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(54) **METHODS AND DEVICES FOR CONTROLLING HEMORRHAGE DURING MINIMALLY INVASIVE SURGICAL PROCEDURES**

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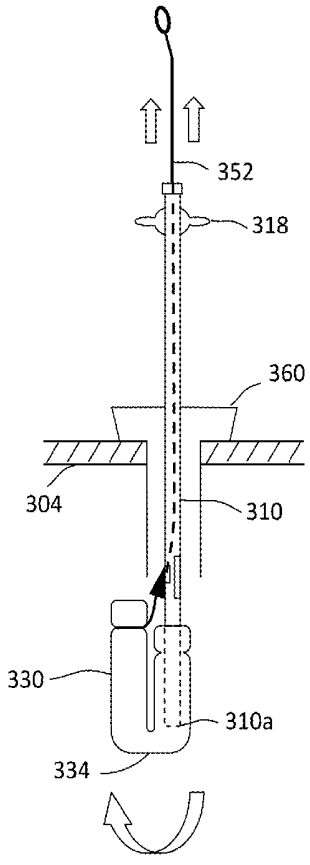
(52) **U.S. Cl.**

CPC ***A61F 13/36*** (2013.01); ***A61B 17/0057*** (2013.01); *A61B 2017/00637* (2013.01)

(57) **ABSTRACT**

In various aspects, methods and systems in accordance with the present teachings are provided that enable the tamponade of an internal hemorrhage site that can potentially occur during a closed, minimally invasive surgical procedure. In the unfortunate instance that an acute hemorrhage requires unscheduled conversion to an open surgery, the exemplary methods and systems described herein can enable the surgeon to prevent excessive blood loss from the hemorrhaged vessel during the conversion or repair process. Whereas in open surgeries hemorrhage is typically provided by a gauze sponge held by a set of ringed clamps (e.g., a sponge stick), the small diameter access ports through trocars used in minimally invasive surgeries can make it difficult to deliver sufficient gauze or other absorptive material to properly, temporarily occlude the hemorrhaged vessel. Moreover, because placing a clamp around the bleeding vessel (e.g., with the laparoscopic/robotic surgical tools present at the surgical site) can be dangerous due to poor visibility and the lack of isolation of the vessel, devices in accordance with the present teachings can be placed in compression with the hemorrhage site to slow blood loss during the conversion to an open surgery.



