STENT DELIVERY SYSTEM WITH PUSHER ASSEMBLY

RELATED APPLICATIONS

[0001] This application claims priority benefit under 35 U.S.C. § 119(e) of U.S. Provisional Patent Application No. 61/433,184, filed January 14, 2011, which is incorporated herein by reference in its entirety.

BACKGROUND

[0002] The present application generally relates to devices and methods for delivering a stent in a body vessel or in a non-body structure such as a polymer tube used for testing or demonstration.

[0003] Body vessels or certain non-body structures such as polymer tubes may be at least partially occluded. A stent can be inserted across a lesion or obstruction in order to restore patency to the vessel. Stents can also be used for other functions, such as trapping embolic material, increasing fluid flow, and the like.

SUMMARY

[0004] In certain embodiments, a system for delivering a stent comprises a stent, a stent delivery catheter, and a handle. The stent has a radially reduced configuration and a radially expanded configuration. The stent has a proximal end, a distal end, and length between the proximal end and the distal end. The stent comprises a plurality of openings along the length. The stent delivery catheter comprises an elongate outer tubular member, an elongate inner tubular member, and a stent-engaging member. The outer tubular member has a proximal end and a distal end. The stent is contained in the radially reduced configuration within the distal end of the outer tubular member. The elongate inner tubular member has a proximal end and a distal end. The inner tubular member extends within the outer tubular member. The inner tubular member at least partially defines a guidewire lumen. The stent-engaging member is coupled to the distal end of the elongate inner tubular member. The stent-engaging member comprises a ratchet having a shovel shape and a curved distal end. The stent-engaging member at least partially defines the guidewire lumen. The stent-

engaging member is configured to engage the openings of the stent when distally advanced relative to the elongate outer tubular member to cause the stent to be moved distally out of the elongate outer tubular member, and is configured to slide past the openings of the stent when proximally retracted relative to the elongate outer tubular member. The handle is at the proximal end of the outer tubular member and the proximal end of the inner tubular member. The handle is adapted to control relative movement of the outer tubular member and the inner tubular member. In some embodiments, the stent-engaging member comprises a flex slot. In some embodiments, the stent-engaging member comprises nickel-titanium alloy. In some embodiments, the ratchet is configured to engage an intersection between filaments of a woven stent. In some embodiments, the ratchet is configured to engage a first intersection between filaments on a first side of a woven stent and a second intersection between filaments on a second side of the woven stent, the second side opposite to the first side. In some embodiments, the stent-engaging member comprises a stem and the ratchet is mechanically coupled to the stem. In some embodiments, the stem has a concave proximal end. In some embodiments, the ratchet is mechanically coupled to the stem by a plurality of longitudinally-spaced arcuate welds. In some embodiments, the ratchet is mechanically coupled to the stem by a plurality of spot welds. In some embodiments, the stent delivery catheter comprises a tubular connector coupling the inner tubular member and the stent-engaging member. In some embodiments, the stent delivery catheter comprises a tube positioned inward of the stent-engaging member and extending from proximate to the distal end of the inner tubular member to distal to the distal end of the stent-engaging member. In some embodiments, the tube comprises nylon. In some embodiments, the system further comprises an atraumatic tip mechanically coupled to the tube. In some embodiments, an outer diameter of the atraumatic tip is at least as large as an inner diameter of the elongate outer member. In some embodiments, the atraumatic tip comprises a generally conical distal end and a generally cylindrical proximal end comprising at least one aperture in fluid communication with an inner surface of the outer tubular member.

[0005] In certain embodiments, a pusher assembly for a stent delivery device comprises a distal end of an elongate inner member, a stent-engaging member having a proximal end and a distal end, and a connector mechanically coupling the distal end of the

inner member and the proximal end of the stent-engaging member. The proximal end of the stent-engaging member is proximate to the distal end of the inner member. The stent-engaging member comprises a portion that radially outwardly extends towards the distal end of the stent-engaging member. The stent-engaging member is configured to move a stent when distally advanced and configured to not move a stent when proximally retracted. In some embodiments, the portion has a shovel shape having a curved distal end. In some embodiments, the portion has a shovel shape having a substantially flat distal end. In some embodiments, the stent-engaging member comprises a flex slot. In some embodiments, the stent-engaging member comprises nickel-titanium alloy. In some embodiments, the portion is configured to engage an intersection between filaments of a woven stent. In some embodiments, the portion is configured to engage a first intersection between filaments on a first side of a woven stent and a second intersection between filaments on a second side of the woven stent, the second side opposite to the first side. In some embodiments, the stent-engaging member comprises a stem and a ratchet mechanically coupled to the stem, the ratchet comprising the portion. In some embodiments, the stem has a concave proximal end. In some embodiments, the ratchet is mechanically coupled to the stem by a plurality of longitudinally-spaced arcuate welds. In some embodiments, the ratchet is mechanically coupled to the stem by a plurality of spot welds. In some embodiments, the inner member comprises an inner layer, a middle layer, and an outer layer, and the distal end of the inner member comprises the inner layer and the middle layer. In some embodiments, the inner member comprises an inner layer, a middle layer, and an outer layer, and the distal end of the inner member does not comprise the outer layer. In some embodiments, the connector comprises a tubular member radially outward of the distal end of the inner member and radially outward of the proximal end of the stent-engaging member. In some embodiments, the outer layer of the inner member has an outer diameter and the tubular member has an outer surface having an outer diameter substantially equal to the outer diameter of the outer layer of the inner member. In some embodiments, the middle layer of the inner member comprises a braid. In some embodiments, the braid comprises stainless steel. In some embodiments, the inner layer comprises nylon. In some embodiments, the outer layer comprises nylon. In some embodiments, the pusher assembly further comprises a tube

positioned inward of the stent-engaging member and extending from proximate to the distal end of the inner member to distal to the distal end of the stent-engaging member. In some embodiments, the tube comprises nylon. In some embodiments, the inner member at least partially defines a guidewire lumen and the tube at least partially defines the guidewire lumen.

[0006] In certain embodiments, a stent delivery device comprises an elongate outer member at least partially defining an outer member lumen, an elongate inner member coaxially positioned within the outer member lumen, and a pusher assembly as described in the previous paragraph. In some embodiments, the pusher assembly further comprises a tube positioned inward of the stent-engaging member and extending from proximate to the distal end of the inner member to distal to the distal end of the stent-engaging member. In some embodiments, the tube comprises nylon. In some embodiments, the inner member at least partially defines a guidewire lumen and the tube at least partially defines the guidewire lumen. In some embodiments, the stent delivery device further comprises an atraumatic tip mechanically coupled to the tube. In some embodiments, the inner member at least partially defines a guidewire lumen, the tube at least partially defines the guidewire lumen, and the atraumatic tip at least partially defines the guidewire lumen. In some embodiments, an outer diameter of the atraumatic tip is at least as large as an inner diameter of the elongate outer member. In some embodiments, the atraumatic tip comprises a generally conical distal end and a generally cylindrical proximal end comprising at least one aperture in fluid communication with the outer member lumen. In some embodiments, the stent delivery device further comprises a handle stationarily coupled to the outer member and movably coupled to the inner member. The handle comprises a switch. Actuation of the switch causes movement of the stent-engaging member.

[0007] In certain embodiments, a tip for a catheter comprises a proximal end, a distal end, a lumen between the proximal end and the distal end, a generally conical portion proximate to the distal end, and a generally cylindrical portion proximate to the proximal end. The generally cylindrical portion has an outside surface and comprises at least one aperture configured to allow fluid communication between the proximal end and the outside surface.

[0008] In certain embodiments, a stent delivery device comprises an elongate outer member at least partially defining an outer member lumen, an elongate inner member having a proximal end and a distal end, and a tip as described in the previous paragraph mechanically coupled to the distal end of the inner member. The inner member is coaxially positioned within the outer member lumen. The at least one aperture of the tip is in fluid communication with the outer member lumen. In some embodiments, the stent delivery device further comprises the pusher assembly described three paragraphs prior. In some embodiments, the pusher assembly further comprises a tube positioned inward of the stent-engaging member and extending from proximate to the distal end of the inner member to distal to the distal end of the stent-engaging member. In some embodiments, the tube comprises nylon. In some embodiments, the inner member at least partially defines a guidewire lumen and the tube at least partially defines the guidewire lumen. In some embodiments, the tip is mechanically coupled to the tube.

[0009] In certain embodiments, a method of manufacturing a pusher assembly comprises mechanically coupling a distal end of an elongate inner member to a proximal end of a stent-engaging member using a connector. The stent-engaging member comprises a portion that radially expands towards a distal end of the stent-engaging member. The stent-engaging member is configured to move a stent when distally advanced and configured to not move a stent when proximally retracted. In some embodiments, mechanically coupling comprises heat shrinking the connector around the distal end of the elongate inner member and around the proximal end of the stent-engaging member. In some embodiments, the method further comprises removing a layer from the distal end of the elongate inner member. In some embodiments, forming the stent-engaging member comprising cutting, deforming, and heat setting a hypotube. In some embodiments, cutting the hypotube comprises forming a flex slot. In some embodiments, the stent-engaging member comprises a ratchet and a stem and the method further comprises welding the ratchet to the stem.

