

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
15 May 2003 (15.05.2003)

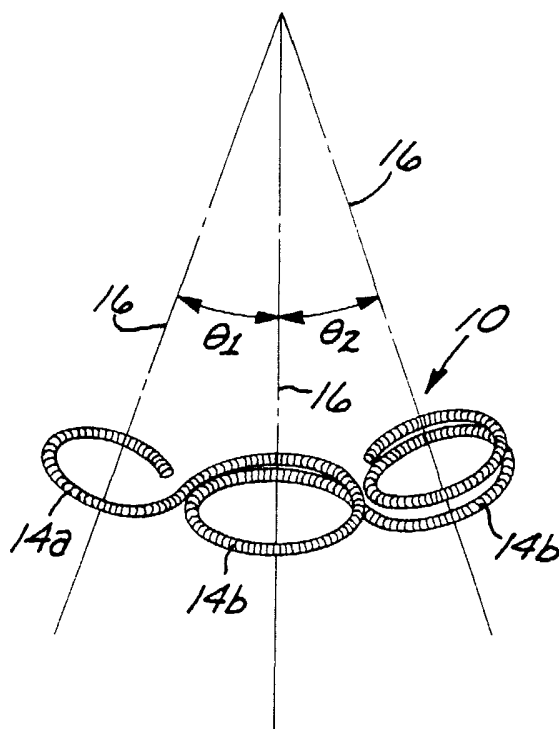
PCT

(10) International Publication Number
WO 03/039376 A1

- (51) International Patent Classification⁷: **A61B 17/12**
- (21) International Application Number: PCT/US01/50970
- (22) International Filing Date:
7 November 2001 (07.11.2001)
- (25) Filing Language: English
- (26) Publication Language: English
- (71) Applicant: **MICROVENTION, INC.** [US/US]; 72 Argonaut, Aliso Viejo, CA 92656 (US).
- (72) Inventors: **SCHAEFER, Dean**; 26035 Moulton Parkway #201, Laguna Hills, CA 92653 (US). **ALMAZAN, Horacio**; 60 Sea Country Lane, Rancho Santa Margarita, CA 92688 (US). **FERRERA, David, A.**; 2001 Lynngrove Drive, Manhattan Beach, CA 90266 (US). **COX, Brian, J.**; 3 Novilla, Laguna Niguel, CA 92677 (US). **GREENE, George, R., Jr.**; 3019 Java Road, Costa Mesa, CA 92626 (US).
- (74) Agent: **KLEIN, Howard, J.**; Klein, O'Neill & Singh, LLP, Suite 510, 2 Park Plaza, Irvine, CA 92614 (US).
- (81) Designated States (*national*): AE, AG, AL, AM, AT (utility model), AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ (utility model), CZ, DE, DK, DM, DZ, EC, EE (utility model), EE, ES, FI (utility model), FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK (utility model), SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.
- (84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, 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, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- Published:**
— with international search report

[Continued on next page]

(54) Title: MICROCOIL VASO-OCCLUSIVE DEVICE WITH MULTI-AXIS SECONDARY CONFIGURATION



(57) Abstract: A vaso-occlusive device (10) includes a microcoil (12) formed into a minimum energy state secondary configuration comprising a plurality of curved segments (14a, 14b, 24), each defining a discrete axis (16), whereby the device, in its minimum energy state configuration, defines multiple axes. In a preferred embodiment, the minimum energy state secondary configuration comprises a plurality of tangentially-interconnected, substantially circular loops (14a, 14b) defining a plurality of discrete axes (16). In an alternative embodiment, the minimum energy state secondary configuration defines a wave-form like structure comprising a longitudinal array of laterally-alternating open loops (24) defining a plurality of separate axes (16). In either embodiment, the device (10), in its minimum energy state secondary configuration, has a dimension that is substantially larger than the largest dimension of the vascular site in which the device is to be deployed. Thus, when the device (10) is deployed in an aneurysm (40), the confinement of the device (10) within the aneurysm (40) causes the device (10) to assume a three-dimensional configuration that has a higher energy state than the minimum energy state.



WO 03/039376 A1



For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

1 MICROCOIL VASO-OCCLUSIVE DEVICE WITH MULTI-AXIS
2 SECONDARY CONFIGURATION

3
4 CROSS-REFERENCE TO RELATED APPLICATIONS

5 Not Applicable

6
7 FEDERALLY-SPONSORED RESEARCH OR DEVELOPMENT

8 Not Applicable

9
10 BACKGROUND OF THE INVENTION

11 This invention relates generally to the field of vascular occlusion
12 devices and methods. More specifically, it relates to an apparatus and
13 method for occluding a blood vessel by embolizing a targeted site (such
14 as an aneurysm) in the blood vessel.

