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(54) ICA ANGIOPLASTY WITH CEREBRAL PROTECTION

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Related U.S. Application Data

(63) Continuation of application No. 09/018,365, filed on Feb. 4, 1998, now Pat. No. 6,295,989, which is a non-provisional of provisional application No. 60/038,040, filed on Feb. 6, 1997 and which is a non-provisional of provisional application No. 60/037,226, filed on Feb. 6, 1997 and which is a non-provisional of provisional application No. 60/038,039, filed on Feb. 6, 1997 and which is a non-provisional of provisional application No. 60/037,225, filed on Feb. 6, 1997.

Publication Classification

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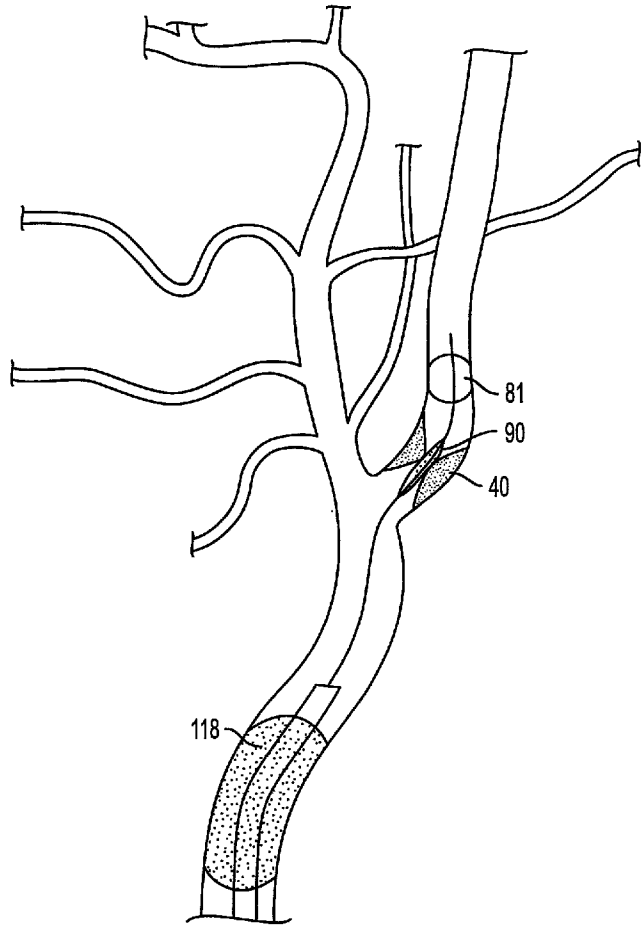
(57) ABSTRACT

A method of performing an operation including angioplasty of the internal carotid artery includes blocking blood flow in the internal carotid artery, performing the angioplasty while the blood flow is blocked in the internal carotid artery, and reversing flow in the internal carotid artery after the angioplasty has been performed to wash material loosened during the angioplasty out of the internal carotid artery. Normal flow in the internal carotid artery is restored after the loosened material is washed out of the internal carotid artery.