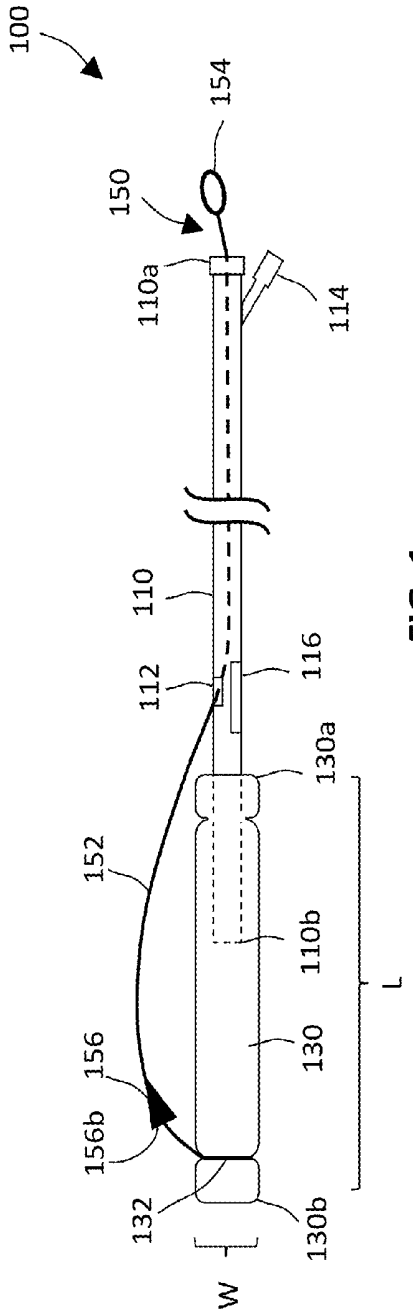

100
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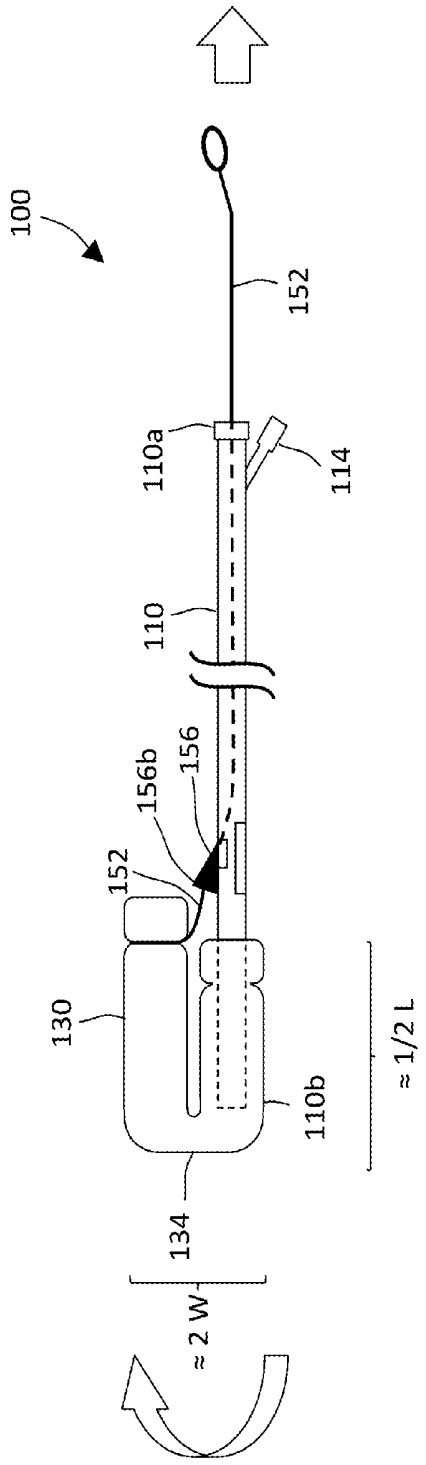
FIG. 1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134
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FIG. 2

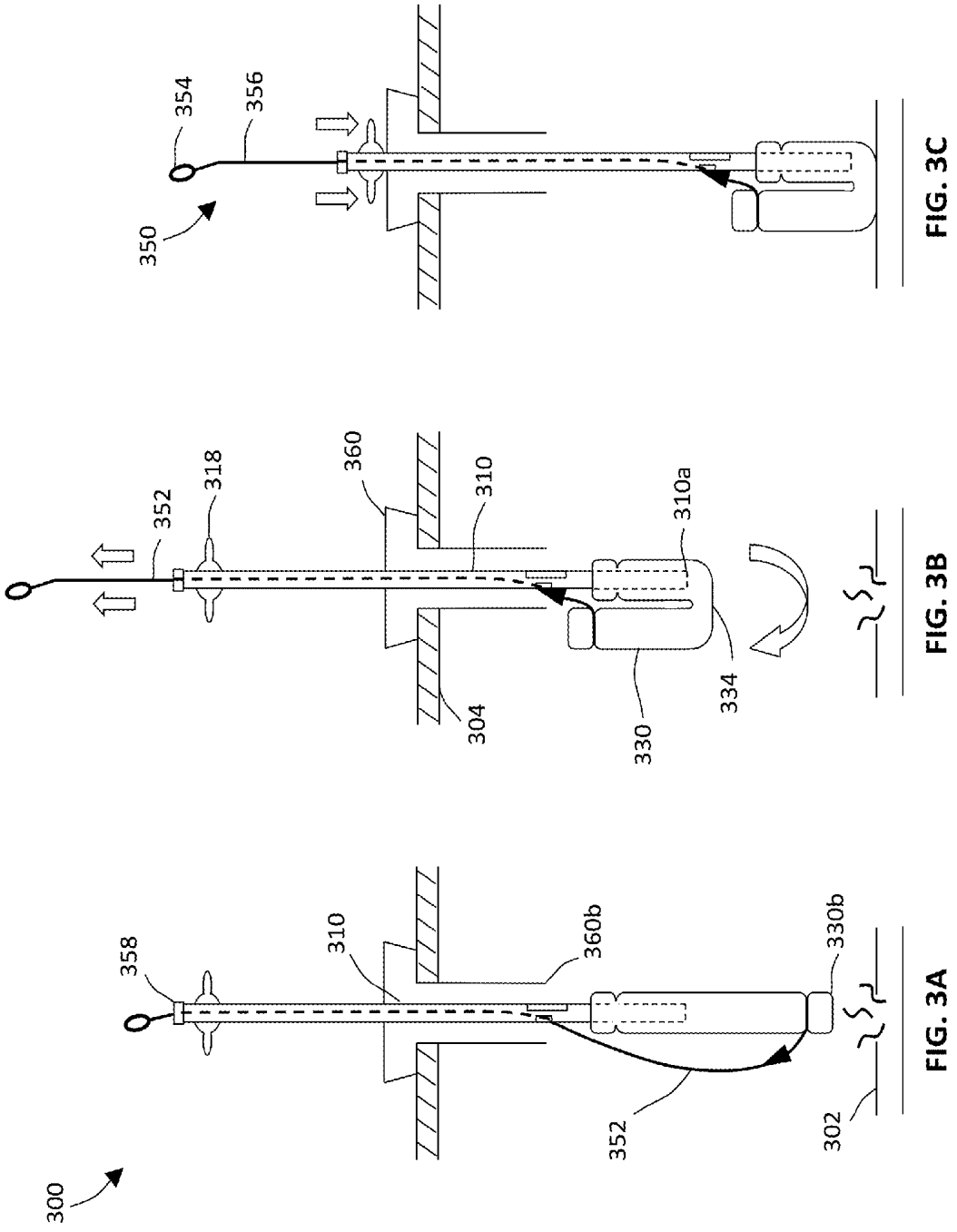
354
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FIG. 3C
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FIG. 3B
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FIG. 3A

