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OCCLUSION DEVICE AND METHODS OF FORMING OCCLUSIONS

CROSS REFERENCE TO RELATED APPLICATION

5 [0001] The application claims the benefit of and priority to U.S. Prov. App. Ser. No. 62/030,458 filed 29 July 2014, the entirety of which is incorporated herein by reference in its entirety.

FIELD OF THE DISCLOSURE

[0001] The disclosure relates generally to occlusion devices and methods of forming occlusions.

BACKGROUND

10 [0002] Tissue adhesive compounds can be used in a variety of medical treatments, including the treatment of vascular malformations and aneurysms, the occlusion of gastric and esophageal varices, the sealing of biliary leaks, and the closure of enteric and pancreatic fistulas. Success rates with such procedures have varied; only reported
15 through small case series and limited case reports. Cyanoacrylates are the compounds most commonly used for these purposes. These compounds are generally liquid monomers that polymerize into longer polymer chains upon exposure to moisture. There are several varieties designed for medical use in humans.

[0003] Problems in using these compounds to close a vascular aneurysm, occlude
20 a leaky bile duct, or otherwise attempt to form an occlusion during a medical procedure arise from the difficulty in maintaining precise control of the polymer material. The material must be exposed only to the desired tissues and cannot be allowed to occlude or obstruct other contiguous tissues or structures. When used to occlude vascular structures, material cannot be allowed to embolize, thus causing injury to tissues downstream.
25 Furthermore, the relatively rapid polymerization time of the occlusion material can result in premature solidification within the needle or other delivery device leading to potential damage to equipment and unwanted extension of the treatment time.

[0004] Additionally, complications can arise when the delivery device becomes
30 entrapped against or within the treatment site. This can occur when the occlusion material is injected too slowly relative to the polymerization rate of the material leading to potentially severe consequences for the patient. Thus, if the occlusion material is injected slowly to ensure formation of an adequate occlusion within the desired treatment area, the risk of getting the delivery device entrapped within the treatment area rises. Conversely, if the occlusion material is injected more rapidly or if the delivery device is

retracted more aggressively to avoid entrapment within the treatment site, an incomplete occlusion may result and the material may be exposed to tissues and structures outside the intended treatment site. These difficulties in safely delivering an adequate occlusion that fully obstructs the intended treatment site will often lead to treatment failure and may even create additional risks to the patient.

BRIEF SUMMARY

[0005] Embodiments of the present disclosure include devices and methods for forming an occlusion. Embodiments of an occlusion device include a reusable delivery device, a connector, a magnetic component disposed a distance in a distal direction from a distal end of the delivery device, and a connecting member disposed between the magnetic component and the delivery device, the connecting member being attached to the magnetic component and extending to the delivery device, the connector being separably connected to the connecting member such that a connection between the connector and the connecting member is configured to be formed and separated. Certain embodiments of the present disclosure are configured to inject a magnetic responsive fluid that may function as an occlusion material. The magnetic responsive fluid may be maintained at a treatment site until polymerization, partial polymerization, or curing of the adhesive has occurred. Embodiments of the present disclosure allow for formation of an occlusion without the occlusion adhering to or attaching to the delivery device and without moving beyond the treatment site to other unintended areas.

[0006] Certain embodiments include an electromagnet conductively associated with the connecting member and/or the connector and a first current source such that electric current can pass to the magnetic component from a first current source. Certain embodiments of the connector include a connector coil, and certain embodiments of the connecting member include a member coil, the connector coil and the member coil being in association with each other.

[0007] Certain embodiments of the connector coil include a connector core in association with the connector coil, and a member core in association with the member coil. In certain embodiments, the connector core and/or member core are permanent magnets. Certain embodiments include a second current source, the second current source being conductively associated with the connector and/or connector coil and being arranged to deliver current in a direction opposite the first current source such that the connection between the connector and the connecting member may be neutralized or separated upon association with or activation of the second current source.

[0008] Certain embodiments include a magnetic component wherein at least a portion of the magnetic component is formed as a conduit, the conduit thereby defining a second delivery device, the second delivery device including a proximal opening and a distal opening. Certain embodiments include an expandable element disposed at the distal opening of the second delivery device and/or at the magnetic component, the expandable element being in association with the magnetic component.

[0009] Certain embodiments of a method of forming a treatment occlusion include: positioning an occlusion device at a treatment site, activating a magnetic component disposed a distance in a distal direction from a distal end of a delivery device, the distance between the magnetic component and the distal end of the delivery device defining a clearance; injecting an amount of a magnetic responsive fluid through the delivery device such that the magnetic responsive fluid is removed from the distal end of the delivery device across the clearance and toward the magnetic component; allowing the magnetic responsive fluid to at least partially polymerize, the at least partially polymerized magnetic responsive fluid and the associated magnetic component defining an occlusion structure; and dissociating the delivery device from the magnetic component such that the delivery device can be removed from the treatment site without disturbing the occlusion structure.

[0010] Certain embodiments of a method of forming a treatment occlusion include an expandable element disposed at the distal opening of a second delivery device, the expandable element being in association with the magnetic component such that activation of the magnetic component brings the magnetic responsive fluid into contact with the expandable element. In certain embodiments, the expandable element is non-porous to the magnetic responsive fluid such that upon movement of the magnetic responsive fluid through the second delivery device and activation of the magnetic component, the magnetic responsive fluid is held on a distal side of the expandable element, and in certain embodiments the expandable element is formed to be at least partially porous to the magnetic responsive fluid such that upon movement of the magnetic responsive fluid through the second delivery device and activation of the magnetic component, the magnetic responsive fluid is held on a distal side of the expandable element, within the structure of the expandable element, on a proximal side of the expandable element, or some combination.

[0011] Certain embodiments of a method of forming a treatment occlusion include injecting a second amount of the magnetic responsive fluid at the treatment site, the second amount enclosing the connecting member and any other portions of the magnetic component extending from the occlusion structure.

[0012] Other aspects and advantages of the invention will be apparent from the following description and the appended claims. The various characteristics described above, as well as other features, will be readily apparent to those skilled in the art upon reading the following detailed description, and by referring to the accompanying drawings. This summary is therefore not intended to identify key or essential features of the claimed subject matter, nor is it intended to be used as an aid in limiting the scope of the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] In order to describe various features and concepts of the present disclosure, a more particular description of certain subject matter will be rendered by reference to specific embodiments which are illustrated in the appended drawings. While each embodiment contemplated hereby may not be drawn to scale, at least some of the appended drawings may be drawn to scale. Understanding that these drawings depict just some example embodiments and are not to be considered to be limiting in scope, various embodiments will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

[0014] FIG. 1 is a cross-sectional side view of an occlusion device in accordance with embodiments disclosed herein.

[0015] FIG. 2 is a top view of an occlusion device in accordance with embodiments disclosed herein.

[0016] FIG. 3 is a cross-sectional side view of an occlusion device in accordance with embodiments disclosed herein.

[0017] FIG. 4 is a cross-sectional side view of an occlusion device in accordance with embodiments disclosed herein.

[0018] FIGS. 5 through 8 illustrate a magnetic component of an occlusion device in accordance with embodiments disclosed herein.

[0019] FIG. 9 is a side view of an occlusion device in accordance with embodiments disclosed herein.

[0020] FIG. 10 is a side view of an occlusion device in accordance with embodiments disclosed herein.

[0021] FIGS. 11 through 13 illustrate a connector and connecting member of an occlusion device in accordance with embodiments disclosed herein.

[0022] FIGS. 14 through 17 illustrate a method of forming an occlusion in accordance with embodiments disclosed herein.

[0023] FIGS. 18 through 22 illustrate a method of forming an occlusion in accordance with embodiments disclosed herein.

DETAILED DESCRIPTION

[0024] The following is directed to various embodiments of the disclosure. The
5 embodiments disclosed should not be interpreted, or otherwise used, to limit the scope of the disclosure including the claims. In addition, those having ordinary skill in the art will appreciate that the following description has broad application, and the discussion of any embodiment is not intended to suggest that the scope of the disclosure, including the claims, is limited to that embodiment.

10 [0025] Certain terms are used throughout the following description and claims to refer to particular features or components. As those having ordinary skill in the art will appreciate, different persons may refer to the same feature or component by different names. This document does not intend to distinguish between components or features that differ in name but not function. Certain features and components herein may be
15 shown exaggerated in scale or in somewhat schematic form and some details of conventional elements may not be shown or described in interest of clarity and conciseness.

[0026] Embodiments of the present disclosure may be configured for use in a variety of treatment settings. For example, the device and methods may be used in the
20 closure of fistulas (such as enterocutaneous, biliary, rectovaginal, enterovesicle, enterourethral, esophageal, etc.), in the treatment of biliary or pancreatic duct leaks, and in the treatment of gastric varices, arteriovenous malformations, and vascular aneurysms. Specifically, aspects of the present disclosure are directed to occlusion devices and methods of forming occlusions that allow precise location and control of an occlusion and
25 that allow a delivery device to be dissociated and extracted from a forming or formed occlusion without disrupting the occlusion or surrounding tissues or structures.

