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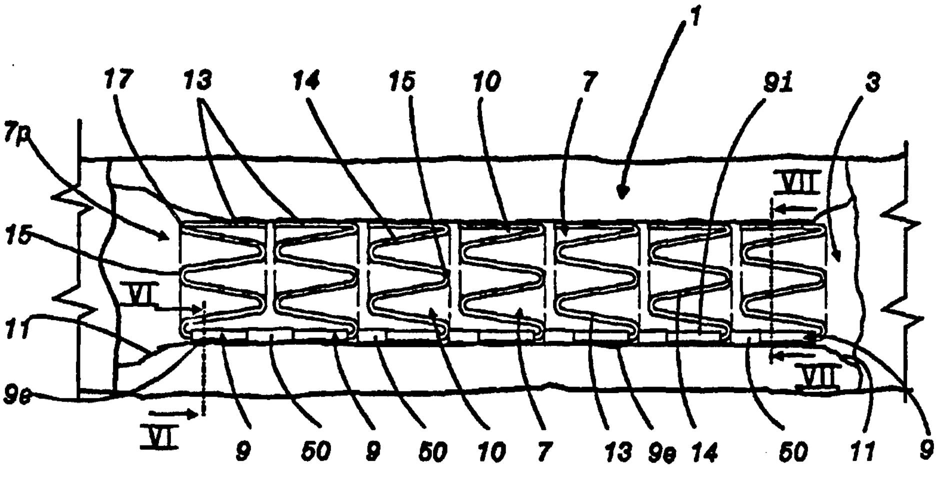

(57) Abstract

An endoluminal stent is formed in a modular construction to include an elongate spine and a plurality of generally tube-defining modules attached to the spine in a longitudinally sequenced array. Each module defines, in cooperation with the spine, a closed ring-like structure, with the modules being aligned in an array to define a generally cage-like tubular structure. Each of the modules is radially expandable from a reduced diameter, low profile configuration, in which it is readily navigated through the body passages, to an expanded diameter engageable with the inner luminal surface of the body lumen. The stent, being of modular construction, can be built to individual specifications for a specific procedure in a specific patient. Modules are formed from a wire shaped in a flat serpentine configuration that is then wrapped in a cylindrical configuration with its free ends connected to the spine. The modules are expandable, as by a balloon, from a low profile to an expanded configuration. During expansion, the modules can wipe against the inner surface of the lumen to smooth sharp points or edges. The spine of the stent defines a substantially greater mass than that of the individual modules such that the spine can be readily observed under X-ray or fluoroscopy. The modular construction enables a wide range of variation in the characteristics of the stent, including longitudinal flexibility, radial expansion characteristics, among others.

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ENDOVASCULAR STENT

Background of the Invention

A number of medical procedures involve or can be supplemented with the placement of an endoluminal prostheses, commonly referred to as a stent, that can be implanted in a lumen, such as a blood vessel or other natural pathway of a patient's body. Such stents typically define a generally tubular configuration, and are expandable from a relatively small diameter (low profile) to an enlarged diameter. In its low profile configuration, the stent can be advanced endoluminally, by a delivery device, through the body lumen to the site where the stent is to be placed. The stent then can be expanded to a larger diameter to firmly engage the inner wall of the body lumen. The delivery device then is removed, leaving the implanted stent in place. In that manner, the stent may serve to maintain open a blood vessel or other natural duct, the functioning of which had become impaired as a result of a pathological or traumatic occurrence.

Among the medical procedures in which stents have had increasing use is in connection with percutaneous transluminal angioplasty (PTA), and particularly percutaneous transluminal coronary angioplasty (PTCA). PTA and PTCA involve the insertion and manipulation of a dilating catheter through the patient's arteries to place the dilatation balloon of the catheter within an obstructed portion (stenosis) of a blood vessel. The balloon then is expanded forcibly within the obstruction to dilate that portion of the blood vessel thereby to restore blood flow through the blood vessel. Among the more significant complications that may result from such angioplasty is that in a significant number of cases, the dilated site again becomes obstructed. By placing a stent within the blood vessel at the treated site, the tendency for such restenosis may be reduced. Accordingly, a number of stents have been proposed and developed.

One such stent is disclosed in U.S. patent 4,800,882 (Gianturco) in which a tubular stent is formed from a single, continuous metal wire that is bent into a planar serpentine configuration extending longitudinally along what will become the axis of the stent. The transversely extending loops of the serpentine wire then are deformably wrapped circumferentially about the axis to define a generally cylindrical surface and the tubular configuration. The stent so formed may be considered to define a plurality of circumferentially curved C-shaped segments, each connected to its adjacent segment at a reversing bend, so that each curved section extends in the opposite circumferential direction than its adjacent curved sections. Consequently, none of the C-shaped curved segments defines a closed circumferential loop. The endoprosthesis then is mounted about the balloon of a delivery catheter and the stent then is crimped about the deflated balloon to its low profile configuration. With the stent so mounted on the balloon, the catheter and stent are advanced through the patient's vasculature to the stenosis where the balloon is inflated to dilate and expand the stent radially and plastically to the dimensions intended. The C-shaped configuration of the curved segments of the stent necessarily and undesirably limits the resistance of the stent to radial compression, as can occur within an artery after an angioplasty has been performed. Increasing the radial resistance to contraction by increasing the thickness of the wire from which the stent is made is an unsatisfactory solution because that necessarily will require an increase in the thickness of the stent which will narrow the cross-section of the lumen. Moreover, the discontinuities in the lateral surface defined by the stent may tend to disturb the fluid dynamics of blood flowing through the blood vessel that, in turn, could induce turbulence with resulting generation of emboli, thrombi and other serious complications.

Also among the difficulties with the above-described device is that it presents little protection for the balloon of the delivery catheter when the catheter is advanced

through the patient's vasculature to the deployment site. As the stent and delivery catheter are advanced, the relatively open configuration of the stent exposes the balloon to the walls of the blood vessel. Those walls may have rigid encrustations of arteriosclerotic plaque that can be irregular and sharp. Consequently, when the stent is advanced past plaque formations, the balloon may be punctured or damaged. That may result in bursting of the balloon when it is subsequently inflated, presenting a danger to the patient.