15 The embolization of blood vessels is desired in a number of
16 clinical situations. For example, vascular embolization has been used
17 to control vascular bleeding, to occlude the blood supply to tumors,
18 and to occlude vascular aneurysms, particularly intracranial
19 aneurysms. In recent years, vascular embolization for the treatment of
20 aneurysms has received much attention. Several different treatment
21 modalities have been employed in the prior art. U.S. Patent No.
22 4,819,637 - Dormandy, Jr. et al., for example, describes a vascular
23 embolization system that employs a detachable balloon delivered to
24 the aneurysm site by an intravascular catheter. The balloon is carried
25 into the aneurysm at the tip of the catheter, and it is inflated inside the
26 aneurysm with a solidifying fluid (typically a polymerizable resin or
27 gel) to occlude the aneurysm. The balloon is then detached from the
28 catheter by gentle traction on the catheter. While the balloon-type
29 embolization device can provide an effective occlusion of many types
30 of aneurysms, it is difficult to retrieve or move after the solidifying

1 fluid sets, and it is difficult to visualize unless it is filled with a contrast
2 material. Furthermore, there are risks of balloon rupture during
3 inflation and of premature detachment of the balloon from the
4 catheter.

5 Another approach is the direct injection of a liquid polymer
6 embolic agent into the vascular site to be occluded. One type of liquid
7 polymer used in the direct injection technique is a rapidly
8 polymerizing liquid, such as a cyanoacrylate resin, particularly
9 isobutyl cyanoacrylate, that is delivered to the target site as a liquid,
10 and then is polymerized *in situ*. Alternatively, a liquid polymer that is
11 precipitated at the target site from a carrier solution has been used. An
12 example of this type of embolic agent is a cellulose acetate polymer
13 mixed with bismuth trioxide and dissolved in dimethyl sulfoxide
14 (DMSO). Another type is ethylene glycol copolymer dissolved in
15 DMSO. On contact with blood, the DMSO diffuses out, and the
16 polymer precipitates out and rapidly hardens into an embolic mass that
17 conforms to the shape of the aneurysm. Other examples of materials
18 used in this "direct injection" method are disclosed in the following
19 U.S. Patents: 4,551,132 - Pásztor et al.; 4,795,741 - Leshchiner et al.;
20 5,525,334 - Ito et al.; and 5,580,568 - Greff et al.

21 The direct injection of liquid polymer embolic agents has proven
22 difficult in practice. For example, migration of the polymeric material
23 from the aneurysm and into the adjacent blood vessel has presented a
24 problem. In addition, visualization of the embolization material
25 requires that a contrasting agent be mixed with it, and selecting
26 embolization materials and contrasting agents that are mutually
27 compatible may result in performance compromises that are less than
28 optimal. Furthermore, precise control of the deployment of the

1 polymeric embolization material is difficult, leading to the risk of
2 improper placement and/or premature solidification of the material.
3 Moreover, once the embolization material is deployed and solidified, it
4 is difficult to move or retrieve.

5 Another approach that has shown promise is the use of
6 thrombogenic microcoils. These microcoils may be made of a
7 biocompatible metal alloy (typically platinum and tungsten) or a
8 suitable polymer. If made of metal, the coil may be provided with
9 Dacron fibers to increase thrombogenicity. The coil is deployed
10 through a microcatheter to the vascular site. Examples of microcoils
11 are disclosed in the following U.S. patents: 4,994,069 - Ritchart et al.;
12 5,122,136 - Guglielmi et al.; 5,133,731 - Butler et al.; 5,226,911 - Chee
13 et al.; 5,304,194 - Chee et al.; 5,312,415 - Palermo; 5,382,259 - Phelps
14 et al.; 5,382,260 - Dormandy, Jr. et al.; 5,476,472 - Dormandy, Jr. et
15 al.; 5,578,074 - Mirigian; 5,582,619 - Ken; 5,624,461 - Mariant;
16 5,639,277 - Mariant et al.; 5,658,308 - Snyder; 5,690,667 - Gia;
17 5,690,671 - McGurk et al.; 5,700,258 - Mirigian et al.; 5,718,711 -
18 Berenstein et al.; 5,891,058 - Taki et al.; 6,013,084 - Ken et al.;
19 6,015,424 - Rosenbluth et al.; and Des. 427,680 - Mariant et al.

20 While many prior art microcoil devices have met with some
21 success in treating small aneurysms with relatively narrow necks, it has
22 been recognized that the most commonly used microcoil vaso-
23 occlusive devices achieve less than satisfactory results in wide-necked
24 aneurysms, particularly in the cerebrum. This has led to the
25 development of three-dimensional microcoil devices, such as those
26 disclosed in U.S. Pat. Nos. 5,645,558 - Horton; 5,911,731 - Pham et
27 al.; and 5,957,948 - Mariant (the latter two being in a class of devices
28 known as "three-dimensional Guglielmi detachable coils", or "3D-

1 GDC's"). See, e.g., Tan et al., "The Feasibility of Three-Dimensional
2 Guglielmi Detachable Coil for Embolisation of Wide Neck Cerebral
3 Aneurysms," *Interventional Neuroradiology*, Vol. 6, pp. 53-57 (June,
4 2000); Cloft et al., "Use of Three-Dimensional Guglielmi Detachable
5 Coils in the Treatment of Wide-necked Cerebral Aneurysms,"
6 *American Journal of Neuroradiology*, Vol. 21, pp. 1312-1314 (August,
7 2000).

