(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
21 January 2010 (21.01.2010)

PCT

(10) International Publication Number
WO 2010/009019 A1

(51) International Patent Classification:
A61B 17/12 (2006.01)

(21) International Application Number:
PCT/US2009/050319

(22) International Filing Date:
10 July 2009 (10.07.2009)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

61/080,742	15 July 2008 (15.07.2008)	US
61/083,111	23 July 2008 (23.07.2008)	US
12/498,752	7 July 2009 (07.07.2009)	US

(71) Applicant *(for all designated States except US)*: **PENUMBRA, INC.** [US/US]; 1351 Harbor Bay Parkway, Alameda, CA 94502 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **TOMPKINS, Ben** [US/US]; 1609 N. Clear Creek Place, Danville, CA 94526 (US). **BOSE, Arani** [JP/US]; 322 East 18th Street, New York, NY 10003 (US). **HUI, Delilah** [US/US]; 119 Via Bellagio, American Canyon, CA 94503 (US). **BARRY, David** [US/US]; 10 Terra Way, Livermore, CA 94550 (US). **PONS, Stephen** [US/US]; 1609 N. Clear Creek Place, San Francisco, CA (US). **LEYNOV, Aleksander** [US/US]; 16 Brandon Oaks Place, Walnut Creek, CA 94597 (US).

(74) Agents: **STALLMAN, Michael, A.** et al.; Morrison & Foerster LLP, 425 Market Street, San Francisco, CA 94105-2482 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

(54) **Title**: EMBOLIC COIL IMPLANT SYSTEM

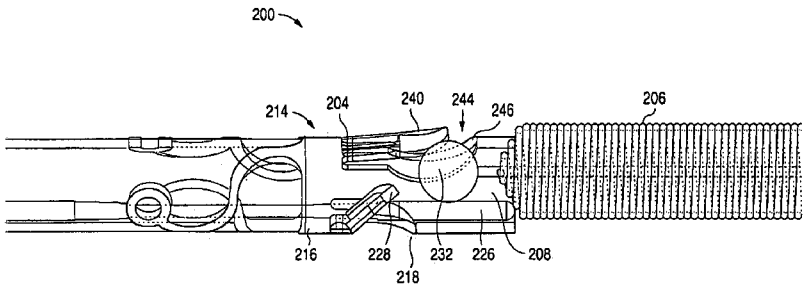


FIG. 11

(57) **Abstract**: Embolic coil implant systems whereby coils (16, 116, 216) are mechanically detachable are disclosed. The coils include a retention element (32, 132, 232) that may be releasably retained within the distal end of an implant tool (14, 114, 214). The implant tool may include a fulcrum (120) configured to engage a first filament (30) and prevent the release of the coil when the first filament is engaged. Alternatively, an urging means (240) and aperture (244) may be disposed within the sidewall of the implant tool, and a first filament may, in conjunction with the aperture and sidewall, releasably retain the coil until the first filament is withdrawn. The implant tool may also include an alignment member (228) for aligning the first filament.

WO 2010/009019 A1

EMBOLIC COIL IMPLANT SYSTEM

PRIORITY

This application claims priority to prior Provisional Application No. 61/080,742, filed July 15, 2008, Provisional Application No. 61/083,111, filed July 23, 2008, and Non-Provisional Application No. 12/498,752, filed July 7, 2009, the disclosures of which are incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates generally to the fields of systems and methods for implanting an intravascular implant device, and more specifically to systems and methods for implanting embolic coils.

BACKGROUND

Coil embolization is a commonly practiced technique for treatment of brain aneurysm, arterio-venous malformation, and other conditions for which vessel occlusion is a desired treatment option, such as, for example, in the occlusion of a tumor "feeder" vessel. A typical occlusion coil is a wire coil having an elongate primary shape with windings coiled around a longitudinal axis. In the aneurysm coil embolization procedure, a catheter is introduced into the femoral artery and navigated through the vascular system under fluoroscopic visualization. The coil in the primary shape is positioned within the catheter. The catheter distal end is positioned at the site of an aneurysm within the brain. The coil is passed from the catheter into the aneurysm. Once released from the catheter, the coil assumes a secondary shape selected to optimize filling of the aneurysm cavity. Multiple coils may be introduced into a single aneurysm cavity for optimal filling of the cavity. The deployed coils serve to block blood flow into the aneurysm and reinforce the aneurysm against rupture.

One form of delivery system used to deliver an embolic coil through a catheter to an implant site includes a wire and a coil attached to the wire. The coil (with the attached wire) is advanced through a catheter as discussed above. To release the coil into an aneurysm, current is passed through the wire, causing electrolytic detachment of the coil from the wire. A similar system is used to deliver a coil to the site of an arterio-venous malformation or fistula. The subject system provides a mechanical alternative to prior art electrolytic detachment systems.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a side elevation view of an embolic coil implant system;

Fig. 2 is a side elevation view of the embolic coil of the implant system of Fig. 1;

Fig. 3A – 3C are a series of side elevation views of the portion of the coil identified by region 3-3 in Fig. 2, illustrating the properties of the pre-tensioned stretch resistant wire.

Fig. 4A illustrates the proximal portion of the coil engaged with the distal portion of the detachment shaft and wire.

Fig. 4B is similar to Fig. 4A and illustrates the proximal portion of the coil and the distal portion of the shaft and wire following detachment.

Figs. 5A through 5G are a sequence of drawings schematically illustrating the steps of occluding an aneurysm using the system of Figs. 1 through 4B.

Figs. 6A and 6B schematically illustrate steps of detaching the coil from the detachment shaft and wire in accordance with the method of Figs. 5A through 5G.

Fig. 7 is an elevation view of an alternate embodiment of a detachment system, in which the distal end of the pusher tube is shown partially transparent.

Fig. 8 is a perspective view of the embodiment of Fig. 7.

Fig. 9 is a plan view of the system of Fig. 7, showing the coil detached from the pusher tube.

Fig. 10 is an elevation view of the system of Fig. 7, showing the coil detached from the pusher tube.

Fig. 11 is a side elevation view of yet another embodiment of a detachment system according to the invention, in which the distal end of the pusher tube is shown partially transparent.

Fig. 12 is a plan view of the embodiment of Fig. 11.

Fig. 13 is a bottom view of the embodiment of Fig. 11.

Fig. 14 is a side elevation view of the embodiment of Fig. 11 following a step in detachment of the embolic coil.

Fig. 15 is a side elevation view of the embodiment of Fig. 11 following detachment of an embolic coil.

Fig. 16 is a side elevation view of yet another alternative embodiment according to the invention.

DETAILED DESCRIPTION

Referring to Fig. 1, general components of an embolic coil implant system 10 include a microcatheter 12, insertion tool 14, and embolic coil 16. These components may be provided individually or packaged together. Additional components of the system may include a guide catheter insertable into the vasculature via an access point (e.g., femoral puncture), and an associated guide wire for facilitating advancement of the guide catheter.

Microcatheter 12 is an elongate flexible catheter proportioned to be received within the lumen of a corresponding guide catheter and advanced beyond the distal end of the guide catheter to the cerebral vasculature where an aneurysm to be treated is located. Suitable dimensions for the microcatheter include inner diameters of 0.010 "to 0.045", outer diameters of 0.024" to 0.056", and lengths from 75 cm to 175 cm. One preferred embodiment utilizes the following dimensions: 0.025in ID, 0.039in Distal OD (3F), 0.045in Proximal OD (3.5F), and length of 145-155cm. Marker bands 18 facilitate fluoroscopic visualization of the microcatheter position during the course of an implantation procedure. Microcatheter 12 includes a lumen 20 proportioned to receive the embolic coil 16 and the shaft of the insertion tool 14. When the coil is within the lumen of the microcatheter, the surrounding lumen walls restrain the coil in

the generally elongated shape shown in Fig. 1. Release of the coil from the microcatheter allows the coil to assume its secondary shape.

