A catheter assembly (10) and related methods include first (12) and second (14) catheter branches that are configured to travel over separate guidewires (36, 38) to a vessel bifurcation treatment site within a patient. The catheter branches can each include a plurality of markers (18, 19, 22, 23). The position of markers on one catheter branch relative to the position of markers on the other catheter branch provide a visual indication of relative twist between the catheter branches, can help distinguish one catheter branch from the other, and help with visual alignment of the catheter branches relative to the vessel bifurcation.
Title: MARKER ARRANGEMENT FOR BIFURCATION CATHETER

Abstract: A catheter assembly (10) and related methods include first (12) and second (14) catheter branches that are configured to travel over separate guidewires (36, 38) to a vessel bifurcation treatment site within a patient. The catheter branches can each include a plurality of markers (18, 19, 22, 23). The position of markers on one catheter branch relative to the position of markers on the other catheter branch provide a visual indication of relative twist between the catheter branches, help distinguish one catheter branch from the other, and help with visual alignment of the catheter branches relative to the vessel bifurcation.

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.
MARKER ARRANGEMENT FOR BIFURCATION CATHETER

Cross Reference to Related Applications
This application is being filed on 22 February 2007 as a PCT International Patent application in the name of Boston Scientific Scimed, Inc., a U.S. national corporation, applicant for the designation of all countries except the US, and Andrzej Malewicz, a citizen of Poland, and Richard C. Gunderson, a citizen of the U.S., applicants for the designation of the US only, and claims priority to U.S. Provisional Application Number 60/776,149 filed on February 22, 2006, and U.S. Utility Application Number 11/677,337, filed February 21, 2007.

Technical Field
This disclosure relates to catheter assemblies configured for use with multiple guidewires. Preferred arrangements provide for catheters assemblies with marker arrangements that are useful in visually aligning features of the catheter assembly and methods related to the same.

Background
Catheters are used with stents and balloon inflatble structures to treat conditions such as strictures, stenoses, and narrowing in various parts of the body. Various catheter designs have been developed for the dilatation of stenoses and to deliver and deploy stents at treatment sites within the body.

Stents are typically intraluminally placed by a catheter within a vein, artery, or other tubular shaped body organ for treating conditions such as, for example, occlusions, stenoses, aneurysms, dissection, or weakened, diseased, or abnormally dilated vessel or vessel wall, by expanding the vessel or by reinforcing the vessel wall. Stents can improve angioplasty results by preventing elastic recoil and remodeling of the vessel wall and treating dissections in blood vessel walls caused by balloon angioplasty of coronary arteries.

While conventional stent technology is relatively well developed, stent technologies related to treatment of the region of a vessel bifurcation are still being developed. One challenge related to treatment of a vessel bifurcation involves alignment of the stent relative to the vessel branches of the vessel bifurcation.
Summary of the Disclosure

The present disclosure relates to catheter assemblies having first and second catheter branches or shafts that are configured for advancement over separate guidewires to a treatment site within a patient. A given catheter assembly includes a marker configuration wherein each catheter branch can include a plurality of markers. A comparison of the position and arrangement of markers on one catheter branch relative to the position and arrangement of markers on the other catheter branch can provide a visual indication of axial and radial positioning of catheter branches relative to each other. Differences in the marker arrangements, including size, shape, and axially positioning on the catheter branches can also be helpful in visually distinguishing one catheter branch from the other.

The markers on the main and side catheter branches can be arranged in any of a plurality of arrangements that result in different marker configurations for the catheter assembly. In one example, the markers on the side catheter branch are spaced apart axially a distance greater than a spacing between the markers of the main catheter branch, and the markers of the main catheter branch are positioned at a location axially between the markers of the side catheter branch. In another example, the markers on the side catheter branch are spaced apart a distance wherein a proximal marker is spaced proximal of a proximal end of a stent carried by the catheter assembly, and a distal marker is positioned distal of the side opening of the stent. In a further example, the side catheter branch markers are spaced apart a distance at least as great as a length of the stent. The markers of the stent delivery system can also be imageably distinct from each other as a result of, for example, different markers sizes, shapes and materials.

Another aspect of the present disclosure relates to the addition of an elongate marker member to at least one of the side and main catheter branches. The elongate marker member can include a coil structure, such as a helical shaped coil, that extends along a portion of the catheter branch length. The elongate marker member can also be configured as, for example, a braid, a series of connected rings, or other structure having a shape that is non-linear relative to an axis of the catheter branch. The marker member can also be defined as part of the catheter branch material composition. The length of the elongate marker member is typically at
least twice as long as common radiopaque markers used with bifurcation stent delivery systems.

Another aspect of the present disclosure relates to a catheter assembly, comprising: a first catheter branch having a distal end portion, the distal end portion of the first catheter branch extending in a first direction; a second catheter branch having a distal end portion, the distal end portion of the second catheter branch extending in a second direction that is generally the same direction as the first direction; a first distal marker and a first proximal marker positioned on the first catheter branch, the first distal marker and the first proximal marker each having a distal portion and a proximal portion; a second distal marker and a second proximal marker positioned on the second catheter branch, the second distal marker and the second proximal marker each having a distal portion and a proximal portion; wherein when the first catheter branch and the second catheter branch are not in a twisted configuration, the distal portion of the first proximal marker is positioned proximal of the proximal portion of the second proximal marker and the proximal portion of the first distal marker is positioned distal of the distal portion of the second distal marker, and when the first catheter branch and the second catheter branch are in a twisted configuration such that the first catheter branch and the second catheter branch are twisted around one another along a longitudinal axis of the catheter assembly, the proximal portion of the first distal marker is positioned proximal of the distal portion of the second distal marker.

Another aspect of the present disclosure relates to a catheter assembly, comprising: a stent having a proximal open end, a distal open end, and a side opening defined in a sidewall of the stent at a location between the proximal and distal open ends; a first catheter branch having a distal end portion, the distal end portion of the first catheter branch extending in a first direction through the side opening of the stent; a second catheter branch having a distal end portion, the distal end portion of the second catheter branch extending through the stent between the distal and proximal open ends, the distal end portion of the second catheter branch extending in a second direction that is generally the same direction as the first direction prior to insertion of the catheter assembly into a body lumen, wherein the second catheter branch includes a main balloon and a side balloon for deploying the stent, the side balloon configured to extend radially outward relative to the main balloon; a first distal marker and a first proximal marker positioned on the first catheter branch, the first distal marker positioned distally of the side opening of the stent and the first proximal marker
positioned proximal of the first distal marker; and a second distal marker and a second proximal marker positioned on the second catheter branch, the second distal marker positioned proximal of the first distal marker and distal of the first proximal marker, and the second proximal marker positioned proximal of the first proximal marker when the first catheter branch and the second catheter branch are in an untwisted configuration and, when the first catheter branch and the second catheter branch are in a twisted configuration such that the first catheter branch is twisted around the second catheter branch and the second catheter branch is twisted around the first catheter branch, the second distal marker is positioned distal of both the first distal marker and the first proximal marker.