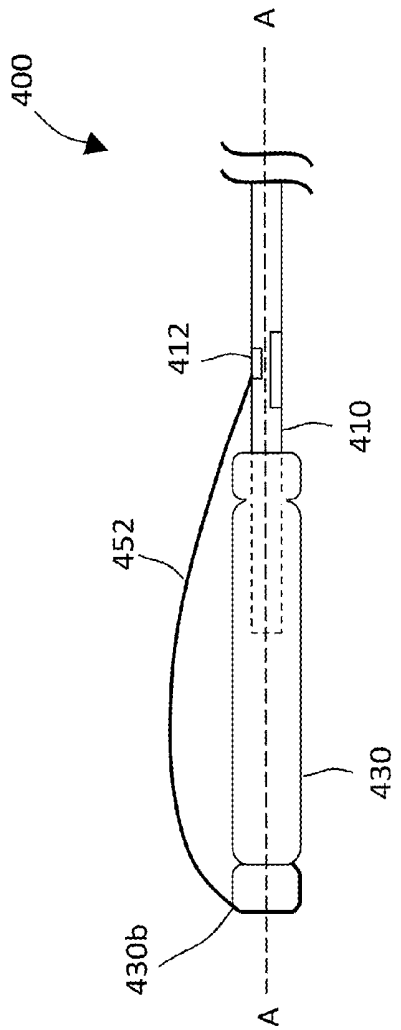

FIG. 4

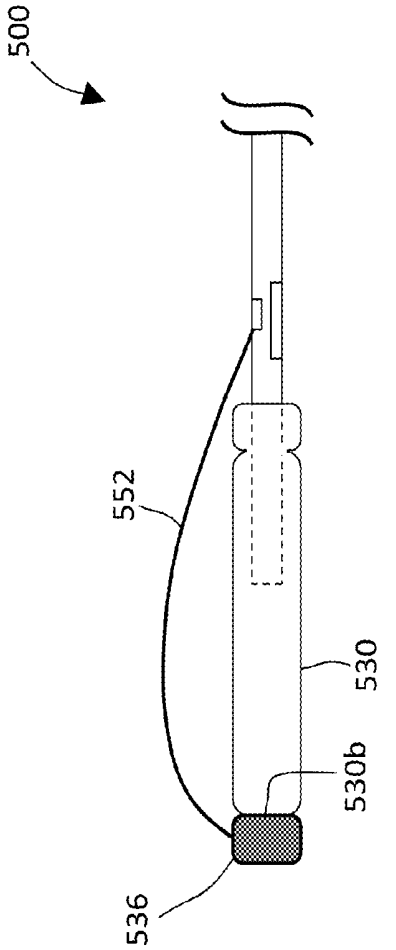

FIG. 5

