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Sanati et al.

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(54) **BALLOON CATHETERS AND METHODS FOR USE**

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A61F 2/958 (2013.01)
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CPC ***A61F 2/954*** (2013.01); ***A61F 2/958*** (2013.01); *A61F 2/95* (2013.01);
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USPC 623/1.11, 1.12, 1.35; 606/191–200; 604/101.01, 101.02, 103.07, 604/103.11–103.13, 916
See application file for complete search history.

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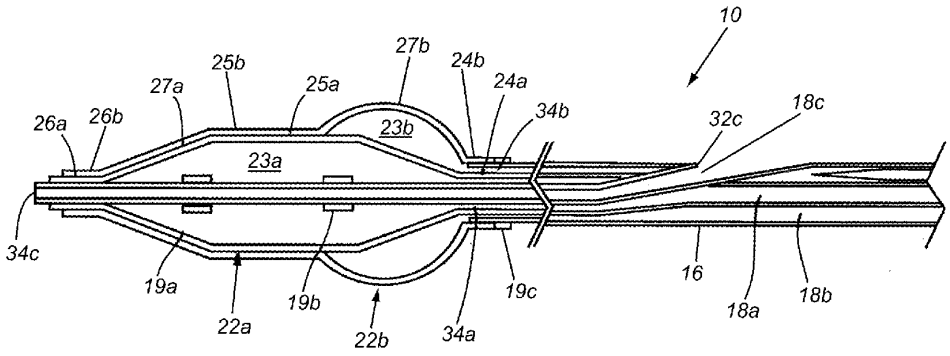
(57) **ABSTRACT**

Apparatus and methods are provided for flaring a stent deployed within a branch vessel including an ostium communicating with a main vessel, a first end of the stent extending at least partially from the branch. A catheter is provided that includes a first balloon carried on its distal end, and a second balloon that includes a distal section overlying at least a portion of the first balloon and a proximal section. The catheter distal end is introduced into the main vessel and positioned through the ostium and stent into the branch until the first balloon is disposed within the stent. The first balloon is expanded to anchor the stent, and the second balloon is expanded to flare the first end of the stent. Optionally, the first balloon is expanded further, e.g., to expand the stent within the branch body lumen and/or dilate the lesion.

24 Claims, 5 Drawing Sheets



Related U.S. Application Data

continuation-in-part of application No. 11/466,439, filed on Aug. 22, 2006, and a continuation-in-part of application No. 12/983,860, filed on Jan. 3, 2011, now abandoned, which is a continuation of application No. 11/136,266, filed on May 23, 2005, now Pat. No. 7,862,601.

(60) Provisional application No. 61/529,890, filed on Aug. 31, 2011.

(51) **Int. Cl.**

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A61M 25/10	(2013.01)
A61F 2/30	(2006.01)
A61F 2/82	(2013.01)

(52) **U.S. Cl.**

CPC *A61F 2002/30322* (2013.01); *A61F 2002/821* (2013.01); *A61F 2230/0071* (2013.01); *A61F 2250/0018* (2013.01); *A61F 2250/0026* (2013.01); *A61F 2250/0039* (2013.01); *A61M 25/1002* (2013.01); *A61M 25/1011* (2013.01)

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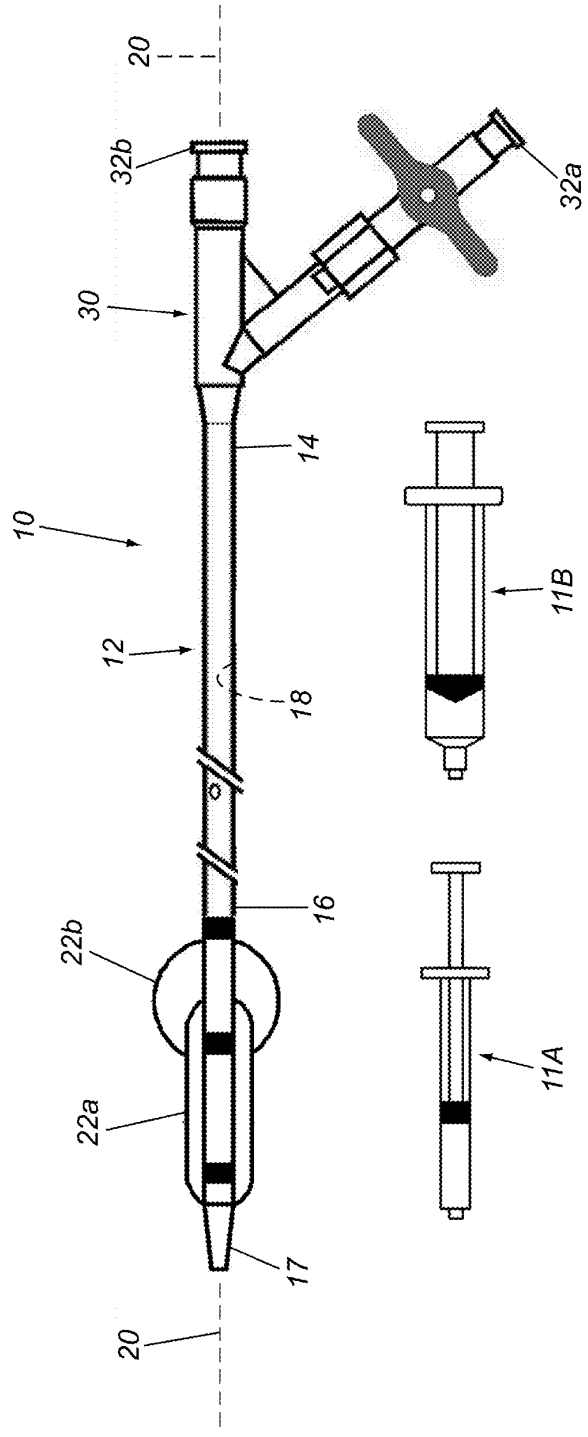

FIG. 1A

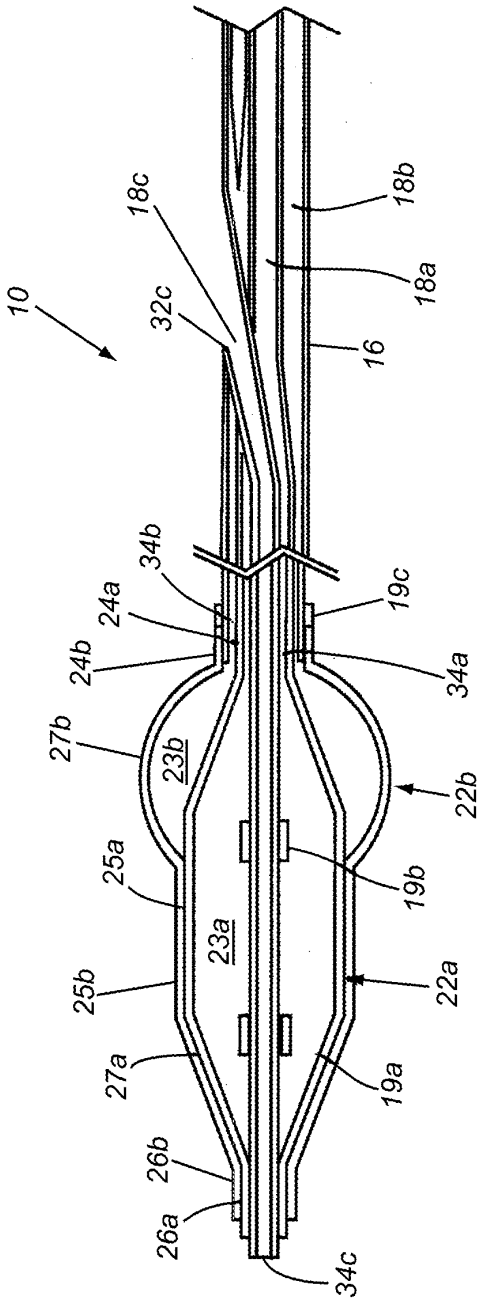
10
18c
18b
18a
32c
16
34b
24a
24b
19c
34a
27b
23b
22b
25a
19b
23a
25b
22a
27a
19a
26b
26a
34c