Another aspect of the present disclosure relates to a catheter assembly, comprising: a first catheter branch having a distal end portion, the distal end portion of the first catheter branch extending through a stent; a second catheter branch having a distal end portion, the distal end portion of the second catheter branch extending through the stent, the distal end portion of the first catheter branch extending adjacent to the distal end portion of the second catheter branch prior to insertion of the catheter assembly into a body lumen; a first distal marker and a first proximal marker positioned on the first catheter branch at axially spaced apart locations; and a second distal marker and a second proximal marker positioned on the second catheter branch at axially spaced apart locations, the first distal marker and the first proximal marker each having a length imageably distinct from a length of each of the second distal marker and the second proximal marker, wherein the first distal marker and second distal marker are in a first longitudinal arrangement when the first catheter branch and the second catheter branch are in an untwisted configuration, and the first distal marker and the second distal marker are in a second different longitudinal arrangement when the first catheter branch and the second catheter branch are twisted around one another in a twisted configuration.

Another aspect of the present disclosure relates to a stent delivery system, comprising: a stent having a distal open end, a proximal open end, and a side opening defined in a sidewall of the stent at a location between the proximal and distal open ends; a main catheter branch, the main catheter branch including a main balloon member and a side balloon member, the main balloon member extending through the stent from the proximal open end to the distal open end, the side balloon member configured to extend radially outward from the main balloon when inflated, and the
main catheter branch configured to advance over a first guidewire to a main vessel of a vessel bifurcation; a side catheter branch extending into the proximal open end of the stent and extending out of the side opening, the side catheter branch configured to advance over a second guidewire to a branch vessel of the vessel bifurcation; a main distal marker and a main proximal marker positioned on the main catheter branch; and a side distal marker and a side proximal marker positioned on the side catheter branch, at least one of the main and side proximal markers being positioned outside of the stent and at least one of the main and side distal markers being positioned outside of the stent, and the main and side distal markers and the main and side proximal markers having a first relative position when the main catheter branch and the side catheter branch are not twisted, and the main and side distal markers and the main and side proximal markers having a second, different relative position when the main catheter branch and the side catheter branch are twisted, wherein when twisted, the main catheter branch and the side catheter branch are twisted around one another.

Another aspect of the present disclosure relates to a use of first and second guidewires and a catheter assembly for treating a vessel bifurcation, wherein: the first guidewire is positionable in a main vessel of the vessel bifurcation, and the second guidewire is positionable in a branch vessel of the vessel bifurcation; the catheter assembly is advanceable over the first and second guidewires to the vessel bifurcation, the catheter assembly including a stent, first and second pairs of markers, and first and second catheter members, the first and second catheter members having a fixed axial position relative to each other, and the first and second catheter members extend through portions of the stent, wherein the first pair of markers is spaced apart a greater axial distance than an axial spacing between the second pair of markers; relative positions of the first and second pair of markers are observable by making observations prior to the first catheter member being advanceable over the first guidewire into the branch vessel, when the first and second catheter members are in an untwisted configuration, and after the first catheter member being advanceable into the branch vessel such that the first and second catheter members are twisted around one another along a longitudinal axis of the catheter assembly; a position of the stent relative to the vessel bifurcation is adjustable based on observed positions of the first and second pairs of markers; and the stent is expandable to treat the vessel bifurcation.

There is no requirement that an arrangement include all features characterized herein to obtain some advantage according to this disclosure.
**Brief Description of the Drawings**

Figure 1 is a schematic side view of a stent delivery system constructed according to principles of this disclosure and positioned adjacent a vessel bifurcation.

Figure 2 is a schematic side view of the stent delivery system shown in Figure 1 with the side catheter branch extending into a branch vessel of the vessel bifurcation.

Figure 3 is a schematic side view of the stent delivery system shown in Figure 2 with the balloon members inflated and the stent expanded.

Figure 4 is a schematic side view of the stent deliver system shown in Figure 4 with the side catheter branch rotated out of alignment relative to the side opening of the branch vessel.

Figure 5 is a schematic side view of some alternative marker arrangements in accordance with principles of the present disclosure.

Figure 6 is a schematic side view of some further alternative marker arrangements in accordance with principles of the present disclosure.

Figures 7A-I schematically illustrate a variety of example marker arrangements in accordance with principles of the present disclosure.

Figure 8 is a schematic side view of some example catheter branches of a stent delivery system in a twisted arrangement.

Figure 9 is a schematic side view of portions of a stent delivery system wherein a portion of the side catheter branch includes radiopaque material.

Figure 10 is a schematic cross-sectional view of a catheter branch of a stent delivery system having an encapsulated marker member.

Figure 11 is a schematic cross-sectional view of a catheter branch of a stent delivery system taken along indicators 11-11 in Figure 10.

Figure 12 is a schematic cross-sectional view of another example catheter assembly having an alternative marker arrangement relative to the stent.
Figure 13 is a schematic side view of another example catheter assembly with markers positioned within the stent.

**Detailed Description**

**General Background**

This disclosure relates to catheter assemblies configured for use with multiple guidewires. Marker bands and other marker features can be used to visually identify the various catheter branches and the relative position of the catheter branches, for example, during treatment of a vessel bifurcation. The disclosed catheter assemblies and related methods include a main catheter branch and a side catheter branch. A main balloon is typically positioned at a distal end portion of the main catheter branch. When using the catheter assemblies for delivery of a stent, the stent is also positioned on the main balloon at the distal end portion of the main catheter branch. The side catheter branch can be used to help orient the stent relative to a branch vessel at a vessel bifurcation.

Bifurcation stent delivery systems are particularly useful for treating vessel bifurcations. A bifurcation stent is typically configured to provide access through a side opening of the stent into a branch vessel of the vessel bifurcation. In some embodiments, the stent also includes extension structure that extends radially outward from the stent to at least partially into the branch vessel.

The use of multiple guidewires simultaneously within a common lumen such as a blood vessel can result in cross-over of the guidewires along their lengths and cross-over of the catheter branches that move over the guidewires. When one guidewire is directed into a branch vessel and another guidewire is maintained in the main vessel of a vessel bifurcation, cross-over or relative rotation of the catheter branches passing over those guidewires can result in misalignment of the stent relative to the opening of the branch vessel.