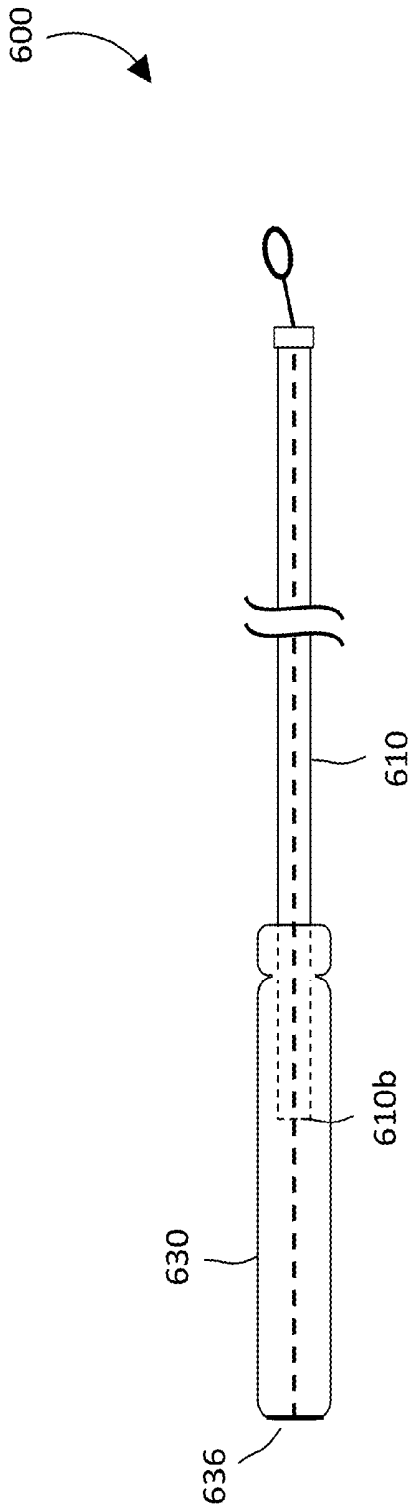

FIG. 6A

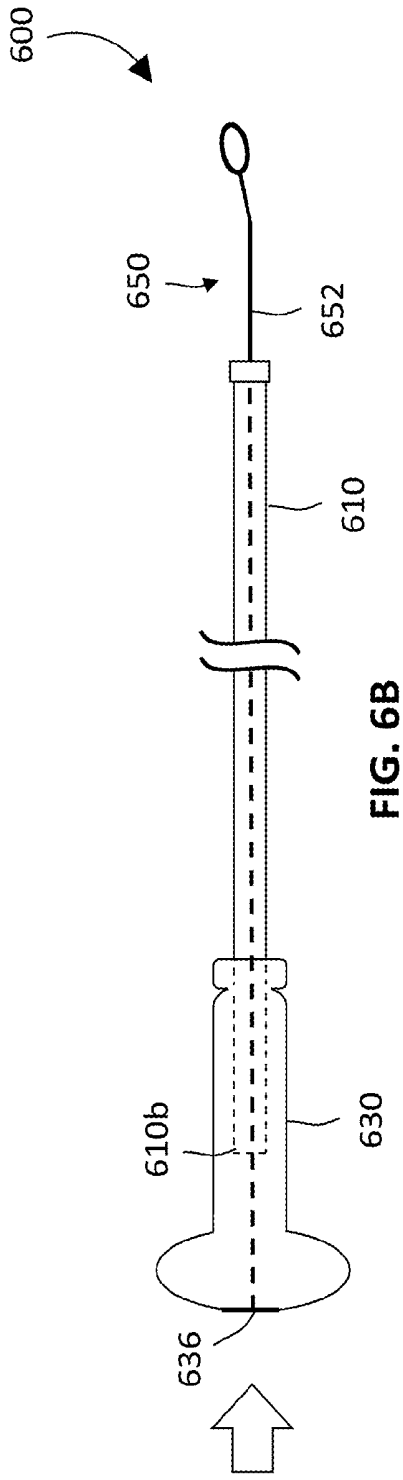

FIG. 6B

