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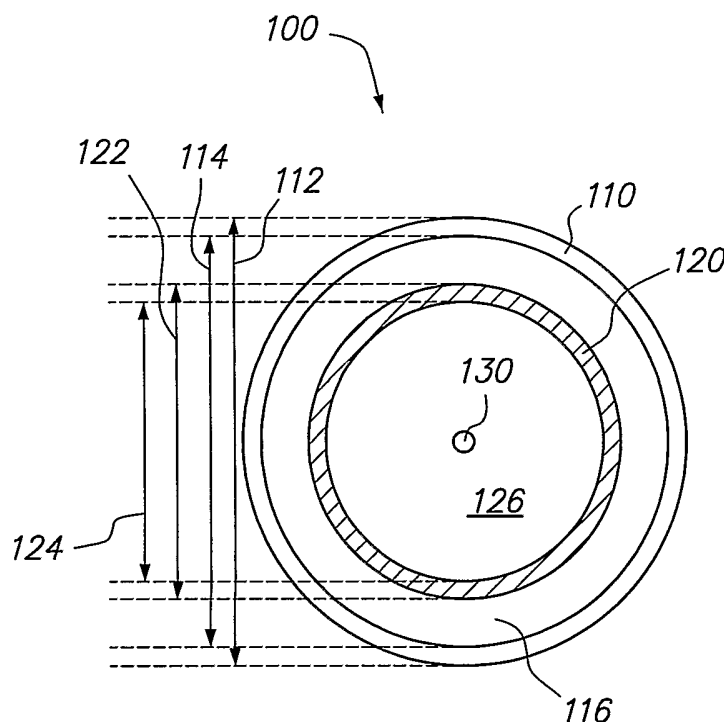
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(54) Title: SYSTEM FOR DELIVERING AN IMPLANT UTILIZING A LUMEN REDUCING MEMBER



(57) Abstract: A system for inserting an implant into a vascular space to a vascular site in a body utilizing a lumen-reducing catheter. A guide (130) is inserted into the vascular space. First (110) and second (120) catheters are inserted into the vascular space along the guide. The first or delivery catheter defines a first cavity, and the second or lumen-reducing catheter defines a second, smaller cavity. The second catheter is inserted within the first catheter. An implant (130) is advanced together with the first and second catheters to a vascular site. Alternately, after the first and second catheters are positioned, the guide and the second catheter are removed from the first cavity, and an implant is inserted through the first cavity. Radial movement of the guide is thereby restricted to the smaller, second cavity rather than the larger, first cavity.

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SYSTEM FOR DELIVERING AN IMPLANT  
UTILIZING A LUMEN REDUCING MEMBER

FIELD OF THE INVENTION

5       The field of the invention relates to implantable devices, and more particularly, to a system for inserting a delivery sheath or catheter through a vascular body using a lumen-reducing catheter and delivering an implantable device through the delivery catheter or the  
10 lumen-reducing catheter.

BACKGROUND

In many clinical situations, blood vessels are occluded with various implants to control bleeding,  
15 prevent blood supply to tumors, block blood flow within an aneurysm or other vascular malformations. Intracranial aneurysms, for example, may rupture causing significant bleeding. The significant bleeding may permanently damage the surrounding brain tissue, possibly  
20 causing serious injury and death. Intracranial aneurysms may be particularly difficult to access and treat when they are formed in remote cerebral blood vessels. If left untreated, hemodynamic forces of normal pulsatile blood flow can rupture fragile tissue in the area of the  
25 aneurysm causing a stroke (not needed).

Various implants have been used to occlude vascular sites. For example, vaso-occlusive devices are surgical implants that are delivered through a catheter in a blood vessel or vascular cavity and placed within aneurysm to  
30 form a thrombus and occlude the aneurysm. In one conventional system, a guide wire is inserted through a vascular cavity. An outer catheter or sheath is guided by the wire and inserted through the vascular cavity, and

the implant is pushed or otherwise forced through the interior of the catheter to an aneurysm site.

Conventional implant delivery systems, however may exhibit a number of problems as a result of a gap between  
5 the guide wire and the outer sheath. First, while the guide wire may be able to turn and maneuver through curved vascular cavities or cavity divisions, such as a "Y" section or other division that splits a blood vessel, the outer sheath that follows the guide wire may not be  
10 able to complete these maneuvers. For example, if a blood vessel makes a sharp turn, the outer portions of the distal end of the sheath may abut against a vessel section or scrape against the inner vessel walls as the sheath attempts to follow the guide wire through sharp  
15 turns. As a result, the outer sheath can weaken or damage the blood vessel or release embolic debris or plaque further down the bloodstream. Second, the applications and treatments using conventional sheaths may be limited since it may not be possible to insert the  
20 sheath through narrow or curved vascular cavity sections to an aneurysm site. Consequently, the aneurysm or containment site can be left untreated or can be treated while causing damage to other blood vessel sections, in the process possibly leading to more serious injury,  
25 stroke and death. These problems are amplified with smaller vessels and vessels having sharp turns and when larger implants are utilized. Third, implants may not be properly retained within an aneurysm as a result of the width or the aneurysm neck. For example, an implant may  
30 be improperly secured or inadvertently released from the aneurysm as a result of slipping through a wide aneurysm neck.

## SUMMARY OF THE INVENTION

In one embodiment of the invention is a system for delivering an implant, such as a vaso-occlusive implant, through a vascular space to a vascular site. The system includes a guide, a first member having a distal end and a proximal end and defining a first cavity, and a second member having a distal end and a proximal end and defining a second cavity. The guide is configured for insertion through the vascular space to the vascular site. The second member is configured for insertion through the first member. When the members are positioned at the site, the second member and the guide are removed from the first cavity, and an implant is inserted through the first cavity and delivered to the vascular site with or without a guide wire.

The first member can be a first annular catheter defining the first cavity, and the second member can be a second annular catheter defining the second cavity. For example, the first annular catheter has an outer diameter of about 0.66mm to about 1.3mm, the first cavity has a diameter of about 0.5mm to about 1.25mm, the second annular catheter has an outer diameter of about 0.45mm to about 1.20mm, and the second cavity having a diameter of about 0.35mm to about 1.0mm. With this configuration, the second member reduces radial movement of the first member relative to the guide, and the guide is confined to the second cavity when the first and second members are inserted through the vascular space. Further, the distal ends of the first and second members can be generally aligned when the are advanced along the guide.

In another embodiment of the invention, a system is provided for delivering a first implant through a vascular space to a vascular site in a body. A first

member has a distal end and a proximal end and defines a first cavity. A second member has a distal end and a proximal end and defines a second cavity. The second member is insertable within the first cavity. The distal  
5 ends of the first and second members are advanced along a guide and through the vascular space to the vascular site, thereby advancing the first implant to the vascular site.

The first implant can be advanced by the distal end  
10 of the first member, the distal end of the second member, or the distal ends of both members. Further, the distal ends of the first and second members can be generally aligned when they are advanced along the guide. A second implant, such as a vaso-occlusive implant, can also be  
15 inserted through the second cavity of the second member into the vascular site. The second implant is contained within the vascular site by the first implant.

The second member reduces the radial movement of the first member relative to the guide, and the guide is  
20 confined to the second cavity when the first and second members are inserted through the vascular space. The first member can be a first annular catheter defining the first cavity, and the second member can be a second annular catheter defining the second cavity. For  
25 example, the first annular catheter has an outer diameter of about 0.66mm to about 1.3mm, the first cavity has a diameter of about 0.5mm to about 1.25mm, the second annular catheter has an outer diameter of about 0.45mm to about 1.20mm, and the second cavity having a diameter of  
30 about 0.35mm to about 1.0mm.