In some applications, such as in bifurcation stent delivery systems, features of the stent (e.g., the side opening) must be axially aligned, radially aligned, or both axially and radially aligned relative to an opening into or ostium of the branch vessel of the vessel bifurcation. If the catheter branches are rotated relative to each other, misalignment of the stent features is likely to result, thereby causing deployment of the stent at an orientation that does not provide most effective
treatment of the vessel bifurcation. Identification of relative rotation between and
the relative axial and radial position of the catheter branches using the example
marker systems described below can provide the system operator with an
understanding of the relative position of the catheter branches so that adjustments
can be made prior to deploying the stent at the vessel bifurcation. In many cases, the
mere distinguishing between the main and side catheter branches can result in
improved treatment and correction by the operator.

The Embodiment of Figures 1-4

An illustrated view of one embodiment of a stent delivery system 10
is shown with reference to Figures 1-4. Stent delivery system 10 includes a catheter
shaft 11, a main catheter branch 12 and a side catheter branch 14. The main catheter
branch 12 is configured to advance over a main guidewire 36. The main catheter 12
includes a distal tip 16 and at least first and second markers 18, 19. The markers 18,
19 are axially spaced apart a length L1 along the main catheter branch 12. The side
catheter branch 14 defines a side branch lumen ("SBL") that is sized to advance over
a branch guidewire 38. The side catheter branch 14 includes a distal end 20 and at
least first and second markers 22, 23. The markers 22, 23 are axially spaced apart a
length L2 along the side catheter branch 14. The length L1 is shown as a minimum
length measurement between the markers 18, 19. The length L2 is shown as a
maximum length measurement between the markers 22, 23.

The main catheter branch 12 includes a main guidewire member 26, a
main balloon 28, and a side balloon 30. The guidewire member 26 defines a main
guidewire lumen sized to advance over the main guidewire 36. The side balloon 30
includes a proximal portion 32 that that intersects the main catheter branch 12
proximal of the main balloon 28, and a distal portion 34 that intersects the main
guidewire member 26 distal of the main balloon 28. The side balloon 30 is
configured to extend radially outward relative to the main balloon 28 when the side
balloon 30 is inflated.

The main balloon 28 is configured to remain in a main vessel of a
vessel bifurcation at an axial position that spans an opening into a branch vessel of
the vessel bifurcation. The side balloon 30 is configured to expand into an opening
of the branch vessel. The side balloon 30, when inflated, typically expands a portion
of the stent structure that defines the side opening of the stent into the side open of the branch vessel.

Typically, the main and side balloons 28, 30 are coupled in fluid communication with a common inflation lumen that is defined in the catheter shaft 11. The common inflation lumen can be conventional, and extend distally from a proximal end of the stent delivery system that remains outside of the patient (not shown). The common inflation lumen is used to supply pressurized inflation fluid to the main and side balloons 28, 30 during inflation and drain the inflation fluid when deflating the balloons 28, 30.

The balloons 28, 30 are illustrated as separate balloons that are positioned adjacent to each other. In other balloon arrangements, the side balloon 30 is positioned on the main balloon 28. For example, the side balloon 30 can be integral with the main balloon 28, or be formed as a separate piece that is secured to the outer surface of the main balloon 30. The side balloon 30 can also be integrated into the side catheter branch 14 or another catheter branch of the catheter assembly, such as described in U.S. Pat. No. 7,220,275, entitled STENT WITH A PROTRUDING BRANCH PORTION FOR BIFURCATING VESSELS. The side catheter branch 14 in this exemplary embodiment is exterior to and distinct from the main catheter branch 12.

In operation, the side catheter branch 14 extends through a sidewall opening 52 of the stent 50 (see Figures 1-3) and be directed along the guidewire 38 into a side branch vessel of a vessel bifurcation as described in more detail below. The side catheter branch 14 and stent 50 can be of the type described in, for example, U.S. Patent Application No. 6,325,826 to Vardi, et al., and U.S. Published Patent Application No. 2004/0138737 to Davidson.

Figures 1-3 illustrate stent delivery system 10 in relation to a vessel bifurcation 40. The vessel bifurcation 40 includes a main vessel 42, a branch vessel 44, and a plurality of obstructions 46A-C. When using the stent delivery system 10 to treat the vessel bifurcation 40, the guidewires 36, 38 are navigated to the treatment site with the guidewire 36 positioned in the main vessel 42 and the guidewire 38 positioned extending from the main vessel 42 into the branch vessel 44 (see Figure 1). The stent delivery system 10 is then advanced over the guidewires 36, 38 into position adjacent to the vessel bifurcation 40 within the main vessel 42.
The stent delivery system 10 is shown in Figure 1 with the main catheter branch 12 extending through the stent 50 and the side catheter branch 14 extending into a proximal end of the stent and out of the stent side opening 52. The side catheter branch 14 maintains a generally parallel arrangement with the main catheter branch 12 prior to being advanced to the vessel bifurcation 40. The catheter branches 12, 14 are shown in Figure 1 extending in parallel without any cross-over or relative twisting of the branches 12, 14. Typically, the catheter branches 12, 14 are secured together at a proximal location and thus maintain a fixed axial position relative to each other.

The markers 18, 19 and 22, 23 are shown in Figure 1 positioned on the main and side catheter branches 12, 14 with a spacing between a proximal end of marker 22 and a distal end of marker 23 (L2) that is at least as great as the spacing between a distal end of marker 18 and a proximal end of marker 19 (L1). With this arrangement, the markers 18, 19 can be positioned axially between the markers 22, 23. If one of the pairs of markers 18, 22 or 19, 23 overlap axially while the other of the pairs of markers are properly aligned end-to-end (e.g., the end-to-end arrangement of markers 18, 22 shown in Figure 1), the operator of the stent delivery system 10 can identify cross-over or twisting of the branches 12, 14 in the area between the sets of markers 18, 22 and 19, 23. Further, if only two or three of the markers 18, 19, 22, 23 are visible at a given time due to overlap of the markers, the operator can be aware that features of the catheter branches 12, 14 are not radially aligned.

Referring now to Figure 2, the side catheter branch 14 has been navigated further along the guidewire 38 and into the branch vessel 44. The stent 50 is properly aligned both axially and radially as confirmed by the relative offset position of the markers 18, 22 and 19, 23. The operator can visually inspect the spatial relationship between markers 18 and 22 by projecting a rotation arch $\beta$ to approximate whether the relative offset positioning shown in Figure 1 is maintained. In a case where the catheter branches have experienced twisting or cross-over such as shown in Figure 4, the incorrect relative spacing between markers 18, 22 along the projected arch $\beta$ shows that the distal end of marker 22 is proximal of the proximal end of marker 18.
In some cases it may be difficult for the operator to visually determine the relative alignment of markers 18, 22 in the case of steep angles $\beta$ or extensive distance of the marker 22 from the stent sidewall opening 52. In such cases, it may be beneficial to provide additional markers or other types of features on one or both of the catheter branches 12, 14. The addition of extra markers can improve visualization of the positioning of the catheter branches relative to each other. Alternative marker arrangements and marker features are described in further detail below with reference to Figures 5-12.

