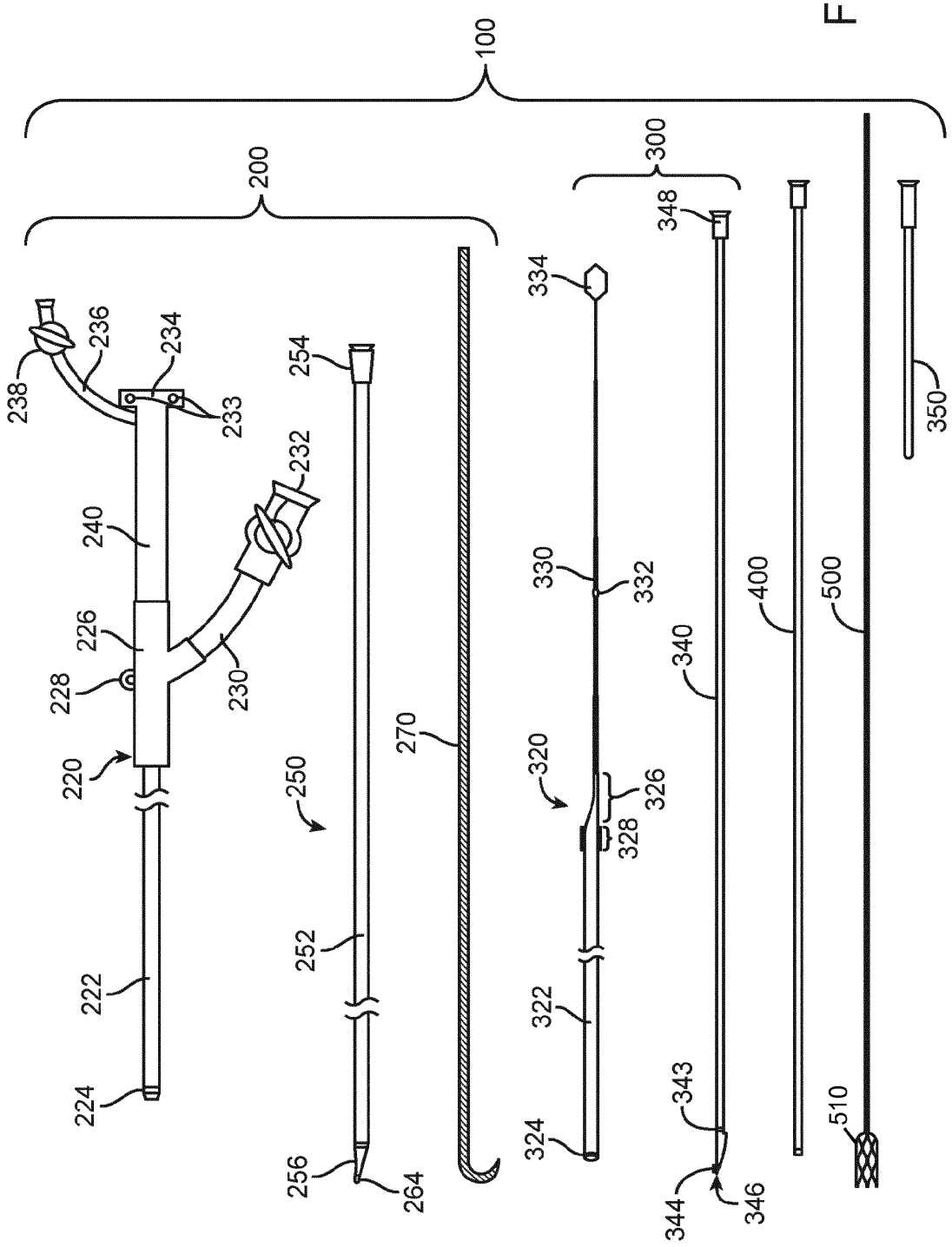

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FIG. 1

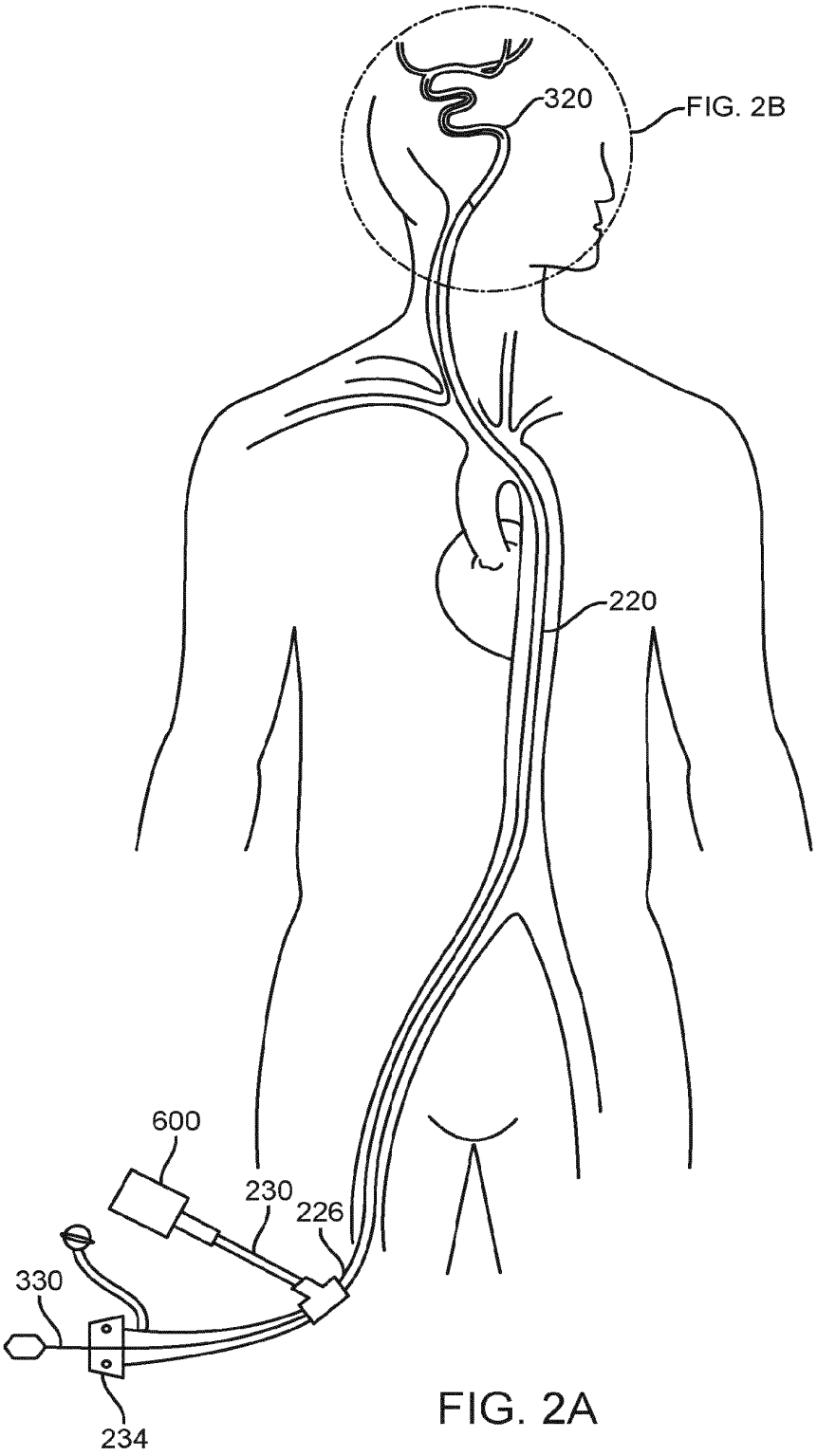



FIG. 2A

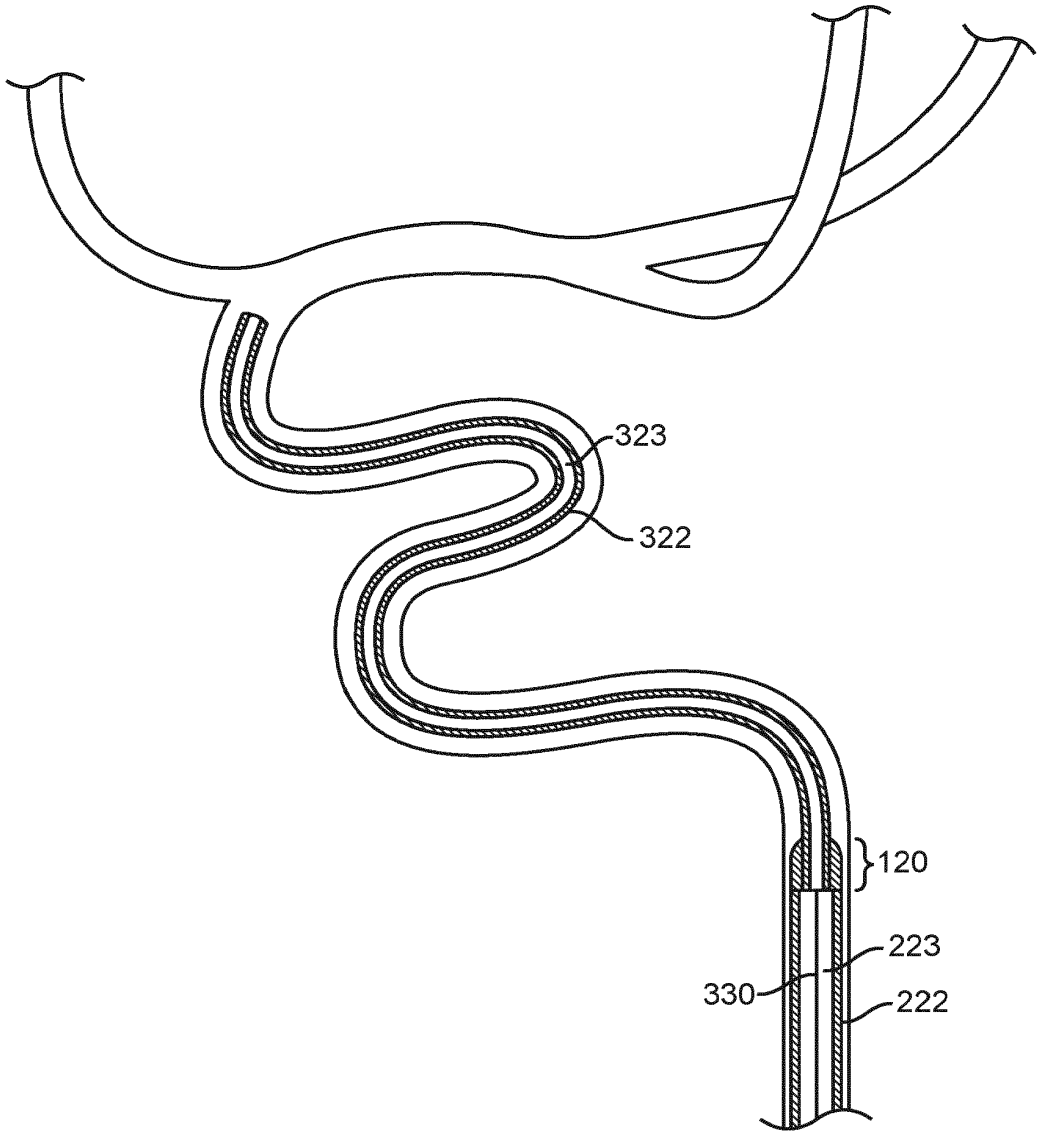



FIG. 2B

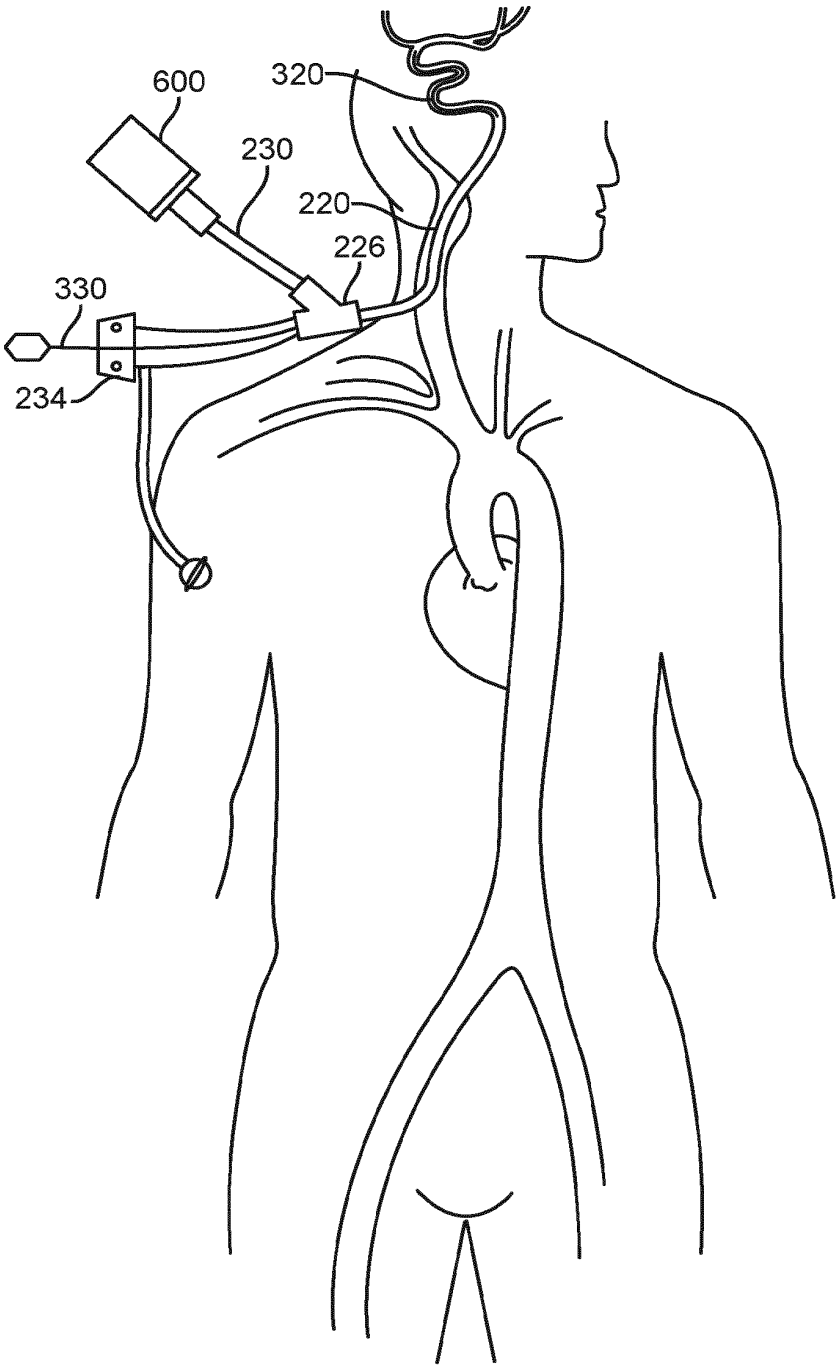



FIG. 3

