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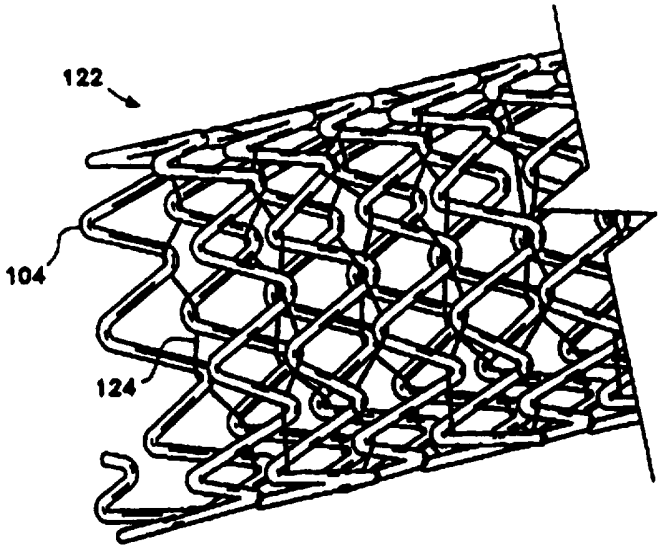

(57) Abstract

This device is a stent-graft which preferably, but not necessarily, uses a kink-resistant stent structure. The graft is attached to the stent in such a way that the graft does not substantially kink when bent and yet the stent is able to conform to curves in the vessel lumen. The graft component cooperating with the stent is tubular and may be mounted either on the interior or the exterior of the stent. The graft is preferably of a polymer such as an expanded polyfluorocarbon. The graft component may be attached to the stent in a variety of ways in keeping with its function of remaining essentially kink-free and conforming to the shape of the interior of the stent such as by binding the graft component to the flexible linkage which holds the stent windings in phase (or to the stent structure itself) at a number of sliding attachment points. This manner of attachment allows the stent to slide locally with respect to the graft structure or, in the case of helically wound stent structure, allows the adjacent undulating shapes in adjacent turns to slide longitudinally with respect to each other as the stent is bent and still support the shape of the graft.

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KINK-RESISTANT STENT-GRAFT

FIELD OF THE INVENTION

This invention is a medical device and a method of using it. The device is a stent-graft which may be percutaneously delivered with (or on) an endovascular catheter or via surgical techniques or using other suitable techniques and then expanded. The stent-graft preferably, but not necessarily, uses a kink-resistant stent structure. The graft is attached to the stent in such a way that the graft does not substantially kink when bent and yet the stent is able to conform to curves in the vessel lumen.

The graft component cooperating with the stent is tubular and may be mounted either on the interior or the exterior of the stent. Although the graft may be made of any of a variety of materials, it preferably is of a polymer such as an expanded polyfluorocarbon. The graft component may be attached to the stent in a variety of ways in keeping with its function of remaining essentially kink-free and conforming to the shape of the interior of the stent. One such very desirable method of attachment is by binding the graft component to the flexible linkage which holds the stent windings in phase (or to the stent structure itself) at a number of sliding attachment points. This manner of attachment allows the stent to slide locally with respect to the graft structure or, in the case of the helically wound stent structure, allows the adjacent undulating shapes in adjacent helical turns to slide longitudinally with

respect to each other as the stent is bent and still support the shape of the graft.

The stent-graft may be used to reinforce vascular irregularities, to provide a smooth nonthrombogenic interior vascular surface for diseased areas in blood vessels, or to increase blood flow past a diseased area of a vessel by mechanically improving the interior surface of the vessel. The inventive stent-graft may be used within smaller vessels between 2mm and 6mm in diameter and is also suitable for significantly larger vessels. The inventive stent-graft may be self-expandable. It is kink-resistant when bent along its longitudinal axis.

Included in the invention are methods for coupling the stent structure to the graft to optimize the flexibility and the kink resistance of the resulting stent-graft.

BACKGROUND OF THE INVENTION

Treatment or isolation of vascular aneurysms or of vessel walls which have been thinned or thickened by disease has traditionally been done via surgical bypassing with vascular grafts. Shortcomings of this procedure include the morbidity and mortality associated with surgery, long recovery times after surgery, and the high incidence of repeat intervention needed due to limitations of the graft or of the procedure. Vessels thickened by disease are currently sometimes treated less invasively with intraluminal stents that mechanically hold these vessels open either subsequent to or as an adjunct to a balloon angioplasty procedure. Shortcomings of current stents include the use of highly thrombogenic materials (stainless steels, tantalum, ELGILOY) which are exposed to blood, the general failure of these materials

to attract and support functional endothelium, the irregular stent/vessel surface that causes unnatural blood flow patterns, and the mismatch of compliance and flexibility between the vessel and the stent.

The most desired variations of this invention involve a stent-graft which has longitudinal flexibility, which has high radial compliance to the vessel lumen, and exposes the blood to a smooth, nonthrombogenic surface capable of supporting endothelium growth.

An area in which the inventive stent-graft is beneficial is in the scaffolding of atherosclerotic lesions in the cardiovascular system to establish vessel patency, prevention of thrombosis, and the further prevention of restenosis after angioplasty. In contrast to many of the stents discussed below having metallic struts intruding into the blood flow in the vessel lumen which generate turbulence and create blood stasis points initiating thrombus formation, the smooth, continuous surface provided by the preferred tubular inner conduit of our invention provides a hemodynamically superior surface for blood flow.

Mechanically, the most desired, linked helical stent structure used in the stent-graft provides a good combination of radial strength and flexibility. The structure is also radially resilient. It can be completely crushed or flattened and yet spring open again once the obstructive loading is removed. This ability is important for use in exposed portions of the body around the peripheral vasculature or around joints. The stent-graft using the preferred stent structure can sustain a crushing traumatic blow or compression from the bending of a joint and still return to the open configuration once the load is removed.

The impermeability of the preferred stent-graft makes it suitable for shunting and thereby hydraulically isolating aneurysms.

Stents

The stents currently described in the open literature include a wide variety of different shapes.

Wallsten, U.S. Patent No. 4,655,771, suggests a vascular prosthesis for transluminal implantation which is made up of a flexible tubular body having a diameter that is varied by adjusting the axial separation of the two ends of the body relative to each other. In general, the body appears to be a woven device produced of various plastics or stainless steel.

U.S. Patent No. 4,760,849, to Kroph, shows the use of a ladder-shaped coil spring which additionally may be used as a filter in certain situations.

Porter, U.S. Patent No. 5,064,435, suggests a stent made up of two or more tubular stent segments which may be deployed together so to produce a single axial length by a provision of overlapping areas. This concept is to permit the use of segments of known length, which, when deployed, may be used together in overlapping fashion additively to provide a stent of significant length.

Quan-Gett, U.S. Patent No. 5,151,105, discloses an implantable, collapsible tubular sleeve apparently of an outer band and an inner spring used to maintain the sleeve in a deployed condition.

Wall, U.S. Patent No. 5,192,307, suggests a stent having a number of holes therein and which is expandable using an angioplasty balloon so to allow ratchet devices or ledges to hold the stent in an open position once it is deployed.

A number of patents show stents using wire as the stent material.

Gianturco, in U.S. Pat. Nos. 4,580,568 and 5,035,706, describes stents formed of stainless steel wire arranged in a closed zigzag pattern. The stents are compressible to a reduced diameter for insertion into and removal from a body passageway. The stents appear to be introduced into the selected sites by discharge of the collapsed zigzag wire configuration from the tip of a catheter.

U.S. Patent Nos. 4,830,003 and 5,104,404, to Wolff et al., shows a stent of a zigzag wire configuration very similar in overall impression to the Gianturco device. The stent is said to be self-expanding and therefore does not need an angioplasty balloon for its expansion.

Hillstead, U.S. Patent 4,856,516, suggests a stent for reinforcing vessel walls made from a single elongated wire. The stent produced is cylindrical and is made up of a series of rings which are, in turn, linked together by half-hitch junctions produced from the single elongated wire.

Wiktor, U.S. Patent Nos. 4,649,922, 4,886,062, 4,969,458, and 5,133,732, shows wire stent designs using variously a zigzag design or, in the case of Wiktor '458, a helix which winds back upon itself. Wiktor '062 suggests use of a wire component made of a low-memory metal such as copper, titanium or gold. These stents are to be implanted using a balloon and expanded radially for plastic deformation of the metal.

Wiktor '458 is similarly made of low-memory alloy and is to be plastically deformed upon its expansion on an angioplasty balloon.

Wiktor '732 teaches the use of a longitudinal wire welded to each turn of the helically wound zig-zag wire which is said to prevent the longitudinal expansion of the stent during deployment. A further variation of the described stent includes a hook in each turn of the helix which loops over a turn in an adjacent turn. WO93/13825, to Maeda et al, shows a self-expanding stent similar to the Gianturco, Wolff, and Wiktor designs, formed of stainless steel wire, which is built into an elongated zig-zag pattern, and helically wound about a central axis to form a tubular shape interconnected with a filament. The bends of the helix each have small loops or "eyes" at their apexes which are interconnected with a filament. Because of the teaching to connect the eyes of the apexes, the stent appears to be a design that axially expands during compression and may tear attached grafts because of the relative change in position of the arms of the zig-zag during compression of the stent.

MacGregor, U.S. Pat. No. 5,015,253, shows a tubular non-woven stent made up of a pair of helical members which appear to be wound using opposite "handedness". The stent helices desirably are joined or secured at the various points where they cross.

Pinchuk, in U.S. Pat. Nos. 5,019,090, 5,092,877, and 5,163,958, suggests a spring stent which appears to circumferentially and helically wind about as it is finally deployed except, perhaps, at the very end link of the stent. The Pinchuk '958 patent further suggests the use of a pyrolytic carbon layer on the surface of the stent to present a porous surface of improved antithrombogenic properties.

U.S. Patent No. 5,123,917, to Lee, suggests an expandable vascular graft having a flexible cylindrical inner tubing and a number of "scaffold members" which are

expandable, ring-like, and provide circumferential rigidity to the graft. The scaffold members are deployed by deforming them beyond their plastic limit using, e.g., an angioplasty balloon.

Tower, in U.S. Pat. Nos. 5,161,547 and 5,217,483, shows a stent formed from a zig-zag wire wound around a mandrel in a cylindrical fashion. It is said to be made from "a soft platinum wire which has been fully annealed to remove as much spring memory as possible." A longitudinal wire is welded along the helically wound sections much in the same way as was the device of Wiktor.

There are a variety of disclosures in which super-elastic alloys such as nitinol are used in stents. See, U.S. Patent Nos. 4,503,569, to Dotter; 4,512,338, to Balko et al.; 4,990,155, to Wilkoff; 5,037,427, to Harada, et al.; 5,147,370, to MacNamara et al.; 5,211,658, to Clouse; and 5,221,261, to Termin et al. None of these references suggest a device having discrete, individual, energy-storing torsional members as are required by this invention.

Jervis, in U.S. Pat. Nos. 4,665,906 and 5,067,957, describes the use of shape memory alloys having stress-induced martensite properties in medical devices which are implantable or, at least, introduced into the human body.

Stent-Grafts

A variety of stent-graft designs are shown in the following literature.

Perhaps the most widely known such device is shown in Ersek, U.S. Pat. No. 3,657,744. Ersek shows a system for deploying expandable, plastically deformable

stents of metal mesh having an attached graft through the use of an expansion tool.

Palmaz describes a variety of expandable intraluminal vascular grafts in a sequence of patents: U.S. Patent Nos. 4,733,665; 4,739,762; 4,776,337; and 5,102,417. The Palmaz '665 patent suggests grafts (which also function as stents) that are expanded using angioplasty balloons. The grafts are variously a wire mesh tube or of a plurality of thin bars fixedly secured to each other. The devices are installed, e.g., using an angioplasty balloon and consequently are not seen to be self-expanding.