[0027] As illustrated in FIGS. 1 and 2, certain embodiments of an occlusion device 102 may include a delivery device 104, a magnetic component 106, a connecting member 108, and a connector 110. The delivery device 104 may be formed so as to be
30 able to carry, transport, channel, or otherwise deliver the material that will form the occlusion from a proximal end 114 to a distal end 116 and/or beyond the distal end 116. For example, the delivery device 104 may be formed as a needle, a catheter, or another lumen-containing structure capable of delivery of the material that will form the occlusion.

[0028] The magnetic component 106 may be disposed a distance in a distal direction from the distal end 116 of the delivery device 104. The distance between the magnetic component 106 and the distal end 116 of the delivery device 104 may define a clearance 112. In some embodiments, the clearance 112 may be 0.1 to 1 cm, or 1 to 2 cm, or 2 to 3 cm, or 3 to 4 cm, or 4 to 5 cm. In some embodiments, the clearance can range from 0.1 to 5 cm, 0.5 to 4 cm, or 1 to 3 cm. In some embodiments, the ratio of the clearance to the diameter of the delivery device 104 (e.g., inside diameter) can be 0.25 to 5, or 0.5 to 4, or 0.75 to 3, or 1 to 2.

[0029] The magnetic component 106 may be capable of generating a magnetic field. For example, the magnetic component 106 may be a permanent magnet and/or an electromagnet, such as an electromagnetic antenna. In the embodiment shown in FIGS. 1 and 2, the magnetic component 106 may be an electromagnet, and the electromagnet may be conductively associated with the connecting member 108 and the connector 110 such that electric current can pass to the magnetic component 106 from a current source 118. In some embodiments, the magnetic component 106 can be configured such that the strength of the magnetic field associated with the magnetic component 106 can be modulated to provide a desired attractive force (e.g., a “pulling” force) disposed away from the distal end 116 of the delivery device 104. In some embodiments, the magnetic component 106 can be configured to provide a resting magnetic field and an augmented magnetic field. For example, the magnetic component may include a permanent magnet component to provide a resting magnetic field, and an electromagnet component to augment the magnetic field upon actuation.

[0030] In some embodiments, the magnetic component 106 can be configured to provide a magnetic flux density ranging from 0.1 mT to 0.5 mT, or from 0.5 mT to 1 mT, or from 1 mT to 3 mT, or from 3 mT to 6 mT.

[0031] As an example of an embodiment including an electromagnet component, the embodiment shown in FIGS. 1 and 2 may include a lead 120 disposed between the current source 118 and the connector 110. The connector 110 may be in conductive association with the connecting member 108 through, for example, direct contact or inductive association. In other embodiments, the lead 120 may be disposed between the current source 118 and the connecting member 108, or between the current source 118 and the magnetic component 106. In such embodiments, the magnetic component 106 may not be in conductive association with the connecting member 108 or connector 110. For example, if the lead 120 is disposed between the connecting member 108 and the

current source 118, the connector 110 may not be in conductive association with the connecting member 108 or the magnetic component 106. Or if the lead 120 is disposed between the magnetic component 106 and the current source 118, the connector 110 and/or the connecting member 108 may not be in conductive association with the magnetic component 106 or with each other. It should be noted that the conductive associations of the components of an embodiment, when an embodiment has such a conductive association, may be established by direct connection, such as by one or more electrical leads, or by inductive association, or by a combination of both.

[0032] The magnetic component 106 may be attached to a connecting member 108. The connecting member 108 may be disposed between the magnetic component 106 and the delivery device 104. In the embodiment shown in FIGS. 1 and 2, the connecting member 108 may have a curved construction. The connecting member 108 may be joined at or near the magnetic component 106 at or near a distal apex of the curve of the connecting member 106, thereby forming a pair of curved struts between the delivery device 104 and the magnetic component 106.

[0033] The connecting member 108 may also be constructed in a variety of other forms. For example, the connecting member 108 may have a linear or non-curved construction. In another example, the connecting member 108 may be formed with portions that are non-curved and portions that are curved. Additionally, the connecting member 108 may be formed with one, two, or more points of connection to the delivery device 104. For example, the embodiment of the connecting member 108 shown in FIGS. 1 and 2 may be constructed with two points of connection to the delivery device 104, but other embodiments may include only one point of connection to the delivery device 104, or may include more than two points of connection to the delivery device 104.

[0034] Furthermore, the occlusion device 102 may include one connecting member 108 or a plurality of connecting members 108 disposed between the magnetic component 106 and the delivery device 104. Additionally, the connecting member 108 or a plurality of connecting members 108 may form one contiguous or integrated formation, or may include one or more separate connecting members 108 not connected directly to each other, or may include some connecting members 108 that are connected and integrated with each other and others that are not. In some embodiments, a portion of the connecting member 108 (or a portion of one or more connecting members, in embodiments including a plurality of such) may be integrated with a magnetic

component. For example, one or more electrical leads may be coiled around a portion of the connecting member so as to provide the portion of the connecting member with electromagnetic functionality.

[0035] The magnetic component 106 may be constructed in a variety of forms.

5 For example, the magnetic component 106 may be formed from a ferromagnetic material, partially ferromagnetic material, other material capable of functioning as a permanent magnet, or combinations thereof. Additionally, or alternatively, as illustrated in FIGS. 1 and 2, the magnetic component 106 may be formed as an electromagnet capable of being modulated, activated and deactivated in response to application of an electrical current. 10 The electromagnet may be capable of being fine-tuned through other alterations of the applied current. For example, the strength of the magnetic field near the magnetic component may be altered by altering the current and/or voltage of the current source.

[0036] Furthermore, the magnetic component 106 may be formed so that only a portion actively generates a magnetic field or is capable of actively generating a magnetic 15 field, thereby defining a magnetically active portion of the magnetic component 106. For example, a portion of the magnetic component 106 may be formed as a permanent magnet, while another portion may be formed as a post, member, pin, or other structure used to support or attach to the magnetically active portion of the magnetic component 106. As another example, a portion of the magnetic component may function as an 20 electromagnet, while another portion may be formed as a post, member, pin, or other structure used to support or attach to the magnetically active portion of the magnetic component 106. In these and other examples, the magnetically active portion can function to provide a magnetic force to draw a magnetic responsive fluid away from the distal end 116 of the delivery device 104, while the non-magnetically active portion can 25 function to provide or augment the clearance 112 separating the magnetically active portion of the magnetic component 106 from the distal end 116 of the delivery device 104.

[0037] In some embodiments, the magnetic component 106 may also include a tip structure 122. The tip structure 122 may be formed as an integral piece with the rest of 30 the magnetic component 106, or may be a separate piece attached or joined to the rest of the magnetic component 106. In embodiments that include a magnetic component 106 with a tip structure 122, the tip structure 122 may be a same or different type of magnet and/or may generate a magnetic field of similar or dissimilar strength relative to the rest of the magnetic component 106. For example, the tip structure 122 may be a permanent

magnet and the magnetic component 106 may also include coils allowing it to function as an electromagnet. In another example, the tip structure 122 may be the only portion of the magnetic component 106 that produces a magnetic field (e.g., the tip structure 122 is a permanent magnet or electromagnet), while the other portions of the magnetic component 106 may not produce a magnetic field or may produce a magnetic field of different strength. In some embodiments, the tip structure 122 may provide a magnetic field of greater magnetic strength relative to the other portions of the magnetic component 106 in order to provide or contribute to a magnetic field gradient. For example, the magnetic component 106 and/or tip structure 122 can be configured to provide a magnetic field that increases in strength in the distal direction.

[0038] The embodiment illustrated in FIGS. 1 and 2 may include a connector 110. The connector 110 may be disposed near the distal end 116 of the delivery device 104. For example, the connector 110 may be disposed within the internal lumen of the delivery device 104 near the distal end 116 of the delivery device 104. The connector 110 may also be disposed at other locations such as other portions of the internal lumen of the delivery device 104, at or along the outer perimeter of the delivery device 104, or at the distal edge of the delivery device 104. The connector 110 may be formed as one integrated component, such as an annular ring or partial ring (e.g., a sectioned and/or perforated ring) disposed along a portion of the inner lumen of the delivery device 104, or may be formed from separate, non-contiguous and/or independent components.

[0039] In the embodiment shown in FIGS. 1 and 2, the connector 110 is in association with the connecting member 108 in such a way as to allow a connection between the connector 110 and a connecting member 108 to be selectively formed and separated. For example, the connector 110 may form a mechanical attachment to the connecting member 108 through the use of a latch, pin, stop, brace, and/or other mechanical attachment or locking mechanism capable of coupling, joining, or engaging a connecting member 108. Additionally, or alternatively, the connector 110 may include magnetic components for selectively forming and separating a connection to the connecting member 108.