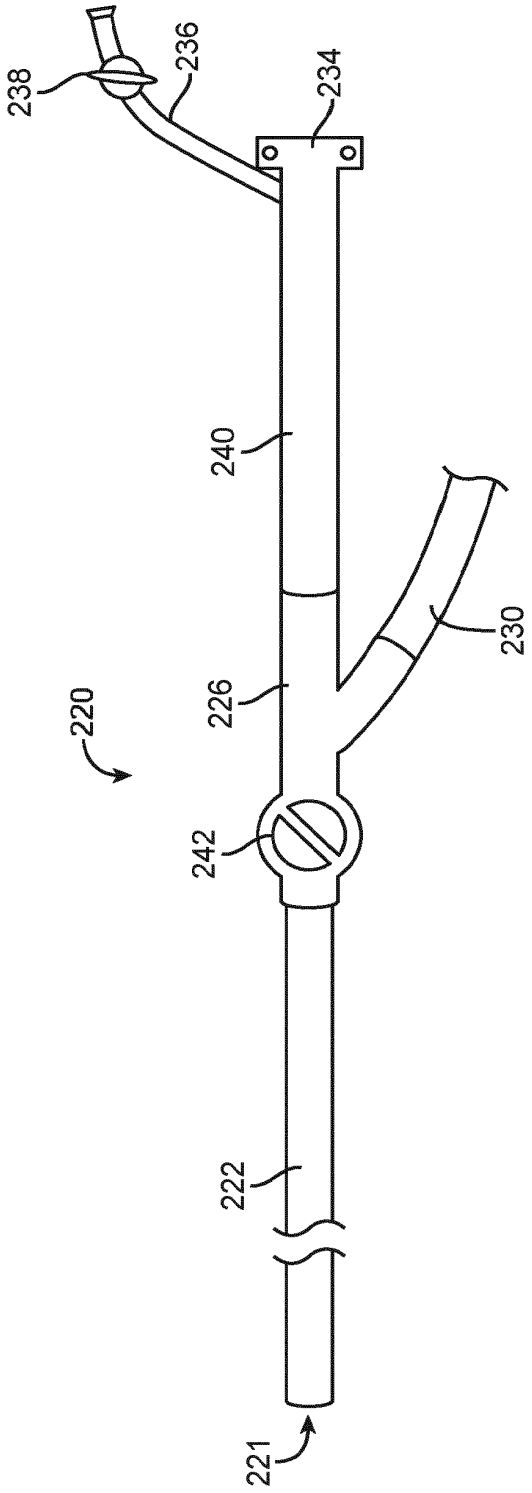



FIG. 4

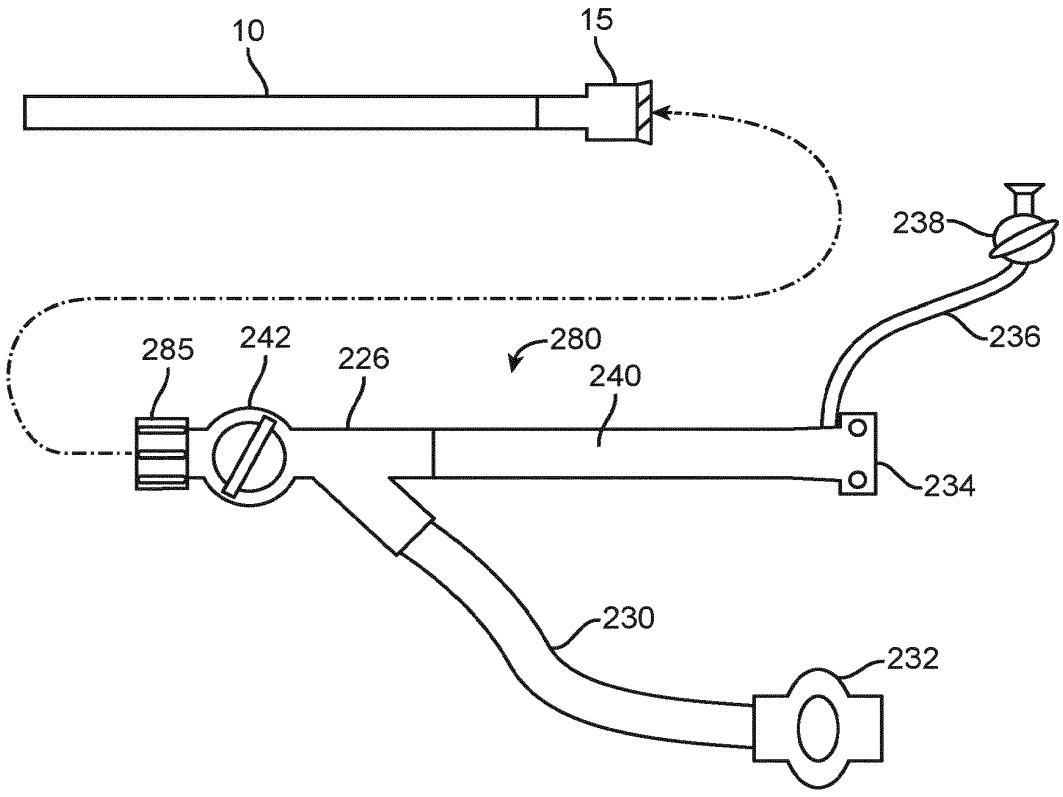



FIG. 5

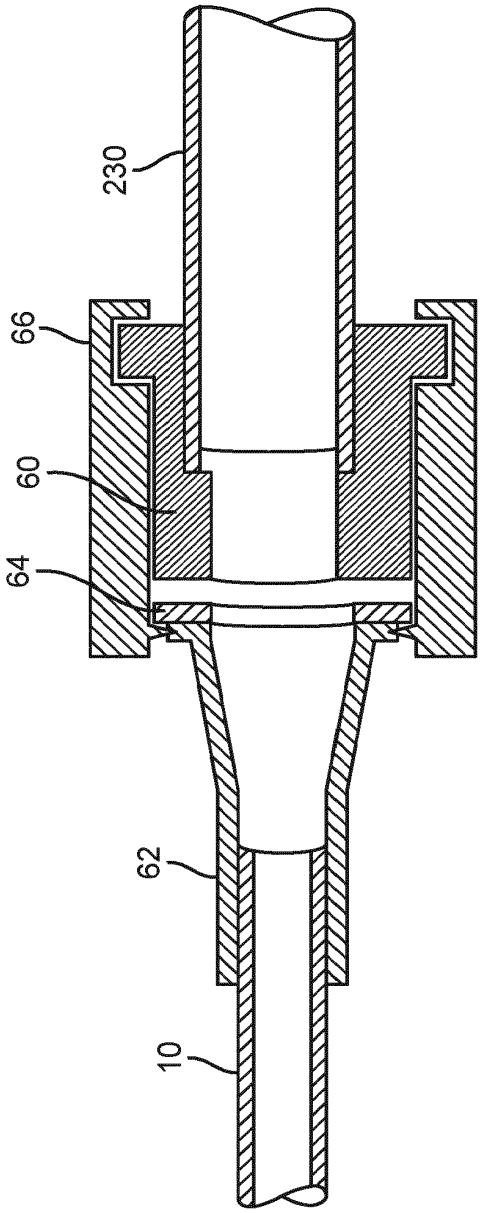



FIG. 6

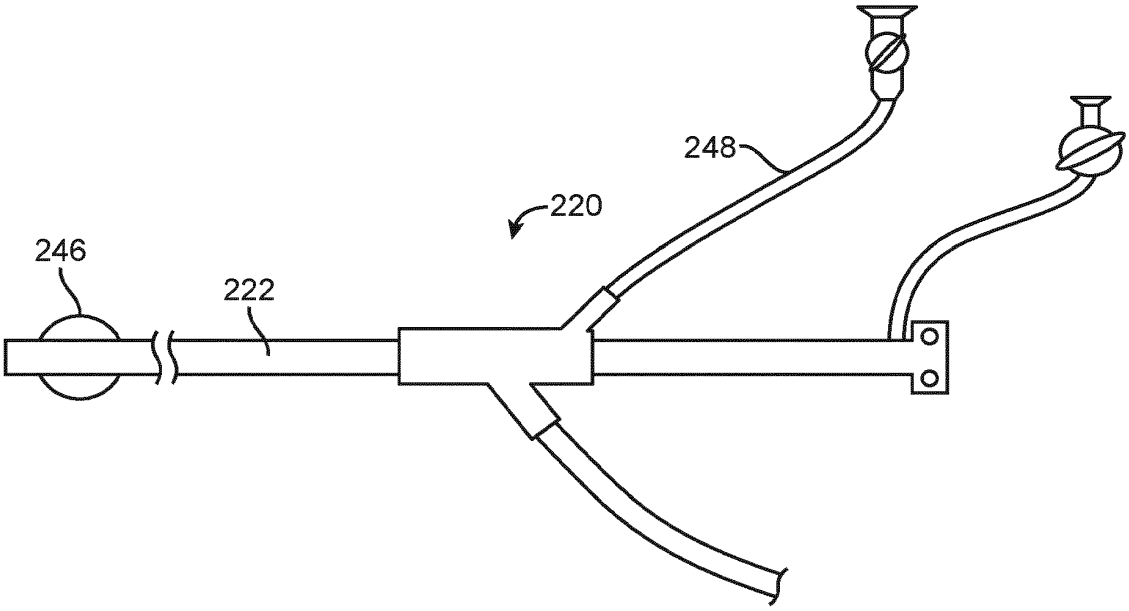



FIG. 7

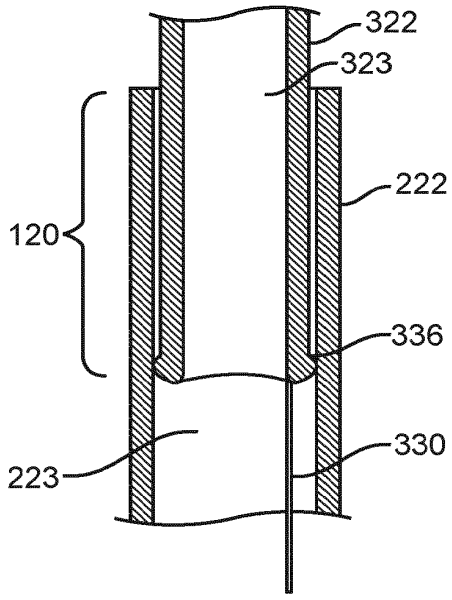



FIG. 8A