Also among the difficulties presented with the above-described stent is that its single wire construction does not readily lend itself to precise matching to the vascular anatomy or pathological situation of the specific patient in whom the stent is to be placed. The construction is adapted, as a practical matter, only to being manufactured in standard lengths. When a standard length of stent does not ideally match the patient's anatomy, the physician must choose among those standard lengths in an effort to select one or more. That is, at best, a compromise.

Still another disadvantage of the stent design described above, as well as other stent designs that have a fixed configuration (see, for example, the stent disclosed in EP 335,341) is that when the endoprosthesis must be positioned near a branch in the blood vessels, the implantation of the endoprosthesis in one of the branches may obstruct flow into the other branch.

It also is important that the location and position of the endoprosthesis be determined during implantation as well as at a later time. The Gianturco stent described above, being formed from a single, slender wire may be difficult, if not impossible, to visualize under fluoroscopy or X-ray.

It is among the general objects of the invention to provide an improved endovascular stent that overcomes the above disadvantages.

Summary of the Invention

In accordance with the invention, a stent is constructed in a modular fashion to include an elongate spine and a plurality of generally tube-defining modules attached to the spine in a longitudinally sequenced array. Each module defines, in cooperation with the spine, a closed ring-like structure, with the modules being aligned in an array to define a generally cage-like tubular structure. Each of the modules is formed from wire and is radially expandable from a reduced diameter, low profile configuration, to an expanded diameter engageable with the inner luminal surface of the blood vessel or other body lumen. The modules may be individually mounted and secured in succession along a support wire and are positioned at selected intervals along the support wire.

In another aspect of the invention, each individual tubular module is formed from a wire shaped in a serpentine configuration defined by a plurality of elongate wire segments connected end-to-end by shorter segments. The serpentine wire is wrapped in the generally cylindrical configuration of the module and its free ends are connected to the spine. The elongate segments of each module are essentially oriented lengthwise along the spine and, in transverse section, define the locus of a closed curved loop. When the module is in its low profile configuration, its elongate segments lie closely adjacent and generally parallel to each other and to the spine.

In another aspect of the invention, the modules can be disposed along the spine so that when in a low profile configuration their adjacent ends can be disposed in close proximity to each other to define a circumferential envelope that extends substantially continuously in a longitudinal direction to contain and protect the balloon received within the tubular array of modules. When the anatomy into which the device is to be placed permits the use of a continuous series of such modules, the balloon can be protected over its full length.

In still another aspect of the invention, the modules can be assembled along the spine at selected locations and spacing, enabling a stent to be easily constructed to fit the specific vessel anatomy of the patient.

In a further aspect of the invention, the expansion of the modules from a low profile to an expanded configuration causes the longitudinal segments of the modules to wipe against the inner surface of the lumen wall to smooth sharp points or edges of the blood vessel thereby to reduce the risk of balloon rupture.

In an additional aspect of the invention, the spine is formed to have a substantially greater mass than that of the individual modules such that the spine can be readily observed under X-ray or fluoroscopy.

In still another aspect of the invention, the spine, to which the modules are attached, may be considered as including the support wire and a plurality of connectors individually mountable on the support wire and in which the connectors also serve to attach the ends of the wire of the module to each other and to the support wire. The connectors are configured to provide a region of increased mass by which the spine can be viewed radiographically.

In an additional aspect of the invention, tubular spacers may be disposed on the support wire between the connectors to define the desired spacing between the modules as well as to provide a continuously radiographically observable spine.

It is among the general objects of the invention to provide an improved endoprosthesis embodying a modular construction.

A further object of the invention is to provide a modular endoprosthesis that can be easily constructed to a selected configuration adapted for use in a specific patient vascular anatomy.

Another object of the invention is to provide a stent that is readily observable radiographically.

An additional object of the invention is to provide a construction for a stent in which obstruction of side branches can be minimized.

A further object of the invention is to provide a balloon expandable stent in which the stent provides protection for the balloon as the balloon is navigated into position in the blood vessel.

Description of the Drawings

The foregoing and other objects and advantages of the invention will be appreciated more fully from the following description thereof, with reference to the accompanying drawings wherein:

FIG. 1 is a somewhat diagrammatic illustration of an endoprosthesis in accordance with the invention disposed within an obstructed portion of a blood vessel with the endoprosthesis in its low profile, unexpanded configuration;

FIG. 2 is a somewhat diagrammatic illustration of the endoprosthesis disposed on a balloon that has been inflated to expand the prosthesis to a larger diameter;

FIG. 3 is a somewhat diagrammatic illustration of a pair of adjacent modules of the endoprosthesis illustrating their connection to the support wire;

FIG. 4 is a partially diagrammatic side illustration of the stent disposed within a blood vessel and incorporating several modifications;

FIG. 5 is an illustration similar to FIG. 4 in which the spine is illustrated in plan;

FIG. 6 is a sectional illustration of the region of the spine as seen along the line VI-VI of FIG. 4;

FIGS. 6A illustrates in transverse cross-section, another embodiment of the connector ring for connecting a module to a support wire;

FIG. 7 is a diagrammatic sectional illustration of the device as seen along the line VII-VII of FIG. 4;

FIGS. 8A-8C illustrate schematically the manner in which the configuration of the modules change as they are expanded from the low profile configuration to an expanded configuration; and

FIG. 9 illustrates, diagrammatically, a portion of a stent expandable by alternative means.

Description of the Illustrative Embodiments

FIG. 1 illustrates the endoprosthesis 1 that may be considered to define a cage-like tubular arrangement formed from wire-like components and having a central longitudinal axis 2. The endoprosthesis 1 is constructed from a plurality of individual modules 7 connected to each other along a spine that may be considered to include a longitudinal support wire 6 and connectors 9. The modules 7 are expandable from a contracted, low profile configuration, to facilitate placement of the stent in the body lumen, to an enlarged diameter as suggested in FIG. 2, by which the modules can be expanded into firm engagement with the inner surface of walls 11 of the body lumen 3 to maintain the body lumen open to facilitate blood flow. In the preferred embodiment, the module is expandable inelastically. The radially expandable generally tubular modules 7 are mounted and aligned in a longitudinally sequenced array on the support wire 6 by a connector 9 associated with each of the modules 7. The modules, when mounted on the support wire 6 may be considered to define a virtual peripheral surface 12 that, in transverse cross-section, is in the form of a virtual closed curve or loop 8 about the longitudinal axis 2.