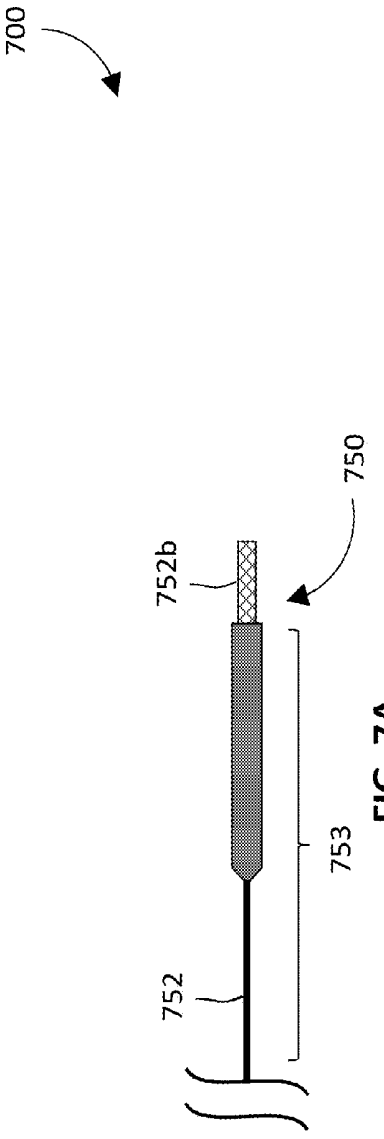

FIG. 7A

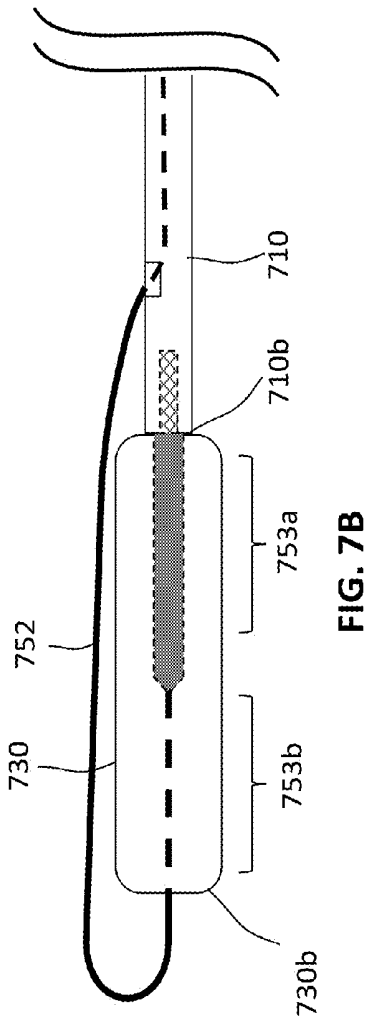

FIG. 7B