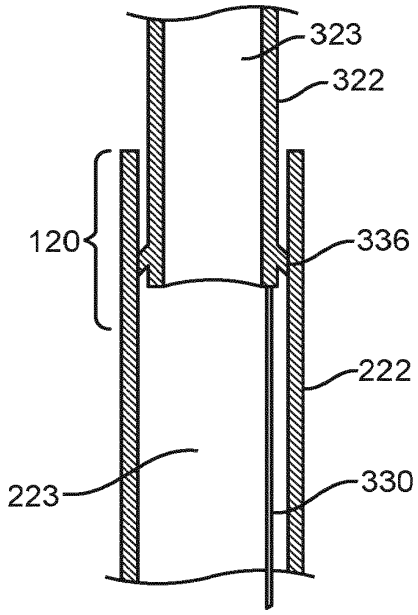



FIG. 8B

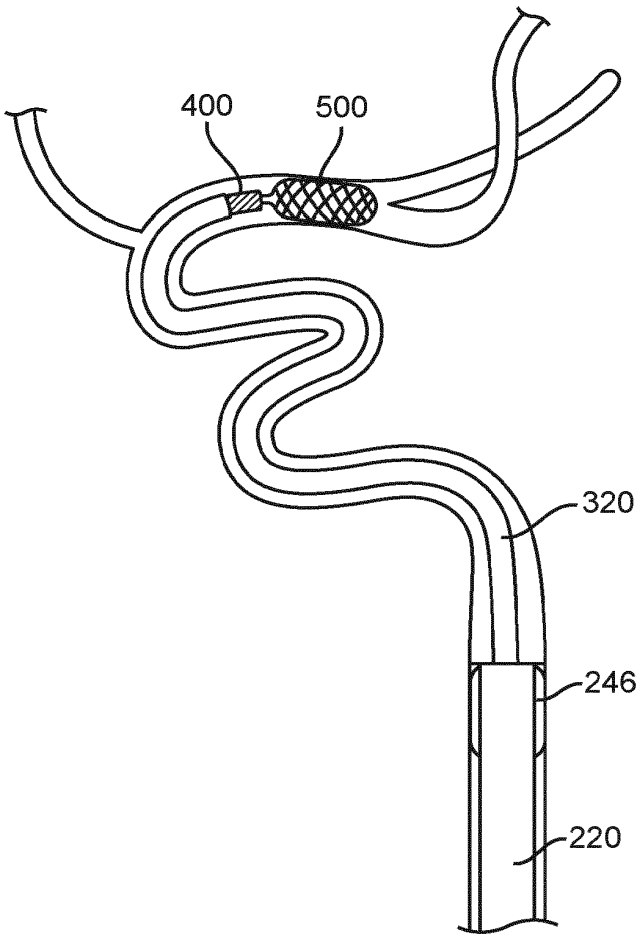



FIG. 9

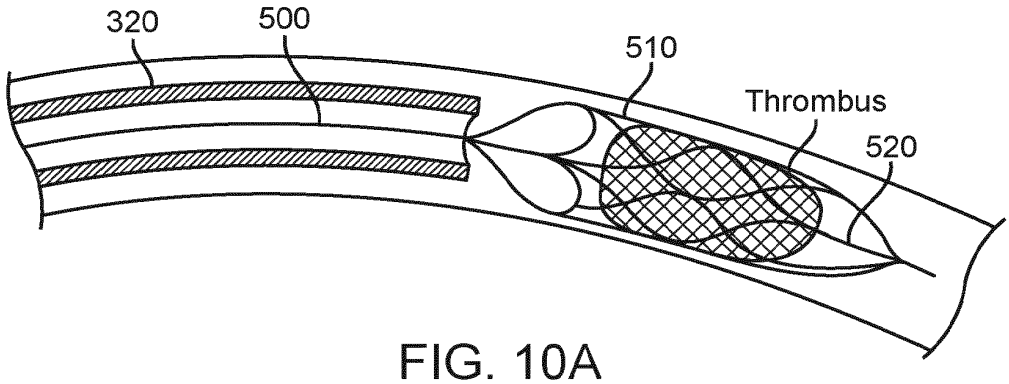



FIG. 10A

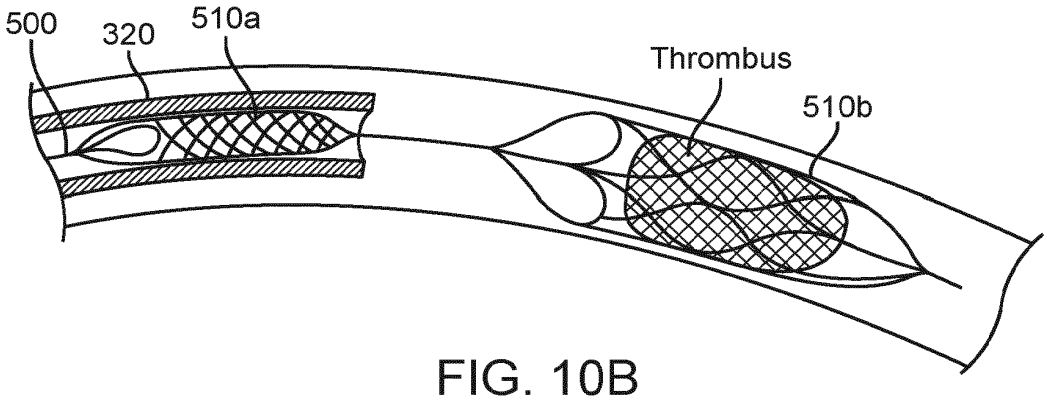



FIG. 10B

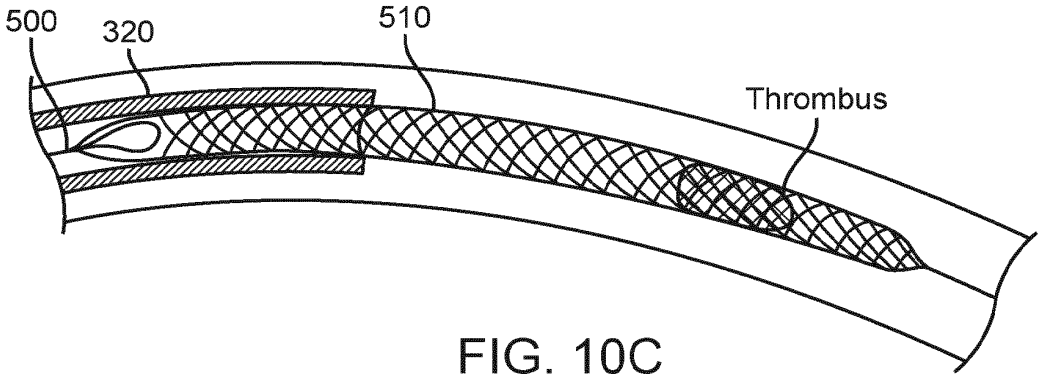



FIG. 10C