8 The typical three-dimensional microcoil is formed from a length
9 of wire that is formed first into a primary configuration of a helical
10 coil, and then into a secondary configuration that is one of a variety of
11 three-dimensional shapes. The minimum energy state of this type of
12 microcoil is its three-dimensional secondary configuration. When
13 deployed inside an aneurysm, these devices assume a three-
14 dimensional configuration, typically a somewhat spherical
15 configuration, that is at or slightly greater than, the minimum energy
16 state of the secondary configuration. Because the overall dimensions
17 of these devices in their non-minimum energy state configuration is
18 approximately equal to or smaller than the interior dimensions of the
19 aneurysm, there is nothing to constrain the device from shifting or
20 tumbling within the aneurysm due to blood flow dynamics.

21 In some of these three-dimensional devices (e.g., U.S. Pat.
22 5,122,136 - Guglielmi et al.), the secondary configuration is itself a
23 helix or some similar form that defines a longitudinal axis. Devices
24 with what may be termed a "longitudinal" secondary configuration
25 form a three-dimensional non-minimum energy state configuration
26 when deployed inside an aneurysm, but, once deployed, they have
27 displayed a tendency to revert to their minimum energy state
28 configurations. This, in turn, results in compaction due to "coin

1 stacking" (i.e., returning to the secondary helical configuration),
2 thereby allowing recanalization of the aneurysm.

3 There has thus been a long-felt, but as yet unsatisfied need for a
4 microcoil vaso-occlusive device that has the advantages of many of the
5 prior art microcoil devices, but that can be used effectively to treat
6 aneurysms of many different sizes configurations, and in particular
7 those with large neck widths. It would be advantageous for such a
8 device to be compatible for use with existing guidewire and
9 microcatheter microcoil delivery mechanisms, and to be capable of
10 being manufactured at costs comparable with those of prior art
11 microcoil devices.

12

13 SUMMARY OF THE INVENTION

14 Broadly, the present invention is a microcoil vaso-occlusive
15 device that has a minimum energy state secondary configuration
16 comprising a plurality of curved segments, each defining a discrete
17 axis, whereby the device, in its minimum energy state configuration,
18 defines multiple axes. More specifically, each segment defines a plane
19 and an axis that is substantially perpendicular to the plane.

20 In a particular preferred embodiment, the present invention is an
21 elongate microcoil structure having a minimum energy state secondary
22 configuration that defines a plurality of tangentially-interconnected,
23 substantially circular loops defining a plurality of separate axes. In one
24 form of the preferred embodiment, the substantially circular closed
25 loops are substantially coplanar and define axes that are substantially
26 parallel. That is, the planes defined by the segments are themselves
27 substantially coplanar. In another form of the preferred embodiment,
28 each pair of adjacent loops defines a shallow angle, whereby their

1 respective axes define an angle of not more than about 90° , and
2 preferably not more than about 45° , between them.

3 In an alternative embodiment, the microcoil structure has a
4 minimum energy state secondary configuration that defines a wave-
5 form like structure comprising a longitudinal array of laterally-
6 alternating open loops defining a plurality of separate axes. As in the
7 preferred embodiment, the alternative embodiment may be in a first
8 form in which the loops are substantially coplanar and their respective
9 axes are substantially parallel, or in a second form in which each pair
10 of adjacent loops defines a shallow angle, whereby their respective axes
11 define an angle of not more than about 90° , and preferably not more
12 than about 45° , between them.

13 In either embodiment, the device, in its minimum energy state
14 secondary configuration, has a dimension that is substantially larger
15 (preferably at least about 25% greater) than the largest dimension of
16 the vascular space in which the device is to be deployed. Thus, when
17 the device is deployed inside a vascular site such as an aneurysm, the
18 confinement of the device within the site causes the device to assume a
19 three-dimensional configuration that has a higher energy state than the
20 minimum energy state. Because the minimum energy state of the
21 device is larger (in at least one dimension) than the space in which it is
22 deployed, the deployed device is constrained by its intimate contact
23 with the walls of the aneurysm from returning to its minimum energy
24 state configuration. Therefore, the device still engages the
25 surrounding aneurysm wall surface, thereby minimizing shifting or
26 tumbling due to blood flow dynamics. Furthermore, the minimum
27 energy state secondary configuration (to which the device attempts to
28 revert) is not one that is conducive to "coin stacking", thereby

1 minimizing the degree of compaction that is experienced.

2 As will be better appreciated from the detailed description that
3 follows, the present invention provides for effective embolization of
4 vascular structures (particularly aneurysms) having a wide variety of
5 shapes and sizes. It is especially advantageous for use in wide-necked
6 aneurysms. Furthermore, as will be described in more detail below,
7 the present invention may be deployed using conventional deployment
8 mechanisms, such as microcatheters and guidewires.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of a microcoil vaso-occlusive device in accordance with a preferred embodiment of the present invention;

Figure 2 is a partial view of the device of Figure 1, taken within the area designated by the numeral 2 in Figure 1;

Figures 3 and 4 are partial views of a microcoil vaso-occlusive device in accordance with another form of the preferred embodiment of the present invention;

Figure 5 is a plan view of a microcoil vaso-occlusive device in accordance with an alternative embodiment of the invention;

Figure 6 is an elevational view of the present invention in the process of being deployed through a microcatheter into a wide-necked aneurysm; and