Each module 7 is formed from a wire 13 shaped and configured to enable radial expansion of the cylindrical peripheral surface 12. The module may be formed by first forming the wire 13 into a flat serpentine configuration and then wrapping the serpentine wire into its looped configuration. The terminal ends 16 of the serpentine

wire are free. The free ends 16 of the wire 13 may be attached to each other and to the support wire 6 by the connector 9. The serpentine arrangement of each of the modules may be considered to include a series of elongate first segments alternated with and connected by bends that may be curved (e.g., circular) or may comprise shorter connective segments 15 connected to the elongate segments 14 at cusps 17. The connective bends between the longitudinal segments 14 may lie along and define a locus of the closed loop 8. Preferably, the wire 13 is formed so that the arrangement of bends will be uniformly circumferentially spaced about the virtual closed loop 8 to provide the modules 7 with uniform strength in directions transverse to the support wire 6.

As illustrated diagrammatically in FIG. 8, when the modules are in their low profile, unexpanded configuration, the bends 15, 17 that define the connection between adjacent elongate segments 14 are such that the elongate segments 14 will lie at an angle α close to zero and at an angle approaching 180° when the module is expanded to a position of maximum expansion as suggested in FIG. 8(c). It should be understood, however, that in practice, the stent preferably should not be expanded beyond a configuration suggested in FIG. 8(b). Preferably, the angle α defined between adjacent elongate segments 14 should be contained between about 45° to about 85°. The configuration of the connective bends, including the cusps 17 may be varied to vary the angle α or to vary their number circumferentially about the closed curve 8 to vary the characteristics of the modules 7 including varying its resistance to compressive radial loads such that the endoprosthesis can further be tailored and made to conform ideally to the specific body lumen 3 in which it is to be implanted.

By way of illustrative example only, a stent may be provided to include modules 7 formed from wire having a diameter of about 0.15 millimeter with elongate segments 14 (not including the connective bends between adjacent segments 14) of a length of

about 1.8 millimeters. When the connective bends between adjacent elongate segments 14 are smoothly curved, they may have a radius of about 0.15 millimeter before expansion. A stent having the foregoing dimensions can be expected to be expandable to diameters between about 2.5 to about 4.0 millimeters without excessive expansion, and that such stent exhibits substantial resistance to radial collapse that is well above the maximum radial compressive loads that can be expected to be imposed on the stent by contraction of an artery having a luminal diameter of about 2.5 to about 4.0 millimeters.

In the preferred embodiment the connectors 9 may be constructed to be mounted on the longitudinal support wire 6, as by threading them on the wire 6. The connector 9 preferably may comprise a ring that defines sufficient internal space to receive and circumscribe the free ends 16 of the wire 13 while also permitting firm connection of the ring to the longitudinal support wire 6. The ring connector 9, free ends 16 of the wire and support wire 6 may be firmly connected by means of a permanent deformation, such as crimping, or may be attached to each other by spot welding. As suggested at points 51 in FIG. 5, laser spot welding is preferred. When assembled using laser spot welding, it is preferred that the terminal portions 16 of the module 7 are first welded to the ring 9 and the ring 9 then is welded to the support wire 6. In some instances, it may be desirable to modify the stent so that one or more of the modules (but not the endmost modules) are not securely attached to the support wire 6 but, instead, are permitted some freedom of sliding movement along the support wire 6. This enables making of a final adjustment to the position of the module after the device has been placed in the patient's blood vessel, should that be desired.

FIG. 6 illustrates, in further detail, the configuration of one embodiment of the ring 9. As shown, the ring 9 may be considered to have an internal face 9i that may be essentially flat and an outside face 9e that may be rounded to adapt more readily to the

generally cylindrical wall of the blood vessel. It should be understood, however, that the inner and outer faces 9i, 9e could be fashioned either to be flat or rounded. FIG. 6A illustrates the cross-section of another embodiment of the connector ring 9' in which the wall of the ring is formed to define an inner arcuate contour corresponding to the contours of the support wire 6 and free ends 16 of the module 7. The outer surface of the ring in this embodiment may have a paralleling contour.

The foregoing construction enables a stent to be specially assembled to conform accurately to the specific anatomy of the patient in whom the stent is to be placed. The modules can be positioned as desired along the support wire 6 and can be secured in that configuration. The support wire 6 may be selected to provide the desired degree of longitudinal flexibility and may be made from wire that is extremely flexible to facilitate positioning of the device in relatively inaccessible body lumen. With the foregoing construction in which the stent has an independent support wire 6, the degree of stiffness or flexibility of the support wire can be selected independently of the wire from which the tubular modules are formed. The support wire 6 may be highly flexible to enable the stent to be carried through narrow, tortuous vessels, such as coronary arteries.

It should be understood that although the presently preferred embodiment of the invention incorporates a metal support wire 6 (e.g., stainless steel), the modular construction of the invention enables a fabrication of a stent in which the support wire may be formed from non-metallic materials, such as polymeric materials, for example, nylon. Other mechanically and biologically suitable classes of materials may be selected, including materials from among those that are biologically absorbable into the tissue of the vessel wall over time. With a bioabsorbable support wire 6, it should be selected to maintain its desirable mechanical characteristics for a sufficient time to enable the modules 7 to become firmly embedded in the vessel wall. Thus, the

modular construction of the invention provides a substantially increased range of materials and properties for the individual components, each being selected to provide optimum results.

The connecting rings 9, especially when assembled about the two end segments 16 of the modules 7 and the support wire 6, present a significantly greater mass than that of the wire 13 from which the modules are fashioned. Thus, the region of the spine that includes the connecting rings 9 will present substantially greater radiopacity than that presented by the wire 13 of the associated module. The substantially increased radiopacity of the connected region enhances substantially the radiographic control of the endoprosthesis 1 during implantation. It also enables the endoprosthesis to be observed radiographically at a later time without requiring use of ultrasound procedures. The configuration of the stent enables the tubular frame 10 to be constructed to have a high mechanical strength while enabling expansion of the device between its low profile and expanded configuration yet in which the wire 13 of the modules 7 will be substantially transparent to X-rays at radiation levels that are typically used in such procedures.

