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(54) **CLOSURE DEVICE**

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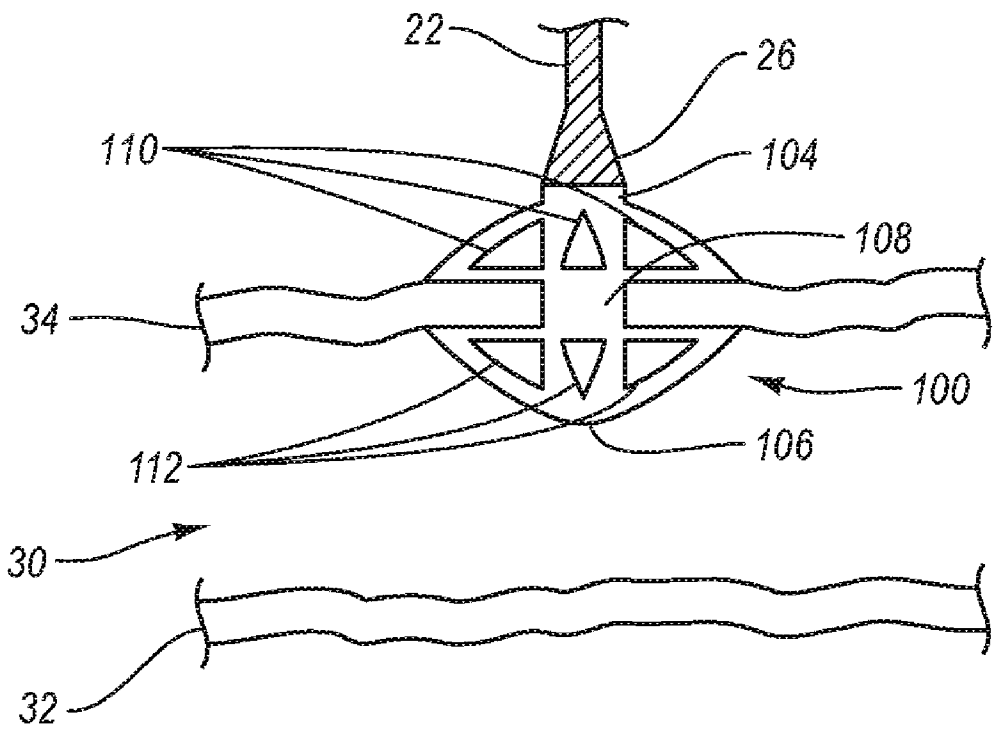
(57) **ABSTRACT**

A closure device for closing an opening in tissue is provided. The closure device according the present invention includes a delivery system for deploying a closure element, wherein the closure element is movable between a delivery configuration and a deployed configuration to close an opening in tissue. The closure device of the present invention may further include a charge of hemostatic material.