[0040] FIG. 3 illustrates another embodiment of an occlusion device 302. The embodiment shown in FIG. 3 may include elements of the embodiment of FIGS. 1 and 2 and therefore, the description of FIGS. 1 and 2 are hereby incorporated by reference. FIG. 3 illustrates an occlusion device 302 wherein the magnetic component 306 is formed as a cylindrical member. The magnetic component 306 of the embodiment shown in FIG.

3 may be formed from a ferromagnetic material, a partially ferromagnetic material, or another material capable of functioning as a permanent magnet. Additionally or alternatively, the magnetic component 306 may be or may include an electromagnet. For example, coils forming the electromagnet (not shown) may be disposed within the structure of the magnetic component 306 or within a portion of the magnetic component 306.

[0041] FIG. 4 also illustrates an occlusion device 402 wherein the magnetic component 406 is formed as a cylindrical member. The embodiment shown in FIG. 4 may include elements of the embodiments of FIGS. 1 through 3 and therefore, the description of FIGS. 1 through 3 are hereby incorporated by reference. The magnetic device 406 may be formed as an electromagnet including one or more coils 422 surrounding a coil core 424. The embodiment of the magnetic component 406 illustrated in FIG. 4 may function as an electromagnet, with coils 422 disposed along the outside perimeter of the coil core 424. The coil core 424 may also be a ferromagnetic material and/or may be a permanent magnet capable of producing a magnetic field when the electromagnet is deactivated.

[0042] In some embodiments, the magnetic component 406 or a portion of the magnetic component 406 may be formed as a conduit, hose, port, or channel to define a second delivery device, such that a magnetic responsive fluid and/or another occlusion forming material leaving the distal opening of the delivery device 404 can enter the proximal opening of the second delivery device and travel toward and out of the distal opening of the second delivery device before associating with the magnetically active portion of the magnetic component 406. For example, the magnetic component 406 illustrated in FIG. 4 may be formed as a second delivery device, such that at least a portion of a magnetic responsive fluid and/or another occlusion forming material leaving the delivery device 404 will be directed through the lumen of the second delivery device and out of the distal opening of the second delivery device before associating with the magnetically active portion of the magnetic component 406 disposed, in this example, along the outside perimeter or a portion of the outside perimeter of the magnetic component 406.

[0043] FIGS. 5 through 8 illustrate other embodiments of magnetic components 506, 606, 706, 806 that may be included in the occlusion device. FIGS. 5 through 8 illustrate that the shape and structure of a magnetic component may be varied. For example, a magnetic component may have a circular structure, an elliptical structure, a

polygonal structure (either regular or irregular), a branched structure, another suitable structure, or combinations thereof. A magnetic component may include a combination of structures and shapes, with or without branched structures that may be different or similar in shape to other branched structures.

5 **[0044]** FIGS. 9 and 10 illustrate other embodiments of an occlusion device 902, 1002 including an expandable element 926, 1026. The embodiments shown in FIGS. 9 and 10 may include elements of the embodiments of FIGS. 1 through 8 and therefore, the descriptions of FIGS. 1 through 8 are hereby incorporated by reference. The expandable element 926 may be formed so as to be disposed in a collapsed or closed state, as
10 illustrated in FIG. 9. For example, the expandable element 926 may be formed from a flexible material designed so as to flex radially outward unless held in place, for example, mechanically, electro-mechanically, magnetically, by another appropriate mechanism, or combinations thereof. Upon release, the expandable element 1026 may move to an open position, as illustrated in FIG. 10. Additionally or alternatively, the expandable element
15 926, 1026 may be formed or partially formed from a self-expanding material that expands upon an induced change or natural occurrence in the environment interacting with the expandable element 926, 1026. For example, the expandable element 926, 1026 may be formed from a shape-memory material, such as a nickel titanium alloy (e.g., nitinol).

20 **[0045]** The expandable element 926 may be formed so as to be one integrated and solid structure or may be formed from separate components or pieces. For example, the expandable element 926 may be formed as a single piece or from an array of plates, sheets, or panels that either overlay or abut each other upon expansion or that leave gaps or breaks between each or some of them. Additionally or alternatively, the expandable element 926 may be formed as a wire frame, hub and spoke, perforated, honeycombed, or
25 porous structure. In some embodiments, the expandable elements 926, 1026 can be configured to open to an angle of 15 to 30, 30 to 45, 45 to 60, 60 to 75, 75 to 90, 90 to 105, 105 to 120, 120 to 135, or 135 to 150 degrees. In some embodiments, the expandable elements 926, 1026 can open greater than 150 degrees.

30 **[0046]** FIGS. 11-13 illustrate other embodiments of connectors and connecting members. The embodiments illustrated in FIGS. 11-13 may be included in part or in combination with any of the embodiments illustrated in FIGS. 1-10, and, therefore, the descriptions of FIGS. 1-10 are hereby incorporated by reference. In some embodiments, such as the embodiment of the connector 1110 and the connecting member 1108 illustrated in FIG. 11, the connector 1110 may include a connector coil 1128 and/or the

associated connecting member 1108 may include a member coil 1130 in a manner capable of forming a magnetic connection between the connector coil 1128 and the associated member coil 1130. For example, a connection between the connector 1110 and the connecting member 1108 can be formed by the magnetic field resulting from passing current through the connector coil 1128 and/or the member coil 1130, and the connection can be separated upon reducing or eliminating such current.

[0047] FIG. 12 illustrates another embodiment of a connector 1210 and connecting member 1208. The embodiment shown in FIG. 12 may include elements of the embodiment of FIG. 11 and, therefore, the description of FIG. 11 is hereby incorporated by reference. In an embodiment, the connector 1210 may include a connector coil 1228 and a connector core 1232 in association with the connector coil 1228. The connecting member 1208 may also include a member coil 1230 and a member core 1234 in association with the member coil 1230. The connector core 1232 and/or the member core 1234 may include a ferromagnetic material, a partially ferromagnetic material, another material capable of functioning as a permanent magnet or capable of altering the strength of the magnetic field upon passing current through the associated coils, or combinations thereof. For example, in some embodiments, the connector core 1232 and the member core 1234 may have no or minimal magnetic attraction to each other in the absence of any applied current, such that any connection between the connector 1210 and the connecting member 1208 is limited or weak and is capable of being easily separated. Upon application of current, the magnetic attraction may strengthen, forming a connection suitable for positioning of the device. Upon discontinuation of the current, the connection may return to a weakened or separated state, easing separation of the connector 1210 and the connecting member 1208. It should be noted that in other embodiments, the connector 1210 may include a plurality of connector coils 1228, with some or each of the connector coils 1228 containing one or more connector cores 1232. Additionally, the connecting member 1208 may include one or more member coils 1230, with some or each of such member coils 1230 containing one or more member cores 1234.

[0048] FIG. 13 illustrates another embodiment of a connector 1310 and connecting member 1308. The embodiment shown in FIG. 13 may include elements of the embodiments of FIGS. 11-12 and therefore, the descriptions of FIGS. 11-12 are hereby incorporated by reference. In an embodiment, a first current source 1318 may pass current to the connector 1310 and the connector coil 1328. When in sufficient

proximity to the member coil 1330, a current passing through the connector coil 1328 may induce a current in the member coil 1330. The connector core 1332 and the member core 1334 may be formed so as to induce or create a magnetic connection between connector 1310 and the connecting member 1308. For example, the connector core 1332 and/or the member core 1334 may be permanent magnets capable of forming a magnetic connection in the absence of a current from the first current source 1318, and/or may act as electromagnet cores that strengthen the magnetic connection as current passes through the connector coil 1328 and/or member coil 1330. This embodiment may also include a second current source 1336 conductively associated with the connector coil 1328. The second current source 1336 may be arranged to deliver current in a direction opposite that of the first current source 1318 such that upon application of the second current source 1336, the magnetic field generated by the connector coil 1328 and/or connector core 1332 is weakened, neutralized, or reversed. The connection between the connector 1310 and the connecting member 1308 may then be separated or more easily separated. In other embodiments, the first and second current sources may be the same, and reversing the direction of current is done simply by reversing a polarity of the current source. In addition to, or alternative to, magnetic-based coupling and decoupling, such as that shown in FIGS. 11-13, a connector and connecting member may be detachably coupled through mechanical means, such as with one or more pins, latches, clasps, and/or friction fitted parts, for example.

[0049] FIGS. 14 through 17 illustrate an embodiment of an occlusion formation method. In this embodiment, an occlusion device 1402 is positioned at a treatment site. The occlusion device 1402 may be any of the embodiments of an occlusion device illustrated in FIGS. 1-13 or any combination of elements described in relation to such embodiments, and therefore the descriptions of FIGS. 1-13 are hereby incorporated by reference. The treatment site may be anywhere an occlusion is required or desired, such as at or near a fistula, such as an enterocutaneous, biliary, rectovaginal, enterovesicle, enterourethral, or esophageal fistula, or at or near a duct, such as a biliary or pancreatic duct. Additionally, the treatment site may be at or near gastric varices, arteriovenous malformations, or vascular aneurysms. Upon positioning the occlusion device 1402 at the treatment site, the magnetic component 1406 of the occlusion device 1402 may be activated. This may be accomplished, for example, by applying current from a current source (not shown) to the magnetic component 1406, which, in the embodiment illustrated in FIGS. 14 through 17, may be an electromagnet. Thus, in this embodiment,

upon application of a current to the magnetic component 1406, a magnetic field may be created originating at the magnetic component 1406.