Figure 4 illustrates twisting of the side catheter branch 14 relative to the main catheter branch 12 along a length of the side catheter branch 14 from the stent opening 52 to the distal tip 20 of the side catheter branch 14. The opening 52 along with the bifurcated balloon 26 and that portion of the catheter branch 14 in the proximal end of the stent 50 are rotated about a longitudinal axis of the main catheter branch 12 an angle $\alpha$ of about 70 to about 80 degrees out of a plane that extends parallel with the longitudinal axis of the main and branch vessels 42, 44 of the vessel bifurcation 40. While the markers 19, 23 are in proper axially offset orientation with both markers visible, the distal end of marker 23 abutting proximal end of marker 19, and marker 23 vertically above marker 19 (in this view), the twist towards the distal end of catheter branch 14 results in the proximal end of marker 22 being positioned proximal of the proximal end of marker 18 (via projection through angle $\beta$). The operator can infer from this arrangement of markers 18, 22 and 19, 23 that the stent opening 52 is not radially aligned with the opening in the branch vessel 44.

After the stent delivery system has been positioned as shown in Figure 1, the markers 18, 19 and 22, 23 are used to determine whether cross-over or twisting of the catheter branches 12, 14 is present along the length of the branches between the pairs of markers 18, 19 and 22, 23. The distal tip 20 of the side catheter branch 14 is navigated into the branch vessel 44 a distance sufficient to illustrate an angle $\beta$ of separation that indicates the branch 14 is within the branch vessel 44.

Sometimes the angle $\beta$ is relatively small when the angle at which the branch vessel 44 extends from the main vessel 42 is large (e.g., greater than 45 degrees). However, when the branch vessel 44 extends from the main vessel 42 at a relatively small angle (e.g., less than 45 degrees), it may be necessary to insert the catheter
branch 14 further into the branch vessel to obtain a visual confirmation that the catheter branch 14 is actually in the branch 14 is actually in the branch vessel. Typically, the greater the angle $\beta$ the more difficult it becomes to visualize the relative axial position of the markers 18, 22.

Once the stent delivery system 10 is positioned with the sidewall opening 52 and auxiliary inflatable portion 34 aligned with the opening into the branch vessel 44, pressurized fluid is supplied to the main and auxiliary inflatable portions 32, 34 to dilate and expand stent 50 (see Figure 3). The main inflatable portion 32 primarily expands a main body portion of the stent. The auxiliary inflatable portion 34 expands the sidewall opening 52 and an extendable structure 54 of the stent 50 that extends radially away from the main body portion of the stent and into the branch vessel 44. After the inflatable portions 32, 34 have been inflated and the stent expanded, the bifurcated balloon 26 is deflated by draining the inflation fluid out of the main catheter branch 12. This allows the inflatable portions 32, 34 to collapse in preparation for withdrawal of the main and side catheter branches 12, 14 from the vessel bifurcation 40.

The extendable structure 54 of the stent 50 can have a variety of configurations such as those configurations disclosed in co-pending U.S. Published Patent Application Nos. 2004/0138737 and 2005/0015108.

**Alternative Marker Configurations**

Figure 5 illustrates an alternative marker configuration in which the markers are imageably distinct from each other. Imageably distinct can be defined in the context of viewing a catheter marker inside a body lumen as being viewable by an imaging system, such as those imaging systems commonly used to view stent delivery procedures. An example imaging system is a C-arm radiographic device that images a vessel using fluoroscopy and provides images of the vessel and in-situ stent delivery features on a screen. The structure and composition of the markers can influence the ability of a viewer to distinguish between markers. For example, the length of the marker is one structural difference that can provide image distinction. The diameter, cross-sectional shape and material thickness of the markers are other example structural differences that provide image distinction. The
type and concentration of radiopaque material in the markers are example
composition differences that provide image distinction. The relative location of the
markers at different positions on the main and side catheter branches 12, 14 as
compared to the embodiment shown in Figures 1-4, alone or in combination with
structural and composition difference between markers can also be useful.

The markers 18 and 19 shown in Figure 5 each have an equal length
L3 whereas the markers 22, 23 have lengths L4 that are different from the length L3.
In one example, the length L4 is about 20% to about 200% of the value of L3, more
preferably about 25% to about 175% of the value of L3, and most preferably about
25% to about 50% greater or about 25% to about 50% smaller than the value of L3.
Thus, the length L3 of markers 18 and 19 can be made greater or smaller than the
length L4 of the markers 22, 23 within, for example, the preferred ranges described
above.

The total length of each of markers 18, 19, 22, 23 is typically in the
range of about 0.5 mm to about 5 millimeters long, more preferably about 0.75 mm
to about 2 millimeters long, and most preferably about 0.75 mm to about 1
millimeter long. The material composition of the markers is a consideration for the
marker length, the marker material thickness, and the cross-sectional size of the
markers. Typically, the materials used for the markers have a greater stiffness than
the stiffness of the material of the catheter branches 12, 14 to which the markers are
mounted. The use of most markers, regardless of the size and shape, can reduce to
some degree the flexibility of the catheter branches to which the markers are
mounted. Shortening the length of the markers can minimize negative effects on
catheter flexibility. Markers that are too short can become difficult to visualize.

Optimizing the size and shape of the markers to provide adequate visualization
while minimizing added stiffness in the catheter is one objection of the markers and
marker arrangements disclosed herein.

One option for providing the appearance of one longer marker is to
position two shorter markers adjacent to each other with a small gap there between.
Figure 5 illustrates marker 22 comprising segments 22A and 22B that are spaced
apart axially a distance B. Typically, the distance B would be made small enough
that the break between segments 22A and 22B is not perceptible, while still
providing some relative movement between the segments that leads to the addition of minimum stiffness to the catheter branch 14.

The markers 18, 19, 22, 23 can comprise different material compositions that provide differing amounts of visualization of the marker, stiffness, ease of handling and forming of the marker, and other considerations. Some example materials used in the markers include platinum, tantalum, and gold plated steel. The markers usually comprise materials that are generally categorized as radiopaque materials that obstruct the transmission of radiant energy, such as the energy emitted from a C-arm radiographic device.

In the arrangement of Figure 5, the marker 18 is positioned on the main catheter branch 12 in axial alignment with the side balloon 30. This position of marker 18 can help the operator visually align the side balloon 30 more accurately with an opening into a branch vessel of a vessel bifurcation. The markers 22, 23 are spaced apart axially a distance substantially equal to a spacing between the markers 18, 19. As a result, the markers 22, 23 can be positioned just proximal of the markers 18, 19 as shown in Figure 5 to provide a parallelogram-type arrangement among the markers 18, 19, 22, 23, wherein lines drawn between markers 18, 22, between markers 22, 23, between markers 23, 19, and between markers 19, 18 provides a parallelogram structure having two pairs of parallel lines.

