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STEERING WIRE ATTACH FOR ANGULATION

Abstract

Various aspects of the present disclosure are directed toward apparatuses, systems, and methods for example device delivery. The apparatuses, systems, and methods may include an actuation wire coupled to the expandable device at one or more locations thereon, the actuation wire being configured to steer the expandable device during delivery.

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Background/Summary

CROSS-REFERENCE TO RELATED APPLICATION [0001] This application is a continuation of U.S. application Ser. No. 16/562,669, filed Sep. 6, 2019, which is a continuation of International Application PCT/US2018/021442, filed Mar. 8, 2018, which claims the benefit of U.S. Provisional Application No. 62/468,618, filed Mar. 8, 2017, all of which are herein incorporated by reference in their entireties.

TECHNICAL FIELD
[0002] The present invention relates to medical devices and methods for treating an anatomical space (e.g., vessels) of the body. More specifically, the invention relates to methods, apparatuses, and systems that include a prosthesis that allows for accurate deployment to treat dissections and aneurysms in the anatomical space.
BACKGROUND
[0003] Disease of the vasculature is increasingly common. Treatment of the vasculature may be difficult because of the tortuous nature and complexity of the vasculature. Aortic dissections, for example, commonly begin at or near the aortic valve root and continue to the ascending aorta and the aortic arch, and may also affect the upper part of the descending aorta. Medical devices implanted at a diseased state may be used for treatment of aortic dissections, aneurysms, and other diseases of the vasculature.
[0004] It remains desirable to provide medical devices, systems and methods for repairing disease along the aorta and also for repairing disease along the aorta and the branches extending therefrom.
SUMMARY
[0005] Various aspects of the present disclosure are directed toward delivery systems. A delivery system, as discussed in further detail below, may include a catheter having a leading end and a trailing end. The delivery system may also include an expandable device arranged near the leading end of the catheter and including a proximal end, a distal end, and a flow lumen extending therebetween. In addition, the delivery system may include an actuation wire coupled to the expandable device at one or more locations thereon with the actuation wire being configured to steer the expandable device during delivery thereof. Further, the delivery system may include at least one tether arranged through a portion of the expandable device arranged through the actuation wire and configured to couple the actuation wire to the expandable device.
[0006] Aspects of the disclosure are also directed toward a delivery system that includes a catheter having a leading end and a trailing end and an expandable device arranged near the leading end of the catheter. The expandable device may include a proximal end, a distal end, and a flow lumen extending therebetween. The delivery system may also include an actuation wire coupled to the expandable device at two or more locations thereon, the actuation wire being configured to steer the expandable device during delivery thereof.
[0007] Various aspects of the present disclosure are directed toward methods of deploying an expandable medical device at a tortious target location within a patient. The method may include delivering the expandable medical device to the tortious target location and manipulating an actuation wire, coupled to the expandable medical device, to arrange an end of the expandable medical device approximately perpendicular to an inflection point in the curvature of the tortious target location.
[0008] According to one example (“Example 1”), a delivery system includes: a catheter having a leading end and a trailing end; an expandable device arranged near the leading end of the catheter and including a proximal end, a distal end, and a flow lumen extending therebetween; an actuation

wire coupled to the expandable device at one or more locations thereon, the actuation wire being configured to steer the expandable device during delivery thereof; and at least one tether arranged through a portion of the expandable device arranged through the actuation wire and configured to couple the actuation wire to the expandable device.

[0009] According to another example ("Example 2"), further to Example 1, the expandable device is configured to deploy at a tortious vessel having a curvature with at least one inflection point, and the actuation wire is configured to maintain the proximal end of the expandable device approximately perpendicular to the inflection point in the curvature of the tortious vessel during delivery of the expandable device.

[0010] According to another example ("Example 3"), further to any one of Examples 1-2, the actuation wire is coupled to the expandable device adjacent the proximal end via the at least one tether being arranged through the actuation wire and the portion of the expandable device.

[0011] According to another example ("Example 4"), further to any one of Examples 1-3, the actuation wire is configured to bidirectionally steer the expandable device proximally and distally during delivery thereof.

[0012] According to another example ("Example 5"), further to any one of Examples 1-4, the at least one tether includes two tethers, and the actuation wire coupled to the expandable device at two or more locations via the two tethers.

[0013] According to another example ("Example 6"), further to Example 5, the actuation wire includes a bifurcation including a first branch and a second branch, and the first branch and the second branch are coupled to the expandable device at the two or more locations via a first of the two tethers being arranged through the first branch, and a second of the two tethers being arranged through the second branch.

[0014] According to another example ("Example 7"), further to any one of Examples 1-6, the at least one tether is arranged through the actuation wire and arranged through the expandable device at the two locations to couple the actuation wire to the expandable device.

[0015] According to another example ("Example 8"), further to Example 7, the at least one tether extends from and through the actuation wire and through the expandable device at the two locations adjacent the proximal end of the expandable device.

[0016] According to another example ("Example 9"), further to Example 7, the at least one tether includes two tethers, and the two tethers extend from and through the actuation wire and through the expandable device at the two locations adjacent the proximal end of the expandable device.

[0017] According to another example ("Example 10"), further to any one of Examples 1-9, the at least one tether comprises a bio-absorbable material.

[0018] According to another example ("Example 11"), further to any one of Examples 1-10, the at least one tether is configured to uncouple and release from the expandable device in response to tension applied to the actuation wire after delivery of the expandable device.

[0019] According to another example ("Example 12"), further to any one of

[0020] Examples 1-10, the actuation wire bifurcates to form a first branch and a second branch to form a y-shaped structure, and the first branch and the second branch are coupled to the expandable device at two locations.

[0021] According to another example ("Example 13"), further to Example 12, further including two tethers arranged configured to couple the actuation wire to the two or more locations on the expandable device.