FIG. 1B

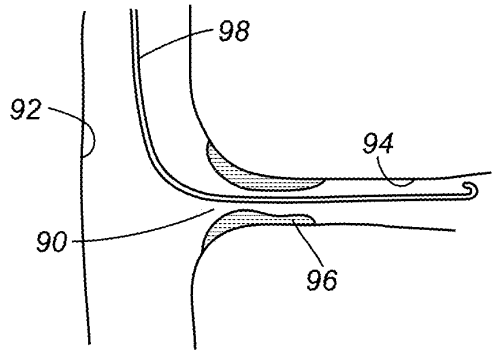

FIG. 2A

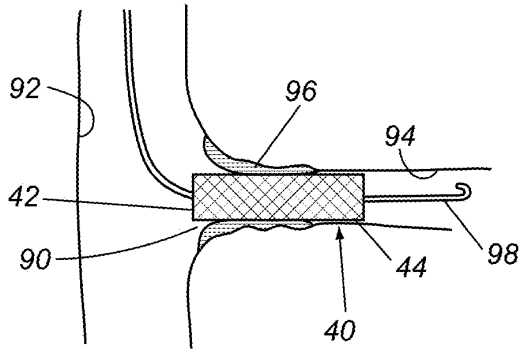

FIG. 2B

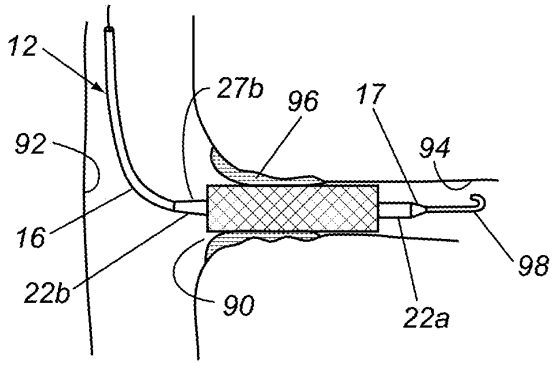

FIG. 2C

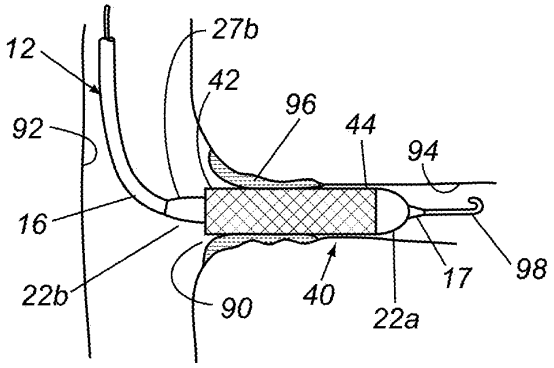

FIG. 2D

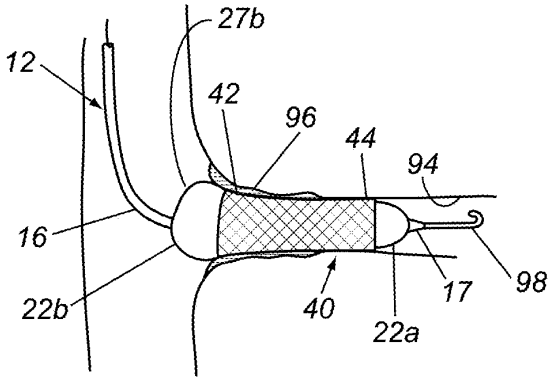

FIG. 2E

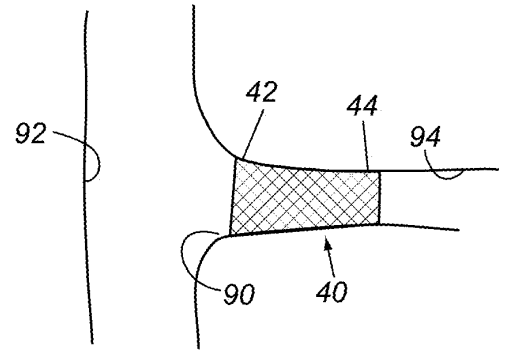

FIG. 2F

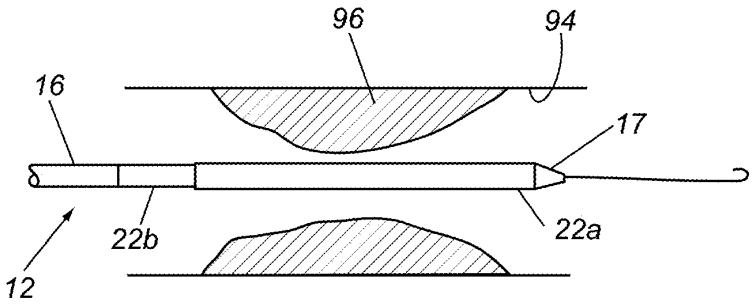

FIG. 3A

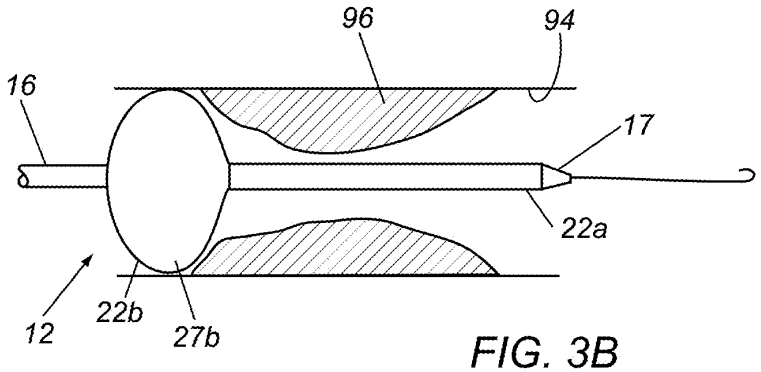

FIG. 3B

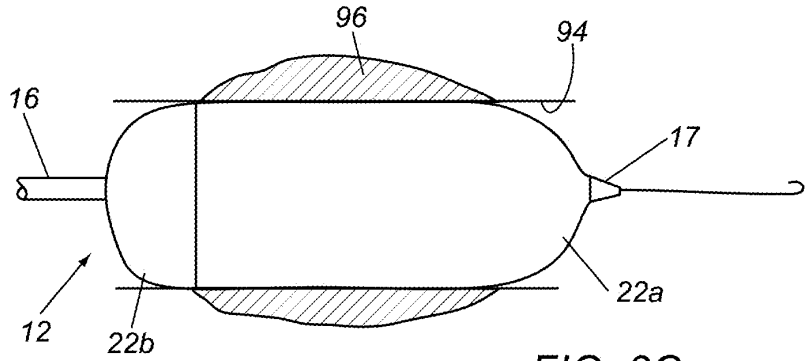

FIG. 3C

BALLOON CATHETERS AND METHODS FOR USE

This application is a continuation of application Ser. No. 13/602,074, filed Aug. 31, 2012, issuing as U.S. Pat. No. 9,034,025, which claims benefit of provisional application Ser. No. 61/529,890, filed Aug. 31, 2011, and is a continuation-in-part of co-pending application Ser. No. 11/466,439, filed Aug. 22, 2006, and Ser. No. 12/983,860, filed Jan. 3, 2011, which is a continuation of Ser. No. 11/136,266, filed May 23, 2005, issued as U.S. Pat. No. 7,862,601. The entire disclosures of these applications are expressly incorporated by reference herein.

FIELD OF THE INVENTION

The present invention relates generally to apparatus and methods for treating stenoses, occlusions, or other lesions within a body lumen, such as an artery or other blood vessel, and, more particularly, to apparatus and methods for flaring or otherwise expanding stents deployed within a body lumen, such as a branch vessel including an ostium extending from a main vessel or trunk.

BACKGROUND

Tubular endoprosthesis or "stents" have been suggested for dilating or otherwise treating stenoses, occlusions, and/or other lesions within a patient's vasculature or other body lumens. For example, a self-expanding stent may be maintained on a catheter in a contracted condition, e.g., by an overlying sheath or other constraint, and delivered into a target location, e.g., a stenosis within a blood vessel or other body lumen. When the stent is positioned at the target location, the constraint may be removed, whereupon the stent may automatically expand to dilate or otherwise line the vessel at the target location. Alternatively, a balloon-expandable stent may be carried on a catheter, e.g., crimped or otherwise secured over a balloon, in a contracted condition. When the stent is positioned at the target location, the balloon may be inflated to expand the stent and dilate the vessel.