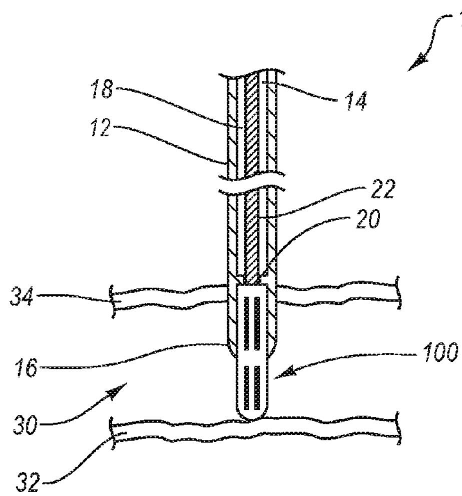


Fig. 1

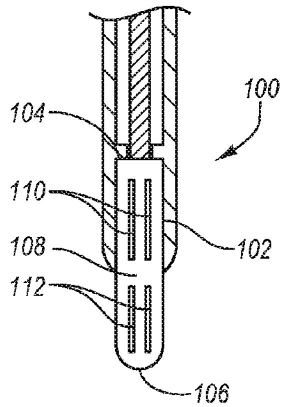


Fig. 2A

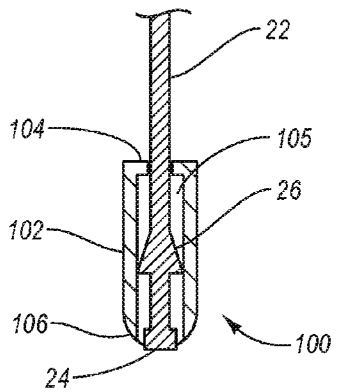


Fig. 2B

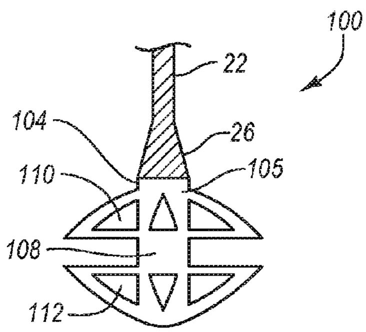


Fig. 2C

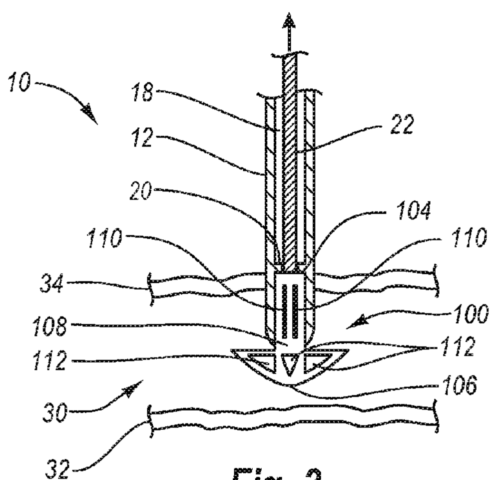


Fig. 3

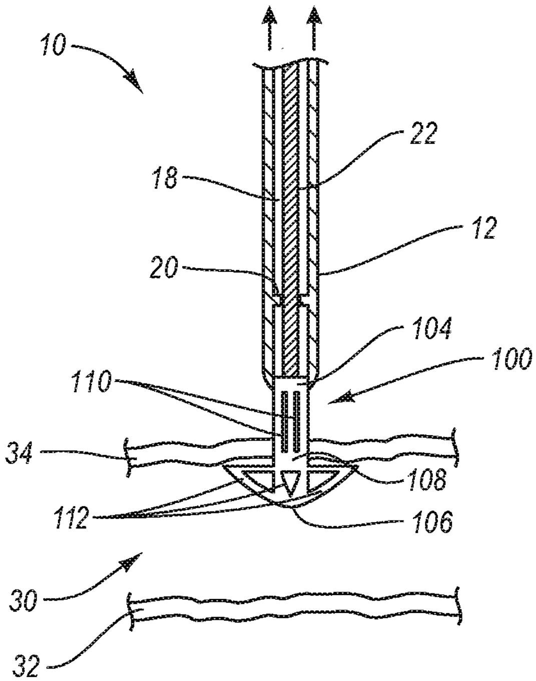


Fig. 4

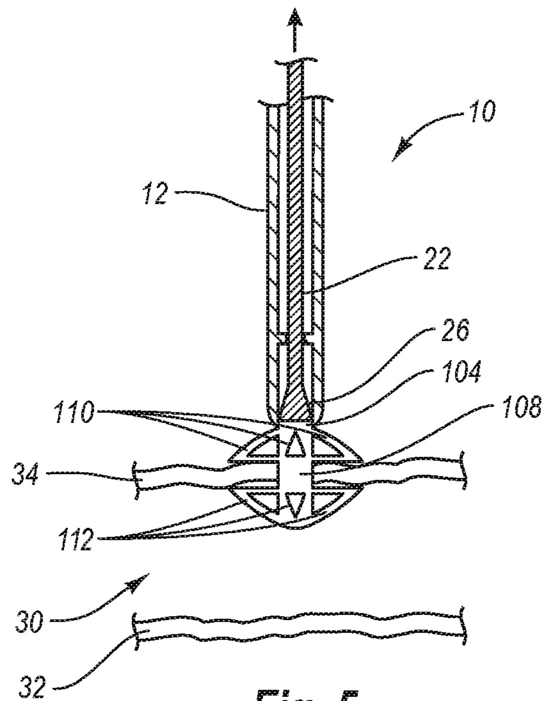


Fig. 5

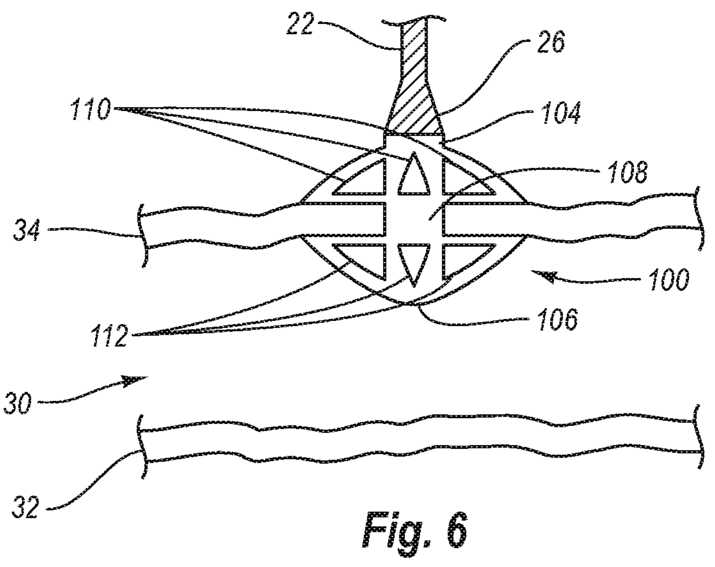


Fig. 6

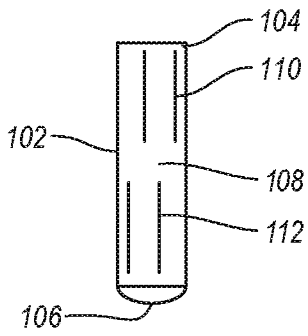


Fig. 7A

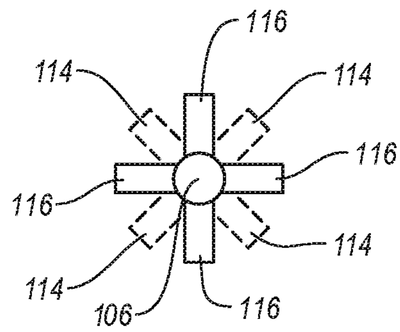


Fig. 7B

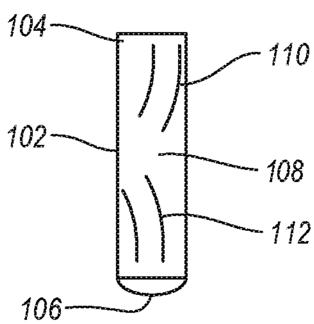


Fig. 8A

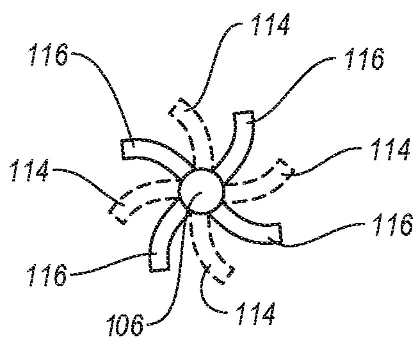


Fig. 8B

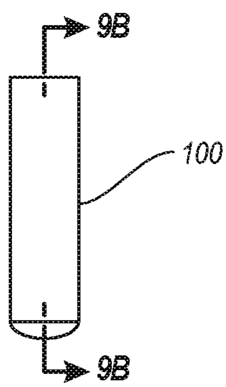


Fig. 9A

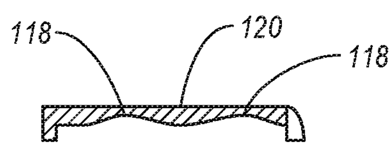


Fig. 9B

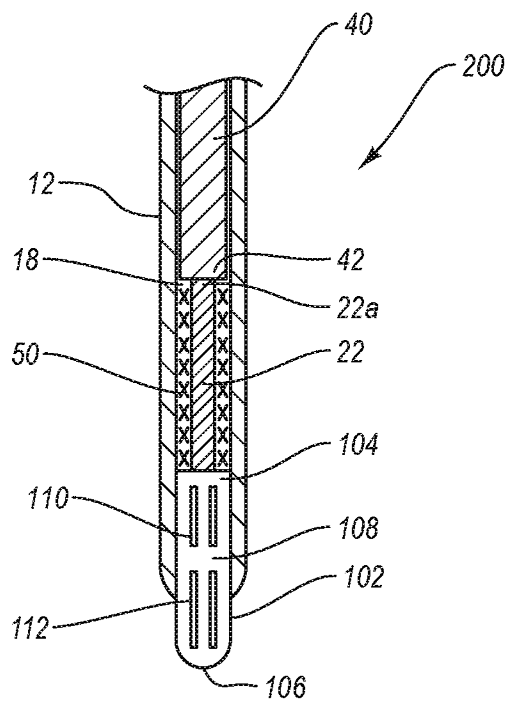

40
200
12
18
42
22a
50
22
104
110
108
102
112
106

Fig. 10

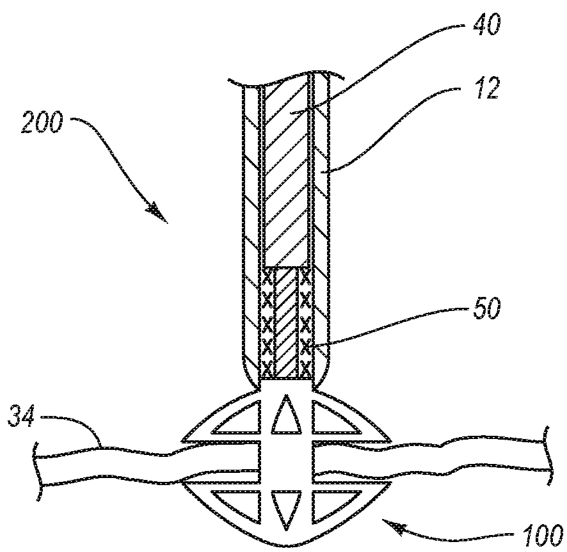

40
12
200
50
34
100

Fig. 11

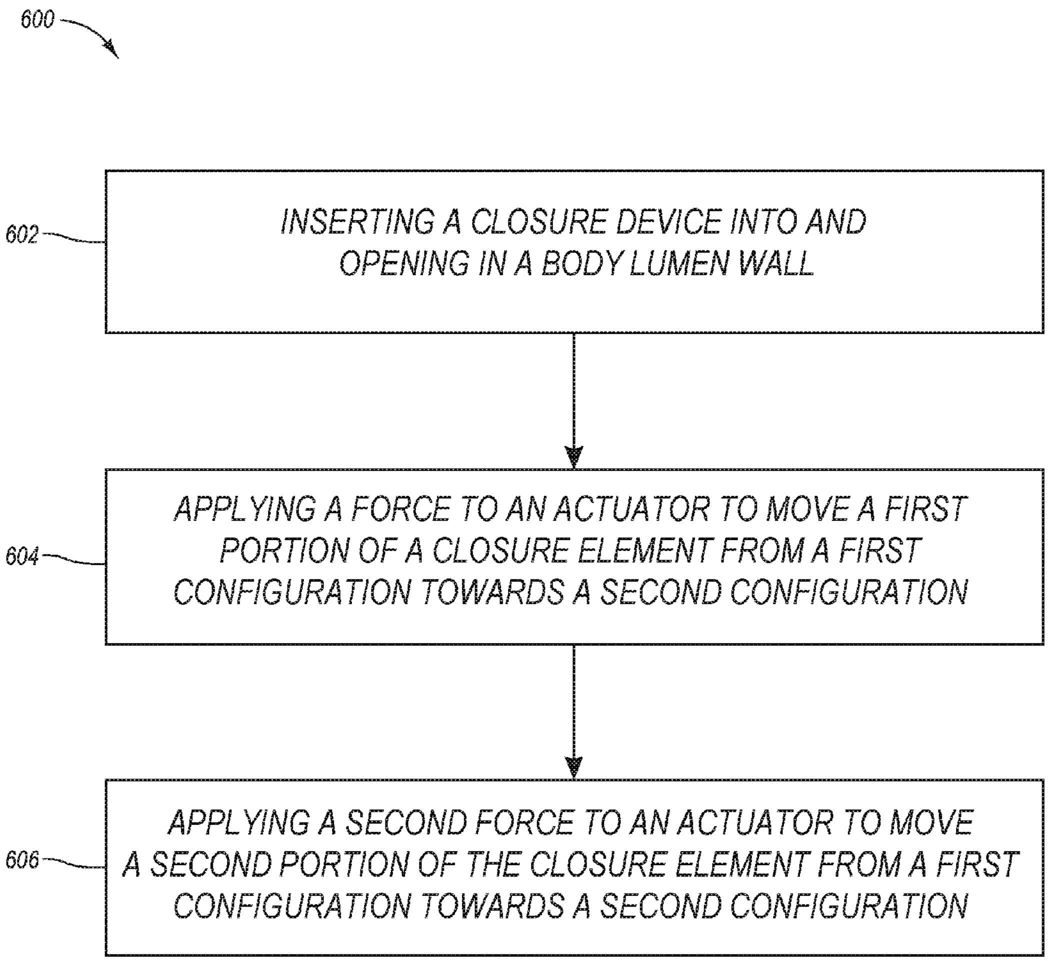

600
602
INSERTING A CLOSURE DEVICE INTO AND OPENING IN A BODY LUMEN WALL
604
APPLYING A FORCE TO AN ACTUATOR TO MOVE A FIRST PORTION OF A CLOSURE ELEMENT FROM A FIRST CONFIGURATION TOWARDS A SECOND CONFIGURATION
606
APPLYING A SECOND FORCE TO AN ACTUATOR TO MOVE A SECOND PORTION OF THE CLOSURE ELEMENT FROM A FIRST CONFIGURATION TOWARDS A SECOND CONFIGURATION