The Palmaz '762 and '337 patents appear to suggest the use of thin-walled, biologically inert materials on the outer periphery of the earlier-described stents.

Finally, the Palmaz '417 patent describes the use of multiple stent sections each flexibly connected to its neighbor.

Rhodes, U.S. Pat. No. 5,122,154, shows an expandable stent-graft made to be expanded using a balloon catheter. The stent is a sequence of ring-like members formed of links spaced apart along the graft. The graft is a sleeve of a material such as expanded a polyfluorocarbon, e.g., GORETEX or IMPRAGRAFT.

Schatz, U.S. Pat. No. 5,195,984, shows an expandable intraluminal stent and graft related in concept to the Palmaz patents discussed above. Schatz discusses, in addition, the use of flexibly-connecting vascular grafts which contain several of the Palmaz stent rings to allow flexibility of the overall structure in following curving body lumen.

Cragg, "Percutaneous Femoropopliteal Graft Placement", Radiology, vol. 187, no. 3, pp. 643-648

(1993), shows a stent-graft of a self-expanding, nitinol, zig-zag, helically wound stent having a section of polytetrafluoroethylene tubing sewed to the interior of the stent.

Cragg (European Patent Application 0,556,850) discloses an intraluminal stent made up of a continuous helix of zig-zag wire and having loops at each apex of the zig-zags. Those loops on the adjacent apexes are individually tied together to form diamond-shaped openings among the wires. The stent may be made of a metal such as nitinol (col. 3, lines 15-25 and col. 4, lines 42+) and may be associated with a "polytetrafluoroethylene (PTFE), dacron, or any other suitable biocompatible material". Those biocompatible materials may be inside the stent (col. 3, lines 52+) or outside the stent (col. 4, lines 6+).

Grafts

As was noted above, the use of grafts in alleviating a variety of vascular conditions is well known. Included in such known grafting designs and procedures are the following.

Medell, U.S. Patent No. 3,479,670, discloses a tubular prothesis adapted to be placed permanently in the human body. It is made of framework or support of a synthetic fiber such as DACRON or TEFLON. The tube is said to be made more resistant to collapse by fusing a helix of a polypropylene monofilament to its exterior. The reinforced fabric tube is then coated with a layer of collagen or gelatin to render the tubing (to be used as an esophageal graft) impermeable to bacteria or fluids.

Sparks, in U.S. Patent Nos. 3,514,791, 3,625,198, 3,710,777, 3,866,247, and 3,866,609, teach procedures for the production of various graft structures

using dies of suitable shape and a cloth reinforcing material within the die. The die and reinforcement are used to grow a graft structure using a patient's own tissues. The die is implanted within the human body for a period of time to allow the graft to be produced. The graft is in harvested and implanted in another site in the patient's body by a second surgical procedure.

Braun, in U.S. Patent No. 3,562,820, shows a biological prosthesis manufactured by applying onto a support of a biological tissue (such as serosa taken from cattle intestine) a collagen fiber paste. The procedure is repeated using multiple layers of biological tissue and collagen fiber paste until a multi-layer structure of the desired wall thicknesses is produced. The prosthesis is then dried and removed prior to use.

Dardik et al, U.S. Patent No. 3,974,526, shows a procedure for producing tubular prostheses for use in vascular reconstructive surgeries. The prosthesis is made from the umbilical cord of a newly born infant. It is washed with a solution of 1% H_2O_2 and rinsed with Ringer's lactate solution. It is then immersed in a hyaluronidase solution to dissolve the hyaluronic acid coating found in the umbilical cord. The vessels are then separated from the cord and their natural interior valving removed by use of a tapered mandrel. The vessels are then tanned with glutaraldehyde. A polyester mesh support is applied to the graft for added support and strength.

Whalen, U.S. Patent No. 4,130,904, shows a prosthetic blood conduit having two concentrically associated tubes with a helical spring between them. Curved sections in the tube walls help prevent kinking of the tube.

Ketharanathan, U.S. Patent No. 4,319,363, shows a procedure for producing a vascular prosthesis suitable for use as a surgical graft. The prosthesis is produced by implanting a rod or tube in a living host and allowing collagenous tissue to grow on the rod or tube in the form of coherent tubular wall. The collagenous implant is removed from the rod or tube and tanned in glutaraldehyde. The prosthesis is then ready for use.

Bell, U.S. Patent No. 4,546,500, teaches a method for making a vessel prosthesis by incorporating a contractile agent such as smooth muscle cells or platelets into a collagen lattice and contracting the lattice around a inner core. After the structure has set, additional layers are applied in a similar fashion. A plastic mesh sleeve is desirably sandwiched between the layers or imbedded within the structure to provide some measure of elasticity.

Hoffman Jr. et al, U.S. Patent No. 4,842,575, shows a collagen impregnated synthetic vascular graft. It is made of a synthetic graft substrate and a cross-linked collagen fibril. It is formed by depositing a aqueous slurry of collagen fibrils into the lumen of the graft and massaging the slurry into the pore structure of the substrate to assure intimate admixture in the interior. Repeated applications and massaging and drying is said further to reduce the porosity of the graft.

Alonoso, U.S. Patent No. 5,037,377, is similar in overall content to the Hoffman Jr. et al patent discussed above except that, in addition to collagen fibers, soluble collagen is introduced into the fabric. A suitable cross-linking agent such as glutaraldehyde is used to bond adjacent collagen fibers to each other.

Slepian et al, U.S. Patent No. 5,213,580, teaches a process described as "paving" or "stabilizing

by sealing the interior surface of a body vessel or organ" by applying a biodegradable polymer such as a polycaprolactone. The polymer is made into a tubular substrate, placed in position, and patched into place.

Finally, there are known vascular grafts using collagenous tissue with reinforcing structure. For instance, Pinchuk, in U.S. Patent Nos. 4,629,458 and 4,798,606, suggests the use of collagen with some other type of fibrous structure supporting the collagen as a biograft. Similarly, Sinofsky et al., U.S. Pat. No. 5,100,429, suggests a partially-cured, collagen-based material used to form a graft within a blood vessel.

Kreamer, U.S. Pat. No. 4,740,207, suggests a intraluminal graft made of a semi-rigid resilient tube, open along a seam extending from one end to the other, which is expanded within the vessel and which resulting larger diameter is maintained by use of a ledge at the longitudinal seam for catching the opposite side of the seam on the expanded graft.

The use of expanded polyfluorocarbons in vascular devices is shown in British patent Nos. 1,506,432, and 1,567,122, which patents show in particular blood vessel linings of the material.

None of the cited references suggest a stent-graft similar to that described herein.

SUMMARY OF THE INVENTION

This invention is a flexible, generally kink-resistant stent-graft which may be percutaneously delivered through or over a catheter, typically an endovascular catheter, or by using surgical techniques or other appropriate methodologies.

The incorporated stent structure preferably utilizes torsional regions which allow it to be folded to

a very small diameter prior to deployment. Preferably, the torsional members have an undulating shape which may be helically wound to form the stent's cylindrical shape. The undulating shape may be aligned to allow the undulations in adjacent turns of the helix to be in phase. Adjacent undulating shapes may be held in the phased relationship using a flexible linkage, often made of a polymeric material. In the helically wound variation of the invention, the undulating torsional members may not have any means at (or near) the apex of the undulating shapes which would tend to constrict the movement of the flexible linkage during compression or bending of the stent. The stent is preferably made of a highly flexible, superelastic alloy such as nitinol, but may be of any suitable elastic material such as various of the medically accepted stainless steels. The stent structure may also be of a series of rings incorporating the torsional members which rings may be axially linked.

The stent desirably has a portion which allows some axial movement of the stent, at the junction of the stent to the graft, relative to the graft when the stent is bent.

The graft component used to complement the stent is typically tubular, placed either within or without the stent, and may be made of a polymeric material which may be attached variously to the filament used to maintain the shape of the stent structure, when such filament is used, or to the stent structure itself. Preferably, the graft component is a biocompatible, expanded polyfluoroethylene polymer. The attachment between the graft component and the stent, e.g., by bonding the graft component to the flexible linkage or by using eyelets or other discrete or continuous linking sites, is carefully crafted to allow various axially

located portions of the stent to slide longitudinally with respect to each other and to the stent component and so generally to maintain the shape of graft. This is to say that the graft component typically is supported at a variety of sites located along its contiguous surface, both circumferentially and longitudinally.

The resulting stent-graft combination has the following specific functions: the stent provides radially directed support both to the graft and to the enclosing body lumen. The radially directed support also provides for minimization of wrinkles or kinks in the graft when the combination is deployed and the stent is bent. Included in this concept is the eventuality that the stent may be multi-component (e.g., as in a series of rings) and, in addition to holding the graft radially open, the spacing of the rings is sufficiently close that the graft is further inhibited from kinking or excessive wrinkling. The graft component (in addition to providing typical "graft" functions) is associated with the stent or integrated into the stent-graft combination so that, because of the stent, the graft is maintained in an open condition without the noted undesirable folds. In particular, use of the most desired variation of the invention results in the graft having a localized, limited, and restricted movement with respect to the stent. Bending that stent-graft combination distributes the flexing movement of the graft over an extended region because of the distributed support of the stent. The tendency of the graft component to kink in a single site is minimized and the resultant flexing is observed to take place in a collection of smaller non-kinking bends located among the tie points to the stent or the stent's filament.

BRIEF DESCRIPTION OF THE DRAWINGS

Figures 1A and 1B are side views of typical stents showing the concepts of the most desirable variation of the inventive stent-graft.

Figures 2A, 2B, 2C, 2D, and 2E are plan views of an unrolled stent form suitable for use in the invention.

Figure 3 is a side view of a stent suitable for use in this invention.

Figure 4A is a close-up of a portion of the stent shown in Figure 2.

Figure 4B is a variation of the close-up of the stent shown in Figure 4A.

Figures 5 and 6 show magnified portions of one variation of the inventive stent-graft depicting methods of attaching the stent to the graft component.

Figures 7 and 8 show front quarter views of variations of the inventive stent-graft.

Figure 9 shows a plan view of an unrolled stent produced from flat stock.

Figure 10 shows a front quarter view of the rolled stent using the flat stock pattern shown in Figure 9.

Figure 11 shows a plan view of an unrolled stent produced from flat stock having a ringed structure.

Figure 12 shows a front quarter view of the rolled ring structured stent using the flat stock pattern shown in Figure 11.

Figures 13, 14, and 15 show plan views of variations of unrolled stents made according to the invention.

Figures 16A-16C show a schematic procedure for deploying the inventive stent-grafts.

DESCRIPTION OF THE INVENTION

As was noted above, this invention is a flexible, kink-resistant stent-graft. The stent-graft is a combination of several components: first, a thin-walled tube forming the graft component which graft component is generally coaxial to and either within or without the stent; second, the stent structure, and, (optionally) one or more filaments woven into or aligning the structure.

The graft material is typically a polymer and may optionally contain a fibrous reinforcement material. The stent structure is a cylindrical body which provides radially directed support both to the graft and to the enclosing body lumen. The radially directed support also provides for minimization of wrinkles or kinks in the graft when the combination is deployed. Included in this concept is the eventuality that the stent may be multi-component (e.g., as in a series of rings) and, in addition to holding the graft radially open, the spacing of the rings is sufficiently close that the graft is further inhibited from kinking or excessive wrinkling. The graft component (in addition to providing typical "graft" functions) is associated with the stent or integrated into the stent-graft combination so that, because of the stent, the graft is maintained in an open condition without the noted undesirable folds. By "kink-resistant" in this document, we mean that any localized or focal kinks caused when the stent is bent along its longitudinal axis do not lessen that cross-sectional area more than 50%. The most desired variation of the invention includes a stent having an integral member which desirably allows some axial movement of the graft with respect to the stent when it is slidably attached to the graft. Typically, the stent will have a member which is aligned with the axis of the stent allowing that

modest sliding movement. The stent structure may be produced variously of a helically placed (wound or otherwise preformed) member having an undulating or serpentine or zig-zag shape or a series of axially situated rings.

