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(54) Title: BLOOD VESSEL OCCLUSION DEVICE

(57) Abstract: Various blood vessel occlusion devices (plugs) are disclosed. In all cases, the plugs, or at least portions thereof, are made of silicone or other biocompatible material and include a pilot hole which permits an insertion device to be used to insert the plug into the blood vessel. The plugs of the present invention allow blood vessels to be rapidly occluded. Certain embodiments of the plug may be used to permanently seal the blood vessel, while other embodiments of the plug are designed to temporarily occlude a blood vessel. The plugs of the present invention are designed to be effective even in cases of deposits in the artery.

BLOOD VESSEL OCCLUSION DEVICE

This is a continuation-in-part of U.S. Serial No. 10/086,753 filed on March 1, 2002, entitled "Blood Vessel Occlusion Device" (Attorney Docket No. EU159411896US), which is hereby incorporated by reference herein in its entirety.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to medical devices that are implanted in the human body. In particular, the present invention relates to medical devices that can be used to occlude blood vessels on a temporary or permanent basis.

2. State of the Art

Various implantable medical devices have been developed for treating ailments of the human body. One such implantable medical device is an occlusion device used to occlude blood vessels i.e. to prevent the flow of blood through these vessels. These occlusion devices may be used to occlude blood vessels either temporarily or permanently. In certain cases, for example, during a surgery, these devices may be used to stem the flow of blood while the surgery is performed. In other cases, such as in treatment of certain cardiovascular diseases, permanent occlusion devices may be used.

There are numerous situations where certain blood vessels such as arteries and veins may have to be occluded. Surgical treatment of an aneurysm is one such situation where occlusion devices are required. An aneurysm is a balloon-like swelling of a blood vessel such as an artery. This swelling may be caused due to diseases such as arteriosclerosis or cystic medial necrosis, or due to infections such as syphilitic or mycotic infections, or even due to trauma. Typically, the aneurysm results in a weakening of the wall of the artery or other blood vessel in which it occurs. The region of the artery (or the blood vessel) that has been affected by the aneurysm may tear or rupture over time because of sustained blood pressure. If the artery tears or ruptures, and consequently bleeding occurs, then there may be severe consequences for the patient. For instance, if an aneurysm affected artery in the brain bursts due to a weakened wall, then cranial hemorrhaging and subsequent death may occur. Hence,

aneurysms occurring in certain regions of the body may lead to life-threatening conditions and therefore need to be detected early and treated suitably.

Although an aneurysm may occur in any location of the human body, it is more likely to occur in the abdominal aorta. This type of aneurysm is referred to as an Abdominal Aortic Aneurysm (AAA). An AAA usually results in a large swelling in the affected region of the aorta. In cases where the aneurysm affected region of the aorta exceeds 6 cm in diameter, surgery may be necessary to treat the aneurysm as the weakened walls of the aorta may not be able to withstand the pressure of blood flowing through the aorta, and in extreme cases, the aorta may rupture in the affected region leading to internal hemorrhaging.

Surgical treatment of AAA typically provides an alternate path for the flow of blood so as to bypass the aneurysm affected region of the aorta. Typically, the bypass is a graft that replaces the affected portion of the aorta.

In this surgery, a surgeon makes an incision in the abdominal wall of the patient and gains access to the aneurysm affected region of the aorta. Then, the surgeon clamps the aorta above and below the aneurysm affected region in order to block the flow of blood through the aorta. In the next step, the surgeon opens the aneurysm affected region of the aorta and provides an alternate path for the flow of blood with the bypass graft. As a result, the affected region is bypassed.

Once the affected portion of the aorta has been opened, the blood vessels that originate from this cut region of aorta (i.e., the collateral circulation system) are exposed and begin to bleed profusely. Hence, in such cases it is necessary to seal these blood vessels to prevent excessive loss of blood. In such cases, occluding means are often employed during the surgery to prevent excessive bleeding from such blood vessels. In a collateral circulation system, two or more arteries are interconnected by multiple smaller arteries and/or capillaries. Such an interconnected network of arteries leads to sufficient redundancy in the network. Therefore, if one of these arteries is blocked or damaged or otherwise rendered ineffective, blood is still supplied to regions of the body. However, this redundancy in the circulation system also leads to problems when one of these arteries is cut or left open to a larger artery such as the aorta. For instance, the exposed branch arteries may start to bleed since the exposed artery would draw blood from the collateral circulation system. Consequently, arteries that are exposed during this surgical procedure need to be quickly and

effectively sealed. In this surgery, opening of the aneurysm affected region of the aorta often exposes 4 to 6or more collateral arteries that originate in this region. The surgeon must occlude these arteries.

Three techniques are usually employed to occlude blood vessels. These include sealing of a blood vessel using a finger, sealing of the blood vessel using a clamp or a clip, and suturing of the blood vessel (which is most commonly used in the AAA surgery).

The first technique is the simplest, as a surgeon or other person assisting in the surgery seals the cut blood vessel using a finger. This technique is regularly used since the finger may be readily applied to seal the cut blood vessel. However, this method is often not suitable due to certain drawbacks. First, the space available in the site of the surgery may be reduced considerably. Second, the hand of the person may not allow the blood vessel to be clearly seen and operated upon, and hence this technique may hinder access to the site of the surgery. Third, where numerous blood vessels must be simultaneously sealed, it is difficult to accomplish this using fingers. Fourth, this technique is not a permanent sealing arrangement. Because of these drawbacks, this technique is rarely used to occlude the affected blood vessels (for the entire duration of the surgery). Instead, this technique is sometimes used while another occluding means is applied to the blood vessel.

In an alternative technique, a clamp or a clip may be used to occlude a blood vessel. In this technique, the clamp or clip is used to constrict the blood vessel so as to minimize blood flow through the narrow opening in the blood vessel. The surgical clamps and "ligating" clips come in a variety of shapes and sizes. In a typical design, a surgical clamp is connected to an elongated arm and is controlled with a handle. The elongated arm allows the surgeon to apply and remove the clamp easily during the surgery. Two such surgical clamps have been disclosed in U.S. Patents 5,133,724 and 5,447,515. However, such designs are not always suitable since the long arm or handle may hinder the surgeon's access to the affected blood vessel.

Alternative designs of clamps also exist where the handle or other such clamp applier may be readily removed from the site of the surgery. U.S. Patent 5,282,812 discloses one such clamp. However, such a surgical clamp has the drawback that it is difficult to quickly loosen or remove the clamp. In this method, the difficulty arises since the surgeon must apply the appropriate amount of force by hand for loosening and removing the clamp. Another

drawback of these occlusion devices is that these may not be effective in completely sealing certain blood vessels. For instance, a blood vessel such as an artery usually has a very thick wall. Therefore, it may not be possible to completely seal such an artery using a clamp or a clip. Furthermore, the clamps may slip and slide out of position if a sufficiently large clamping force is not applied. However, this large clamping force may permanently damage the wall of the artery. Finally, the use of ligating clips and clamps is a temporary arrangement because it is not desirable to leave a metallic clamp inside a human body for a long duration. Thus, clamps and clips may not always be suitable for occluding blood vessels.

A third technique to occlude blood vessels is to suture these vessels. This technique allows the blood vessel to be completely sealed. However, suturing is usually a time-consuming procedure as compared to other methods mentioned above. Consequently, suturing may not be suitable for all surgical procedures. For instance, consider the surgical procedure used to treat an aneurysm in the lumbar region of the body. In this surgical procedure, a large number of blood vessels must be occluded in order to treat the aneurysm. Hence, if the vessels are cut and sutured, as is done currently, then there may be considerable loss of blood before all blood vessels have been occluded. Moreover, there may be difficulties in the suturing process itself if there are calcium deposits in the area of the aneurysm. Calcium deposits are likely to occur in this region since aneurysms usually begin as micro-tears in the wall of the blood vessel, and calcium and other blood coagulating material are likely to deposit at the site of these tears. Furthermore, these calcium deposits may also weaken sutures that have been applied thereby decreasing the effectiveness of this technique.

Consequently, there is a need to quickly and effectively occlude blood vessels during surgical procedures. It should be noted that the need for occluding blood vessels occurs not only in surgery for treating aneurysms but also in other surgeries. Therefore, it would be desirable to have sealing devices capable of permanently and/or temporarily occluding a variety of blood vessels in different regions of the body.

SUMMARY OF THE INVENTION

It is therefore an object of the present invention to provide several means for permanently and temporarily occluding blood vessels such as an artery.

It is another object of the invention to provide means for occluding a blood vessel which has calcium or arteriosclerosis plaque deposits therein.

It is a further object of the invention to provide blood vessel occluding plugs and tools for inserting those plugs into a blood vessel.

In accord with the objects of the invention which will be discussed in more detail hereinafter, various blood vessel occlusion devices (plugs) are disclosed. In all cases, the plugs, or at least portions thereof, are made of silicone or other biocompatible material and include a pilot hole which permits an insertion device to be used to insert the plug into the blood vessel. The plugs of the present invention allow blood vessels to be rapidly occluded. Certain embodiments of the plug may be used to permanently seal the blood vessel, while other embodiments of the plug are designed to temporarily occlude a blood vessel. The plugs of the present invention are designed to be effective even in cases of deposits, such as calcium and/or plaque deposits, in the artery.

Additional objects and advantages of the invention will become apparent to those skilled in the art upon reference to the detailed description taken in conjunction with the provided figures.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a first embodiment of a permanent occlusion device inserted in a blood vessel in accordance with the present invention.

FIG. 2 is a bottom perspective view of the occlusion device of FIG. 1.

FIG. 3 is a perspective view of an insertion device in accordance with the present invention.

FIG. 4 is an exploded view of the insertion device of FIG. 3.

FIGS. 5 - 9 shows a second embodiment of a temporary occlusion device that includes a large diameter disc-like section in accordance with the present invention.

FIGS. 10 and 11 are cross-sectional views of third and fourth embodiments of the present invention where inserts formed from hard plastic are provided.

FIGS. 12A and 12B are perspective views of a fifth embodiment of the present invention; where a slidable insert formed from hard plastic is seen in first and second positions.

FIGS. 13A and 13B are perspective views of a sixth embodiment of the present invention; where a disc-like flap is section formed from an elastomeric biocompatible material.

FIG. 13C is a cross-sectional view through the central axis of the device of FIG. 13A.

DESCRIPTION OF PREFERRED EMBODIMENTS

FIG. 1 illustrates an artery 104 that has been occluded using a plug 102 in accordance with the present invention. Artery 104 has a lumen 106 through which the blood flows and plug 102 has been inserted axially into lumen 106 to occlude artery 104. Preferably, the external surface 107 of plug 102 is symmetric about an axis 108 as shown. Furthermore, the external surface 107 preferably tapers from a base 109 disposed at one end to a rounded top portion 110 as shown. To facilitate insertion of the plug 102 into artery 104, the cross-sectional diameter of the rounded end 110 is smaller than the diameter of lumen 106. Moreover, to ensure that the plug 102 remains at its desired position in the artery 104, the cross-sectional diameter of the base 109 is larger (typically on the order of 10 to 35 percent larger and preferably between 25 to 30 percent larger) than the diameter of lumen 106. The plug 102 also preferably includes spring-biased prongs 208 that extend below the base 109 and radially outward with respect to axis 108 as shown.

