A delivery system incorporating a belt for accomplishing relative movement between components of the system. In one aspect, a handle assembly of the delivery system includes a trigger as well as a thumbwheel assembly each configured to activate longitudinal movement of the belt.
HANDLE ASSEMBLY FOR A DELIVERY SYSTEM

BACKGROUND OF THE INVENTION

The present invention relates generally to handles for medical device delivery systems and, more particularly, to a handle for a vascular stent delivery system.

Stents are generally cylindrically shaped devices which function to hold open and sometimes expand a segment of a blood vessel or other arterial lumen, such as coronary artery. Stents are usually delivered in a compressed condition to the target site and then deployed at that location into an expanded condition to support the vessel and help maintain it in an open position. They are particularly suitable for use to support and hold back a dissected arterial lining which can occlude the fluid passageway there through. Stents are particularly useful in the treatment and repair of blood vessels after a stenosis has been compressed by percutaneous transluminal coronary angioplasty, percutaneous transluminal angioplasty, or removed by atherectomy or other means, to help improve the results of the procedure and reduce the possibility of restenosis. Stents, or stent like devices, are often used as the support and mounting structure for implantable vascular grafts which can be used to create an artificial conduit to bypass the diseased portion of the vasculature, such as an abdominal aortic aneurism.

A variety of devices are known in the art for use as stents and have included coiled wires in a variety of patterns that are expanded after being placed intraluminally on a balloon catheter; helically wound coiled springs manufactured from an expandable heat sensitive metal; and self expanding stents inserted into a compressed state for deployment into a body lumen. One of the difficulties encountered in using prior art stents involve maintaining the radial rigidity needed to hold open a body lumen while at the same time maintaining the longitudinal flexibility of the stent to facilitate its delivery and accommodate the often tortuous path of the body lumen.

Prior art stents typically fall into two general categories of construction. The first type of stent is expandable upon application of a controlled force, often through the inflation of the balloon portion of a dilatation catheter which, upon inflation of the balloon or other expansion means, expands the compressed stent to a larger diameter to be left in place within the artery at the target site. The second type of stent is a self expanding stent formed from shape memory metals or superelastic nickel titanium alloys, which will automatically expand from a compressed state when the stent is advanced out of the distal end of the delivery, or
when a restraining sheath which holds the compressed stent in its delivery position is retracted to expose the stent.

Some prior art stent delivery systems for delivery and implanting self expanding stents include an inner member upon which the compressed or collapsed stent is mounted and an outer restraining sheath which is initially placed over the compressed stent prior to deployment. When the stent is to be deployed in the body vessel, the outer sheath is moved in relation to the inner member to "uncover" the compressed stent, allowing the stent to move to its expanded condition. Some delivery systems utilize a "push pull" type technique in which the outer sheath is retracted while the inner member is pushed forward. Another common delivery system utilizes a simple pull back delivery system in which the self expanding stent is maintained in its compressed position by an outer sheath. Once the mounted stent has been moved at the desired treatment location, the outer sheath is pulled back via a deployment handle located at a remote position outside of the patient, which uncovers the stent to allow it to self expand within the patient. Still other delivery systems use an actuating wire attached to the outer sheath. When the actuating wire is pulled to retract the outer sheath and deploy the stent, the inner member must remain stationary, preventing the stent from moving axially within the body vessel.

Controlled deployment of the stent can be a desirable feature in various applications. This can be particularly true when attempting to deploy a self-expanding stent which may tend to spring forwardly when withdrawing the sheath. Further, it can be desirable to employ a system which provides such control and which can accomplish both effectively concerning a medical device.

Accordingly, it has been found to be desirable to have a handle for a delivery system which provides additional control. It has been contemplated that a handle including multiple structures providing varied control may address this need.

The present invention disclosed herein satisfies these and other needs.

SUMMARY OF THE INVENTION

Briefly and in general terms, the present invention is directed towards a system for delivering a medical device within vasculature. In one aspect, the medical device is a self-expanding stent.

In one embodiment, the handle assembly includes a plurality of sub-assemblies which cooperate to accomplish the delivery of a medical device within a patient's body. The handle assembly can include a trigger assembly and a thumbwheel assembly each of which are
operatively associated with a shuttle assembly. A locking mechanism can be further provided to lock these assemblies in place prior to use.

