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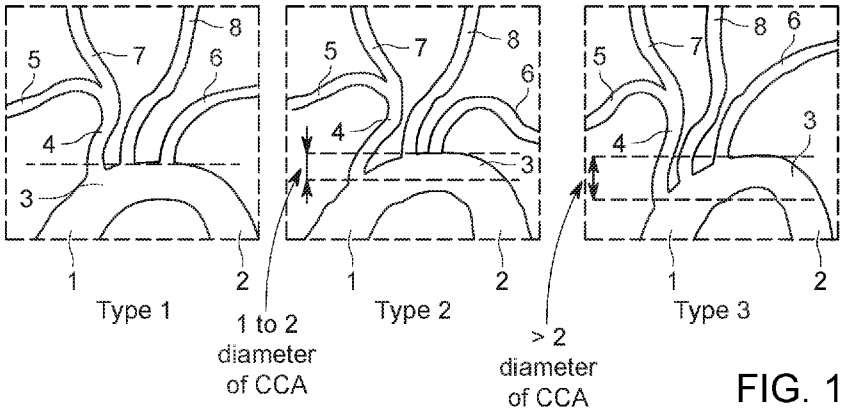


FIG. 1

(57) **Abstract:** Systems and methods to provide end to end stabilization support to the operational catheter and reduce the need to stabilize or push from the lateral wall of the aorta during coronary interventions. This reduces the potential for stroke from plaque breaking off the wall of the aorta during intervention procedures. A support and stabilization wire having one end at the femoral percutaneous access and the second end at a radial percutaneous access is established for end to end stabilization. A bifurcated catheter having a wide lumen for procedural catheters and a narrow lumen for the support wire or catheter is advanced over the support wire to the aortic arch. A procedural catheter and a variety of different shaped guide wires may be deployed from the wide lumen of the bifurcated catheter into the right or left coronary artery to accommodate a range of aortic anatomical considerations during the coronary interventions.

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BIFURCATED "Y" ANCHOR SUPPORT FOR CORONARY INTERVENTIONS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation-in-part of U.S. Patent Application No. 14/929,030, titled: APPARATUS AND METHOD FOR A BIFURCATED CATHETER FOR USE IN HOSTILE AORTIC ARCHES, filed October 30, 2015, the entirety of which is hereby incorporated by reference.

[0002] This application is also related to PCT Application No. PCT/US2016/024795, entitled APPARATUS AND METHOD FOR A BIFURCATED CATHETER FOR USE IN HOSTILE AORTIC ARCHES, filed March 29, 2016, U.S. Application No. 15/227,189, entitled APPARATUS AND METHOD FOR STABILIZATION OF PROCEDURAL CATHETER IN TORTUOUS VESSELS, filed August 3, 2016, PCT Application No. PCT/US2016/047165, entitled APPARATUS AND METHOD FOR STABILIZATION OF PROCEDURAL CATHETER IN TORTUOUS VESSELS, filed August 16, 2016, U.S. Application No. 15/420,790, entitled APPARATUS AND METHOD FOR STABILIZATION OF PROCEDURAL CATHETER IN TORTUOUS VESSELS, filed January 31, 2017, U.S. Application No. 15/492,667, entitled APPARATUS AND METHOD FOR IMPROVED ACCESS OF PROCEDURAL CATHETER IN TORTUOUS VESSELS, filed 4/20/2017, U.S. Provisional Application No. 62/352,353, entitled APPARATUS AND METHOD FOR STABILIZATION OF PROCEDURAL CATHETER IN TORTUOUS VESSELS, filed June 20, 2016, U.S. Provisional Application No. 62/467,785, entitled APPARATUS AND METHOD FOR IMPROVED ACCESS OF PROCEDURAL

CATHETER IN TORTUOUS VESSELS WITH A PULL COMPONENT ON THE STABILIZATION WIRE/CATHETER, IN ADDITION TO PUSH COMPONENT FROM THE PERCUTANEOUS ACCESS, filed March 6, 2017, the entireties of which are hereby incorporated by reference.

BACKGROUND

1. Field

[0003] The invention relates to improved methods and apparatus used in catheter based interventional procedures, and, in particular, coronary interventions that utilize a bifurcated catheter.

2. Related Art

[0004] Stenting of the carotid artery (CA) is relatively new to interventional procedures. It is a challenging procedure because accessing the left or right carotid artery can be dependent on the anatomical disposition of the aortic arch.

[0005] Figure 1 illustrates the aortic arch. As shown in Figure 1, the aorta 1 includes an aortic arch region 3, a descending aorta 2, and an innominate 4. Three types of arches shown in Fig. 1: Type I, Type II and Type III arches. Also shown in Figure 1 is the right subclavian artery (RSA) 5, left subclavian artery (LSA) 6, right common carotid artery (RCCA) 7 and left common carotid artery (LCCA) 8.

[0006] The arch types are defined by the height of the top of the aortic arch 3 from the base location where the innominate 4 attaches to the aorta. In a type I arch, the height is less than the diameter of the common carotid artery (CCA). Similarly, in a type II arch, the height of the top of the arch 3 from the base of the innominate 4 is of the order of 1 to 2 times the diameter of the CCA. In a type III arch, the height is more than twice the diameter of the CCA. As the height of the arch increases the

procedures within the carotid arteries become more and more difficult due to the tortuous nature of the arterial connections to the aorta at the arch.

[0007] In type III hostile aortic arches, the arch itself can be very acute thus making the access of the left or right carotid arteries ostium difficult. Subsequent placement of a stent delivery system in a stable mode into the arterial system above it therefore becomes more difficult. The stenting procedure itself is meant to re-establish a more normalized blood flow through the carotid and internal carotid artery into the brain by opening up regions of the artery constricted by plaque deposits which inhibit flow. The stents themselves can be self-expanding, balloon expandable, bio-absorbable, and/or covered. The stent delivery systems are designed to accommodate very acute bends but are reliant upon the guide catheter and guide wires and or embolic protection devices to stabilize them during deployment. Stents have been used to open "stenosis"– semi-occluded sections of the arterial system - for many years. They come in a wide variety and are designed for specific areas of the body, these include: balloon expandable, self-expanding, covered and bio-absorbable stents. Stenting in the neck and procedures above the neck are challenging when confronted with a type III hostile aorta, in particular stenting of the left or right carotid artery.

[0008] During the insertion, manipulation and stabilization of the stent delivery mechanism and during removal of the guide wire and secondary wire, injuries to the subclavian artery and the tortuous aortic arch can happen. This can be caused by uncontrolled collapse of the sheath, embolic protection device (EPD) and stent / stent delivery system in the ascending aorta during procedure. This type of prolapse can result in the patient suffering cerebral embolism or stroke by dragging the fully deployed EPD over the carotid stenosis. Further, dragging the guide wires over the

tortuous arterial regions can cause cutting into the arterial walls or otherwise injuring the artery resulting in dissections and trauma to the vessels involved. These traumas can be dangerous to the patient as they can ultimately directly affect blood flow by leakage at the dissections or by creating accumulation of thrombus, an organization of blood cells, which is a natural reaction to vessel injury. These may require additional procedures to repair and heal the damaged artery walls and prevent problems.

[0009] Accordingly, systems and methods are needed to stabilize the sheath, catheters and procedural instruments within the coronary arterial system to reduce injury to the arterial walls during coronary interventions.

SUMMARY

[0010] The following summary of the invention is included in order to provide a basic understanding of some aspects and features of the invention. This summary is not an extensive overview of the invention and as such it is not intended to particularly identify key or critical elements of the invention or to delineate the scope of the invention. Its sole purpose is to present some concepts of the invention in a simplified form as a prelude to the more detailed description that is presented below.

[0011] In accordance with one aspect of the invention, a coronary percutaneous intervention system is disclosed that includes a sheath catheter; a stabilization wire routeable through the sheath catheter; a bifurcated catheter having a wide lumen and a narrow lumen, wherein the narrow lumen is routeable along the stabilization wire; and, a procedural instrument for performing a coronary intervention, the procedural instrument routeable through the wide lumen of the bifurcated catheter.

[0012] The stabilization wire may include a guide wire insertable through a vessel in the thoracic cavity via radial access. The bifurcated catheter may be insertable

through the sheath catheter over the stabilization wire. The wide lumen of the bifurcated catheter may be operable as a procedural lumen, and the narrow lumen of the bifurcated catheter may be operable as a stabilization lumen. The stabilization lumen may be used to slideably receive a snare catheter and the stabilization wire. The stabilization wire may be configured to snare the guide wire and pull a portion of the guidewire within the bifurcated catheter.

[0013] In accordance with another aspect of the invention, a coronary percutaneous intervention system is disclosed that includes a sheath catheter percutaneously insertable via femoral access and having a distal end positionable in an aortic arch; a stabilization wire deliverable to the aortic arch through right radial access; a snare wire comprising a snare slideably insertable through the sheath catheter, the snare wire configured to snare the stabilization wire and pull it through the sheath catheter until the stabilization wire extends from an entry point of the right radial access to an entry point of the femoral access, with an extension for gripping and feeding at each exposed end; a bifurcated catheter insertable through the sheath catheter over the stabilization wire, a distal portion of the bifurcated catheter extending beyond the ostium of the sheath catheter, the bifurcated catheter further comprising a narrow sheath, a wide sheath and a "Y"-shaped junction between the narrow sheath and wide sheath, the "Y"-shaped junction positionable in the aortic arch, wherein the narrow sheath of the bifurcated catheter is advanceable along the stabilization wire such that the stabilization wire enters the right subclavian artery at the origin of the right subclavian artery; a first special purpose guidewire slideably inserted into the sheath catheter, occupying the wide sheath of the bifurcated catheter, extending from the ostium of the wide sheath into the left or right coronary artery; a first procedural instrument advanced along the first special purpose guidewire to the

location of a first procedure; and, wherein a predetermined coronary intervention is performed using the first procedural instrument.

[0014] The bifurcated catheter may further include a common catheter portion at a proximal end of the bifurcation catheter, wherein the narrow sheath and the wide sheath join with the common catheter portion at the "Y"-shaped junction.

[0015] The bifurcated catheter may be pre-loaded into the sheath catheter.

[0016] In accordance with a further aspect of the invention, a method for performing a coronary percutaneous intervention is disclosed that includes inserting a first sheath catheter percutaneously via a first femoral access, having a first distal end positionable in an aortic arch; inserting a first stabilization wire to the aortic arch via a first radial access; slideably inserting a first snare wire through the first sheath catheter, the first snare wire configured to snare the first stabilization wire and pull it through the first sheath catheter until the first stabilization wire extends from an entry point of the first radial access to an entry point of the first femoral access, with an extension for gripping and feeding at each exposed end; inserting a first bifurcated catheter through the first sheath catheter over the first stabilization wire, a distal portion of the first bifurcated catheter extending beyond the ostium, the bifurcated catheter further comprising a narrow sheath, a wide sheath and a "Y"-shaped junction between the narrow sheath and wide sheath, the "Y"-shaped junction positionable in the aortic arch; slideably inserting a first special purpose guidewire into the first sheath catheter such that it occupies the first wide sheath of the first bifurcated catheter, extending from the ostium of the first wide sheath into a first selected coronary artery; advancing a first procedural instrument along the first special purpose guidewire to a first location in the selected coronary artery; inserting a second

sheath catheter percutaneously via a second femoral access and having a second distal end positionable in the aortic arch; delivering a second stabilization wire to the aortic arch through a second radial access; slideably inserting a second snare wire through the second sheath catheter, the second snare wire configured to snare the second stabilization wire and pull it through the second sheath catheter until the second stabilization wire extends from an entry point of the second radial access to an entry point of the second femoral access, with an extension for gripping and feeding at each exposed end; inserting a second bifurcated catheter through the second sheath catheter over the second stabilization wire, a distal portion of the second bifurcated catheter extending beyond the ostium, the bifurcated catheter further comprising a narrow sheath, a wide sheath and a "Y"-shaped junction between the narrow sheath and wide sheath, the "Y"-shaped junction positionable in the aortic arch; slideably inserting a second special purpose guidewire into the second sheath catheter, occupying the second wide sheath of the second bifurcated catheter and extending from the ostium of the second wide sheath into a second selected coronary artery;advancing a second procedural instrument along the second special purpose guidewire to a second location in the selected coronary artery; and, cooperatively operating the first and second procedural instruments to perform the coronary percutaneous intervention.

[0017] The first and second locations may be closely spaced. The first and second locations may be juxtaposed. The first and second locations may each be adjacent to a coronary occlusion.

[0018] In accordance with yet another aspect of the invention, a method for percutaneous coronary intervention is disclosed that includes utilizing a primary access point for catheters and at least one procedural instrument, the primary access

point comprising an artery having a wide ostium such as a femoral artery; utilizing at least one secondary access point for a stabilization wire, the at least one secondary access point comprising a brachial artery, an ulnar artery, a branch of the carotid artery, a superficial temporal artery, or a unique branch of an upper extremity artery; and performing a coronary intervention using the at least one procedural instrument, wherein the at least one secondary access point enables positioning of a stabilization wire for stabilization of the system during the coronary intervention.

[0019] In yet a further aspect of the invention, a method for performing a coronary intervention is disclosed that includes advancing a main sheath to the aortic arch vial femoral access; advancing a stabilization wire to the aortic arch via right radial access using radiographic imaging; advancing a snare wire into the aortic arch via the main sheath; ensnaring a distal end of the stabilization wire with the snare wire; pulling the stabilization wire into the main sheath and extracting the stabilization wire at the femoral access for providing end-to-end stabilization capability from an entry point of the right radial access to an entry point of the femoral access, with extensions for gripping and feeding each end of the stabilization wire; advancing a bifurcated catheter along the stabilization wire and through the main sheath, into the aortic arch, wherein the bifurcated catheter comprises a narrow lumen and a wide lumen and the stabilization wire occupies the narrow lumen; fully deploying a "Y" sheath of the bifurcated catheter in the aortic arch, wherein the "Y" sheath comprises the narrow lumen and the wide lumen and further comprises a narrow sheath corresponding to the narrow lumen and a wide sheath corresponding to the wide lumen; advancing the narrow sheath along the stabilization wire using the narrow lumen of the fully deployed "Y" sheath into the right subclavian artery at its origin; advancing at least one special purpose guide wire through the wide lumen of

the "Y" sheath into the right or left coronary artery; inserting and deploying a procedural catheter over the at least one special purpose guide wire to a procedure location; removing the guide wire from the procedural catheter and replacing it with at least one procedural instrument; and, performing a predetermined coronary intervention using the at least one procedural instrument.

[0020] The method may further include applying tension to the stabilization wire.

BRIEF DESCRIPTION OF THE DRAWINGS

[0021] The accompanying drawings, which are incorporated into and constitute a part of this specification, illustrate one or more examples of embodiments and, together with the description of example embodiments, serve to explain the principles and implementations of the embodiments.

[0022] Figure 1 is a schematic diagram illustrating the three types of aortic arches encountered in humans.

[0023] Figure 2 is a schematic diagram illustrating a distal end of a device with a snare wire extended from the main guide catheter capturing a stabilization wire from the subclavian artery (SA) in accordance with one embodiment of the invention.

[0024] Figure 3 is a schematic diagram illustrating the aortic arch with a stabilization guide wire snared and pulled into the main guide catheter and out the proximal end in accordance with one embodiment of the invention. The bifurcated catheter may or may not be at this stage located just inside the distal tip of the main guide catheter. The bifurcated catheter in one embodiment may be advanced over the wire after step S808A (Figure 8A) while in another embodiment the bifurcated catheter may be pre-loaded at the distal tip of the main guide catheter (Figure 8B).

[0025] Figure 4 is a schematic diagram illustrating a reverse curve diagnostic catheter with a guide wire coming out of in the distal tip of the main guide catheter and up into the left common carotid artery in accordance with one embodiment of the invention. In one embodiment, the reverse curve diagnostic catheter with the guide wire is extended out of the sheath or the main guide catheter, and in another embodiment, the bifurcated catheter is at the distal tip of the main guide catheter and the reverse curve diagnostic catheter with the guide wire comes out of the larger leg of the bifurcated catheter.

[0026] Figure 5 is a schematic diagram illustrating removal of a reverse curve diagnostic catheter, leaving behind a stiff guide wire in the left common carotid artery in accordance with one embodiment of the invention.

[0027] Figure 6 is a schematic diagram illustrating a bifurcated catheter being advanced out of a main guide catheter over respective guide wires, the large leg over the stiff guide wire into the left common carotid artery and the small leg being advanced over the guide wire into the right subclavian artery in accordance with one embodiment of the invention.

[0028] Figure 6A is a cross-sectional view of a portion of the bifurcated catheter in accordance with one embodiment of the invention.

[0029] Figure 7 is a schematic diagram of the legs of the bifurcated catheter advanced out of the main guide catheter and parked into their respective vessels in accordance with one embodiment of the invention. In some embodiments, the atraumatic tips are removed from each leg and the stabilized catheter is ready for procedures.

[0030] Figure 8A is a flow chart of a procedure for stabilizing the process catheter and stenting systems in accordance with one embodiment of the invention.

[0031] Figure 8B is a flow chart of a procedure for stabilizing the process and stent catheters in which one of bifurcations of the pre-loaded bifurcated catheter is used to accommodate the snare/ stabilization catheter in accordance with one embodiment of the invention.

[0032] Figure 9 is a schematic diagram showing the snare wire extended from a protective sheath through the subclavian artery (AS) in accordance with one embodiment of the invention.

[0033] Figure 10 is a schematic diagram showing a wire extended out of a side hole of the initial reverse curve diagnostic catheter to be captured by the snare in accordance with one embodiment of the invention.

[0034] Figure 11 is a schematic diagram illustrating capturing the stabilization wire by the snare wire loop in accordance with one embodiment of the invention.

[0035] Figure 12 is a schematic diagram of the extension of a stiff guide wire from the reverse curve Simmons catheter into the carotid artery in accordance with one embodiment of the invention.

