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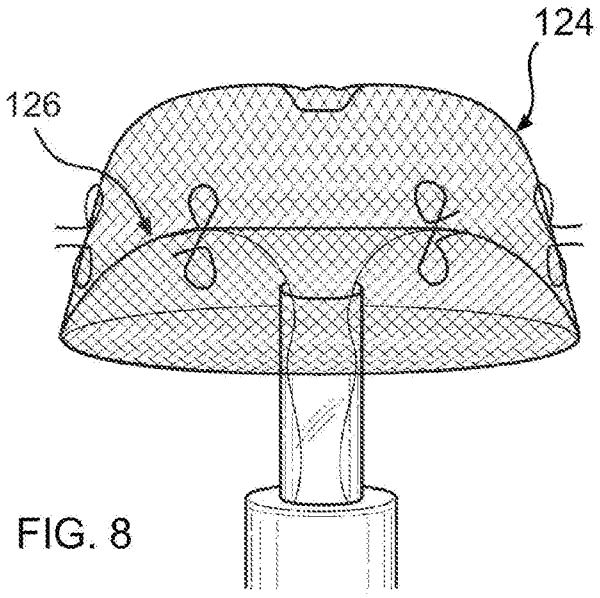


FIG. 8

(57) Abstract: An elongate resilient tube of a mesh of shape memory alloy is used to therapeutically occlude an opening in body tissue. The tube is compressible so that it can be delivered to the opening in the body within a catheter. The tube self-expands as it is released from the catheter to contiguously form, sequentially, the following shapes: an outer bell-shaped structure; an inner bell-shaped structure disposed within the outer bell-shaped structure to conformingly engage an inner side of the outer bell-shaped structure; a tubular connector having a diameter substantially smaller than the inner bell-shaped structure, the tubular connector extending away from an apex of the inner bell-shaped structure; an inner plate- shaped structure; an outer plate-shaped structure; and a releasable connector. The bell shape is placed on one side of the opening, and the plate shape is placed on the other side of the opening, the connector passing through the opening.

OCCLUDING ANATOMICAL STRUCTURES

FIELD OF THE DISCLOSURE

The disclosure relates to a system and method for occluding anatomical structures, and more particularly to a catheter delivered flexible self-anchoring cover for an internal body opening.

BACKGROUND OF THE DISCLOSURE

Occlusion devices are used to occlude or cover extra anatomical anomalies or malformations in the body which include for example appendages and aneurysms which can critically alter the normal functioning of a vessel or organ in the body. These anatomical structures can create a risk of clot formation which can lead to stroke or other serious or life threatening conditions. The risk can be greatly reduced by plugging or covering an opening into the structure.

SUMMARY OF THE DISCLOSURE

In an embodiment of the disclosure, a device for occluding an opening in body tissue, comprises an elongate resilient tube formed of a mesh of shape memory alloy, the tube compressible to be delivered to the opening within a catheter, the tube self-expanding as it is released from the catheter to contiguously form, sequentially: an outer curved structure; an inner curved structure disposed within the outer curved structure to conformingly engage an inner side of the outer curved structure; a tubular connector having a diameter substantially smaller than the inner curved structure, the tubular connector extending away from an apex of the inner curved structure; an inner plate-shaped structure; an outer plate-shaped structure; and a releasable connector.

In variations thereof, the shape memory alloy is nitinol; a distal end of the device, which emerges from the catheter first, forms a closed end; the shape memory alloy is braided; a proximal end of the device, which emerges from the catheter last, forms a closed end including the releasable connector; the outer plate-shaped structure is spaced apart from the inner plate-shaped structure; and/or the mesh shape is braided with at least one of a 72 and 142 carrier medical braider.

In further variations thereof, the device further includes a second elongate resilient tubed disposed within the elongate resilient tube, the outer curved structure, inner curved structure, tubular connector, inner plate-shaped structure, and outer plate-shaped structure are formed

from both the elongate resilient tube and the second resilient tube; and optionally the elongate resilient tube is braided with a first braider and the second elongate resilient tube is braided with a second braider, the first and second braiders having a different braid carrier count.

In other variations thereof, the inner curved structure, connector, and plate, and the outer curved structure, connector, and plate are all formed from a single braided tube which is involuted to form overlapping sleeves which are shaped together to form the inner and outer curved structures, connector, and inner and outer plate-shaped structures; the inner and outer curved structures together form a bell shaped structure when the tube is self-expanded; and/or the outer curved structure and the inner curved structure form a balloon shaped structure when the tube is self-expanded.

In another embodiment of the disclosure, a method for occluding an opening in body tissue, comprises delivering by a catheter an elongate resilient tube formed of a mesh of shape memory alloy, the tube compressible within the catheter, the tube self-expanding as it is released from the catheter to contiguously form, sequentially: an outer curved structure; an inner curved structure disposed within the outer curved structure to conformingly engage an inner side of the outer curved structure; a tubular connector having a diameter substantially smaller than the inner curved structure, the tubular connector extending away from an apex of the inner curved structure; an inner plate-shaped structure; an outer plate-shaped structure; and a releasable connector.

In variations thereof, the device is delivered into a left atrial appendage; the shape memory alloy is nitinol; the shape memory alloy is braided; a proximal end of the device, which emerges from the catheter last, forms a closed end including the releasable connector; and/or the inner curved structure, connector, and plate, and the outer curved structure, connector, and plate are all formed from a single braided tube which is partially involuted to form inner and outer sleeves which are then shaped.

In another embodiment of the disclosure, a device for occluding an opening in body tissue, comprises an elongate resilient tube formed of a mesh of shape memory alloy, the tube compressible to be delivered to the opening within a catheter, the tube self-expanding as it is released from the catheter to contiguously form, sequentially: an outer bell-shaped structure;

an inner bell-shaped structure disposed within the outer bell-shaped structure to conformingly engage an inner side of the outer bell-shaped structure; a tubular connector having a diameter substantially smaller than the inner bell-shaped structure, the tubular connector extending away from an apex of the inner bell-shaped structure; an inner plate-shaped structure; an outer plate-shaped structure; and a releasable connector.

BRIEF DESCRIPTION OF THE DRAWINGS

A more complete understanding of the present disclosure, and the attendant advantages and features thereof, will be more readily understood by reference to the following detailed description when considered in conjunction with the accompanying drawings wherein:

FIG. 1 depicts a side view of an occlusion device of the disclosure;

FIG. 2A depicts a cactus type left atrial appendage (LAA);

FIG. 2B depicts a windsock type LAA;

FIG. 2C depicts a cauliflower type LAA;

FIG. 2D depicts a chicken wing type LAA;

FIG. 2E depicts a wall or septum within the body having an opening or perforation;

FIG. 3 depicts the device of FIG. 1 secured in place within an LAA;

FIG. 4 depicts the device of FIG. 1 beginning to emerge from a catheter;

FIG. 5 depicts the device of FIG. 1, continuing to emerge and beginning to form an outer bell-shape structure;

FIG. 6 depicts the device of FIG. 1, continuing to emerge and form the outer bell-shape structure;

FIG. 7 depicts the device of FIG. 1, continuing to emerge and completing formation of the outer bell-shape structure;

FIG. 8 depicts the device of FIG. 1, continuing to emerge and beginning to form an inner bell-shape structure;

FIG. 9 depicts the device of FIG. 1, continuing to emerge and completing formation of the inner bell-shape structure;

FIG. 10 depicts the device of FIG. 1, continuing to emerge and forming a connector portion, and beginning to form a cover structure;

FIGS. 11-12 depict the device of FIG. 1, continuing to emerge and continuing to form the cover structure;

FIG. 13 depicts the device of FIG. 1, fully emerged from the catheter and fully formed;

FIG. 14 depicts a perspective view of the device of FIG. 13;

FIG. 15 depicts an attachment mechanism between the device and a deployment cable of the cathether;

FIG. 16 depicts retrieval of the device of FIG. 1, the cover returning to a balloon-like shape as it is pulled into the catheter;

FIG. 17 depicts retrieval of the device of FIG. 1, the cover fully withdrawn into the catheter;

FIG. 18 depicts retrieval of the device of FIG. 1, the inner bell-shape withdrawn;

FIG. 19-21 depicts retrieval of the device of FIG. 1, the outer bell-shape in progressive stages of being withdrawn;

FIG. 22 depicts all but a distal end of the device of FIG. 1 withdrawn into the catheter;

FIG. 23 depicts an isometric view of a set of hooks of the disclosure;

FIG. 24 depicts a side view of the hooks of FIG. 23;

FIG. 25 depicts a top view of a device of the disclosure, the dual plate configuration including a filtering membrane;

FIG. 26 depicts the device of FIG. 25, detailing a threaded connector of the disclosure;

FIG. 27 is a detailed view of hooks of the disclosure, attached using sutures to an outer bell-shaped structure of a device of the disclosure;

FIG. 28 depicts a cross-section of the device of FIG. 1, in place to occlude a perforation in a septum;

FIG. 29 depicts an alternative anchor configuration including an additional plate-shaped structure;

FIG. 30 depicts an alternative anchor configuration including a balloon shaped structure;

FIG. 31 depicts an alternative anchor configuration including a reverse bell-shaped structure;

FIG. 32A diagrammatically depicts a single layer tubular structure used to form a device of the disclosure;

FIG. 32B depicts a dual layer structure which can be formed by turning a longer single layer tubular structure inside out, or by nesting two tubular structures;

FIG. 32C diagrammatically depicts a dual layer structure forming a device of the disclosure;

FIG. 33A depicts a dual layer structure formed of an inside tubular structure that has a different braid or mesh structure than an outer tubular structure; and

FIG. 33B depicts the inside and outside tubular structures of FIG. 33A in a mutually reversed location.