Fig. 12

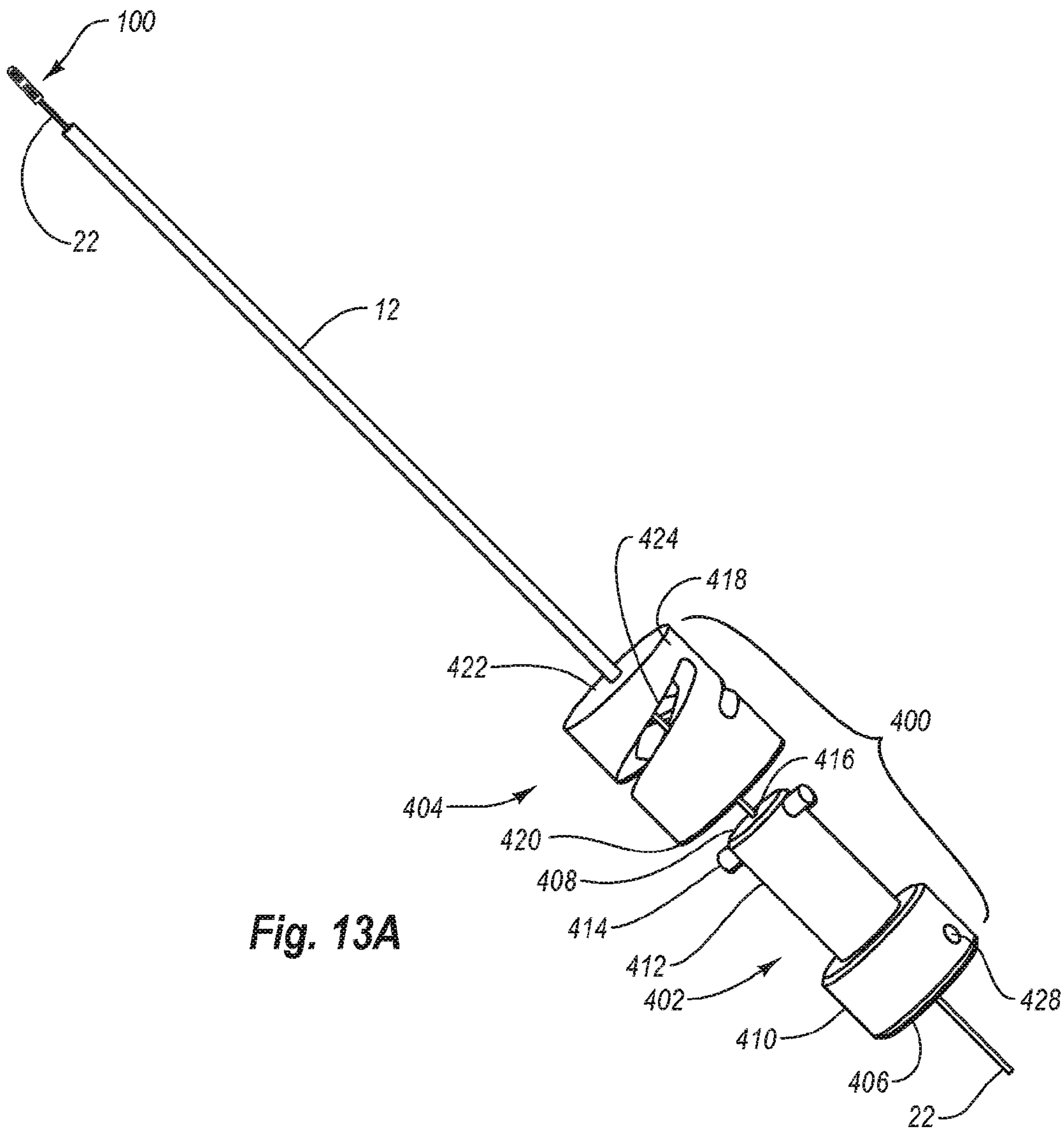


Fig. 13A

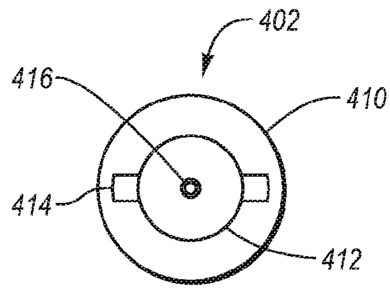


Fig. 13B

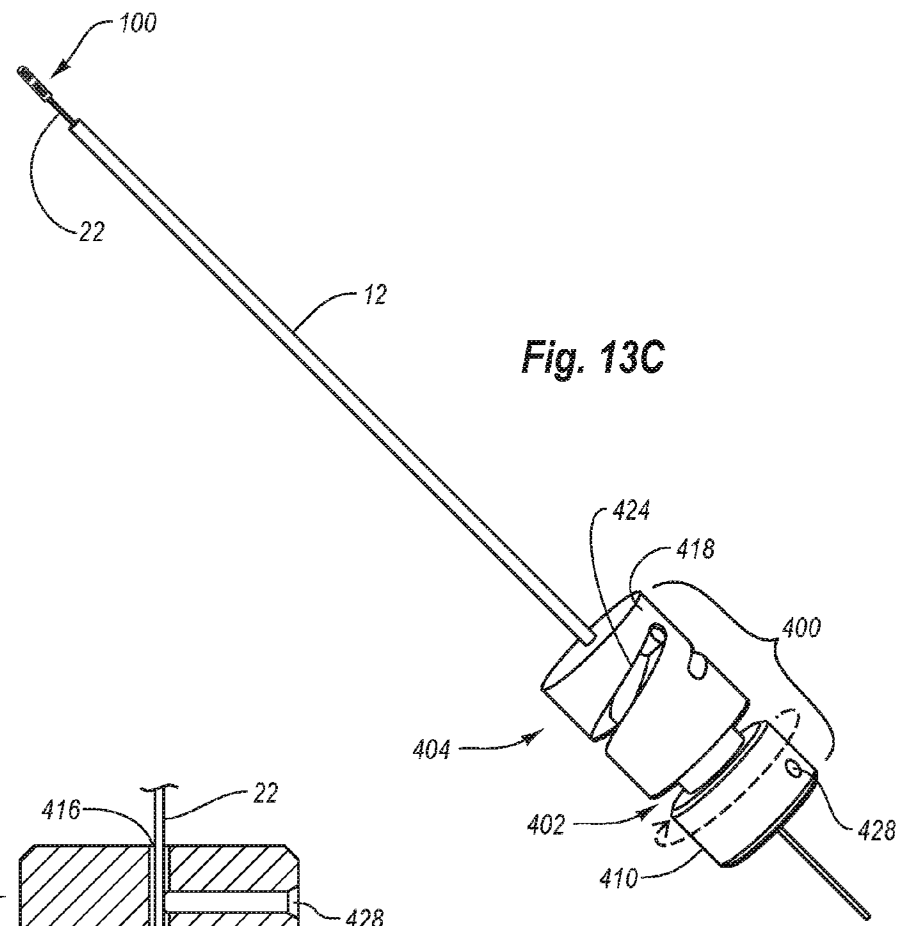


Fig. 13C

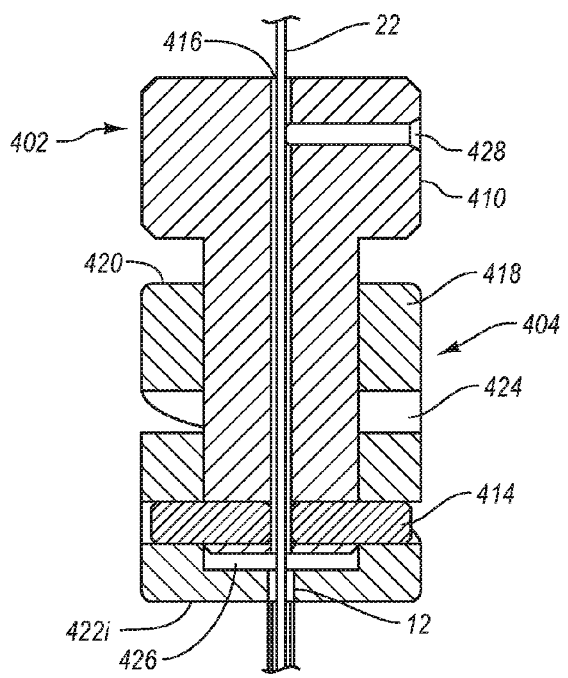


Fig. 13D

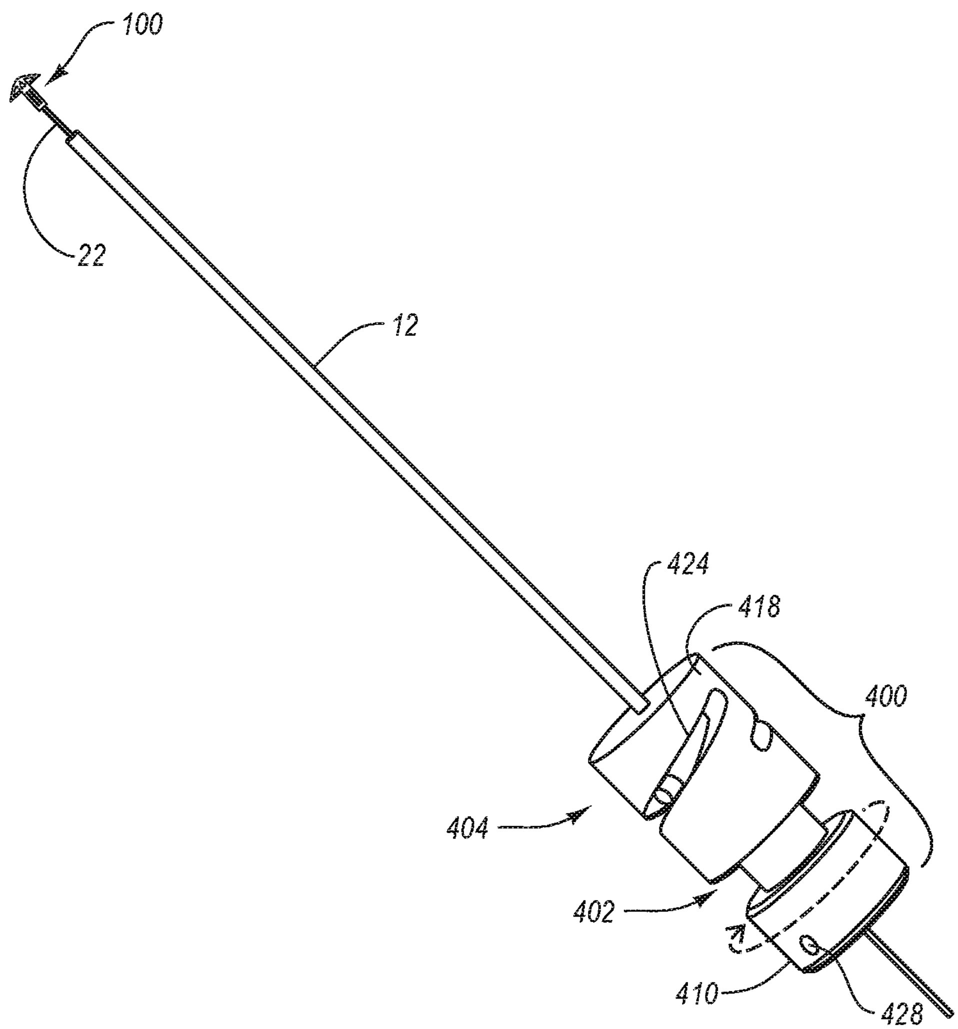


Fig. 13E

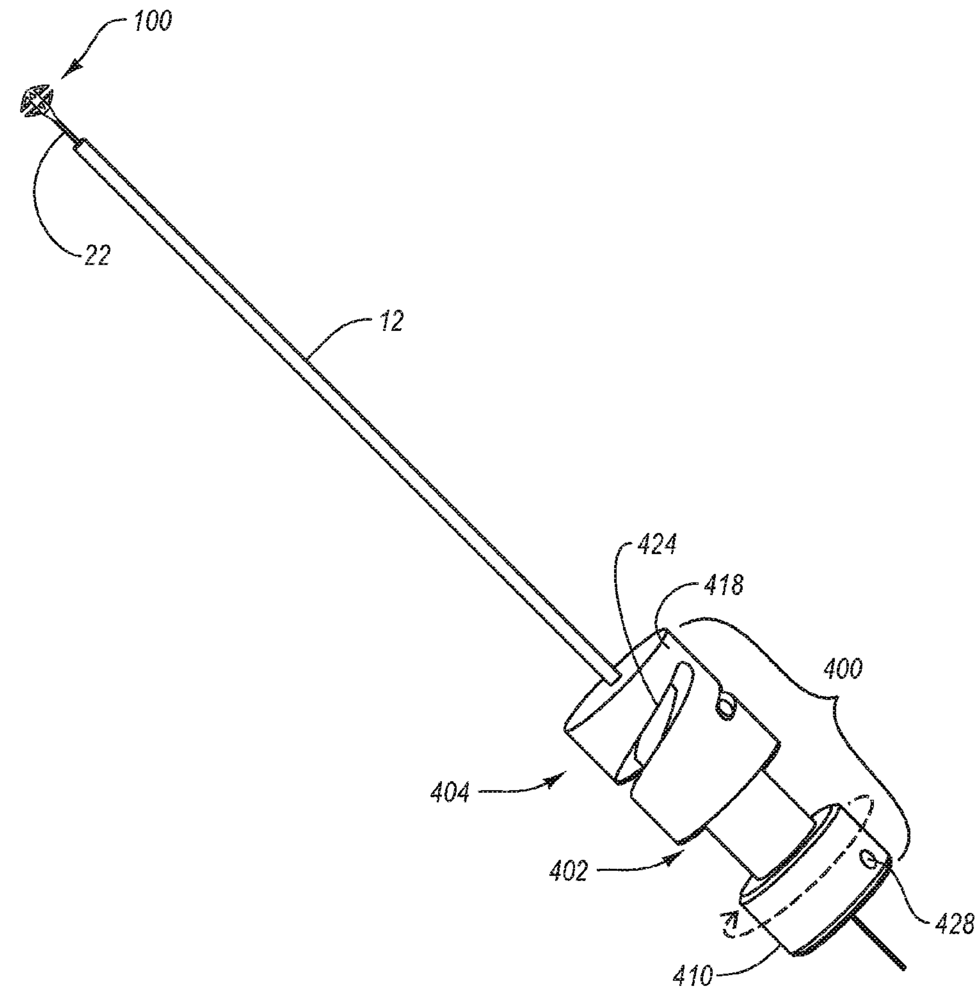


Fig. 13F

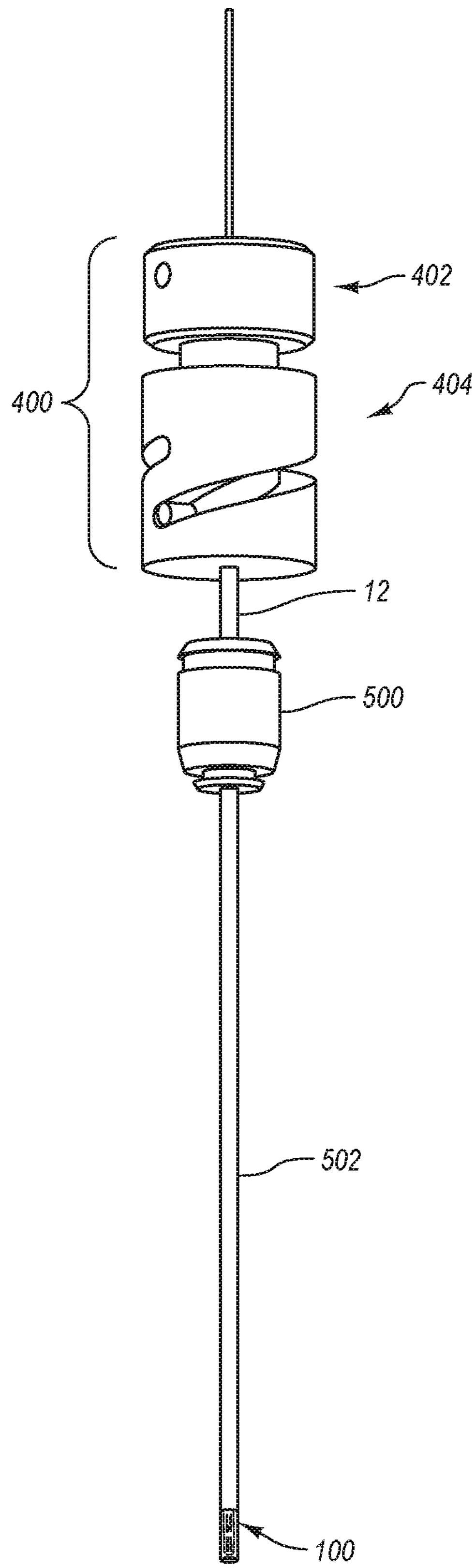


Fig. 13G

CLOSURE DEVICE

CROSS REFERENCE

[0001] This application is a continuation of U.S. patent application Ser. No. 12/608,773, filed Oct. 29, 2009 and entitled "CLOSURE DEVICE", which claims the benefit of, and priority to, U.S. Provisional Patent Application Ser. No. 61/109,822, filed on Oct. 30, 2008 and entitled "CLOSURE DEVICE," and Ser. No. 61/143,748, filed on Jan. 9, 2009 and entitled "CLOSURE DEVICE," all of which are incorporated in their entireties herein by this reference.

BACKGROUND

[0002] 1. The Field of the Invention

[0003] The present disclosure relates generally to systems, devices, and methods for blocking an opening in body lumens. More particularly, the present disclosure relates to techniques for percutaneous closure of arterial and venous puncture sites, which are usually accessed through a tissue tract.

[0004] 2. The Relevant Technology

[0005] A number of diagnostic and interventional vascular procedures are now performed translumenally. A catheter is introduced to the vascular system at a convenient access location and guided through the vascular system to a target location using established techniques. Such procedures require vascular access, which is usually established during the well-known Seldinger technique. Vascular access is generally provided through an introducer sheath, which is positioned to extend from outside the patient body into the vascular lumen. When vascular access is no longer required, the introducer sheath is removed and bleeding at the puncture site stopped.

[0006] One common approach for providing hemostasis (the cessation of bleeding) is to apply external force near and upstream from the puncture site, typically by manual compression. This approach suffers from a number of disadvantages. For example, the manual compression procedure is time consuming, frequently requiring one-half hour or more of compression before hemostasis is achieved. Additionally, such compression techniques rely on clot formation, which can be delayed until anticoagulants used in vascular therapy procedures (such as for heart attacks, stent deployment, non-optical PTCA results, and the like) wear off. The anticoagulants may take two to four hours to wear off, thereby increasing the time required before completion of the manual compression procedure.

[0007] Further, the manual compression procedure is uncomfortable for the patient and frequently requires analgesics to be tolerable. Moreover, the application of excessive pressure can at times totally occlude the underlying blood vessel, resulting in ischemia and/or thrombosis. Following manual compression, the patient typically remains recumbent from four to as much as twelve hours or more under close observation to assure continued hemostasis. During this time, renewed bleeding may occur, resulting in blood loss through the tract, hematoma and/or pseudo-aneurysm formation, as well as arteriovenous fistula formation. These complications may require blood transfusion and/or surgical intervention.

[0008] The incidence of complications from the manual compression procedure increases when the size of the introducer sheath grows larger, and/or when the patient is anticoagulated. The compression technique for arterial closure can be risky, and is expensive and onerous to the patient. Although the risk of complications can be reduced by using highly trained individuals, dedicating such personnel to this task is both expensive and inefficient. Nonetheless, as the number and efficacy of translumenally performed diagnostic and interventional vascular procedures increases, the number of patients requiring effective hemostasis for a vascular puncture continues to increase.

[0009] To overcome the problems associated with manual compression, the use of bioabsorbable sealing bodies is one example approach that has been proposed. Generally, this example approach relies on the placement of a thrombogenic and bioabsorbable material, such as collagen, at the superficial arterial wall over the puncture site. While potentially effective, this approach suffers from a number of problems. For example, bioabsorbable sealing bodies may lack a solid mechanical attachment of the sealing body to the tissue. Due to the lack of a solid mechanical attachment, the sealing body can wander within the tissue tract or move out of the puncture site, thus causing late bleeds. Conversely, if the sealing body wanders and intrudes too far into the arterial lumen, due to the lack of a solid mechanical attachment, intravascular clots and/or collagen pieces with thrombus attached can form and embolize downstream, causing vascular occlusion.

[0010] In addition to not having a solid mechanical attachment to the tissue, the sealing bodies may rely upon expandable materials to achieve hemostasis. Again, the expandable materials lack the security of a hard mechanical closure, thus potentially causing late bleeds and prolonging hemostasis.

BRIEF SUMMARY

[0011] This Summary is provided to introduce a selection of concepts in a simplified form that are further described below in the Detailed Description. This Summary is not intended to identify key features or essential features of the claimed subject matter, nor is it intended to be used as an aid in determining the scope of the claimed subject matter. Embodiments of the present invention provide systems, methods, and devices for closing an opening in tissue. Embodiments of the invention can be configured to close an opening within a body lumen.

[0012] In one example embodiment, a device for closing an opening in tissue includes a tubular body member having a wall thickness, a proximal end, and a distal end. The tubular body member of the device may include slits formed within the tubular member through the wall thickness. The slits are arranged above and below a waist portion located between the proximal end and distal end of the tubular body member.

[0013] In another example embodiment, a device for closing an opening in a body lumen wall includes a tubular body element having a first portion, a second portion, and a waist portion located between the first portion and second portion. The first and second portions have a delivery configuration and a deployed configuration. When the first and second portions are in the delivery configuration they have a delivery cross-sectional dimension, and when the first and second portions are in a deployed configuration they have a deployed cross-sectional dimension. The deployed cross-sectional dimension is larger than the delivery cross-sectional dimension.

