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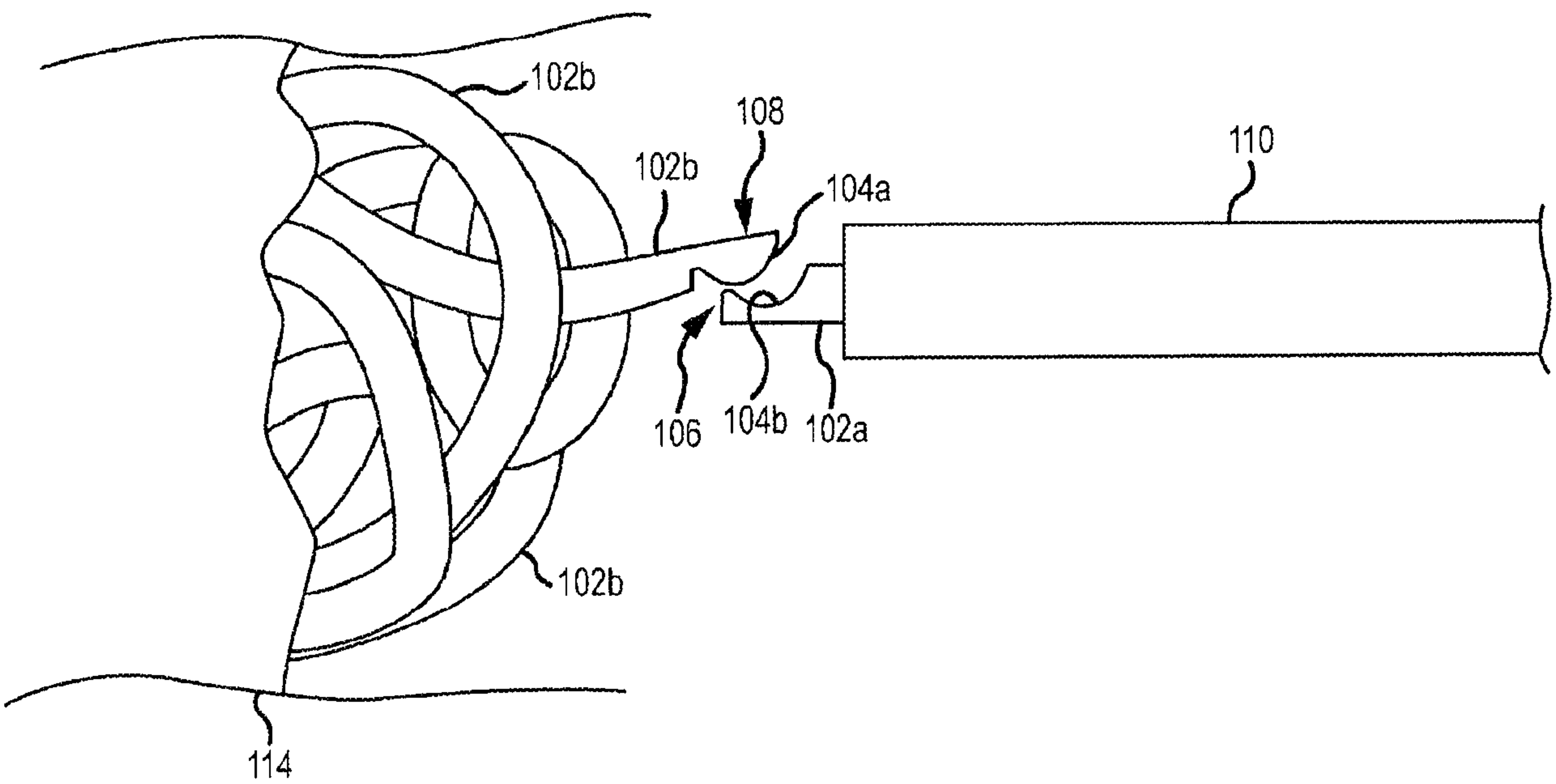

(57) Abrégé/Abstract:

Shape memory materials (SMM) are formed as coil-shaped vascular occlusion devices upon deployment. Shape memory polymer (SMP) materials are tailored through formulation for specific mechanical behavior of the coils. Concurrent coil diameter changes enhance the relative change in stiffness along the length of the coil. Interconnecting structures (104a/b) are formed on ends of elongated members (102a) in the pre-deployment shape for multiple coil insertion capability within an introducer. Channels (206) are formed in pre-deployment shape, elongate members (202) that allow access for injection of imaging contrast agent or concurrent placement of instruments. A single SMM occlusive device (300) transforms into multiple, smaller diameter coils (302b) in the deployed state to generate a complex occlusive structure. A SMM occlusive device (400) has a collapsed fabric (404) component attached to and extending along a sidewall during storage and insertion, and then deploys as a coil (402b) to form a single- or multiple-layer occlusive fabric surface within a center of the coil (402b).

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Declarations under Rule 4.17:
— *as to the identity of the inventor (Rule 4.17(i))*

[Continued on next page]

(54) Title: VASCULAR OCCLUSION DEVICES

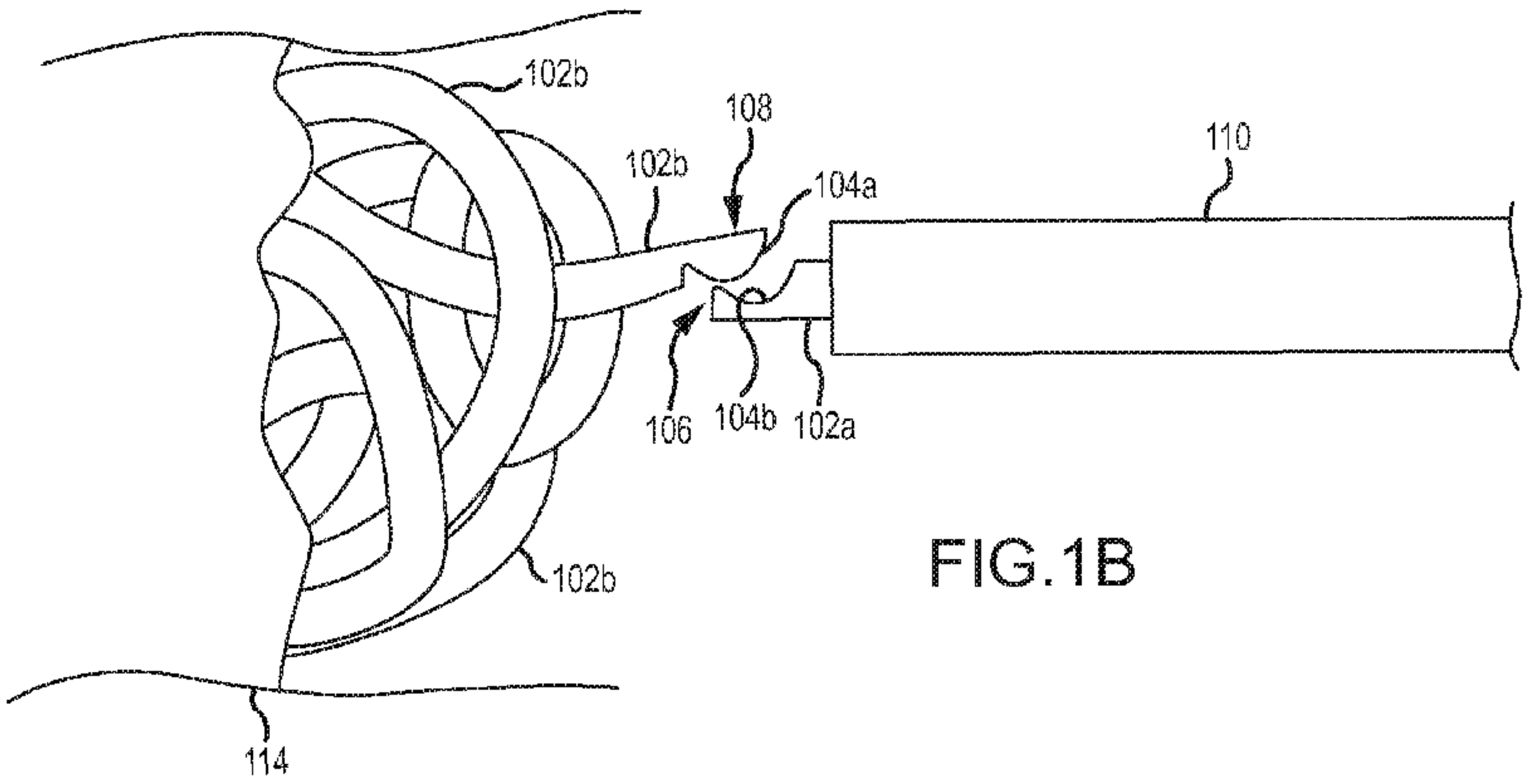

FIG.1B

(57) Abstract: Shape memory materials (SMM) are formed as coil-shaped vascular occlusion devices upon deployment. Shape memory polymer (SMP) materials are tailored through formulation for specific mechanical behavior of the coils. Concurrent coil diameter changes enhance the relative change in stiffness along the length of the coil. Interconnecting structures (104a/b) are formed on ends of elongated members (102a) in the pre-deployment shape for multiple coil insertion capability within an introducer. Channels (206) are formed in pre-deployment shape, elongate members (202) that allow access for injection of imaging contrast agent or concurrent placement of instruments. A single SMM occlusive device (300) transforms into multiple, smaller diameter coils (302b) in the deployed state to generate a complex occlusive structure. A SMM occlusive device (400) has a collapsed fabric (404) component attached to and extending along a sidewall during storage and insertion, and then deploys as a coil (402b) to form a single- or multiple-layer occlusive fabric surface within a center of the coil (402b).