DETAILED DESCRIPTION OF THE DISCLOSURE

As required, detailed embodiments are disclosed herein; however, it is to be understood that the disclosed embodiments are merely examples and that the systems and methods

described below can be embodied in various forms. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a basis for the claims and as a representative basis for teaching one skilled in the art to variously employ the present subject matter in virtually any appropriately detailed structure and function. Further, the terms and phrases used herein are not intended to be limiting, but rather, to provide an understandable description of the concepts.

The terms "a" or "an", as used herein, are defined as one or more than one. The term plurality, as used herein, is defined as two or more than two. The term another, as used herein, is defined as at least a second or more. The terms "including" and "having," as used herein, are defined as comprising (i.e., open language). The term "coupled," as used herein, is defined as "connected," although not necessarily directly, and not necessarily mechanically.

With reference to FIGS. 1-3, a device 100 of the disclosure includes an anchor 120 sized to conformingly engage interior sidewalls of a malformed or anomalous anatomical structure within the body (hereinafter the 'anatomical structure'), and a cover 160 sized to occlude or overlie an opening into the structure. Devices 100 of the disclosure can be used to occlude any opening of the body. Examples are shown in FIGS. 2A-2D, diagrammatically illustrating various known types of left atrial appendages (LAAs), and FIG. 2E illustrating any type of tissue wall having an undesired opening.

FIG. 3 illustrates a 'windsock' type LAA 302 of a human heart 300, in cross-section, closed off or occluded with device 100. Additionally shown in part are the left atrium 306, and the left superior pulmonary vein 308. It may be seen that an outer anchor sidewall, or outer bell-shape 124 is conforming to a convoluted geometry of the interior surface 304 of the LAA. It may further be seen that cover 160 conforms to the surface of anatomy, in this example the interior of atrium 306, and is eventually covered over by body tissue.

Device 100 is attached to a deployment cable 180 (visible in FIG. 15), and is inserted into a catheter 182 for deployment or retrieval. In the example of the LAA, the catheter is passed through a vein in the leg, and passes into the left atrium through a transseptal puncture of the interatrial septum, or by other known method. A pigtail catheter can be used to reduce a possibility of LAA perforation, and a preloaded delivery catheter can be advanced over the pigtail into the LAA, as would be understood within the art. The preloaded delivery catheter is advanced into the tip of an access sheath, and is deployed by first pushing the device into the sheath. Then, while the sheath remains in place at the mouth of the LAA, device 100 is pushed out using cable 180 which is connected to device 100. A final position can be

confirmed with Transesophageal Echocardiography (TEE), intracardiac echocardiography (ICE), fluoroscopy, or any other known method.

A catheter can likewise be used to access any other body structure into which device 100 is to be deployed or retrieved. Device 100 is constructed as a mesh of resilient expandable material. In the embodiment shown, the mesh is formed from woven strands of memory wire. Alternatively, device 100 can be formed by stamping apertures in a sheet of such material. Within the catheter, device 100 forms an elongated tubular structure that is held in a compressed form. In an embodiment, the mesh is formed from a polymeric material, and can be woven from strands; stamped from a sheet which then fused along an edge to form a tube; or is molded into the form described herein. The tube can be braided or knitted, and is molded in specific shapes disclosed herein in order to be able to be compressed, delivered inside the body, and released to resume the molded shape.

Whether stamped or formed as a wire mesh, the resilient expandable material can be a shape memory metal or alloy such as nitinol, although another material that is super-elastic, resilient, has a shape memory effect to resume a pre-formed shape, and is durable and biocompatible. Specific shape memory materials that can be used include copper-aluminum-nickel, and nickel titanium alloys, although other materials having similar characteristics may be used, which are either known or are to be hereinafter developed. The material can be a combination of a shape memory metal and a polymeric material, wherein the polymeric fibers are interspaced within the strands of Nitinol, as shown in the illustrations. Additionally, cladded materials can be used, for example wherein the Nitinol is cladded on the outside with platinum, gold, another biocompatible noble metal, or any other passive materials. The disclosed device 100 shapes are made by forcing the braid or the knit into a mold corresponding to the desired final shape, and then applying a prescribed heat for a predetermined time, in accordance with the requirements of the material selected, to heat set the mold shape.

In various embodiments, the tubular structure 102 (FIG. 32A) of device 100 is open at each end, or is closed at one or both ends. In the embodiment illustrated, the woven material is closed at each end. At a distal end 132 which emerges from the catheter into the body first, the woven material is gathered into a crimp 122, although other forms of closure can be carried out, including using adhesive, brazing, soldering, fusing, sewing, or a clip or other fastener, for example. At a proximal end of device 100, material is gathered and attached to a connector 170, so that device 100 can be releasably attached to deployment cable 180. Attachment can be by any means, including a threaded connection or twist-lock connection,

for example, and can be fabricated using a biocompatible metal or plastic material, for example. By gathering and crimping distal end 132, a potential for piercing of body tissue is reduced. In an embodiment, connector 170 includes a female threaded portion connected to device 100, and a mating male threaded portion at the end of cable 180. Connector 170 enables cable 180 to push device 100 out of the sheath and into the anatomical structure where device 100 can be released by unthreading connector 170. If needed, cable 180 can be rethreaded to connector 170, whereupon device 100 can be retrieved from the body by pulling cable 180.

Device 100 is pushed by deployment cable 180 through catheter 182. Accordingly, the material of device 100 must be sufficiently stiff to resist collapsing and allowing cable 180 to advance past device 100. As portions of device 100 are released from catheter 182, the memory function of the shaped memory metal causes the formation of predetermined shapes, as shown in the Figures and as described herein.

In FIG. 4, crimp 122 at distal end 132 emerges from catheter 180 first. It may be seen that the woven structure of device 100 is compressed together to enable device 100 to fit within the catheter. In FIGS. 5 and 6, device 100 self-expands based upon the resilient spring-like nature of the shape memory alloy. Initially, this self-expansion forms a balloon-like structure, as the mesh is permitted to expand upon release from the catheter. In FIG. 7, an edge appears, and a general outline of an outer bell-shape 124 of anchor 120 becomes evident. As can be seen in FIG. 7, the bell-shaped structure is hollow, and is formed with a single wall. In FIG. 8, a lower edge 130 reverses upon itself, and an inner bell-shape 126 forms within the outer bell-shape 124. In FIG. 9, it may be seen that inner bell-shape 126 abuts, and reinforces, outer bell shape 124, forming the hollow, double-walled bell shape of anchor 120. Inner bell-shape 126 conformingly engages an inner side of outer bell-shape 124, and thereby locks outer bell-shape into conforming engagement with body tissue of the anatomical structure.

In FIG. 10, the structure of cover 160 begins to emerge from catheter 182, and to expand. A tubular connector 128 extends between a distal end 132 of device 100, at an apex of inner bell-shape 126, to cover 120. In FIG. 11, it may be seen that cover 120, as with anchor 160, is formed of dual layers, which initially appear as a balloon-like structure during expansion. In FIG. 12, distal and proximal cover surfaces 162 and 164, respectively, begin to form. In FIG. 13, cover 160 has taken its final dual layer, dual plate-shape configuration. FIG. 15 is a perspective view, in which it may be seen that cover 160 has a distal surface, adjacent anchor 120, that is substantially planar, although it can be curved to conform to

particular anatomy to be occluded. Other shapes can be formed which are best suited for a particular anatomical structure to be covered. Proximal cover surface 164 can lie spaced apart from distal cover surface 162, for example by forming a depression 168, so that it can resiliently press outer cover edge 166 firmly against body tissue while distal cover surface conforms to body tissue.

In an embodiment, at least proximal cover surface 164 is coated with a tissue growth factor, to promote integration of cover 160 into the body, further securing device 100 within the body, and further reducing a possibility of clot formation. It may be advantageous to coat all of device 100 with such growth factor, or to integrate the growth factor into a coating of the shape memory material of device 100, where it may be released slowly over time. Other substances can be used to coat part or all of device 100, for example including a blood thinner, antibiotic, drug, or other therapeutic substance. Device 100 may be covered with a flexible fabric, for example a polymeric fabric such as polyethylene terephthalate (PET) or other biocompatible material. This can be advantageous if it is desired to filter particles from entering or leaving the anatomical structure which are smaller than the openings in the mesh of device 100. Similarly, a nano-material can be used to cover device 100.

Additionally or alternatively, nanomaterials such as platinum or gold or another passive material can be used to coat the occluding device. In such coatings, each individual wire is coated using vapor deposition technology or nano-layering technology, so that individual wires or fibers in device 100 are coated with a thin or ultrathin layer of material.