[0022] According to another example ("Example 14"), further to Example 13, a first of the two tethers is arranged through a proximal end of the first branch and through the expandable device, and a second of the two tethers is arranged through a proximal end of the second branch and through the expandable device to couple the actuation wire to the two or more locations on the expandable device.

[0023] According to another example ("Example 15"), further to any one of Examples 1-14, the

actuation wire includes an eyelet, and the at least one tether arranged through the eyelet of the actuation wire to couple the actuation wire to the expandable device.
[0024] According to another example (“Example 16”), a delivery system includes: a catheter having a leading end and a trailing end; an expandable device arranged near the leading end of the catheter and including a proximal end, a distal end, and a flow lumen extending therebetween; and an actuation wire coupled to the expandable device at two or more locations thereon, the actuation wire being configured to steer the expandable device during delivery thereof.
[0025] According to another example (“Example 17”), further to Example 16, wherein the actuation wire bifurcates to form a first branch and a second branch to form a y-shaped structure, and the first branch and the second branch are coupled to the expandable device at two locations.
[0026] According to another example (“Example 18”), further to Example 17, further including two tethers arranged configured to couple the actuation wire to the two or more locations on the expandable device.
[0027] According to another example (“Example 19”), further to Example 18, a first of the two tethers being arranged through a proximal end of the first branch and through the expandable device, and a second of the two tethers being arranged through a proximal end of the second branch and through the expandable device to couple the actuation wire to the two or more locations on the expandable device.
[0028] According to another example (“Example 20”), further to Example 17, further including at least one tether arranged through the actuation wire and arranged through the expandable device at two locations to couple the actuation wire to the expandable device.
[0029] According to another example (“Example 21”), further to Example 20, the at least one tether and the actuation wire form a y-shaped structure.
[0030] According to another example (“Example 22”), a method of deploying an expandable medical device at a tortuous target location within a patient where the method includes: delivering the expandable medical device to the tortious target location; and manipulating an actuation wire, coupled to the expandable medical device, to arrange an end of the expandable medical device approximately perpendicular to an inflection point in the curvature of the tortious target location.
[0031] According to another example (“Example 23”), further to Example 22, where the step of manipulating the actuation wire includes bidirectionally steering the expandable medical device relative to the inflection point in the curvature of the tortious target location.
[0032] According to another example (“Example 24”), further to Example 22, where the step of manipulating the actuation wire includes actuating the expandable medical device by applying force to two or more locations on the expandable medical device.
[0033] According to another example (“Example 25”), further to Example 22, further including releasing the actuation wire from the expandable medical device by releasing a tether configured to couple the actuation wire to the expandable medical device.

Description

BRIEF DESCRIPTION OF THE DRAWINGS
[0034] FIG. **1** shows an expandable device and an actuation wire in accordance with various aspects of the present disclosure.
[0035] FIG. **2** shows another expandable device and an actuation wire in accordance with various aspects of the present disclosure.
[0036] FIG. **3** shows yet another expandable device and an actuation wire in accordance with various aspects of the present disclosure.
[0037] FIGS. **4**A-E shows side view illustrations of expandable device angulation relative to a target location in accordance with various aspects of the present disclosure.

[0038] FIG. **5**A shows a front view of an expandable device and an actuation wire in accordance with various aspects of the present disclosure.
[0039] FIG. **5**B shows a side view of the expandable device and the actuation wire, shown in FIG. **5**A, in accordance with various aspects of the present disclosure.
[0040] FIG. **6**A shows a front view of another expandable device and an actuation wire in accordance with various aspects of the present disclosure.
[0041] FIG. **6**B shows a side view of the expandable device and the actuation wire, shown in FIG. **6**A, in accordance with various aspects of the present disclosure.
[0042] FIG. **7**A shows a front view of yet another expandable device and an actuation wire in accordance with various aspects of the present disclosure.
[0043] FIG. **7**B shows a side view of the expandable device and the actuation wire, shown in FIG. **7**A, in accordance with various aspects of the present disclosure.
[0044] FIG. **8** shows an actuation wire and tether attachment to an expandable device in accordance with various aspects of the present disclosure.
[0045] FIG. **9**A-D show a tether attachment arrangement in accordance with various aspects of the present disclosure.
[0046] FIG. **10**A-C show another tether attachment arrangement in accordance with various aspects of the present disclosure.

DETAILED DESCRIPTION

[0047] Persons skilled in the art will readily appreciate that various aspects of the present disclosure can be realized by any number of methods and apparatus configured to perform the intended functions. It should also be noted that the accompanying figures referred to herein are not necessarily drawn to scale, but may be exaggerated to illustrate various aspects of the present disclosure, and in that regard, the figures should not be construed as limiting.
[0048] Various aspects of the present disclosure are directed toward apparatuses, systems, and methods that include an expandable device that may be used in treatment of the vasculature. The expandable device is delivered to the vasculature using a delivery system. The delivery system may be configured to position and/or steer the expandable device for accurate placement in the vasculature. The expandable device may include a flow lumen between ends of the expandable device. The delivery system may be configured to arrange the expandable device such that one or both of the ends of the expandable device is perpendicular to a portion of the vasculature.
[0049] In addition, the expandable devices described herein may be substantially cylindrical or include a bifurcation. Further, the expandable devices may be configured to conform to the vasculature into which the expandable device is implanted, low-profile in order to enable delivery thereof using a minimally invasive procedure (e.g., transcatheter), and withstand forces and other stresses that occur once implanted in the vasculature.
[0050] FIG. **1** shows an expandable device **100** and an actuation wire **102** in accordance with various aspects of the present disclosure. The expandable device **100** is releasably coupled to a delivery system for delivery of the expandable device **100** to a target location within a patient's vasculature. The delivery system may include a catheter **104** that includes a leading end **106** and a trailing end (not shown in FIG. **1**). The expandable device **100** may be arranged near the leading end **106** of the catheter **104**. The catheter **104** may extend through a lumen of the expandable device **100** toward and past a proximal end **108** of the expandable device **100**. The catheter **104** may also include a tip (not shown) at the leading end **106**.
[0051] The expandable device **100** may include a proximal end **108**, a distal end **110**, and a flow lumen extending therebetween. The proximal end **108** of the expandable device **100** may be considered the end of the expandable device **100** that is closest to the target location within the patient's vasculature. The actuation wire **102** is coupled to the expandable device **100** at one or more locations thereon. As shown in FIG. **1**, the actuation wire **102** is attached adjacent to or near the proximal end **108** of the expandable device **100** and accessible to a user of the delivery system.