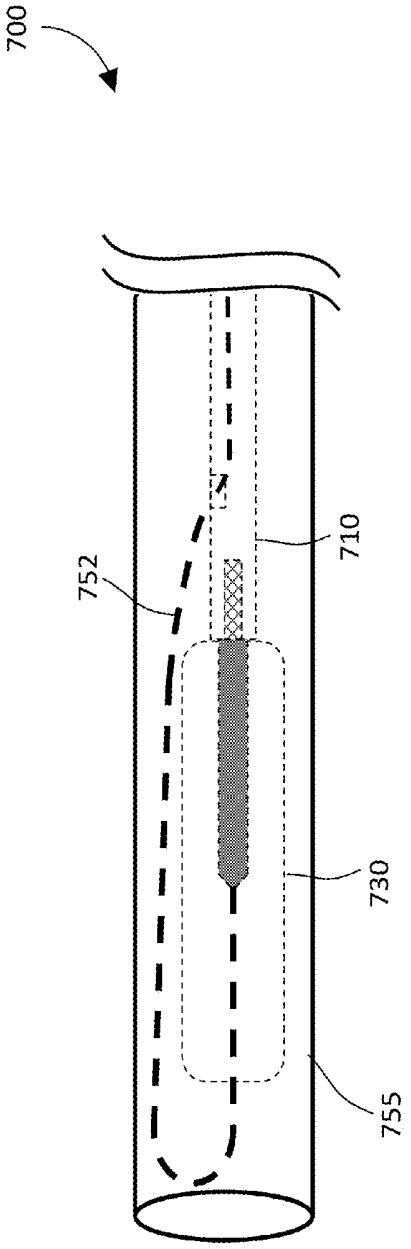

FIG. 7C

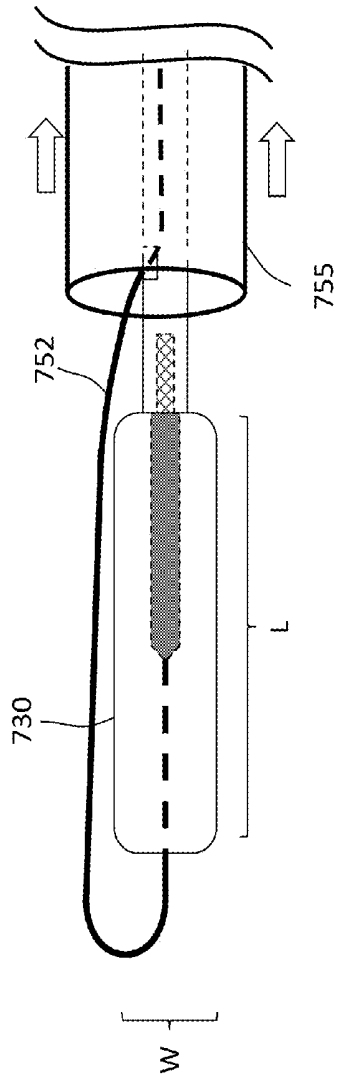

FIG. 7D