[0014] Another example embodiment discloses a system for closing an opening in a body lumen. The system includes a closure element having a delivery configuration and a deployed configuration. The system further includes an actuator that is coupled to the closure element and operatively associated with a handle assembly. The handle assembly includes a rotatable handle element that may be inserted into a hub member such that when the handle element is rotated, the closure element changes from the delivery configuration to the deployed configuration.

[0015] In another example embodiment, a method for closing an opening in a body lumen is disclosed. The method includes inserting a closure device into an opening in a body lumen wall, the closure device including a closure element and actuator. After inserting the closure device, a force is applied to the closure element by way of the actuator such that a first portion of the closure element changes from a delivery configuration to a deployed configuration. Next, a second force may be applied to the closure element by way of the actuator such that a second portion of the closure element changes from a delivery configuration to a deployed configuration.

[0016] These and other advantages and features of the present invention will become more fully apparent from the following description and appended claims, or may be learned by the practice of the invention as set forth hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] To further clarify the above and other advantages and features of the present invention, a more particular description of the invention will be rendered by reference to specific embodiments thereof which are illustrated in the appended drawings. It is appreciated that these drawings depict only typical embodiments of the invention and are therefore not to be considered limiting of its scope. The invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

[0018] FIG. **1** is a cross-sectional view of the closure device in accordance with one embodiment of the present invention;

[0019] FIG. **2**A is a close-up cross-sectional view of an example embodiment of a closure device in accordance with the present invention;

[0020] FIG. **2**B is a close-up cross-sectional view of an example embodiment of a closure device in accordance with the present invention and further illustrating a locking mechanism formed therewith;

[0021] FIG. **2**C is a cross-section view of an example embodiment of a closure element in a deployed configuration;

[0022] FIGS. **3** through **6** illustrate the use of an example closure device in accordance with the present invention;

[0023] FIGS. **7**A through **9**B illustrate various embodiments of a closure element in accordance with the present invention;

[0024] FIGS. **10** and **11** are cross-sectional views of an alternative embodiment of a closure device including a charge of a hemostatic material;

[0025] FIG. **12** is a flow chart showing an example method of closing an opening in tissue in accordance with the present invention;

[0026] FIG. **13**A is an exploded illustration of a delivery system of one embodiment of the present invention;

[0027] FIG. **13**B is a top view of a portion of the delivery system of FIG. **13**A according to one embodiment of the present invention;

[0028] FIG. **13**C is another illustration of the delivery system of FIG. **13**A according to one embodiment of the present invention;

[0029] FIG. **13**D is a cross-section illustration of a portion of the delivery system of FIG. **13**A;

[0030] FIG. **13**E is a further illustration of the delivery system of FIG. **13**A;

[0031] FIG. **13**F is a yet further illustration of the delivery system of FIG. **13**A; and

[0032] FIG. **13**G is a perspective illustration of the delivery system of FIG. **13**A in combination with an introducer sheath according to another embodiment of the present invention.

DETAILED DESCRIPTION

[0033] In accordance with the present invention there is provided a closure device configured to close an opening formed in tissue. The closure devices described herein may be formed of a bioabsorbable material or may be formed of a biocompatible material. It is further contemplated the closure device may be coated with a covering membrane and/or another biocompatible coating as will be described in greater detail below. In one embodiment, the closure device may be configured to be received within the lumen of a medical sheath, for example, in accessing the patient's femoral artery, the physician will typically utilize a 6 French sheath. The closure device may be configured to be received within the lumen of this 6 French sheath. However, it can be understood that embodiments of the closure device may be configured to be received within multiple sizes of sheaths and should not be limited to the example above.

[0034] FIG. **1** illustrates one example embodiment of a closure device **10**. As shown in FIG. **1** the closure device **10** may include an elongate member **12** that has a proximal end **14** and a distal end **16**. The elongate member **12** may also include a passage **18** that extends from the proximal end **14** towards the distal end **16**. Within the passage **18** of the elongate member **12**, a protrusion **20** extends into the passage **18**, thus reducing the cross-sectional dimension of the passage **18** at a location that is between the proximal end **14** and the distal end **16** of the elongate member **12**. The closure device **10** further includes an actuator **22** that extends through the passage **18** of the elongate member **12**. A closure element **100** extends beyond the elongate member **12** and may be coupled to the actuator **22**.

[0035] In operation, the closure device **10** may be inserted into a body lumen **30** as illustrated in FIG. **1**. In one embodiment, the elongate member **12** and the closure element **100** pass through the proximal luminal wall **34** of the body lumen **30**. While within the body lumen **30** the closure element **100** is changed from a delivery configuration, as illustrated in FIG. **1**, to a deployed configuration as illustrated in FIG. **2**C. While in the deployed configuration the closure element **100** is able to block or otherwise close a puncture in the proximal luminal wall **34**.