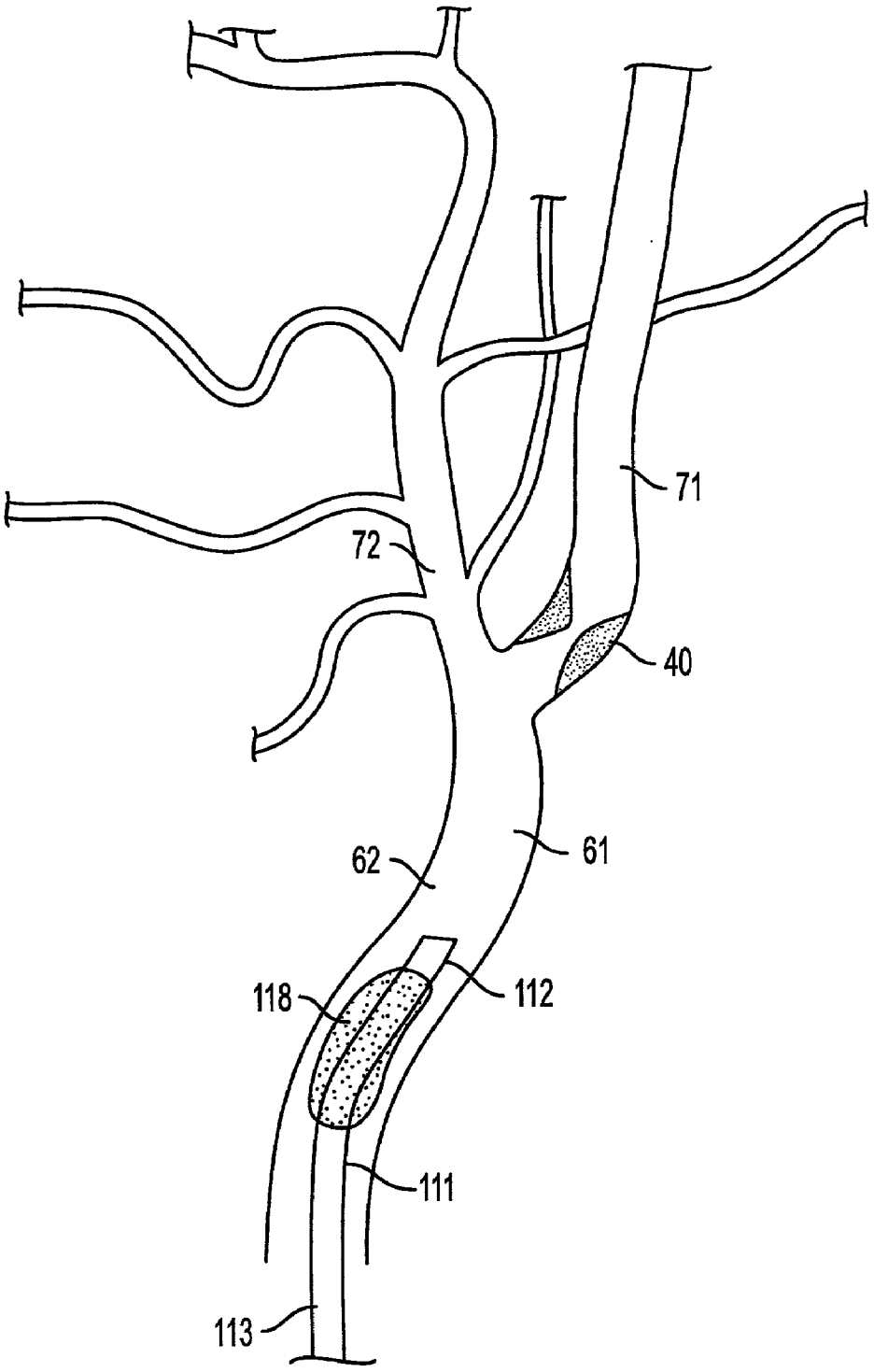


FIG. 1

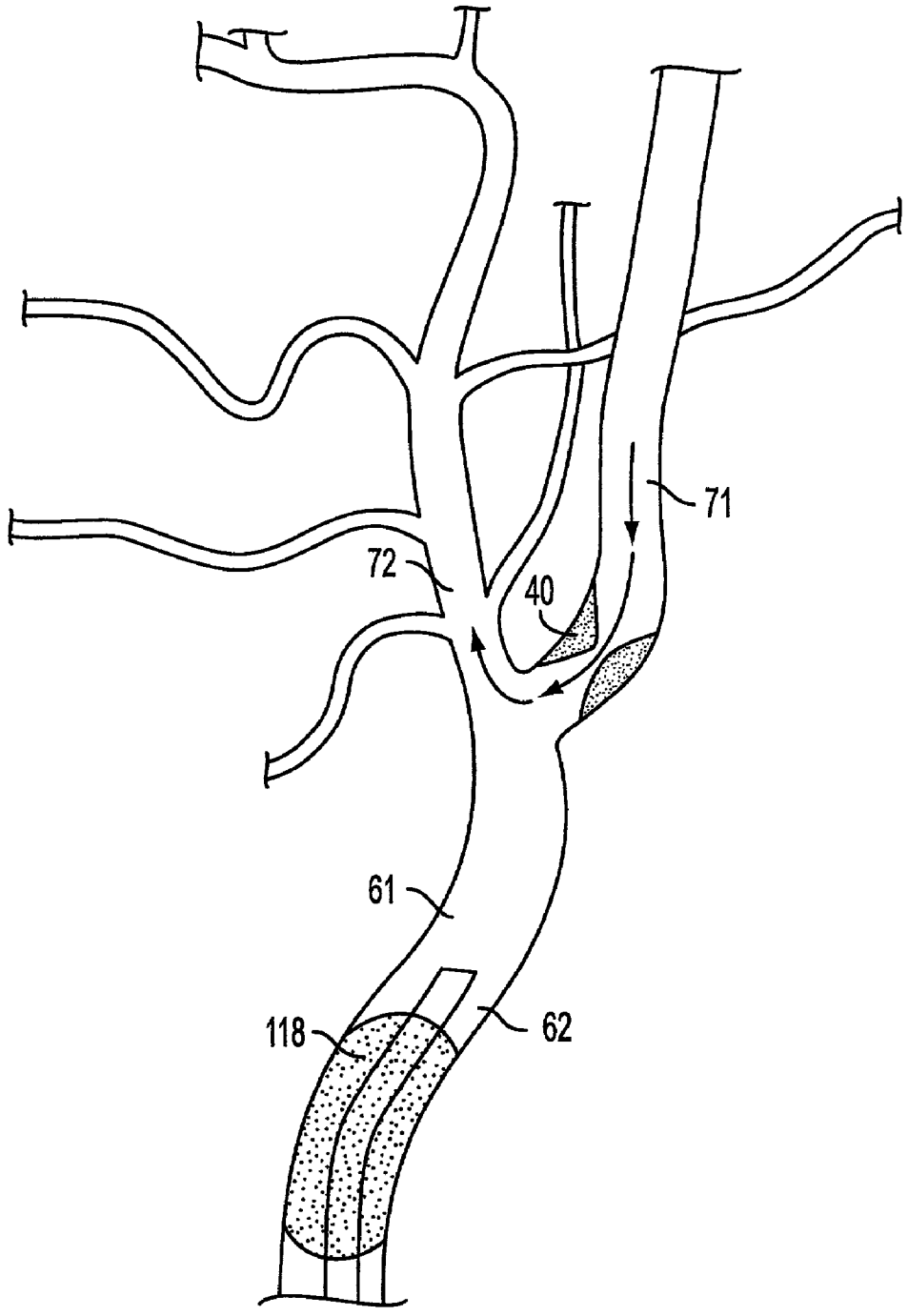


FIG. 2

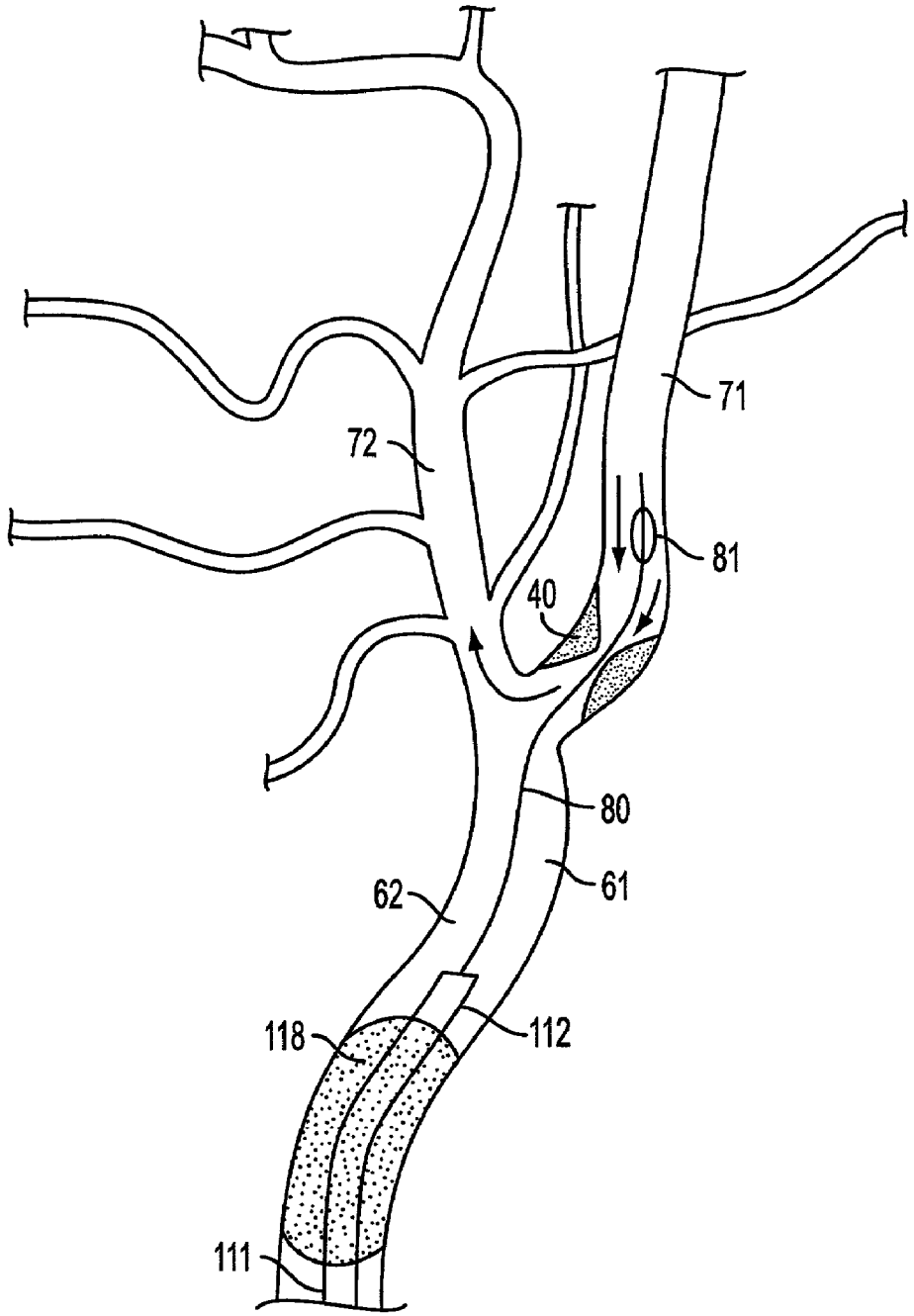
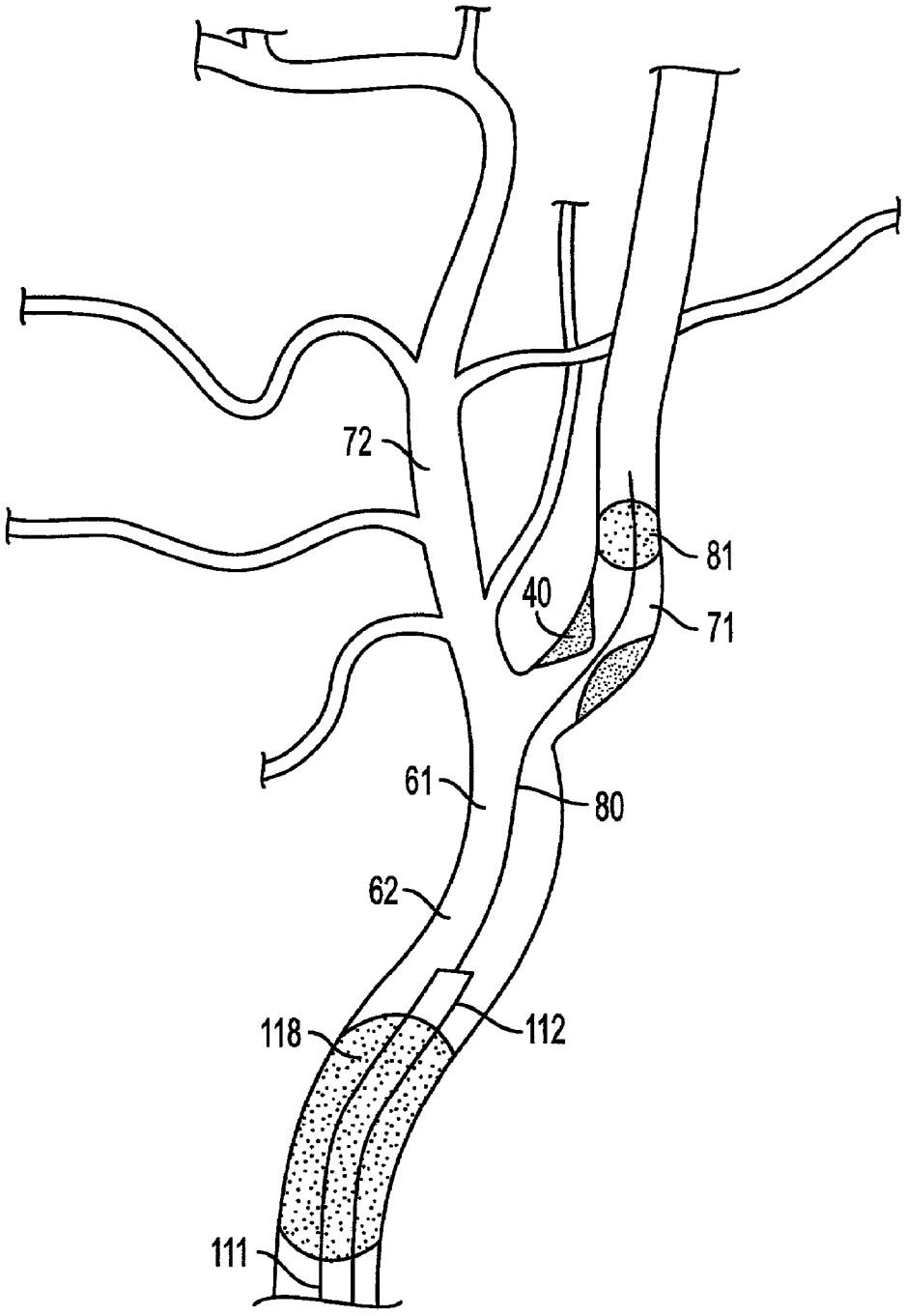


FIG. 3



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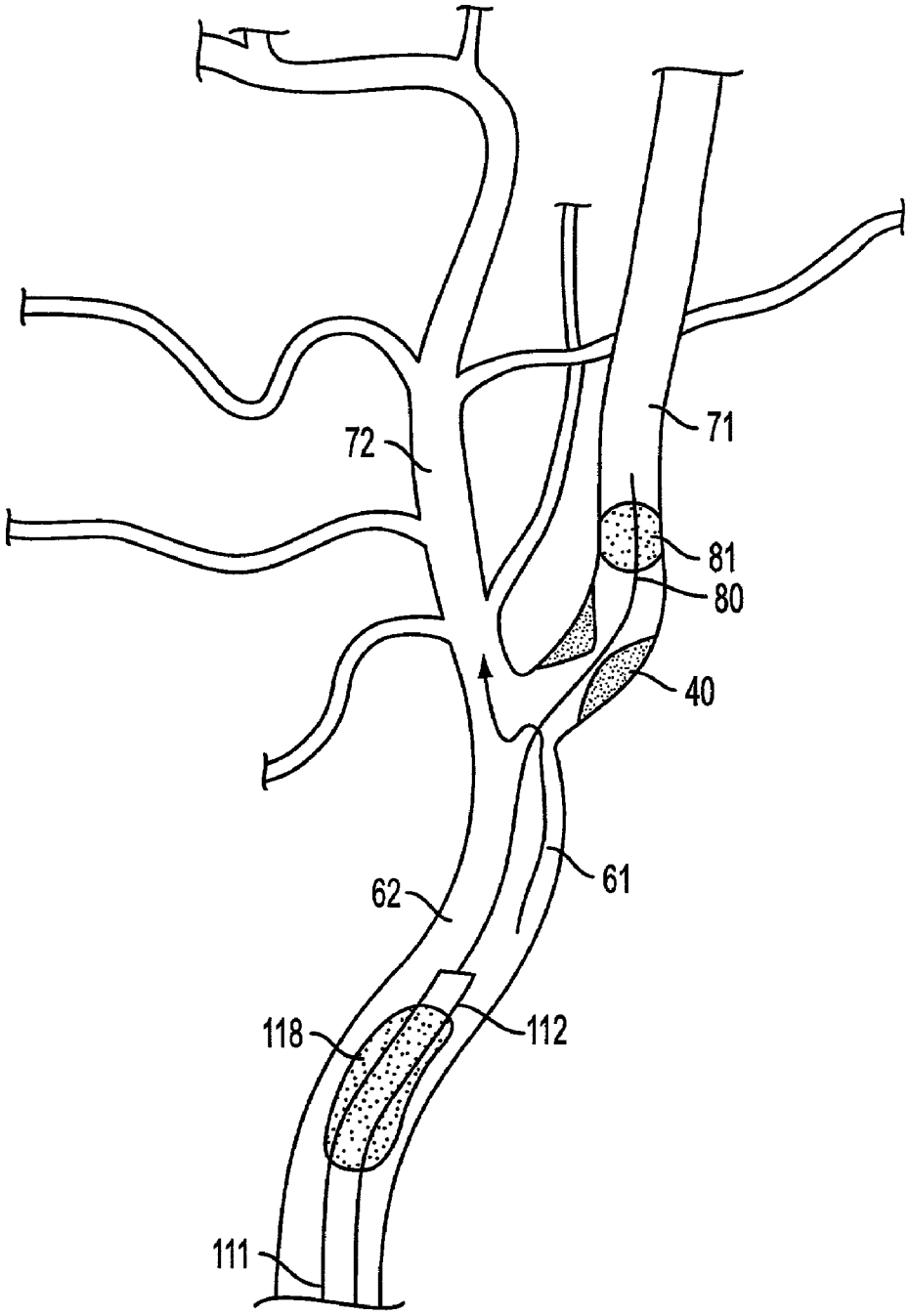
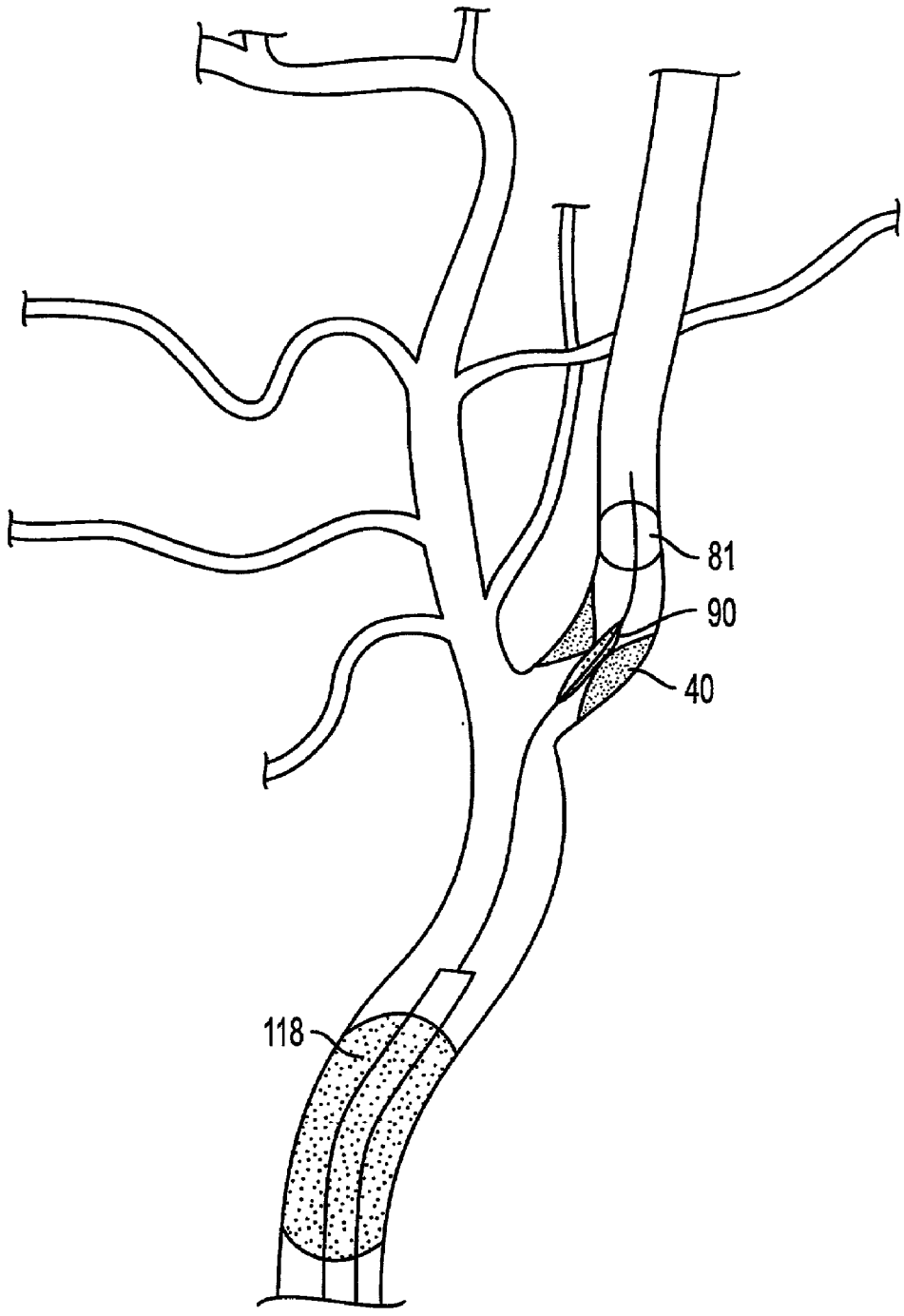