WO 2010/115076 A3

WO 2010/115076 A3

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TITLE

Vascular occlusion devices

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CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of priority pursuant to 35 U.S.C. § 119(e) of U.S. provisional application no. 61/166,120 filed 2 April 2009 entitled "Vascular occlusion devices," which is hereby incorporated herein by reference in its entirety for the purposes of PCT Rule 20.6.

[0002] The present application is also related to Patent Cooperation Treaty application no. PCT/US2006/060297 filed 27 October 2006 entitled "A polymer formulation a method of determining a polymer and a method of determining a polymer fabrication," and Patent Cooperation Treaty application no. PCT/US2007/065691 filed 30 March 2007 entitled "Shape memory polymer medical devices," which are hereby incorporated herein by reference in their entirety for the purposes of PCT Rule 20.6.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0003] This technology was developed in part with sponsorship by National Science Foundation Grant Nos. 0823015 and 0848626 and the U.S. federal government has certain rights to this technology.

TECHNICAL FIELD

[0004] The technology described herein relates generally to implantable devices for interventional therapeutic treatment or vascular surgery, and more particularly concerns a endoluminally delivered device for vascular occlusion and or aneurysm repair.

BACKGROUND

[0005] Interventional radiology and interventional neuroradiology are medical disciplines expanding minimally invasive treatments for vascular defects and vascular malformations while avoiding the cost and burden of open surgery. Clinicians utilize various imaging modalities (primarily fluoroscopy) along with percutaneous (vascular access) guide and delivery catheters to routinely conduct vascular “stenting” to open or maintain patency of a diseased vessel lumen and vascular occlusion or embolization to stop the blood flow in a vessel or isolate a vascular area from blood flow.

[0006] Peripheral vascular (PV) intervention treatments include vascular occlusion for treating hemorrhages, aneurysms, and tumor isolation, including nephroma, hematoma, peripheral aneurysms, and other vascular malformations, and uterine fibroids among other conditions. Interventional neuroradiology (INR) treatments include treating cerebral vascular malformations such as arteriovenous malformations (AVMs) wherein the artery and vein are connected and a variety of cerebral aneurysms or bulging and weakening of a vessel wall. Vaso-occlusive (V-o) devices are used to isolate and/or fill the defect. Other INR procedures include occlusion of ateriovenous fistulae (AVF), parent vessel sacrifice (PVS), and tumor indications among other conditions.

[0007] The V-o devices can take a variety of configurations, and are generally formed of one or more members that are larger in the deployed configuration than when they are within the delivery catheter prior to placement. One widely used V-o device is a helical wire coil having a deployed configuration which may be dimensioned to engage the walls of the vessels. Some known anatomically shaped V-o devices form into a shape of an anatomical cavity such as an aneurysm and are made of a pre-formed strand of flexible, biocompatible material such as stainless steel, platinum, or a shape memory alloy, e.g., a nickel-titanium alloy (NiTinol). Such V-o devices comprise one or more members formed in a generally spherical or ovoid shape in a relaxed, or deployed state and the device is sized and shaped to fit within a vascular cavity or anomaly, such as for treatment of aneurysm or fistula. The V-o members are first formed in a generally linear fashion as a helical winding or braid. The generally linear V-o member is then configured and captured around an appropriately shaped mandrel or form and heat-treated so that the V-o members retain the complex shape in the relaxed or deployed state. The V-o device is then manipulated within its elastic deformation range into a less complex, generally straight, shape, i.e., its pre-deployed state, for insertion through a cannula and catheter. As such, the V-o member is a helical winding or braid on which a complex secondary shape is imposed.

[0008] Delivery of such a coil in the treatment of aneurysms or other types of arteriovenous malformations can be accomplished by a variety of means, including via a catheter in which a series of single coil devices is pushed through the catheter by a pusher to deploy the coil. The coils pass through the lumen of the catheter in a linear shape and take on a complex shapes as originally formed after being deployed into the area of interest, such as an aneurysm. A variety of detachment mechanisms to release the single coil from a pusher have been developed. To complete an occlusion procedure, the physician must sequentially reload the catheter with several individual coils until it is determined the occlusion is sufficient. This physician typically determines whether sufficient coils have been deployed by assessing the level of occlusion of the vessel flow or by evaluating the density of the coil packed into the aneurysm sack (i.e., the coil pack), both performed by typical medical imaging techniques. This "place and assess" method can extend the time and cost of the medical procedure and also can increase the imaging exposure (i.e., radiation exposure) to both the patient and the physician.

[0009] There are many known variations of metal embolic coils including those with offset helical and twisted shapes having multiple axially offset longitudinal or focal axes with a secondary shape having coiled ends and a middle loop. A stretch-resistant V-o coil is also known that is formed from a helically wound primary coil and a stretch resistant member, that can also have a secondary shape with coiled ends ad a middle loop, and an embolization coil having a single closed loop. Highly flexible coils with secondary shapes are also known that form occlusive implants that are sufficiently flexible that each can be folded upon itself and maintain that configuration. It has been found that single strands of small diameter nickel-titanium alloys, as well as other metal alloys, used to form metal V-o coils can be kinked if twisted and pulled as can occur during or after deployment from a catheter, especially if the doctor wishes to withdraw a partially deployed coil because it is somehow incorrect in size, shape, or length to effect the desired repair. Other coils utilize multiple strands of small diameter metal alloy wire to overcome this limitation. However, all of these methods of construction rely upon a costly metal alloy and significant processing costs to fabricate the embolic coil.

[0010] Wire wound coils can be further enhanced through coating and/or fiber attachment to induce specific tissue or thrombus response. However, the mechanical performance of these devices is limited by the single material properties of the base wire and the fabrication techniques associated with wire forming.

[0011] For larger vessel occlusion, metal wire coils present significant limitation and/or require a significant number of devices to achieve suitable vessel occlusion. Other, non-coil devices are known that may utilize an articulating mesh structure fabricated from similar metal alloys and wire-forming methods. While these devices can effectively occlude larger vessels, they are similarly very expensive and have proven to be challenging for the physician to place accurately due to the length of their pre-deployed state.

[0012] Traditional polymers that are not shape memory polymers cannot provide suitable "shape fixity" after storage in a stressed condition for extended periods. Traditional polymers suffer from "creep" resulting in a loss of shape fixity.

[0013] Polyester fibers and braiding have been added to the wire devices as a means to enhance thrombogenic response. Some coils are coated with a bioabsorbable polymer (PLGA, etc) as a means of enhancing blood/tissue interaction. Other coils are coated with a hydrogel to cause them to swell in-situ and provide a tighter coil pack. However, all of these products rely on an underlying metal coil design. Typically resilient materials such as shape memory metal alloys or superelastic metal alloys are used to maintain the unique coiled sample post deployment while the device is being held in a straight configuration inside of a coil holder (tube/hub device) that allows easy physician loading into the proximal end of the delivery catheter. Again, these devices suffer performance limitations and high cost constraints due to the underlying materials of construction.

[0014] The information included in this Background section of the specification, including any references cited herein and any description or discussion thereof, is included for technical reference purposes only and is not to be regarded subject matter by which the scope of the invention is to be bound.

SUMMARY

[0015] Various implementations of coil-shaped vascular occlusion (V-o) devices formed of shape memory polymer materials are disclosed. SMP material properties of the coil devices can be tailored, through formulation, for specific mechanical behavior and "clinician feel" of the coils. Concurrent coil diameter changes can enhance the relative change in stiffness along the length of the coil. SMP materials provide "shape fixity" properties, which enable unique configurations and shapes for storage and in-situ deployment, respectively. These two definitive shapes provide significant feature advantages over traditional elastomeric or flexible materials undergoing compression within the elastic range of such traditional materials.

[0016] In one implementation, multiple coil insertion capability is achieved via chaining coils within the coil introducer. The pre-deployment shape and configuration of a series of SMP coils allows for interconnection between coils and interconnection with a pusher to enable clinician control of the coil position and release from the catheter.

[0017] In another implementation, non-round cross sections in the SMP coil shape and configuration, as well as in the shape and configuration of the pusher, provide an effective channel that allows access for injection of imaging contrast agent or concurrent placement of small tools or instruments.

[0018] In an alternate embodiment, a single shape memory material occlusive device that transforms into multiple, smaller diameter coils in the deployed state may be used to generate a complex occlusive structure.

[0019] In a further implementation, a shape memory material occlusive device may be configured to deploy in an organized spring form. A fabric component may be attached to and extends along a length of the coil. The fabric may be collapsed or furled around the device in a pre-deployed state for storage and insertion in an introducer and catheter and then deploy with the spring-like coil in a deployed state. The fabric forms a single- or multiple-layer occlusive surface within a center of the spring-like coil resulting in an effective "vascular plug" from a single coil-type of device.