[0052] As shown, the actuation wire **102** is coupled to the expandable device **100** via at least one tether **112**. The tether **112** may be arranged through a portion of the expandable device **100** and through the actuation wire **102** to couple the actuation wire **102** to the expandable device **100**. In certain instances and as shown in FIG. **1**, the at least one tether **112** is arranged through the expandable device **100** near or adjacent to the proximal end **108** of the expandable device **100**. The at least one tether **112** may be a single tether, as shown in FIG. **1**.
[0053] In certain instances, the actuation wire **102** is configured to steer the expandable device **100** during delivery thereof. The actuation wire **102** may include a stiffness such that a user operating the delivery system may apply force to the actuation wire **102** and bidirectionally steer (e.g., proximally and distally relative to the target location within the patient's vasculature) the expandable device **100**. For example, the actuation wire **102** may have a stiffness that is greater than a stiffness of the tether **112**. The stiffness of the actuation wire **102** and/or the location to which the actuation wire **102** is coupled to the expandable device **100** may facilitate deploying and arranging the expandable device **100** relative to the target location within the patient's vasculature. For example, the expandable device **100** may be configured to deploy at a tortious vessel having a curvature with at least one inflection point. In certain instances, the actuation wire **102** is configured to maintain the proximal end **108** of the expandable device **100** approximately perpendicular to the inflection point in the curvature of the tortious vessel during delivery of the expandable device **100**.
[0054] The actuation wire **102** may be uncoupled or released from the actuation wire **102** subsequent to the expandable device **100** being positioned and deployed at the target location within the patient's vasculature and removed from the patient. In certain instances, the tether **112** is configured to remain coupled or threaded through the expandable device **100** after the actuation wire **102** is released or uncoupled from the expandable device **100** (e.g., as shown in further detail in FIG. **8**). In addition, the tether **112** may be formed from a bio-absorbable material that dissolves to release or uncouple the actuation wire **102** from the expandable device **100**. In other instances, the tether **112** is configured to be removed or unthreaded from the expandable device **100** after the actuation wire **102** is released or uncoupled from the expandable device **100** (e.g., as shown in further detail in FIGS. **9**A-D and FIGS. **10**A-C).
[0055] FIG. **2** shows another expandable device **200** and an actuation wire **202** in accordance with various aspects of the present disclosure. The expandable device **200** may be releasably coupled to a delivery system. The delivery system may include a catheter **204** that includes a leading end **206** and a trailing end (not shown in FIG. **2**). The expandable device **200** may be arranged near the leading end **206** of the catheter **204**. The delivery system may be configured to deliver the expandable device **200** to a target location within a patient's vasculature. In certain instances, the expandable device **200** may be configured to deploy at a tortious vessel having a curvature with at least one inflection point. To facilitate deploying of the expandable device **200**, the delivery system may include the actuation wire **202** configured to maintain a proximal end **208** (or distal end **210**) of the expandable device **200** approximately perpendicular to the inflection point in the curvature of the tortious vessel during delivery of the expandable device **200**.
[0056] The actuation wire **202** (and accessible to a user of the delivery system), for example, is configured to steer the expandable device **200** during delivery thereof, and is releasably coupled to the expandable device **200** via at least one tether **212**. The tether **212** may be arranged through a portion of the expandable device **200** and through the actuation wire **202** to couple the actuation wire **202** to the expandable device **200**. In certain instances and as shown in FIG. **2**, the at least one tether **212** is arranged through the expandable device **200** near or adjacent to the proximal end **208** of the expandable device **200**. In certain instances, the tether **212** is configured to remain coupled or threaded through the expandable device **200** after the actuation wire **102** is released or uncoupled from the expandable device **200** (e.g., as shown in further detail in FIG. **8**) or the tether **212** may be configured to be removed or unthreaded from the expandable device **200** after the

actuation wire **202** is released or uncoupled from the expandable device **200** (e.g., as shown in further detail in FIGS. **9**A-D and FIGS. **10**A-C).

[0057] In addition, the actuation wire **202** may be arranged through a sleeve **214** that is attached to an exterior portion of the expandable device **200**. The expandable device **200** may include a graft component and one or more stent components (e.g., as shown in further detail with reference to FIG. **5**). The sleeve **214** may be formed of a similar material or the same material as the graft component of the expandable device **200**. The sleeve **214** may include a lumen through which the actuation wire **202** is arranged. In certain instances, the sleeve **214** is an enclosed structure which forms the lumen, or the sleeve **214** is a layer of graft material that forms a lumen between the sleeve **214** and the expandable device **200**. The sleeve **214** may facilitate the actuation wire **202** steering the expandable device **200**. The sleeve **214** may prevent traumatic interaction between the actuation wire **202** and a vessel wall. In addition, the sleeve **214** may enhance the connection between the actuation wire **202** and the expandable device **200** when a user applies force or tension to the actuation wire **202**. As shown, the sleeve **214** has a length similar to a length of the expandable device **200**. In other instances, the sleeve **214** may have a shorter length than the expandable device **200** or a longer length than the expandable device.

