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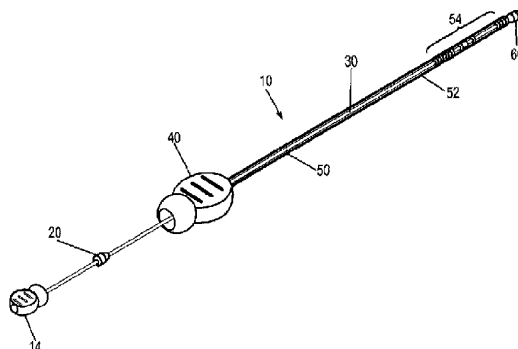
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(54) Title: MEDICAL APPLIANCE DEPLOYMENT APPARATUS AND METHOD OF USE



(57) Abstract: INTERNATIONAL SEARCH REPORT International application No. PCT/US03/33967 Box III TEXT OF THE ABSTRACT (Continuation of Item 5 of the first sheet) NEW ABSTRACT The present invention, in an exemplary embodiment, provides a stent deployment apparatus comprising excellent features. A stent deployment apparatus in the present invention can facilitate the precise delivery of stents in a safe and repeatable fashion. In particular, a preferred deployment apparatus allows the physician to concentrate on correct placement by providing a physical safety mechanism that limits deployment to the critical deployment point. Moreover, to exceed this threshold, an audible and/or tactile indicator informs the physician that she can no longer retract the stent beyond this point. The stent deployment apparatus guide, wire may also be extended rather than retracting the outer catheter to deliver the stent. Moreover, the distal tip is designed to facilitate the removal of the deployment apparatus even if a defective stent is only partially radially expanded. In alternative embodiments, the stent deployment apparatus allows for the insertion of an optical scope to facilitate stent delivery.

WO 2004/039242 A3



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## MEDICAL APPLIANCE DELIVERY APPARATUS AND METHOD OF USE

### FIELD OF THE INVENTION

The present invention relates generally to medical devices directed to the prevention of nonvascular vessel or passageway occlusion, and more particularly to stent deployment apparatuses and methods for utilizing these devices in the treatment of both benign and malignant conditions.

### BACKGROUND OF THE INVENTION

Stents are devices that are inserted into a vessel or passage to keep the lumen open and prevent closure due to a stricture, external compression, or internal obstruction. In particular, stents are commonly used to keep blood vessels open in the coronary arteries and they are frequently inserted into the ureters to maintain drainage from the kidneys, the bile duct for pancreatic cancer or cholangiocarcinoma or the esophagus for strictures or cancer. Nonvascular stenting involves a range of anatomical lumens and various therapeutic approaches, however, accuracy of installation is universally important.

In order to serve its desired function, the stent must be delivered precisely and oriented correctly. In order to facilitate the delivery of stents, medical device companies began to design deployment apparatuses that allow physicians to deploy stents more precisely. Unfortunately, guidance of the stent has substantially remained a function of physician skill resulting from substantial practice. This fact has become particularly evident with the advent

of radially expanding stents. If after full deployment of the stent, the physician discovers the stent has been implemented incorrectly, there is no conventional way of correcting the error short of removing the stent. In particular, as a rule of thumb, once the exterior catheter, of conventional  
5 delivery devices, has been retracted beyond 60%, it generally cannot be realigned with respect to the stent. As a result, physicians must be sure of their stent placement prior to deploying the stent beyond the 60% point. We will refer to this 60% point throughout the application as the critical deployment point.

10 Conventional stent delivery devices, however, do not have any safety mechanism to prevent excessive deployment of a misaligned stent. Generally, conventional delivery devices require the physician to estimate extent of deployment, which results in either overly conservative or excessive deployment – both of which leads to stent misplacement.

15 An additional limitation of conventional stent delivery devices is the distal tip of conventional stent delivery devices are not adequately designed to (1) facilitate the clearance of obstructed lumen, or (2) facilitate the removal of the delivery device once the stent is radially expanded. In particular, most distal tips are not configured to comfortably guide the delivery device through  
20 a diseased or occluded lumen so that the stent can be delivered in the most beneficial location. Moreover, once a stent is radially expanded conventional designs rely primarily on dimensional mismatching to ensure proper removal of the delivery device. In the event the stent does not adequately expand to preset dimensions, a conventional delivery device would be stuck in the  
25 patient until some invasive procedure is performed to remove it and the defective stent.

Therefore, there remains an existing need for a stent deployment apparatuses that has a safety mechanism to prevent excessive deployment of misaligned stent. Preferably it would be desirable if the safety mechanism  
30 had a physical and/or audible indication means to inform the physician when she has reached maximum reversible deployment. As an additional safety feature, there is an existing need for a distal tip designed to allow for the

removal of the deployment apparatus even if the stent does not radially expand to its preset expansion diameter. An existing need also exists for a stent deployment apparatus that has a distal tip adequately configured to navigate through diseased and/or occluded lumens so that the stent can be delivered to this target area.

There also remains an existing need for a stent deployment apparatus that increases physician control during stent deployment. Moreover, there exists a need for a stent deployment apparatus that allows for the insertion of an optical scope to facilitate stent delivery.