[0036] Figure 13 is a schematic diagram showing the removal of the reverse catheter leaving the guide wire and the stabilization wire in place in accordance with one embodiment of the invention.

[0037] Figure 14 is a schematic diagram of the working sheath catheter, having an atraumatic tip and the working sheath catheter having a second chamber for the guide

wire extending out of a side hole, being advanced over the guide wire in accordance with one embodiment of the invention.

[0038] Figure 15 is a schematic diagram of the working sheath catheter advanced to the location of the procedure and the guide wire removed in readiness for a procedure in accordance with one embodiment of the invention.

[0039] Figure 16 is a flow diagram for stabilizing the process catheters and systems in accordance with one embodiment of the invention.

[0040] FIG. 17 is a schematic diagram depicting the preliminary steps in performing a coronary intervention, including the use of a snare wire, in accordance with one embodiment of the invention.

[0041] FIG. 18 is a schematic diagram showing how the snare is tightened around the guide wire, and drawn into a narrow arm of the main sheath, in accordance with one embodiment of the invention.

[0042] FIG. 19 is a schematic diagram illustrating a bifurcated "Y" sheath being formed at the distal end of the main sheath, and being advanced along the guide wire toward the right subclavian artery in accordance with one embodiment of the invention.

[0043] FIG. 20 is a schematic diagram illustrating the fully deployed "Y" sheath and a narrow protective sheath being advanced along the guide wire and into the right subclavian artery at its origin in accordance with one embodiment of the invention.

[0044] FIG. 21A is a schematic diagram illustrating the narrow protective sheath being further advanced into the right subclavian artery, and a variety of different shaped guides that may deploy from the "Y" sheath into the coronary arteries.

[0045] FIG. 21B is a schematic diagram illustrating the simultaneous use of more than one procedural instrument in accordance with one embodiment of the invention.

[0046] FIG. 22 is a flow chart depicting a method for performing a coronary intervention in accordance with one embodiment of the invention.

[0047] FIG. 23 is a flow chart illustrating a method for performing a coronary intervention in accordance with another embodiment of the invention.

DETAILED DESCRIPTION

[0048] Embodiments of the invention are directed to new devices and associated methods for the placement of stents in the carotid artery, and especially into the left or right carotid arteries, for procedures above the neck. These new devices and associated methods stabilize the working lumen or delivery sheath for the carotid stent delivery system. These new devices and associated methods also protect the innominate and subclavian artery as well as the aortic arch from trauma during stenting and other procedures above the neck where there is a possibility for trauma to the arteries as a result of tension on the secondary or stabilization guidewire. This is especially true in the case of patients with type II and Type III aortic arch.

[0049] Embodiments of the invention are also directed to new devices and associated methods for the placement of procedural instruments in coronary arteries. A methodology to provide end to end stabilization support to the operational catheter and reduce the need to stabilize or push from the lateral wall of the aorta

during coronary interventions. This reduces the potential for stroke from plaque breaking off the wall of the aorta during intervention procedures. A support and stabilization wire having one end at the femoral percutaneous access and the second end at a radial percutaneous access is established for end to end stabilization. A bifurcated catheter that comprises a wide lumen for procedural catheters and a narrow lumen for the support wire or catheter is advanced over the support wire of the aortic arch. A procedural catheter and a variety of different shaped guides may deploy from the wide lumen of the bifurcated catheter into the right or left coronary artery, to accommodate a range of aortic anatomical considerations during the coronary interventions.

[0050] Embodiments of the invention are directed to the application and use of guide wires for stabilization of the catheters used to access the left or right carotid arteries (CA) for carotid percutaneous intervention of the vessels originating from a tortuous aortic arch.

[0051] Embodiments of the invention use a bifurcated catheter having a main catheter arm that is used to extend into the region of the procedure and a support catheter arm that extends into the right subclavian artery to provide protection to that vessel during tightening of a support and stabilization wire through the right subclavian artery. The head of a sheath/ guide catheter is at that time placed in the aorta, at the branching of either innominate or the left or right carotid artery through which the procedural arm of the bifurcated catheter, that is the second branch of the bifurcated catheter, has to be extended to conduct the procedure or place the stent. The correct placement of the head of the sheath catheter and the extension of the

support catheter to cover the support wire enable the wires to be extended and retracted without damage to the arch and the arterial vessels used during procedure.

[0052] In some embodiments, the bifurcated catheter includes a main catheter that divides into two separate catheters forming a "Y" shape. One leg of the bifurcated catheter has a smaller diameter with a smaller working lumen (inner diameter) to carry the stabilizing wire and the second leg of the bifurcated catheter has a larger working lumen for arterial stenting operations/procedures. This bifurcated catheter addresses the percutaneous intervention related trauma to the vessels that arise from type-II or type-III hostile aortic arches, from uncontrolled prolapse of the sheath, embolic protection device and stent delivery system, by stabilizing the systems, using a through-and-through stabilization wire for applying tension during stenting of the left and right carotid arteries.

[0053] In one embodiment, a sheath catheter is percutaneously inserted at the groin and directed through the descending aorta to the aortic arch. A snare is inserted through the sheath and linked with a .014 inch or .018 inch guide wire from the right subclavian artery (via the right radial or brachial artery access) to provide a stabilization wire for the operational catheter. At this stage, the stabilization wire and the main guide wire occupy the sheath catheter. A reverse curve catheter is then inserted through the sheath catheter over the main guide wire, parallel to the stabilization wire and guided to the common carotid artery from the aortic arch. A stiff guide wire is then inserted through the reverse catheter to the location of the procedure. The reverse curve catheter is then removed leaving the guide wire in the location of the procedure. The bifurcated catheter is then guided to the aortic arch with one stabilization leg over the stabilization wire and the other operational leg over

the stiff guide wire such that the operational leg is guided into the common carotid artery while the stabilization leg is guided over the stabilization wire into the subclavian artery. The stiff guide wire is then removed leaving the operational leg of the bifurcated catheter in place for treatment procedures.

[0054] In one embodiment, a secondary stabilization wire having a small diameter, e.g., .014 or .016 inch, is guided through a, for example, Fr-3 or Fr-5, micro sheath, which is placed percutaneously through the right radial or brachial artery and threaded through the subclavian artery and snared into the main guide catheter to stabilize the distal tip. This way, the tension can be applied to the distal tip of the guide catheter to stabilize it in a more planar orientation by putting tension on the stabilization wire, as discussed above, to aid in the stabilization of the guide catheter, which is placed under fluoroscopy (C Arm) in the aorta using percutaneous access. This secondary stabilization wire is hence inserted into the right radial or brachial artery and guided through the right subclavian artery and down and out of the guide catheter. Though the description is provided for the secondary access via the right radial of brachial artery, it should not be considered limiting. It is possible to provide the secondary access via the left radial or brachial artery, external carotid artery or common carotid artery (instead of just the right radial or brachial artery). It may also be possible to have more than one accessory access to complete the procedure using the device. Once the stabilization wire is established, a tension is applied to one or both ends of the secondary stabilization wire to help stabilize the distal end of the guide catheter during the accessing of the left or right internal carotid artery. This allows the stent delivery system to track more easily through the acute anatomy of the arch, especially one such as a type III arch.

[0055] In another embodiment, the bifurcated catheter is pre-loaded into the end of the main guide catheter or long sheath. In this embodiment, the bifurcated catheter has a procedural lumen and a second lumen that can accommodate a snare catheter and wire. It will be appreciated, however, that a potential disadvantage of this device is that the catheter will need to be a bigger device to accommodate the two lumens, but the advantage is that it separates the wires from the beginning so that the wires do not inadvertently wrap around each other during the procedure and cause problems. In this embodiment, the guide catheter is provided with a bifurcated distal configuration having two legs in the form of a Y at the distal end. One leg is of a large diameter, typically having an inner diameter or "working lumen" sufficient to allow the passage of a stent delivery system or other therapeutic devices. The second leg is of a smaller diameter than the first leg with an inner diameter sufficient to accept a snare wire and snare the stabilization guide wire. This bifurcated catheter is sized so as to fit easily through the main guide catheter placed at the start of the procedure and is of sufficient length so as to allow the main leg of the bifurcated catheter to be placed into the carotid artery for stenting and other procedures there and above the neck. The secondary leg is of sufficient length so as to be placed over a stabilization wire from the right subclavian artery and cover it sufficiently to prevent damage to the vessels it passes through while providing the necessary stabilization to the main guide catheter and the bifurcated catheter, during procedural manipulations. Both legs of the bifurcated catheter need not be of the same stiffness or durometer to be able to navigate their respective vessels. For instances the main carotid leg may be of a lesser durometer so as to navigate the arch into the selected carotid artery without affecting the natural anatomic configuration whereas the small leg may be stiffer so as to help with the stabilization of the main guide catheter.

[0056] In one embodiment, another practical device and method for safely accessing the carotid artery is disclosed. In this a first reverse curve catheter is inserted percutaneously and directed into the right or left common carotid artery (RCCA or LCCA). A secondary wire is inserted in the reverse curve catheter and out of a hole in the catheter at the location of the arch to be captured by a snare wire that is extended out of a protective sheath extended through the subclavian artery (typically via right radial artery access). Once the snare has captured the stabilization wire a more rigid guide wire is extended through the reverse catheter into the common carotid artery towards the location of the procedure. The reverse catheter is then removed leaving both the rigid guide wire and the stabilization wire in place. A sheath/ procedural catheter with a conical atraumatic tip and also having therein a second chamber with a hole close to the distal end for providing an exit for the stabilization wire is advanced over the guide wire and stabilization wires to the aortic arch and the sheath catheter is extended on to the location of procedure. Tension is applied to the stabilization wire for providing support to any working catheter that is inserted through the sheath catheter after removal of the stiff guide wire for conducting the procedure as needed.

[0057] In some embodiments, a sheath cover may be used for the stabilization wire as it extends into the subclavian artery when tension is applied prevent unwanted damage to the artery. The stabilized main sheath helps the procedure to be completed and the operational catheter and the sheath catheter to be removed safely.

[0058] In some embodiments, a reverse curve guide catheter with a lumen large enough for stenting is used to select the common carotid artery. A secondary wire is inserted in the reverse curve catheter through a parallel lumen in the reverse curve

catheter and out of a hole in the catheter at the location of the arch. This secondary wire is then captured by a snare wire with a loop that is extended out of a protective sheath extended through the subclavian artery, typically inserted via right radial artery access. The carotid stenting procedure can now proceed in the standard way described above since the reverse curve guiding catheter itself is stabilized and is usable for procedure.

[0059] In percutaneous procedures of the vessels originating from a tortuous aortic arch, the use of stabilization wires in addition to guide wires to guide and stabilize the delivery catheters used to access the left or right carotid arteries is disclosed. The need for the stabilization of the sheath, the embolic protection device (EPD) and the stent delivery system (SDS) is to prevent the uncontrolled prolapse of the sheath, EPD and SDD during stenting procedure in the ascending aorta. This type of prolapse can result in cerebral embolism or stroke in patients by the dragging of the fully deployed EPD across critical carotid internal artery stenosis. Embodiments of the invention provide for stabilizing the sheath, the EPD and the SDS within the left or right carotid arteries by providing a secondary stabilization wire that holds the primary sheath in place within the tortuous aortic arch during the procedure, thereby providing the necessary stability for the SDS within the carotid artery during the procedure. These stabilizing wires typically originate from a low profile radial or brachial artery access and provide a through-and-through tension and support to the sheath by enabling the application of tension to one or either end of the stabilization wire through a typical micro-sheath or catheter. In this embodiment the brachial artery or a small radial artery is usable with the micro-sheath, and similarly in the case of another embodiment described the sheath catheter is used to puncture the radial artery or the brachial artery for entry, to provide adequate hemostasis while keeping

the entry profile low. In one embodiment, the stabilization wire has a small diameter, e.g., 0.014 or .018 inch diameter, the micro-sheath has a 3 Fr. Diameter, and the sheath catheter has a 5 Fr. Diameter. The use of the small size wire and micro-sheath is useful in preventing hematoma in the brachial artery, which can be devastating in patients receiving anticoagulation drugs, such as Heparin, and anti-platelet therapy such as Plavix, during or after the procedure. The stabilizing wire from the brachial artery enters the aortic arch through the right subclavian artery to be captured and brought out through the sheath at its proximal end. Due to their diameter and forces applied during the procedures, the guide wires, if used without proper covering can inadvertently cause trauma to the associated tortuous vessels walls. The bifurcated catheter disclosed herein provides the necessary protection to the arch and the subclavian artery while providing the necessary stabilization to the sheath, SDS and EPD for access and procedures within the carotid arteries, especially for above the neck procedures. The bifurcated catheter disclosed includes a main catheter that divides into two separate catheters forming a "Y" shape. One leg of the catheter has a smaller diameter with a smaller working lumen (inner diameter), to carry the stabilizing wire, than the second leg of the catheter that has a larger working lumen for arterial stenting operations. This device provides the necessary stability to the system for stenting of the carotid arteries while addressing the percutaneous intervention related trauma to the vessels associated with type-III hostile aortic arches that arise therefrom. Multiple embodiments of the invention are described here under. Even though in the examples described the secondary access is shown as being established via the right radial or brachial artery, it should not be considered limiting in any way. The secondary access may be established via any of the left radial or brachial artery, external carotid artery or common carotid artery (instead of just the

right radial or brachial artery). It may also be possible to have more than one accessory access to complete the procedure using the device.

[0060] A first embodiment of the invention is described with reference to the schematic diagrams shown in Figures 2 to 7 and the flow chart of Figure 8A. This embodiment illustrates the ability to conduct procedures such as stenting in the left internal carotid artery (LICA) 16 using a procedural catheter that can be inserted through the aortic arch 13 and left common carotid artery 15.

[0061] As shown in Fig. 2, a sheath catheter 18 is initially inserted percutaneously and guided using fluoroscopic tracking using the opaque metal ring 20 at its distal end. In one embodiment, the sheath catheter 18 is a 7 French (Fr) or 8 Fr sheath; it will be appreciated that differently sized sheath catheters may be used as known to those of skill in the art. The sheath 18 is guided through the femoral artery and the descending thoracic aorta 12 to the aortic arch 13. A snare wire is inserted through the sheath 18 and extended to the aortic arch 13 with a snare loop 21. In one embodiment, the snare loop has a diameter that is any value or range of values between about 20 to 30 mm; it will be appreciated that the diameter may be less than about 20mm or greater than about 30mm.

[0062] A second stabilization wire 19 is inserted through the radial artery and guided through the subclavian artery 14 to the aortic arch 13. In one embodiment, the second stabilization wire has about a 0.014 inch diameter. The stabilization wire 19 is captured by the snare 21 and then pulled into the sheath catheter 18, as shown in Figure 3. In one embodiment, the snare 21 pulls the stabilization wire such that it exits the proximal end of the sheath 18 to form a through-and-through stabilization wire. In one embodiment, a 3 Fr. to 5 Fr. sheath may be used over the 0.014

stabilization wire 19 to reduce slicing and trauma to the arteries the wire is guided through.

[0063] A reverse curve catheter 24 with an atraumatic tip is then inserted in parallel with the stabilization wire 19 through the sheath catheter 18, as shown in Fig. 4. The reverse curve catheter 24 is used to select the left common carotid artery 15. A stiff wire 23 is then inserted through the reverse curve catheter 24 to the site of the procedure. In one embodiment, the stiff wire has an approximately 0.035 inch diameter.

[0064] Next, the reverse curve catheter 24 is removed, leaving the stiff wire 23 in the area of the procedure and the stabilization wire 19 in place, as shown in Fig. 5. Both the stiff wire 23 and stabilization wire 19 occupy the large sheath catheter 18, as shown in Fig. 5.

[0065] A bifurcated catheter having bifurcations 25 and 26 is then advanced over both the stiff wire 23 and the stabilization wire 19 respectively and out of the guide catheter 18. The large leg (or bifurcation) 25 which contains a procedural catheter tracks along the stiff guide wire 23 into the left common carotid artery 15. The small leg (or bifurcation) 26 tracks along the stabilization wire 19 coming from the right subclavian /innominate artery. Both legs 25, 26 have atraumatic tips 28 to reduce trauma, as shown in Fig. 6.

[0066] Fig. 6A is a cross-sectional view of a portion of the bifurcation catheter within the sheath catheter 18. The bifurcation catheter includes a common catheter portion that bifurcates into two separate bifurcations or legs 25, 26 at junction 30. As shown in Fig. 6A, each of the bifurcations of legs 25, 26 include lumens that extend from a distal end of the bifurcation catheter to a proximal end of the bifurcation

catheter. As shown in Fig. 6A, the bifurcated leg 25 is configured to slideably receive the guidewire 23, and the bifurcated leg 26 is configured to slideably receive the stabilization wire 19.

[0067] Once the bifurcated catheter is in place, the stiff wire and the atraumatic tips are removed and tension is applied to the stabilization wire from both ends to stabilize and position the operational end of the bifurcated catheter, as shown in Fig. 7.

[0068] The bifurcated catheter is now ready for stenting or other procedures in the left internal carotid artery 16.

[0069] Figure 8A illustrates the process 800A described above with reference to Figures 2-7.

[0070] The process 800A begins by inserting a sheath catheter 18 catheter through the groin access and guided using radiographic imaging using the opaque ring 20 at its distal end through the descending aorta 12 to a location in the aortic arch 13 suitable for access into the left common carotid artery 15 (block S801A).

[0071] The process 800A continues by inserting and advancing a snare wire through the sheath catheter 18 and out its distal end into the aortic arch 13 (block S802A).

[0072] The process 800A continues by inserting a second stabilization guide wire 19 through the radial artery and guiding it through the right subclavian artery 14 to the aortic arch 13 (block S803A).

[0073] The process 800A continues by using the snare loop 21 of the snare wire to capture the guide wire 19 and pull it through the sheath catheter 18 to its proximal end to provide an end-to-end stabilization wire over which tensions can be applied (block S804A).