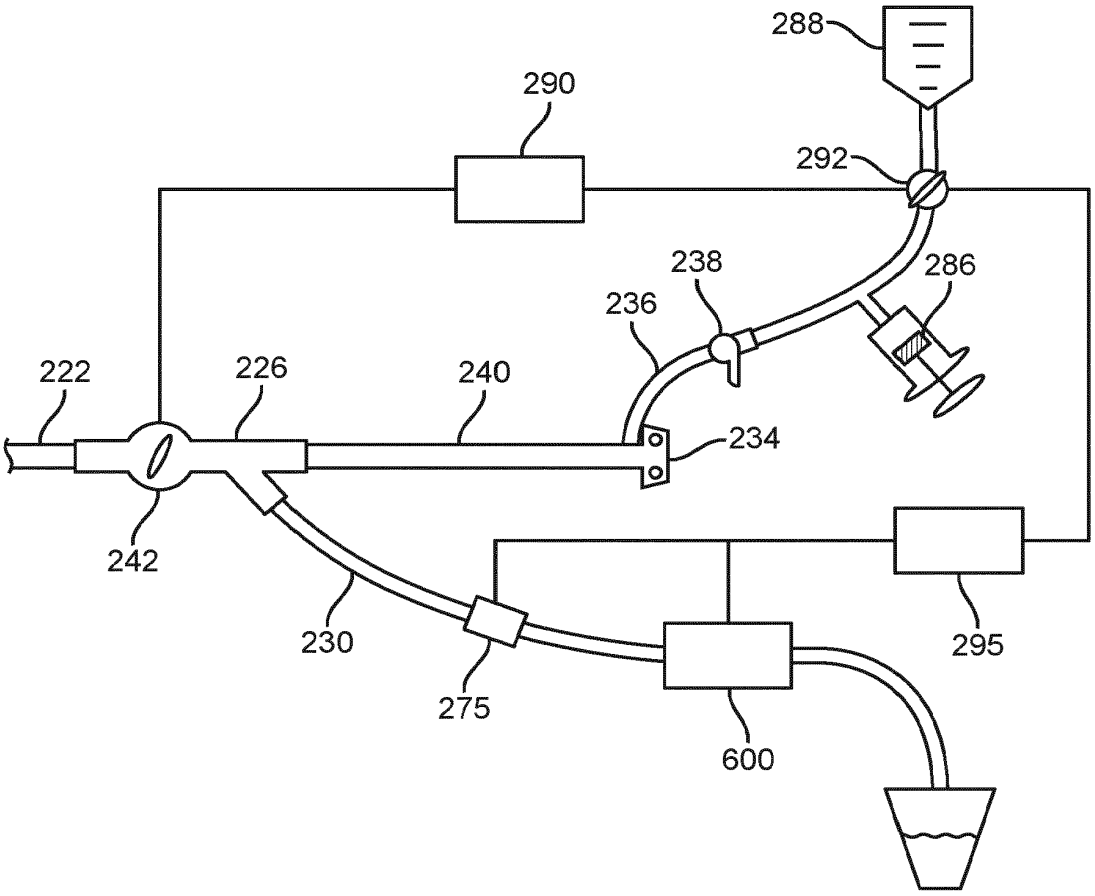



FIG. 11

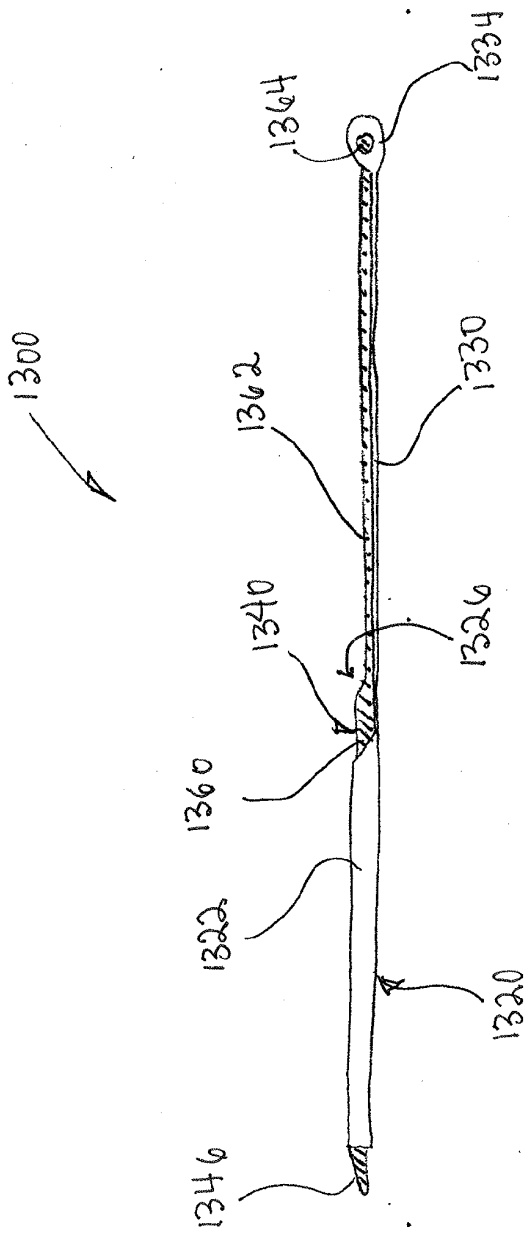



FIG. 12A

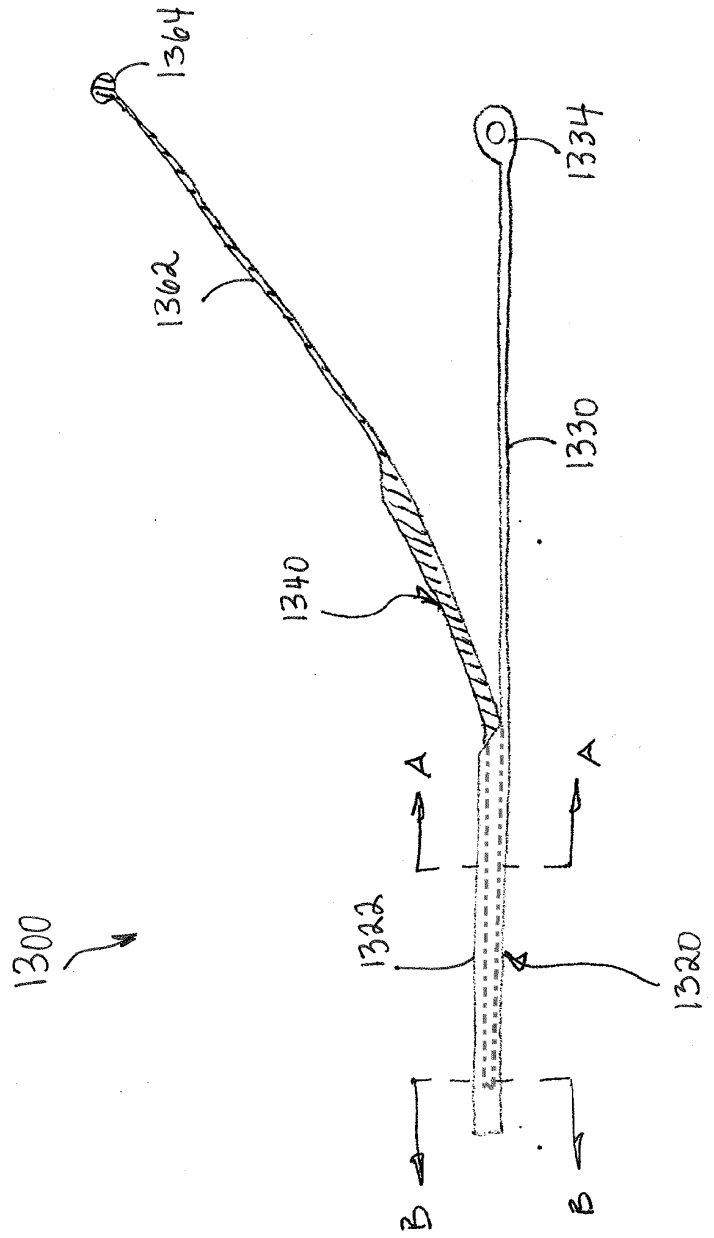



FIG. 12B

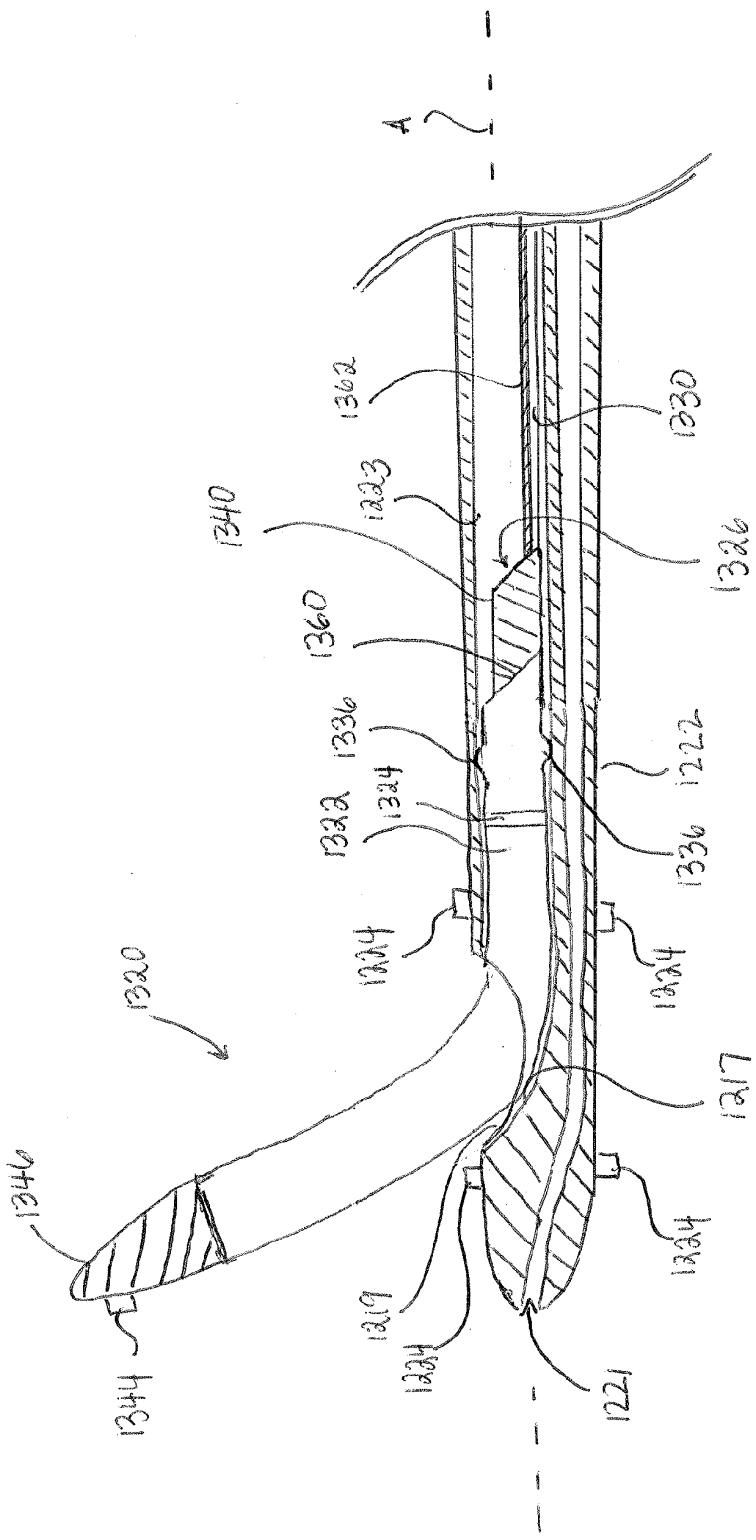
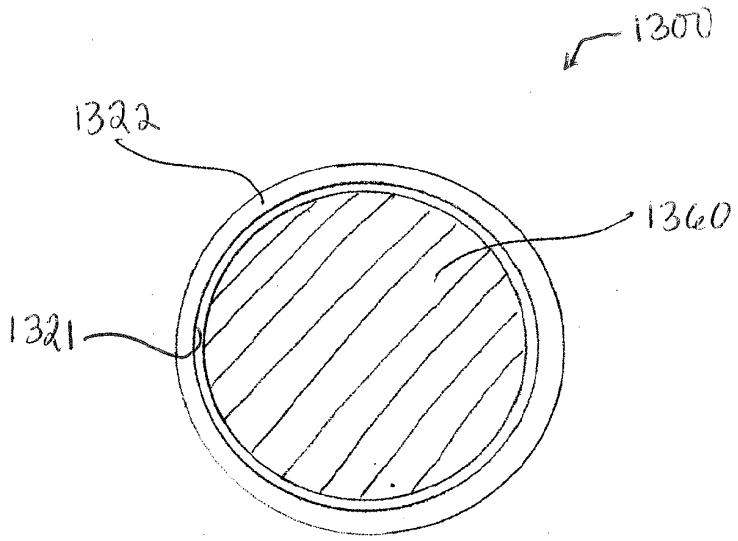
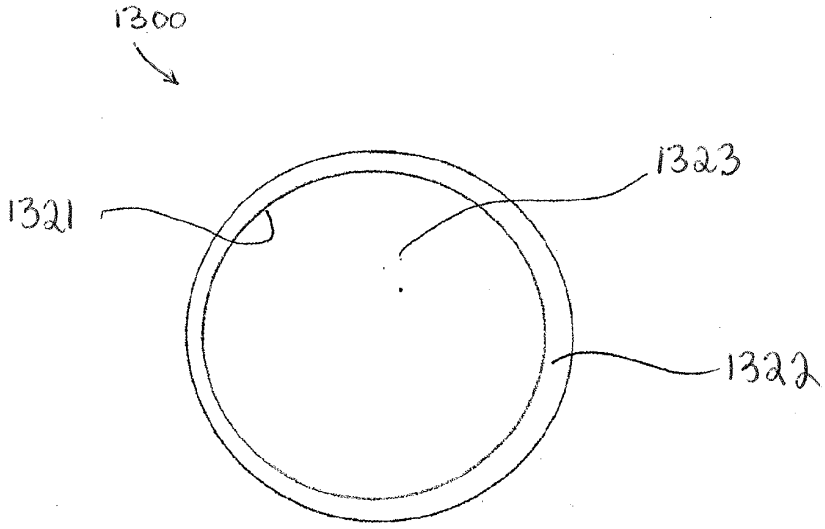