FIG. 5



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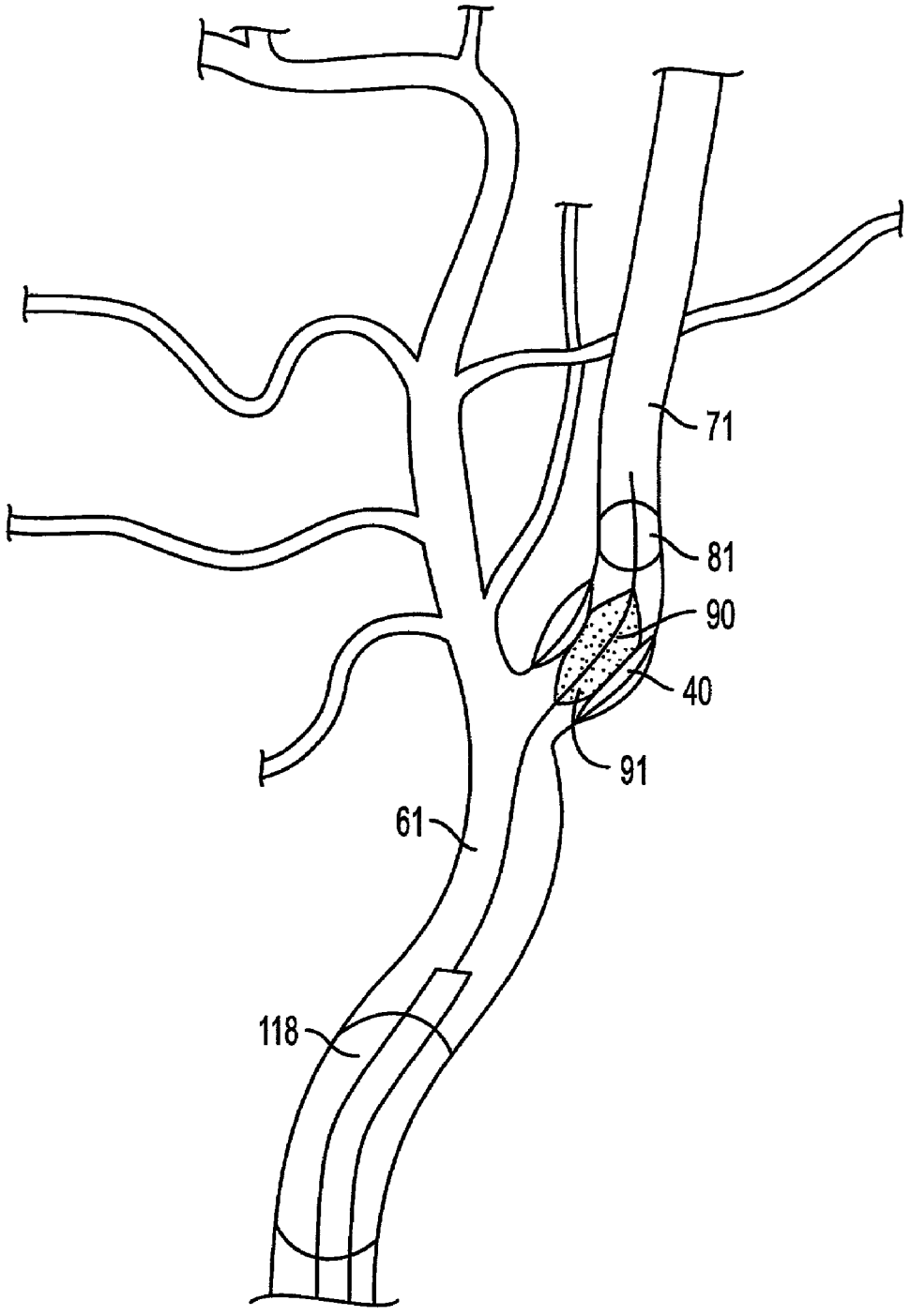
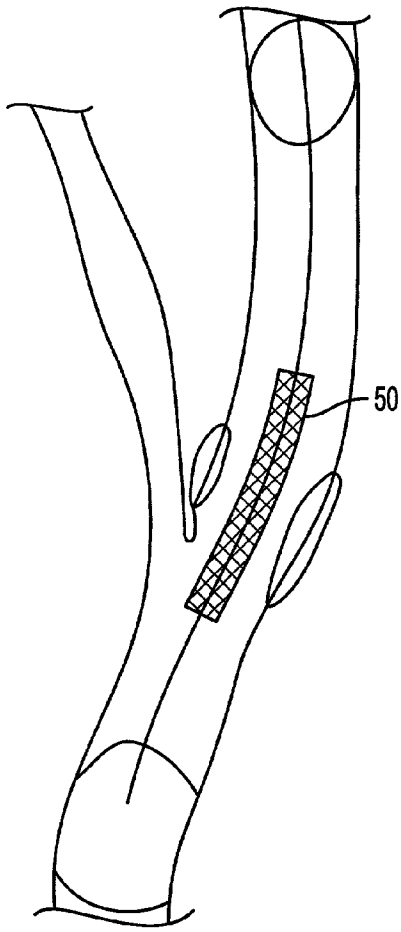


FIG. 7



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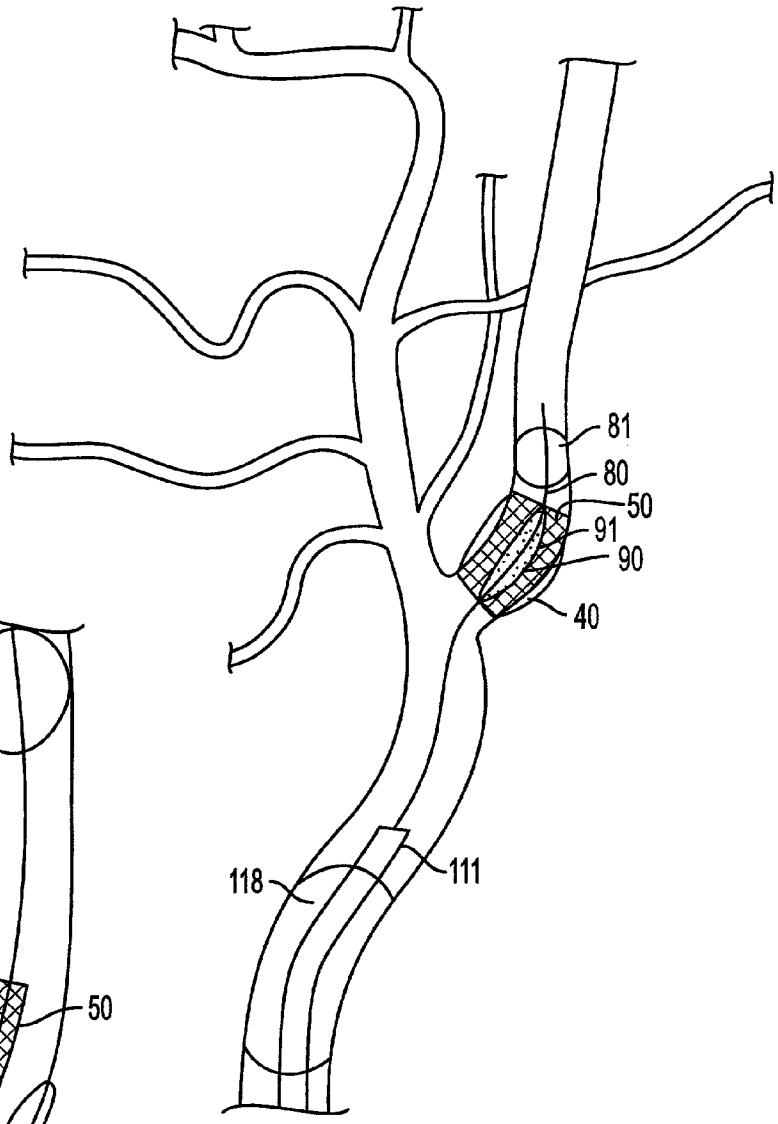

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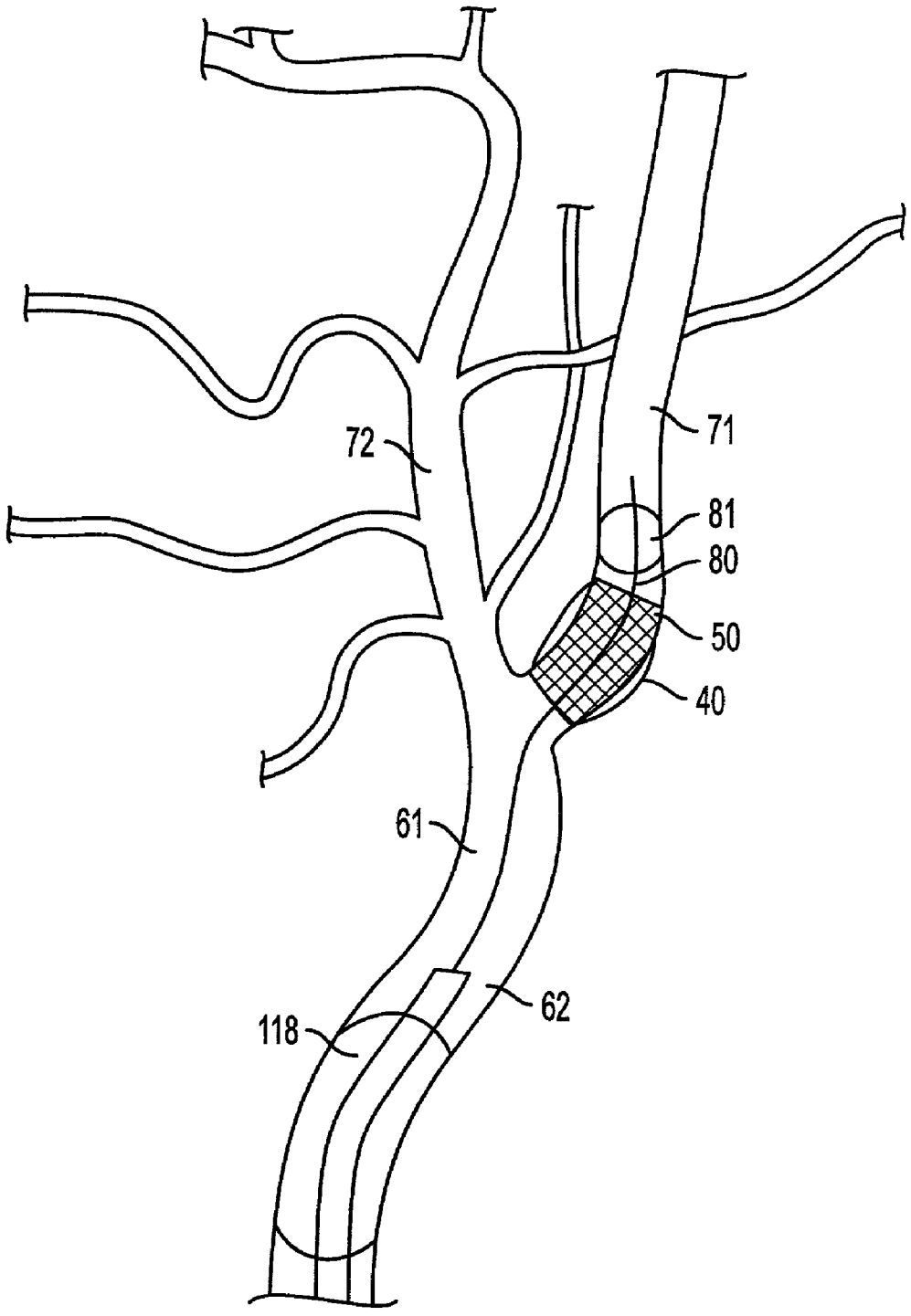