Details of the embolic coil 16 are shown in Fig. 2. Coil 16 is formed of a wire 22 coiled to have a primary coil diameter D1 of approximately 0.020 inches, although smaller diameters, and diameters as large as 0.035 inches, may instead be used. The pitch of the coil may be uniform as shown, or it may vary along the length of the coil, or different sections of the coil may be formed to have different pitches. The wire material selected for the coil is preferably one capable of fluoroscopic visualization, such as Platinum/Iridium, Platinum/Tungsten, or other suitable material. In one embodiment, the wire forming the coil has a diameter of approximately 0.0015 – 0.0020 inches. Coil 16 is then formed into a secondary three-dimensional shape. The secondary shape can be helical, spherical, multi-lobal or any other shape desired to fill the aneurysm void. The process for forming this shape is to temperature set the stretch resistant wire 30 into the desired shape. The stretch-resistant member could be a shape-memory polymer or metal such as nitinol. Stretch-resistant member 30 can be in a diameter range of 0.0005" to 0.003".

One or more reduced-diameter windings 24 are positioned at the proximal end of the coil 16, forming a stop 26. An atraumatic distal tip 28, which may be formed of gold or tin solder or other material, is mounted to the distal end of the coil 16. A stretch resistant wire 30 or other type of elongate filament or strand is attached to the distal tip 28 and extends through the coil 16. Stretch resistant wire 30 includes an element 32 on its proximal end that is sufficiently broad that it will not pass through the lumen of the windings of stop 26, but will instead rest against the stop 26. Element 32 may be a ball (e.g., formed of gold/tin solder, PET, platinum, titanium or stainless steel) as shown, or an alternative element having features that will engage with or be unable to pass the stop 26 or other parts of the proximal portion of the coil 16. The stretch resistant wire helps to maintain the pitch of the coil even when the coil is placed under tension. During implantation, the stretch resistant wire helps in repositioning of the coil (if needed). The stretch resistant wire makes the coil easier to retract, and maintains close positioning of coil windings during manipulation of the coil.

Stretch resistant wire 30 is pre-tensioned, so that the ball 32 naturally sits firmly against the stop 26 as shown in Fig. 3A. When tension is applied to the wire 30 as shown in Fig. 3B, and then released as in Fig. 3C, the ball will return to its firm seating against the stop. The stretch resistant wire prevents the coil from stretching when deployed, repositioned, or withdrawn from the aneurysm. This stretch resistant wire will not yield when placed in tension during repositioning. Conversely, stretch resistant wire will prevent compaction of adjacent coils, likely improving long term performance of coil 16 following implantation. Stretch resistant wire 30 will have a yield strength approximately 0.5 lbs. In a preferred embodiment, the stretch resistant wire is shape set to give the embolic coil 16 its predetermined secondary shape. In other words, the shape set of the wire will cause the coil 16 to assume the secondary shape (Fig. 5C) once it is advanced from the microcatheter 12. In alternative embodiments, the coil itself, or both the coil and the wire may be shape set to give the coil its secondary shape.

Referring again to Fig. 1, insertion tool 14 includes a flexible elongate tubular shaft 34, and a handle 36 on the proximal portion of the shaft 34. An actuator 38 on the handle 36 is manipulatable by a user to effect detachment of an embolic coil from the shaft 34 as will be discussed in detail below. Although the actuator is shown in this drawing as a slidable button, any number of other types of slidable, rotatable, pivotable, depressible, etc., actuators may instead be used using techniques well known in the art. Although the handle 36 is shown coupled to insertion tool 14, in other embodiments, the handle 36 may be attached and removed for use with multiple coils to effect detachment.

Figs. 4A and 4B show cross-section views of the distal portion of the shaft 34. As shown, a detachment wire 40 or other type of elongate filament or strand extends through the lumen of the shaft 34. During use, shaft 34 would be inserted through microcatheter 12 to the aneurysm. A pair of engaging elements 42 is positioned on the wire 40. Engaging elements 42 are elements that will couple the detachment wire 40 to the stretch resistant wire 30, preferably by engaging the element 32. In the illustrated embodiment, the engaging elements 42 are spaced apart elements having a broader diameter than the wire. Suitable examples include spaced apart beads 42 deposited onto the wire. These may be formed of gold/tin solder, PET, stainless steel, or alternate materials.

As shown in Fig. 4A, embolic coil 16 is coupled to the insertion tool 14 by positioning ball 32 between the engaging elements 42 within the shaft 34. The ball 32 is constrained between the engagement elements 42 and the surrounding walls of the shaft lumen. This positioning retracts the ball 32 proximally relative to the coil 16, adding tension to the stretch resistant wire 30.

Referring to Fig. 4B, to release the embolic coil 16 from the insertion tool 14, the actuator is manipulated to cause relative advancement of the detachment wire 40 relative to the shaft 34. In other words, the actuator may withdraw the shaft and/or advance the wire 40. Other embodiments may be provided without an actuator, in which case the user may manually advance the wire 40 and/or retract the shaft 34. The more proximal sections of the wire 40 and/or shaft 34 may be thicker than the distal sections as shown in Figs. 6A and 6B to facilitate manual actuation by the user's fingers or by an actuator.

The relative movement between the shaft and wire causes the distal portion of the wire 40 to extend from the shaft, thereby releasing the constraints on the ball 32. The ball 32 and attached stretch resistant wire 30 retract towards the coil 16, and the ball 32 comes to rest at the stop 26.

Figs. 5A through 5G illustrate use of the system to implant the coil 16. Prior to implantation, the coil is coupled to the insertion tool 14 as illustrated in Fig. 1.

The microcatheter 12 is introduced into the vasculature using a percutaneous access point, and it is advanced to the cerebral vasculature. As discussed above, a guide catheter and/or guide wire may be used to facilitate advancement of the microcatheter. The microcatheter is advanced until its distal end is positioned at the aneurysm A. Fig. 5A.

The coil 16 is advanced through the microcatheter 12 to the aneurysm A. Fig. 5B. The coil and insertion tool may be pre-positioned within the microcatheter 12 prior to introduction of the microcatheter 12 into the vasculature, or they may be passed into the proximal opening of the microcatheter lumen after

the microcatheter has been positioned within the body. The insertion tool 14 is advanced within the microcatheter 12 to deploy the coil from the microcatheter into the aneurysm A. As the coil exits the microcatheter, it assumes its secondary shape as shown in Fig. 5C due to the shape set of the stretch resistant wire 30.

Referring to Fig. 6A, the detachment wire 40 may include fluoroscopically visible markers that indicate to the user when the coil has been advanced sufficiently for detachment. For example, the user may watch for alignment of a marker 44 on the wire 40 with the markers 18 on the microcatheter. Note, however, that the detachment step may be performed with the proximal end of the coil inside or outside the microcatheter.

At the appropriate time, the coil is released from the insertion tool by withdrawing the shaft 34 relative to the detachment wire 30 to cause the distal end of the wire to extend from the shaft 34. Figs. 5D and 6B illustrate retraction of the shaft 34 while holding the wire 30 stationary, although the detachment may instead be performed by advancing the wire while holding the shaft stationary, or by combined motion of retracting the shaft and advancing the wire. The coil detaches from the wire 30, and the ball 32 of the coil 16 retracts into contact with the stop 26. Fig. 5E. The insertion tool 14 is withdrawn from the microcatheter 12. Fig. 5F. If additional coils are to be implanted, an insertion tool 14 with an attached coil is passed into the microcatheter 12 and the steps of Figs. 5B through 5E are repeated. The method is repeated for each additional coil need to sufficiently fill the aneurysm A. Once the aneurysm is fully occluded, the microcatheter 12 is removed. Fig. 5G.

Figs.7 – 10 illustrate an alternative embodiment of an insertion tool 114 that may be used to deploy the embolic coil 16 in the manner similar to that shown in Figs. 5A – 5G.

Referring to Fig. 7, the insertion tool 114 comprises an elongate pusher tube 116 having a tubular distal tip 118 (shown partially transparent in Fig. 7). A fulcrum 120 having a slot 122 (best shown in Fig. 9) is cut into a side wall of the distal tip 118. The distal end of the fulcrum can be moved into an inwardly-extending position in which it extends into the lumen of the distal tip 118 as shown in Figs. 7 and 8. The fulcrum 120 is shape set to return to an open (or neutral) position generally flush with the pusher tube wall (Fig. 9) when it is released from the inwardly-extending position. A pull wire 126 is extendable through the lumen of the pusher tube 116 and into the slot 122 in the fulcrum 120 to retain the fulcrum in the inwardly-extending position shown in Figs. 7 and 8.

The distal tip 118 is preferably formed of shape memory material such as nitinol, shape memory polymer, or an injection molded material having elastic properties. The more proximal sections of the pusher tube 116 can be made of polymeric tubing, with the distal tip 118 mounted to polymeric tubing. In the illustrated embodiment, the distal tip 118 includes a plurality of proximally-extending fingers 124 laminated into the polymeric tubing of the pusher tube 116 to secure the distal tip in place.