[0074] The process 800A continues by advancing a reverse curve catheter 24 up the lumen of the sheath catheter 18 and into the left common carotid artery 15, again using the opaque ring 25 at its distal end (block S805A).

[0075] The process 800A continues by advancing a reasonably stiff guide wire 23 up the reverse curve catheter 24 and into the left common carotid artery 15 to the location of the procedure near the left internal carotid artery 16 (block S806A).

[0076] The process 800A continues by removing the reverse curve catheter 24, leaving the stabilization wire 19 and the stiff guide wire 23 in place, both occupying the lumen of the sheath catheter 18 (block S807A).

[0077] The process 800A continues by inserting a bifurcated catheter having a main operational leg 25 over the stiff guide wire 23 and having a stabilization leg 26 over the stabilization wire 19 (block S808A).

[0078] The process 800A continues by advancing the bifurcated catheter having atraumatic tips 28 on the end of the main operational catheter leg 25 to the aortic arch 13 through the sheath catheter 18 (block S809A).

[0079] The process 800A continues by advancing the main operational leg 25 to the location of the procedure by advancing the main operational catheter leg 25 over the stiff wire 23 (block S810A).

[0080] The process 800A continues by extending the second leg 26 of the bifurcated catheter over the stabilization wire 19 through the innominate and the subclavian artery 14 (block S811A).

[0081] The process 800A continues by removing the stiff wire 23 and the atraumatic tips 28 and applying tension to the stabilization wire 19 to stabilize the working lumen leg 25 at just below the left internal carotid artery 16 (block S812A).

[0082] The process continues by performing any treatment procedure, including stenting of the left internal carotid artery 16, through the main operational catheter leg 25 (block S813A).

[0083] In another embodiment, the bifurcated catheter accommodates the snare catheter in the secondary lumen. In this embodiment, one leg 25 of the bifurcated catheter is used as the procedural catheter and the other leg of the bifurcated catheter 26 is used initially to send in the snare loop 21 and capture the stabilization wire 19. A reverse curve catheter 24 is sent through the procedural leg 25 of the bifurcated catheter into the LCCA 15 or RCCA and the stiff guide wire 23 is placed at the location of the procedure site. The second leg of the bifurcated catheter already at the aortic arch 13 is equipped with an atraumatic tip 28 and guided along the wire 23 to the location of the procedure. At the same time, the first leg 26 of the bifurcated catheter is extended to cover the stabilization wire 19 into the subclavian artery 15. The atraumatic tip 28 and the stiff wire 23 are then removed and the second leg 25 of the bifurcated catheter is ready for the next treatment steps at the site, including stenting or other procedures. This embodiment is further described with reference to Figures 2-7 and Figure 8B.

[0084] In this embodiment, a bifurcated catheter is inserted with the main sheath catheter. In this embodiment, the bifurcated catheter has two chambers therein, one for the procedure and the second chamber for the snare catheter, snare loop/wire, and stabilization wire. This enables passing a snare catheter, snare loop/wire and stabilization wire all through a second chamber/branch of the bifurcated catheter when it is at the apex of the curve of the aortic arch similar to the process described earlier. The process is described below with reference to Figures 2-7 and flow chart 800b of Figure 8B.

[0085] Figure 2 illustrates the distal end of sheath catheter device 18, showing the distal end 20 of the device percutaneously inserted and advanced through the descending thoracic aorta 12 to the aortic arch 13. The bifurcated catheter (not shown) is inserted with the sheath catheter and advanced to the aortic arch 13. A snare wire with a 20 to 30 mm snare is shown extended from the sheath catheter in Figure 2. In this embodiment, the snare is within the smaller chamber of the bifurcated catheter within the sheath catheter. The snare captures a stabilization wire 19 that is extended into the aortic arch 13 from the right subclavian artery (RSA) 14, as shown in Figure 2. Figure 2 further shows the ascending aorta 11, the LCCA 15, the left internal carotid artery 16 and the heart 50.

[0086] Figure 3 shows the snare being tightened 22. In this embodiment, the snared stabilization wire 19 is pulled into the smaller lumen of the bifurcated catheter (not shown) and to the proximal end of the same to provide and end-to-end stabilization for the procedural catheter.

[0087] Figure 4 shows a reverse curve catheter 24 such as a Simmons catheter with a stiff wire 23 being extended from the sheath catheter 18. The reverse curve

catheter 24 is extended through the second, larger chamber of the bifurcated catheter into the CCA 15 and advanced to the site of the procedure at just below the left internal carotid artery 16.

[0088] The left carotid artery is shown in the figures but it is not meant to be limiting as procedures in both right and left carotid can be addressed with this implementation. Also the carotid artery may be selected with the same reverse guide catheter and a softer guidewire. Once selection has occurred the softer guidewire may be exchanged for the stiffer guidewire.

[0089] Figure 5 shows the stiff wire /guide wire 23 being left at the intended site of the procedure after removal of the reverse catheter.

[0090] Figure 6 shows the bifurcated catheter being advanced with the large lumen 25 over the stiff wire 23 to the site of the procedure and the small lumen 26 over the stabilization wire 19. An atraumatic tip is used to reduce trauma to the artery during this catheter advance.

[0091] Figure 7 shows the catheter 25 with the wire and the atraumatic tips removed and ready for the procedure. Stabilization for the process catheter is provided by applying tension to the stabilization wire 19, to stabilize and fix the location of the sheath catheter and the position of the bifurcation.

[0092] Figure 8B illustrates a process 800B for stabilizing and fixing the location of the sheath catheter and the position of the bifurcation catheter in accordance with one embodiment of the invention.

[0093] The process 800B begins by inserting a guide wire 23 through the femoral artery percutaneously (block S801B).

[0094] The process 800B continues by advancing the guide wire 23 through the descending thoracic aorta 12 to the aortic arch 13 using radiographic imaging (block S802B).

[0095] The process 800B continues by inserting a guide or sheath catheter18 having a platinum ring 20 that is opaque to X-ray at its distal end through the groin access and guiding the sheath catheter 18 through the descending aorta over the guide wire to the aortic arch 13 to a location suitable for access into the left common carotid artery 15 and the left internal carotid artery 16 that is being accessed for the procedure using x-ray fluoroscopy (block S803B).

[0096] The process 800B continues by inserting the larger leg of the bifurcated catheter 25 with the smaller leg 26 arranged parallel to it and guiding the bifurcated catheter over the guide wire 23 to the distal edge 20 of the sheath catheter 18 (block S804B).

[0097] The process 800B continues by inserting a stabilization guide wire 19 through the brachial artery preferably using a micro sheath and advancing the stabilization guide wire 19 through the right subclavian artery 14 into the aortic arch 13 (block S805B).

[0098] The process 800B continues by extending a second segment of the stabilization guide wire having a snare 21 at its distal end out of the smaller leg 26 of the bifurcated catheter to capture the stabilization wire 19 from the subclavian artery and pull it through the smaller leg of the bifurcated catheter and out to its proximal end providing an end to end stabilization wire for stabilizing the sheath and the bifurcated catheter (block S806B).

[0099] The process 800B continues by advancing a reverse guide catheter 24 through the tortuous connection of the left common carotid artery 15 to the aorta at the aortic arch 13 over a reasonably stiff wire 23 up the working lumen of the larger leg of the bifurcated catheter through the left common carotid artery 15 just below the left internal carotid artery 16 where the procedure is to be carried out (block S807B).

[00100] The process 800B continues by removing the reverse guide catheter 24 and leaving the stiff guide wire 23 in place as a guide to the bifurcated catheter (block S808).

[00101] The process 800B continues by advancing the bifurcated catheter out of the guide catheter, the large leg 25 of the bifurcated catheter tracking along the stiff guide wire 23 into the left common carotid artery 15 and the small leg 26 tracking along the guide wire 19 coming from the right subclavian /innominate artery (block S809).

[00102] The process 800B continues by removing the guide wire 23 and the atraumatic tips 28 and applying tension to the stabilization wire 19 to stabilize the main catheter leg 25 extending to just below the left internal carotid artery 16 (block S810).

[00103] The process 800B continues by performing a treatment procedure, such as stenting or other procedures as needed, at the treatment site (block S811).

[00104] Figures 9 to 15 and Figure 16 illustrate another embodiment of the invention in which a modified snare bifurcated sheath with a side hole is used instead of the bifurcated catheter to provide stability to the procedural catheter used for stenting and other procedures in the carotid arteries. In this embodiment, the snare

loop is inserted through the subclavian artery to capture the snare wire and provide a through-and-through capability for stabilization of the procedural catheter. In some embodiments, the snare loop is inserted through the subclavian artery via a right radial or brachial artery access.

[00105] Figure 9 shows a snare wire 19 having a snare loop at its distal end inserted through the radial artery using a sheath 52 extended through the right subclavian artery 14 into the aortic arch 13. In one embodiment, the sheath 52 is a Fr 5 sheath. In one embodiment, the snare loop 51 has a 30 to 40 mm diameter. A reverse curve catheter 53, such as a Simmons catheter, is inserted through the groin access and guided through the descending aorta 12 to select the left common carotid artery 15 (it can also be used to select the right carotid artery). In one embodiment, the reverse curve catheter 53 is a Fr. 5 catheter.

[00106] Figure 10 further shows a secondary stabilization wire 55 that is inserted from the proximal end of the reverse curve catheter 53 and exited out of a hole 54 on the side of the catheter 53 at the location at the apex of the curve of the aortic arch 13. In one embodiment, the secondary stabilization wire has a 0.014 diameter.

[00107] Figure 11 shows the stabilization wire 55 being snared by the snare 56 to provide a tensionable stabilization capability comprising the snare 56 from the sheath catheter 52 coming from the right subclavian artery and the snared wire 55 coming from the reverse curve catheter 53.

[00108] Figure 12 further shows a stiff guide wire 57 being extended from the reverse catheter 53 into the left common carotid artery 15 and below the left internal carotid artery 16 where the procedure is expected to be carried out once the tensionable stabilization is established.

[00109] Figure 13 shows the withdrawal of the reverse catheter 53 leaving both the snare 56, snared stabilization wire 55, and the stiff guide wire 57 into the left common carotid artery 15, and below the left internal carotid artery 16.

[00110] Figure 14 shows a bifurcated sheath catheter 58 having two chambers - one for the stabilization wire and the other for the process catheter with an atraumatic dilator tip 59, being guided over the stiff guide wire and the stabilization wire 55, which exits the sheath through a hole 60, in the sheath catheter 58. In one embodiment, the bifurcated sheath catheter 58 is a Fr.6 or Fr.7 sized catheter.

[00111] Figure 15 shows the sheath catheter 58 with the stiff wire and atraumatic tip removed with the snared stabilization wire 55, forming an end-to-end wire enabling stabilization tension to be applied to stabilize the sheath catheter 58 extending into the left internal carotid artery 16 for inserting the procedural catheter for stenting and other procedures from the aortic arch 13.

[00112] In yet another embodiment, the initial sheath catheter may have two lumens, one for the support and stabilization wire and a second as the operational catheter. Further, the operational catheter may be made with a softer operational leg at its distal end which can be used as a reverse curve guiding catheter as well. By combining the application capabilities of such a catheter, it is possible to reduce the number of catheters used and hence the number of steps needed for set up and completion of the procedure.

[00113] Figure 16 is flow chart illustrating a process 1600 according to another embodiment of the invention.

[00114] The process 1600 begins by inserting a wire with a snare 51 through a sheath 52 that is inserted through the radial artery and directed through the right subclavian artery 14 such that the snare is in the aortic arch 13 (block S1601).

[00115] The process 1600 continues by percutaneously inserting and advancing a reverse curve catheter 53 up the femoral artery into the descending thoracic aorta 12 into the left common carotid artery 15 using radiographic imaging (block S1602).

[00116] The process 1600 continues by inserting a secondary stabilization wire 55 into the reverse curve catheter 53 at the proximal end and exited from a hole 56 near the distal end of the reverse curve catheter at the aortic arch 13 to be snared by the snare 51 from the subclavian artery 14 (block S1603).

[00117] The process 1600 continues by snaring the stabilization wire 55 to provide an end to end stabilization (55) to the catheter, and extending a stiff guide wire 57 through the reverse curve catheter 53 into the left common carotid artery 15 to the location of the procedure (block S1604).

[00118] The process 1600 continues by removing the reverse curve catheter 53, leaving both the stabilization wire 55 and the stiff guide wire 57 in place in the arteries (block S1605).

[00119] The process 1600 continues by advancing a bifurcated sheath catheter 58 having two partitions (one for the stabilization wire 55 with a side hole 60 near the distal end and another with a dilator tip 59 for the guide wire 57) over the two wires into position such that the sheath catheter for process 58 is extended into the carotid artery 16 while the stabilization wire 55 through the hole 60 in the bifurcated sheath catheter 58 extends from the proximal end of the sheath catheter 58 through the hole

60, through the aortic arch13 and subclavian artery 14 to provide a through and through capability to provide tension and stabilization to the operating catheter 58 (block S1606).

[00120] The process 1600 continues by extending the sheath catheter into the left internal carotid artery 16 to the location of the procedure (block S1607).

[00121] The process 1600 continues by removing the stiff guide wire 57 and the atraumatic dilator tip 58 and tensioning the stabilization wire 55 to provide stability to the sheath catheter 58 (block S1608).

[00122] The process 1600 continues by inserting the catheter for the procedure through the main chamber of the sheath 58 to the location of the procedure in the left internal carotid artery 16 (block S1609).

[00123] The process 1600 continues by performing a stenting or other procedure at the treatment site (block S1610).

[00124] In another embodiment, a reverse curve catheter with a lumen sufficiently large for stenting instead of a sheath catheter may be used. In this embodiment, the reverse curve catheter having two lumens, one large procedural lumen and the other a smaller stabilization lumen, is used to select the carotid artery. A secondary wire is inserted in the reverse curve catheter (through the stabilization lumen) and out of a hole in the reverse curve catheter at the location of the arch. This secondary wire is then captured by a snare wire with a loop that is extended out of a protective sheath extended through the subclavian artery. The carotid stenting procedure can now proceed in the standard way using the procedural lumen of the reverse curve catheter since the reverse curve guiding catheter itself is stabilized and is usable for procedure.

[00125] A methodology is described for providing end to end stabilization support to the operational catheter and reducing the need to stabilize or push from the lateral wall of the aorta during coronary interventions. This reduces the potential for stroke from plaque breaking off the wall of the aorta during intervention procedures. A support and stabilization wire having one end at the femoral percutaneous access and the second end at a radial percutaneous access is established for end to end stabilization. A bifurcated catheter that comprises a wide lumen for procedural catheters and a narrow lumen for the support wire or catheter is advanced over the support wire of the aortic arch. A procedural catheter and a variety of different shaped guides may deploy from the wide lumen of the bifurcated catheter into the right or left coronary artery, to accommodate a range of aortic anatomical considerations during the coronary interventions.

[00126] Figure 17 depicts a heart 171 with a descending thoracic aorta 172. A main sheath 173 enters the aortic arch via femoral access, and has a radiopaque tip 174 for visibility using radiographic imaging. A main sheath utilizing femoral access may have a lumen measuring around 8 FR (FR = "French", a unit used in medical device measurements, wherein 1 FR is approximately equal to 1/3 mm). A snare 175 is shown extending from the distal end of the main sheath, the snare having a preferred opening that measures 20-30mm in diameter. A guidewire 176 which functions as a stabilization wire is shown entering the aortic arch via the right subclavian artery 177. In this case, the right subclavian artery is serving as a secondary access point. Secondary access points may have a typical lumen of 4-5 FR. In one particular embodiment, the guide wire 176 has a diameter of about 0.014 inches. It will be appreciated that the diameter of the guidewire may be less than or greater than 0.014 inches.

[00127] The left coronary artery 178 and the right coronary artery 179 are also shown, representing pathways that may be used as lumens for guiding catheters and procedural instruments for performing coronary interventions. Prior to inserting catheters and procedural instruments, special purpose guidewires may be used to establish access into the left 178 and right 179 coronary arteries for example. The catheters and procedural instruments may be inserted over the special purpose guidewires, which serve to guide their entry. The special purpose guidewires may have a tip that is shaped by the surgeon so that it can be maneuvered through a coronary artery without damaging it. Shaping of the tip may be used to enhance passage through an anatomical bend in a vessel; the anatomical bend may include an acute angle or a complex curve as examples. The tips may also be particularly strong or particularly stiff, as required to burrow through an occlusion, for example, or a stenosis (narrowing of a vessel), as a further example. Special purpose guidewires are also known as "working guidewires".

[00128] A snare is described herein as an embodiment of a wire retrieval device. Other forms of wire retrieval devices may be used, such as a funnel device that guides a wire through a wide opening and into a catheter. Similarly, although the aortic arch is used herein as the vessel wherein snare capture is described, any suitable vessel may be used with the funnel or the snare. For example, wire retrievals may be performed in the iliac artery or the abdominal aorta.

[00129] Figure 18 further illustrates the use of the snare 175 of FIG. 17. The loop of snare 175 is tightened around the guidewire 176 and the guidewire is drawn into a narrow lumen of a bifurcated sheath described in reference to Figures 19, 20, and 21A.

[00130] Figure 19 shows a bifurcated sheath 191 advancing toward the right subclavian artery along the guidewire 176.

[00131] Figure 20 depicts a fully deployed "Y" sheath 201 extending from the distal end of main sheath 173. "Fully deployed" means that the bifurcated sheath has fully opened or "flowered" after emerging from a catheter for example. A narrow arm 202 of fully deployed "Y" sheath 201 advances along guide wire 176 from the narrow lumen of "Y" sheath 201, and enters right subclavian artery 177 at its origin. This narrow arm 202 helps to prevent injury to the right subclavian artery. Radiopaque bands 204 may be provided for enhanced visibility using radiographic imaging. The larger arm 205 of the bifurcated catheter is shown.