[0020] The SMP coils may contain other materials within the SMP matrix, included during formulation or during molding or extrusion processes that impart other beneficial properties. These materials may include, for example, radio-opacity, CT compatibility, bioactive agents, thrombogenic enhancing materials, fibers, or fabrics. The SMP coils may also be coated to provide beneficial characteristics, for example, reduction in friction from hydrophilic coatings. Smooth surface characteristics improve coil pack through reduction in friction between coil loops.

[0021] This Summary is provided to introduce a selection of concepts in a simplified form that are further described below in the Detailed Description. This Summary is not intended to identify key features or essential features of the claimed subject matter, nor is it intended to be used to limit the scope of the claimed subject matter. Other features, details, utilities, and advantages of the present invention will be apparent from the following more particular written description of various embodiments of the invention as further illustrated in the accompanying drawings and defined in the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0022] FIG. 1A is a cross-section view of a catheter delivering a series of SMP coils connected in a chain and separable upon deployment from a distal end of the catheter.

[0023] FIG. 1B is side plan view of an occlusive mass of SMP coils deposited in a vessel from the distal end of a catheter after disengaging from the connective chain of pre-deployed coils in the catheter.

[0024] FIG. 2A is an end plan view of an SMP coil formed with a channel in a pre-deployment state.

[0025] FIG. 2B is a side plan view of the SMP coil of FIG. 2A formed with a channel in a pre-deployment state.

[0026] FIG. 2C is a cross-section view of the SMP coil of FIG. 2A formed with a channel inserted within a catheter.

[0027] FIG. 3A is a cross-section view of a catheter delivering a shape memory coil device in a pre-deployed state formed with a collection of coil tendrils attached to a base.

[0028] FIG. 3B is a side plan view of the coil device of FIG. 3A deploying from a catheter and forming a complex occlusive coil structure.

[0029] FIG. 4A is a cross-section view of a catheter delivering a shape memory occlusive device in a pre-deployed state formed with a fabric component attached to and furled around a sidewall of the device.

[0030] FIG. 4B is a side plan view of the device of FIG. 4A deployed within a vessel and forming a spring-shape coil with the fabric unfurled within the center of the coil.

[0031] FIG. 4C is an isometric view of the device of FIG. 4A in a pre-deployed state with the fabric component threaded along the length of the device.

[0032] Fig. 4D is an isometric view in cross section of the device of FIG. 4B deployed within a vessel and forming a spring-shape coil with the fabric unfurled within the center of the coil.

[0033] FIG. 5 is a side elevation view in partial cross section of an alternate implementation of a vascular occlusive device deployed within a vessel and forming a spring-shape coil with a series of fabric panels attached at points along the coil to hang within the center of the coil.

DETAILED DESCRIPTION

[0034] As indicated, embolic coils come in a variety of shapes and sizes for specific purposes. Typically embolic coils are made from platinum and/or NiTinol metal wire, with and without exposed polyester fiber, which limits not only the clinical performance of such devices, but induces a high manufacturing cost.

[0035] In contrast, a shape memory polymer (SMP) formulation in an adapted molding or extrusion process significantly reduces the manufacturing cost while enabling unique cross-sectional shapes and forms unavailable using wire-forming fabrication techniques. Further, a shape memory polymer can be uniquely formulated to provide specific mechanical properties that result in superior occlusive performance through enhanced interaction between the coil, vessel tissue, and flow characteristics of the vessel or vascular malformation it is occluding. Meanwhile, the SMP occlusive coil is configured to be deployed using an existing delivery catheter using standard techniques.

[0036] Shape memory polymers demonstrate the phenomena of shape memory based on fabricating a segregated linear block co-polymer, typically of a cross-linked hard segment monomer and a soft segment monomer. The SMP generally is characterized by defining phases that result from glass transition temperature (Tg). Mechanical properties of the phases, i.e., the stored or pre-deployed shape (e.g., below the Tg) and the deployed shape (e.g., above the Tg), as well as setting the Tg, may be tailored by adjusting the formulation of the SMP through different weight percentages of the monomers and cross linker. (See Patent Cooperation Treaty application nos. PCT/US2006/060297 and PCT/US2007/065691.) Shape memory polymers can be formulated for a Tg that allows use of an external heat source to initiate the phase change or a Tg that utilizes the body heat of the patient to initiate the phase change.

[0037] The target vasculature for occlusion and/or vascular malformations (e.g., aneurysms, AVMs, etc.) are pathologic structures and present significant anatomical variability. The coil form and complex intertwining of coil loops provides a flexible and adaptive structure for achieving occlusion in these procedures. Coiling is well established in medical practice but generally utilizes coils manufactured from metals that will retain their unique coil shape after deployment subsequent to significant storage time being held in a straight coil introducer.

[0038] An SMP occlusive coil and its various configurations address key clinical needs that are currently unmet with existing metal coils. These may include the following:

Reduced procedure cost and time;

Better immediate occlusions (e.g., through better anchoring to the vasculature and better packing efficiency to block blood flow) which results in better clinical performance and clinical outcomes; and

Capability for occluding larger diameter vessels from a small delivery catheter than currently achievable with existing coils.

The implementation of SMP materials in an occlusive coil or vascular plug also enables a device that generates much larger and more complex features while providing for deployment from a very small catheter.

[0039] SMP material mechanical properties may be tailored to achieve a preferred stiffness or softness for the coil. Further, the coil can be fabricated from SMPs of different formulations to create a multi-modulus material that results in varying stiffness along the length of the coil. This may, for example, allow the first few loops of a coil to be stiff for anchoring within the vascular tissue and the balance of the coil to be soft for improved packing efficiency and greater occlusion. Further, this material effect can be combined with diameter (dimensional) changes along the coil length to enhance the change in relative stiffness.

[0040] Competitive devices made from metal wire suffer from compromises so that their device is stiff enough to handle/insert and anchor on the vascular tissue and yet soft enough to fold and create a tightly packed occlusive mass. If the material is too stiff, it will not pack effectively allowing blood flow around the coil. If the material is too soft, it will not effectively anchor on the tissue wall and can migrate due to blood flow or manipulation of the sequential coil during the procedure. This compromise limits their design and undermines optimizing these conditions.

[0041] The SMP's "shape fixity" (representing two definitive and accurate shapes, those of pre- and post- thermal deployment/activation) provides the ability to accurately define and provide a straight insertion configuration that flexes and tracks down the long, small lumen of a delivery catheter placed in the body in a tortuous path to reach the target site, and separately define and provide a deployment configuration of a complex "secondary" coil shape that enables an efficient occlusive mass. These definitive shapes and features are enabled using a low cost fabricated SMP device in comparison to high cost shape memory alloys (SMA) such as NiTinol or in comparison to traditional polymers without shape memory. Traditional polymers without shape memory undergo continuous stress in a straight packaged configuration and could not survive the shelf life and packaging duration necessary and retain appropriate shape fixity post deployment.

[0042] As SMP materials are formulated for use, other ingredients can be added to the formulation to induce specific properties or behavior that may include, for example, radio-opacity, computed tomography (CT) compatibility, tissue response, thrombogenicity, or others, or any combination thereof. For example, barium methacrylate (in solution) or tungsten powder (in suspension), or a combination of these or similar ingredients may be added to the SMP material to induce radio-opacity. Fibers or fabric from materials such as polyester may be added and positioned for surface exposure to induce thrombogenicity. Bioactive agents (e.g., fibroblast growth factor) and eluting pharmaceuticals (e.g., NSAIDs such as ibuprofen) may be integrated in the matrix of the material. Further, the SMP material can be treated with coatings, for example, hydrophilic coatings to reduce friction or biodegradable coatings (e.g., polyglycolic acid) to induce a desired tissue response.

[0043] SMP materials using common molding and/or extrusion processing methods can result in very smooth and continuous coil surfaces. These surfaces can be beneficial for improving the effective coil pack in occlusion devices by reducing the friction between the coil loops. SMP materials can be combined in part with hydrogel materials to induce additional functionalities along the length of the coil, for example, preferred hydration-associated swelling at pre-set points along the length of the coil.

Interlocking Coil Configuration

[0044] In one implementation as shown in FIGS. 1A and 1B, occlusive vascular coils 102b may be formed in a pre-deployment state as elongate members 102a with the ability to chain elongate members 102a such that a coil introducer (i.e., the hub/tube holder that is used to insert the coil into the proximal end of a delivery catheter) can be filled with multiple, chained, sequential elongate members 102a. Interlocking the elongate members 102a in a serial chain allows greater control on position (e.g., push out, pull back) as needed. The chain connection is detachable such that, as the most distal elongate member 102a is pushed beyond the limit of the distal tip of the catheter 110, the engagement between successive interlocked elongate members 102a detaches and the deployed elongate member 102ais free to transform into a coil 102b. The chained elongate members 102a are further interlocked with a dedicated "pusher," a guidewire 112 that runs the length of the catheter 110 and which is connected at the proximal end of the chain of elongate members 102a. This pusher 112 may be used by the physician to advance (push) or retract (pull) the elongate members 102a from the proximal end of the catheter 110 outside the patient's body.

