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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61F 2/06

A1

(11) International Publication Number: WO 99/55257

(43) International Publication Date: 4 November 1999 (04.11.99)

(21) International Application Number: PCT/US99/09383

(22) International Filing Date: 30 April 1999 (30.04.99)

(30) Priority Data:
09/070,476 30 April 1998 (30.04.98) US

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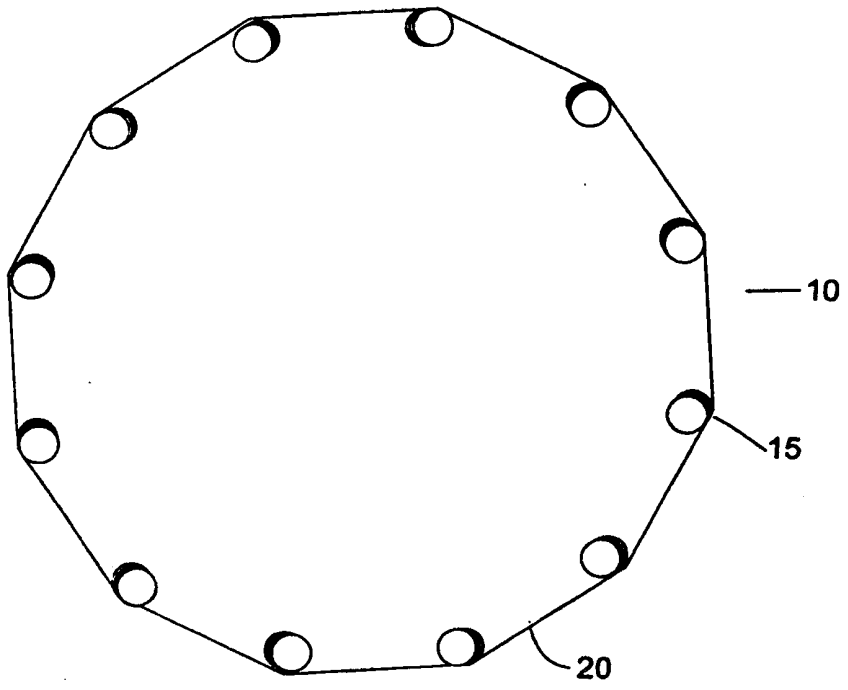
(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: EXPANDABLE SPACE FRAME

(57) Abstract

An expandable space frame (10) is manufactured by linking a plurality of flexible joints (15) through spacing arms (20) to form a closed structure. The spacing arms are sterically offset, linking the bottom of one joint to the top of the next joint in an upwards stepwise fashion, and then reversing the steps downwards. The offset allows the frame to be collapsed with minimal steric hindrance between the centered joints. This lack of steric hindrance permits a very high ratio of the expansion to compression diameters for the frame. The space frame forms the basis for different types of a stent. A series of individual frames are linked to each other to form a luminal stent. Two or more frames are linked to longitudinal struts to form the support structure for a stent. The stent formed from the expandable space frame can be designed to have a number of additional features as set forth herein.



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EXPANDABLE SPACE FRAME

BACKGROUND OF THE INVENTION

In a variety of situations, it is desirable to have a radially stiff framework that can be collapsed to a very small diameter. The ability to expand five to ten-fold or greater has great utility in applications where space is at a premium. One use for an expandable space frame is in the construction of luminal stents, where the term "stent" is generically used to describe structural devices that support living tissues.

Stents are implanted in a body lumen for treating abnormal conditions. For example, these devices have found use in maintaining the patency of collapsing and partially occluded blood vessels, particularly to prevent acute closure and restenosis after a vessel has been enlarged by angioplasty. These devices have also been used to reinforce other body lumens, such as the urinary tract, the bile tract, the intestinal tract, and the tracheobronchial tree.

Conventional stents are cut from a tube or formed from a wire that has been bent back and forth in a zig-zag pattern and wound in a circumferential direction to form one or more loops of a pre-determined circumference. Typically, the stent is radially expandable from a collapsed condition. It is desirable to minimize the diameter of the collapsed stent so that it can be delivered as unobtrusively as possible through the vasculature. Once in position it is expanded to the predetermined size, to support and reinforce the lumen.

The stent is normally inserted in the collapsed condition by a catheter during intraluminal delivery to the repair site. Once properly located, the stent is removed from the catheter and radially expanded until its circumference firmly contacts the interior wall of the lumen. Usually the radial expansion is caused by the dilation of an angioplasty balloon placed axially within the stent. Alternatively, the stent may be made from a shape memory metal, whereby the stent will automatically assume its expanded circumference as its temperature increases upon implantation, or stents can be made that expand through spring action.

An important attribute of the stent is its ability to provide radial support. This capability is a concern not only where the stent is being used to maintain the patency

of the lumen in which it is located, but also where the stent is being used in conjunction with a prosthetic graft to keep the graft open and to hold it at the location at which it is implanted.

The patent literature contains descriptions of many different stent designs. A few of the more recent patents include U.S. Patent no. 5,702,419, "Expandable, Intraluminal Stent"; U.S. Patent no. 5,707,388, "High Hoop Strength Intraluminal Stent"; U.S. Patent no. 5,707,387, Flexible Stent"; and U.S. Patent no. 5,681,345, "Sleeve Carrying Stent"; Palmaz, U.S. Patent no 5,102,417, "Expandable intraluminal graft, and method and apparatus for implanting an expandable intraluminal graft"; and Sigwart, U.S. Patent no. 5,443,500, "Intravascular stent".

Scientific reviews of stent design and function may be found in Wong *et al.* (1996) Catheterization and Cardiovascular Diagnosis **39**:413-419; Sniderman (1996) Progress in Cardiovascular Diseases, vol. XXXIX:141-164. Fontaine and dos Passos (1997) Journal of Vascular and Interventional Radiology **8**:107-111 present an example of pre-clinical analysis for a prototype stent. Hong *et al.* (1997) Coronary Artery Disease **8**:45-48, describe pre-clinical use of a self-expanding nitinol stent.

Features desirable in a stent are reviewed by Palmaz (1992) Cardiovasc. Intervent. Radiol. **15**:279-284. A highly desirable stent would combine a high expansion ratio with radial stiffness and lengthwise flexibility to facilitate insertion and/or conform to curves of the vessel once in place. The present invention provides this and other useful features.

SUMMARY OF THE INVENTION

An expandable space frame linking a plurality of flexible joints, *e.g.* springs; riveted or pinned joints; *etc.*, joined through spacing arms to form a closed structure, *e.g.* circle, ellipse, rectangle, *etc.* is provided. The spacing arms are sterically offset, linking the bottom of one junction to the top of the next junction in an upwards stepwise fashion for a portion of the circle, and then reversing the steps to go down. The offset allows the frame to be collapsed with minimal steric hindrance, which permits a very high ratio of the expansion to compression diameters for the frame. The space frame forms the basis for different types of stents. A series of individual frames are linked to each other to form a stent. Alternatively, two or more frames are

linked to longitudinal struts to form the support structure for a stent. The stents formed from the expandable space frame can be designed to have a number of additional features as set forth herein.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1A shows a top view of a circular space frame with spring junctions, in the expanded configuration. **Figure 1B** shows a detail of the spacing arms and a spring junction in the expanded (anti-parallel) configuration.

Figure 2A shows a top view of a circular space frame in a semi-compressed configuration, and **Figure 2B** is the space frame in a fully compressed configuration. **Figure 2C** shows a the compressed configuration of a space frame with four changes in offset. **Figure 2D** is a detail of the spacing arms and a spring in the compressed (parallel) configuration.

Figure 3A is a view of the space frame drawn to show the steric offset of the spacing arms between the spring junctions. **Figure 3B** is a top view showing the point at which the steric offset changes direction, and the coil of the springs is changed; **Figure 3C** shows the same object in a side view.

Figure 4A shows a top view of a frame using pinned joints. **Figure 4B** is a detail of a pinned joint. **Figure 4C** is a detail of a riveted joint.

Figure 5A is a detailed view of a sleeve attachment between two spacing arms, allowing for adjustment in the diameter of the frame, with a cutaway showing the overlapping position of the two spacing arms. **Figure 5B** is a detailed view of a compression spring attachment between spacing arms, with a sleeve covering.