#### SUMMARY OF EXEMPLARY EMBODIMENTS

It is a principal objective of the present invention to provide a device that can facilitate the delivery of stents in a safe and repeatable fashion. In one aspect the present invention provides a device for allowing a user to deploy a stent in an anatomical lumen of a patient, the device including a longitudinally extending inner tubular member having distal and proximal ends, the distal end including a tip a longitudinally extending outer tubular member having an outer and inner diameter, the outer tubular member being longitudinally and axially displaceable relative to the inner tubular member, a handle, coupled with a portion of the outer tubular member, the handle having first and second ends and the second end defining a cavity having at least one stop compatible locking member formed therein, a hypotube having a first end, a second end, an outer surface, an inner surface, and a stop formed on the hypotube between the first and second ends, the outer surface of the stop including at least one locking member complementary to the handle cavity to form a safety mechanism, wherein the extent of displaceability of the outer tubular member and inner tubular member relative to each other is limited after a free axial displacement, said free axial displacement not requiring rotational motion of the handle with respect to the hypotube, by the safety mechanism to a predetermined threshold absent intervention by the user of the device such that the degree of stent deployment is limited absent the user intervention.

In an embodiment, the present deployment apparatus has a physical safety mechanism that limits deployment to the critical deployment point (i.e., ~60%). The critical deployment point may range from 5% to 95% but is preferably about 60%. At this point, if the physician is satisfied with placement, she can engage the safety means to what is referred to in the specification as the Proceed Orientation (PO) and fully deploy the stent. In an embodiment, when the safety mechanism is engaged to the PO, a physical twist and a possible audible indicator sounds to inform the physician that if she deploys the stent any further, she can no longer retract the stent beyond this point. Though the present stent and delivery system ameliorates the need for repositioning, such safety features are still preferable. In another embodiment, the slight audible indication is the sound of a tab of stop snapping to allow free deployment of the stent.

In another embodiment, removal of a stent is facilitated by providing a distal tip that has a substantially bidirectional conic shape. This allows for the removal of the deployment apparatus, whereas conventional deployment apparatuses may become lodged in the patient until an invasive procedure is performed to remove it and the defective stent. This result from the conventional deployment apparatus designs relying primarily on dimensional mismatching between the distal tip and the radially expanded stent to ensure proper removal of the deployment apparatus. In an embodiment of the present invention, the compressed stent is adequately retained in place and does not prematurely creep up the proximally facing conic end of the distal tip and prematurely deploy.

In another embodiment, the device is capable of letting a flexible optical scope of about 5-6mm diameter be coupled along the exterior of the outer tubular member thereof. Alternatively, it is envisioned that an ultra thin optical scope may pass along side the guidewire through the internal diameter of the internal tubular member of the device.

An exemplary stent may have one or more of the following characteristics: (1) applicable for various interventional applications such as addressing stenosis; (2) biocompatible; (3) compliant with radially expanding

stents; (4) capable of distal or proximal stent release; (5) smooth and clean outer surface; (6) length of the device variable according to the insertion procedure to be employed; (7) outer dimensions as small as possible (depends on the diameter of crimped stent); (8) dimensions of the device  
5 must offer enough space for the crimped stent; (9) radiopaque markers, preferably on the inner tubular member, to indicate proximal and distal ends of the stent; (10) sufficient flexibility to adapt to luminal curvatures without loss of ability to push or pull; (11) low friction between the inner tubular member and the outer tubular member; (12) sufficient resistance to kinking;  
10 (13) good deployment, ability to reposition partially deployed stent; (14) added with a scale to observe the stent position during the insertion procedure; (15) insertion procedure should require low force; or (16) sufficiently economical to manufacture so as to make the deployment apparatus disposable.

15 In another aspect, the present invention provides a method of deploying a radially expandable stent including the steps of providing a stent deployment apparatus including a stent, a longitudinally extending outer tubular member having distal and proximal ends and a safety catch assembly disposed between the distal and proximal ends, and a longitudinally  
20 extending inner tubular member having distal and proximal ends, the inner tubular member being longitudinally and axially displaceable relative to the outer tubular member and wherein the distal end includes a tip, the inner tubular member further includes at least one catch along the longitudinal  
25 expanse thereof for operative interaction with the safety catch assembly of the longitudinally extending outer tubular member to limit extent of stent deployment, inserting the deployment apparatus through a portion of the anatomy of a patient positioning the distal tip of the inner tubular member about a target area within the patient; displacing the outer tubular member, with respect to the inner tubular member so as to expose the stent short of its  
30 full deployment position, and deploying the stent such that the stent expands forming a lumen therethrough that is larger than the compressed diameter of the stent.



**BRIEF DESCRIPTION OF THE FIGURES**

Further features of embodiments of the invention will be apparent from the following detailed description taken in conjunction with the accompanying drawings, in which:

5           FIG. 1 is a perspective view of a device for delivering and deploying a radially self-expanding stent in accordance with an embodiment of the present invention;

10           FIG. 2 is a side view of the device for delivering and deploying a radially self-expanding stent in accordance with an embodiment of the present invention.

            FIG. 3A depicts enlarged views of portions of the deployment safety mechanism along lines 3A-3A of the device of FIG. 2

            FIG. 3B shows a cross section view of the deployment safety mechanism along lines 3B-3B of FIG. 3A;

15           FIG. 3C is a perspective view of a portion of a complementary portion of the deployment safety mechanism region of the handle as shown along lines 3C-3C of FIG. 3A;

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FIG. 3D is a perspective view of the stop of the deployment safety mechanism as shown along lines 3C—3C of the device of FIG. 3A.