Figure 7 is a perspective view of a heat treatment fixture used to manufacture the preferred embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Referring first to Figures 1-4 and 8, a microcoil vaso-occlusive device 10, in accordance with a preferred embodiment of the invention is shown. The device 10 comprises a suitable length of wire formed into the primary configuration of a helical microcoil 12 (Figure 2). Suitable materials for the device 10 include platinum, rhodium, palladium, rhenium, tungsten, gold, silver, tantalum, and various alloys of these metals. Various surgical grade stainless steels may also be used. Preferred materials include the platinum/tungsten alloy known as Platinum 479 (92% Pt, 8% W, available from Sigmund Cohn, of Mount Vernon, NY) and titanium/nickel alloys (such as the

1 titanium/nickel alloy known as "nitinol"). Another material that may
2 be advantageous is a bimetallic wire comprising a highly elastic metal
3 with a highly radiopaque metal. Such a bimetallic wire would also be
4 resistant to permanent deformation. An example of such a bimetallic
5 wire is a product comprising a nitinol outer layer and an inner core of
6 pure reference grade platinum, available from Sigmund Cohn, of
7 Mount Vernon, NY, and Anomet Products, of Shrewsbury, MA.
8 Wire diameters of about 0.0125 mm to about 0.150 mm may be used.

9 The microcoil 12 has a diameter that is typically in the range of
10 about 0.125 mm to about 0.625 mm, with a preferred a preferred
11 range, for most neurovascular applications, of about 0.25 mm to about
12 0.40 mm. The axial length of the microcoil 12 may be anywhere from
13 about 5 mm to about 1000 mm, with about 20 mm to about 400 mm
14 being typical.

15 The primary winding of the microcoil 12 is applied under
16 tension. The amount of tension, and the pitch of the primary winding,
17 determine the stiffness of the microcoil 12. These parameters can be
18 varied along the length of the microcoil 12 to form a microcoil having
19 different degrees of stiffness along its length, which may be
20 advantageous in certain applications.

21 The microcoil 12 is formed into a secondary configuration that
22 comprises a plurality of curved segments, each defining an axis,
23 whereby the microcoil 12 defines multiple axes. More specifically,
24 each of the curved segments defines a plane an axis that is substantially
25 perpendicular to the plane. In the preferred embodiment of Figures 1-
26 4, the curved segments are tangentially-interconnected, substantially
27 circular loops 14a, 14b defining a plurality of separate axes 16. In one
28 form of the preferred embodiment, shown in Figure 1, the substantially

1 circular loops 14a, 14b are substantially coplanar and define axes 16
2 that are substantially parallel. In another form of the preferred
3 embodiment, shown in Figures 3 and 4, each pair of adjacent loops
4 14a, 14b defines a shallow angle, whereby their respective axes 16
5 define an angle (θ_1 , θ_2 , θ_3 , and θ_4) of not more than about 90° between
6 them, and preferably not more than about 45° .

7 The preferred embodiment of the invention typically includes a
8 pair of end loops 14a and at least one intermediate loop 14b.
9 Typically, there will be up to four intermediate loops 14b, depending
10 on the vascular site to be embolized, but there may be as many as six
11 or more, for use in very large vascular sites. The intermediate loops
12 are sized to have a diameter approximately equal to the maximum
13 diameter of the target vascular site (e.g., an aneurysm), while the end
14 loops 14a have a slightly smaller diameter (preferably, approximately
15 1.5 mm smaller), for purposes to be described below.

16 The primary microcoil 12 is formed into the secondary
17 configuration by heat treatment, as is well known in the art. For
18 example, the annealed primary coil may be initially placed into the
19 secondary configuration by winding or wrapping around a suitably
20 shaped and sized mandrel of refractory material, and then subjected to
21 an annealing temperature for a specified period of time. For Platinum
22 479, for example, an annealing temperature of about 500°C to about
23 1000°C , preferably approximately 670°C , is maintained for about 30
24 to 90 minutes, preferably about 60 minutes, then cooled to room
25 temperature and ultrasonically cleaned. The resultant secondary
26 configuration is thereby made permanent, and it becomes the
27 minimum energy state configuration of the microcoil 12.

28 Figure 7 shows a heat treatment fixture 50 used in the

1 manufacture of the preferred embodiment of the invention. The
2 fixture 50 is made of a refractory material, and it includes a base 52
3 having a surface on which is provided a mandrel for the secondary
4 winding. The mandrel comprises a plurality of winding pins 54a, 54b
5 extending upwardly from the surface of the base 52. The exemplary
6 fixture 50 shown in the drawing has six pins arranged in roughly a
7 hexagonal pattern. There are two end winding pins 54a adjacent each
8 other, and four intermediate winding pins 54b. A pair of fastening
9 pegs 56 is located near one end of the fixture, for fastening the ends of
10 the primary coil 12.

11 The diameters of the end winding pins 54a are slightly smaller
12 than the diameters of the intermediate winding pins 54b to achieve the
13 size relationships described above. The spacings between the pins 54a,
14 54b are only slightly greater than the diameter of the primary coil 12,
15 so that only one wind of the primary coil can be passed around the
16 pins with each winding of the secondary coil. Each subsequent
17 winding of the secondary coil is thus stacked on top of the previous
18 winding. This eliminates any straight sections in the secondary coil,
19 which, during deployment, would tend to push the coil into the parent
20 artery.

21 During the secondary winding process, the primary coil 12 is
22 kept under tension. The amount of tension can be adjusted to control
23 the degree of spring-back of the loops 14a, 14b of the microcoil 12.