Vascular stenoses, e.g., within arteries supplying the heart, can lead to hypoflow conditions in the vessel, which may cause ischemia and/or infarction of the organ being supplied by that vessel, e.g., the heart. Sometimes, a stenosis or other lesion may occur at an ostium or bifurcation, i.e., where a branch vessel extends from a main vessel or trunk. In such situations, it may be difficult to visualize the lesion and/or accurately position a stent within the ostium and/or branch vessel.

Often, when the stent is deployed in such anatomy, one end of the stent may extend out from the ostium into the main vessel, e.g., into the aorta from a coronary artery, common carotid artery, or peripheral artery. Such a position of the stent may cause difficulty in future endoluminal interventions, e.g., reentering the branch vessel, which may require recrossing the stent. In addition, there may be risk that the end of the stent extending from the ostium may cause damage to neighboring structures, such as aortic valve leaflets adjacent to the ostium of a coronary vessel.

To address these problems, it has been suggested to over-expand or flare the end of the stent extending into the main vessel, e.g., to direct the end of the stent against or closer to the wall of the ostium. Thereafter, it may be easier to recross the stent in case future endovascular study or intervention is required. In addition, in the case of coronary stents, flaring the end of the stent extending into the aorta may also move the end further from the aortic lumen and decrease the risk of damage to the aortic leaflets.

Accordingly, apparatus and methods for flaring and/or otherwise expanding stents would be useful.

SUMMARY OF THE INVENTION

The present invention is directed to apparatus and methods for treating stenoses, occlusions, or other lesions within a body lumen, such as an artery or other blood vessel. More particularly, the present invention is directed to apparatus and methods for flaring and/or otherwise expanding stents deployed within a body lumen, such as a branch vessel including an ostium extending from another main vessel or trunk.

In accordance with one embodiment, a method is provided for flaring a stent deployed within a branch body lumen including an ostium communicating with a main body lumen, a first end of the stent extending at least partially from the branch body lumen into the ostium and/or main body lumen. To accomplish this, a catheter or other elongate member may be used that includes a proximal end, a distal end, a first balloon carried on the distal end that includes a main section when expanded, and a second balloon carried on the distal end that includes a distal section overlying at least a portion of the main section of the first balloon and a proximal section extending proximally from the distal section and/or the first balloon.

The distal end of the elongate member may be introduced into the main body lumen, e.g., with the first and second balloons in contracted conditions. The distal end of the elongate member may be positioned through the ostium and stent into the branch body lumen until the main section is disposed within the stent and/or distally beyond the stent, e.g., using external imaging and markers on the distal end to facilitate positioning the proximal section of the second balloon adjacent the ostium.

The first balloon may be expanded to substantially anchor the stent relative to the branch body lumen, and the proximal section of the second balloon may be expanded to flare the first end of the stent within the ostium. Optionally, after expanding the proximal section of the second balloon, the first balloon may be expanded further, e.g., to expand the stent within the branch body lumen and/or dilate the lesion.

In accordance with another embodiment, a method is provided for treating a lesion within a branch body lumen including an ostium communicating with a main body lumen that includes introducing a distal end of a delivery catheter into the main body lumen, the delivery catheter distal end carrying a stent in a contracted condition; positioning the delivery catheter distal end within the branch body lumen such that a first end of the stent is disposed adjacent the ostium and a second end of the stent is disposed further within the branch body lumen; and expanding the stent to a substantially uniform diameter such that the stent engages surrounding tissue of the branch body lumen.

Thereafter, the first end of the stent may be flared, e.g., using a flaring catheter including a proximal end, a distal end, a first balloon carried on the flaring catheter distal end that includes a main section when expanded, and a second balloon carried on the flaring catheter distal end that includes a distal section overlying at least a portion of the main section of the first balloon and a proximal section extending proximally from the distal section and/or the first balloon. The flaring catheter distal end may be introduced

into the main body lumen, and positioned through the ostium and stent into the branch body lumen until the main section is disposed within the stent.

The first balloon may be expanded to substantially anchor the stent relative to the branch body lumen, and the proximal section of the second balloon may be expanded to flare the first end of the stent within the ostium. Optionally, after expanding the proximal section of the second balloon, the first balloon may be expanded further, e.g., to expand the stent within the branch body lumen and/or dilate the lesion. In addition or alternatively, the lesion may be dilated when the stent is expanded, e.g., to a substantially uniform diameter by the main section of the first balloon.

In accordance with still another embodiment, a method is provided for expanding a stent previously deployed within a body lumen using an elongate member including a proximal end, a distal end, a first balloon carried on the distal end that includes a substantially uniform diameter main section when expanded, and a second balloon carried on the distal end that includes a distal section overlying at least a portion of the uniform diameter section of the first balloon and a proximal section extending proximally from the distal section and the first balloon. The distal end of the elongate member may be positioned within the body lumen until the main section is disposed within the stent, and the proximal section of the second balloon may be expanded to substantially anchor the elongate member distal end, and consequently, the first balloon, relative to the stent. The main section of the first balloon may then be expanded to expand the stent and/or dilate a lesion surrounding the stent, the second balloon preventing axial migration of the distal end.

In accordance with yet another embodiment, a method is provided for treating a stenosis within a body lumen using an elongate member including a proximal end, a distal end, a first balloon carried on the distal end that includes a substantially uniform diameter main section when expanded, and a second balloon carried on the distal end that includes a distal section overlying at least a portion of the uniform diameter section of the first balloon and a proximal section extending proximally from the distal section and the first balloon. The distal end of the elongate member may be positioned within the body lumen until the main section is disposed within the stenosis, and the proximal section of the second balloon may be expanded to substantially anchor the elongate member distal end relative to the stenosis. The main section of the first balloon may then be expanded to dilate the stenosis, the second balloon preventing axial migration of the distal end.

In accordance with still another embodiment, a method is provided for treating a stenosis within a body lumen using an elongate member including a proximal end, a distal end, a first balloon carried on the distal end that includes a substantially uniform diameter main section when expanded, and a second balloon carried on the distal end adjacent the main section of the first balloon, e.g., proximal or distal to the main section. The distal end of the elongate member may be positioned within the body lumen until the main section is disposed within the stenosis, e.g., such that the second balloon is positioned adjacent, i.e., proximal or distal to, the stenosis. The second balloon may then be expanded to substantially anchor the elongate member distal end relative to the stenosis. The main section of the first balloon may then be expanded to dilate the stenosis, the second balloon preventing axial migration of the distal end.

In accordance with yet another embodiment, a method is provided for treating a region within a body lumen using an elongate member including a proximal end, a distal end, a first balloon carried on the distal end that includes a substantially uniform diameter main section when expanded, and a second balloon carried on the distal end that includes a first section overlying at least a portion of the uniform diameter section of the first balloon and a second section disposed adjacent the main section of the first balloon. The distal end of the elongate member may be positioned within the body lumen until the main section is disposed within a treatment region, and the second section of the second balloon may be expanded to substantially anchor the elongate member distal end relative to the treatment region. The main section of the first balloon may then be expanded to contact and treat the treatment region, the second balloon preventing axial migration of the elongate member distal end.

In one embodiment, the second section of the second balloon extends proximally from the main section of the first balloon. In another embodiment, the second section of the second balloon extends distally from the main section of the first balloon. In yet another embodiment, a second section may be provided proximal to the main section and a third section may be provided distal to the main section, e.g., such that the second balloon expands both proximally and distally to the main section of the first balloon, e.g., substantially simultaneously. In addition or alternatively, the first section of the second balloon may extend entirely over the main section of the first balloon or may extend only partially over the main section.

In an exemplary embodiment, the treatment region may be a stenosis within a blood vessel, e.g., within a branch vessel adjacent an ostium communicating with a main vessel. In another embodiment, the treatment region may be the site of a natural or prosthetic valve, e.g., the site of an aortic valve.