[0045] SMP elongate members 102a/coils 102b may be fabricated in specific lengths with end treatments that result in the interlocking connective features 104a/b. Elongate members 102a are linked together to support both push and pull actions. As shown in FIGS. 1A and 1B, the interlocking features 104a/b may be formed as complementary, hook-like features on opposite ends of each elongate member 102a for attachment with adjacent elongate members 102a. The functionality of the interlocking features 104a/b is dependent upon constraint of the elongate members 102a within the lumen of the catheter to delay deployment as coils 102b. Once the interconnection of the distal elongate member 102a is pushed beyond the distal end 106 of the catheter 110, the proximal end 108 of the distal elongate member 102a is no longer constrained and is free to separate from the distal end of the adjacent, proximal elongate member 102a in sequence remaining within the catheter 110. Sequential elongate members 102a are delivered this way to the target occlusive site until a desired number of coils 102b is placed within the vessel 114.

[0046] The chain of elongate members 102a is similarly connected to the dedicated pusher 112 in the control of the physician. If an elongate member 102a is only partially deployed, the proximal end is still connected and contained within the lumen of the catheter 110. If the physician dislikes the position or configuration of the distal end of the deploying elongate member 102a/coil 102b, he can pull the elongate member 102a/coil 102b back into the catheter 110 to reposition it before deploying and releasing the coil 120b. In this way, the elongate members 102a/coils 102b are applied in a push/pull motion. Because the coils 102b are fabricated from a very tough SMP material, they do not suffer permanent deformation of stretch or kinking that result from the push/pull motion and has been associated with thin metal alloy wire coils.

Channeled Coil Configuration

[0047] In other implementations as shown in FIGS. 2A-2C, SMP coils 202 may be fabricated with unique cross-sectional designs. While wire coils are round in shape, SMP coil forms are derived by extrusion die shapes or mold shapes. A contiguously connected channel 206 along the length of the elongated pre-deployment shape of the coils 202 can be formed cost-effectively through these processes. The cross-section of this SMP coil 202 in a pre-deployed shape may appear as a "C" or "U" in shape, or the pre-deployed coil 202 may be hollow. The open area channel 206 or lumen within and along the length of the pre-deployed coil 202, resident in the lumen of the catheter 210, may form a pathway or conduit for fluids, e.g., contrast media, or tools or instruments, e.g., a trimming device or micro-forceps. The shape of the channel 206 may be maintained through the interconnection structures 204 in chained pre-deployed coils 200 described above, providing continuity through the series of pre-deployed coils 202 within the catheter 210. The shape of the channel 206 is also accessible or maintained in the "pusher" wire 212 that the physician controls to advance or retract the coils 202.

[0048] The resulting channel path may be continuous from the distal end of the coil 202 in the catheter 210 within the patient to a Y-connector (not shown) that is connected to the proximal end of the catheter 210, outside the patient. The pusher 212 may enter the Y-connector from a straight port incorporating a sliding anti-backflow valve to allow injection of fluids from the side port on the Y-connector without leaking back and out the straight port. The Y-connector may incorporate a circumferential channel feature that eliminates the need to align the channel with the side port for fluid injection. However for tool access through the side port, the channel 206 may need to be rotated and aligned with the side port.

[0049] During typical coil deployment for occluding a flowing vessel, the physician may periodically inject contrast media for imaging enhancement to assess the quality of the coil pack. Typical prior art serial coils preclude the ability to inject contrast through a typical single lumen catheter after an individual coil is placed. In contrast, the present implementation provides, in both the chained coils and the detachable pusher, a cross-section for each of these elements that is defined such that a channel is formed that enables liquid contrast media to be injected from the proximal end (outside the patient) through the catheter holding the coils into the patient. This "puff while you place" configuration is unique to the molded/extruded aspects of the SMP coil as metal coils cannot be cost effectively formed with this channel. The channels line up through the assembly and communicate with the Y-connector at the proximal end to provide the path for the contrast media injected from a standard syringe.

<u>Medusa Coil Configuration</u>

[0050] In another implementation, a unique shape memory material occlusive coil configuration is depicted in FIGS. 3A and 3B. Within a given diameter of the delivery catheter 310, multiple (smaller diameter) coils 302b may be configured adjacent to each other resulting in a pre-deployed elongate shape 302a sized to fit within the single lumen catheter 310. The multiple elongate members 302a/coils 302b may be joined at a plug 304 the proximal end 308 or alternatively, also at the distal end 306 (not shown). These multiple coils 302b are not sequential but parallel in delivery. Upon deployment, the multiple coils 302b are expressed from the catheter 310 changing shape and generating a much more complex coil mass that could be achieved by expressing a single coil. This multi-coil approach provides the ability to occlude larger vessels and/or generate an effective occlusive mass quickly.

[0051] Note that this configuration is not the same as a multiple-strand wire coil. In the latter, the multiple strands are gathered together to form a single member that deploys into a single coil shape. This shape memory material coil implementation utilizes multiple, separate coils 302b connected together at plug 304 at one end to deploy simultaneously. This facilitates quickly achieving an occlusive mass for larger vessels with one device. In this implementation, the shape memory material may be an SMP as described herein, a shape memory metal alloy, or other shape memory material.

Vascular Plug

[0052] In yet another implementation depicted in FIGS. 4A-4D, SMP coil vascular plugs 400 may be utilized for larger diameter vessels in which coil nests are not very effective or results in a massive number of coils used to achieve the occlusion. Existing metal vascular plug devices present other challenges by requiring larger catheters for delivery and imposing longer rigid portions of the device, ultimately making it more difficult to reach and precisely locate its deployed position. Delivering a shape memory material vascular plug using a coiling technique provides many advantages in addressing these issues. A shape memory vascular plug 400 allows significantly larger deployed coil-shape (i.e., a large diameter) from a small delivery catheter 410. In this implementation, the shape memory coil 402b does not form an occlusive mass of coil loops. Instead, the vascular plug 400 organizes, like a coil spring 402b, against the wall of the vessel 414. In this implementation, the shape memory material may be an SMP as described herein, a shape memory metal alloy, or other shape memory material.

[0053] Inherent in the coil plug 400 is a section of fabric 404 (e.g., a biocompatible polyester fabric) attached to and rolled along a length of the elongated member 402a when straightened for introduction through the catheter 410. The fabric 404 has a specific configuration and attachment to the elongated member 402a/coil 402b. In one implementation, the fabric 404 defines multiple holes 406 along an edge, like a shower curtain. The vascular occlusion device 400 in its pre-deployed state is passed through the holes 406 of the fabric 404. The fabric 404 is free to slide along the elongate member 402a as shown in FIG. 4C. The fabric 404 is then rolled up around the straight elongate member 402 and the device 400 is placed in the catheter 410 as shown in FIG. 4A. Upon deployment from the catheter 410, as the coil spring 402b forms from the pre-deployment elongate shape, the fabric 404 unfurls and positions itself across the vessel lumen 416 as shown in FIG. 4B resulting in physical blockage of the lumen 416. The length of the fabric 404 is such that as the coil spring form takes shape, the fabric 404 presents redundant layers across the lumen 416 to form the effective vascular plug 400 as shown to good advantage in FIG. 4D.

[0054] In an alternate implementation of a vascular occlusive device 500 as shown in FIG. 5, the device 500 is deployed within a vessel 514 and forms a spring-shape coil 502 as in FIG. 4D. However, in this embodiment a series of fabric panels 504 are attached at points along the coil 502 to hang between turns of the coil 502 within the center of the coil 502. The fabric panels 504 may be adhered to the surface of the coil 502, partially embedded in the material of the coil 502 during manufacturing, or attached by other methods. Again, in this implementation, the shape memory material may be an SMP as described herein, a shape memory metal alloy, or other shape memory material.

[0055] In each of these implementations, the coil thus acts as an anchor along the vessel wall and the fiber/fabric forms an occlusive barrier to blood flow within the lumen. The fabric is designed and cut to a specific shape and flexibility to enable proper deployment. The fabric may be attached at strategic points along the coil to facilitate packaging wherein the fabric is rolled around the coil or otherwise condensed in size such that both the coil and the fabric fit within the diameter of the coil introducer and associated catheter. The straightened coil with fabric is deployed by advancing it down the catheter, using a typical pusher, and pushing it out the distal end at the target occlusion site. As the coil deploys and regains its memorized shape, the coil expands radially and pushes against the vessel wall to develop the anchor function while achieving a round, generally spring-like shape. The fabric unrolls/unfurls and is biased to be positioned within the center of the lumen. Sections of the fabric may overlap with each turn of the coil spring such that a redundant flow barrier is achieved upon complete deployment.

[0056] All directional references (e.g., proximal, distal, upper, lower, upward, downward, left, right, lateral, front, back, top, bottom, above, below, vertical, horizontal, clockwise, and counterclockwise) are only used for identification purposes to aid the reader's understanding of the present invention, and do not create limitations, particularly as to the position, orientation, or use of the invention. Connection references (e.g., attached, coupled, connected, and joined) are to be construed broadly and may include intermediate members between a collection of elements and relative movement between elements unless otherwise indicated. As such, connection references do not necessarily infer that two elements are directly connected and in fixed relation to each other. The exemplary drawings are for purposes of illustration only and the dimensions, positions, order and relative sizes reflected in the drawings attached hereto may vary.

[0057] The above specification, examples and data provide a complete description of the structure and use of exemplary embodiments of the invention. Although various embodiments of the invention have been described above with a certain degree of particularity, or with reference to one or more individual embodiments, those skilled in the art could make numerous alterations to the disclosed embodiments without departing from the spirit or scope of this invention. In particular, it should be understood that the described technology may be employed independent of a personal computer. Other embodiments are therefore contemplated. It is intended that all matter contained in the above description and shown in the accompanying drawings shall be interpreted as illustrative only of particular embodiments and not limiting. Changes in detail or structure may be made without departing from the basic elements of the invention as defined in the following claims.