To couple the pusher tube 116 and coil 16 for use, the pull wire 126 is introduced into the pusher tube. Ball 32 is separated slightly from the coil 16 and is inserted into the pusher tube 116 and held in place while the fulcrum 120 is pressed into the inwardly-extending position to prevent movement of the

ball 32 out of the distal tip 118. The pull wire 126 is passed through the slot 122 to retain the fulcrum in the inwardly-extending position.

To deploy the coil 16, the coil and pusher tube 116 are passed through a delivery catheter as described above. At the site of the aneurysm, the pusher tube 116 is advanced to push the coil out of the delivery catheter. The pull wire 126 is pulled proximally from the slot 122 of the fulcrum 120, allowing the fulcrum 120 to return to its open position and out of contact with the ball 32. As with the previous embodiments, the ball 32 retracts into contact with the proximal end of the coil 16 and in doing so exits the proximal end of the pusher tube 116.

Figures 11-15 illustrate another alternate embodiment of a detachment system. Figures 11, 14 and 15 illustrate detachment system 200 following successive steps to detach embolic coil 206 from insertion tool 214. Beginning with Figure 11, a side elevation view of the distal end of insertion tool 214 is shown as partially transparent. Insertion tool 214 comprises an elongate pusher tube 216 having a tubular distal tip 218, and side wall 204 defining lumen 208 therethrough. Side wall 204 is cut, molded, or otherwise configured to define paddle 240, partial aperture 244 surrounding a portion of paddle 240, and shoulder 246. Paddle 240 and partial aperture 244 may be of various alternative sizes and/or shapes. An example of a suitable shape for paddle 240 can be seen in a plan view in Fig. 12, which also reveals a possible position of ball 232 prior to deployment of system 200. As explained in greater detail below, prior to deployment of system 200 to release coil 206, ball 232 has freedom of movement within lumen 208, both axially and rotationally. The exact position of ball 232 will consequently vary from that illustrated in Fig. 12.

Also cut or otherwise configured or disposed upon a side wall 204 is alignment member 228, shown in the example of Fig. 11 as opposite paddle 240. As seen from a bottom view of the device in Fig. 13, alignment member is illustrated as a loop cut from sidewall 204. Alternatively, an alignment member may be formed by placing one or more circumferential cuts into the sidewall to define a band and bending the band inwardly into the lumen. It will be appreciated that alignment member 228 may alternatively be, for example, a hook, tab, or any other suitable structure for guiding the position of pull wire 226. Pull wire 226 is axially moveable within alignment member 228, however, alignment member 228 helps prevent unintended longitudinal translation of pull wire 226.

In preparation for deploying system 200, pull wire 226 is loaded through alignment member 228, through lumen 208, until it reaches ball 232, or as far as coil 206. Prior to loading coil 206, pull wire 226, which may be tapered, may be threaded through the distal end of insertion tool 214 to permit loading of ball 232, and then retracted slightly to releasably retain coil 206. When positioned within distal tip 218 via alignment member 228, and occupying lumen 208 pull wire 226 urges ball 232 against paddle 240, and ball has freedom of movement within aperture 244. Partial aperture 244 permits paddle 240 to be urged slightly out of the plane of sidewall 204, and paddle 240 in turn places some pressure on ball 232. Ball 232 is prevented by shoulder 246 from exiting the distal tip 218. Though ball 232 is retained within distal tip of insertion tool 214 prior to deployment of system 200, ball 232 advantageously has both axial

and rotational freedom of movement within the distal tip 218 of insertion tool 214 prior to retraction of pull wire 226 by an operator.

As shown in Fig. 14, during deployment of detachment system 200, pull wire 226 is retracted proximally of ball 232. (Alternatively, insertion tool 214 may be moved distally to pull wire 226.) Once pull wire 226 is proximal of ball 232, ball 232 is urged by paddle 240 into the lumen 208 of insertion tool 214. Axial movement of ball 232 is no longer restricted in a distal direction by shoulder 246, and ball 232 (and hence coil 206) is free to exit distal tip 218. Fig. 15 illustrates coil 206 following its exit from distal tip 218.

Fig. 16 illustrates a similar detachment mechanism which operates generally according to the same principles of the embodiment described in relation to Figs. 11-15 above. However, in the embodiment illustrated in Fig. 16, paddle 340 is oriented perpendicularly to the longitudinal access of insertion tool 214. Further, no aperture surrounds paddle 340. Other, alternative configurations of paddle 340 are also possible according to the invention.

We claim:

1. An embolic coil deployment system, comprising:

an implant tool including a shaft having a lumen, a first filament disposed in the lumen, and at least one engaging element on the first filament; and

an implant including a coil and a second filament extending through the coil, the second filament including a distal end coupled to the coil and a proximal end including a retention element disposed in the lumen of the shaft, the retention element positioned in contact with and releasably restrained in a restrained position by the engaging element and a sidewall of the lumen.

2. The system of claim 1, wherein the engaging element includes a pair of broadened elements on the first filament, and wherein the retention element of the implant is releasably restrained between the broadened elements and the sidewall of the lumen.

3. The system of claim 1, further including a catheter, wherein the implant tool and implant are positionable within the catheter.

4. The system of claim 1, wherein the second filament is a stretch-resistant wire.

5. The system of claim 1, wherein the first filament and shaft are relatively moveable between a first position in which the distal portion of the first filament is within the shaft and a second position in which a distal portion of the first filament extends distally from the lumen by an amount sufficient to release the retention element from the restrained position.

6. The system of claim 1, wherein the second filament is in tension such that release of the retention element from the restrained position causes the retention element to retract into contact with a proximal portion of the implant.

7. The system of claim 6, wherein the implant includes a stop on a proximal portion of the coil, and wherein release of the retention element from the restrained position cause the retention element to retract into contact with the stop.

8. An embolic coil deployment system comprising:

an implant tool including a shaft having a lumen, a sidewall, at least one fulcrum, and a first filament disposed in the lumen; and

an implant including a coil and a second filament extending through the coil, the second filament including a distal end coupled to the coil and a proximal end including a retention

element disposed in the lumen of the shaft, the retention element positioned in contact with and releaseably retained within the lumen by the first filament and the fulcrum.

9. The system of claim 1, wherein said fulcrum comprises at least one aperture for releaseably receiving said first filament.

10. The system of claim 1, wherein said first filament is moveable from a first position in which the first filament is engaged with said fulcrum, and a second position in which said first filament is disengaged from said fulcrum.

11. The system of claim 10, wherein in said first position said fulcrum releaseably retains said retention element within the lumen, and when in said second position, said fulcrum does not retain said retention element within the lumen.

12. The system of claim 1, wherein said fulcrum comprises a first and second aperture for releaseably receiving said first filament, said first filament is moveable from a first position in which said first filament depresses said fulcrum into the lumen distal to said retention element thereby releasably retaining the retention element within the lumen, and a second position whereby said first filament is retracted in a proximal direction to release said fulcrum, thereby releasing said retention element from the lumen.

13. The system of claim 1, wherein said fulcrum is formed with the side wall of the implant tool.

14. An embolic coil deployment system comprising:

an implant tool including a shaft having a lumen, a sidewall, at least one urging element, and a first filament disposed in the lumen; and

an implant including a coil and a second filament extending through the coil, the second filament including a distal end coupled to the coil and a proximal end including a retention element disposed in the lumen of the shaft, the retention element positioned in contact with and releaseably retained within the lumen by the first filament, the urging element and the side wall.

15. The system of claim 14, wherein said urging element is formed within said side wall.

16. The system of claim 14, wherein said sidewall further comprises an aperture.

17. The system of claim 16, wherein said urging element is disposed at least partially within said aperture.

18. The system of claim 16, wherein said urging element is at least partially surrounded by said aperture.

19. The system of claim 16, wherein said side wall and said aperture define a shoulder, and wherein said first filament and said shoulder prevents the exit of said retention element from the distal end of the lumen.

20. The system of claim 14, wherein said first filament is relatively moveable between a first position in which the first filament, the side wall and the urging element releaseably retain said retention element within the lumen, and a second position in which said retention element is not retained within said lumen.