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Fig. 12C




A - A
FIG. 13




B - B
FIG. 14

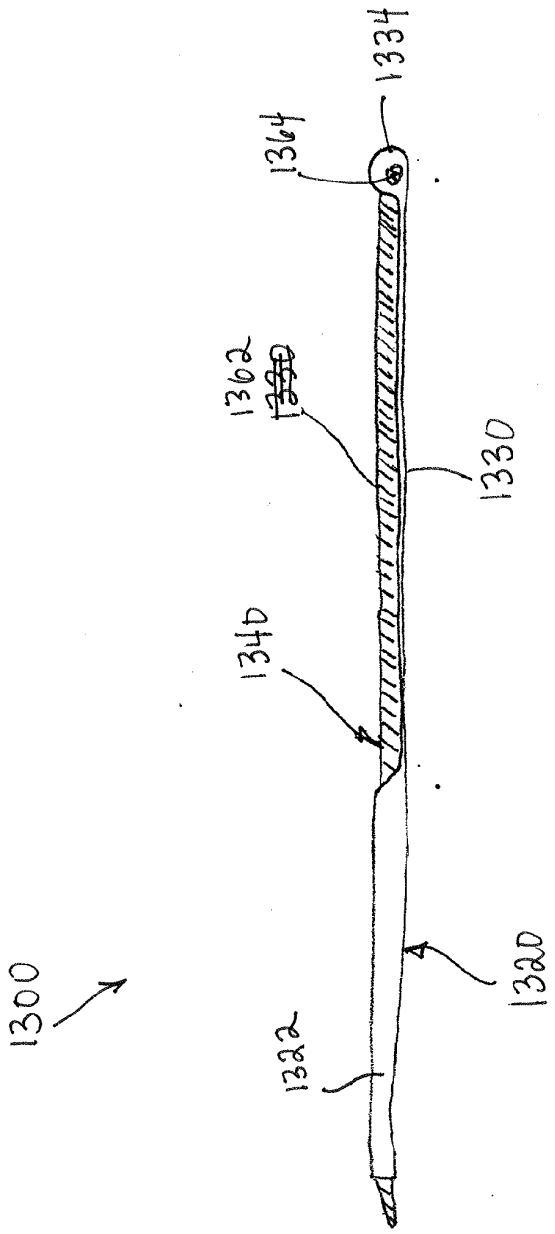



FIG. 15A

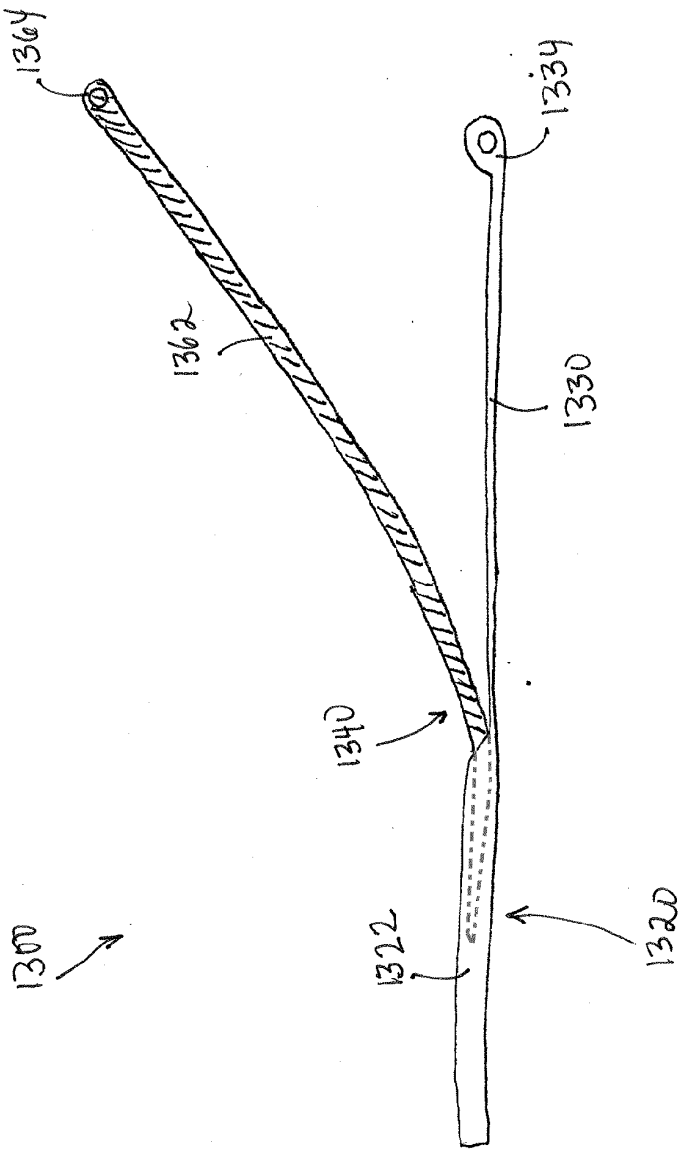



FIG. 15B

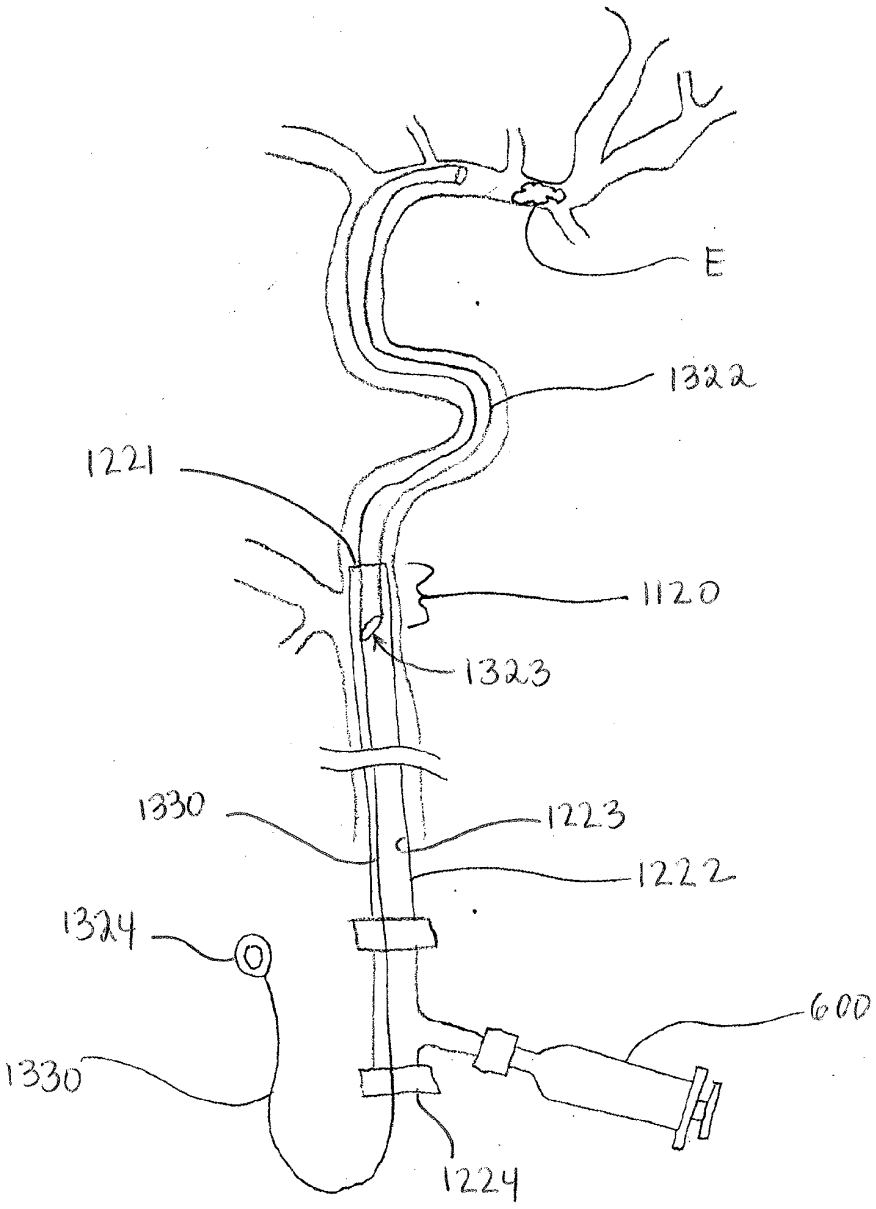



FIG. 16

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# EUROPEAN SEARCH REPORT

Application Number
EP 19 20 5500

## DOCUMENTS CONSIDERED TO BE RELEVANT

| Category | Citation of document with indication, where appropriate, of relevant passages | Relevant to claim | CLASSIFICATION OF THE APPLICATION (IPC) |
|---|---|---|---|
| X | US 2007/185522 A1 (DAVIES GARETH [CA] ET AL) 9 August 2007 (2007-08-09)<br>* figures 1, 5 *<br>* paragraph [0025] - paragraph [0033] *<br>----- | 1-15 | INV.<br>A61M29/00<br>A61M25/01<br>A61B17/22 |
| X | US 2008/243222 A1 (SCHAFERSMAN JESSICA A [US] ET AL) 2 October 2008 (2008-10-02)<br>* figures 1,4 *<br>* paragraphs [0033], [0034] *<br>----- | 1-15 | ADD.<br>A61B17/221<br>A61M25/06 |
| A | US 2003/050600 A1 (RESSEMANN THOMAS V [US] ET AL) 13 March 2003 (2003-03-13)<br>* figures 1A, 6A-I, 11E, 11G *<br>* paragraph [0086] - paragraph [0089] *<br>* paragraph [0095] - paragraph [0125] *<br>* paragraph [0208] - paragraph [0209] *<br>----- | 1-15 | |

TECHNICAL FIELDS SEARCHED (IPC)

A61M
A61B

The present search report has been drawn up for all claims

| Place of search | Date of completion of the search | Examiner |
|---|---|---|
| The Hague | 29 November 2019 | Emirdag, Eda |

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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E : earlier patent document, but published on, or after the filing date
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EPO FORM 1503 03.82 (P04C01)

## ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 19 20 5500

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29-11-2019

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EPO FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

## REFERENCES CITED IN THE DESCRIPTION

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Espacenet

CN106178227A Device for locking catheter sheath and dilator

Applicants: SHANGHAI MICROPORT MEDICAL (GROUP) CO LTD

Inventors: LIU ZHIYONG,ZHANG JIULI,HE JIAN,YI KEJING

Classifications:
IPC ***A61M25/01; A61M29/00;***

Priorities: CN201510218753A 2015-04-30

Application: CN201510218753A·2015-04-30

Publication: CN106178227A·2016-12-07

Published as: CN106178227A;**CN106178227B**

Device for locking catheter sheath and dilator

Abstract

The invention provides a device for locking and unlocking a catheter sheath and a dilator. With the adoption of the device, the catheter sheath and the dilator are convenient and fast to lock and unlock, and vascular injury is reduced. The catheter sheath comprises a sheath base and a sheath tube connected to the sheath base; the dilator comprises a dilator base and a dilator tube connected onto the dilator base; the dilator tube penetrates through the sheath base and is inserted into the sheath tube; the device is used for locking and unlocking the sheath base and the dilator base and comprises a fastening mechanism and a releasing mechanism which are arranged between the sheath base and the dilator base, wherein the fastening mechanism is suitable for fastening the dilator and the sheath base when the dilator tube is pushed into the sheath tube, the releasing mechanism is suitable for enabling the dilator to produce moving force of the dilator relative to the sheath tube in a rotating process of the dilator base relative to the sheath base, and then the sheath base is forced to be released from the dilator.

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(21)申请号 201510218753.4

(22)申请日 2015.04.30

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代理人 喻学兵

(51)Int.Cl.
*A61M 25/01*(2006.01)
*A61M 29/00*(2006.01)

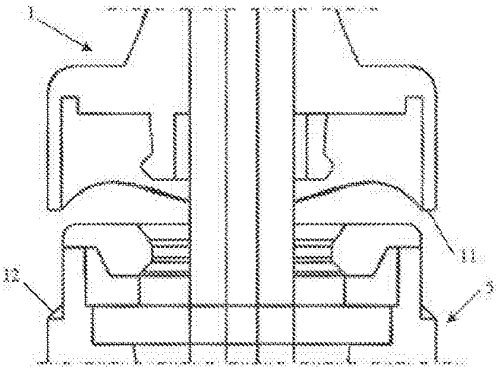
权利要求书1页 说明书4页 附图7页

(54)发明名称

锁定导管鞘和扩张器的装置

(57)摘要

一种锁定和解锁导管鞘和扩张器的装置，导管鞘和扩张器的锁定和解锁方便便捷，并减少血管损伤。其中，导管鞘包括鞘座以及连接在鞘座上的鞘管，扩张器包括扩张器座和连接在扩张器座上的扩张器管，扩张器管穿过所述鞘座插入到所述鞘管，所述装置用于将所述鞘座和所述扩张器座锁定解锁，其中，所述装置包括在所述鞘座与所述扩张器座之间配置的扣接机构以及脱扣机构，所述扣接机构适合于在所述扩张器管推入到所述鞘管的过程中，使得所述扩张器与所述鞘座扣接，所述脱扣机构适合于在所述扩张器座相对所述鞘座转动的过程中，使得所述扩张器产生所述扩张器相对所述鞘座的移动力，进而迫使所述鞘座和所述扩张器脱扣。




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1. 用于锁定和解锁导管鞘和扩张器的装置，所述导管鞘包括鞘座以及连接在所述鞘座上的鞘管，所述扩张器包括扩张器座和连接在所述扩张器座上的扩张器管，所述扩张器管穿过所述鞘座插入到所述鞘管，其特征在于，所述装置用于将所述鞘座和所述扩张器座锁定和解锁，并包括在所述鞘座与所述扩张器座之间配置的扣接机构以及脱扣机构，所述扣接机构适合于在所述扩张器管推入到所述鞘管的过程中，使得所述扩张器座与所述鞘座扣接；所述脱扣机构适合于在所述扩张器座相对所述鞘座转动的过程中，使得所述扩张器产生相对所述鞘座的移动力，进而迫使所述鞘座和所述扩张器座脱扣。

2. 如权利要求 1 所述的装置，其特征在于，所述脱扣机构配置成使所述扩张器座能以任意旋动方向相对所述鞘座转动，并进而使得所述扩张器产生相对所述鞘座的所述移动力。

3. 如权利要求 1 所述的装置，其特征在于，所述脱扣机构包括所述鞘座与所述扩张器座中的至少一方提供的脱扣斜面，以及另一方提供的抵接所述脱扣斜面的抵接部，所述扩张器座能转动以借助于所述抵接部沿所述脱扣斜面的相对运动来使所述鞘座与所述扩张器座相对分离，进而使所述鞘座和所述扩张器脱扣。

4. 如权利要求 3 所述的装置，其特征在于，所述脱扣斜面为波浪形结构的波峰和波谷之间的光滑斜面。

5. 如权利要求 4 所述的装置，其特征在于，所述波浪形结构的任意波峰两侧都有波谷。

6. 如权利要求 4 所述的装置，其特征在于，所述波浪形结构包括第一波浪形结构和第二波浪形结构，所述扩张器座具有第一波浪形结构，所述鞘座具有第二波浪形结构，其中所述第一波浪形结构和所述第二波浪形结构中的一方提供所述脱扣斜面，另一方提供所述抵接部。

7. 如权利要求 6 所述的装置，其特征在于，所述第一波浪形结构和所述第二波浪形结构之间呈几何相似并且彼此互补地嵌合。

8. 如权利要求 1 所述的装置，其特征在于，所述扣接机构包括所述扩张器座上轴向伸出的爪扣以及位于所述鞘座上的倒扣，所述鞘座和所述扩张器座通过所述爪扣和所述倒扣扣接。

9. 如权利要求 8 所述的装置，其特征在于，所述倒扣形成于所述鞘座的内周侧壁上，所述爪扣能相对所述鞘座轴向推动而于所述内周侧壁处径向向内弹性形变，并且所述爪扣能随所述扩张器座的推动，发生回弹并与所述倒扣相卡，以实现所述锁定。

10. 如权利要求 8 所述的装置，其特征在于，所述鞘座包括鞘帽，所述鞘帽包括上帽和下帽，所述上帽的外周侧为渐缩结构，所述下帽的内周侧为渐缩结构，所述上帽坐落于所述下模，所述上帽的外周侧和所述下帽的内周侧彼此结合，所述上帽相对所述下帽径向向内突出，形成所述倒扣。

# 锁定导管鞘和扩张器的装置

## 技术领域

[0001] 本发明涉及一次性使用医疗器械领域，具体地说是一种用于经皮介入手术，将导丝、手术器具、医疗器械等引入病人血管系统（特别是动脉）的具有止血功能的辅助器材。

## 背景技术

[0002] 现代医疗技术发展迅速，产生了许多经皮介入手术的方法，在这些方法中，经皮冠脉腔内血管成形术 (PTCA)、X-射线造影术以及其它类似的手术是经常使用的。有许多技术可将相关的医疗器械引入到人体血管系统中，其中得到广泛运用的是 Seldinger 技术（经皮血管穿刺技术）。在 Seldinger 技术中，首先用穿刺针在动脉或静脉上开一个小口，再将导丝通过穿刺针的内腔引入动脉或静脉，取出穿刺针。将扩张器穿过导管鞘止血阀进入导管鞘内腔，两者锁定后一起通过导丝的引导进入动脉或静脉。待导管鞘的鞘管位置固定后，撤出扩张器，最终导管鞘可提供进出或更换各种介入器材的通道。

[0003] 导管鞘和扩张器通过卡扣连接而锁定，锁定完成后，鞘管与扩张器管一起进入动脉或静脉。待鞘管位置固定后，需使导管鞘和扩张器分离，后撤出扩张器。对于卡扣式结构，导管鞘和扩张器分离需施加一轴向分离力，此时鞘管与扩张器管均处于人体血管当中，在分离的瞬间鞘管极易发生抖动而触及血管壁，导致血管痉挛或损伤。对于初学 Seldinger 技术的术者，该情况发生的概率更高，显著增加手术时间及术者的痛苦。

## 发明内容

[0004] 本发明的目的在于提供一种锁定导管鞘和扩张器的装置，使得导管鞘和扩张器的锁定和解锁方便便捷，并减少血管损伤。

[0005] 根据本发明的用于锁定和解锁导管鞘和扩张器的装置，所述导管鞘包括鞘座以及连接在所述鞘座上的鞘管，所述扩张器包括扩张器座和连接在所述扩张器座上的扩张器管，所述扩张器管穿过所述鞘座插入到所述鞘管，其中，所述装置用于将所述鞘座和所述扩张器座锁定和解锁，并包括在所述鞘座与所述扩张器座之间配置的扣接机构以及脱扣机构，所述扣接机构适合于在所述扩张器管推入到所述鞘管的过程中，使得所述扩张器座与所述鞘座扣接；所述脱扣机构适合于在所述扩张器座相对所述鞘座转动的过程中，使得所述扩张器产生相对所述鞘座的移动力，进而迫使所述鞘座和所述扩张器座脱扣。

[0006] 根据本发明的较佳实施例中，所述的装置的所述脱扣机构配置成使所述扩张器座能以任意旋动方向相对所述鞘座转动，并进而使得所述扩张器产生相对所述鞘座的所述移动力。

[0007] 根据本发明的较佳实施例中，所述的装置的所述脱扣机构包括所述鞘座与所述扩张器座中的至少一方提供的脱扣斜面，以及另一方提供的抵接所述脱扣斜面的抵接部，所述扩张器座能转动以借助于所述抵接部沿所述脱扣斜面的相对运动来使所述鞘座与所述扩张器座相对分离，进而使所述鞘座和所述扩张器脱扣。