In the embodiment of FIGS. 25-26, a polymeric filtering fabric filter 178 is inserted between proximal and distal cover surfaces 162, 164, and provides further protection from migration of clots or particles from within the anatomical structure to the blood stream. Filter 178 can be held in place by being attached to connector 170, or it can be sutured or adhered in place at least until deployment, when it is maintained in position by being constrained between surfaces 162 and 164. Filter 178 can be fabricated from any biocompatible material that is compressible during deployment, including for example PET fabric, and which has a desired mesh or pore size.

In FIGS. 14-15, deployment cable 180 is visible as a rod of coiled wire, although any known construction can be used. Cable 180 can be rotated axially to unthread or otherwise disconnect cable mating connector portion 170, attached to deployment cable 180, from a device mating connector portion 170.

In FIG. 15, device 100 begins to be recaptured or retrieved into catheter 182, causing some distortion in proximal cover surface 164. Retrieval can be carried out for repositioning

device 100 within the same procedure, or for removing device 100 after an extended period of time. In FIG. 16, a collapsing pressure is applied by an end of catheter 182, and cover 160 is stretched to once again form a balloon shape, which has entered the catheter in FIG. 17. In FIG. 18, inner bell-shape 126 is pulled away from outer bell-shape 124, and is drawn into catheter 182. In FIG. 19, inner bell-shape 126 has inverted, forming a balloon shape together with outer bell-shape 124. In FIGS. 21 and 22, inner bell-shape 126 is drawn into catheter 182, and finally, in FIG. 22, outer bell-shape 124 is drawn into catheter 182, where only clip 122 is visible. Device 100 can be fully removed from the body by continuing to withdraw deployment cable 180 from catheter 182.

Additionally visible in the Figures, and with reference to FIGS. 23-24, are hooks 140, attached to anchor 120. It should be understood that anchor 120 can securely attach to body tissue by pressing outwards against inner walls of the anatomical structure into which it has been inserted, and by resiliently conforming to the interior surface, as shown and described herein. Accordingly, hooks 140 are optional, but can be used where it is desired to provide an additional safeguard against device 100 becoming dislodged or embolized. Hooks 140 include a barb portion 142, which projects at an angle from the surface of outer bell-shape 124 of anchor 120, whereby hooks 140 can insert into body tissue as anchor 120 expands to its final conforming shape within the body.

A flattened portion 144 is woven into or otherwise attached to outer bell-shape 124, for example using sutures 176, as shown in FIGS. 14 and 27 (omitted in other figures, for clarity), to maintain a particular angular disposition with respect to a surface of device 100 after deployment. Where anchor 120 is formed as a stamping, barbs 142 can be bent to form the required angle. Barbs 142 are resiliently attached to flattened portion 144, so that they can be folded to lie against flattened portion 144 during deployment and retrieval of device 100 through catheter 182. The particular shape of the hook structure in FIGS. 23 and 24 is one example of how hooks can be formed and attached to a mesh material of device 100. Other shapes and styles of hooks or barbs are known in the art, and can be used with device 100 of the disclosure. Additionally, the number of hooks 140, if used at all, can be varied in accordance with the requirements of the particular deployment. The attaching sutures can be made with Polyethylene terephthalate (PET), Polypropylene, or Polytetrafluoroethylene (PTFE), for example.

Anchor 120 of the disclosure, due to its bell shape, can compress to a small proportion of its deployed diameter, enabling it to conform to, and securely attach to, a wide range of anatomical structure diameters. In particular, anchor 120 forms a bell shape with elongated

sidewalls, wherein the bell is open at the bottom, facilitating close and undistorted tracking of the elongated sidewalls to the geometry of body tissue in an interior of the anatomical structure. The wide range of compression further ensures that it can maintain engagement with internal sidewalls despite substantial motion of body tissues, particularly within the heart. For occluding an LLA, for example, outer bell-shape 124 can have a diameter of as small as about 18mm, up to about 36mm, for typical anatomy. While each device can accommodate a wide range of variation in a diameter of the body tissue, for an optimal fit, outer bell-shape 124 can be provided in sizes at increments of 2mm, for example 18mm, 20mm, 22mm, 24mm, 26mm, 28mm, 30mm, 32mm, 34mm and 36mm. Inside bell-shape 126 has a diameter of about 2mm less than outside bell-shape 124, when device 100 is not pressed against body tissue, so would be sized at 16mm, 18mm, 20mm, 22mm, 24mm, 26mm, 28mm, 30mm, 32mm and 34mm.

In addition, the wide range of compression enables it to conform to substantial changes in the internal diameter of the anatomical structure over time. The wide range of resiliency, and large surface area of tissue contact, enable device 100 to be atraumatic, for embodiments without hooks 140. The extended contact area of device 100 further eliminates a need for oversizing in order to form a tight fit against body tissue, thereby avoiding tearing of body tissue, particularly in view of continuous movement of the body tissue, as in the heart. Further due to the wide range of compression, a reduced range of sizes for device 100 need to be maintained on-hand. The expanded diameter size of device 100 is determined by the range of diameters of anatomical structures to be occluded. For use in occluding LAAs, device 100 can be provided in one or more expanded diameters of between 21 and 33 mm, for example, and using, for example, a 9-Fr to 14-Fr catheter.

Cover 160, being formed of two layers of mesh, is also resilient, and can compress and deform to a substantial extent, to conform to the anatomy external to, or at the entrance to, the anatomical structure. In particular, distal cover surface 162 can contact and follow a tissue surface shape, while proximal cover surface 164, which is separated from distal cover surface 162, can maintain its shape while exerting a compressive force against distal cover surface 162.

Because device 100 is formed as a fine mesh, for example having openings of less than 1 mm, it can tightly seal against the body, and function as a filter immediately upon deployment, whether or not an overcoating fabric is provided. In addition, the mesh structure contacts body tissue with an even and diffuse application of pressure, improving grip with body tissue, while reducing trauma. The aperture sizes is determined by the pitch width and

the pitch angle of the wires from which the mesh of device 100 is formed. These factors can be predetermined to form a mesh opening of a desired size, for example less than 1mm, when the braid construction is completed. In this manner, the mesh is very compact, enabling retention of any clots inside the anatomical structure cavity.

By forming a separate anchor 120 and cover 160, device 100 enables anchor 120 to independently compress and conform to a wide variety of internal structures, while cover 160, which is separated from anchor 120 by tubular connector 128, can remain expanded to its fullest diameter, completely covering an opening to the anatomical structure. Moreover, as tubular connector 128 is highly flexible, it can bend to enable cover 160 to lie in close contact with body tissue outside of, or at an entrance to the anatomical structure, at an angle that is independent of an angular disposition of anchor 120.

Outer bell-shape 124 and inner bell-shape 126 interact to form a snap-fit or locking button, which prevents displacement of device 100 within the body. More particularly, and without being bound to a particular theory, outer bell-shape 124 conformingly engages an interior surface of the anatomical structure while it is still in a very flexible deformable balloon shape. When inner bell-shape 126 snaps into its memory shape, aligned within outer bell-shape 124, it locks the outer bell-shape 124 in this conformed configuration, by completing the shape memory inner-outer bell shape. Once the shape memory has been allowed to reform, it is resistant to further changes, particularly by displacement along a longitudinal axis extending between a proximal end at connector 170, and distal end 132, which would need to overcome the memory imposed shape. This prevents outer bell-shape 124 from rolling or otherwise moving along a surface of body tissue. Additionally, the force applied by inner bell-shape 126 against outer bell-shape 124 stiffens outer bell-shape 124 within its current conforming configuration, further resisting displacement of outer bell-shape 124 with respect to body tissue.

When occluding an opening or gap 320 in a tissue wall 322, for example of the type shown in FIG. 2E, device 100 can be positioned with cover 160 and anchor 120 on opposite sides of the wall, as shown in FIG. 2B. Anchor 120 compresses by displacing lower edge 130 in a direction towards distal end 132, causing cover 160 to compress against opposite side of wall 320.

While the inventors have found that anchor 120 is advantageously a bell-shaped structure connected to and cooperative with a plate-shaped which remains in place in the left atrium. However, device 100 can be configured for other areas of the body where the bell-shaped structure can have an alternate configuration which is better adapted to different

anatomical geometry than the left atrium. For example, in other areas of the body, other structures can be formed, such as another plate-shaped structure 120A (FIG. 29), a balloon shape 120B (FIG. 30) which is generally spherical, ovoid, or pear shape, for example; or alternatively, a reverse bell 120C (FIG. 31) can be formed.

The inventor has further found that a dual layer structure 102A, 102B, 102C (FIG. 32B-33) of device 100 provides for improved pushability through the catheter and into the body, improving a resistance to twisting and further maintaining a desired post-expansion shape. Dual layers can provide for improved radial strength, and provide increased surface density for desired blocking or occlusion of anatomy after deployment, and as well as an improved scaffold for tissue growth.

FIG. 32A illustrates a single layer tubular structure 102, and figure 32B illustrates tubular structure 102A which has been folded in on itself to form a dual layer tubular structure 102A. This double layer structure is then formed and the desired post-expansion shape is formed as otherwise described elsewhere herein, as shown in FIG. 32C.