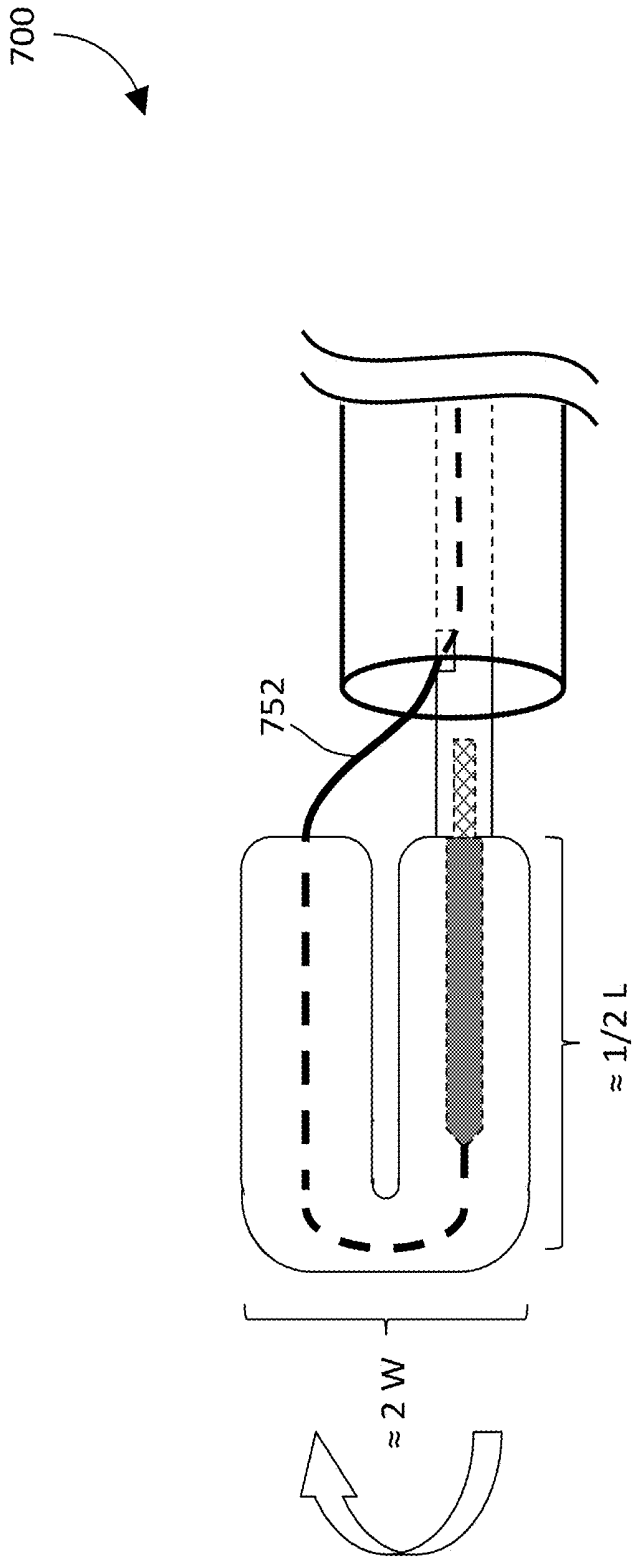

FIG. 7E

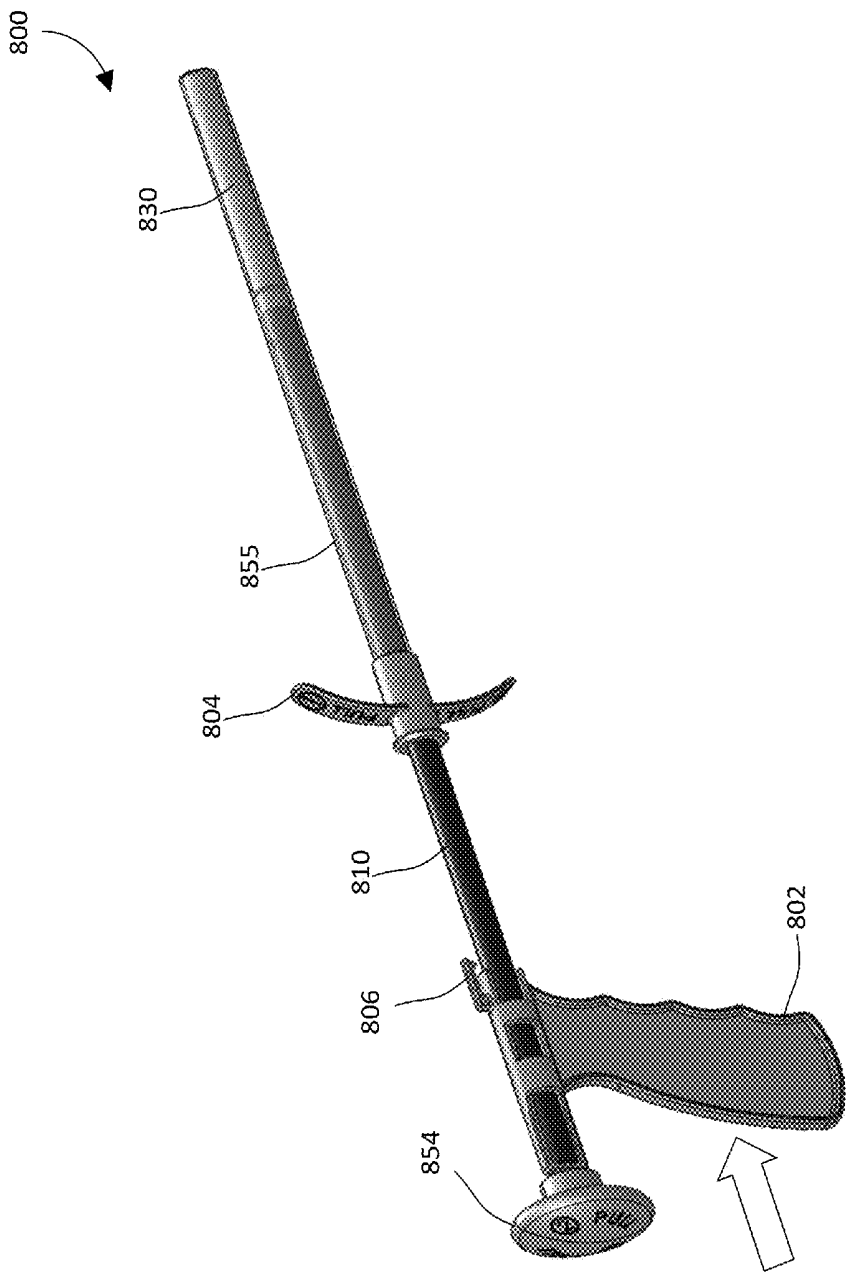

FIG. 8A