[00132] Figure 21A shows that the sheath 203 shown in Figure 20 is advanced further 211 into right subclavian artery 177, protecting the artery from damage. The narrow arm of the "Y" sheath 202, anchored as shown in right subclavian artery 177, acts as an anchor 212 for main sheath 173, improving the "pushability" of various guides, catheters or instruments that may be deployed through the larger arm 205 of the "Y" sheath. Arm 205 of the "Y" sheath has a lumen sufficient to accommodate a 6 FR guide catheter for example. Accordingly, a variety of different shaped guides 213 may deploy from the "Y" sheath into either the left coronary artery 178 or the right coronary artery 179, to accommodate a range of aortic anatomical considerations.

[00133] Figure 21B depicts the general case of a bifurcated vessel 210, having a left branch 214a and a right branch 214b. Left branch 214a and right branch 214b are each shown as substantially occluded due to plaque formations 215a and 215b. A first special purpose guidewire 216a and a second special purpose guidewire 216b are shown. The first special purpose guidewire 216a and second special purpose

guidewire 216b may be inserted using right and left femoral access. The region where two guidewires move in parallel is described as a "rendezvous" 218. In some embodiments, a stent site 217a is located in the left branch 214a and a stent site 217b is located in the right branch 214b. Sequentially inserting stents at sites such as 217a and 217b may create a problem wherein plaque from branch 214a oozes into branch 214b during insertion of the stent at site 217a, potentially shutting off branch 214b and making its repair much more difficult. Procedural instruments guided by guidewires 216a and 216b may include balloons and stents as non-limiting examples. The procedural instruments may be operated sequentially or simultaneously. Two simultaneously deployed procedural instruments may be used to address vessel anatomies including bifurcated vessels and other vessel anatomies. Accordingly, in one embodiment, the simultaneous use of more than one special purpose guidewire and more than one procedural instrument may be used to perform such coronary interventions. As shown in Figure 21B, the procedural instruments may be closely spaced or juxtaposed.

[00134] Secondary wires such as stabilization wires may be inserted at secondary access points, such as, for example, the right and left radial or brachial arteries.

[00135] Figure 22 is a flow chart showing an exemplary process for performing a coronary intervention 220.

[00136] The process 220 begins by advancing a main sheath to the aortic arch via femoral access (block 221).

[00137] Process 220 includes advancing a stabilization wire to the aortic arch via right radial access using radiographic imaging (block 222).

[00138] Process 220 further includes advancing a snare wire into the aortic arch via the main sheath (block 223).

[00139] Process 220 further includes ensnaring a distal end of the stabilization wire with the snare wire (block 224).

[00140] Process 220 further includes pulling the stabilization wire into the main sheath and extracting it at the femoral access for providing end-to-end stabilization capability from an entry point of the right radial access to an entry point of the femoral access, with extensions for gripping and feeding each end of the stabilization wire (block 225).

[00141] Process 220 further includes advancing a bifurcated catheter along the stabilization wire and through the main sheath, into the aortic arch, the bifurcated catheter having a narrow lumen and a wide lumen and the stabilization wire occupying the narrow lumen (block 226).

[00142] Process 220 further includes fully deploying a "Y" sheath of the bifurcated catheter in the aortic arch (block 227). The "Y" sheath is the sheath catheter that includes a narrow lumen and a wide lumen.

[00143] Process 220 further includes advancing along the stabilization wire a narrow sheath using the narrow lumen of the fully deployed "Y" sheath into the right subclavian artery at its origin (block 228).

[00144] Process 220 further includes advancing at least one special purpose guide wire using the wide lumen of the "Y" sheath into the right or left coronary artery (block 229).

[00145] Process 220 further includes inserting a procedural catheter and deploying it over the special purpose guide wire to the location of the procedure, with support of the special purpose guide wire (block 230).

[00146] Process 220 further includes removing the guide wire from the procedural catheter and replacing it with the procedural instruments (block 231).

[00147] Process 220 continues by performing a predetermined coronary intervention using the procedural instruments (block 232).

[00148] The stabilization wire may be tensioned to provide improved support of the main sheath and its contents, as well as improved support of guides and instruments that may be deployed in the coronary arteries.

[00149] Figure 23 is a flow chart showing a further exemplary process for performing a coronary intervention 240.

[00150] The process 240 begins by inserting a first sheath catheter percutaneously via a first femoral access, having a first distal end positionable in an aortic arch (block 241).

[00151] Process 240 includes inserting a first stabilization wire to the aortic arch via a first radial access (block 242).

[00152] Process 240 further includes slideably inserting a first snare wire through the first sheath catheter, the first snare wire configured to snare the first stabilization wire and pull it through the first sheath catheter until the first stabilization wire extends from an entry point of the first radial access to an entry point of the first

femoral access, with an extension for gripping and feeding at each exposed end (block 243).

[00153] Process 240 further includes inserting a first bifurcated catheter through the first sheath catheter over the first stabilization wire, a distal portion of the first bifurcated catheter extending beyond the ostium, the bifurcated catheter having a narrow sheath, a wide sheath and a "Y"-shaped junction between the narrow sheath and wide sheath, the "Y"-shaped junction positionable in the aortic arch (block 244).

[00154] Process 240 further includes slideably inserting a first special purpose guidewire into the first sheath catheter such that it occupies the first wide sheath of the first bifurcated catheter, extending from the ostium of the first wide sheath into a first selected coronary artery (block 245).

[00155] Process 240 further includes advancing a first procedural instrument along the first special purpose guidewire to a first location in the selected coronary artery (block 246).

[00156] Process 240 further includes inserting a second sheath catheter percutaneously via a second femoral access and having a second distal end positionable in the aortic arch (block 247).

[00157] Process 240 further includes delivering a second stabilization wire to the aortic arch through a second radial access (block 248).

[00158] Process 240 further includes slideably inserting a second snare wire through the second sheath catheter, the second snare wire configured to snare the second stabilization wire and pull it through the second sheath catheter until the second stabilization wire extends from an entry point of the second radial access to an

entry point of the second femoral access, with an extension for gripping and feeding at each exposed end (block 249).

[00159] Process 240 further includes inserting a second bifurcated catheter through the second sheath catheter over the second stabilization wire, a distal portion of the second bifurcated catheter extending beyond the ostium, the bifurcated catheter having a narrow sheath, a wide sheath and a "Y"-shaped junction between the narrow sheath and wide sheath, the "Y"-shaped junction positionable in the aortic arch (block 250).

[00160] Process 240 further includes slideably inserting a second special purpose guidewire into the second sheath catheter, occupying the second wide sheath of the second bifurcated catheter and extending from the ostium of the second wide sheath into a second selected coronary artery (block 251).

[00161] Process 240 further includes advancing a second procedural instrument along the second special purpose guidewire to a second location in the selected coronary artery (block 252).

[00162] Process 240 finally concludes by cooperatively operating the first and second procedural instruments to perform the coronary percutaneous intervention (block 253).

[00163] Though the examples provide show specific access points for the procedural catheter and the stabilization wires it is not meant to be limiting. There may be other scenarios possible. For example, in an alternate scenario, the main access is through the right radial artery and the stabilization wire or snare is introduced from the groin access or even the left radial artery access. Also, the main

access may be from the left radial artery while the stabilization wire or snare still comes out through the right subclavian artery.

[00164] As will be understood by those familiar with the art, the invention may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. Likewise, the particular naming and division of the members, features, attributes, and other aspects are not mandatory or significant, and the mechanisms that implement the invention or its features may have different structural construct, names, and divisions. Accordingly, the disclosure of the invention is intended to be illustrative, but not limiting, of the scope of the invention.

[00165] While the invention has been described in terms of several embodiments, those of ordinary skill in the art will recognize that the invention is not limited to the embodiments described, but can be practiced with modification and alteration within the spirit and scope of the appended claims. The description is thus to be regarded as illustrative instead of limiting. There are numerous other variations to different aspects of the invention described above, which in the interest of conciseness have not been provided in detail. Accordingly, other embodiments are within the scope of the claims.

[00166] The invention has been described in relation to particular examples, which are intended in all respects to be illustrative rather than restrictive. Those skilled in the art will appreciate that many different combinations will be suitable for practicing the present invention. Other implementations of the invention will be apparent to those skilled in the art from consideration of the specification and practice of the invention disclosed herein. Various aspects and/or components of the described embodiments may be used singly or in any combination. It is intended that the

specification and examples be considered as exemplary only, with a true scope and spirit of the invention being indicated by the following claims.

CLAIMS

What is claimed is:

1. A coronary percutaneous intervention system comprising:

a sheath catheter;

a stabilization wire routeable through the sheath catheter;

a bifurcated catheter having a wide lumen and a narrow lumen, wherein the narrow lumen is routeable along the stabilization wire; and,

a procedural instrument for performing a coronary intervention, the procedural instrument routeable through the wide lumen of the bifurcated catheter.

2. The system of claim 1, wherein the stabilization wire comprises a guide wire insertable through a vessel in the thoracic cavity via radial access.

3. The system of claim 2, wherein the bifurcated catheter is insertable through the sheath catheter over the stabilization wire.

4. The system of claim 3, wherein the wide lumen of the bifurcated catheter is operable as a procedural lumen, and the narrow lumen of the bifurcated catheter is operable as a stabilization lumen.

5. The system of claim 4, wherein the stabilization lumen is used to slideably receive a snare catheter and the stabilization wire.

6. The system of claim 5, wherein the stabilization wire is configured to snare the guide wire and pull a portion of the guidewire within the bifurcated catheter.

7. A coronary percutaneous intervention system comprising:

a sheath catheter percutaneously insertable via femoral access and having a distal end positionable in an aortic arch;

a stabilization wire deliverable to the aortic arch through right radial access;

a snare wire comprising a snare slideably insertable through the sheath catheter, the snare wire configured to snare the stabilization wire and pull it through the sheath catheter until the stabilization wire extends from an entry point of the right radial access to an entry point of the femoral access, with an extension for gripping and feeding at each exposed end;

a bifurcated catheter insertable through the sheath catheter over the stabilization wire, a distal portion of the bifurcated catheter extending beyond the ostium of the sheath catheter, the bifurcated catheter further comprising a narrow sheath, a wide sheath and a "Y"-shaped junction between the narrow sheath and wide sheath, the "Y"-shaped junction positionable in the aortic arch, wherein the narrow sheath of the bifurcated catheter is advanceable along the stabilization wire such that the stabilization wire enters the right subclavian artery at the origin of the right subclavian artery;

a first special purpose guidewire slideably inserted into the sheath catheter, occupying the wide sheath of the bifurcated catheter, extending from the ostium of the wide sheath into the left or right coronary artery;

a first procedural instrument advanced along the first special purpose guidewire to the location of a first procedure; and,

wherein a predetermined coronary intervention is performed using the first procedural instrument.

8. The system of claim 7, wherein the bifurcated catheter further comprises:

a common catheter portion at a proximal end of the bifurcation catheter;

wherein the narrow sheath and the wide sheath join with the common catheter portion at the "Y"-shaped junction.

9. The system of claim 7, wherein the bifurcated catheter is pre-loaded into the sheath catheter.

10. A method for performing a coronary percutaneous intervention comprising:

inserting a first sheath catheter percutaneously via a first femoral access, having a first distal end positionable in an aortic arch;

inserting a first stabilization wire to the aortic arch via a first radial access;

slideably inserting a first snare wire through the first sheath catheter, the first snare wire configured to snare the first stabilization wire and pull it through the first sheath catheter until the first stabilization wire extends from an entry point of the first radial access to an entry point of the first femoral access, with an extension for gripping and feeding at each exposed end;

inserting a first bifurcated catheter through the first sheath catheter over the first stabilization wire, a distal portion of the first bifurcated catheter extending beyond the ostium, the bifurcated catheter further comprising a narrow sheath, a wide

sheath and a "Y"-shaped junction between the narrow sheath and wide sheath, the "Y"-shaped junction positionable in the aortic arch;

slideably inserting a first special purpose guidewire into the first sheath catheter such that it occupies the first wide sheath of the first bifurcated catheter, extending from the ostium of the first wide sheath into a first selected coronary artery;

advancing a first procedural instrument along the first special purpose guidewire to a first location in the selected coronary artery;

inserting a second sheath catheter percutaneously via a second femoral access and having a second distal end positionable in the aortic arch;

delivering a second stabilization wire to the aortic arch through a second radial access;

slideably inserting a second snare wire through the second sheath catheter, the second snare wire configured to snare the second stabilization wire and pull it through the second sheath catheter until the second stabilization wire extends from an entry point of the second radial access to an entry point of the second femoral access, with an extension for gripping and feeding at each exposed end;

inserting a second bifurcated catheter through the second sheath catheter over the second stabilization wire, a distal portion of the second bifurcated catheter extending beyond the ostium, the bifurcated catheter further comprising a narrow sheath, a wide sheath and a "Y"-shaped junction between the narrow sheath and wide sheath, the "Y"-shaped junction positionable in the aortic arch;

slideably inserting a second special purpose guidewire into the second sheath catheter, occupying the second-wide sheath of the second bifurcated catheter and extending from the ostium of the second-wide sheath into a second selected coronary

artery; advancing a second procedural instrument along the second special purpose guidewire to a second location in the selected coronary artery; and

cooperatively operating the first and second procedural instruments to perform the coronary percutaneous intervention.

11. The method of claim 10, wherein the first and second locations are closely spaced.

12. The method of claim 10, wherein the first and second locations are juxtaposed.

13. The method of claim 10, wherein the first and second locations are each adjacent to a coronary occlusion.

14. A method for percutaneous coronary intervention comprising:

utilizing a primary access point for catheters and at least one procedural instrument, the primary access point comprising an artery having a wide ostium such as a femoral artery;

utilizing at least one secondary access point for a stabilization wire, the at least one secondary access point comprising a brachial artery, an ulnar artery, a branch of the carotid artery, a superficial temporal artery, or a unique branch of an upper extremity artery; and

performing a coronary intervention using the at least one procedural instrument, wherein the at least one secondary access point enables positioning of a stabilization wire for stabilization of the system during the coronary intervention.

15. A method for performing a coronary intervention comprising:

advancing a main sheath to the aortic arch vial femoral access;

advancing a stabilization wire to the aortic arch via right radial access using radiographic imaging;

advancing a snare wire into the aortic arch via the main sheath;

ensnaring a distal end of the stabilization wire with the snare wire;

pulling the stabilization wire into the main sheath and extracting the stabilization wire at the femoral access for providing end-to-end stabilization capability from an entry point of the right radial access to an entry point of the femoral access, with extensions for gripping and feeding each end of the stabilization wire;

advancing a bifurcated catheter along the stabilization wire and through the main sheath, into the aortic arch, wherein the bifurcated catheter comprises a narrow lumen and a wide lumen and the stabilization wire occupies the narrow lumen;

fully deploying a "Y" sheath of the bifurcated catheter in the aortic arch, wherein the "Y" sheath comprises the narrow lumen and the wide lumen and further comprises a narrow sheath corresponding to the narrow lumen and a wide sheath corresponding to the wide lumen;

advancing the narrow sheath along the stabilization wire using the narrow lumen of the fully deployed "Y" sheath into the right subclavian artery at its origin;

advancing at least one special purpose guide wire through the wide lumen of the "Y" sheath into the right or left coronary artery;

inserting and deploying a procedural catheter over the at least one special purpose guide wire to a procedure location;

removing the guide wire from the procedural catheter and replacing it with at least one procedural instrument; and,

performing a predetermined coronary intervention using the at least one procedural instrument.