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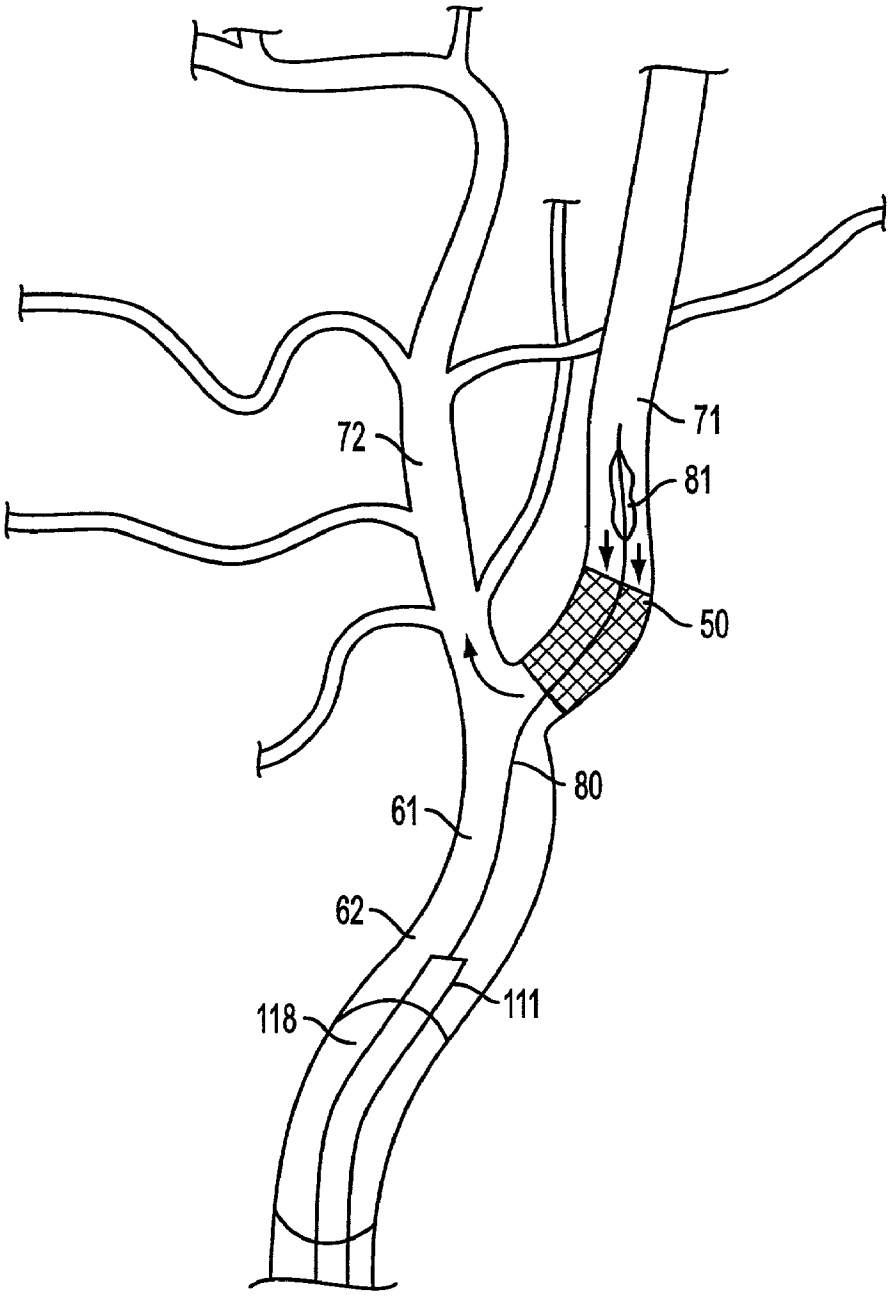
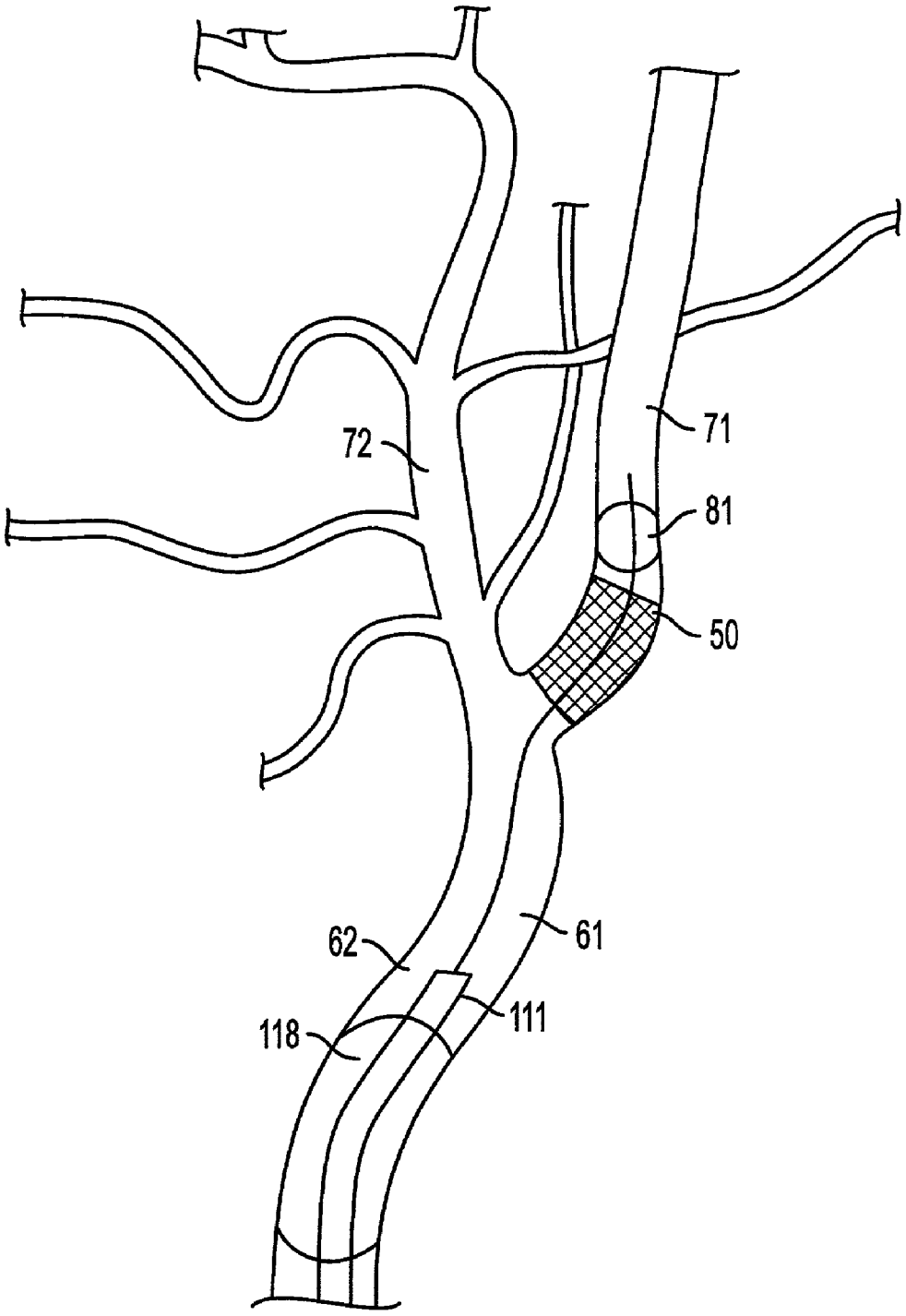


FIG. 11



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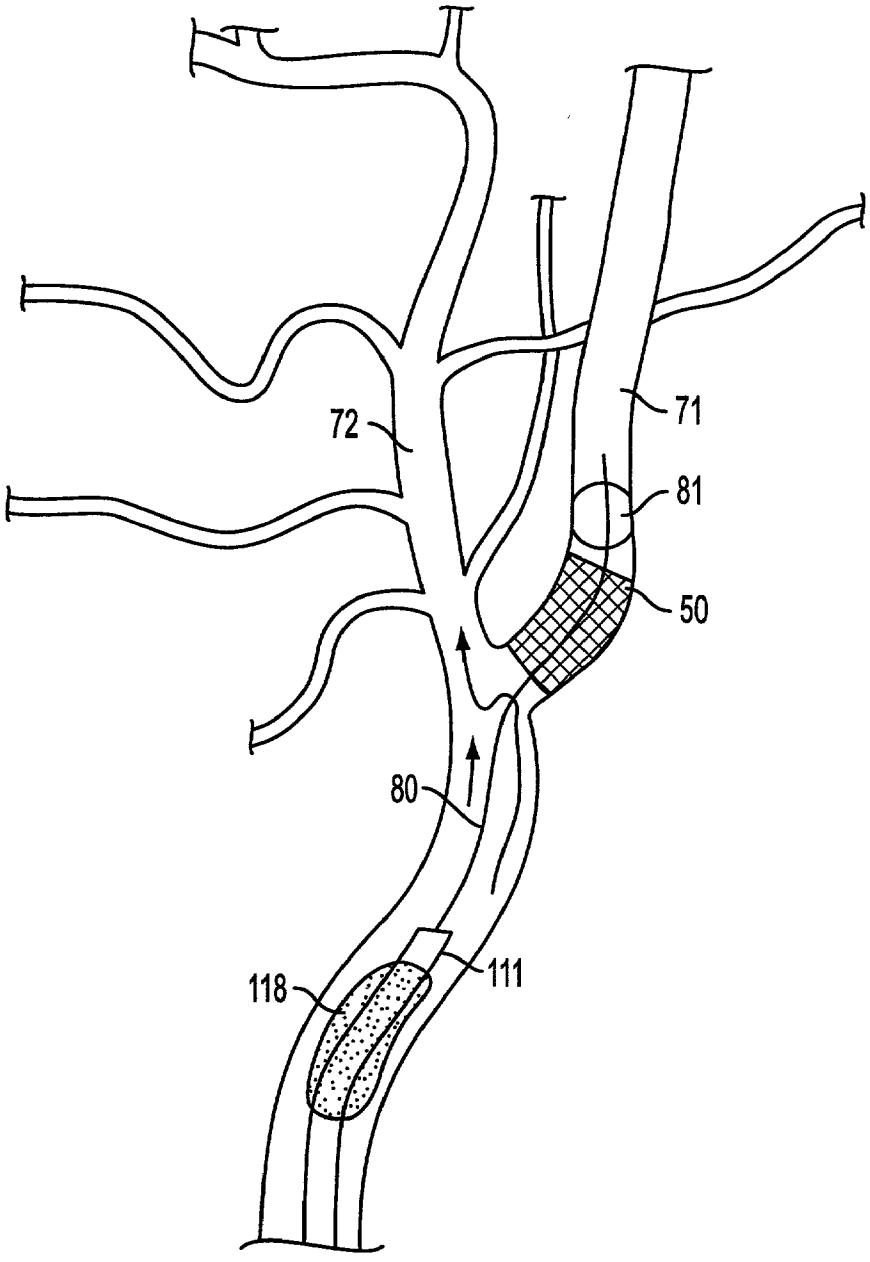