[0010] In certain embodiments, a system for delivering a stent comprises a stent, a stent delivery catheter, and a handle. The stent has a radially reduced configuration and a radially expanded configuration. The stent has a proximal end, a distal end, and length between the proximal end and the distal end. The stent comprises a plurality of openings

along the length. The stent delivery catheter comprises an elongate outer tubular member, an elongate inner tubular member, and a stent-engaging member. The outer tubular member has a proximal end and a distal end. The stent is contained in the radially reduced configuration within the distal end of the outer tubular member. The elongate inner tubular member has a proximal end and a distal end. The inner tubular member extends within the outer tubular member. The inner tubular member at least partially defines a guidewire lumen. The stent-engaging member is configured to engage the openings of the stent when distally advanced relative to the elongate outer tubular member to cause the stent to be moved distally out of the elongate outer tubular member, and is configured to slide past the openings of the stent when proximally retracted relative to the elongate outer tubular member. The stent-engaging member comprises a ratchet and a stem. The ratchet has a proximal end and a shovel-shaped distal end. The stem is inward of the ratchet and is coupled to the ratchet. The stem has a proximal end and a distal end. The proximal end of the stem extends proximal to the proximal end of the ratchet. The proximal end of the ratchet is at least partially inside the distal end of the elongate inner tubular member. The distal end of the stem extends distal to the distal end of the ratchet. The handle is at the proximal end of the outer tubular member and the proximal end of the inner tubular member. The handle is adapted to control relative movement of the outer tubular member and the inner tubular member. In some embodiments, the ratchet is configured to engage an intersection between filaments of a woven stent. In some embodiments, the stem comprises a helical cutout. In some embodiments, the stem comprises a plurality of apertures. In some embodiments, the ratchet has a flat distal end. In some embodiments, the ratchet has a flared distal end. In some embodiments, the system further comprises an atraumatic tip mechanically coupled to the stem. In some embodiments, the atraumatic tip comprises a generally conical distal end and a generally cylindrical proximal end comprising at least one aperture in fluid communication with an inner surface of the outer tubular member.

[0011] In certain embodiments, a pusher assembly for a stent delivery device comprises a distal end of an elongate inner member and a stent engaging member. The stent-engaging member has a proximal end and a distal end. The proximal end of the stent-engaging member is at least partially inside the distal end of the elongate inner member. The

stent-engaging member comprises a portion that radially outwardly extends towards the distal end of the stent-engaging member. The stent-engaging member is configured to move a stent when distally advanced and configured to not move a stent when proximally retracted. In some embodiments, the stent-engaging member has a first internal diameter, the elongate inner member has a second internal diameter proximal to the proximal end of the stent-enganging member, and the first internal diameter is substantially equal to the second internal diameter. In some embodiments, the portion has a shovel shape having a curved distal end. In some embodiments, the portion has a shovel shape having a flat distal end. In some embodiments, the portion has a shovel shape having a flared distal end. In some embodiments, the stent-engaging member comprises nickel-titanium alloy. In some embodiments, the portion is configured to engage an intersection between filaments of a woven stent. In some embodiments, the stent-engaging member comprises a stem and a ratchet mechanically coupled to the stem, the ratchet comprising the portion. In some embodiments, the proximal end of the stent-engaging member comprises the stem. In some embodiments, the ratchet is mechanically coupled to the stem by a plurality of spot welds. In some embodiments, the proximal end of the stent-engaging member comprises an aperture, the elongate inner member comprises an inner layer, and the inner layer of the elongate inner member at least partially fills the aperture. In some embodiments, the aperture comprises a plurality of holes. In some embodiments, the distal end of the stent-engaging member comprises a cutout and wherein the pusher assembly further comprises a tube positioned around the distal end of the stent-engaging member and at least partially filling the cutout. In some embodiments, the cutout comprises a plurality of helical slots. In certain embodiments, a stent delivery device comprises an elongate outer member at least partially defining an outer member lumen, an elongate inner member coaxially positioned within the outer member lumen, and the pusher assembly. In some embodiments, the stent delivery device further comprises an atraumatic tip mechanically coupled to the stent-engaging member. In some embodiments, the elongate inner member at least partially defines a guidewire lumen, the stent-engaging member at least partially defines the guidewire lumen, and the atraumatic tip at least partially defines the guidewire lumen. In some embodiments, the atraumatic tip

comprises a generally conical distal end and a generally cylindrical proximal end comprising at least one aperture in fluid communication with the outer member lumen.

[0012] In certain embodiments, a method of manufacturing a pusher assembly comprises mechanically coupling a proximal end of a stent-engaging member at least partially inside a flared distal end of an elongate inner member. The stent-engaging member comprises a portion that radially expands towards a distal end of the stent-engaging member. The stent-engaging member is configured to move a stent when distally advanced and configured to not move a stent when proximally retracted. In some embodiments, mechanically coupling comprises heat shrinking the flared distal end of the elongate inner member around the proximal end of the stent-engaging member. In some embodiments, the method further comprises forming the flared distal end of the elongate inner member. In some embodiments, forming the stent-engaging member comprising cutting, deforming, and heat setting a hypotube. In some embodiments, the stent-engaging member comprises a ratchet and a stem and wherein the method further comprises welding the ratchet to the stem.

[0013] For purposes of summarizing the invention and the advantages achieved over the prior art, certain objects and advantages of the invention are described herein. Of course, it is to be understood that not necessarily all such objects or advantages need to be achieved in accordance with any particular embodiment. Thus, for example, those skilled in the art will recognize that the invention may be embodied or carried out in a manner that achieves or optimizes one advantage or group of advantages as taught or suggested herein without necessarily achieving other objects or advantages as may be taught or suggested herein.

[0014] All of these embodiments are intended to be within the scope of the invention herein disclosed. These and other embodiments will become readily apparent to those skilled in the art from the following detailed description having reference to the attached figures, the invention not being limited to any particular disclosed embodiment(s).

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] These and other features, aspects, and advantages of the present disclosure are described with reference to the drawings of certain embodiments, which are intended to illustrate certain embodiments and not to limit the invention.

[0016] FIG. 1A illustrates an example embodiment of a stent delivery device;

[0017] FIG. 1B illustrates another example embodiment of a stent delivery device;

[0018] FIG. 2A illustrates an example embodiment of a proximal portion of the stent delivery device encircled by the line 2 in FIG. 1A;

[0019] FIG. 2B illustrates an example embodiment of a portion of the proximal portion encircled by the line in FIG. 2A;

[0020] FIG. 2C illustrates another example embodiment of a proximal portion of the stent delivery device encircled by the line 2 in FIG. 1A;

[0021] FIG. 2D illustrates an example embodiment of an inner member;

[0022] FIG. 2E illustrates an example embodiment of a proximal portion of the stent delivery device encircled by line 2 in FIG. 1B;

[0023] FIG. 3A is a cross-sectional view of the proximal portion of the stent delivery device illustrated in FIG. 2A;

[0024] FIG. 3B is a cross-sectional view of an example embodiment of a portion of the proximal portion of the stent delivery device illustrated in FIG. 2A;

[0025] FIG. 3C is a cross-sectional view of an example embodiment of portions of the stent delivery device illustrated in FIG. 1;

[0026] FIG. 3D is a top elevational and partial cross-sectional view of the proximal portion of the stent delivery device illustrated in FIG. 2A;

[0027] FIG. 3E illustrates an example embodiment of a portion of the proximal portion encircled by the line 3E in FIG. 3D;

[0028] FIG. 3F is a cross-sectional view of an example embodiment of a portion of the proximal portion of the stent delivery device illustrated in FIG. 2E;

[0029] FIG. 4A illustrates an example embodiment of a distal portion of the stent delivery device encircled by the line 4 in FIG. 1;

[0030] FIG. 4B is a cross-sectional view of the distal portion of the stent delivery device illustrated in FIG. 4A;

[0031] FIG. 5A is a cross-sectional view of an example embodiment of a pusher assembly;

[0032] FIG. 5B is a cross-sectional view of another example embodiment of a pusher assembly;

[0033] FIG. 5C is a cross-sectional view of an example embodiment of a distal portion of another example embodiment of a stent delivery device;

[0034] FIG. 5D is a cross-sectional view of an example embodiment of a distal portion of another example embodiment of a stent delivery device;

[0035] FIG. 5E is a cross-sectional view of the stent delivery device of FIG. 5A having a pusher assembly in a distally advanced position;

[0036] FIG. 5F is a cross-sectional view of the stent delivery device of FIG. 5B having a pusher assembly in a distally advanced position;

[0037] FIG. 6 illustrates an example embodiment of an intermediate portion of the stent delivery device encircled by the line 6 in FIG. 1;

[0038] FIG. 7A illustrates an example embodiment of a stent-engaging portion;

[0039] FIG. 7B illustrates another example embodiment of a stent-engaging portion;

[0040] FIG. 7C illustrates another example embodiment of a stent-engaging portion;

[0041] FIG. 7D illustrates another example embodiment of a stent-engaging portion;

[0042] FIG. 7E illustrates an example cross-sectional view of the stent-engaging portion of FIG. 7E along the line 7E-7E;

[0043] FIGS. 7F and 7G illustrate another example embodiment of a stent-engaging portion;

[0044] FIG. 8 schematically depicts an example embodiment of a stent-advancement process.

[0045] FIGS. 9 and 10 schematically depict an example embodiment of deploying a stent in a vessel;

[0046] FIG. 11 illustrates an example embodiment of an intermediate portion of the stent delivery device encircled by the line 2 in FIG. 1;

[0047] FIG. 12A illustrates an example embodiment of a stent-retention element;

[0048] FIG. 12B illustrates another example embodiment of a stent-retention element;

[0049] FIG. 13 illustrates another example embodiment of a proximal portion of the stent delivery device encircled by the line 2 in FIG. 1;

[0050] FIG. 14 is a cross-sectional view of the proximal portion of the stent delivery device illustrated in FIG. 13;

[0051] FIG. 15A schematically depicts another example embodiment of deploying a stent in a vessel;

[0052] FIG. 15B schematically depicts yet another example embodiment of deploying a stent in a vessel;

[0053] FIG. 15C schematically depicts still another example embodiment of deploying a stent in a vessel; and

[0054] FIG. 16 illustrates an example embodiment of a computer system.

