



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61B 17/12		A1	(11) International Publication Number: WO 99/09893
			(43) International Publication Date: 4 March 1999 (04.03.99)
(21) International Application Number: PCT/US98/17650 (22) International Filing Date: 26 August 1998 (26.08.98) (30) Priority Data: 08/924,010 29 August 1997 (29.08.97) US 08/942,856 2 October 1997 (02.10.97) US 09/018,278 4 February 1998 (04.02.98) US (63) Related by Continuation (CON) or Continuation-in-Part (CIP) to Earlier Application US 09/018,278 (CIP) Filed on 4 February 1998 (04.02.98) (71) Applicant (for all designated States except US): BOSTON SCIENTIFIC LIMITED [BB/BB]; Financial Services Centre, P.O. Box 111, Bishop's Court Hill, St. Michael (BB). (72) Inventors; and (75) Inventors/Applicants (for US only): WALLACE, Michael, P. [US/US]; 3515 D Bernal Avenue, Pleasanton, CA 94566 (US); LEVINE, Marc-Alan [US/US]; 1392 28th Avenue, San Francisco, CA 94122 (US); HUI, Delilah, Yin [US/US]; 84889 Herringbone Way, Union City, CA 94587 (US); CHEN, Mary, M. [-/US]; 364 Haas Avenue, San Leandro,		CA 94577 (US). HO, Liem [VN/US]; 2235 California Street #157, Mountain View, CA 94040 (US). (74) Agents: PASTERNAK, Dahna, S. et al.; Morrison & Foerster LLP, 755 Page Mill Road, Palo Alto, CA 94304-1018 (US). (81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published With international search report.	
(54) Title: ANATOMICALLY SHAPED VASO-OCCLUSIVE DEVICE AND METHOD OF MAKING SAME			
(57) Abstract			
<p>This is an implantable vaso-occlusive device. The device has a complex, three-dimensional structure in a relaxed configuration that may be used in the approximate shape of an anatomical cavity. It may be deployed in the approximate shape of a sphere, an ovoid, a clover, a box-like structure or other distorted spherical shape. The loops forming the relaxed configuration may pass through the interior of the structure. The device is a self-forming shape made from a pre-formed linear vaso-occlusion member. Fibers may be introduced onto the device and affixed to the pre-formed linear member. The constituent member may be also covered with a fibrous braid. The device is typically introduced through a catheter. The device is passed axially through the catheter sheath and assumes its form upon exiting the catheter without further action. The invention also includes methods of winding the anatomically shaped vaso-occlusive device into appropriately shaped forms and annealing them to form various devices.</p>			

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

ANATOMICALLY SHAPED VASO-OCCLUSIVE DEVICE AND METHOD OF MAKING SAME

Related Applications

5 This application is a continuation-in-part of U.S. Serial No. 08/942,856, filed October 2, 1997, which is a continuation-in-part of U.S. Serial No. 08/924,010, filed August 29, 1997.

Field of the Invention

10 This invention is an implantable vaso-occlusive device. More particularly, it is a vaso-occlusive device which, in a relaxed configuration, has a stable three-dimensional structure which may be used to fill an anatomical cavity. The vaso-occlusion member may be one or more strands of a helical coil or braid variously comprising a suitable metal, or, in the case of a braid, such metal may
15 be co-woven with various polymeric or natural fibers. The relaxed configurations are comprises of a series of overall shapes including spherical, elliptical, oval, clover or box-like. The relaxed configurations may be substantially hollow or may have one or more strands or loops of the coil passing though the interior of the structure. The device is a self-forming shape made
20 from a pre-formed vaso-occlusion member.

Background of the Invention

 Vaso-occlusion devices are surgical implements or implants that are placed within the vasculature of the human body, typically via a catheter,
25 either to block the flow of blood through a vessel making up that portion of the vasculature through the formation of an embolus or to form such an embolus within an aneurysm stemming from the vessel. One widely used vaso-occlusive device is a helical wire coil having windings which may be dimensioned to engage the walls of the vessels. Other less stiff helically coiled devices have been
30 described, as well as those involving woven braids.

For instance, U.S. Patent No. 4,994,069, to Ritchart et al., describes a vaso-occlusive coil that assumes a linear helical configuration when stretched and a folded, convoluted configuration when relaxed. The stretched condition is used in placing the coil at the desired site (by its passage through the catheter) and the coil assumes a relaxed
5 configuration -- which is better suited to occlude the vessel -- once the device is so placed. Ritchart et al. describes a variety of shapes. The secondary shapes of the disclosed coils include "flower" shapes and double vortices. A random shape is described, as well. U.S. Patent No. 5,648,082 to Sung et al., describes methods for treating arrhythmia using coils which assume random configurations upon deployment from a catheter.

10 Other three dimensional vaso-occlusive coils have been described. U.S. Patent No. 5,624,461 to Mariant describes a three-dimensional in-filling vaso-occlusive coil. U.S. Patent No. 5,639,277 to Mariant et al. describe embolic coils having twisted helical shapes and U.S. Patent No. 5,649,949 to Wallace et al. describes variable cross-section conical vaso-occlusive coils.

15 U.S. Patent No. 5,334,210 to Gianturco, describes a vascular occlusion assembly comprising a foldable material occlusion bag and a filler member, for example, a helical coil with a J-hook on the proximal end. The bag expands to form a diamond shape structure and the filler member inside the bag is forced into a convoluted configuration as it advanced into the cavity of the foldable bag.

20 Implantable devices using variously shaped coils are shown in U.S. Patent No. 5,537,338 to Purdy. Purdy describes a multi-element intravascular occlusion device in which shaped coils may be employed. U.S. Patent No. 5,536,274 to Neuss shows a spiral implant which may assume a variety of secondary shapes. Some complex shapes can be formed by interconnecting two or more of the spiral-shaped implants.

25 Spherical shaped occlusive devices are described in U.S. Patent No. 5,645,558 to Horton. Horton describes how one or more strands can be wound to form a substantially hollow spherical or ovoid shape when deployed in a vessel.

There are a variety of ways of discharging shaped coils and linear coils into the human vasculature. In addition to those patents which apparently describe only the
30 physical pushing of a coil out into the vasculature (e.g., Ritchart et al.), there are a number

of other ways to release the coil at a specifically chosen time and site. U.S. Patent No. 5,354,295 and its parent, 5,122,136, both to Guglielmi et al., describe an electrolytically detachable embolic device.

A variety of mechanically detachable devices are also known. For instance,
5 U.S. Patent No. 5,234,437, to Sepetka, shows a method of unscrewing a helically wound coil from a pusher having interlocking surfaces. U.S. Patent No. 5,250,071, to Palermo, shows an embolic coil assembly using interlocking clasps mounted both on the pusher and on the embolic coil. U.S. Patent No. 5,261,916, to Engelson, shows a detachable pusher-vaso-occlusive coil assembly having an interlocking ball and keyway-type coupling. U.S.
10 Patent No. 5,304,195, to Twyford et al., shows a pusher-vaso-occlusive coil assembly having an affixed, proximally extending wire carrying a ball on its proximal end and a pusher having a similar end. The two ends are interlocked and disengage when expelled from the distal tip of the catheter. U.S. Patent No. 5,312,415, to Palermo, also shows a method for discharging numerous coils from a single pusher by use of a guidewire which
15 has a section capable of interconnecting with the interior of the helically wound coil. U.S. Patent No. 5,350,397, to Palermo et al., shows a pusher having a throat at its distal end and a pusher through its axis. The pusher sheath will hold onto the end of an embolic coil and will then be released upon pushing the axially placed pusher wire against the member found on the proximal end of the vaso-occlusive coil.

20 Vaso-occlusive coils having little or no inherent secondary shape have also been described. For instance, in U.S. Patent Application 07/978,320, filed November 18, 1992, entitled "Ultrasoft Embolization Coils with Fluid-Like Properties" by Berenstein et al., is found a coil having little or no shape after introduction into the vascular space.

None of these devices are stable coil designs having complex three-
25 dimensional winding patterns. The complex winding patterns can be formed using mandrels of various designs, including a single center post having one or more side pins, a center post having one or more top pins or other random patterns having shape breaks.

SUMMARY OF THE INVENTION

This invention is a vaso-occlusive device comprising one or more vaso-occlusive members which are wound to form complex winding patterns when relaxed. The vaso-occlusive member itself may be a helically wound coil or braid typically comprising a biocompatible metal. Fibrous materials may be woven into the member or tied or wrapped onto it. The stable coils of the invention are formed by first winding a wire into a first helix; the first helix is then wound into a secondary form which is wound back onto itself, for example on a mandrel, to form two or more layers of the primary coil. The reverse winding may be on the same axis as the first winding axis or may be on a different axis.

The overall form may be selected to be a variety of shapes deployed, including generally spheroid, elliptical, clover or box shapes. Generally, the shape of the relaxed configuration is formed by the outermost loops of the primary coil having the largest diameter. Loops having smaller diameters pass through the relaxed configuration. Desirably, the vaso-occlusive device is of a size and shape suitable for fitting snugly within a vascular cavity (e.g., an aneurysm, or perhaps, near a fistula). The stiffness of the various parts of the coil may be selected to enhance the utility of the device for specific applications. Fibrous materials may be woven into the member or tied or wrapped onto it.

The device is used simply by temporarily straightening the device and introducing it into a suitable catheter, the catheter already having been situated so that its distal opening is within the mouth of the vascular cavity or opening to be filled. The device is then pushed through the catheter and, upon its ejection from the distal end of the catheter into the vascular cavity, assumes its relaxed shape. The relaxed configuration of a device deployed into the body may be different than a device deployed in the open, due to constraints of vessels and the like.

The device is typically used in the human vasculature to form emboli but may be used in any site in the human body where an occlusion such as one produced by the inventive device is needed.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows the relaxed configuration of a conventional helical coil.

Figure 2 shows the relaxed configuration of a coil made according to the invention using a helical coil.

5 Figures 3A and 3B are top and side views of a coil wound around a mandrel suitable for making a device according to the present invention. The mandrel is a round center post, four top-pin design.

 Figures 4A, 4B, 4C and 4D show coils made using the mandrel of Figures 3A and 3B.

10 Figures 5A and 5B are side view of a coil wound around a mandrel suitable for making a device according to the present invention. The mandrel is a round center post, round stagger side-pin design.

 Figure 6 shows a coil made using the mandrel of Figures 5A and 5B.

 Figures 7A and 7B are side views of a coil wound around a mandrel
15 suitable for making a device according to the present invention. The mandrel is a round center post, round staggered side-pin design. Figure 7C shows a coil made using the mandrel of Figures 7A and 7B.

 Figures 8A and 8B are top and side views, respectively of a coil wound around a mandrel suitable for making a device according to the present invention. The
20 mandrel is a round center post, round side-pin design.