FIGS. 4-6 illustrate a further feature of the invention in which the stent 1 can be provided with spacers 50 disposed between pairs of successive rings 9 before the rings are secured to the support wire 6. The spacers preferably are cylindrical in shape and have a central hole by which the spacers can be slid, in bead-like fashion, onto and along the longitudinal wire 6. When a series of connectors 9 and spacers 50 have been placed on the support wire 6, each successive pair of connectors 9 or spacers 50 may embrace one of the other. The length of the spacer(s) may be predetermined to enable precise control over the spacing between two successive modules as well as to reduce the risk of the support wire 6 being twisted or otherwise becoming damaged. An additional result that can be achieved by using the spacers 50 is that it enables a stent

to be assembled with only the two endmost connectors 9 anchored securely to the support wire 6. In such an embodiment, the intermediate components (the connectors 9 and spacers 50) will be retained in position on the support wire and will not separate. Whether all or only the endmost connectors 9 are secured to the longitudinal support wire 6, the intermediate spacers 50 need not be directly secured to the wire 6 but, instead, can be retained in place by and between their adjacent connectors 9. By way of dimensional example, the cylindrical spacers that may be used with a device having the above described dimensions may be about 1.10 millimeters in length, 0.30 millimeter in outer diameter and having a wall thickness of about 0.075 millimeter.

The spacers 50, being circular in cross-section may be arranged to lie substantially flush with the rounded outside face 9e of the adjacent connecting ring 9 as shown in FIG. 6. The spacers 50 may remain marginally proud of the inside face 9i of the connectors 9 as shown in FIGS. 4 and 6. When used with a connector 9 as illustrated in FIG. 6A, the outer surface of the spacer may define a continuation of the outer curved contour in the middle section of the connector 9.

A further advantage in the use of spacers 50 is that together with the rings and the portions of the wire that extend through the rings, the arrangement defines a spine that presents a substantially continuous elongate mass having a radiopacity considerably greater than that of the serpentine wires 13.

All components of the device should be formed from materials that are compatible with each other and will not form microcells that might give rise to electrochemical corrosion of any part of the device after it has been implanted into the blood vessel. The longitudinal support wire 6, wire 13 and connector 9 should have the same chemical composition. Exemplary materials that are preferable in making the endoprosthesis include those from the group of annealed stainless steels, titanium alloys, gold-nickel alloys, nickel-chromium alloys, and titanium-chromium alloys.

The support wire 6 and modules 7 may be treated and formed to vary the mechanical and functional characteristics independently of each other to obtain a desired configuration adapted to treat the anatomy of a specific patient. For example, the wire 13 from which the module is formed may be subjected to an annealing heat treatment to control the malleability of the wire.

Also among the characteristics of the invention is the manner in which the tubular modules 7 protect the balloon of a balloon catheter 4 used in the placement of the endoprosthesis 1. When the device is mounted on the folded balloon of the catheter and is in its low profile phase adapted for delivery, the elongate segments 14 will be disposed in close, substantially parallel and close proximity to each other circumferentially about the balloon. Additionally, the individual tubular modules can be arranged in close longitudinal proximity so that the balloon can be fully protected within the stent longitudinally as well as circumferentially. After the device and catheter 4 have been navigated to locate the deployment site, expansion of the device causes the elongate segments 14 to spread and expand circumferentially along the walls 11 to the body lumen 3 to wipe against the walls 13 and smooth surface roughness that may be present including, particularly, smoothing of sharp or hard regions that otherwise could damage the balloon and possibly result in balloon puncture. As the segments 14 of the module wipe against the walls 11 of the passage 3, they effect a significant shearing action.

In the example illustrated in FIGS. 4 and 5, the endmost tubular modules are arranged in a reversed configuration. As shown, the first tubular module 7p on the left of that example is reversed such that the terminal portions 16 of the wire 13 are directed toward the opposite end of the device, that is, toward the adjacent spacer 50. The reversed arrangement lessens the risk that sharp edges may remain exposed or that a crevice within the endmost connector may be presented to the blood flow. Such

a crevice could become invested with blood from facing the blood flow and could result in the development of a localized thrombosis that could lead to restenosis of the lumen.

FIG. 7 illustrates diagrammatically a further modification in which a second support wire 6' is positioned diametrally opposite the first support wire 6. The addition of a second support wire may make the stent more secure as well as to provide a second highly radiopaque spine to further facilitate localization of the stent during examination. The second support wire 6' is connected to each module in the same manner as with the first support wire 6. In order to accommodate the second support wire 6', the module 7 is formed from two serpentine wires each arranged about the longitudinal axis 2 of the stent to define a portion of the virtual cylindrical surface 12. Each partially curved module segment includes two free ends 16, each adapted to be received within its respective connector 9.

If desired, the wires embodied in the stent may be coated with a protective material such as carbon or with an anticoagulant substance such as heparin.

In a further alternative embodiment, the stent may be expandable by other means, for example, by forming the module 7 from a shape memory alloy such as nitinol. The stent may be provided with electrical resistance heaters 5 to generate sufficient heat to induce thermally controlled expansion of the shape memory alloy module. Such a device is illustrated schematically in FIG. 9.

It should be understood that the foregoing description of the invention is intended merely to be illustrative thereof and that other embodiments, modifications and equivalents thereof will be apparent to those skilled in the art without departing from its principles.

Claims

1. An endoprosthesis for a body lumen comprising:

an elongate support wire;

a plurality of modules supported on the support wire at sequential locations along the support wire, each of the modules being connected to the support wire by a connector secured to the module and attached to the support wire;

each module defining a closed circumferential loop, the modules being arranged on the support wire to define a generally tubular configuration; and

the modules being constructed to be expandable from a radially contracted configuration in which it can be positioned in the body lumen to a radially expanded configuration.

2. An endoprosthesis as defined in claim 1 further comprising a spacer mounted on the support wire between at least one pair of the modules.

3. An endoprosthesis as defined in claim 1 wherein the region of the connection between the module and the support wire has a mass that has greater radiopacity than the expandable modules.

4. An endoprosthesis as defined in either one of claims 2 or 3 wherein the spacers have a greater mass than the modules to present greater radiopacity than the modules.

5. An endoprosthesis as defined in claim 1 wherein each tubular module is formed from a serpentine wire having a plurality of elongate segments alternated with

shorter connective bends.

6. An endoprosthesis as defined in claim 5 wherein the serpentine wire has free terminal ends attached to the connector to secure the serpentine module in its closed circumferential loop configuration.

