ONE-PIECE RETRACTABLE STENT

Inventor: Albert Wong, Carrollton, TX (US)

Correspondence Address:
ALBERT WONG
24 ADAMS STREET
SOMERVILLE, MA 02145 (US)

Appl. No.: 11/439,052

Filed: May 23, 2006

Related U.S. Application Data

Provisional application No. 60/710,825, filed on Aug. 25, 2005.

Publication Classification

Int. Cl. A61F 2/84 (2007.01)
A61F 2/94 (2007.01)

U.S. Cl. 600/227; 623/1.11; 623/1.17

ABSTRACT

An intraluminal medical device having a flowpath therethrough, the device consisting of a one-piece elastic or semi-elastic sheet of material which defines a generally tubular body. The medical device has a collapsed and expanded diameter and is constructed and arranged such that it can exist in two stable states, consisting of the initial collapsed state (12) and the expanded state (10). In conjunction with a retractor device (6), the medical device may be converted between the two stable states within a body lumen as necessary.

provides a 3-D sideways view of the collapsed stent after manufacture
FIG. 1 provides a view of the initial sheet of material and shows how it is curled into a stent.
FIG 2 provides a 3-D view of the fully expanded stent
FIG. 3 provides a 2-D cross sectional view of the configuration the stent is in after it is collapsed in the final stage of the manufacturing process.
FIG 4 provides a 3-D sideways view of the collapsed stent after manufacture.
FIG 5 is a detailed view of the retractor illustrating the twin clamps for delivery and retrieval of the stent.
FIG 6 is a detailed end-on view of the retractor about to collapse the expanded stent and retrieve it.
FIG. 7 shows one possible alternative embodiment for the sheet of material from which the stent is made.
FIG. 8 provides a 3-D view of a stent made from the possible alternative sheet embodiment shown in FIG. 7.
FIG. 9 provides a 2-D cross-sectional view of the state the stent is in after it is collapsed by the retractor.
FIG 10 is a detailed view of the retractor and shows how it can be attached to a catheter.
FIG. 11 shows another possible embodiment of the sheet of material from which the stent is made.
ONE-PIECE RETRACTABLE STENT

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of provisional patent application Ser. No. 60/710,825, filed 2005 Aug. 25 by the present inventor.

FEDERALLY SPONSORED RESEARCH

[0002] Not Applicable

SEQUENCE LISTING OR PROGRAM

[0003] Not Applicable

BACKGROUND OF THE INVENTION

[0004] 1. Field of Invention

[0005] This invention relates to endoprostheses devices adapted for implantation into a body lumen such as, but not limited to, a blood vessel or a bile duct to maintain the patency thereof. More particularly, the present invention relates to a retractable stent.

[0006] 2. Prior Art

[0007] Coronary angioplasty is a medical procedure used to prop open clogged arteries. This is often accomplished by insertion of an intraluminal medical device, for example, a stent, to help keep the artery open. However, current stents, while sufficient in strength to keep clogged arteries open, fail in that they cause inflammation and immune responses that encourage re-blocking of the artery in a condition known as restenosis. On top of inflammation and re-clogging (restenosis) problems, retrieving the implanted stent (usually because of restenosis, and sometimes because of severe inflammatory or immune responses) is a problem. All current stents must be retrieved and replaced sooner or later due to restenosis (the rate of restenosis varies in different people), usually within 10 years. People with severe inflammatory or immune responses often need to have their stent removed within a few months or a year. Doctors have to perform an open heart surgery to retrieve the implanted stent. There are numerous health related issues, risks, and concerns, including death, that can be caused by open heart surgery.

[0008] Biliary stent implantation is a medical procedure used to treat problems associated with blockages in the bile ducts. The procedure involves the implantation of a stent to help keep the passageway open. Current stents used in the bile ducts can cause inflammation and immune responses and also are not easily retrievable, sometimes requiring surgery. Biliary stents often need to be replaced every few months (because they get clogged up); thus, the fact that current stents are not easily retrievable is a major problem as they need to be replaced frequently.

[0009] Stents are also implanted in other structures, such as, but not limited to, peripheral arteries and veins, esophagus, trachea or large bronchi, ureters, and urethra. Any of these medical procedures involves the implantation of a stent to assist in maintaining the patency of the passageway the stent is implanted in. Current stents used in these structures can cause inflammation and immune responses and often are not easily retrievable, sometimes requiring surgery. Stents in some of these structures also need to be replaced relatively frequently, something that presents a major problem associated with current stents since current stents are not easily retrievable once placed.