Figure 6A shows a locking sleeve for a spring junction. The position of the spring is shown in **Figure 6B** and **Figure 6C**. **Figure 6D** is a top view of the locking mechanism, showing the angle at which the arms are locked.

Figure 7A and **Figure 7B** show a locking mechanism for a pinned joint in the parallel and anti-parallel configuration, respectively.

Figure 8A, **Figure 8B** and **Figure 8C** show linked stents constructed of multiple frames.

Figure 9A is a side view of a strutted stent formed from space frames linked by longitudinal struts. **Figure 9B** shows the strutted stent covered with a flexible sock.

Figure 10A is a side view of the flexible arm embodiment in an elongated configuration. **Figure 10B** is a side view of the flexible arm embodiment is a contracted position.

DETAILED DESCRIPTION OF THE EMBODIMENTS

An expandable space frame is provided, comprising a plurality of flexible joints, *e.g.* springs; riveted or pinned joints; *etc.*, joined through spacing arms to form a closed structure, *e.g.* circle, ellipse, rectangle, *etc.* **Figure 1A** illustrates a circular frame having spring joints. The frame is shown with all the spring joints on the inside of the frame. An alternative configuration has all the spring joints outside of the frame. Where the spring joints are partially outside and partially inside, the coil direction of the springs will change at the points where the inside/outside orientation changes. The frame is also shown with arms of equal length, although for some purposes it will be desirable to vary the length of the arms.

The frame **10** is comprised of spacing arms **20** and spring joints **15**. Each joint has two spacing arms, one at the top of the joint **20** and one at the bottom **25**, which extend from roughly the same point on the spring. The spacing arms form the linkage between joints, linking the bottom of one spring to the top of the next spring in a stepwise fashion. When linked, the spacing arms form a closed structure.

Depending on whether the frame is in the collapsed or expanded configuration, the two spacing arms are differently oriented with respect to the attached flexible joint. The arms can be in an expanded configuration where the two

arms face outward from the joint in a roughly antiparallel orientation, shown in **Figure 1B**, where upper arm **20** is antiparallel to the lower arm **25**. It will be understood by one of skill in the art that the top arm of one joint is the bottom arm of the adjoining joint. The designation as "upper" or "lower" is arbitrary, and merely used to clarify the geometric relationships in the frame. In a compressed configuration, the two arms face outward from the joint in a roughly parallel orientation, shown in **Figure 2D**. The joint **15** is tightened so that the upper arm **20** is parallel to the lower arm **25**.

In one embodiment of the invention, as shown in **Figures 10A** and **10B**, the arms **25** are flexible, and can contract and elongate to provide variable spacing between the joints. The arms can be made to elongate from a contracted position by spring action, memory alloy, etc., or through the use of a balloon catheter.

In the expanded state, shown in **Figure 1A**, all of the joints are on the perimeter of the frame, with the spacing arms forming the circumference of the frame. In a compressed configuration **35**, the joints alternate: a joint with both arms facing inwards (toward the center of the circle) with a joint with both arms facing outwards (towards the perimeter of the circle). **Figures 2A** and **2B** show the compression of the frame, with **Figure 2A** partially compressed and **Figure 2B** in the fully compressed configuration. Alternating joints **15** are drawn to the center of the frame. In the compressed configuration half the joints are located in the centers **30** and **31**, and half are on the perimeter. Inner joints will not all come together. As shown in **Figure 2B**, there will be at least two joints that are side by side, **30** and **31**, for a frame that has two changes in offset direction (as described below). If there are four changes of offset direction, shown in **Figure 2C** then 4 joints, **30**, **31**, **32**, and **33** will meet in the center.

Figure 3 shows a side view of the space frame **10** to illustrate the geometry of the spacing arms. The spacing arms **20** are sterically offset, linking the bottom of one joint **15** to the top of the next joint in a stepwise fashion, and then reversing the steps with a change in offset direction. The "up staircases" may comprise half of the frame, with a "down staircases" comprising the other half of the frame. Alternatively, one quarter of the frame can be an "up staircase", followed by one quarter as a "down staircase"; and so on. The minimum steric hindrance will occur with an "up

staircase" for one half the frame and a "down staircase" for the other half, as drawn in the figure.

The offset direction for a half circle staircase changes at two points, **40** and **45**. Where the joints are spring joints, the direction of the spring winding changes at these points. **Figure 3B** and **Figure 3C** provide a side and top view at the change in offset direction **40**, illustrating the change in the winding of the springs **15**.

The offset allows the frame to be in a collapsed configuration with minimal steric hindrance between the centered joints. This lack of steric hindrance permits a very high ratio of the expansion to compression diameters for the frame. The degree of expansion will be at least 3-fold, usually at least about 5-fold, and preferably at least about 10-fold, or higher.

The joints between the spacer arms may be any joining mechanism that is flexible enough to accommodate the collapsed and expanded configurations. The joint may be a spring, as shown in **Figures 1** and **2**. The use of springs allow the frame to be self-expanding: the frame is held in a compressed state until expansion is desirable, then the hold is released and the frame springs to the expanded configuration. Alternatively, pinned or riveted joints may be used.

Figures 4A, 4B and 4C illustrate a riveted and pinned joint. The space frame **10** is comprised of flexible joints **16** and spacer arms **21**. Each joint has two spacing arms, one at the top **21** and one at the bottom **26**. The spacing arms form the linkage between joints. The joint eyelet **17** and spacing arm **21** may be formed as a single structure, **19**. The eyelets **17** of two arms are aligned and held in place with a fastening means, *e.g.* a pin **18** or a rivet **22**.

The number of joints in a frame can be varied according to the size and the degree of expansion that is desired for a particular use, although an even number of joints will generally be used. The compressed radius (r_{col}) of the frame, expanded radius (r_{exp}) of the frame, number of joints (n) and distance between two adjoining joints (L_a) have a straightforward geometric relationship, and can be used to calculate the degree of expansion ($E = (r_{exp} / r_{col})$) that will be achieved with a given number of joints. L_a is roughly equal to the spacing arm length(s). In frames having an adjustable spacing arm length, that length should also be accounted for in the calculation.

In the case where the spacing arms are a continuous filament, the radius of the compressed frame is equal to L_a plus the radius of the two joints, hence $r_{col} = L_a + 2\ r_j$. When the frame is expanded, the circumference (C_e) will be equal to the number of joints multiplied by distance between joints, therefore $r_{exp} = n\ L_a/2\pi$. The degree of expansion can therefore be calculated as

$$E = \frac{nL_a}{2\pi\ (L_a + 2r_j)}$$

To determine the appropriate geometry for a frame, one need only know the desired compressed radius and spacing arm length, degree of expansion, and joint radius to determine the number of joints that are required.

In some embodiments of the invention, the spacing arms are connected through an adjustable sleeve, as shown in **Figure 5A**. To determine the degree of expansion in a frame where the distance between two joints can be adjusted in this way, the calculation must take into account the sleeve length, (w). If the assumption is made that all spacing arms are linked by a sleeve, and that E reflects the maximum expansion, then E is calculated as follows:

$$E = \frac{n\ (2\ L_a - w)}{2\pi\ (L_a + 2r_j)}$$

In some embodiments of the invention, the spacing arms are connected through a compression spring encased in a sleeve, as shown in **Figure 5B**. To determine the degree of expansion in a frame where there is a spring connection, the calculation must account for the spring length when compressed (w_s), and the fully expanded length of the spring (w), assuming that the fully expanded spring length is equal to the length of the sleeve. Again making the assumption that all spacing arms are connected in this way, and that E reflects the maximum expansion, then E is calculated as follows:

$$E = \frac{n\ [L_a + (w - w_s)]}{2\pi\ (L_a + 2r_j)}$$

The size of the frame can be widely varied, from a collapsed radius of less than 1 mm to a radius of several feet or more. As an example, for use in a stent, (making the assumption for simplicity that the spacing arms are a continuous filament) one might want a compressed radius of 1 mm, in order to easily

accommodate delivery to the site of placement. The expanded radius, 5 mm is determined by the size of the vessel to be repaired. The frame will therefore have an expansion (E) of 5, using 40 spring joints with a radius of 0.1 mm, and spacing arms that are 0.8 mm in length.

The spacing arms between two springs can be joined by a variety of means. In one embodiment of the invention, the two arms are continuous, joined by any convenient method, *e.g.* formed from a continuous filament material, welded together, glued, *etc.* to provide a single spacing element between two joints, as shown in **Figure 1A**.