DETAILED DESCRIPTION

[0055] Although certain embodiments and examples are described below, those of skill in the art will appreciate that the invention extends beyond the specifically disclosed embodiments and/or uses and obvious modifications and equivalents thereof. Thus, it is intended that the scope of the invention herein disclosed should not be limited by any particular embodiments described below.

[0056] Certain aspects of the delivery systems described herein are described in U.S. Patent Application Serial No. 11/876,764, published as U.S. Patent Pub. No. 2008/0097572, which is incorporated herein by reference in its entirety.

[0057] Figure 1A illustrates an example embodiment of a stent delivery device 10. The stent delivery device 10 has a proximal portion 2, one or more intermediate portions

11, 6, and a distal portion 4, each of which is described in more detail herein. The stent delivery device 10 comprises a device body or handle 90 and an outer sheath or outer member 20. In certain embodiments, the outer diameter of the outer sheath 20 is 7 French (0.092 inches; 2.3 mm). In certain embodiments, the outer diameter of the outer sheath 20 is 6 French (0.079 inches; 2.0 mm). Other diameters of the outer sheath 20 are also possible.

[0058] Figure 1B illustrates another example embodiment of a stent delivery device 10. The stent delivery device 10 has a proximal portion 2, one or more intermediate portions 11, 6, and a distal portion 4, each of which is described in more detail herein. The stent delivery device 10 comprises a device body or handle 90 and an outer sheath or outer member 20. In certain embodiments, the outer diameter of the outer sheath 20 is 7 French (0.092 inches; 2.3 mm). In certain embodiments, the outer diameter of the outer sheath 20 is 6 French (0.079 inches; 2.0 mm). Other diameters of the outer sheath 20 are also possible.

[0059] An example embodiment of a proximal portion of the stent delivery device 10 is illustrated in perspective in Figure 2A and in cross-section in Figure 3A. Another example embodiment of a proximal portion of the stent delivery device 10 is illustrated in perspective in Figure 2E and in cross-section in Figure 3F. The stent delivery device 10 comprises user-actuatable element or switch 50 that is coupled to (and, in the embodiment illustrated in Figures 2A, 2E, 3A and 3F, mounted so as to be longitudinally slidable with respect to) the device body or handle 90. The switch 50 is also coupled to an element 40 (Figure 3C), which in the embodiment illustrated in Figure 2A, 2E, 3A and 3F has a passageway and is configured to fit within the outer sheath 20. The switch 50 is slidably mounted on the device body 90 and coupled to the element 40 via a block 51. In some embodiments, the block 51 may include a biasing element (e.g., a spring) that biases the switch 50 toward the position shown in Figure 3A or 3F. In some embodiments, the block 51 does not include a biasing element.

[0060] The switch 50, block 51, and element 40 of the device 10 are movable in the proximal and distal directions (which are along the longitudinal axis (not shown) of the device 10), and are generally constrained in other directions. Thus, proximal movement of the switch 50 (towards the proximal side 92) results in proximal movement of the element 40, and distal movement of the switch 50 (towards the distal side 91) results in distal

movement of the element 40. In some embodiments, the distance that the switch 50 moves (either proximally or distally) translates into movement of the element 40 by the same distance. In some embodiments, the distance that the switch 50 moves (either proximally or distally) translates into movement of the element 40 by a different distance (e.g., by being geared up or down). As explained in greater detail herein, the element 40 is coupled to a stent-engaging element 45, which engages and drives a loaded stent 30 distally from the outer sheath 20 during at least a portion of the time that the switch 50 is operated distally.

[0061] The outer sheath 20 extends distally from device body 90. The device 10 can also include inner member 60, a portion of which is located within (e.g., coaxially positioned within) the outer sheath 20. As illustrated in, for example, Figure 4A, the inner member 60 (and, in certain embodiments such as illustrated in Figure 2D, an inner sleeve 61) is coupled at its distal end to an atraumatic tip or nose cone 150. The inner member 60, which is not constrained axially by the outer sheath 20 (e.g., because the inner diameter of the outer sheath 20 is sufficiently different from the outer diameter of the inner member 60 that they do not necessarily touch), facilitates motion of the nose cone 150 relative to the outer sheath 20. The inner member 60 at least partially defines a guidewire lumen through which a guidewire (e.g., having a diameter of 0.018 inches (approx. 0.46 mm)) may be passed. The nose cone 150 at least partially defines the guidewire lumen through which a guidewire (e.g., having a diameter of 0.018 inches (approx. 0.46 mm)) may be passed.

[0062] A radiopaque marker 27 may be placed at any suitable location along the outer sheath 20 to provide a means for aiding deployment of a stent 30. For example, the distance from the distal end of the outer sheath 20 and the marker 27 may be the nominal length of the stent 30 being delivered in its deployed state.

[0063] Figure 4B illustrates the distal end 31 of the stent 30 within the outer sheath 20. In some embodiments, neither the element 40 nor the stent-engaging member 45 is attached to inner member 60. In certain such embodiments, the element 40 may be moved proximally and over the inner member 60 while the inner member 60 is stationary, and the stent-engaging member 45 may be moved proximally and distally over the inner member 60 while the inner member 60 is stationary.

[0064] Referring to Figures 2A, 2C, 2E, 3A, and 3F, the allowable proximal-distal travel of the switch 50 is constrained by the length of a slot 52 in the device body 90, as well the position of one or more stoppers 120. The first position 121 of the stopper 120 shown in Figures 2A and 2E limits the distal travel of the switch 50 to less than the full length of the slot 52. In some embodiments, the first position 121 corresponds to a distal-most position of the switch 50 in which the stent-engaging member 45 remains within the outer sheath 20. This corresponds to an example configuration for advancement of the stent 30. The stopper 120 is preferably biased to the first position 121 with, e.g., a spring. In Figures 2C and 3A, the stopper 120 has been rotated to a second position 122 that allows the switch 50 to slide past the stopper 120.

[0065] Figure 2D is a cross-sectional view of a sub-assembly of an example embodiment of the device 10 that includes an example embodiment of the inner member 60 in the form of an inner sleeve 61 that extends the length of the inner member 60 and that is configured to accept a guidewire (not shown). In some embodiments, the inner member 60 includes an intermediate sleeve 62 that may be secured at its distal end or any other suitable location to the inner sleeve 61 in any suitable fashion, such as by Loctite® 4014 adhesive. The intermediate sleeve 62 (e.g., comprising a hypotube) may also extend to the proximal end of the inner member 60. In some embodiments, the inner member 60 includes an outer sleeve 63 (e.g., comprising a hypotube) connected at its distal end or any other suitable location to the intermediate sleeve 62 in any suitable manner (e.g., soldering). The outer sleeve 63 may also extend to the proximal end of the inner member 60. In some embodiments, the inner member 60 includes a travel-limiting sleeve 64 connected at its distal end or any other suitable location to the outer sleeve 63 in any suitable manner (e.g., soldering). The sleeve 64 may be configured to restrict the travel of the inner member 60 with respect to the device body 90. The sleeve 64 can be configured to interfere (e.g., due to its size) with the proximal opening of a cavity 55 of the device body 90 (e.g., as illustrated in Figure 3A). The sleeve 64 can be configured to interfere distally with the block 51 (e.g., if a Luer fitting 100 does not first interfere with the Y-adapter 95).

[0066] Figure 3B is an enlarged, cross-sectional view, showing the interaction between the element 25 and a seal 31 of the hemostasis valve of the introducer 35. In certain

embodiments, the device 10 includes an element 25 that is coupled (e.g., slidably coupled) to the outer sheath 20. In some embodiments, the element 25 is configured to slide relatively freely along the outer surface of the outer sheath 20. In certain such embodiments, the element 25 is configured to interface with a hemostasis valve of an introducer 35. The element 25 be configured to fit at least partially inside the introducer 35 and to interface with the hemostasis valve such that fluid does not flow back toward the handle 90 of the device 10, but still allows the outer sheath 20 of the device to slide relatively freely within the element 25 and the introducer 35. The element 25 can reduce the friction between the outer sheath 20 of the device 10 and an introducer 35 through which the outer sheath 20 of the device 10 is inserted, while maintaining a substantial fluid seal between the outer sheath 20 and the exterior of the patient.

[0067] Figure 3C is a cross-sectional view of a sub-assembly of an example embodiment of the device 10 that includes an example embodiment of the element 40 comprising a proximal hypotube 41 secured in any suitable fashion to block 51, such as by a press fit that terminates at a shoulder 57 or with a suitable adhesive, such as one of the Loctite® adhesives (e.g., 4014, 4305, 3321, etc.). The block 51 is secured to the switch 50 through a pin 54, which can be bonded to the switch 50 and press fit or bonded to the block 51. The element 40 may also include an intermediate tube 42 that is connected at its proximal end to a proximal hypotube 41 in any suitable manner, such as through Loctite® 4305, and at its distal end to a support tube or stem 46 (that is in turn connected to stent-engaging member 45). In some embodiments, the element 40 includes a support tube 43 positioned over an intermediate tube 42 and abuts the distal end of the proximal hypotube 41.

[0068] In certain embodiments, a support tube 43 is connected at any suitable location to the intermediate tube 42 (e.g., using any suitable adhesive). The support tube 43 may be configured to increase the rigidity of the intermediate tube 42.

[0069] The element 40 may also include a resheathing stop 44 that is threaded over the intermediate tube 42 and that abuts the distal end of the support tube 43. The resheathing stop 44 may be connected at any suitable location to intermediate tube 42 using any suitable adhesive. The resheathing stop 44 may be configured to prevent proximal movement of a stent 30 enclosed by outer sheath 20 if the stent 30 is re-sheathed during the

delivery process. The sub-assembly illustrated in Figure 3C also includes a seal 56 (e.g., comprising silicone) designed to reduce (e.g., prevent) the backflow of fluid around the outside of the inner member 60, and an outer hypotube in certain embodiments of inner member 60, and that is held in place by a retainer 58 (e.g., comprising stainless steel).