CLAIMS:

1. An endolumenally delivered device for vascular occlusion comprising

a shape memory material that is formed

in a pre-deployed state as a elongate member having a base portion and a plurality of separate strands attached to and extending in parallel from the base portion; and

in a deployed state as a plurality of coiled members attached to and extending from the base portion and corresponding respectively to the strands to form a complex intertwining of coiled members to form an occluding mass that substantially occludes fluid flow through a lumen.

2. The device of claim 1, wherein the shape memory material is a shape memory polymer.

3. The device of claim 1, wherein the shape memory material is a metal, a shape memory metal alloy, or a superelastic metal alloy.

4. A method of making an endolumenally delivered device for vascular occlusion comprising

placing multiple formulations of shape memory polymer material serially within a first form of a deployed state of the occlusive vascular device to vary a modulus and diameter of the shape memory polymer material along a length of the first form;

setting the shape memory polymer material within the first form; and

removing the shape memory polymer material from the first form.

5. The method of claim 4 further comprising reforming the shape memory polymer material into a pre-deployed shape comprising a plurality of separate strands; and

attaching a base portion to the plurality of separate strands, the strands extending in parallel from the base portion.

6. The method of claim 5 further comprising positioning the occlusive vascular device in a pre-deployed state into a catheter for delivery.

7. The method of claim 6, wherein the catheter is a single lumen catheter.

8. The method of claim 4 further comprising attaching a base portion to the shape memory polymer material after removing the shape memory polymer material from the first form.

9. The method of claim 8 further comprising positioning the occlusive vascular device in a pre-deployed state into a catheter for delivery.

10. The method of claim 9, wherein the catheter is a single lumen catheter.

11. The method of claim 4, wherein the shape memory polymer material comprises one of more of the following additional materials: a radio-opacity material, a computed tomography (CT) compatible material, a tissue response material, a medication, or a thrombogenicity agent or material.

12. The method of claim 4, wherein the shape memory polymer material is coated with one of more of the following additional materials before, during, or after being placed in the first form: a hydrophilic coating, a thrombogenic coating, or a biodegradable coating.

13. The device of claim 1, wherein ends of the coiled members opposite the base portion are unconstrained.

14. The device of claim 1, wherein a diameter of one or more of the coiled members varies along a length of the one or more of the coiled members in the deployed state.

15. The device of claim 2, wherein the shape memory polymer material comprises multiple formulations within the occlusive vascular device and a modulus of the shape memory polymer material varies along a length of one or more of the coiled members in the deployed state.

16. The device of claim 2, wherein the shape memory polymer material comprises one of more of the following additional materials: a radio-opacity material, a computed tomography (CT) compatible material, a tissue response material, a medication, or a thrombogenicity agent or material.

17. The device of claim 2, wherein the shape memory polymer material is coated with one of more of the following additional materials: a hydrophilic coating, a thrombogenic coating, or a biodegradable coating.

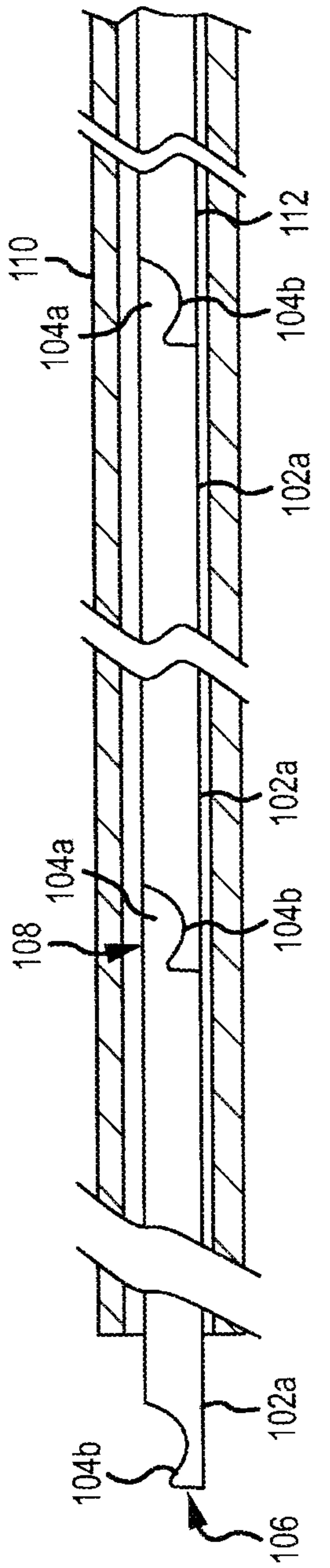
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FIG.1A

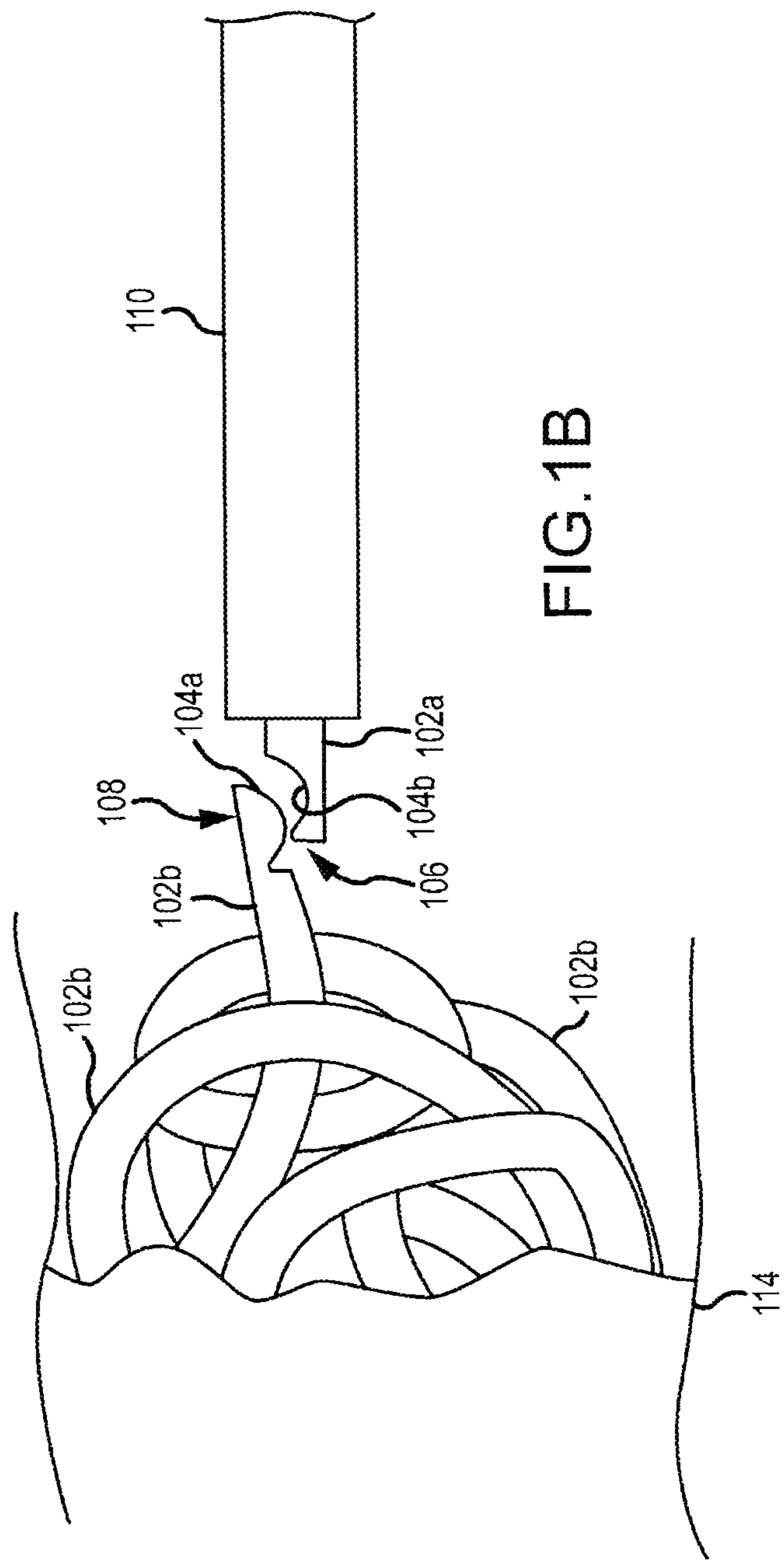
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FIG.1B