Figure 6 illustrates another marker arrangement that includes a third marker 17 positioned on the main catheter branch 12 at a location between the markers 18, 19, and a third marker 21 positioned on the side catheter branch 14 at a location between the markers 22, 23. Branch 12 includes markers 18, 17, 19 that are positioned at distal, center, and proximal locations, respectively, relative to the bifurcated balloon 26. The branch 14 includes markers 22, 21, 23 arranged adjacent to markers 22, 21, 23, respectively. The markers 22, 23 are spaced apart a distance sufficient for the distal end of marker 18 and the proximal end of marker 19 to be arranged axially between proximal and distal end of markers 22 and 23, respectively. When the markers 18, 19 are arranged between the markers 22, 23 the marker 21 is axially aligned with marker 17. Other embodiments may include any combination of numbers and positions for the markers relative to other markers on the same catheter branch or relative to markers on the adjacent catheter branch. For example, the six marker arrangement shown in Figure 6 can be modified so that the
distal end of each of markers 21, 22, 23 are positioned proximal of the proximal end of markers 17, 18, 19, respectively.

Figures 7A-I illustrate a few different marker arrangements that include two or three markers positioned on each of the catheter branches 12, 14. The markers 17, 18, 19, 21, 22, 23 can have the same or different lengths and sizes. The markers 17, 18, 19, 21, 22, 23 can be arranged in axial alignment with each other or be at least partially offset axially from each other. The number of markers on each catheter branch can be equal or unequal. The markers 17, 18, 19, 21, 22, 23 can be positioned at various locations along the catheter branches 12, 14 relative to a stent (e.g., stent 50 shown in Figure 1) positioned on the catheter branches 12, 14 (e.g., positioned within, overlapping, or outside of the stent). For example, catheter assembly 200 shown in Figure 13 illustrates the markers 18, 23 positioned inside the stent 50 and the markers 19, 20 outside of the stent. The markers 17, 18, 19, 21, 22, 23 can be positioned on other portions of a catheter assembly such as a main or side balloon member (e.g., portions 28, 30 of the side balloon 30 shown in Figure 1), a guidewire member that defines a guidewire lumen, or a primary catheter shaft that defines an inflation lumen of the catheter assembly. Typically, the branches 12, 14 maintain a fixed axial relationship relative to each other prior to and during insertion of the catheter assembly into a patient.

Many other variations of the marker arrangements to create any of a number of marker arrangement shapes are possible. For example, in addition to parallelogram shapes, rectangle, rhombus, rhomboid, triangle, trapezoid, and various quadrilaterals shapes are possible marker arrangement shapes.

The markers 18, 19, 22, 23 can be configured as marker bands having a circular cross-section. The markers can also have a semi-circular, oval, or semi-oval cross-section. The markers should have sufficient circumferential shape to be mounted and then stay retained in position when secured to the catheter branch. The markers can be secured to the catheter branches in a variety of ways. For example, the markers can be secured to an outer or inner surface of the catheter branch, or embedded in or otherwise integrated within the sidewall structure of the catheter branch. Figures 10 and 11 illustrate swage mounting of a marker band 18 to a catheter branch 12. A swage mounting provides for the outer facing surface of the marker to be flush mounted with the outer surface of the catheter branch.
Preferably, swaging a marker band onto a catheter branch does not create a decreased internal dimension of the catheter branch. Other types of mounting methods and configurations may be used for the markers include, for example, crimping, co-molding, and depositing techniques.

The axial spacing between pairs of proximal markers (e.g., markers 19, 23) and distal markers (e.g., markers 18, 22) is another variable that can be adjusted. The axial spacing between the distal ends of markers 22, 23 and the proximal ends of markers 18, 19 in Figure 5 is substantially zero distance, which results in an end-abutting arrangement. Other embodiments can include spacing up to a length equal to two or three times the length of one of the markers being axially spaced apart. For example, in an embodiment wherein the length of marker 19 is about 1 mm and the length of marker 23 is about 1.5 mm, the spacing between the distal end of marker 23 and the proximal end of marker 19 is in the range of about 0 mm to about 3 mm (e.g., about three times the length of marker 19). Preferably, the spacing between the distal end of a marker on one catheter branch (e.g., a distal-most marker) and the proximal end of a corresponding marker on a separate catheter branch (e.g., a corresponding distal-most marker) is about 0 mm to about 3 mm, and more preferably about 0 mm to about 2 mm. While the size and shape of the markers can influence the general visibility of the markers themselves, the ability to visually assess the relative axial spacing between markers on separate catheter branches is typically not significantly influenced by the size and shape of the markers. The further the relative axial spacing between corresponding markers on separate catheter branches becomes, the more difficult it is to accurately assess whether that relative axial spacing is maintained during operation of a stent delivery system that includes the markers.

Referring now to Figure 8, catheter branches 12, 14 are shown in a 360° symmetrical twisted relationship relative to each other. This symmetric twisted relationship between branches 12, 14 illustrates how a twist may be difficult to identify in some situations. The spacing between markers 18, 22 and between markers 19, 23 is the same as when the catheter branches are not twisted or crossed over (e.g., the spacing shown in Figure 1). However, in the twisted configuration shown in Figure 6, the markers 18, 22 are not the same axial distance from the markers 19, 23, respectively, due to the twisted arrangement. Further, in the case
wherein markers 18, 19, 22, 23 each have the same shape, size, and material composition, it is difficult to distinguish between the catheter branches 12, 14.

In order to more clearly distinguish the catheter branch 14, the branch 14 can include a helical coil 24 extending along a portion of a length of the branch 14. The helical coil comprises a visible material such as the radiopaque material described above for use with markers 18, 19, 22, 23. The helical coil 24 extends from the marker 22 to the marker 23. The helical coil can also have different lengths and extend over different portions of the branch 14. For example, the helical coil can have an axial length at least as great as an axial length of the stent being deployed using the catheter branches 12, 14. The helical coil can be positioned on the catheter branch so that it overlaps axially with the stent. In another example, the coil extends axially from near a distal tip of the catheter branch 14 to a proximal end of the stent. For these and other examples, it is assumed that the branch 14 is secured or otherwise fixed axially relative to the main catheter branch 12 at a location proximal of the side opening in the stent through which the side catheter branch 14 extends.

The helical coil 24 can be used in combination with one or more markers on a given catheter branch. The helical coil 24 can also be used by itself on a catheter branch without any other markers on that catheter branch. The helical coil can provide visualization of the catheter branch for at least the purpose of distinguishing the catheter branches 12, 14 from each other. The helical coil can also be useful for positioning the catheter branch to which it is mounted relative to other features of a stent delivery system and vessel bifurcation.