[0070] Figure 6 illustrates an element 40 extending such that a portion of it is located within the outer sheath 20. In some embodiments, the element 40 is hollow and its passageway accommodates a portion of inner member 60 being located within it. Some embodiments of the element 40 may be non-hollow.

[0071] Figure 5A schematically illustrates an example embodiment of a pusher assembly or ratchet assembly 500. The pusher assembly 500 includes the distal end of the inner member 60, a stent-engaging member 45, and a connector 74. The proximal end of the stent-engaging member 45 is proximate to the distal end of the inner member 60. The connector 74 mechanically couples the distal end of the inner member 60 to the proximal end of the stent-engaging member 45.

[0072] In certain embodiments, the inner member 60 comprises three layers: (1) an inner layer 60a (e.g., comprising nylon); (2) a middle layer 60b (e.g., comprising braided stainless steel ribbons); and (3) an outer layer 60c (e.g., comprising nylon). In some embodiments, the distal end of the inner member 60 comprises the inner layer 60a and the middle layer 60b. In certain such embodiments, the outer layer 60c is removed (e.g., milled, stripped, etched) from the distal end of the inner member 60.

[0073] Figures 7A-7G illustrate example embodiments of a stent-engaging member 45. The stent-engaging member 45 includes a portion that radially outwardly extends towards the distal end of the stent-engaging member 45. In the embodiments illustrated in Figures 7A, 7B, 7F, and 7G, the stent-engaging member 45 includes a portion that has a shovel or scoop shape having a curved distal end. In the embodiment illustrated in Figures 7C and 7D, the stent-engaging member 45 includes a portion that has a shovel or scoop shape having a flat distal end. In some embodiments, the stent-engaging member 45 may be formed into shape by cutting (e.g., laser cutting), deforming, and heat setting a hypotube (e.g., comprising a nickel-titanium alloy). For example, Figures 7A-7D, 7F, and 7G depict a generally cylindrical handle portion and a cut, deformed, and heat set shovel-

shaped or scoop-shaped portion that radially outwardly extends towards the distal end of the stent-engaging member 45.

[0074] Figure 7B illustrates an embodiment of a stent-engaging member 45 comprising a flex slot 48 configured to alleviate fatigue stress fractures and the like and to allow the stent-engaging member 45 to more easily deform inwardly as the stent-engaging member slides proximally within the lumen of a stent 30. In some embodiments, the flex slot 48 has a dumbbell or dog bone shape. In some embodiments, the flex slot 48 is formed during cutting a hypotube. Other shapes of flex slots are also possible. Combinations of flex slots with other stent-engaging members 45 (e.g., the stent-engaging members 45 illustrated in Figures 7A, 7C, 7D, 7F, and 7G) are also possible.

[0075] In some embodiments, the stent-engaging member 45 comprises a stem 46 and a ratchet mechanically coupled to the stem 46. The stem 46 may comprise a hypotube (e.g., comprising a nickel-titanium alloy) having a smaller outer diameter than the diameter of the ratchet. Referring again to Figures 5A and 5B, the stem 46 may have a concave or scalloped proximal surface 49 that can reduce stress when the stent-engaging member 45 is mechanically coupled to the distal end of the inner member 60. In some embodiments, the outer diameter of the stem 46 is substantially similar to the inner diameter of the ratchet. In some embodiments, the outer diameter of the stem 46 is substantially equal to the outer diameter of the middle layer 60b of the inner member 60.

[0076] In some embodiments, the stem 46 comprises a portion configured to enhance bonding with a polymer. Figure 7A illustrates an example embodiment of a stent-engaging member 45 comprising stem 46 comprising a cutout 460. In some embodiments, the cutout 460 is laser cut. In some embodiments, the cutout 460 may be deformed and heat set after cutting (e.g., to inwardly bias projections in the cutout 460). Other shapes of cutouts are also possible. Combinations of stems 46 with a cutout 460 with other shapes (e.g., the shapes illustrated in Figures 7B-7D, 7F, and 7G) are also possible.

[0077] Figure 7D illustrates an example embodiment of a stent-engaging member 45 comprising a stem 46 comprising a plurality of apertures 464. In some embodiments, the apertures 464 are laser cut. In some embodiments, the plurality of apertures 464 comprises three through-holes or six individual holes. In certain embodiments, the plurality of apertures

464 comprises a first through-hole 464a, a second through-hole 464b, and a third through-hole 464c. The first through-hole 464a and the second through-hole 464b are circumferentially aligned and longitudinally spaced. The third through-hole 464c is rotated about 90° circumferentially from the first through-hole 464a and the second through-hole 464b. The third through-hole 464c is longitudinally between the first through-hole 464a and the second through-hole 464b. The third through-hole 464c may include portions that longitudinally overlap with potions of the first through-hole 464a and/or the second through-hole 464b. Other numbers of apertures 464 and orientations of apertures 464 are also possible (e.g., apertures that are not through-holes, apertures that are circumferentially offset by about 30°, about 45°, about 60°, about 90°, about 120°, about 135°, about 150°, about 180°, and ranges therebetween, apertures that are longitudinally offset, etc.).

[0078] In some embodiments, combinations of cutouts 460 and apertures 464 may be used and/or substituted for each other. For example, the stem 46 of the stent-engaging member 45 illustrated in Figure 7A or 7B may comprise the plurality of apertures 464 illustrated in Figure 7D. For another example, the stem 46 of the stent-engaging member 45 illustrated in Figure 7D may comprise the cutout 460 illustrated in Figure 7A.

[0079] In some embodiments, the stem 46 extends through the ratchet, for example to a length beyond the distal end of the ratchet. For example, Figure 7D illustrates an example embodiment of a stent-engaging member 45 comprising a stem 46 extending through the ratchet to a length beyond the distal end of the shaped portion of ratchet.

[0080] In some embodiments, the stem 46 comprises a laser cut 462 proximate to the distal end, for example configured to increase the flexibility of the stem 46. In some embodiments, the laser cut 462 comprises one or more helices. For example, the laser cut 462 may comprise a first helix winding in a first direction and starting a first circumferential position and a second helix also winding in the first direction but starting in a second circumferential position (e.g., about 180° from the first circumferential position).

[0081] In some embodiments, the stem 46 is mechanically coupled to the ratchet by two longitudinally-spaced arcuate welds (e.g., laser welds). For example, Figures 5A and 7A illustrate two longitudinally-spaced arcuate (e.g., fully circumferential) welds 47 coupling the ratchet to the stem 46. In some embodiments, the arcuate welds begin at about the same

circumferential position. In some embodiments, the stem 46 is mechanically coupled to the ratchet by a plurality of arcuately-spaced spot welds (e.g., laser welds). For example, Figure 7E, which is a cross-section taken along the line 7E-7E in Figure 7D, illustrates three arcuately-spaced spot welds 472a, 472b, 472c coupling the ratchet to the stem 46. Other numbers of spot welds are also possible (e.g., five or less, three or less, 1, etc.). In some embodiments, the welds 472a, 472b, 472c are spaced by about 30°, about 45°, about 60°, about 75°, about 90°, about 120°, and ranges therebetween, in which the angles may be measured between lines connecting the welds 472a, 472b, 472c and a common spot (e.g., the center of the stem 46, the center of the ratchet, or elsewhere). For example, in the embodiment illustrated in Figure 7E, the weld 472a is spaced from the weld 472c by about 90°, and the weld 472b is spaced from the welds 472a, 472c by about 45°.

[0082] When a first weld is made (e.g., the weld 472b), the stem 46 is pulled off-center of the ratchet at the point of the weld 472b. This pulling can create a gap 474 between the ratchet and the stem 46 at the opposite side. In an arcuate weld, the connection between the ratchet and the stem 46 can become worse as the weld approaches the largest distance of the gap 474, perhaps even to the extent that portions of the weld may have no coupling effect. A plurality of spot welds may produce at least as much coupling effect as an arcuate weld, may reduce processing time, and may produce a more robust coupling. In the embodiment depicted in Figure 7E, the welds 472a, 472b, 472c each have a coupling effect between the ratchet and the stem 46. In embodiments in which the ratchet has a side with more material (e.g., the shovel or scoop portion of the ratchets illustrated in Figures 7A-7D), the spot welds 472a, 472b, 472c may be made on that side to provide additional room for error (e.g., longitudinal welding error). In certain embodiments, the gap 474 may be at least partially filled (e.g., by a polymer).

[0083] Figures 7F and 7G illustrate another example embodiment of a stent-engaging member 45. The stent-engaging member 45 includes a portion that radially outwardly extends towards the distal end of the stent-engaging member 45. In the embodiment illustrated in Figure 7D, the stent-engaging member 45 includes a portion that has a shovel or scoop shape having a curved distal end and distally and/or outwardly flared tips 452. In some embodiments, the stent-engaging member 45 may be formed into shape by

cutting (e.g., laser cutting), deforming, and heat setting a hypotube (e.g., comprising a nickel-titanium alloy). Figures 7F and 7G depict a generally cylindrical handle portion and a cut, deformed, and heat set flared-tip shovel-shaped or scoop-shaped portion that radially outwardly extends towards the distal end of the stent-engaging member 45.

[0084] Figure 5A illustrates an example embodiment in which the proximal end of the stent-engaging member 45 is mechanically coupled to the distal end of the inner member 60 at a slightly spaced butt joint. A connector 74 (e.g., comprising a tubular member (e.g., comprising nylon)) is heat shrunk (e.g., by being radially inwardly compressed by a heat shrink sleeve) around the distal end of the inner member 60 and around the proximal end of the stent-engaging member 60. In some embodiments, portions of the connector 74 may seep into the gap between the inner member 60 and the stent-engaging member 45. In certain embodiments, the distal end of the inner member may be modified prior to the mechanical coupling (e.g., by removing the outer layer 60c).