The stent component or components may be linked, typically with the flexible linkage mentioned above to maintain the phased relationship of the undulations to select and control the size of the stent-graft as desired for the specific design of the chosen stent. These stent configurations are generally kink-resistant and flexible, particularly when flexed along the longitudinal axis of the stent.

Central to the invention is the radially directed support of the graft by the stent so to minimize the wrinkles or kinks in the graft. In a highly desirable variation of the invention, the stent provides radially directed support of the graft via distributed attachment of the stent component to the graft component through, e.g., the bonding of the graft to the filament which may used to maintain the stent in its tubular shape or via bonding to other loops, eyelets, or fasteners associated with or adhering to the stent component.

Figures 1A and 1B show the concept depicted in one variation of the invention. Figure 1A is a side view of stent graft (10) typical of the invention. The interior of the stent-graft (10) is a tubular graft, the composition of which is discussed in more detail below. In this instance, the graft (12) is attached to the exterior stent (14) by a number of stitches (16) which are loosely looped over the stent (14) to attach the graft (12) to the stent. This loose attachment permits some relative axial movement between the stent (14) and the graft (12) when the stent-graft (10) is bent. The

graft (12) is shown as interior to the stent (14), but it need not be so constructed; the graft (12) may also be exterior to the stent (14).

Figure 1B shows the results of such axial bending. When the stent-graft (10) is bent, the graft (12) straightens (or stretches) in the regions (18) at the outer periphery of the bent graft (10) and forms only small wrinkles (e.g., 20) on the inner periphery (22) of the bent graft (10). The stent (12) allows flexing and conformance of the stent-graft (10) to vessel walls but maintains sufficient axial stiffness to prevent large kinks in the graft (12). It is the dual concepts of distributing the linkages between the stent and the graft over the exterior surface of the graft and structuring those links to allow some local axial movement between the stent and the graft which provides these benefits for this variation of the invention. The structure of the link is not important if they are widely distributed and local slippage of the link is achieved.

Stent Component

The stent component may be constructed of a reasonably high strength material, i.e., one which is resistant to plastic deformation when stressed. The structure may be of any of a variety of sources, such as:

1.) a wire form in which a wire is first formed into an undulating or zig-zag shape and the resulting shape is helically wound to form a cylinder,

2.) an appropriate shape formed from a flat stock and wound into a cylinder, and

3.) a length of tubing formed into an appropriate shape.

These stent structures are typically oriented coaxially with the tubular graft component on the interior of the stent. We have observed that an additional graft structure placed on the outer surface of the stent is also possible but the stent-graft combination must be more carefully crafted to achieve attainment of the advantages listed above because of the additional thickness of the resulting wall.

In order to minimize the wall thickness of the stent-graft, the stent material should have a high strength-to-volume ratio. As will be discussed below, materials suitable in these stents and meeting these criteria include various metals and some polymers.

A percutaneously delivered stent-graft must expand from a reduced diameter, necessary for delivery, to a larger deployed diameter. The diameters of these devices obviously vary with the size of the body lumen into which they are placed. For instance, the stents of this invention may range in size (for neurological applications) from 2.0mm in diameter to 30mm in diameter (for placement in the aorta). A range of about 2.0mm to 6.5mm (perhaps to 10.0mm) is believed to be desirable. Typically, expansion ratios of 2:1 or more are required. These stents are capable of expansion ratios of up to 5:1 for larger diameter stents.

The thickness of the stent materials obviously varies with the size (or diameter) of the stent and the ultimate required yield strength of the folded stent. These values are further dependent upon the selected materials of construction. Wire used in these variations are typically of stronger alloys, e.g., nitinol and

stronger spring stainless steels, and have diameters of about 0.002 inches to 0.005 inches. For the larger stents, the appropriate diameter for the stent wire may be somewhat larger, e.g., 0.005 to 0.020 inches. For flat stock metallic stents, thicknesses of about 0.002 inches to 0.005 inches is usually sufficient. For the larger stents, the appropriate thickness for the stent flat stock may be somewhat thicker, e.g., 0.005 to 0.020 inches.

Figure 2A is a plan view of an isolated section of a stent design which may be used in the stent-graft of the invention. The Figure is intended both to identify a variation of the invention and to provide conventions for naming the components of the torsion member (100). Figure 2A shows, in plan view, an undulating torsion member (100) formed from a wire stock into a U-shape. A torsion pair (102) is made up of an end member (104) and two adjacent torsion lengths (106). Typically, then, each torsion length (106) will be a component to each of its adjacent torsion pairs (102). The U-shaped torsion pair (102) may be characterized by the fact that the adjacent torsion lengths are generally parallel to each other prior to formation into the stent.

The stents of this invention preferably use undulating torsion members which are "open" or "unconfined" at their apex or end member (104). By "open" or "unconfined" we mean that the apex or end member (104) does not have any means in that apex which would tend to inhibit the movement of the flexible linkage (discussed below) down between the arms or torsion lengths (106) of the torsion pair (102).

Figure 2B shows another variation of the stent having a sinusoidal shaped torsion member (108). In this variation, the adjacent torsion lengths (110) are not

parallel and the wire forms an approximate sinusoidal shape before being formed into a cylinder.

Figure 2C shows a variation of the stent having an ovoid shaped torsion member (112). In this variation, the adjacent torsion lengths (114) are again not parallel. The wire forms an approximate open-ended oval with each torsion pair (116) before being formed into a cylinder.

Figure 2D shows another variation of the stent having a V-shaped torsion member (118). In this variation, the adjacent torsion lengths (120) form a relatively sharp angle at the torsion end (122) shape before being formed into a cylinder.

Figure 2E shows a variation in which adjacent torsion members on the stent (117) have differing amplitude. The peaks of the high amplitude torsion members (119) may be lined up "out of phase" or "peak to peak" with short amplitude (121) or high amplitude torsion members in the adjacent turn of the helix or may be positioned "in phase" similar to those discussed with regard to Figure 3 below.

The configurations shown in Figs 2A-2E are exceptionally kink-resistant and flexible when flexed along the longitudinal axis of the stent.

As ultimately deployed, the preferred variation of the inventive stent graft uses a section of the torsion member found in one of Figures 2A - 2E. Such a section would be helically wound about a form of an appropriate size so that the end members (e.g., 104 in Figure 2A) would be centered between the end members of the torsion member on an adjacent turn of the helix. This is said to be "in phase". "Out of phase" would be the instance in which the adjacent members meet directly, i.e., end member-to-end member. In any event, once so

aligned, the phasic relationship may be stabilized by weaving a flexible linkage through the end members from one turn of the helix to the next.

Figure 3 shows a side view of one typical stent (122) made according to this invention including the phased relationship of the helical turns of the stent and the flexible linkage (124).

Figure 4A shows a close-up of the Figure 3 stent and depicts the phased relationship (within box A) and shows in detail a typical way in which the flexible linkage (124) is looped through the various end members (104) to maintain the phased relationship. It may be noted that the flexible linkage (124) is free to move away from the apex at the end members (104) without constraint.

Figure 4B shows a variation of the close-up shown in Figure 4A and shows in detail a different to loop the flexible linkage (124) through the various end members (104) to maintain their phased relationship. The flexible linkage (124) is looped throught he end members in a "two-up/ two-down" relationship but is still free to move away from the apex at the end members (104) without constraint.

Figure 5 shows a magnified portion of a stent-graft (viewed from the outside of the stent-graft) incorporating a stent such as is shown in Figures 3 and 4A and depicts a method for distributively attaching the stent to the graft component. Specifically, end member or apex (104) is flanked by side lengths (106) and is looped therethrough by a filament (124). The graft component (134) is seen in the background. The filament (124) adheres to the graft (134) at the locations of contact (130) between the filament (124) and the graft component (134). It should be apparent that the apexes

(104) are free to move in the direction shown by arrows (132) when the stent-graft is flexed. This shows the ability of the various apexes to move longitudinally with respect to each other and yet retain the graft component (134) reasonably snug against the inner surface of the stent and thereby prevent kinking of that graft component (134).

Figure 6 shows a close-up of a section of a stent-graft according to the invention that is similar to the stent-graft portion shown in Figure 5 but in which the stent is attached to the graft using loops (136) or eyelets on the stent. Again this shows a manner of distributively attaching the stent to the graft component (134). Again, end member or apex (104) is flanked by side lengths (106). Although no filament (124 in Figure 4) is shown in the variation in Figure 6, it is contemplated that the filament (124) may be used in conjunction with loops (136). The graft component (134) is seen in the background. These loops (136) may be of a material which adheres to the graft component (134) at the junctions shown at (138). It is also contemplated that the filament (124) may be of material which is either adherent to (such as a melt-miscible thermoplastic polymer) or not adherent to (such as a metal or thermoset polymer) the graft component (134) when used with the loops (136).

The scope of materials for the filament (124), graft component (134), and loops (136) will be discussed in detail below.

It is also contemplated that the inventive concept utilize other variations in which the stent is not in phase. For instance, Figure 7 shows a stent-graft (140) using an interior graft (141), an outer stent (142), and links (143).

Figure 8 shows a variation in which the stent-graft (144) uses a stent (145) which may (or may not) be produced of a helically wound component but is of a zig-zag configuration having eyes (146) at the apex of the zig-zag sections. Loops (147), such as are discussed above, may be used to attach the stent (145) to the graft (149). Alternatively, the graft (149) may be attached to the stent (145) using a line (148) looping through the eyes (146) of the stent (145), also in the manner discussed above.

The stent support structure may also be made by forming a desired structural pattern out of a flat sheet. The sheet may then be rolled to form a tube. Figure 9 shows a plan view of torsion members (160) which may be then rolled about an axis to form a cylinder. As is shown in Figure 10, the end caps (162) may be aligned so that they are "out of phase". The flexible linkage (164) may then be included to preserve the diameter of the stent. The graft component (166) is shown on the inner surface of the stent. Loops may be used as was described above. The graft may be attached to the loops or filament in the manner discussed above.

The stent shown in Figure 10 may be machined from tubing. If the chosen material is nitinol, careful control of temperature during the machining step may be had by EDM (electro-discharge-machining), laser cutting, chemical machining, or high pressure water cutting.

Figure 11 is a conceptual schematic of an isolated ring section of another variation of the stent component useful in this invention. Figure 11 shows, in plan view, of the layout of the various components of a ring as if they were either to be cut from a flat sheet and later rolled into tubular formation for use as a stent with welding or other suitable joining procedures

taking place at the seam or (if constructed from tubing) the layout as if the tubing was cut open. The portion of the stent between tie members (170) is designated as a ring (172) or ring section. Tie members (170) serve to link one ring (172) to an adjacent ring (172). A torsion pair (174) is made up of a cap member (176) and two adjacent torsion members (178). Typically, then, each torsion member (178) will be a component to each of its adjacent torsion pairs (174).

As ultimately deployed, a roll of the sheet found in Figure 11 would be entered into the body lumen. Typically, it would be folded in some fashion which will be discussed below. A front quarter perspective view of the rolled stent (178) is shown in the Figure 12.