21. The system of claim 20, wherein when said first filament is in said first position, said retention element is urged against said urging member, and said retention element at least partially enters said aperture.

22. The system of claim 20, wherein said first filament is retracted proximally from said first position to said second position, and said urging element biases said retention element to exit said lumen.

23. The system of claim 14, wherein said first filament is axially moveable within said lumen, and said implant tool further comprises an alignment feature for releaseably aligning the position of said first filament within the lumen.

24. The system of claim 14, wherein when said retention element is releaseably retained within said lumen, said retention element has axial and rotational freedom of movement within said lumen.

25. A method of implanting an embolic coil, comprising the steps of:

providing an implant tool including a shaft having a lumen, a first filament disposed in the lumen, and at least one engaging element on the first filament;

providing an implant including a coil and a second filament extending through the coil, the second filament including a distal end coupled to the coil and a proximal end including a retention element;

coupling the implant and implant tool by introducing the retention element into the lumen of the shaft, the retention element and positioning the retention element in a restrained position between the engaging element and a sidewall of the lumen;

advancing the implant and implant tool intravascularly to an implant site;

effecting relative longitudinal movement between the shaft and the first filament such that a distal portion of the first filament extends proximally into the lumen by an amount sufficient to release the retention element from the restrained position; and

removing the implant tool, leaving the implant at the implant site.

26. The method of claim 25, wherein:

providing the implant includes providing the coil to include a proximal stop and providing the retention element seated against the step;

introducing the retention element implant tool includes pulling the first filament in a proximal direction to separate the retention element from the stop, and restraining the first filament in tension within the lumen; and

releasing the retention element from the restrained position causes the retention element to retract into contact with the stop.

27. The method of claim 25, wherein the implant includes an elongate primary shape and an expanded secondary shape, and wherein the method includes:

positioning the implant within a catheter, the implant in the catheter having the primary shape; and

advancing the implant from the catheter at the implant site, causing the implant to expand to the secondary shape.

28. A method of implanting an embolic coil, comprising the steps of:

providing an implant tool including a shaft having a lumen, a side wall, at least one engaging element and a first filament disposed in the lumen;

providing an implant including a coil and a second filament extending through the coil, the second filament including a distal end coupled to the coil and a proximal end including a retention element;

coupling the implant and implant tool by introducing the retention element into the lumen of the shaft, and positioning the retention element in a releaseably retained position between the fulcrum and a sidewall of the lumen;

advancing the implant and implant tool intravascularly to an implant site;

effecting relative longitudinal movement between the shaft and the first filament such that the retention element is not retained within the lumen; and

removing the implant tool, leaving the implant at the implant site.

29. The method of claim 28, wherein the step of coupling the implant and implant tool comprises releaseably engaging said first filament with said engaging element.

30. The method of claim 29, wherein said engaging element comprises a fulcrum.

31. The method of claim 28, wherein said step of coupling the implant and implant tool comprises providing said first filament with at least one engaging element, and positioning said engaging element to releaseably retain said retention element.

32. A method of implanting an embolic coil, comprising the steps of:

providing an implant tool including a shaft having a lumen, a side wall, at least one urging element, and a first filament disposed in the lumen;

providing an implant including a coil and a second filament extending through the coil, the second filament including a distal end coupled to the coil and a proximal end including a retention element;

coupling the implant and implant tool by introducing the retention element into the lumen of the shaft, and positioning the retention element in a releaseably retained position between the urging element, the first filament and a sidewall of the lumen;

advancing the implant and implant tool intravascularly to an implant site;

effecting relative longitudinal movement between the shaft and the first filament such that the retention element is not retained within the lumen; and

removing the implant tool, leaving the implant at the implant site.

33. The method of claim 32, wherein the urging element is formed within the sidewall of the implant tool.

34. The method of claim 32, wherein the sidewall further comprises an aperture and wherein the step of coupling the implant and implant tool further comprises positioning the retention element partially within said aperture.

35. The method of claim 32, wherein the step of effecting relative longitudinal movement between the shaft and the first filament permits the urging element to urge the retention element to exit the lumen.

36. An embolic coil deployment system comprising:

an implant including an elongated coil and a first filament positioned within the coil, with the proximal end of the filament terminating in a retention element;

a hollow shaft with an open distal end for receiving the retention element, said shaft including a cut-out in the side thereof, close to, but spaced from the distal end thereof, said shaft further including a biasing member disposed within the cut-out; and

a second filament slidably receivable within the shaft in a manner such that the distal end thereof is wedged between the retention element and the side wall of the shaft opposite said cut-out, said distal end of the second filament forcing the retention element into engagement with an edge of the cut-out to prevent the retention element from exiting the distal end of the shaft, and wherein when the relative positions of the second filament and the shaft are adjusted so that the distal end of the second filament no longer bears on the retention element and the biasing member aids in disengaging the retention member from edge of the cut-out.

37. A system as recited in claim 36, wherein said shaft further includes guide member affixed to the side wall of the shaft and extending in the interior of the shaft, said guide member including an aperture for receiving said second filament.

38. A system as recited in claim 36, wherein the retention element is spherical.

39. A system as recited in claim 36, wherein when the second filament is wedged between the retention element and the side wall, the retention element forces the biasing member to pivot outwardly from the centerline of the shaft.