 Figures 9A and 9B are side and top views of a coil wound around a mandrel suitable for making a device according to the present invention. The mandrel is a round center post, four round side-pin design.

 Figures 10A and 10B show the relaxed configuration of coils made using
25 the mandrels of Figures 9A and 9B.

 Figures 11A and 11B are side and top views of a coil wound around a mandrel suitable for making a device according to the present invention. The mandrel is a square center post, four round side-pin design.

 Figure 12 shows the relaxed configuration of a coil made using the
30 mandrels of Figures 11A and 11B.

Figures 13A and 13B are side views of a coil wound around a mandrel suitable for making a device according to the present invention. The mandrel is a round center post, elliptical, staggered side-pin design.

Figure 14 shows the relaxed configuration of a coil made using the
5 mandrels of Figures 13A and 13B.

Figures 15A and 15B are side and top views of a coil wound around a mandrel suitable for making a device according to the present invention. The mandrel is a round center post, three elliptical side-pin design.

Figure 16 shows the relaxed configuration of a coil made using the
10 mandrels of Figures 15A and 15B.

Figures 17A and 17B are top and side views of a coil wound around a mandrel suitable for making a device according to the present invention. The mandrel is a square center post, four round side-pin design.

Figures 18A and 18B are side and top views of a coil wound around a
15 mandrel suitable for making a device according to the present invention. The mandrel is a square center post, four elliptical side-pin design.

Figures 19A and 19B are side views of a coil wound around a mandrel suitable for making a device according to the present invention. The mandrel is a square center post, four staggered elliptical side-pin design.

Figures 20A, 20B, 20C and 20D are side (20A, 20B) and top (20C, 20D)
20 views of a randomly wound coil on a mandrel suitable for making a device according to the present invention. The mandrel is a box-like (rubix) shape.

Figures 21A and 21B are side and top views of a coil wound around a
mandrel suitable for making a device according to the present invention. The mandrel is a
25 clover shape.

Figures 22A and 22B show the relaxed configuration of coils made using the mandrels of Figures 21A and 21B.

Figures 23A and 23B show side and top views, respectively, of a mandrel having a round center post and six round side pin design.

30

DESCRIPTION OF THE INVENTION

Throughout this application, various publications, patents, and published patent applications are referred to by an identifying citation. The disclosure of the publications, patents, and published patent specifications referenced in this application are hereby incorporated by reference into the present disclosure to more fully describe the state of the art to which this invention pertains.

The complex coil designs of the present invention are particularly useful in treating aneurysms. The shapes described herein provide an improved blood flow baffle design at the neck and dome of the aneurysm, thereby providing extra protection for aneurysms which because of their fragility cannot be densely packed with other coil types. The basket-shaped coil, for instance, is easily packed into the aneurysm. The stability of the coils of the present invention reduces the incidence of coil compaction, a phenomena that may occur over time when coils move back to the shape of their first configuration. In addition, each stable coil of the present invention can fit a variety of aneurysms.

Figure 1 shows an overview of the relaxed configuration of a helically wound coil (100) as it can appear after deployment. Note that the primary form is a helical coil. The coil (100) is 7 mm in diameter and 20 cm long.

Figure 2 shows one highly desirable variation of the stable coils of this invention -- a generally spherical coil (200). The variation shown would be formed on a mandrel such as those depicted herein. The coil (200) is the same diameter (7 mm) and length (20 cm) as the standard coil shown in Figure 1, but provides a three-dimensional structure in which many loops or strands pass through the interior of the structure. The overall device (200) is made up of a primary coil which has been initially wound in a linear strand form and then wound into a secondary form which assumes the relaxed, three-dimensional configuration shown.

The material used in vaso-occlusive member (202) may be any of a wide variety of materials; preferably, the wire is a radio-opaque material such as a metal or a polymer. Suitable metals and alloys for the wire making up the primary coil include the Platinum Group metals, especially platinum, rhodium, palladium, rhenium, as well as tungsten, gold, silver, tantalum, and alloys of these metals. These metals have significant

radiopacity and in their alloys may be tailored to accomplish an appropriate blend of flexibility and stiffness. They are also largely biologically inert. Highly preferred is a platinum/tungsten alloy.

5 The wire may also be of any of a wide variety of stainless steels if some sacrifice of radiopacity may be tolerated. Very desirable materials of construction, from a mechanical point of view, are materials which maintain their shape despite being subjected to high stress. Certain "super-elastic alloys" include nickel/titanium alloys (48-58 atomic % nickel and optionally containing modest amounts of iron); copper/zinc alloys (38-42 weight % zinc); copper/zinc alloys containing 1-10 weight % of beryllium, silicon, tin,
10 aluminum, or gallium; or nickel/aluminum alloys (36-38 atomic % aluminum). Particularly preferred are the alloys described in U.S. Patent Nos. 3,174,851; 3,351,463; and 3,753,700. Especially preferred is the titanium/nickel alloy known as "nitinol". These are very sturdy alloys which will tolerate significant flexing without deformation even when used as a very small diameter wire.

15 If a superelastic alloy such as nitinol is used in the device, the diameter of the coil wire may be significantly smaller than that used when the relatively more ductile platinum or platinum/tungsten alloy is used as the material of construction.

Finally, the overall diameter of the device (200) is generally between 3 and 20 millimeters. Advantageously, many different size aneurysms can be treated by one
20 stable coil of the present invention. Of course, the device may be used with a wide range of diameters for this and other anatomical applications.

The coils may be made of radiolucent fibers or polymers (or metallic threads coated with radiolucent or radiopaque fibers) such as Dacron (polyester), polyglycolic acid, polylactic acid, fluoropolymers (polytetrafluoro-ethylene), Nylon
25 (polyamide), or even silk. Should a polymer be used as the major component of the vaso-occlusive member, it is desirably filled with some amount of a known radiopaque material such as powdered tantalum, powdered tungsten, bismuth oxide, barium sulfate, and the like.

Generally speaking, when the device is formed of a metallic coil as the
30 vaso-occlusive member and that coil is a platinum alloy or a superelastic alloy such as

nitinol, the diameter of the wire used in the production of the coil will be in the range of 0.0005 and 0.006 inches. The wire of such diameter is typically then wound into a primary coil having a primary diameter of between 0.005 and 0.025 inches. Preferably, the primary coil is wound into a helical shape (Figure 1). For most neurovascular indications, the preferable diameter is 0.010 to 0.018 inches. We have generally found that the wire may be of sufficient diameter to provide a hoop strength to the resulting device sufficient to hold the device in place within the chosen body cavity without distending the wall of the cavity and without moving from the cavity as a result of the repetitive fluid pulsing found in the vascular system.

The axial length of the primary shape will usually fall in the range of 0.5 to 100 cm, more usually 2 to 40 cm. Depending upon usage, the coil may well have 10-75 turns per centimeter, preferably 10-40 turns per centimeter. The device may also be made in other dimensions. However, only dimensions suitable for use in occluding sites within the human body are included in the scope of this invention.

The variation shown in the Figures is a "coil of a coil." In other words, as used herein, the "first configuration" or "primary configuration" refers to the structure obtained when a wire is shaped into a coil, for example, as a strand of a linear helically wound coil. The "secondary configuration" refers to the structures obtained when at least one strand of the first configuration is further shaped, for example, by winding around a mandrel. The relaxed configuration refers to the three-dimensional configuration assumed by the secondary configuration after it has been deployed from the catheter. The relaxed configuration may be different depending on whether the device is deployed into the open or whether it is deployed into a body cavity which may influence the three-dimensional structures. The relaxed configurations generally comprise overlapping and intertwining loops or ovals of the strand of the first configuration. The loops or ovals can form a closed structure such as an "O" shape (e.g., circle, oval, etc.) or can be open such as a "C" or "U" shape. Both open and closed loops are shown in the attached Figures.

The stable coils of the present invention have complex secondary and relaxed configurations, including spherical, ovoid, elliptical, clover and box-like shapes.

The approximate diameter of the relaxed configurations can be determined from the

outermost loops of the strand. In one embodiment, the complex, relaxed configurations can be substantially hollow or cage-like in configuration.

In a preferred embodiment, one or more loops (or ovals) comprising the relaxed, three-dimensional structure of the device passes through the interior of the three-dimensional structure, away from the outer edge of the diameter, providing an overall meshed or net-like appearance. Generally, the loops will have a diameter less than diameter of the overall structure (which is also the diameter of the body cavity). Preferably, greater than about 25% of the loops have a diameter less than the overall structure or cavity, more preferably greater than about 50% and even more preferably greater than about 90%. Similarly, more than 10% of the strand making the up the loops which comprise the three-dimensional relaxed configuration is in the inner 15% of the diameter of the device, as shown in the Figures herein.

Another important feature of the claimed invention is that the coils are stable when deployed. Over time, many conventional vaso-occlusive devices move back to their "coin-stacked" shape and thereby provide less occlusiveness. The coil of the present invention, however, has a complex, *in vivo* shape that is similar to its annealed memory, making it less likely that the coil will lose its shape over time.

The procedure for winding the coil will be known to those in the art. Although methods for production of the inventive devices may be apparent to the skilled worker based upon our description of the device, one method for winding is described herein. A portion of wire is first wound to produce a linear coil. Preferably, the wire is solid and, when wound, produced a coil having one lumen. The linear coil is then wound onto a mandrel. As disclosed in detail below, mandrels used to form the stable coils of the present invention may be of variety of shapes. In one embodiment, the mandrel comprises a center post having one or more side pins. In another embodiment, the mandrel comprises a center post having one or more top pins. In these embodiments, the center post can be round, square, elliptical, rubix (box-like), clover or otherwise shaped. Preferably, the center post is round, square, rubix or clover.

The one or more side or top pins can also be formed in a variety of shapes as shown in the Figures, for example, elliptical, round, ovoid, square or clover shaped.

The pins can also be aligned along the post in rows or staggered with respect to each other. Various arrangements and shapes are shown in the Figures herein and other possibilities are known to one of ordinary skill in the art.

It is common to anneal the linear coil to prevent it from unwinding during these later fabrication steps. The linear coil is then wound around the mandrel and the complete assemblage of coil and mandrels is then subjected to an appropriate annealing step to set the secondary shape prior to disassembly of the fabrication apparatus and loading of the coil into a carrier for introduction into the delivery catheter.

The various mandrels shown are of sufficient heat resistance to allow such annealing steps. The mandrels are typically made of a refractory material such as alumina or zirconia (for heat-treating devices made of purely metallic components) or may be made of a ball of a metallic coil material. The function of the mandrels is simply to form a support for winding, not pollute the device during the heat-treatment step, and provide a specific form to the device during that heat-treatment step. A typical annealing step for a platinum/tungsten alloy would involve a 1100°F heating step in air for about 15-20 minutes.