Figure 13 shows a variation of the stent having a ring section (180) similar in configuration to that shown above and joined by tie members (182). Those tie members (182) extend from the inside of a torsion pair (184) to the outside of a torsion pair (186) in the adjacent ring section. The tie members (182) experience no twisting because of their placement in the middle of end cap (188). The tie members may be offset on the end cap, if so desired, to allow the tie members to accept some of the twisting duty.

Figure 14 shows a plan view of a variation of the inventive stent in which the number of torsion members (190) in a selected ring member (192) is fairly high. This added number of torsion members may be due to a variety of reasons. For instance, the material of construction may have a significantly lower tolerance for twisting than the materials in those prior Figures. Adding more torsion bars lessens the load carried on each of the several bars. Alternatively, for the same

material,the stent may need be folded to a smaller diameter for deployment than those earlier variations.

Figure 15 shows a variation of the invention in which the end caps (194) are bound by a long torsion member (195) and two short torsion members (196). This torsion set (197) is in turn separated from the adjacent torsion set (197) by a bridge member (198) which shares the bending load of the stent when the stent is rolled and the ends (199) joined by, e.g., welding. The torsion members (196) have a greater width than that of the long torsion member (195) so to balance the load around the ring during deformation and thereby to prevent the bridge members from becoming askew and out of the ring plane.

It should be apparent that the number and spacing of the rings along the axis of the graft is a parameter which is should be carefully controlled to minimize the apparent kinking.

It should be clear that a variety of materials variously metallic, super-elastic alloys, and preferably nitinol, are suitable for use in these stents. Although it is highly desirable that the stent materials be suitably springy, even when fashioned into very thin sheets or small diameter wires, such springiness is not a requirement of the invention. Various stainless steels which have been physically, chemically, and otherwise treated to produce high springiness are suitable as are other metal alloys such as cobalt chrome alloys (e.g., ELGILOY), platinum/tungsten alloys, and especially the nickel-titanium alloys generically known as "nitinol".

Nitinol is especially preferred because of its "super-elastic" or "pseudo-elastic" shape recovery properties, i.e., the ability to withstand a significant amount of bending and flexing and yet return to its original form without deformation. These metals are

characterized by their ability to be transformed from an austenitic crystal structure to a stress-induced martensitic structure at certain temperatures, and to return elastically to the austenitic shape when the stress is released. These alternating crystalline structures provide the alloy with its super-elastic properties. These alloys are well known but are described in U.S. Pat. Nos. 3,174,851, 3,351,463, and 3,753,700. Typically, nitinol will be nominally 50.6% ($\pm$0.2%) Ni with the remainder Ti. Commercially available nitinol materials usually will be sequentially mixed, cast, formed, and separately cold-worked to 30-40%, annealed, and stretched. Nominal ultimate yield strength values for commercial nitinol are in the range of 30 psi and for Young's modulus are about 700 Kbar.

The '700 patent describes an alloy containing a higher iron content and consequently has a higher modulus than the Ni-Ti alloys.

Nitinol is further suitable because it has a relatively high strength to volume ratio. This allows the torsion members to be shorter than for less elastic metals. The flexibility of the stent-graft is largely dictated by the length of the torsion member components in the stent structural component. The shorter the pitch of the device, the more flexible the stent-graft structure can be made. Materials other than nitinol are suitable. Spring tempered stainless steels and cobalt-chromium alloys such as ELGILOY are also suitable as are a wide variety of other known "super-elastic" alloys.

Although nitinol is preferred in this service because of its physical properties and its significant history in implantable medical devices, we also consider it also to be useful in a stent because of its overall suitability with magnetic resonance imaging (MRI)

technology. Many other alloys, particularly those based on iron, are an anathema to the practice of MRI causing exceptionally poor images in the region of the alloy implant. Nitinol does not cause such problems.

Other materials suitable as the stent include certain polymeric materials, particularly engineering plastics such as thermotropic liquid crystal polymers ("LCP's"). These polymers are high molecular weight materials which can exist in a so-called "liquid crystalline state" where the material has some of the properties of a liquid (in that it can flow) but retains the long range molecular order of a crystal. The term "thermotropic" refers to the class of LCP's which are formed by temperature adjustment. LCP's may be prepared from monomers such as p,p'-dihydroxy-polynuclear-aromatics or dicarboxy-polynuclear-aromatics. The LCP's are easily formed and retain the necessary interpolymer attraction at room temperature to act as high strength plastic artifacts as are needed as a foldable stent. They are particularly suitable when augmented or filled with fibers such as those of the metals or alloys discussed below. It is to be noted that the fibers need not be linear but may have some preforming such as corrugations which add to the physical torsion enhancing abilities of the composite.

The flexible linkage between adjacent turns of the helix or the loops may be of any appropriate filamentary material which is blood compatible or biocompatible and sufficiently flexible to allow the stent to flex and not deform the stent upon folding. Although the linkage may be a single or multiple strand wire (platinum, platinum/tungsten, gold, palladium, tantalum, stainless steel, etc.), much preferred in this invention is the use of polymeric biocompatible

filaments. Synthetic polymers such as polyethylene, polypropylene, polyurethane, polyglycolic acid, polyesters, polyamides, their mixtures, blends, copolymers, mixtures, blends and copolymers are suitable; preferred of this class are polyesters such as polyethylene terephthalate including DACRON and MYLAR and polyaramids such as KEVLAR, polyfluorocarbons such as polytetrafluoroethylene with and without copolymerized hexafluoropropylene (TEFLON or GORETEX), and porous or nonporous polyurethanes. Natural materials or materials based on natural sources such as collagen may also be used is this service.

As will be discussed below, the material chosen for the linkage or the loops is preferably of a material which can be bonded to the graft liner in a distributed sequence of points along the outside surface of the graft liner. By bonding the liner to the linkage or the loops in such fashion, the flexibility and resistance to kinking of the stent is maintained in the resulting stent-graft. To state the central concept of the invention in another way, the graft component is to be distributively attached to the stent structure at a number of sites. The attachments should allow some movement between the graft component and the stent at the attachment points. This may be accomplished by causing adherence of the graft independently to at least some of the linkage, to the loops, or to one or the other. Other structural attachments may be used to meet the functional requirements recited here.

Tubular Component Materials

The tubular component or graft member of the stent-graft may be made up of any material which is suitable for use as a graft in the chosen body lumen.

Many graft materials are known, particularly known are those used as vascular graft materials. For instance, natural materials such as collagen may be introduced onto the inner surface of the stent and fastened into place. Desirable collagen-based materials include those described in U.S. Pat. No. 5,162,430, to Rhee et al, and WO 94/01483 (PCT/US93/06292), the entirety of which are incorporated by reference. Synthetic polymers such as polyethylene, polypropylene, polyurethane, polyglycolic acid, polyesters, polyamides, their mixtures, blends, copolymers, mixtures, blends and copolymers are suitable; preferred of this class are polyesters such as polyethylene terephthalate including DACRON and MYLAR and polyaramids such as KEVLAR, polyfluorocarbons such as polytetrafluoroethylene with and without copolymerized hexafluoropropylene (TEFLON or GORETEX), and porous or nonporous polyurethanes. Especially preferred in this invention are the expanded fluorocarbon polymers (especially PTFE) materials described in British. Pat. Nos. 1,355,373, 1,506,432, or 1,506,432 or in U.S. Pat. Nos. 3,953,566, 4,187,390, or 5,276,276, the entirety of which are incorporated by reference.

Included in the class of preferred expanded fluoropolymers are polytetrafluoroethylene (PTFE), fluorinated ethylene propylene (FEP), copolymers of tetrafluoroethylene (TFE) and per fluoro(propyl vinyl ether) (PFA), homopolymers of polychlorotrifluoroethylene (PCTFE), and its copolymers with TFE, ethylene-chlorotrifluoroethylene (ECTFE), copolymers of ethylene-tetrafluoroethylene (ETFE), polyvinylidene fluoride (PVDF), and polyvinyfluoride (PVF). Especially preferred, because of its widespread use in vascular prostheses, is expanded PTFE.

In addition, one or more radio-opaque metallic fibers, such as gold, platinum, platinum-tungsten, palladium, platinum-iridium, rhodium, tantalum, or alloys or composites of these metals like may be incorporated into the device, particularly, into the graft, to allow fluoroscopic visualization of the device.

The tubular component may also be reinforced using a network of small diameter fibers. The fibers may be random, braided, knitted, or woven. The fibers may be imbedded in the tubular component, may be placed in a separate layer coaxial with the tubular component, or may be used in a combination of the two.

Production of the Stent-Graft

The preferred method of constructing the stent-graft is to first construct the stent incorporating a filamentary linkage of the type discussed above and then to place the tubular component inside the stent. The tubular component is then expanded using a mandrel or the like and heated to allow the materials of the filamentary linkage and the tubular graft component to merge and self-bind.

Loops may be molded into or glued onto the graft component and later attached to the stent or linkage or the loops may be independently introduced and tied onto the stent structure.

Deployment of the Invention

The stent-graft is folded, crushed, or otherwise collapsed to a reduced diameter by folding or by reducing the diameter of the stent-graft. The stent-graft is then restrained from springing open. The stent-graft is then deployed by removing the restraining

mechanism, thus allowing it to spring open against the vessel wall.

The attending physician will choose a stent or stent-graft having an appropriate diameter. However, inventive devices of this type are typically selected having an expanded diameter of up to about 10% greater than the diameter of the lumen to be the site of the stent deployment.

The stent-graft may be tracked through the vasculature to the intended deployment site and then unfolded against the vessel lumen. The graft tube component of the stent-graft is flexible and easy to fold. Folding or otherwise collapsing the stent structure allows it to return to a circular, open configuration.

Figures 16A-16C show a method for deployment of the devices of the present invention and allow them to self-expand. Figure 16A shows a target site (202) having, e.g., a narrowed vessel lumen. A guidewire (204) having a guide tip (206) has been directed to the site using known techniques. The stent-graft (208) is mounted on guidewire (204) and is held in place prior to deployment by distal barrier (210) and proximal barrier (212). The distal barrier (210) and proximal barrier (212) typically are affixed to the guidewire tube (214). The tether wire (216) is shown extending through loops (218) proximally through the catheter assembly's (220) outer jacket (222) through to outside the body.

Figure 16B shows the removal of the tether wire (216) from a portion of the loops (218) to partially expand the stent-graft (208) onto the selected site (202).

Figure 16C shows the final removal of the tether wire (216) from the loops (218) and the retraction

of the catheter assembly (220) from the interior of the stent-graft (208). The stent-graft (208) is shown as fully expanded.

Other methods of deployment are suitable for use with this device and are described in U.S. Pat. Application Nos. 07/927,165 and 07/965,973, the entirety of which are incorporated by reference.

Many alterations and modifications may be made by those of ordinary skill in the art without departing from the spirit and scope of the invention. The illustrated embodiments have been shown only for purposes of clarity and examples, and should not be taken as limiting the invention as defined by the following claims, which include all equivalents, whether now or later devised.

WE CLAIM AS OUR INVENTION:

1. A kink-resistant stent-graft for introduction into a body lumen, said stent-graft having a generally cylindrical form with two ends, a passageway with a radius extending between those ends, and an axis extending along said passageway, said stent-graft comprising:

a tubular graft member substantially coaxial with the passageway, and

a stent component of at least one helically aligned member defining said cylinder,

wherein the tubular graft member is attached to said stent component so to minimize kinks and the stent component provides radial support to the tubular graft member.

2. The stent-graft of claim 1 wherein the tubular graft member is distributively and slidably connected to said stent component.