The diameter or thickness of the wires forming the mesh of device 100 can be selected based upon the patient size, the dimensions of the implant site and target anatomy, and the strength required. The disclosure can be carried out with any wire thickness which will yield a device 100 having the properties shown and described herein. In one embodiment not intended to be limiting, the wires are of a very thin size suitable for 144 carrier medical braider, or heavier wires suitable for a 72 carrier braider. In another embodiment, the inner layer and outer layer are formed with different braider carrier types, for example a relatively thicker 72 carrier for the inner layer, and a thinner 144 carrier for the outer layer. in this manner, the outside layer of 144 carrier braids provides relatively greater metal coverage due to the thinner wires more densely woven, while the inside layer of 72 braids provides relatively greater axial and radial strength to maintain the desired form shapes, for example cover 160 and anchor 120, and to maintain the shapes in a desired location.

FIG. 33A illustrates, diagrammatically, an outer layer 104 which has a lower braid count, and an inner layer 106 with a higher braid count, the two layers joined at their ends. The resulting dual layer structure is then formed into the desired shape as described herein (e.g. as shown in FIG. 32C). FIG. 33B depicts the layers reversed, with the lower braid count 106 on the outside. The dual layer configurations described herein are otherwise formed and used as described herein.

Dissimilar braid sizes for the inside and outside surfaces can be joined at seams using any known method, including for example welding, brazing, soldering, weaving stamping pinching, crimping, braiding, or other method. When both layers are made from the same braid size, the inner layer can be formed by partially involuting or folding a portion of the braided material inside the other, or turning inside-out, a part of a braided tube, for example half of a tube. The interaction of the dual layers of braided or woven metals facilitates the various properties described herein, including enabling the expanded formation of structures having a desired variable depth and width to accommodate a wide variety of anatomical structures which need to be closed. Examples of such anatomical structures are found in a variety of anatomical indications like Neurological procedures, Cardiovascular procedures, Peripheral procedures, and procedures involving other systems.

All references cited herein are expressly incorporated by reference in their entirety. It will be appreciated by persons skilled in the art that the present disclosure is not limited to what has been particularly shown and described herein above. In addition, unless mention was made above to the contrary, it should be noted that all of the accompanying drawings are not to scale. There are many different features to the present disclosure and it is contemplated that these features may be used together or separately. Thus, the disclosure should not be limited to any particular combination of features or to a particular application of the disclosure. Further, it should be understood that variations and modifications within the spirit and scope of the disclosure might occur to those skilled in the art to which the disclosure pertains. Accordingly, all expedient modifications readily attainable by one versed in the art from the disclosure set forth herein that are within the scope and spirit of the present disclosure are to be included as further embodiments of the present disclosure.

What is claimed is:

1. A device for occluding an opening in body tissue, comprising:

an elongate resilient tube formed of a mesh of shape memory alloy, the tube compressible to be delivered to the opening within a catheter, the tube self-expanding as it is released from the catheter to contiguously form, sequentially:

an outer curved structure;

an inner curved structure disposed within the outer curved structure to conformingly engage an inner side of the outer curved structure;

a tubular connector having a diameter substantially smaller than the inner curved structure, the tubular connector extending away from an apex of the inner curved structure;

an inner plate-shaped structure;

an outer plate-shaped structure; and

a releasable connector.

2. The device of claim 1, wherein the shape memory alloy is nitinol.

3. The device of claim 1, wherein a distal end of the device, which emerges from the catheter first, forms a closed end.

4. The device of claim 1, wherein the shape memory alloy is braided.

5. The device of claim 1, wherein a proximal end of the device, which emerges from the catheter last, forms a closed end including the releasable connector.

6. The device of claim 1, wherein the outer plate-shaped structure is spaced apart from the inner plate-shaped structure.

7. The device of claim 1, wherein the mesh shape is braided with at least one of a 72 and 142 carrier medical braider.

8. The device of claim 1, further including a second elongate resilient tubed disposed within the elongate resilient tube, the outer curved structure, inner curved structure, tubular connector, inner plate-shaped structure, and outer plate-shaped structure are formed from both the elongate resilient tube and the second resilient tube.

9. The device of claim 8, wherein the elongate resilient tube is braided with a first braider and the second elongate resilient tube is braided with a second braider, the first and second braiders having a different braid carrier count.

10. The device of claim 1, wherein the inner curved structure, connector, and plate, and the outer curved structure, connector, and plate are all formed from a single braided tube which is involuted to form overlapping sleeves which are shaped together to form the inner and outer curved structures, connector, and inner and outer plate-shaped structures.

11. The device of claim 1, wherein the inner and outer curved structures together form a bell shaped structure when the tube is self-expanded.

12. The device of claim 1, wherein the outer curved structure and the inner curved structure form a balloon shaped structure when the tube is self-expanded.

13. A method for occluding an opening in body tissue, comprising:

delivering by a catheter an elongate resilient tube formed of a mesh of shape memory alloy, the tube compressible within the catheter, the tube self-expanding as it is released from the catheter to contiguously form, sequentially:

an outer curved structure;

an inner curved structure disposed within the outer curved structure to conformingly engage an inner side of the outer curved structure;

a tubular connector having a diameter substantially smaller than the inner curved structure, the tubular connector extending away from an apex of the inner curved structure;

an inner plate-shaped structure;

an outer plate-shaped structure; and

a releasable connector.

14. The method of claim 13, wherein the device is delivered into a left atrial appendage.

15. The method of claim 13, wherein the shape memory alloy is nitinol.

16. The method of claim 13, wherein the shape memory alloy is braided.

17. The method of claim 13, wherein a proximal end of the device, which emerges from the catheter last, forms a closed end including the releasable connector.

18. The method of claim 13, wherein the inner curved structure, connector, and plate, and the outer curved structure, connector, and plate are all formed from a single braided tube which is partially involuted to form inner and outer sleeves which are then shaped.

19. A device for occluding an opening in body tissue, comprising:

an elongate resilient tube formed of a mesh of shape memory alloy, the tube compressible to be delivered to the opening within a catheter, the tube self-expanding as it is released from the catheter to contiguously form, sequentially:

an outer bell-shaped structure;

an inner bell-shaped structure disposed within the outer bell-shaped structure to conformingly engage an inner side of the outer bell-shaped structure;

a tubular connector having a diameter substantially smaller than the inner bell-shaped structure, the tubular connector extending away from an apex of the inner bell-shaped structure;

an inner plate-shaped structure;

an outer plate-shaped structure; and

a releasable connector.