7. An endoprosthesis as defined in claim 6 wherein the connector includes an aperture receptive to the support wire and by which the connector can be slid onto and along the support wire.

8. An endoprosthesis as defined in claim 6 wherein the connector comprises a ring adapted to surround each of the free terminal ends of its associated module and the support wire.

9. An endoprosthesis as defined in claims 1 or 8 wherein the module, connector and support wire are connected by one of or a combination of spot welding and crimping.

10. An endoprosthesis as defined in claim 1 wherein the radially outward facing surface of the connector is formed in a curved shape to facilitate its conformance to the curved shape of the wall of the blood vessel.

11. An endoprosthesis as defined in claim 2 wherein the outer surface of the spacer is curved to facilitate its conformance to the curved shape of the wall of the body lumen.

12. An endoprosthesis as defined in claim 11 wherein the outwardly exposed surface of the spacer is contoured to correspond substantially to the contour presented by the outwardly facing surface of its adjacent connectors thereby to present a substantially smooth and continuous surface adapted to bear against and conform with the contour of the body lumen.

13. An endoprosthesis as defined in claim 1 wherein the modules define a cage-like tubular structure connected to each other along a longitudinally flexible spine.

14. An endoprosthesis as defined in claim 5 wherein adjacent elongate segments are connected to each other by arcuate bends.

15. An endoprosthesis as defined in claim 5 wherein adjacent elongate sections are connected to each other by short segments and cusps connecting the short segments to the elongate segments.

16. An endoprosthesis as defined in claim 5 wherein the bends are arranged in a substantially uniform circumferential distribution along the locus of the closed loop.

17. An endoprosthesis as defined in claim 1 further comprising a second longitudinal wire connected to the modules and extending generally parallel to the first mentioned support wire.

18. An endoprosthesis as defined in claim 1 wherein at least one of the modules or support wire has a malleability different from the other.

19. An endoprosthesis as defined in claim 1 wherein each of the modules, support wire and connectors are formed from a material having sufficient similarity to avoid development of corrosion at the juncture of such components.

20. An endoprosthesis as defined in claim 19 wherein the module is formed from a material belonging to the group comprising annealed stainless steel, titanium alloys, nickel gold alloys, nickel chromium alloys and titanium chromium alloys.

21. An endoprosthesis as defined in claim 1 wherein the endoprosthesis is coated with a protective material.

22. An endoprosthesis as defined in claim 21 wherein the protective material comprises carbon.

23. An endoprosthesis as defined in claim 1 wherein the endoprosthesis is coated with a drug.

24. An endoprosthesis as defined in claim 23 wherein the drug comprises an anticoagulant.

25. An endoprosthesis as defined in claim 6 wherein the end modules of the endoprosthesis are attached to the support wire with their free terminal ends oriented toward each other.

26. An endoprosthesis as defined in claim 1 wherein the module is constructed to be inelastically deformable during expansion.

27. An endoprosthesis as defined in claim 1 dimensioned to be receivable in a human coronary artery while in a low profile configuration and to be expandable within the artery into engagement with the walls of the coronary artery.

28. An endoprosthesis for placement in a human body lumen comprising:

the endoprosthesis being formed from a plurality of components arranged to define a generally tubular configuration, all of the components being formed from the same material and being connected to each other at joints formed to be free of corrosion inducing properties.

29. An endoprosthesis as defined in claim 28 wherein the joints are formed from one or both of mechanical crimping and spot welding.

30. An endoprosthesis as defined in claim 29 wherein said welding comprises laser welding.

31. An endovascular stent comprising:

a plurality of modules connected at spaced locations to and along a spine, the spine having a substantially greater mass than the modules whereby the spine will be substantially more visible radiographically than the modules.

32. A stent as defined in claim 31 wherein all of the structural components of the stent are formed from the same material and wherein the relative mass of the components is a function of their dimensions.

33. A stent as defined in either one of claims 31 or 32 wherein the spine

comprises an elongate support wire and a plurality of connectors mounted on the support wire and being connected to the modules.

34. A stent as defined in claim 33 further comprising at least one spacer disposed on the support wire between a pair of connectors for spacing the connectors and their associated expandable members.

35. A stent as defined in claim 2 wherein each of the endmost modules is securely connected to the support wire and where at least one of the connectors between the endmost modules is not rigidly connected to the support wire, the longitudinal position of said unsecured connector being determined by its adjacent spacers.

36. A stent and delivery device therefor comprising, in combination:

a delivery catheter having an expandable balloon at its distal end;

a stent comprising an elongate support wire, a plurality of modules supported on the support wire at spaced locations along the support wire, each of the modules being connected to the support wire by a connector secured to the module and attached to the support wire, each module defining a closed circumferential loop, the modules being arranged on the support wire to define a generally tubular configuration, the modules being constructed to be expandable from a radially contracted configuration to facilitate positioning in the body lumen to a radially expanded configuration;

at least some of the modules being disposed in close longitudinal proximity to each other to surround and protect the balloon.

37. A stent and delivery device therefor as defined in claim 36 further comprising:

the stent module each being formed from a serpentine wire having a plurality of elongate segments alternated with shorter bends, the elongate segments in each module lying in close, longitudinal, paralleling proximity to each other in surrounding protective relation to the balloon.

38. A stent and delivery device defined in claim 37 wherein the elongate segments of the stent are constructed so that when the balloon is inflated to expand the stent, the elongate segments of the stent will spread apart and wipe against the inner luminal surface of the blood vessel thereby to smooth the surface of the inner lumen of the artery.

39. An endoprosthesis for a body lumen comprising:

an elongate support wire;

a plurality of modules disposed at spaced locations along the support wires;

means for connecting each of the modules to the support wire;

each of the modules defining a closed circumferential loop, the modules being arranged on the support wire to define a generally tubular configuration; and

the modules being constructed to be expandable from a low profile to an expanded configuration.

40. An endoprosthesis as defined in claim 39 wherein the modules are constructed to be inelastically expandable from their low profile to their expanded configuration.

41. A method for making an endovascular stent comprising:

providing an elongate support wire;

providing a plurality of modules, each defining a closed circumferential loop;

providing a connector for connecting each of the modules to the support wire; and

attaching the connectors to their associated modules; and

connecting the modules, support wire and connector together at selected spaced locations along the length of the support wire.

42. A method as defined in claim 41 wherein the step of attaching comprises simultaneously connecting an individual module and its associated connector to the support wire.