In a particular aspect, the present invention includes a handle assembly including a belt attached at one end to a shuttle assembly and configured about a thumbwheel spool at its other end. In one embodiment, the shuttle assembly is configured to move longitudinally with respect to a handle casing of the handle assembly. The shuttle assembly can further be attached to a sheath or other structure enclosing the medical device. Further, the shuttle assembly can be activated in a plurality of ways. That is, the shuttle assembly can be manipulated via a trigger assembly operatively connected to the shuttle and can alternatively be translated by rotating the thumbwheel assembly which includes the thumbwheel spool.

In a further aspect of the present invention, the belt has a thickness and a width, the width being greater than the thickness. The belt is configured generally vertically at its connection to the shuttle assembly which is slideably configured within a distal portion of the handle assembly. From this connection, the belt extends proximally past a first side of the thumbwheel assembly and around a proximal spool. The belt is directed distally and is turned counterclockwise to assume a horizontal configuration when viewing the belt from a proximal location. While horizontal, the belt passes a second side of the thumbwheel assembly, extending distally to and about a pair of idler trigger sleeves and a pulley trigger then back proximally to the spool of the thumbwheel assembly.

Accordingly, the present invention contemplates dual methods of the withdrawal of a sheath of the delivery system. In this manner, the operator is provided with enhanced control of the delivery and implantation of a medical device.

These and other features of the present invention become apparent from the following detailed description and the accompanying exemplary drawings.

**BRIEF DESCRIPTION OF THE DRAWINGS**

FIGURE 1 is a perspective view, depicting a right side view of a delivery system of the present invention;

FIG. 2 is a perspective view, depicting the delivery system of FIG. 1 with a right handle casing removal;

FIG. 3 is a perspective view, depicting a left side view of a delivery system of the present invention;

FIG. 4 is a perspective view, depicting the delivery system of FIG. 3 with a left handle casing removal;
FIG. 5 is a perspective view, depicting belt and shuttle assemblies of the delivery system of FIG. 1:

FIG. 6 is a perspective view, depicting thumbwheel and guide rail assemblies of the delivery system of FIG. 1:

FIG. 7 is an enlarged view, depicting a belt and shuttle connection with various other components removed for ease of illustration;

FIG. 8 is an enlarged view, depicting components cooperating with the trigger assembly with various other components removed for ease of illustration; and

FIG. 9 is an enlarged view, depicting a locking mechanism of the delivery system with various other components removed for ease of illustration.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention relates to a system that delivers and deploys a medical device at a target site within a patient's body, such as a body lumen. For illustration purposes, the following exemplary embodiments are directed to a handle assembly for a system for delivering and deploying a self expanding stent, although it is understood that the present invention is applicable to other medical devices which are implantable in a body lumen as well as other parts of the body. Additionally, the medical device can be either a self-expanding device or a non self-expanding device.

Referring now to FIGS. 1-4, a system 20 incorporating a handle assembly 22 of the present invention is illustrated. The handle assembly 22 includes a superior or distal end portion 24 and an inferior or proximal end portion 26. The handle assembly 22 is generally elongate and includes a gripping portion 27 that comfortably fits in an operator's hand. Additionally, encasing internal components of the handle assembly are a first handle housing 28 which mates with a second handle housing 30.

Further, in one aspect, the handle assembly includes a trigger sub-assembly 32 and a thumbwheel sub-assembly 34 each of which are mounted to or within the handle housings 28, 30 and which can be alternatively actuated to effect longitudinal movement of a shuttle assembly 36 (See FIG. 2). The thumbwheel assembly 34 is conveniently located at a mid-section of the handle assembly 22 so that an operator can use the thumb of the hand holding the gripping portion 27 to actuate the thumbwheel assembly 34. Actuation of the trigger sub-assembly 32 can be manipulated by the operator's other hand. The distal end portion 24 of the handle assembly 22 is further configured with a strain relief device 38. The proximal end portion 26 further includes a luer fitting 40. A channel or space is provided between the luer
fitting 40 and strain relief device 38 for receiving other portions of a delivery system 20 such as a lumen (not shown) for receiving longitudinal members such as a guide wire.

The system 20 can further be equipped with a locking mechanism 42. This locking mechanism 42 cooperates both with the thumbwheel sub-assembly 34 and the shuttle subassembly 36 to inhibit activation of those assemblies when the device is not in use.

Turning now to FIG. 5, along with reference to FIG. 4, components of the trigger sub-assembly 32 are identified. Various of the components of the trigger sub-assembly 32 are supported by a trigger retainer assembly 44. The trigger retainer assembly 44 is generally rectangular in shape and includes a central cavity 46 forming a channel along which components of the trigger sub-assembly 32 can be translated longitudinally there along and within the handle assembly 22. The trigger retainer assembly 44 further includes various indentations and recesses for securely mounting the assembly within the handle housings 28, 30.