The helical coil 24 can provide certain advantages due to the helical structure. A helical coil can provide for flexibility in a lateral direction relative to an axis of the catheter branch so that the catheter branch maintains its ability to navigate through a vessel to a vessel treatment site. A helical coil can also be easily mounted to an outer surface of a cylindrical member such as the main and side catheter branches 12, 14. A helical coil can be embedded in a catheter branch using methods such as, for example, co-molding or extrusion techniques.

Other structures can be used in place of the helical coil 24 and provide similar advantages. For example, a braid structure, a plurality interconnected rings, or a thin layer or film can provide at least some of the same
advantages and function of a helical coil. Referring to Figure 12, one construction for mounting a helical coil 24 or other marker structure to a catheter branch is shown. Figure 9 illustrates an inner layer 60 over which a marker layer 62 (e.g., helical coil) can be applied to an outer circumference thereof. In order to provide a smooth outer surface for the catheter branch, an outer layer 64 can be added to encapsulate the marker layer 62.

Referring to Figure 9, another configuration is shown that addresses some of the issues described above related to distinguishing between a main and side catheter branch of a stent delivery system. Side catheter branch 14 shown in Figure 8 comprises a marker material that is part of the material composition of the catheter branch 14. The catheter branch material can comprise, for example, a polymeric material extruded or otherwise formed into a lumen shape and comprise a radiopaque material such as platinum or tantalum. This material composition for the catheter branch 14 can be in any portion along the length of the side catheter branch 14, such as along the length L5 shown in Figure 8. The concentration of radiopaque material in the catheter branch composition can vary to alter the visibility of the catheter branch. The length L5 of the marker material can vary. The location of the proximal and distal relative to a distal tip of the side catheter branch 14 can also vary. In one example, wherein a stent is carried by the main catheter branch 12 and the side catheter branch 14 extends through a side opening in the stent, the length L5 is at least as great as a distance between the side opening of the stent and a distal open end of the stent.

In many embodiments, the distal tips 16, 20 of the catheter branches 12, 14 include some type of marker or marker material composition. Marking the distal tip of a catheter branch can help with determining a relative position of the catheter branch relative to other features of a stent delivery system and features of the vessel through which the catheter branch travels. In one example, a marked distal tip 20 of a side catheter branch 14 can help in determining that the branch 14 has entered the vessel branch of a vessel bifurcation. By providing a length of a catheter branch (e.g., L5) with a marker material that provides visualization along that length, it may be easier to identify cross-over and twisting of the catheter branches 12, 14 relative to each other.
Materials and Other Considerations

The example systems disclosed herein may be used in over-the-wire or rapid exchange systems. Some example rapid exchanges systems are disclosed in U.S. Published Patent Application No. 2003/0181923 to Vardi et al.

The materials used in the balloons, catheter shafts, and other components of the catheter assemblies disclosed herein can be made of any suitable material including, for example, thermoplastic polymers, polyethylene (high density, low density, intermediate density, linear low density), various co-polymers and blends of polyethylene, ionomers, polyesters, polycarbonates, polyamides, polyvinyl chloride, acrylonitrile-butadiene-styrene copolymers, polyether-polyester copolymers, and polyetherpolyamide copolymers. One suitable material is Surlyn®, a copolymer polyolefin material (DuPont de Nemours, Wilmington, Del.). Still further suitable materials include thermoplastic polymers and thermoset polymeric materials, poly(ethylene terephthalate) (commonly referred to as PET), thermoplastic polyamide, polyphenylene sulfides, polypropylene. Some other example materials include polyurethanes and block copolymers, such as polyamide-polyether block copolymers or amide-tetramethylene glycol copolymers. Additional examples include the PEBAX® (a polyamide/polyether/polyester block copolymer) family of polymers, e.g., PEBAX® 70D, 72D, 2533, 5533, 6333, 7033, or 7233 (available from Elf AtoChem, Philadelphia, Pa.). Other examples include nylons, such as aliphatic nylons, for example, Vestamid L21011F, Nylon 11 (Elf Atochem), Nylon 6 (Allied Signal), Nylon 6/10 (BASF), Nylon 6/12 (Ashley Polymers), or Nylon 12. Additional examples of nylons include aromatic nylons, such as Grivory (EMS) and Nylon MXD-6. Other nylons and/or combinations of nylons can also be used. Still further examples include polybutylene terephthalate (PBT), such as CELANEX® (available from Ticona, Summit, NJ.), polyester/ether block copolymers such as ARNITEL® (available from DSM, Erionspilla, Ind.), e.g., ARNITEL® EM740, aromatic amides such as Trogamid (PA6-3-T, Degussa), and thermoplastic elastomers such as HYTREL® (Dupont de Nemours, Wilmington, Del.). In some embodiments, the PEBAX®, HYTREL®, and ARNITEL® materials have a Shore D hardness of about 45D to about 82D. The balloon materials can be used pure or as blends. For example, a blend may include a PBT and one or more
PBT thermoplastic elastomers, such as RITEFLEX®, (available from Ticona), ARNITEL®, or HYTREL®, or polyethylene terephthalate (PET) and a thermoplastic elastomer, such as a PBT thermoplastic elastomer. Additional examples of balloon material can be found in U.S. Pat. No. 6,146,356. It should be understood that the specific materials disclosed below for the individual embodiments does not limit the embodiment to those materials.

In the example catheter assemblies described above, the branch balloon can include a lubricious coating on an exterior surface thereof. The coating can promote insertion of the branch balloon into the branch vessel of a vessel bifurcation. The coating can also improve removal of the branch balloon from the branch vessel and the branch aperture of the stent when deflating and removing the catheter assembly from the vessel bifurcation after expansion of the stent. Some example coating for use with the branch balloon include hydrophilic polymers such as polyarylene oxides, polyvinylpyrrolidones, polyvinylalcohol, hydroxy alkyl celluloses, algin, saccharides, caprolactones, and the like, and mixtures and combinations thereof. Hydrophilic polymers can be blended among themselves or with formulated amounts of water insoluble compounds (including some polymers) to yield coating with suitable lubricity, bonding and solubility. In some examples, portions of the devices described herein can be coated with a hydrophilic polymer or a fluoropolymer such as polytetrafluoroethylene (PTFE), better known as TEFLO®.