## BRIEF DESCRIPTION OF THE DRAWINGS

Referring now to the drawings in which like reference numbers represent corresponding parts throughout:

5        FIG. 1A is a front view and FIG. 1B is a partial cross-sectional view of a system having a cavity-reducing or lumen-reducing sheath according to an embodiment of the invention;

10        FIGS. 2A-J are partial cross-sectional views showing the manner in which an implant is inserted through a vascular space to a vascular site using an outer or delivery sheath, a lumen reducing sheath and guide wire; and

15        FIGS. 3A-F show how an embolic containment implant is delivered to a neck of an aneurysm and a second implant is then inserted into and retained within an aneurysm using a system according to an embodiment of the invention.

20        DETAILED DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

Referring to Figures 1A-B, a system or assembly 100 according to one embodiment of the invention includes a first or delivery member 110, such as an outer, annular catheter or sheath, a second or reducing member 120, such as an inner, annular catheter or sheath, and a guide 130, such as a guide wire. The system 100 is used to deliver an implant (not shown) through a vascular space to a vascular site, such as an aneurysm, tumor, a site for capturing embolic debris, or other vascular malformation (generally vascular site).

30        The embodiment is suitable for delivering or advancing various devices or implants into the body of a patient for different applications. For example, the

invention can be used to deliver a vaso-occlusive implant, such as a coil and a liquid, to treat or occlude an aneurysm. Further, the embodiment can be used to deliver an embolic containment implant which facilitates  
5 delivery of a vaso-occlusive implant by, for example, reducing the size of the aperture formed by a neck of an aneurysm to contain the vaso-occlusive device in the aneurysm without risk of embolic migration. Typically, an embolic containment implant would be positioned  
10 slightly inside the neck of the aneurysm. Additionally, the embodiment can be used to deliver a stent to ensure that a vessel remains open or unblocked. The stent can also be used to help contain subsequent delivery of embolic materials (liquids, coils) into the aneurysm,  
15 similar to an embolic containment implant. Unlike the embolic containment system, however, the stent is placed outside the neck of the aneurysm or into the parent vessel. An "implant" in this specification refers to the various types of implants that can be delivered with the  
20 embodiment of the invention.

Persons of ordinary skill in the art will recognize that the implant can be delivered into the body through various entry points, e.g., percutaneously through a peripheral vessel, such as a femoral, carotid, or radial  
25 artery, or other vein, artery or vascular space, to treat various vascular sites. This specification, describes and illustrates a system related to treating a vascular cranial aneurysm sites with various implants for purposes of explanation and illustration, but the invention is not  
30 so limited.

Various guides 130 can be used with the system 100. One exemplary guide is a guide wire, such as a 1014 to GC18 guide wire, having diameters from about 0.01" to

about 0.018". The guide wire can also have a rounded or modified tip, such as a "J hook" or a smoothed or rounded tip that allows the guide wire to be inserted through a vascular space more smoothly. Other exemplary guides  
5 include a guiding catheter or other guide rail. The particular guide 130 that is utilized may depend on the particular application. Thus, the invention is not limited to using a particular guide 130, but this specification refers to and illustrates a guide wire for  
10 purposes of explanation and illustration.

The outer, first or delivery catheter or sheath ("delivery catheter 110") may be a micro-catheter or other elongated delivery device. The size of the delivery catheter 110 can vary depending on the  
15 particular patient, treatment, and implant to be delivered to the aneurysm site. For example, when accessing a brain aneurysm in a small vessel, an appropriately sized delivery catheter 110 can be quite small and flexible.

20 Exemplary delivery catheters 110 for treating cranial aneurisms are 3.0F to 3.8F catheters having an outer diameter (OD) 112 from about 1.0mm to about 1.3mm. The inner diameter (ID) 114 of the lumen or cavity 116 of the delivery catheter 110 can be from about 0.8mm to  
25 about 1.1mm. Different delivery catheters 110 with different IDs 114 and ODs 112 can be utilized depending on the particular application and size of the implant. . The ID 114 of the delivery catheter 110, however, should be made large enough to accommodate a second or cavity-  
30 reducing or lumen-reducing catheter ("reducing catheter 120") and the implant.

The delivery catheter 110 can be made of different materials and have various coating to facilitate

insertion through a vascular space. Exemplary delivery catheter 110 materials include Polypropylene, PE, Urethanes, Nylons, and Pebax. One exemplary coating applied to the outer surface of the delivery catheter 110 is a hydrophilic coating. Persons of ordinary skill in the art will recognize that various delivery catheter 110 sizes, materials, and coatings can be utilized depending on the particular application and treatment.

The second or reducing catheter 120 is inserted within the cavity or lumen 116 defined by the delivery catheter 110. The Outer Diameter (OD) 122 of the reducing catheter 120 should be smaller than the ID 114 of the delivery catheter 110 so that the reducing catheter 120 can be inserted through the lumen 116 of the delivery catheter 110. For example, if the delivery catheter 110 defines a lumen 116 with an ID 114 from about 0.5mm to about 0.8mm, then the OD 122 of the reducing catheter 120 can be from about 0.66mm to about 1.0mm. In one embodiment, the delivery catheter 110 defines a cavity having an ID 114 of about 0.033", and the reducing catheter 120 defines a reduced cavity or lumen 126 having an ID 124 from about 0.012" to about 0.021". As a result, with the reducing catheter 120, movement of the guide wire 130 is restricted to a smaller cavity or lumen compared to a larger lumen or cavity of a conventional delivery catheter. Similarly, with the reducing catheter 120, movement of the system 100 around the guide wire 130 is restricted to the smaller or lumen cavity 126, rather than a larger cavity of an outer catheter 110.

Thus, radial movement (e.g., up-down, side-to-side) of the assembly 110 including the delivery and reducing catheters 110 and 120 is limited compared to conventional

systems, while allowing for the catheters to be inserted into a vascular space. With these exemplary configurations, the amount of movement or play between the guide wire 130 and the delivery catheter 110 is  
5 reduced so that the delivery catheter 110 can be inserted through a vascular space more easily and efficiently. For example, in one embodiment, the area of the first lumen 120 is reduced by about 35% to about 75%. Persons of ordinary skill in the art will recognize that  
10 different sizes and thickness of the catheters 110 and 120 can produce reduced cavities 126 of different sizes. Further, the gap between the catheters 110 and 120 can be adjusted as needed.

In use, the delivery and reducing catheters 110 and  
15 120 are positioned in a vessel so that the distal ends 118 and 128 of the catheters 110 and 120 are advanced over or otherwise in conjunction with a guide wire 130 to a vascular site. For example, the distal ends 118 and 128 of the delivery and reducing catheters 110 and 120  
20 may be generally aligned with each other when being advanced through the vascular space over the guide wire 130. The lumen-reducing catheter 120 can also extend somewhat ahead of the delivery catheter 110 if necessary.

If a vaso-occlusive implant is being delivered to an  
25 aneurysm site, the reducing catheter 120 and the guide wire 130 are removed after they are properly positioned at the vascular site. A displacement member, such as a pusher wire, advances the implant through the delivery catheter 110. Various other displacement members can be  
30 utilized, such as a plunger that is attached to the guide wire 130 to advance the implant or fluid pressure through the delivery catheter 110. When vaso-occlusive implants 230 are placed within or at a neck an aneurysm 220, they

tend to induce the formation of fibrin network (clot or thrombus). The thrombus provides a high-surface-area substrate on which the cells responsible for wound healing (such as fibroblasts) migrate and proliferate as they deposit collagen to replace the clot with more stable collagenous fibrous tissue.

In cases involving a first implant being delivered to an aneurysm site to retain or contain a second implant within an aneurysm site, the containment implant is inserted through a vessel together with the delivery and lumen-reducing catheters to a neck of the aneurysm. The containment implant reduces the width of a neck of an aneurysm. A second implant, such as a vaso-occlusive implant, is delivered through the reducing catheter to the aneurysm site and is secured or retained within the aneurysm by the previously deployed containment implant.