Alternatively, the connection between spacing arms can be exploited to provide additional features. The arms may be joined by encasing two overlapping arms in a sleeve, as shown in **Figure 5A**. The upper spacing arm **20** of a joint **15** overlaps with the lower spacing arm **25** of an adjoining joint **15**. At the point of overlap, the two arms are encased in a sleeve **50**. The spacing arms extend through the sleeve **50** and have a "stop" **51** at the end to prevent them from sliding out of the sleeve. The sleeve comprises a close-fitting member that holds the two arms in position, but allows for sliding of the arms past each other in order to further expand or contract the frame circumference. The sleeve is usually tubular, but the cross-sectional geometry will be designed to accommodate the particular spacing arms, and may be rectangular, circular, oval, *etc.*

The sleeve allows a precise adjustment of frame size prior to its use and placement, by moving the arms in the sleeve to achieve the desired size. In addition, after the space frame is expanded, the diameter can be adjusted again, by moving the arms relative to each other within the sleeve. The adjustment may be from about 1 to 70% of the circumference of the frame. The sleeve adjustment mechanism may be present on one or more spacing arm connections for a frame, up to and including all of the spacing arms. In addition to providing a means of adjusting the expansion, the overlapping arm connection may serve other purposes. It can be used to increase the expansion ratio, E. It can also be used to encase the spacing arm joint so as to decrease turbulent flow, to increase biocompatibility, strengthen the frame, protect the spacing arms from damage due to external forces, *etc.*

The sleeve will usually extend from at least about 30% of the spacing arm length, up to as much as about 95% of the spacing arm length, usually not more than about 90% of the spacing arm length. The sleeve may be constructed of any biocompatible metal; plastic; fabric; film, *e.g.* ePTFE, dacron, *etc.* The sleeve may be optionally coated to decrease thrombogenicity, *e.g.* with heparin, and increase biocompatibility. For example, the overlap between two spacing arms may be wrapped with a sheet of metal or fabric which is secured along its length by glue, welding, *etc.*

Shown in **Figure 5B**, the spacing arms **20** and **25** can be joined through a compression spring **55**, to provide flexibility in the frame. Preferably, a sleeve **60** is used to encase the springs. The sleeve is similar in design to the sleeve **50**, but may be looser fitting, as it is not necessary to hold the arms in place. The spring spacer can be used where a continuous frame structure is desired. It can be used as a parameter to affect the circumferential stiffness of the frame, *i.e.* the stiffness of the compression springs may be chosen to tailor the circumferential stiffness of the frame. The materials for the sleeve are typically as those described above. The length of the sleeve will usually be at least about the desired expansion length of the spring, and may extend up to the full length of the distance between the two joints.

The spacing arms may be locked in position with a sleeve, which will ensure that the spacing arms are kept at a fixed angle apart. **Figures 6A** to **6D** illustrate a locking mechanism **64** for a spring joint. **Figure 6A** shows a sleeve, **65**, which encases the spring **15**. The sleeve **65** is a tubular member, with a cross-sectional geometry suitable for the shape of the spring, *e.g.* circular, oval, rectangular, *etc.* As shown in the drawing it is open at the top **66** and bottom **67**, although the bottom **67** may be closed, as the bottom of the spring is always locked in place. Attached to the sleeve are supports **70** and **75** for the spacing arms. The supports **70** and **75** are essentially in the form of a channel, which is open along its length to form a continuous opening with the sleeve **66** and **67**, respectively.

Figure 6B is a side view that illustrates when the spring is in a parallel configuration (refer to **Figure 2C**), the upper arm of the spring **20** rests on the top of the sleeve **65**. The spring is stretched inside the sleeve, and the bottom arm of the spring **25** is fixed inside the bottom support **75**. **Figure 6C** shows that when the

spring is moved to an antiparallel configuration (refer to **Figure 1B**) the upper arm **20** is fixed inside the top support **70** and the bottom arm **25** is fixed inside the bottom support **75**. The angle at which the arms are fixed, θ, (shown in **Figure 6D**) may be any angle, usually not less than about 90° and not more than 300°, more usually not less than about 180° and not more than about 270°.

The locking mechanism **64** will closely fit around the spring. It will typically be of a stiff material, which will not be deformed by the tension of the spring. Suitable materials include any biocompatible metal or plastic.

A locking mechanism for a pinned or riveted joint is shown in **Figure 7A** and **Figure 7B**. The mechanism comprises a fastening means **36** and **37**, *e.g.* rivets or pins; a shaft **27** and an extensional spring **28**. The shaft has cut-outs at the top **38** and the bottom **39**. The upper spacing arm **21** always extends through the top cut-out **38** and is always fixed in place. The upper fastening means **36** always rests on the top of the shaft **27**. When the frame is in a compressed configuration, shown in **Figure 7A**, with the arms oriented to be parallel, the spring **28** is extended to allow the lower arm **26** to rest on the lip of the shaft **41**. The lower fastening means **37** rests on the bottom of the eyelet of the lower arm **26**. When the frame is in an expanded configuration, shown in **Figure 7B**, with the arms oriented to be anti-parallel, the spring **28** is less extended because it has pulled the lower arm **26** into the bottom cut-out **39**. The lower fastening means **37** now rests on the bottom of the shaft **27**, closing off the bottom of the shaft **27**.

The basic space frame finds particular utility in the manufacture of stents. A series of individual frames are linked to each other to form a linked stent, as shown in **Figure 8A, Figure 8B** and **Figure 8C**. Two or more frames are linked to longitudinal struts to form the support structure for a strutted stent, shown in **Figure 9**. The stents formed from the expandable space frame can be designed to have a number of additional features.

Other utilities for the subject frame include astronautics. Spacecraft or satellites often employ expandable structures because storage space during launch is limited. The expandable structures used in space could be as small as several centimeters and length, to as large as several meters in diameter and length. The frame and stent-like devices are useful to repair piping in construction and/or

machinery that is difficult to access. The repair method is analogous to surgical techniques, *i.e.* the device in compressed in diameter and snaked into the proper position, at which point it is deployed. The device could also be used for tent construction, *e.g.* for military or recreational purposes, where it is desirable to use minimal space when packed.

Composition of the Frame

In its simplest form, the space frame is comprised of flexible joints and spacing arms. The flexible joint may be a spring, or other joints as previously described. The coils of a spring and the spacing arms are typically formed from wire or filament, where filament may encompass any suitable material. The entire frame can be formed from a single filament, if desired, or the joints and spacing arms may be separately formed and attached by any suitable method as known in the art. Filaments may have any cross-sectional geometry, *e.g.* square, round oval, triangular, *etc.* The springs and arms may be made of the same or different material, and combinations of materials may be used, *e.g.* alternating springs may be formed from different materials. The arms may also be variable in length, or may be of equal lengths. Where the flexible joints are pinned or riveted joints, the spacing arm and eyelet may be a single molded piece, or separate molded pieces which are then glued, welded, *etc.*

For use in stents, the frame will be formed from biologically compatible materials. Biologically compatible metals include stainless steel, titanium, tantalum, gold, platinum, copper and the like, as well as alloys of these metals. Low shape memory plastic may also be used. Alternatively the filament is formed from a shape-memory plastic or alloy, such as nitinol, which automatically transforms from one shape to another as its temperature passes through a critical point.

Diameter of the filament or formed pieces will vary widely depending on the use of the frame. For the manufacture of stents, a filament will range from about 0.05 mm to 0.15 mm in diameter for stents in relatively small coronary arteries, to as large as about 0.5 mm diameter for stents used in much larger abdominal aorta. Stents for use in larger vessels, *e.g.* trachea, may use filaments of a larger diameter.

The cross-section of a filament need not be constant along its entire length, but may include portions having a larger or smaller cross-section as desired.

Springs of varying sizes are commercially available. Each spring will have at least one coil, usually multiple coils. The number of coils will determine both the degree of offset in the frame, and the stiffness of the spring. The stiffness of the spring will vary with the specific use of the frame. By selecting the appropriate material and spring stiffness, the overall radial stiffness of the frame can be tailored to the desired use.

The radius of the spring will also vary with the desired use of the frame. For use in coronary stents, the radius will usually be at least about 1.5 mm, and may be as large as 15 mm. The height of the spring, *i.e.* the height of the stacked coils, will range from 0.10 mm to 1 mm for coronary stents.

