BRAID BALL EMBOLIC DEVICE FEATURES

BACKGROUND

[0001] Commonly-assigned U.S. Patent Application Serial No. 12/465,475 to Becking, et al. (also PCT/US2009/041313) describes a new class of braid-based embolization devices and delivery system interfaces. The implants may be used for occluding blood flow at endovascular sites. One use is in intracranial aneurysm embolization or occlusion and another in parent vessel occlusion (PVO) or sacrifice. Improvements to those devices are disclosed herein.

SUMMARY

[0002] Braid-ball devices formed with folded-over and folded-flat distal end are among the architectures described in Becking, et al. These architectures are the ones best suited for treating brain aneurysms. Distal marker approaches are described that are especially suited for such devices. In addition, proximal end finishing approaches are described that are suitable for these and the rest of the devices described in Becking et al. All of the features and technologies presented in Becking, et al. (U.S. Patent Application Serial No. 12/465,475 and PCT/US2009/041313) are incorporated herein by reference.

[0003] Regarding the distal marker approaches, one improvement comprises a tether to/for the distal marker included in the implant. Specifically, with the marker affixed adjacent the distal end of the implant (as in the folded-flat embodiments in the incorporated application), the length of the tether/tie extends to the proximal hub of the implant. It has a length set so that when the implant is compressed, the marker is pulled into alignment with the implant and/or catheter.

[0004] When a suture is employed for the tether, it can tie around the interior of the distal fold with minimal interference. However, it may be advantageous to use a wire ribbon (e.g., Pt or Nitinol) for other reasons.

[0005] Namely, a tether ribbon (especially when pre-formed into a "V" shape) can be threaded through the gap/hole and around as few as one wire from the braid. So-disposed, there is no interference with the compression of the distal end of the implant. What is more, spring action in the ribbon tether (whether comprising two filaments or trimmed to one after crimping, gluing, welding or otherwise affixing at least one marker) can help position the marker against/across the top of the implant when deployed. Such a ribbon can also contribute to marker radiopacity, thereby allowing a smaller marker size.

[0006] Another option is to include fibers and/or other thrombus promoting material in connection with the tether. Whatever material option is selected and/or additional features are provided, the proximal end of the tether is advantageously captured between the layers of braid or between the braid and either one of optional inner or outer bands. It may be glued-in, affixed by welding or otherwise.

[0007] Yet another set of improvements concerns the manner in which the implant is finished. By "finished", what is meant is the manner in which the proximal side of the implant is managed to define a hub and/or delivery system detachment interface.

[0008] In one advantageous approach, in which use of an inner band is desired for interface with detachment system components (such as those described in the referenced application), processing is done with an elongate hypotube set within the braid. The hypotube (e.g., about 2-5 cm long) serves as a means to hold and manipulate an implant preform construct. In addition, when the tube is trimmed off (or when the final or near-final implant is trimmed off relative to the tube being held) the remaining portion of the hypotube within the implant (now the "inner band") defines the detachment interface lumen. Likewise – especially when a more radiopaque material such as Pt/Ir or CoCr is used for the tube, the same structure will improve and/or offer the requisite radiopacity at the proximal end of the implant.

[0009] In all, the approach (optionally characterized as a "sacrificial hypotube length" approach) is useful for gluing but may also be applied in a welding technique. In fact, it may be especially useful in the latter context by providing shielding from weld slag and deformation for the proximal aperture/port to be exposed by trimming the tube to define the inner band in the implant. Namely, after welding, a clean cut can be made (e.g., with a diamond saw, laser cutting, EDM, etc. – as above) and then any deburring (by mechanical action, etching, EP or otherwise) can be performed on the newly-exposed face as desired.

[0010] In conjunction with a sacrificial hypotube length approach for gluing, or the original gluing approach described in the referenced application, another advantageous option is offered by a different post-processing step. Namely, after an outer band is used at the proximal end of the implant to define an outer casting boundary for adhesive/glue (e.g., Loctite 4014), it then may be removed leaving the underlying glue casting in place. Outer band removal offers potential to reduce all of the height, diameter and appearance of the size of the proximal feature of the implant. Accordingly, it may assist in developing a system with 0.021" catheter crossing profile.

[0011] To facilitate removal, the band may advantageously comprise NiTi alloy (that naturally forms a passivation layer) or it may be coated or otherwise plated. A Titanium Nitride coating may be desirable. Spray mold release (e.g., 3M) or dip-coating in mold release may alternatively be employed to assist in slipping-off the band after adhesive application and curing. Otherwise, the band can be cut off the glue casting.

[0012] Another approach for achieving minimal implant hub diameter – while maintaining necessary radiopacity – involves affixing a platinum band on top of an inner NiTi band (i.e., in a linear arrangement). The proximal/lower NiTi section can be easily welded to the NiTi braid in the ball (when so-constructed) and the Pt (including Pt/Ir and other alloys) provides an in-line radiopaque marker. The detachment system control and anchor wires are received through both bands. The bands may be attached (e.g., by welding, gluing or soldering) or merely associated with each other until detachment system wire removal. In either case, they may include interference fit, puzzle-piece or other groove or tongue-and-groove features to make or assist in making a connection between the bodies.