FIG. 4A is a side perspective view of the distal region of the device of FIG. 2, along lines 4A—4A;

FIG. 4B depict an enlarged sectional view of the distal region of the device of FIG. 2, along lines 4B—4B.

#### DETAILED DESCRIPTION OF AN EMBODIMENT

A general problem in the diagnosis and therapy of both vascular and nonvascular anomalies is the fact that the instruments must be inserted into or pass the area of maximum diameter of about 15 mm. As a result, the inserted instruments take away a very large portion of the free lumen and may increase the danger of injury to the patient.

Therefore, it is the primary objective of the present invention to provide an instrument, which can be inserted gently, ensures a good utilization of the available space and makes it possible to carry out active therapeutic measures, wherein the instrument is to be particularly suitable for the introduction and placement of stents.

A preferred embodiment of the present deployment apparatus comprises inner and outer tubular members interactively coupled with each other in a manner that one can move rotationally and proximally or distally with respect to the other. The tubular members are preferably nonpyrogenic. In order to deliver the stent, the deployment apparatus comprises a distal tip and a stent retaining hub, between which the stent is placed. The distal tip and the stent-retaining hub are both functionally coupled with the inner tubular member. The inner tubular member terminates with a luer or in a

preferred embodiment, a proximal handle similar to the outer handle hub. The luer is preferably a female threaded luer, but alternative termini are within the skill of the stent deployment device engineer. In fact, a suitable alternative would be a handle having similar internal diameter characteristics as the luer while providing greater surface area for manipulating the deployment apparatus. As stated above, a preferred alternative would be a proximal handle that is similar in geometrical shape but preferably smaller than the outer handle hub, to facilitate movement, however the proximal handle may be of any size functionally acceptable by the user. The deployment apparatus is preferably sterilized by a validated sterilization cycle EtO. Moreover, the device is capable of resterilization (validated cycle) with no degradation of performance. However, it is preferable to provide a disposable device.

The deployment apparatus is preferably about 100 cm  $\pm$  2 cm total. The inner diameter of the inner tubular member is approximately about 1 mm and the outer diameter of the outer tubular member is preferably about 5 to 6 mm in diameter. For purposes of this discussion, the usable length of the inner tubular member shall be from the inner tubular member distal hub/handle end to the distal tip. The usable length of the outer tubular member shall be from the distal hub/handle end of the outer tubular member to the distal tip. The overall length of the device shall be from the distal hub/handle end of the outer tubular member to the distal tip of the inner tubular member when assembled and not deployed. There will also be preferably three radiopaque (platinum iridium) markers for marking the stent, the stent deployment distance, and depth. The outer tubular member is preferably manufactured of stiffer synthetic

material. In a preferred embodiment, the length of the outer tubular member is preferably shorter than that of the inner tubular member.

However, these dimensions may differ as a function of the stent diameter and/or if an optical scope is employed to facilitate stent  
5 delivery. The outer tubular member may be configured to allow for the coupling of an optical stent along the outer diameter thereof. Alternatively, the inner diameter of the inner tubular member may be enlarged sufficiently to accommodate the optical scope and additionally the increased crimped stent diameter. However, it is  
10 expected, though not required, that the smallest diameter that allows for example a bronchoscope to pass will be employed in this alternative embodiment. It should be understood that through hindsight, after exposure to the present specification, one of ordinary skill would be able to adapt the current device to receive an ultra  
15 thin optical scope to the internal diameter of the device without undo experimentation and without departing from the spirit of the present objectives.

An exemplary deployment apparatus in accordance with the present invention is durable while affording adequate flexibility to  
20 navigate through anatomical lumens without kinking. To this end, it is preferable that the deployment apparatus is formed of biocompatible synthetics and in a preferred embodiment reinforced with metal structure. This should allow for deployment within an accuracy of about  $\pm 3$  mm. Moreover, the stent is preferably released  
25 with a force lower than 30 Newtons at 37°C though the force and deployment temperatures may be modified to suit the needs of specific anatomical conditions.

The inner tubular member is composed of a thin elastic synthetic material, such as polyurethane or Teflon®. At its proximal end, the

inner tubular member has a standard adaptor or connector. At its distal end, the inner tubular member is equipped with a tip specific for various anatomical lumens.

The inner tubular member and the outer tubular member can be  
5 displaced relative to each other in longitudinal direction as well as in a radial direction. The deployment apparatus in accordance with the present invention can be used most advantageously for the placement of stents. Such stents are available in various embodiments of metal and/or synthetic material. They usually are  
10 composed of a fabric of metal wires, which expand by themselves as a result of their natural tension. Stents of a so-called shape memory alloy are also known. These stents have a small radial diameter at a low temperature, while they expand radially when exceeding an upper threshold temperature, so that they can keep a stenosis open in  
15 this manner. It is particularly advantageous to use stents of an alloy of nickel and titanium, the so-called nitinol.

An exemplary deployment apparatus according to the present invention can be used for the placement of various stents, whether they are self-expanding stents or stents, which require an activation.  
20 For this purpose, the stent is placed in the free space between the outer tubular member and the inner tubular member. Positioning of the stent in the deployment apparatus can be carried out in the area between the tip and the stent retaining hub at the distal end of the inner tubular member. Alternatively, in its insertion position, fasteners  
25 or other suitable retaining elements may hold the stent.