16. The method of claim 15, further comprising applying tension to the stabilization wire.

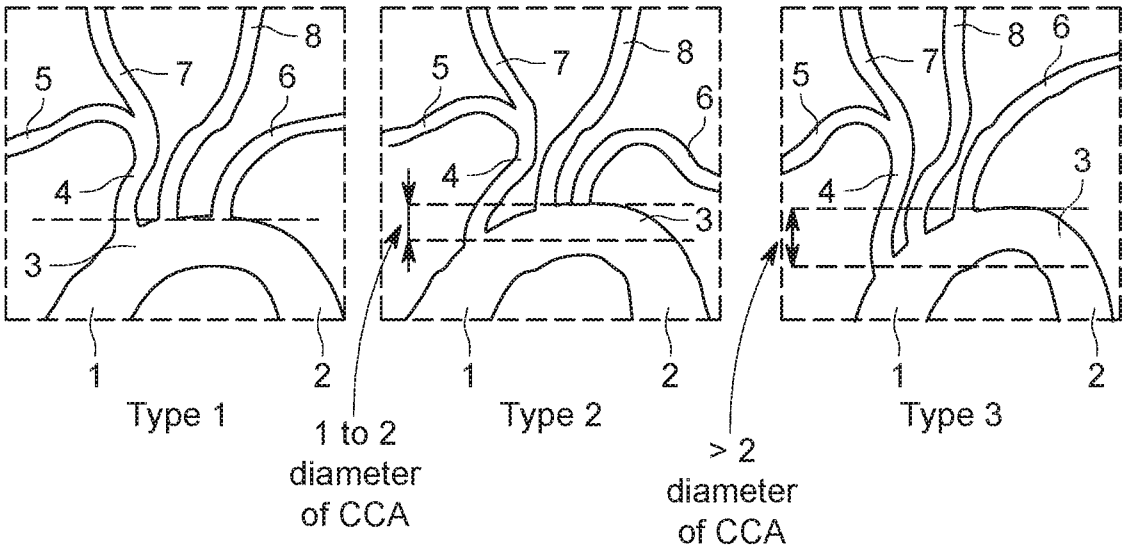

5
7
8
6
4
3
1
2
Type 1
1 to 2
diameter
of CCA
Type 2
> 2
diameter
of CCA
Type 3

FIG. 1

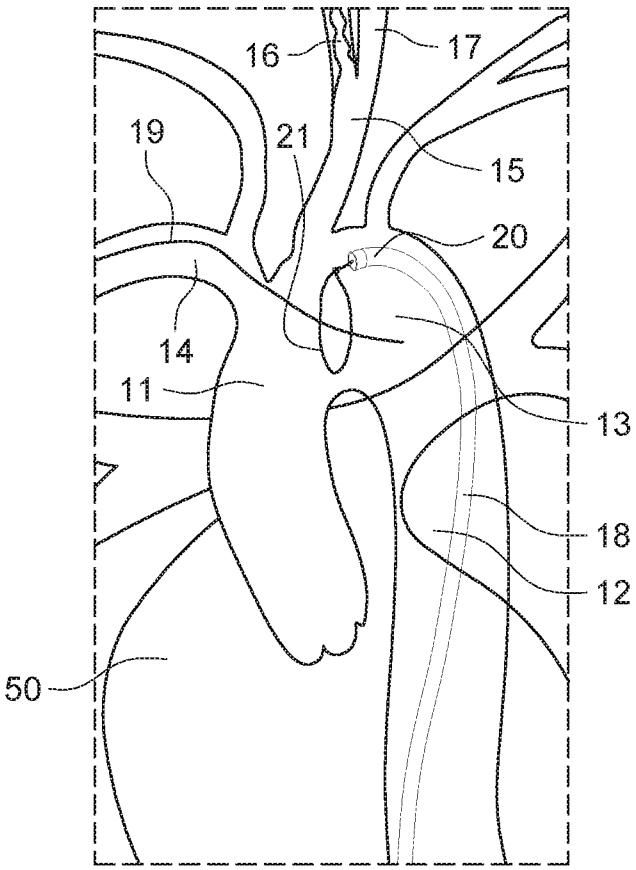


FIG. 2

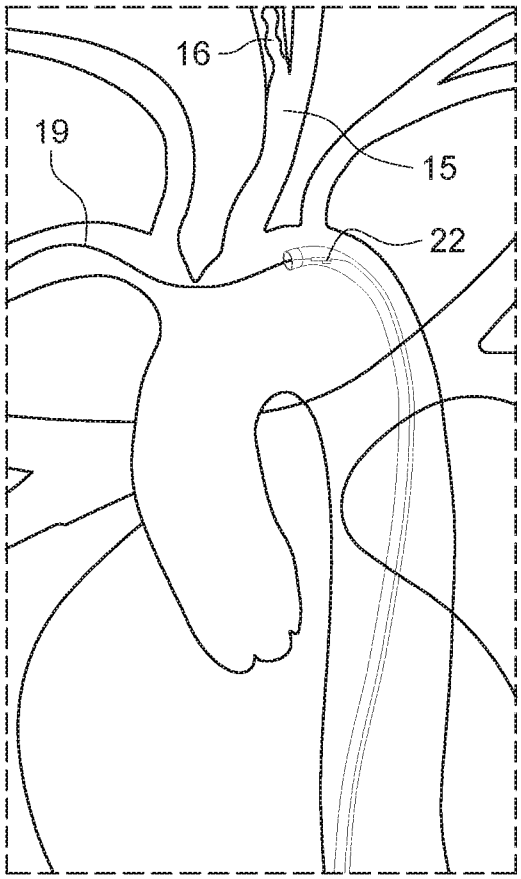


FIG. 3

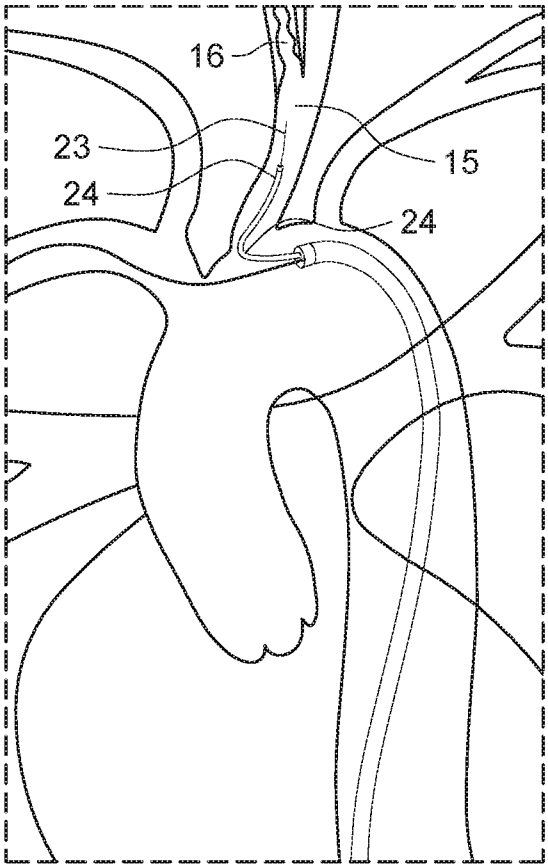


FIG. 4

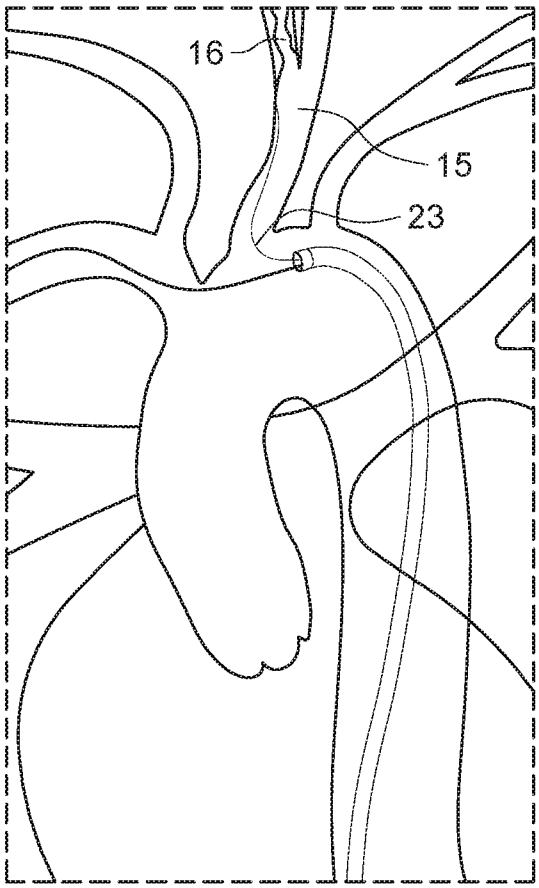


FIG. 5

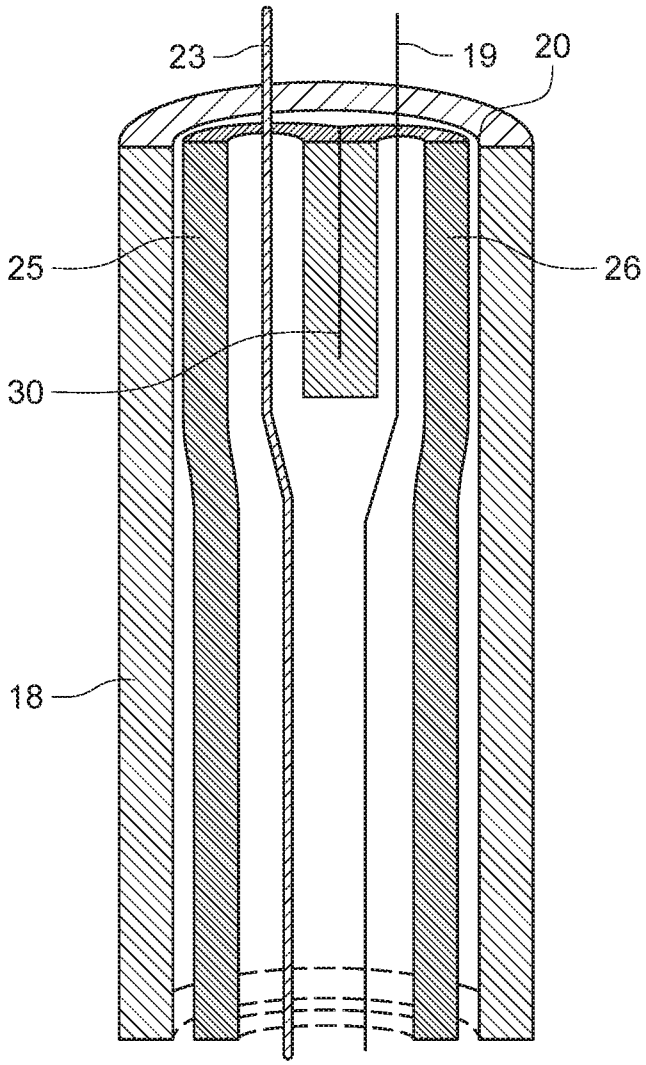


FIG. 6A

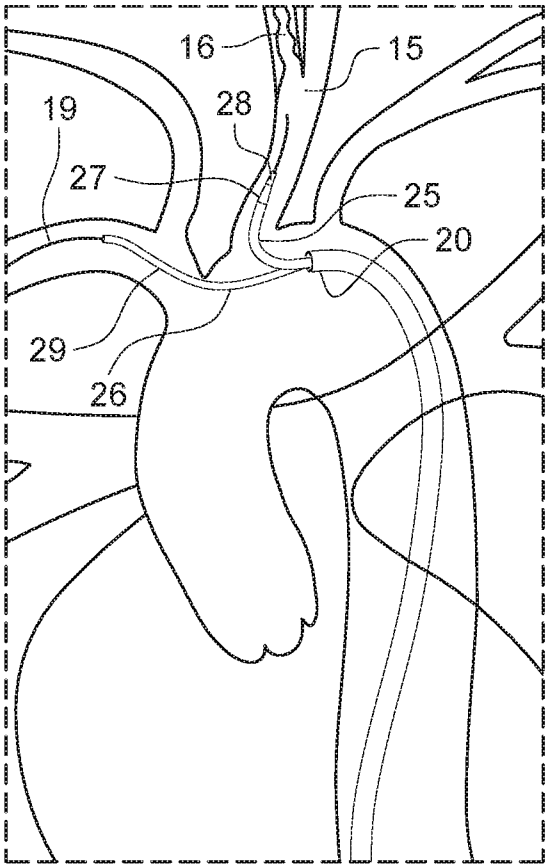


FIG. 6

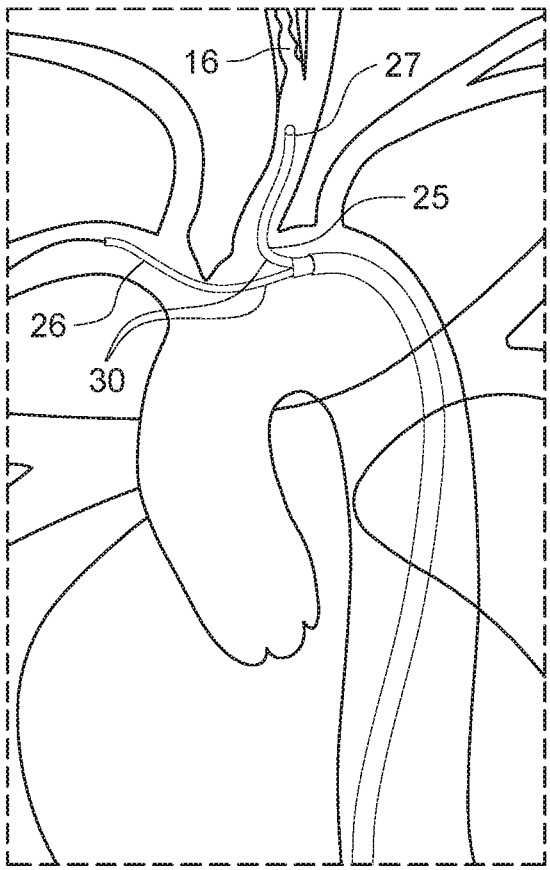


FIG. 7

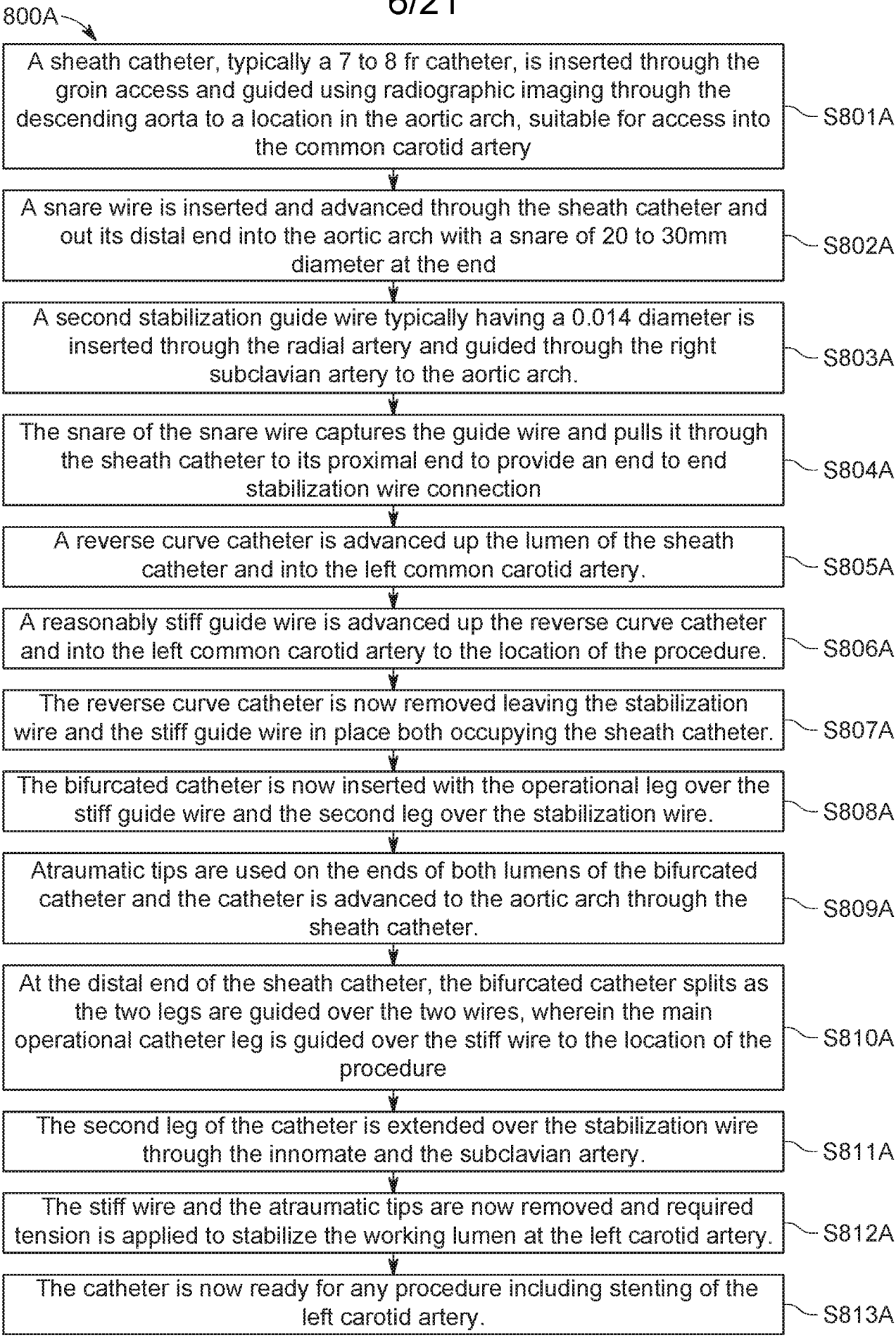

800A
A sheath catheter, typically a 7 to 8 fr catheter, is inserted through the groin access and guided using radiographic imaging through the descending aorta to a location in the aortic arch, suitable for access into the common carotid artery
S801A
A snare wire is inserted and advanced through the sheath catheter and out its distal end into the aortic arch with a snare of 20 to 30mm diameter at the end
S802A
A second stabilization guide wire typically having a 0.014 diameter is inserted through the radial artery and guided through the right subclavian artery to the aortic arch.
S803A
The snare of the snare wire captures the guide wire and pulls it through the sheath catheter to its proximal end to provide an end to end stabilization wire connection
S804A
A reverse curve catheter is advanced up the lumen of the sheath catheter and into the left common carotid artery.
S805A
A reasonably stiff guide wire is advanced up the reverse curve catheter and into the left common carotid artery to the location of the procedure.
S806A
The reverse curve catheter is now removed leaving the stabilization wire and the stiff guide wire in place both occupying the sheath catheter.
S807A
The bifurcated catheter is now inserted with the operational leg over the stiff guide wire and the second leg over the stabilization wire.
S808A
Atraumatic tips are used on the ends of both lumens of the bifurcated catheter and the catheter is advanced to the aortic arch through the sheath catheter.
S809A
At the distal end of the sheath catheter, the bifurcated catheter splits as the two legs are guided over the two wires, wherein the main operational catheter leg is guided over the stiff wire to the location of the procedure
S810A
The second leg of the catheter is extended over the stabilization wire through the innomate and the subclavian artery.
S811A
The stiff wire and the atraumatic tips are now removed and required tension is applied to stabilize the working lumen at the left carotid artery.
S812A
The catheter is now ready for any procedure including stenting of the left carotid artery.
S813A