In accordance with still another embodiment, a method is provided for treating a valve within a body lumen of a patient using an elongate member including a proximal end, a distal end, a first balloon carried on the distal end that includes a substantially uniform diameter main section when expanded, and a second balloon carried on the distal end that includes a first section overlying at least a portion of the uniform diameter section of the first balloon and a second section adjacent the main section of the first balloon. The distal end of the elongate member is positioned within the body lumen with the first and second balloons collapsed until the main section is disposed within a valve. The second section of the second balloon is expanded to substantially anchor the distal end relative to the valve, and then the main section of the first balloon is expanded to dilate leaflets of the valve.

Other aspects and features of the present invention will become apparent from consideration of the following description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

The drawings illustrate exemplary embodiments of the invention, in which:

FIG. **1**A is a side view of an exemplary embodiment of a catheter including overlapping balloons for flaring and/or otherwise expanding a stent previously deployed within a body lumen.

FIG. **1**B is a cross-sectional detail of a distal end of the catheter of FIG. **1**A with the balloons expanded.

FIGS. **2**A-**2**F are cross-sectional views of a patient's body including an ostium communicating between a main vessel

and a branch vessel, showing a method for flaring a stent previously deployed within the branch vessel using the apparatus of FIGS. **1**A and **1**B.

FIGS. **3**A-**3**C are cross-sectional views of a patient's body including a stenosis within a blood vessel, showing a method for dilating the stenosis using the apparatus of FIGS. **1**A and **1**B.

DETAILED DESCRIPTION OF THE EXEMPLARY EMBODIMENTS

Turning to the drawings, FIGS. **1**A and **1**B show an exemplary embodiment of an apparatus **10** for flaring and/or otherwise expanding a stent or other prosthesis (not shown), e.g., within or adjacent an ostium or other bifurcation between a main lumen and a branch lumen (also not shown). Generally, the apparatus **10** includes a catheter or other elongate tubular member **12** having a proximal end **14**, a distal end **16**, and one or more lumens **18** extending between the proximal and distal ends **14**, **16**, thereby defining a longitudinal axis **20** extending between the proximal and distal ends **14**, **16**.

As shown, the catheter **12** may include a pair of overlapping balloons or other expandable members **22** on the distal end **16**, e.g., for flaring and/or otherwise expanding a stent previously deployed within a body lumen (not shown), as described further below. In addition, the distal end **16** may include one or more markers, e.g., one or more bands of radiopaque material **19**, to facilitate positioning the catheter **12** relative to a stent and/or anatomical structures within a patient's body. In addition or alternatively, the catheter **12** may include one or more therapeutic and/or diagnostic elements (not shown) on the distal end **16**, e.g., within or carried by the balloon(s) **22**, as described further below.

Optionally, the apparatus **10** may be provided as a kit or system including one or more additional components, such as syringes **11**, a guide catheter, and/or one or more guidewires (not shown).

The catheter **12** may be formed from one or more tubular bodies, e.g., having variable flexibility along its length. For example, the distal end **16** may be substantially flexible to facilitate introduction through tortuous anatomy, e.g., terminating in a rounded, tapered, and/or other substantially atraumatic distal tip **17**. The distal end **16** may be sized and/or shaped for introduction into a body lumen, e.g., having a diameter between about one and seven millimeters (1-7 mm), or less than 1.7 millimeters. The proximal end **14** may be substantially flexible, semi-rigid, or rigid, e.g., having sufficient column strength to facilitate advancing the distal end **16** through a patient's vasculature by pushing on the proximal end **14**. Optionally, a shaft support wire or other stiffener (not shown) may be provided within the proximal end **14**, if desired, e.g., to facilitate pushing the catheter **12** from the proximal end **14**. The catheter **12** may be formed from plastic, metal, or composite materials, e.g., a plastic material having a wire, braid, or coil core, which may preventing kinking or buckling of the catheter **12** during advancement.

As shown in FIG. **1**A, the catheter **12** may include a handle **30** on the proximal end **14**, e.g., to facilitate manipulating the catheter **12**. The handle **30** may include one or more ports **32** communicating with respective lumens **18** within the catheter **12**, as described further below. The handle **30** may be molded, machined, or otherwise formed from plastic, metal, or composite material, e.g., providing an outer casing, which may be contoured or otherwise shaped to ease manipulation. The proximal end **14** of the catheter **12** may be attached to the handle **30**, e.g., by bonding, cooperating connectors, interference fit, and the like. Optionally, if the apparatus **10** includes any actuatable components (not shown) on the distal end **16**, the handle **30** may include one or more actuators (also not shown), such as one or more slides, dials, buttons, and the like, for actuating or otherwise manipulating the components from the proximal end **14**.

In the exemplary embodiment shown in FIG. **1**B, the catheter **12** includes at least three lumens **18** extending between the proximal and distal ends **14**, **16**. For example, the catheter **12** may include inflation lumens **18***a*, **18***b* that extend from ports **32***a*, **32***b* in the handle **30** through the catheter **12** to openings **34***a*, **34***b* and communicate within interiors **23***a*, **23***b* of respective balloons **22***a*, **22***b*. The ports **32***a*, **32***b* on the handle **30** may include connectors, e.g., a luer lock connector (not shown), one or more seals (also not shown), and the like. A source of inflation media and/or vacuum, e.g., one of the syringes **11** filled with saline or other inflation media, may be connected to the ports **32***a*, **32***b*, e.g., directly or via tubing (also not shown), for expanding and/or collapsing the balloons **22***a*, **22***b*.

In addition, the catheter **12** may include an instrument lumen **18***c* that extends from port **32***c* to an opening **34***c* in the distal tip **17**. The instrument lumen **18***c* may have sufficient size to allow a guidewire or other rail or instrument (not shown) to be inserted therethrough, e.g., to facilitate advancing the catheter **12** over the rail, as explained further below. Alternatively, rather than a "rapid exchange" instrument lumen **18***c*, an instrument lumen (not shown) may be provided that extends from the handle **30** to the distal end **16**. In this alternative, the handle **30** may include a port (not shown) and/or one or more seals (also not shown) that prevent fluid, e.g., blood, from flowing proximally out of the port, yet allow one or more instruments to be inserted therethrough and into the instrument lumen **18***c*.

As shown in FIG. **1**B, the lumens **18** are disposed adjacent one another. Alternatively, the lumens **18** may be disposed in concentric or other arrangements within the body of the catheter **12**. In addition, if the apparatus **10** includes additional balloons (not shown) on the distal end **16**, the catheter **12** may include one or more additional inflation lumens (also not shown), and the handle **30** may include one or more additional ports (also not shown).

Alternatively, other configurations of lumens may be provided for delivering fluid to and/or aspirating fluid from one or both balloons **22**. For example, a single lumen may be provided (not shown) that communicates with the interiors **23** of both balloons **22**. This embodiment may allow the balloons **22** to be expanded and/or collapsed substantially simultaneously using a single syringe or other source of fluid/vacuum. In another alternative, the catheter **12** may include separate inflation lumens **18***a*, **18***b*, but the handle **30** may include a single side port (not shown) to which a syringe or other source of fluid/vacuum may be connected. In this alternative, the handle **30** may include a switch, stopcock, valve, or other device (not shown) for selectively connecting one or both inflation lumens **18***a*, **18***b* to the side port, similar to embodiments in the applications incorporated by reference herein.

Returning to FIGS. **1**A and **1**B, the catheter **12** includes a first or inner balloon **22***a* and a second or outer balloon **22***b* on the distal end **16**, which are expandable independently of one another. The balloons **22** may be bonded or otherwise secured to the distal end **16** of the catheter **12**, e.g., by bonding with adhesive, sonic welding, using an annular collar or sleeve, and the like. For example, as best seen in FIG. **1**B, the inner balloon **22***a* may include a proximal end

24*a* attached directly to the distal end **16** of the catheter **12** distal to instrument lumen port **32***c* and a distal end **26***a* attached directly to the distal end **16** adjacent the distal tip **17**.

The outer balloon **22***b* includes a first or distal section **25***b* that extends at least partially over the inner balloon **22***a* and a second or proximal section **27***b*. For example, the first section **25***b* may extend entirely over the inner balloon **22***a* and a distal end **26***b* of the outer balloon **22***b* may be attached over or adjacent to the distal end **26***a* of the inner balloon **22***a*, e.g., by bonding, sonic welding, and the like, as described elsewhere herein. A proximal end **24***b* of the outer balloon **22***b* may be attached to the distal end **16** of the catheter **12**, e.g., proximal or adjacent to the inner balloon proximal end **24***a* and distal to the instrument lumen port **32***c*.