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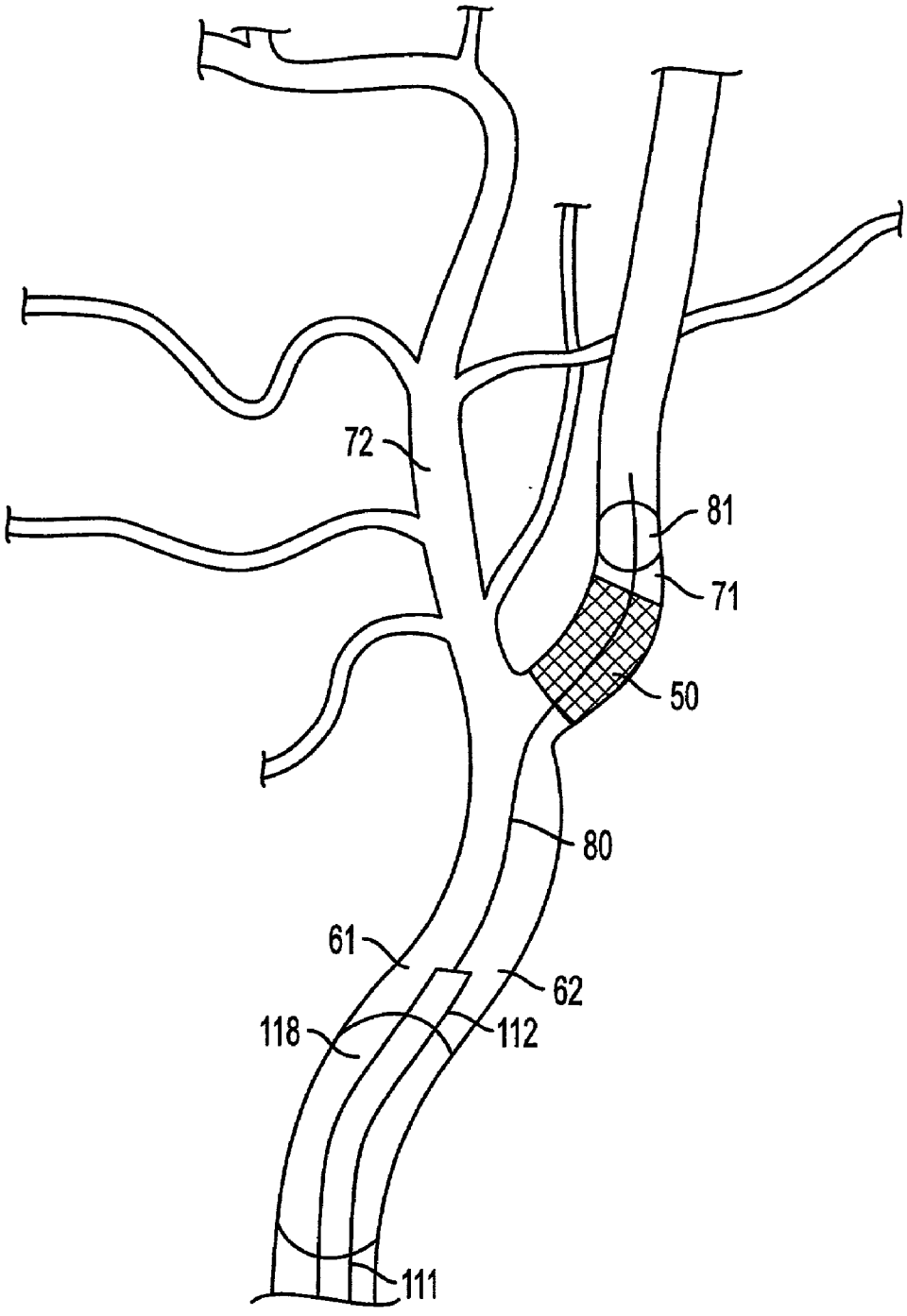

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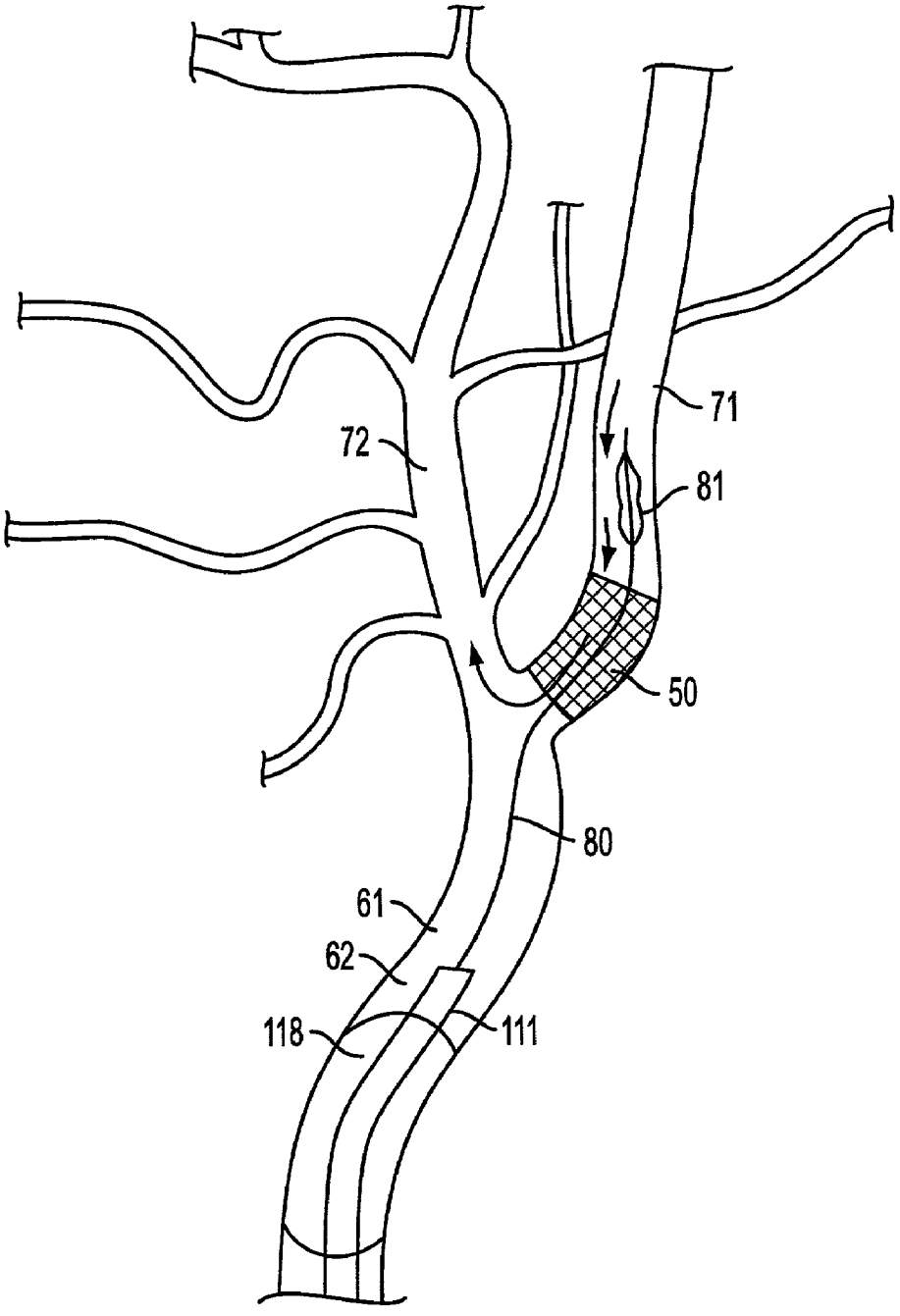

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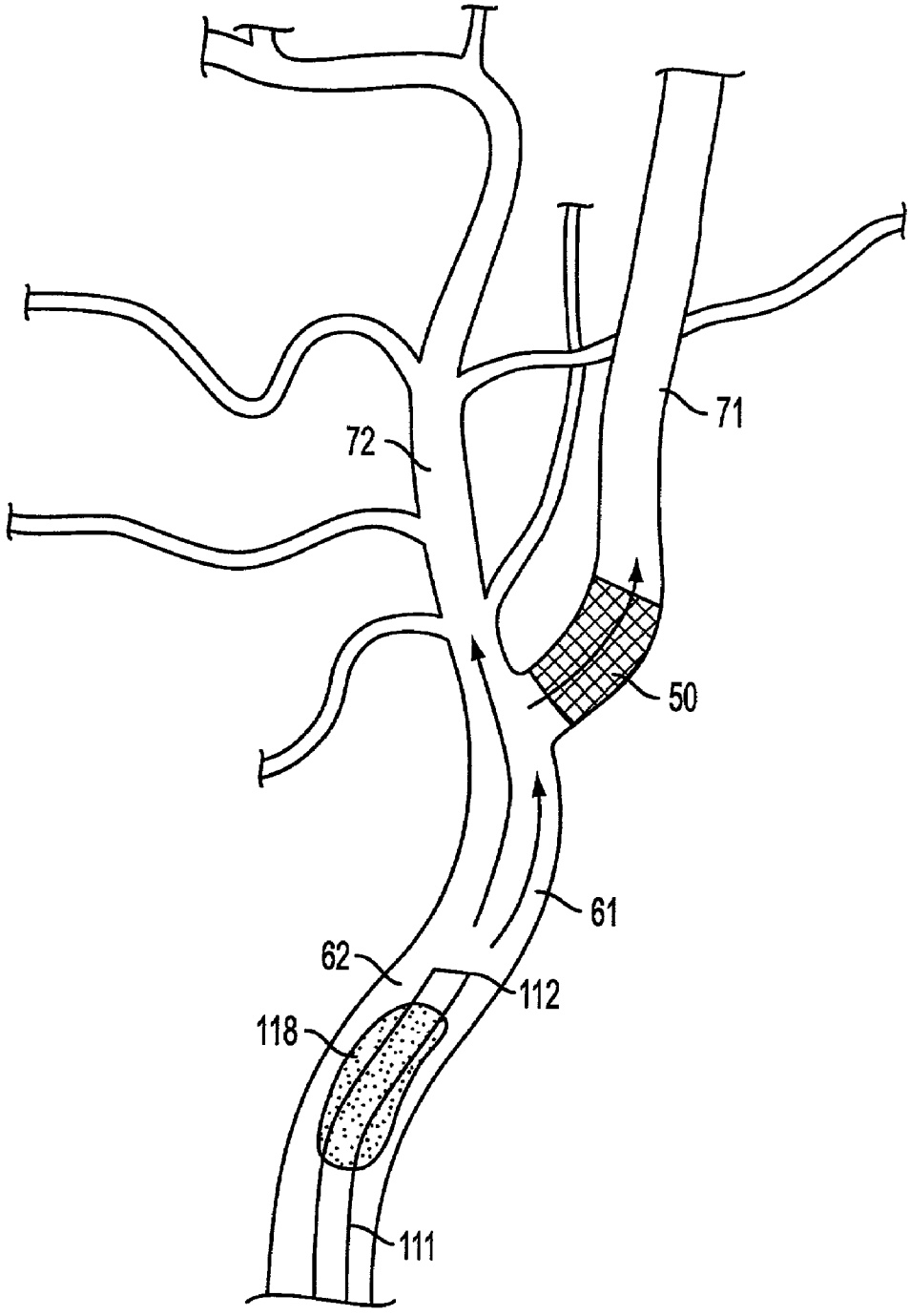