[0058] The actuation wire **202** may include a stiffness such that a user operating the delivery system may apply force to the actuation wire **202** and bidirectionally steer (e.g., proximally and distally relative to the target location within the patient's vasculature) the expandable device **200**. For example, the actuation wire **202** may have a stiffness that is greater than a stiffness of the tether **212**. The stiffness of the actuation wire **202** and/or the location to which the actuation wire **202** is coupled to the expandable device **200** may facilitate deploying and arranging the expandable device **200** relative to the target location within the patient's vasculature.

[0059] FIG. **3** shows yet another expandable device **300** and an actuation wire **302***a-c* in accordance with various aspects of the present disclosure. The actuation wire **302***a-c* is shown arranged along the expandable device **300** in three different patterns. The patterns of the actuation wire **302***a-c* shown in FIG. **3** may facilitate the ability of the actuation wire **302***a-c* to steer the expandable device by distributing forces that result from a user applying force or tension to the actuation wire **302***a-c* to steer the expandable device **300** (e.g., as described above in detail with reference to FIGS. **1-2**).

[0060] The actuation wire **302***a-c* may be attached to the expandable device **300** via a tether **304***a-c*. The tether **304***a-c* may be arranged through the actuation wire **302***a-c* at any portion along a length thereof that is in contact with the expandable device **300**.

[0061] The illustrative expandable device **300** and actuation wire **302***a-c* shown in FIG. **3** is not intended to suggest any limitation as to the scope of use or functionality of embodiments of the discussed throughout this disclosure. Neither should the illustrative expandable device **300** and actuation wire **302** be interpreted as having any dependency or requirement related to any single component or combination of components illustrated therein. For example, in various embodiments, the illustrative actuation wire **302***a-c* may include a stiffness and bidirectional steering as described above with reference to FIGS. **1-2**. Additionally, any one or more of the components depicted in FIG. **3** can be integrated with various ones of the other components depicted therein (and/or components not illustrated). For example, the patterns of the actuation wire **302***a-c* may be used in connection with the actuation wires **102**, **202** shown in FIGS. **1-2**.

[0062] FIGS. **4**A-E shows side view illustrations of expandable device angulation relative to a target location **400***a-e* in accordance with various aspects of the present disclosure. Each of FIGS. **4**A-E show a side profile of a leading (or proximal) end **400***a-e* of an expandable device, consistent with various aspects of the present disclosure. In certain instances, the target location **400***a-e* may be at a tortious vessel of a patient. The target location **400***a-e* into which the expandable device is implanted may have angulation (e.g., a curvature with at least one inflection point **404***a-e*). The target location **400***a-e* may be an angulated abdominal aortic aneurism (AAA).

[0063] In certain instances, one of the ends **402***a-e* of the expandable device may be deployed perpendicular to the inflection point in the curvature of the tortious vessel during delivery of the expandable device. Non-perpendicularity may negatively affect the ability of the expandable device to seal against the target location **400***a-e*. FIG. **4**A shows the leading (or proximal) end **402***a* deployed perpendicular to the inflection point **404***a*. In certain instances, perpendicularity of the expandable device may be a function of device flatness, angulation, and rotational alignment. FIG. **4**B shows the leading (or proximal) end **402***b* of an expandable device angled relative to the inflection point **404***b* of the target location **400***b*. FIG. **4**C shows the leading (or proximal) end **402***c* of an expandable device rotated relative to the inflection point **404***c* of the target location **400***c*. FIG. **4**D shows the leading (or proximal) end **402***d* of an expandable device deformed relative to the inflection point **404***b* of the target location **400***d*. FIG. **4**E shows the leading (or proximal) end **402***e* of an expandable device deformed or flat, rotated, and angled relative to the inflection point **404***e* of the target location **400***e*.

[0064] Device deployment and performance can be enhanced by steering the device to an appropriate location while maintaining one of the ends of the expandable device perpendicular to the target location **400***a-e* (e.g., curvature of a vessel with at least one inflection point **404***a-e*) during and after deployment. The actuation wires and arrangements thereof discussed herein facilitate maintaining the expandable device perpendicular during and after deployment (as shown in FIG. **4**A) and mitigate against non-perpendicular, angled, or flat deployment (as shown in FIGS. **4**B-E).

[0065] FIGS. **5**A-B show a side view and a front view of an expandable device **500** and an actuation wire **502** in accordance with various aspects of the present disclosure. The expandable device **500** may include a graft component **504** and one or more stent components **506**. The delivery system may include a catheter **508** that includes a leading end **510** and a trailing end (not shown in FIGS. **5**A-B). The expandable device **500** may be arranged near the leading end **510** of the catheter **508**. In addition, the expandable device **500** may include a proximal end **512**, a distal end **514**, and a flow lumen extending therebetween. The proximal end **512** of the expandable device **500** is considered the end of the expandable device **500** closest to the target location within the patient's vasculature. The actuation wire **502** is configured to releasably couple the expandable device **500** to the delivery system for delivery of the expandable device **500** to a target location within a patient's vasculature and accessible to a user of the delivery system.

[0066] In certain instances, the actuation wire **502** is coupled to the expandable device **500** at one or more locations thereon. As shown in FIG. **5**B, the actuation wire **502** bifurcates to form a first branch **516** and a second branch **518**. The first branch **516** and the second branch **518** are coupled to the expandable device **500** at the two or more locations thereon. The first branch **516** and the second branch **518** are coupled to the expandable device **500** near the proximal end **512**. In addition, the actuation wire **502** is configured to steer the expandable device **500** during delivery thereof. The first branch **516** and the second branch **518** may facilitate the ability of the actuation wire **502** to steer the expandable device **500** by distributing forces that result from a user manipulating or applying force to the actuation wire **502** to steer the expandable device **500**.