[0085] In some embodiments, the outer diameter of the connector 74 is substantially equal to the outer diameter of the inner member 60. In some embodiments, the inner diameter of the connector 74 is substantially equal to the outer diameter of the middle layer 60b of the inner member 60. When both conditions are satisfied, the proximal section of the connector 74 may effectively take the place of a removed outer layer 60c.

[0086] In some embodiments, the outer diameter of the connector 74 is substantially equal to the outer diameter of a portion of the stent-engaging member 45 that does not radially outwardly extend towards the distal end of the stent-engaging member 45 (e.g., the cylindrical portion of a hypotube described herein). In some embodiments, the inner diameter of the connector 74 is substantially equal to the outer diameter of a stem 46. When both conditions are satisfied, the distal section of the connector 74 may provide a substantially seamless surface between the connector 74 and the stent-engaging member 45. When also combined with the conditions in the preceding paragraph, the connector 74 can provide the pusher assembly 500 with a substantially uniform outer diameter other than the portion of the stent-engaging member 45 that radially outwardly extends. This may provide a uniform appearance to the pusher assembly 500. Thus may also reduce the chances of portions of the pusher assembly 500 other than the radially outwardly extending portion of

the stent-engaging member 45 interacting with a stent 30 and/or the outer sheath 20 (e.g., becoming undesirably snagged).

[0087] Figure 5B illustrates another example embodiment in which the proximal end of the stent-engaging member 45 is mechanically coupled to the distal end of the catheter shaft or inner member 60. The distal end of the inner member 60 is flared, for example using a tool having an outer diameter that is approximately the outer diameter of the proximal end of the stent-engaging member 45. The proximal end of the stent-engaging member 45 (e.g., comprising a cutout 462 or apertures 464) is placed in the flared distal end of the inner member 60. Heat shrink tubing or other means may be used to radially inwardly force the inner member 60 to collapse around the stent-engaging member 45. Portions of the inner layer of the inner member 60 extrude into the cutout 462 or apertures 464. The coupled structure has a uniform inner diameter based on the inner diameter of the inner member 60 and the inner diameter of the stent-engaging member 45. The coupled structure may advantageously have no discrete sheer plane. The coupled structure may have a slight outward flare, for example along the portion of the stent-engaging member 45 proximal to the proximal end of the ratchet. This coupling structure may advantageously simplify manufacturing by using fewer discrete pieces (e.g., not using a connector 74), not modifying the inner member 60 (e.g., not removing the layer 60c), and/or not modifying the stem 46 (e.g., not forming the scallop 49).

[0088] The stent-engaging member 45 is configured to engage a stent 30 when distally advanced and is configured to not engage a stent when proximally retracted. For example, the radially outwardly extending portion of the stent-engaging member 45 may be configured to engage one or more intersections between filaments of a woven stent (e.g., a first intersection between filaments on a first side and a second intersection between filaments on a second opposite side, as depicted by the engagement at 33 in Figure 5D). For another example, the radially outwardly extending portion of the stent-engaging member 45 may be configured to engage one or more cutouts in a laser cut hypotube stent. For additional examples, the radially outwardly extending portion of the stent-engaging member 45 may be configured to engage one or more engageable features of other types of stents (e.g., comprising metal, plastic, combinations thereof, etc.) and the radially outwardly

extending portion of the stent-engaging member 45 may be configured to engage one or more engageable features of a graft (e.g., comprising an inner stent surface), combinations thereof, and the like.

[0089] In some embodiments, the pusher assembly 500 comprises a tube 75 (e.g., comprising nylon) positioned inward of the stent-engaging member 45 and extending from proximate to the distal end of the inner member 60 to distal to the distal end of the stent-engaging member 45. For example, as illustrated in Figures 5A, the tube 75 extends from approximately the proximal end of the stent-engaging member 45, through the stent-engaging member 45, and for some length beyond the stent engaging member 45.

[0090] In some embodiments, the pusher assembly 500 optionally comprises a second tube 76 (e.g., comprising polyimide) radially outward of the tube 75 proximate to the portion of the tube 75 within the radially outwardly extending portion of the stent-engaging member 45, for example to protect the tube 75 from being damaged by any sharp edges of the stent-engaging member 45. In certain such embodiments the second tube extends from the proximal end of the radially outwardly extending portion of the stent-engaging member 45 to the distal end of the stent-engaging member 45.

[0091] In some embodiments, an atraumatic tip 150 is mechanically coupled to the distal end of the tube 75 and is longitudinally spaced from the distal end of the stent-engaging member 45. The tip 150 has a proximal end 151 and a distal end 152. Figures 5A and 5B are schematic, so the longitudinal spacing of the stent-engaging member 45 and the tip 150 may not be accurately depicted (e.g., as implied by the curved pairs of lines across the tube 75). In some embodiments, the distal end of the stent-engaging member 45 is, for example, at least about 30 mm from the proximal end 151 of the tip 150. The tip 150 may comprise a generally cylindrical portion 153 proximate to the proximal end 151 and having an outside surface 154. The tip 150 may comprise a generally conical or frustoconical portion 155 proximate to the distal end 152 and having an outside surface 156.

[0092] In some embodiments, the tip 150 comprises at least one aperture 157, 158. The aperture 157, 158 is configured to allow fluid communication from outside of the outer sheath 20 to inside the outer sheath 20. In certain such embodiments, the at least one aperture 157 is configured to allow fluid communication between the proximal end 151 and

the outside surface 154 and/or the at least one aperture 158 is configured to allow fluid communication between the proximal end 151 and the outside surface 156. The at least one aperture 157 may advantageously be less prone to accumulating fluid during advancement of the distal end of the device 10. In some embodiments, the at least one aperture 157, 158 comprises a groove (e.g., a U-shaped groove) in the tip 150. In some embodiments, the at least one aperture 157, 158 comprises a second lumen in the tip 150. The at least one aperture 157, 158 may be formed, for example, during molding of the tip 150 and/or may result from removing material (e.g., via etching, drilling, etc.) from the tip 150. In some embodiments, the at least one aperture comprises two grooves 180° apart in the generally cylindrical portion 153.

[0093] The at least one aperture 157, 158 may be useful for sterilizing the device 10. For example, ethylene oxide gas may flow through the at least one aperture 157, 158 to sterilize the stent 30, the stent-engaging member 45, and other components within the lumen of the outer sheath 20. In some embodiments, the cylindrical portion 153 has an outer diameter greater than the inner diameter of the outer sheath 20 (e.g., being substantially equal to the diameter of the outer sheath 20), for example so as to substantially occlude the lumen of the outer sheath 20 during advancement of the device 10. As described herein, the lumen of the outer sheath 20 is exposed to the operational environment, for example during operation of the switch 50, and foreign material may accumulate in the lumen of the outer sheath 20. The at least one aperture 157, 158 may be useful for flushing air from the device 10 before use (e.g., allowing flushing of saline through the device 10 while the tip 150 is proximate to the outer sheath 20).

[0094] Figure 5B illustrates another example embodiment of a coupling structure between a tip 150 and a stent-engaging member 45. As described herein, the stent-engaging member 45 may comprise a stem 46 protruding beyond the distal end of the ratchet, and the distally extending portion may comprise features such as the helices 462. In some embodiments, the tube 75 is heat shrunk (e.g., by being radially inwardly compressed by a heat shrink sleeve) around the distal end of the stem 46, and material of the tube 75 extrudes into the features 462. The pusher assembly 500 may optionally comprise a melt coupler 76 coupling the stem 46 and the tube 75.

[0095] Figure 5C illustrates an embodiment of a distal end 550 of a stent delivery device 10 comprising a pusher assembly 500 in which the outer sheath 20 of the device 10 comprises three layers: (1) an inner layer 20a (e.g., comprising polytetrafluoroethylene (PTFE or Teflon®)); (2) a middle layer 20b (e.g., comprising braided stainless steel ribbons); and (3) an outer layer 20c (e.g., comprising Pebax®). The outer diameter of the cylindrical portion of the tip 150 may be configured to correspond to (e.g., being aligned with the outer diameter of) one or more of the layers 20a, 20b, 20c of the outer sheath 20.

[0096] Figure 5D illustrates an embodiment of a distal end of a stent delivery device 10 comprising a pusher assembly 500 in which the outer sheath 20 of the device 10 comprises three layers: (1) an inner layer 20a (e.g., comprising polytetrafluoroethylene (PTFE or Teflon®)); (2) a middle layer 20b (e.g., comprising braided stainless steel ribbons (e.g., having a different lattice density than the braided stainless steel ribbons illustrated in Figure 5B); and (3) an outer layer 20c (e.g., comprising a first material (e.g., comprising Pebax®) and a second material different than the first material (e.g., comprising nylon)). For example, in some embodiments in which the outer layer 20c has a length of about 90 cm (or 900 mm), the proximal 70 cm (or 700 mm) may comprise a first material (e.g., comprising nylon) and the distal 20 cm (or 200 mm) may comprise a second material different than the first material (e.g., comprising Pebax®). For another example, in some embodiments in which the outer layer 20c has a length of about 120 cm (or 1,200 mm), the proximal 100 cm (or 1,000 mm) may comprise a first material (e.g., comprising nylon) and the distal 20 cm (or 200 mm) may comprise a second material different than the first material (e.g., comprising Pebax®). Other lengths and materials of the first material and the second material are also possible.

[0097] In certain embodiments, the outer layer 20c comprises one or a plurality of markers (e.g., marker bands) (not shown). In some embodiments, one or more of the markers may comprise a tungsten-infused polymer. A marker may be wide enough to provide a user information about the position of the device. In some embodiments, one or more of the markers may have a width between about 1 mm and about 2 mm (e.g., about 1.5 mm), less than about 2 mm, etc.