FIG. 2A

FIG. 2B

FIG. 2C

FIG. 2D

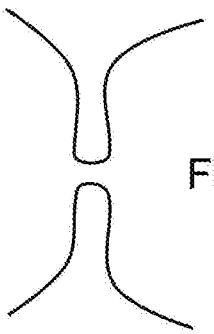


FIG. 2E

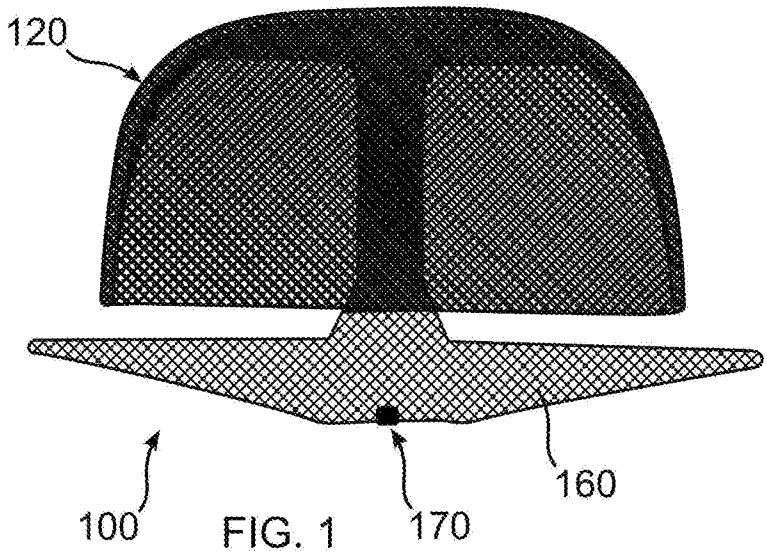


FIG. 1

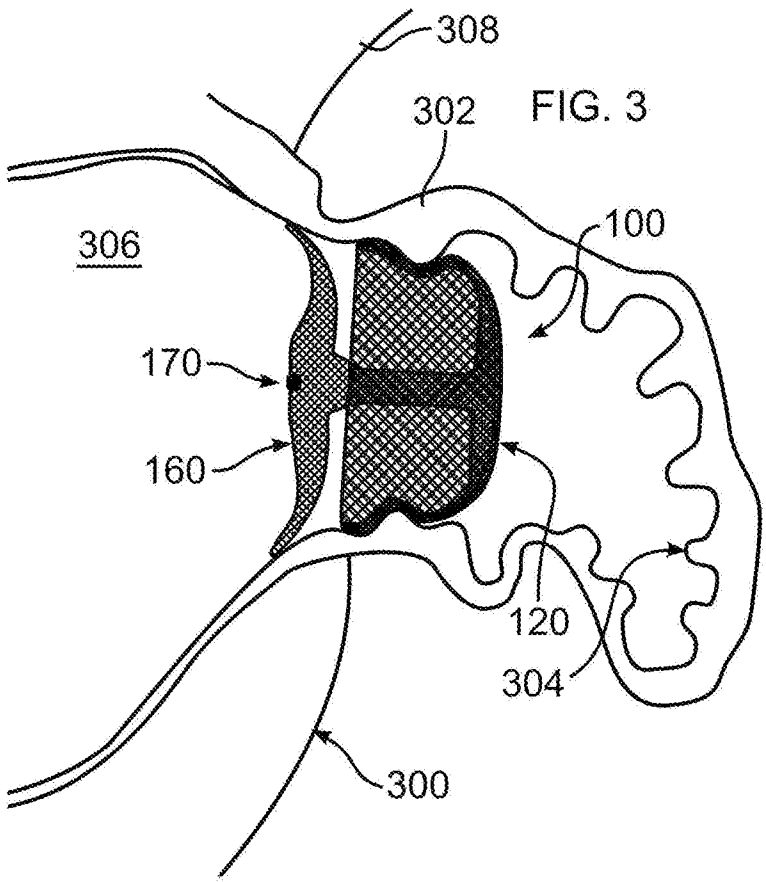


FIG. 3

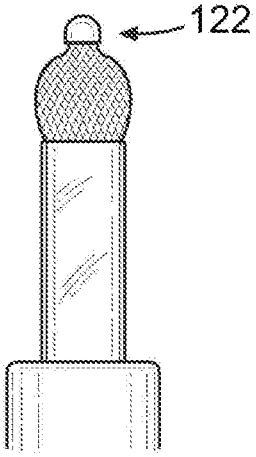


FIG. 4

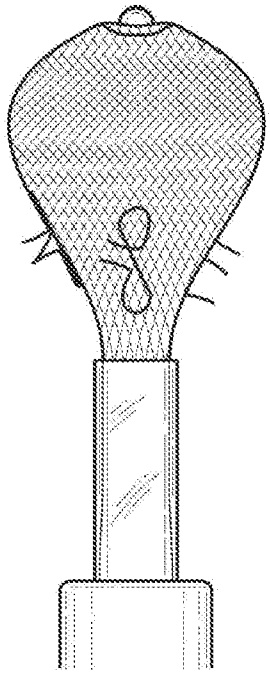


FIG. 5

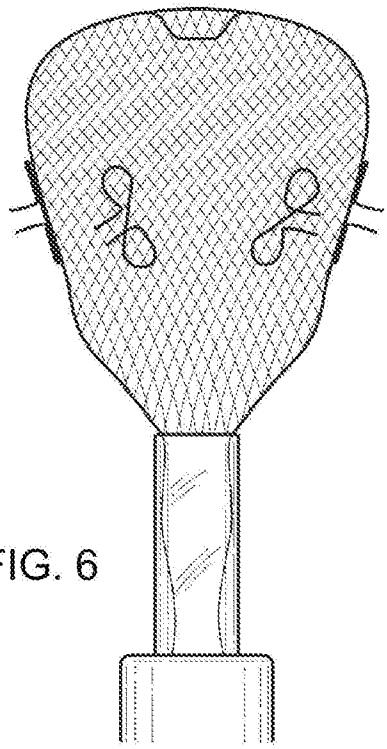


FIG. 6

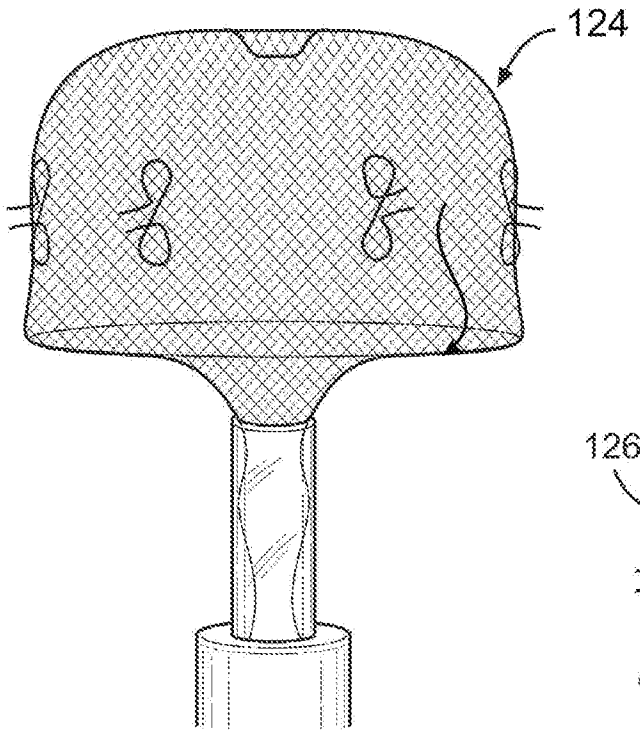


FIG. 7

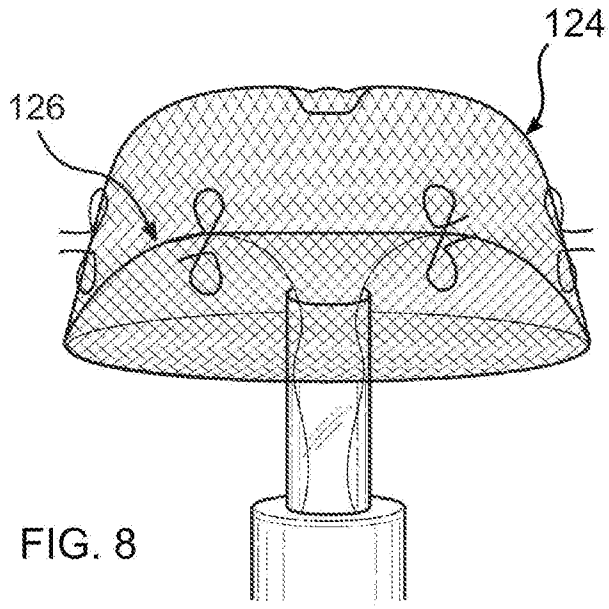


FIG. 8

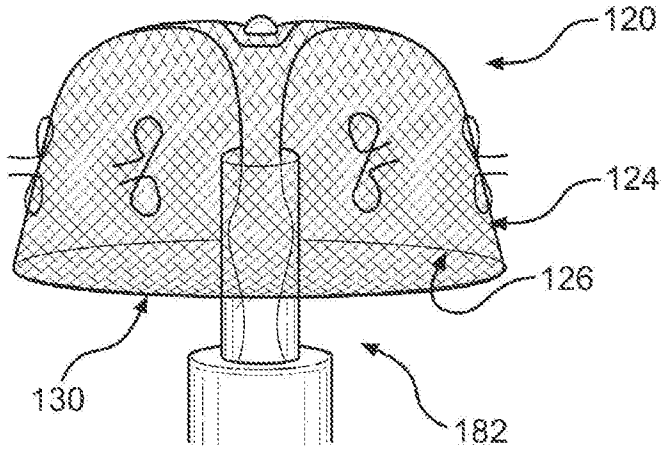


FIG. 9

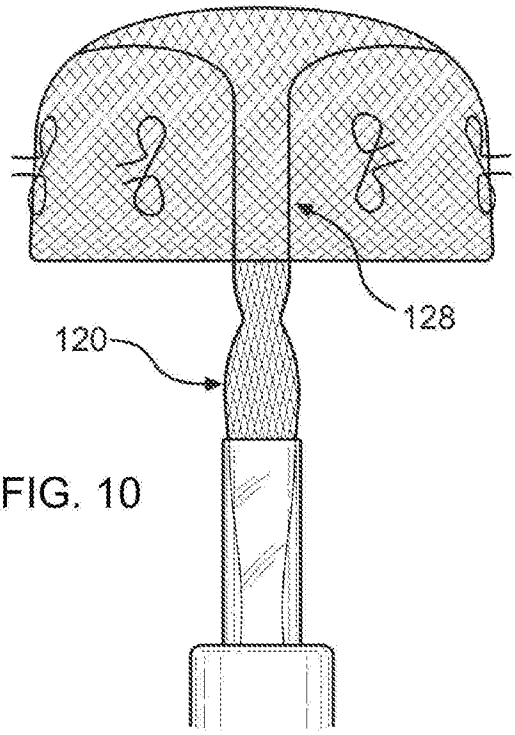
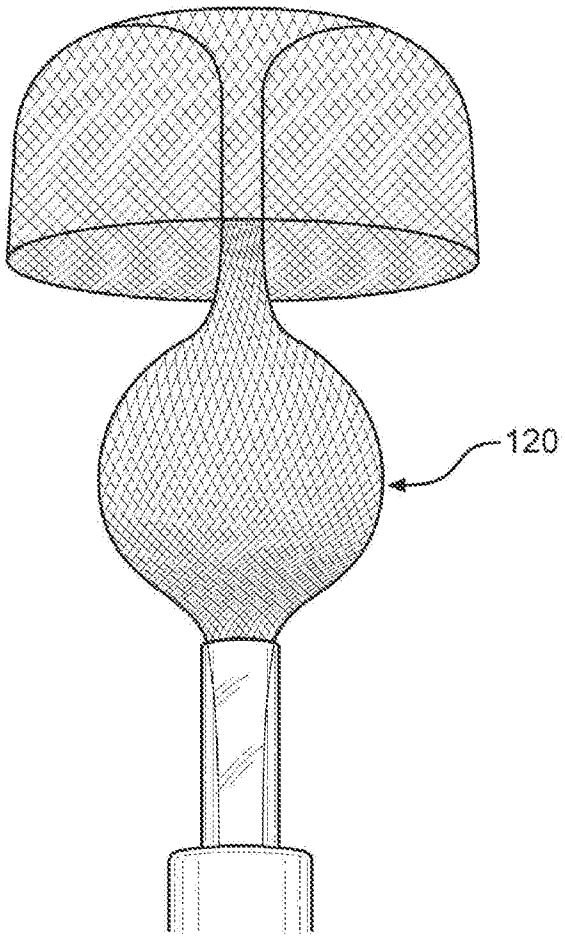