Having described components of a system 100 according to the invention and the different manners in which they can be used, Figures 2A-I illustrate components of the system 100 at different stages showing in further detail how the system 100 is used in a method 200 to advance an implant, such as a stent, a coil, a filter or an implant that removes part of a vessel clot, to an aneurysm site.

Initially, referring to Figure 2A, the guide wire 130 is inserted and fed through a vascular cavity or space 210. The delivery catheter 110 and the reducing catheter 120 are advanced over the guide wire 130. For example, as previously discussed, the delivery and lumen-reducing catheters 110 and 120 can be advanced together over the guide wire 130, and the catheters 110 and 120 can be generally aligned with each other as they are advanced over the guide wire 130. The reducing catheter

120 can also extend somewhat ahead of the delivery catheter if necessary.

As the catheters 110 and 120 are advanced through the vascular space 210, as shown in Figure 2B, the distal ends 118 and 128 of the delivery and reducing catheters 110 and 120 are positioned at or near the vascular site 220 (shown generally as a dotted line.) The site 220 is then said to be catheterized. Referring to Figure 2C, the reducing catheter 120 and the guide wire 130 are retracted from the site 220 after the outer catheter 110 is positioned and, as shown in Figure 2D, removed or pulled from the cavity 116 of the delivery catheter 110. As a result, only the delivery catheter 110 remains inserted within the vascular cavity 210 at the vascular site 220, and the lumen 116 of the delivery catheter 110 is empty.

Referring to Figure 2E, the guide wire 130 is re-inserted (or a different guide wire is inserted) into the lumen or cavity 116 of the delivery catheter 110. An implant 230, such as a vaso-occlusive coil, , a stent, a filter, or an implant that removes part of a vessel clot is inserted into the proximate end 119 of the delivery catheter 110. An insertion or displacement device 240 advances the implant 230 along the guide wire 130 and through the cavity 116 of the delivery catheter 110 until the implant 230 exits or reaches the distal end 118 of the outer catheter 110, as shown in Figure 2F. In an alternative embodiment, the implant 230 is pushed by the displacement device 240 through the cavity 116 of the delivery catheter 110 without a guide wire 130, however, a guide wire that directs the implant 230 to the site 220 is shown for purposes of illustration.

Referring to Figure 2G, the displacement device 240 is detached or released from the implant 230 (if necessary), and the displacement device 240 and the guide wire 130 are removed from the lumen 116 of the delivery catheter 110. As a result, as shown in Figure 2H, the implant 230 remains at the vascular site 220. As shown in Figure 2I, the delivery catheter 110 may be removed from the vascular space 210, leaving the implant 230 at the site 220. The implant (e.g., a filter) may later be removed from the vascular space if necessary.

Figures 3A-F illustrate an alternative embodiment of the invention directed to delivering an embolic containment implant and a second implant, such as a vaso-occlusive implant, utilizing a lumen-reducing catheter. For example, a containment implant can be delivered to the aneurysm neck to reduce the width of the neck, and a vaso-occlusive coil can then be delivered through the lumen reducing catheter into the aneurysm. As a result, the containment implant reduces the width of the neck to contain the coil within the aneurysm and retains the coil in the aneurysm while reducing the possibility that the coil will be inadvertently released from the aneurysm through the neck.

Specifically, referring to Figure 3A, an embolic containment device 300, such as containment implants 300a and 300b (generally 300), are advanced together with the delivery and lumen-reducing catheters 110 and 120 and guided through a vessel 210 by a guide wire 130. As shown in Figure 3A, an aneurysm 310 includes a sack or body 315 and a neck 320 with a width  $W_1$ . Referring to Figure 3B, the delivery system is advanced further through the vessel 210 so that the containment implants 300 are inserted into the aneurysm neck 320. As shown in

Figure 3C, the containment implants 300 are arranged so that they are placed within the aneurysm sack 315 and over part of the neck 320. As a result, the containment device 300 reduces the original width W1 of the neck 320 to a smaller width W2. The containment device 300 can expand to fill in the neck 320 and lower part of the aneurysm 310 in, for example, a disc-like shape or other shapes, depending on the site to be occluded.

Referring to Figure 3D, a vaso-occlusive device 330, such as a coil, is inserted through the lumen-reducing catheter 120 until, as shown in Figure 3E, the distal end 332 of the coil 330 exits the distal end of the lumen reducing catheter 120 and is inserted into the sack 315 of the aneurysm 310 through or between the containment implants 300. In Figure 3F, the coil 330 is inserted into the aneurysm sack 315 and retained by the containment implants 300. The delivery catheter 110, the lumen-reducing catheter 120, and the guide wire 130 can then be removed from the vessel 210, leaving the coil 330 and containment implants 300 behind at the aneurysm 310. The coil 330 can then assist in forming a thrombus to occlude the aneurysm 310.

Having described different systems 100 and a methods 200 of their use according to the invention, persons of ordinary skill in the art will appreciate that the invention can be implemented with various types of guides 130, delivery catheters 110, reducing catheters 120, implants 230, and displacement or pusher members 240 to deliver the implants 230 through a vascular cavity 210 to a vascular site 220. The implant can be solely a vaso-occlusive implant, solely a containment implant that contains a vaso-occlusive implant, or serve as both a vaso-occlusive and a containment implant.

For example, one exemplary vaso-occlusive implant 230 is a vaso-occlusive coil that occludes the interior or sack of an aneurysm, such as a Guglielmi Electrolytically Detachable Coil (GDC). A coil can  
5 assume a linear helical configuration when stretched and a folded convoluted configuration when relaxed. The coil has a stretched configuration when placed in the delivery catheter 110, which is used in placement of the coil at the desired aneurysm site, and assumes the convoluted  
10 configuration when the coil is ejected from the delivery catheter 110 and the coil relaxes. Other shapes, such as "flower" shapes, double vortices, and random shapes can also be used. Vaso-occlusive coils having more complex, three-dimensional structures in a relaxed configuration  
15 can also be utilized. The coils may be deployed in the approximate shape of a sphere, an ovoid, a clover, a box-like structure or other distorted spherical shape. Vaso-occlusive coils may also be made of various other biocompatible polymers or of carbon fibers. The vaso-  
20 occlusive implant may be covered or connected with fibrous materials tied to the outside of the coil or braided onto the outer cover of the coil as desired.

For occluding peripheral or neural sites, coils will typically be made of 1 mil to 5 mil diameter wire (e.g.,  
25 platinum or platinum/tungsten alloy) that may be wound to have an inner diameter of 5 mils to 60 mils with a minimum pitch. The outer diameter is then typically between 0.007 and 0.700 inch. The length of the coil 230 will normally be in the range of 0.5 to 60 cm, preferably  
30 0.5 to 40 cm. The coils may also be formed in such a way that they are essentially linear as they pass through the delivery catheter 110 and yet assume a randomly oriented

relaxed condition after they are released from the end  
118 of the delivery catheter 110.

A further exemplary implant 230 is a vaso-occlusive  
implant that includes an inner core wire covered with a  
5 polymer. The polymeric material includes protein based  
polymers, absorbable polymers, non-protein based  
polymers, and combinations thereof. The polymer  
facilitates forming of emboli to occlude a body cavity.

Other exemplary vaso-occlusive implants 230 include  
10 multiple vaso-occlusive members with electrolytically  
disintegratable links between the members. For example,  
a link may be relatively more susceptible to electrolysis  
in an ionic solution such as blood or most other bodily  
fluids than is a vaso-occlusive member. The link may  
15 also be tapered or otherwise modified, or coated with an  
insulative polymer and scored to limit the area of  
electrolytic disintegration of the link to a more  
discrete region or point.