[0010] Prior art (i.e., current stents) consists of stents in the two existing categories: metallic wire mesh, and biodegradable. Both such categories have flaws. The metallic wire mesh stents cause inflammatory and immune responses that may lead to restenosis, besides causing other localized tissue damage and trauma. The biodegradable stents' only advantage over metallic wire mesh stents is that they degrade and go away after 5-10 years. Otherwise, they behave exactly the same as wire mesh stents: a similar, if not increased, rate of immune responses (especially due to breakdown/degradation products generated during stent degradation), a requirement for surgical intervention if removal becomes necessary, and a similar, if not increased, rate of inflammatory responses (especially due to breakdown/degradation products generated during stent degradation).

[0011] Biodegradable stents were invented to deal with the core problem of metal stents: inflammatory and immune responses eventually lead to restenosis, blocking the duct or vessel the stent originally opened, and requiring retrieval of the stent, which often involves surgery (although other stents can occasionally be retrieved without surgery, retrieving coronary stents in particular always requires open heart surgery). Biodegradable stents attempted to solve this problem by degrading automatically within five to ten years; however, serious immune and inflammatory responses caused by this degradation often occur before the stent is completely degraded, in which case it must be surgically removed; also, the associated memory immune responses associated with the immune responses and inflammation often preclude biodegradable stents from being used more than once in a person (that is, it is often impossible to implant a second biodegradable stent in a person after the first biodegradable stent has degraded or been retrieved).

[0012] The one-piece retractable stent of the present invention belongs to a completely different stent category and is the first and only member of this new category. It is made of a one-piece sheet material (an elastic metallic polymer, for example, is a good candidate). Also, it is not biodegradable. Because it is one-piece (which minimizes damage to the luminal membranes of ducts or vessels the stent is deployed in), and because it is not biodegradable, it prevents, or at least minimizes, inflammation, immune responses, and restenosis. Unlike the stents in both existing categories of stents, the structure of the invention allows it to be collapsed when desired at any time and retrieved easily, without need for surgical intervention (e.g., if deployed in a coronary artery, open heart surgery would not be necessary to retrieve my stent). Existing stents cannot be collapsed due to their design; once expanded/deployed, their many pieces lock into place permanently, making it impossible to collapse the stent, and thus making it impossible to retrieve the stent without open heart surgery in the case of coronary stents, or at least making it quite difficult to retrieve the stent, in the case of other stents. As such, there is no relevant prior art pertaining to the invention.

[0013] The present invention further relates to the one-piece retractable stent in combination with a retractor device.
Various methods may be employed for delivery and implantation of the invention. One method involves the stent being attached to a retractor device, which may be attached to a delivery device, for example, a catheter delivery device, if necessary. Variations of this method may be used without departing from the spirit of the method. Other methods may be used to deliver the stent depending on where the stent needs to be delivered to.

Various methods may be employed for retrieval of the invention. One method involves a retractor device, attached to a delivery device, for example, a catheter delivery device, being delivered to the location of the stent. The retractor then attaches to or exerts force on one or more portions of the stent, and pulls it into the collapsed state. The delivery device is then employed to extract the retractor device and the attached stent. Variations of this method may be used without departing from the spirit of the method.

OBJECTS AND ADVANTAGES

Current stents fall into two broad categories: metallic and bioresorbable. Both metallic and bioresorbable stents are non-retractable and are made up of many interconnected parts, similarly to a metal wire fence. This invention is in a new third category: one-piece (sheet) retractable stent. It consists of a much simpler one-piece design rather than a wire mesh and is simply made of a material (e.g., an elastic metallic polymer) fabricated into a continuous non-porous sheath. Thus, there is no prior art relevant to the invention.

This invention provides much needed improvements over both metallic and bioresorbable stents. It provides retractability, thus never requiring open heart surgery for removal, over both metallic and bioresorbable stents. Also, it provides reduced inflammation and immune responses over both metallic and bioresorbable stents.