FIG. 10



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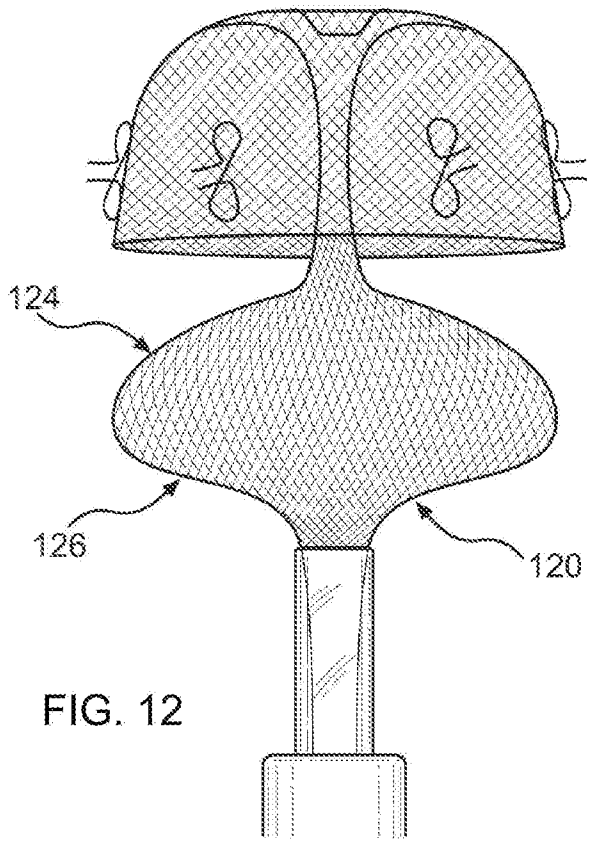