[0050] Upon activating the magnetic component 1406, an occlusion forming material may be injected through the delivery device 1404 toward the distal end of the delivery device 1404. The occlusion forming material may include a magnetic responsive fluid. A magnetic responsive fluid may be a cyanoacrylate mixed with a compound having a magnetic potential. Upon injection, the magnetic responsive fluid and any other associated occlusion forming material may move from the distal end of the delivery device 1404 across the clearance 1412 and toward the magnetic component 1406. It should be noted that the magnetic component 1406 may help prevent the magnetic responsive fluid from interacting with and potentially adhering to the delivery device 1404. Additionally, the magnetic component 1406 may help prevent the magnetic responsive fluid and any other associated occlusion forming material from passing beyond the magnetic component 1406 and into other areas beyond the treatment site.

[0051] Upon associating with the magnetic component 1406, the magnetic responsive fluid may polymerize or at least partially polymerize to form an occlusion structure 1438 as illustrated in FIG. 15. The occlusion structure 1438 is disposed across the clearance 1412 such that the delivery device 1404 is not in direct contact with any portion of the occlusion structure 1438 formed around and containing the magnetic component 1406. Upon formation of the occlusion structure 1438, the connection between the connector (not shown) and the connecting member 1408 may be neutralized or separated, and the delivery device 1404 may be dissociated from the occlusion structure 1438 and the connecting member 1408 as illustrated in FIG. 16.

[0052] In some embodiments, a second amount of magnetic responsive fluid may then be injected at the treatment site. The second amount may preferably be an amount sufficient to cover or enclose the connecting member 1408 and any other portions of the magnetic component 1406 extending from the occlusion structure 1438 as illustrated in FIG. 17.

[0053] FIGS. 18 through 22 illustrate another embodiment of an occlusion formation method. In this embodiment, an occlusion device 1502 is positioned at a treatment site. The occlusion device 1502 may include an expandable element. The occlusion device 1502 may incorporate elements of any of the embodiments of an occlusion device illustrated in FIGS. 1-13, and therefore the descriptions of FIGS. 1-13 are hereby incorporated by reference. Additionally, the embodiment illustrated in FIGS.

18 through 22 is similar to the embodiment illustrated in FIGS. 14 through 17, and therefore the descriptions of FIGS. 14 through 17 are hereby incorporated by reference. In this embodiment, the occlusion device 1502 includes an expandable element 1526. During positioning of the occlusion device 1502 at the treatment site, the expandable
5 element 1526 may be contained in a closed or collapsed state. Upon positioning the occlusion device 1502 at the treatment site, the expandable element 1526 may expand. For example, the expandable element 1526 may expand so as to contact a duct wall or other areas of the treatment site as illustrated in FIG. 19.

[0054] Upon expansion of the expandable element 1526, the magnetic component
10 1506 of the occlusion device 1502 may be activated. Upon activating the magnetic component 1506, a magnetic responsive fluid may be injected through the delivery device 1504 toward the distal end of the delivery device 1504. In this embodiment, the magnetic responsive fluid is further injected through a second delivery device defined by a conduit formed within at least a portion of the magnetic component 1506 such that at least
15 a portion of the magnetic responsive fluid is channeled through and out of the distal opening of the second delivery device and onto the expandable element 1526. In this particular embodiment, the magnetic responsive fluid is channeled to the distal side of the expandable element 1526, where it is held within or against the expandable element 1526 by the magnetic force of the magnetic component 1506 as illustrated in FIG. 20.

[0055] Upon associating with the expandable element 1526, the magnetic
20 responsive fluid may polymerize or at least partially polymerize to form an occlusion structure 1538. The occlusion structure 1538 can be disposed within or against the expandable element 1526 such that the delivery device 1504 is not in direct contact with any portion of the occlusion structure 1538. Upon formation of the occlusion structure
25 1538, the connection between the connector (not shown) and the connecting member 1508 may be neutralized or separated, and the delivery device 1504 may be dissociated from the occlusion structure 1538 and the connecting member 1508 as illustrated in FIG. 21. In some embodiments, a second amount of magnetic responsive fluid may then be
30 injected at the treatment site. The second amount may preferably be an amount sufficient to cover or enclose the connecting member 1508 and any other portions of the magnetic component 1506 and/or the expandable element 1526 extending from the occlusion structure as illustrated in FIG. 22.

[0056] The terms “approximately,” “about,” and “substantially” as used herein represent an amount or condition close to the stated amount or condition that still

performs a desired function or achieves a desired result. For example, the terms “approximately,” “about,” and “substantially” may refer to an amount that deviates by less than 10%, or by less than 5%, or by less than 1%, or by less than 0.1%, or by less than 0.01% from a stated amount or condition.

5 **[0057]** In addition, unless expressly described otherwise, all stated amounts (e.g., angle measurements, dimension measurements, etc.) are to be interpreted as being “approximately,” “about,” and/or “substantially” the stated amount, regardless of whether the terms “approximately,” “about,” and/or “substantially” are expressly stated in relation to the stated amount(s).

10 **[0058]** Further, elements described in relation to any embodiment depicted and/or described herein may be combinable with elements described in relation to any other embodiment depicted and/or described herein. For example, any element described in relation to an embodiment depicted in Figures 1 through 13 may be combinable with an embodiment described in relation to an embodiment depicted in Figures 14 through 22.

15 **[0059]** The present disclosure may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the disclosure is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the
20 claims are to be embraced within their scope.

CLAIMS

What is claimed is:

1. An occlusion device, comprising:

5 a delivery device comprising a proximal end, a distal end, and a connector;
a magnetic component disposed a distance in a distal direction from the distal end of the delivery device, wherein the distance between the magnetic component and the distal end of the delivery device defines a clearance; and

10 a connecting member disposed between the magnetic component and the delivery device, the connecting member being attached to the magnetic component and extending to the delivery device, the connecting member being detachably coupled to the connector.

15 2. The device of claim 1, wherein the magnetic component is an electromagnet conductively associated with the connecting member and/or the connector such that electric current can pass to the magnetic component from a first current source.

20 3. The device of claim 1 or claim 2, wherein the connector comprises a connector coil and a member coil, the connector coil and the member coil being in association with each other such that the connector coil and the member coil can selectively form an inductive magnetic connection.

25 4. The device of claim 3, further comprising a connector core in association with the connector coil, and further comprising a member core in association with the member coil.

5. The device of claim 4, wherein the connector core and/or the member core are permanent magnets.

30 6. The device of any of claims 3 to 5, further comprising a second current source conductively associated with the connector coil, the second current source arranged to deliver current in a direction opposite the first current source such that the connection between the connector and the connecting member may be neutralized or separated upon association with the second current source.

7. The device of any of claims 1 to 6, wherein at least a portion of the magnetic component is formed as a conduit, the conduit thereby defining a second delivery device, the second delivery device comprising a proximal opening and a distal opening.

5 8. The device of claim 7, further comprising an expandable element disposed at the distal opening of the second delivery device and/or at the magnetic component, the expandable element being in association with the magnetic component.

10 9. The device of any of claims 1 to 8, wherein the magnetic component is configured to attract a magnetic responsive fluid such that a magnetic responsive fluid delivered through the delivery device is pulled away from the distal end of the delivery device and toward the magnetic component.

15 10. The device of any of claims 2 to 9, wherein the electromagnet is configured to provide a magnetic field of adjustable strength in relation to current delivered by the first current source.

11. A device for delivering an occlusion forming fluid to a treatment site, the device comprising:

20 a delivery catheter comprising a proximal end, a distal end, and a connector;
an electromagnet disposed a distance in a distal direction from the distal end of the delivery device;

a connecting member extending between the electromagnet and the distal end of the delivery catheter, the connector being coupled to the electromagnet and selectively
25 coupled to the delivery device; and

a current source in electrical communication with the electromagnet such that the electromagnet may be actuated through the delivery of current from the current source.

12. A method of forming a treatment occlusion, comprising:

positioning an occlusion device of any of claims 1 to 11 at a treatment site;

activating a magnetic component disposed a distance in a distal direction from a distal end of a delivery device, the distance between the magnetic component and the distal end of the delivery device defining a clearance;

injecting an amount of a magnetic responsive fluid through the delivery device such that the magnetic responsive fluid is removed from the distal end of the delivery device across the clearance and toward the magnetic component;

allowing the magnetic responsive fluid to at least partially polymerize, the at least partially polymerized magnetic responsive fluid and the associated magnetic component defining an occlusion structure; and

dissociating the delivery device from the magnetic component such that the delivery device can be removed from the treatment site without disturbing the occlusion structure.