[0008] 根据本发明的较佳实施例中，所述脱扣斜面为波浪形结构的波峰和波谷之间的光

滑斜面。

[0009] 根据本发明的较佳实施例中，所述波浪形结构的任意波峰两侧都有波谷。

[0010] 根据本发明的较佳实施例中，所述波浪形结构包括第一波浪形结构和第二波浪形结构，所述扩张器座具有第一波浪形结构，所述鞘座具有第二波浪形结构，其中所述第一波浪形结构和所述第二波浪形结构中的一方提供所述脱扣斜面，另一方提供所述抵接部。

[0011] 根据本发明的较佳实施例中，所述第一波浪形结构和所述第二波浪形结构之间呈几何相似并且彼此互补地嵌合。

[0012] 根据本发明的较佳实施例中，所述扣接机构包括所述扩张器座上轴向伸出的爪扣以及位于所述鞘座上的倒扣，所述鞘座和所述扩张器座通过所述爪扣和所述倒扣扣接。

[0013] 根据本发明的较佳实施例中，所述倒扣形成于所述鞘座的内周侧壁上，所述爪扣能相对所述鞘座轴向推动而于所述内周侧壁处径向向内弹性形变，并且所述爪扣能随所述扩张器座的推动，发生回弹并与所述倒扣相卡，以实现所述锁定。

[0014] 根据本发明的较佳实施例中，所述鞘座包括鞘帽，所述鞘帽包括上帽和下帽，所述上帽的外周侧为渐缩结构，所述下帽的内周侧为渐缩结构，所述上帽坐落于所述下模，所述上帽的外周侧和所述下帽的内周侧彼此结合，所述上帽相对所述下帽径向向内突出，形成所述倒扣。

[0015] 借助于扣接机构，在推入时可实现导管鞘与扩张器锁定，借助于旋转机构，通过旋转可实现导管鞘与扩张器的脱扣，因此本发明提供了一种能够在介入手术过程中提供一种良好的导管鞘与扩张器锁定及分离方案，使两者可有效且便捷的锁定且避免分离时鞘管抖动，有效减少血管损伤。

## 附图说明

[0016] 本发明的上述的以及其他的特征、性质和优势将通过下面结合附图和实施例的描述而变得更加明显，其中：

[0017] 图 1 为本发明一实施例中配套的导管鞘和扩张器的部分分解视图；

[0018] 图 2 为图 1 中导管鞘的鞘帽的分解视图；

[0019] 图 3 为图 2 中鞘帽的剖视图；

[0020] 图 4 为图 1 中将扩张器座推入到鞘座的示意图，其显示了内部构造；

[0021] 图 5 为图 1 中将扩张器座推入到鞘座的示意图，其显示了外部构造；

[0022] 图 6 为图 1 中扩张器座与鞘座相扣合的示意图，其显示了内部构造；

[0023] 图 7 为图 1 中扩张器座与鞘座相扣合的示意图，其显示了外部构造；

[0024] 图 8 为图 1 中导管鞘和扩张器装配后的立体图；

[0025] 图 9 为图 8 中导管鞘和扩张器旋转分离瞬间的示意图，其显示了内部构造；

[0026] 图 10 为图 8 中导管鞘和扩张器旋转分离瞬间的示意图，其显示了外部构造；

[0027] 图 11 为图 9 中导管鞘和扩张器旋转分离后的示意图；

[0028] 图 12 为图 10 中导管鞘和扩张器旋转分离后的示意图；

[0029] 图 13 为图 8 中导管鞘和扩张器旋转分离后的示意图。

## 具体实施方式

[0030] 下面结合具体实施例和附图对本发明作进一步说明，在以下的描述中阐述了更多的细节以便于充分理解本发明，但是本发明显然能够以多种不同于此描述的其它方式来实施，本领域技术人员可以在不违背本发明内涵的情况下根据实际应用情况作类似推广、演绎，因此不应以此具体实施例的内容限制本发明的保护范围。

[0031] 需要注意的是，这些以及后续其他的附图均仅作为示例，其并非是按照等比例的条件绘制的，并且不应该以此作为对本发明实际要求的保护范围构成限制。

[0032] 如图 1 所示，导管鞘 A 包括鞘座 5 以及连接在鞘座 5 上的鞘管 7，扩张器 B 包括扩张器座 1 和连接在扩张器座 1 上的扩张器管 8，扩张器管 8 穿过鞘座 5 插入到鞘管 7 中。根据本发明的锁定导管鞘 A 和扩张器 B 的装置用于将鞘座 5 和扩张器座 1 锁定，其包括鞘座 5 与扩张器座 1 之间配置的扣接机构以及脱扣机构，扣接机构适合于在扩张器管推入到鞘管的过程中使得鞘座 5 与扩张器座 1 扣接，脱扣机构适合于在扩张器座相对鞘座转动的过程中产生扩张器座相对鞘座的移动力，进而迫使鞘座和扩张器座脱扣。扣接机构和脱扣机构的实现方式较多，后面将结合附图例举一较佳实施例，值得一提的是，本发明的扣接机构和脱扣机构不限于此。导管鞘 A 还包括鞘座 5 内设置的止血阀 4 和套在鞘管 7 外周侧上的扩散应力管 6，这些与已有的导管鞘一样，不赘述其详情。

[0033] 如图 2 和图 3 所示，鞘座 5 包括鞘帽，鞘帽包括上帽 2 和下帽 3，上帽 2 的外周侧为渐缩结构，类似于碗状，下帽 3 的内周侧为渐缩结构，也类似于碗状，上帽 2 坐落于下模 3，上帽 2 的外周侧和下帽 3 的内周侧彼此结合，上帽 2 相对下帽 3 径向向内突出，形成倒扣 10。鞘帽由上帽 2 和下帽 3 分体成形，这主要为了便于制造的角度考虑。在其他实施例中，鞘帽也可以是一体成型件。

[0034] 如图 4 和图 6 所示，扩张器座 1 具有环形的裙边 11A 以及轴向伸出的多个爪扣 9，多个爪扣 9 形成的圆的外径大于上帽 2 的最小内径。在将扩张器 B 推入到导管鞘 A 中时，爪扣 9 能相对鞘座 5 轴向移动而于上帽 2 的内周侧壁处径向向内弹性变形，并能随扩张器座 1 的推动，爪扣 9 回弹与倒扣 10 相卡合，以实现锁定。爪扣 9 的数量不限，可以多于三个或少于三个。爪扣 9 和倒扣 10 构成所述扣接机构。扣接机构的实现不限于此，例如可以在鞘帽和扩张器座的一方形成凸环，另一方形成环形槽，凸块卡入到环形槽中也可以使得鞍座 5 和扩张器座 1 扣接。扣接机构还可以通过其他方式实现。

[0035] 如图 5 和图 7 所示，扩张器座 1 具有第一波浪形结构 11，鞘座 5 具有第二波浪形结构 12，二者结构呈几何意义上的相似，这样第一波浪形结构 11 与第二波浪形结构 12 就能彼此互补，呈嵌合状态。更为重要的是，第一波浪形结构 11 和第二波浪形结构 12 容许彼此相对转动，这样在转动的过程中，由于波峰和波谷之间的斜面会产生一个迫使彼此分离的力。本领域的技术人员将可以理解到第一波浪形结构 11 与第二波浪形结构 12 构成所述脱扣机构，不过脱扣机构的实现不限于此，例如可以在鞘座 5 与扩张器座 1 中一方提供的脱扣斜面，另一方提供抵接脱扣斜面的抵接部，抵接部也可以是斜面，例如斜面在转动过程中产生的升力来迫使二者分离，进一步可以使得前述扣接机构分离。脱扣机构主要是将旋转转换为直线运动，从而产生一个直线分离的力。

[0036] 在前述的实施例中，波浪形结构可以沿鞘座 5 和扩张器座 1 的部分外周或者整个外周形成。波峰或波谷数量不限。可以在一个波谷的一侧设置波峰，或者两侧都设置波峰。

[0037] 如图 4 和图 5 所示，第一波浪形结构 11 为扩张器座 1 的外周侧的裙边 11A 的端面，

第二波浪形结构 12 为鞘座 5 的外周侧壁的轴肩面。

[0038] 如图 9 至图 11 所示，分离过程中，只需手持导管鞘 A 及扩展器 B，顺时针或逆时针轴向转动扩张器座 1，此时无需顾及转动方向，使其与鞘座 5 相对分离直至爪扣 9 从倒扣 10 中脱离，然后向导管鞘 A 及扩张器 B 施加轴向分离力即可实现无抖动分离。

[0039] 相对于前述实施例，卡扣式锁定结构在导管鞘和扩张器分离过程中，因术者施加轴向分离力而使得鞘座及扩张器座在分离的瞬间，两者间束缚力显著下降。而此时术者来不及调整分离力，导致滞留在血管中的鞘管显著抖动，造成血管痉挛或损伤。另外，若鞍座 5 和扩张器座 1 通过螺纹等旋转式锁定结构来连接，无论是锁定还是解除锁定过程都需要进行旋转，且只有固定某一方向旋转才能实现锁定或解除锁定，增加操作繁琐程度。前述实施例通过其结构设计可通过任意方向的旋转，例如顺时针旋转或逆时针旋转，使扩张器座 1 与鞘座 5 平缓分离，避免鞘座 5 在分离时的抖动，从而减小血管痉挛及损伤。在本发明的一实施例中，脱扣机构也可以配置成在一个方向旋转可以使得扣接机构脱扣。

[0040] 值得注意的是，除非另有定义，否则前述描述中所使用的所有技术术语具有与本领域的普通技术人员通常所理解的相同的含义。本申请案中描述了特定方法、装置，但与前述内容中所述的方法和装置类似或等价的任何方法和材料可在本技术的实践中使用。尽管已相当详细地且通过说明来描述技术的实施方式，但所述说明仅用于清楚地理解，且并非意在限制。已在描述中使用各种术语来传达对本技术的理解，应理解，所述各种术语的含义延伸到各种术语的常见语言或语法变化或形式。也应理解，当术语是指装置或设备时，所述术语或名称作为当代的实例而提供，且本技术步骤不受所述文字范围的限制。前述的术语将被理解为已由现今当代术语描述，所述前述的术语可合理地理解为当代术语或当代术语所包含的体系子集命名的衍生物。此外，在不脱离所公开技术的范围的情况下，技术的任何实施方式的任何一个或多个特征可与技术的任一实施方式的任何一个或多个其他特征组合。更进一步地，应理解，本技术不限于已为了例证而阐述的实施方式，但本技术仅由对本专利申请案所附权利要求书的公平解读来定义，包括将本技术的每一元件有权享有的整个范围的同等效力。因此，本发明虽然以较佳实施例公开如上，但其并不是用来限定本发明，任何本领域技术人员在不脱离本发明的精神和范围内，都可以做出可能的变动和修改。因此，凡是未脱离本发明技术方案的内容，依据本发明的技术实质对以上实施例所作的任何修改、等同变化及修饰，均落入本发明权利要求所界定的保护范围之内。