The first section **25***b* of the outer balloon **22***b* may overlie but remain separate from the underlying inner balloon **22***a*. Alternatively, the first section **25***b* may be bonded or otherwise attached to the inner balloon **22***a*, e.g., continuously or intermittently along the inner balloon **22***a*. Alternatively, the orientation of the outer balloon **22***b* may be reversed, if desired, e.g., with the second section **25***b* of the outer balloon **22***b* extending distally relative to the main section **25***a* of the inner balloon **22***a* rather than proximally. In a further alternative, a substantially spherical or bulbous section may be provided on the outer balloon **22***b* both proximally and distally to the main section **25***a* of the inner balloon **22***a* (not shown). In this alternative, the proximal and distal sections may be expanded simultaneously or independently of one another, as desired.

The inner balloon **22***a* may be expandable from a contracted condition (not shown) to an enlarged condition (shown in FIGS. **1**A and **1**B). Similarly, the outer balloon **22***b* may also be expandable from a contracted condition (not shown) to an enlarged condition (shown in FIGS. **1**A and **1**B). One or both balloons **22**, e.g., inner balloon **22***a*, may be formed from substantially inelastic material, e.g., PET, nylon, or PEBAX, such that the balloon **22** expands to a predetermined size in its enlarged condition once sufficient fluid is introduced into the interior of the balloon **622**. In addition or alternatively, one or both balloons **22**, e.g., outer balloon **22***b*, may be formed from substantially elastic material, e.g., silicone, polyurethane, or polyethylene, such that the balloon **22** may be expanded to a variety of sizes depending upon the volume and/or pressure of fluid within the interior. In an exemplary embodiment, the inner balloon **22***a* may be formed from a semi-compliant or substantially non-compliant material, e.g., mid to high durometer PEBAX, nylon, or PET, and the outer balloon **22***b* may be formed from a substantially complaint or semi-compliant material, e.g., polyethylene, polyurethane, and low to mid durometer PEBAX.

To provide the proximal and distal sections **27***b*, **25***b* of the outer balloon **22***b*, the balloon material may be formed into a shape including a substantially spherical or other bulbous shape for the proximal section **27***b* and a substantially uniform, smaller diameter shape for the distal section **25***b*. For example, the balloon material may be blow molded within a mold having the desired shape for the outer balloon **22***b* when inflated. Because of the compliance of the balloon material, the outer balloon **22***b*, e.g., the proximal section **27***b*, may be expanded greater than the relaxed molded shape, yet may substantially maintain that shape unless constrained by external forces.

The outer balloon **22***b* may have a substantially uniform wall thickness, e.g., between the proximal and distal sections **27***b*, **25***b*. Alternatively, the wall thickness may vary; for example, the proximal section **27***b* may have a thinner wall thickness than the distal section **25***b*. Optionally, the outer balloon **22***b* may include one or more features thereon for enhancing traction, friction, or other engagement with structure contacted by the outer balloon **22***b* when expanded. For example, the outer surface of at least the proximal section **27***b* may be treated or textured, may include ribs or other protrusions, and the like (not shown) to increase friction or other engagement upon expansion.

In addition or alternatively, the balloons **22** may operate under different internal pressures and/or may require different pressures sufficient to fully expand the respective balloons **22**. For example, the inner balloon **22***a* may require a greater inflation pressure to fully expand than the outer balloon **22***b*. This may allow the proximal section **27***b* of the outer balloon **22***b* to be expanded using a lower inflation pressure to flare and/or shape a flaring portion of a stent without substantial expansion of a main portion of the stent, as described further elsewhere herein and in the applications incorporated by reference herein.

Alternatively, during use, the outer balloon **22***b* may be inflated based upon delivering one or more predetermined volumes of fluid therein, e.g., in multiple stages of expansion, as described further below. For example, the proximal section **27***b* of the outer balloon **122***a* may be inflated upon delivering a first predetermined volume of fluid therein to flare the stent, e.g., between about 0.25-2 cubic centimeters or between about 0.5-4.2 cubic centimeters. Volume-based delivery may be useful for describing the function of the outer balloon **22***b* because of its relative compliance and/or low pressure requirements, as explained in the applications incorporated by reference herein.

As shown in FIGS. **1**A and **1**B, the proximal section **27***b* of the outer balloon **22***b* may be shaped to expand to a substantially spherical shape in the enlarged condition, e.g., having a diameter between about ten and twenty millimeters (10-20 mm) when expanded using an inflation pressure between about one and five atmospheres (1-5 ATM). In an exemplary embodiment, the proximal section **27***b* of the outer balloon **22***b* may have a diameter of about thirteen millimeters (13 mm) at an inflation pressure of about two atmospheres (2 ATM). In contrast, the inner balloon **122***b* may be shaped to expand to a substantially cylindrical shape in the enlarged condition, e.g., having a diameter between about two and eight millimeters (2-8 mm) when expanded using an inflation pressure between about eight and twenty atmospheres (8-20 ATM).

In addition, a main section **25***a* of the inner balloon **22***a* may have a substantially uniform diameter, e.g., having a length between about eight and thirty millimeters (8-30 mm). Beyond the uniform diameter portion, the inner balloon **22***a* may have a transition portion **27***a* adjacent the distal tip **17**. The transition portion **27***a* may be tapered, as shown, or may be substantially blunt, i.e., extending inwardly to the distal tip **17** (not shown). As shown, the main portion **25***a* of the inner balloon **22***a* may underlie at least a portion of the outer balloon **22***b*, e.g., the distal section **25***b*, as shown in FIG. **1**B and as disclosed in the applications incorporated by reference elsewhere herein. In an exemplary embodiment, the main section **27***a* of the inner balloon **22***a* may have a diameter of between about five and six millimeters (5-6 mm) in the enlarged condition and may have a length of at least about seventeen millimeters (17 mm) distally beyond the proximal section **27***b* of the outer balloon **22***b*.

Optionally, the balloons **22** may include one or more diagnostic and/or therapeutic elements. For example, in one embodiment, the outer balloon **22***b* may carry one or more therapeutic agents, e.g., at or adjacent the transition zone between the proximal and distal sections **27***b*, **25***b*. The therapeutic agent(s) may be pressed against the wall of a vessel, e.g., at an ostium, lesion, or within a branch, as described further below.

In another embodiment, one or more electrodes or other elements (not shown) may be provided on the balloons for delivering energy to tissue contacted by the balloons **22**. For example, one or more electrodes may be provided on the outer balloon **22***b*, e.g., at or adjacent the transition zone between the proximal and distal sections **27***b*, **25***b*. Alternatively, one or more ultrasound elements may be provided on the distal end **16**, e.g., on an inner surface of the outer balloon **22***b*, on the inner balloon **22***a*, and/or on the distal end **16** itself within the balloons **22**. In this alternative, the inflation media used to expand the balloons **22** may be selected that easily transmits ultrasonic energy to facilitate application of ultrasound to tissue surrounding the balloons **22**. In these options, the handle **30** may include one or more actuators (not shown) for selectively activating and deactivating the energy element(s) on the distal end **16**. In addition or alternatively, one or more connectors (also not shown) may be provided on the handle **30** for coupling the energy element(s) to a driver, controller, or other source of electrical, ultrasound, or other energy (not shown).

Turning to FIGS. **2**A-**2**F, an exemplary method is shown for using the apparatus **10** to flare and/or otherwise expand a stent **40** deployed within a patient's body, e.g., including an ostium **90**. As shown, the ostium **90** may be an opening in a wall of a first or main body lumen or trunk **92** that communicates with a second body lumen or branch **94**. In exemplary embodiments, the main body lumen **92** may be the ascending or descending aorta, and the branch body lumen may be a coronary artery, a common carotid artery, or a peripheral artery. A stenosis, occlusion, or other lesion **96** may exist at and/or adjacent to the ostium **90**, e.g., extending at least partially into the branch **94**. The lesion **96** may include atherosclerotic plaque or other material that partially or completely occludes blood or other fluid flow between the trunk **92** and the branch **94**.