The implant 230 can also have a fibrous structure  
20 carried by the core member. One exemplary fibrous  
structure includes one or more nano-scale fibers or  
nanofibers having diameters ranging from, for example, 50  
to 10000 nm. The nanofibers may provide or enhance  
thrombogenic properties of the vaso-occlusive device.  
25 The core member is preferably made of a biodegradable  
material. Biodegradable or absorbable materials suitable  
for the core member may include, but are not limited to,  
synthetic polymers, polysaccharides, and proteins.  
Suitable polymers may include, for example, polyglycolic  
30 acid, polylactic acid, polycaprolactone,  
polyhydroxybutyrate, polyhydroxyvalerate, polydioxanone,  
polycarbonates, polyanhydrides, polyhydroxyalkanoates,  
polyarylates, polysaccharides, polyamino acids, and

copolymers thereof. In addition or alternatively, proteins may be used, such as collagen, elastin, fibrin, fibrinogen, fibronectin, vitronectin, laminin, silk, and/or gelatin. In addition or alternatively,

5 polysaccharides may be used, such as chitin, chitosan, cellulose, alginate, hyaluronic acid, and chondroitin sulfate. Many of these materials are commercially available. Fibrin-containing compositions are commercially available, for example from Baxter.

10 Collagen-containing compositions are commercially available, for example, from Cohesion Technologies, Inc., of Palo Alto, California. Absorbable materials may be used alone or in any combination with each other. The absorbable material may also be a mono-filament or multi-

15 filament strands.

The implant 230 can also be a device that disrupts an endothelium of a well of the aneurysm in this matter reduces the risk of the aneurysm wall expanding, thinning and/or rupturing.

20 As discussed in connection with Figures 3A-J, a further exemplary implant 230 is an embolic containment device. The embolic containment device is used to contain or secure a second implant, such as a vaso-occlusive implant, within an aneurysm by reducing the

25 size of the aneurysm neck. One exemplary embolic containment device expands or opens in a "disc" like shape to fill the lower portion of the aneurysm sack, the neck of the aneurysm. The device can also extend down into the blood vessel to capture embolic debris.

30 Exemplary embolic containment implant materials include, but are not limited to, braided polyester, nanofibers, and various mesh materials. In addition to containing a vaso-occlusive device within an aneurysm, the embolic

containment device can also assist with healing the aneurysm since it serves as a scaffold across the aneurysm neck, thereby reducing blood flow and facilitating clotting.

5           A further exemplary implant 230 is a stent. A stent can serve as an embolic containment implant or a vaso-occlusive implant. For example, a stent can be used to reduce the size of the aneurysm neck, and a vaso-occlusive coil is inserted between stent sections into an  
10   aneurysm. A stent can also be covered or coated with materials that facilitate clotting so that the stent can be inserted into the aneurysm and occlude the aneurysm. For example, with reference to the embodiment shown in Figures 2A-J, a self-expanding stent can be attached to  
15   the distal end of the pusher member 240 as they are advanced through the outer catheter 110 and then be released upon reaching the aneurysm site.

One type of stent that can be delivered with the invention is a self expanding stent, e.g., a NiTi self  
20   expanding stent. A balloon expandable stent, such as a polymer or stainless steel expandable stent, can also be utilized.. Other exemplary stents include coated or non-coated stents, covered or partially covered stents, high density braid stents, and stents covered in-situ.

25           Other implants suitable for use with the invention include blood filters and clot grabbers or implants that secure a segment of a clot in a vessel. These implants, however, may be removed from the vessel instead of being detached or released into an aneurysm or vascular site.

30           Further, persons of ordinary skill in the art will recognize that various implants 230 may be coated or mixed with radiopaque materials for fluoroscopy tracking through the vascular space 210. Exemplary radiopaque

materials include, but are not limited to, metals (e.g. tantalum, gold, silver, tungsten, rhenium, palladium, rhodium, or platinum), barium sulfate, bismuth oxide, bismuth subcarbonate, and the like. One exemplary  
5 coating is a platinum/tungsten alloy, e.g., 8% tungsten and the remainder platinum. These metals have significant radiopacity and in their alloys may be tailored to accomplish an appropriate blend of flexibility and stiffness. They are also largely  
10 biocompatible. Certain polymers are also suitable as vaso-occlusive member material either alone or in conjunction with metallic markers to provide radiopacity. These materials are chosen so that the procedure of locating the vaso-occlusive member within the vessel may  
15 be viewed using radiography.

The particular type, design and configuration of an implant 230 that can be delivered with the lumen reducing catheter system 100 of the invention can be selected based on various factors, such as the particular  
20 application, treatment, and patient.

The system of the invention allows a delivery catheter to be inserted at a vascular site more effectively, while reducing or minimizing damage to surrounding vascular tissue and walls. The gap between  
25 the guide wire and the outer catheter is effectively minimized or reduced with the reducing catheter, allowing the distal ends of the delivery and reducing catheters to be maneuvered along the guide wire through sharper turns, "Y" sections and other divisions in blood vessels  
30 by limiting radial movement of the distal ends of the assembly. The delivery catheter is less likely to scrape against vessel walls or impact middle portions of "Y" sections or other divisions of vascular bodies, while

following the guide wire through sharper turns, curves or blood vessel divisions compared to conventional systems.

Further, the invention allows a vaso-occlusive implant, such as a coil, to be inserted within an  
5 aneurysm and to be retained in the aneurysm by a containment implant that effectively reduces the width of a neck of an aneurysm. As a result, the invention reduces the likelihood that a coil will be improperly secured or inadvertently released from the aneurysm as a  
10 result of slipping through a wide aneurysm neck.

Various types and sizes of implants can then be inserted through the positioned outer or delivery catheter. Having described the system for delivering an implant according to the invention, persons of ordinary  
15 skill in the art will recognize that the system can be modified in various ways to reduce the effective diameter or size of a delivery catheter lumen or cavity. For example, other delivery and reducing catheters with different sizes and proportions can be utilized.

20 Further, various types and sizes of implants can be utilized including vaso-occlusive implants, such as a coil, an embolic containment device that facilitates delivery of a vaso-occlusive device, a stent and a filter.

25

## CLAIMS

1. The system of claim 23, the vascular site comprising  
5 a tumor.

38. A system for delivering a first implant through a  
vascular space to a vascular site in a body, comprising:  
10 a guide;  
a first member having a distal end and a proximal  
end and defining a first cavity;  
a second member having a distal end and a proximal  
end and defining a second cavity, the second member being  
15 insertable within the first cavity;  
the distal ends of the first and second members  
being advancable along the guide and through the vascular  
space to the vascular site, thereby advancing the first  
implant to the vascular site.

20 2. The system of claim 1, the first implant comprising  
a containment implant.

3. The system of claim 1, the first implant being  
25 advanced by the distal end of the first member.

4. The system of claim 1, the first implant being  
advanced by the distal end of the second member.

30 5. The system of claim 1, the first implant being  
advanced by the distal ends of the first and second  
members.

6. The system of claim 1, the first member, the second member and the guide being removed from the vascular space after the first implant is delivered to the vascular site.

5

7. The system of claim 1, further comprising a second implant, the second implant being inserted through the second cavity of the second member and into the vascular site.

10

8. The system of claim 7, the first implant containing the second implant within the vascular site.

9. The system of claim 7, the second implant comprising  
15 inserting a vaso-occlusive implant.

10. The system of claim 9, the vaso-occlusive implant comprising a vaso-occlusive coil.

20 11. The system of claim 1, the guide comprising a wire guide.