Artery 104 has a thick elastic wall surrounding lumen 106. This thick wall has been provided so as to withstand flow of blood at high pressure through artery 104. The elastic nature of artery 104 allows plug 102 to be tightly grasped by artery 104. More specifically, when the plug 102 is inserted into its desired position in artery 104, the larger diameter base 109 and possibly the spring-biased prongs 208 (which extend radially into the elastic wall of the artery 104) cause the elastic wall of the artery 104 to be deformed such that the plug 102 is tightly grasped by the wall of the artery 104 as shown. Therefore, the elastic nature of the walls enables the plug 102 to be effective in occluding artery 104. Furthermore, the elastic walls of artery 104 also permit a small range of plugs 102 of varying diameter to be used for different sizes of arteries 104. Thus, plug 102 of a certain size may be used for occluding

arteries of different sizes. Typically, plug 102 ranges from 1 mm to 4 mm in maximum cross-sectional diameter.

As shown in FIG. 2, the exterior surface 107 of plug 102 is formed by a layer 202 of biocompatible material. Preferably, silicone is used to form layer 202. Silicone is useful since it is non-toxic, chemically inert, substantially insoluble in blood and substantially non-immunogenic. In addition to silicone, newer elastomeric biocompatible materials may also be used to manufacture the layer 202. Ongoing research and development in biocompatible materials have created materials with a longer life, better strength and lower cost - all of which are desirable qualities of the material of the exterior surface layer 202. Typical examples of such materials include polyurethanes and polyisobutylene-based polymers.

Plug 102 is preferably provided with a frame structure 204 that supports the exterior surface layer 202 such that surface layer 202 withstands the forces acting upon it when the plug 102 is inserted into the artery 104. More specifically, upon inserting the plug 102 into artery 104, the elastic walls of the artery exert a compressive force on the exterior surface layer 202. Furthermore, pressure of blood in the artery 104 exerts an axial force on the exterior surface layer 202. The frame structure 204 mechanically supports the exterior surface layer 107 to counteract these forces. Preferably, the frame structure is corrugated and includes projections 206 that extend radially inward toward the central axis 108 as shown. These features provide for increased strength of the frame structure 204. In the exemplary plug shown, the frame structure 204 includes four projections that are spaced 90 degrees apart. The radial width of each projection tapers from a point near the top of the projection to the bottom of the projection as shown. The top of the frame structure 204 mechanically supports a prong structure which includes a plurality of spring-biased (preferably metal) prongs 208 and an integral base 209 which is joined to the prongs by joints 211. In the exemplary plug shown, the four spring-biased prongs 208 are spaced 90 degrees apart. In addition, the base 209 of the prong structure and the top of the frame structure 204 includes pilot holes 210a, 210b. These pilot holes are sized to receive an insertion device 300 and thereby enable plug 102 to be mounted on an insertion device 300 as described below with respect to FIG 3. Preferably, the frame structure 204, including projections 206 and prongs 208, are made of hard plastic and/or metal (such as titanium) or some other material of sufficient rigidity and strength.

In an alternative embodiment (not shown) of plug 102 of FIGS. 1 and 2, the plug 102 may be constructed without any prongs 208. In this embodiment, plug 102 may be manufactured using materials of sufficient structural rigidity and strength. Furthermore, the prongs 208 may be avoided by suitably increasing the thickness of the frame structure 204.

In a typical surgery, the plug 102 is inserted into artery 104 by substantially aligning the axis 108 of the plug 102 with the longitudinal axis of the artery 104, and by applying a force along the axis 108. The surgeon may apply this force either by hand (if feasible) and/or by using a deployment mechanism such as insertion device 300 shown in FIG. 3. This insertion device 300 has a casing 302 and a lever 306. The surgeon uses the lever 306 to operate the insertion device 300. Lever 306 enables a needle 308, housed in a tubular needle guard 310, to be retracted inwards. To insert the plug, the surgeon mounts a plug 102 on the needle 308 of the insertion device (if the plug is not already pre-mounted). This is done by inserting the needle 308 into the pilot holes 210 of the plug 102 such that the distal end 311 of the needle guard butts up against the base 209 of the prong structure. Next, the surgeon aligns the axis 108 of the plug 102 with the longitudinal axis of the artery 104, and applies an axial force to the insertion device 300, thereby inserting the needle 308 and the plug 102 mounted thereon to a desired position in artery 104. As the plug is pushed in the lumen of the artery, the downward angle of the ends of the prongs 208 enables the prongs 208 and plug body (107, 204, 206) to slide along the walls of the artery. In addition, the constricting force of the artery compresses the plug body (107, 204, 206), which in turn causes the ends of the prongs 208 to be retracted inward with respect to the central axis. In this manner, any damage caused by the prongs 208 to the inner walls of the artery is limited. When force is no longer applied by the surgeon, the prongs 208 spring outwardly and dig into the walls of the artery. The prongs 208 together with small diameter of plug 102 with respect to the diameter of the lumen of the artery 104 enables the elastic walls of the artery 104 to tightly grip and secure the plug 102 as described above. The surgeon then presses button 306 to retract the needle 308 inward such that it is housed in the needle guard 310 and becomes disengaged from the pilot holes 210, thereby releasing the plug 102 from the insertion device 300.

FIG. 4 shows an exploded view of insertion device 300. This device is essentially a spring activated device. A spring 400 and a needle guide 402 have been shown encased in casing 302. When the lever 306 is activated, it propels needle guide 402 toward the back end 312. In turn, this needle guide propels the needle 308 inwards such that it retracts into the distal end 311 of needle guard 310. Hence, the needle 308 is released from plug 102. When

the lever 306 is not activated, the spring 400 propels needle guide 402 such that it moves away from the back end 312. In turn, the needle guide propels needle 308 outward such that it is extends from the distal end 311 of guard 310. It will be apparent to one skilled in the art that alternative ways to propel the needle may be employed by the insertion device 300. A lock may be added to deactivate the lever 306 and needle guide 402 such that once the lever 306 has been activated to deploy the plug, the needle 308 remains inside and shrouded by the guard 310 to avoid accidental trauma to the patient, surgeon or nurse.

The plug device 102 of FIGS. 1 and 2 is designed to provide a permanent occlusion of an artery 104. In other words, it is not meant to be removed. Such a design is useful in many different surgical procedures, for example those requiring that one or more of the intercostal arteries (or lumbar arteries) be permanently occluded. However, in certain circumstances, it may be desirable to provide a mechanism to remove the "permanent" occlusion device. This may be accomplished by pushing on the base 209 of the prong structure 208 (e.g., by inserting a rigid needle/guide structure into pilot holes 210 and pushing with axial force). This will cause the spring-biased prongs 208 to retract radially inward. A relatively rigid sleeve may then be slipped over the retracted prongs so that the prongs 208 do not impale the arterial walls and so that the plug 102 may be pulled from the lumen 106 of the artery 104.

FIGS. 5 - 9 illustrate a second embodiment of blood vessel occlusion device 500 in accordance with the present invention. Device 500 is a plug intended for temporary occlusion of a vessel such as an artery. Preferably, the external surface 507 of plug 102 is symmetric about an axis 508 as shown. Furthermore, the external surface 507 preferably tapers from a base 509 to a rounded top portion 510 as shown. As best shown in FIGS. 8 and 9, a disc-shaped section 511 extends from the base 509, and a bottom section 512 extends from the underside of the disc-shaped section 511 as shown. The bottom section 512 includes holes 514A, 514B that pass through corresponding flat walls structures 515A, 515B as shown. A thread 513, which may be realized by a braided silk suture, a monofilament suture, other suture material, natural or artificial fibers, single filament or multifilament threads, or other suitable material that provides suitable tensile strength (hereinafter referred to as a "thread"), is provided. The thread 513 extends through the holes 514A,514B (and may be knotted as shown). The thread 513 enables the surgeon to pull on the plug device 500 and thereby remove it from artery 104. Preferably, a needle is threaded with the thread 513, and the needle/thread 513 is used to puncture the flat walls structures 515A, 515B to form the holes 514A,514B therein and contemporaneously pass the thread 513 through these holes. In

addition, the bottom section 512 preferably includes a pilot hole 516. This pilot hole 516 enables plug device 500 to be mounted on an insertion device 300, as described above with respect to FIGS. 1-4.

To facilitate insertion of the plug device 500 into artery 104, the cross-sectional diameter of the rounded end 510 is smaller than the diameter of lumen 106. Moreover, to ensure that the plug device 500 remains at its desired position in the artery 104, the cross-sectional diameter of the disc-shaped section 511 (labeled D in FIG. 5) is larger (typically on the order of 10 to 35 percent larger and preferably between 25 to 30 percent larger) than the diameter of lumen 106. Artery 104 has a thick elastic wall surrounding lumen 106. This thick wall has been provided so as to withstand flow of blood at high pressure through artery 104. The elastic nature of artery 104 allows plug 500 to be tightly grasped by artery 104. More specifically, when the plug device 500 is inserted into its desired position in artery 104, the larger diameter disc-shaped portion 511, which extends radially into the elastic wall of the artery 104, cause the elastic wall of the artery 104 to be deformed such that the plug device 500 is tightly grasped by the wall of the artery 104 as shown. Therefore, the elastic nature of the walls enables the plug device 500 to be effective in occluding artery 104. Furthermore, the elastic walls of artery 104 also permit a small range of plugs 500 of varying diameter to be used for different sizes of arteries 104. Thus, plug device 500 of a certain size may be used for occluding arteries of different sizes. Typically, plug device 500 ranges from 1 mm to 3 cm (and preferably in the range between 2 mm and 2 cm) in maximum cross-sectional diameter.

In a typical surgery, the plug device 500 is inserted into artery 104 by substantially aligning the axis 508 of the plug device 500 with the longitudinal axis of the artery 104, and by applying a force along the axis 508. The surgeon may apply this force either by hand (if feasible) and/or by using an insertion device such as insertion device 300 shown in FIG. 3. This insertion device 300 has a casing 302 and a lever 306. The surgeon uses the lever 306 to operate the insertion device 300. Lever 306 enables a needle 308, housed in a tubular needle guard 310, to be retracted inwards. To insert the plug device 500, the surgeon mounts plug device 500 on the needle 308 of the insertion device (if the plug is not already pre-mounted). This is done by inserting the needle 308 into the pilot hole 516 of plug device 500 such that the distal end 311 of the needle guard butts up against the bottom section 512. Next, the surgeon aligns the axis 508 of the plug device 500 with the longitudinal axis of the artery 104, and applies an axial force to the insertion device 300 thereby inserting the needle 308

and the plug device 500 mounted thereon to a desired position in artery 104. This force inserts plug device 500 into artery 104; the artery has a smaller diameter than that of plug device 500; further, the elastic walls of artery 104 tightly grip and secure plug device 500 as described above. The surgeon then presses button 306 to retract the needle 308 inward such that it is housed in the needle guard 310 and becomes disengaged from the pilot hole 526, thereby releasing the plug device 500 from the insertion device 300. In order to remove the plug device 500 from its occluding position in artery 104, the surgeon grasps onto and pulls thread 513, which is attached to the bottom section 512, such that the plug device 500 is pulled from the lumen 106 of the artery 104.