3. The stent-graft of claim 1 wherein the tubular graft member is interior to the stent component.

4. The stent-graft of claim 1 wherein the tubular graft member is exterior to the stent component.

5. The stent-graft of claim 1 additionally comprising at least one flexible link passing through said helically aligned member and wherein the tubular graft member is connected to the flexible link.

6. The stent-graft of claim 1 additionally comprising at least one polymeric loop passing around said stent

component and wherein the at least one polymeric loop is connected to the tubular graft member.

7. The stent-graft of claim 1 where the stent component has an axial component paralleling the axis of the stent.

8. The stent-graft of claim 1 where the stent is formed of wire and portions of the stent have shapes selected from sinusoidal, U-shaped, V-shaped, and ovaloid shapes.

9. The stent-graft of claim 1 where the stent comprises a material selected from stainless steels, cobalt/chromium alloys, platinum/tungsten alloys, titanium alloys, and nickel-titanium alloys.

10. The stent-graft of claim 1 where the stent comprises nitinol.

11. The stent-graft of claim 1 where the stent is produced from a sheet material or tubing.

12. The stent-graft of claim 1 where the tubular member comprises one or more materials selected from polyethylene, polypropylene, polyglycolic acid, polyesters, polyamides, their mixtures, blends, copolymers, mixtures, blends and copolymers; polyesters, polyaramids, polyfluorocarbons, and porous or nonporous polyurethanes; and collagenous materials.

13. The stent-graft of claim 1 where the tubular member comprises polyethylene terephthalate.

14. The stent-graft of claim 1 where the tubular member comprises porous or non-porous polytetrafluoroethylene.

15. The stent-graft of claim 14 where the porous or non-porous polytetrafluoroethylene is expanded.

16. The stent-graft of claim 14 where the porous or non-porous polytetrafluoroethylene is copolymerized with hexafluoropropylene.

17. The stent-graft of claim 14 where the porous or non-porous polytetrafluoroethylene is copolymerized with hexafluoropropylene.

18. The stent-graft of claim 12 additionally comprising radiopaque fibers within said tubular member.

19. The stent-graft of claim 5 where the linkage is of a material selected from polyethylene, polypropylene, polyglycolic acid, polyesters, polyamides, their mixtures, blends, copolymers, mixtures, blends and copolymers; polyesters, polyaramids, polyfluorocarbons, and porous or nonporous polyurethanes; and metals.

20. The stent-graft of claim 19 where the linkage is of the same material as the tubular member.

21. The stent-graft of claim 6 where the at least one loop is of a material selected from polyethylene, polypropylene, polyglycolic acid, polyesters, polyamides, their mixtures, blends, copolymers, mixtures, blends and copolymers; polyesters, polyaramids, polyfluorocarbons, and porous or nonporous polyurethanes.

22. The stent-graft of claim 21 where the at least one loop is of the same material as the tubular member.

23. A kink-resistant stent-graft for introduction into a body lumen having a generally cylindrical form, said stent-graft having two ends, a passageway with a radius extending between those ends, and an axis extending along said passageway, said stent-graft comprising:

a tubular graft member substantially coaxial with the passageway slidably connected to said stent component, and

a stent component of at least one ring assembly extending circumferentially about said passageway, and

wherein the tubular graft member is attached to said stent component so to prevent kinks and the stent component provides radial support to the tubular graft member.

24. The stent-graft of claim 23 wherein the tubular graft member is distributively and slidably connected to said stent component.

25. The stent-graft of claim 23 wherein the tubular graft member is interior to the stent component.

26. The stent-graft of claim 23 wherein the tubular graft member is exterior to the stent component.

27. The stent-graft of claim 26 wherein the stent component comprises more than one ring assembly.

28. The stent-graft of claim 29 wherein the ring assemblies are joined by tie members which are generally parallel to said axis.

29. The stent-graft of claim 26 where the ring assemblies comprise a material selected from stainless steels, cobalt chromium alloys, platinum/tungsten alloys, titanium alloys, and nickel-titanium alloys.

30. The stent-graft of claim 26 where the ring assemblies comprise nitinol.

31. The stent-graft of claim 26 where the ring assemblies are produced from a sheet material or tubing.

32. The stent-graft of claim 26 where the tubular member comprises a material selected from polyethylene, polypropylene, polyglycolic acid, polyesters, polyamides, their mixtures, blends, copolymers, mixtures, blends and copolymers; polyesters, polyaramids, polyfluorocarbons, and porous or nonporous polyurethanes; and collagenous materials.

33. The stent-graft of claim 26 where the tubular member comprises polyethylene terephthalate.

34. The stent-graft of claim 26 where the tubular member comprises porous or non-porous polytetrafluoroethylene.

35. The stent-graft of claim 34 where the porous or non-porous polytetrafluoroethylene is expanded.

36. The stent-graft of claim 35 where the porous or non-porous polytetrafluoroethylene is copolymerized with hexafluoropropylene.

37. The stent-graft of claim 35 where the porous or non-porous polytetrafluoroethylene is copolymerized with hexafluoropropylene.

38. The stent-graft of claim 26 additionally comprising radiopaque fibers within said tubular member.

39. The stent-graft of claim 26 additionally comprising at least one polymeric loop passing around said ring assembly and wherein the at least one polymeric loop is connected to the tubular graft member.

40. The stent-graft of claim 39 where the at least one loop is of a material selected from polyethylene, polypropylene, polyglycolic acid, polyesters, polyamides, their mixtures, blends, copolymers, mixtures, blends and copolymers; polyesters, polyaramids, polyfluorocarbons, and porous or nonporous polyurethanes.