13. The method of claim 12, wherein the at least a portion of the magnetic component is formed as a conduit, the conduit thereby defining a second delivery device, and wherein the magnetic responsive fluid is removed from the distal end of the delivery device and toward the magnetic component by movement through the second delivery device.

14. The method of claim 12 or claim 13, wherein an expandable element is disposed at the distal opening of the second delivery device, the expandable element being in association with the magnetic component such that activation of the magnetic component brings the magnetic responsive fluid into contact with the expandable element.

15. The method of any of claims 12 to 14, wherein the expandable element is formed to be non-porous to the magnetic responsive fluid such that upon movement of the magnetic responsive fluid through the second delivery device and activation of the magnetic component, the magnetic responsive fluid is held on a distal side of the expandable element.

16. The method of any of claims 12 to 14, wherein the expandable element is formed to be at least partially porous to the magnetic responsive fluid such that upon movement of the magnetic responsive fluid through the second delivery device and activation of the magnetic component, the magnetic responsive fluid is held on a distal side of the expandable element, within the structure of the expandable element, on a proximal side of the expandable element, or some combination.

17. The method of any of claims 12 to 16, further comprising injecting a second amount of the magnetic responsive fluid at the treatment site, the second amount enclosing the connecting member.

1 / 10

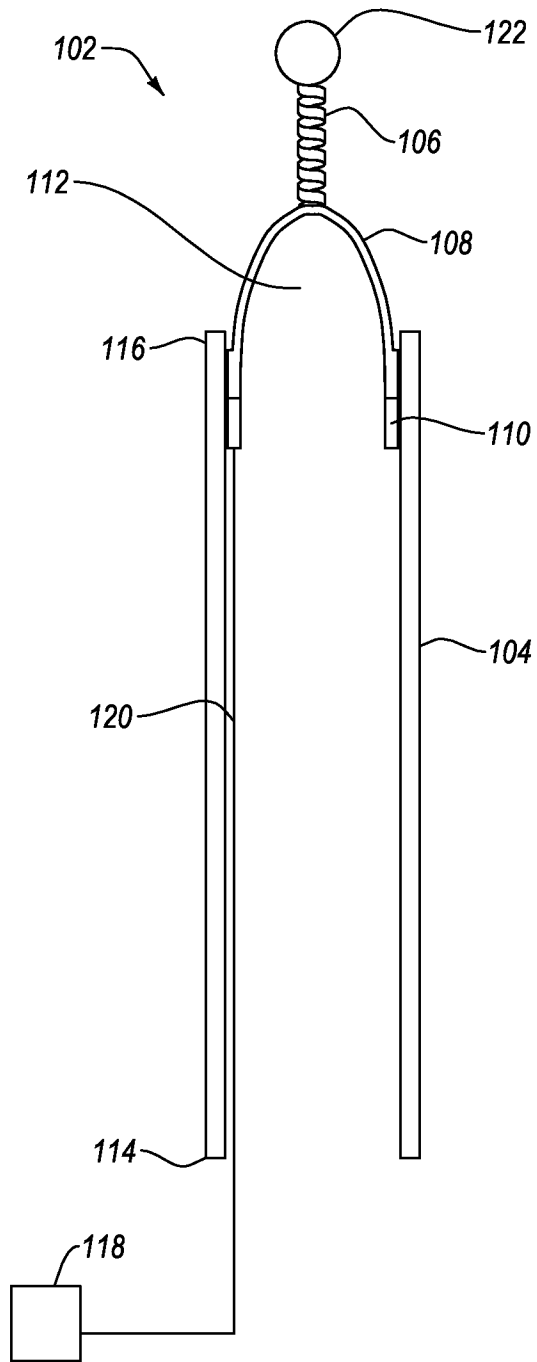


FIG. 1

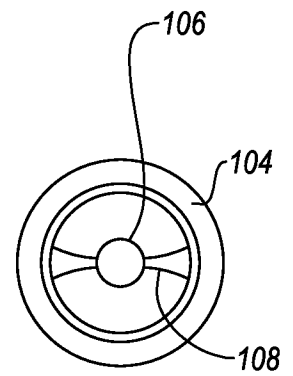


FIG. 2

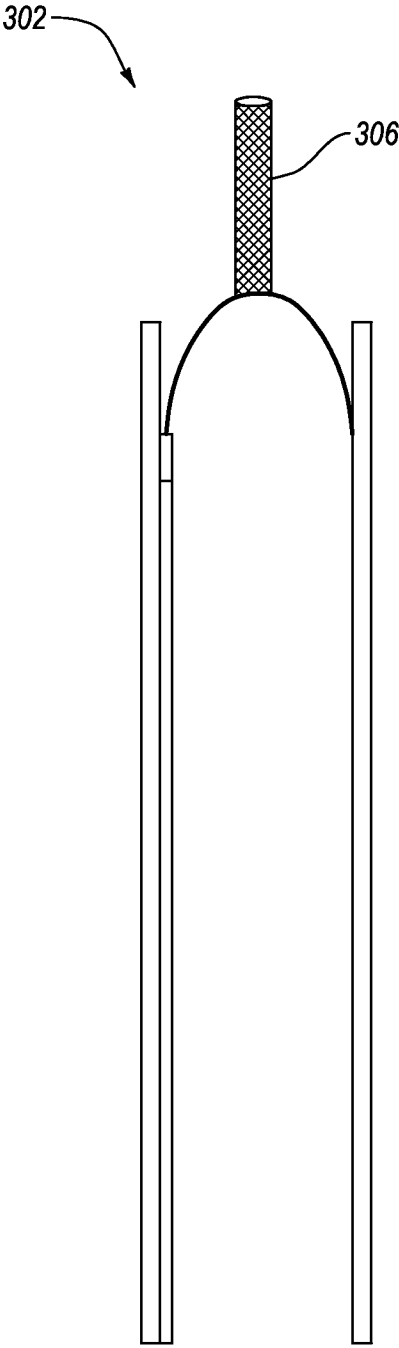


FIG. 3

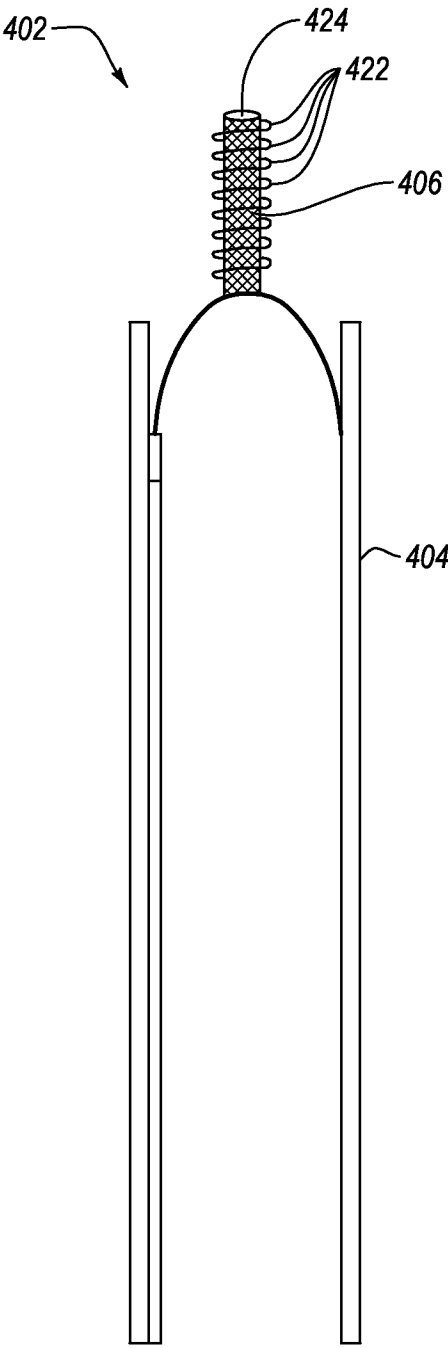


FIG. 4

3 / 10

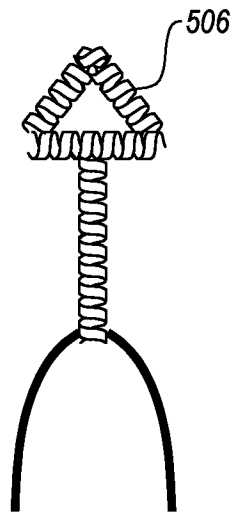


FIG. 5

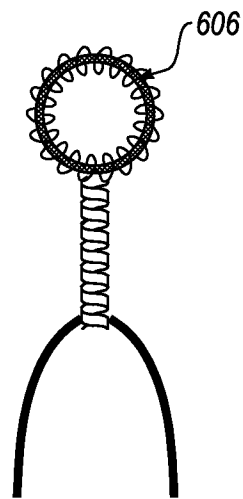


FIG. 6

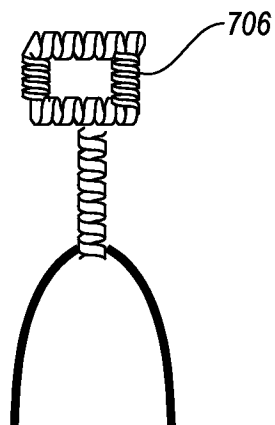


FIG. 7

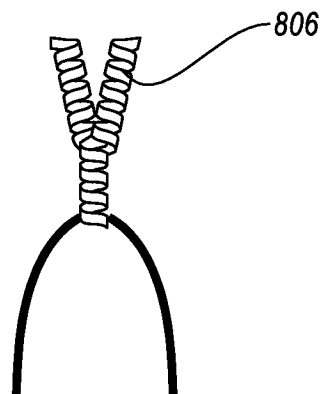


FIG. 8

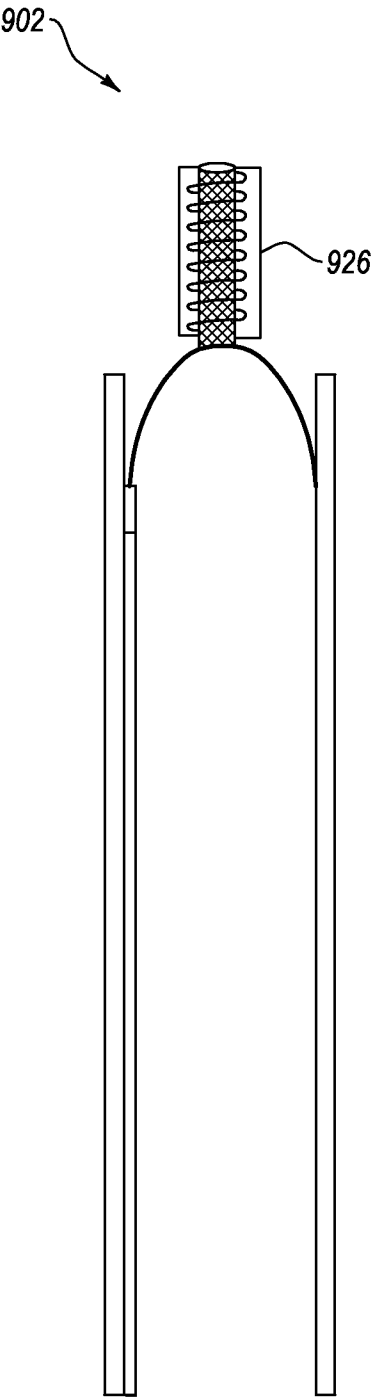


FIG. 9

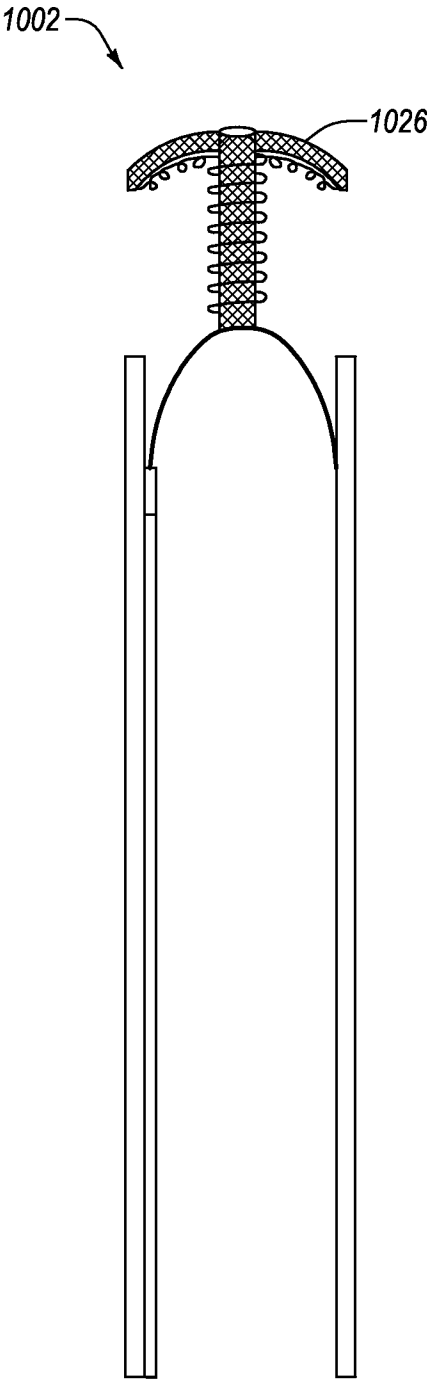
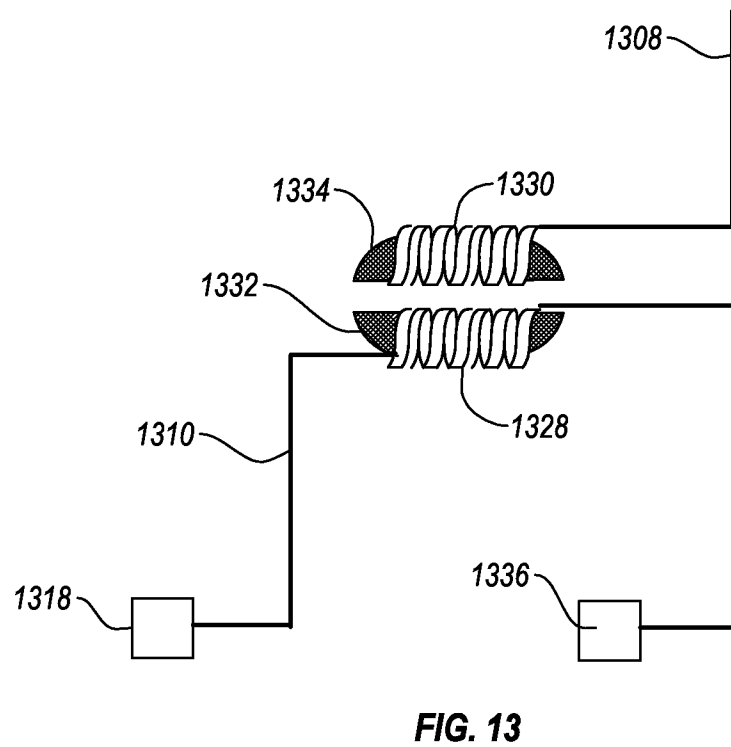
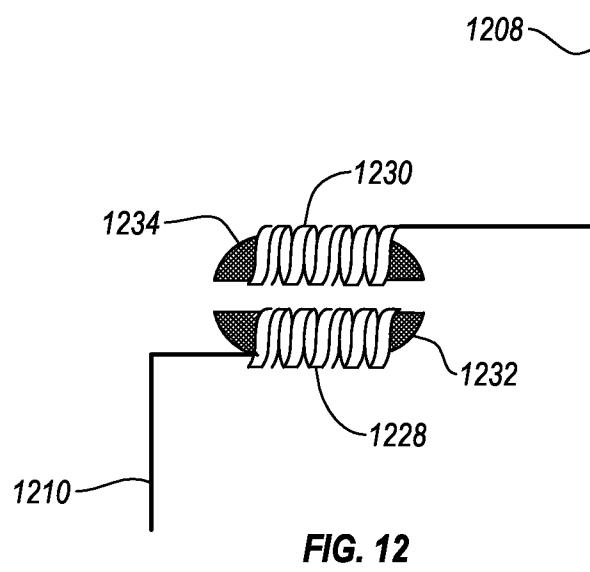
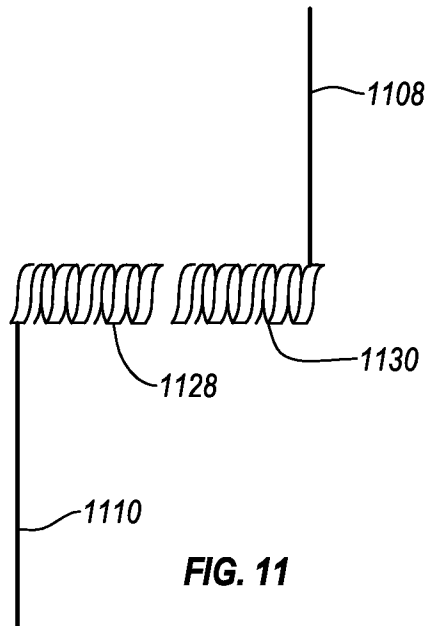