[0013] Another set of improvements concerns shaping the distal end of a "folded-flat" type implant. It may be provided with a flattened top. The flattened top derives from a flat formed in the round tooling over which the braid is shaped. The flat can be produced by milling about 0.010" off the form. This depth cut allows sufficient "table" for desired shaping and can be consistently applied across a range of implants sized from about 5 mm to 12 mm in diameter with little effect on the perceived shape. The resulting crease in the implant wire shaped by such a form offers an immediate advantage to implant deployment. With the flat placed so close to the distal end of the device, shape recovery of the bend/crease around the flattened top drives early opening of the implant when unsheathed (as compared to a situation where a crease formed around the flat is set further away – or none is provided).

[0014] Yet another set of implant improvements described herein augments the density of the ball. Stated otherwise, provision is made for an additional layer of braid material to further decrease the braid matrix porosity, and possibly do so without any increase in device crossing profile/delivery (micro)catheter compatibility.

[0015] These improvements involve a third layer of braid that is added to the two layers preferably already present in the folded-flat base implant architecture. In one variation, a third layer of braid is captured between the two layers and captured within the hub region, but trimmed proximal to the distal folded-over/flat section. In another

variation, an inner layer is set within the envelope of the aforementioned two layers. It is advantageously attached to a distal end of the inner marker band (above/distal) to any outer marker band provided. As such, the braid's attachment will not increase the hub profile. To avoid any profile increase at the distal end of the implant, the inner layer will typically be trimmed so its compressed length is located proximal to the folded-over braid at the distal end of the implant when compressed. In its unconstrained form, the inner layer may simply define a cup. Alternatively, it may define a secondary ball shape. Such a ball shape may be substantially spherical or ovoid. One advantageous configuration further includes unterminated distal ends to the braid. The ends of the braid defining the inner ball may be secured in a band or welded together. So-configured they can offer another radiopaque marker feature within the ball. However, it may be preferred that the braid ends of the inner layer (in cup, ball form, or otherwise) are unterminated. As such, they may improve thrombus formation within the body of the implant.

[0016] Finally, delivery system improvements are described. The features described are "improvements" – as are the features noted above – in a contextual sense. For example, certain of the delivery system architectures may not be as space-efficient as others. Yet, such larger system(s) may be desirable for reason of reduced manufacturing complexity and/or cost.

[0017] The subject implant and delivery devices, kits in which they are included, methods of use and manufacture are all included within the scope of the present description. A number of aspects of such manufacture are discussed above. More detailed discussion is presented in connection with the figures below.

BRIEF DESCRIPTION OF THE FIGURES

[0018] The figures provided herein are not necessarily drawn to scale, with some components and features exaggerated for clarity. Variations from the embodiments pictured are contemplated. Accordingly, depiction of aspects and elements of embodiments in the figures are not intended to limit the scope of the description.

[0019] In the figures, Figs. 1A and 1B show an implant with a marker tether as expanded and being compressed, respectively; Figs. 2A and 2B show the distal end and a side view of another tethered-marker embodiment, respectively; Fig. 3 is a detail view of a marker/tether subassembly; Fig. 4 diagrammatically illustrates the assembly in Fig. 3 set within an implant; Fig. 5 shows an implant preform prepared for proximal end finishing; Fig. 6 shows the proximal end welded; Figs. 7 shows an implant preform prepared for proximal end finishing according to another approach; Fig. 8 shows the

proximal end cut and welded; Figs. 9A and 9B show implants employing alternative proximal end finishing approaches, with a detail view in Fig. 9B of a low-profile embodiment; Figs. 10A and 10B show additional proximal end radiopaque features as may be employed with various end-finishing approaches; Fig. 11 shows in implant formed with a distal flattened top; Fig. 12 shows implant forms for imparting an implant shape as shown in Fig. 11 across a number of different implants of a given size range; Figs. 13A and 13B, respectively, illustrate the operation of an implant shaped according to Fig. 11/12 as compared to one that is not; Figs. 14-17 diagrammatically illustrate improved density implants as compared to the architecture presented in Fig. 4; Fig. 18 shows an overview of an implant/detachment system interface as may be employed in connection with the present invention; Figs. 19A-19E and 20A-20E illustrate the stages of operation (handle-side and implant-side, respectively) of the system shown in Fig. 18; Fig. 21 shows an optional improvement to the architecture of the same system; Figs. 22A and 22B show an alternative delivery system interface engaged and disengaged, respectively; Fig. 23 is an end-on view of the delivery system interface as pictured in Fig. 22B. Figs. 24A and 24B illustrate alternative end-on views of the configuration of a pusher shaft in the same system; Figs 25A and 25B show alternative delivery system interface options (engaged and disengaged, respectively) based on the pusher shaft configuration in Fig. 24B; Fig. 26 shows an alternative implant-side interface with a delivery system as presented in Figs. 25A and 25B; Fig. 27 shows an implant-side interface like that presented in Fig. 26 with an alternative pusher-side architecture; Figs. 28A and 28B show an alternative engagement/disengagement interface for a system like that shown in Figs. 22A and 22B; Figs. 29 and 30 show yet another engagement/disengagement architecture for each of a braid-type implant and embolic coil, respectively.