Initially, as shown in FIG. **2**A, a guidewire **98** or other rail may be introduced from the trunk **92** through the ostium **90** into the branch **94**, e.g., using conventional methods. For example, a percutaneous puncture or cut-down may be created at a peripheral location (not shown), such as a femoral artery, carotid artery, or other entry site, and the guidewire **98** may be advanced through the patient's vasculature from the entry site, e.g., alone or with the aid of a guide catheter (not shown). For example, a distal end of a guide catheter (not shown) may be advanced over the guidewire **98** into the trunk **92**, e.g., until the distal end is disposed adjacent or proximal to the ostium **90**. The guide catheter may be used to advance one or more instruments (such as any of the catheters or other devices described herein) over the guidewire **98** and into the trunk **92** and/or branch **94**.

If the lesion **96** completely occludes the branch **94**, the guidewire **98** may be directed through the occlusion, or other devices (not shown) may be advanced over the guidewire **98** or otherwise in conjunction with the guidewire **98** to create a passage through the lesion **96** for the guidewire **98**.

After the guidewire **98** is directed into the branch **94** beyond the lesion **96**, it may be desirable to at least partially dilate the lesion **96**. For example, an angioplasty catheter (not shown) may be advanced through the guide catheter and/or over the guidewire **98** into and through the lesion **96**, whereupon a balloon or other element on the catheter may be expanded to at least partially dilate the lesion **96**. If desired, other procedures may also be performed at the lesion **96**, e.g., to soften, remove, or otherwise treat plaque or other material forming the lesion **96**, before the stent **40** is implanted. After completing any such procedures, any instruments advanced over the guidewire **98** may be removed.

To deliver the stent **40**, any delivery catheter and/or conventional procedure may be used. For example, a distal end of a delivery catheter (not shown) may be advanced over the guidewire **98** and/or through the guide catheter from the entry site into the trunk **92**. For example, with the distal end of the guide catheter against or adjacent the ostium **90**, the distal end of the delivery catheter may be advanced from the guide catheter, through the ostium **90**, and into the branch **94**. The delivery catheter may be positioned such that the stent **40** extends into and through the lesion **96** and/or branch **94**. The stent **40** may be expanded and/or otherwise deployed from the delivery catheter to place the stent **40** across the lesion **96** and/or within the branch **94**. For example, as shown in FIG. **2**B, the stent **40** may be deployed such that a first end **42** of the stent **40** extends at least partially into the ostium **90** and/or the trunk **92**, and a second end **44** of the stent **40** is disposed within the branch **94** beyond the lesion **96**.

As shown, the stent **40** may have a substantially uniform diameter cross-section once deployed. For example, the stent **40** may be expanded to dilate and/or otherwise engage the lesion **96** and/or branch **94**. Alternatively, the stent **40** may be partially expanded using the delivery catheter, allowing the stent **40** to be further expanded by the apparatus **10**, as described below.

Turning to FIG. **2**C, thereafter, the distal end **16** of the flaring catheter **12** (with the balloons **22** in their contracted conditions) may be introduced into the trunk **92** to flare and/or otherwise expand the stent **40**. For example, the delivery catheter may be removed, and the distal end **16** of the catheter **12** may be advanced over the same guidewire **98** into the trunk **92**. In the embodiment shown in FIG. **1**B, a proximal end (not shown) of the guidewire **98** may be backloaded into the opening **34***c* through the instrument lumen **18***c* and out the port **32***c*. The distal end **16** may then be advanced over the guidewire **98** into the patient's body over the guidewire **98**.

As shown in FIG. **2**C, the distal end **16** may be advanced through the stent **40** and ostium **90** at least partially into the branch **94**. For example, the distal end **16** may be positioned such that the inner balloon **22***a* is positioned within and/or beyond the stent **40**, e.g., beyond the first end **42**, and the proximal section **27***b* of the outer balloon **22***b* is positioned adjacent the ostium **90**, e.g., within and/or proximal to the first end **42** of the stent.

Optionally, to facilitate positioning, the catheter **12** may be monitored using fluoroscopy or other external imaging, e.g., to observe and monitor markers **19** (not shown, see FIG. **1**B) on the distal end **16**. For example, markers **19***a* and **19***b* may be located on the distal end **16** to identify the ends of the substantially uniform main section **25***a* of the inner balloon **22***a*, while proximal marker **19***c* may be located on the distal end **16** to identify the proximal end **24***b* and/or proximal section **27***b* of the outer balloon **22***b*. Thus, with the markers **19**, the inner balloon **22***a* may be aligned with the distal end **44** and/or portion of the stent **40** within the branch **94** beyond the ostium **90** and the proximal section

27*b* of the outer balloon **22***b* may be aligned with the first end **42** of the stent **40** and/or the ostium **90**, as desired.

Turning to FIG. **2**D, with the catheter **12** positioned as desired, the inner balloon **22***a* may be expanded, e.g., by coupling syringe **11***a* to port **32***a* (not shown in FIG. **2**D) and delivering saline, nitrogen, or other inflation media into the interior **23***a* via inflation lumen **18***a*, to engage the stent **40** and/or wall of the branch **94**. For example, the inner balloon **22***a* may be expanded to engage both the second end **44** of the stent **40** and the wall of the branch **94** beyond the stent **40** to prevent substantial axial migration of the stent **40**.

Thereafter, as shown in FIG. **2**E, the proximal section **27***b* of the outer balloon **22***b* may be expanded, e.g., by coupling syringe **11***b* to port **32***b* (not shown in FIG. **2**E) and delivering saline, nitrogen, or other inflation media into the interior **23***b* via inflation lumen **18***b*, to flare the stent **40**. For example, as the proximal section **27***b* is expanded, the first end **42** of the stent **40** is expanded, e.g., into a flared configuration, which may conform to the shape of the proximal section **27***b* and/or the ostium **90**.

With the inner balloon **22***a* expanded, the stent **40** and catheter **12** may remain substantially stationary during this inflation and flaring. Otherwise, without the inner balloon **22***a* engaging the stent **40** and wall of the branch **94**, there may be a tendency for the stent **40** to migrate distally into the branch **94** rather than flaring in place, e.g., maintaining its substantially uniform diameter, which may shear or otherwise remove material from the lesion **96** and/or wall of the branch **94** and potentially release the material within the branch **94**. In addition or alternatively, without the inner balloon **22***a* expanded, there may be a tendency of the distal end **16** of the catheter **12** to move proximally away from the stent **40** and ostium **90**. Thus, the inner balloon **22***a* may provide an anchor that ensures the first end **42** of the stent **40** is flared in a desired manner with the stent **40** and catheter **16** substantially fixed relative to one another and the ostium **90**.

Optionally, after inflating the proximal section **27***b* and flaring the first end **42** of the stent **40**, the inner balloon **22***a* may be inflated further, if desired, e.g., to expand the stent **40** and further dilate the lesion **96**. With the stent **40** fully deployed, the balloons **22** may be deflated or otherwise collapsed, and the catheter **12** may be withdrawn from the branch **94** and trunk **92**, and from the patient's body, e.g., into the guide catheter (not shown). The guide catheter and/or guidewire **98** may then be removed from the patient's body, leaving the stent **40** in place, as shown in FIG. **2**F.

In alternative embodiments, other inflation sequences may be used, as desired, e.g., to initially deliver and deploy a stent and then flare the stent, e.g., within an ostium **90**. For example, after the stent **40** has been deployed within the branch **94**, the distal end **16** may be introduced into the trunk **92**. With the proximal section **27***b* within the trunk **92**, the outer balloon **22***b* may be partially inflated to expand the proximal section **27***b* before advancing the distal end **16** into the branch **94**. When so advanced, the proximal section **27***b* may partially seat within the ostium **90** and/or within the first end **42** of the stent **40**. Alternatively, the distal end **16** may be positioned within the branch **94** with the proximal section **27***b* collapsed until the inner and/or outer balloons **22***a*, **22***b* are aligned as desired relative to the ostium **90** and/or stent **40**. Once positioned as desired relative to the ostium **90**, lesion **96**, and/or stent **40**, e.g., by observing the markers **19** on the distal end **16**, the proximal section **27***b* of the outer balloon **22***b* may be at least partially expanded, e.g., to engage the first end **42** of the stent **40** and/or the ostium **90**. During this initial inflation, the first end **42** may be flared or may not be expanded substantially. With the proximal section **27***b* expanded, the distal end **16** may be substantially anchored relative to the stent **40** and branch **94**, e.g., to prevent migration of the distal end **16**.