[0098] The outer diameter of the cylindrical portion of the tip 150 may be configured to correspond to (e.g., being aligned with the outer diameter of) one or more of the layers 20a, 20b, 20c of the outer sheath 20.

[0099] The inner member 60 at least partially defines a guidewire lumen through which a guidewire (e.g., having a diameter of 0.018 inches (approx. 0.46 mm)) may be passed. In embodiments comprising a tube 75, the tube 75 at least partially defines a guidewire lumen through which a guidewire (e.g., having a diameter of 0.018 inches (approx. 0.46 mm)) may be passed. In certain such embodiments, the inner diameter of the tube 75 is substantially equal to the inner diameter of the inner member 60 (e.g., the inner layer 60a). The nose cone 150 at least partially defines the guidewire lumen through which a guidewire (e.g., having a diameter of 0.018 inches (approx. 0.46 mm)) may be passed. The pusher assembly 500 thus includes a guidewire lumen through which a guidewire (e.g., having a diameter of 0.018 inches (approx. 0.46 mm)) may be passed.

[0100] The proximal end of the outer sheath 20 is stationarily coupled to the handle 90 and the proximal end of the inner member 60 is coupled to the switch 50. The switch 50 can slide along a handle path having two different longitudinal lengths: (1) a first length in which the stent-engaging member 45 cannot exit the distal end of the outer sheath 20, and (2) a second length in which the stent-engaging member 45 can exit the distal end of the outer sheath 20 (e.g., after removal of the stop 120). A user can push and pull the switch 50 back and forth relative to the handle 90 to distally extend and proximally retract the stent-engaging member (coupled to the distal end of the inner member 60, as described herein) relative to the outer sheath 20, which is stationary with respect to the handle 90.

[0101] During distal advancement of the switch 50, the stent-engaging member 45 engages an inner surface of the stent 30 at position 33 (e.g., "catching" on an intersection between braided filaments, as illustrated in Figures 5C-5F), thereby distally pushing the stent 30 out of the outer sheath 20.

[0102] During proximal retraction of the switch 50, the stent-engaging member 45 does not engage the stent 30 because the stent-engaging member 45 radially inwardly flexes and non-catchingly slides along the inner surface of the stent 30. The stent 30 is deployed by moving the switch 50 back and forth, each forward moving pushing a portion of

the stent 30 out of the outer sheath 20. Figures 5E and 5F each illustrates a stent 30 being deployed in a vessel, duct, or tube 160. Expansion of the stent 30 and engagement of the stent 30 with the vessel, duct, or tube wall 160 may cause the outer sheath 20 to move proximally, but the user does not perform any function to withdraw or to pull back the outer sheath 20. Once the stent 30 has been deployed, the device 10 is withdrawn from the vessel, duct, or tube 160.

[0103] Figure 6 illustrates an embodiment in which the element 40 (e.g., comprising the inner member 60) is mechanically coupled to a stent-engaging member 45. In the embodiment illustrated in Figure 6, the intermediate tube 42 of the element 40 is connected to the support tube 46, which is connected to the stent-engaging member 45. The stent-engaging member 45 is positioned at least partially within the lumen of a stent 30. As the element 40 moves distally in response to distal movement of the switch 50, the stent-engaging member 45 engages the stent 30, advancing the stent 30 along the outer sheath 20. Proximal motion of the stent-engaging member 45 results in no motion of the stent 30. Repeated reciprocating distal and proximal motion of the element 40 in this manner results in advancement of the stent 30 until it exits the outer sheath 20. Skilled artisans will appreciate that the illustrated embodiment of device 10 is configured such that a user can advance the stent 30 distally out of the outer sheath 20 through multiple engagements of the stent 30 by the stent-engaging member 45, where each engagement: occurs proximal to the distal end of the stent 30, drives the stent 30 distally without a concomitant withdrawal of the outer sheath 20, and is separated from any subsequent engagement by a period of not driving the stent 30 distally; and that the user's proximal-most point of contact with the device 10 that causes each engagement (which occurs at the switch 50) is located at or distal of the proximal end of device body 90. The stent-engaging member 45 may include a flex slot 48 provided with rounded, dumbbell-shaped ends that help alleviate fatigue stress fractures and the like and that allow the stent-engaging member 45 to fold inwardly as it slides proximally within the lumen of the stent 30.

[0104] The performance of stent-engaging member 45 may be achieved by appropriate shape selection, as depicted in Figures 7A and 7B. Alternate embodiments may employ stent-engaging elements 45 that flex, are hinged, or otherwise change shape to

achieve stent advancement. The configuration of the stent-engaging member 45 may be chosen to best suit the type of stent 30 to be deployed. When the stent 30 is a woven, self-expanding stent, such as the kind disclosed in U.S. Patent No. 7,018,401, which is incorporated herein by reference in its entirety, the stent-engaging member 45 may be configured (a) to engage wire intersections on opposing sides of the stent 30 when driving the stent 30 distally, and (b) to deform inwardly (e.g., due at least partially to a flex slot 48) and to slide proximally within the lumen of the stent 30. When the stent 30 is a laser-cut hypotube stent, the stent-engaging member 45 may be configured (a) to engage cut portions of the stent 30 when driving the stent 30 distally, and (b) to deform inwardly and to slide proximally within the lumen of the stent 30.

[0105] Figure 8 provides a schematic depiction of a process for advancing and deploying a stent 30. The distal end 31 of the stent 30 has exited the outer sheath 20 and has expanded (e.g., to the size of the vessel or tube or as constrained by its expanded outer diameter). The element 40 moves proximally and distally, as indicated by the arrows. As the stent-engaging member 45 travels distally, it engages the stent 30 (e.g., cut portions of a laser-cut hypotube stent or the intersection between filaments of a woven stent), and distally advances the stent 30, thus driving the stent 30 out of the outer sheath 20. When the stent-engaging member 45 travels proximally, no advancement of the stent 30 occurs due to the shape of stent-engaging member 45. Instead, the configuration of stent-engaging member 45 enables it to bend or flex inwardly as it moves over and encounters portions (e.g., wire portions) of the stent 30 during the proximal movement of the switch 50 without disturbing the axial position of the stent 30 relative to the outer sheath 20. In some embodiments, advancement of the stent 30 is achieved without a mechanized concomitant withdrawal of the outer sheath 20 and without motion of the outer sheath 20 relative to the device body 90 (aside from incidental motion caused by patient's body movements, vibrations, etc.).

[0106] Figures 9 and 10 illustrate schematically deployment of a stent 30 in a body vessel 160. Figure 9 depicts the stent 30 in a constrained, or elongated, configuration. This is an example of a configuration of the stent 30 when it is within the outer sheath 20 of the device 10 (e.g., as illustrated in Figure 5B). Figure 10 shows the stent 30 in an expanded

state in the body vessel 160, which is one state a self-expanding stent 30 may take when it exits the outer sheath 20.

[0107] In some embodiments, the device 10 includes a stent-retention element 70 configured to allow an operator to re-sheath the stent 30 during the advancement and/or deployment process, provided that the stent 30 has not been advanced completely out of the outer sheath 20. Referring to Figures 11 and 12A, the device 10 includes a stent-retention element 70 coupled to the proximal end 32 of the stent 30. Contact between the distal portion 71 of the stent-retention element 70 and the stent 30 exists as long as the proximal end 32 of the stent 30 is within the outer sheath 20, even during proximal movement of the stent-engaging member 45. When the proximal end 32 of the stent 30 is advanced outside of the outer sheath 20, the stent 30 expands to a radius larger than the greatest width (taken in the radial direction shown in the figures) of the distal portion 71 of the stent-retention element 70. As a result, contact between the stent 30 and the stent-retention element 70 ceases, and deployment of the stent 30 is irreversible. Accordingly, the stent-retention element 70 is operable to withdraw the stent 30 proximally back into the outer sheath 20 (through action by an operator) provided that a proximal portion of the stent 30 (specifically, the proximal portion coupled to the stent-retention element 70) remains disposed within the outer sheath 20.

[0108] The proximal portion 72 of the stent-retention element 70 may comprise a cable or similar device that facilitates withdrawal of the stent 30 proximally back into the outer sheath 20 and that may be characterized as a stent-retention line, provided that a proximal portion of the stent 30 is disposed within the outer sheath 20. The distal portion 71 of the stent-retention element 70 may comprise a piece of tubing (e.g., a hypotube) including a plurality of radially-projecting prongs 73 configured to engage openings in the stent 30 (e.g., windows between filaments, cut portions of a hypotube). The tubing of the stent-retention element 70 may be coupled in any suitable fashion (e.g., soldering) to the proximal portion 72 of the stent-retention element 70.

[0109] As shown in Figures 1A and 2A, a Y-adapter 95 may be coupled to the proximal portion of device body 90. The inner member 60 may be placed through a straight arm 96 and the proximal portion 72 may be placed through an angled arm 97 of the Y-adapter

95. As shown in Figure 2B, a stent-retention element position marker 93 may be coupled to the line 72 and may be positioned along the line 72 to the relative position of a stent 30 that is coupled to the stent-retention element 70. For example, the marker 93 (e.g., comprising a piece of heat shrink tubing), may be positioned along the line 72 such that when the lien 72 extends into the perimeter of the angled arm 97, the stent 30 will completely exit the outer sheath 20. In this way, an operator has a visual indicator that conveys how far the stent 30 has exited the outer sheath 20. Figures 1A and 2A also show that the stent-retention element 70 may include a finger element 98 coupled to the line 72 in any suitable manner (e.g., though Loctite® adhesive), to provide a user with something to hold to enable manipulation of the stent-retention element 70. Figure 12B illustrates an embodiment of a stent-retention element 70 in which the finger element 98 is in cross-section, and depicts an example connection location 99 (e.g., comprising adhesive) between the line 72 and the finger element 98 (which may have inner and outer components that are threaded together).