DETAILED DESCRIPTION

[0020] Various exemplary embodiments are described below. Reference is made to these examples in a non-limiting sense,as it should be noted that they are provided to illustrate more broadly applicable aspects of the devices, systems and methods. Various changes may be made to these embodiments and equivalents may be substituted without departing from the true spirit and scope of the invention. In addition, many modifications may be made to adapt a particular situation, material, composition of matter, process, process act(s) or step(s) to the objective(s), spirit or scope of the present invention. All such modifications are intended to be within the scope of the claims made herein.

[0021] To the extent any dimensions are stated in the summary or detailed description, such are intended to be merely examples and are not to limit the inventive subject matter unless explicitly recited in the claims.

[0022] Furthermore, the various features of the embodiments described herein are intended to be complement each other and are not intended to be purely alternatives unless stated so. In other words, features from one embodiment may be freely combined with features of another embodiment, as one of ordinary skill in the art will readily recognize, unless it is stated that those features are only to be used in the alternative. Applicants therefore intend this paragraph to provide written support for any present or future claim that recites features taken from different embodiments, should such not already be clear from the summary, detailed description, and claims.

[0023] Turning to the figures, Figs. 1A and 1B show an implant 10. In Fig. 1A, only the hub (not visible) of implant 10 is received within a sheath or catheter 2. Roughly 40% of implant 10 is received within sheath 2 in Fig. 1B. A radiopaque marker 20 (e.g., a Pt band) is visible in both views. As in Becking, et al., and with further reference to Fig. 4, implant 10 includes a tie 22 positioned between braid layers 12 and 14 adjacent a distal fold 16 in the braid, which defines aperture 18 (also referred to herein as the hole or gap in the braid). Marker 20 is held by tie 22. Tie 22 may also assist in closing or limiting the size to which aperture 18 may open.

[0024] While tie 22 terminates adjacent marker 20 in Becking et al., it extends to proximal hub 30 of implant 10 in the present description. The extension "tether" portions, or members, 24 so-provided operate to ensure axial alignment of marker 20 when implant 10 is captured (especially when re-capturing) in a catheter/sheath.

[0025] The length of tether member(s) 24 is therefore set such that slack is present when the implant is expanded (as shown in Fig. 1A) and the slack is removed when the implant is fully compressed or tending thereto (as shown in Fig. 1B).

[0026] Whereas the tie and/or tether member shown in Figs. 1A and 1B is typically made of suture material, it may be made of any other biocompatible material including stainless steel, titanium, Nitinol (possibly wire that is martinistic at body temperature – commonly referred to as "muscle wire"), and the like. When suture material is employed it can tie around the interior of distal fold 16 with minimal interference and be knotted at point 26 (see Fig. 1A) to easily secure the position of marker 20. The same approach may be accomplished with fine wire (e.g., 0.001 inch round wire.)

[0027] It may instead be advantageous to use a wire ribbon (e.g., Pt or Nitinol) for other reasons. A construction as detailed in the next figures was made using a

superelastic NiTi ribbon with dimensions set at about 0.001 inches by about 0.003 inches.

[0028] A tether ribbon 22 heatset into a tight loop or "V" shape was threaded through gap 20 and around as few as one wire from the braid at a distal end of implant 10 as shown in Fig. 4. So-disposed, tether ribbon 22 does not substantially interfere with compression of the distal end of the implant. What is more, spring action in the tether ribbon (whether comprising two filaments or trimmed to just one filament (as indicated by the broken line) after crimping, gluing, welding or otherwise affixing marker 20 as shown in Fig. 3) can help position marker 20 against (or across) the top of implant 10 when deployed, as shown in Figs. 2A and 2B. As for affixing the marker, it is notable that the paired ribbon sections, stacked upon each other, provide a good interface upon which to crimp marker 20 without drastically altering the marker's shape.

[0029] Also, the length of the tether may optionally be set in a general "question-mark" shape to match (or more closely match) the curvature of the implant when unconstrained (e.g., as the tether appears in Fig. 4). Pre-shaping the tether to "match" (or approximately match) one or more implant sizes can help ensure predictable and similar performance of implants across a range of different implant sizes and compressions.