Should the make-up of the vaso-occlusive element not be solely metal -- in that it contains readily meltable plastic or the like -- the temperature at which the heat treatment takes place and would be appropriate for the material may be significantly lower and typically for a significantly shorter period of time. The flexural modulus of most plastics being significantly lower than those of metals, the bulk of the polymer-based device will be significantly larger than that of the metal-based device.

Figure 3A is a top view of a coil (300) wound around mandrel (310). At one end of the round center post (315 in Figure 3B) are two intersecting round posts (311, 312) that form a cross shaped structure (320). Four round pins (321, 322, 323, 324) extend from the intersection (320) of the round posts comprising cross-shaped structure at the end of the center post. Figure 3B is a side view of the coil (300) wound around the four round pins (321, 322, 323, 324) extending from the cross-shaped structure (320) at the end of the center post (315). The mandrel shown in Figures 3A and 3B forms coils having a "four pintop omega" configuration.

Figures 4A, 4B, 4C and 4D show relaxed configurations of coils which were formed using the four pintop omega mandrels shown in Figures 3A and 3B. Figure 4 shows that it is clearly not necessary that the coil's three-dimensional shape be precisely shaped as the mandrel with pin structures, but, rather, that various space-filling complex and stable secondary structures are formed.

Figure 5A is side view of a coil (350) wound around a mandrel (360) made up of a center post (370) having a three rows of round pins (351, 352, 353) staggered around the center post (370). Each row of pins is shown with four pins. Figure 5B shows the coil and mandrel of Figure 5A rotated approximately 45° so that the coil (350) wrapped around the round pins (351, 352, 353) is more easily seen.

Figure 6 shows the relaxed configuration of a coil formed using the three-pin round staggered mandrel shown in Figures 5A and 5B.

Figures 7A and 7B shows a mandrel (400) having three rows of pins (401, 402, third row not shown) staggered around a center post (404) and having another pin (405) offset from the staggered rows. A coil (420) is shown wrapped around the pins (401, 401, 405) and center post (404). Each row is shown with five pins. Figure 7C shows the relaxed configuration of a coil formed on the mandrel of Figures 7A and 7B.

Figures 8A and 8B show another variation of stable coil of the present invention formed using a "three pin round cross mandrel." The mandrel (450) comprises a round center post (460) with three round side pins (451, 452, 453) positioned at approximately 120° relative to each adjacent pin. The coil (470) is shown wrapped around the pins (451, 452, 453) and center post (460).

Figures 9A and 9B show a coil being formed using a "four pin round box shape coil." The mandrel (500) is made up a round center post (510) with four round side-pins (511, 512, 513, 514) extending from the center post (510). The four round side-pins are positioned at approximately 90° relative to each adjacent pin. The coil (520) is shown wrapped around the mandrel.

Figure 10A is a top view and Figure 10B is a side view of a coil formed using the mandrel shown in Figures 9A and 9B.

Figures 11A and 11B show side and top views, respectively, of a mandrel having a round center post (560) with four round top pins (551, 552, 553, 554) on the top of the post (560). The coil (550) is then wrapped around the four round tops pins.

Figure 12 shows the relaxed configuration of a coil (550) formed using the
5 mandrel shown in Figures 11A and 11B.

Figures 13A and 13B show side views of a mandrel having a round center post (600) with rows of elliptical side pins (601, 602, 603). Each row of elliptical side pins is staggered with respect to the others. Each row is shown with three elliptical side pins (611, 612, 613). The coil (620) is shown wrapped around the elliptical side pins.

10 Figure 14 shows a top view of a relaxed configuration of a coil (620) formed using the mandrel shown in Figures 13A and 13B.

Figures 15A and 15B are side and top views, respectively, of a mandrel having a round center post (650) with three elliptical side pins (651, 652, 653) positioned at approximately 120° relative to the each other pin. The coil (660) is wrapped around the
15 pins (651, 652, 653) and center post (650).

Figure 16 shows one part of a coil (660) formed using the mandrel shown in Figures 15A and 15B.

Figures 17A and 17B are top and side views, respectively, of a mandrel having a square center post (700) with four round side pins (701, 702, 703, 704) positioned
20 at approximately 90° relative to two adjacent pins. The coil (720) is wrapped around the round side pins (701, 702, 703, 704) and the square center post (700).

Figures 18A and 18B are side and top views, respectively, of a mandrel having a square center post (750) with four elliptical side pins (751, 752, 753, 754) positioned at approximately 90° relative to two adjacent pins. The coil (760) is wrapped
25 around the elliptical side pins (751, 752, 753, 754) and the square center post (750).

Figures 19A and 19B are two side views of a mandrel having a square center post (800) with four staggered rows of elliptical side pins (801, 802, 803, 804) positioned on each side of the square. Each row is shown with three pins (805, 806, 807). The coil (820) is wrapped around the pins and the square post (800).

Figures 20A, 20B, 20C and 20D shown various random winding patterns of a coil (850) around a rubix shaped mandrel (860).

Figures 21A and 21B show side and top views of a clover shaped mandrel, essentially a clover shape center post (900). The coil (910) is wrapped around the center post (900).

Figures 22A and 22B show the relaxed configurations of coils formed using the mandrel shown in Figures 21A and 21B.

Figures 23A and 23B show side and top view, respectively, of a mandrel having a round center post (950) with six round side pins (951, 952, 953, 954, 955, 956).

The six pins are spaced approximately 30° from each adjacent pin. The coil (960) is shown wound around the center post (950) and side pins.

Also contemplated in this invention is the attachment of various fibrous materials to the inventive coils for the purpose of adding thrombogenicity to the resulting assembly. The fibrous materials may be attached in a variety of ways. A series of looping fibers may be looped through or tied to coil and continue axially down the coil. Another variation is by tying the tuft to the coil. Tufts may be tied at multiple sites through the coil to provide a vast area of embolus forming sites. The primary coil may be covered by a fibrous braid. The method for producing the former variation is described in U.S. Patent Nos. 5,226,911 and 5,304,194 to Chee. The method of producing the fibrous braid is described in U.S. Patent 5,382,259, issued January 17, 1995, to Phelps and Van.

The complex stable coils of the invention are deployed by methods known in the art. One common deployment method for introduction of the inventive vaso-occlusive devices described here. It may be observed that these procedures are not significantly different than those described in the Ritchart et al. patent mentioned above.

The major difference in the procedure is the ability of the vaso-occlusive device to form the secondary shapes discussed above as the coil exits the catheter. Specifically, a delivery catheter is placed within the opening of an aneurysm found in an artery. The vaso-occlusive device is within the catheter and can be forced to exit the catheter. As the coil exits the distal end of the catheter (210) it "self-winds" to begin forming the complex

structure. The catheter is withdrawn, leaving the vaso-occlusive device within the aneurysm.

Because of the configurations of these devices, the procedure of introducing them into an open space in the human body involves placement of the delivery catheter tip
5 at that space and the introduction of a coil that self-winds into a series of loops or ovals, each having a larger diameter which is significantly smaller than the open space to be filled. The filling of the space, therefore, place by passage of the coil through a central region of the space (*e.g.*, aneurysm), rather than along its wall.

Modification of the above-described variations of carrying out the invention
10 that would be apparent to those of skill in the fields of medical device design generally, and vaso-occlusive devices specifically, are intended to be within the scope of the following claims.

WE CLAIM AS OUR INVENTION:

1. A vaso-occlusive device comprising at least one substantially linear strand of a vaso-occlusive member wound into and self-forming a stable, complex three-dimensional relaxed configuration.
5
2. The vaso-occlusive device of claim 1 wherein the relaxed configuration comprises loops of the vaso-occlusive member and the relaxed configuration fills a body cavity having a diameter.
10
3. The device of claim 2 wherein the inner loops of the relaxed configuration have a diameter which is less than 25% of the diameter of the body cavity.
4. The device of claim 2 wherein the inner loops of the relaxed configuration have a diameter which is less than 50% of the diameter of the body cavity.
15
5. The device of claim 2 wherein the inner loops of the relaxed configuration have a diameter which is less than 90% of the diameter of the body cavity.
- 20 6. The device of claim 1 wherein said vaso-occlusive member passes through the interior of said relaxed configuration.
7. The device of claim 1 more than about 10% of the at least one substantially linear strand is in inner 85% of the diameter of said relaxed configuration.
25
8. The device of claim 1 wherein the vaso-occlusive member is selected from at least one helically wound coil and braided tubular members.
9. The device of claim 8 wherein the vaso-occlusive member is a helically wound coil.
30

10. The device of claim 1 wherein the relaxed configuration is spherical, oval, elliptical, clover or box-like.

5 11. The device of claim 1 wherein the relaxed configuration is spherical.

12. The device of claim 1 wherein the relaxed configuration is oval.

13. The device of claim 1 wherein the relaxed configuration is elliptical.

10

14. The device of claim 1 wherein the relaxed configuration is box-shaped.

15. The device of claim 1 wherein the vaso-occlusive member comprises a metal selected from the group consisting of platinum, palladium, rhodium, gold, tungsten, and their alloys.

15

16. The device of claim 15, wherein the vaso-occlusive member comprises an alloy of platinum and tungsten.

20 17. The device of claim 1 wherein the vaso-occlusive member comprises an alloy selected from stainless steels and super-elastic alloys.

18. The device of claim 17 wherein the vaso-occlusive member comprises nitinol.

25

19. A method of producing a vaso-occlusive device comprising a vaso-occlusive member would into and self-forming into a complex three-dimensional relaxed configuration comprising:

a) winding at least one strand of a generally linear vaso-occlusive member onto a mandrel having a center post,

30

b) heating the mandrel and vaso-occlusive member to produce said vaso-occlusive device.

20. The method of claim 19 wherein said mandrel further comprises side or top pins on said center post.

21. The method according to claim 19 wherein the center post is square, round, box-like, elliptical or clover-shaped.

22. The method according to claim 20 wherein the center post is square, round, rubix or clover shaped and wherein the side or top pins are square, round or elliptical.

23. The method according to claim 20, wherein the side or top pins are staggered with respect to each other.

24. The method according to claim 20, wherein the staggered side pins are in rows along the center post.

25. The method of claim 19 wherein the step b) is at about 1100°F.

26. A vaso-occlusive device produced by the method of claim 19.

27. A vaso-occlusive device produced by the method of claim 20.

28. A vaso-occlusive device produced by the method of claim 21.

29. A vaso-occlusive device produced by the method of claim 22.

30. A vaso-occlusive device produced by the method of claim 23.

31. A vaso-occlusive device produced by the method of claim 24.

32. The device of claim 1 wherein the vaso-occlusive member has a first end and a second end and additionally comprising a deployment tip attached to at least one of the first end and second end.

33. The device of claim 32 wherein the deployment tip comprises a mechanically detachable end adapted to attach to and detach from a pusher.

34. The device of claim 33 wherein the deployment tip comprises an electrolytically detachable end adapted to detach from a pusher by imposition of a current on said pusher.