To summarize, several advantages of the present invention are:

(a) to allow retractability, solving an important problem associated with both metal and bioresorbable stents. The invention functions similarly to a regular metal stent, but, because of its special one-piece sheet design, it can be retracted with a special retractor in a minor surgical procedure similar to the procedure for implanting the stent (without major surgery, such as open heart surgery in the case of coronary stents) and replaced with a new stent if and when it needs to be replaced with a new one;

(b) to provide a simple, inexpensive, and easily constructed unit that can be manufactured in several standard lengths and diameters, but can also be made to special non-standard specifications easily and cheaply, upon order;

(c) to naturally (due to the smooth one-piece nature of the invention) inhibit the mechanical mechanisms leading to restenosis, leading to a longer functional operating time per stent.

Still further objects and advantages will become apparent from a consideration of the ensuing description and drawings.

SUMMARY

The present invention provides a generally tubular, expandable, retractable intraluminal device having a central longitudinal axis generally referred to as a stent. The stent of the present invention is comprised of a one-piece sheath and, in a collapsed state, has at least some portions which project inward into the central longitudinal axis.

DRAWINGS—FIGURES

A brief description of the invention is hereafter described by non-limiting examples with specific reference being made to the drawings in which the stent is portrayed at various angles.

FIG. 1 provides a view of the initial sheet of material 14 (e.g., a metallic polymer) and shows how it is curled into a fully expanded stent 10.

FIG. 2 provides a 3-D view of the fully expanded stent 10 as it is right after the first step of manufacturing (and also later in the stent’s life when it is deployed in a patient in vivo).

FIG. 3 provides a 2-D cross-sectional view of the configuration the stent is in after it is collapsed in the final stage of the manufacturing process 12.

FIG. 4 provides a 3-D view of the fully collapsed stent after manufacture 12.

FIG. 5 is a detailed view of the retractor 6 illustrating the twin clamps 2 and 4 for delivery and retrieval of the stent.

FIG. 6 is a detailed end-on view of the retractor 6 about to collapse the expanded/deployed stent 10 and retrieve it.

FIG. 7 shows one possible alternative embodiment of the initial sheet of material 16 from which the stent can be made.

FIG. 8 provides a 3-D view of one possible alternative embodiment 18 of the fully expanded stent as it is right after the final step of manufacturing (and also later in the stent’s life when it is deployed in a patient in vivo).

FIG. 9 provides a 2-D cross-sectional view of the stent in the final collapsed state 8, after it is retracted.

FIG. 10 provides a view of a sample catheter delivery device 20 that could be used in conjunction with the retractor 6 to deliver the stent.

FIG. 11 shows another possible alternative embodiment of the initial sheet of material 22 from which the stent can be made.

REFERENCE NUMERALS

2—inner forks of retractor
4—outer forks of retractor
6—retractor
8—stent in final collapsed state
10—fully expanded stent
12—stent in initial collapsed state
14—sheet of material from which stent is made
16—alternative embodiment of sheet of material from which stent is made
While this invention may be embodied in many different forms, there are described in detail herein specific embodiments of the invention. This description is an exemplification of the principles of the invention and is not intended to limit the invention to the particular embodiments illustrated.

Turning now to the figures, a view of the initial sheet of material 14 (e.g., a metallic polymer) that shows how it is curled into a stent 10 is provided by FIG. 1. The dimensions of the initial sheet of material 14 may be altered as necessary to produce stents of different sizes and dimensions.

A 3-D view of the fully expanded stent 10 as it is right after the first step of manufacturing, in this particular embodiment, and also later in the stent’s life when it is deployed in a patient in vivo, is provided in FIG. 2. The manufacturing protocol is only a sample and is not intended to be the sole means by which the stent can be made. Other possible manufacturing protocols may bypass this stage.

FIG. 3 provides a 2-D cross-sectional view of the configuration the stent 12 is in after it is collapsed in the final stage of the manufacturing process. Note that it may be possible to use a manufacturing protocol not stated here to directly manufacture the stent in this configuration 12, bypassing the configuration 10 in FIG. 2 and eliminating the need for a step to collapse the stent.

A detailed view of the retractor 6 in this particular embodiment is provided in FIG. 5, illustrating inner 2 and outer 4 forks/clamps for delivery and retrieval of the stent. Other retractor configurations or geometries may be used without deviating from the intended purpose of the retractor.

Operation—FIGS. 4, 6, 9, 10

A 3-D sideways view of the collapsed stent after manufacture 12, in the preferred embodiment, is provided by FIG. 4.