[0036] Referring back to FIG. **1**, the structure of the closure device **10** will be discussed in more detail. In particular, the closure device **10** may have configurations and characteristics that vary from one embodiment to the next. For example, the elongate member **12** is one aspect of the closure device **10** that may vary from one embodiment to the next. In particular, the elongate member **12** may have various geometric configurations. As illustrated in FIG. **1**, the elongate member **12** may have a substantially circular cross-sectional geometric configuration. In other embodiments, however, the cross-sectional configuration of the elongate member **12** may vary and take various other configurations such as oval, square, triangular or any other configuration or combination of configurations.

[0037] Along with the various cross-sectional configurations of the elongate member **12**, the passage **18** may also have various cross-sectional configurations. The cross-sectional configuration of the elongate member **12** may or may not match the cross-sectional configuration of the passage **18**. Moreover, the cross-sectional configurations of the elongate member **12** and the passage **18** may vary from the proximal end to the distal end of the elongate member **12**.

[0038] Notwithstanding variations in the geometric configuration, the elongate member **12** may be configured to retain the closure element **100** at the distal end **16** of the elongate member **12**. In one example embodiment, illustrated in FIG. **1**, the elongate member **12** further includes a protrusion **20** that protrudes inwardly into the passage **18** such that the closure element **100** is not permitted to pass the protrusion **20**. The protrusion **20**, as illustrated in FIG. **1**, also may include a passage such that the actuator **22** may pass through the protrusion section **20** and contact or couple to the closure element **100**.

[0039] In one example, and as illustrated in FIG. **1**, the closure element **100** is generally allowed to be inserted only about halfway into the passage **18** of the elongate member **12** and thereafter is blocked from being inserted further into the elongate member **12** by the protrusion **20**. The location of the protrusion **20** may vary from one embodiment to the next. In other example embodiments, the protrusion **20** may be positioned more proximally within the passage **18** of the elongate member **12**, or alternatively, the protrusion **20** may be positioned more distally within the elongate member **12**. Thus, the position of the protrusion **20** may allow the closure element **100** to either be further inserted into the elongate member or have more of the closure element **100** positioned outside the elongate member **12**.

[0040] In addition to variations of the protrusion **20** within the passage **18** of the elongate member **12**, the distal end **16** of the elongate member **12** may also vary. For example and as illustrated in FIG. **1**, the distal end **16** of the elongate member **12** may have a radius. This radius, for instance, may assist when inserting the elongate member **12** into a tissue tract and subsequently into the body lumen **30** through the proximal luminal wall **34**. In other example embodiments, the distal end **16** of the elongate member **12** may have various other configurations. For example, they may have various ranges of radii as well as various other geometric configurations, for example, square, triangular, or rectangular.

[0041] In addition to the geometric configuration variations, the elongate member **12** may also have various material characteristics. For example, in one embodiment the elongate member **12** may be formed of a rigid material such as a stainless steel or other biocompatible material that is rigid. Alternatively, the elongate member **12** may be formed of a flexible material such as those materials utilized to form catheter shafts, introducer sheaths, or other medical devices. Suitable materials include polyvinyl chloride (PVC), peak, PTFE, nylon, or any other similar materials.

[0042] As discussed, the actuator **22** may extend through the elongate member **12**. The actuator **22** is another aspect of the closure device **10** that may vary from one embodiment to the next. As shown in FIG. **1**, the actuator **22** extends through the passage **18** of the elongate member **12** and couples to or attaches to the closure element **100**. One way in which the actuator **22** may vary is the cross-sectional geometric configuration of the actuator. FIG. **1** illustrates an actuator **22** that has a substantially circular cross-sectional configuration. In other example embodiments, the cross-sectional geometric configuration of the actuator **22** may vary and include configurations such as square, triangular, rectangular or any other geometric configuration. In one example embodiment, the geometric configuration of the actuator **22** may be configured to match the cross-sectional geometric configuration of the passage **18** within the elongate member **12**.

[0043] Another way in which the actuator **22** may vary is the material from which the actuator **22** is made. For example, the actuator **22** may be made from a rigid material such as stainless steel or other biocompatible materials that are rigid. Alternatively, the actuator **22** may be formed of a flexible material, for example, if the elongate member **12** is made from a flexible material. Examples of flexible actuator **22** materials include polyvinyl chloride (PVC), peak, PTFE, nylon, or similar materials. Generally, the actuator **22** material may be made from any material that is able to have enough strength and structural properties to change the closure element **100** from a delivery configuration, as shown in FIG. **2**A, to a deployed configuration, as shown in FIG. **2**C.

[0044] Another way in which the actuator **22** may vary is the way in which it connects to or attaches to the closure element **100**. FIG. **2**B illustrates a cross-sectional view of the closure element **100** that shows one example of connecting the actuator **22** to the closure element **100**. For example, actuator **22** may include a coupler element **24** that is configured to couple to the distal end **106** of the closure element **100**. In one example embodiment, and as illustrated in FIG. **2**B, the coupler element **24** includes a section that has a larger cross-sectional dimension than the actuator **22**. In this example, the coupler element **24** may interface with the distal end **106** of the closure element **100** such that the coupler element **24** is held by the material of the closure element **100** (e.g., the closure element **100** material surrounds the coupler element **24**. In other example embodiments, the coupler element may simply attach to or couple to the distal end **106** of the closure element **100** by an adhesive or other bonding means.

[0045] In addition to the coupler element **24**, the actuator **22** may also include a locking element **26**, as illustrated in FIG. **2**B. The locking element **26** may vary from one embodiment to the next. For example, and as illustrated in FIG. **2**B, the locking element **26** has a triangular configuration, however, in other example embodiments the geometric configuration of the locking element may take various forms such as square, rectangular, oval, circular or any other configuration.

[0046] In particular, the geometric configuration of the locking element **26** is configured such that the locking element **26** and the proximal end **104** of the closure element **100** cooperate to lock the closure element **100** in the deployed configuration. For example, and as illustrated in FIGS. **2**B and **2**C, the locking element **26** may be pulled through the proximal end **104** of the closure element **100**. Once pulled through the proximal end **104** of the closure element **100**, the locking element **26** and/or the proximal end **104** of the closure element **100** may be configured such that the locking element **26**, in combination with the proximal end **104** of the closure element **100**, restricts the actuator from moving distally with respect to the closure element **100**. In other words the locking element **26** may be configured to facilitate removal of the locking element **26** from within the closure element **100**, but after removal from the closure element **100**, the locking element **26** may not be allowed to re-enter the closure element **100**.

[0047] Notwithstanding the various configurations and characteristics of both the elongate member **12** and the actuator **22**, the closure element **100** may be configured to be operatively associated with the elongate member **12** and the actuator **22** in order to be delivered and deployed in an opening within a body lumen. Continuing now with FIGS. **2**A, **2**B, and **2**C, the closure element **100** will be discussed in more detail. As illustrated in FIG. **2**A, the closure element **100** may include a body member **102** that has a proximal end **104** and a distal end **106**. The body member **102** may also include a waist portion **108** that separates a plurality of proximal slits **110** from a plurality of distal slits **112**. Moreover, the closure element **100** may have a delivery configuration, as illustrated in FIG. **2**A, and a deployed configuration, as illustrated in FIG. **2**C.

[0048] As with other aspects of the closure device **10**, the closure element **100** may vary from one embodiment to the next. One way in which the closure element **100** may vary is the cross-sectional configuration of the closure element **100** body member **102**. For example, and as illustrated in FIG. **2**A, the body member **102** may have a generally cylindrical cross-sectional configuration. In other example embodiments, the cross-sectional configuration of the body member **102** may take various forms such as square, rectangular, triangular or any other cross-sectional configuration.

[0049] Another way in which the closure element **100** may vary is the geometric dimensions of the proximal slits **110** and/or distal slits **112**. For example, the geometric configuration of the upper and lower slits **110** and **112**, as shown in FIG. **2**A, may be a generally rectangular configuration. However, in other example embodiments the geometric configuration of the proximal slits **110** and/or the distal slits **112** may take various other geometric configurations such as more square, triangular, oval or any other configuration or combination configurations. The slits may be formed within the wall of the body member **102** using known manufacturing techniques such as cutting, laser cutting, water jet cutting. Alternatively, the slits may be integrally formed within the body member **102** during manufacturing such as through the use of injection molding.

[0050] Furthermore, and as illustrated in the example embodiment in FIG. **2**A, the proximal slits **110** may have substantially the same configuration and dimensions as the distal slits **112**. In other example embodiments, however, the proximal slits may have a different geometric configuration and/or dimension compared to the distal slits **112**. For example, in one embodiment, the proximal slits **110** may have a different length and width as the distal slits **112**, or the proximal slits **110** may have a different geometric configuration relative to the distal slits **112**.

[0051] In addition to variations between the proximal slits **110** and the distal slits **112**, the geometric configuration and the dimensions of the proximal slits **110** and/or distal slits **112** may vary from one slit to the next. For instance, the upper slits **110** may have a variety of different sized and configured slits that make up the plurality of upper slits **110**. Similarly, the lower slits **112** may be made up of a variety of different sized and configured individual slits.

[0052] Another way in which the proximal slits **110** and distal slits **112** may vary is the alignment configuration between the proximal slits **110** with respect to the distal slits **112**. For example, as illustrated in FIG. **2**A, the proximal slits **110** may be substantially aligned with the distal slits **112**. However, in other example embodiments, the proximal slits **110** may be positioned such that the proximal slits are misaligned with the distal slits **112**. In the same respect, the number of proximal slits **110** compared to the number of distal slits **112** may vary from one embodiment to the next. As shown in FIG. **2**A, there are an equal number of proximal slits **110** relative to the number of distal slits **112**. In other examples, however, the closure element **100** may have more proximal slits **110** compared to distal slits **112**. For example, a closure element may be configured such that there are six distal slits equally spaced around the body member **102** of the closure element **100**, while there are only four proximal slits **110** positioned and equally spaced around the body member **102** of the closure element **100**.

[0053] As can be understood, the spacing between each individual slit may also vary from one embodiment to the next, as well as from one slit to the next. For example, and as previously mentioned, the upper and/or lower slits **110** and **112** may have the slits positioned and equally spaced around the body member **102**. Alternatively, the slits may be positioned around the body member **102** such that the spacing between slits varies.

[0054] The distance between the proximal slits **110** and the distal slits **112** is another aspect of the closure element **100** that may vary from one embodiment to the next. In one example embodiment, the distance between the proximal slits **110** and the distal slits **112** is a distance that would be approximately equal to the width of a body lumen wall. For example, the distance between the upper and distal slits may be equal to the width of the proximal lumen wall **34**, illustrated in FIG. **1**. In this manner, the closure element **100**, when in the deployed configuration, would assist in blocking an opening within the proximal lumen wall **34**.