35. A method for deploying a vaso-occlusive device according to any one of claims 1 through 18 comprising:

- (a) placing the vaso-occlusive device in a delivery catheter;
- (b) placing the delivery catheter within an opening of a body cavity;
- (c) ejecting the vaso-occlusive device from the delivery catheter into the opening of the body cavity; and
- (d) withdrawing the delivery catheter, wherein the vaso-occlusive device assumes a relaxed configuration within the body cavity when ejected from the catheter.

36. A method of introducing a vaso-occlusive device into a body space or cavity, comprising:

- (a) placing the vaso-occlusive device in a delivery catheter having a tip;
- (b) inserting the tip of the delivery catheter into the body cavity;
- (c) ejecting the coil from the tip of the delivery catheter into the central region body cavity, wherein the coil self-winds into a stable, complex three-dimensional relaxed configuration.

37. The method according to claim 36 wherein the relaxed configuration comprises a series of loops which are less than the diameter of the body cavity.

1/14

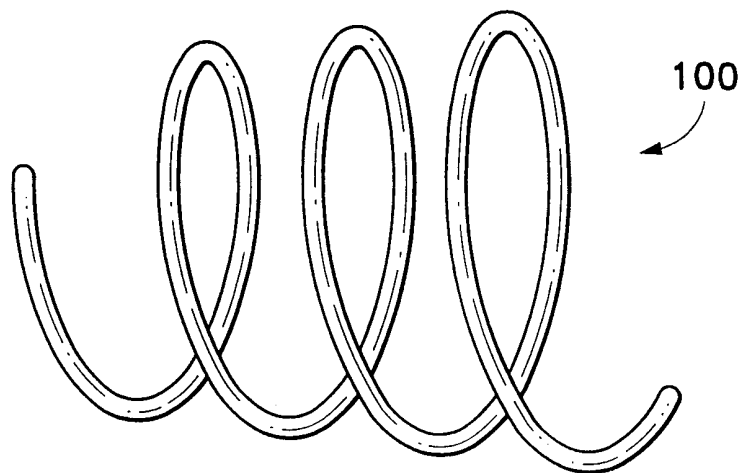


Fig. 1

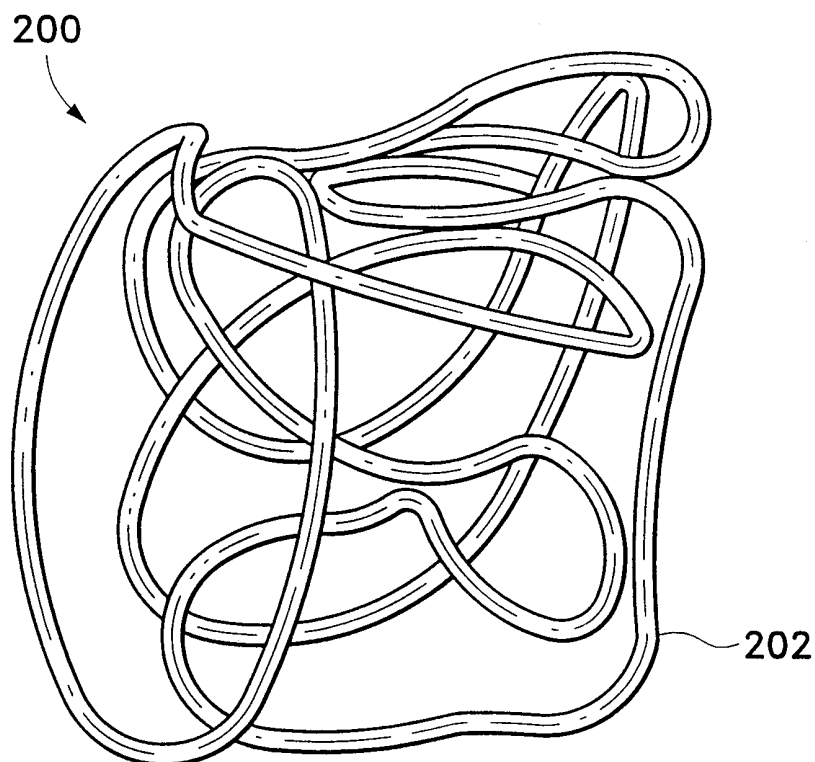