[0030] As stated above, another improvement to the subject implants concerns the manner of proximal end finishing. Fig. 5 shows an implant preform 60 prepared for proximal end finishing. Here, implant preform 60 such as prepared in Becking, et al. is prepared, leaving an additional overhang section 50 extending past a proximal marker band 32. In many respects, the setup resembles that shown in Fig. 13A of Becking et al. with the implant preform 60 including an inner NiTi tube 34 and the assembly set upon a mandrel 52. To maintain the position of the components as shown, glue (e.g., Loctite 4014) is applied. Even so, and referring also to Fig. 6, the hub region 30 can be welded effectively with a weld bead 54 incorporating the overhanging braid 50, inner tube 34 and at least tack-welding an outer Pt band 32. It is noteworthy that achieving such a near-optimal welding result through (or into) the glue stabilized braid was a surprising result. In other words, it was neither predictable nor expected by those of skill in the art of welding (laser or otherwise). In any case, the length of the braid overhang incorporated into weld 54 may vary depending on a number of factors including implant diameter, wire diameter, braid density, etc. As shown, the overhang is about 0.005 to about 0.010 inches in length.

[0031] Another proximal end finishing approach is described in connection with Fig. 7. Specifically, preform 62 is not trimmed and stabilized for welding as shown in Fig. 5. Rather, preform 62 is prepared upon an elongate hypotube 54. The hypotube body provides a means to hold the construct and stabilize its elongate "tail" section 56 of braid layer 12 and/or layer 14 (e.g., by a wrap 58) thereon.

[0032] With a narrow window defined (e.g., with about 0.010 to about 0.025 inches of – preferably – exposed braid) laser energy is applied as indicated by the larger area. The energy is sufficient to weld the braid to the hypotube. The welding process does not, however, weld the hypotube to the optional underlying mandrel 52.

[0033] After such welding, the majority of the length of hypotube 54 is "sacrificed". It is trimmed-off to define the inner band 34 of the implant as shown in Fig. 8. This inner band may provide some or all of the radiopacity required in the hub region 30. However an outer band (especially if it comprises Pt) can be tack welded to the braid as indicated by the arrow Z in Fig. 7.

[0034] Irrespective of whether an outer marker band is included, Fig. 8 illustrates an advantage of the finishing approach, namely, the avoidance of weld bead flow artifacts associated with surface tension at the end of a body (as seen in Fig. 6). Rather, the weld 64 is neatly faced and the inner lumen of the remaining band 34 de-burred and/or reamed. Both actual and apparent hub size can be minimized accordingly.

[0035] Figs. 9A and 9B illustrate another advantageous proximal end finishing approach for minimizing proximal hub size. Fig. 9A shows an implant with an outer marker band 32 as it will generally appear as affixed by glue or welding. In instances where such a band is affixed by glue, once a glue cast is formed therein the band can be removed. An implant 10' will then include a proximal hub 30' that is reduced in diameter (by as much as about 0.004 inches depending on band thickness) and is also less noticeable by offering less contrast. Outside the body (e.g., in packaging) a physician will see a glaze or sheen of adhesive/glue 70 as a cast 72 in which the braid is embedded instead of a high contrast marker 32.

[0036] While seemingly unimportant to function, this visual aspect can indeed be relevant. The impression of physicians regarding the bulk of the proximal feature can affect whether the physician adopts the product. Conventional implants have been designed with the proximal hub completely inset within the inner volume of the implant. This is done to make the implant's appearance more attractive to physicians. However, the implant suffers in performance as a result (e.g., the implant is more difficult to recapture; the requirements on the implant's wire size and strength are

heightened to force the implant to recover the inset shape, leading to an undesirable increase in implant dimension; and other performance deficiencies). In the present aspect of the invention, the perceived hub size is reduced, which increases the visual appeal without compromising performance.

[0037] Figs. 10A and 10B illustrate additional embodiments that eliminate the outer band while providing relatively increased radiopacity. Specifically, minimal implant hub size can be achieved by relocating a radiopaque band feature to an in-line arrangement with the inner band 34. A simple Pt band 74 can be set atop the inner band 34 as shown in Fig. 10A. These members may be joined using conventional techniques (i.e., gluing, soldering, welding, etc.) or be held in relation to one another on a temporary basis by utilizing delivery system interface members as shown in Fig. 18, etc. to the embodiment of Fig. 10B interlocks members 34 and 74 through the use of lock 76 and key 78 features.

[0038] Another implant feature is illustrated in connection with Figs. 11 and 12. The implant optionally includes a flattened top 80 adjacent distal aperture 18. The flattened top is generated by providing a table surface 82 in the molding element 88 used to define the bulk shape of the implant. Molding elements, or "forms," in different sizes 88, 88' and 88" are shown in Fig. 12. They are milled down from a spherical form to define flat 82 surrounded by edge 84. The edge produces a crease 86 in the braid wire. Note that flat 80 and crease 86 are shown in alternate views in Figs. 2A and 2B.