FIG. 12

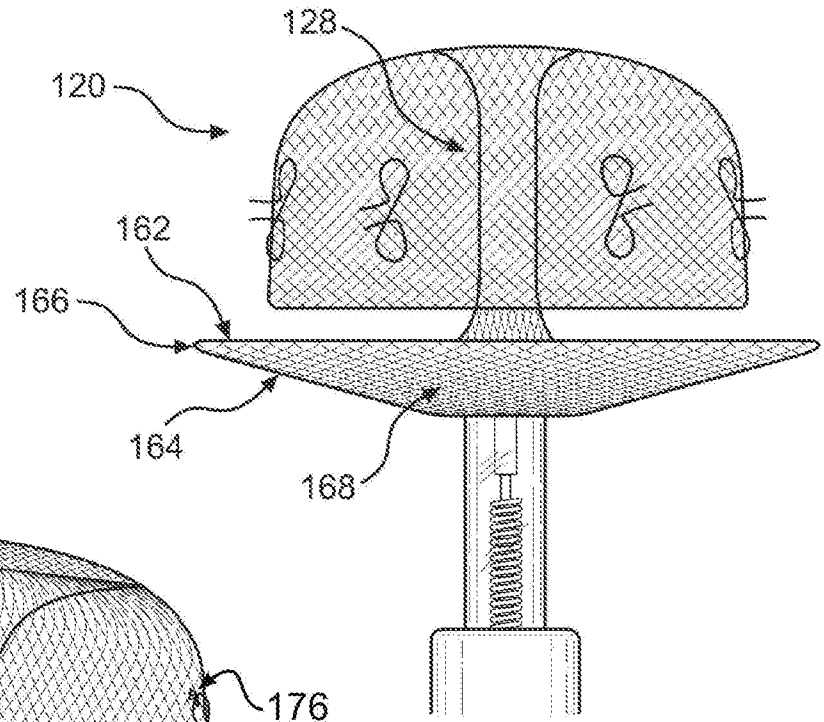


FIG. 13

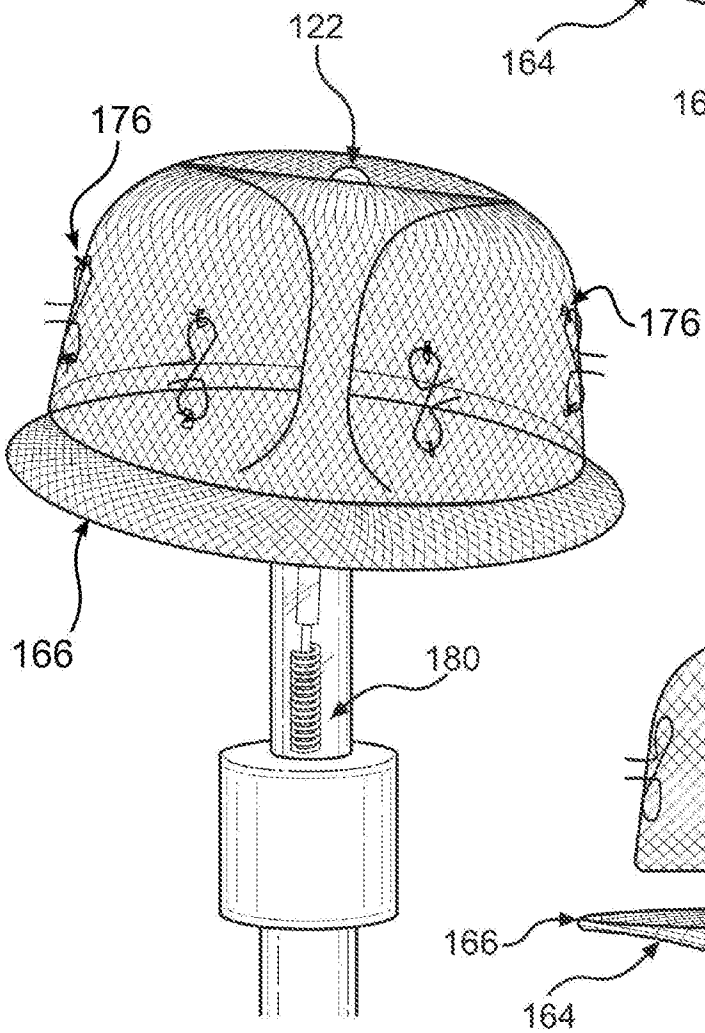


FIG. 14

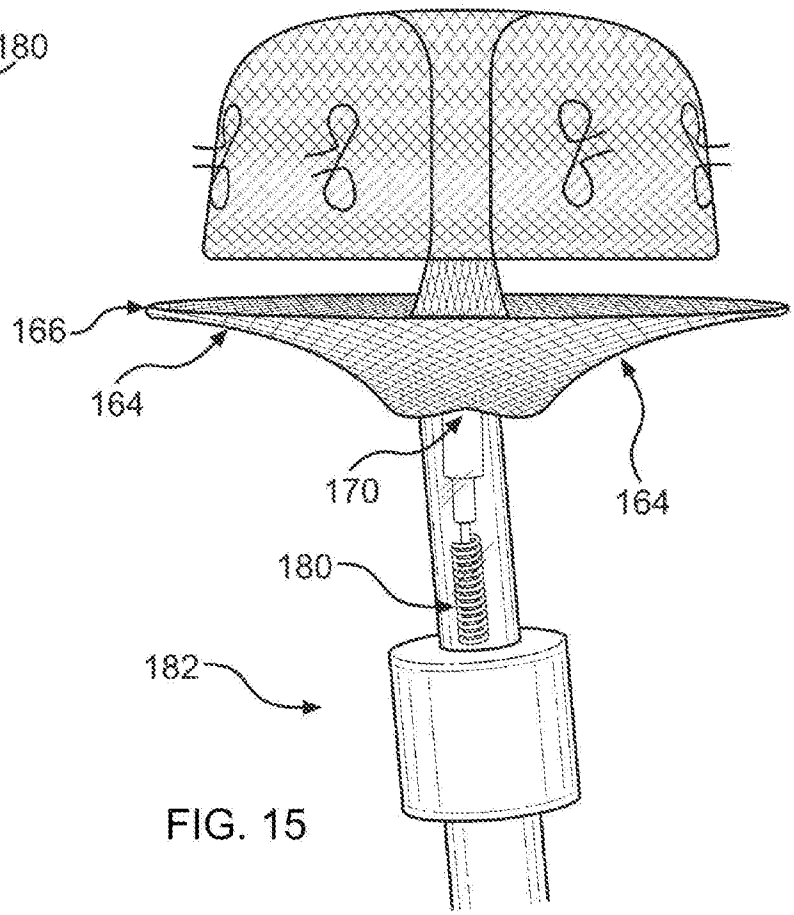


FIG. 15

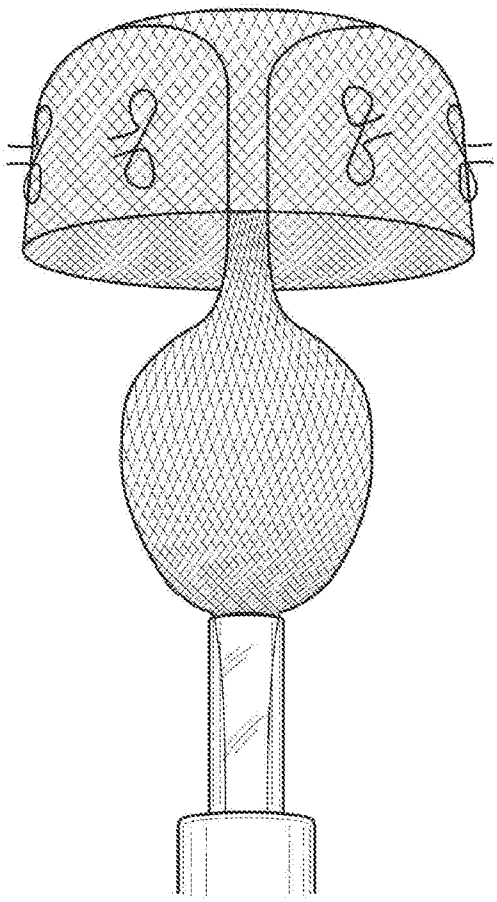
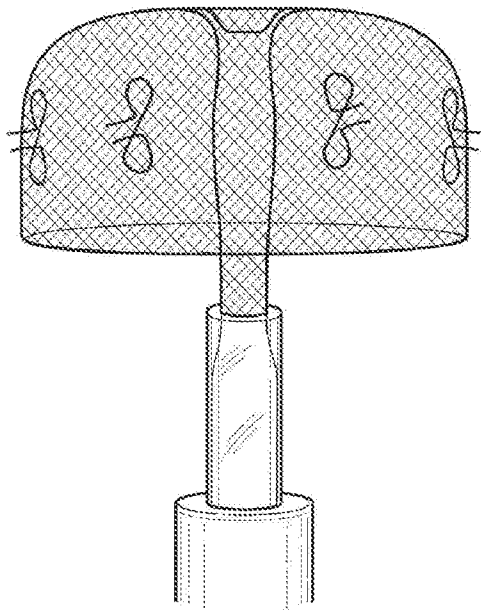