The plug device 500 is formed preferably from an elastomeric biocompatible material such as silicone. As described above, silicone is useful since it is non-toxic, chemically inert, substantially insoluble in blood and substantially non-immunogenic. In addition to silicone, newer elastomeric biocompatible materials may also be used such as polyurethanes and polyisobutylene-based polymers. Moreover, plug 500 is preferably formed via molding techniques such that the structural elements described above are formed from a unitary piece of material.

Preferably, the outer portion of the disc-like section 511 of the plug device 500 is capable of deflecting downward (backward toward the insertion device) when the plug device 500 is inserted into the artery 104 as shown in FIG. 6, and is capable of deflecting upward (forward away from the insertion device) when the plug device is removed from the artery 104 as shown in FIG. 7. Such deflection facilitates the insertion and removal of the plug device 500 as described above. Such deflection is preferably enhanced by forming the plug with an annular void (e.g., cutaway section) 517 in the bottom part of the disc-like section 511 adjacent the bottom section 512 as best shown in FIGS. 8 and 9. This annular void 517 provides a hinge-like effect which enables the outer portion of the disc-like section 511 to deflect downward (backward) and upward (forward) when the plug device 500 is respectively inserted into and removed from the artery 104 as shown in FIGS. 6 and 7. Preferably, the upward (forward) deflection of the disc-like section 511 has a greater range than its downward (backward) deflection. The limited range of downward (backward) deflection afforded by void 517 enables the plug 500 to resist blood pressure and be readily removed at the appropriate time during treatment.

As described above, the removal thread 513 passes through holes in the bottom section 512 of the plug device 500. In alternate embodiments, the thread 513 may pass through holes that are formed in other portions of the plug device 500. For example, the thread 513 may pass through the annular void 517 and further through holes formed in the disc-like section 513 such that it wraps around the top (forward) part of the disc-like section 513.

FIGS. 10 and 11 illustrate third and fourth embodiments of blood vessel occluding devices which are similar in various ways to the second embodiment described above with respect to FIGS. 5 through 9. In the embodiment of FIG. 10, plug 500' is provided with an insert 521 is disposed along the central axis 508 of the plug device 500'. The insert 521, which is preferably formed from a hard plastic such as nylon or Liquid Crystal Polymer (LCP), includes a barbed section 522 that mechanically affixes the insert 521 to the plug body (sections 511, 509, 510). An eyelet 523 in the insert 521 is provided such that a thread 513 can extend therethrough. The thread 513, enables the surgeon to pull on the plug device 500' and thereby remove it from artery 104. The insert 521 also includes a pilot hole 524 that enables plug device 500' to be mounted on an insertion device 300, as described above.

In the embodiment of FIG. 11, plug 500" is provided with an insert 525 which is disposed along the central axis 508 of the plug device 500''. The insert 525, which is preferably formed from a hard plastic such as nylon, includes a middle section 526 disposed between a rounded top section 527 and a bottom section 528. The plug body (sections 509, 511) is slid over the rounded top section 527 such that it is mechanically supported by the middle section 536 and positioned between the rounded top section 527 and the bottom section 528. Alternatively, the plug body is molded around the middle section 536 of the insert. An eyelet 529 in the bottom (rear) section of the insert is provided such that the thread 513 can extend therethrough. The thread 513 enables the surgeon to pull on the plug device 500'' and thereby remove it from artery 104. The bottom section 528 of the insert 525 also includes a pilot hole 530 that enables plug device 500'' to be mounted on an insertion device 300, as described above with respect to FIGS. 3 and 4, or other needle-based insertion device.

The embodiments of FIGS. 10 and 11 advantageously utilize hard plastic to attachment the thread 513 to the plug device, thereby minimizing the risk of tearing the plug body when pulling on the thread 513 during removal of the plug device.

FIGS. 12A and 12B illustrate another alternative embodiment of a blood vessel occluding device 600 in accordance with the present invention. The plug device 600 includes a sliding insert 601 disposed along the central axis 608 of the plug device 600. The sliding insert 601, which is preferably formed from a hard plastic such as nylon, includes a top rounded portion 602, a coupling shaft 603, a bulbous section 604 and a bottom section 605. An umbrella-shaped plug body 606, preferably formed from an elastomeric biocompatible material such as silicone, surrounds the coupling shaft 603 and has a tapered structure that accepts the bulbous section 604 when the insert 601 is moved upward along the central axis 608 with respect to the plug body 606. In this manner, by moving the insert 601 upward along the central axis 608 with respect to the plug body 606, the bulbous section supports the plug body 606 in an expanded state whereby the diameter of the plug body 606 is increased as shown in FIG. 12A. An eyelet 607 in the sliding insert 601 is provided such that a thread 613 can extend therethrough. The thread 613 enables the surgeon to pull on the plug device 600 and thereby remove it from the lumen 106 of artery 104. When the surgeon pulls on the thread 613, the insert 601 moves downward along the central axis 608 with respect to the plug body 606, and the bulbous section 604 no longer supports the plug body 606. As a result, the plug body 606 relaxes and may be placed in a relaxed/natural state (by the artery 104) whereby the diameter of the plug body 606 is decreased as shown in FIG. 12A. This relaxed state and decreased plug diameter facilitates easy removal of the plug device 600 from the artery. The sliding insert 601 also includes a pilot hole 624 that enables plug device 600 to be mounted on an insertion device 300, as described above.

To facilitate insertion of the plug device 600 into artery 104, the cross-sectional diameter of the rounded end 602 is smaller than the diameter of lumen 106. Moreover, to ensure that the plug device 600 remains at its desired position in the artery 104, the maximum cross-sectional diameter of the plug body 606 in its expanded state is larger (typically on the order of 10 to 35 percent larger and preferably between 25 to 30 percent larger) than the diameter of lumen 106. Artery 104 has a thick elastic wall surrounding lumen 106. This thick wall has been provided so as to withstand flow of blood at high pressure through artery 104. The elastic nature of artery 104 allows plug 500 to be tightly grasped by artery 104 when the plug 600 is in its expanded state. More specifically, when the plug device 600 is inserted into its desired position in artery 104, the larger diameter plug body 606 (in its expanded state), which extends radially into the elastic wall of the artery 104, causes the elastic wall of the artery 104 to be deformed such that the plug device 600 is tightly grasped

by the wall of the artery 104 as shown in FIG. 12A. Therefore, the elastic nature of the walls enables the plug device 600 to be effective in occluding artery 104. Furthermore, the elastic walls of artery 104 also permit a small range of plugs 600 of varying diameter to be used for different sizes of arteries 104. Thus, plug device 600 of a certain size may be used for occluding arteries of different sizes. Typically, plug device 600 ranges from 1 mm to 3 cm (and preferably in the range between 2 mm and 2 cm) in maximum cross-sectional diameter.

FIGS. 13A - 13C illustrate another exemplary blood vessel occlusion device 700 in accordance with the present invention. Preferably the external surface 707 tapers from a base 709 to a rounded top portion 710 as shown. As best shown in the cross-section of FIG. 13C, a large diameter disc-shaped flap 711 extends from the base 709, and a bottom section 712 extends from the underside of the disc-shaped flap 711 as shown. The bottom section 712 includes holes 714A, 714B that pass through corresponding flat walls structures 715A, 715B as shown. A thread 713 extends through the holes (and may be knotted). The thread 713 enables the surgeon to pull on the plug device 700 and thereby remove it from artery 104. In addition, the bottom section 712 preferably includes a pilot hole 716 as best shown in

Fig. 13C. This pilot hole 716 enables plug device 700 to be mounted on an insertion device 300, as described above.

To facilitate insertion of the plug device 700 into artery 104, the cross-sectional diameter of the rounded end 710 is smaller than the diameter of lumen 106. Moreover, to ensure that the plug device 700 remains at its desired position in the artery 104, the cross-sectional diameter of the disc-shaped flap 711 is larger (typically on the order of 10 to 35 percent larger and preferably between 25 to 30 percent larger) than the diameter of lumen 106 when inserted into the lumen of the artery. This inserted state is shown in Fig. 13A. Artery 104 has a thick elastic wall surrounding lumen 106. This thick wall has been provided so as to withstand flow of blood at high pressure through artery 104. The elastic nature of artery 104 allows plug 700 to be tightly grasped by artery 104. More specifically, when the plug device 700 is inserted into its desired position in artery 104, the larger diameter disc-shaped flap 711, which extends radially into the elastic wall of the artery 104, cause the elastic wall of the artery 104 to be deformed such that the plug device 700 is tightly grasped by the wall of the artery 104. Therefore, the elastic nature of the walls enables the plug device 700 to be effective in occluding artery 104. Furthermore, the elastic walls of artery 104 also permit a small range of plugs 700 of varying diameter to be used for different sizes of arteries 104.

Thus, plug device 700 of a certain size may be used for occluding arteries of different sizes. Typically, plug device 700 ranges from 1 mm to 3 cm (and preferably in the range between 2 mm and 2 cm) in maximum cross-sectional diameter. In order to remove the plug device 700 from its occluding position in artery 104, the surgeon grasps onto and pulls thread 713, which is attached to the bottom section 712, such that the disc-like flap 711 collapses as shown in FIG. 13B, and the plug device 700 is pulled from the lumen 106 of the artery 104.

Preferably, the plug device 700 is formed from an elastomeric biocompatible material such as silicone. As described above, silicone is useful since it is non-toxic, chemically inert, substantially insoluble in blood and substantially non-immunogenic. In addition to silicone, newer elastomeric biocompatible materials may also be used such as polyurethanes and polyisobutylene-based polymers. Moreover, plug 700 is preferably formed via molding techniques such that the structural elements described above are formed from a unitary piece of material.

The plug devices of FIGS. 5-13C are designed to provide temporary occlusion of an artery 104. In other words, they are meant to be easily removed. Such a design is useful in many different surgical procedures that require temporary replacement of an artery. This function is typically provided by a clamp or balloon device.