In relevant embodiments, when the stent is inserted and after the stenosis has been passed, the outer tubular member is retracted, so that the stent is released. Alternatively, the distal end of the outer tubular member may be placed about the stenosis so that the inner

tubular member may be extended so that the stent is placed in direct contact with the desired location prior to expansion. A self-expanding stent then by itself assumes the expanded position. This eliminates the need for post expansion positioning techniques. With  
 5 an alternative embodiment of the device, the device has fasteners that retain contact with a portion of the stent in the event that the stent needs to be retracted or repositioned. A stent suitable for such procedures would be one in accordance with the disclosure in co-pending U.S. Patent Application Serial No. 10/190,770, which is  
 10 incorporated herein in its entirety by this reference.

The following reference numbers and corresponding stent placement and deployment device components are used when describing the device in relation to the figures:

15	10	Stent Delivery & Deployment Device
	12	Guidewire
	14	Proximal Handle/Female Threaded Luer
	16	Hypotube
	18	Safety Mechanism
	20	Stop
20	22	Female Locking Member on the Stop
	24	Tab of the Stop
	30	Inner Tubular Member
	32	Inner Diameter of Inner Tube
	40	Handle
25	42	Cavity in Proximal Portion of Handle
	44	Base of Handle Cavity
	46	Male Locking Member
	48	Inner Handle Hub
	49	Outer Handle Hub
30	50	Outer Tubular Member
	52	Outer Diameter of Outer Tubular Member
	54	Distal Region of Outer Tubular Member
	56	Inner Diameter of Outer Tubular Member
	60	Distal Tip
35	62	First End of the Tip
	64	Medial Region of the Tip
	66	Second End of the Tip

	68	Axial Passage
	70	Retaining Hub
	72	Distal Region of Retaining Hub
	74	Proximal Hub of Retaining Hub
5	76	Pusher
	80	Proximal Marker
	82	Medial Marker
	84	Distal Marker

The figures show an exemplary placement and deployment  
10 device 10 in accordance with the present invention. Referring in  
particular to FIGS. 1-2, the present invention provides a stent  
deployment apparatus 10 that includes an outer tubular member 50  
and an inner tubular member 30, wherein the outer tubular member 50  
and the inner tubular member 30 can be displaced relative to each  
15 other. At the proximal end of an exemplary device 10 is a threaded  
female luer 14, coupled with a portion of the inner tubular member 30  
and preferably a portion of a hypotube 16. As stated earlier, a  
suitable alternative terminus may be employed as long as it provides  
the minimum benefits provided by a luer. The hypotube 16 is disposed  
20 about the inner tube 30 and extends from a location adjacent to the  
luer 14 through a portion of the handle 40 of the deployment  
apparatus 10. In an alternative embodiment, the hypotube 16  
terminates within the luer 14. A safety mechanism 18 is provided that  
is formed in part by the complementary fitting of a portion of the  
25 handle 40 and a stop 20 coupled with the hypotube 16 between the  
luer 14 and the handle 40. The stop 20 is preferably molded onto the  
hypotube 16, the molding process resulting in a tab 24 formed on the  
stop 20 that is subsequently broken when the physician desires to  
place the deployment apparatus 10 in the proceed orientation. In an  
30 exemplary embodiment, when the tab 24 is broken and the  
deployment apparatus 10 is placed in the proceed orientation; the

stop 20 may potentially rotate freely about the hypotube 16. It should be kept in mind that the stop 20 may take a variety of shapes, including but not limited to, rectangular, round, conical etc. In a preferred embodiment, the stop 20 is conical with a tapered effect to facilitate entrance and removal from the base handle cavity 44.

As illustrated in FIGS. 3A-3D, a preferred stop 20 includes female locking members 22 comprising channels formed along the exterior thereof that are complementary to the male locking members 46 formed on the interior cavity 42 along the proximal region of the handle 40. The cavity 42 of the handle 40 is designed to receive the stop 20 and prevent further deployment. As a result, the stop 20 is molded at a distance along the hypotube 16 such that the distance between the distal end of the stop and the base 44 of the complementary cavity 42 of the handle 40 roughly corresponds to the critical deployment point. It should be noted that the female locking members 22 and male locking members 46 of the safety mechanism 18 might be reversed so that the female locking members 22 and male locking members 46 are on the handle 40 and the stop 20, respectively. Additionally, alternative safety mechanisms may be employed to ensure accurate deployment beyond the critical deployment point.

The handle 40 is preferably molded to a portion of the outer tubular member 50, which extends from the handle 40 to the distal tip 60 of the device 10. The outer tubular member 50 is disposed about the inner tubular member 30. In an exemplary embodiment, the outer tubular member 50 is clear so that the inner tubular member 30 is visible there through. Moreover, markers 80-84 preferably formed on portions of the inner tubular member 30 are also visible through the outer tubular member 50.



Referring now to FIGS. 4A-4B, in the distal region 54 of the device 10, there is a stent placement hub 70, which holds the stent (not shown) during the placement procedure. In a preferred embodiment, the stent placement hub 70 comprises two double conical shaped elements, one disposed at each end of the stent and coupled with the inner tubular member 30. In an exemplary form, the distal most double conical shaped element is the distal tip of the device 60. In alternative embodiments, the stent placement hub may also comprise proximal 72 and distal 74 stops between which the stent rests in its crimped state. Moreover, the proximal end of the stent may also be restrained by conventional coupling methods (not shown) to facilitate retrieval if necessary. By way of example, which is in no way to be construed as limiting, a stent having suture disposed about its proximal end may be retained by the stent retaining hub 70 that has releasable finger-like members engaging the suture.