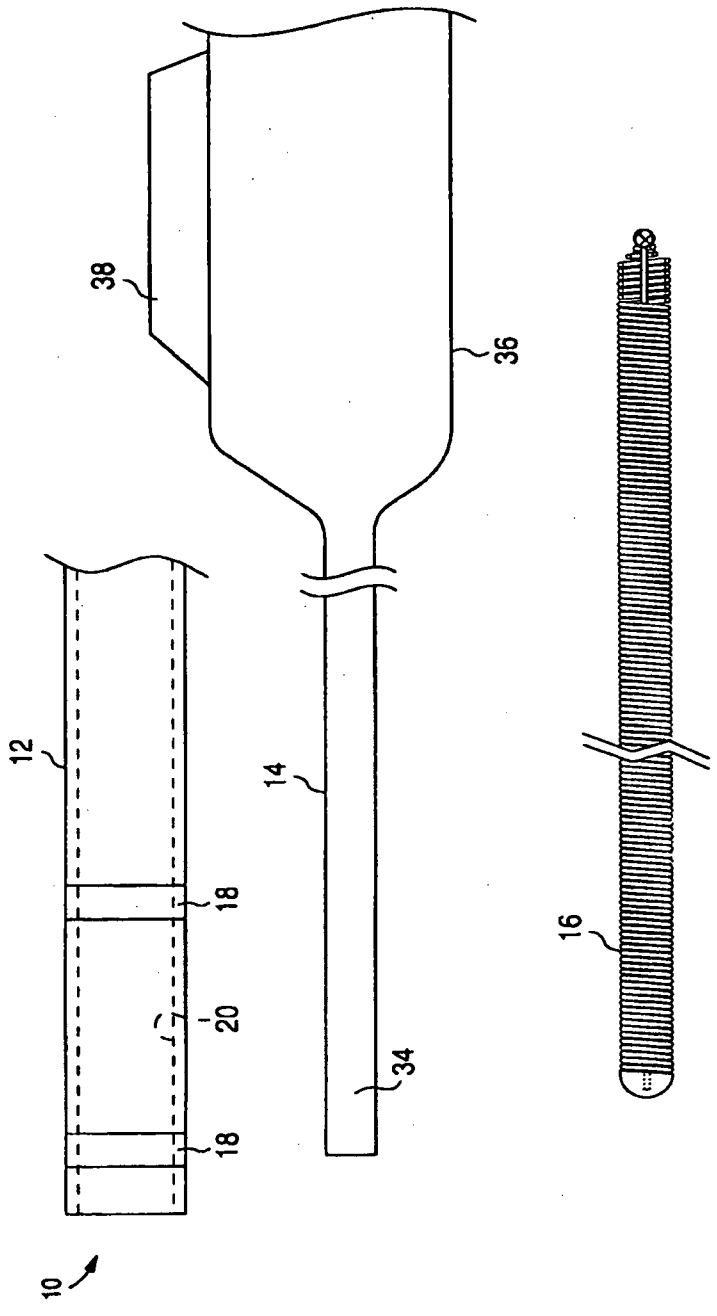


FIG. 1

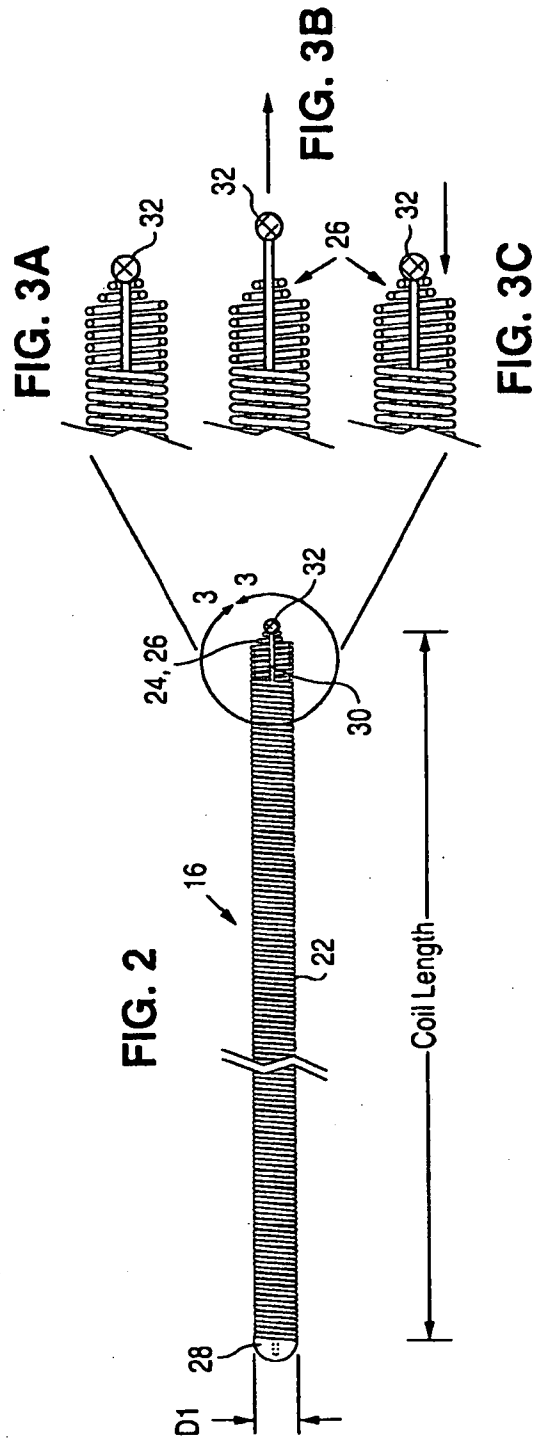


FIG. 2

FIG. 4A

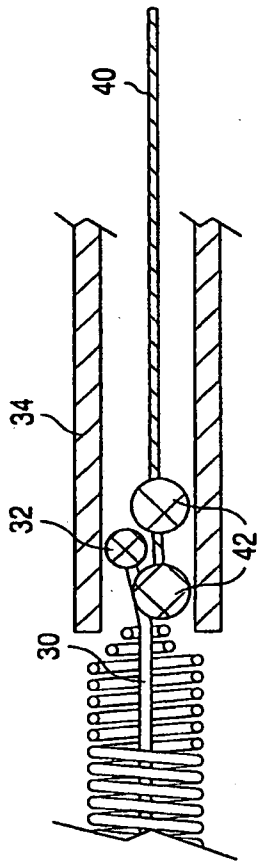
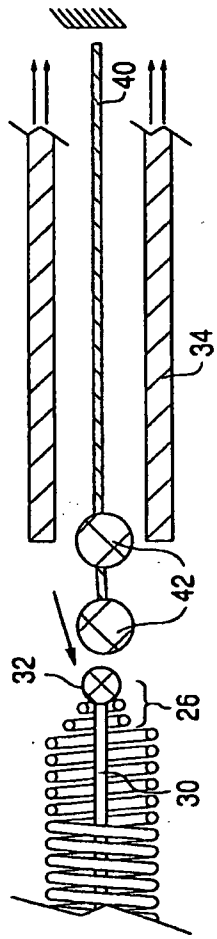