While the present invention has been discussed above in connection with surgical repair of an abdominal aortic aneurysm, it will be apparent to those skilled in the art that it may also be applied to treat other aneurysms, such as abdominal iliac aneurisms, whereby it is required that the supply of blood be cut off to the diseased vessel. In can also be used in other surgical procedures. For example, it can be used to occlude an artery in conjunction with an artery bypass procedure, such as coronary artery bypass, tibial artery bypass which is typically calcified or other vessel bypass procedures. It can also be used as a substitute for modern embolization treatments wherein one of a variety of materials (such as gel-foams, Polyvinyl alcohol material, metal coils, glue), depending on whether vessel occlusion is to be temporary or permanent, is passed through a catheter whose tip lies in or near the vessel to be closed. Such embolization treatments are commonly used to control bleeding from injury (e.g., car accident, gun shot wound, knife wound), a tumor, an ulcer or some other cause on an emergency basis. In addition, such embolization treatments are commonly used to treat arteriovenous malformations (AVMs) . In other instances, the plugs of the present invention may be used to occlude arteries in other regions of the body. Furthermore, these plugs may

also be used to occlude other blood vessels such as veins and capillaries. The plugs may be utilized in permanent or temporary procedures.

There have been described and illustrated herein several embodiments of plugs for occlusion of a blood vessel and methods for the use thereof. While particular embodiments of the invention have been illustrated and described, it is not intended that the invention be limited thereto, as it is intended that the invention be as broad in scope as the art will allow and that the specification be read likewise. Thus, while particular materials have been disclosed, it will be appreciated that other materials can be used as well. In addition, while particular sizes of plugs have been disclosed, it will be understood that different sized plugs can be used for use in certain blood vessels. Further, while the plugs have been disclosed with reference to relative direction (e.g., top, bottom, front, rear, etc.), it will be understood that these terms are relative terms and not intended to be limiting with respect to the orientation of the plugs in space. In addition, while the plugs have been disclosed as being provided separately from an insertion device, it will be appreciated that the plugs may be pre-mounted on insertion devices, and sets of plugs and insertion devices may be sold as a kit for a particular surgery. In addition, while it has been disclosed that a thread may be affixed to the plug devices described herein and pulled to thereby remove the plug device from the occluded vessel, it will be appreciated that other material with sufficient tensile strength, such as metal or plastic, can be substituted for this purpose. Numerous other modifications, changes, variations, substitutions and equivalents will be apparent to those skilled in the art. It will therefore be appreciated by those skilled in the art that those modifications, changes, variations, substitutions and equivalents could be made to the provided invention without deviating from its spirit and scope as claimed.

What is claimed is:

1. A device for occluding a blood vessel having an interior diameter, comprising:

a body comprising a forward section having a tapered outer surface, and a flexible large diameter section adjacent said forward section having a diameter greater than the interior diameter of the blood vessel; and

removal means attached to said body and extending behind said body, said removal means adapted for being held and pulled in order to remove said body from the blood vessel.

2. The device according to claim 1, wherein:

said removal means is a thread attached to said body.

3. The device according to claim 1, which is inserted into the blood vessel by use of an insertion device, further comprising:

said body has a longitudinal axis and a pilot hole along said longitudinal axis for receiving the insertion device.

4. The device according to claim 1, wherein:

said flexible large diameter section is capable of flexing in a first direction when said body is inserted into the blood vessel in order to reduce a diameter of said device during insertion, and is capable of flexing in a second direction opposite said first direction when said body is removed from the blood vessel in order to reduce said diameter of said device during removal.

5. The device according to claim 1, wherein:

said body comprises a unitary piece of elastomeric biocompatible material formed via molding.

6. The device according to claim 5, wherein:

said elastomeric biocompatible material comprises silicone.

7. The device according to claim 1, wherein:

said large diameter section comprises a disc-like section.

8. The device according to claim 7, further comprising:

an annular recess formed on a bottom side of said disc-like section to facilitate flexing of said disc-like section.

9. The device according to claim 1, wherein:

said forward section of said body increases in diameter from a forward rounded tip back toward said flexible large diameter section.

10. The device according to claim 2, wherein:

said body further comprises at least one substantially flat wall disposed behind said large diameter section, said wall defining at least one hole for receiving said thread.

11. The device according to claim 10, wherein:

said at least one hole is formed by piercing said wall with a needle.

12. The device according to claim 2, wherein:

said body defines at least one hole for receiving said thread.

13. The device according to claim 1, further comprising:

an insert disposed along a central axis of said body and mechanically attached to said body.

14. The device according to claim 13, wherein:

said insert is formed from a hard material relative to said body.

15. The device according to claim 14, wherein:

said insert includes an eyelet for receiving said removal means.

16. The device according to claim 14, wherein:

said insert includes a plurality of barbs which engage said body.

17. The device according to claim 14 which is inserted into the blood vessel by use of an insertion device, wherein:

said insert has a longitudinal axis and a pilot hole along said longitudinal axis for receiving the insertion device.

18. The device according to claim 17, wherein:

said insert includes a top rounded portion and a shaft, said body coupled around said shaft.

19. The device according to claim 13, further comprising:

said insert is a sliding insert disposed along a central axis of the device, said sliding insert including a top rounded portion, a coupling shaft, a bulbous section and a bottom section.

20. The device according to claim 19 which is inserted into the blood vessel by use of an insertion device, wherein:

said bottom section of said sliding insert includes a pilot hole for receiving the insertion device, said body is substantially umbrella-shaped and formed from an elastomeric biocompatible material that surrounds said coupling shaft and that has a tapered structure that accepts said bulbous section when said sliding insert is moved forward along a longitudinal axis of said body by the insertion device such that said bulbous section supports said body in an expanded state whereby a diameter of said body is increased.

21. The device according to claim 20, wherein:

said bottom section of said sliding insert includes an eyelet for receiving said removal means, wherein when an axial force on said removal means is exerted whereby the sliding insert moves backward along the central axis with respect to said body such that said bulbous section does not support said body, thereby placing said body in a relaxed state wherein said diameter of said body is decreased.

22. The device according to claim 21, wherein:

said removal means is a thread that passes through said eyelet.

23. Apparatus for occluding a blood vessel having an interior diameter, comprising:

a) a plug device including

(i) a body comprising a forward section having a tapered outer surface, and a flexible large diameter section adjacent said forward section having a diameter greater than the interior diameter of the blood vessel, and

(ii) removal means attached to said body and extending behind said body, said removal means adapted for being held and pulled in order to remove said body from the blood vessel; and

b) an insertion device having means to attach said body to the insertion device.

24. The apparatus according to claim 23, wherein:

said body has a pilot hole which receives said means to attach.

25. An apparatus according to claim 24, wherein:

said insertion device comprises a needle, a tubular needle guard surrounding said needle, said needle fitting into said pilot hole of said body, and a spring-biased lever operable to retract said needle into said tubular needle guard.

26. An apparatus according to claim 23, wherein:

said plug device includes an insert formed of hard material relative to said body, said insert extending along a longitudinal axis of said plug device, said insert including a pilot hole receiving said means to attach.

27. An apparatus according to claim 26, wherein:

said insertion device comprises a needle, a tubular needle guard surrounding said needle, said needle fitting into said pilot hole of said insert, and a spring-biased lever operable to retract said needle into said tubular needle guard.

28. An apparatus according to claim 23, wherein:

said plug device is mounted on said insertion device.

29. A kit including at least one insertion device according to claim 23 and a plurality of plug devices according to claim 23.

30. A kit including a plurality of insertion devices according to claim 23 and a plurality of plug devices according to claims 23 mounted on said plurality of insertion devices.

31. A device for occluding a blood vessel having an interior diameter, comprising:

a body comprising a tapered outer surface and a flexible large diameter section having a diameter greater than the interior diameter of the blood vessel; and

an insert into said body comprising a plurality of spring-biased prongs extending beyond said body and radially outward with respect to a central axis of said device.

32. The device according to claim 31, wherein:

said body includes an exterior surface layer of elastomeric biocompatible material supported by an interior frame structure.

33. The device according to claim 32, wherein:

said frame structure includes projections that extend radially inward toward said central axis of said device, said insert being held in place by said projections.

34. The device according to claim 32, wherein:

said elastomeric biocompatible material comprises silicone.

35. The device according to claim 31 which is inserted into the blood vessel by use of an insertion device, wherein:

said insert includes a pilot hole for receiving said insertion device.

36. Apparatus for occluding a blood vessel having an interior diameter, comprising:

a) a plug device including a body comprising a tapered outer surface and a flexible large diameter section having a diameter greater than the interior diameter of the blood vessel, and an insert into said body comprising a plurality of spring-biased prongs extending beyond said body and radially outward with respect to a central axis of said device; and

b) an insertion device having means for attaching said plug device to said insertion device.

37. An apparatus according to claim 36, wherein:

said insert includes a pilot hole for receiving said insertion device, and

said insertion device comprises a needle, a tubular needle guard surrounding said needle, said needle fitting into said pilot hole of said insert, and a spring-biased lever operable to retract said needle into said tubular needle guard.

38. A method of occluding a blood vessel having an interior diameter, the method comprising:

providing a plug body comprising a tapered outer surface and a flexible large diameter section having a diameter greater than the interior diameter of the blood vessel, said plug body having a central axis;

substantially aligning said central axis of said plug body with a longitudinal axis of a portion of said blood vessel;

applying an axial force to insert said plug body into said portion of said blood vessel with said flexible large diameter section flexing; and

removing said axial force such that a wall section of said blood vessel grasps onto said plug body to hold it in place.

39. A method of occluding a blood vessel according to claim 38, wherein:

the axial force is applied with an insertion device having means to attach said plug body to the insertion device.

40. A method of occluding a blood vessel according to claim 39, wherein:

the insertion device comprises a needle, a tubular needle guard surrounding the needle, the tubular needle guard fitting into a pilot hole of the plug body, and a spring-biased lever operable to retract the needle into the tubular needle guard to release an attached plug body,

the method further comprising the step of operating said lever to release said plug body.

41. A method of occluding a blood vessel according to claim 38, wherein:

said plug body further comprises removal means for applying an axial force to said plug body to thereby remove said plug body from said lumen,

the method further comprising the step of cooperating with said removal means to apply said axial force to said plug body to thereby remove said plug body from said lumen.

42. A method of occluding a blood vessel according to claim 41, wherein:

said removal means comprises a thread attached to said plug body.

43. The device according to claim 4, wherein:

said flexible large diameter section is capable of flexing in said second direction with a greater range than in said first direction.

44. A device for occluding a blood vessel having an interior diameter, comprising:

a body comprising a forward section having a tapered outer surface, and a large diameter section adjacent said forward section having a diameter greater than the interior diameter of the blood vessel; and

an insert disposed along a central axis of said body and mechanically attached to said body, wherein said insert is formed from a hard material relative to said body.

45. The device according to claim 44, wherein:

said body comprises an elastomeric biocompatible material and said insert comprises metal.

46. The device according to claim 45, wherein:

said elastomeric biocompatible material of said body comprises silicone and said metal of said insert comprises titanium.