[0039] During implant preform heatsetting, it has been found that the flat section improves the quality of the distal fold 16 in the implant, helping to maximize uniformity and minimize the bend radius in the wires. As such, device trackability through tortuous anatomy within a catheter is also improved. The crease at the edge of the flattened area set in the implant also helps with delivery performance upon deployment. Specifically, as illustrated in Fig. 13A, the crease 86 represents multiple bends in the wires forming the implant braid matrix. Upon exit from the microcatheter, the bends recover and cause the implant distal end to open more than an implant without such a crease as shown in Fig. 13B (see also, the implant in Fig. 1B). As a more open body, the implant is softer, with more relaxed braid angle should it contact any fragile tissue – such as the dome of an aneurysm.

[0040] Other architectural changes or augmentations that may be applied to implants are shown in Figs. 14-17. Each approach offers the potential for diagrammatically improved density relative to the parent architecture illustrated in Fig. 4.

[0041] Specifically, implant 90 includes an intermediate braid layer 92 set between outer layer 12 and inner layer 14. Layer 92 is captured in hub 30 as are the other layers at a proximal attachment 94. The distal extent 96 can be set at a number of positions. Advantageously, it extends to around the half-way point or equator of the device. This way, the layer will contribute to implant density (or – stated otherwise – reduce porosity) even for wide-neck aneurysms.

[0042] As shown in Fig. 14, the distal extent 96 of the braid is adjacent to the folded-over section 16 of the implant. Here, the density is highest so the inner layer wires will tend to stay best trapped between layers 12 and 14. Yet, since the ends 96 do not interfere with the fold 16 (which can be the highest profile aspect of the implant) little or no increase in crossing profile need result.

[0043] In production, the inner layer 92 of the implant can be produced simply by cutting a preform (like preform 62) in half at the distal fold. This produces a set of two inner layer sections that can be used in two different devices from a single formation procedure. However produced, because the inner layer may rely on the other layers for structural definition, it may be made of finer wire and/or with lower braid count than the other layers. For instance, the inner layer may comprise 72-end 0.0008 inch wire braid, whereas the outer layers comprise 96-end 0.0008 inch wire braid. However, the reverse may be true, in which the inner layer is more robust. In any case, it may be advantageous to mismatch the number of wire ends included in the braid (such as in the example directly above) to help avoid wire match-up, thereby minimizing porosity.

[0044] Implant 100 shown in Fig. 15 illustrates another advantageous approach to improving flow disruption effect, without increasing device crossing profile. As in device 90, an intermediate braid layer 90 is employed. However its proximal end is not secured within the hub, thereby easing space constraints in that region.

[0045] Instead, braid matrix integrity is maintained by coating the braid layer with a polymer (e.g., TICOPHILIC coating by Lubrizol, Inc.) or other coatings or processing. Hydrogel coating also offers an appealing option, such as a hydrogel-based polymer network capable of entrapping therapeutic agents as described in USPN 6,905,700 to Won et al. Likewise, while the implant elements advantageously comprise Nitinol braid (typically superelastic NiTi), the braid used for any of the layers may instead comprise polymer – especially high strength biodegradable polymer such as MX-2 (MAX-Prene), synthetic absorbable monofilament (90/10 Glycolide/L-Lactide) and/or G-2 (Glycoprene), synthetic absorbable monofilament (Glycolide (PGA), ε-Caprolactone (PCL), Trimethylene Carbonate (TMC) Copolymer) that is heat set into

shape (e.g., at 110 degrees centigrade for an hour) and/or coated with the same to stabilize the braid matrix as described.

[0046] Implant 110 shown in Fig. 16 offers another yet another approach for improved embolizing (or flow disrupting) effect with little or no effect on crossing profile. Such effect is accomplished by affixing an innermost/third braid layer 112 to inner band 34 at its proximal end 114. It may be welded, glued, soldered or otherwise affixed thereto. The distal end of the braid 116 may be trimmed and formed as shown or otherwise. For example, the cup so-formed may closely follow the inner periphery of the device up to or past its equator.

[0047] As with variations in the previous figures, the third layer incorporated in the implant simply deploys and recaptures in unison with the rest of the implant. Unique, however, to the architecture of Fig. 16 is that the proximal end 114 of the braid is stably secured, but secured such that it does not require space in the hub (e.g., within the outer marker band 32) without dimensional stackup.

[0048] A related implant configuration is shown in Fig. 17. Here, in implant 120, the same proximal end 114 attachment approach is employed. Yet, instead of forming (e.g., by heatsetting) the inner layer of braid into a cup shape, an inner ball 118 is formed. The proximal side of the ball improves overall proximal-side implant density, and also defines separated flow stagnation zones A and B within the implant to further assist in thrombus formation within the implant.