FIG. 10

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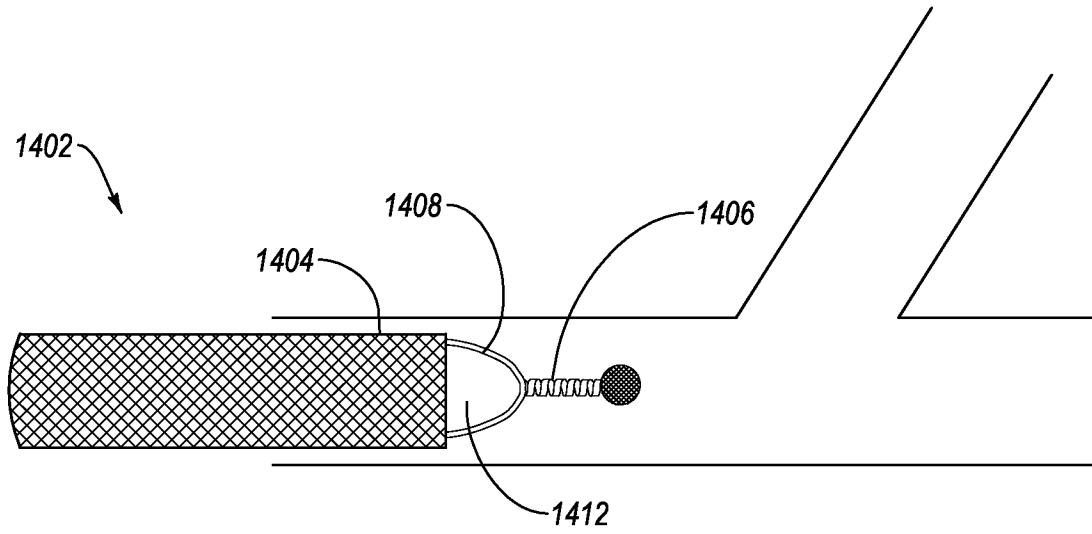


FIG. 14

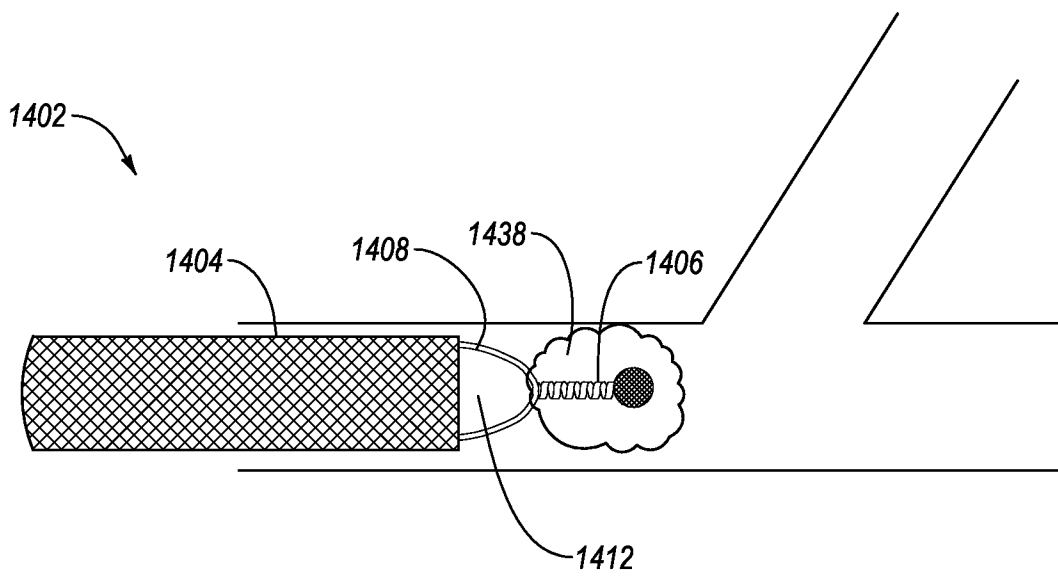


FIG. 15

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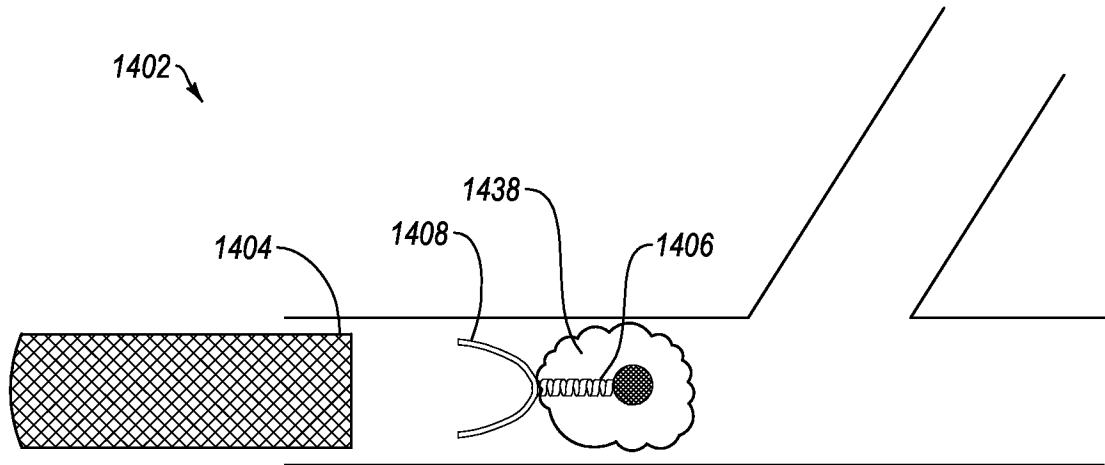


FIG. 16

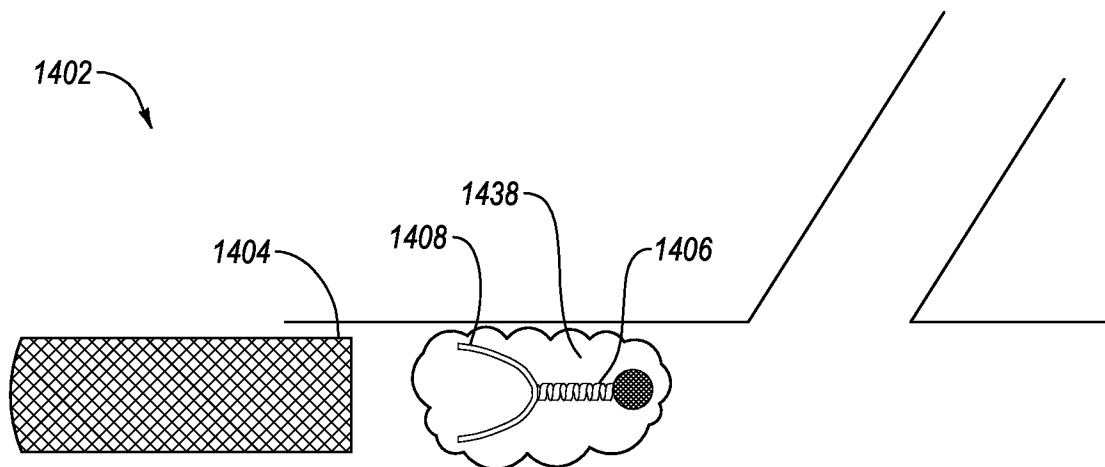


FIG. 17

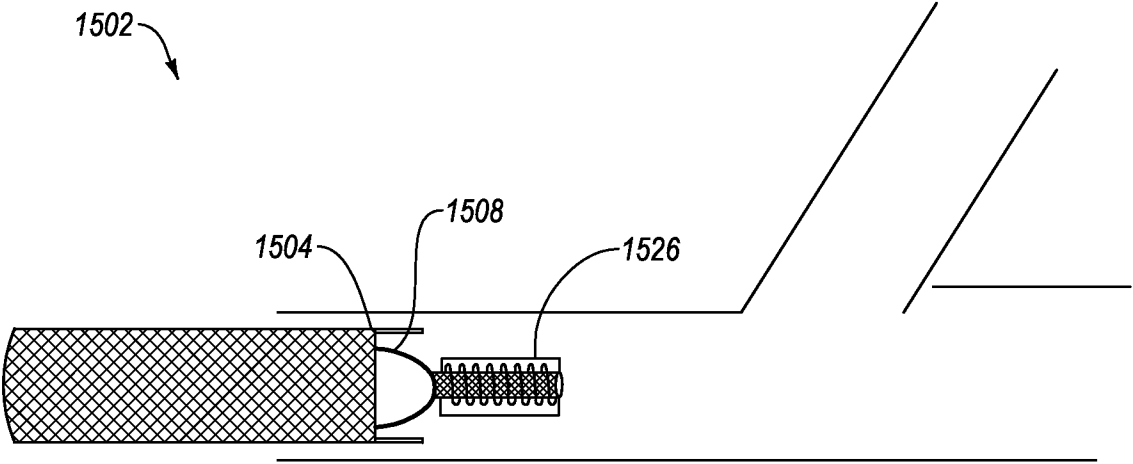


FIG. 18

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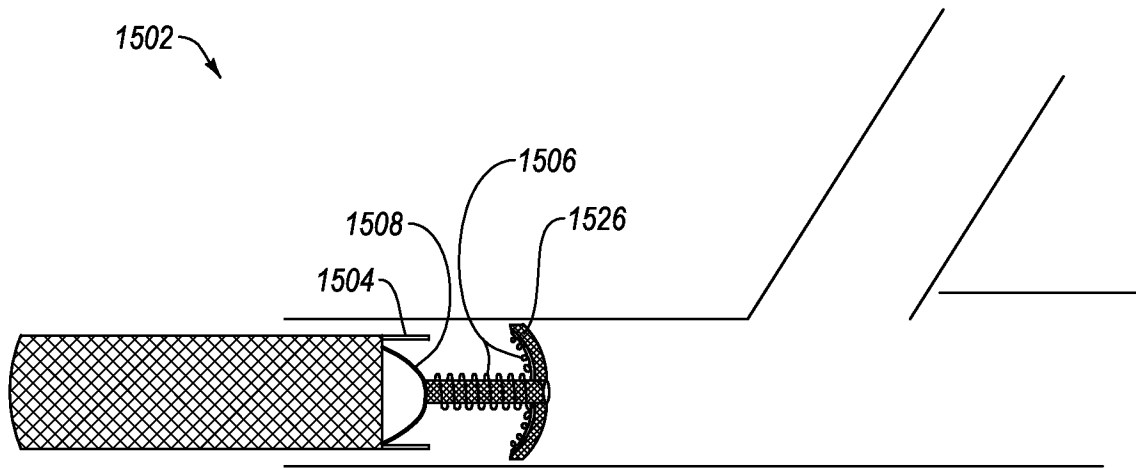