Furthermore, the trigger sub-assembly 32 includes a trigger handle 48 which is connected to a trigger sliding component 50 (See FIG. 4). The trigger slider 50 mates with a pulley retainer 52 and is sized and shaped to move longitudinally along the trigger retainer assembly 44. The pulley retainer 52, in turn, engages an idler retainer 54 when the trigger handle 48 is located in its most forward position (See FIG. 5).

The trigger sub-assembly further including a belt 56 which extends back and forth through a plurality of turns within the handle assembly 27. The belt 56 has a thickness and a width, the width being greater than the thickness. In one aspect, the belt 56 has a generally constant width and has generally orthogonally arranged surfaces. As described in more detail below, one end 58 of the belt 56 is attached to the shuttle assembly 36 (See FIG. 3) and another end 60 is wrapped about a thumbwheel pulley.

As shown in FIG. 6, with continued reference to FIG. 4, the thumbwheel sub-assembly 34 includes a thumbwheel 62 about a circumference thereof is configured a thumbwheel overmold 64. The overmold 64 can be formed of elastomeric or similar material which makes the assembly easy to manipulate. As best seen in FIG. 4, a center portion of the thumbwheel is equipped with a thumbwheel pulley 66 about which the belt gathers upon actuation or rotation of the thumbwheel 62.

Moreover, the thumbwheel sub-assembly 34 includes an elongate, thumbwheel pivot web assembly 68. The pivot web assembly 68 defines a rail-like sub-structure which extends substantially a length of the handle assembly 22 (See FIG. 4) and includes various indentations and recesses for mounting structure thereto and for affixing the assembly within
the handle housings 28, 30. At a proximal end of the pivot web assembly 68 there is configured a proximal spool 70 held between opposing members so that it can rotate in place. A mid section of the web 68 includes structure about which the thumbwheel 62 is supported and can rotate.

With reference now to FIG. 7, the shuttle assembly 36 is shown in its most distal configuration. The shuttle assembly 36 is slideably received between opposing, spaced members 72, 74 of the pivot web assembly 68. The distal terminal end portion 68 of the belt 56 is attached to an internal surface of the shuttle assembly 36. A distal end portion 76 of the shuttle assembly 36 can be attached to a sheath 78 or other structure to be withdrawn to thereby deliver a medical device (not shown) within a patient's body. At its distal terminal end 58, the belt is configured vertically at its attachment to the shuttle assembly 36.

From its distal terminal end connection to the shuttle assembly 36, the belt 56 extends proximally. As best seen in FIG. 5 along with reference to FIG. 4, the belt 56 continues in its generally vertical configuration proximally to and about the proximal spool 70. The belt 56 then changes direction and proceeds distally for a length. The belt 56 then makes a ninety degree (90°) counterclockwise turn (when viewing the assembly from a proximal standpoint) and continues distally in a horizontal fashion.

Upon reaching a distal portion 80 of the handle housing 28, the belt 56 is routed first about a lower idler 82 then proximally again about a trigger pulley 84. The belt 56 takes yet another turn of direction distally and is routed about an upper idler 86. From here, the belt 56 extends proximally once again in the direction of the thumbwheel sub-assembly 34 (See also FIG. 4). Upon reaching the thumbwheel sub-assembly 34, the belt is received about the thumbwheel spool 66.

Prior to use, the locking mechanism 42 is placed into engagement with both the shuttle assembly 36 and thumbwheel sub-assembly 34 (See FIGS. 7 and 9). A distally configured wing 88 of the locking mechanism is placed into engagement with a proximal face of the shuttle assembly 36. A transversely extending locking tab 90 configured at a proximal end portion of the locking mechanism 42 is placed within a circular recess 92 formed in one side of the thumbwheel 62. In this way, the locking mechanism 42 restrains the movement of both the shuttle assembly 36 and the thumbwheel sub-assembly 34.

As stated, in use, either the thumbwheel sub-assembly 34 or the trigger sub-assembly 32 can be actuated to effect longitudinal relative movement between a sheath or similar structure and a medical device to accomplish deployment of the medical device at a treatment
Moreover, each of the thumbwheel 34 and trigger 32 sub-assembly can be actuated alternatively or in exclusion of the other to accomplish such deployment.