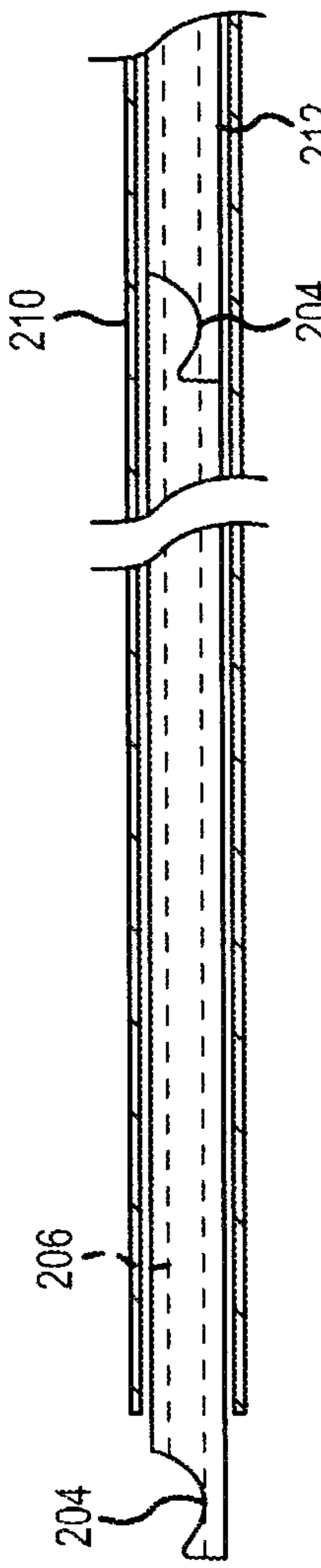

FIG.2B

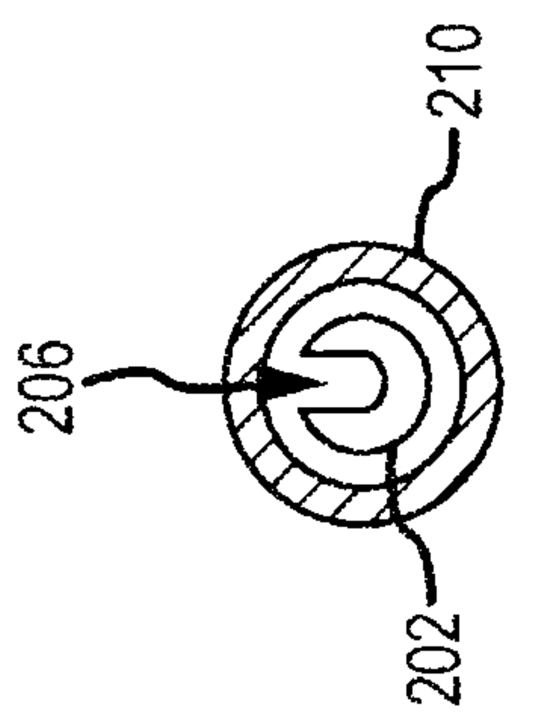

FIG.2C

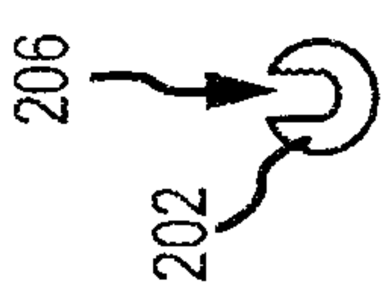

FIG.2A