FIG. 8A

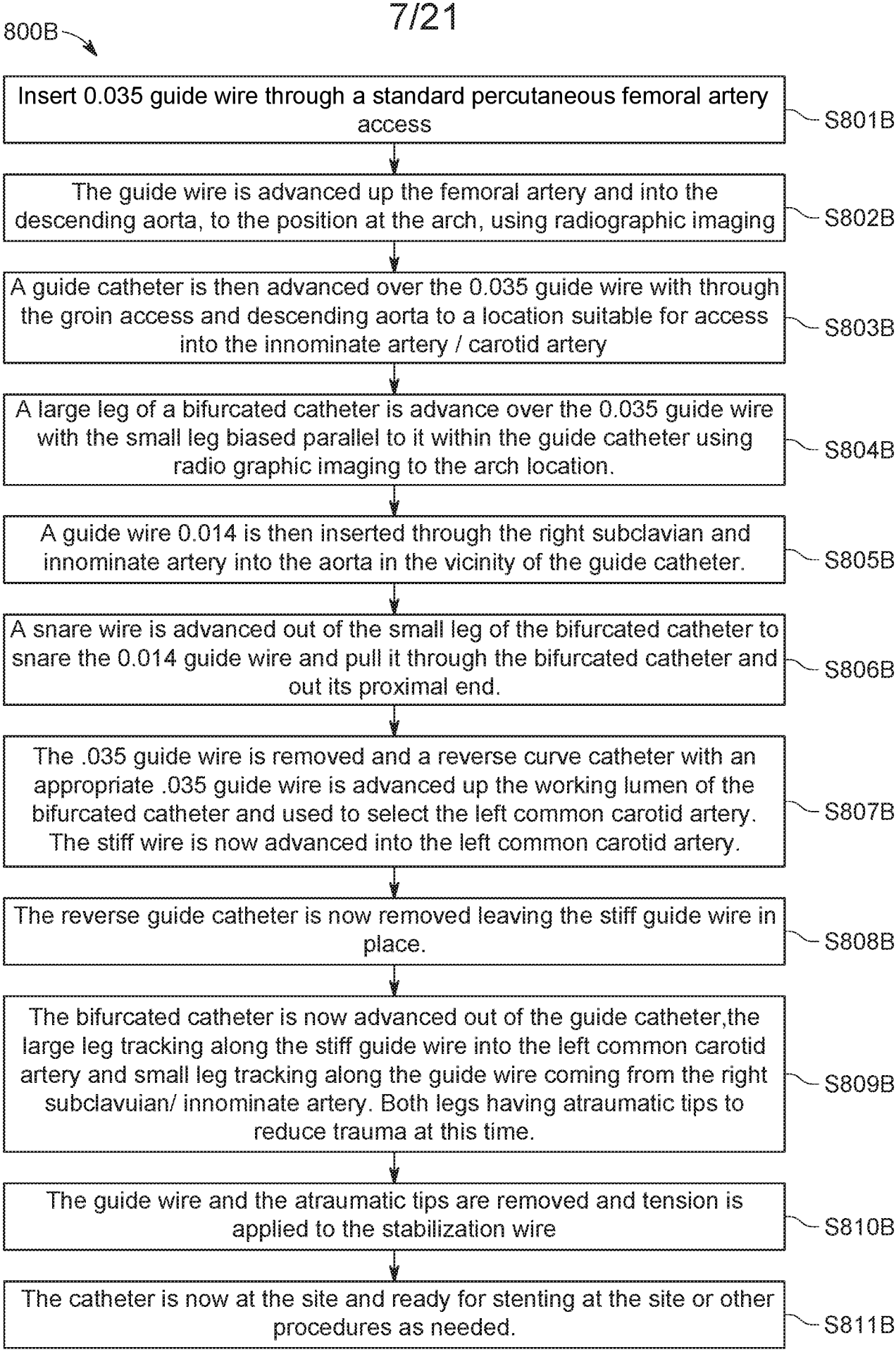

800B
Insert 0.035 guide wire through a standard percutaneous femoral artery access
S801B
The guide wire is advanced up the femoral artery and into the descending aorta, to the position at the arch, using radiographic imaging
S802B
A guide catheter is then advanced over the 0.035 guide wire with through the groin access and descending aorta to a location suitable for access into the innominate artery / carotid artery
S803B
A large leg of a bifurcated catheter is advance over the 0.035 guide wire with the small leg biased parallel to it within the guide catheter using radio graphic imaging to the arch location.
S804B
A guide wire 0.014 is then inserted through the right subclavian and innominate artery into the aorta in the vicinity of the guide catheter.
S805B
A snare wire is advanced out of the small leg of the bifurcated catheter to snare the 0.014 guide wire and pull it through the bifurcated catheter and out its proximal end.
S806B
The .035 guide wire is removed and a reverse curve catheter with an appropriate .035 guide wire is advanced up the working lumen of the bifurcated catheter and used to select the left common carotid artery. The stiff wire is now advanced into the left common carotid artery.
S807B
The reverse guide catheter is now removed leaving the stiff guide wire in place.
S808B
The bifurcated catheter is now advanced out of the guide catheter,the large leg tracking along the stiff guide wire into the left common carotid artery and small leg tracking along the guide wire coming from the right subclavuian/ innominate artery. Both legs having atraumatic tips to reduce trauma at this time.
S809B
The guide wire and the atraumatic tips are removed and tension is applied to the stabilization wire
S810B
The catheter is now at the site and ready for stenting at the site or other procedures as needed.
S811B