41. The stent-graft of claim 40 where the at least one loop is of the same material as the tubular member.

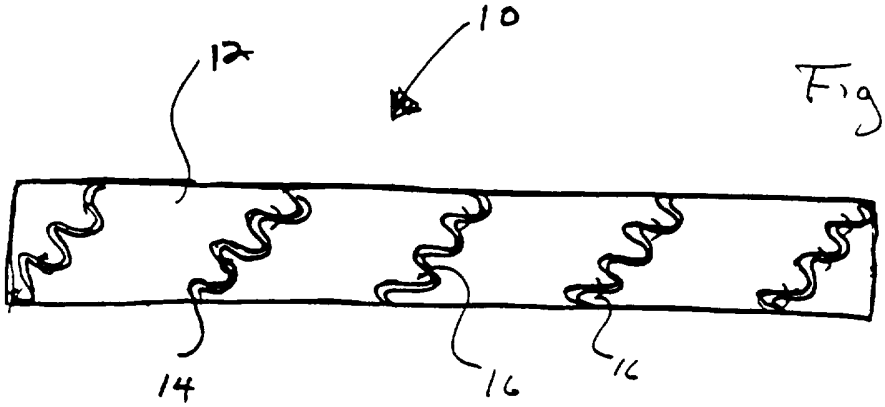


Figure 1A

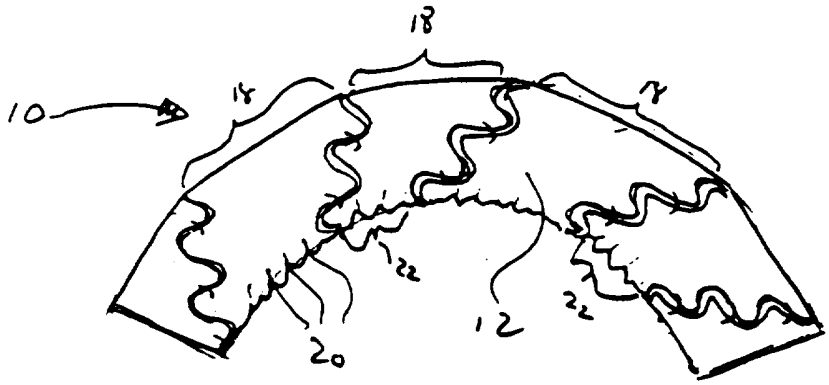


Figure 1B

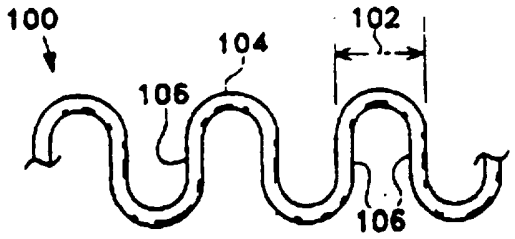


Fig. 2A

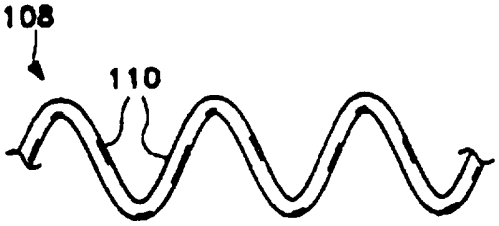


Fig. 2B

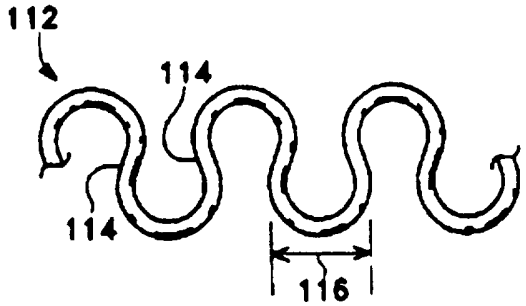


Fig. 2C

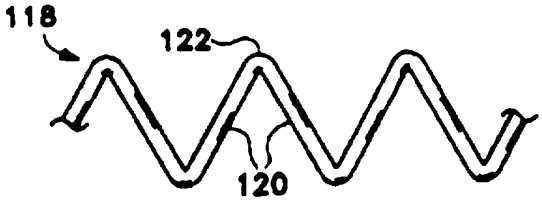


Fig. 2D

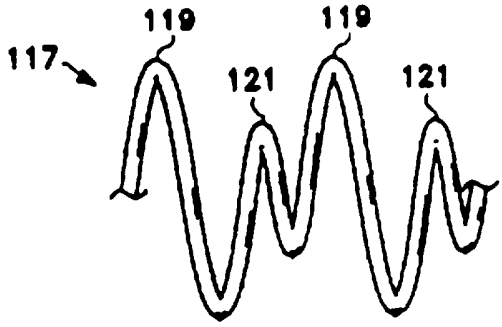


Fig. 2E

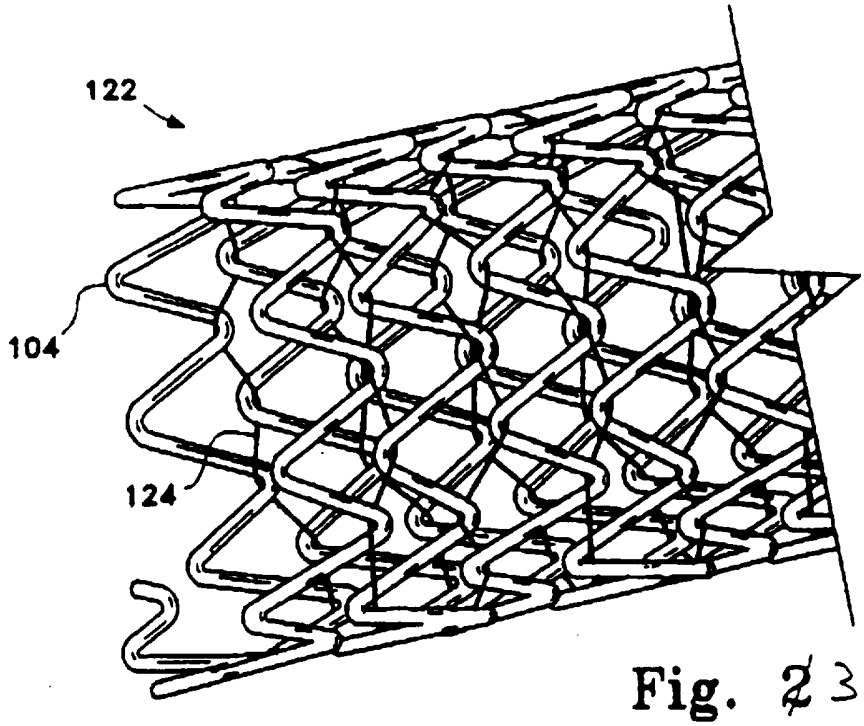


Fig. 3

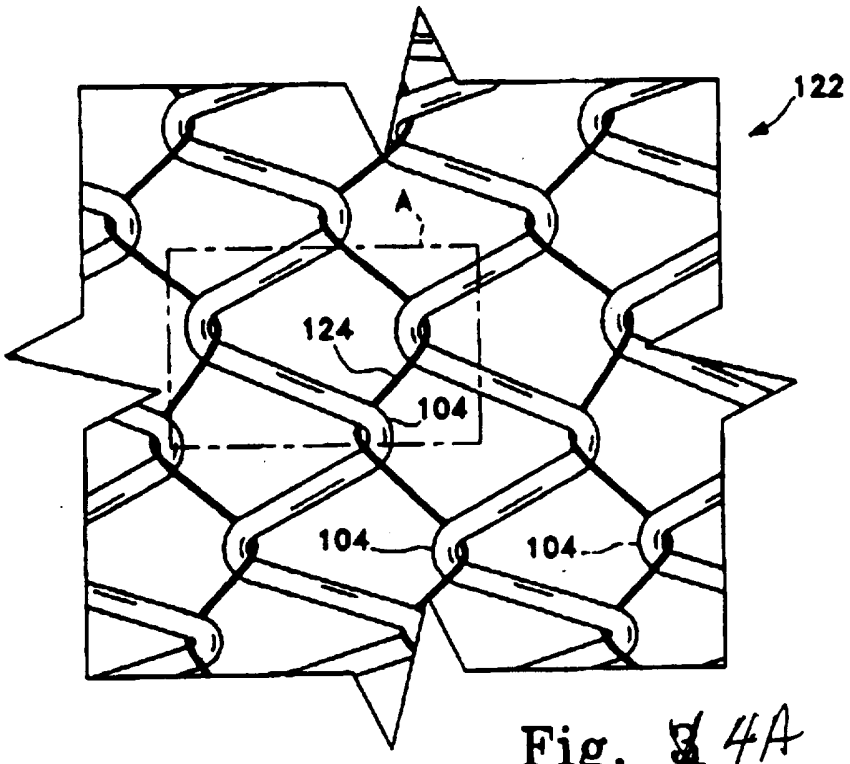


Fig. 4A

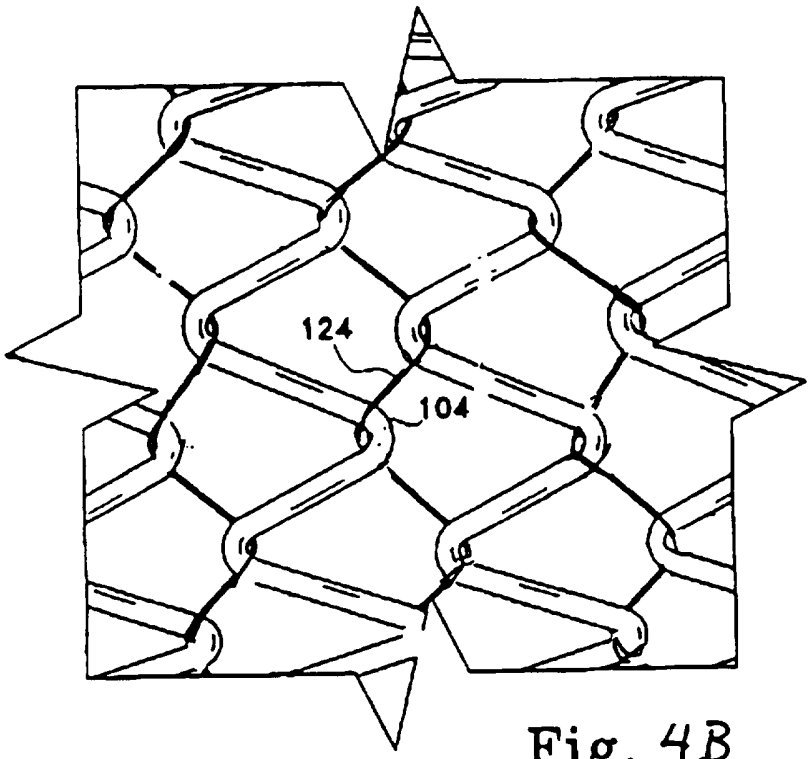
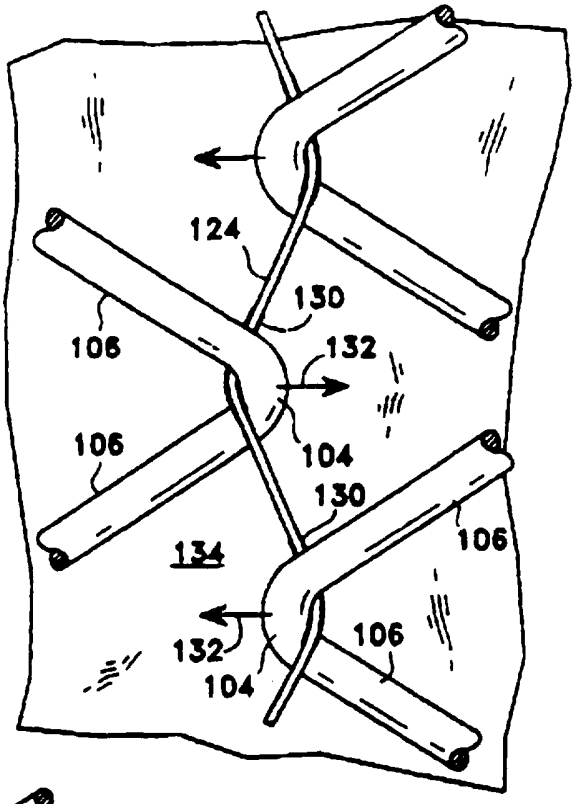


Fig. 4B

Fig. 5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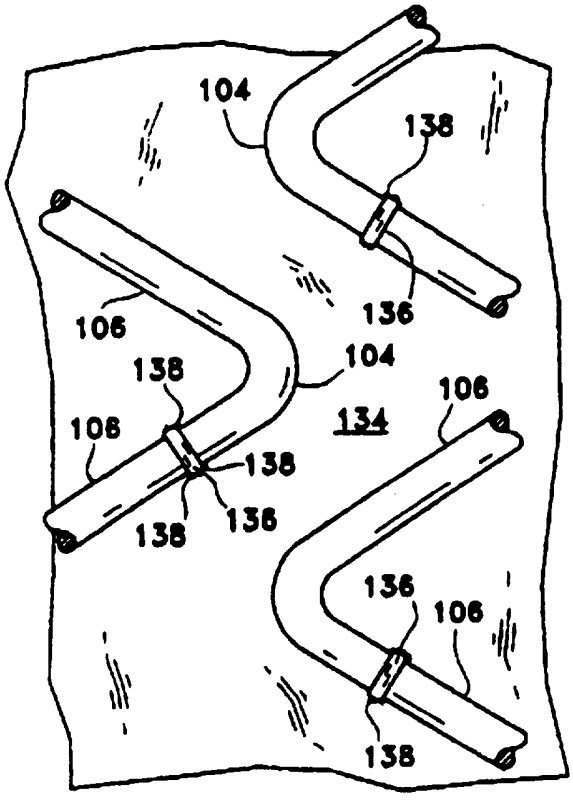
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Fig. 6