47. The device according to claim 44, which is inserted into the blood vessel by use of an insertion device, further comprising:

said insert has a longitudinal axis and a pilot hole along said longitudinal axis for receiving the insertion device.

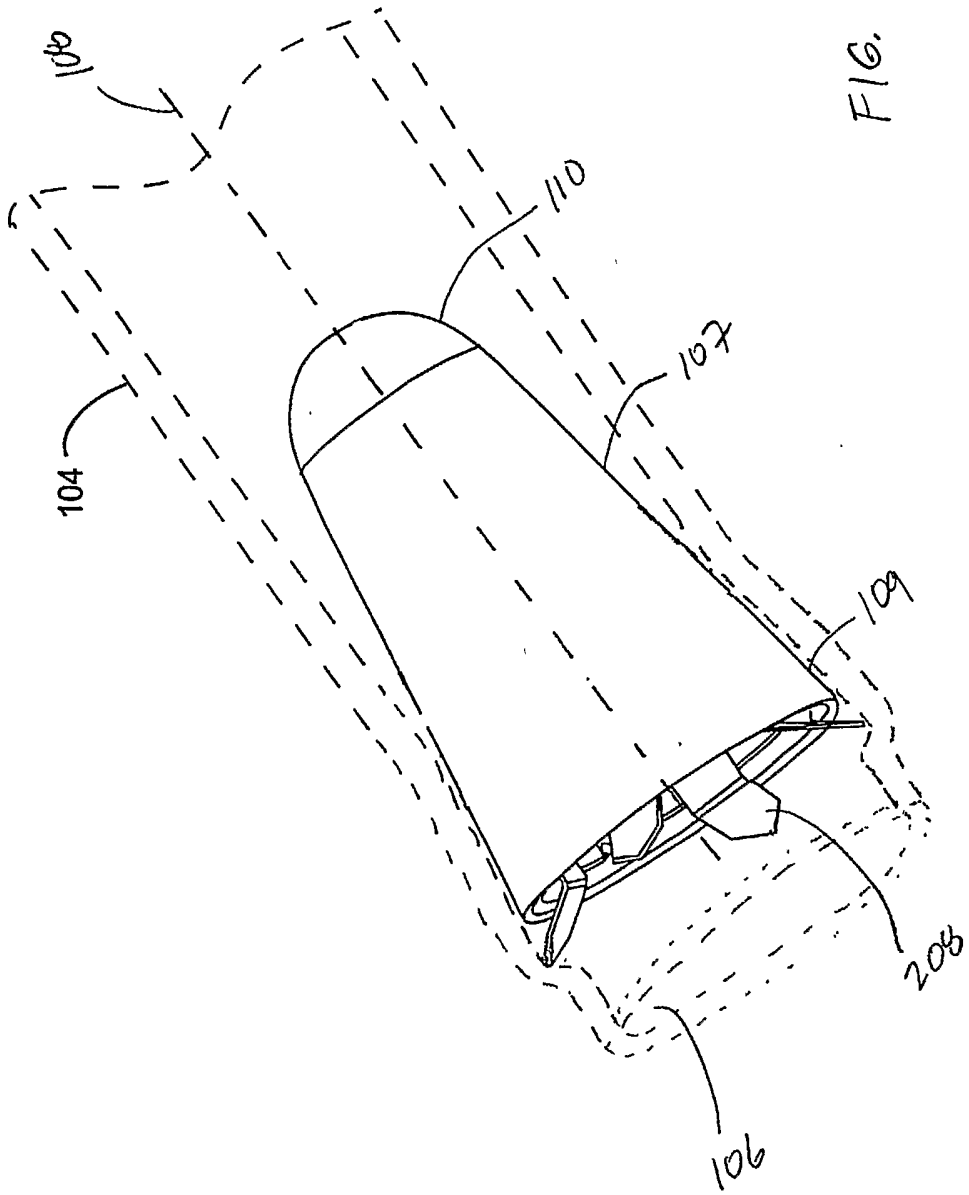
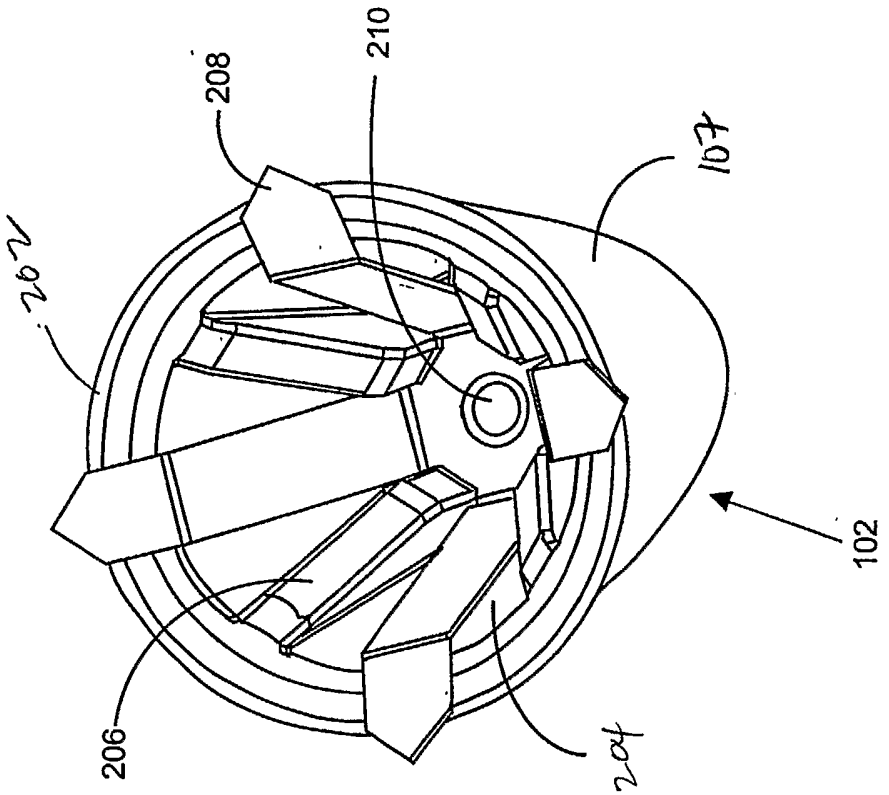