[0067] In certain instances, one of the proximal end **512** and the distal end **514** of the expandable device **500** may be deployed perpendicular to a portion of the target location. The target location may be tortious vessel, which may include one or more inflection points in the curvature of the tortious vessel. In certain instances, perpendicularity of an end of the expandable device **500** is enhanced by the actuation wire **502** being configured to steer the expandable device **500** to the target location while maintaining one of the ends (the proximal end **512** or the distal end **514**) of the expandable device **500** perpendicular to the target location. The first branch **516** and the second branch **518** may facilitate maintaining the expandable device perpendicular during and after deployment (as shown in FIG. **4**A) and mitigate against non-perpendicular deployment (as shown in FIGS. **4**B-E).

[0068] The first branch **516** and the second branch **518** may distribute forces applied to the actuation wire **502** in steering the expandable device **500**. For example, a user operating the delivery system may apply force to the actuation wire **500** and bidirectionally steer (e.g., proximally and distally relative to the target location within the patient's vasculature) the expandable device **500**. The actuation wire **502** is configured to remain in tension through a length thereof when force is applied to the actuation wire **502** by the user. The actuation wire **502**, for example, may have a stiffness such that the actuation wire **502** does not become relaxed or slacked in response to the user applying force (e.g., tension) to steer the expandable device **500** proximally and distally.

[0069] In certain instances, the actuation wire **502** is coupled to the expandable device **500** via an adhesive (e.g., fluorinated ethylene propylene (FEP)). Each of the first branch **516** and the second branch **518** are releasably adhered to the expandable device **500** along any portion thereof. In certain instances, portions of the actuation wire **502** are arranged through expandable device **500**. The portions may be the first branch **516** and the second branch **518** threaded through the graft component **504**. After the user has steered the expandable device **500** to a desired location and after deployment thereof, the actuation wire **502** may be released from the expandable device **500** and removed from the patient. In certain instances where the actuation wire **502** is directly attached to the expandable device **500**, and when force applied by the user, in excess of the force used to steer, may release the actuation wire **502**. Friction between the target location (e.g., vessel wall) and the expandable device **500** may allow user to apply a greater force or tension to the actuation wire **502** than during steering to release the actuation wire **502**.

[0070] In addition, the delivery system may include one or more tethers (not shown) arranged through a portion of the expandable device **500** and arranged through the actuation wire **502**. The tethers (e.g., as shown in FIGS. **8**-**9**) are configured to couple the actuation wire **502** to the expandable device **500**. One of the tethers is arranged through the first branch **516**, and a second of the two tethers is arranged through the second branch **518**. The tethers may be arranged through the first branch **516** and the second branch **518** of the actuation wire **502** adjacent the proximal end **512** of the expandable device **500**. In addition, the tethers may be configured to uncouple and release from the expandable device **500** in response to force or tension applied to the tethers after delivery of the expandable device. The tethers may break in response to the force or tension (and remain with the expandable device **500** after release of the actuation wire **502**) or the tethers may unthread and be removed with the actuation wire **502** (e.g., as show in FIGS. **9**A-D and FIGS. **10**A-C).

[0071] FIGS. **6**A-B show a side view and a front view of an expandable device **600** and an actuation wire **602** in accordance with various aspects of the present disclosure. The expandable device **600** may include a graft component **604** and one or more stent components **606**. The delivery system may include a catheter **608** with a portion **610** of the catheter **608** arranged through the expandable device **600**. The actuation wire **602** may be configured to releasably couple the expandable device **600** to the delivery system for delivery of the expandable device **600** to a target location within a patient's vasculature. In addition, the expandable device **600** may include a proximal end **612**, a distal end **614**, and a flow lumen extending therebetween.

[0072] In certain instances, the actuation wire **602** is coupled to the expandable device **600** at one or more locations thereon and accessible to a user of the delivery system. The actuation wire **602** may be coupled to the expandable device **600** by at least one tether **616**. As shown in FIG. **6**B, the at least one tether **616** and the actuation wire **602** may form a y-shaped structure. In certain instances, the least one tether **616** is configured to couple the actuation wire **602** to the two or more locations on the expandable device **602**. The least one tether **616** is secured to the actuation wire **602** or arranged through the actuation wire **602** (e.g., as shown in FIG. **8**). In certain instances, the at least one tether **616** is a plurality of tethers (e.g., two tethers) coupled to the actuation wire **602**. The least one tether **616** (or plurality of tethers) is coupled to the expandable device **600** adjacent the proximal end **612** thereof.