43. A method as defined in claim 41 wherein the module is first attached to the connector to form a subassembly which then is connected to the support wire.

44. A method as defined in claim 41 further comprising:

interposing spacers on the support wire between pairs of adjacent connectors thereby to define the space between adjacent connectors.

45. A method as defined in claim 42 wherein the spacers are substantially the same length.

46. A method as defined in claim 41 where all of the support wire, modules

and connectors are formed from the same material.

47. A method as defined in claim 46 wherein the spacer is formed from the same material as the connectors.

48. An endoprosthesis as defined in claim 5 wherein the connective bends of the modules are substantially uniformly circumferentially spaced about the closed loop.

49. An endoprosthesis as defined in claim 1 further comprising a second longitudinal support wire.

50. An endoprosthesis as defined in claim 5 wherein at least the wire forming the module is treated to induce its malleability.

51. An endoprosthesis as defined in claim 1 wherein the connector comprises a ring having an inside face and an opposite outside face, the outside face being rounded and adapted to conform to the nominally cylindrical wall of a blood vessel.

52. An endoprosthesis as defined in claim 51 wherein the inside face of the ring is substantially flat.

53. An endoprosthesis as defined in claim 51 further comprising a spacer element disposed on the support wire adjacent a connector, the external surface of the spacer element defining a rounded profile substantially corresponding to that presented by the outside face of the connector ring.

54. A method for inserting an endoprosthesis into a body lumen comprising:

inserting a catheter having a contracted balloon into an endoprosthesis comprising a succession of expandable tubular modules carried by a longitudinal support wire;

inserting the catheter and endoprosthesis into the passage of a living body;

simultaneously expanding the endoprosthesis while causing the endoprosthesis to smooth the surface of the walls of the body lumen;

continuing expansion of the endoprosthesis to cause the endoprosthesis to be firmly associated with the walls of the passage.

55. A method for inserting a vascular endoprosthesis comprising:

preliminarily determining the vascular anatomy into which the endoprosthesis is to be placed;

thereafter constructing, in module fashion, an endoprosthesis with reference to said determined coronary anatomy by providing a longitudinal support wire and mounting a plurality of tubular radially expandable modules on the support wire, the modules being selected and placed along the wire in conformity to said determined anatomy;

mounting the endoprosthesis on a delivery catheter; and

advancing the delivery catheter to the intended placement site.

56. An endoprosthesis as defined in claim 1 wherein at least the connectors associated with the endmost modules on the support wire are secured to the support wire and where at least one of the connectors intermediate the end modules is not secured to the support wire thereby enabling the at least one unsecured module to be

slid longitudinally along at least a portion of the support wire.

57. An endoprosthesis as defined in claim 1 further comprising:

at least one of the connectors associated with a module being attached to the support wire to enable the module to be slid along at least a portion of the support wire.

58. An endoprosthesis as defined in claim 1 further comprising:

a second elongate support wire extending parallel to the first mentioned elongate support wire and associated with at least some of the modules;

each of the modules associated with the second support wire being formed in segments that together define the closed circumferential loop, each of the segments associated with the second support wire being connected to the second support wire by a connector secured to the segment and attached to the second support wire.

59. An endoprosthesis as defined in claim 8 wherein the internal contour of the ring is adapted to surround closely and substantially conform to the external contour of the free terminal ends and support wire.

60. An endovascular stent as defined in claim 31 further comprising at least one additional spine having a substantially greater mass than the modules, the additional spine extending parallel to the first mentioned spine.

61. An endoprosthesis as defined in claim 1 wherein at least the elongate support wire is formed from a non-metallic material.

62. An endoprosthesis as defined in claim 61 wherein the non-metallic material comprises a polymeric material.

63. An endoprosthesis as defined in claim 62 wherein the material comprises nylon.

64. An endoprosthesis as defined in claim 62 wherein the material for the elongate support wire comprises a bioabsorbable material.

FIG 1

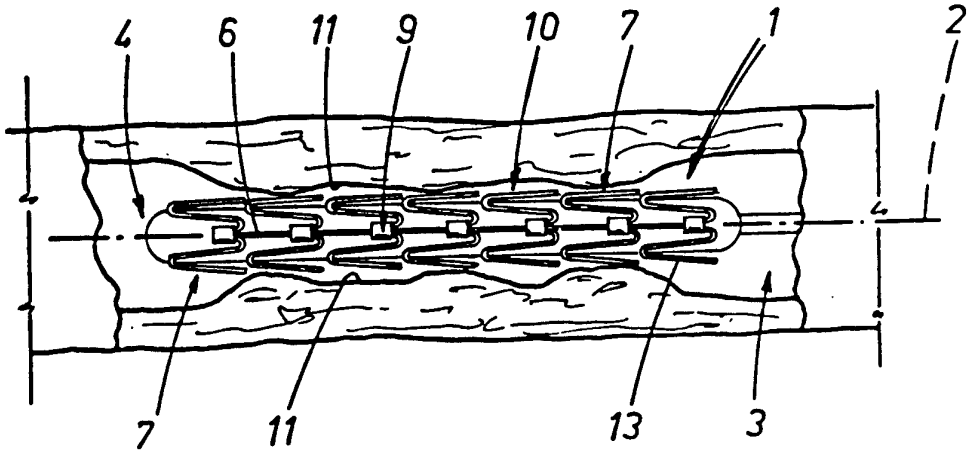
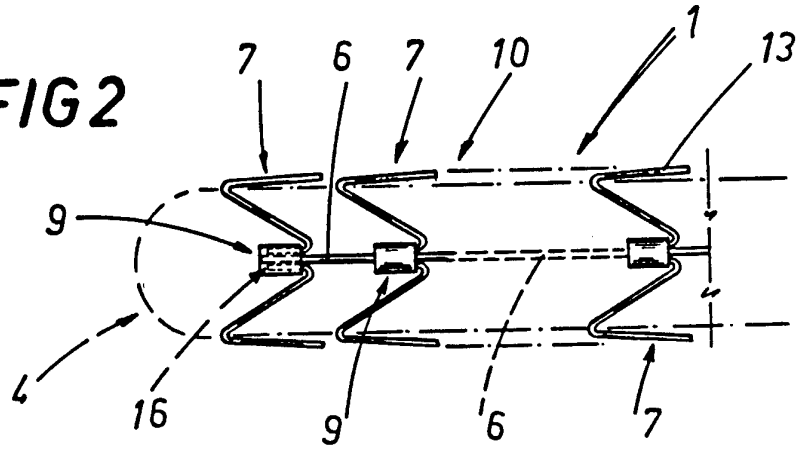