FIG. 16

FIG. 17



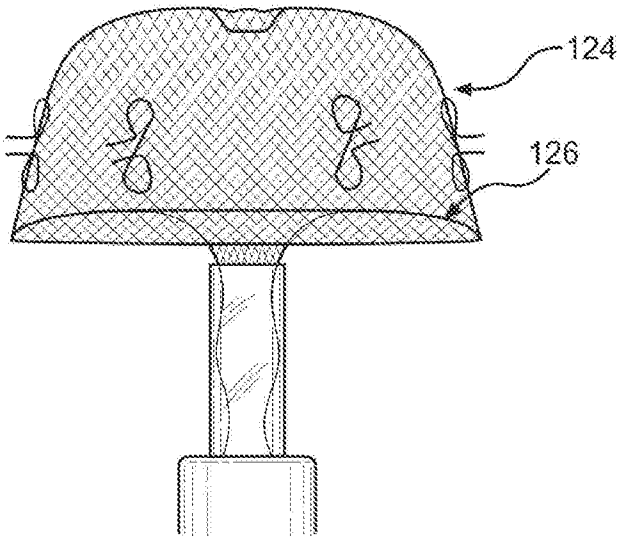


FIG. 18

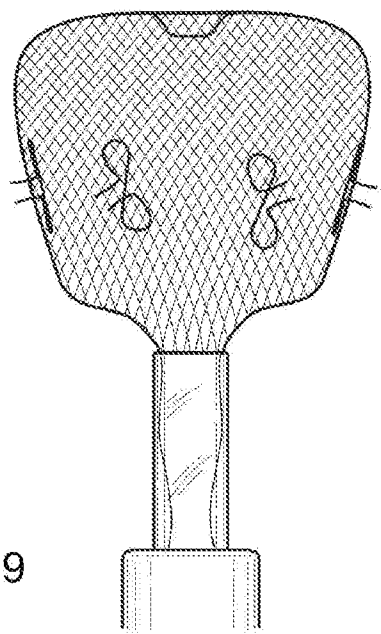


FIG. 19

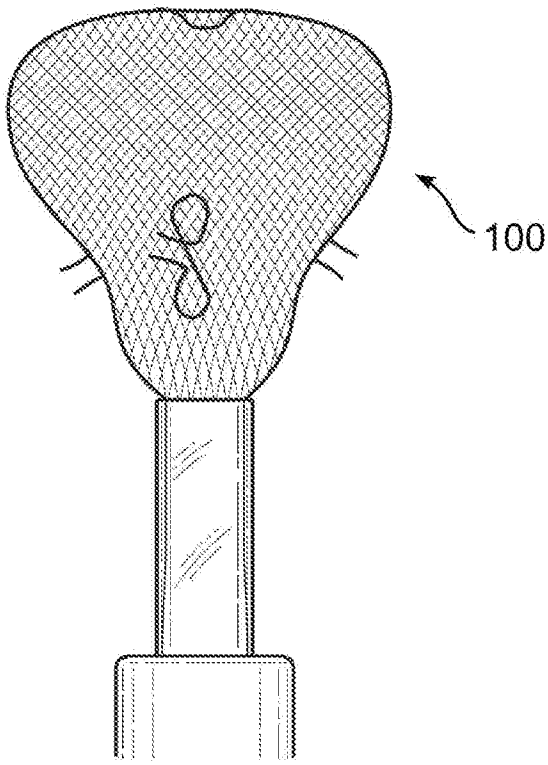


FIG. 20

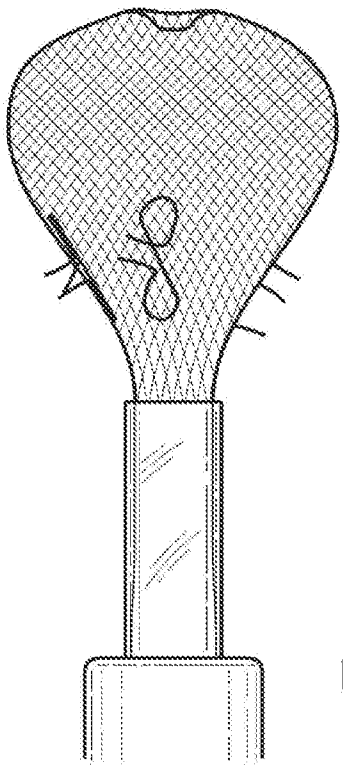


FIG. 21

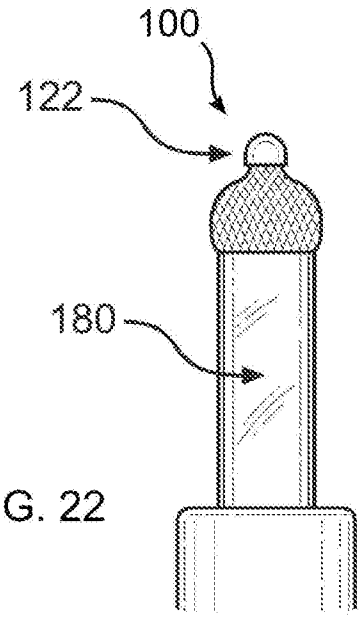


FIG. 22

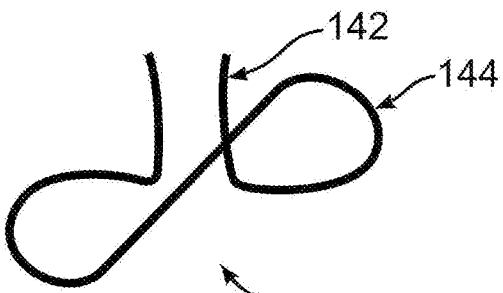


FIG. 23

FIG. 24

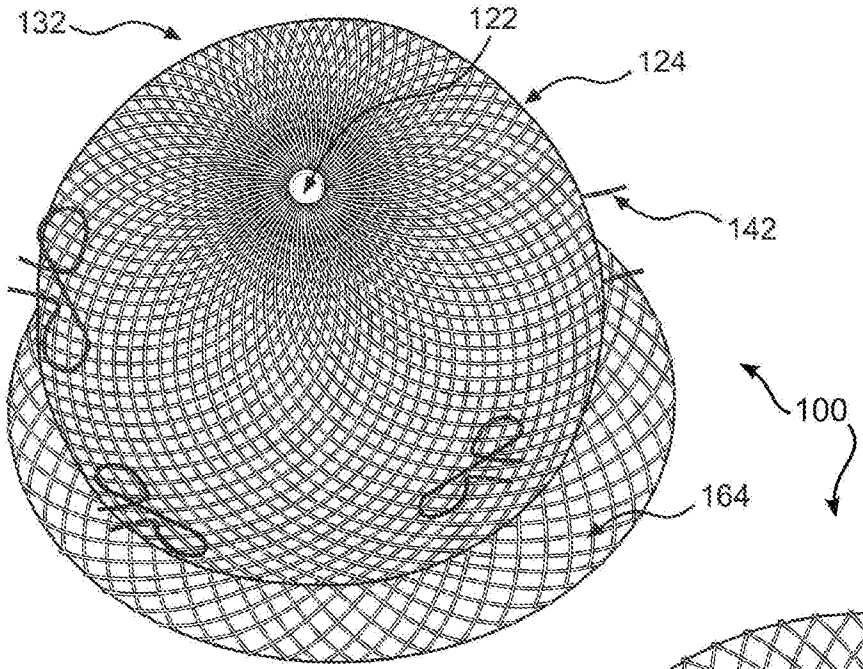


FIG. 25

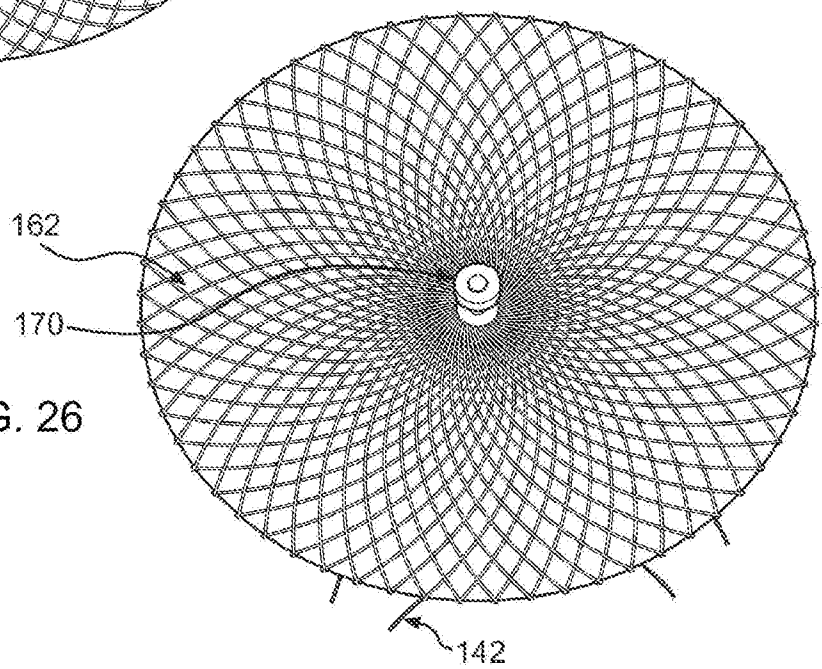
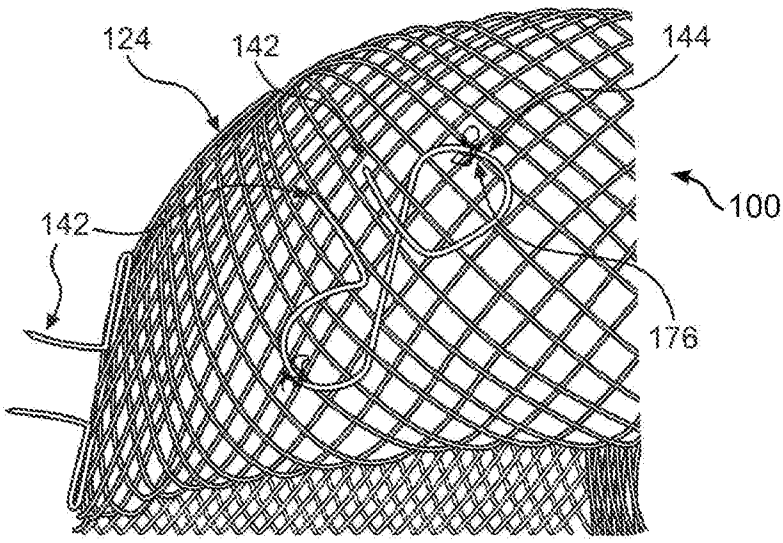


FIG. 26

FIG. 27



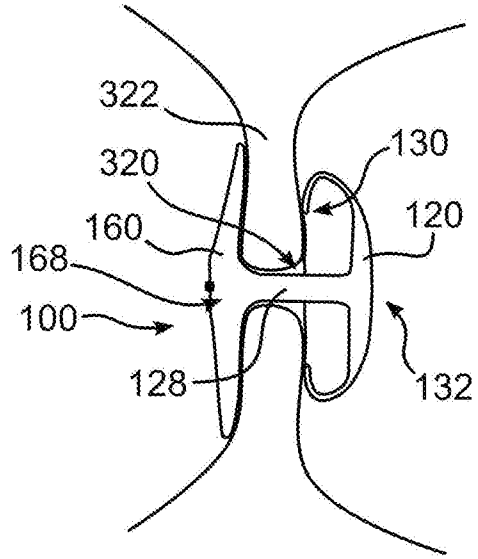


FIG. 28

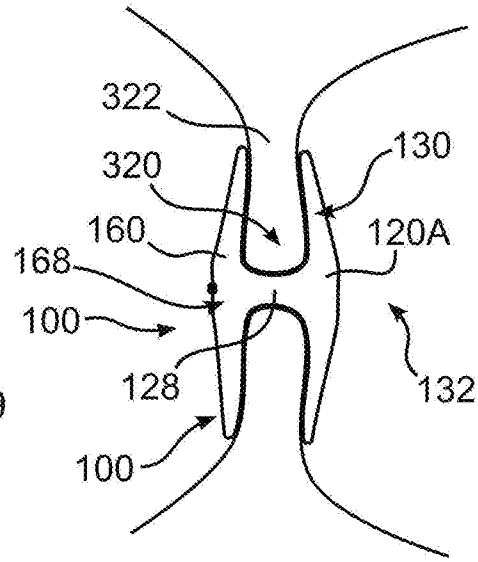


FIG. 29

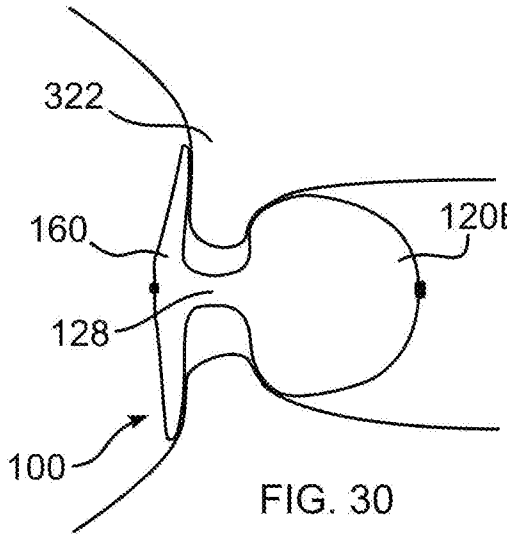


FIG. 30

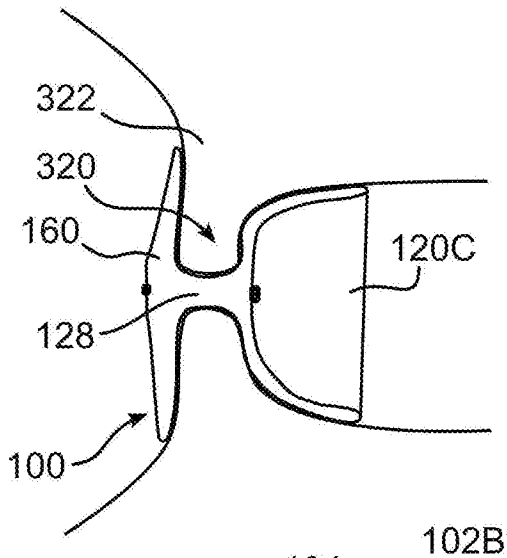


FIG. 31

FIG. 32A

FIG. 32B

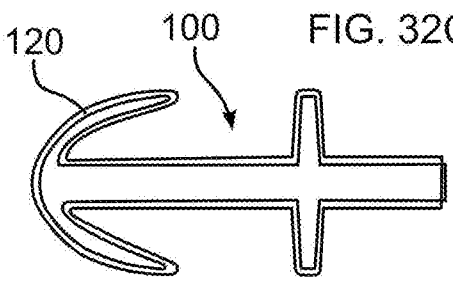


FIG. 32C

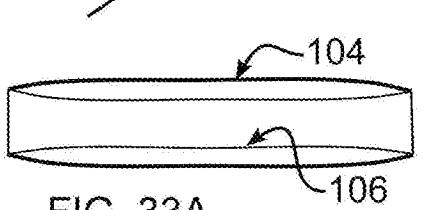


FIG. 33A

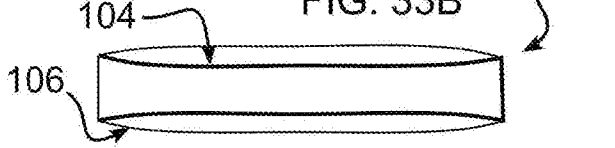


FIG. 33B

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 2017/022986

A. CLASSIFICATION OF SUBJECT MATTER

A61B 17/03 *(2006.01)*
A61F 2/90 *(2006.01)*

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61F 2/90, 2/82, A61M 29/00, A61B 17/00

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

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

PatSearch (RUPTO internal), PubMed, NCBI, Rambler, Yandex

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 2011/0152993 A1 (SEQUENT MEDICAL INC.) 23.06.2011	1-6, 8-13, 15-19 7, 14
Y	US 8747432 B1 (INSERA THERAPEUTICS, INC.) 10.06.2014	7
Y	US 6786898 B2 (MEDTRONIC, INC.) 07.09.2004	14

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
15 May 2017 (15.05.2017)	08 June 2017 (08.06.2017)

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