FIG. 8B

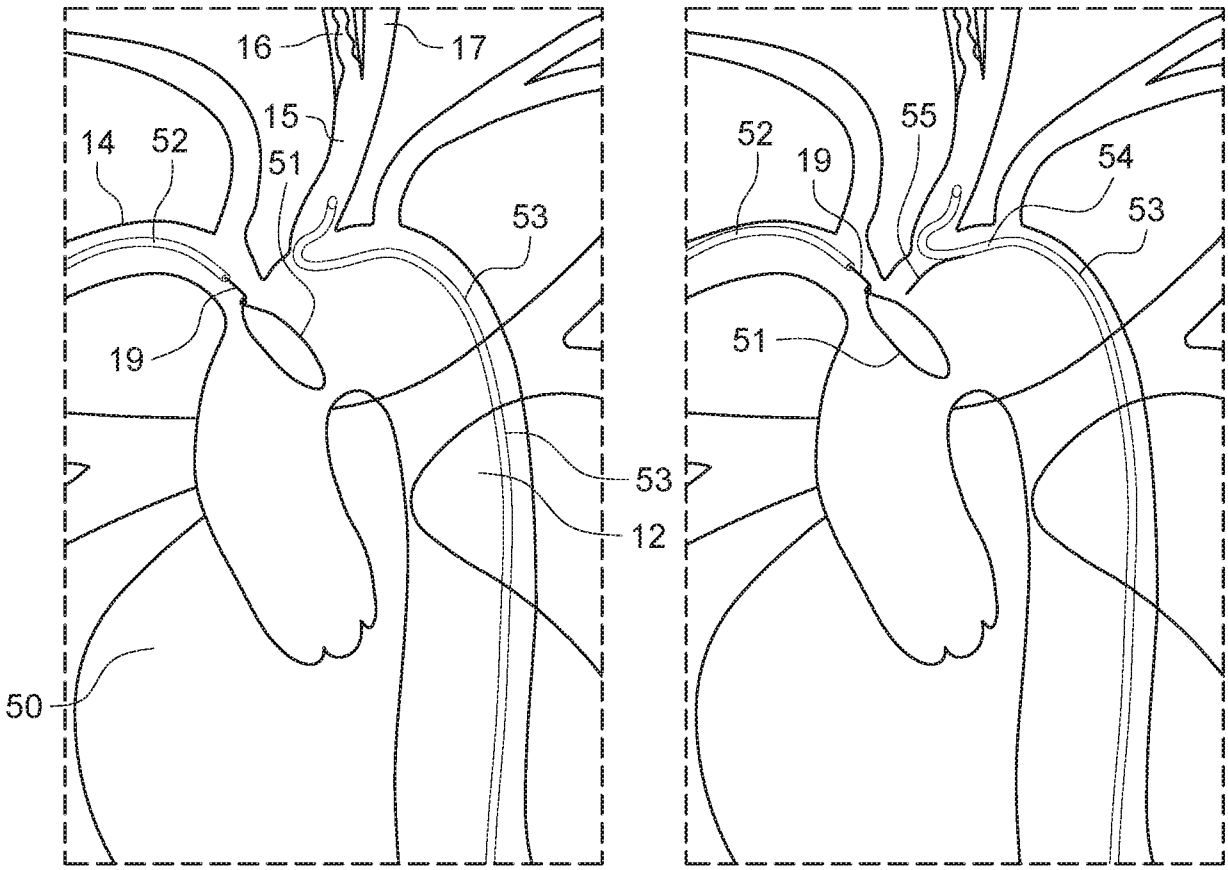


FIG. 9

FIG. 10

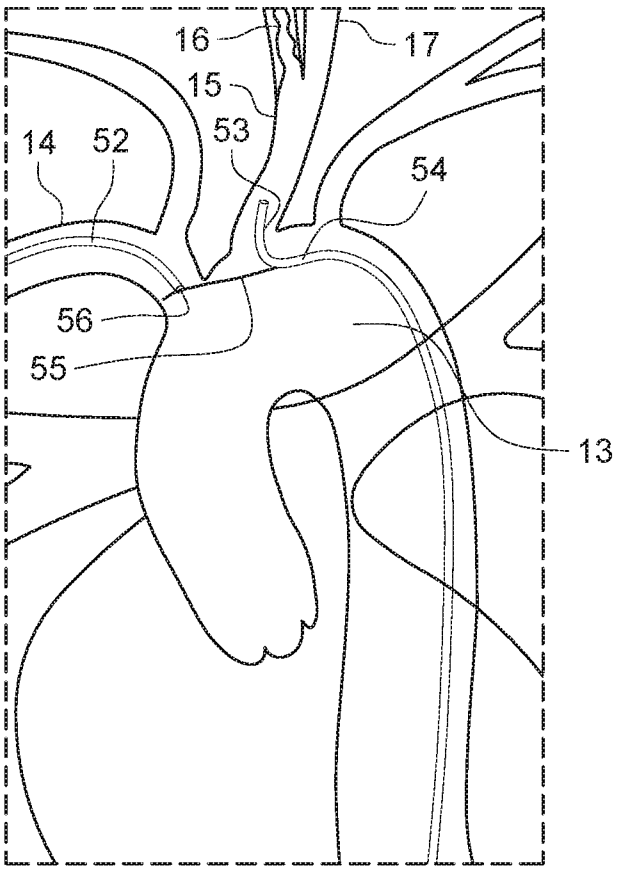


FIG. 11

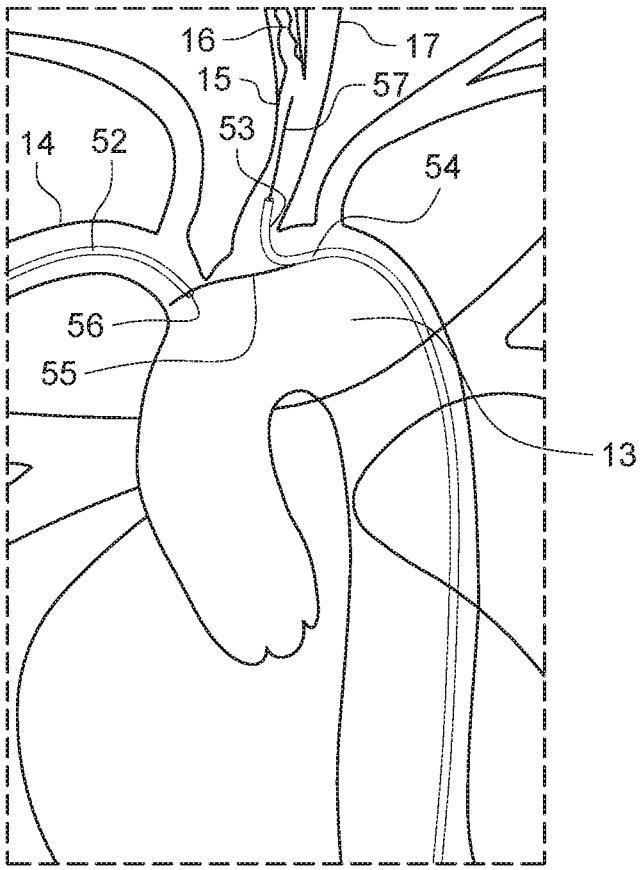


FIG. 12

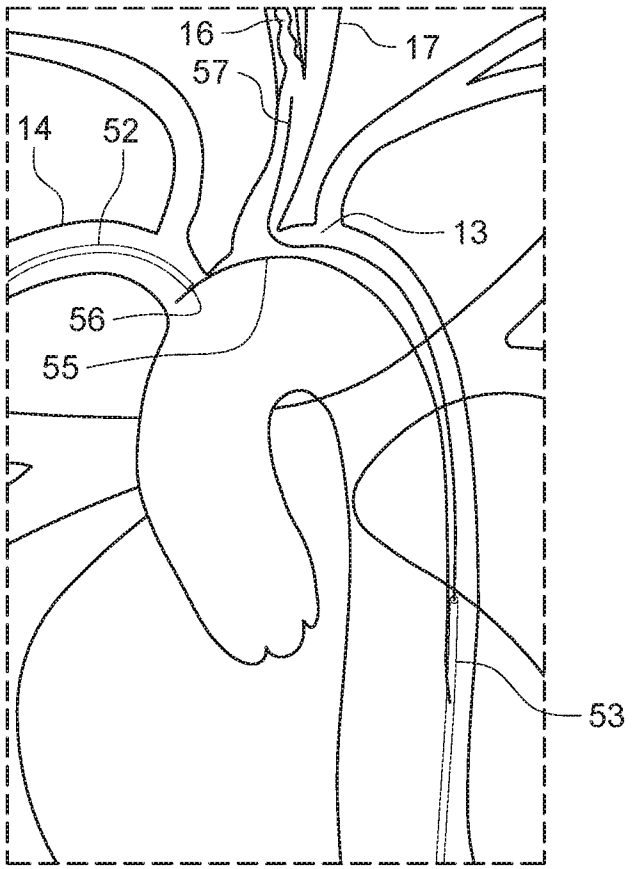


FIG. 13

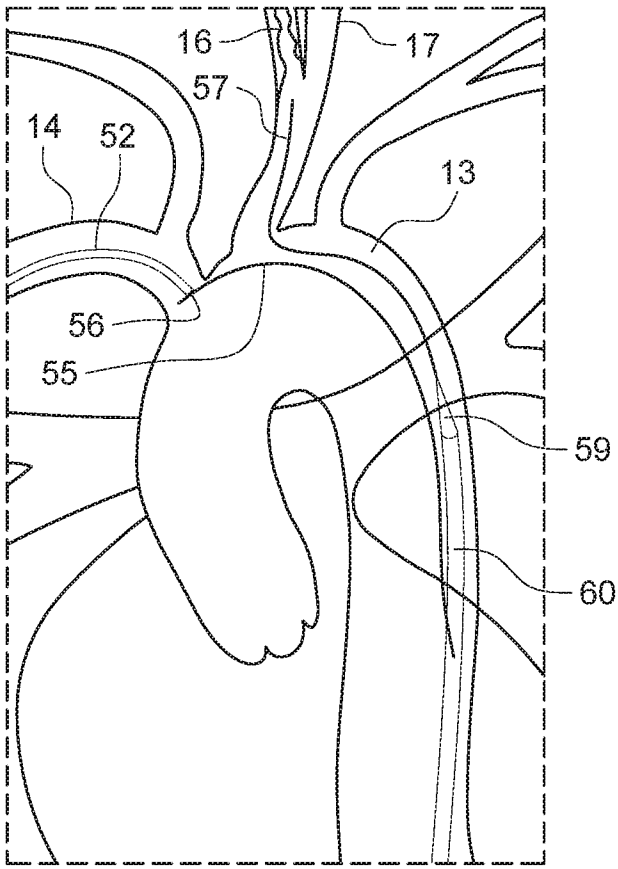


FIG. 14

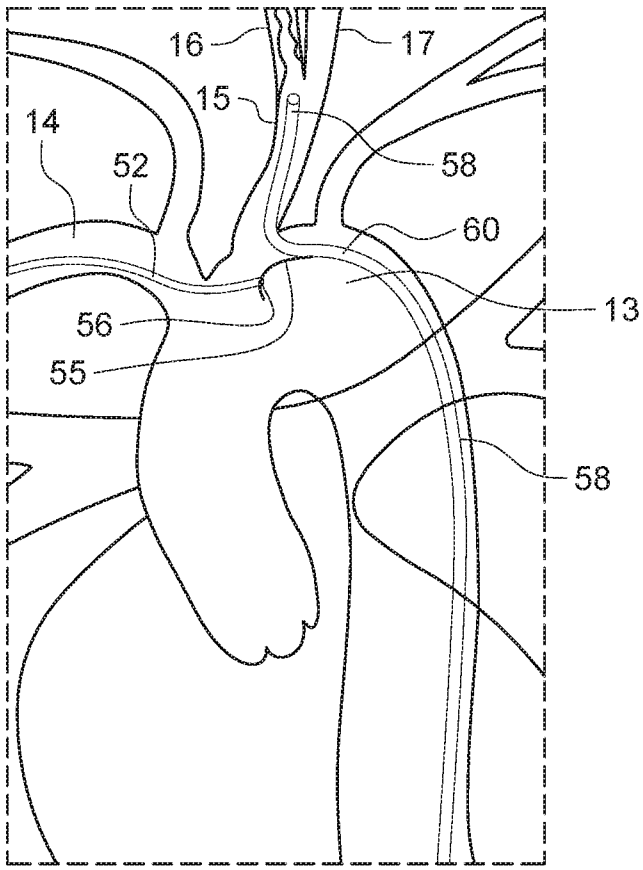


FIG. 15

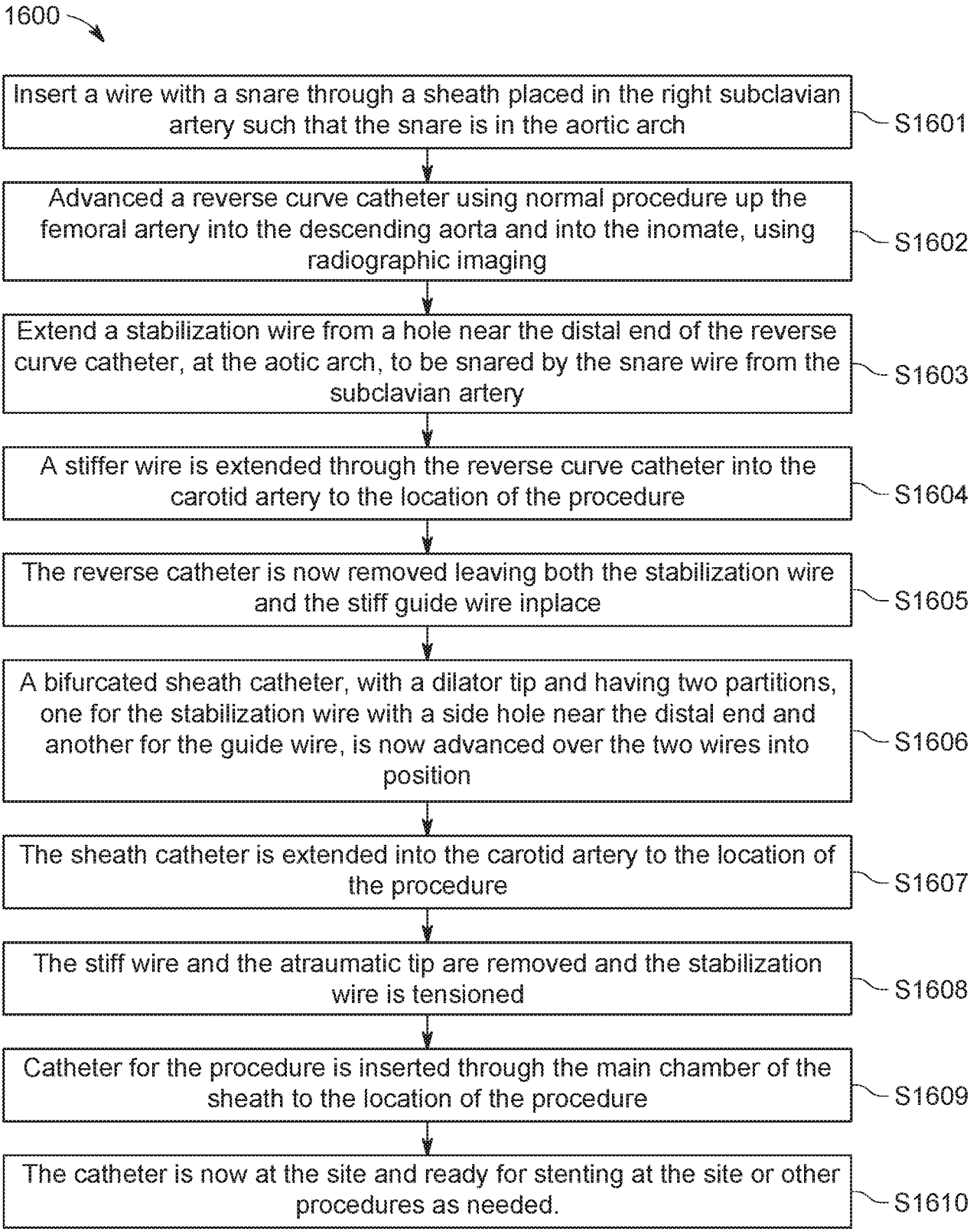

1600
Insert a wire with a snare through a sheath placed in the right subclavian artery such that the snare is in the aortic arch
S1601
Advanced a reverse curve catheter using normal procedure up the femoral artery into the descending aorta and into the inomate, using radiographic imaging
S1602
Extend a stabilization wire from a hole near the distal end of the reverse curve catheter, at the aotic arch, to be snared by the snare wire from the subclavian artery
S1603
A stiffer wire is extended through the reverse curve catheter into the carotid artery to the location of the procedure
S1604
The reverse catheter is now removed leaving both the stabilization wire and the stiff guide wire inplace
S1605
A bifurcated sheath catheter, with a dilator tip and having two partitions, one for the stabilization wire with a side hole near the distal end and another for the guide wire, is now advanced over the two wires into position
S1606
The sheath catheter is extended into the carotid artery to the location of the procedure
S1607
The stiff wire and the atraumatic tip are removed and the stabilization wire is tensioned
S1608
Catheter for the procedure is inserted through the main chamber of the sheath to the location of the procedure
S1609
The catheter is now at the site and ready for stenting at the site or other procedures as needed.
S1610