Where the spacing arms or springs are encased in a sleeve, the sleeve will typically be formed from a sheet or tube of a material that is compatible with the filaments used in the rest of the frame, as previously discussed.

Stent Design

As discussed above, an important use for the space frame is in the manufacture of stents for the support of biological tissues *in situ*. Stents are commonly used to open blood vessels, *e.g.* clearing obstructions, and to repair damage to vascular tissues, *e.g.* arteries and veins. Two different types of stent design may utilize the space frame: a linked stent and a strutted stent. The stents are used conventionally, for preventing restenosis or other narrowing of vessels, to provide support for the vessel at the site of an aneurysm or other weakening of the vessel wall. The use of stents for the support of blood vessels is well known in the art and need not be further elaborated here. A modification of stents where there is a flexible cover attached to the stent frame is commonly referred to as stent graft. The purpose of stent grafts is to seal off vascular abnormalities, such as aneurisms.

In addition to blood vessels, other vessels of the body may be repaired with a stent, including the trachea for breathing disorders, renal and urethral tubules, fallopian tubes for the treatment of infertility, eustachian tubes for the treatment of chronic ear infection and other hearing disorders, large and small intestines, etc.

The stent design is not limited to any particular body tissue, but will be manufactured with a size, expansion, and radial stiffness suitable for the different purposes.

The recipient for the stent may be any mammalian species, including canines; felines; equines; bovines; ovines; *etc.* and primates, particularly humans. Animal models, particularly small mammals, *e.g.* murine, lagomorpha, *etc.* are of interest for experimental investigations.

The stents are useful for any vascular surgery, such as may be used in any situation in which the flow of blood through a vessel has been compromised. There are a variety of conditions where there is restricted blood flow through that vessel. Occlusive vascular conditions of interest include atherosclerosis, graft coronary vascular disease after transplantation, vein graft stenosis, peri-anastomatic prosthetic graft stenosis, restenosis after angioplasty, coronary artery disease, peripheral vascular disease or other forms of occlusive arterial disease, and the like.

Any convenient method for the placement of the stent may be used. As known in the art, a stent is inserted into a catheter for delivery in a non-expended condition. In one embodiment of the invention, wires **200** and **201** are threaded through the centered springs **30** and **31**, as shown in **Figure 2B**, in order to hold the frame in the compressed form. The catheter is used to thread the stent through the vasculature, to the site for placement. The stent is then pushed or otherwise maintained in position while the catheter is withdrawn. When a holding wire is used, the wire is then removed to allow expansion of the frame(s).

Where spring joints are used, in the initial placement of the stent it will self-expand to a pre-determined diameter. A frame formed from pinned or riveted joints will be expanded by balloon catheter, as is well-known in the art.

In some cases, it may be desirable for the stent to continue to expand after the insertion procedure is performed. The stent configuration with an adjustable diameter, utilizing a sleeve to hold overlapping spacing arms, addresses this problem. A balloon catheter may be positioned inside the stent *in situ* after the original placement, and used to further expand the diameter. If compression springs are used to link the spacing arms, then the stent will continue to self-expand *in situ* as much as the vessel will allow, or until it reaches the maximum diameter.

An optional feature for stents or stent grafts is the addition of "barbs" or needles facing outward from the frame, to anchor the stent in place. Barbs may be attached to the spacing arms, sleeves, or springs. The barbs will be of sufficient length to penetrate the walls of the vessel, but will not be so long that they protrude out through the vessel outer wall. The number of barbs is variable, but when present will usually be at least two, on opposite sides of the frame.

Stents will generally have an overall length of from about 2mm to about 200 mm. Stents, such as may be used to prevent narrowing of blood vessels, are usually from about 2 to 100 mm in length. Stent grafts, such as may be used to repair an aneurysm, are generally longer, and will usually range from about 50 to 200 mm in length.

The linked stent is formed by linking two or more space frames, as shown in **Figures 8A** to **8C**. A frame **10** is joined to a second frame **10** through a flexible linkage means. A plurality of frames may be linked in this manner. The number of frames to be linked is determined by length of vessel wall to be repaired. The linkages can be one or two flexible struts located on the coil, on the spacing arms, or on the sleeves that join the spacing arms. Alternatively, the linkage can be a flexible membrane that links the spacing arms. The struts or membranes can be of any desired flexibility, and may even be very rigid, depending on the application. For stents and stent-grafts, a high degree of flexibility is desirable.

For stents, the length of space to be repaired may be between about 2 mm and 200 mm. This would require from between about 3 to 300 linked frames, depending on the height of the joints.

Figure 8A shows a linked stent **101** formed by joining two frames **10** linked through two struts **102** connected at the spring joints **15**. The struts are joined to the frames by any convenient method, *e.g.* glue, welding, *etc.* The struts may be formed of any biocompatible metal or plastic that is compatible with the material used in the frames. The struts in such an embodiment are typically short, and will be closely positioned on the frame perimeter, as shown in the drawing. The struts are typically at least about 0.1 mm, usually at least about 0.5 mm, and not more than about 5 mm, usually not more than about 2 mm. The struts do not necessarily have to be the same length throughout the linked structure.

Figure 8B shows an alternative linked stent **103** formed by joining two frames **10** with a flexible sleeve **105** that fits over two frames. The figure has omitted details of the frame, and is drawn with exaggerated diameter for clarity.

The linked stents in both **Figure 8A** and **Figure 8B** will frequently join the "top" of a frame with the "bottom" of a second frame, and so on with a third, fourth, *etc.* frame. However, to achieve maximum flexibility in all directions along the length of the stent, a slightly different configuration is required, as shown in **Figure 8C**.

Figure 8C shows a flexible linked stent formed of dimer frames, such as **101** or **103** in **Figures 8A** and **8B**. For convenience, the dimer linkage is shown **105** as a single element. The next element **106** is rotated 90 degrees about the z-axis and then linked **107** to the first element **105**. The following element **108** is rotated 90 degrees about the z-axis again and linked **109** to the previous element **106**.

For both the linked stent and the strutted stent, the orientation of each frame along the length of the structure can be completely independent of the other frames. However, frames that are adjacent along the length of the structure will most likely be either "in-sync" (*in phase*), completely "out-of-sync" (*180 degrees out of phase*), or half-way between the two (*90 degrees out of phase*). As an example of *in phase*, the bottom of a "down staircase" of one frame is linked to the bottom of a "down-staircase" of the adjacent frame. An example of *180 degrees out of phase* would link the bottom of a "down-staircase" to the top of an "up-staircase" of an adjacent frame. A *90 degrees out of phase* would link the bottom of a "down-staircase" to the middle of either an "up- or down-staircase" of the adjacent frame.

Most conventional stents undergo longitudinal shortening when there is an increase in diameter, creating a problem of movement against the vessel wall. It is therefore desirable to minimize longitudinal shortening, both to prevent tissue damage *in situ*, and to improve deployment accuracy. The subject design addresses this problem by having a constant longitudinal length when the strutted stent is expanded in diameter.

A strutted stent **110** is shown in **Figure 9A**. Two or more space frames **10** are linked by longitudinal struts **95**. The struts can be attached through the coils of the springs or can be welded to the spacing arms or to the sleeves that join the spacing arms. They can be attached with a fastener, or they can be welded, glued, *etc.* The

struts may be any flexible biocompatible material, *e.g.* plastics, metals, *etc.* The stiffness of the strut is an important consideration, as it should be flexible enough to be placed in curved vessels, as is typical for arteries and veins.

For use in a strutted structure to be used as a stent or stent-graft, the length of a strut will usually range from about 2 to 200 mm. The strut length will be partly determined by the number of frames placed along the length of the structure. There will usually be at least 2 frames, and not more than about 10 frames. The number of struts employed will depend on the desired stiffness of the stent, but generally will have at least three to four struts.

The stent, particularly a strutted stent, may be covered with a "sock", or graft, of flexible material, as known in the art. **Figure 9B** shows a strutted stent **110** with a cut-away view of a flexible sock **96**. The sock may be completely on the inside of the frame; completely outside the frame; or woven in between the struts. Conveniently, the sock is attached with stitches or glue. The sock forms a synthetic vessel, where the vessel is a tubular member usually having a substantially uniform bore. Suitable materials for the vessel include, for example, expanded polytetrafluoroethylene (e-PTFE) and dacron. High porosity ePTFE may be used for some purposes, where the slit-like fissures in the vessel well are in the range of 90 μm in size. For vascular repair, the vessel will generally be at least about 1 mm in internal diameter, more usually at least about 15 to 25 mm in diameter, and not more than about 50 mm in diameter.