FIG. 1

FIG. 2



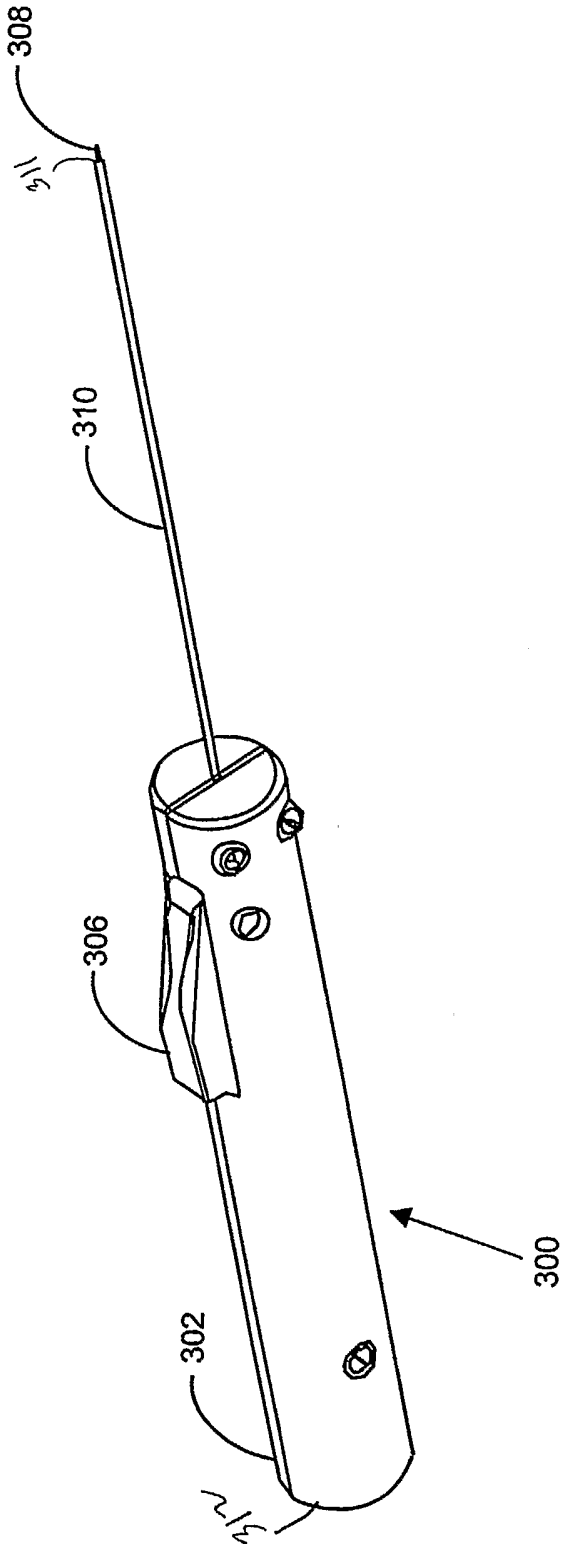


FIG. 3

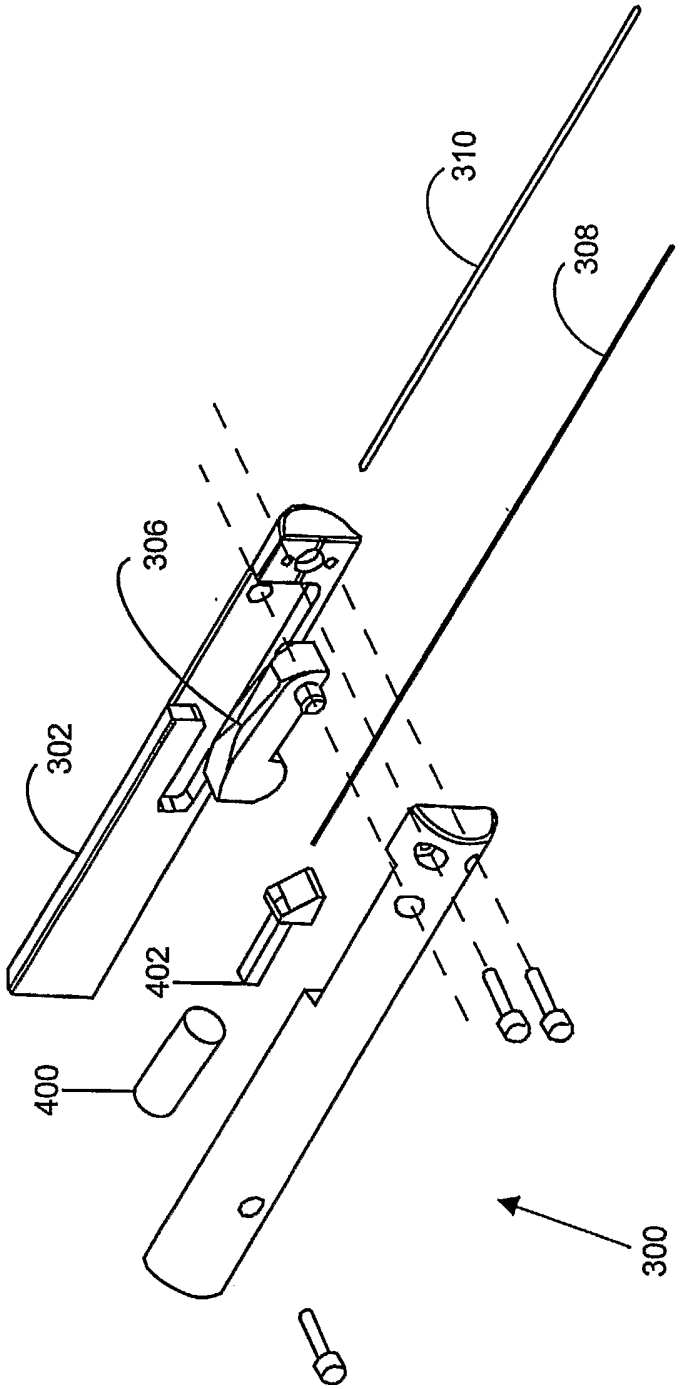


FIG. 4

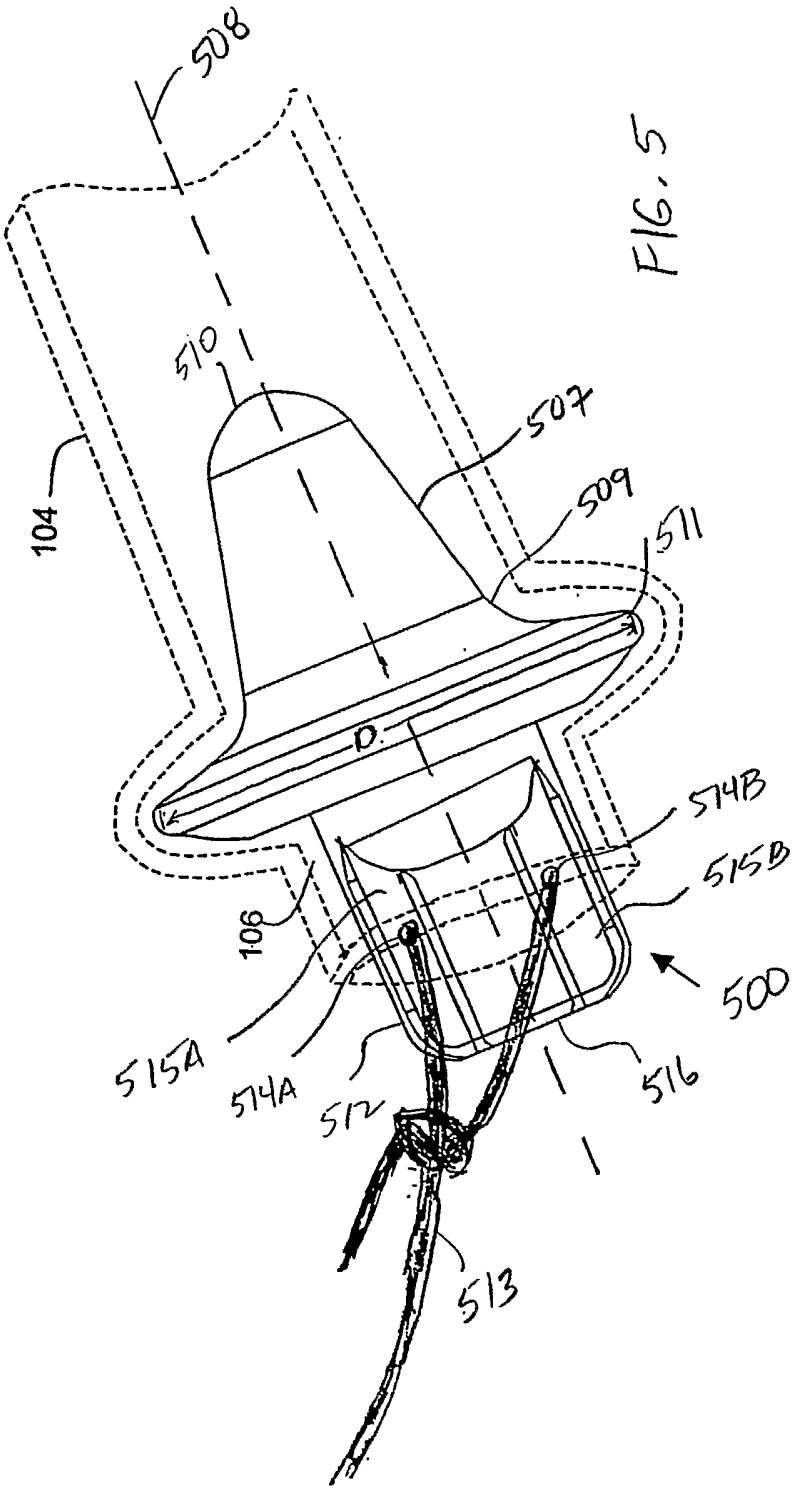

508
510
507
509
511
104
D
514B
515B
106
500
515A
514A
512
516
513

FIG. 5

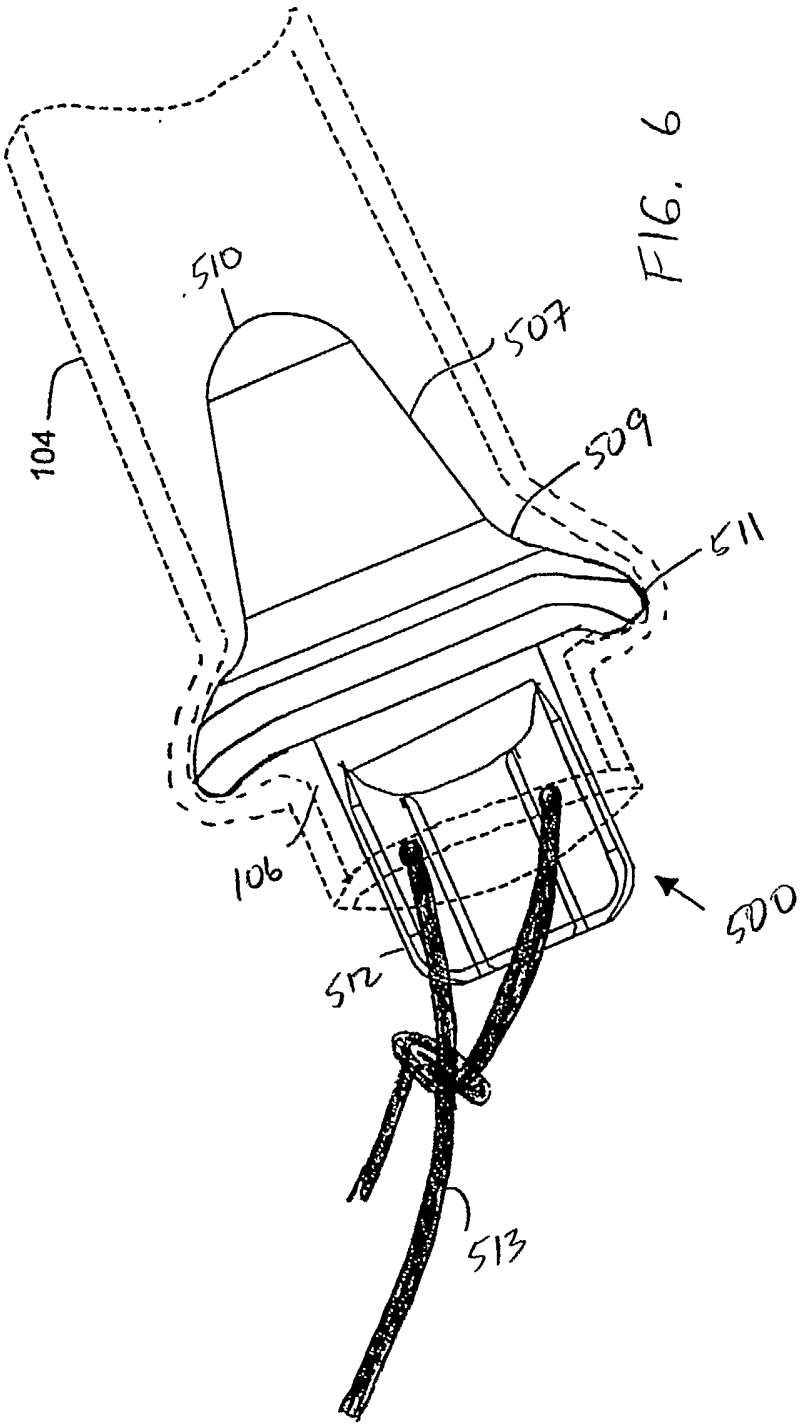


FIG. 6

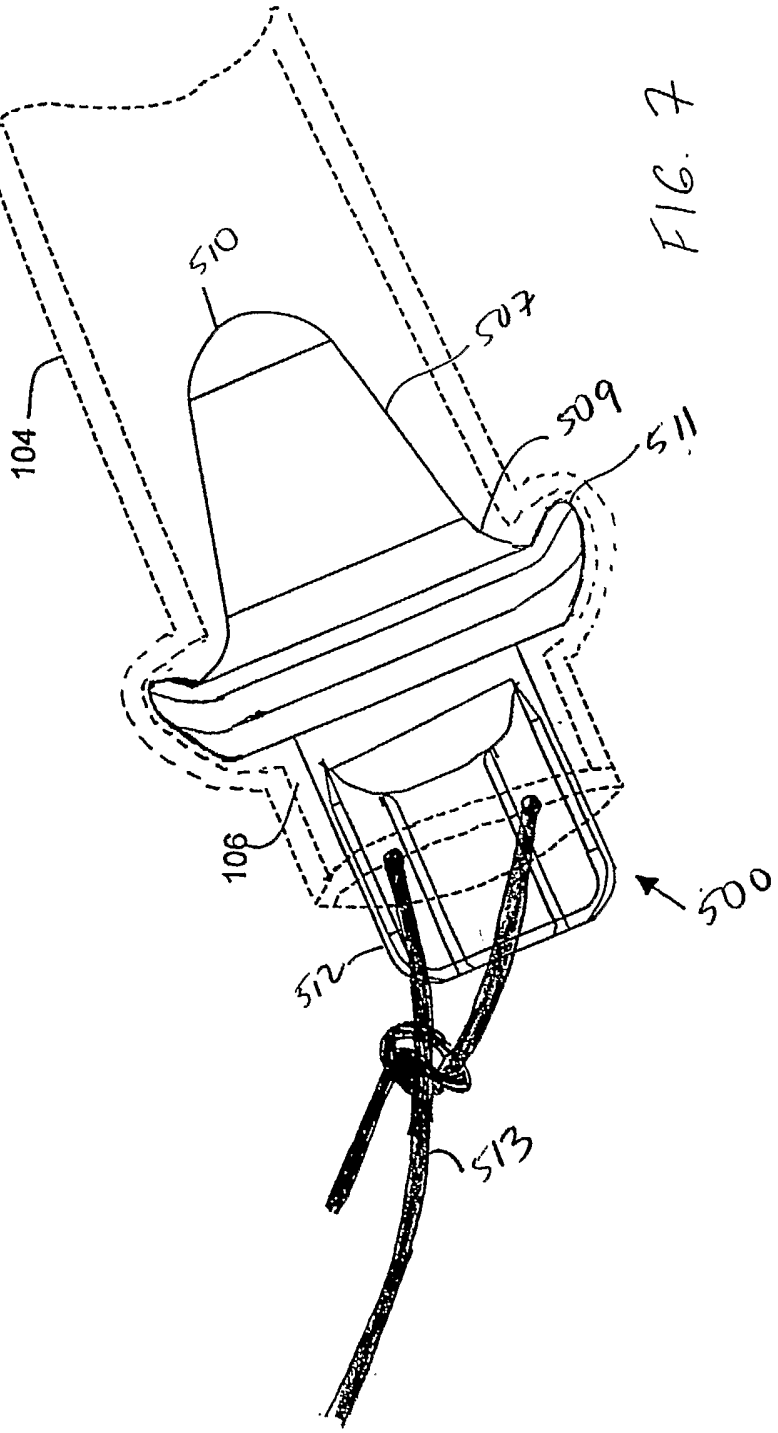