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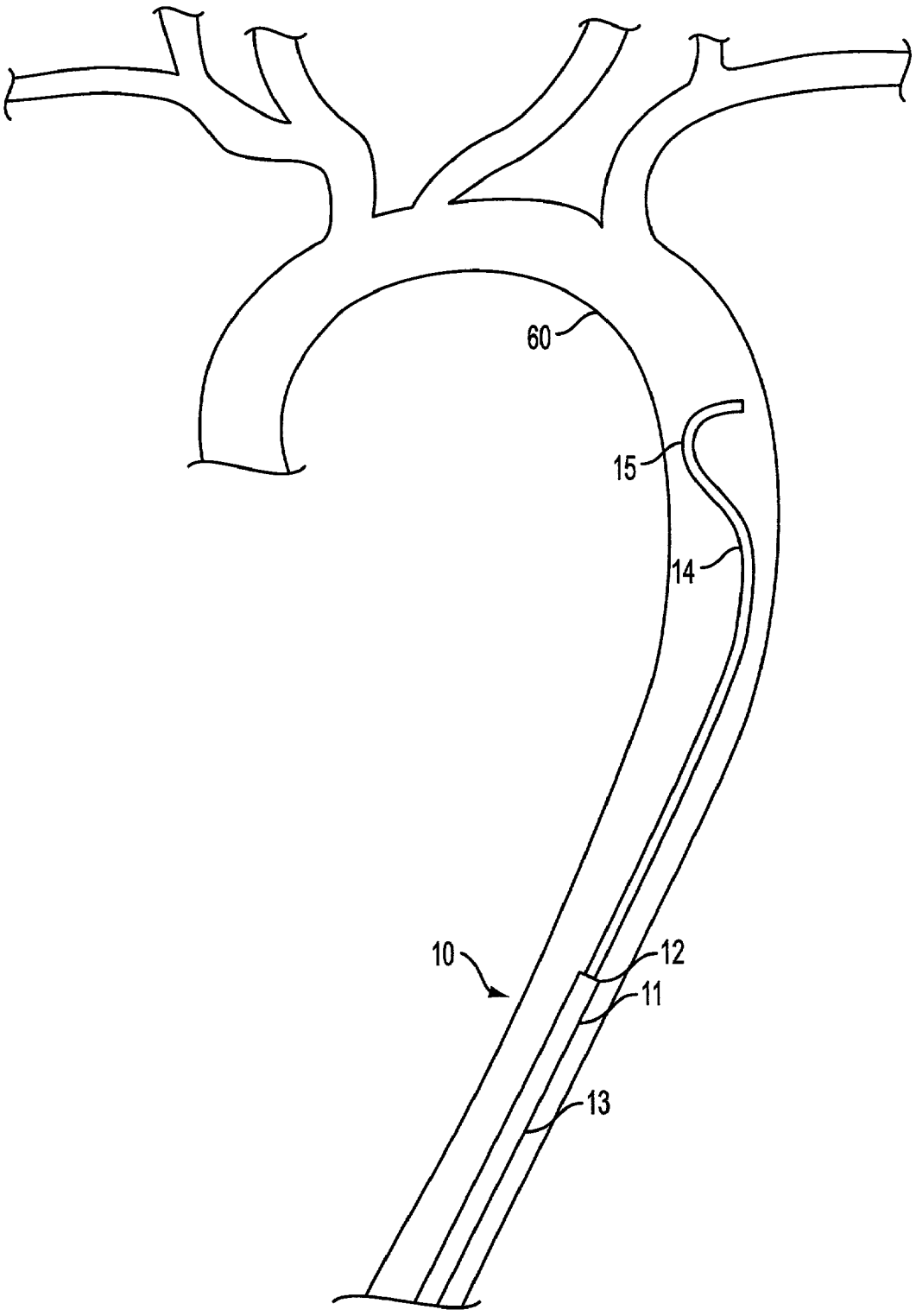
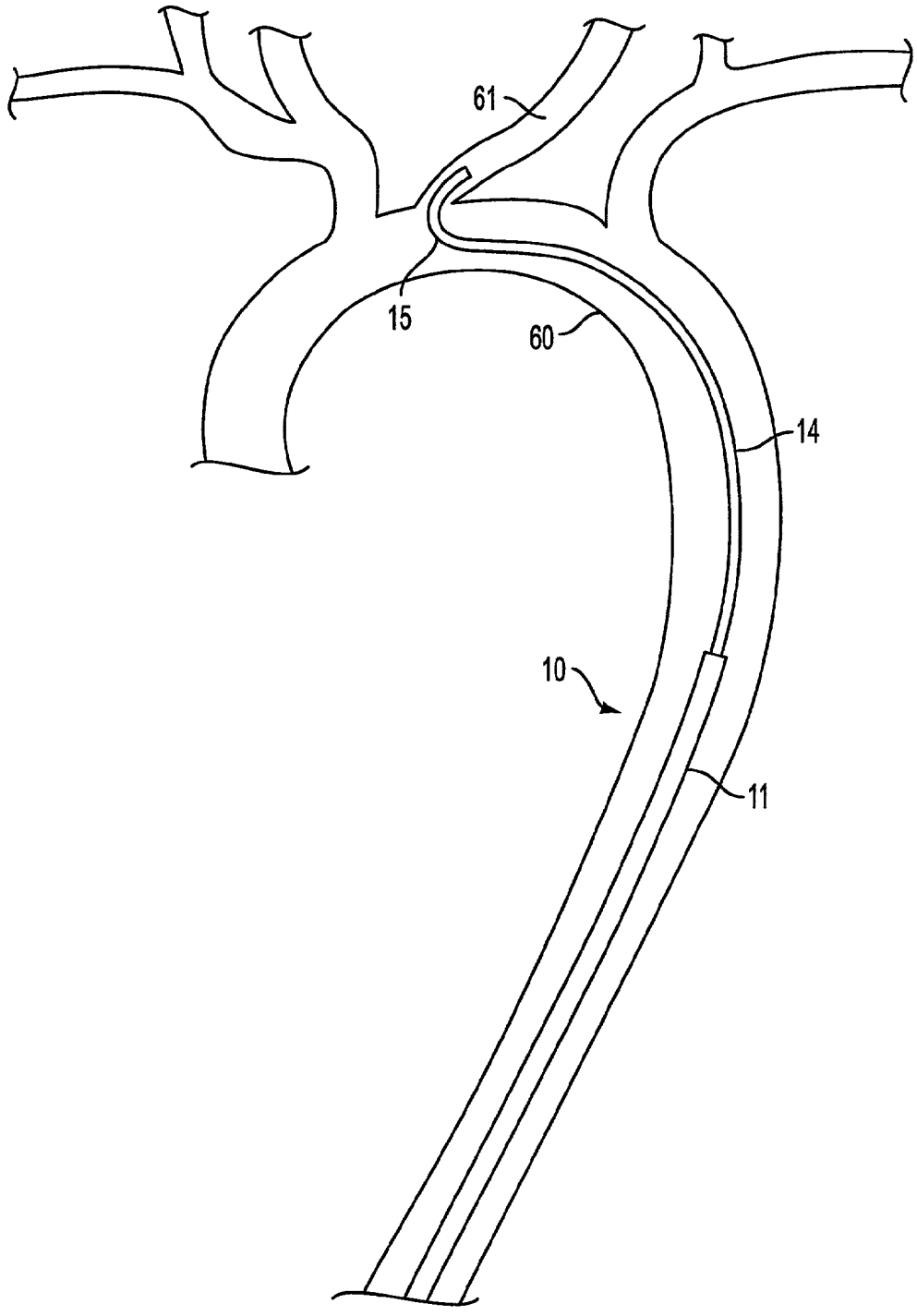


FIG. 17



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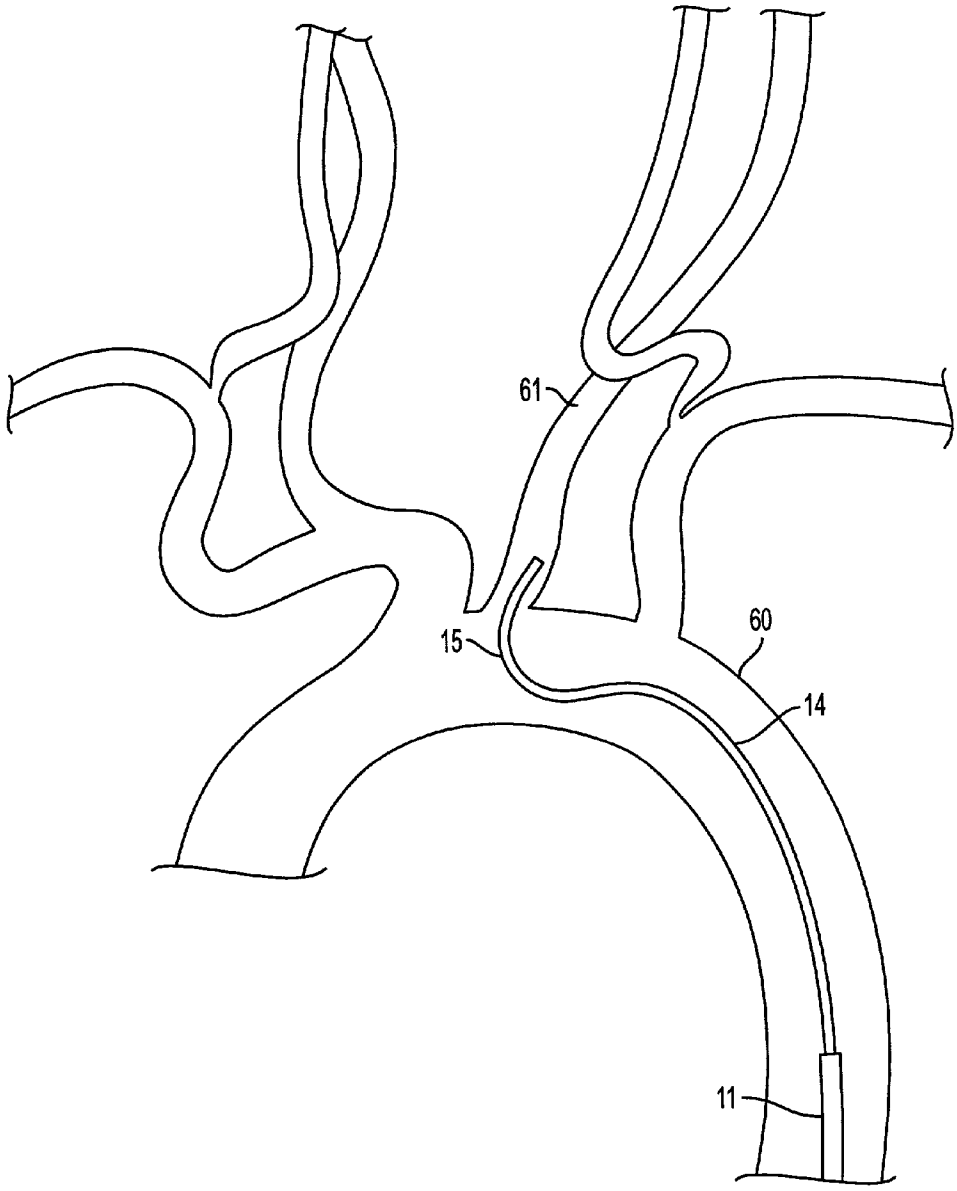