To reduce the thrombogenicity of the graft, the vessel may be sodded or seeded with endothelial cells. Sodding procedures place the cells directly onto the polymeric internal surface of the vessel as well as into the interstices of the vessel, generally under mild pressure. For example, one termini of the vessel may be clamped, and the cells injected with a syringe through the open end. The vessel is porous to water, and so the media is forced through the interstices of the wall, while the cells are retained.

Seeding procedures mix the cells with blood or plasma, and then add to the vessel during the pre-clotting period. There are several versions of the technique known as seeding. The synthetic grafts can be coated with collagen or fibronectin prior to the addition of endothelial cells into the lumen. The synthetic graft is then

incubated *in vitro* with rotation to allow the binding of the endothelial cells to the luminal surface. After several hours or days culture, the graft can be implanted. Alternatively, autologous blood can be forced under pressure through the interstices of the synthetic graft to allow retention of blood cells and protein onto and into the graft prior to addition of the endothelial cells (either passively are actively under pressure). A third alternative is to mix the endothelial cells with the blood prior to the application onto and into the graft.

Endothelial cells may be genetically modified to express factors that encourage the growth of endothelial cells, *e.g.* VEGF; PlGF; TGF-β1; aFGF and bFGF; and hepatocyte growth factor; or a protein that inhibits the growth of intimal cells, for example, inducible nitric oxide synthase (iNOS) or endothelial cell nitric oxide synthase (ecNOS). Proteins that inhibit thrombosis, *e.g.* tissue plasminogen activator (tPA), urokinase, and streptokinase, are also of interest.

Alternatively, the stent may include a reservoir of biologically active materials, *e.g.* antibiotics, anti-thrombogenic factors, growth factors, *etc.* Such a reservoir may be a coating on the stent filaments, embedded in plastics or the graft, deposited as a gel inside the spring coils, *etc.* Often stent grafts are impregnated with biocompatible substances are coated with heparin or hydrogel.

It is contemplated that a kit may be provided for the use of the stent in medical procedures. Such a kit may include two or more of the following: a stent, optionally wired in a compressed configuration, a sock for a stent-graft, and a catheter for insertion of the stent. The compressed stent may be pre-loaded into the catheter for ease of use.

It is evident that the subject invention provides for a frame that allows a high degree of expansion from a compressed configuration, while maintaining flexibility and conformability. The frame forms the basis of a number of structures having utility in medical and other applications.

All publications and patent applications cited in this specification are herein incorporated by reference as if each individual publication or patent application were specifically and individually indicated to be incorporated by reference.

Although the foregoing invention has been described in some detail by way of illustration and example for purposes of clarity of understanding, it will be readily apparent to those of ordinary skill in the art in light of the teachings of this invention that certain changes and modifications may be made thereto without departing from the spirit or scope of the appended claims. The examples are put forth so as to provide those of ordinary skill in the art with a complete disclosure and description of how to make and use the subject invention, and are not intended to limit the scope of what is regarded as the invention.

WHAT IS CLAIMED IS:

1. An expandable space frame, comprising:

a plurality of flexible joints linked by offset spacing arms; and wherein said space frame is compressible by moving alternating flexible joints to the center of the frame; wherein the compression achieves a more than three-fold decrease in diameter.

2. An expandable space frame according to Claim 1, wherein said flexible joints are torsion spring joints.

3. An expandable space frame according to Claim 2, wherein said frame comprises two changes in offset direction, and wherein the coil winding of said torsion springs is changed at said changes in offset direction.

4. An expandable space frame according to Claim 3, wherein said frame is a circular frame.

5. An expandable space frame according to Claim 3, wherein said space frame is in the compressed configuration and further comprising wires threaded through the centered torsion springs.

6. An expandable space frame according to Claim 3, wherein said torsion springs are enclosed by a locking mechanism.

7. An expandable space frame according to Claim 1, wherein said flexible joints are pinned or riveted joints.

8. An expandable space frame according to Claim 1, wherein said offset spacing arms between two flexible joints are continuous.

9. An expandable space frame according to Claim 1, wherein at least one pair of said offset spacing arms between two adjoining joints are overlapping and

encased in a sleeve, said overlap being adjustable to provide for variable spacing between adjoining joints.

10. An expandable space frame according to Claim 9, wherein all of said offset spacing arms in said frame are overlapping and encased in a sleeve.

11. An expandable space frame according to Claim 1, wherein at least one pair of said offset spacing arms between two adjoining joints are linked by a compression spring and encased in a sleeve.

12. An expandable space frame according to Claim 11, wherein all of said offset spacing arms in said frame are linked by a compression spring and encased in a sleeve.

13. An expandable space frame according to Claim 1, wherein said number of joints is at least about 64, and said compression of diameter is at least ten-fold.

14. An expandable space frame according to Claim 3, wherein said compressed diameter is less than about 5 mm.

15. A linked stent, comprising:

at least two expandable space frames, each space frame comprising: a plurality of flexible joints linked by offset spacing arms; and wherein said space frame is compressible by moving alternating flexible joints to the center of the frame; wherein the compression achieves a more than three-fold decrease in diameter;

said expandable space frames being linked by a flexible connection.

16. A linked stent according to Claim 15, wherein said flexible connection is a sleeve.

17. A linked stent according to Claim 15, wherein said flexible connection is one or more struts.

18. A linked stent according to Claim 15, wherein said flexible joints are torsion spring joints.

19. A linked stent according to Claim 18, wherein each of said frames comprises two changes in offset direction, and wherein the coil winding of said torsion springs is changed at said changes in offset direction.

20. A linked stent according to Claim 18, wherein said flexible connection links said space frame at said changes in offset direction.

21. A linked stent according to Claim 18, wherein said space frame is in the compressed configuration and further comprising wires threaded through the centered torsion springs.

22. A linked stent according to Claim 17, wherein said torsion springs are enclosed by a locking mechanism.

23. A linked stent according to Claim 15, wherein said flexible joints are pinned or riveted joints.

24. A linked stent according to Claim 23, wherein said flexible joints are enclosed in a locking mechanism.

25. A linked stent according to Claim 15, wherein said offset spacing arms between two flexible joints are continuous.

26. A linked stent according to Claim 15, wherein at least one pair of said offset spacing arms between two adjoining springs are overlapping and encased in a sleeve, said overlap being adjustable to provide for variable spacing between adjoining joints.

27. A linked stent according to Claim 26, wherein all of said offset spacing arms in said frame are overlapping and encased in a sleeve.

28. A linked stent according to Claim 15, wherein at least one pair of said offset spacing arms between two adjoining joints are linked by a compression spring and encased in a sleeve.

29. A linked stent according to Claim 28, wherein all of said offset spacing arms in said frame are linked by a compression spring and encased in a sleeve.

30. A linked stent according to Claim 15, wherein said number of joints is at least about 64, and said compression of diameter is at least ten-fold.

31. A linked stent according to Claim 15, wherein said compressed diameter is less than about 5 mm.

32. A strutted stent, comprising:

at least two expandable space frames, each space frame comprising: a plurality of flexible joints linked by offset spacing arms; and wherein said space frame is compressible by moving alternating flexible joints to the center of the frame; wherein the compression achieves a more than three-fold decrease in diameter;

said expandable space frames being linked by two or more longitudinal struts.

33. A strutted stent according to Claim 32, wherein said longitudinal struts are about 2 to 200 mm in length.

34. A strutted stent according to Claim 32, wherein said flexible joints are torsion spring joints.

35. A strutted stent according to Claim 34, wherein each of said frames comprises two changes in offset direction, and wherein the coil winding of said torsion springs is changed at said changes in offset direction.

36. A strutted stent according to Claim 35, in the compressed configuration and further comprising wires threaded through the centered torsion springs.

37. A strutted stent according to Claim 34, wherein said torsion springs are enclosed by a locking mechanism.

38. A strutted stent according to Claim 32, wherein said flexible joints are pinned or riveted joints.

39. A strutted stent according to Claim 38, wherein said flexible joints are enclosed in a locking mechanism.

40. A strutted stent according to Claim 32, wherein said offset spacing arms between two flexible joints are continuous.

41. A strutted stent according to Claim 32, wherein at least one pair of said offset spacing arms between two adjoining springs are overlapping and encased in a sleeve, said overlap being adjustable to provide for variable spacing between adjoining joints.