24 The secondary winding of the microcoil 12 is performed so that
25 the loops 14a, 14b reverse direction as the microcoil 12 is wrapped
26 around each successive pin on the fixture. This ensures that loops will
27 not coin stack, and that they will disperse randomly throughout the
28 aneurysm once deployed. Furthermore, in the preferred embodiment,

1 each loop is wound a complete 360° before the next loop is wound.
2 This ensures that each loop will completely seat within the aneurysm
3 before the microcoil 12 reverses direction. With a complete loop
4 intact, the loop strength is maximized, and the loop distributes loads
5 evenly.

6 Figure 5 shows a microcoil vaso-occlusion device 20 in
7 accordance with an alternative embodiment of the invention. This
8 embodiment includes a primary microcoil 22 formed into a secondary
9 minimum energy state configuration that defines a wave-form like
10 structure comprising a longitudinal array of laterally-alternating open
11 loops 24 defining a plurality of separate axes 26. As in the preferred
12 embodiment, the alternative embodiment may be in a first form in
13 which the loops 24 are substantially coplanar and their respective axes
14 26 are substantially parallel, or in a second form in which each pair of
15 adjacent loops 24 defines a shallow angle, whereby their respective
16 axes 26 define an angle of not more than about 90°, and preferably not
17 more than about 45°, between them. The materials, dimensions, and
18 method of manufacture of this alternative embodiment are, in all
19 material respects, similar to those of the preferred embodiment
20 described above.

21 The method of using the present invention is shown in Figure 6.
22 In use, the proximal end of the microcoil 12 (or 22) is attached to the
23 distal end of a guidewire or microcatheter (not shown). The
24 attachment may be by any of a number of ways known in the art, as
25 exemplified by the following U.S. patents, the disclosures of which are
26 expressly incorporated herein by reference: 5,108,407 - Geremia et al.;
27 5,122,136 - Guglielmi et al.; 5,234,437 - Sepetka; 5,261,916 - Engelson;
28 5,304,195 - Twyford, Jr. et al.; 5,312,415 - Palermo; 5,423,829 -Pham

1 et al.; 5,522,836 - Palermo; 5,645,564 - Northrup et al.; 5,725,546 -
2 Samson; 5,800,453 - Gia; 5,814,062 - Sepetka et al.; 5,911,737 - Lee et
3 al.; 5,989,242 - Saadat et al.; 6,022,369 - Jacobsen et al. 6,063,100 -
4 Diaz et al.; 6,068,644 - Lulo et al.; and 6,102,933 - Lee et al.

5 A target vascular site is visualized, by conventional means,
6 well-known in the art. The target vascular site may be an aneurysm
7 40 branching off a parent artery 42. The aneurysm 40 has a dome 44
8 connected to the branch artery by a neck 46. A catheter 30 is passed
9 intravascularly until it enters the dome 44 of the aneurysm 40 via the
10 neck 46. The microcoil 12 is passed through the catheter 30 with the
11 assistance of the guidewire or microcatheter until the microcoil 12
12 enters the dome 44 of the aneurysm 40.

13 The undersized end loop 14a at the distal end of the microcoil
14 12 enters the aneurysm first. This assists in seating the first loop
15 properly, because the smaller size keeps the first loop inside the neck
16 46 of the aneurysm, avoiding the parent artery 42.

17 The intermediate loops 14b then enter the aneurysm. Because
18 they are sized to fit the aneurysm, they can deploy freely and smoothly
19 with minimal friction against the wall of the aneurysm. Because the
20 secondary configuration of the microcoil 12 is essentially coplanar, all
21 of the intermediate loops exert a force against the walls of the
22 aneurysm dome 44, thereby improving the resistance of the microcoil
23 12 to shifting due to pulsatile blood flow.

24 As the microcoil 12 enters the aneurysm, it attempts to assume
25 its secondary configuration. Because the microcoil, in its secondary
26 configuration, is larger than the aneurysm, however, it is constrained
27 into a deployed configuration in which it tends to fill the interior
28 volume of the aneurysm. In this deployed configuration, the microcoil

1 is in an energy state that is substantially higher than its minimum
2 energy state. Thus, when the device is deployed inside a vascular site
3 such as an aneurysm, the confinement of the device within the site
4 causes the device to assume a three-dimensional configuration that has
5 a higher energy state than the minimum energy state. Because the
6 minimum energy state of the device is larger (in at least one
7 dimension) than the space in which it is deployed, the deployed device
8 is constrained by its intimate contact with the walls of the aneurysm
9 from returning to its minimum energy state configuration. Therefore,
10 the device still engages the surrounding aneurysm wall surface, thereby
11 minimizing shifting or tumbling due to blood flow dynamics.
12 Furthermore, the minimum energy state secondary configuration (to
13 which the device attempts to revert) is not one that is conducive to
14 "coin stacking", thereby minimizing the degree of compaction that is
15 experienced.

16 The undersized end loop 14a at the proximal end of the
17 microcoil 12 enters the aneurysm last. After the microcoil is fully
18 deployed, it is controllably detached from the guidewire by any
19 suitable means well-known in the art, thereby allowing the
20 microcatheter or guidewire to be withdrawn, leaving the microcoil in
21 place to embolize the aneurysm. After detachment, the proximal end
22 loop 14a curls into the neck 46 of the aneurysm 40, avoiding the parent
23 artery 42.