12. The system of claim 1, the first member comprising a first annular catheter defining the first cavity.

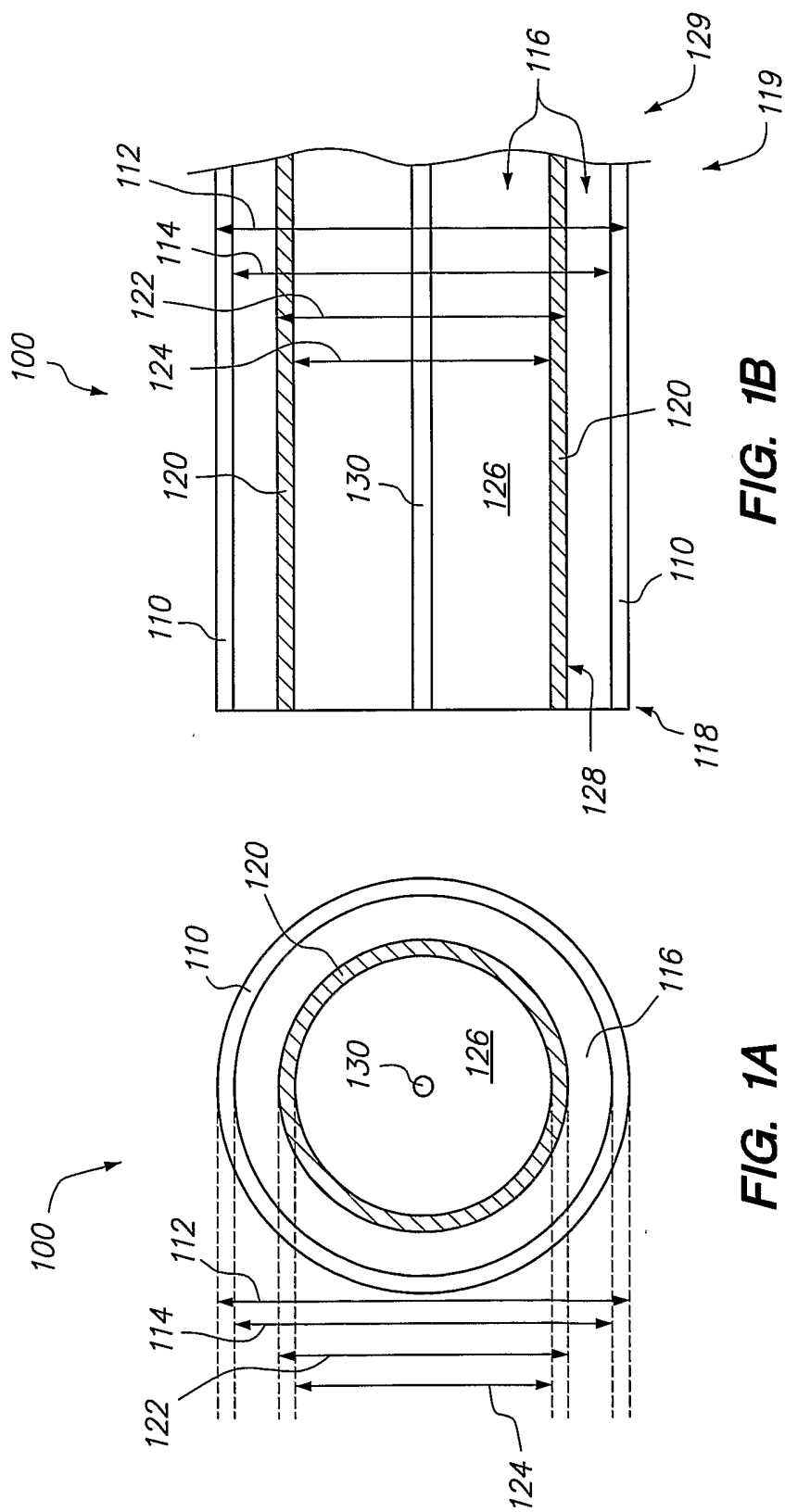
25

13. The system of claim 12, the first annular catheter having outer diameter of about 0.66mm to about 1.3mm.

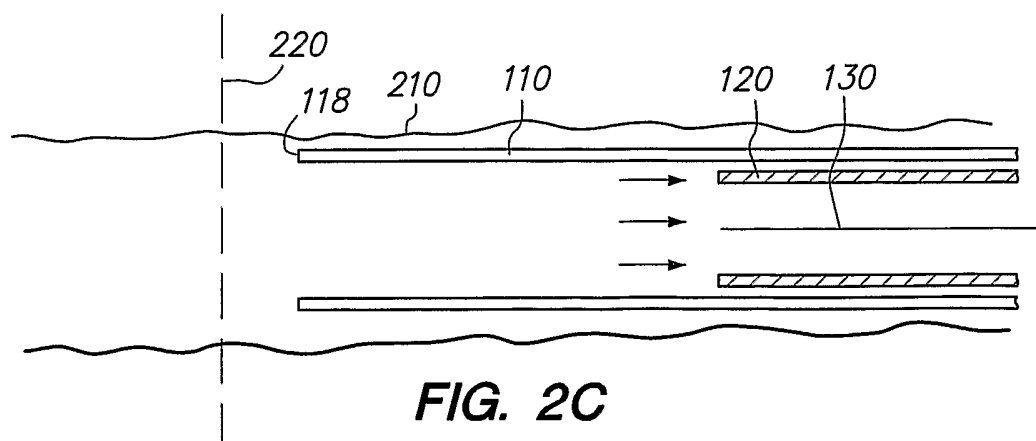
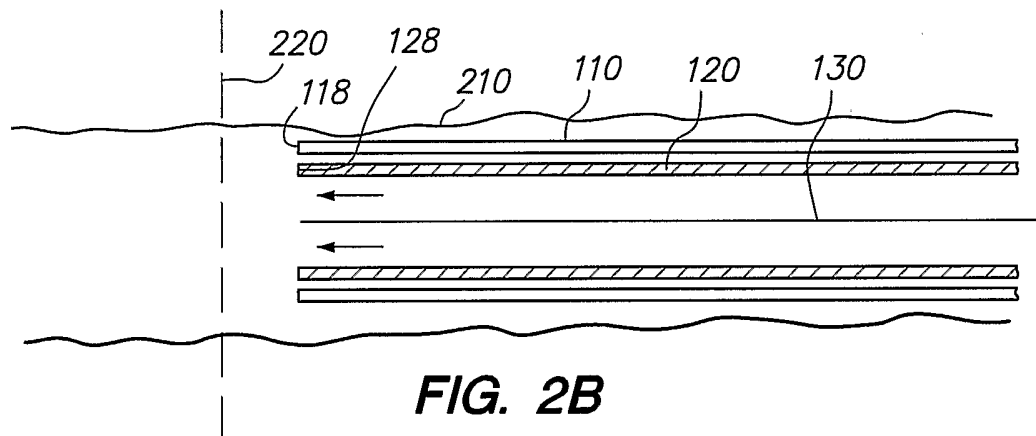
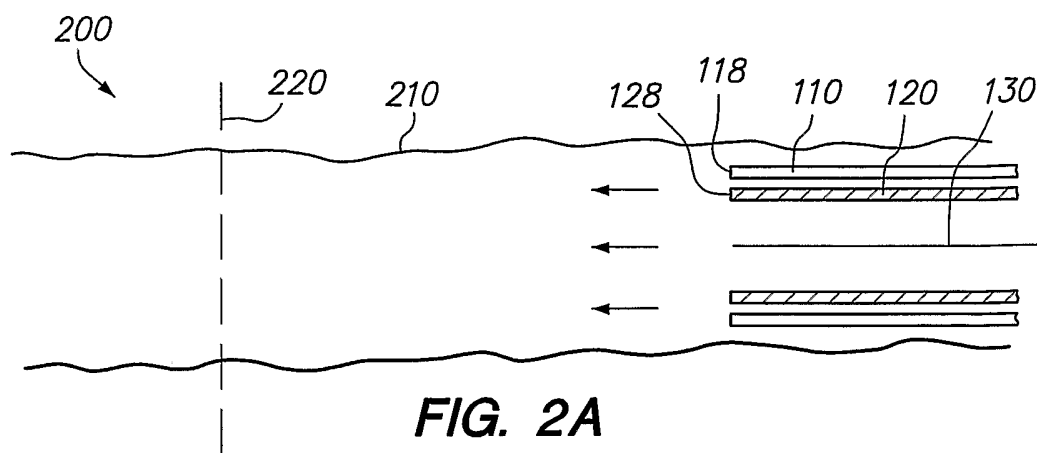
14. The system of claim 12, the first cavity having a  
30 diameter of about 0.5mm to about 1.25mm.