FIG. 19

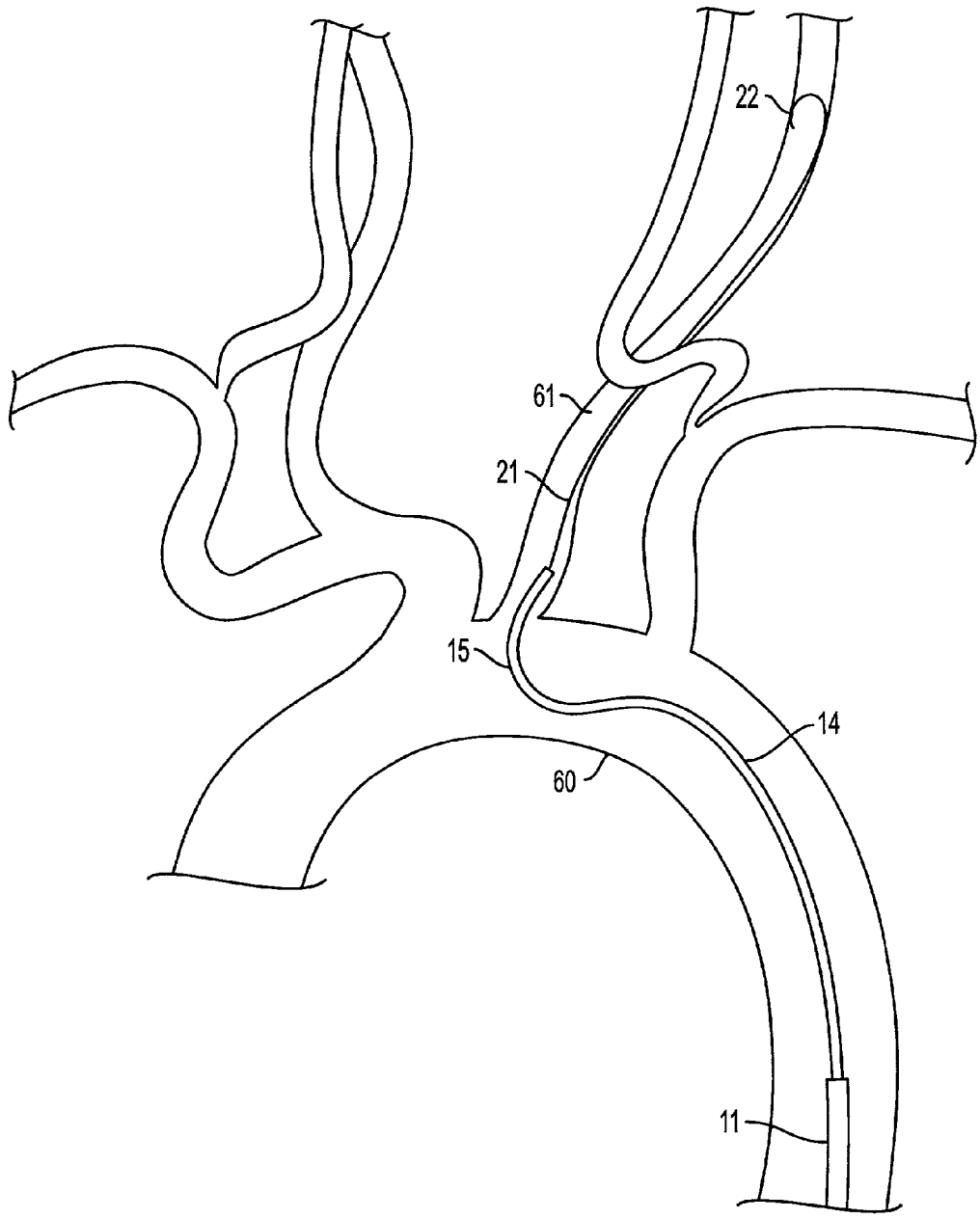

FIG. 20

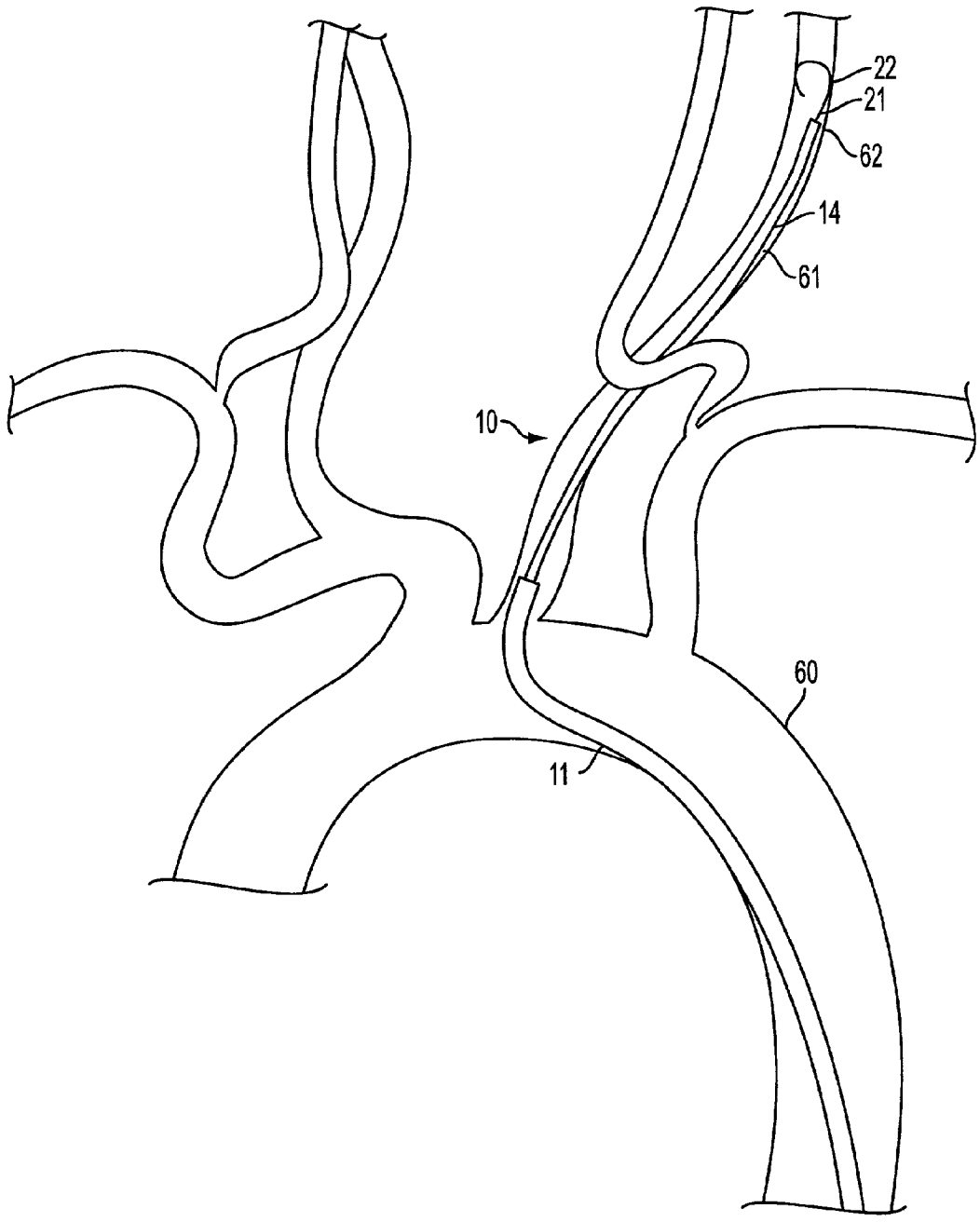

FIG. 21

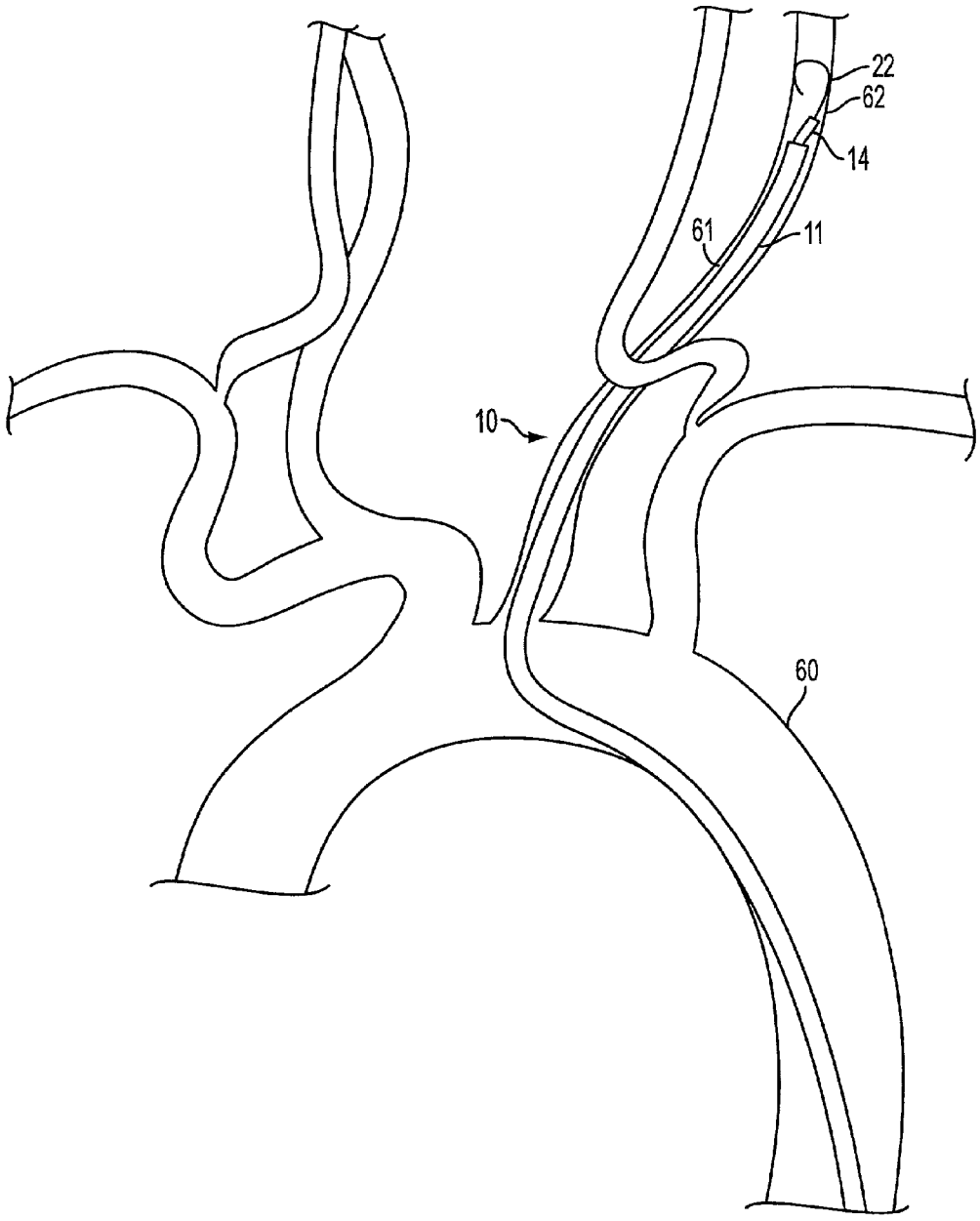

FIG. 22

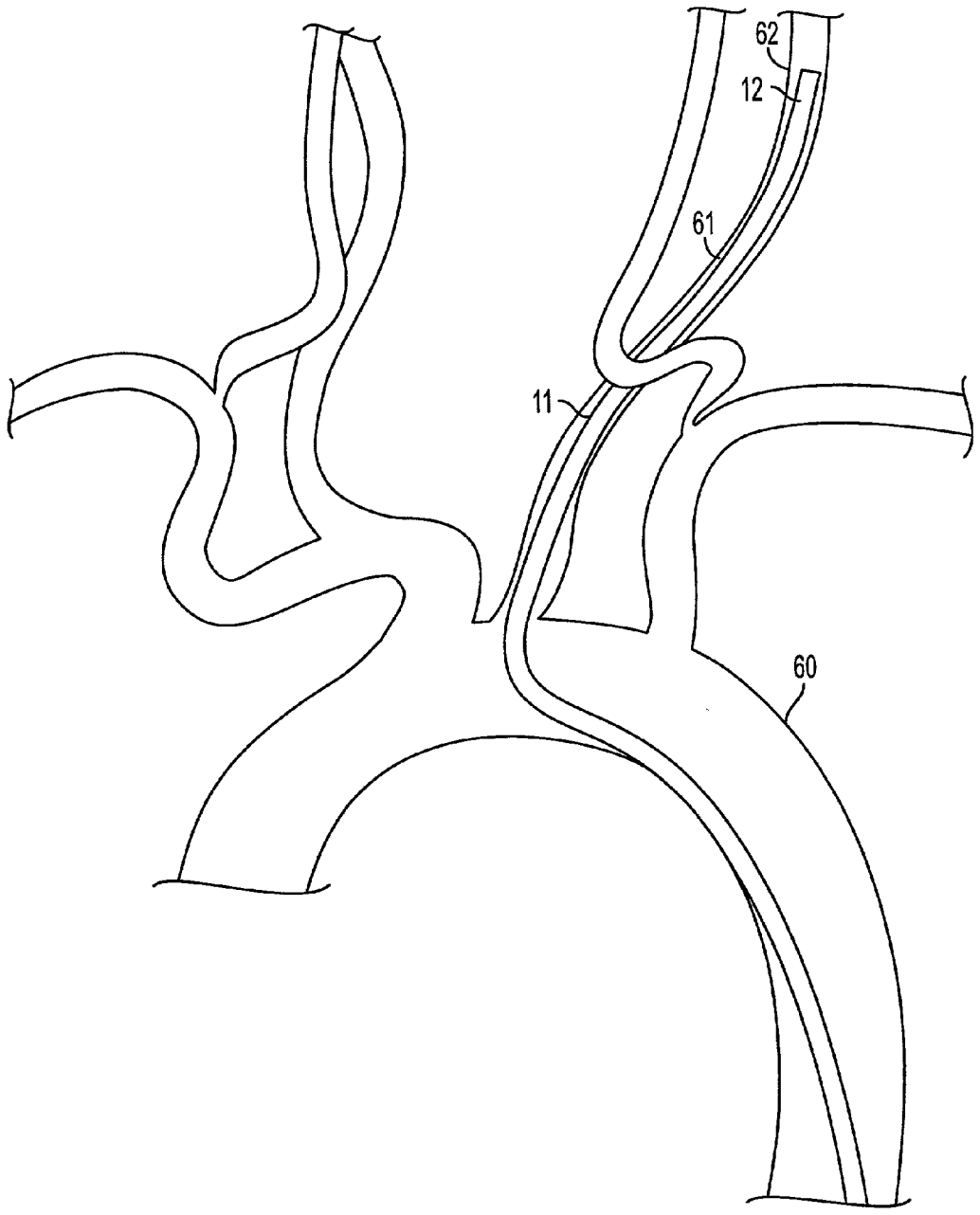

FIG. 23

ICA ANGIOPLASTY WITH CEREBRAL PROTECTION

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority of my U.S. Provisional Patent Application Ser. Nos. 60/038,040; 60/037,226; 60/037,225; and 60/038,039, all filed Feb. 5, 1997 and all incorporated herein by reference. This application also claims priority of my U.S. Provisional Patent Application also filed on Feb. 6, 1997 with the four above-mentioned provisional patent applications and entitled "ICA ANGIOPLASTY WITH CEREBRAL PROTECTION" and bearing attorney docket number V97004US (16064/4). That application is also incorporated herein by reference.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0002] Not applicable

REFERENCE TO A "MICROFICHE APPENDIX"

[0003] Not applicable

BACKGROUND OF THE INVENTION

[0004] 1. Field of the Invention

[0005] The present invention relates to internal carotid artery (ICA) angioplasty with cerebral protection. More particularly, the present invention relates to a system for conducting angioplasty while minimizing risk of strokes.