[0055] FIG. **2**B illustrates various other aspects of the closure element **100** that may vary from one embodiment to the next. For example, FIG. **2**B illustrates that the closure element **100** may include an aperture **105** located on the proximal end **104** of the body member **102**. In one embodiment, the proximal end **104** of the body member **102** of the closure element **100** may be made of material that is flexible such that the locking element **26** of the actuator may be pulled in a proximal direction through the aperture **105** located on the proximal end **104** of the closure element **100**. Moreover, the proximal end **104** of the body member **102** may have a geometric and/or material configuration that allows the locking element **26** or similar feature of the actuator to pass through in one direction (i.e. the proximal direction) but not pass through in the opposite direction (i.e. the distal direction).

[0056] For example, the proximal end **104** may be configured with a plurality of cuts that are arranged in a generally circular pattern around the aperture **105** such that each cut extends away from the aperture along a radius line. The cuts may be formed at an angle such that the material on the proximal end **104** between the cuts are allowed to flex in a direction that would allow the locking element **26** to pass through the aperture **105** of the closure element **100**. However, once the locking element **26** has passed through the aperture **105**, the proximal end **104** material between the cuts is not permitted to flex to allow the locking element **26** to again pass through the aperture **105**. In other words, the material at the proximal end **104** of the closure element **100** may only flex in one direction and thus resist movement of the locking element **26** in the distal direction after the locking element **26** has passed through the aperture **105**.

[0057] The locking element **26**, along with the configuration of the closure element **100** assist to change the closure element **100** from a delivery configuration, shown in FIGS. **1** and **2**A, to a deployed configuration shown in FIG. **2**C. In one embodiment, the actuator **22** cooperates with the closure element **100** to collapse the body member **102** of the closure element such that the proximal slits **110** and the distal slits **112** allow the portions of the body member **102** between the proximal slits **110** and distal slits **112** to collapse and flex radially outwardly. Moreover, when in the deployed configuration, the actuator **22**, with the locking element **26** and the coupler element **24** may cooperate with the closure element **100** such that the body member **102** of the closure element **100** may be changed into, and held locked in, the deployed configuration. Specifically, the locking element **26** cooperates with the coupler element **24** such that the body member **102** of the closure element **100** is held in place in the deployed configuration between the locking element **26** and the coupler element **24**.

[0058] The deployed configuration of the closure element **100** may have various configurations. For example, in one embodiment, the deployed configuration of the closure element **100** may provide a clamping force upon the body lumen wall, thus holding the closure element **100** in place within the opening in the body lumen. Additional characteristics and configurations of the closure element **100** in the deployed configuration will be discussed with respect to FIGS. **6** through **9**B.

[0059] Another way in which the closure element **100** may vary is the type of material used to make the closure element **100**. In one embodiment the closure element **100** is manufactured from a bioabsorbable, bioresorbable, bioerodible, and/or biodegradable material. Examples of suitable materials for use are metals, metal alloys, polymers or combinations thereof that decompose or biodegrade in a biological environment such as within a body lumen. For example, and not by limitation, suitable bioabsorbable materials may include magnesium, zinc, silicon, lithium, zinc titanium, magnesium lithium, polyglocic acid (PGA), polyhydroxybutyric acid, polyL-Lactic acid (PLLA), polydilactidel glycolide acid, polydilactid acid, PolyDL Lactide-co-gycolide, Polylactic acid, Polylicolic acid, Polyhydroxyalkanoates or derivatives thereof and any combination thereof.

[0060] In addition to the various types of materials that may be used to manufacture the closure element **100**, the closure element **100** may include additional material properties that may be useful. For example, the closure element **100** may be covered with a flexible membrane to aid in sealing the opening. The flexible membrane may be formed of a flexible bio-compatible or bioabsorbable material such as any of those that were described above. Moreover, the closure element **100** may further include a beneficial agent either disposed thereon as a coating or integrally formed within the absorbable material wherein the beneficial agent would be configured to aid in healing and/or reduce the potential for infection.

[0061] Moreover, material properties may be included in the closure element **100** to help a user place the closure element **100**. For example, the closure component **100** may further include a radiopaque marker or radiopaque coating in order to aid the user in positioning the closure element **100** within the puncture site of the body lumen. The radiopaque marker may be formed within the wall of the body member **102** in the form of a rivet. Alternatively, a radiopaque coating may be disposed on the body member **102** as a thin coating of radiopaque metal such as gold, tantalum, alydium, platinum, uridium or similar metals.

[0062] Referring now to FIGS. **3** through **6**, the operation of the closure device **10** will be explained in more detail. Initially, the closure device **10** is inserted in a tissue tract and disposed through an opening or puncture within a body lumen. For example and as shown in FIG. **1**, the closure device **10** may be disposed through the proximal lumen wall **34** of the body lumen **30**. After disposing the closure device **10** through the opening in the proximal lumen wall **34** the closure element **100** may be changed from a delivery configuration to a deployed configuration.

[0063] In one embodiment, the process of changing the closure element **10** from a delivery configuration to a deployed configuration begins with positioning the closure element **100** within the elongate member **12** such that the distal slits **112** are located outside of the elongate member **12** and the proximal slits **110** are located within the elongate member **12**. In one example, this position of the closure element **100** may correspond to the protrusion **20** located within the elongate member **12** as discussed above and as illustrated in FIG. **3**.

[0064] With the distal slits **112** positioned outside of the elongate member **12**, the actuator **22** may be moved in the proximal direction (as indicated by the arrow in FIG. **3**) such that the portions of the body member **102** located in-between the distal slits **112** are forced to collapse, bend, and/or buckle and extend in an outward direction as shown in FIG. **3**. In particular, the actuator **22** may pull the distal end **106** of the closure element **100** in a proximal direction by way of the coupler element **24** that is coupled to the distal end **106** of the closure element **100**. The distal slits **112** may weaken the body member **102** such that upon experiencing the force associated with pulling the distal end **106** of the closure element **100** in the proximal direction, the portions of the body member **102** in-between the distal slits **112** collapse, the collapsing portions of the body member **102** extending out from the closure element **100**. On the other hand, because the proximal slits **110** are positioned within and stabilized by the elongate member **12**, the portions of the body member **102** in-between the proximal slits **110** may not collapse.

[0065] Once the portions of the body member **102** in-between the distal slits **112** have collapsed, the closure device **10** may be moved in the proximal direction such that the deployed lower section of the closure element **100** is generally in contact with the inside portion of the proximal lumen wall **34**, as illustrated in FIG. **4**. At this position, the deployed section of the closure element **100** is within the body lumen **30**, the waist portion **108** of the closure element **100** extends through the opening in the proximal lumen wall **34**, and the proximal slits **110** are located outside the body lumen **30**.

[0066] When in this position, the elongate member **12** may be moved in a proximal direction relative to the closure element **100** such as to reveal or release the proximal slits **110** from the elongate member **12**. In one example embodiment, the actuator **22** is held in substantially a constant position, while the elongate member **12** is pulled or otherwise moved in a proximal direction with respect to the closure element **100**. Moreover, the distal end **16** of the elongate member **12** may be configured with a bias that applies a radially compressive force on the closure element **100**. Thus, once the closure element is released from the elongate member **12**, the user may sense the release and/or feel that the resistance to the movement of the elongate member **12** has changed indicating that the proximal slits **110** have been released from the elongate member **12**.

[0067] At this point the proximal slits **110** are now in position for the proximal portion of the closure element **100** to be deployed. As illustrated in FIG. **5**, the proximal portion of the closure element **100** is deployed by having the portions of the body member **102** in-between the proximal slits **110** collapse such that the portions of the body member **102** in-between the proximal slits **110** extend radially outwardly as illustrated in FIG. **5**. In order to deploy the upper portion of the closure element **100**, the actuator **22** may be moved in a proximal direction (as illustrated by the arrow in FIG. **5**) thus applying a force to the closure element **100** that causes the portions of the body member **102** in-between the proximal slits **110** to collapse and extend outwardly.

[0068] Moreover, and as illustrated in FIG. **5**, during or after the deployment of the proximal portion of the closure element **100**, the locking element **26** located on the actuator **22** may be pulled through the aperture **105** in the proximal end **104** of the closure element **100**. The locking element **26** is then allowed to rest or push on the proximal end **104** of the closure element **100** such that the closure element is held in the deployed configuration between the locking element **26** and the coupler element **24** of the actuator.

[0069] FIG. **6** shows a close-up view of a deployed closure element **100** within an opening of a body lumen **30**. As shown in FIG. **6**, the proximal slits **110** and distal slits **112** have allowed the proximal and distal portions of the body member **102** to collapse, and thus the portions of the body member **102** in-between the slits have extended outwardly such that the proximal lumen wall **34** is located between the collapsed proximal portion and the collapsed distal portion of the closure element **100**. The waist portion **108** of the body member **102** may be located at least partially within the opening in the proximal lumen wall **34** of the body lumen **30**.

[0070] FIG. **6** further illustrates that the deployed closure element **100** may be held in a deployed configuration by the coupler element **24** and the locking element **26**. In particular, the locking element **26** cooperates with the coupler element **24** such that the closure element **100** is squeezed or otherwise restricted between the coupler element **24** and the locking element **26**. In this way, the portions of the body member **102** that have collapsed are held in the collapsed or deployed configuration and are not permitted to return to the pre-collapsed or delivery configuration.

[0071] Once the closure element **100** is locked in the deployed configuration, the actuator **22** portion proximal to the locking element **26** may be severed or cut using a secondary cutting device or, alternatively, the actuator **22** may be configured such that upon application of another proximal force a weakened portion of the actuator **22** allows the actuator to break free at a location on the actuator **22** that is proximal to the locking element **26**. The severed actuator **22** and the elongate member **12** are then removed from the tissue tract leaving the deployed closure element **100** within the puncture or opening within the body lumen **30**.

[0072] FIGS. **7**A through **8**B illustrate various additional example embodiments of the closure element **100**. For example, FIG. **7**A illustrates a closure element **100** that includes a body member **102** with a proximal end **104** and a distal end **106**. The body member **102** has proximal slits **110** and distal slits **112** formed within the body member **102** of the closure element **100**. The proximal slits **110** and the distal slits **112** may have various arrangements and alignments with respect to one another. The arrangement and alignment of the proximal slits **110** and the distal slits **112** may affect the deployed configuration of the closure element **100**. Thus, the proximal slits **110** and the distal slits **112** may have almost any arrangement and alignment configurations that subsequently determine the deployed configuration of the closure element **100**.

[0073] For example, and as illustrated in FIGS. **7**A through **7**B, the closure element **100** may take various forms. In particular, the example closure element **100**, illustrated in FIG. **7**A, includes proximal slits **110** that are offset from the distal slits **112**. In other words, the proximal slits **110** are not vertically aligned with the distal slits **112**. This example offset arrangement of the proximal and distal slits **110** and **112** may result in the closure element **100** having a deployed configuration as illustrated in FIG. **7**B.

[0074] Specifically, when in the deployed configuration, the closure element **100** has upper extensions **114** and lower extensions **116**. As illustrated in FIG. **7**B, the upper extensions **114** may be offset from the lower extensions **116** such that the upper extensions **114** and lower extensions **116** alternate as viewed from the distal end **106** of the closure element **100**. In other example embodiments, the upper extensions **114** and lower extensions **116** may be configured such to have any pattern of alignment or arrangement with respect to one another or with respect to other portions of the closure element **100** depending on the alignment or arrangement of the proximal slits **110** with respect to the distal slits **112**.