Fig. 2

2/14

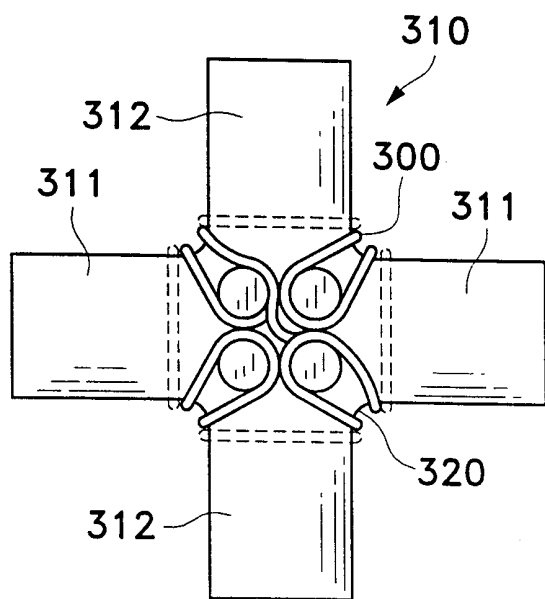


Fig. 3A

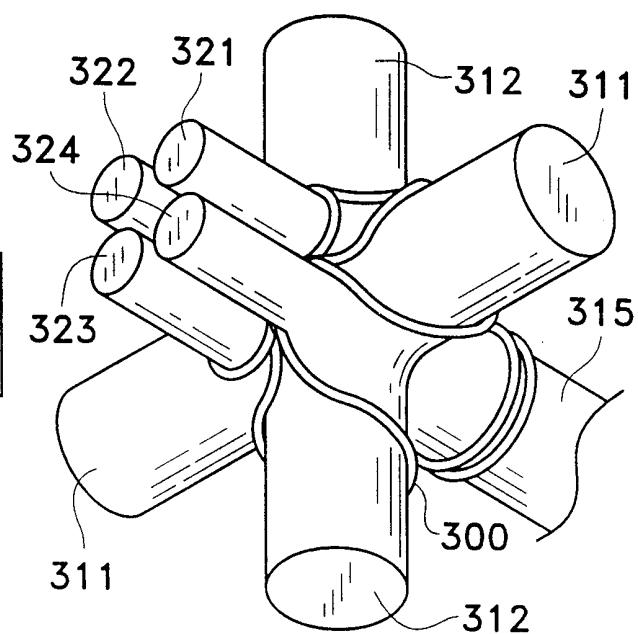


Fig. 3B

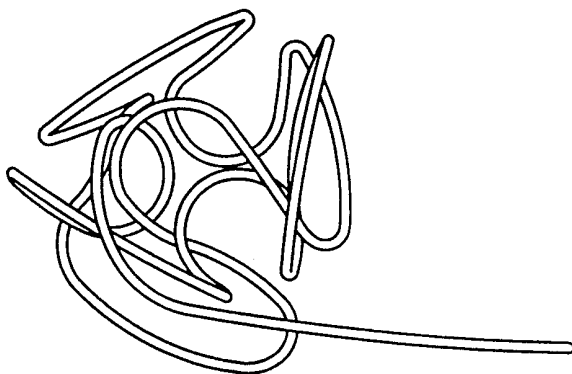


Fig. 4A

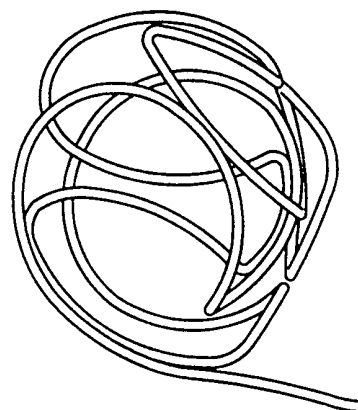


Fig. 4B

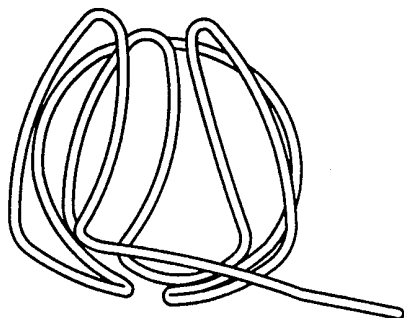


Fig. 4C

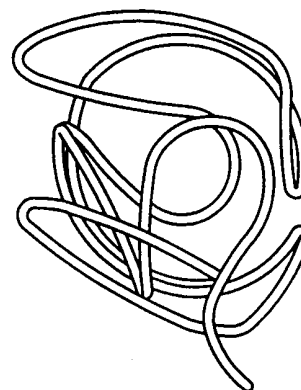


Fig. 4D

3/14

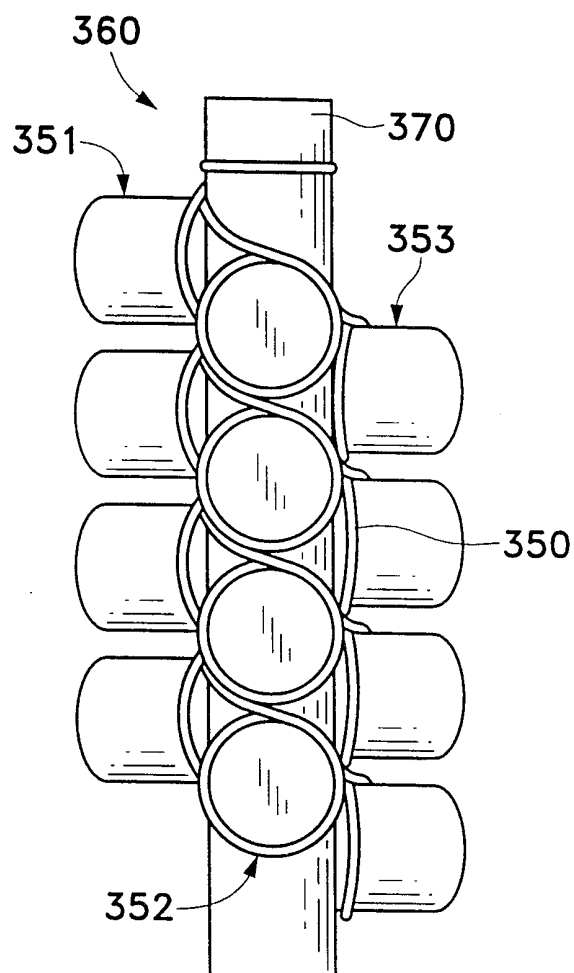


Fig. 5A

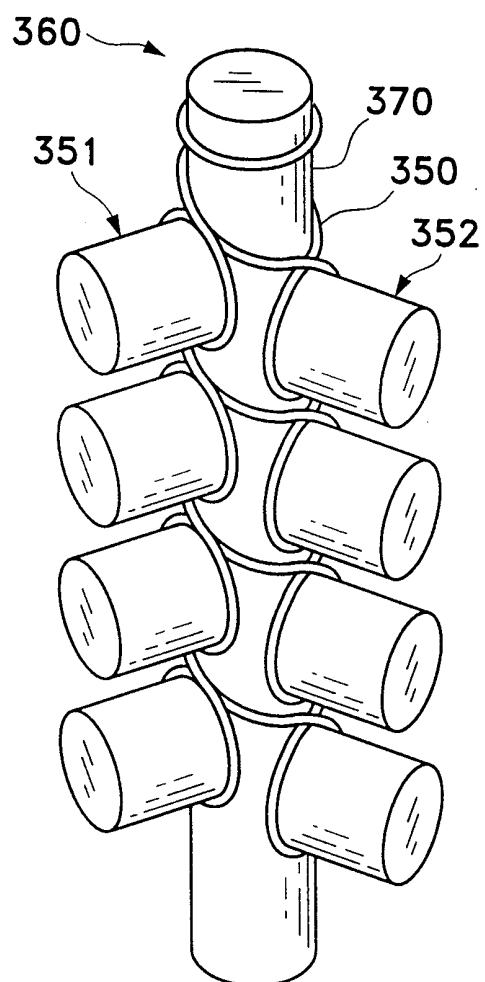


Fig. 5B

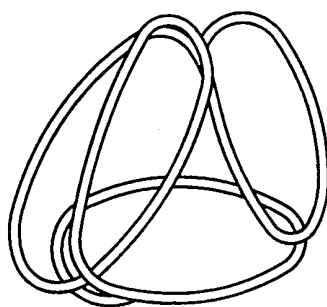


Fig. 6

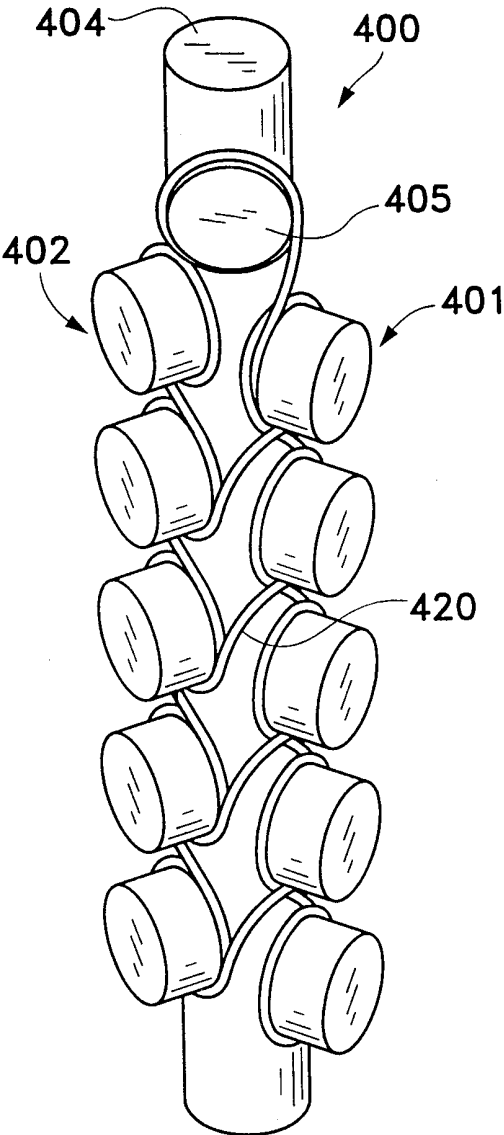


Fig. 7A

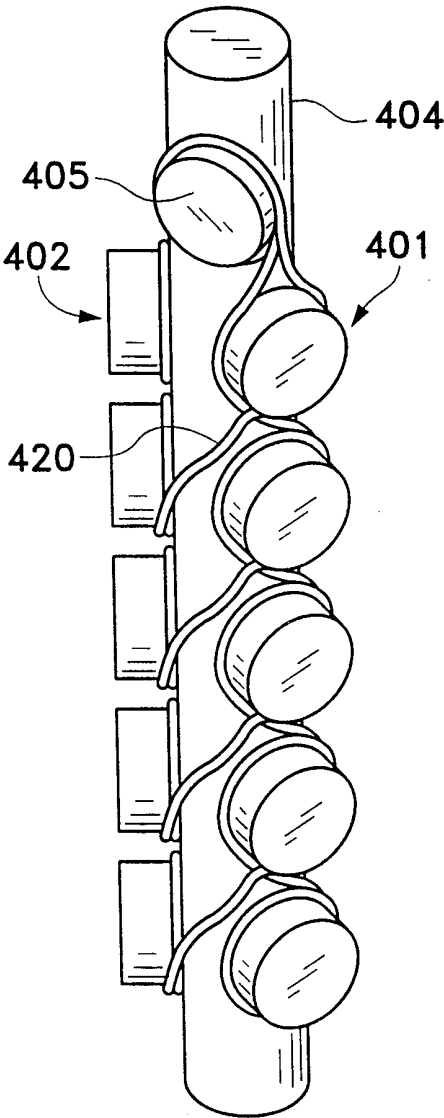


Fig. 7B

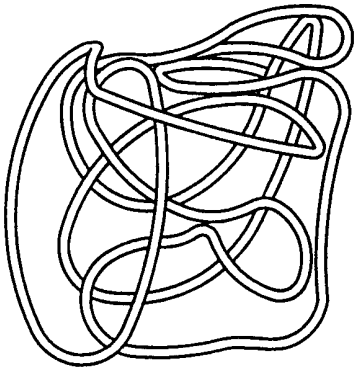


Fig. 7C

5/14

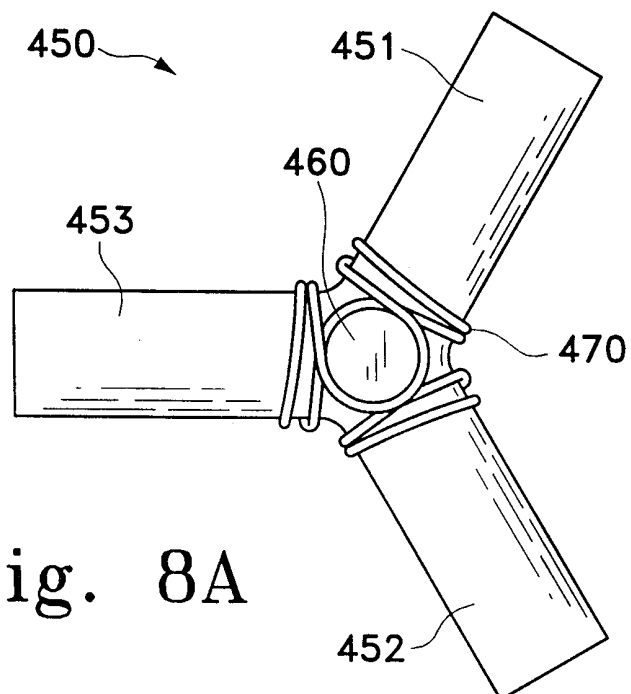


Fig. 8A

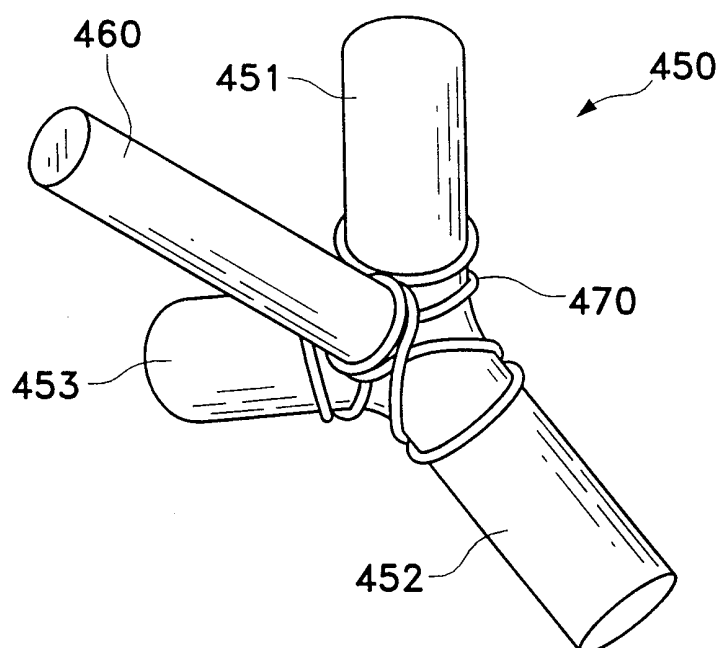


Fig. 8B

6/14

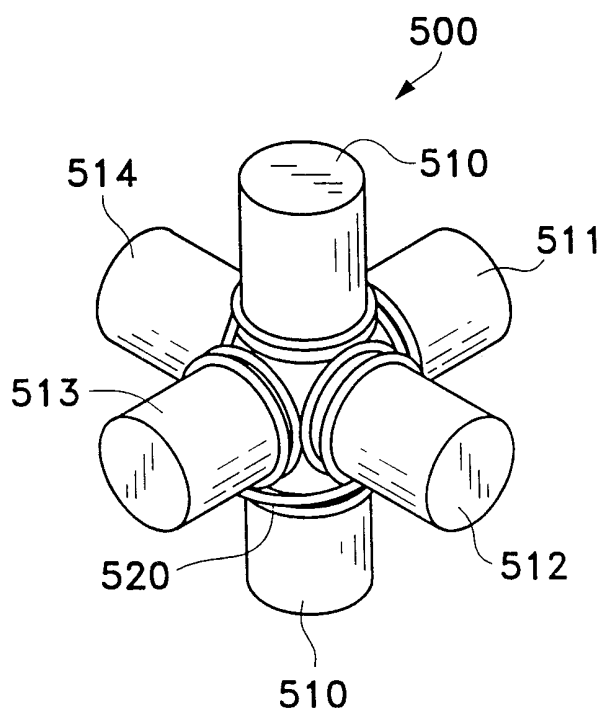


Fig. 9A

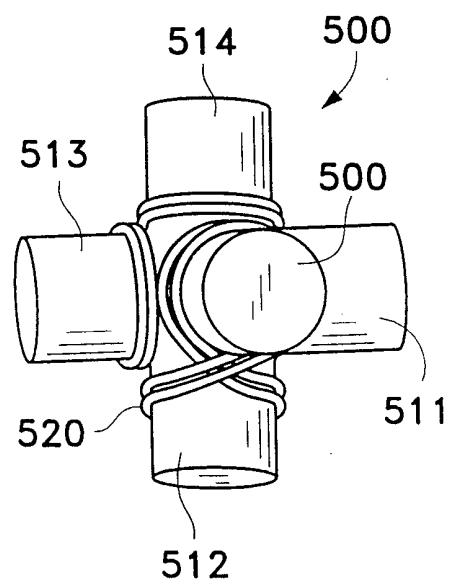


Fig. 9B

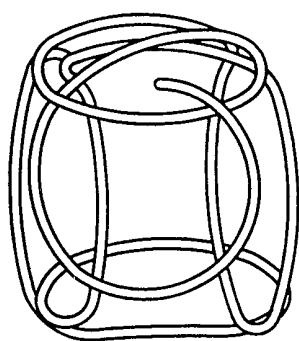


Fig. 10A

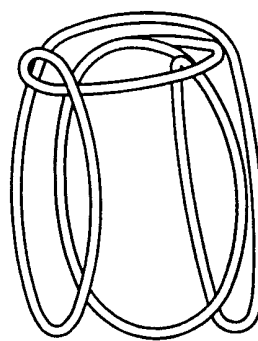


Fig. 10B

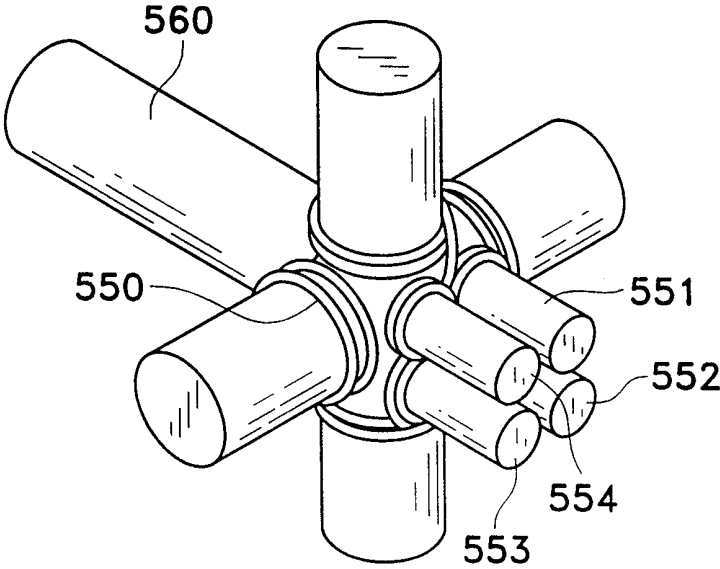


Fig. 11A

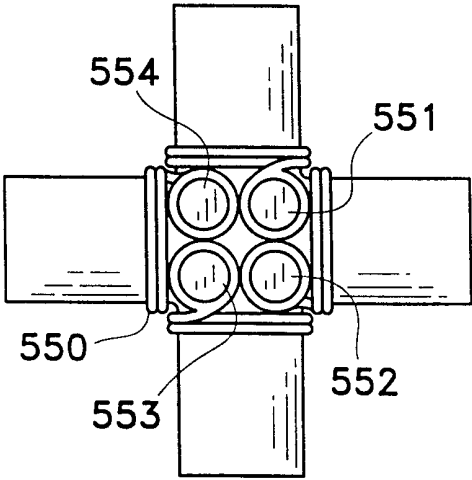


Fig. 11B

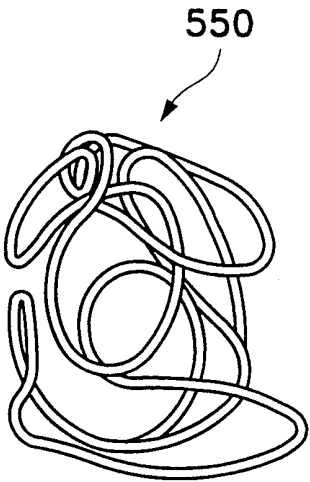


Fig. 12

8/14

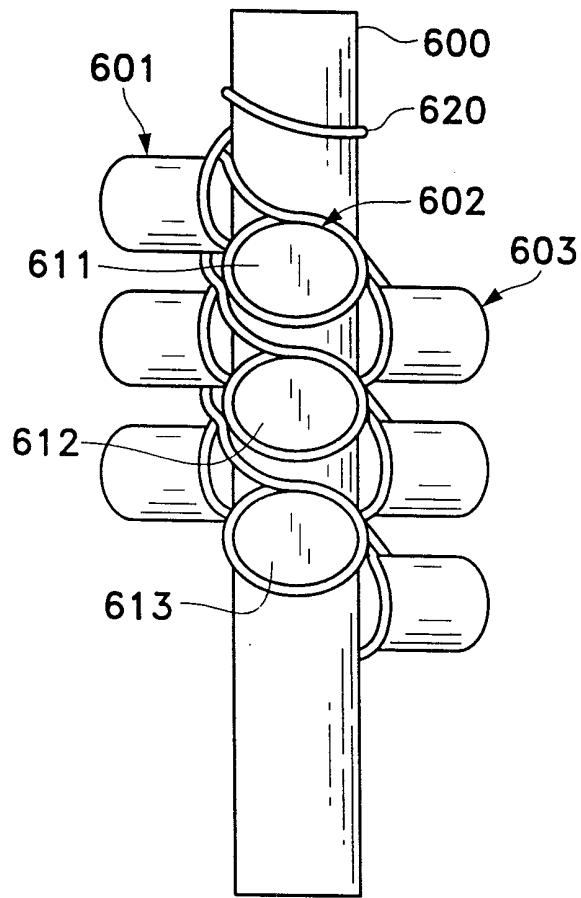