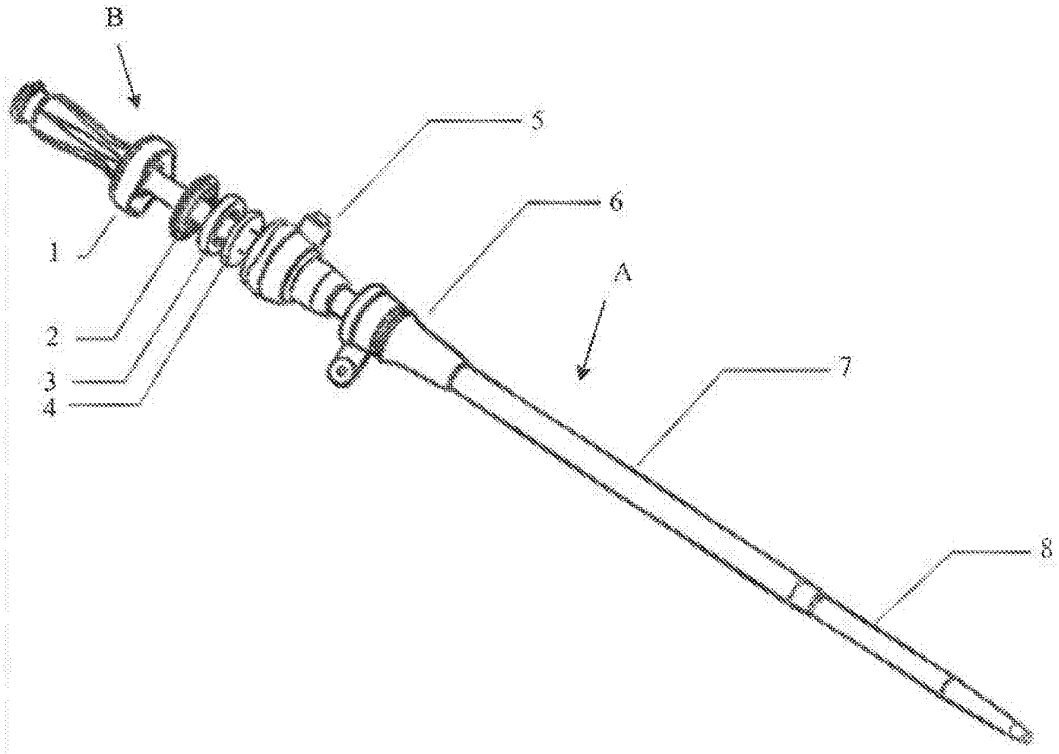



图 1

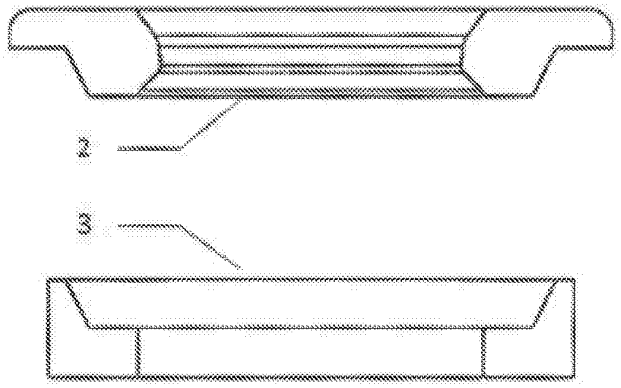



图 2

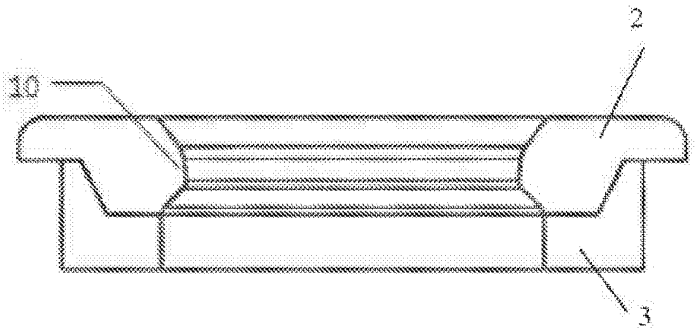



图 3

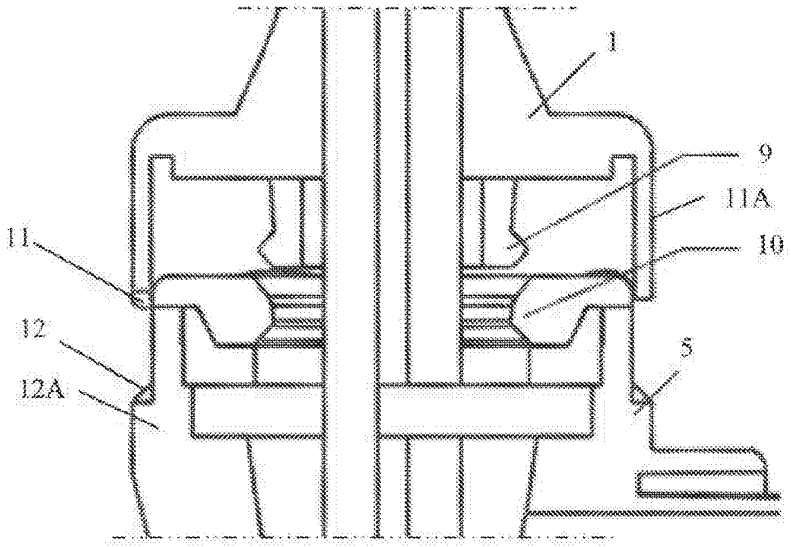



图 4

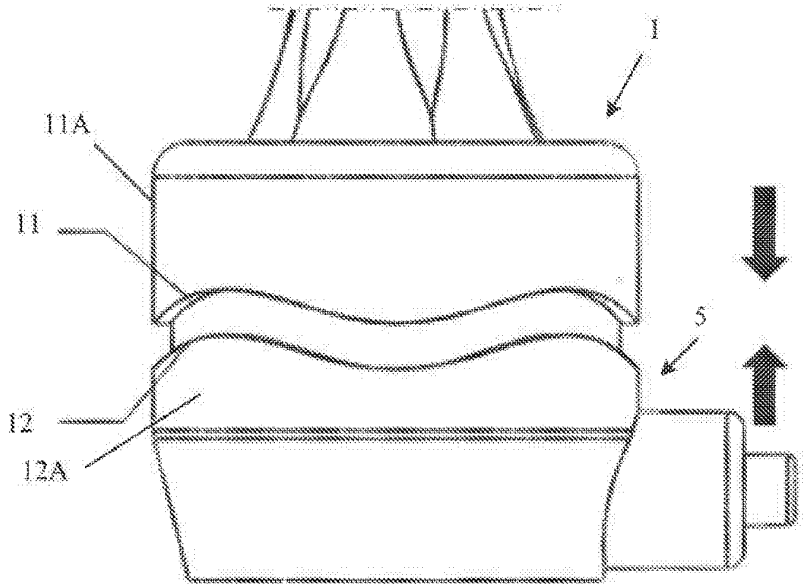



图 5

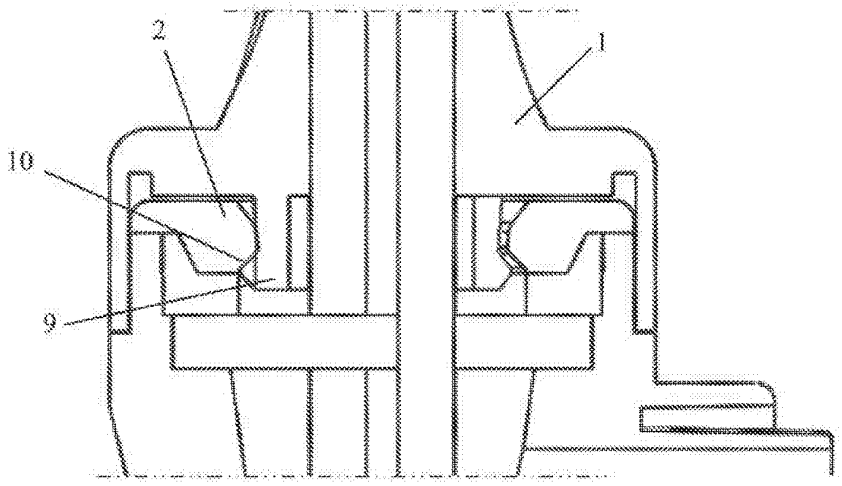



图 6

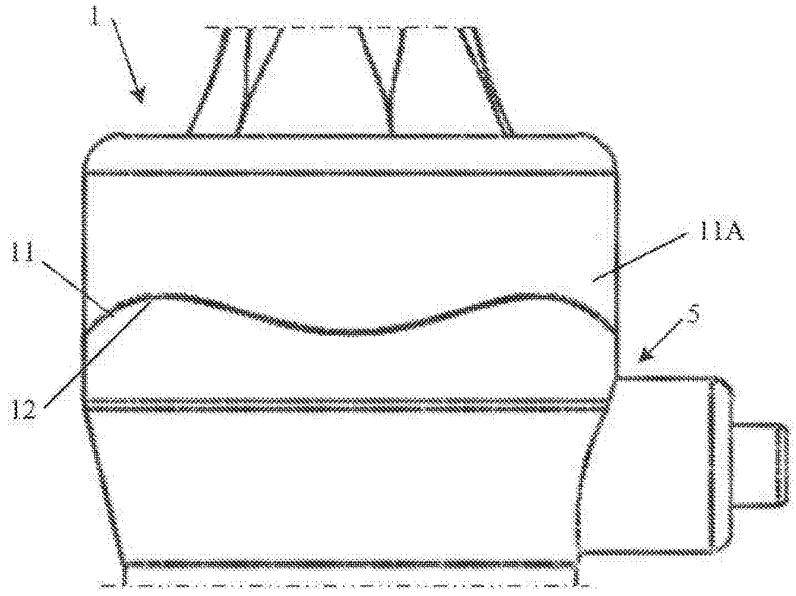



图 7

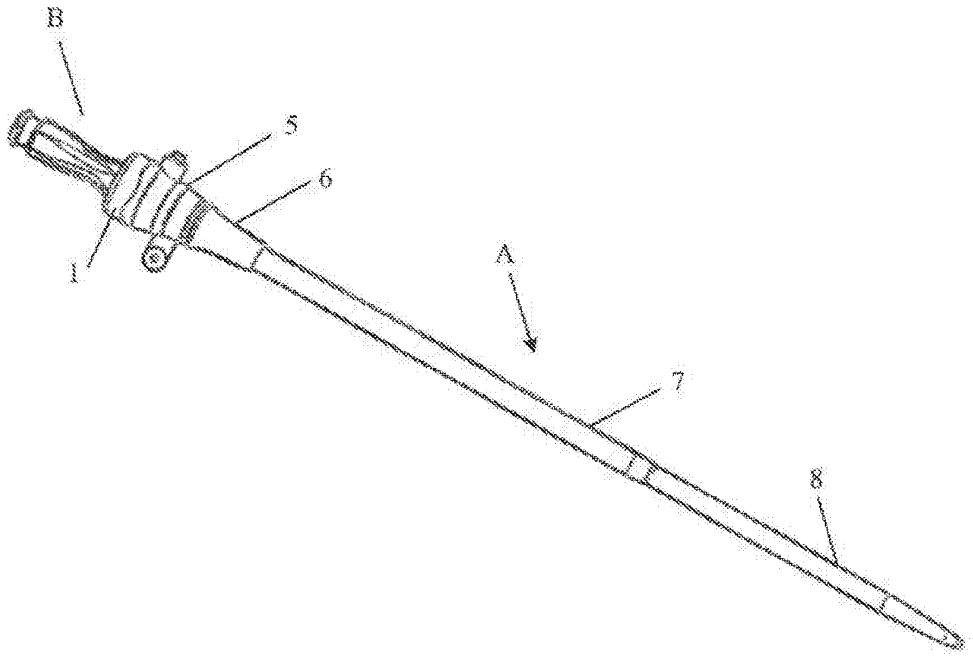



图 8

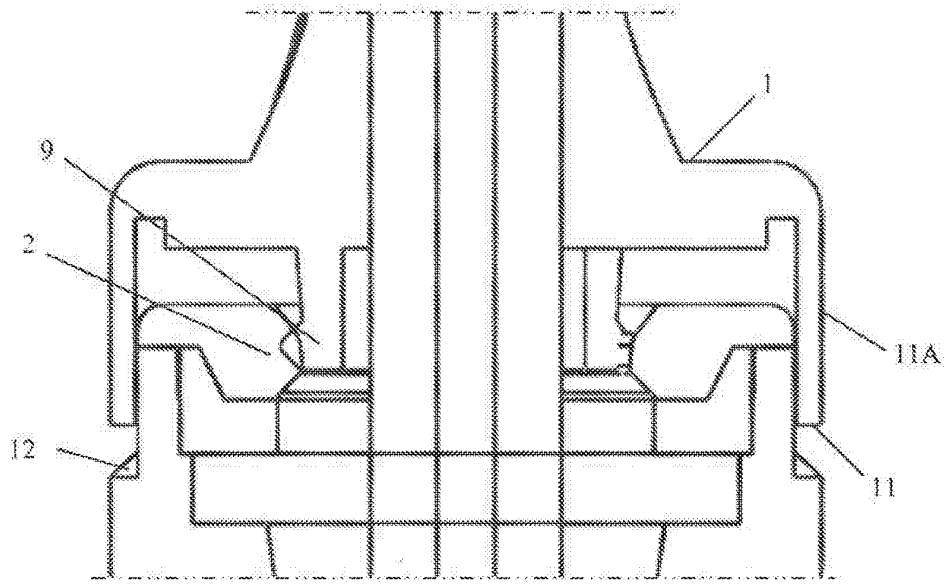



图 9

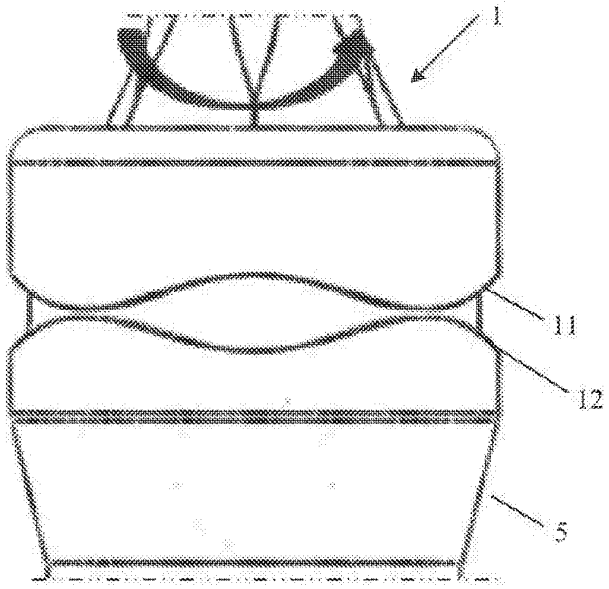



图 10

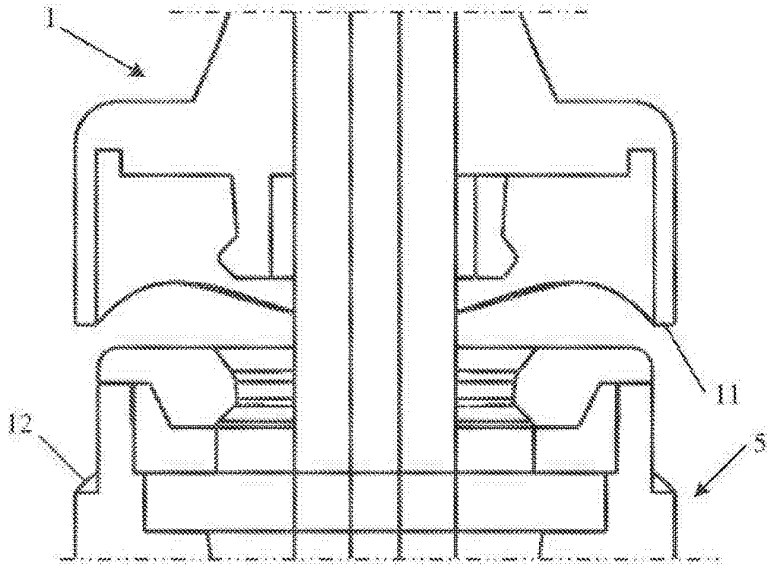



图 11

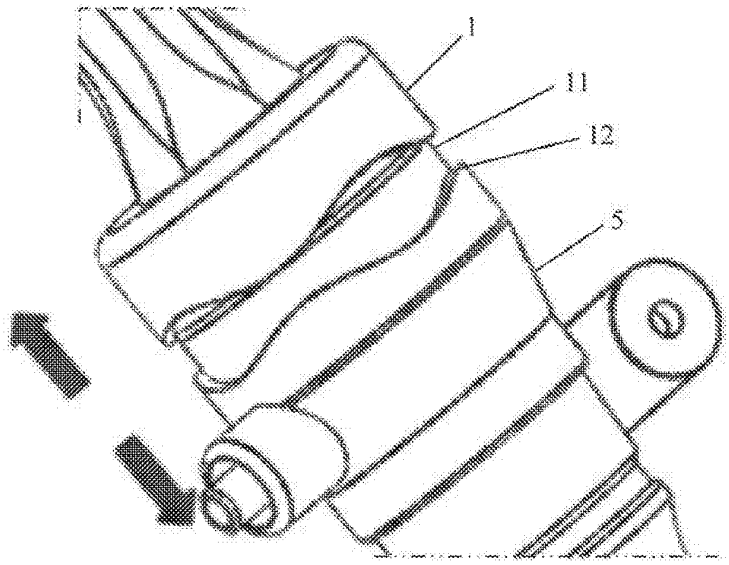



图 12

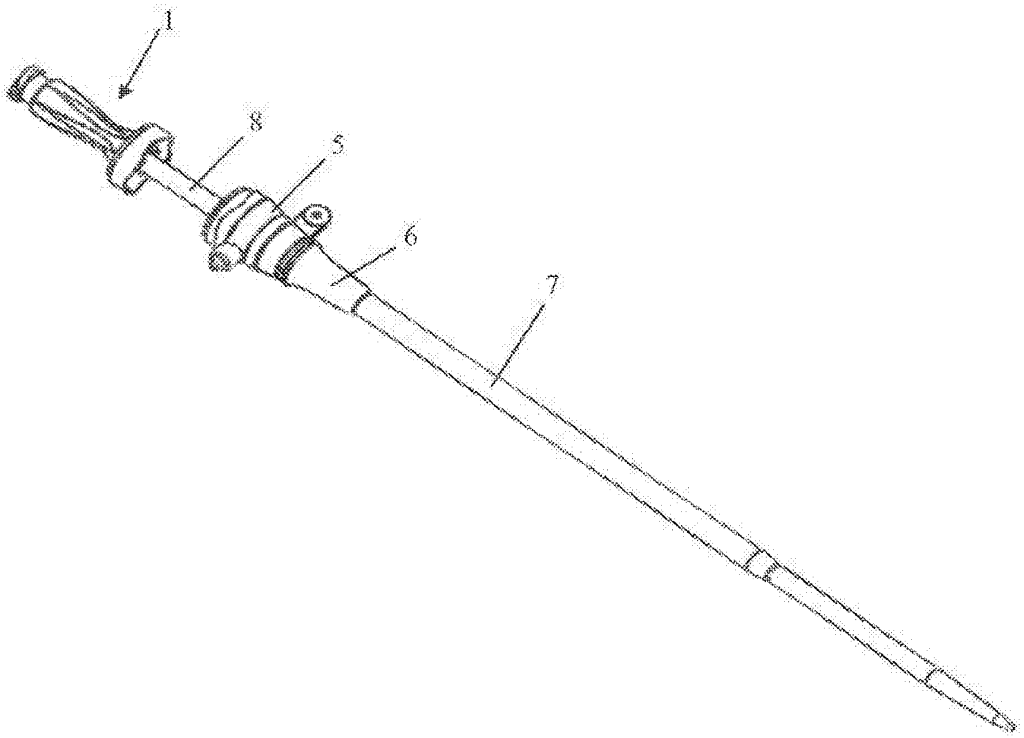



图 13

# PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: BENJAMIN D. CASHDOLLAR
PERKINS COIE LLP
P.O. BOX 1247
SEATTLE, WA 98111-1247

RECEIVED
PATENT DOCKETING

JUL 25 2023

PERKINS COIE LLP

# PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

| | |
|---|---|
| | Date of mailing *(day/month/year)* JUL 20 2023 |
| Applicant's or agent's file reference 111552-8033WO00 | FOR FURTHER ACTION See paragraphs 1 and 4 below |
| International application No. PCT/US 23/60927 | International filing date *(day/month/year)* 19 January 2023 (19.01.2023) |
| Applicant INARI MEDICAL, INC. | |

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   **Filing of amendments and statement under Article 19:**
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   **When?** The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   **How?** Directly to the International Bureau preferably through ePCT, or on paper to:
   The International Bureau of WIPO, 34, chemin des Colombettes, 1211 Geneva 20, Switzerland

   **For more detailed instructions,** see the *PCT Applicant's Guide*, International Phase, paragraphs 9.004 – 9.011.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to any protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.
   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   The applicant may **submit comments on an informal basis on the written opinion of the International Searching Authority** to the International Bureau. These comments will be made available to the public after international publication. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established.

   **Shortly after the expiration of 18 months from the priority date, the international application will be published** by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90*bis*.1 and 90*bis*.3).

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for **entry into the national phase** before those designated Offices. In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months. For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the *PCT Applicant's Guide*, National Chapters.

   **Within 22 months from the priority date, the applicant may request that a supplementary international search be carried out** by a different International Searching Authority that offers this service (Rule 45*bis*.1). The procedure for requesting supplementary international search is described in the *PCT Applicant's Guide*, International Phase, paragraphs 8.006-8.032.

| | |
|---|---|
| Name and mailing address of the ISA/US<br>Mail Stop PCT, Attn: ISA/US<br>Commissioner for Patents<br>P.O. Box 1450, Alexandria, Virginia 22313-1450<br>Facsimile No. 571-273-8300 | Authorized officer<br>Kari Rodriquez<br>Telephone No. PCT Helpdesk: 571-272-4300 |

Form PCT/ISA/220 (revised January 2020)

# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

| Applicant's or agent's file reference | | FOR FURTHER ACTION |
|---|---|---|
| 111552-8033WO00 | | see Form PCT/ISA/220 as well as, where applicable, item 5 below. |
| International application No. | International filing date *(day/month/year)* | (Earliest) Priority Date *(day/month/year)* |
| PCT/US 23/60927 | 19 January 2023 (19.01.2023) | 08 February 2022 (08.02.2022) |
| Applicant<br>INARI MEDICAL, INC. | | |

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the language, the international search was carried out on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

   b. ☐ This international search report has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

   c. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (see Box No. II).

3. ☒ **Unity of invention is lacking** (see Box No. III).

4. With regard to the title,

   ☒ the text is approved as submitted by the applicant.

   ☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

   ☒ the text is approved as submitted by the applicant.

   ☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the drawings,

   a. the figure of the drawings to be published with the abstract is Figure No. 2A

   ☒ as suggested by the applicant.

   ☐ as selected by this Authority, because the applicant failed to suggest a figure.

   ☐ as selected by this Authority, because this figure better characterizes the invention.

   b. ☐ none of the figures is to be published with the abstract.

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 23/60927

**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I: Claims 1-13 directed to a cap assembly for a catheter.

Group II: Claims 14-36 directed to a vascular access system and associated methods of use.

-*-Continued in extra sheet-*-

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-13

**Remark on Protest**

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 23/60927

A. CLASSIFICATION OF SUBJECT MATTER

IPC - INV. A61M 25/18, A61M 39/10 (2023.01)
ADD.

CPC - INV. A61M 25/0097, A61M 39/1011

ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
See Search History document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | CN 106178227 A (Shanghai Microport Medical Group Co., Ltd.); 7 December 2016 (07.12.2016); entire document, especially | 1-2, 5, 7-11 |