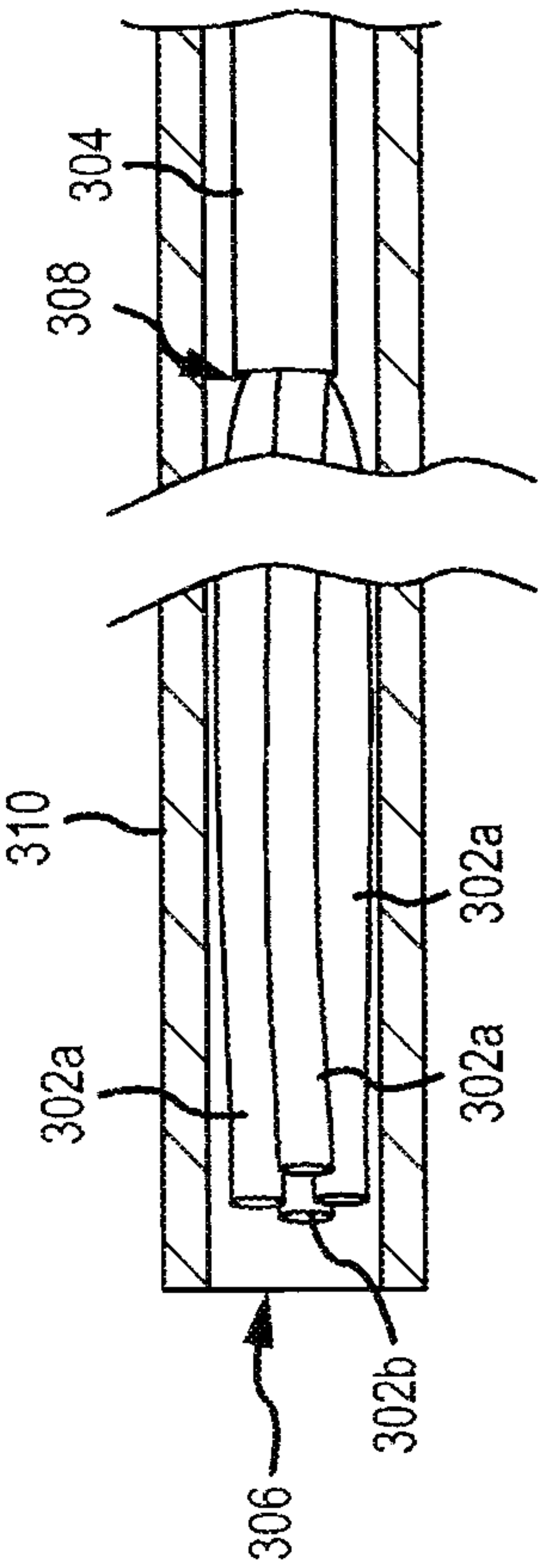

FIG.3A

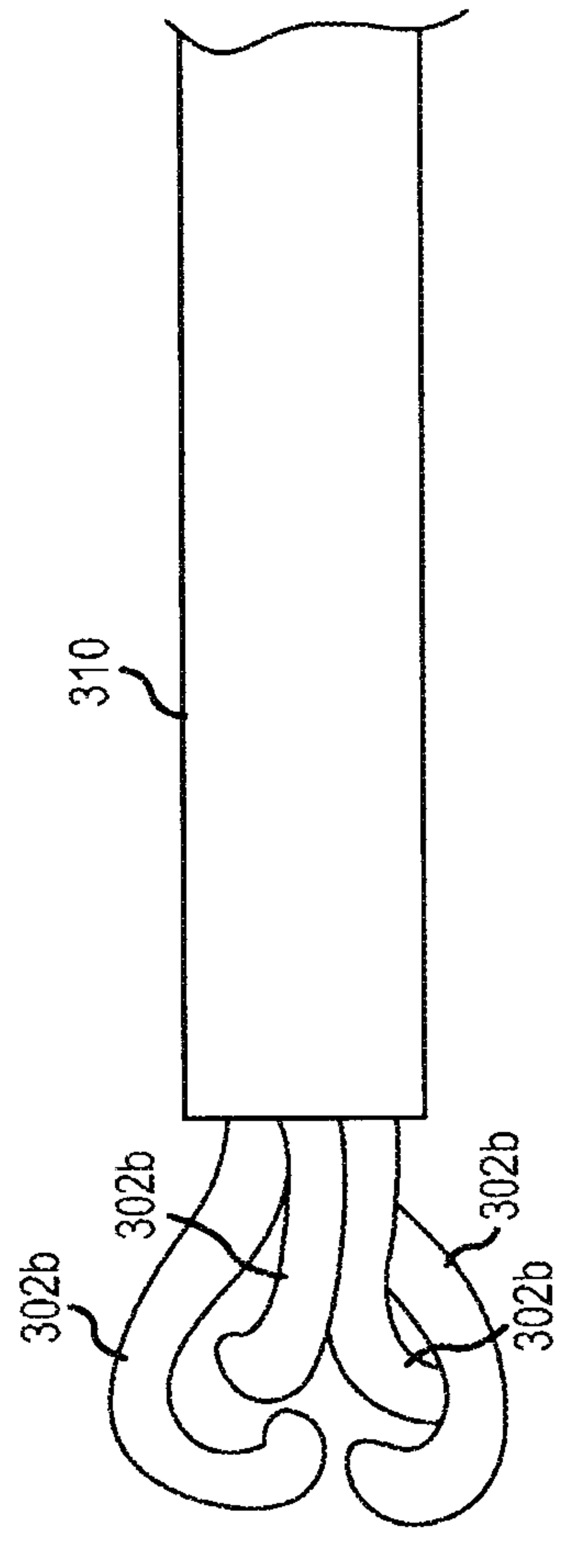

FIG.3B

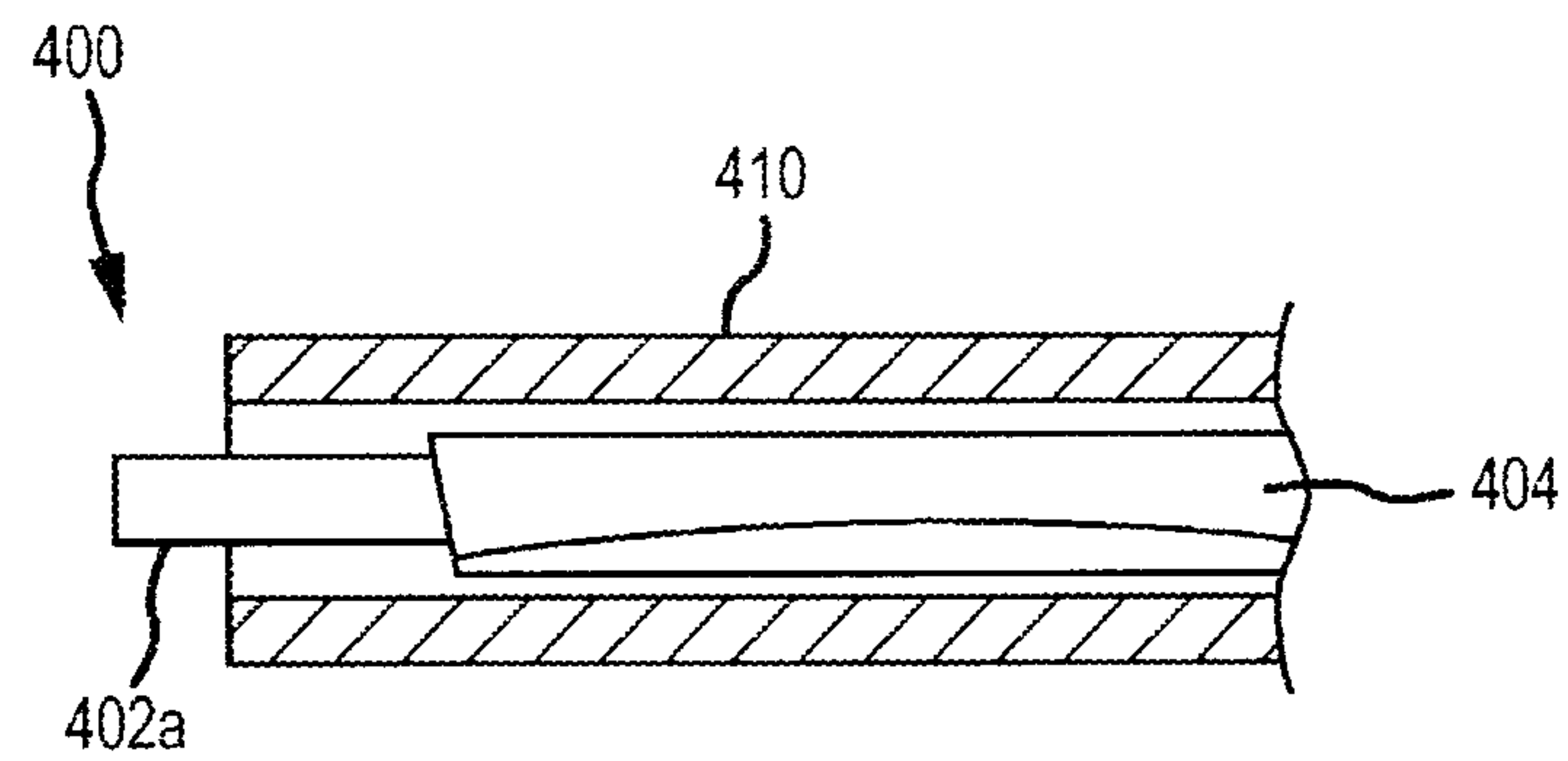

FIG.4A

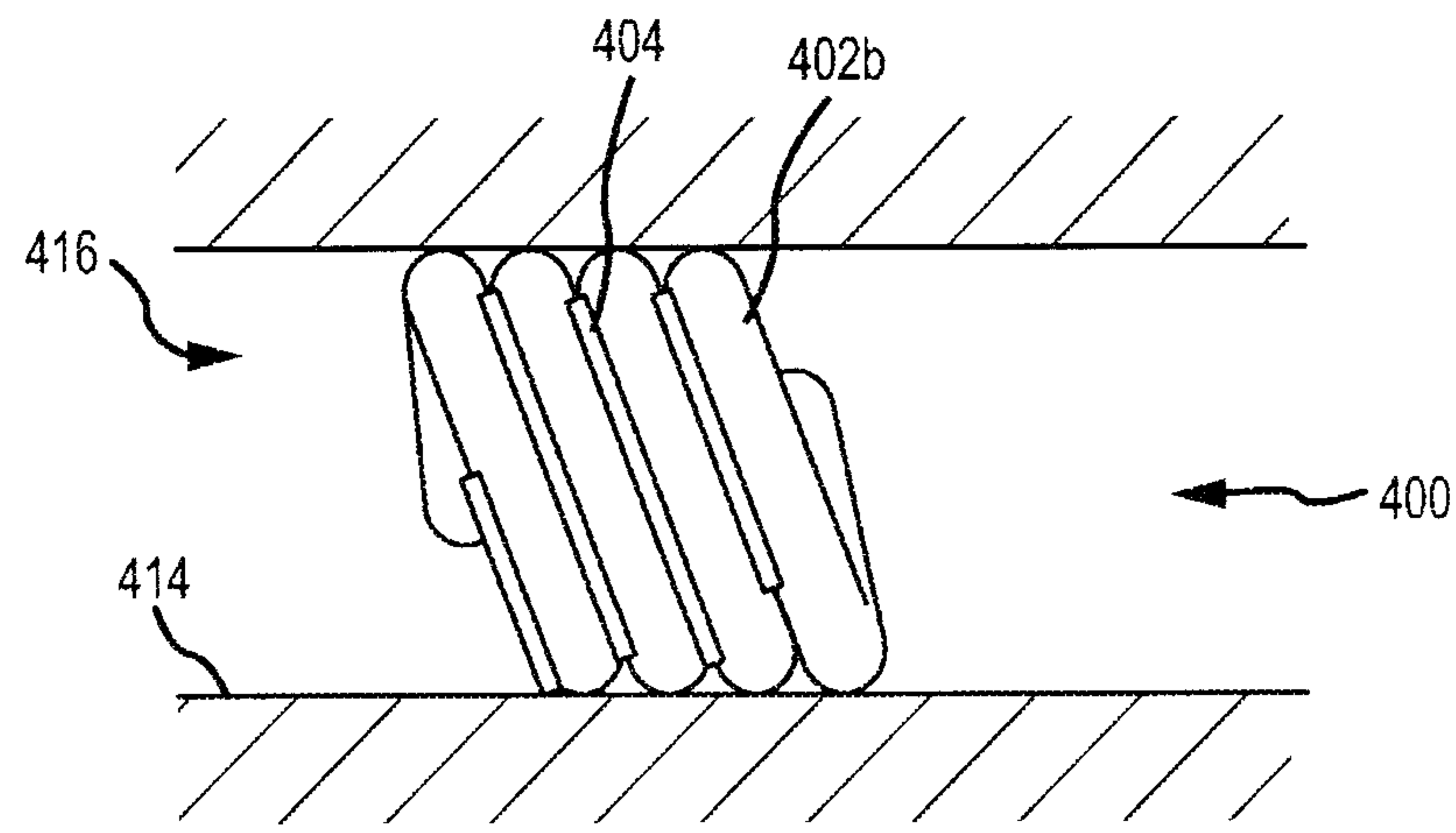