While the example stent delivery systems described above illustrate a balloon expandable stent having a predetermined side opening (i.e., branch aperture), other types of stents can be used with the catheter features described above. A variety of stents can be used with the systems and methods disclosed herein. Examples of such stents can be found in, for example, in U.S. Pat. Nos. 6,210,429 and 6,325,826 to Vardi et al., and U.S. Pat. No. 7,220,275, filed on August 21, 2003, and titled “Stent With A Protruding Branch Portion For Bifurcated Vessels.” In general, the aforementioned stents have a tubular shape with a continuous sidewall that extends between the proximal and distal ends. Proximal and distal stent apertures are defined at respective proximal and distal ends of the stent. A branch aperture is defined in the sidewall of the stent. The branch aperture
provides access between an interior of the stent and an exterior of the stent. In some stents, the branch aperture includes expandable structure around a peripheral edge thereof that expands in a generally radial outward direction relative to a longitudinal axis of the stent. The expandable structure can be configured to extend into the branch lumen of the bifurcation upon expansion of the stent. The stent includes a plurality of strut structures that define the sidewall. The struts are expandable from a first, unexpanded state to a second, expanded state. Typically, the stent is configured to maintain the expanded state. The struts define a plurality of cell openings or cells along a length of the stent. The size and shape of the cells is typically different than the size and shape of the branch aperture. The stent is typically expanded once the stent is properly positioned in the main lumen of the bifurcation with the branch aperture aligned radially and axially with an opening into the branch lumen. The stent, including the expandable structure surrounding the branch aperture, can be expanded with a single expansion or with multiple expansions using, for example, one or more inflatable balloons.

**Conclusion**

One aspect of the present disclosure relates to a catheter assembly that includes a first catheter branch, a second catheter branch, first distal and proximal markers, and second distal and proximal markers. The first catheter branch includes a distal end portion that extends in a first direction. The second catheter branch includes a distal end portion that extends in a second direction that is generally the same direction as the first direction. The first distal marker and the first proximal marker are positioned on the first catheter branch. The second distal marker and the second proximal marker are positioned on the second catheter branch. The first distal marker, the first proximal marker, the second distal marker and the second proximal marker each include a distal portion and a proximal portion. The proximal portion of the first distal marker is positioned distal of the distal portion of the second distal marker, and the distal portion of the first proximal marker is positioned proximal of the proximal portion of the second proximal marker.

Another aspect of the present disclosure relates to a catheter assembly that includes a stent, a first catheter branch, a second catheter branch, first distal and
proximal markers, and second distal and proximal markers. The stent includes a proximal open end, a distal open end, and a side opening defined in a sidewall of the stent at a location between the proximal and distal open ends. The first catheter branch includes a distal end portion that extends in a first direction through the side opening of the stent. The second catheter branch includes a distal end portion that extends through the stent between the distal and proximal open ends. The distal end portion of the first catheter extends in a second direction that is generally the same direction as the first direction prior to insertion of the catheter assembly into a body lumen. The first distal marker and the first proximal marker are positioned on the first catheter branch. At least a portion of the first distal marker is positioned distally of the side opening of the stent and the first proximal marker is positioned proximal of the first distal marker. The second distal marker and the second proximal marker are positioned on the second catheter branch. At least a portion of the second distal marker is positioned further proximally than a proximal portion of the first distal marker, and at least a portion of the second proximal marker is positioned further proximally than a proximal portion of the first proximal marker.

Another aspect of the present disclosure relates to a catheter assembly that includes a first catheter branch, a second catheter branch, first distal and proximal markers, and second distal and proximal markers. The first catheter branch includes a distal end portion that extends through the stent. The second catheter branch includes a distal end portion that extends through the stent in an adjacent orientation to the distal end portion of the second catheter branch prior to insertion of the catheter assembly into a body lumen. The first distal marker and the first proximal marker are positioned on the first catheter branch at axially spaced apart locations. The second distal marker and a second proximal marker are positioned on the second catheter branch at axially spaced apart locations. The first distal marker and the first proximal marker each have a length that is imageably distinct from a length of each of the second distal marker and the second proximal marker.

A further aspect of the present disclosure relates to a stent delivery system that includes a stent, a main catheter branch, a side catheter branch, main distal and proximal markers, and side distal and proximal markers. The stent includes a distal open end, a proximal open end, and a side opening defined in a
sidewall of the stent at a location between the proximal and distal open ends. The main catheter branch includes a balloon member that extends through the stent from the proximal open end to the distal open end. The main catheter branch is configured to advance over a first guidewire to a main vessel of a vessel bifurcation. The side catheter branch extends into the proximal open end of the stent and extends out of the side opening. The side catheter branch is configured to advance over a second guidewire to a branch vessel of the vessel bifurcation. The main distal marker and the main proximal marker are positioned on the main catheter branch, and the side distal marker and the side proximal marker are positioned on the side catheter branch. At least one of the main and side proximal markers is positioned outside of the stent and at least one of the main and side distal markers are positioned outside of the stent. A relative position of the main and side distal markers and the main and side proximal markers provides an indication of relative twist between the main and side catheter branches and alignment of the stent sidewall opening relative to an opening from the main vessel into the branch vessel of the vessel bifurcation.

A further aspect of the present disclosure relates to a stent delivery system that includes a stent, a main catheter branch, and a side catheter branch. The stent includes a distal open end, a proximal open end, and a side opening at a location between the proximal and distal open ends. The main catheter branch includes a balloon member at least partially positioned within the stent, and the main catheter branch is configured to advance over a first guidewire into a main vessel of a vessel bifurcation. The side catheter branch extends through the side opening of the stent and includes marker material along a length of the side catheter branch. The marker material extends along a distal end portion of the side catheter branch and has a length at least as great as a distance from the side opening of the stent to the distal open end of the stent. The side catheter branch is configured to advance over a second guidewire into a branch vessel of the vessel bifurcation. A still further aspect of the present disclosure relates to a method of treating a vessel bifurcation. The method includes positioning a first guidewire in a main vessel of the vessel bifurcation, positioning a second guidewire in a branch vessel of the vessel bifurcation, advancing a catheter assembly over the first and second guidewires to the vessel bifurcation, wherein the catheter assembly includes
a stent, first and second pairs of markers, and first and second catheter members. The first and second catheter members have a fixed axial position relative to each other, and the first and second catheter members extend through portions of the stent. The method further includes observing relative positions of the first and second pair of markers, adjusting a position of the stent relative to the vessel bifurcation based on observed positions of the first and second pairs of markers; and expanding the stent to treat the vessel bifurcation.

The above specification, examples and data provide a complete description of the manufacture and use of the composition of the invention. Since many embodiments of the invention can be made without departing from the spirit and scope of the invention, the invention resides in the claims hereinafter appended.
What is claimed is:

1. A catheter assembly, comprising:
   a first catheter branch having a distal end portion, the distal end portion of the first catheter branch extending in a first direction;
   a second catheter branch having a distal end portion, the distal end portion of the second catheter branch extending in a second direction that is generally the same direction as the first direction;
   a first distal marker and a first proximal marker positioned on the first catheter branch, the first distal marker and the first proximal marker each having a distal portion and a proximal portion;
   a second distal marker and a second proximal marker positioned on the second catheter branch, the second distal marker and the second proximal marker each having a distal portion and a proximal portion;
   wherein when the first catheter branch and the second catheter branch are not in a twisted configuration, the distal portion of the first proximal marker is positioned proximal of the proximal portion of the second proximal marker and the proximal portion of the first distal marker is positioned distal of the distal portion of the second distal marker, and when the first catheter branch and the second catheter branch are in a twisted configuration such that the first catheter branch and the second catheter branch are twisted around one another along a longitudinal axis of the catheter assembly, the proximal portion of the first distal marker is positioned proximal of the distal portion of the second distal marker.