42. A strutted stent according to Claim 41, wherein all of said offset spacing arms in said frame are overlapping and encased in a sleeve.

43. A strutted stent according to Claim 32, wherein at least one pair of said offset spacing arms between two adjoining joints are linked by a compression spring and encased in a sleeve.

44. A strutted stent according to Claim 43, wherein all of said offset spacing arms in said frame are linked by a compression spring and encased in a sleeve.

45. A strutted stent according to Claim 32, wherein said number of joints is at least about 64, and said compression of diameter is at least ten-fold.

46. A strutted stent according to Claim 32, wherein said compressed diameter is less than about 5 mm.

FIGURE 1A

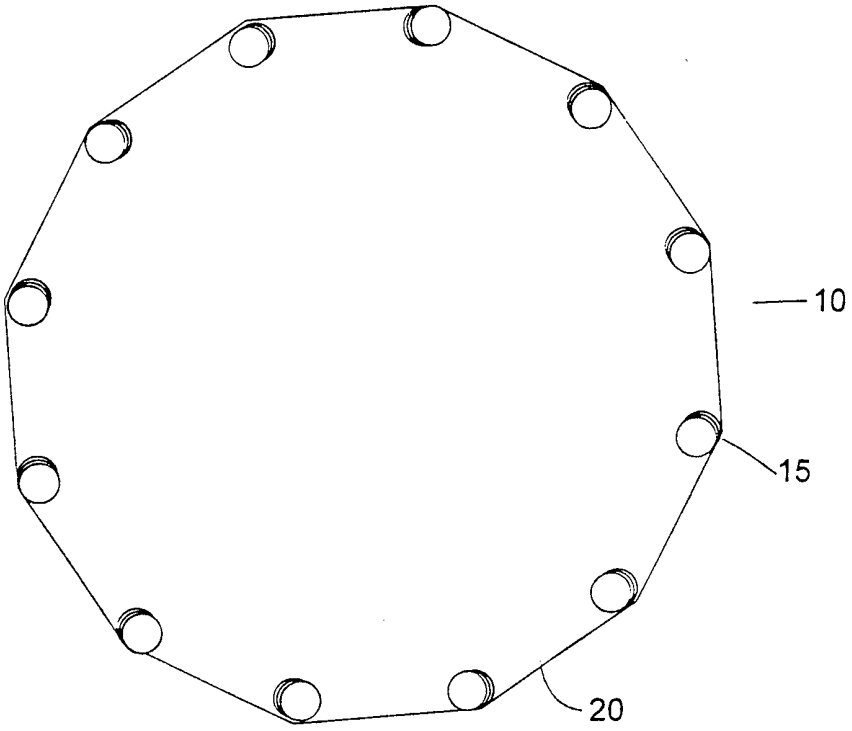


FIGURE 1B

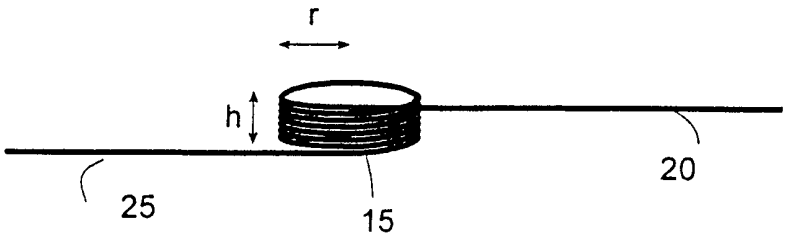


FIGURE 2A

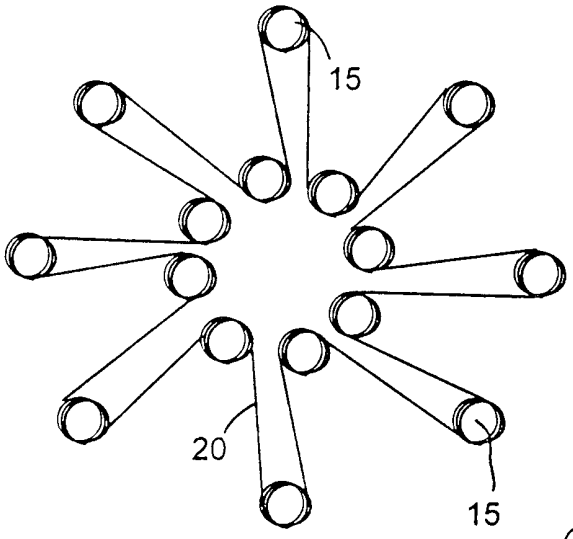


FIGURE 2B

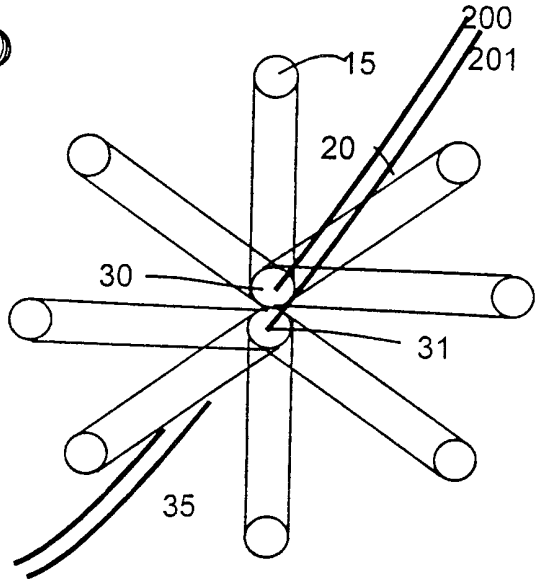


FIGURE 2C

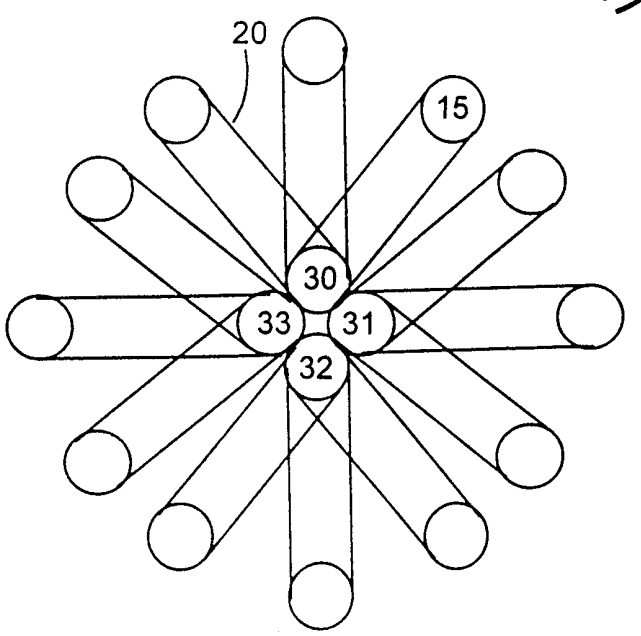


FIGURE 2D