FIG. 4B



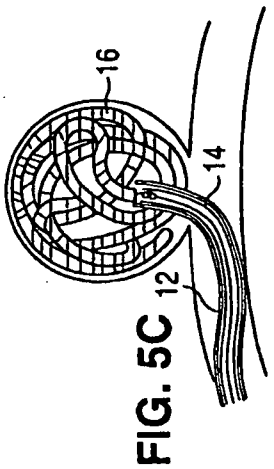


FIG. 5C

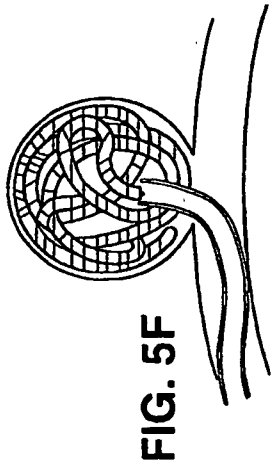


FIG. 5F

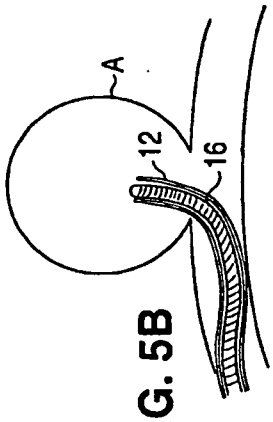


FIG. 5B

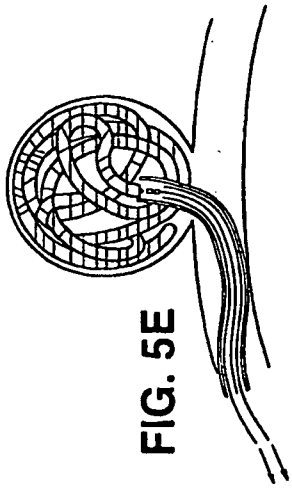


FIG. 5E

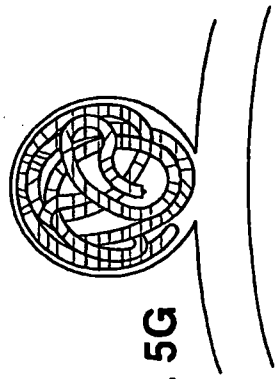


FIG. 5G

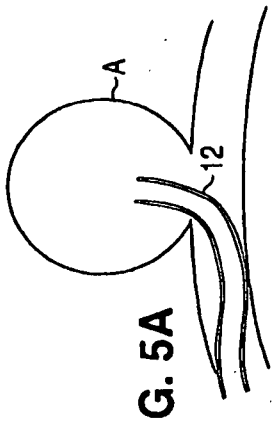


FIG. 5A

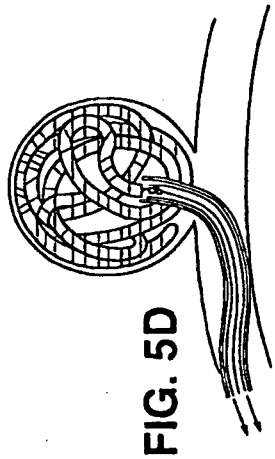


FIG. 5D

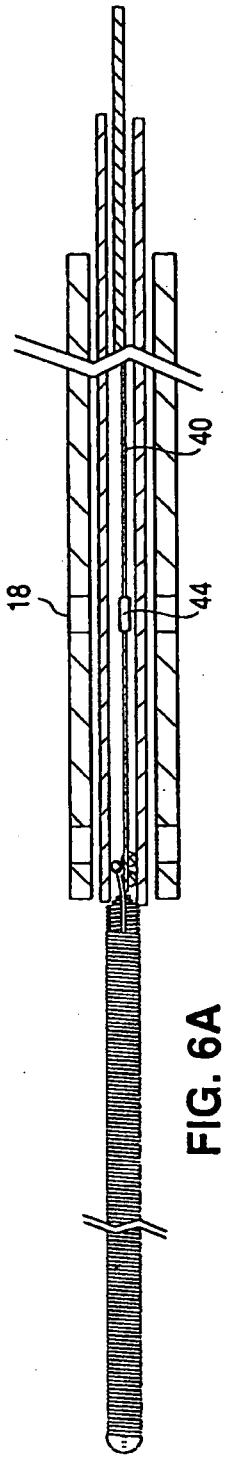


FIG. 6A

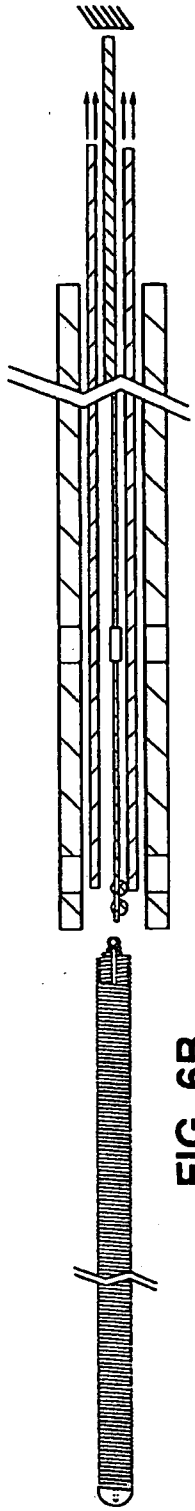


FIG. 6B

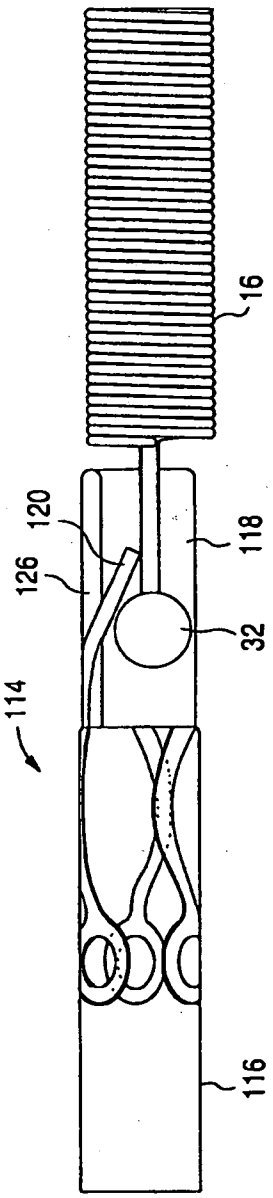


FIG. 7

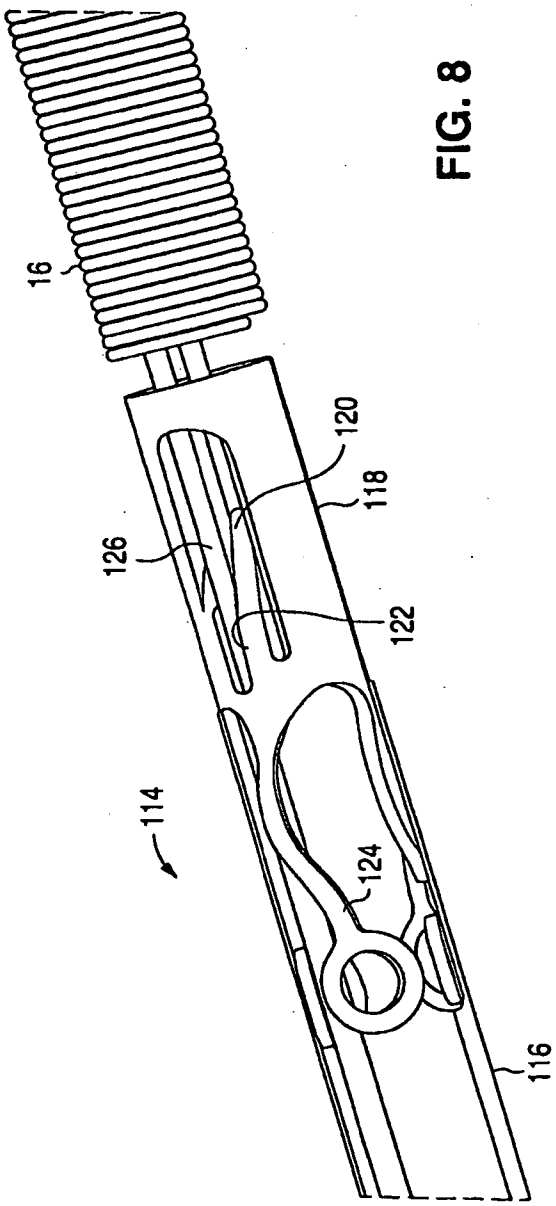


FIG. 8

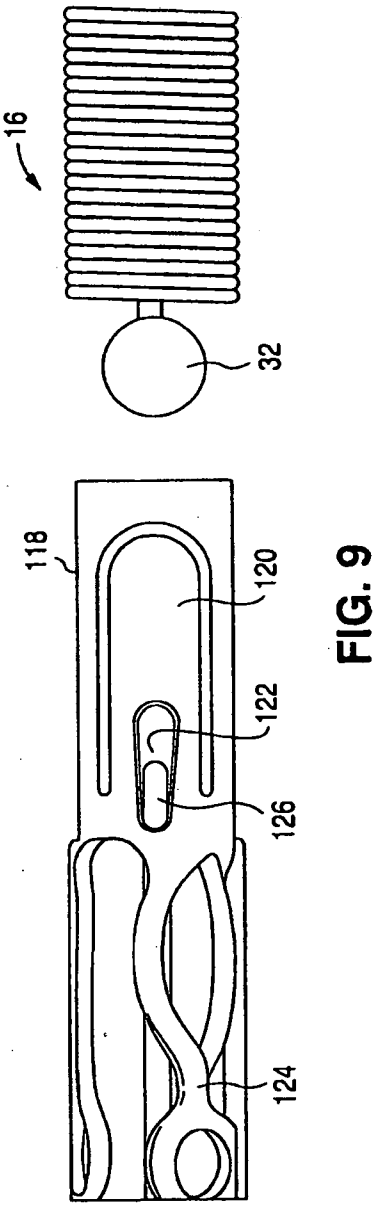


FIG. 9

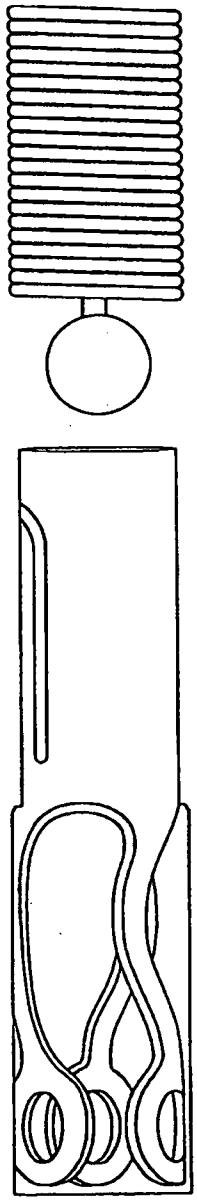


FIG. 10

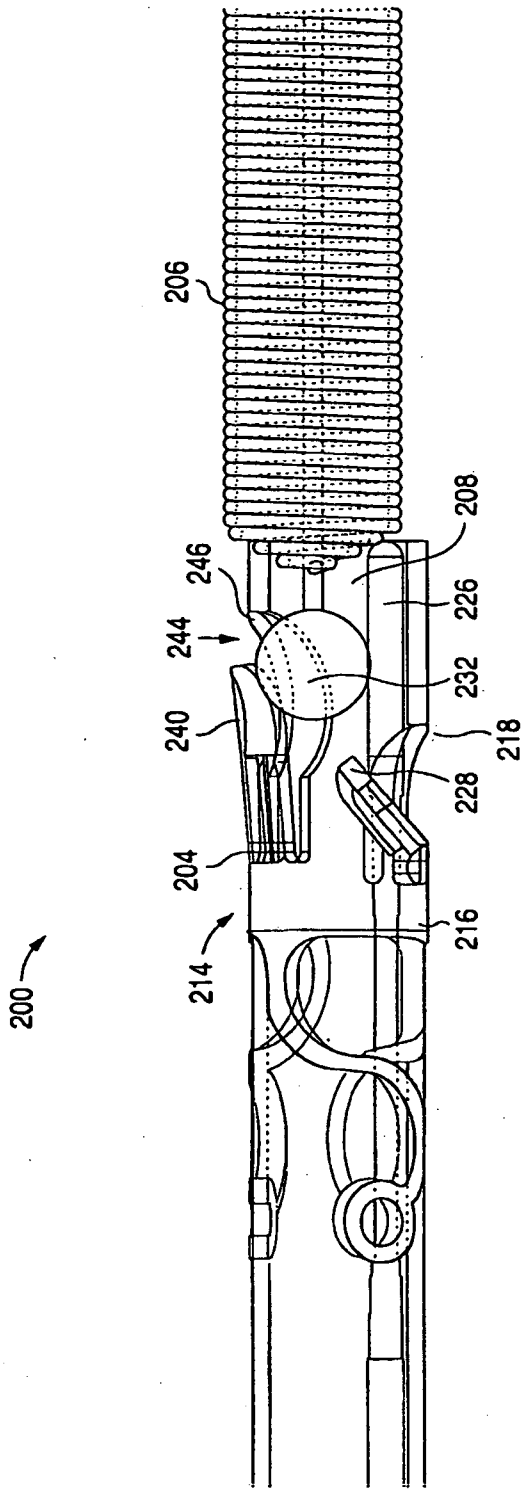


FIG. 11

FIG. 12

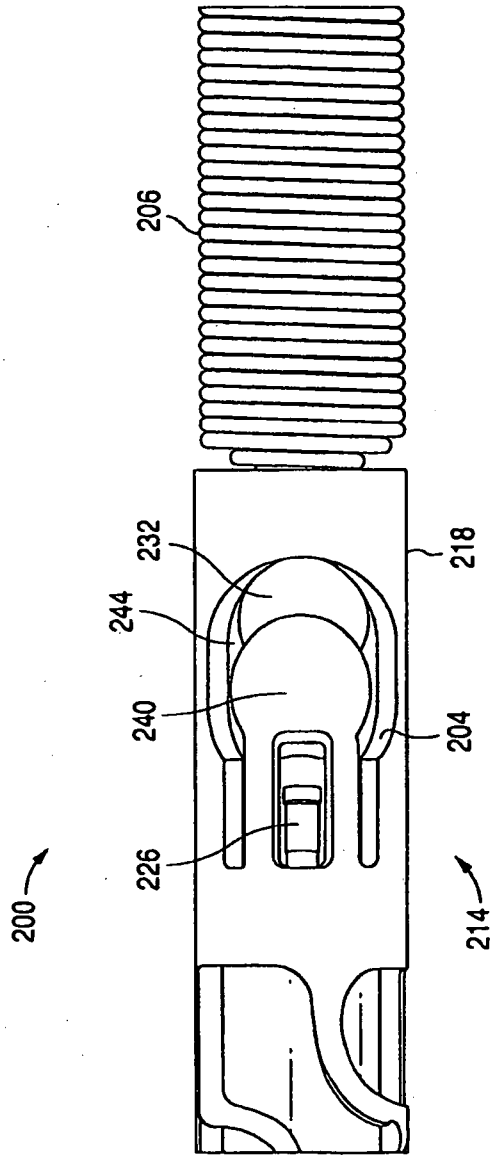
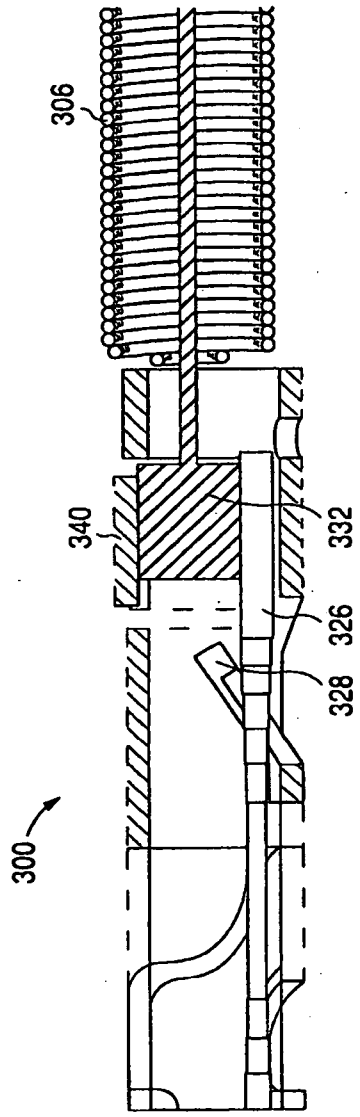


FIG. 16



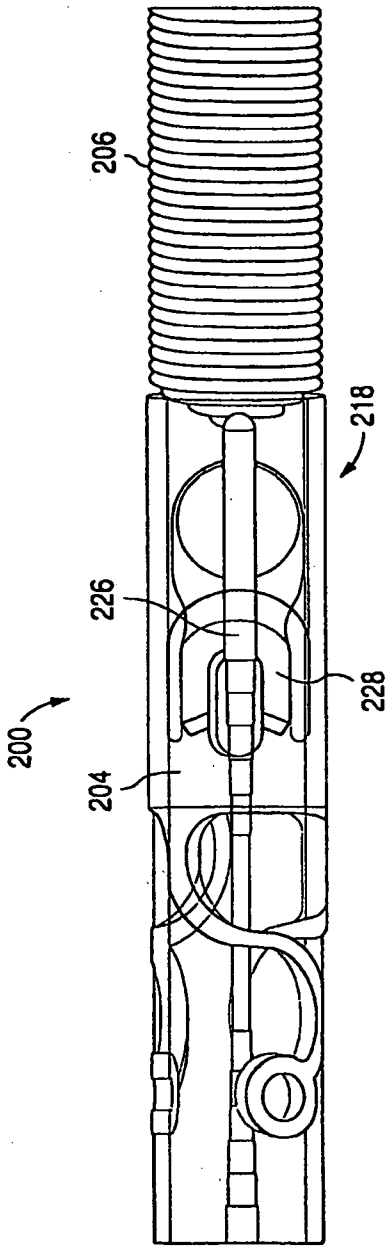


FIG. 13