2. The catheter assembly of claim 1, wherein the second catheter branch includes a guidewire shaft that defines a guidewire lumen, an inflation shaft that defines an inflation lumen, and a balloon member coupled in fluid communication with the inflation lumen, and the second proximal and distal markers are positioned on the guidewire shaft.

3. The catheter assembly of claim 1 or 2, wherein the first catheter branch includes a guidewire shaft that defines a guidewire lumen, an inflation shaft that defines an inflation lumen, and a balloon member coupled in fluid communication with the
inflation lumen, and the first proximal and distal markers are positioned on the guidewire shaft.

4. A catheter assembly, comprising:
   a stent having a proximal open end, a distal open end, and a side opening defined in a sidewall of the stent at a location between the proximal and distal open ends;
   a first catheter branch having a distal end portion, the distal end portion of the first catheter branch extending in a first direction through the side opening of the stent;
   a second catheter branch having a distal end portion, the distal end portion of the second catheter branch extending through the stent between the distal and proximal open ends, the distal end portion of the second catheter branch extending in a second direction that is generally the same direction as the first direction prior to insertion of the catheter assembly into a body lumen, wherein the second catheter branch includes a main balloon and a side balloon for deploying the stent, the side balloon configured to extend radially outward relative to the main balloon;
   a first distal marker and a first proximal marker positioned on the first catheter branch, the first distal marker positioned distally of the side opening of the stent and the first proximal marker positioned proximal of the first distal marker; and
   a second distal marker and a second proximal marker positioned on the second catheter branch, the second distal marker positioned proximal of the first distal marker and distal of the first proximal marker, and the second proximal marker positioned proximal of the first proximal marker when the first catheter branch and the second catheter branch are in an untwisted configuration and, when the first catheter branch and the second catheter branch are in a twisted configuration such that the first catheter branch is twisted around the second catheter branch and the second catheter branch is twisted around the first catheter branch, the second distal marker is positioned distal of both the first distal marker and the first proximal marker.

5. The catheter assembly of claim 4, wherein at least a portion of the first distal marker is positioned distal of a distal end of the stent, and at least a portion of the first proximal marker is positioned proximal of a proximal end of the stent.
6. The catheter assembly of claim 5, wherein at least a portion of the second distal marker is positioned distal of the distal end of the stent, and at least a portion of the second proximal marker is positioned proximal of the proximal end of the stent.

7. The catheter assembly of any one of claims 4 to 6, wherein the first distal marker and the first proximal marker each having a distal portion and a proximal portion, the second distal marker and the second proximal marker each having a distal portion and a proximal portion, wherein when the first and second catheter branches are in the untwisted configuration, the proximal portion of the first distal marker is positioned distal of the distal portion of the second distal marker, and the proximal portion of the first proximal marker is positioned distal of the distal portion of the second proximal marker.

8. The catheter assembly of claim 7, wherein the first distal marker and the first proximal marker are each imageably distinct from the second distal marker and the second proximal marker.

9. The catheter assembly of any one of claims 4 to 8, further comprising a first middle marker positioned on the first catheter branch at a location between the first distal marker and the first proximal marker.

10. The catheter assembly of any one of claims 4 to 9, further comprising a second middle marker positioned on the second catheter branch at a location between the second distal marker and the second proximal marker.

11. A catheter assembly, comprising:
   a first catheter branch having a distal end portion, the distal end portion of the first catheter branch extending through a stent;
   a second catheter branch having a distal end portion, the distal end portion of the second catheter branch extending through the stent, the distal end portion of the first catheter branch extending adjacent to the distal end portion of the second catheter branch prior to insertion of the catheter assembly into a body lumen;
a first distal marker and a first proximal marker positioned on the first catheter branch at axially spaced apart locations, and

a second distal marker and a second proximal marker positioned on the second catheter branch at axially spaced apart locations, the first distal marker and the first proximal marker each having a length imageably distinct from a length of each of the second distal marker and the second proximal marker,

wherein the first distal marker and second distal marker are in a first longitudinal arrangement when the first catheter branch and the second catheter branch are in an untwisted configuration, and the first distal marker and the second distal marker are in a second different longitudinal arrangement when the first catheter branch and the second catheter branch are twisted around one another in a twisted configuration.

12. The catheter assembly of claim 11, wherein the length of the first distal marker and the first proximal marker is at least 25% greater than the length of the second distal marker and the second proximal marker.

13. A stent delivery system, comprising:

a stent having a distal open end, a proximal open end, and a side opening defined in a sidewall of the stent at a location between the proximal and distal open ends;

a main catheter branch, the main catheter branch including a main balloon member and a side balloon member, the main balloon member extending through the stent from the proximal open end to the distal open end, the side balloon member configured to extend radially outward from the main balloon when inflated, and the main catheter branch configured to advance over a first guidewire to a main vessel of a vessel bifurcation;

a side catheter branch extending into the proximal open end of the stent and extending out of the side opening, the side catheter branch configured to advance over a second guidewire to a branch vessel of the vessel bifurcation;

a main distal marker and a main proximal marker positioned on the main catheter branch; and

a side distal marker and a side proximal marker positioned on the side catheter branch, at least one of the main and side proximal markers being positioned outside of the stent and at least one of the main and side distal markers being positioned
outside of the stent, and the main and side distal markers and the main and side proximal markers having a first relative position when the main catheter branch and the side catheter branch are not twisted, and the main and side distal markers and the main and side proximal markers having a second, different relative position when the main catheter branch and the side catheter branch are twisted, wherein when twisted, the main catheter branch and the side catheter branch are twisted around one another.

14. The stent delivery system of claim 13, wherein at least a portion of the side distal marker is positioned distal of a distal portion of the main distal marker when in the first relative position and wherein at least a portion of the side distal marker is positioned proximal of a distal portion of the main distal marker when in the second relative position.

15. The stent delivery system of claim 14, wherein at least a portion of the side proximal marker is positioned further proximally than a proximal portion of the main proximal marker.

16. The stent delivery system of claim 14 or 15, wherein the second relative position includes twisting of the main and side catheter branches relative to each other at a location between at least the main distal marker and the main proximal marker.

17. Use of a catheter assembly of any one of claims 1 to 12 for treating a vessel bifurcation.

18. Use of a stent delivery system of any one of claims 13 to 16 for treating a vessel bifurcation.