The sample catheter delivery device 20 shown attached to the retractor 6 in FIG. 10 is intended for illustrative purposes only. Catheter delivery devices useful for delivery of a medical device of the type described herein are well known to those of ordinary skill in the art and as such any suitable delivery catheter may be employed herein. Additionally, in certain applications of the stent, it may not be necessary to use a catheter delivery device.

The stent 12 and the retractor 6 are typically attached to the catheter for delivery to the implantation site where the retractor expands the stent. The stent is now in its fully expanded state 10. The retractor is then disconnected from the stent. The retractor is collapsed and the catheter 20 and retractor 6 are then removed from the body lumen leaving the stent 10 behind.

FIG. 6 is a detailed end-on view of the retractor’s inner 2 and outer 4 forks about to collapse the expanded/deployed stent 10 and retrieve it. Other retractor configurations or geometries may be used without deviating from the intended purpose of the retractor.

A 2-D cross-sectional view of the state the stent is in after it is collapsed by the retractor’s inner 2 and outer 4 forks (this is the final stage of the stent’s life and the stent is now in its final collapsed state 8) is provided by FIG. 9.

The stent may be formed according to any method known in the art including the following sample manufacturing protocol, which has been designed for an average-sized stent made using an elastic metallic polymer. Please note that this invention can be produced for any size and can also be made with materials other than elastic metallic polymers.

1) First, get a rectangular sheet of the elastic metallic polymer 14 (16 mm × 9.42 mm × 50 μm).

2) Then, the long ends of the sheet are sewn together seamlessly to form a cylinder. The stent 10 at this stage looks exactly like a section of a straw/pipe. Refer to FIG. 1. This cylinder is the stent as it is in its expanded form 10. Refer to FIG. 2.

3) Then, the stent is collapsed by three hard, non-deformable rods (e.g., iron rods) parallel to the stent’s length. The three rods are applied at angles of 120 degrees to each other. Care must be taken to avoid the generation of sharp edges at any point in the stent’s structure after collapse. Refer to FIG. 3 and FIG. 4. The purpose of this step to collapse the stent is to make the stent smaller and easier to insert. The stent is now in its initial collapsed state 12.

4) The stent 12 is now ready to be used.

Additional Embodiments

FIG. 7 shows one possible alternative embodiment of the sheet of material 16 from which the stent is made. This sheet 16 has regularly shaped rectangular holes cut into it from both ends at regular intervals to allow blood vessel endothelium to grow onto and along the stent’s luminal surface easier. Please note that this is only one of very many possible additional embodiments of the sheet geometry.

FIG. 8 provides a 3-D view of a stent 18 made from the possible alternative sheet embodiment 16 shown in FIG. 7.

FIG. 11 shows another possible alternative embodiment for the sheet of material 22 from which the stent is made. This sheet 22 has regularly shaped circular holes cut into it at regular spaces to allow blood vessel endothelium to grow onto and along the stent’s luminal surface easier. Please note that this is only one of many possible additional embodiments of the sheet geometry.

Advantages

From the description above, a number of advantages of my retractable stent become evident:

(a) The retractable stent can be easily modified from the preferred embodiment to contain perforations or holes of varying shapes, sizes, and amounts in the stent wall.
The presence of such holes can help to further reduce the incidents and severity of inflammation and immune responses. When deployed in a blood vessel, for example, the presence of such holes would allow for easier and faster growth of endothelial tissue onto and then along the luminal surface of the stent; the presence of endothelial tissue coating the luminal surface of the stent would inhibit inflammatory and immune responses, which can be triggered or enhanced by the detection of foreign material.

(b) The retractable stent can be made easily at any length desired without altering any aspect of its design. This feature makes it possible, in the case of very short clots, clots, or blockages, to avoid using a stent that is longer than necessary; the shorter the stent, the lower the chance of inflammation and immune responses. Many current stents, on the other hand, have a minimum length which they can be made of.

(c) The retractable stent can be made easily at any diameter desired without altering any aspect of its design. This feature makes it possible to use the stent in any duct or vessel desired even if said duct or vessel has a small or non-standard diameter. Many current stents, on the other hand, have a minimum diameter which they can be made at, meaning that they could not be used in vessels or ducts with a diameter less than said minimum diameter.