The inner balloon **22***a* may then be inflated to expand the stent **40** and/or dilate the lesion **96**. During such inflation, there is a tendency for the distal end **16** of the catheter **12** to migrate distally relative to the stent **40** and lesion **96**, which may risk causing a dissection distally beyond the stent **40** (what is sometimes called "watermelon seeding"). However, with the proximal section **27***b* expanded to engage the first end **42** of the stent **40** and/or ostium **90**, the distal end **16** may be substantially anchored, thereby preventing such migration.

Once the stent **40** is expanded and/or the lesion **96** is dilated by the inner balloon **22***a*, the outer balloon **22***b* may be inflated further, if desired, e.g., to expand the proximal section **27***b* and flare the first end **42** of the stent **40**. Thus, the inner and outer balloons **22***a*, **22***b* may be alternately expanded one or more times, as desired, until the stent **40** achieves the desired final configuration.

In another alternative, after initially expanding the proximal section **27***b* of the outer balloon **22***b* within the ostium **90** and/or first end **42** of the stent, the inner balloon **22***a* may be inflated to engage the second end **44** of the stent **40** and the wall of the branch **94** to substantially anchor the stent **40** and catheter **12** relative to one another without necessarily expanding the stent **40** further. The outer balloon **22***b* may then be inflated further to expand the proximal section **27***b* and flare or otherwise shape the first end **42** of the stent **40** relative to the ostium **90**.

In still another alternative, the apparatus **10** may be used to expand a stent previously placed within a substantially straight or other non-bifurcated body lumen, such as within a carotid, iliac, renal, coronary artery, or other blood vessel. For example, the distal end **16** of the catheter **12** may be introduced into the vessel until the inner balloon **22***a* is aligned with the stent **40**. The outer balloon **22***b* may then be inflated such that the proximal section **27***b* engages a first end of the stent and/or the wall of the vessel adjacent the stent **40** to substantially anchor the stent **40**, e.g., without dilating the stent **40** and/or vessel. The compliant nature of the outer balloon **22***b* may frictionally engage the vessel wall and/or the stent **40** to prevent substantial migration, e.g., without applying a substantial dilating force. Optionally, at least the proximal section **27***b* of the outer balloon **22***b* may include a surface treatment and/or one or more features that enhance frictional or other engagement with the vessel wall and/or stent **40**.

Thereafter, the inner balloon **22***a* may be inflated to expand the stent **40** and/or dilate the lesion or body lumen surrounding the stent **40**, as desired, with the outer balloon **22***b* preventing migration of the distal end **16** relative to the stent **40**. The balloons **22***a*, **22***b* may then be deflated and the distal end **16** removed from the stent **40** and/or vessel.

In a further alternative, a stent or other prosthesis, such as those disclosed in the applications incorporated by reference herein, may be provided on the distal end **16** of the catheter **12**. For example, a stent (not shown) may be delivered directly on the catheter **12**, e.g., on one or more both of the balloons **22***a*, **22***b*, rather than on a separate delivery catheter, if desired, using similar methods to those described herein and in the applications incorporated by reference herein. Alternatively, a delivery balloon (not shown) may be provided on the distal end **16** of the catheter **12**, e.g., proximal or distal to the balloons **22**, and a stent may be introduced and deployed on the delivery balloon into an

ostial or substantially straight implantation site. The balloons **22***a*, **22***b* may then be used to flare and/or expand the stent using similar methods to those described above.

In still another alternative, the apparatus and methods herein may be used to treat a stenosis, occlusion, or other lesion **96** within a body lumen **94** without a stent. For example, as shown in FIGS. **3**A-**3**C, during an angioplasty procedure, after positioning the main section **25***a* of the inner balloon **22***a* across a stenosis **96**, the proximal section **27***b* of the outer balloon **22***b* may be inflated to substantially anchor the distal end **16** relative to the body lumen **94**. Alternatively, the outer balloon may be provided distal to the inner balloon or outer balloons may be provided both proximally and distally to the main section **25***a* of the inner balloon (not shown), as described elsewhere herein.

The inner balloon **22***a* may then be inflated to expand the main section **25***a* to dilate the stenosis **96**, as desired. In this alternative, the body lumen **94** may be a non-bifurcated body lumen or a body lumen including a branch extending from a trunk. In the latter example (not shown), the distal end **16** may be positioned within the branch, and the outer balloon **22***b* may be inflated to expand the proximal section **27***b* to dilate the ostium and/or stenosis therein before or after expanding the main section **25***a* of the inner balloon **22***a* within the branch, similar to the methods described elsewhere herein.

In other alternatives, the apparatus and methods herein may be used for treating other structures within a patient's body. For example, the catheter **12** may be used to perform valvuloplasty on heart valves, e.g., an aortic valve of a patient's heart. In this alternative, the main section **25***a* of the inner balloon **22***a* may be expandable to diameters of at least nineteen millimeters (19 mm) or more, and the proximal section **27***b* of the outer balloon **22***b* may be expandable to larger diameters, e.g., to substantially anchor the distal end **16** of the catheter **12** while the inner balloon **22***a* is introduced into and expanded to treat the valves, and/or to facilitate additional treatment. For such applications, the inner balloon **22***a* may be formed from ultra-high pressure materials, such as single resin combinations of balloon materials, such as those described above in combination with PTFE, reinforced fiber composite materials, and/or metallic or polymeric braids, weaves, or other reinforcement structures, e.g., similar to balloons disclosed in U.S. Pat. No. 7,744,620, the entire disclosure of which is expressly incorporated by reference herein.

During use, the inner balloon **22***a* may be introduced through the site of a natural or prosthetic valve, such as an aortic valve (not shown), and the outer balloon **22***b* may be expanded to prevent migration and/or otherwise stabilize the distal end **16** relative to the valves. The inner balloon **22***a* may then be expanded to treat the valve, e.g., to dilate the valve leaflets (not shown) of the valve. In one embodiment, the outer balloon **22***b* may be located distal to the inner balloon **22***a* such that the outer balloon **22***b* is positioned within the left ventricle of the patient's heart, and the inner balloon **22***a* may extend through the valve annulus, e.g., into the coronary sinus. With the outer balloon **22***b* expanded within the left ventricle, the outer balloon **22***b* may contact the heart wall adjacent the aortic valve, thereby preventing the distal end **16** from migrating out of the heart into the aorta. The inner balloon **22***a* may be expanded one or more times and/or to one or more diameters to dilate the leaflets, e.g., to increase their flexibility and/or separate plaque or other materials on the leaflets.

Optionally, a filter or other embolic protection device (not shown) may be provided on the catheter **10**, e.g., proximal to the balloons **22***a*, **22***b*, or otherwise introduced into the coronary sinus or aorta of the patient to capture any plaque or other material released during the treatment. For example, an expandable filter (not shown) may be provided on the distal end **16** spaced apart proximally from the balloons **22***a*, **22***b*, which may be expanded downstream to the aortic valve before expanding the outer balloon **22***b* and/or the inner balloon **22***a*. After the treatment, the filter may be collapsed to capture the released material, e.g., after collapsing the inner balloon **22***a* and either before or after collapsing the outer balloon **22***b*. The catheter **10** may be removed from the valve site.

Alternatively, the outer balloon **22***b* may be provided proximal to the inner balloon **22***a*. For example, the distal end **16** may be positioned such that the main section of the inner balloon **22***a* is disposed within the valve annulus, e.g., with the outer balloon **22***b* located adjacent the leaflets, e.g., within the coronary sinus. The inner balloon **22***a* may be expanded to initially dilate the leaflets of the valve, and thereafter, if desired, the outer balloon **22***b* may be expanded to further dilate the leaflets, e.g., direct them outwardly towards or against the wall of the coronary sinus. For example, the inner balloon **22***a* may be expanded to a first diameter to at least partially dilate the leaflets into the coronary sinus, and then the outer balloon **22***b* may be expanded to a second larger diameter to further dilate the leaflets. The inner and/or outer balloons **22***a*, **22***b* may be expanded and collapsed one or more times, as desired to perform a desired treatment on the valve.