[0049] Inner ball body 118 may be shape set over a form. Alternatively, and more advantageously, the shape can be formed without either an external or internal form by bunching the braid up and tying it onto a mandrel for heatsetting. Such a "free-forming" approach is functionally advantageous because it maximizes braid angle (hence, density) in the final body. Yet, any resulting inconsistency in shape is manageable given that the only outer body of the implant defined by braid layers 12 and 14 is in contact with an aneurysm.

[0050] Irrespective of how it is formed (and the particular braid configuration selection) the inner ball 118 within the architecture will be configured so that it will not interfere with the distal end of the implant body/shell and/or marker and tether when the device is compressed for delivery or recapture.

[0051] More generally, Fig. 18 provides an overview of implant-side of a treatment system 200. The system includes an implant 10 (90, 100, 110, 120) and a pusher/catheter shaft 210 ultimately attached to a handle 220 (e.g., as shown in Figs.

19A-19-E). Any of these may be constructed according to the teachings herein and/or incorporated by reference.

[0052] One handle construction includes a single plunger. The plunger pulls a collar that progressively engages and pulls sockets connected to the wires; first each control wire 212 is pulled (one at a time), then the anchor wire 214. Such action is illustrated in Figs. 19A-19E and 20A-20E. Figs. 19A and 20A show the device components as removed from packaging. Fig. 19B illustrates unlocking the handle plunger 222 with a 120 degree rotation relative to handle body 224. Such action has no effect on the detachment interface 216 shown in Fig. 20B. However, progressive pull of the plunger in Figs. 19C-19E effect the release of the system as shown in Figs. 20C-20E.

[0053] Fig. 21 shows an optional improvement to the architecture of system 200. Here, system 200' has only one "true" control wire 212 is received within the hub or inner band 30/34 of the implant 10. Even so, the implant remains securely/stably attached to the catheter shaft by virtue of the control wire interaction with anchor ball 216 (e.g., as formed by laser or as otherwise configured).

[0054] Release of the implant is effected as if progressing from the steps in Figs. 19C and 20C to 19E and 20E. However, a third (floating or actuated) "dummy" wire 218 is still loaded within the lumen of pusher shaft 210. Use of this wire maintains a close-packed arrangement of the wires inside shaft 210, which can be important in determining wire position within a tortuous setting. Yet, release angle may be increased and plunger pull force reduced because the wires within the implant have more space between them allowing for spatial accommodation.

[0055] Note that the length "L" by which wire 218 is inset within the pusher shaft may vary depending on purpose. It may have no inset (i.e., essentially abut the implant proximal end). It may be inset by about 1 mm so that any forward motion in a tortuous setting does not result in contact with the implant. Or it may be inset to a greater degree (e.g., between about 1 cm and 5 cm) to improve distal tip flexibility of delivery pusher shaft 210.

[0056] Figs. 22A and 22B show an alternative delivery system interface in engaged and disengaged states, respectively. Here, system 230 comprises a catheter/pusher shaft 232 actuated with the assistance of a typical torque 234. Torquer 234 locks a position of a central wire 236 including an anchor ball for implant 10 delivery. A bumper or shoulder 240 may be affixed to the catheter (optionally a Pt band also serving as a marker) to abut a hub 30 of the implant for pushing.

[0057] Engagement is achieved between the implant and pusher shaft by virtue of extension 242 that is offset into an interfering relationship with an inner band 34 of the implant when the anchor ball 238 is in a retracted position as shown in Fig. 22A. When wire 236 (and its terminal ball feature 238) is advanced as shown in Fig. 22B, extension section 242 is free to move (e.g., to return to its original position by elastic action or upon catheter shaft withdrawal) and slide out of the implant.

[0058] Fig. 23 is an end-on view of the delivery system interface as pictured in Fig. 22B. As shown, no interference between the ball 238 and/or extension persists once wire 236 is advanced. Fig. 24A portrays a similar view without the wire in place. It shows extension 242 and catheter body 232. And while they are illustrated as formed in one manner (i.e., with a 90 degree cut-down), it is to be appreciated that the extension may instead be formed by an angular cut or otherwise. Indeed, Fig. 24B shows an approach in which the extension section is formed by pushing over the catheter wall on one side to meet the other and optionally heat setting, fusing or gluing the component parts 242 and 242' together.

[0059] Figs 25A and 25B show an alternative delivery system interface 250 option (engaged and disengaged, respectively) based on the pusher shaft extension configuration in Fig. 24B. Due to the increased wall thickness offered by the double wall layer, the system can work much as that shown in Figs. 22A and 22B, except without need for a distal interference feature (i.e., anchor ball/band). As such, withdrawal of wire 236 will relieve the interference and unlock the pusher shaft 232 (specifically, the associated extension) for withdrawal from the implant 10.