[0110] In some embodiments, the device 10 comprises a side port 110 (coupled to device body 90) and a Luer fitting 100 (coupled to the proximal end 62 of the inner member 60), for example to allow flushing of the outer sheath 20 and the inner member 60, respectively. The flushing may be with saline and may occur prior to a procedure (e.g., thorough the at least one apertures 157, 158 as described herein). Some embodiments of the devices described herein may include designs for flushing the outer sheath 20 and/or the inner member 60, or may be configured to not allow for flushing of the outer sheath 20 and/or the inner member 60. Figure 3D is a top view of the device 10 and identifies a cutaway detail near the distal end of the device body 90 that is shown in greater detail in Figure 3E.

[0111] Referring to Figure 2C, the second position 122 of the stopper 120 allows the switch 50 to travel distally the full length of the slot 52. The distal-most position of the switch 50 in the slot 52 (e.g., with the stopper 120 in the second position 120) corresponds to a position in which the stent-engaging member 45 is outside or distal to the distal end of the outer sheath 20, and therefore in a region where the stent 30 will be driven out of the outer sheath 20 and in its expanded state. A stent 30 in this position that is de-coupled from the distal portion 71 of the stent-retention element 70 can no longer be withdrawn back into the outer sheath 20. Furthermore, a stent 30 in an expanded condition has radial clearance over

the stent-engaging member 45. Alternate embodiments of the devices disclosed herein may employ other designs to limit the travel of the switch 50, or have no adjustable travel-limiting feature.

[0112] Figures 13 and 14 depict another example embodiment of devices 10 that include a capture device 80 coupled to the proximal portion 72 of the stent-retention element 70. The capture device 80 serves to release appropriate amounts of the proximal portion 72 as the stent-engaging member 45 advances the stent 30. The capture device 80 includes a stop that serves to halt distal advancement of the stent 30 prior to full deployment of the stent 30 from the outer sheath 20. The stop (which can be a piece of tubing, such as hypotube, that is coupled at an appropriate location to the proximal portion 72) provides operator feedback at the point where further advancement would result in deployment of the stent 30 (thus, the stop can be used as an indicator of the location at which withdrawal of the stent 30 will no longer be possible). Here, the operator may choose to withdraw the stent 30 into the outer sheath 20 for repositioning by pulling proximally on the stent-retention element 70, or proceed with deployment of the stent 30 by depressing a deployment stop lever 81 (which allows the stop to bypass the deployment stop lever and permits continued distal advancement of the stent-retention element 70) and continuing with advancement via the switch 50.

[0113] If the operator chooses to withdraw the stent 30 back into the outer sheath 20 for repositioning, the operator can actuate retention pull a lever 84, which, in the depicted embodiment, de-couples the capture device 80 from the device body 90 and allows the operator to proceed with drawing back the stent 30 by proximally pulling the proximal portion 72 of the stent-retention element 70. After withdrawal of the stent 30 back into outer the sheath 20, the retention pulley 82 and the spring 83 of the capture device 80 operate to accumulate excess slack of the stent-retention element 70. In this embodiment, the proximal portion 72 of the stent-retention element 70 may be threaded through a portion of device body 90 that is not centrally disposed within the device body 90. Alternate embodiments of the devices disclosed herein may include capture devices that are configured differently from the capture device 80, such as automated capture devices. Furthermore, the capture device 80

may be coupled to the angled arm 97 in the embodiment of the device 10 shown in Figure 1A, in place of the finger element 98.

[0114] The devices 10 described herein may be disposable and packaged in a bag, pouch, box, or other suitable container, after having been sterilized using any suitable technique, such as sterilization using ethylene oxide gas. There may be a small gap between the distal end of the outer sheath 20 and the proximal end of the nose cone 150 to allow for the sterilizing gas to flow throughout the device 10. The container may include instructions for using the device 10 that are printed on the container or included inside the container. After the device 10 is removed from the container, saline may be used to flush the outer sheath 20 and its contents and the inner member 20 (e.g., through the side port 110). The gap between the nose cone 150 and the outer sheath 20 can then be closed by pulling proximally on the inner member 60 to which the nose cone 150 is coupled. If the procedure involves stenting a blood vessel, any suitable technique for positioning the device 10 in the appropriate location may be used (e.g., the Seldinger technique). The nose cone 150 of the device 10, which may be any suitable flexible atraumatic tip, may be radiopaque and may represent a distal-most marker for the device 10. Another radiopaque marker made from any suitable material (e.g., a platinum or platinum-alloy band) may be coupled to a portion of the device 10 that is proximal to the nose cone 150, such as to the outer sheath 20 (as discussed above), the element 40, or the inner member 60, to create a proximal-most marker for the device 10. These two markers may be used by the operator to position the device 10 relative to the site of interest to enable accurate deployment of the stent 30.

[0115] A stent (e.g., the stent 30) may be distally driven out of a sheath (e.g., the outer sheath 20) and into a tubular structure 160 using the device 10. In some embodiments, the tubular structure 160 is animal tissue (such as a human blood vessel). In other embodiments, the tubular structure 160 is not animal tissue and comprises a polymer structure that can be used to test a given device technique or to demonstrate a stent advancement to one or more persons, such as a doctor considering using the device 10 or a stent advancement technique in his or her practice.

[0116] Some methods include distally driving a stent (e.g., the stent 30) out of a sheath (e.g., outer sheath 20) and into a tubular structure 160 by repeatedly engaging the stent

with a stent-engaging element (e.g., the stent-engaging member 45), where at least two of the engagements are separated by a period of non-engagement; and as the stent is distally driven out of the sheath, allowing varying of the axial density of the stent within the tubular structure 160 by varying the axial position of the sheath relative to the tubular structure 160. As the stent is driven distally out of the sheath, the remainder of the device 10 is withdrawn proximally by the operator relative to the tubular structure 160 so that the deployed portion of the stent remains stationary relative to the tubular structure 160 (e.g., human tissue) into which the stent is deployed. The rate at which the remainder of the device 10 is withdrawn may be varied to vary the axial density of the stent: a slower withdrawal rate increases the axial density of the stent, whereas a faster rate decreases the axial density of the stent. Increasing the axial density of the stent may, for example, provide greater hoop strength at a location where a greater hoop strength may be needed to maintain patency of the tubular structure 160, such as along a stenosed region 210 of an artery 200, for example as shown in Figure 15A. Decreasing the axial density of the stent in may, for example, be at a location where fluid flow into or out of a section of the stent from the side is anticipated or desired, or may be at the location of penetration of a second stent, either of which may be true at an anatomical side branch 260 of a vessel 250, for example as shown in Figure 15B.

[0117] Some embodiments of stent advancement methods include distally driving a stent (e.g., the stent 30) out of a sheath (e.g., the outer sheath 20) and into a tubular structure 160 by repeatedly engaging the stent between its distal and proximal ends with a stent-engaging element (e.g., the stent-engaging member 45), where at least two of the engagements are separated by a period of non-engagement; and optionally engaging the stent at its proximal end with a stent-retention element (e.g., the stent-retention element 70) that is positioned within the sheath.

[0118] In some embodiments, engagements that drive the stent distally from the sheath may be achieved using a device that is configured to not mechanically concomitantly withdraw the sheath as the stent is driven distally, such as the versions of the devices 10 described herein. The tubular structure 160 in those embodiments can be an anatomical tubular structure, such as a vessel or duct, or a tubular structure that is not animal tissue, such as a polymer tube 300, for example as illustrated in Figure 15C. Regardless of the type of

tubular structure 160, in some embodiments, the method may also include engaging the stent at its proximal end with a stent-retention element (e.g., the stent-retention element 70) that is positioned within the sheath. The stent-retention element may include a stent-retention line (e.g., the line 72), and the method may also include, after the stent is partially-driven out of the sheath, withdrawing the stent back into the sheath by moving the stent-retention line. An operator may accomplish driving of the stent by moving a user-actuatable element (e.g., the switch 50) with the operator's thumb. If the stent is woven, a stent-engaging element may engage on or more wire intersections of the stent and move distally during the engagements that drive the stent, and the stent-engaging element may slide proximally within the lumen of the stent during the period of non-engagement.

[0119] Some of the methods described herein are methods of instructing another or others on how to advance a stent out of sheath and into a tubular structure. In some embodiments, the method includes instructing a person on how to use a stent delivery device (e.g., the device 10) that includes a sheath (e.g., the outer sheath 20) and a stent (e.g., the stent 30) disposed in the sheath. The instructing may include demonstrating the following steps to the person: distally driving the stent out of the sheath and into a tubular structure by repeatedly engaging the stent with a stent-engaging element (e.g., the stent-engaging member 45), where at least two of the engagements are separated by a period of non-engagement; and, as the stent is distally driven out of the sheath, optionally varying the axial density of the stent within the tubular structure by varying the axial position of the sheath relative to the tubular structure.

[0120] In some embodiments, the method includes instructing a person on how to use a stent delivery device (e.g., the device 10) that includes a sheath (e.g., the outer sheath 20) and a stent (e.g., the stent 30) disposed in the sheath. The instructing may include demonstrating the following steps to the person: distally driving the stent out of the sheath and into a tubular structure by repeatedly engaging the stent with a stent-engaging element (e.g., the stent-engaging member 45), where at least two of the engagements are separated by a period of non-engagement; and, optionally, engaging the stent at its proximal end with a stent-retention element (e.g., the stent-retention element 70) that is positioned within the sheath.