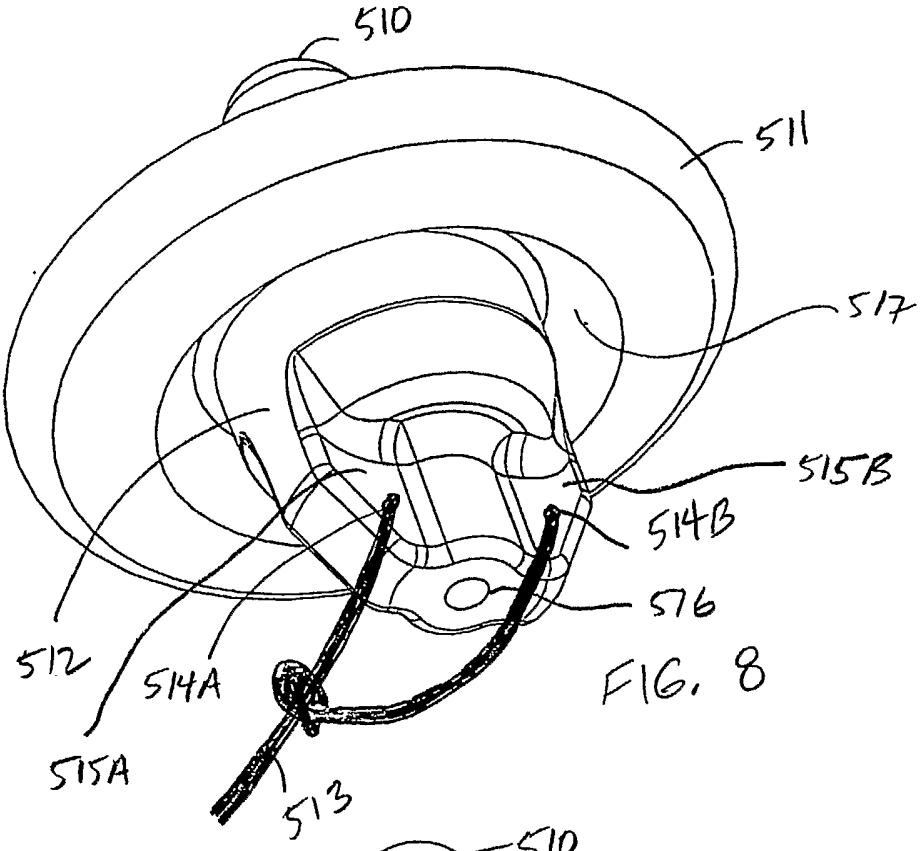


FIG. 7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517
515B
514B
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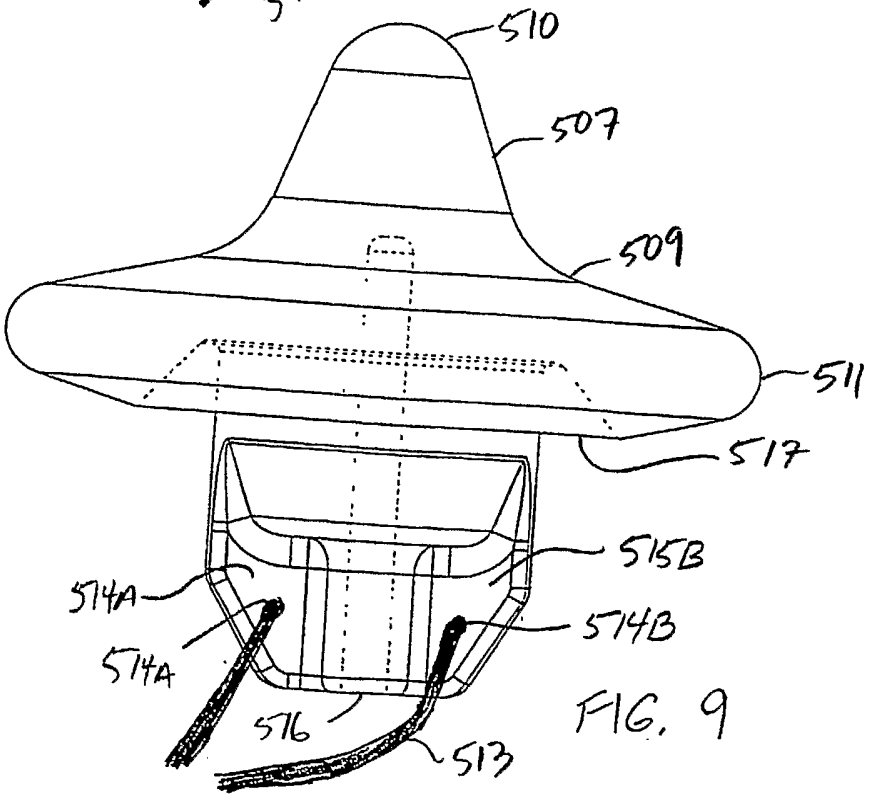
512
514A
515A
513

FIG. 8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515B
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514B
514A
516
513