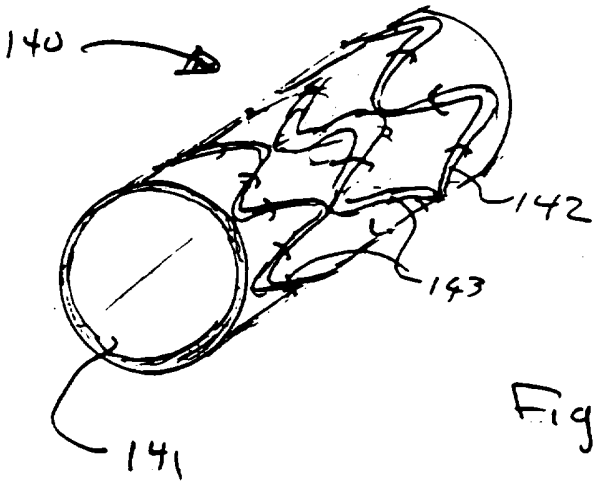

Figure 7

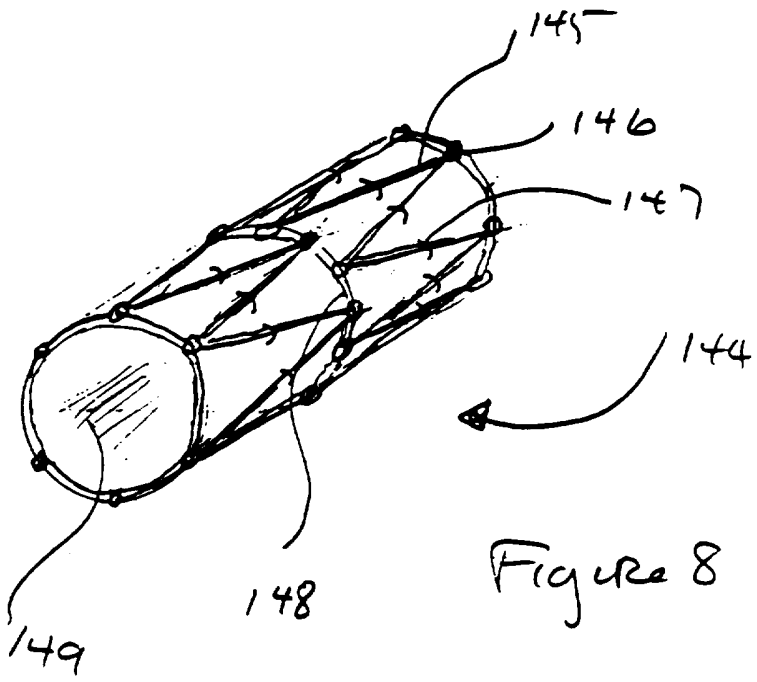

Figure 8

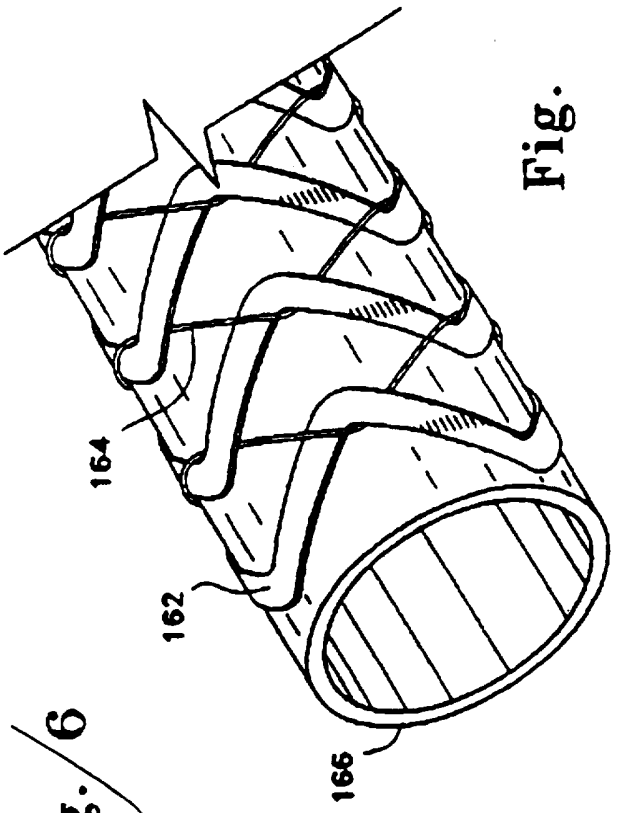

Fig. 6

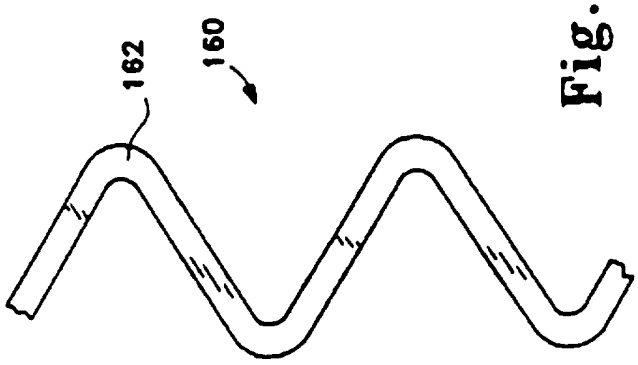

Fig. 9

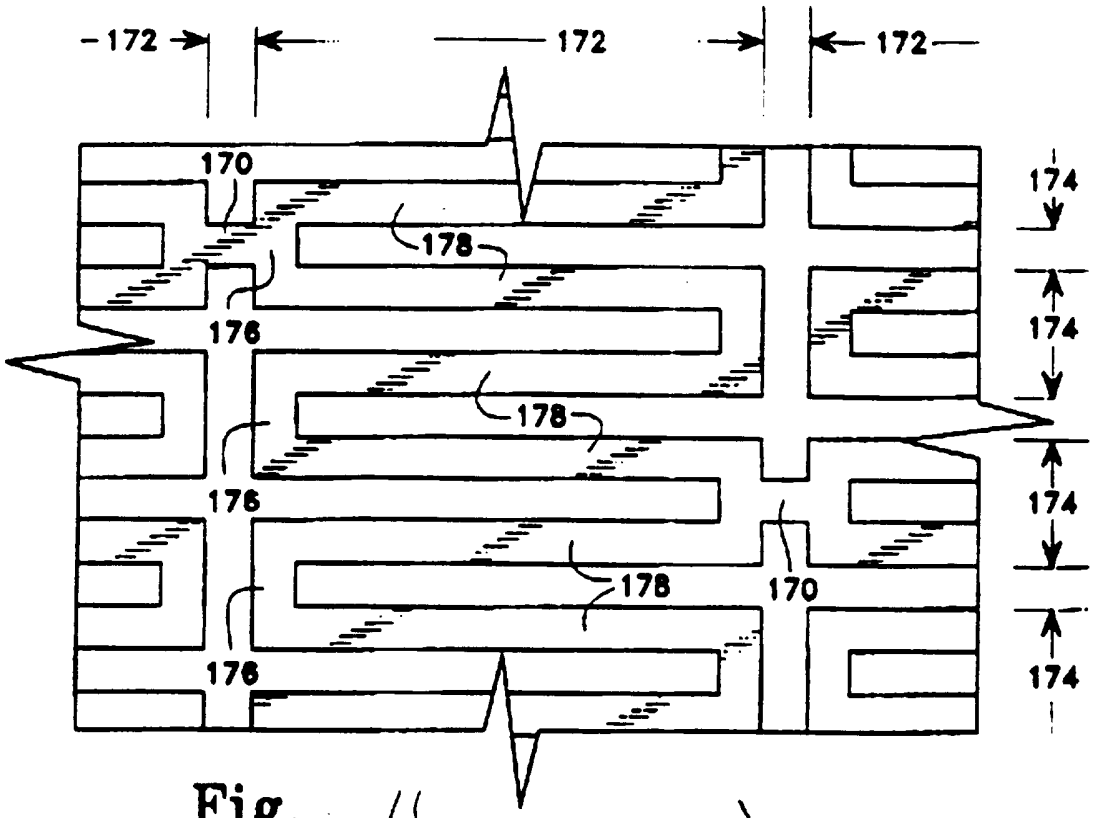

Fig. 11

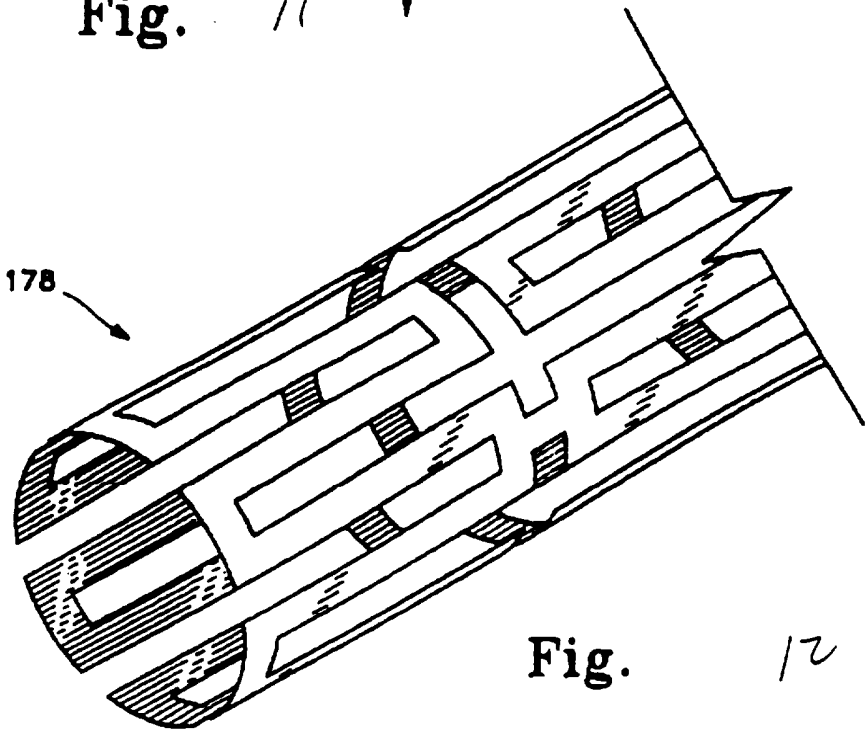

Fig. 12

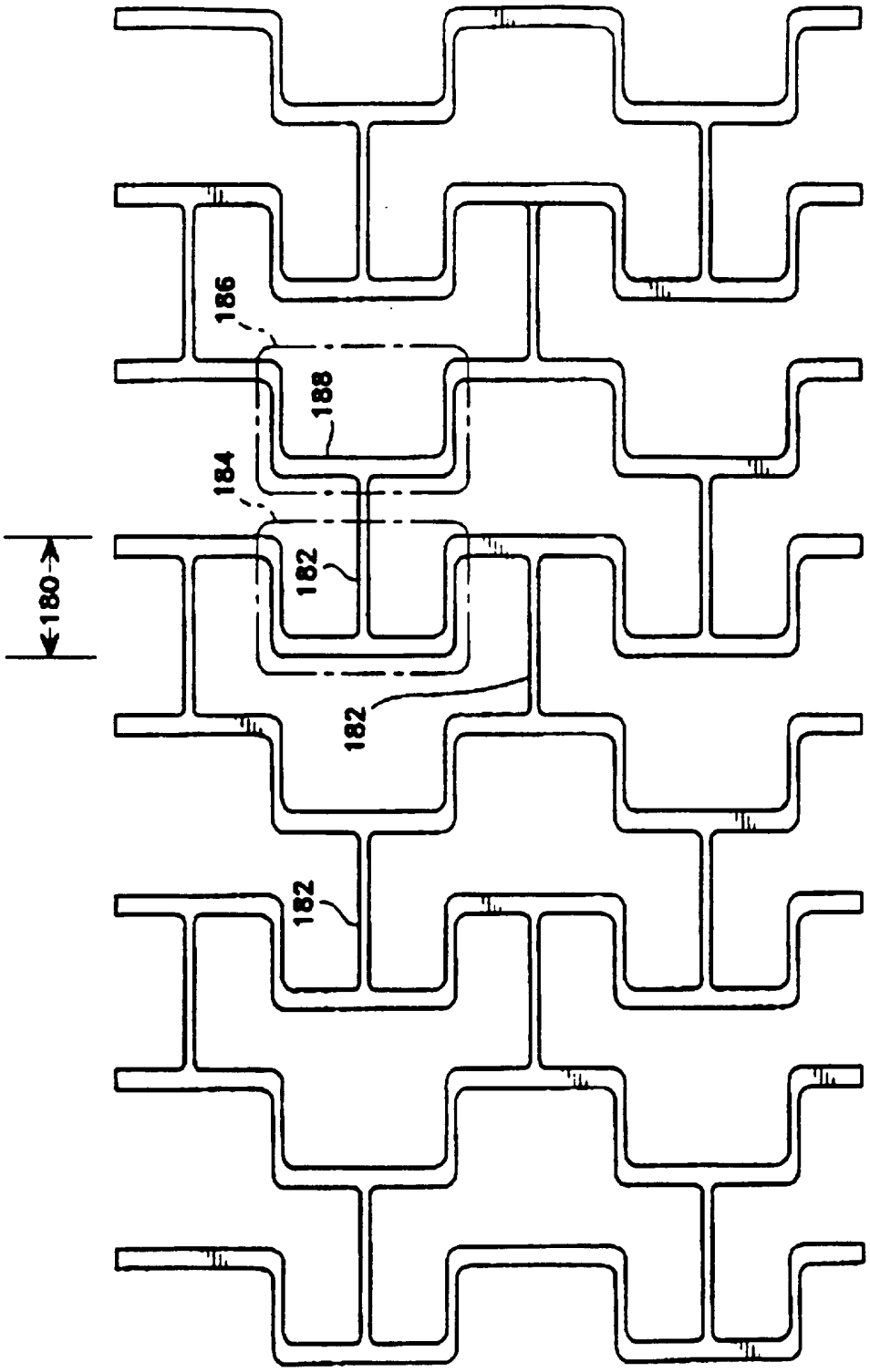

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Fig.