[0073] In addition, the actuation wire **602** is configured to steer the expandable device **600** during delivery thereof. The at least one tether **616** being coupled to two locations on the expandable device **600** may facilitate the ability of the actuation wire **602** to steer the expandable device **600** by distributing forces that result from a user applying force or tension to the actuation wire **602** to steer the expandable device **600**.
[0074] In certain instances, one of the proximal end **612** and the distal end **614** of the expandable device **600** are deployed perpendicular to a portion of the target location (e.g., a tortious vessel). Perpendicularity of the expandable device **600** may be enhanced by the actuation wire **602** being configured to steer the expandable device **600** to the target location while maintaining one of the ends (the proximal end **612** or the distal end **614**) of the expandable device **600** perpendicular to the target location. Further, a user operating the delivery system may apply force to the actuation wire **600** and bidirectionally steer (e.g., proximally and distally relative to the target location within the patient's vasculature) the expandable device **600**. The actuation wire **602** may be configured to remain in tension through a length thereof when tension is applied to the actuation wire **602** by the user.
[0075] After the user has steered the expandable device **600** to a desired location and after deployment thereof, the actuation wire **602** may be released from the expandable device **600** and removed from the patient. In certain instances, the force or tension applied to at least one tether **616** causes the tether **616** to uncouple from the expandable device **600**.
[0076] FIGS. **7**A-B show a side view and a front view of an expandable device **700** and an actuation wire **702** in accordance with various aspects of the present disclosure. The expandable device **700** may include a graft component **704** and one or more stent components **706**. The delivery system may include a catheter **708** with a leading end **710** of the catheter **708** arranged near an end of the expandable device **700**. The actuation wire **702** may be configured to releasably couple the expandable device **700** to the delivery system for delivery of the expandable device **700** to a target location within a patient's vasculature. In addition, the expandable device **700** may include a proximal end **712**, a distal end **714**, and a flow lumen extending therebetween.
[0077] The actuation wire **702** is configured to steer the expandable device **700** and is accessible to a user of the delivery system. In certain instances, one of the proximal end **712** and the distal end **714** of the expandable device **700** are deployed perpendicular to a portion of the target location (e.g., a tortious vessel). Further, a user operating the delivery system can apply force to the actuation wire **702** and bidirectionally steer (e.g., proximally and distally relative to the target location within the patient's vasculature) the expandable device **700**. The actuation wire **702** may be configured to remain in tension through a length thereof when tension is applied to the actuation wire **702** by the user.
[0078] In addition, at least one tether **716** may be coupled to two (or more) locations **728**, **730** on the expandable device **700** to facilitate the ability of the actuation wire **702** to steer the expandable device **700** by distributing forces that result from a user applying force to the actuation wire **702** to steer the expandable device **700**.
[0079] In certain instances, tethers **716**, **718** are configured to couple the actuation wire **702** to the expandable device **700**. The tethers **716**, **718** are arranged through the expandable device **700** (e.g., through the graft component **704**) at one or locations thereon. The tethers **716**, **718** may be arranged through the expandable device **700** near the proximal end **712**. In addition, the tethers **716**, **718** may extend from the proximal end **712** of the expandable device **700** and may also be accessible to the user. In addition and as shown in FIG. **6**B, the at least one tethers **716**, **718** and the actuation wire **702** may form a y-shaped structure.
[0080] The tethers **716**, **718** may each include two portions. In certain instances, first portions **720**, **722** of the tethers **716**, **718** are arranged internal to the expandable device and may be accessible to the user, and second portions **724**, **726** of the tethers **716**, **718** are arranged between the eyelet **720** and an eyelet **720** of the actuation wire **702**. In certain instances, the first portions **720**, **722** and the

second portions **724**, **726** of the tethers **716**, **718** are distinct threads attached or knotted together at the locations **728**, **730** on the expandable device **700**. The first portions **720**, **722** and/or the second portions **724**, **726** may be thread through the graft component **704**. In other instances, the first portions **720**, **722** and the second portions **724**, **726** of the tethers **716**, **718** are integral with one another and are thread through the graft component **704** at the locations **728**, **730** on the expandable device **700**.

[0081] After the user has steered the expandable device **700** to a desired location and after deployment thereof, the actuation wire **702** may be released from the expandable device **700** and removed from the patient. The user may apply tension to ends of the tethers **716**, **718** to unthread the tethers **716**, **718** from the expandable device **700** and through the eyelet **720**. In various examples, the first portions **720**, **722** and the second portions **724**, **726** of the tethers **716**, **718** are integral with one another and are concurrently releasable by tensioning the ends of the tethers **716**, **718**. In the instances where the first portions **720**, **722** and the second portions **724**, **726** of the tethers **716**, **718** are attached or knotted together, tension is applied to the first portions **720**, **722** of the tethers **716**, **718** for release thereof. As a result, the first portions **720**, **722** may release from the second portions **724**, **726**, and the first portions **720**, **722** of the tethers **716**, **718** may be removed from the expandable device **700**.

[0082] The expandable device **700** shown in FIGS. **7**A-B is not intended to suggest any limitation as to the scope of use or functionality of embodiments of the disclosure disclosed throughout this document. Neither should the illustrative prosthesis **200** be interpreted as having any dependency or requirement related to any single component or combination of components illustrated therein. For example, in some embodiments, the illustrative expandable device **700** may include additional components such as described in further detail with reference to FIGS. **1**-**6** and **8**-**9**. Additionally, any one or more of the components depicted in FIGS. **7**A-B can be, in embodiments, integrated with various ones of the other components depicted therein (and/or components not illustrated).

[0083] FIG. **8** shows an actuation wire **802** and tether **804** attachment to an expandable device **800** in accordance with various aspects of the present disclosure. The actuation wire **802** may include an eyelet **806** arranged at an end thereof. The tether **804** may be threaded through the eyelet **806** to releasably couple the expandable device **800** to a delivery system.

[0084] The tether **804** may also be threaded through the expandable device **800** to releasably couple the expandable device **800** to the delivery system. In other instances, the tether **804** is directly attached to the expandable device **800** via an adhesive. In addition, the actuation wire **802** may have a stiffness greater than a stiffness of the tether **804** as is described in further detail above.

[0085] FIG. **9**A-D show a tether attachment **902** arrangement in accordance with various aspects of the present disclosure. The tether attachment **902** may be threaded through an expandable medical device **900** at two locations **904**. The tether attachment **902** may include a looped end **906**. As shown in FIG. **9**B, the tether attachment **902** is threaded through the looped end **906**. As shown in FIG. **9**C, the tether attachment **902** is threaded back through the looped end **906**. As shown in FIG. **9**D, the tether attachment **902** is pulled tight to form a releasable slip knot. The tether attachment **902** may be used to couple an expandable device to an actuation wire as discussed herein.