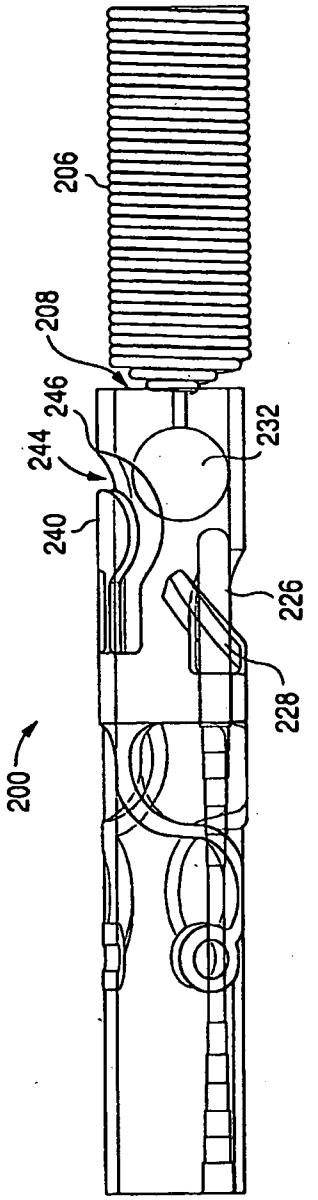


FIG. 14

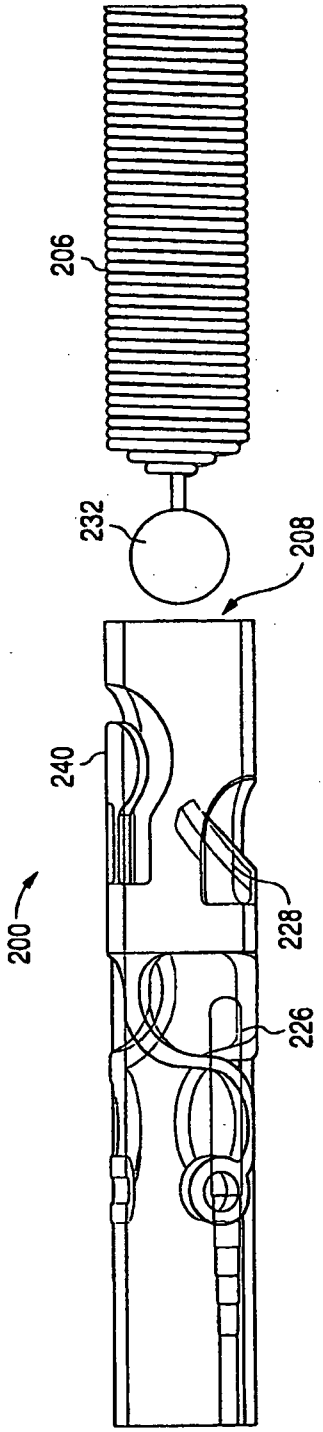


FIG. 15

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/050319

A. CLASSIFICATION OF SUBJECT MATTER
INV. 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)
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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 93/11719 A (TARGET THERAPEUTICS INC [US]) 24 June 1993 (1993-06-24) page 5, line 3 - page 8, line 26; figures	1,3-7
X	US 5 853 418 A (KEN CHRISTOPHER G M [US] ET AL) 29 December 1998 (1998-12-29) column 4, line 10 - column 6, line 37 column 7, line 21 - line 67; figures 4A,4B	1,3-7
X	WO 99/02094 A (TARGET THERAPEUTICS INC [US]; ENGELSON ERIK T [US]) 21 January 1999 (1999-01-21) page 9, line 20 - page 11, line 26; figure 1B	1,3-7
A	US 2005/192621 A1 (WALLACE MICHAEL P [US] ET AL) 1 September 2005 (2005-09-01) paragraphs [0077], [0078]; figures 5a,5b	1-7