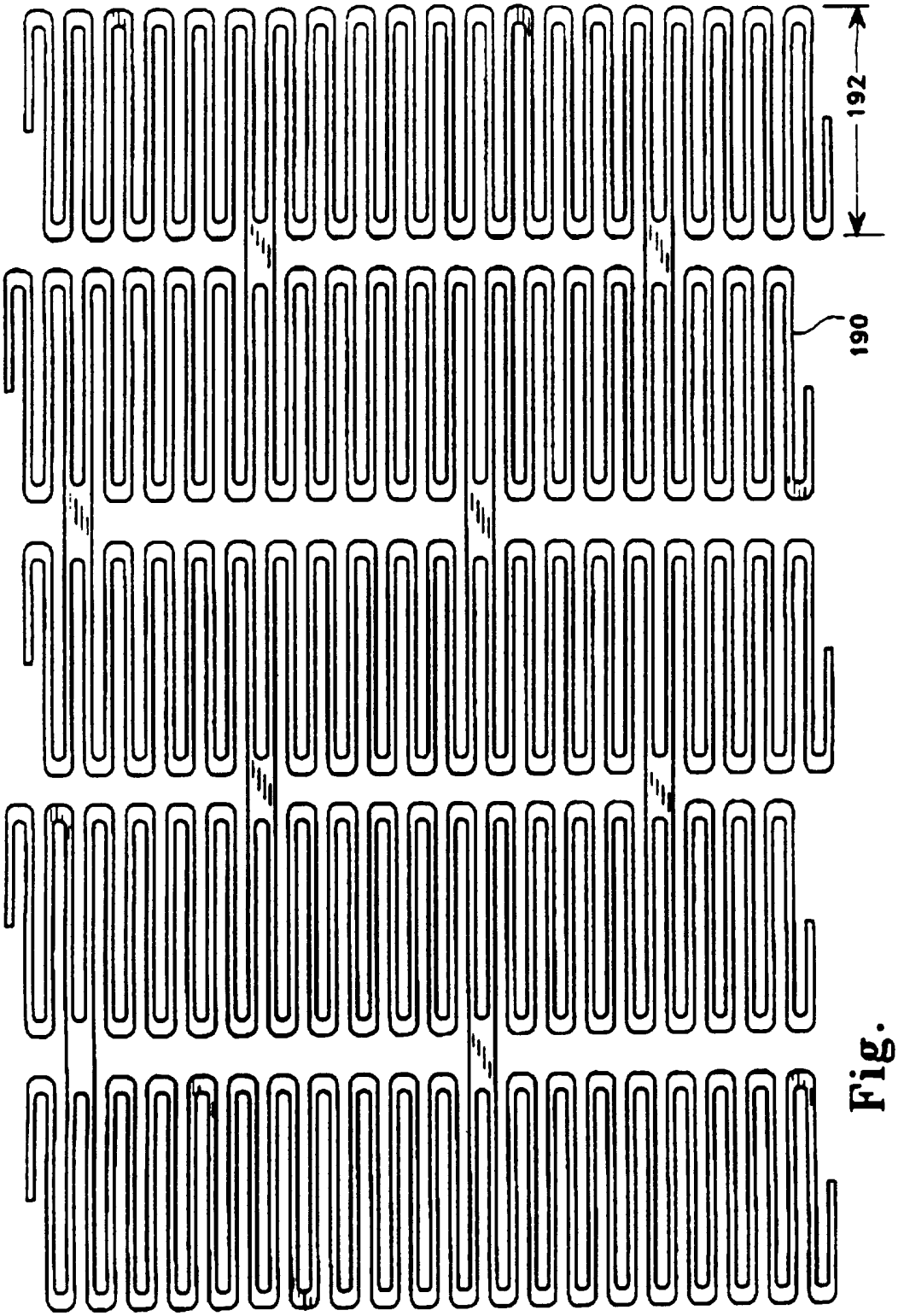

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Fig.

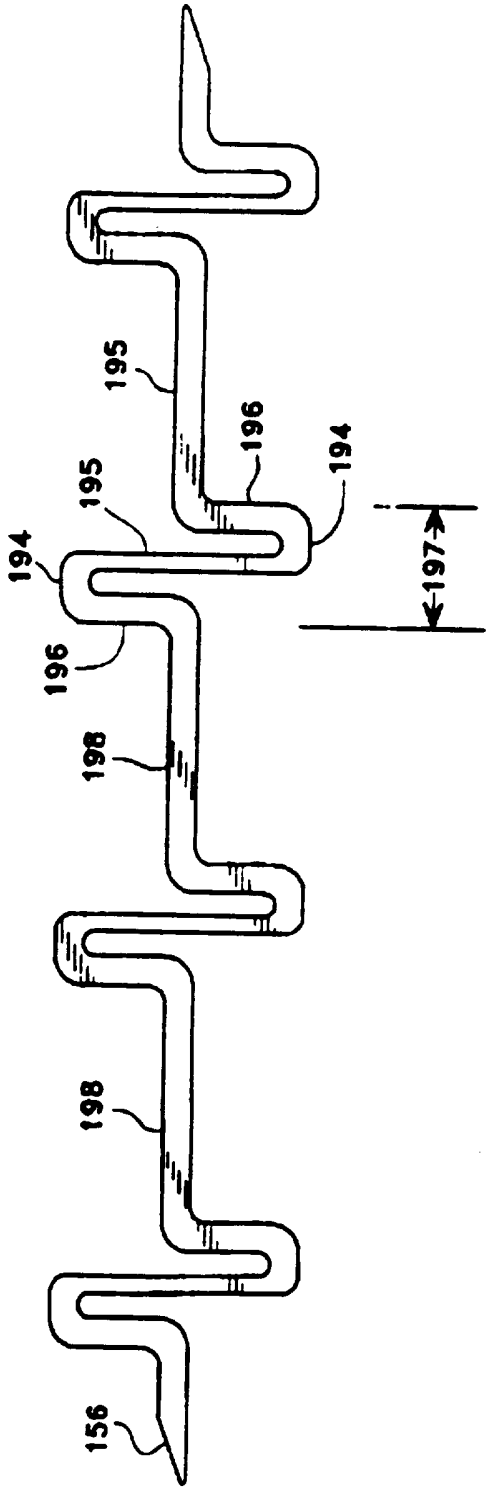

Fig. 15

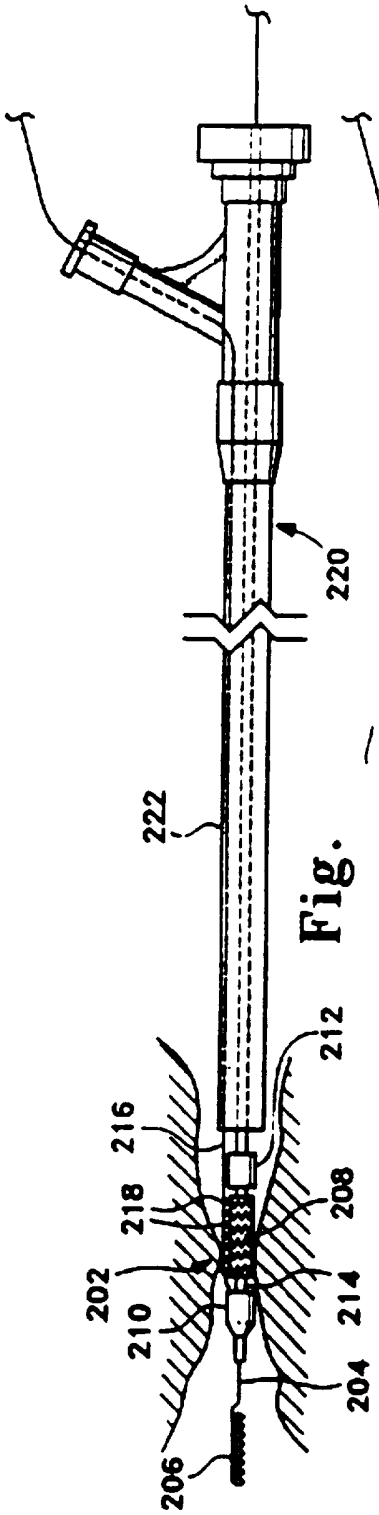

Fig. 16A

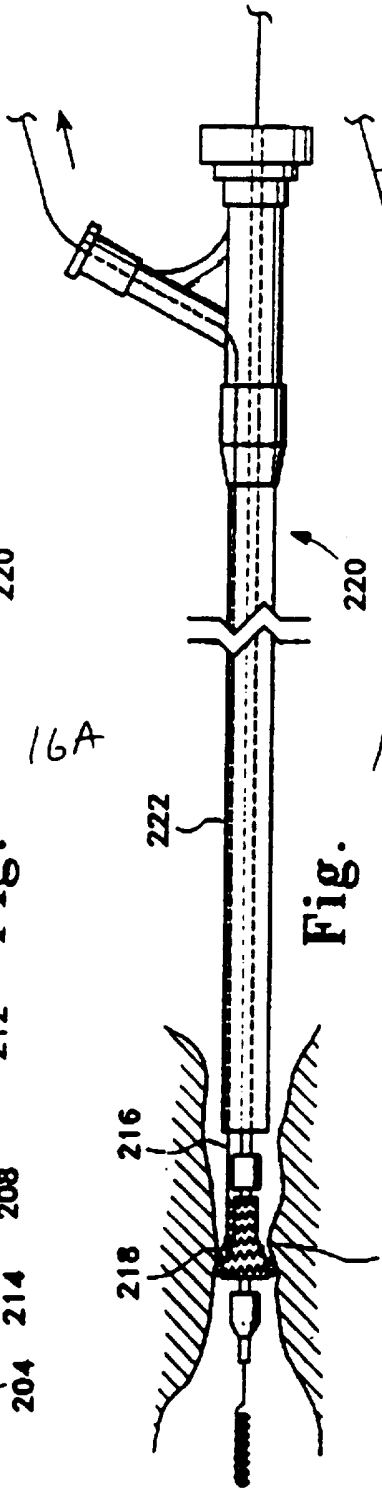

Fig. 16B

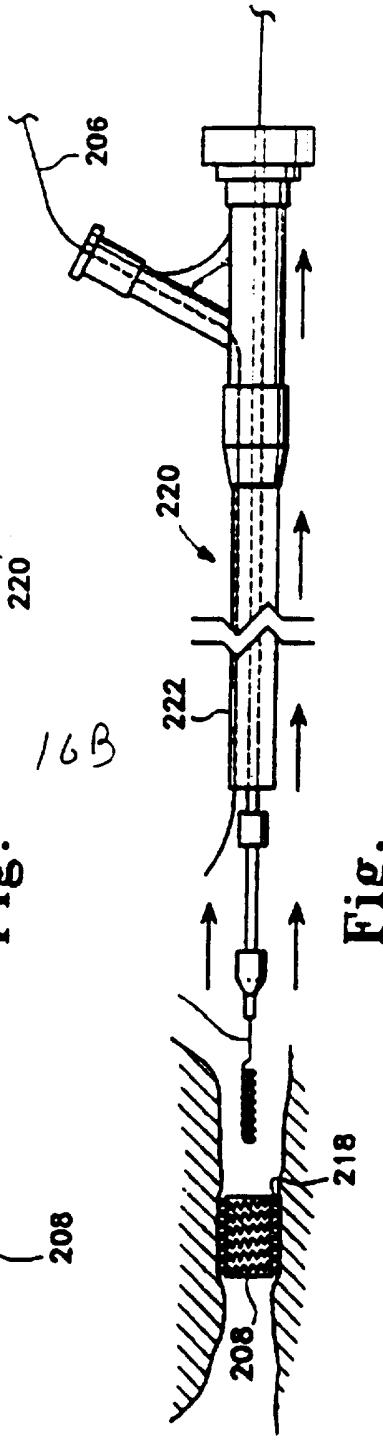

Fig. 16C

INTERNATIONAL SEARCH REPORT

Intern al Application No
PCT/US 96/00574

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06

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)
IPC 6 A61F

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y A	EP,A,0 556 850 (ENDOTECH) 25 August 1993 cited in the application see the whole document ---	1,3,7,9, 10,14 5,23,25, 29,30,34
Y A	EP,A,0 435 518 (MED INSTITUTE) 3 July 1991 see abstract; figures 2-4 ---	1,3,7,9, 10,14 23
A	WO,A,92 03107 (MEADOX MEDICALS) 5 March 1992 see abstract; claim 5 ---	1,13,23, 33
A	WO,A,93 13825 (THE STATE OF OREGON) 22 July 1993 cited in the application see the whole document --- -/--	5,9,29

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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

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Date of the actual completion of the international search	Date of mailing of the international search report
4 June 1996	11.06.96

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Klein, C

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INTERNATIONAL SEARCH REPORT

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PCT/US 96/00574

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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A	US,A,5 100 429 (SINOFSKY) 31 March 1992 cited in the application see abstract	12,32
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P,X	WO,A,95 26695 (PROGRAFT MEDICAL) 12 October 1995 see the whole document	1-41
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