[0060] Fig. 26 shows an alternative implant-side interface with a delivery system as presented in Figs. 25A and 25B. Here an implant socket 260 is provided. Socket 260 may be defined by a cup 262 attached to one or more implant braid layers (12/14), by welding or otherwise, and a reducer tube 264 threaded, pressed or otherwise affixed in the proximal end of the cup. Note that with such an arrangement that implant pushing can be accomplished without a shoulder or other proximal interface. Instead, both push and pull (for withdrawal) force application can occur within the socket chamber. While such a socket will typically be larger than the previous interfaces shown, it is easily retrofit or used as and alternative to the screw-type release approaches employed in many vessel sacrifice and closure devices as sold by AGA Medical, Inc. and others.

[0061] The delivery system configuration in Fig. 27 shows the same implant-side interface 260, with an alternative pusher-side engagement/disengagement (or latch) architecture 270. This architecture is a simplified version of that shown in Fig. 18 of

Becking et al. Specifically, a pusher shaft 272 (e.g., metal hypotube) is provided with a single window cutout 274. The window (configured as a square cutout, rounded, or a simple kerf) allowing a core member 276 (e.g., NiTi ribbon) to pass therethrough and provide interference against pusher shaft distal face 276 to prevent delivery system detachment until core member withdrawal.

[0062] Figs. 28A and 28B show an alternative latch interface 280 for a system like that shown in Figs. 22A and 22B. In this system, a bent back wire hook 282 serves the function of the ball in the former system. Such a system offers the advantage of very low cost production, as well as a secure anchoring feature. Fig. 29 shows a system 290 most closely related to that in Fig. 21, except that multiple control and/or dummy wires are replaced with a single ribbon 292.

[0063] Finally, Fig. 30 shows a detachment system 300. As in system 290 a ribbon 292 may be used in conjunction with a round anchor wire 214 with a ball-shaped anchor 216. An alternative approach that may be used in either system is to employ a ribbon as the "anchor wire" and form the interference feature at its end by tying a knot therein (as a substitute for a laser-formed ball). Such a knot can be shape set, glued or welded to stabilize its shape. It can be reliably be produced at low cost at a very small size, on a ribbon. A socket-type interface can be formed within the coil by fitting a collar feature 302 within its proximal end. The collar may be threaded-in (i.e., into the coils like a thread pitch). An alternative approach involves flowing solder between the coils and defining a lumen therein using a removable mandrel. The mandrel may be prepared in any manner to facilitate its removal, including those described for the removable hub in connection with the improvement described in connection with Fig. 9B.

[0064] In the various delivery system architectures, the catheter/pusher shaft comprise a simple extrusion (e.g., PTFE, FEP, PEEK, etc.) or may be constructed using conventional catheter construction techniques and include a liner, braid support and outer jacket (not shown). An exemplary construction is available through MicroLumen, Inc. as Braid Reinforced Polyimide. A distal section of the Polyimide may be ablated and replaced with fused Pebax to provide a softer or progressively-flexible end to the catheter. A loading sheath is typically provided over the pusher shaft. Advantageously, the loading sheath is splittable.

[0065] If not preloaded, after removal from sterile packaging (not shown), the implant is pulled into the loading sheath. The loading sheath is received within the hub of the catheter to be used for implant delivery and the implant is advanced into the catheter. Then, the implant may be advanced to and deployed at a treatment site. Or it may be

retrieved in exchange for another size implant – else repositioned, if desired, prior to ultimate detachment as illustrated in the incorporated patent application subject matter.

[0066] In the present invention, the subject methods may include each of the physician activities associated with implant positioning and release. As such, methodology implicit to the positioning and deployment of an implant device forms part of the invention. Such methodology may include placing an implant within a brain aneurysm, or at parent vessel targeted for occlusion, or other applications. In some methods, the various acts of implant introduction to an aneurysm or parent vessel are considered.

[0067] More particularly, a number of methods according to the present invention involve the manner in which the delivery system operates in reaching a treatment site, for example. Other methods concern the manner in which the system is prepared for delivering an implant, for example attaching the braid ball to the delivery system. Any method herein may be carried out in any order of the recited events which is logically possible, as well as in the recited order of events, or slight modifications of those events or the event order.

[0068] It is contemplated that any optional feature of the inventive variations described may be set forth and claimed independently, or in combination with any one or more of the features described herein. Reference to a singular item, includes the possibility that there is a plurality of the same items present. More specifically, as used herein and in the appended claims, the singular forms "a," "an," "said," and "the" include plural referents unless specifically stated otherwise. In other words, use of the articles allow for "at least one" of the subject item in the description above as well as the claims below. It is further noted that the claims may be drafted to exclude any optional element. As such, this statement is intended to serve as antecedent basis for use of such exclusive terminology as "solely," "only" and the like in connection with the recitation of claim elements, or use of a "negative" limitation.

[0069] Without the use of such exclusive terminology, the term "comprising" in the claims shall allow for the inclusion of any additional element irrespective of whether a given number of elements are enumerated in the claim, or the addition of a feature could be regarded as transforming the nature of an element set forth in the claims. Except as specifically defined herein, all technical and scientific terms used herein are to be given as broad a commonly understood meaning as possible while maintaining claim validity.