[0075] FIG. **8**A shows another alternative embodiment of the closure element **100** that varies the configuration of the proximal slits **110** and the lower slits **112** to produce another example of the deployed configuration of the closure element **100**. As illustrated in FIG. **8**A, the closure element **100** has a body member **102** that has a proximal end **104** and distal end **106** and also includes a waist portion **108**. The waist portion **108** is positioned between proximal slits **110** and distal slits **112**. In this example embodiment, the proximal and distal slits **110** and **112** are curved or have a radius, as illustrated in FIG. **8**A. The curved proximal slits **110** and curved distal slits **112** produce curved upper and lower extensions **114** and **116** when the closure element **100** is changed into the deployed configuration. Moreover, and as illustrated in FIG. **8**B, the curved upper and lower extensions **114** and **116** may alternate one from another. As with the embodiment shown in FIG. **7**A, the curved upper and lower extensions **114** and **116** may have any alignment or arrangement configuration with respect to one another.

[0076] In addition to the two embodiments of the closure element **100**, illustrated in FIG. **7**A through FIG. **8**B, the upper and distal slits **110** and **112** may have various other configurations such as a zigzag pattern, an oval pattern or any other pattern or configuration that would produce various arrangement and alignment configurations of the upper extensions **114** and/or lower extensions **116**. Moreover, there can be any combination between the proximal slits **110** and the distal slits **112**. For example, the proximal slits may take on a more rectangular configuration, as shown in FIG. **7**A, and the distal slits **112** may take on a curved configuration as shown in **8**A. Thus, the deployed configuration of the closure element **100** may have upper extensions **114** that are rectangular, as shown in **7**B, and lower extensions **116** that are curved, as shown in FIG. **8**B.

[0077] Although FIGS. **7**A through **8**B addresses various example configurations of the closure element **100** that have proximal and distal slits **110** and **112**, the closure element **100** may be configured to not contain any slits. For example, FIGS. **9**A and **9**B show an example embodiment of a closure element **100** that does not include any proximal or distal slits; however, the closure element **100** is still able to collapse such to form the deployed configuration of the closure element **100**. In particular, the sidewall of the closure element **100**, as illustrated in FIG. **9**B, may include indentations **118** or other areas within the wall that create natural weaknesses or breaking points. The indentations **118** within the closure element wall **120** may be configured such that when a compressive force is applied from the actuator **22**, the closure element **100** collapses around the weakened portions of the indentation **118**.

[0078] The indentations **118**, shown in FIG. **9**B, may vary from one embodiment to the next. For example, the number of indentations that are located on the sidewall **120** of the closure element **100** may vary. In one example embodiment illustrated in FIG. **9**B, the sidewall **120** of the closure element **100** includes two indentations **118**. Each indentation **118** would produce extensions when the closure device is changed to the deployed configuration, thus two extensions (for example an upper and lower extension) would be made from the example embodiment shown in FIG. **9**B. However, in other example embodiments, more or less indentations may be used in order to create various or multiple sections of that collapse to form a barrier within an opening of a body lumen.

[0079] FIGS. **10** and **11** show another optional embodiment of a closure device **200**. As illustrated in FIG. **10**, closure device **200** may include an elongate member **12** that has a passage **18** extending through from a proximal end to a distal end. The elongate member **12** may be configured to accept and retain a closure element **100**. The closure element may include a proximal end **104**, a distal end **106**, and a waist portion **108** that is located between the proximal end **104** and the distal end **106**. In one embodiment, the closure element **100** may contain proximal slits **110** and distal slits **112**, as previously discussed. Closure device **200** further includes an actuator **22** that is connected to the closure element **100**. The actuator **22** is associated with a second actuator **40**. Located within the passage **18** within the elongate member **12** may be a hemostatic agent **50**.

[0080] In one example embodiment of the closure device **200**, the second actuator **40** has a slightly larger cross-sectional dimension than the cross-sectional dimension of the actuator **22**. In this way a space is located in the passage **18** between the elongate member **12** and the actuator **22** such that a hemostatic agent **50** may be placed next to the actuator **22**. Moreover, the second actuator **40** may be configured and sized appropriately such that the clearance between the second actuator **40** and the elongate member **12** through the passage **18** is minimal, allowing the second actuator **40** to press or move the hemostatic agent **50** through the passage **18** of the elongate member **12**.

[0081] As shown in FIG. **11**, the basic operation of the closure device **200** may be similar to the basic operation previously discussed with closure device **10**. However, in this embodiment after the closure element **100** is secured in the deployed configuration about the proximal lumen wall **34**, the second actuator **40** will then be positioned to press the hemostatic agent **50** out of the elongate member **12**. Specifically, once the closure element **100** is in the deployed configuration, the elongate member **12** may be moved in the proximal direction and the second actuator **40** may be pressed in the distal direction such that the hemostatic agent **50** is forced out of the elongate member **12** and onto the surface of the deployed closure element **100**, and thus the hemostatic agent may be deposited onto the portion of the proximal lumen wall **34** that is in the general area of the deployed closure element **100**.

[0082] The hemostatic agent **50** may be any material configured to aid in the healing of the body lumen wall as well as to cause the cessation of bleeding. Moreover, the hemostatic agent **50** may contain any material or agent that may be used to avoid infection. Suitable hemostatic materials for any of the embodiments described above may include chitosan, collagen, thrombin, PEG or other biocompatible materials. In one embodiment, chitosan may be utilized. The chitosan hemostatic composition may provide a strong clotting action to seal a hole, puncture, incision, or any other bleeding site to promote enhanced healing of the bleeding site and reduce opportunities for infection. Additionally, the chitosan hemostatic composition can be configured to swell in the presence of blood to form a hemostatic barrier that covers or otherwise plugs the bleeding site.

[0083] Chitosan is a polycationic polymer derived from chitin, which can also be used as described herein. Chitosan has a positive charge from primary amine groups that can interact with the negative charge of the lipids present on cell surfaces, such as blood cells. This electrostatic interaction has been identified as an aspect of the hemostatic properties of chitosan. Dry chitosan compositions can have increased hemostatic properties by increasing surface area, and thereby the contact area with blood. Processing methods, such as freeze drying, puffing, foaming, sponging, ballooning, combinations thereof, or the like, can be used to provide a porous, open cellular, or closed cellular structure with increased surface area. In addition to chitosan and/or chitin, other polymers having N-acetylglucosamines and N-glucosamines, such as poly-beta-1→4-N-acetylglucosamines with or without one or more monosaccharides being deacetylated and poly-beta-1→4-N-glucosamines, and derivatives thereof.

[0084] The chitosan or other similar polymer used in various embodiments of the present invention may be purified to facilitate use in a medical device and or used within the body of a subject. This may include being purified to remove proteins, other organic or inorganic contaminants. Such purification and processing of chitosan is well known in the art. Accordingly, the chitosan or other similar polymer can be considered to be biocompatible, immunoneutral, and/or generally recognized as safe for use with or within a subject, such as a human or other animal.

[0085] Once the hemostatic agent **50** has been deployed next to the deployed closure element **100**, the elongate member **12** along with the associated actuator **22** and second actuator **40** may be removed from the patient.

[0086] The closure device discussed with the various example embodiments of the present invention may include various other configurations. For example, any configuration of the closure device that includes a closure element that is able to anchor on the inside surface of the body lumen wall as well as on the outside surface of the body lumen wall (i.e. sandwich the wall of the body lumen between two closure elements or two closure element portions) may be used with the closure device contemplated with the present invention.

[0087] Accordingly, the previous figures and the corresponding text provide a number of different components and systems that may be used to close an opening in a body lumen. In addition to the foregoing, other example embodiments may also be described in terms of flowcharts comprising one or more acts in a method for accomplishing a particular result. For example, FIG. **12** illustrates a method **600** of closing an opening in tissue. The acts of method **600** are discussed more fully below with respect to the disclosures of FIGS. **1** through **11**.

[0088] For example, FIG. **12** shows that a method in accordance with an example implementation of the invention may include inserting **602** a closure device into an opening in a body lumen wall. Inserting a closure device may involve inserting a closure device into an opening formed in tissue, the closure device including a delivery tube, an actuator, and a closure element, the closure element defined by a body having a proximal portion, a distal portion and a waist. For example, as shown in FIG. **3**, the closure element **100** may be inserted through the proximal lumen wall **34**.

[0089] After the closure device is inserted into an opening, a force may be applied **604** to the actuator to move a first portion of a closure element from a first configuration to a second configuration. Applying a force may involve applying a force to the actuator to move the distal portion of the closure element from a first configuration toward a second configuration, wherein in the second configuration, portions of the closure element protrude from the body. For example, as shown in FIG. **3**, the actuator **22** may be moved in a proximal direction (as indicated by the arrow) such that the portions of the body member **102** located in-between the distal slits **112** are forced to collapse, bend, and/or buckle and extend in an outward direction thus causing the distal portion of the closure element **100** to change from a delivery configuration to a deployed configuration.

[0090] Next, a second force may be applied **606** to an actuator to move a second portion of the closure element from a first configuration towards a second configuration. Applying a second force may involve applying a second force to the actuator to move the proximal portion of the closure element from a first configuration toward a second configuration. For example, and as illustrated in FIG. **5**, the actuator **22** may be moved in a proximal direction, thus causing the portions of the body member **102** in-between the proximal slits **110** to collapse and extend outwardly.

[0091] FIGS. **13**A through **13**G illustrate an example embodiment of a closure device that uses a handle assembly **400**. In particular, FIG. **13**A illustrates a closure device that includes a handle assembly **400** that has a handle element **402** and a hub member **404**. The handle element **402** has a proximal end **406**, a distal end **408**, a grip portion **410**, and an extended portion **412**. Projections **414** may extend from the extended portion **412**. Moreover, the handle element **402** includes a port **416** through which an actuator **22** may extend.

[0092] The handle element **402** is operatively associated with a hub member **404**. The hub member **404** includes a hub body **418** that has a proximal end **420** and a distal end **422**. A channel **424** is formed within the hub body **418** of the hub member **404**, the channel **424** configured to cooperate with the projections **414** located on the handle element **402**. An elongate member **12** may be connected to the hub member **404**. The elongate member **12** may be configured such that an actuator **22** may extend through the elongate member **12**. Attached to a distal end of the actuator **22** is a closure element **100**, as illustrated in FIG. **13**A.

[0093] Briefly, in operation, the handle assembly **400** assists a user in deploying the closure element **100** within an opening in a body lumen. For example, after the closure element **100** is positioned appropriately within the opening in the body lumen, as discussed above, the user may turn the handle element **402**, which in turn assists to deploy the closure element **100**. Specifically, the handle element **402** may be coupled to the actuator **22** such that as the handle element **402** is rotated, the actuator applies a force upon the closure element **100** that causes the closure element **100** to change from a delivery configuration to a deployed configuration, as discussed above.

[0094] The handle assembly **400**, shown in FIG. **13**A, may vary from one embodiment to the next. For example, the handle element **402** is one example aspect of the handle assembly **400** that may vary. FIG. **13**B shows a bottom view of the handle element **402**. The bottom view of the handle element **402** illustrates the grip portion **410**, the extended portion **412**, and the projections **414** that extend from or project out from the extended portion **412**. Moreover, FIG. **13**B illustrates the port **416** through which the actuator **22** may extend.