| X | US 5,391,152 A (PATTERSON); 21 February 1995 (21.02.1995); entire document, especially Abstract, Figs. 7-9; col. 4, ln 42-46; col. 5, ln 24-55. | 1, 3-4, 6, 12 |
| Y | | 13 |
| Y | US 2021/0404464 A1 (S.P.M. Flow Control, Inc.); 30 December 2021 (30.12.2021); entire document, especially Abstract, para. [0008], [0071], [0074]. | 13 |
| A | US 5,971,958 A (ZHANG); 26 October 1999 (26.10.1999); entire document. | 1-13 |
| A | US 3,660,006 A (PATEL); 14 January 1975 (14.01.1975); entire document. | 1-13 |
| A | US 2013/0150793 A1 (BEISSEL et al.); 13 June 2013 (13.06.2013); entire document. | 1-13 |

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"D" document cited by the applicant in the international application
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 12 April 2023 (12.04.2023) | JUL 20 2023 |
| Name and mailing address of the ISA/US<br>Mail Stop PCT, Attn: ISA/US, Commissioner for Patents<br>P.O. Box 1450, Alexandria, Virginia 22313-1450<br>Facsimile No. 571-273-8300 | Authorized officer<br>Karl Rodriquez<br>Telephone No. PCT Helpdesk: 571-272-4300 |

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 23/60927

-*-Box No. III - Lack of unity-*-

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical features of [a first cap including a locking member], wherein [the locking member] includes an end portion and [a tab] positioned proximate the end portion; and [a second cap including a locking feature], wherein the locking feature includes a slot extending at least partially through [the second cap], in [the locked position], [the locking feature is configured to receive the locking member] through the slot [such that the tab engages a portion of the second cap] to inhibit movement of the [first cap] relative to [the second cap], not required in Group II.

The invention of Group II includes the special technical features of a vascular access system, comprising: a valve having a proximal end and a distal end; a catheter defining a lumen and coupled to the distal end of the valve, the catheter defining a longitudinal axis of the vascular access system; a dilator configured to extend at least partially through the valve and the lumen; wherein [the cap assembly] includes (i) [a] valve [cap] connected to the proximal end of the valve and [including a coupling feature], and (ii) [a] dilator [cap] coupled to the dilator and [including a] coupling tab insertable into the coupling feature], wherein [in the locked configuration, the coupling feature is configured to receive the coupling tab such that the coupling tab engages a portion of the] valve [cap] to inhibit movement of the dilator relative to the valve along the longitudinal axis, not required in Group I.

COMMON TECHNICAL FEATURES

The inventions of Groups I-II share the technical features of a cap assembly, the cap assembly including first cap including a locking member, wherein the locking member includes a tab, and a second cap including a locking feature, wherein the cap assembly is movable between a locked configuration and an unlocked configuration, wherein in the locked configuration, the locking feature is configured to receive the locking member such that the tab engages a portion of the second cap to inhibit movement, and the first cap is configured to rotate relative to the second cap to move the tab out of engagement with the second cap to move the first cap from the locked position to an unlocked position. The common technical features are known in prior art as shown in US 5,391,152 A to Patterson (hereinafter 'Patterson'). Therefore, Groups I-II lack unity since the shared technical features do not represent a contribution over:

Patterson teaches a cap assembly (hubs of catheter assembly complementary and rotatably engageable, Abstract, Figs. 7-9), the cap assembly including:
a first cap (hub 25, Fig. 7, col. 5, ln 24-29) including a locking member (locking member defined by first tab 29, Fig. 7, col. 5, ln 29-34), wherein the locking member includes a tab (pin 100 axially disposed on distal end of first tab 29, Fig. 7, col. 5, ln 29-31), and
a second cap (hub 35, Fig. 7-9, col. 5, ln 24-29) including a locking feature (locking element of hub 35 including first projection 150 and first slot 105, Fig. 7-9, col. 5, ln. 31-34),
wherein the cap assembly is movable between a locked configuration and an unlocked configuration (dilator hub 25 and introducer hub 35 are releasably interlocked, col. 5, ln 24-29),
wherein in the locked configuration, the locking feature is configured to receive the locking member (mechanically interlocked by inserting tab 29 with pin 100 into enlarged open end of slot 105, col. 5, ln 45-49) such that the tab engages a portion of the second cap to inhibit movement (once tab 29 with pin 100 us engaged with slot 105, axial disengagement is precluded by projection 150, col. 5, ln 50-55), and
wherein the first cap is configured to rotate relative to the second cap to move the tab out of engagement with the second cap to move the first cap from the locked position to an unlocked position (dilator hub 25 and introducer hub 35 are releasably interlocked to provide resistance to rotational disengagement, col. 5, ln 24-29; resistance posed by interfering portions of slot 105 inhibits accidental rotational disengagement [in the opposite circumferential direction], col. 5, ln 53-55, col. 4, ln 42-46; unlocked position, Fig. 7; implicitly, hubs 25 and 35 can be intentionally rotated in the opposite circumferential direction to overcome the resistance posed and to release the interlock).

As the common features were known in the art at the time of the invention, they cannot be considered special technical features that would otherwise unify the groups.

Therefore, Groups I-II lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.