FIG.4B

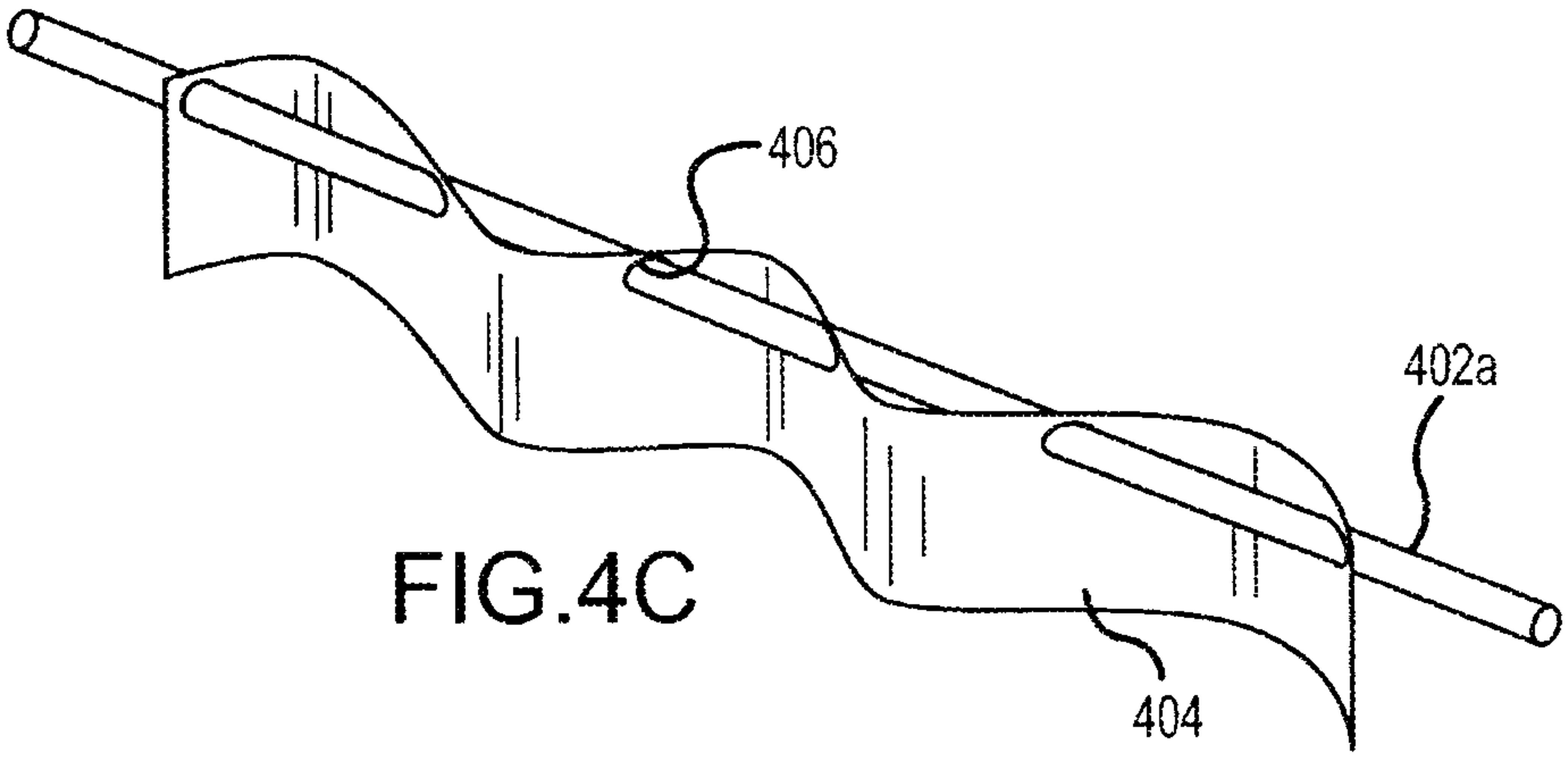

FIG.4C

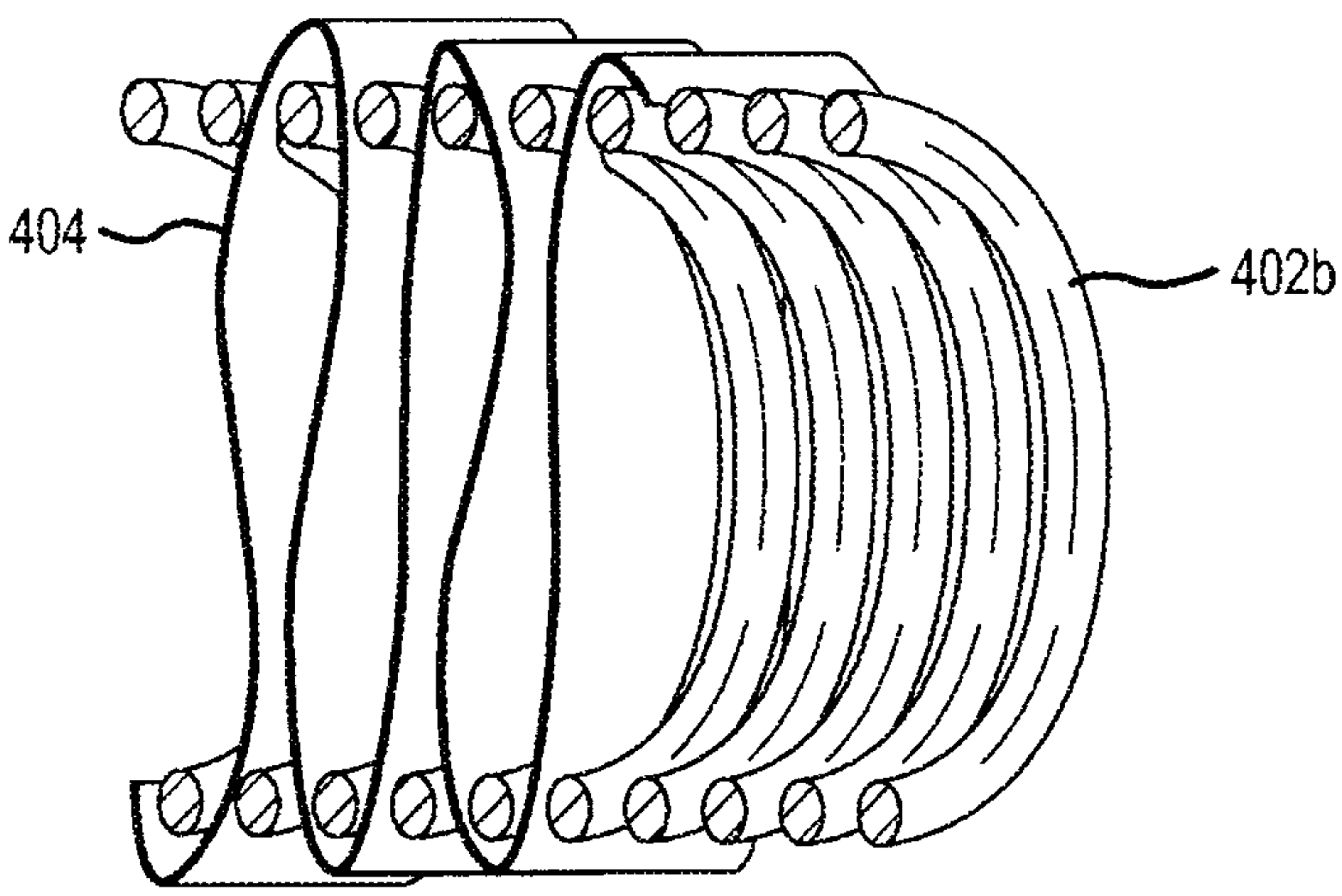

FIG.4D

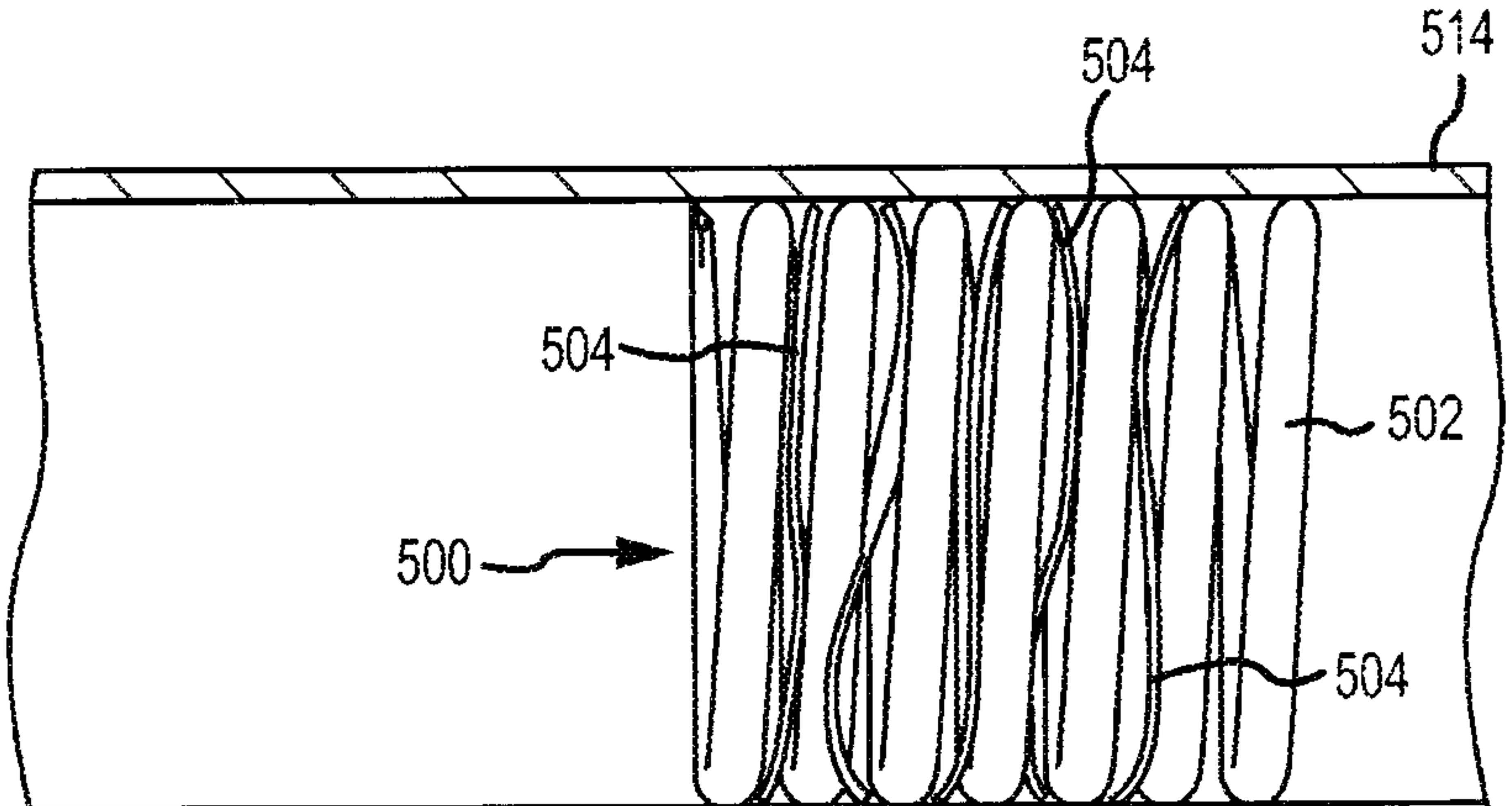

FIG.5

FIG.1B