15. The system of claim 1, the second member comprising a second annular catheter defining the second cavity.

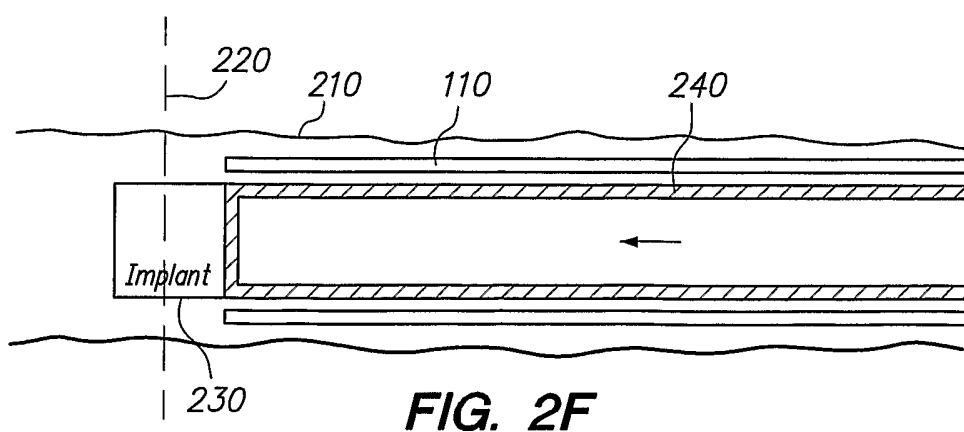
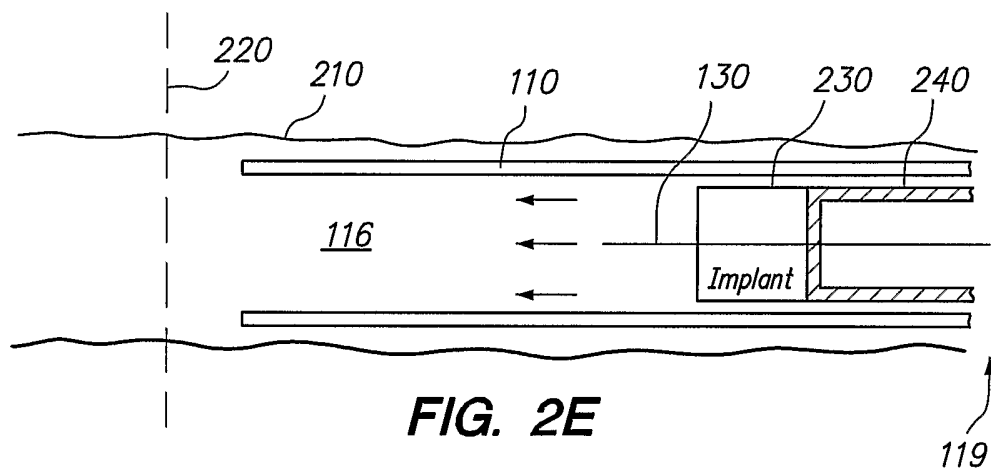
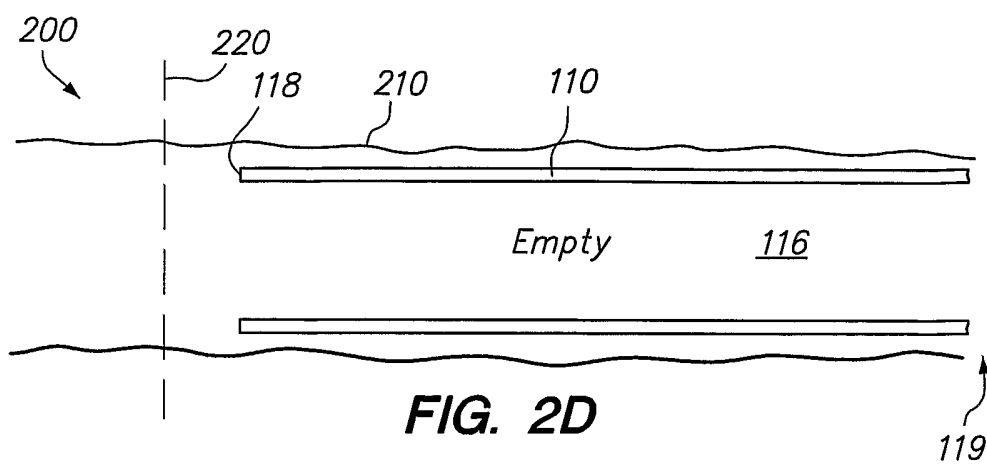
16. The system of claim 15, the second annular catheter having an outer diameter of about 0.45mm to about 1.20mm.
- 5 17. The system of claim 15, the second cavity having a diameter of about 0.35mm to about 1.0mm.
18. The system of claim 1, the distal ends of the first and second members being generally aligned when they are  
10 advanced along the guide and through the vascular space.
19. The system of claim 1, the vascular site comprising an aneurysm.
- 15 20. The system of claim 1, the vascular site comprising a tumor.