Through the rotation of the thumbwheel 62, the proximal terminal end 60 of the belt 56 gathers about the thumbwheel spool 66 (See FIG. 4 and 5). This action consequently reduces the extended length of the belt 56 and thereby causes the shuttle assembly 36 to move proximally along the pivot web assembly 68.

Actuation or rather proximal movement of the trigger 48 of the trigger sub-assembly 32 likewise causes the shuttle assembly 36 to move proximally along the pivot web assembly 68. Here, as the trigger is moved proximally, the trigger slider 50 travels proximally along the trigger retainer assembly 44 (See FIGS. 4 and 5). By way of a fixed connection, the trigger slider 50 brings the pulley proximally thereby reconfiguring the pattern through which the belt 56 must travel from its connection to the shuttle assembly 36. Since this path reconfiguration is essentially an attempt to lengthen an otherwise fixed length belt 56, the shuttle assembly 36 is caused to move proximally.

Therefore, the handle assembly of the present invention provides a system including a plurality of means for accomplishing relative motion.

It is to be understood that even though numerous characteristics and advantages of the present invention have been set forth in specific description, together with details of the structure and function of the invention, the disclosure is illustrative only and changes may be made in detail, such as size, shape and arrangement of the various components of the present invention, without departing from the spirit and scope of the present invention. It would be appreciated to those skilled in the art that further modifications or improvement may additionally be made to the delivery system disclosed herein without departing from the scope of the invention. Accordingly, it is not intended that the invention be limited, except as by the appended claims.
We Claim:
1. A system for delivering a medical device within vasculature, comprising:
a sheath assembly;
a medical device retained in the sheath assembly; and
a handle assembly including a shuttle assembly connected to the sheath assembly, the
handle assembly further including a belt attached at one end to the shuttle assembly and at
another end to a thumbwheel assembly, the handle assembly further including a trigger
attached to the shuttle assembly;
wherein the sheath assembly is attached to the shuttle assembly;
wherein longitudinal movement of the shuttle assembly is alternatively effected by
actuation of the trigger assembly and the thumbwheel assembly.
2. The system of claim 1, wherein the belt is arranged vertically at its connection
to the shuttle assembly.
3. The system of claim 2, wherein the belt extends proximally from the shuttle
assembly to a proximal spool.
4. The system of claim 3, wherein the belt extends distally from the proximal
spool.
5. The system of claim 4, wherein the belt is horizontal along a portion of its
length when extending distally from the proximal spool.
6. The system of claim 5, wherein the belt is routed about a pair of idlers and a
pulley trigger each being in operative cooperation with the trigger.
7. The system of claim 6, wherein the belt extends proximally from the pair of
idlers and is connected to the thumbwheel assembly.
8. The system of claim 1, wherein the belt is configured both vertically and
horizontally.
9. The system of claim 1, wherein the belt is configured to assume a plurality of
turns.
10. The system of claim 1, wherein the belt makes four turns.
11. The system of claim 1, further including a thumbwheel lock.
12. The system of claim 1, wherein the belt has a width and a thickness, the width
being greater than the thickness.
13. A handle for delivering a medical device within vasculature, comprising:
a body;
a shuttle assembly housed by the body; and
a belt attached to the shuttle, the belt being configured both horizontally and vertically within the body.

14. A system of claim 13, further comprising a thumbwheel assembly connected to one end of the belt.

15. The system of claim 14, further comprising a trigger operatively attached to the shuttle assembly.

16. The system of claim 15, wherein the thumbwheel assembly includes a thumbwheel spool which takes up a length of the belt when the shuttle assembly is translated proximally.

17. The system of claim 16, further comprising a thumbwheel lock.

18. The system of claim 13, wherein the belt makes a plurality of turns.

19. The system of claim 18, wherein the belt makes four changes of direction.

20. The system of claim 13, wherein actuation of either the thumbwheel assembly or the trigger accomplishes longitudinal movement of the shuttle with respect to the body.
**A. CLASSIFICATION OF SUBJECT MATTER**

INV. A61F2/84

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

A61F A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

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Further documents are listed in the continuation of Box C

See patent family annex

* Special categories of cited documents

'A' document defining the general state of the art which is not considered to be of particular relevance

'E' earlier document but published on or after the international filing date

'IL' document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

'O' document referring to an oral disclosure, use, exhibition or other means

'P' document published prior to the international filing date but later than the priority date claimed

'T' document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

'X' document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

'Y' document of particular relevance, the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

'S' document member of the same patent family

**Date of the actual completion of the international search**

20 February 2009

**Date of mailing of the international search report**

04/03/2009

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