[0121] In some embodiments, the instruction methods may be accomplished by a live demonstration in the presence of the person or by a recorded or simulated demonstration that is played for the person. An example of a recorded demonstration is one that was carried out by a person and captured on camera. An example of a simulated demonstration is one that did not actually occur, and that instead was generated using a computer system and a graphics program. In the case of a recorded or simulated demonstration, the demonstration may exist in any suitable form – such as on DVD or in any suitable video file (such as .3gp, .avi, .dvx, .flv, .mkv, .mov, .mpg, .qt, .rm, .swf, .vob, .wmv, etc.) – and the instructing may be accomplished by playing the demonstration for the viewer using any suitable computer system. The viewer or viewers may cause the demonstration to play. For example, the viewer may access the recorded or simulated demonstration file using the internet, or any suitable computer system that provides the viewer with access to the file, for example as illustrated in Figure 16.

[0122] In some embodiments, the method involves delivery of a stent into an anatomical structure, and in which the device used to accomplish the method is in a desired location within a patient to start the stent advancement, the movement (e.g., the ratcheting movement) of the stent-engagement element can begin such that the distal end of the stent (which can also be provided with one or more radio opaque markers to enable easier viewing of its position during the procedure) exits the sheath of the device, but not to such an extent that it expands to contact the anatomical structure. If the distal end of the stent is proximal of where the operator wants it, and a stent-retention element is used, the stent-retention element can be pulled proximally to resheath the stent and reposition the device; if the stent is distal of where the operator wants it, the entire device can be withdrawn proximally and the deployment process continued.

[0123] The features of the devices described herein can be made from commercially-available, medical-grade materials. For example, the nose cone 150 may comprise a polyether block amide (such as Pebax® resin, available from Arkema Inc, Philadelphia, Pa.). A distal portion of inner member 60 (such as inner sleeve 61) may comprise polyimide and coupled to a more proximal portion comprising stainless steel hypotube (such as 304 or 316L stainless steel). The Luer fitting 100 coupled to the inner

member 60 (e.g., outer sleeve 63) may comprise polycarbonate. The outer sheath 20 may comprise a braided polyether block amide (e.g., comprising a braided Pebax® resin). The device body 90, switch 50, block 51, and stopper 120 may comprise acrylonitrile butadiene styrene (ABS) plastic, polycarbonate, Delrin® acetal resin (available from DuPont), and the like. The stopper 120 may be coupled to a stainless steel spring that biases it as described above. The element 40 may comprise a shaft comprising polyimide (or, a series of shafts comprise from polyimide or a hypotube comprising nickel-titanium alloy), and the stent-engaging member 45 may include or be coupled to a stem 46 (e.g., comprising a hypotube comprising nickel-titanium alloy) coupled to the polyimide shaft with a suitable adhesive (e.g., Loctite® adhesive, which includes cyanoacrylates) and a piece of hypotube (e.g., comprising nickel-titanium alloy) fashioned in the desired shape and welded (e.g., laser welded) to the stem 46. The stent-retention element 70 may include an intertwined stainless steel wire (used as proximal portion 72) that is covered with a material such as nylon, fluorinated ethylene propylene (FEP) tubing, or polyester (PET) tubing, and the distal portion 71 may comprise a hypotube (e.g., comprising stainless steel). Furthermore, steps may be taken to reduce the friction between the parts that contact or may contact either other during use of the present devices, such as contact between the stent and the outer sheath.

[0124] The devices described herein may be used to deliver self-expending stents that are woven, including stents woven from multiple strands, such as wires. Some examples of weaving techniques that may be used include those in U.S. Patent Nos. 6,792,979 and 7,048,014, which are each incorporated herein by reference in its entirety. The strands of a woven stent may terminate in strand ends (e.g., wire ends) that are then joined together using small segments of material, such as nitinol hypotube, when the stent strands are wires made from nitinol. The stent may be passivated through any suitable technique in order to remove the oxide layer from the stent surface that can be formed during any heat treating and annealing, thus improving the surface finish and corrosion resistance of the stent material. Suitable stent creation techniques for stents that may be used with the present devices (including the strand crossings that may be engaged by stent-engaging member 45) are set forth in U.S. Patent Application No. 11/876,666, published as U.S. Patent Pub. No. 2008/0290076, which is incorporated herein by reference in its entirety.

[0125] It will be appreciated that the devices and methods described herein are not intended to be limited to the particular forms disclosed. Rather, they cover all modifications, equivalents, and alternatives falling within the scope of the example embodiments. For example, while the embodiments of the devices shown in the figures included a stent-engaging element 45 and a switch 50 that move the same distances in response to operator input, other embodiments could include gears or other mechanisms that create a ratio between the distance that the switch 50 moves and the resulting distance that the stent-engaging element 45 moves that is not 1:1 (such that the reciprocating element distance can be greater or less than the distance of the switch 50). For another example, devices may lack features such as a flush port 110 and/or a stent-retention element 70. Furthermore, still other embodiments may employ other structures for achieving periodic engagement of a stent 30 in order to advance it distally, such as a through a squeeze-trigger mechanism similar to the one shown in U.S. Patent No. 5,968,052 or in U.S. Patent No. 6,514,261, each of which is incorporated herein by reference in its entirety, or through a stent-engaging element that rotates rather than translates and that possesses a cam portion configured to engage the stent during part of a given rotation and not engage the stent during another part of that rotation. Moreover, still other embodiments may employ other forms of reciprocating movement of a stent-engaging element (such as the stent-engaging member 45), such as through another form of operator input like a rotational user-actuatable input (rather than a longitudinal translation input) coupled to the stent-engaging element via a cam.

[0126] Although this invention has been disclosed in the context of certain embodiments and examples, it will be understood by those skilled in the art that the invention extends beyond the specifically disclosed embodiments to other alternative embodiments and/or uses of the invention and obvious modifications and equivalents thereof. In addition, while several variations of the embodiments of the invention have been shown and described in detail, other modifications, which are within the scope of this invention, will be readily apparent to those of skill in the art based upon this disclosure. It is also contemplated that various combinations or sub-combinations of the specific features and aspects of the embodiments may be made and still fall within the scope of the invention. It should be understood that various features and aspects of the disclosed embodiments can be combined

with, or substituted for, one another in order to form varying modes of the embodiments of the disclosed invention. Thus, it is intended that the scope of the invention herein disclosed should not be limited by the particular embodiments described above.

WHAT IS CLAIMED IS:

1. A pusher assembly for a stent delivery device, the pusher assembly comprising:

a distal end of an elongate inner member; and

a stent-engaging member having a proximal end and a distal end, the proximal end of the stent-engaging member being at least partially inside the distal end of the elongate inner member, the stent-engaging member comprising a portion that radially outwardly extends towards the distal end of the stent-engaging member, the stent-engaging member configured to move a stent when distally advanced and configured to not move a stent when proximally retracted, wherein the stent-engaging member comprises an aperture, wherein the elongate inner member comprises an inner layer, and wherein the inner layer of the elongate inner member at least partially fills the aperture.

2. The pusher assembly of Claim 1, wherein the stent-engaging member has a first internal diameter, wherein the elongate inner member has a second internal diameter proximal to the proximal end of the stent-engaging member, and wherein the first internal diameter is substantially equal to the second internal diameter.

3. The pusher assembly of Claim 1 or 2, wherein the portion has a shovel shape having a curved distal end, or wherein the portion has a shovel shape having a flat distal end, or wherein the portion has a shovel shape having a flared distal end.

4. The pusher assembly of any of Claims 1-3, wherein the stent-engaging member comprises a stem and a ratchet mechanically coupled to the stem, the ratchet comprising the portion.

5. The pusher assembly of Claim 4, wherein the stem comprises the aperture.

6. The pusher assembly of Claim 4 or 5, wherein the proximal end of the stent-engaging member comprises the stem.

7. The pusher assembly of any of Claims 4-6, wherein the ratchet is mechanically coupled to the stem by a plurality of spot welds.

8. The pusher assembly of any of Claims 1-7, wherein the aperture comprises a plurality of holes.

9. The pusher assembly of any of Claims 1-8, wherein the distal end of the stent-engaging member comprises a cutout and wherein the pusher assembly further

comprises a tube positioned around the distal end of the stent-engaging member and at least partially filling the cutout.

10. The pusher assembly of Claim 9, wherein the cutout comprises a plurality of helical slots.

11. The pusher assembly of any of Claims 1-10, wherein the stent is plain woven, and wherein the portion is configured to engage an intersection between filaments of the woven stent.

12. The pusher assembly of any of Claims 1-11, wherein the stent-engaging member comprises a nickel-titanium alloy.

13. A stent delivery device comprising:

an elongate outer member at least partially defining an outer member lumen;

an elongate inner member coaxially positioned within the outer member lumen;

the pusher assembly of any of Claims 1-12; and

an atraumatic tip mechanically coupled to the stent-engaging member.

14. The stent delivery device of Claim 13, wherein the elongate inner member at least partially defines a guidewire lumen, wherein the stent-engaging member at least partially defines the guidewire lumen, and wherein the atraumatic tip at least partially defines the guidewire lumen.

15. The stent delivery device of Claims 13 or 14, wherein the atraumatic tip comprises:

a generally conical distal end; and

a generally cylindrical proximal end comprising at least one aperture in fluid communication with the outer member lumen.

16. A method of manufacturing a pusher assembly, the method comprising mechanically coupling a proximal end of a stent-engaging member at least partially inside a distal end of an elongate inner member, the stent-engaging member comprising a portion that radially expands towards a distal end of the stent-engaging member, the stent-engaging member configured to move a stent when distally advanced and configured to not move a stent when proximally retracted, the stent-engaging member comprising an aperture and the elongate member comprising an inner layer, wherein mechanically coupling comprises at least partially filling the aperture with the inner layer.

17. The method of Claim 16, wherein mechanically coupling comprises heat shrinking a flared distal end of the elongate inner member around the proximal end of the stent-engaging member.

18. The method of Claims 16 or 17, wherein the stent-engaging member comprises a ratchet and a stem and wherein the method further comprises spot welding the ratchet to the stem.

19. The method of any of Claims 16-18, wherein forming the stent-engaging member comprises cutting, deforming, and heat setting a hypotube.