Fig. 13A

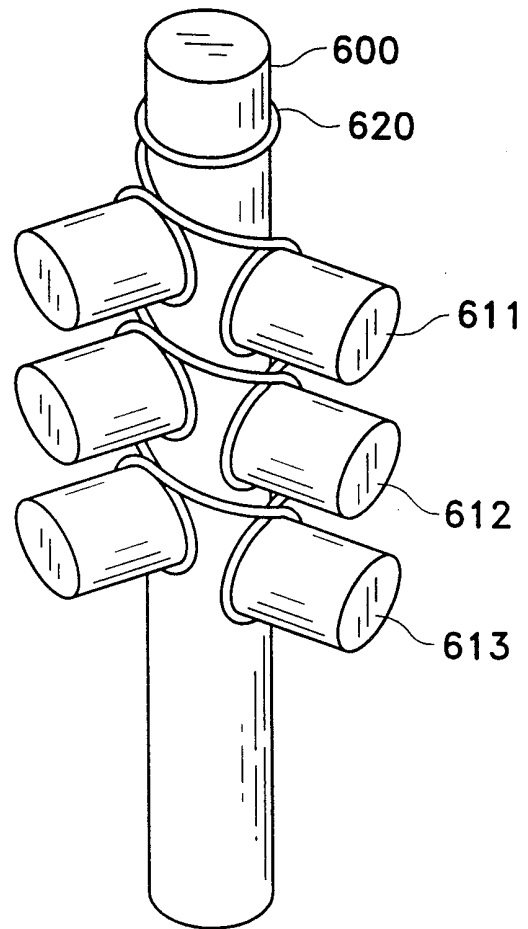


Fig. 13B

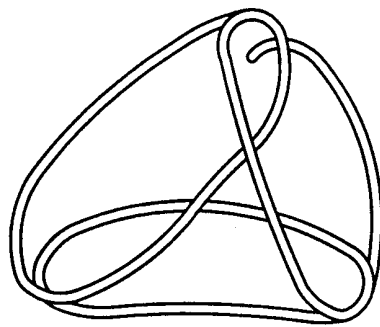


Fig. 14

9/14

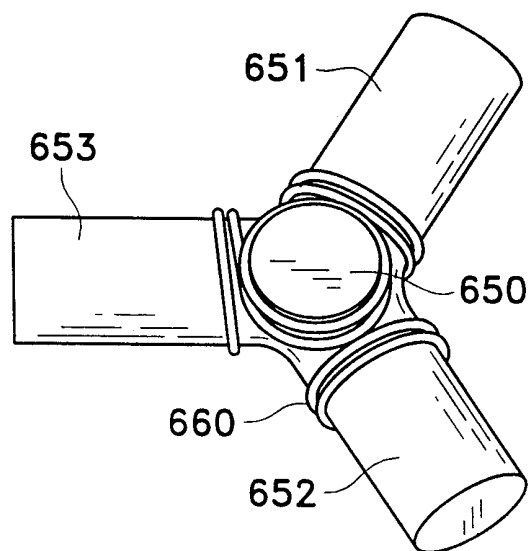


Fig. 15B

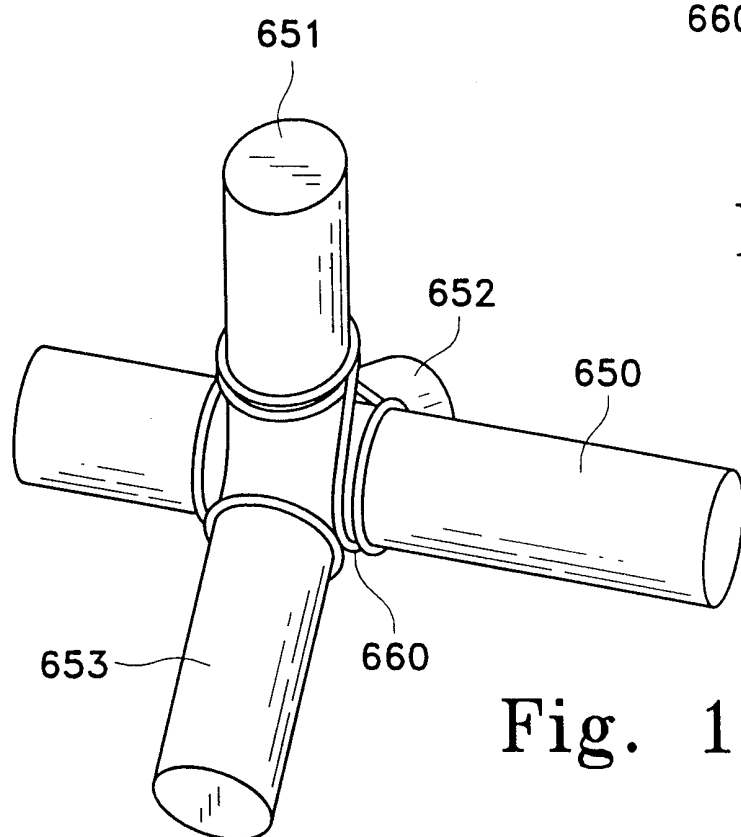


Fig. 15A

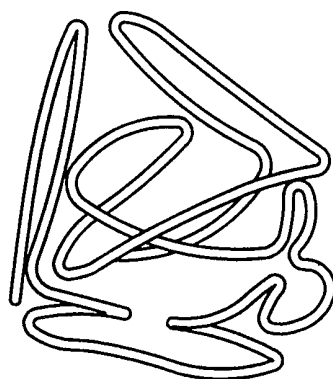


Fig. 16

10/14

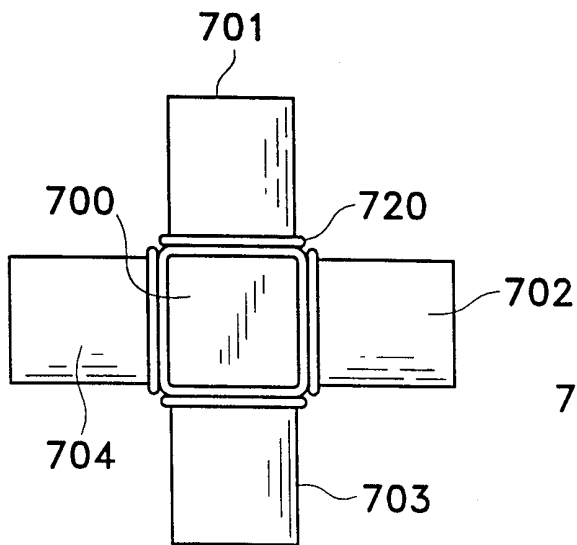


Fig. 17A

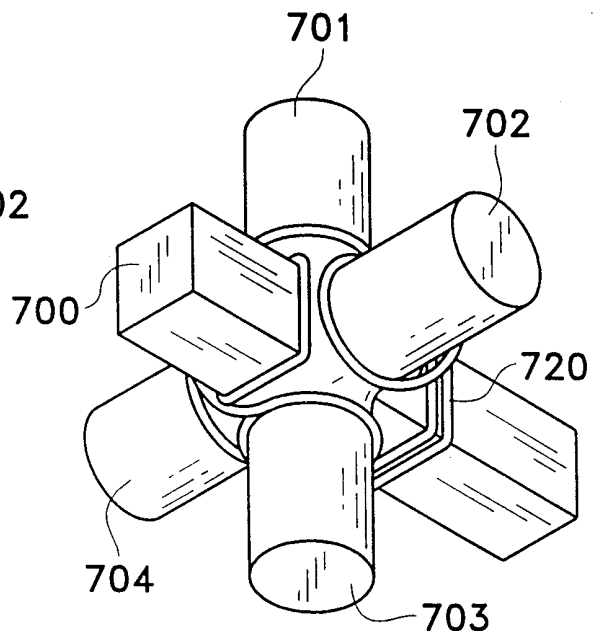


Fig. 17B

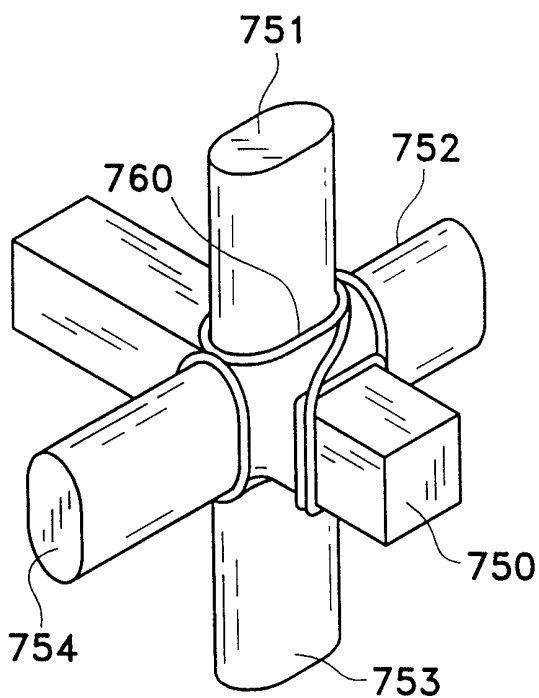


Fig. 18A

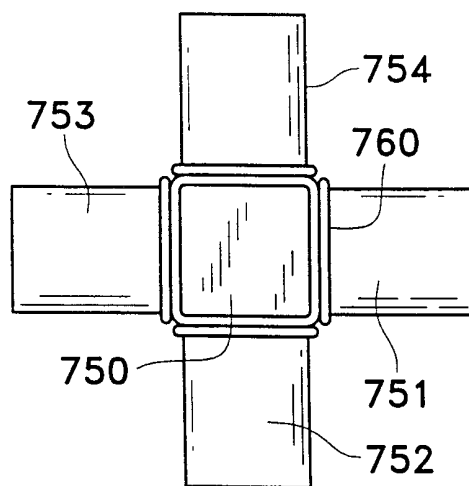


Fig. 18B

11/14

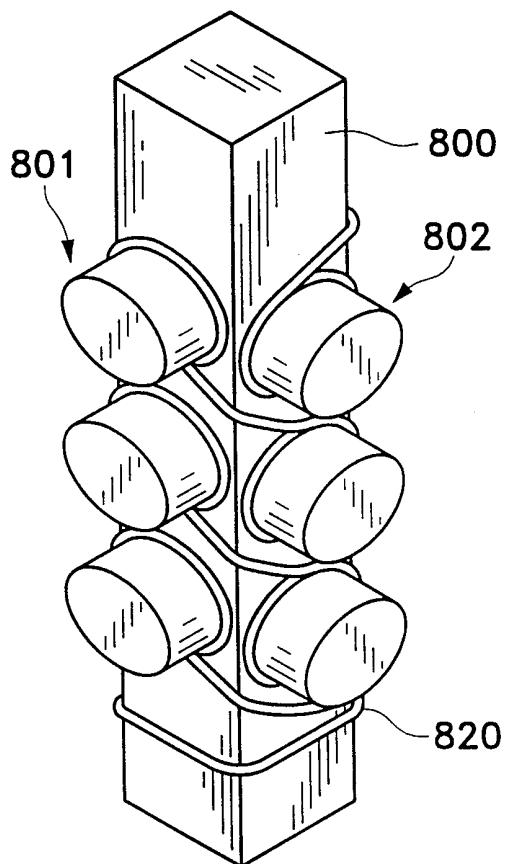


Fig. 19A

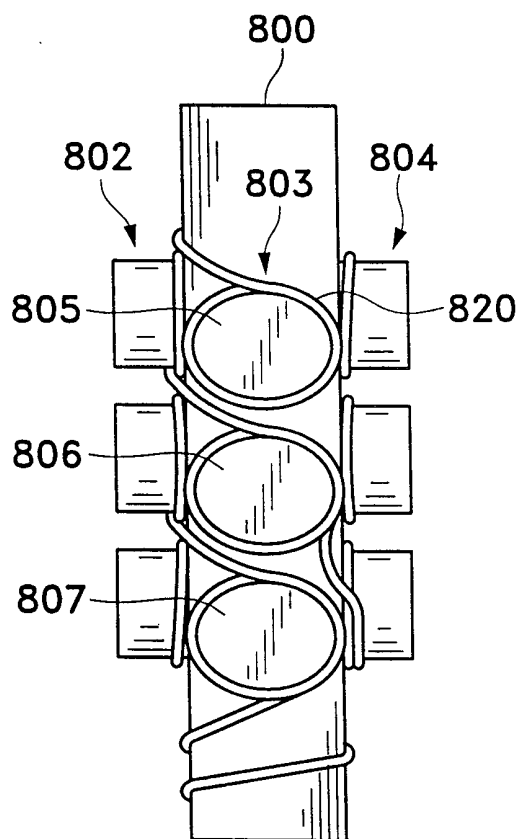


Fig. 19B

12/14

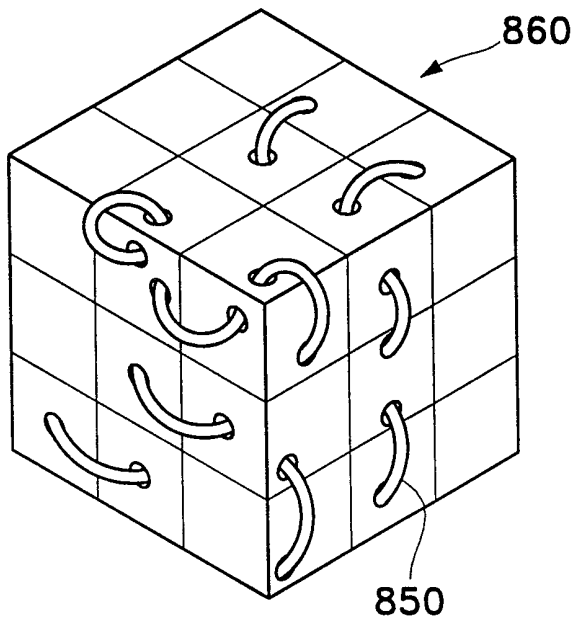


Fig. 20A

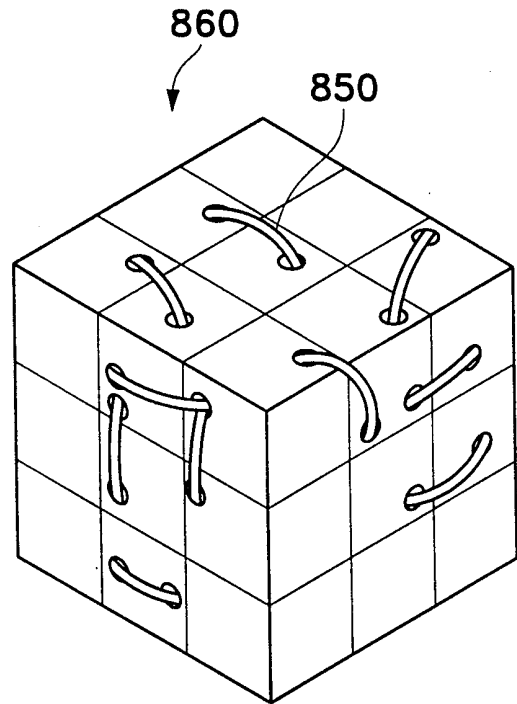


Fig. 20B

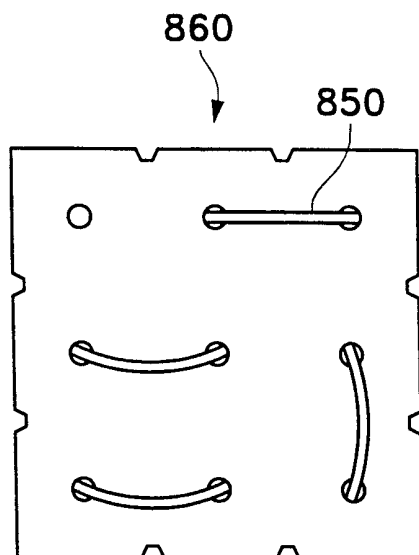


Fig. 20C

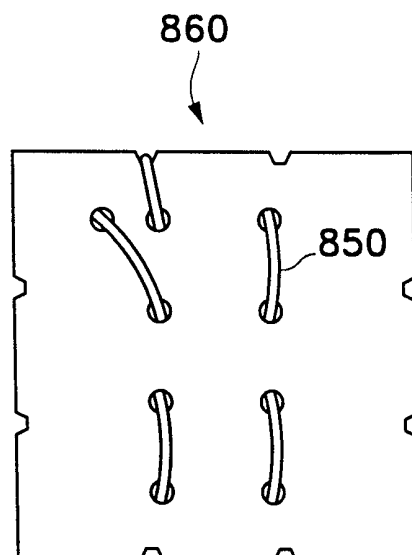


Fig. 20D

13/14

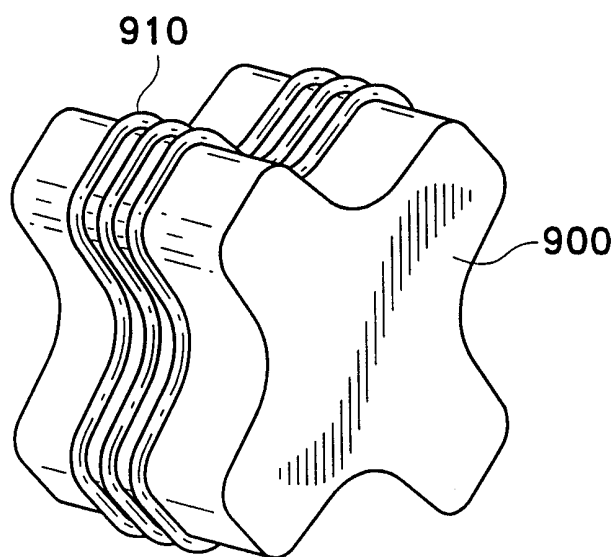


Fig. 21A

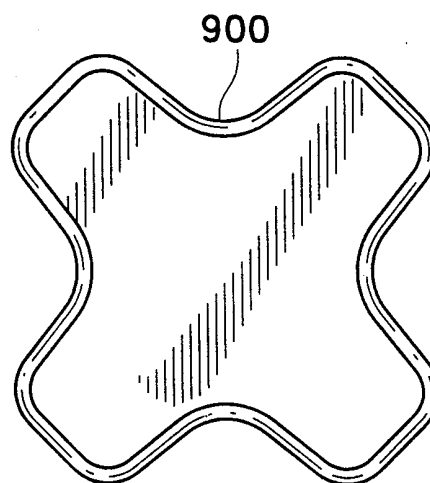


Fig. 21B

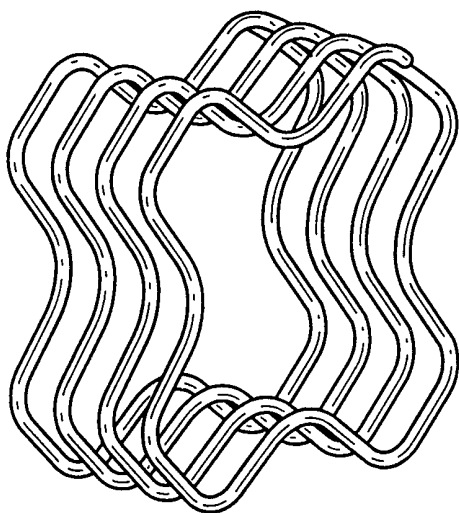


Fig. 22A

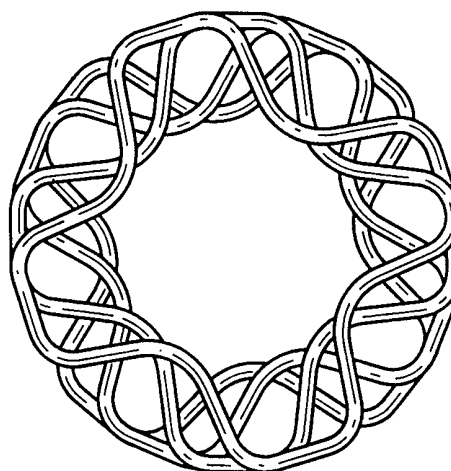
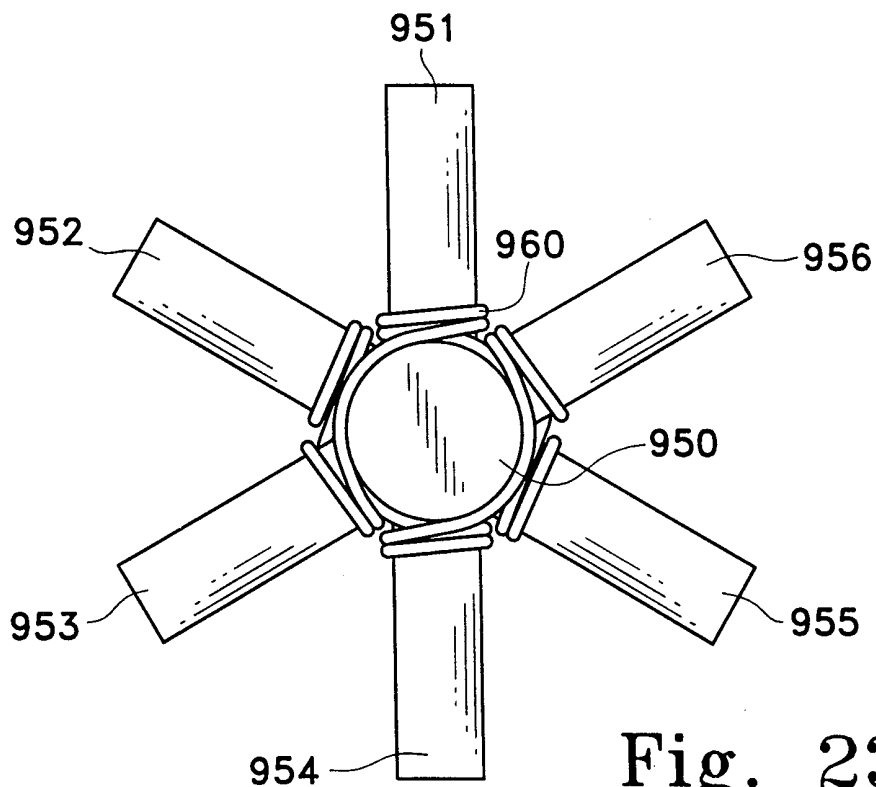
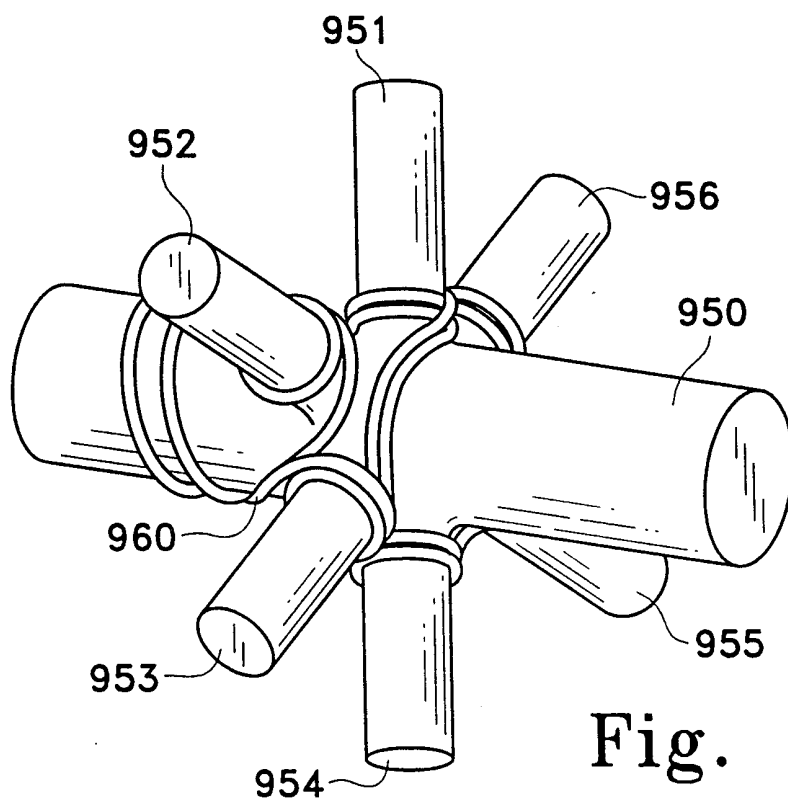


Fig. 22B

14/14



INTERNATIONAL SEARCH REPORT