[0095] The geometric configuration is one way in which the handle element **402** may vary. As illustrated in FIG. **13**B, the geometric configuration of the handle element **402** may have a substantially circular cross-sectional configuration. However, in other example embodiments, the cross-sectional configuration of the handle element including the extended portion **412** and the grip portion **410** may have various other geometric configurations such as square, rectangle, triangle or any other configuration or combination of configurations.

[0096] Moreover, and as shown in FIGS. **13**A and **13**D, the handle element **402** may include a set screw **428**. The set screw **428** may be positioned in the grip portion **410** such that a set screw may be used to secure the position of the actuator **22**. FIG. **13**D illustrates how the set screw **428** may be positioned such to enter from the side of the grip portion **410** and into the port **416**, and thus, secure the actuator **22**.

[0097] Another way in which the handle element **402** may vary is the characteristics of the projections **414**. As shown in FIG. **13**D, the projections **414** may be made from a different piece of material than the extended portion **412**. In alternate embodiments, the projections **414** may be manufactured out of the same piece of material as the extended portion **412**.

[0098] Not only can the manufacture method vary with respect to the projections **414**, but the location of the projections **414** on the extended portion **412** may vary from one embodiment to the next. As illustrated in FIGS. **13**A and **13**D, the projections **414** may be located on the distal end **408** of the handle element **402**. However, in alternative embodiments, the projections **414** may be located at various other locations or almost any location on the extended portion **412**.

[0099] Another aspect of the handle element **402** that may vary from one embodiment to the next is the grip portion **410**. The grip portion **410** may be sized such that a human finger or a human hand would be able to easily turn and twist the grip portion **410**. In order to help with the twisting of the handle element **402**, the grip portion **410** may include a friction provider such as a piece of rubber or a pattern within the sidewall of the grip portion to aid in helping a human hand grip the grip portion **410** and turn the handle element **402**.

[0100] In addition to various geometric characteristics, the handle element **402** may vary in material composition. For example, in one example embodiment the handle element **402** may be made from a metal such as stainless steel. Other materials may be used to make the handle element **402** such as plastics, ceramics or any other material that would have structurally suitable properties.

[0101] Just as the handle element **402** may vary from one embodiment to the next, so too may the hub member **404**. For example, the cross-sectional configuration of the hub member **404** may vary from one embodiment to the next. The hub member, as illustrated in FIG. **13**A, has a substantially circular cross-sectional geometric configuration. Alternatively, in other example embodiments, the hub member **404** may have a cross-sectional geometric configuration that is square, rectangular, hexagonal, or any other configuration or combination of configurations.

[0102] Notwithstanding the cross-sectional configuration of the hub member **404**, the way in which the channel **424** is located throughout the hub member **404** may vary. For example, and as illustrated in FIG. **13**A, the channel **424** is configured such that the handle element **402** is allowed to rotate one full turn within the hub member **404**. Alternatively, the channel **424** may be configured to allow more or less rotation of the handle element **402**. In one example embodiment, the channel **424** may only allow for a half turn of the handle element **402**. Alternatively, in other embodiments of the invention, the channel **424** may allow for multiple rotations of the handle element **402**.

[0103] In addition to the number of rotations in which the channel **424** allows the handle element **402** to make, the channel **424** may also be configured with various pathways. For example, and as illustrated in FIG. **13**A, the pathway of the channel **424** is relatively smooth from the bottom portion of the channel **424** around to the top portion of the channel **424**. However, in alternative embodiments, the channel **424** may have step sections such that the projections **414** on the handle element **402** move within the channel at various steps from one depth to the next. In another example embodiment, the channel **424** may direct the handle element **402** to move with a combination of relatively smooth movements and stepped movements.

[0104] The operation of the handle assembly **400** will be discussed in further detail with reference to FIGS. **13**C through **13**G. The handle element **402** is inserted within a receiving area **426** located within the hub member **404**, as illustrated in FIG. **13**D. The projections **414** located on the extended portion **412** of the handle element **402** interact with the channel **424** on the hub member **404** such that as the handle element **402** is turned, the position of the handle element relative to the hub member **404** changes.

[0105] For example, and as illustrated in FIG. **13**C, the handle element **402** is located towards the distal end of the hub member **404**. When the handle element **402** is rotated, the projections **414** follow the channels **424** such that the handle element **402** moves in the proximal direction with respect to the hub member **404**, as illustrated in more detail in FIGS. **13**E and **13**F. Moreover, if the actuator **22** is secured to the handle element **402** by way of the set screw **428**, then as the handle element **402** moves in the proximal direction with respect to hub member **404**, the handle element **402** also pulls the actuator **22** in the proximal direction. Thus, as the handle element **402** is rotated, the actuator **22** is pulled in a proximal direction and the closure element **100** may be deployed, as previously described with relation to FIGS. **3** through **6**.

[0106] In one specific embodiment, the closure element **100** with the handle assembly **400** cooperates with an introducer sheath **500**, as illustrated in FIG. **13**G. The introducer sheath **500** may include an introducer elongate member **502**. The elongate member **12** and the closure element **100** are passed through the introducer sheath **500** and extend through the introducer elongate member **502** such that the closure element **100** protrudes from the distal end of the introducer elongate member **502**. In one example embodiment, the closure element **100** has the distal slits protruding from the introducer elongate member **502**.

[0107] In operation, the introducer sheath **500** may already be positioned such that the introducer elongate member **502** is located at least partially within the body lumen or extended through an opening in a body lumen wall. The closure element **100**, along with the elongate member **12**, may then be introduced into the introducer sheath **500** and positioned within the opening in the body lumen. With the closure device located within the introducer sheath **500**, the handle element **402** may be rotated such that the actuator **22** is pulled in the proximal direction and the lower or distal region of the closure element **100** changes from a delivery configuration to a deployed configuration, as shown in FIG. **13**E.

[0108] After the first portion of the closure element has been deployed, the introducer sheath **500** and the introducer elongate member **502** may be moved in the proximal direction such as to uncover the proximal slits **110**. At this point, the handle element **402** may be again twisted or rotated such that the actuator **22** is moved or pulled in the proximal direction, thus deploying the upper portion of the closure element **100**, as shown in FIG. **13**F.

[0109] The amount of rotation that may be needed to deploy the closure element **100** or change the closure element **100** from a delivery configuration to a deployed configuration may vary. In one example embodiment, the handle element **402** may be turned one half of a turn to deploy the first portion of the closure element **100** and then turned another half of a turn to deploy the second portion of the closure element **100**. However, in other example embodiments it is understood that larger or smaller rotation may be used to deploy the closure element **100**.

[0110] Once the closure element **100** is deployed and in place within the body lumen wall, the remainder of the closure device and the introducer sheath can be removed in a similar manner as described with respect to FIGS. **3**-**6**.

[0111] The present invention 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 invention 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 claims are to be embraced within their scope. It shall be further understood that although the present invention has been described in relation to vessel closure, it is contemplated that the closure component of the present invention may be utilized to close other openings in the body such as PFO openings, or openings formed in organs such as the stomach for certain surgical procedures.

1.-**25**. (canceled)

26. A method of closing an opening in a blood vessel, the method comprising:

positioning a closure element through the opening in the blood vessel and within a lumen of a tubular member, the tubular member applying a radial compressive force to the closure element;

following expanding of a distal portion of the closure element from a pre-deployed configuration to a deployed configuration, engaging an inside portion of the blood vessel with the distal portion of the closure element; and

following engaging the inside portion of the blood vessel with the closure element through proximal movement of the closure element and deployment of a proximal portion of the closure element from a pre-deployed configuration to a deployed configuration, engaging a proximal portion of the closure element with an outside portion of the blood vessel.

27. The method of claim **26**, further comprising releasing the closure element from an elongate member releasably connected to the closure element.

28. The method of claim **27**, wherein releasing the closure element comprises cutting the elongate member.

29. The method of claim **27**, wherein releasing the closure element comprises applying a force to a weakened portion to break the elongate member.

30. The method of claim **27**, wherein the closure element is made from bioabsorbable, bioerodible, biodegradable, and/or bioresorbable material.

31. The method of claim **26**, further comprising positioning the closure element at a predetermined depth within the tubular member with at least a portion of the closure element extending beyond a distal end of the tubular member.

32. The method of claim **26**, wherein the closure element has a curved distal end in cross section.

33. A method of closing an opening in tissue of a blood vessel, the method comprising:

positioning a closure element within a lumen of a tubular member and within the blood vessel, the tubular member having a bias and applying a radial compressive force to the closure element, a portion of the closure element extending distally beyond a distal end of the tubular member in a pre-deployed configuration of a distal portion of the closure element;

following expanding of the distal portion of the closure element from the pre-deployed configuration to a deployed configuration, withdrawing the closure element proximally to engage an inside portion of the blood vessel with the distal portion of the closure device;

following contacting the inside portion of the blood vessel with the closure element, deploying a proximal portion of the closure element from a pre-deployed configuration to a deployed configuration;

engaging the proximal portion of the closure element with an outside portion of the blood vessel; and

releasing the closure element from an elongate member releasably connected to the closure element.

34. The method of claim **33**, wherein expanding of the distal portion of the closure element comprises proximally withdrawing the elongate member to at least partially move the portion of the closure element which is distal an intermediate portion of the closure element towards the intermediate portion.

35. The method of claim **33**, wherein deploying the proximal portion of the closure element comprises proximally withdrawing the elongate member to at least partially move the portion of the closure element which is distal the intermediate portion of the closure element towards a proximal portion of the closure element.

36. The method of claim **35**, further comprising locking the proximal portion in the deployed configuration.

37. The method of claim **33**, wherein engaging the proximal portion of the closure element with the outside portion of the blood vessel applies a clamping force upon the blood vessel.

38. The method of claim **33**, further comprising positioning a hemostatic agent proximal the proximal portion.

39. The method of claim **33**, further comprising deploying a hemostatic material on or adjacent to the opening in the tissue.

40. A method of closing an opening in a blood vessel, the method comprising:

positioning a closure element within the blood vessel and at least partially extending from a distal end of a tubular member, the tubular member having a bias and applying a radial compressive force to the closure element;

reconfiguring a distal, tissue engaging portion of the closure element from a pre-deployed configuration to a deployed configuration;

withdrawing the closure element proximally to engage an inside portion of the blood vessel with the distal, tissue engaging portion, a portion of the distal;

following contacting the inside portion of the blood vessel with the closure element, deploying a proximal portion of the closure element from a pre-deployed configuration to a deployed configuration;

engaging the proximal portion of the closure element with an outside portion of the blood vessel; and

releasing the closure element from an elongate member releasably connected to the closure element.

41. The method of claim **40**, further comprising locking a position of the distal portion.

42. The method of claim **40**, further comprising locking a position of the proximal portion.

43. The method of claim **40**, wherein a portion of the closure element to which the elongate member extends through is positioned proximal the proximal portion engaging with the outside portion of the blood vessel.

44. The method of claim **40**, wherein the elongate member extends through a portion of the closure element.

45. The method of claim **40**, further comprising compressively restraining the proximal portion of the closure device within the tubular member.

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