In a further alternative, the outer balloon **22***b* may be expanded within the coronary sinus or otherwise distal to the valve site before expanding the inner balloon **22***a*. The outer balloon **22***b* may contact surrounding tissue to prevent migration of the distal end **16** and/or to prevent plaque or other released material from traveling downstream. Optionally, a filter or other embolic protection device may be deployed proximal to the outer balloon **22***b*, if desired, as described above. The inner balloon **22***a* may then be expanded one or more times to treat the leaflets, as described above, and then the balloons **22***a*, **22***b* may be collapsed and the catheter **10** removed from the valve site. Optionally, in this alternative, the catheter **10** may include an aspiration port adjacent the balloons **22***a*, **22***b* for aspirating released material captured by the outer balloon **22***b*.

It will be appreciated that elements or components shown with any embodiment herein are exemplary for the specific embodiment and may be used on or in combination with other embodiments disclosed herein.

While the invention is susceptible to various modifications, and alternative forms, specific examples thereof have been shown in the drawings and are herein described in detail. It should be understood, however, that the invention is not to be limited to the particular forms or methods disclosed, but to the contrary, the invention is to cover all modifications, equivalents and alternatives falling within the scope of the appended claims.

We claim:

1. A method for flaring a stent previously deployed within a branch body lumen including an ostium communicating with a main body lumen, a first end of the stent extending at least partially from the branch body lumen into the ostium, the method comprising:

providing an elongate member including a proximal end, a distal end, an expandable member carried on the distal end that includes a substantially uniform diameter distal section, and a proximal section extending proximally from the distal section, wherein at least the

proximal section comprises compliant material molded to a shape in which the proximal section has a bulbous shape defining a first diameter and wherein the distal section has a substantially cylindrical shape defining a second diameter smaller than the first diameter;

introducing the distal end into the main body lumen;

positioning the distal end of the elongate member through the ostium and stent into the branch body lumen until the distal section is disposed within the stent;

initially expanding the expandable member to engage the distal section within the stent to substantially anchor the stent axially relative to the branch body lumen;

expanding the proximal section to flare the first end of the stent within the ostium; and

after expanding the proximal section, further expanding the expandable member to expand the stent within the branch body lumen.

2. The method of claim **1**, wherein the diameter of the branch body lumen does not increase substantially when the expandable member is initially expanded to engage the distal section within the stent, and wherein the branch body lumen is dilated when the expandable member is further expanded to expand the stent.

3. The method of claim **1**, wherein positioning the distal end of the elongate member comprises positioning the distal end of the elongate member such that the proximal section is disposed adjacent the ostium before initially expanding the expandable member.

4. The method of claim **3**, further comprising monitoring markers on the distal end of the elongate member to facilitate positioning the proximal section adjacent the ostium.

5. The method of claim **1**, wherein initially expanding the expandable member prevents the stent from migrating substantially when the proximal section is expanded.

6. The method of claim **1**, wherein the material of the expandable member has a thinner wall thickness along the proximal section than along the distal section.

7. The method of claim **1**, further comprising delivering energy from one or more elements on the expandable member to surrounding tissue adjacent the stent.

8. A method for treating a lesion within a branch body lumen including an ostium communicating with a main body lumen, the method comprising:

introducing a distal end of a delivery catheter into the main body lumen, the delivery catheter distal end carrying a stent in a contracted condition;

positioning the delivery catheter distal end within the branch body lumen such that a first end of the stent is disposed adjacent the ostium and a second end of the stent is disposed further within the branch body lumen;

expanding the stent such that the stent engages surrounding tissue of the branch body lumen;

removing the delivery catheter from the branch body lumen and main body lumen;

introducing a distal end of a flaring catheter into the main body lumen, the flaring catheter comprising a proximal end, a distal end, an expandable member carried on the flaring catheter distal end that includes a substantially uniform diameter distal section when expanded, and a proximal section extending proximally from the distal section; wherein at least the proximal portion comprises compliant material molded to a shape in which the proximal section has a bulbous shape defining a first diameter and the distal section has a substantially cylindrical shape defining a second diameter smaller than the first diameter;

positioning the flaring catheter distal end through the ostium and stent into the branch body lumen until the distal section is disposed within the stent;

initially expanding the distal section to substantially anchor the stent axially relative to the branch body lumen; and

thereafter, continuing expanding the proximal section to flare the first end of the stent within the ostium; and

after expanding the proximal section, further expanding the expandable member to expand the stent within the branch body lumen.

9. The method of claim **8**, wherein the lesion is dilated when the stent is initially expanded on the delivery catheter to a substantially uniform diameter.

10. The method of claim **9**, further comprising, after expanding the proximal section, further expanding the expandable member to expand the distal section to expand the stent further within the branch body lumen and dilate the lesion further.

11. The method of claim **8**, wherein the diameter of the branch body lumen does not change when the expandable member is initially expanded, and wherein the branch body lumen is dilated when the expandable member is further expanded to expand the stent.

12. The method of claim **8**, further comprising introducing a distal end of a guidewire into the main body lumen and through the ostium into the branch body lumen, and wherein the delivery catheter distal end is introduced into the main body lumen and positioned within the branch body lumen over the guidewire.

13. The method of claim **12**, wherein the flaring catheter distal end is introduced into the main body lumen over the guidewire after removing the delivery catheter.

14. The method of claim **8**, wherein positioning the distal end of the flaring catheter comprises positioning the flaring catheter distal end such that the proximal section is disposed adjacent the ostium before initially expanding the expandable member.

15. The method of claim **14**, further comprising monitoring markers on the flaring catheter distal end to facilitate positioning the proximal section adjacent the ostium.

16. The method of claim **8**, wherein initially expanding the expandable member prevents the stent from migrating substantially when the proximal section is expanded.

17. The method of claim **8**, further comprising delivering energy from one or more elements on the expandable member to surrounding tissue adjacent the stent.

18. The method of claim **8**, wherein the proximal section has a thinner wall thickness than a wall thickness of the distal section.

19. A method for expanding a stent previously deployed within a body lumen, comprising:

providing an elongate member including a proximal end, a distal end, an expandable member carried on the distal end that includes a substantially uniform diameter distal section when expanded, and a proximal section extending proximally from the distal section; wherein at least the proximal section is formed from compliant material molded to a shape in which the proximal section has a bulbous shape defining a first diameter and the distal section has a substantially cylindrical shape defining a second diameter smaller than the first diameter;

positioning the distal end of the elongate member within the body lumen until the main section is disposed within the stent;

expanding the proximal section to substantially anchor the distal end relative to the stent; and

after expanding the proximal section, expanding the distal section to expand the stent.

20. The method of claim **19**, wherein the body lumen comprises a non-bifurcated body lumen.

21. The method of claim **20**, wherein the body lumen comprises a branch body lumen including an ostium communicating with a main body lumen, wherein the stent is deployed within the branch body lumen, and wherein positioning the distal end of the elongate member comprises positioning the distal end of the elongate member through the ostium and stent into the branch body lumen until the main section is disposed within the stent.

22. A method for treating a stenosis within a body lumen, comprising:

providing an elongate member including a proximal end, a distal end, an expandable member carried on the distal end that includes a substantially uniform diameter distal section when expanded, and a proximal section extending proximally from the distal section, wherein at least the proximal section is formed from compliant material molded to a shape in which the proximal section has a bulbous shape defining a first diameter and the distal section has a substantially cylindrical shape defining a second diameter smaller than the first diameter;

positioning the distal end of the elongate member within the body lumen with the expandable member collapsed until the distal section is disposed within the stenosis;

expanding the proximal section to substantially anchor the distal end relative to the stenosis; and

after expanding the proximal section, continuing expanding the distal section to dilate the stenosis.

23. The method of claim **22**, wherein the body lumen comprises a non-bifurcated body lumen.

24. The method of claim **22**, wherein the body lumen comprises a branch body lumen including an ostium communicating with a main body lumen and having the stenosis therein, and wherein positioning the distal end of the elongate member comprises positioning the distal end of the elongate member through the ostium and stenosis into the branch body lumen until the distal section is disposed within the stenosis.

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