[0086] FIG. **10**A-C show a tether attachment **1002** arrangement in accordance with various aspects of the present disclosure. The tether attachment **1002** may be threaded through an expandable medical device **1000** at four locations **1004**. The tether attachment **1002** is threaded through the four locations **1004**. The tether attachment **1002** may include a looped end **1010**. The tether attachment **1002** may be used to couple an expandable device to an actuation wire **1006** as discussed herein.

[0087] As shown in FIG. **10**A, the tether attachment **1002** is arranged through an eyelet **1008** of the actuation wire **1006**.

[0088] As shown in FIGS. **10**B-C, the tether attachment **1002** is threaded through the looped end **1010**, and then back therethrough. The tether attachment **1010** is pulled tight to form a releasable

slip not. Other release mechanisms may be used to couple an actuation wire to an expandable medical device as discussed herein.

[0089] The actuation wires discussed herein may be formed from metallic, polymeric or natural materials such as stainless steels, cobalt-chromium alloys and nitinol. Further, actuation wires can also be formed from high strength polymer fibers such as ultra high molecular weight polyethylene fibers (e.g., Spectra™, Dyneema Purity™, etc.) or aramid fibers (e.g., Technora™, etc.).

[0090] The graft components may be made up of any material which is suitable for use as a graft in the chosen body lumen and being resistant to expansion as discussed herein. The graft components may be composed of the same or different materials. Furthermore, the graft components may include multiple layers of material that can be the same material or different material. In one embodiment, said materials can be used in combination and assembled together to comprise a graft. The graft materials used in a stent graft can be extruded, coated or formed from wrapped films, or a combination thereof. Polymers, biodegradable and natural materials can be used for specific applications.

[0091] Examples of synthetic polymers include, but are not limited to, nylon, polyacrylamide, polycarbonate, polyformaldehyde, polymethylmethacrylate, polytetrafluoroethylene, polytrifluorochlorethylene, polyvinylchloride, polyurethane, elastomeric organosilicon polymers, polyethylene, polypropylene, polyurethane, polyglycolic acid, polyesters, polyamides, their mixtures, blends and copolymers are suitable as a graft material. In one embodiment, said graft is made from a class of polyesters such as polyethylene terephthalate including DACRON® and MYLAR® and polyaramids such as KEVLAR®, polyfluorocarbons such as polytetrafluoroethylene (PTFE) with and without copolymerized hexafluoropropylene (TEFLON® or GORE-TEX®), and porous or nonporous polyurethanes. In another embodiment, said graft comprises expanded fluorocarbon polymers (especially PTFE) materials described in British. Pat. No. 1,355,373; 1,506,432; or 1,506,432 or in U.S. Pat. No. 3,953,566; 4,187,390; or 5,276,276, the entirety of which are incorporated by reference. Included in the class of preferred fluoropolymers are polytetrafluoroethylene (PTFE), fluorinated ethylene propylene (FEP), copolymers of tetrafluoroethylene (TFE) and perfluoro (propyl vinyl ether) (PFA), homopolymers of polychlorotrifluoroethylene (PCTFE), and its copolymers with TFE, ethylene-chlorotrifluoroethylene (ECTFE), copolymers of ethylene-tetrafluoroethylene (ETFE), polyvinylidene fluoride (PVDF), and polyvinyfluoride (PVF). Especially preferred, because of its widespread use in vascular prostheses, is ePTFE. In another embodiment, said graft comprises a combination of said materials listed above. In another embodiment, said graft is substantially impermeable to bodily fluids. Said substantially impermeable graft can be made from materials that are substantially impermeable to bodily fluids or can be constructed from permeable materials treated or manufactured to be substantially impermeable to bodily fluids (e.g. by layering different types of materials described above or known in the art). In another embodiment, said outermost tube comprises ePTFE. In another embodiment, said innermost tube comprises ePTFE. In another embodiment, said innermost and outermost tube comprises ePTFE film that has been wrapped into a tube. In another embodiment, said secondary stent is covered with any of the material disclosed herein or known in the art. In another embodiment, the secondary stent covering comprises ePTFE.

[0092] Additional examples of graft materials include, but are not limited to, vinylidinefluoride/hexafluoropropylene hexafluoropropylene (HFP), tetrafluoroethylene (TFE), vinylidenefluoride, 1-hydropentafluoropropylene, perfluoro (methyl vinyl ether), chlorotrifluoroethylene (CTFE), pentafluoropropene, trifluoroethylene, hexafluoroacetone, hexafluoroisobutylene, fluorinated poly (ethylene-co-propylene (FPEP), poly (hexafluoropropene) (PHFP), poly (chlorotrifluoroethylene) (PCTFE), poly (vinylidene fluoride (PVDF), poly (vinylidene fluoride-co-tetrafluoroethylene) (PVDF-TFE), poly (vinylidene fluoride-co-hexafluoropropene) (PVDF-HFP), poly (tetrafluoroethylene-co-hexafluoropropene) (PTFE-HFP), poly (tetrafluoroethylene-co-vinyl alcohol) (PTFE-VAL), poly (tetrafluoroethylene-co-vinyl

acetate) (PTFE-VAC), poly (tetrafluoroethylene-co-propene) (PTFEP) poly (hexafluoropropene-co-vinyl alcohol) (PHFP-VAL), poly (ethylene-co-tetrafluoroethylene) (PETFE), poly (ethylene-co-hexafluoropropene) (PEHFP), poly (vinylidene fluoride-co-chlorotrifluoroe-thylene) (PVDF-CTFE), and combinations thereof, and additional polymers and copolymers described in U.S. Publication 2004/0063805, incorporated by reference herein in its entirety for all purposes. Additional polyfluorocopolymers include tetrafluoroethylene (TFE)/perfluoroalkylvinylether (PAVE). PAVE can be perfluoromethylvinylether (PMVE), perfluoroethylvinylether (PEVE), or perfluoropropylvinylether (PPVE), as described in U.S. Publication 2006/0198866 and U.S. Pat. No. 7,049,380, both of which are incorporated by reference herein for all purposes in their entireties. Other polymers and copolymers include, polylactide, polycaprolacton-glycolide, polyorthoesters, polyanhydrides; poly-aminoacids; polysaccharides; polyphosphazenes; poly (ether-ester) copolymers, e.g., PEO-PLLA, or blends thereof, polydimethyl-siolxane; poly (ethylene-vingylacetate); acrylate based polymers or copolymers, e.g., poly (hydroxyethyl methylmethacrylate, polyvinyl pyrrolidinone; fluorinated polymers such as polytetrafluoroethylene; cellulose esters and any polymer and copolymers described in U.S. Publication 2004/0063805, incorporated by reference herein in its entity.