(d) The retractable stent’s smooth one-piece design prevents injury to the wall of a duct or vessel during expansion/deployment of said stent in said duct or vessel. One of the major triggers of inflammation, immune responses, and restenosis associated with current stents is damage to the wall of a duct or vessel caused by the struts on said current stents during expansion/deployment in said duct or vessel.

CONCLUSIONS, RAMIFICATIONS, AND SCOPE

Accordingly, the reader will see that the retractable stent of this invention allows all of the benefits associated with the use of current stents while eliminating most, if not all, of the drawbacks. It can be deployed as a normal stent but can also be retracted easily when necessary or if desired. It reduces inflammation and immune responses and naturally inhibits restenosis, one of the main problems associated with the use of stents. Its simple one-piece design allows it to be manufactured cheaply and easily for a variety of dimensions, and also allows custom dimensions to be made upon order. Furthermore, the retractable stent of this invention has an additional advantage in that it can be made with holes or perforations of varying shapes, sizes, and amounts to improve its function and lengthen its longevity in some applications, such as when using in a coronary artery; the stent can also be made without holes or perforations if desired.

The above disclosure is intended for illustrative purposes only and is not exhaustive. From the foregoing description, one skilled in the art can readily ascertain the essential characteristics of the invention and, without departing from the spirit and scope thereof, can adapt the invention to various usages and conditions. Changes in the form and substitution of equivalents are contemplated as circumstances may suggest or render expedient, and although specific terms have been employed herein, they are intended in a descriptive sense and not for purposes of limitation. Furthermore, any theories attempting to explain the mechanism of actions have been advanced merely to aid in the understanding of the invention and are not intended as limitations, the purview of the invention being delineated by the following claims and their legal equivalents.

I claim:

1. An intraluminal medical device having a central longitudinal axis having a collapsed state and an expanded state, said intraluminal medical device comprising:
   a one-piece sheath which defines a generally tubular body;
   said intraluminal medical device in a collapsed state having at least some portions which project inward into the central longitudinal axis.

2. The intraluminal medical device of claim 1 wherein said intraluminal medical device is a stent.

3. The intraluminal medical device of claim 2 wherein said intraluminal medical device is comprised of at least one metal, at least one plastic or composites thereof.

4. The intraluminal medical device of claim 2 wherein said intraluminal medical device is elastically expandable.

5. The intraluminal medical device of claim 2 wherein said intraluminal medical device is semi-elastically expandable.

6. The intraluminal medical device of claim 2 wherein said intraluminal medical device is elastically collapsible.

7. The intraluminal medical device of claim 2 wherein said intraluminal medical device is semi-elastically collapsible.

8. The intraluminal medical device of claim 2 wherein said intraluminal medical device is plastically collapsible.

9. The intraluminal medical device of claim 2 wherein said intraluminal medical device is destructively collapsible.

10. The intraluminal medical device of claim 2 wherein said intraluminal medical device is a thin-walled tubular member.

11. A retractor device comprised of one or more connected prongs, forks, or clamps, one or more connected stems, or combinations thereof.

12. The retractor device of claim 11 wherein said retractor device is comprised of at least one metal, one plastic or composites thereof.

13. The intraluminal medical device of claim 2 in combination with the retractor device of claim 11, said intraluminal medical device disposed about a portion of said retractor device.

14. The intraluminal medical device of claim 13, one or more portions of said retractor device capable of exerting force on one or more portions of said intraluminal medical device.

15. The intraluminal medical device of claim 13, one or more portions of said retractor device attached to one or more portions of said intraluminal medical device.

16. The intraluminal medical device of claim 2 wherein there are one or more perforations, holes or openings in the wall of said intraluminal medical device.

17. The intraluminal medical device of claim 2 wherein there are no perforations, holes or openings in the wall of said intraluminal medical device.
18. The intraluminal medical device of claim 2 wherein the length of said intraluminal medical device can be any positive value.

19. The intraluminal medical device of claim 2 wherein the expanded diameter of said intraluminal medical device can be any positive value.

20. The intraluminal medical device of claim 2 wherein the initial collapsed or crimped diameter of said intraluminal medical device can be any positive value.

21. The intraluminal medical device of claim 2 wherein the final collapsed or crimped diameter of said intraluminal medical device can be any positive value.

* * * * *