FIG 2



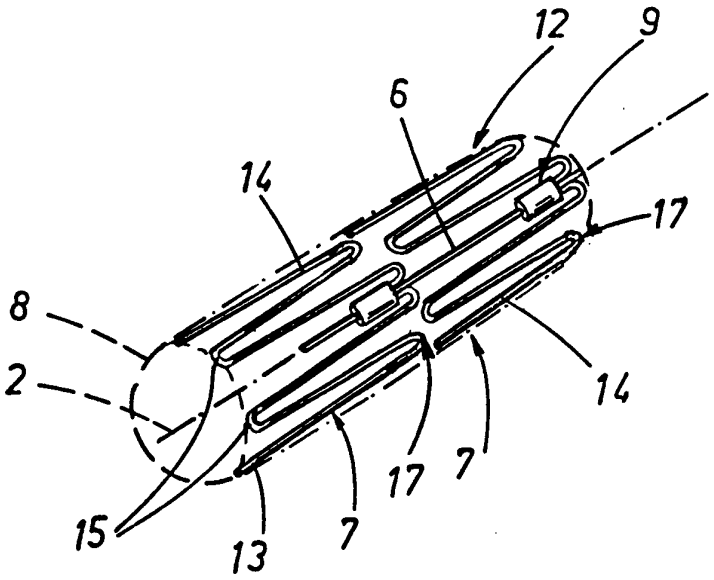


FIG 3

FIG 6

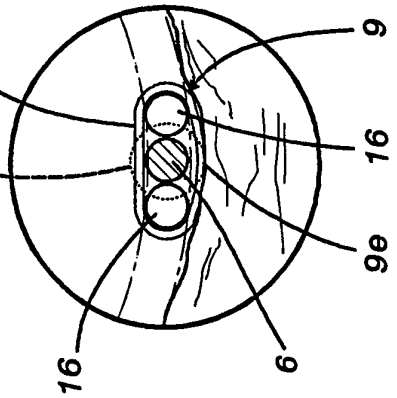


FIG 7

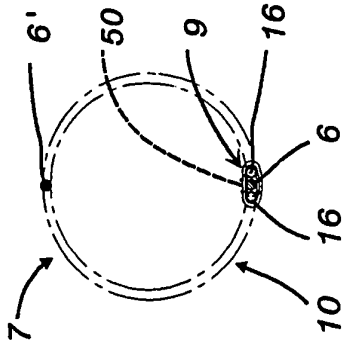


FIG 4

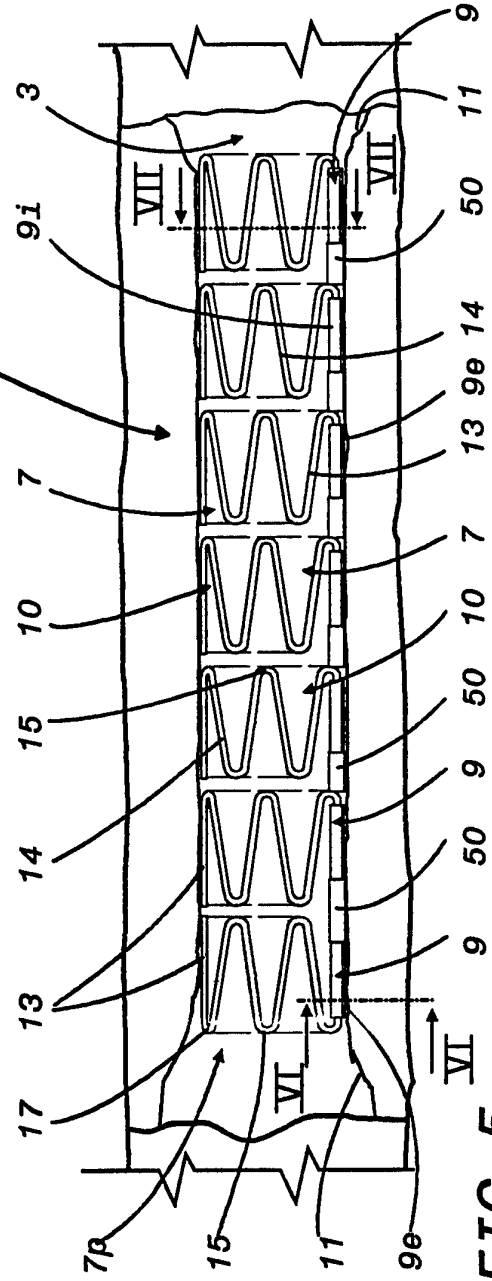


FIG 5

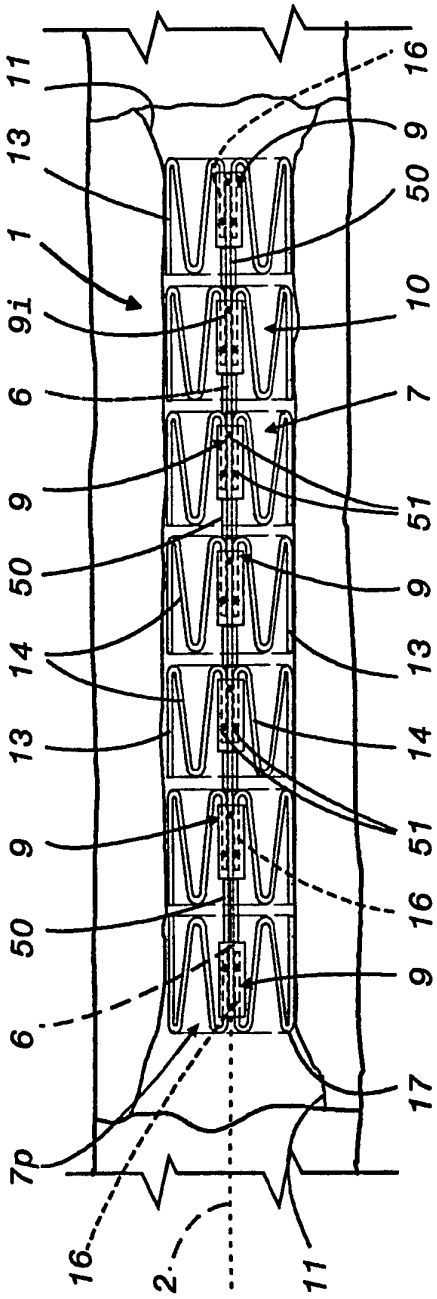


FIG 8a

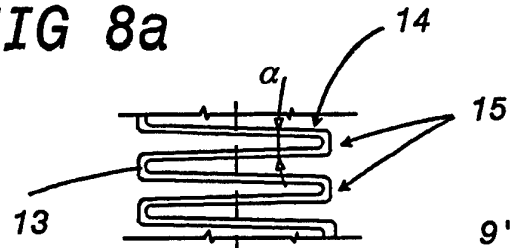


FIG 6A

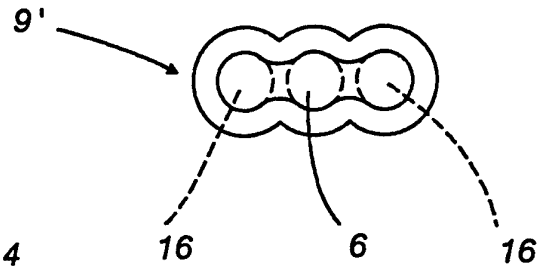


FIG 8b

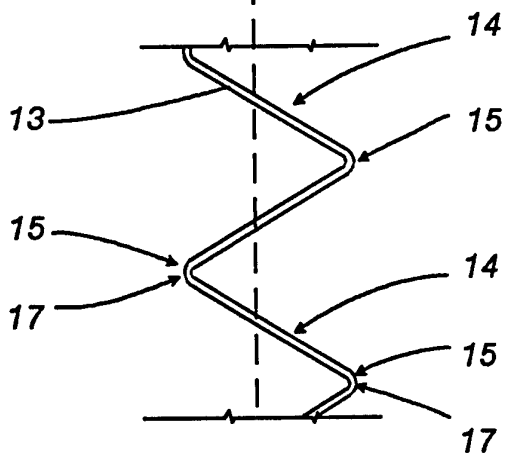


FIG 8c

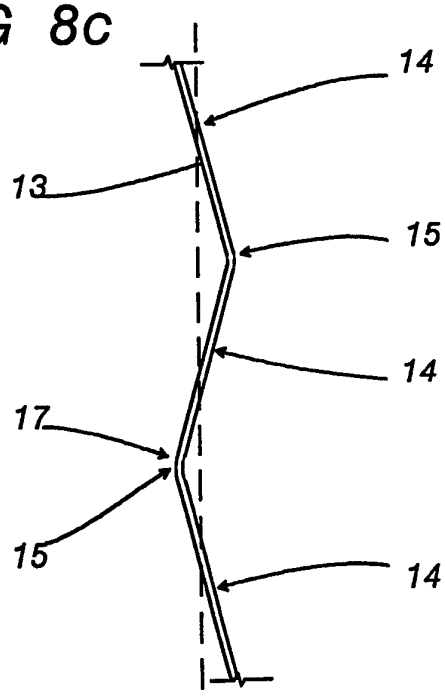
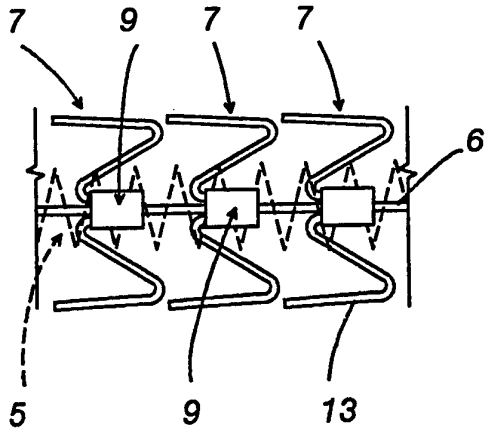


FIG 9



INTERNATIONAL SEARCH REPORT

Int onal Application No
PCT/IB 96/00568

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 A61B

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.
X	US,A,5 160 342 (REGER VINCENT A ET AL) 3 November 1992 see column 2, line 64 - column 3, line 5 see column 6, line 27 - line 33 see figures 2,4	1-4, 9-13,18, 19,21, 27,35, 39,40, 51-53, 56,57, 61,62
Y		20,22-24
A		5-8,25, 26,48, 50,59

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

[X] Patent family members are listed in annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
20 September 1996	01. 10. 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	Chabus, H

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INTERNATIONAL SEARCH REPORT

Inte ɔnal Application No
PCT/IB 96/00568

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP,A,0 540 290 (ADVANCED CARDEOVASCULAR SYSTEM) 5 May 1993 see column 4, line 37 - line 41 see column 7, line 23 - line 26; figures 6,7	20