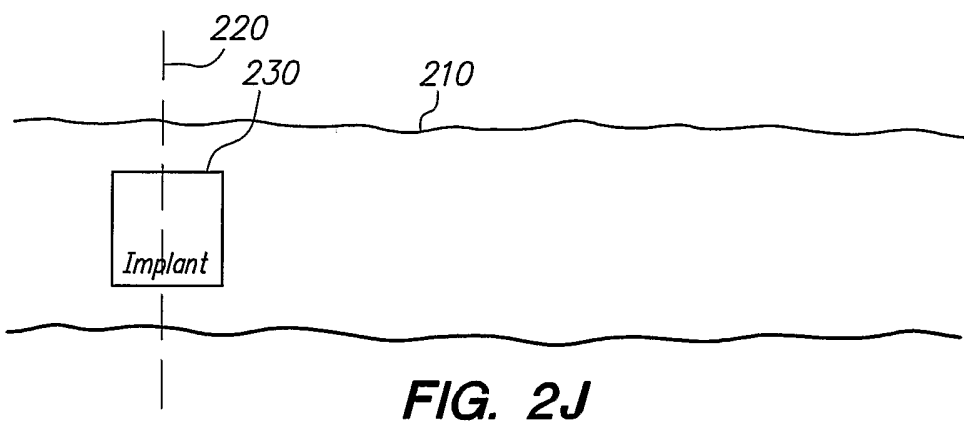
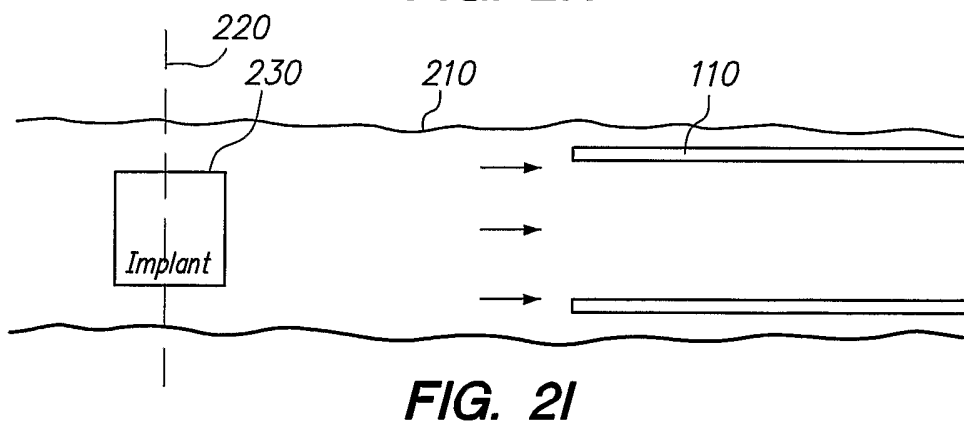
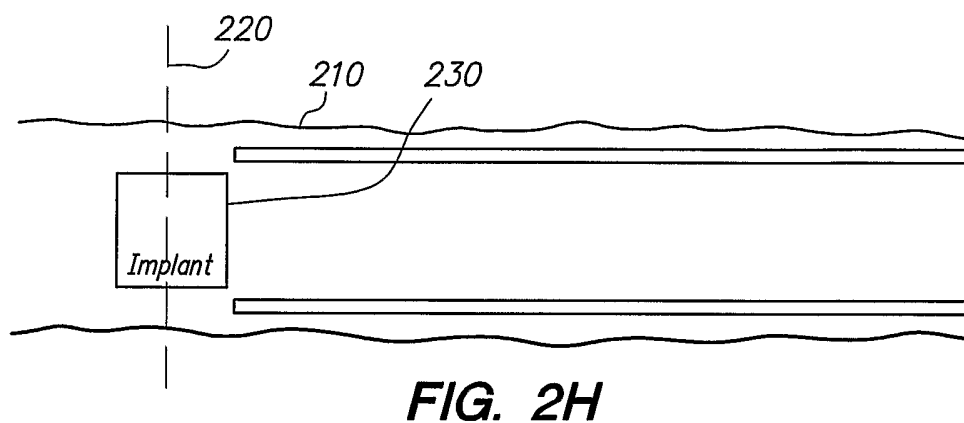
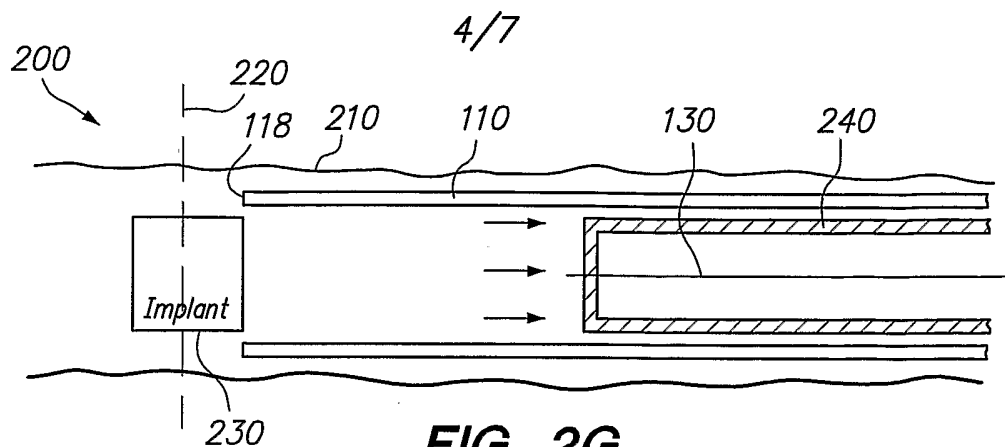
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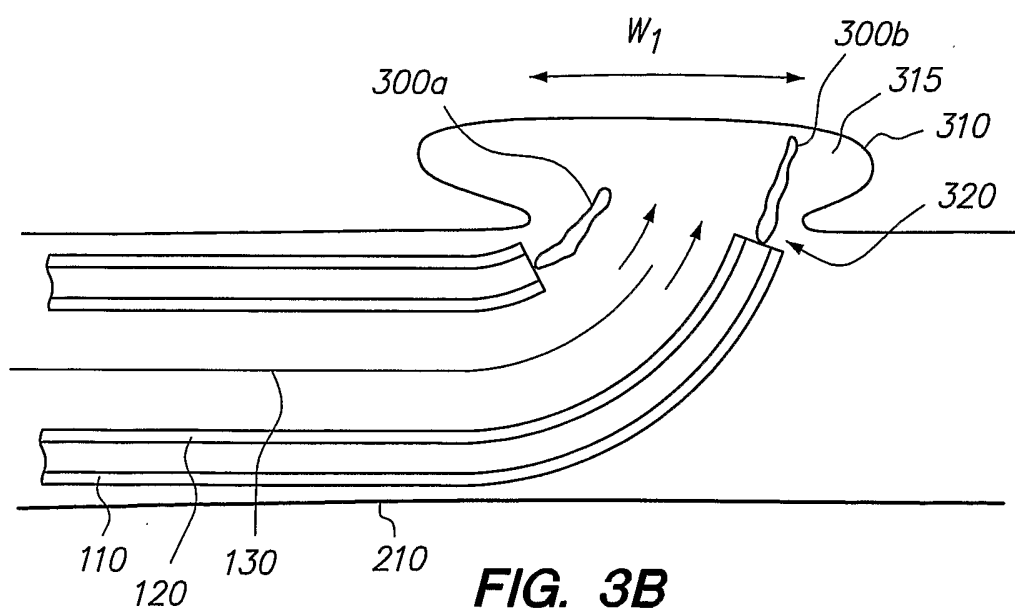
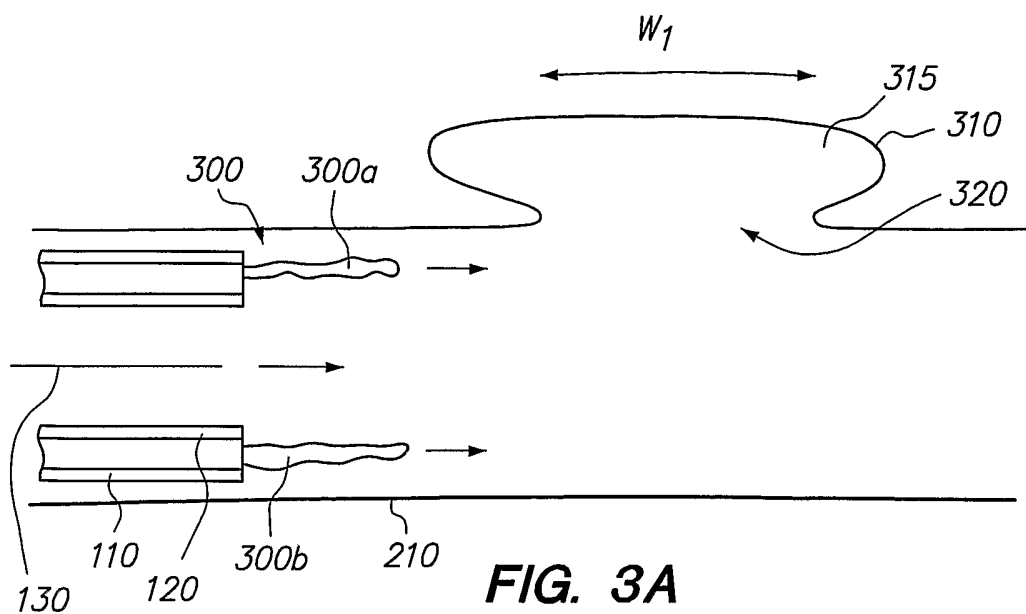