24 The present invention thus exhibits several advantages over
25 prior art three-dimensional microcoils. For example, there is increased
26 coverage of the aneurysm neck, due to the presence of loops across the
27 neck, yet the probability of any part of the device intruding into the
28 parent artery is reduced. The secondary coil configuration also

1 provides smoother deployment, and, once deployed, the device
2 exhibits greater resistance to coil compaction, thereby increasing
3 positional stability in the face of pulsatile blood flow. This stability is
4 achieved with lower overall friction between the device and the
5 aneurysm wall. Moreover, the random distribution of loops
6 throughout the aneurysm allows the device to maintain a complex
7 shape inside the aneurysm, yielding improved embolization.

8 While a preferred embodiment and an alternative embodiment
9 of the invention have been described herein, it will be appreciated that
10 a number of variations and modifications will suggest themselves to
11 those skilled in the pertinent arts. For example, other secondary
12 configurations than those described herein may be found that will yield
13 most, if not all, of the significant advantages of the invention for
14 treatment of the typical aneurysm, or that will prove especially
15 advantageous in specific clinical applications. Also, for specific
16 applications, the dimensions and materials may be varied from those
17 disclosed herein if found to be advantageous. These and other
18 variations and modifications are considered to be within the spirit and
19 scope of the invention, as defined in the claims that follow.

1 WHAT IS CLAIMED IS:

2 1. A microcoil vaso-occlusive device comprising a microcoil
3 formed into a minimum energy state secondary configuration
4 comprising a plurality of curved segments, each defining a discrete
5 axis, whereby the device, in its minimum energy state configuration,
6 defines multiple axes.

7
8 2. The device of Claim 1, wherein each of the curved segments
9 defines a plane and an axis that is substantially perpendicular to the
10 plane.

11
12 3. The device of Claim 1, wherein the multiple axes are
13 substantially parallel.

14
15 4. The device of Claim 1, wherein each adjacent pair of the
16 multiple axes forms an acute angle.

17
18 5. The device of Claim 1, wherein the curved segments are
19 substantially closed loops, interconnected to each other substantially
20 tangentially.

21
22 6. The device of Claim 1, wherein the curved segments are
23 wave-like open loops.

24
25 7. The device of Claim 1, wherein the microcoil is formed
26 from a bimetallic wire.

27
28 8. The device of Claim 7, wherein the bimetallic wire includes a

1 radiopaque metal and a super-elastic metal.

2

3

4 9. The device of Claim 8, wherein the bimetallic wire
5 comprises a platinum core and a nitinol outer layer.

6

7 10. A microcoil vaso-occlusive device comprising a microcoil
8 formed into a minimum energy state secondary configuration
9 comprising a plurality of tangentially-interconnected substantially
10 circular loops, each defining a plane and a discrete axis that is
11 substantially perpendicular to the plane.

12

13 11. The device of Claim 10, wherein the axes are substantially
14 parallel.

15

16 12. The device of Claim 10, wherein each adjacent pair of the
17 axes forms an acute angle.

18

19 13. The device of Claim 10, wherein the microcoil is formed
20 from a bimetallic wire.

21

22 14. The device of Claim 13, wherein the bimetallic wire
23 includes a radiopaque metal and a super-elastic metal.

24

25 15. The device of Claim 14, wherein the bimetallic wire
26 comprises a platinum core and a nitinol outer layer.

27

28 16. A method of embolizing an aneurysm, comprising the steps

1 of:

2 (a) providing microcoil vaso-occlusive device comprising a
3 microcoil formed into a minimum energy state secondary
4 configuration comprising a plurality of curved segments, each defining
5 a discrete axis, whereby the device, in its minimum energy state
6 configuration, defines multiple axes and has at least one dimension
7 that is larger than the interior dimension of the aneurysm; and

8 (b) deploying the device into the interior of the aneurysm so that
9 device is contained within the aneurysm in a configuration having an
10 energy state that is substantially higher than its minimum energy state,
11 whereby the device is constrained by its contact with the aneurysm
12 from returning to its minimum energy state configuration.

13

14 17. The method of Claim 16, wherein the device, in its
15 minimum energy state secondary configuration, comprises a plurality
16 of tangentially-interconnected, substantially circular loops, each
17 defining a discrete axis.

18

19 18. The method of Claim 16, wherein the device, in its
20 minimum energy state configuration, comprises a plurality of
21 interconnected wave-like open loops, each defining a discrete axis.