The device is configured such that an optional guidewire 12 may be passed through the internal diameter 32 of the device through the luer 14 at the proximal end, the distal tip 60 at the distal end and the inner tubular member 30 there between. In an alternative embodiment, the internal diameter 32 of the device 10 is sufficient to receive an optical scope (not shown) there through.

Referring to the functional aspects of the device 10, there is shown in FIG. 1 a deployment apparatus 10 that includes an elongate and flexible outer tubular member 50 constructed of at least one biocompatible thermoplastic elastomer, e.g. such as polyurethane and nylon, typically with an outside diameter 52 in the range of about between 6-9 mm. A central lumen 56 runs the length of the outer tubular member 50. A distal region 54 of the outer tubular member 50 surrounds the stent to be placed (not shown), and maintains the stent

in a crimped delivery configuration, against an elastic restoring force of the stent. The stent, when in a normal unrestrained configuration, generally has a diameter (for example, 10-20mm) substantially larger than the interior diameter 32 of the inner tubular member 30. Typically the expanded stent is larger in diameter than the body lumen in which the stent is fixed, and the restoring force tends to maintain the stent against the tissue wall.

Outer tubular member 50 is mounted at its proximal end to a handle 40. Outer tubular member 50 can be pushed and pulled relative to inner tubular member 30 by hand manipulation of the handle 40 at the proximal end of the outer tubular member 50 and holding the proximal end of the handle 14.

A guidewire 12 is preferably disposed within the interior lumen 32 of an elongate and flexible inner tubular member 30, which can be constructed of materials similar to those employed to form the outer tubular member 50. However, it is preferable that inner tubular member 30 is formed from a more durable material. A distal tip 60 is coupled with inner tubular member 30 about the distal end thereof. Also attached to the inner tubular member 30 are a proximal marker 80, at least one medial marker 82 and a distal marker 84. The markers are constructed of a radiopaque material, e.g. platinum iridium, and surround the inner tubular member 30. Markers, 80, 82 and 84 are axially spaced apart to mark the length of the stent and to mark the critical deployment distance for that stent length. The markers identify a stent-retaining hub 70 of the inner tubular member 30, more particularly the distal region of the inner tubular member 30 is surrounded by stent 12. The markers may also be of varying sizes and shapes to distinguish distance between distal and proximal regions. Markers 80 and 84 may have outer diameters slightly smaller than the

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interior diameter of outer tubular member 50. The outer tubular member 50 thus functions as a carrier for the stent, with inner tubular member 30 providing a retaining means for radially compressing the stent and maintaining the stent along the stent retaining hub 50, so long as the outer tubular member 50 surrounds the stent.

In an alternative embodiment, items 72 and 74 are marker bands (not retaining hubs) formed on the outer tubular member 50. These marker bands visually mark the ends of the stent and thus will be over the step area of the tip and the pusher 76. All the marker bands - including 80, 82 and 84 are preferably either Platinum Iridium or Stainless Steel. Moreover, the marker bands of 80, 82, and 84 will be depth marks and will be spaced in preferably 1cm intervals. These depth marks are preferably formed on the inner tubular member 30 and are a visual aid for the physician to assist with determining the depth at which the stent has been advanced.

Inner tubular member 30, along its entire length, has an interior lumen 56 open to both the proximal and distal ends of the inner tubular member 30. An axial passage 68 through distal tip 60 continues lumen 32 to allow the guidewire 12 to pass from the luer 14 through the distal tip 60.

Handle 40 and outer tubular member 50 are movable relative to inner tubular member 30. More particularly, the handle 40 is moved proximally relative to the stent-retaining hub 70, facilitating the movement of outer tubular member 50 relative to inner tubular member 30 so as to provide a means for controllably withdrawing the outer tubular member 50, relative to the inner tubular member 30, resulting in the release of the stent for radial self-expansion.

When the device 10 is used to position the stent, the initial step is to position guidewire 12 within the anatomy of a patient. This can be

accomplished with a guide cannula (not illustrated), leaving guidewire 12 in place, with the exchange portion of the guidewire extended proximally beyond the point of entry into the anatomy of the patient. Deployment apparatus 10 is then advanced over the guidewire 12 at the exchange portion, with the guidewire 12 being received into passage 68 of distal tip 60. As device 10 is inserted into the body, the proximal portion of guidewire 12 travels proximally (relative to the device) to the proximal end of guidewire lumen 32.

Once device 10 is positioned, the physician maintains a guidewire of 12 and inner tubular member 30 substantially fixed with one hand, while moving handle 40 in the proximal direction with the other hand, thus to move outer tubular member 50 proximally relative to inner tubular member 30. As the outer tubular member 50 is retracted, the stent remains substantially fixed relative to inner tubular member 30, and thus radially self expands. As the handle 40 and correspondingly the outer tubular member 50 is retracted, the handle 40 encounters the safety mechanism 18 of the critical deployment point. The inner tubular member 30, via the handle 14, may have to be rotated to align and insert the stop 20 into the handle 40. When fully inserted, further deployment cannot occur without twisting and snapping the tab 24 portion of the stop 20. Continued reaction of the outer tubular member 50 results in complete deployment of the stent.