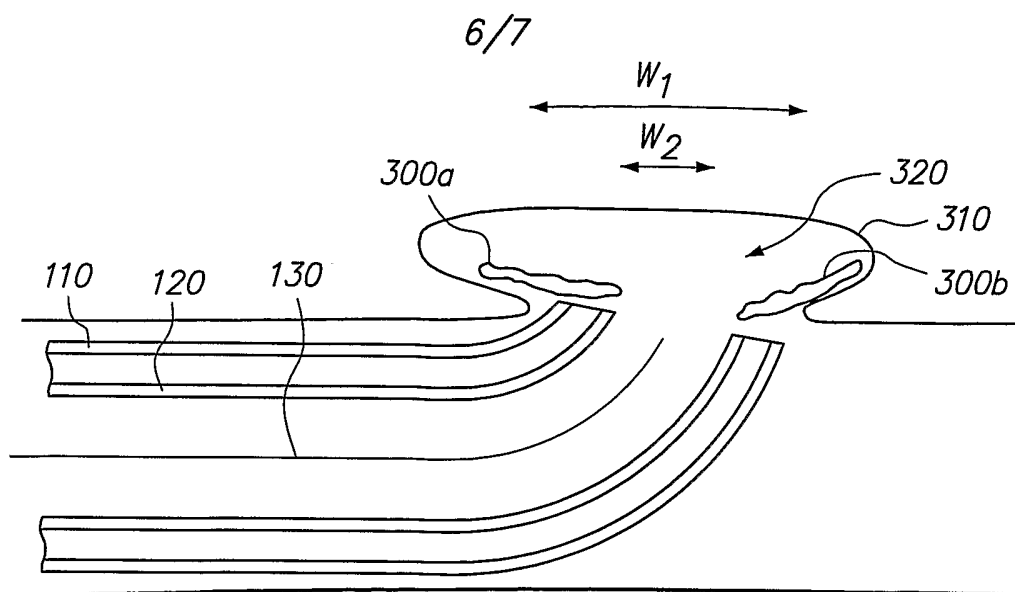
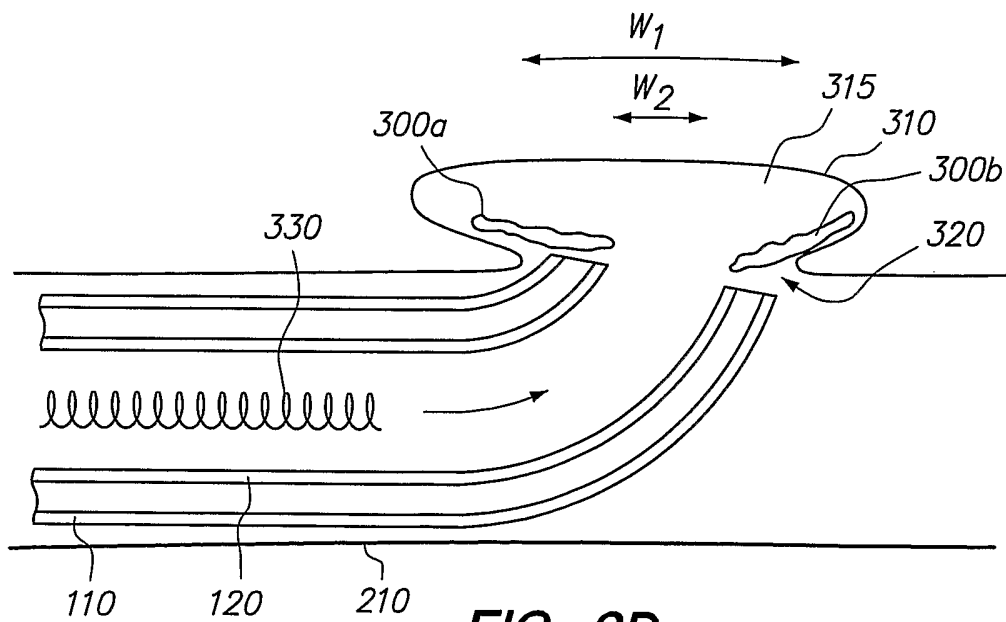
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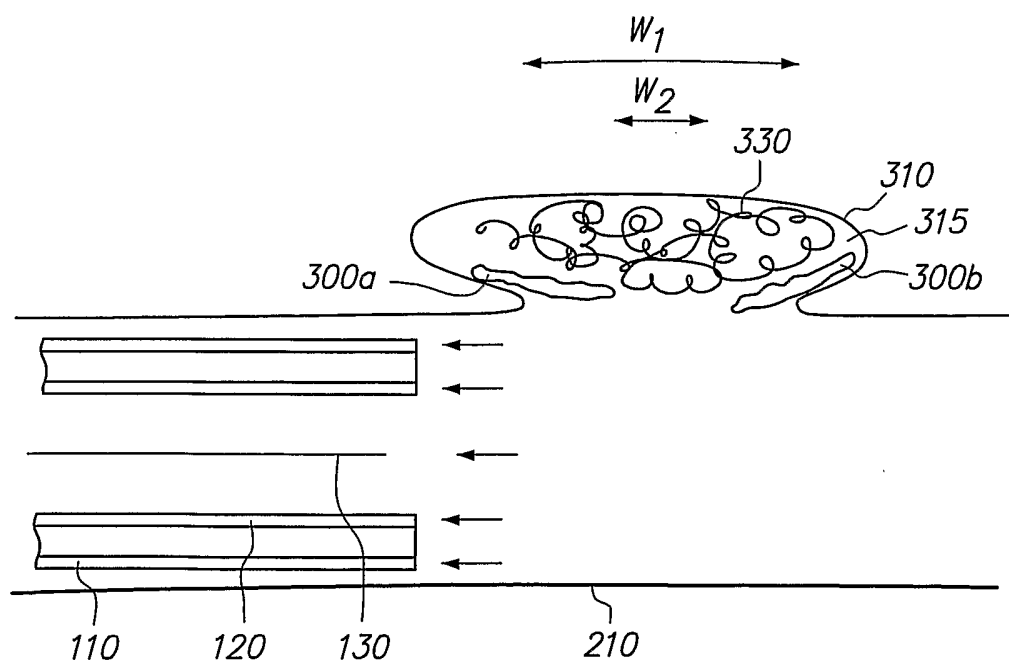
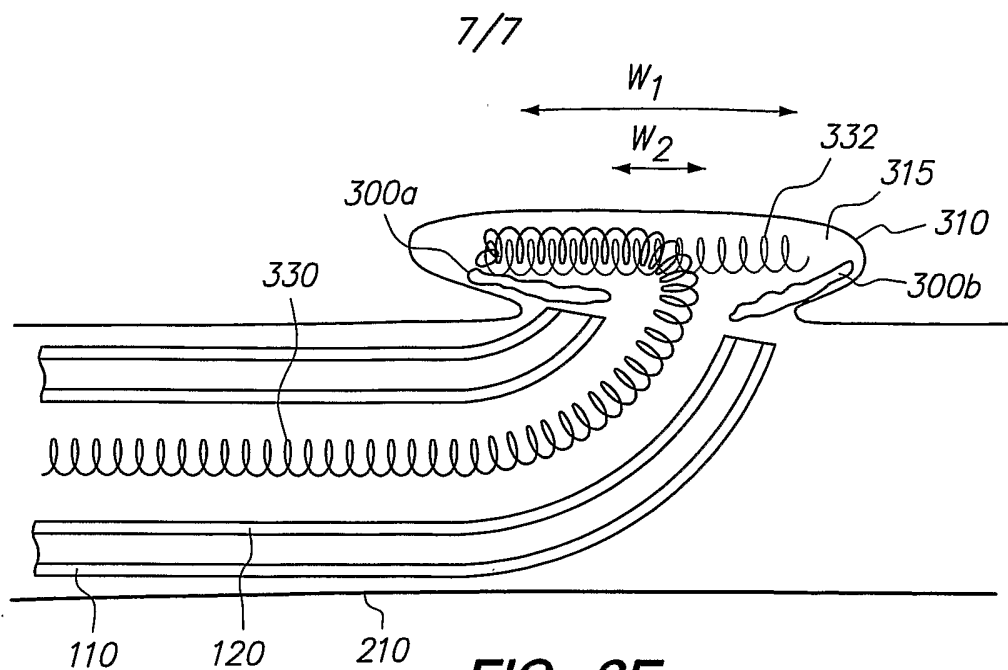




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**FIG. 3C****FIG. 3D**



# INTERNATIONAL SEARCH REPORT

PCT/US2004/016966

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

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## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages                                                                     | Relevant to claim No. |
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

26 November 2004

Date of mailing of the international search report

02/12/2004

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