A		31-34, 36-38, 41-47,60

Y	EP,A,0 603 959 (DEREUME JEAN PIERRE GEORGE EMI) 29 June 1994 see page 3, line 11 - line 13	22

Y	WO,A,93 06792 (SCIMED LIFE SYSTEMS INC) 15 April 1993 see page 20, line 16 - line 20 see page 22, line 12 - line 15	23,24
A		63,64

X,P	EP,A,0 669 114 (FISCHELL ROBERT ;FISCHELL DAVID R (US); FISCHELL TIM A (US)) 30 August 1995 see column 3, line 40 - line 58 see column 4, line 40 - line 43 see column 5, line 34 - line 38 see column 6, line 4 - line 9; figures 1-6	1,9,13, 17, 19-21, 26-30, 36,39, 40,49,58

X	EP,A,0 421 729 (MEDTRONIC INC) 10 April 1991 see column 4, line 18 - line 27 see column 4, line 44 - line 48	28-30
A		31

X	EP,A,0 335 341 (EXPANDABLE GRAFTS PARTNERSHIP) 4 October 1989 see column 9, line 13 - line 33 see column 12, line 27 - line 40; figures 7,9	28
A		5,14-16, 36-40

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

'ternational application No.
PCT/IB 96/00568

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 54,55
because they relate to subject matter not required to be searched by this Authority, namely:
Method for treatment of the human or animal body by surgery.
See Rule 39.1(iv) PCT.

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter[illegible]al Application No
PCT/IB 96/00568

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