After deployment, the stent ideally radially self-expands to a diameter greater than the diameter of outer tubular member 50. Accordingly, device 10 can be withdrawn proximally through the stent. However, in the event that the stent does not radially expand fully, distal tip 60 is configured to facilitate removal of deployment apparatus 10 through the lumen of the stent.

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Guidewire 12 can be withdrawn as well. The guidewire 12 emerges from the proximal end of the luer 14. However, should the medical procedure involve further treatment, e.g., placement of a further stent, the deployment apparatus 10 can be removed without removing the guidewire 12. Device 10 is removed by progressively pulling the device away from the guidewire 12 (which removes the guidewire from within the inner tubular member 30), all while maintaining guidewire 12 in place.

Returning to distal tip 60, as illustrated in FIGS 4A-4B, distal tip 60 can have a variety of configurations, but by way of non-limiting example, distal tip 60 comprises first 62 and second 66 ends having a smaller diameter than the medial region 64 thereof. In a preferred embodiment, each end is conical in shape so as to allow the tip 60 to wedge through an incompletely expanded stent when pulled proximally with respect to the stent. Moreover, the dual conical end design facilitates removal but sufficiently prevents the crimped stent from releasing from the stent retaining hub 70 and prematurely expanding. Distal tip 60 may alternatively have a flared medial region 64 so as to facilitate retrieval and retraction of a misaligned stent 12.

With respect to additional safety features incorporated in the present device 10, in a preferred embodiment, the device 10 has a deployment safety mechanism 18 that comprises male 46 and female 22 locking members that are brought into functional engagement as the stent is being deployed. Once the stent has reached the critical deployment point, the distal end of the stop 20 is substantially flush with the base 44 of the handle cavity 42 and the female locking members 22 of the stop 20 are in operative communication with the corresponding male locking members 46 formed on the interior

surface of the cavity 42 of the handle. When the safety mechanism 18 is engaged as described above, the stent cannot be deployed further without physician intervention. In order to deploy the stent beyond this point, the physician has to rotate the stop 20 to cause the tab 24 to break. Once the tab 24 is broken, the device 10 is in the proceed orientation and deployment may proceed.

In a preferred embodiment, the physician will feel a tactile indication that the device 10 can be deployed further. Alternatively, the breaking of the tab may also, or as a substitute to tactile indication, results in an audible indication that further deployment is possible. Additionally, the physician is apprised of the fact that deployment beyond this point is irreversible except for interventional retrieval methods. As discussed earlier, the critical deployment point is preferably about 60% deployment, beyond which retraction is not recommended. As a result, the safety mechanism 18 removes the need to estimate extent of deployment and provides a reliable means of accurately deploying stents. Alternative locking mechanisms may be provided as long as they retain the important characteristic of giving the physician a sensory indication of extent of stent deployment and removes the need to estimate extent of deployment. By way of non-limiting example only, the locking mechanism could comprise a breakable seal, tab/stop lock, diverted channel locking mechanism, etc.

Referring particularly to FIG. 5, an alternative safety mechanism 118 is presented that is a principally a diverted channel mechanism. In practice, a detent 90 formed preferably on the hypotube has free proximal/distal travel to the critical deployment point at which time physician intervention is required to continue deployment. In a preferred embodiment, the Inner Tubular Member 30 is rotated until

the travel of the detent is no longer obstructed. The channel in which the detent travels may be of a variety of geometrical shapes such as M, W, L, S Z, etc; the preferred geometry being substantially Z shaped, as shown in FIG. 5.

5 In an additional embodiment (not shown) of deployment safety mechanism 118, the device 10 has a deployment safety mechanism that comprises male and female locking members that are brought into functional engagement as the stent 12 is being deployed. Once the stent 12 has reached the critical deployment point, the male  
10 locking member cannot be advanced further because of a detent formed on the inner diameter of the outer tubular member catches the cavity formed on the corresponding portion of the male locking member. As a result, in order to further advance the device 10 to fully  
15 deploy stent 12, the inner tubular member must be rotated so as to break the detent. Once the detent is broken, the physician will feel a tactile indication that the device 10 can be deployed further.

Alternatively, the breaking of the detent may also, or as a substitute to tactile indication, results in an audible indication that further deployment is possible. Additionally, the physician is apprised  
20 of the fact that deployment beyond this point is irreversible except for interventional retrieval methods. As discussed earlier, the critical deployment point is preferably about 60% deployment, beyond which retraction is not recommended. As a result, the safety locking system  
25 removes the need to estimate extent of deployment and provides a reliable means of accurately deploying stents. Alternative locking mechanisms may be provided as long as they retain the important characteristic of giving the physician a sensory indication of extent of stent deployment.

The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative, and not restrictive. The scope of the invention is, therefore, indicated by the  
5 appended claims, rather than by the foregoing description. All changes, which come within the meaning and range of equivalency of the claims, are to be embraced within their scope.

Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as  
10 "comprises" and "comprising", will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.

The reference to any prior art in this specification is not, and should not be taken as, an acknowledgement or any form or suggestion that the  
15 prior art forms part of the common general knowledge in Australia.