[0070] The breadth of the present invention is not to be limited to the examples provided and/or the subject specification, but rather only by the scope of the claim

language. Use of the term "invention" herein is not intended to limit the scope of the claims in any manner. Rather it should be recognized that the "invention" includes the many variations explicitly or implicitly described herein, including those variations that would be obvious to one of ordinary skill in the art upon reading the present specification. Further, it is not intended that any section of this specification (e.g., the Summary, Detailed Description, Abstract, Field of the Invention, etc.) be accorded special significance in describing the invention relative to another or the claims. All references cited are incorporated by reference in their entirety. Although the foregoing invention has been described in detail for purposes of clarity of understanding, it is contemplated that certain modifications may be practiced within the scope of the appended claims.

CLAIMS

What is claimed is:

1. An embolic device comprising a body having proximal and distal sides, with a radiopaque marker positioned within the body and held adjacent the distal side by at least one filament, the improvement comprising:

the at least one filament extending from the marker to the proximal side, and having a length to cause the marker to align with the body when the body is in a compressed configuration.

2. The embolic device of claim 1, wherein the at least one filament comprises suture material, and the suture material is knotted to secure a proximal side of the marker.

3. The embolic device of claim 1, wherein the at least one filament comprises a metal ribbon of material weldable to the body for securement at the proximal side of the body.

4. An embolic device comprising a multi-filament body having proximal and distal sides, the improvement comprising:

a flat formed across the distal side of the body, providing a circular crease in the filaments.

5. An embolic device comprising braid forming inner and outer layers of the device, the layers defining an open volume and being adapted to compress for delivery through a catheter and expand when unconstrained, the inner and outer layers meeting at a folded section closed at one end of the device and at a hub closing and holding at least the outer braid layer at the other end of the device, the improvement comprising:

an intermediate layer of braid positioned between the inner and outer layers.

6. The device of claim 5, wherein the intermediate layer is not attached at either a proximal side or a distal side of the device, and the intermediate layer is positioned between the compressed and expanded states.

7. The device of claim 5, wherein a proximal side of the intermediate layer is incorporated into the hub of the device.

8. The device of claim 7, where a distal side of the intermediate layer is positioned adjacent the folded section.

9. An embolic device comprising braid forming inner and outer layers of the device, the layers defining an open volume and being adapted to compress for delivery through a catheter and expand when unconstrained, the inner and outer layers

meeting at a folded section, closed at one end of the device, and at a hub, closing and holding at least the outer braid layer at the other end of the device, the improvement comprising:

an elongate band within the hub and an additional braid layer connected to the band distal to the hub.

10. The device of claim 9, wherein the additional layer is cup-shaped when the device is expanded.

11. The device of claim 9, wherein the additional layer is ball-shaped when the device is expanded.

12. An detachable implant pusher system comprising an implant including a proximal port section, an elongate pusher sleeve, a plurality of elongate members received within a lumen of the sleeve, wherein the sleeve is locked to the implant through interference with a distal surface of the port section until the at least one of the plurality of elongate members is drawn into the sleeve, the improvement comprising:

not all of the plurality of elongate members exiting at proximal and distal ends of the pusher sleeve and received through the implant port.

13. An detachable implant pusher system comprising:

an implant including a proximal port section;

an elongate pusher sleeve;

an elongate member received within a lumen of the sleeve, exiting at proximal and distal ends of the sleeve;

the elongate member and the distal end of the sleeve received through the implant port section,

wherein the sleeve is adapted to lock to the implant, through interference with a distal surface of the port section, until the elongate member is displaced.

14. An detachable implant pusher system comprising an implant including a proximal port section, an elongate pusher sleeve, at least one elongate member received within a lumen of the sleeve, exiting at proximal and distal ends and received through the implant port, wherein the sleeve is adapted to lock to the implant, through interference with a distal surface of the port section, until the at least one elongate member is drawn into the sleeve, the improvement comprising:

the proximal port configured as a socket.

15. An embolic device comprising braid forming inner and outer layers of the device, the layers defining an open volume and being adapted to compress for delivery through a catheter and expand upon release from constraint, the inner and outer

layers meeting at a folded section closed at one end of the device and at a hub closing and holding at least the outer braid layer at the other end of the device, the improvement comprising:

an elongate band welded within the hub and another adjacent band aligned therewith the adjacent band comprising a material that is relatively more radiopaque than the elongate band.

16. A method of making an embolic device, the method comprising:

forming a body of the implant over a hypotube;

affixing the braid to the hypotube; and

trimming the hypotube, leaving a band within the implant.

17. A method of making an embolic device, the method comprising:

forming a multi-filament body of the device;

setting a band for a hub region of the device;

applying adhesive to secure filament ends within the hub region; and

removing the band from the hub region with the filaments secured in the hub region.