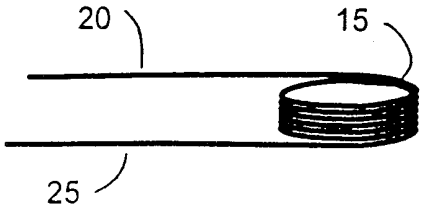


FIGURE 3A

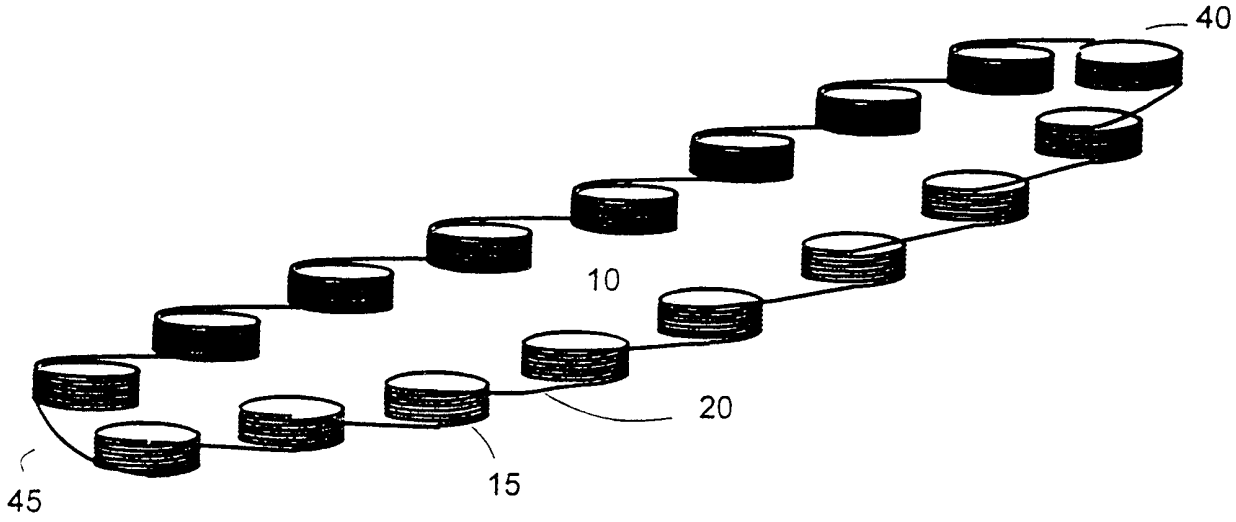


FIGURE 3B

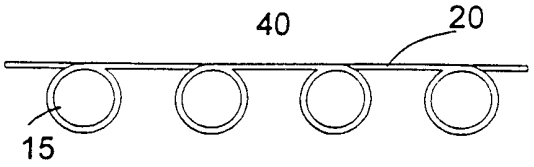


FIGURE 3C

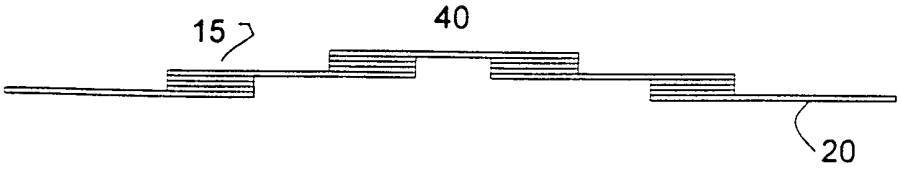


FIGURE 4A

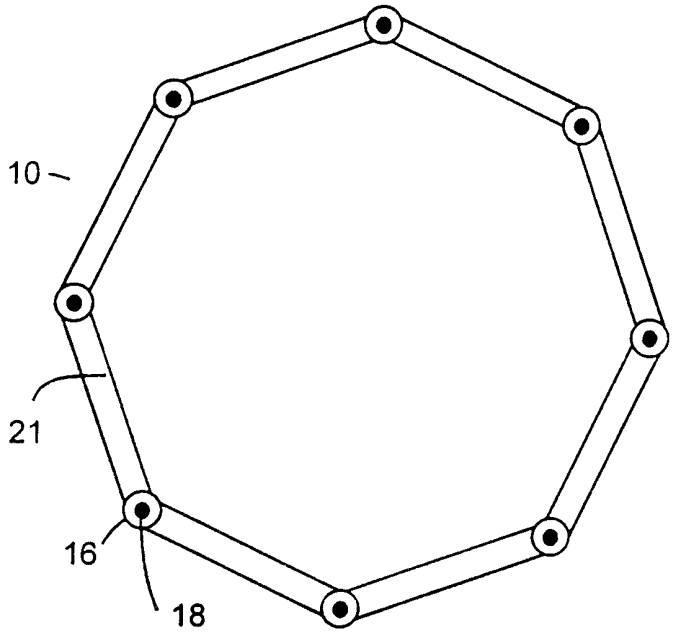


FIGURE 4B

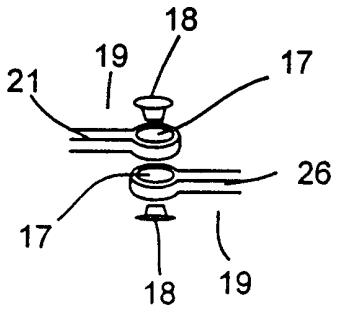


FIGURE 4C

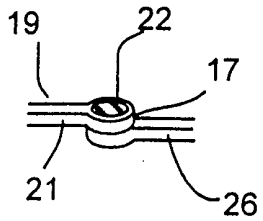


FIGURE 5A

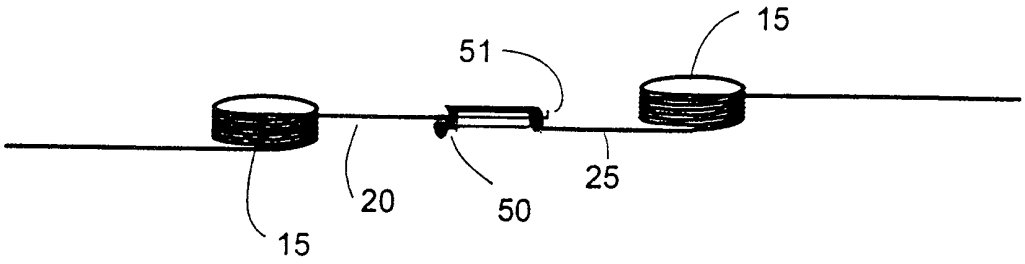


FIGURE 5B

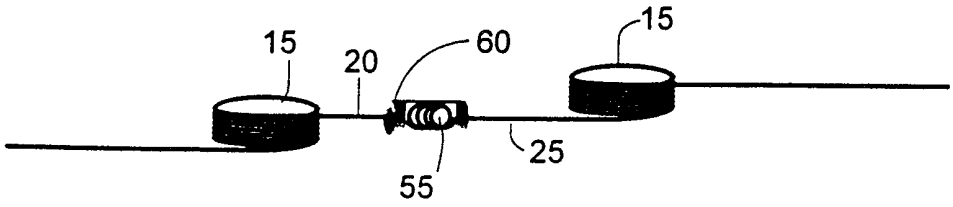


FIGURE 6A

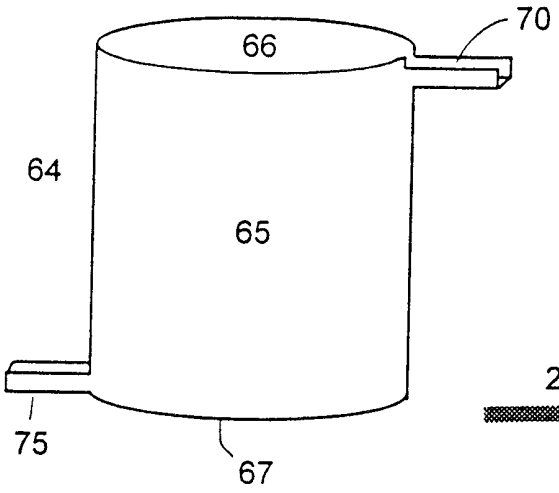


FIGURE 6B

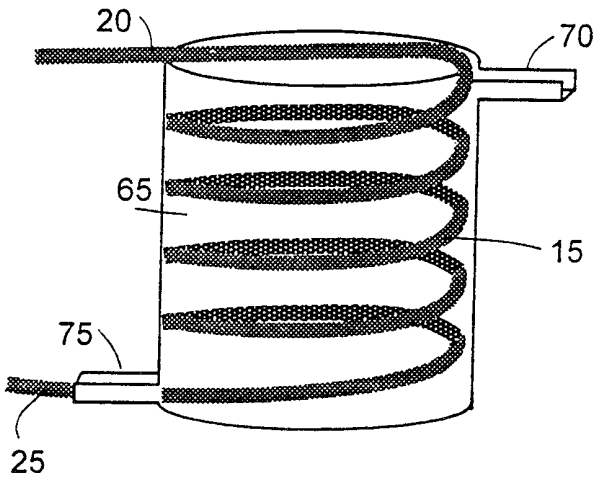


FIGURE 6C

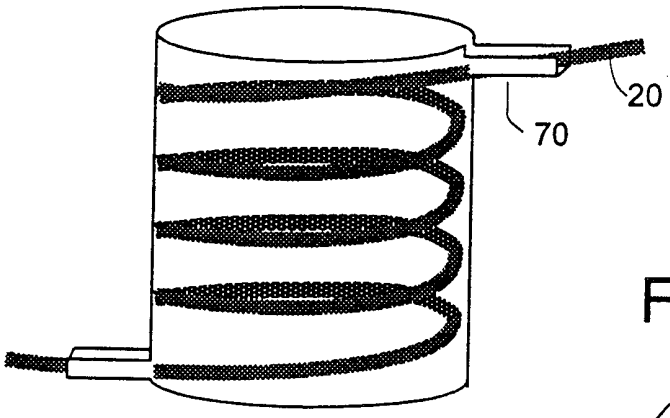


FIGURE 6D

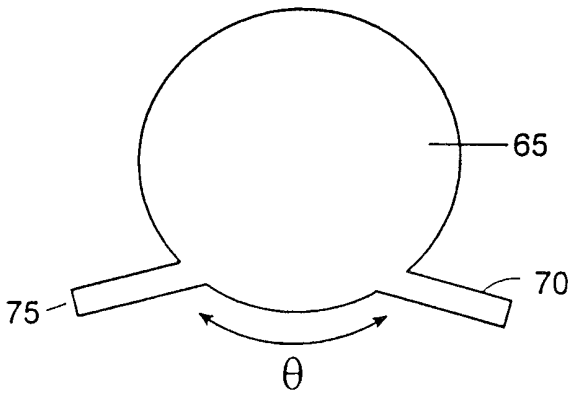


FIGURE 7A

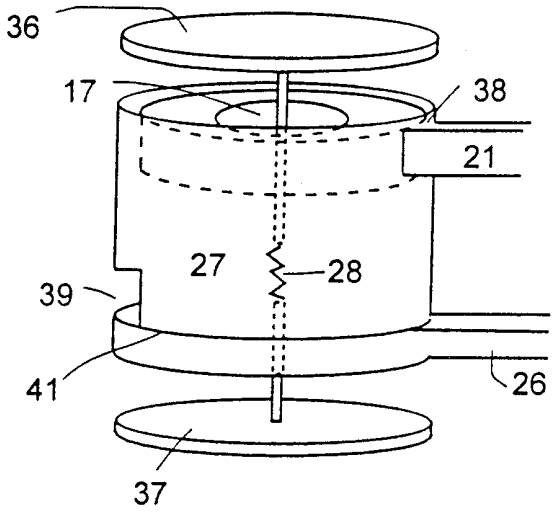


FIGURE 7B

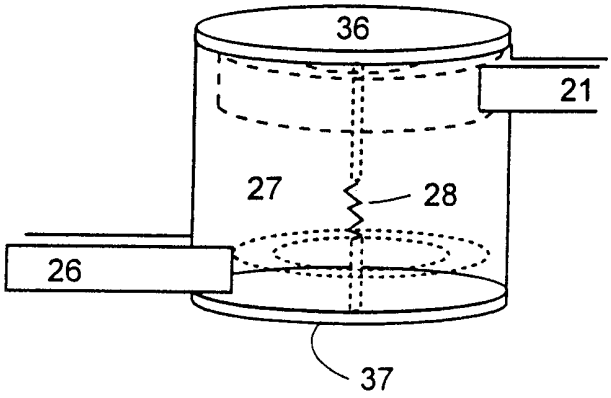


FIGURE 8A

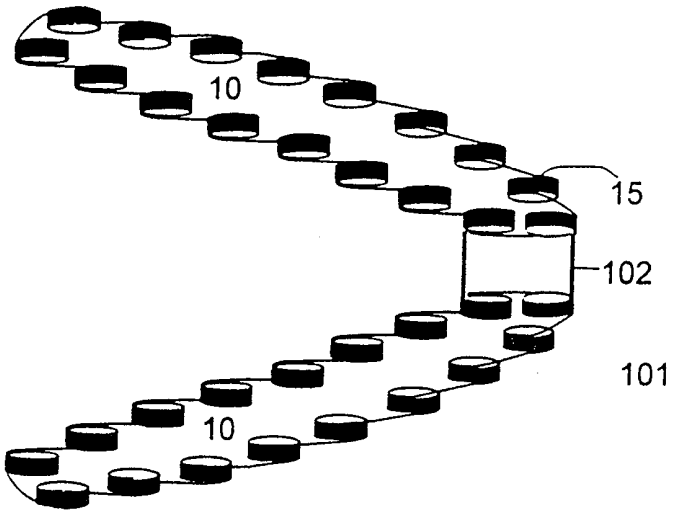


FIGURE 8B

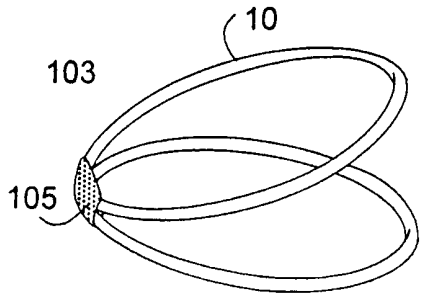


FIGURE 9A

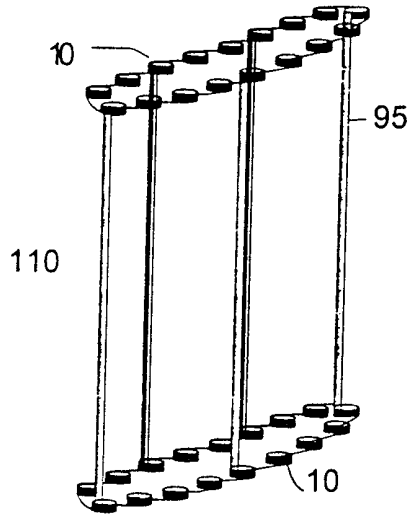


FIGURE 9B

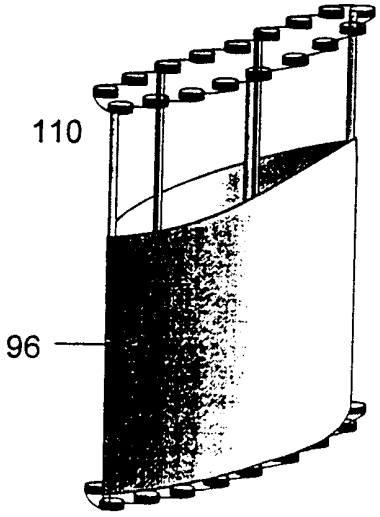


FIGURE 10A

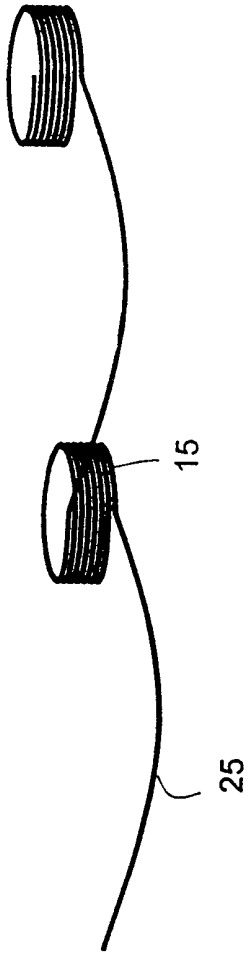