1/3

FIG. 1

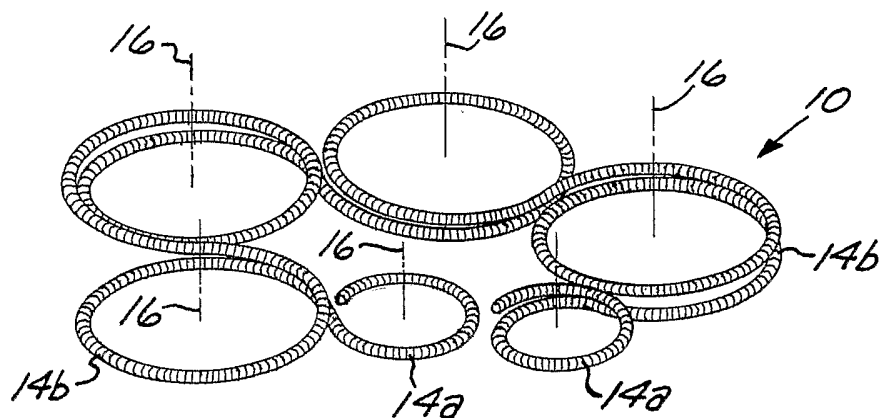


FIG. 2

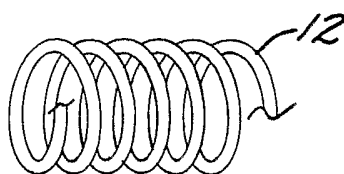


FIG. 3

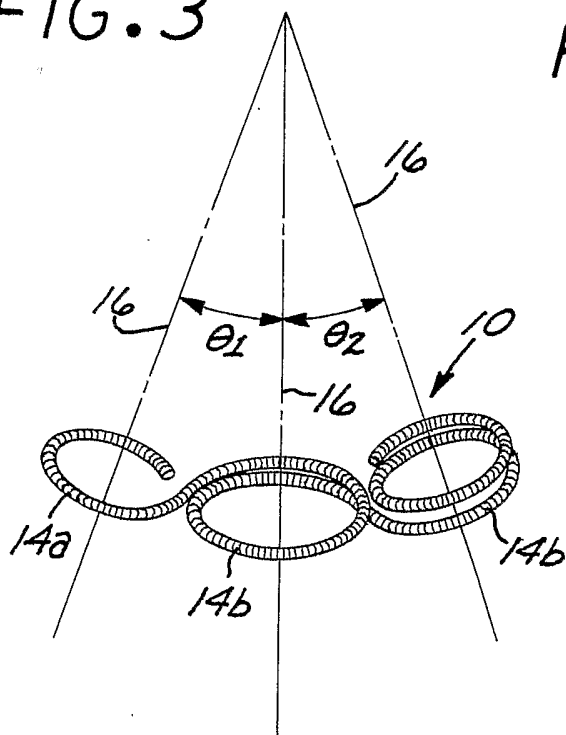
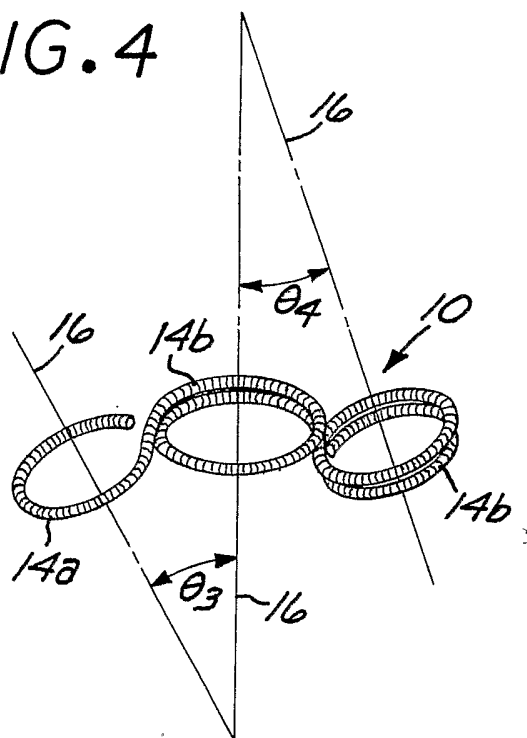
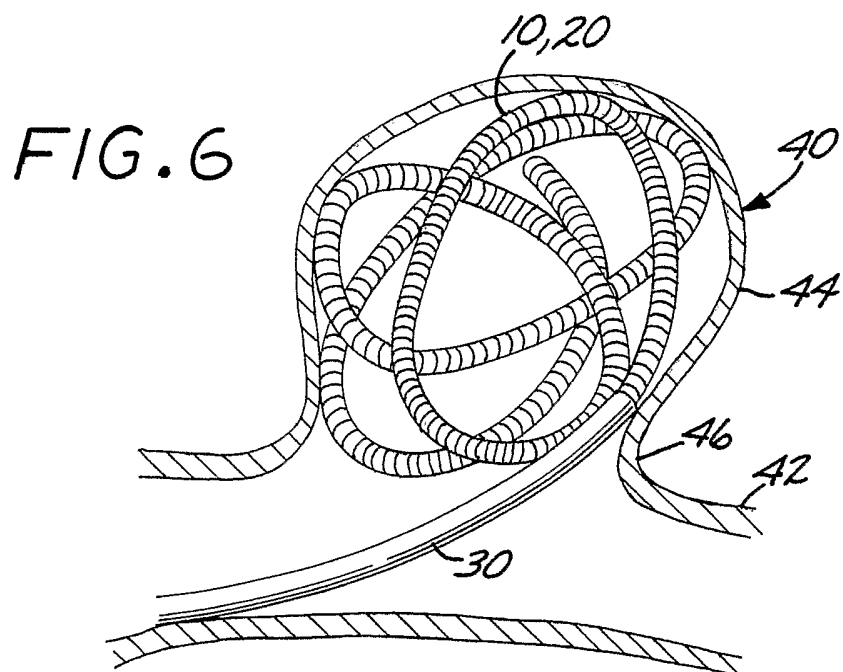
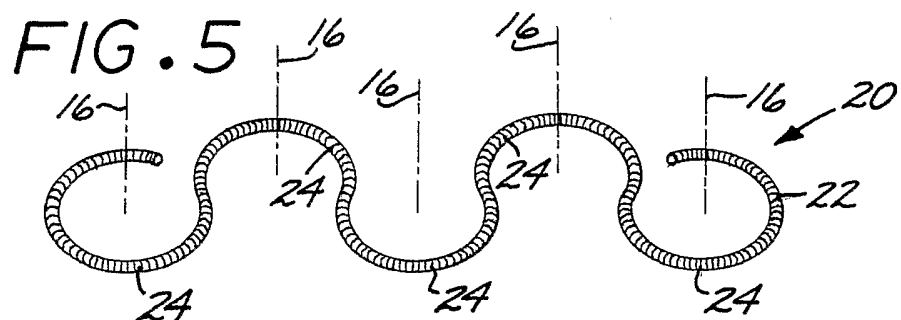