FIG. 19

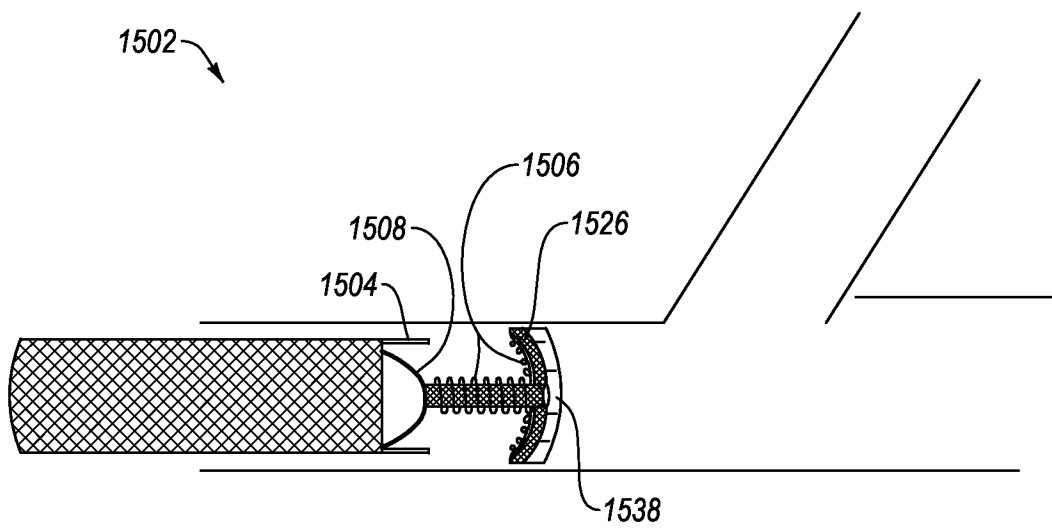


FIG. 20

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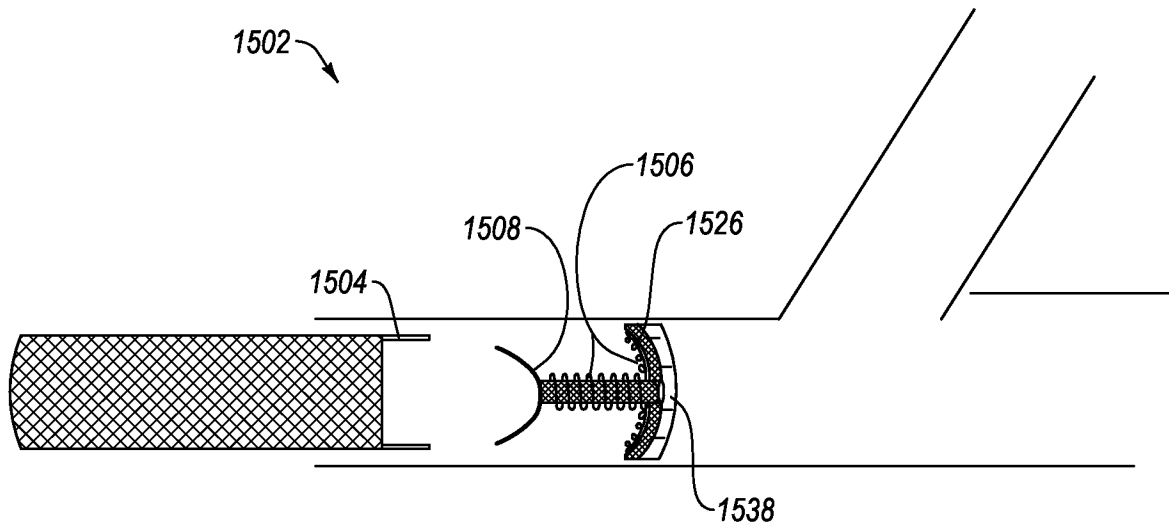


FIG. 21

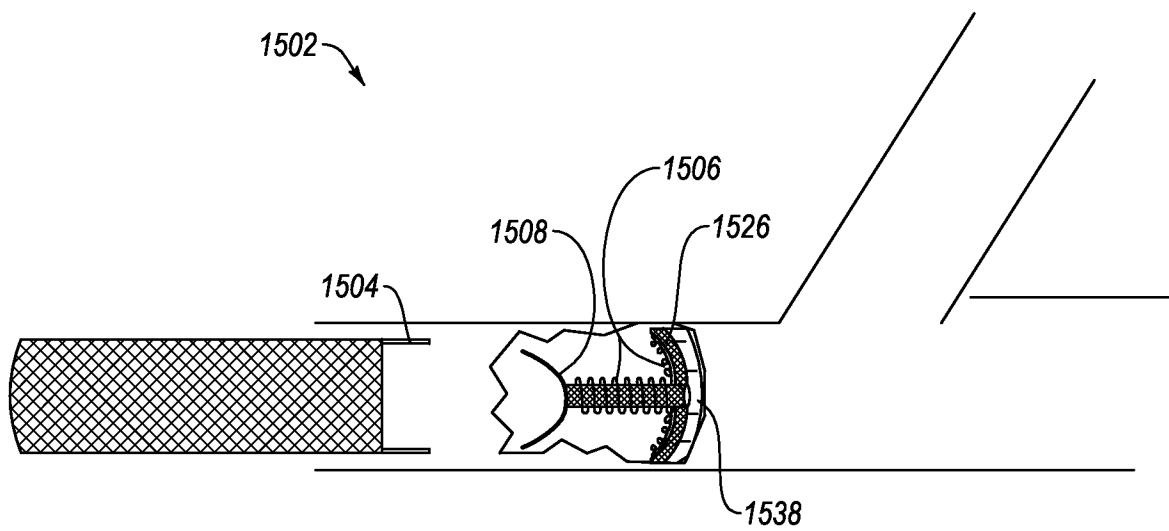


FIG. 22

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US15/42601

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61M 25/00; A61B 17/00 (2015.1)

CPC - A61M 25/0074; A61B 17/0057; A61N 2/02

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8) Classification(s): A61M 25/00; A61B 17/00 (2015.1); CPC Classification(s): A61B 17/0057, 2017/00477; A61M 25/0069, 25/0074, 25/0082, 25/0127, 39/00, 2205/0272, 2205/0283; A61N 2/02; H01F 27/00

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)

PatSeer (US, EP, WO, JP, DE, GB, CN, FR, KR, ES, AU, IN, CA, INPADOC Data); Google, Google Scholar, Google Patents, PubMed/Medline, Proquest; Catheter, electromagnet, connect, detach, occlusion, permanent magnet, core

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2002/0087044 A1 (CROSS, III, DT et al.) July 4, 2002; figure 10; paragraphs [0037]-[0040]	1-2, 11
---		3/1-2, 4/3/1-2, 5/4/3/1-2
Y	US 2004/0133189 A1 (SAKURAI, T) July 8, 2004; figure 2A; paragraphs [0038]-[0039]	3/1-2, 4/3/1-2
Y	US 6,414,577 B1 (HOFFMAN, J) July 2, 2002; figure 2; column 2, lines 50-65	5/4/3/1-2
A	US 3,995,209 A (WESTON, SR., JAD) November 30, 1976; entire document	1-5, 11
A	US 6,364,823 A (GARIBALDI, JM et al.) April 2, 2002; entire document	1-5, 11
A	US 6,409,721 A (WHEELLOCK, ET et al.) June 25, 2002; entire document	1-5, 11

☐ 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 application or patent 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

29 September 2015 (29.09.2015)

Date of mailing of the international search report

29 OCT 2015

Name and mailing address of the ISA/

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450

Facsimile No. 571-273-8300

Authorized officer

Shane Thomas

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US15/42601

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☒ Claims Nos.: 6-10 and 12-17
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.