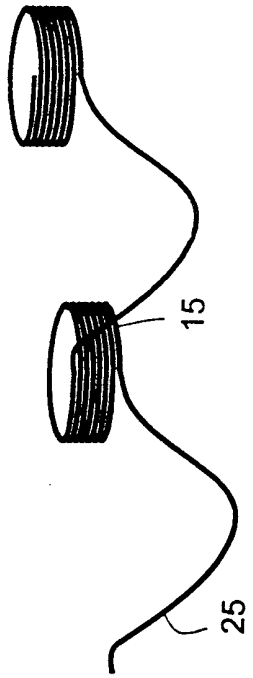


FIGURE 10B



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/09383

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61F 2/06
US CL :623/1

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)

U.S. : 606/108, 151, 194, 213; 623/1, 12

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 practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,334,217 A (DAS) 02 August 1994, entire document.	1-4, 8, 14
X,P	US 5,843,170 A (AHN) 01 December 1998, entire document.	1-4, 8, 14-16, 18-20, 25, 31
A	US 5,507,771 A (GIANTURCO) 16 April 1996, entire document.	1-46

☐ 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

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Date of the actual completion of the international search	Date of mailing of the international search report
10 JUNE 1999	28 JUN 1999
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer BRUCE E. SNOW Telephone No. (703) 308-3255

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