The claims defining the invention are as follows:

1. A device for allowing a user to deploy a stent in an anatomical lumen of a patient, the device including:
  - 5 a longitudinally extending inner tubular member having distal and proximal ends, the distal end including a tip:
    - a longitudinally extending outer tubular member having an outer and inner diameter, the outer tubular member being longitudinally and axially displaceable relative to the inner tubular member;
    - 10 a handle, coupled with a portion of the outer tubular member, the handle having first and second ends and the second end defining a cavity having at least one stop compatible locking member formed therein;
      - a hypotube having a first end, a second end, an outer surface, an inner surface, and a stop formed on the hypotube between the first and  
15 second ends, the outer surface of the stop including at least one locking member complementary to the handle cavity to form a safety mechanism;
        - wherein the extent of displaceability of the outer tubular member and inner tubular member relative to each other is limited after a free axial displacement, said free axial displacement not requiring rotational motion of  
20 the handle with respect to the hypotube, by the safety mechanism to a predetermined threshold absent intervention by the user of the device such that the degree of stent deployment is limited absent the user intervention.
  - 25 2. The device of claim 1, wherein the inner tubular member defines a lumen longitudinally extending substantially the distance from the distal end to the proximal end of the inner tubular member, which allows a guidewire to extend through the lumen thereof.
  - 30 3. The device of claim 1, wherein the user intervention includes displacing the outer tubular member axially relative to the inner tubular member.

2003301732 30 May 2007

- 24 -

4. The device of claim 3, wherein an audible indication follows the user intervention.
5. The device of either claim 3 or claim 4, wherein a tactile indication follows the user intervention.
6. The device of claim 3, further including at least one tab formed on the stop when the stop is molded on the hypotube, which serves as the audible indication when broken during user intervention.
7. The device of claim 1, wherein the predetermined threshold is about between 10% and 90% deployment.
8. The device of claim 7, wherein the predetermined threshold is about 60% deployment.
9. The device of claim 3, wherein the outer tubular member when moved longitudinally relative to the inner tubular member in a proximal direction away from the selected location, releases the stent for radial self-expansion.
10. The device of claim 1, wherein a guidewire is coupled to a portion of the outer diameter of the outer tubular member.
11. The device of claim 1, wherein the inner tubular member is configured to receive an optical scope.
12. The device of claim 1, wherein the outer tubular member is clear.
13. The device of claim 1, wherein there is at least one marker coupled with a portion of the inner tubular member.

3065/07 claims amendments without changes tracked 24

14. The device of claim 1, wherein the inner tubular member is of a material that is kink resistant.

5 15. The device of claim 12, wherein the outer tubular member is kink resistant.

10 16. The device of claim 1, wherein the distal end including the tip has first, medial and second sections, the first and second sections having outer diameters that are less than that of the medial section.

17. The device of claim 1, wherein a portion of the inner tubular member about the proximal end further includes a stent carrier adapted to carry a radially self-expanding stent in a radially contracted state.

15 18. The device of claim 17, further including a radially self-expanding stent carried by the stent carrier, extended along and surrounding at least part of the distal end region, and surrounded by a portion of the outer tubular member and thereby maintained in the radially contracted state.

20 19. A device of allowing a user to deploy a stent in an anatomical lumen of a patient, the device including:

a longitudinally extending outer tubular member having distal and proximal ends and a safety catch assembly disposed between the distal and proximal ends; and

25 a longitudinally extending inner tubular member having distal and proximal ends, the inner tubular member being longitudinally and axially displaceable relative to the outer tubular member and wherein the distal end includes a tip, the inner tubular member further includes at least one detent along the longitudinal expanse thereof for operative interaction with the safety catch assembly of the longitudinally extending outer tubular member;

30 whereby the extent of displaceability of the outer tubular member and inner tubular member relative to the other is limited to a predetermined

threshold absent intervention by the user of the device such that the degree of stent deployment is limited absent the user intervention.

20. A method of deploying a radially expandable stent including the steps  
5 of:

providing a stent deployment apparatus including a stent, a  
longitudinally extending outer tubular member having distal and proximal  
ends and a safety catch assembly disposed between the distal and proximal  
ends; and a longitudinally extending inner tubular member having distal and  
10 proximal ends, the inner tubular member being longitudinally and axially  
displaceable relative to the outer tubular member and wherein the distal end  
includes a tip, the inner tubular member further includes at least one catch  
along the longitudinal expanse thereof for operative interaction with the  
safety catch assembly of the longitudinally extending outer tubular member to  
15 limit extent of stent deployment;

inserting the deployment apparatus through a portion of the anatomy  
of a patient;

positioning the distal tip of the inner tubular member about a target  
area within the patient;

20 displacing the outer tubular member, with respect to the inner tubular  
member so as to expose the stent short of its full deployment position; and

deploying the stent such that the stent expands forming a lumen  
therethrough that is larger than the compressed diameter of the stent.

25 21. the method of claim 19, further including the step of:

removing the deployment apparatus through the lumen of the  
deployment stent.

22. A device according to claim 1 or claim 19 substantially as  
30 hereinbefore described with reference to the accompanying figures.