Int'l Application No

PCT/US 98/17650

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/12

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 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	EP 0 765 636 A (TARGET THERAPEUTICS, INC.) 2 April 1997	1-12, 15-22, 25-29
Y	see the whole document	14
Y	US 5 649 949 A (WALLACE ET AL.) 22 July 1997 cited in the application see abstract; claims 1,7-10,17-20,23,26-28; figures see column 5, line 53-55	14



Further documents are listed in the continuation of box C.



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

29 October 1998

Date of mailing of the international search report

05/11/1998

Name and mailing address of the ISA

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

Authorized officer

Giménez Burgos, R

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 98/17650

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>EP 0 747 014 A (TARGET THERAPEUTICS, INC.) 11 December 1996</p> <p>see abstract; claims; figures ---</p>	<p>1-13, 15-19, 21, 25-27, 32-34</p>
X	<p>US 5 624 461 A (MARIANT) 29 April 1997 cited in the application</p> <p>see abstract; claims; figures ---</p>	<p>1-11, 15-22, 25-29, 32-34</p>
A	<p>DE 32 03 410 A (VEB KOMBINAT WAEZLAGER UND NORMTEILE) 25 November 1982 see page 4, line 27 - page 5, line 12; claims 1,7 -----</p>	

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 98/ 17650

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. ☒ Claims Nos.: 35-37
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
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 searched 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

International Application No

PCT/US 98/17650

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
EP 0765636	A	02-04-1997	CA 2186768 A		30-03-1997
			JP 9168541 A		30-06-1997
US 5649949	A	22-07-1997	AU 1629897 A		20-11-1997
			CA 2199988 A		14-09-1997
			EP 0795300 A		17-09-1997
EP 0747014	A	11-12-1996	AU 682635 B		09-10-1997
			AU 5583796 A		09-01-1997
			CA 2178375 A		07-12-1996
			JP 9099094 A		15-04-1997
			NO 962336 A		09-12-1996
			US 5749891 A		12-05-1998
US 5624461	A	29-04-1997	AU 679408 B		26-06-1997
			AU 5583196 A		16-01-1997
			CA 2178126 A		07-12-1996
			EP 0747013 A		11-12-1996
			JP 2670257 B		29-10-1997
			JP 8336537 A		24-12-1996
			NO 962301 A		09-12-1996
DE 3203410	A	25-11-1982	DD 158084 A		29-12-1982