FIG. 4



2/3



3/3

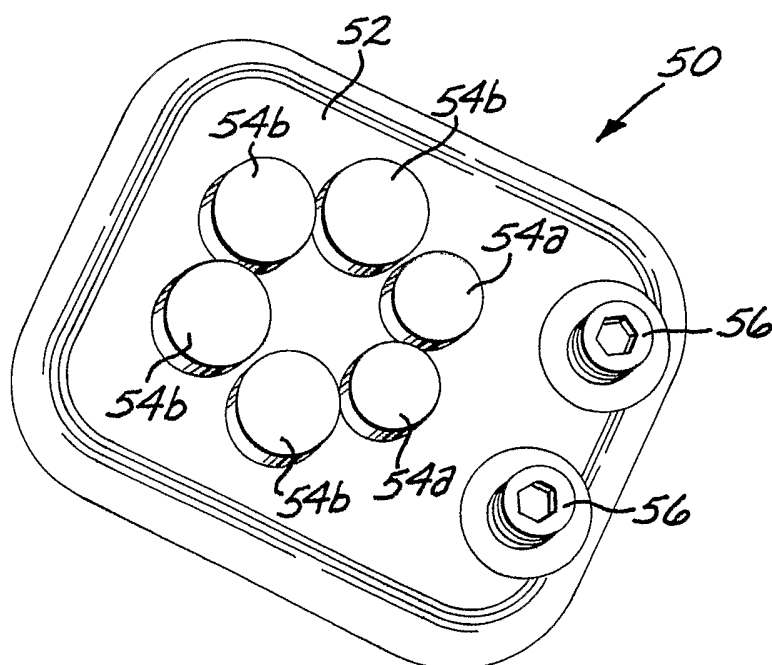


FIG. 7

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 01/50970

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 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 7 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)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 00 74577 A (SCIMED LIFE SYSTEMS INC) 14 December 2000 (2000-12-14)	1-4,6
Y	page 7, line 23 -page 8, line 23 page 11, line 15 -page 12, line 6 page 13, line 25 -page 14, line 9; figure 2E	7-9
X	WO 94 11051 A (TARGET THERAPEUTICS INC) 26 May 1994 (1994-05-26)	1-3,5, 10,11
Y	page 2, line 30 -page 5, line 9 page 6, line 28 -page 7, line 6; figure 5	7-9, 13-15
Y	WO 01 45571 A (JAYARAMAN SWAMINATHAN) 28 June 2001 (2001-06-28) page 17, line 31 -page 20, line 23 -/--	7-9, 13-15

☒ 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

23 May 2002

Date of mailing of the international search report

10/06/2002

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

Angeli, M

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 01/50970

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 00 21443 A (COOK INC) 20 April 2000 (2000-04-20) page 14, line 17 -page 15, line 12; figures 20,21 -----	1-4
A	US 6 165 194 A (DENARDO ANDREW J) 26 December 2000 (2000-12-26) column 3, line 56 -column 4, line 60 -----	1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 01/50970

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 0074577	A	14-12-2000	US 6280457 B1	28-08-2001
			AU 5300700 A	28-12-2000
			EP 1185204 A1	13-03-2002
			WO 0074577 A1	14-12-2000
			US 2002002382 A1	03-01-2002
WO 9411051	A	26-05-1994	AU 681073 B2	21-08-1997
			AU 3603793 A	08-06-1994
			CA 2144725 A1	26-05-1994
			EP 0743866 A1	27-11-1996
			JP 8500273 T	16-01-1996
			WO 9411051 A1	26-05-1994
WO 0145571	A	28-06-2001	AU 2449101 A	03-07-2001
			WO 0145571 A1	28-06-2001
			US 2002010481 A1	24-01-2002
WO 0021443	A	20-04-2000	AU 6288799 A	01-05-2000
			WO 0021443 A1	20-04-2000
US 6165194	A	26-12-2000	AU 5214799 A	14-02-2000
			EP 1143878 A2	17-10-2001
			WO 0004845 A2	03-02-2000
			US 2001000798 A1	03-05-2001