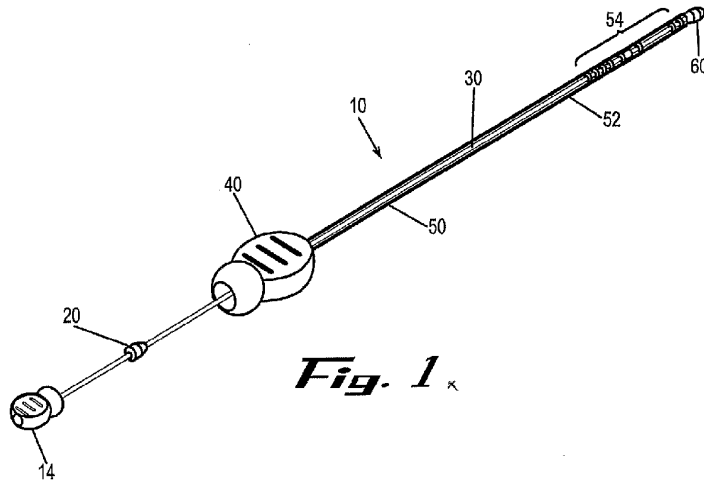
2003301732 30 May 2007

- 27 -

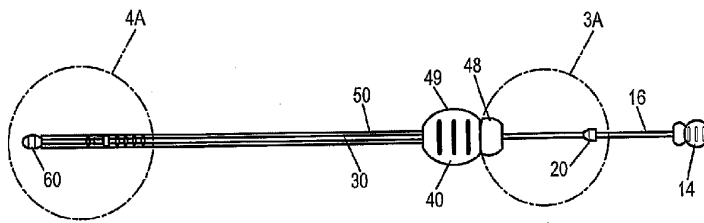
23. A method according to claim 20 substantially as hereinbefore described with reference to the accompanying figures.

30/05/07, claims amendments without changes tracked, 27

1/4



**Fig. 1**



**Fig. 2**

REPLACEMENT SHEET

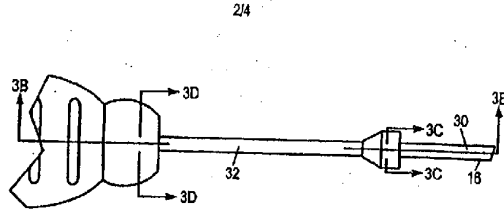


Fig. 3A

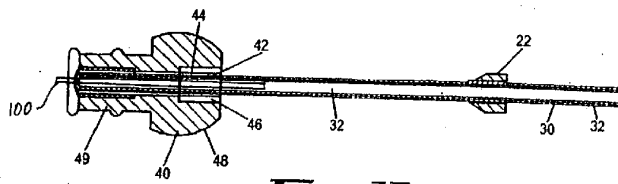


Fig. 3B

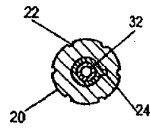


Fig. 3C

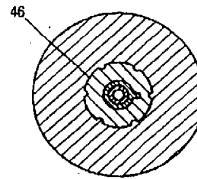
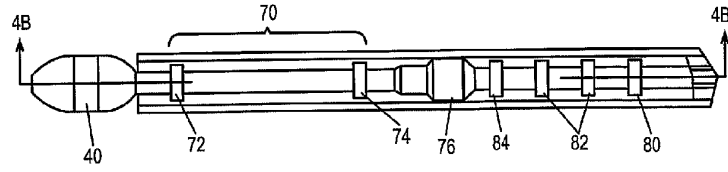
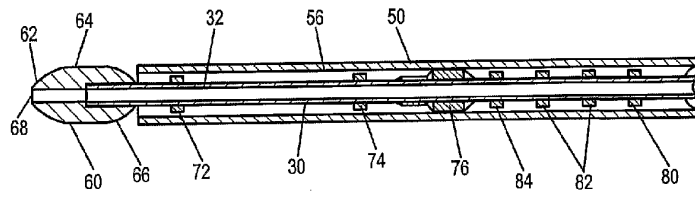


Fig. 3D

3/4



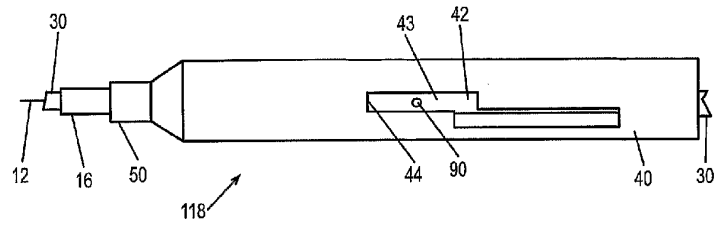
**Fig. 4A**



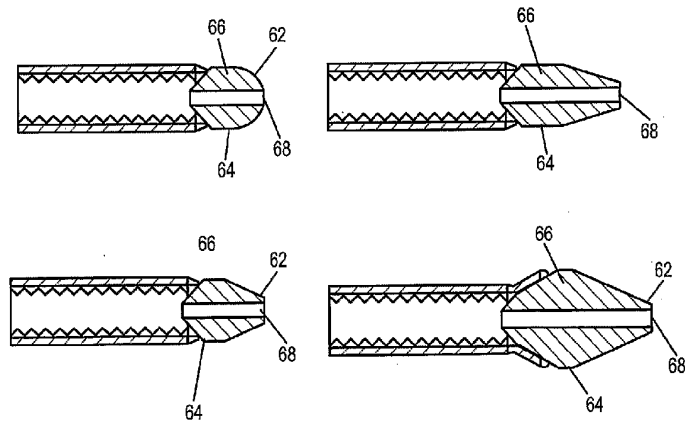
**Fig. 4B**



4/4



*Fig. 5*



*Fig. 6*