FIG. 16

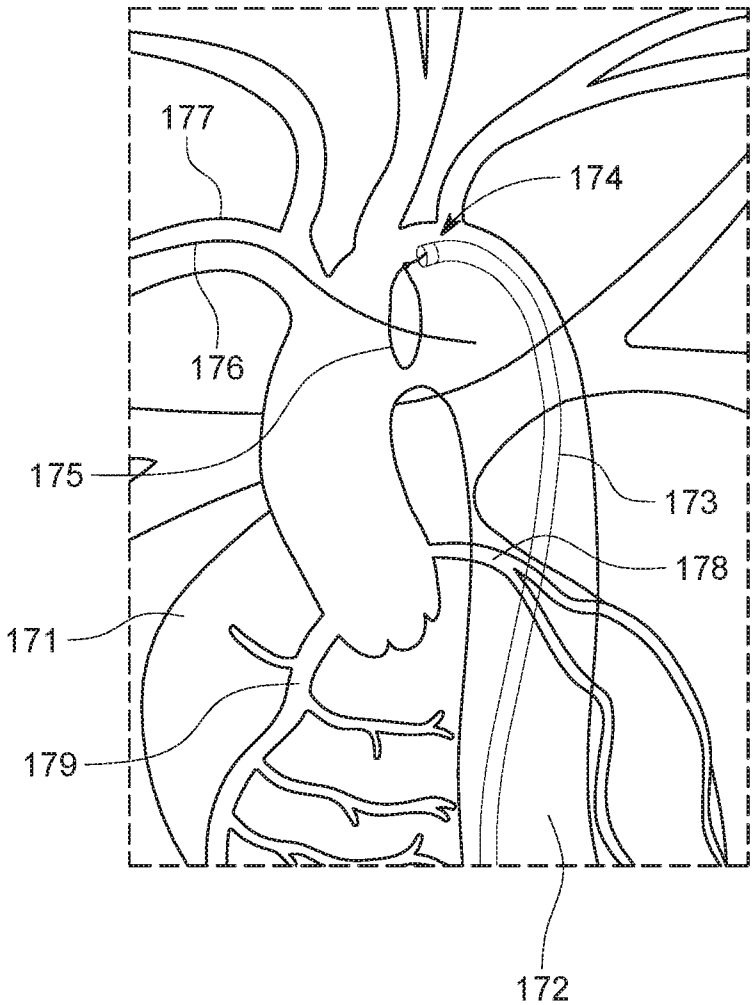


FIG. 17

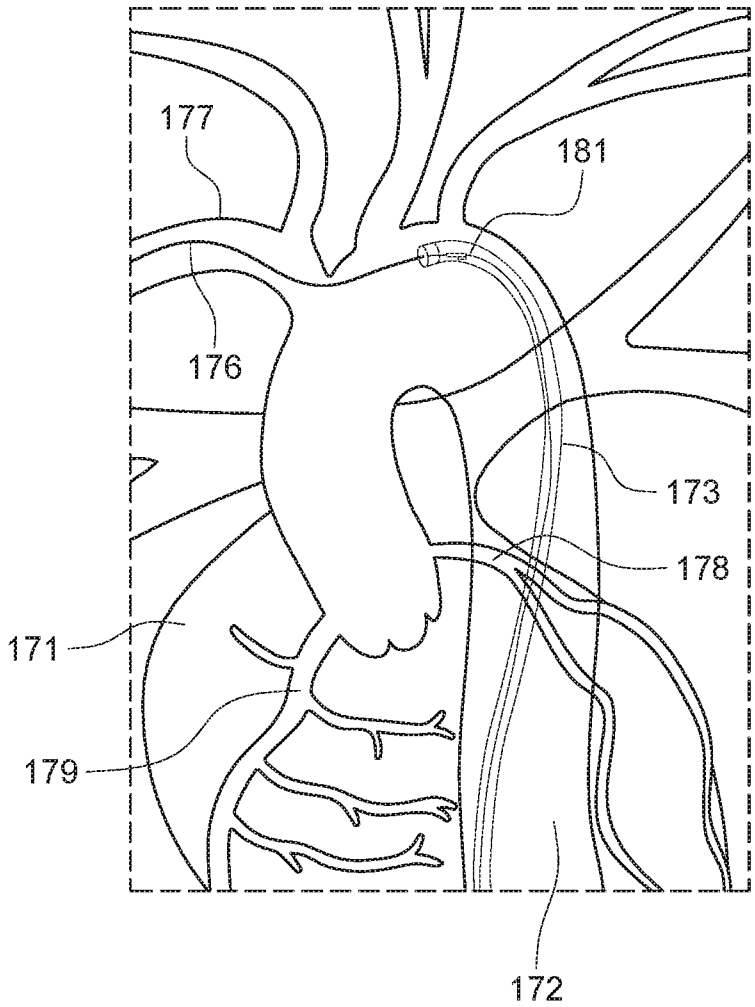


FIG. 18

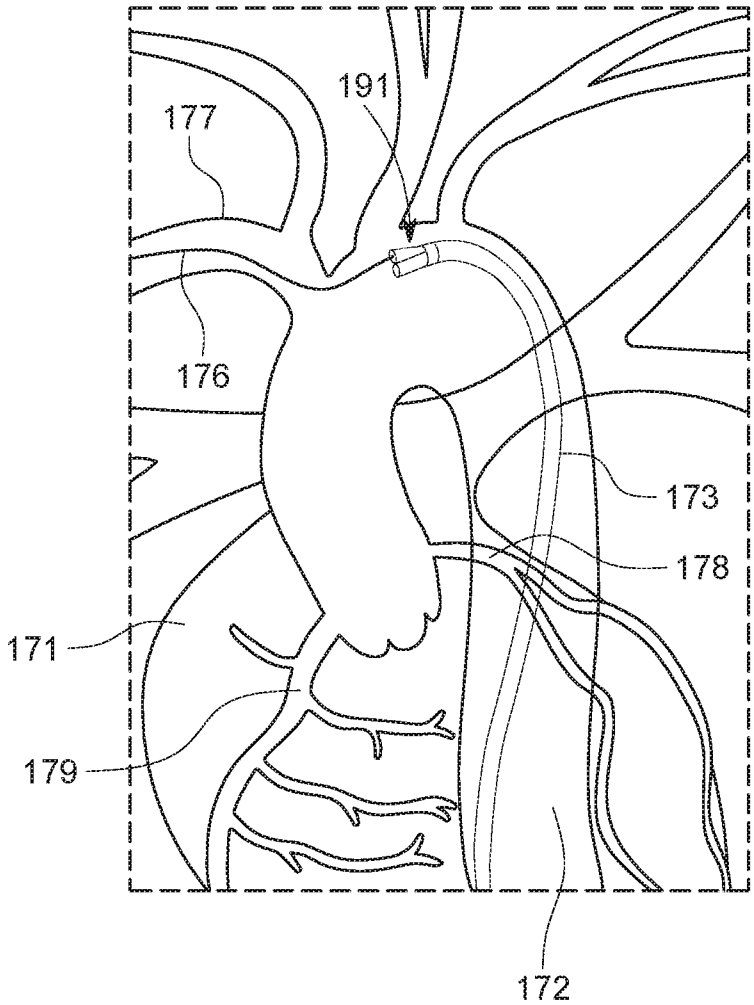


FIG. 19

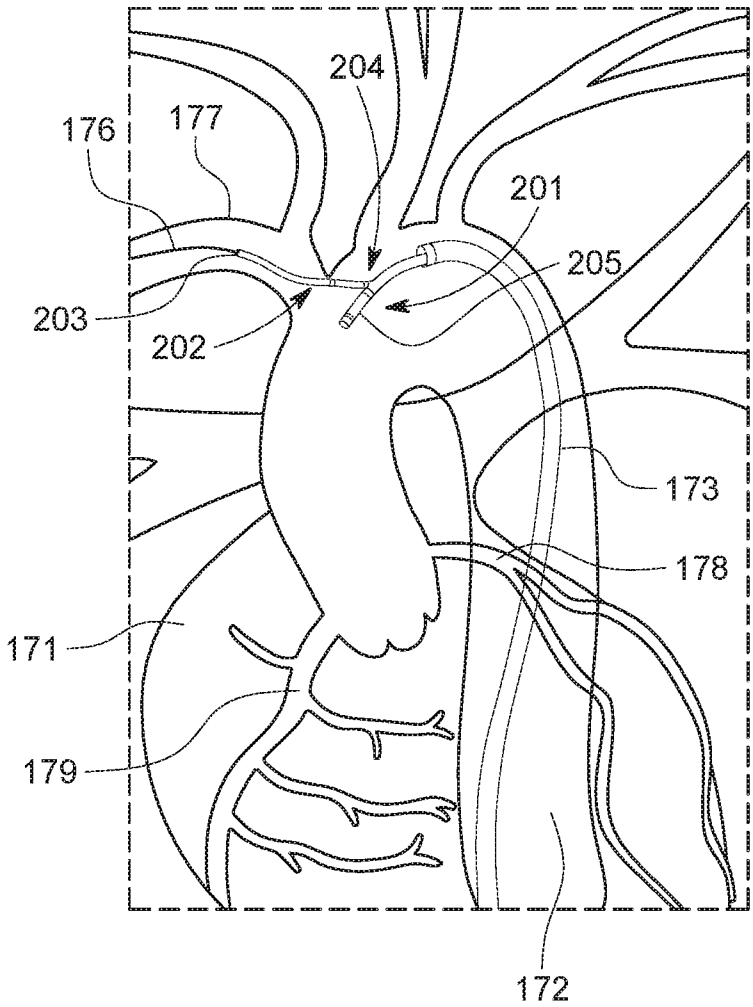


FIG. 20

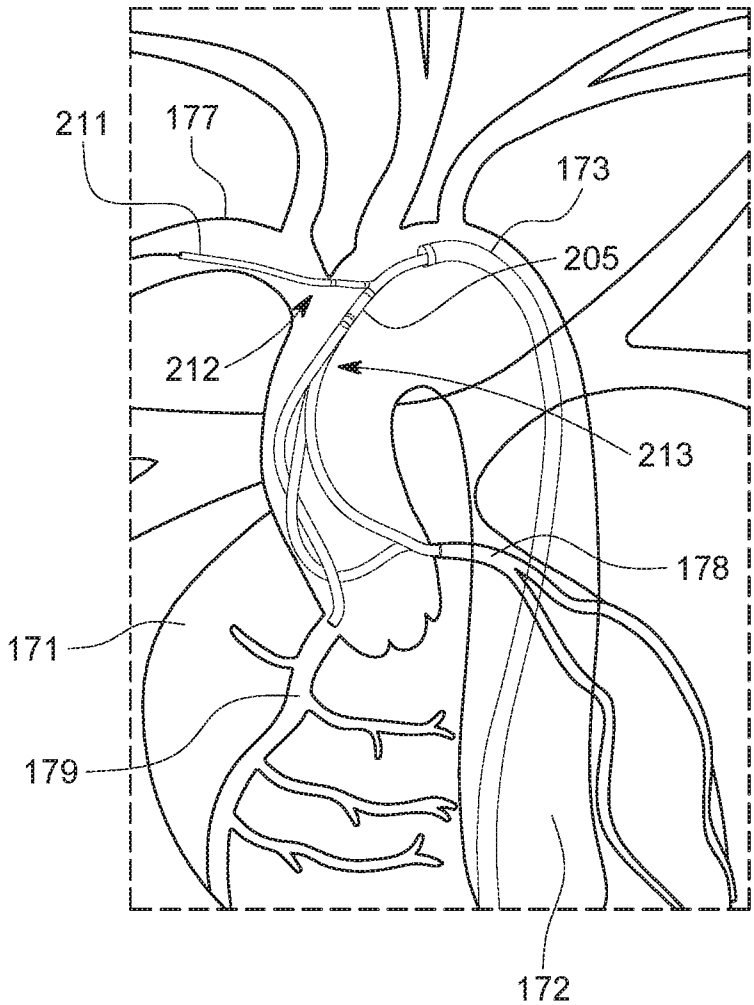


FIG. 21A

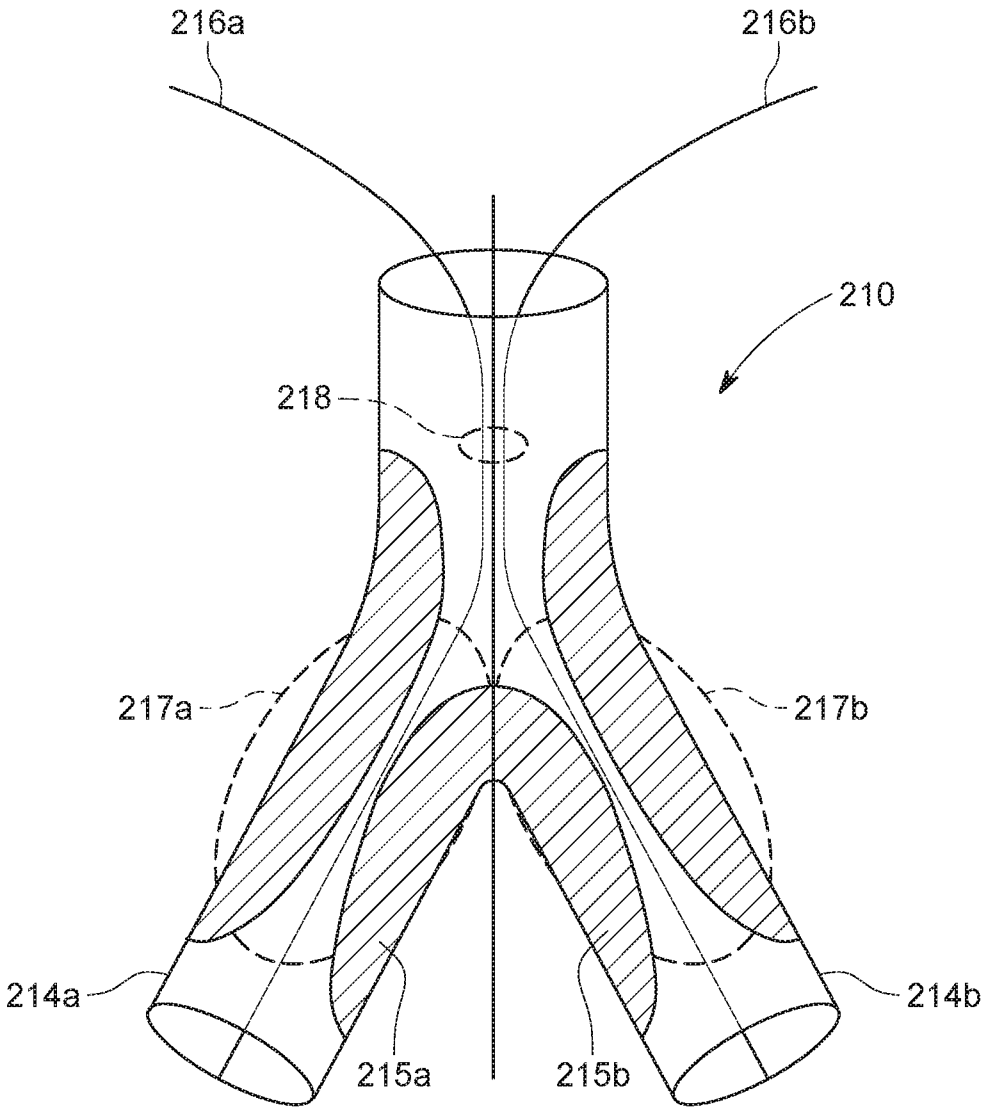


FIG. 21B

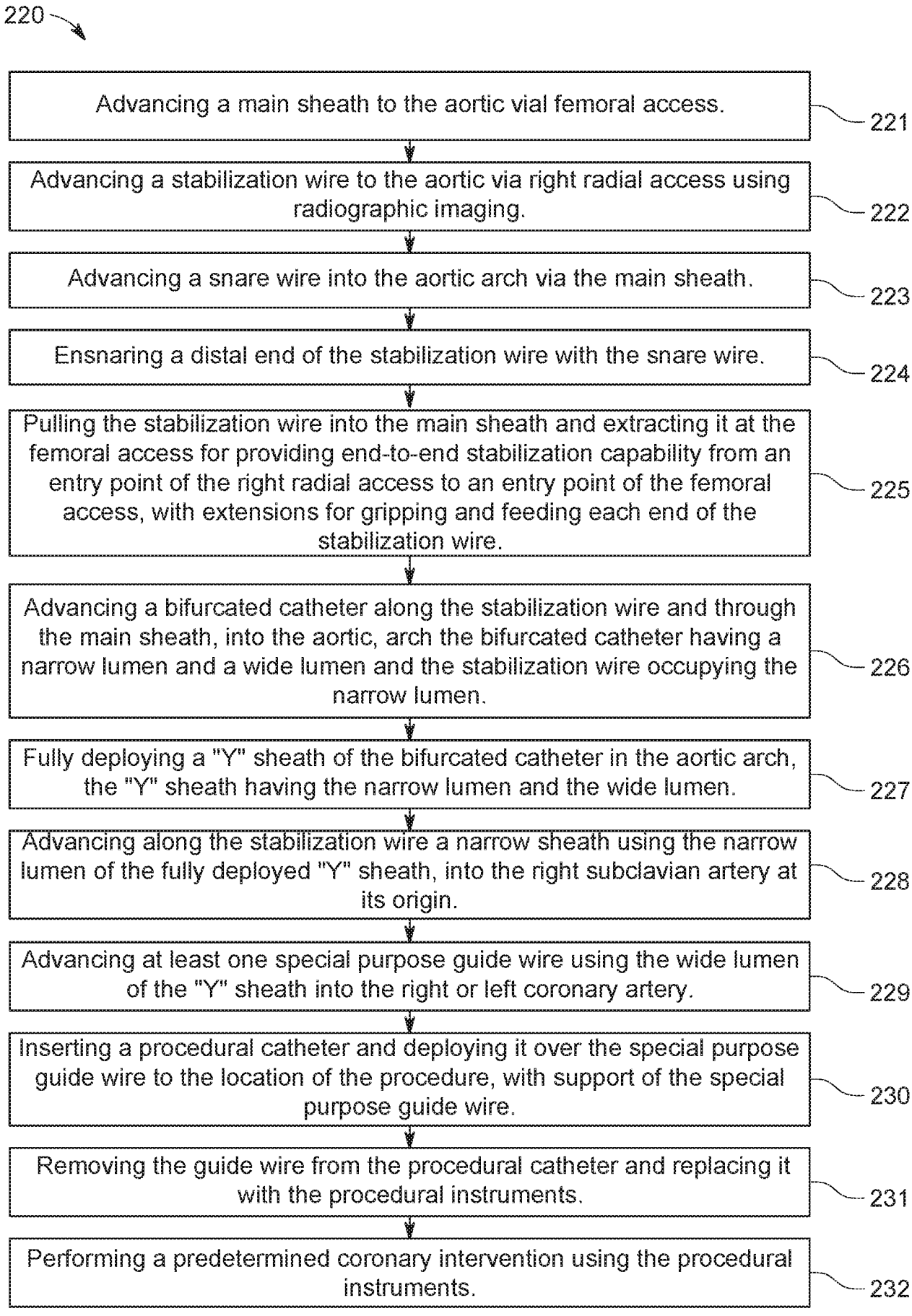

220
Advancing a main sheath to the aortic vial femoral access.
221
Advancing a stabilization wire to the aortic via right radial access using radiographic imaging.
222
Advancing a snare wire into the aortic arch via the main sheath.
223
Ensnaring a distal end of the stabilization wire with the snare wire.
224
Pulling the stabilization wire into the main sheath and extracting it at the femoral access for providing end-to-end stabilization capability from an entry point of the right radial access to an entry point of the femoral access, with extensions for gripping and feeding each end of the stabilization wire.
225
Advancing a bifurcated catheter along the stabilization wire and through the main sheath, into the aortic, arch the bifurcated catheter having a narrow lumen and a wide lumen and the stabilization wire occupying the narrow lumen.
226
Fully deploying a "Y" sheath of the bifurcated catheter in the aortic arch, the "Y" sheath having the narrow lumen and the wide lumen.
227
Advancing along the stabilization wire a narrow sheath using the narrow lumen of the fully deployed "Y" sheath, into the right subclavian artery at its origin.
228
Advancing at least one special purpose guide wire using the wide lumen of the "Y" sheath into the right or left coronary artery.
229
Inserting a procedural catheter and deploying it over the special purpose guide wire to the location of the procedure, with support of the special purpose guide wire.
230
Removing the guide wire from the procedural catheter and replacing it with the procedural instruments.
231
Performing a predetermined coronary intervention using the procedural instruments.
232

FIG. 22

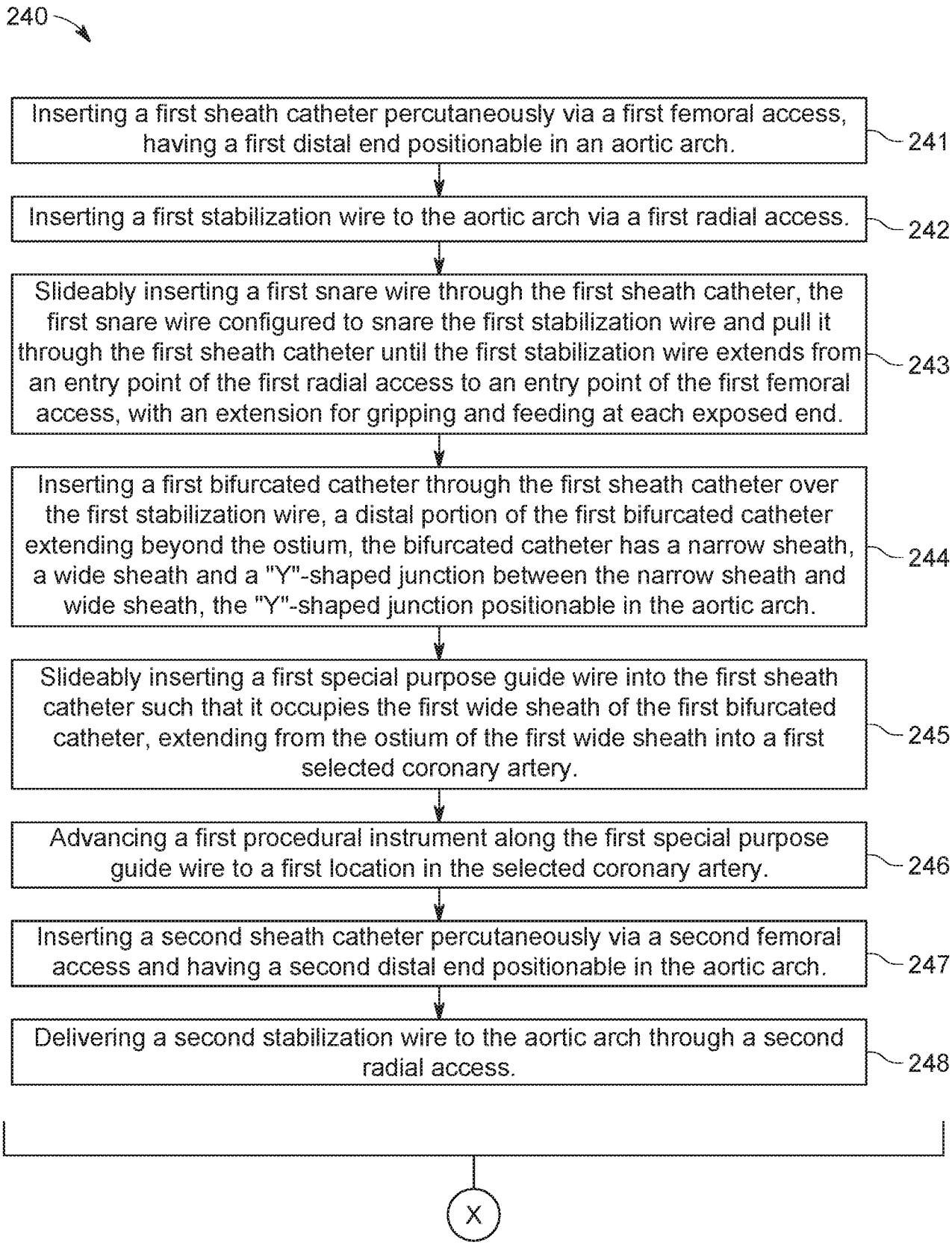

240
Inserting a first sheath catheter percutaneously via a first femoral access, having a first distal end positionable in an aortic arch.
241
Inserting a first stabilization wire to the aortic arch via a first radial access.
242
Slideably inserting a first snare wire through the first sheath catheter, the first snare wire configured to snare the first stabilization wire and pull it through the first sheath catheter until the first stabilization wire extends from an entry point of the first radial access to an entry point of the first femoral access, with an extension for gripping and feeding at each exposed end.
243
Inserting a first bifurcated catheter through the first sheath catheter over the first stabilization wire, a distal portion of the first bifurcated catheter extending beyond the ostium, the bifurcated catheter has a narrow sheath, a wide sheath and a "Y"-shaped junction between the narrow sheath and wide sheath, the "Y"-shaped junction positionable in the aortic arch.
244
Slideably inserting a first special purpose guide wire into the first sheath catheter such that it occupies the first wide sheath of the first bifurcated catheter, extending from the ostium of the first wide sheath into a first selected coronary artery.
245
Advancing a first procedural instrument along the first special purpose guide wire to a first location in the selected coronary artery.
246
Inserting a second sheath catheter percutaneously via a second femoral access and having a second distal end positionable in the aortic arch.
247
Delivering a second stabilization wire to the aortic arch through a second radial access.
248
X

FIG. 23A

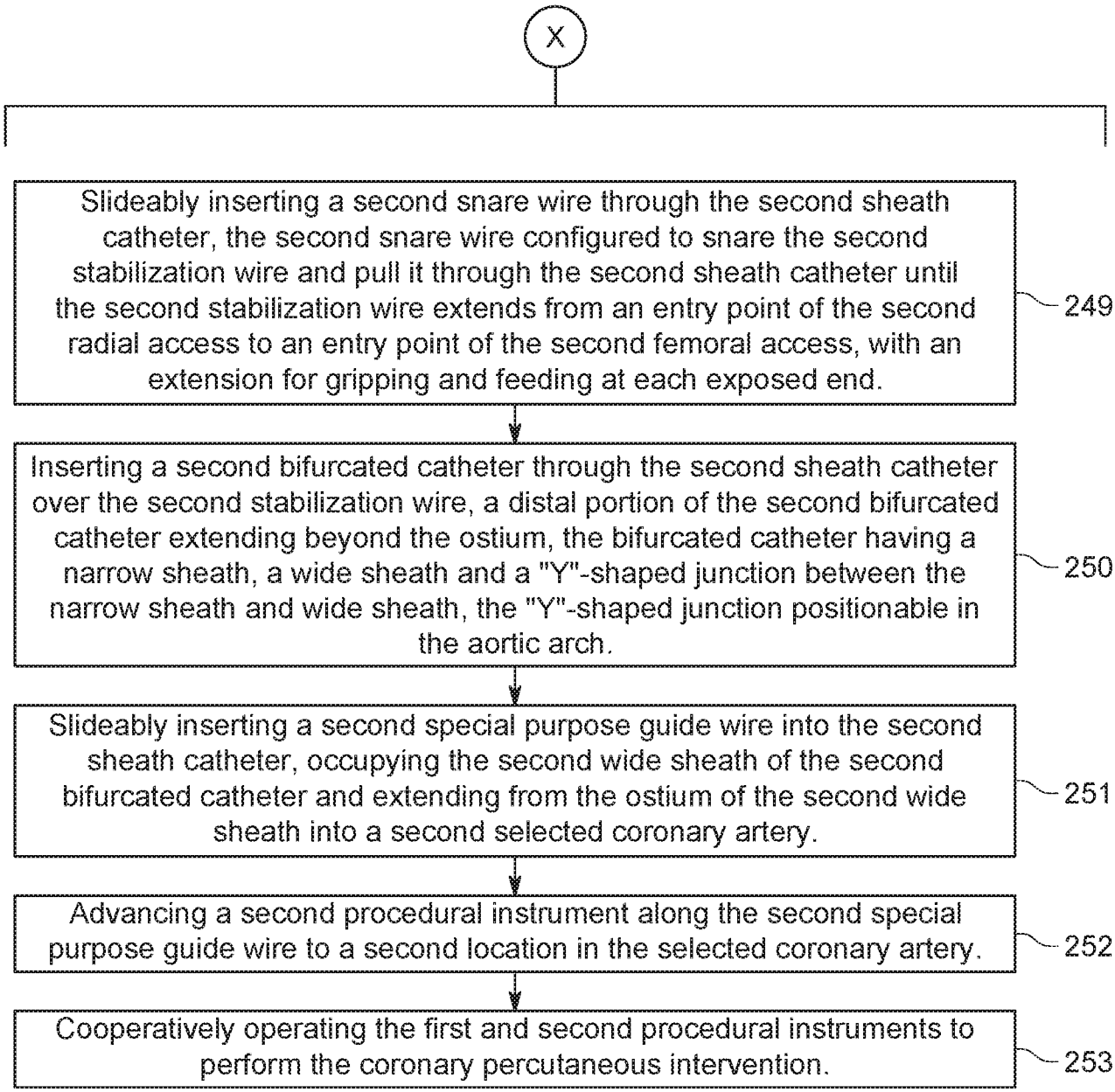

X
Slideably inserting a second snare wire through the second sheath catheter, the second snare wire configured to snare the second stabilization wire and pull it through the second sheath catheter until the second stabilization wire extends from an entry point of the second radial access to an entry point of the second femoral access, with an extension for gripping and feeding at each exposed end.
249
Inserting a second bifurcated catheter through the second sheath catheter over the second stabilization wire, a distal portion of the second bifurcated catheter extending beyond the ostium, the bifurcated catheter having a narrow sheath, a wide sheath and a "Y"-shaped junction between the narrow sheath and wide sheath, the "Y"-shaped junction positionable in the aortic arch.
250
Slideably inserting a second special purpose guide wire into the second sheath catheter, occupying the second wide sheath of the second bifurcated catheter and extending from the ostium of the second wide sheath into a second selected coronary artery.
251
Advancing a second procedural instrument along the second special purpose guide wire to a second location in the selected coronary artery.
252
Cooperatively operating the first and second procedural instruments to perform the coronary percutaneous intervention.
253

FIG. 23B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 18/47372

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/954, 2/962, 2/95, 2/01, 2/07, 2/82, A61M 25/00, 25/01, 25/02 (2018.01)
CPC - A61F 2/954, 2/962, 2/95, 2/01, 2/07, 2/82, A61M 25/0043, 25/01, 25/02

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 --- A	US 2017/0119562 A1 (SYED) 4 May 2017 (04.05.2017) entire document, especially Figs, 6, 8A-B; para [0013]-[0019], [0074], [0080]-[0086]	1-6, 14 --- 7-13, 15-16
A	US 2013/0331921 A1 (ROUBIN) 12 December 2013 (12.12.2013) entire document	1-16
A	WO 2017/074536 A1 (SYED) 4 May 2017 (04.05.2017) entire document	1-16
A	US 6,428,567 B2 (WILSON et al.) 6 August 2002 (06.08.2002) entire document	1-16
A	US 6,494,875 B1 (MAUCH) 17 December 2002 (17.12.2002) entire document	1-16
&, P	US 2018/0042743 A1 (RAM Medical, LLC) 15 February 2018 (15.02.2018) entire document	1-16

☐ 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
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"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
27 October 2018 (27.10.2018)	02 JAN 2019
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (January 2015)