FIG. 9

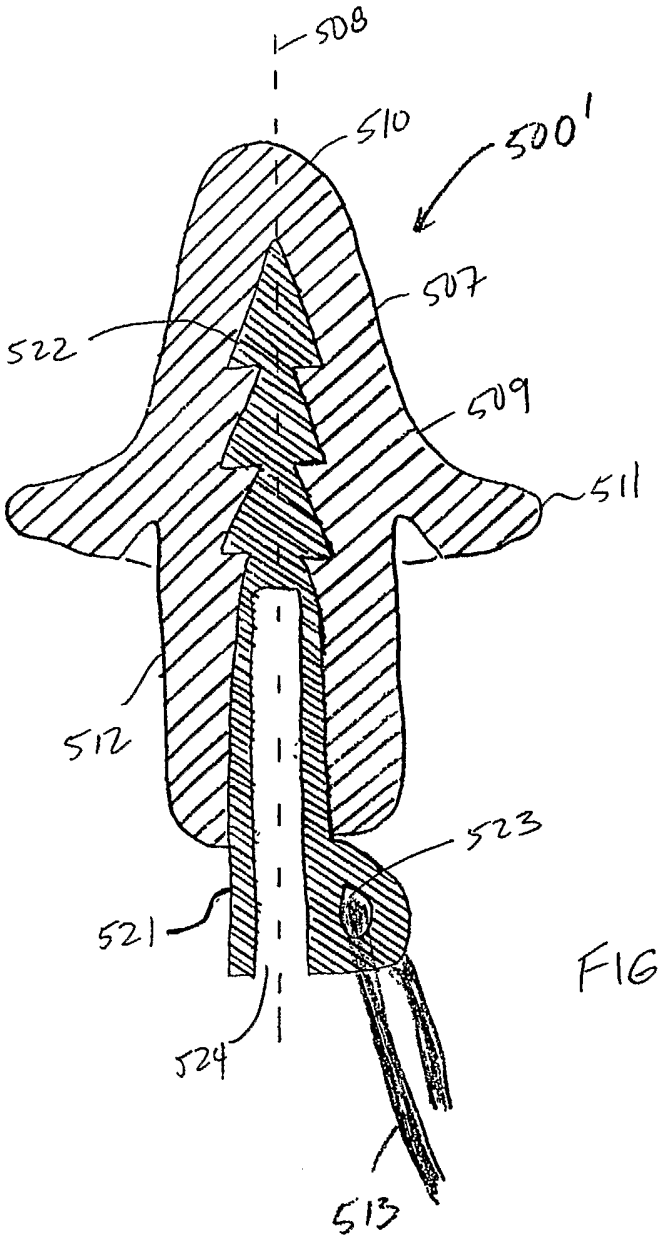


FIG. 10

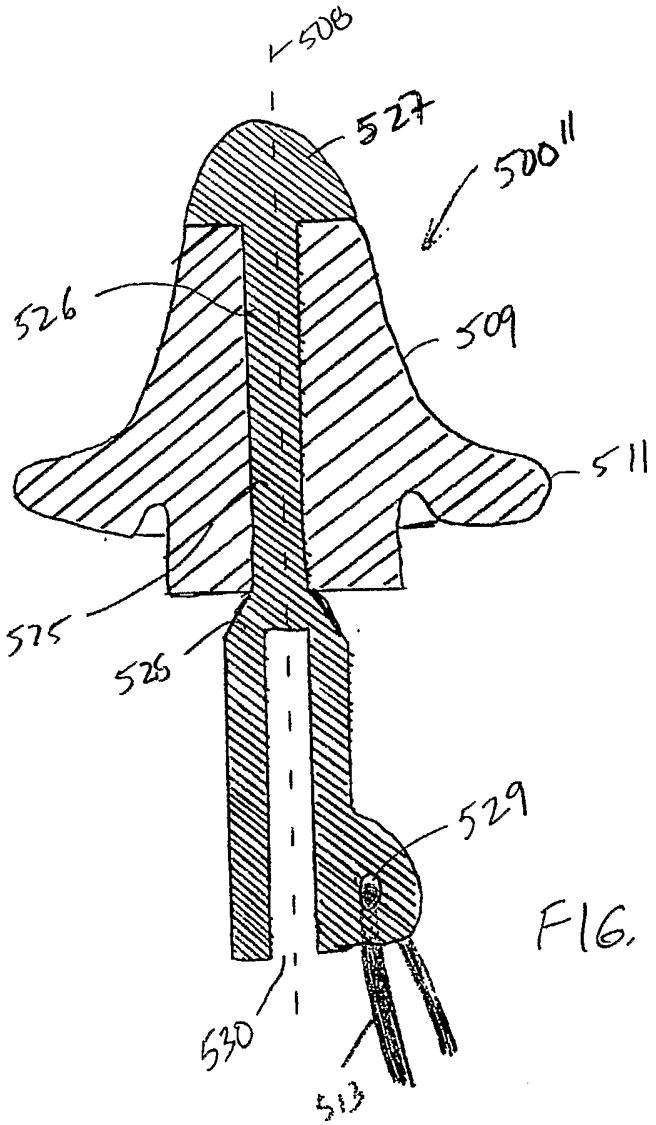


FIG. 11

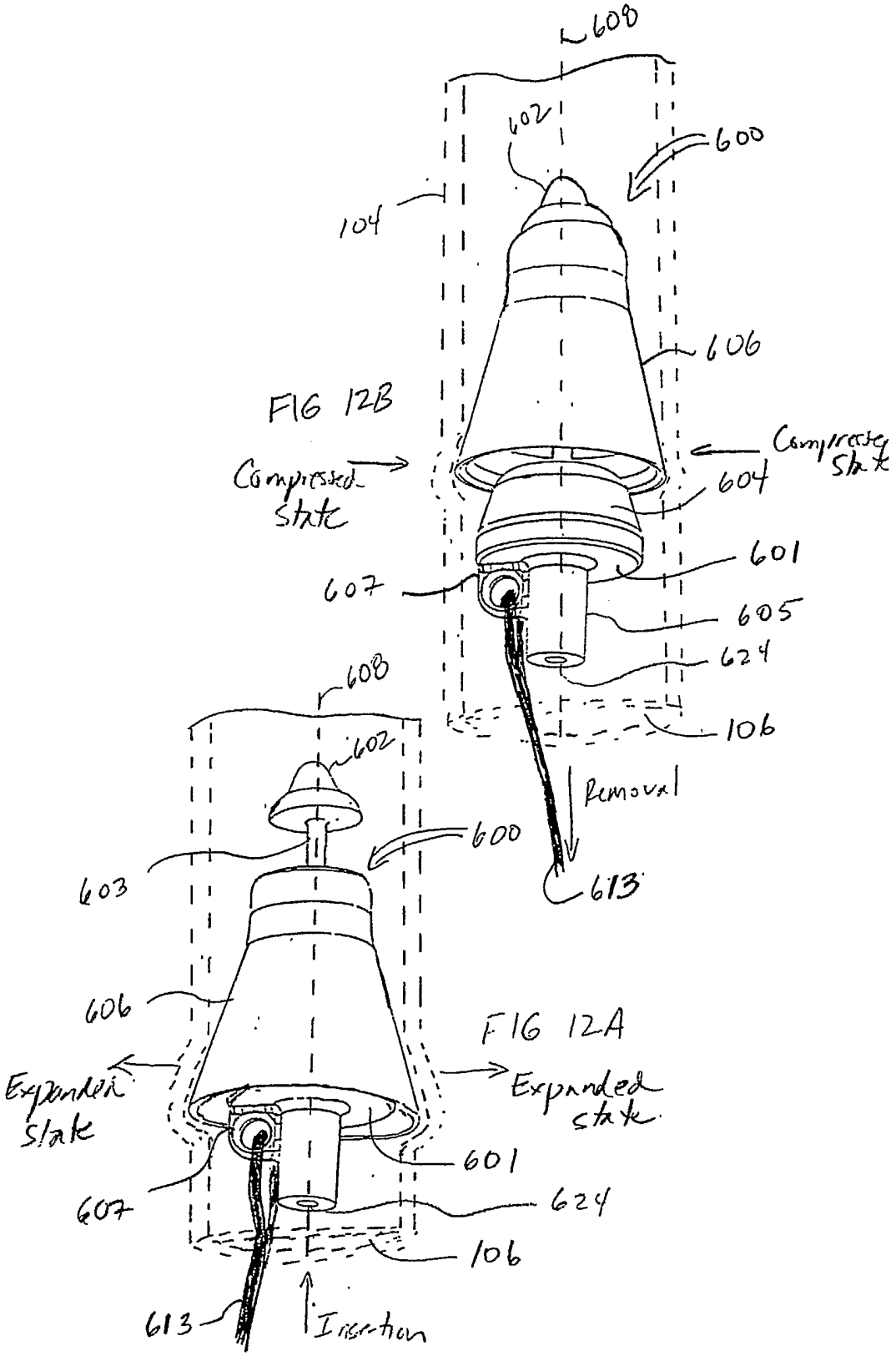

608
602
600
104
606
604
601
607
605
624
106
Removal
613
FIG 12B
Compressed state
Compressed State
608
602
600
603
606
FIG 12A
Expanded state
Expanded State
601
607
624
106
613
Insertion

FIG. 13A

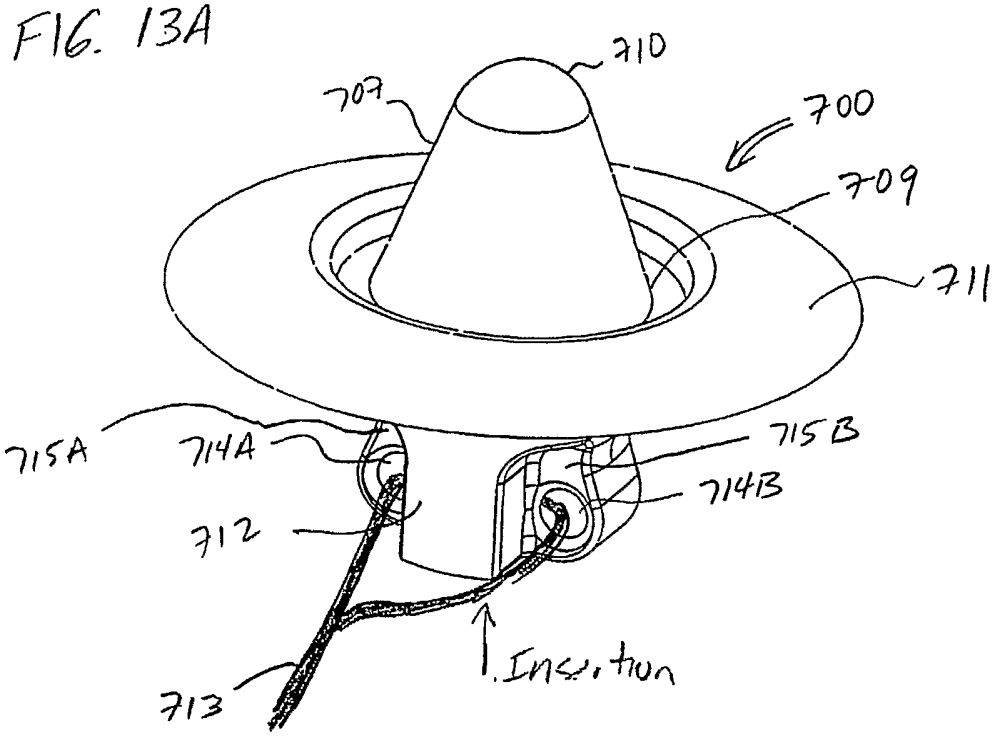
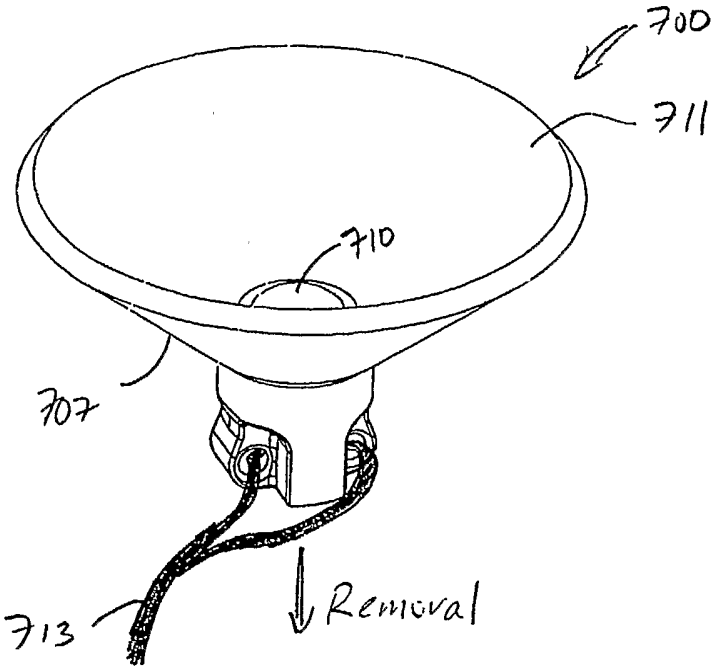


FIG. 13B



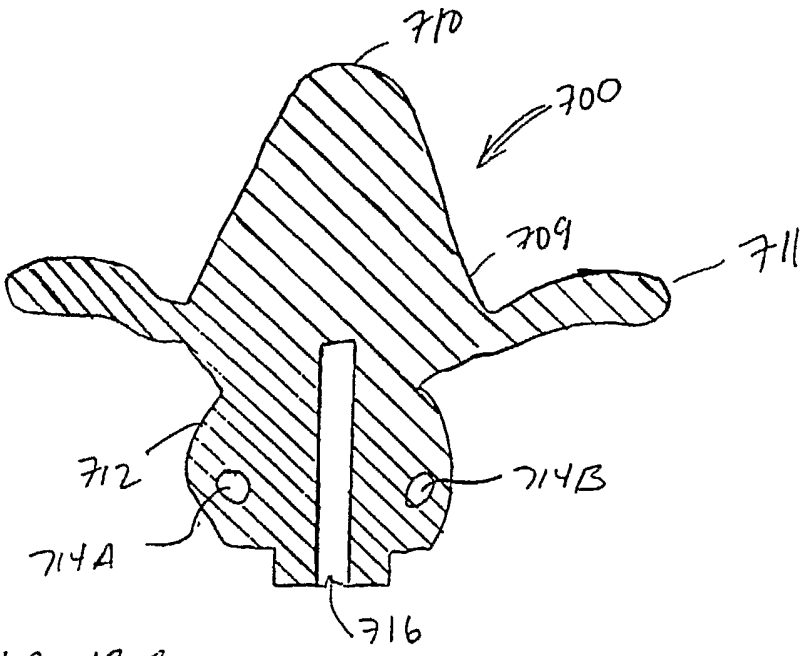


FIG 13C