-/--

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

[X] See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
11 December 2009	22/12/2009

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Nistor, Loredana

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/050319

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 93/11825 A (TARGET THERAPEUTICS INC [US]) 24 June 1993 (1993-06-24) page 4, line 30 - page 8, line 8; figures	1-7
X	EP 1 797 833 A (CORDIS NEUROVASCULAR INC [US]) 20 June 2007 (2007-06-20) paragraph [0027] - paragraph [0037]; figures	1-11,14, 20,23-24
X	US 2006/276832 A1 (BALGOBIN KEITH [US] ET AL) 7 December 2006 (2006-12-07) paragraph [0027] - paragraph [0037]; figures	14,20
X	US 2008/097462 A1 (MITELBERG VLADIMIR [US] ET AL) 24 April 2008 (2008-04-24) paragraph [0025] - paragraph [0046]; figures	8-12,14, 16-18, 20-23
X	WO 2007/070797 A2 (CORDIS DEV CORP [US]; JOHNSON KIRK L [US]; LULO ROBERT [US]; LORENZO J) 21 June 2007 (2007-06-21) paragraph [0021] - paragraph [0048]; figures	8-11, 13-14, 23-24
X	US 2007/293928 A1 (TOMLIN DAMIAN [US]) 20 December 2007 (2007-12-20) paragraph [0023] - paragraph [0040]; figures	8,14
X	EP 1 728 477 A1 (CORDIS NEUROVASCULAR INC [US]) 6 December 2006 (2006-12-06) paragraph [0025] - paragraph [0031]; figures	8-11
X	EP 1 813 213 A2 (CORDIS DEV CORP [US]) 1 August 2007 (2007-08-01) paragraph [0014] - paragraph [0041]; figures	14, 16-17, 20,22-24
X	EP 0 832 607 A (TARGET THERAPEUTICS INC [US] BOSTON SCIENT LTD [BB]) 1 April 1998 (1998-04-01)	14,16, 19-24
A	column 4, line 18 - column 6, line 13; figure 3	36-39
A	WO 2007/121405 A (MICRO THERAPUTICS INC D B A EV [US]; STRAUSS BRIAN MICHAEL [US]; SLEE) 25 October 2007 (2007-10-25) paragraph [0074] - paragraph [0105]; figures 1-14	14,36

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/050319

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

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

1. [X] Claims Nos.: 25-35
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 therapyRule 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 No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

see additional sheet

1. [X] 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 fees, this Authority did not invite payment of additional fees.

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 and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

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

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-7

An embolic coil deployment system, comprising an implant tool with a shaft having a lumen, a first filament disposed in the lumen and at least one engaging element on the first filament and an implant including a coil and a second filament extending through the coil, the second filament including a distal end coupled to the coil and a proximal end including a retention element disposed in the lumen of the shaft, the retention element positioned in contact with and releasably restrained in a restrained position by the engaging element and a sidewall of the lumen.

---

2. claims: 8-13

An embolic coil deployment system with an implant tool including a shaft having a lumen, a sidewall, at least one fulcrum, and a first filament disposed in the lumen; and an implant including a coil and a second filament extending through the coil, the second element disposed in the lumen of the shaft, the retention elementpositioned in contact with and releaseably retained within the lumen by the first filament and the fulcrum.

---

3. claims: 14-24, 36-39

An embolic coil deployment system comprising an implant tool with a shaft having a lumen, a sidewall, at least one urging element, and a first filament disposed in the lumen and an implant including a coil and a second filament extending through the coil, the second filament including a distal end coupled to the coil and a proximal end including a retention element disposed in the lumen of the shaft, the retention element positioned in contact with and releaseably retained within the lumen by the first filament, the urging element and the side wall.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2009/050319

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9311719 A	24-06-1993	AT 160494 T	15-12-1997
		AT 187053 T	15-12-1999
		AU 2665492 A	19-07-1993
		CA 2084524 A1	13-06-1993
		DE 69223329 D1	08-01-1998
		DE 69223329 T2	19-03-1998
		DE 69230385 D1	05-01-2000
		DE 69230385 T2	06-04-2000
		DK 617594 T3	02-02-1998
		DK 0791333 T3	01-05-2000
		EP 0617594 A1	05-10-1994
		IL 103239 A	31-03-1996
		JP 2602625 B2	23-04-1997
		JP 7503152 T	06-04-1995
		NO 942115 A	07-06-1994
		NZ 244436 A	22-09-1997
		PT 100910 A	31-05-1994
		US 5304195 A	19-04-1994
US 5853418 A	29-12-1998	US 6004338 A	21-12-1999
		US 6013084 A	11-01-2000
WO 9902094 A	21-01-1999	AU 8574798 A	08-02-1999
		CA 2297452 A1	21-01-1999
		DE 69826668 D1	04-11-2004
		DE 69826668 T2	13-10-2005
		EP 0996372 A1	03-05-2000
		ES 2226161 T3	16-03-2005
		JP 2001509414 T	24-07-2001
		US 5944733 A	31-08-1999
US 2005192621 A1	01-09-2005	NONE	
WO 9311825 A	24-06-1993	AT 170765 T	15-09-1998
		AU 666698 B2	22-02-1996
		AU 3247993 A	19-07-1993
		CA 2125653 A1	24-06-1993
		DE 69226960 D1	15-10-1998
		DE 69226960 T2	04-02-1999
		DE 616543 T1	12-10-1995
		EP 0616543 A1	28-09-1994
		ES 2074971 T1	01-10-1995
		IL 104021 A	18-06-1996
		JP 2552812 B2	13-11-1996
		JP 6511174 T	15-12-1994
		NO 942114 A	07-06-1994
WO 9311825 A		US 5261916 A	16-11-1993
EP 1797833 A	20-06-2007	CA 2571004 A1	14-06-2007
		JP 2007160111 A	28-06-2007
US 2006276832 A1	07-12-2006	US 2006276829 A1	07-12-2006
		US 2006276833 A1	07-12-2006
		US 2006276834 A1	07-12-2006
		US 2007010849 A1	11-01-2007
		US 2007270903 A1	22-11-2007

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2009/050319

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2008097462 A1	24-04-2008	NONE	
WO 2007070797 A2	21-06-2007	EP 1959873 A2	27-08-2008
		US 2009270877 A1	29-10-2009
US 2007293928 A1	20-12-2007	NONE	
EP 1728477 A1	06-12-2006	CA 2549140 A1	02-12-2006
		JP 2006334407 A	14-12-2006
		US 2006276823 A1	07-12-2006
EP 1813213 A2	01-08-2007	JP 2007216010 A	30-08-2007
		US 2007179520 A1	02-08-2007
EP 0832607 A	01-04-1998	AT 253867 T	15-11-2003
		AU 694917 B2	06-08-1998
		AU 3917897 A	02-04-1998
		CA 2216613 A1	27-03-1998
		DE 69726084 D1	18-12-2003
		DE 69726084 T2	26-08-2004
		ES 2208832 T3	16-06-2004
		JP 3054112 B2	19-06-2000
		JP 10201766 A	04-08-1998
		NO 974435 A	30-03-1998
		US 5895391 A	20-04-1999
WO 2007121405 A	25-10-2007	CA 2649702 A1	25-10-2007
		EP 2015683 A2	21-01-2009
		JP 2009533202 T	17-09-2009
		KR 20090008347 A	21-01-2009