[0093] The graft components, as discussed herein, may be attached to the self-expanding stent elements by using a coupling member that is generally a flat ribbon or tape having at least one generally flat surface. In certain instances, the tape member is made from expanded PTFE (ePTFE) coated with an adhesive. The adhesive may be a thermoplastic adhesive. In certain instances, the thermoplastic adhesive may be fluorinated ethylene propylene (FEP). More specifically, an FEP-coated side of the ePTFE may face toward and contacts an exterior surface of the self-expanding stent and graft component, thus attaching the self-expanding stent to the graft component. Materials and method of attaching a stent to the graft is discussed in U.S. Pat. No. 6,042,605 o Martin, incorporated by reference herein for all purposes.

[0094] The stent component(s) discussed herein can be fabricated from a variety of biocompatible materials. These materials may include 316L stainless steel, cobalt-chromium-nickel-molybdenum-iron alloy (“cobalt-chromium”), other cobalt alloys such as L605, tantalum, Nitinol, or other biocompatible metals. In certain instances, as discussed in detail above, the stent (and graft) may be self-expanding. In other instances, the prosthesis may be balloon expandable.

[0095] The stent component(s) discussed herein may be constructed from a reasonably high strength material, i.e., one which is resistant to plastic deformation when stressed. In one embodiment, the stent component(s) comprise a wire which is helically wound around a mandrel having pins arranged thereon so that the helical turns and undulations can be formed simultaneously. Other constructions may also be used. In certain instances, the stent component(s) are made from a super-elastic alloy. There are a variety of disclosures in which super-elastic alloys such as nitinol are used in stents. See for example, U.S. Pat. Nos. 4,503,569, to Dotter; 4,512,338, to Balko et al.; 4,990,155, to Wilkoff; 5,037,427, to Harada, et al.; 5,147,370, to MacNamara et al.; 5,211,658, to Clouse; and 5,221,261, to Termin et al.

[0096] A variety of materials variously metallic, super elastic alloys, such as Nitinol, are suitable for use in the stent component(s). Primary requirements of the materials are that they be suitably springy even when fashioned into very thin sheets or small diameter wires. Various stainless steels which have been physically, chemically, and otherwise treated to produce high springiness are suitable as are other metal alloys such as cobalt chrome alloys (e.g., ELGILOY®), platinum/tungsten alloys, and especially the nickel-titanium alloys generically known as “nitinol”.

[0097] Persons skilled in the art will readily appreciate that various aspects of the present disclosure can be realized by any number of methods and apparatus configured to perform the intended functions. It should also be noted that the accompanying figures referred to herein are not necessarily drawn to scale, but may be exaggerated to illustrate various aspects of the present disclosure, and in that regard, the figures should not be construed as limiting.

Claims

1. A delivery system comprising: a catheter having a leading end and a trailing end; an expandable device arranged near the leading end of the catheter and including a proximal end, a distal end, and a flow lumen extending therebetween; an actuation line including a first branch and a second branch coupled to the expandable device at different locations configured to facilitate maintaining at least a portion of the expandable device substantially perpendicular to a target area.
2. The delivery system of claim 1, wherein the actuation line is configured to maintain the portion of the expandable device substantially perpendicular to the target area expandable during and after deployment.
3. The delivery system of claim 1, wherein the actuation line is configured to mitigate against non-perpendicular, angled, or flat deployment.
4. The delivery system of claim 1, wherein the actuation line is configured to maintain the proximal end or the distal end of the expandable device approximately perpendicular to an inflection point in a curvature of a tortious vessel during delivery of the expandable device.
5. The delivery system of claim 1, wherein the actuation line is coupled to the expandable device adjacent the proximal end via the at least one tether being arranged through the actuation wire and the portion of the expandable device.
6. The delivery system of claim 1, wherein the first branch and the second branch are coupled to the expandable device near the proximal end thereof.
7. The delivery system of claim 1, wherein the first branch and the second branch are configured to steer the expandable device by distributing forces that result from a user manipulating or applying force to the actuation line to steer the expandable device.
8. The delivery system of claim 7, wherein the actuation line is configured to remain in tension through a length thereof when force is applied to the actuation line by the user.
9. The delivery system of claim 8, wherein the actuation line includes a stiffness such that the actuation line does not become relaxed or slacked in response to the user applying force to steer the expandable device proximally or distally.
10. The delivery system of claim 1, further comprising two tethers arranged configured to couple the actuation wire to the two or more locations on the expandable device.
11. The delivery system of claim 1, further comprising a sleeve attached to an exterior portion of the expandable device through which the actuation wire is arranged.
12. The delivery system of claim 11, wherein the sleeve comprises layer of graft material that forms a lumen between the sleeve and the expandable device.
13. The delivery system of claim 11, wherein the sleeve includes a shorter length than the expandable device.
14. The delivery system of claim 1, wherein the actuation lines includes a bifurcation including the first branch and the second branch.
15. The delivery system of claim 1, wherein the first branch and the second branch are coupled to the expandable device by an adhesive.