[0006] 2. General Background of the Invention

[0007] When angioplasties are performed, sometimes plaque gets dislodged and travels into the brain, sometimes causing strokes.

[0008] The following references are hereby incorporated by reference: U.S. Pat. Nos. 3,726,269; 4,033,331; 4,169,464; 4,573,966; 4,925,445; 4,935,017; 5,120,323; 5,163,906; 5,199,951; 5,203,776; 5,215,540; 5,219,355; 5,267,982; 5,290,229; 5,304,131; 5,342,306; 5,348,545; 5,368,566; 5,389,090; 5,458,574; 5,462,529; 5,480,380; 5,484,412; European Patent Specification Publication Nos. 0 339 799 B1 and 0 277 366 A1 and PCT International Application Publication No. WO 96/26758.

BRIEF SUMMARY OF THE INVENTION

[0009] The apparatus of the present invention solves the problems confronted in the art in a simple and straightforward manner. What is provided is a method of performing an operation including angioplasty of the internal carotid artery comprising the following steps: (a) blocking blood flow in the internal carotid artery; (b) performing the angioplasty while the blood flow is blocked in the internal carotid artery; (c) reversing flow in the internal carotid artery after the angioplasty has been performed to wash material loosened during the angioplasty out of the internal carotid artery; and (d) restoring normal flow in the internal carotid artery.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0010] For a further understanding of the nature, objects, and advantages of the present invention, reference should be had to the following detailed description, read in conjunction with the following drawings, wherein like reference numerals denote like elements and wherein:

[0011] In **FIG. 1** initial placement of the flow control guide catheter **111** has been made, but the balloon **118** has not been inflated; antegrade flow is still present in the common carotid artery **61** and internal and external carotid arteries **71**, **72**.

[0012] In **FIG. 2**, inflation of the guide catheter balloon **118** stops flow in the common carotid artery **61** and reverses flow in the internal carotid artery **71**. The high pressure intracranial vascular system will supply the low pressure sump of the external carotid artery **72**.

[0013] In **FIG. 3**, while flow reversal is occurring, a soft tipped "wire with a balloon"**80** is advanced safely through the lesion **40**; any material displaced during passage will flow in a retrograde course out the external carotid artery **72**.

[0014] In **FIG. 4**, the distal balloon **91** is inflated, stopping all flow in the internal carotid artery **71**.

[0015] In **FIG. 5**, the guide catheter balloon **111** is deflated, washing out the stagnant blood and debris in the region of the stenosis **40**.

[0016] In **FIG. 6**, both balloons **81**, **118** are inflated and the angioplasty catheter **90** is delivered safely to its intended location.

[0017] In **FIG. 7**, the angioplasty is performed while flow is arrested in the common carotid **61** and internal carotid **71** arteries.

[0018] In **FIG. 8**, after initial angioplasty, a stent **50** is delivered into the closed system, again with both the distal and proximal flow occluded.

[0019] In **FIG. 9**, the stent **50** is safely deployed under flow arrest.

[0020] In **FIG. 10**, the angioplasty catheter **90** is withdrawn, leaving the stent **50** in place with flow arrested in the carotid arteries **61**, **71**, **72**.

[0021] In **FIG. 11**, the distal balloon **81** is deflated, allowing reversal of flow again in the internal carotid artery **71**. This allows any retained material to be washed into the external carotid artery **72** again.

[0022] In **FIG. 12**, the distal balloon **81** is re-inflated, again stopping flow in the internal carotid artery **71**.

[0023] In **FIG. 13**, the proximal balloon **118** is deflated. This allows high pressure antegrade flow into the external carotid artery **72** and allows contrast injection through the inner lumen of the guide catheter **111**. Evaluation of the result of the angioplasty/stent is now possible. Any retained material is now forcefully washed out of the system into the external carotid artery **72**.

[0024] In **FIG. 14**, the proximal balloon **118** is again inflated.

[0025] In **FIG. 15**, the distal balloon **81** is deflated. While flow is again reversed in the internal carotid artery **71**, the distal wire/balloon **80** is safely withdrawn, again with no chance of dislodging any material into the intracranial flow.

[0026] In **FIG. 16**, once the inner wire/balloon **80** has been withdrawn, the guide catheter balloon **118** is deflated, allowing final contrast injection through the guide catheter lumen to evaluate the results.

DETAILED DESCRIPTION OF THE INVENTION

[0027] This is also the technique of choice for internal carotid artery stenting due to its excellent cerebral protection.

[0028] 1. Select the common carotid artery **61** using a selective diagnostic cerebral catheter; evaluate the path available to the angioplasty site.

[0029] 2. Exchange the diagnostic catheter for a flow control guide catheter utilizing a safe "neuro" exchange wire.

[0030] (Instead of the first two steps listed above, one could instead use the flow control guide catheter **111** of the present invention which is a modified version of the guide catheter disclosed in the attached provisional patent application entitled "Guide Catheter System", which modified version is discussed below).

[0031] 3. Inflate the balloon **118** on the flow control catheter **111**, occluding flow in the common carotid artery **61** and resulting in reversal of flow in the internal carotid artery **71** or cessation of flow (at the very least).

[0032] 4. Load a micro-occlusion balloon catheter **80** containing a microwire through the selected angioplasty balloon catheter **90**. (This will necessitate the placement of a microballoon on a microcatheter after loading, or the use of a proprietary device, currently in development.) Carefully navigate the micro-occlusion balloon **81** past the stenosis **40** with the angioplasty balloon **91** remaining proximal within the guide catheter lumen. The occluded common carotid artery **61** thus protects this initial dangerous crossing.

[0033] 5. Before inflating the distal balloon **81**, aspirate through the guide catheter **111** to remove any debris dislodged during the initial crossing of the plaque **40**; any remainder will flow in a retrograde direction into the external carotid artery **72**.

[0034] 6. Inflate the distal micro-occlusion balloon **81**, stopping all flow in the internal carotid artery **71**.

[0035] 7. Deflate the guide catheter occlusion balloon **118**; this now allows the previously stagnant blood in the common carotid artery **61** to wash out into the external carotid artery **72** and refreshes this territory. It also further washes out the potentially disturbed stenotic region, with debris again going into the external carotid artery **72**.

[0036] 8. Reinflate the guide catheter occlusion balloon **118**, ceasing flow in the common carotid artery **61**.

[0037] 9. Advance the angioplasty catheter **90** over the wire/micro-occlusion balloon **80** into place and perform the angioplasty (and stent placement, if applicable).

[0038] 10. Deflate the angioplasty balloon **91** and withdraw this catheter **90**.

[0039] 11. Slowly infuse contrast through the guide catheter **111** to visualize the angioplasty site.

[0040] 12. Repeat if necessary (and place stent if necessary).

[0041] 13. Open the external lumen of the guide catheter **111** to the air.

[0042] 14. Deflate the distal occlusion balloon **81** and let backbleeding occur for a few seconds, both into the external carotid artery **72** and out the guide catheter **111**.

[0043] 15. Close the external drainage of the guide catheter **111**; let the retrograde flow from the internal carotid artery **71** continue into the external carotid artery **72**. Perfuse with ReoPro, etc., as indicated.

[0044] 16. Perform repeat angiogram to evaluate the status of the angioplasty site by injecting through the guide catheter lumen, slowly.

[0045] 17. Remove all indwelling catheters/balloons except for the guide catheter **111**.

[0046] 18. Deflate the guide catheter balloon **118** and perform final angioplasty site evaluation.

[0047] 19. Perform final evaluation of intracranial cerebral vasculature.

[0048] The preferred guide catheter system for getting the balloon catheter **111** to its intended location is the guide catheter system disclosed in the attached U.S. Provisional Patent Application Ser. No. 60/037,225 entitled "Guide Catheter System", but modified to include a balloon **118** on the guide catheter **111** disclosed herein. Thus, one could use the system disclosed therein, replacing the catheter **11** disclosed therein with balloon catheter **111**, which is the same as catheter **11** except that catheter **111** also includes a balloon **118** and means for inflating and deflating balloon **118**.

[0049] Parts list

[0050] **40** stenosis

[0051] **50** stent (made of stainless steel and could be, e.g., a stent commercially available from Palmaz)

[0052] **61** selected vessel (common carotic artery)

[0053] **62** intended location of tip **112** of catheter **111**

[0054] **71** internal carotid artery

[0055] **72** external carotid artery

[0056] **80** wire with balloon (e.g., a wire with balloon commercially available from Johnson & Johnson as part no. P104)

[0057] **81** balloon of wire **80**

[0058] **90** angioplasty catheter (e.g., a Diamond TM brand angioplasty catheter commercially available from Boston Scientific having a balloon which is 6 mm in diameter by 20 mm long)

[0059] **91** balloon of angioplasty catheter

[0060] **110** guide catheter system

[0061] **111** guide catheter (e.g., a catheter commercially available as FasGuide made by Target Therapeutic)

[0062] **112** soft, atraumatic tip of guide catheter **11**

[0063] **113** very stiff proximal shaft of guide catheter **111**

[0064] Enclosed is an appendix with more information about the present invention.

[0065] All measurements disclosed herein are at standard temperature and pressure, at sea level on Earth, unless indicated otherwise. All materials used or intended to be used in a human being are biocompatible, unless indicated otherwise.

[0066] The foregoing embodiments are presented by way of example only; the scope of the present invention is to be limited only by the following claims.

1. A method of performing an operation including angioplasty of the internal carotid artery comprising the following steps:

(a) blocking blood flow in the internal carotid artery;

(b) performing the angioplasty while the blood flow is blocked in the internal carotid artery;

(c) reversing flow in the internal carotid artery after the angioplasty has been performed to wash material loosened during the angioplasty out of the internal carotid artery;

(d) restoring normal flow in the internal carotid artery.

2. A method of performing an operation including angioplasty of the internal carotid artery comprising the following steps:

(a) blocking flow in the common carotid artery, thus causing retrograde blood flow in the internal carotid artery;

(b) blocking flow in the internal carotid artery, distal of the stenosis;

(c) performing angioplasty on the stenosis;

(d) unblocking flow in the internal carotid artery, thus allowing retrograde blood flow in the internal carotid artery into the external carotid artery; and

(e) unblocking flow in the common carotid artery.

3. Apparatus for performing angioplasty, including:

(a) a guide catheter having a first occlusion balloon adjacent a distal end thereof, the first occlusion balloon being sized to stop blood flow in a first artery;

(b) a wire which can be advanced through the guide catheter and which includes a second occlusion balloon adjacent a distal end thereof the second occlusion balloon being sized to stop blood flow in a second artery;

(c) means for selectively inflating and deflating the first balloon;

(d) means for selectively inflating and deflating the second balloon;

(e) an angioplasty balloon catheter which can be advanced through the guide catheter and along the wire to the site of a stenosis in the second artery.

* * * * *