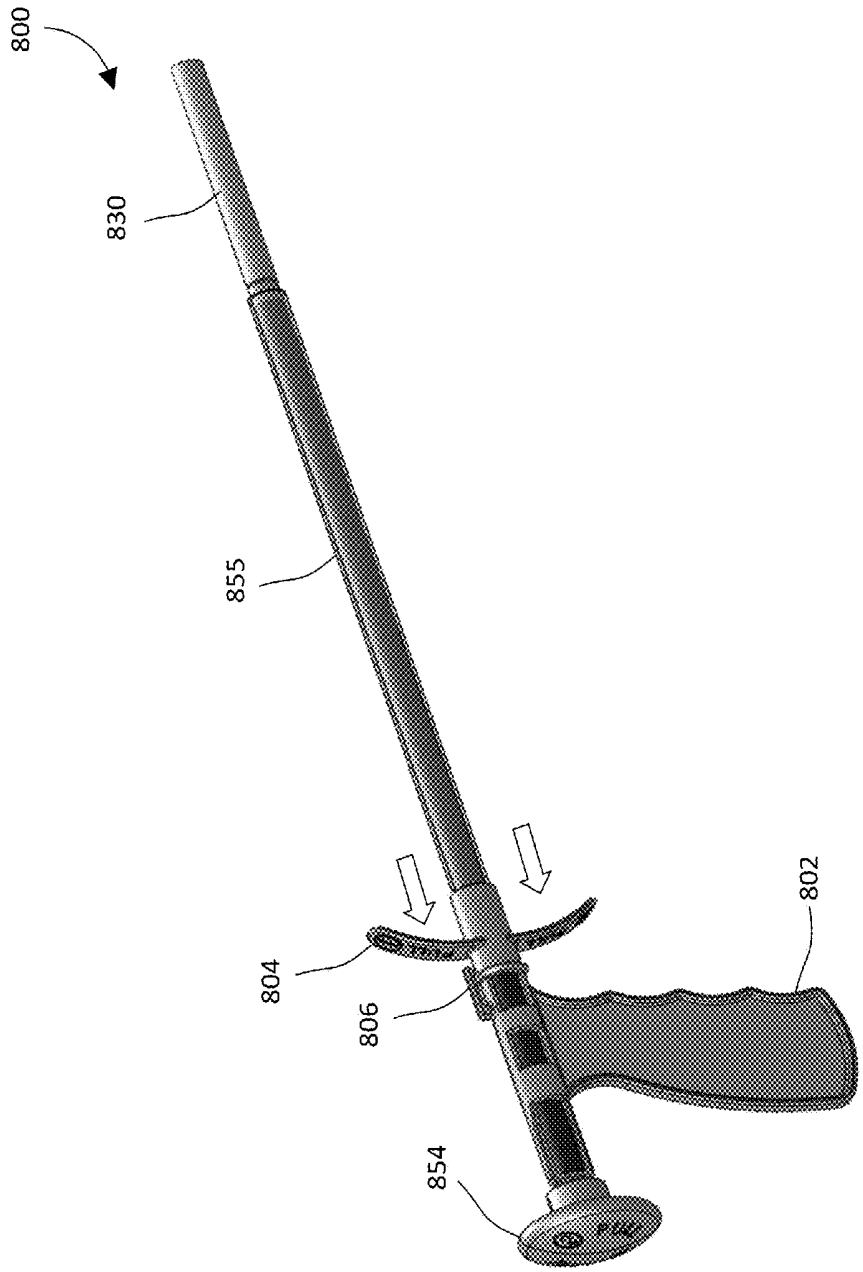

FIG. 8B

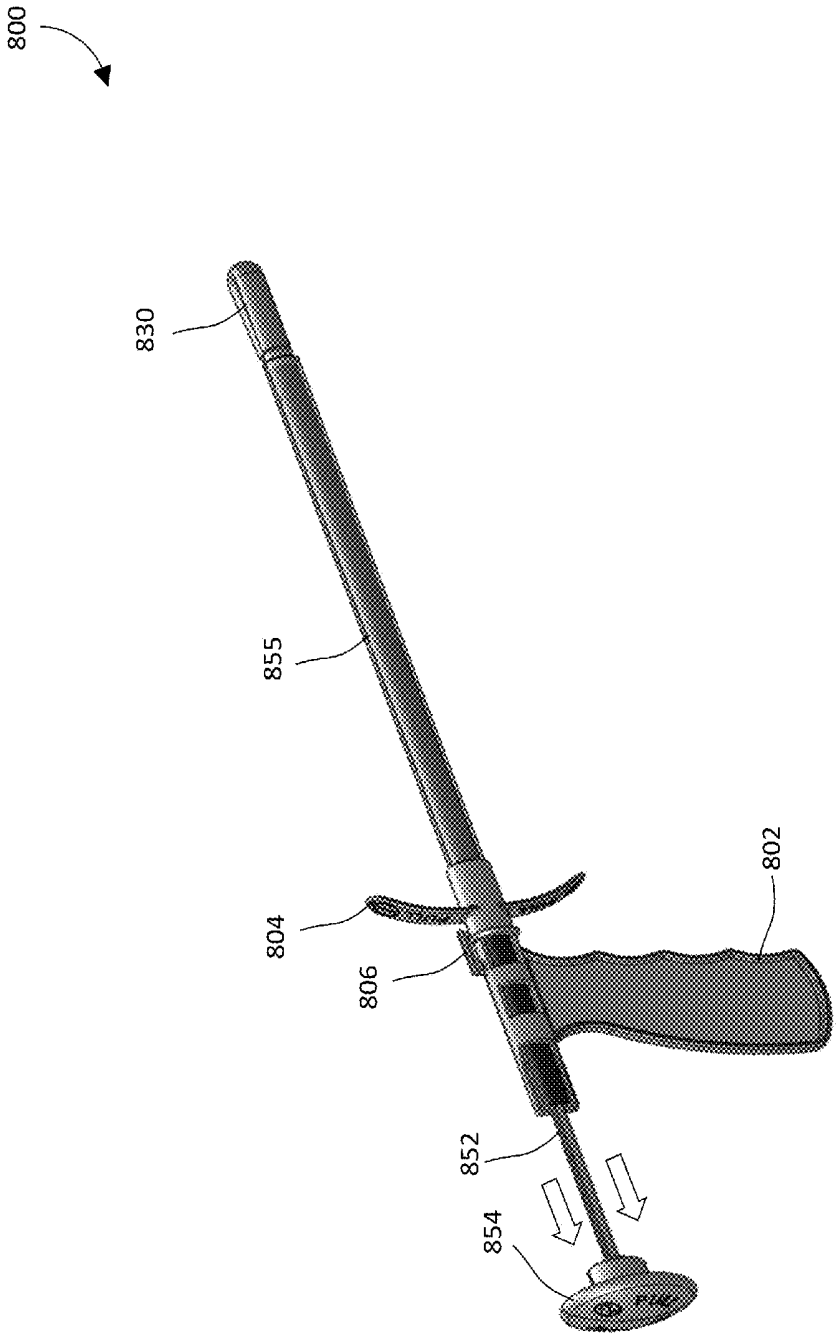

FIG. 8C

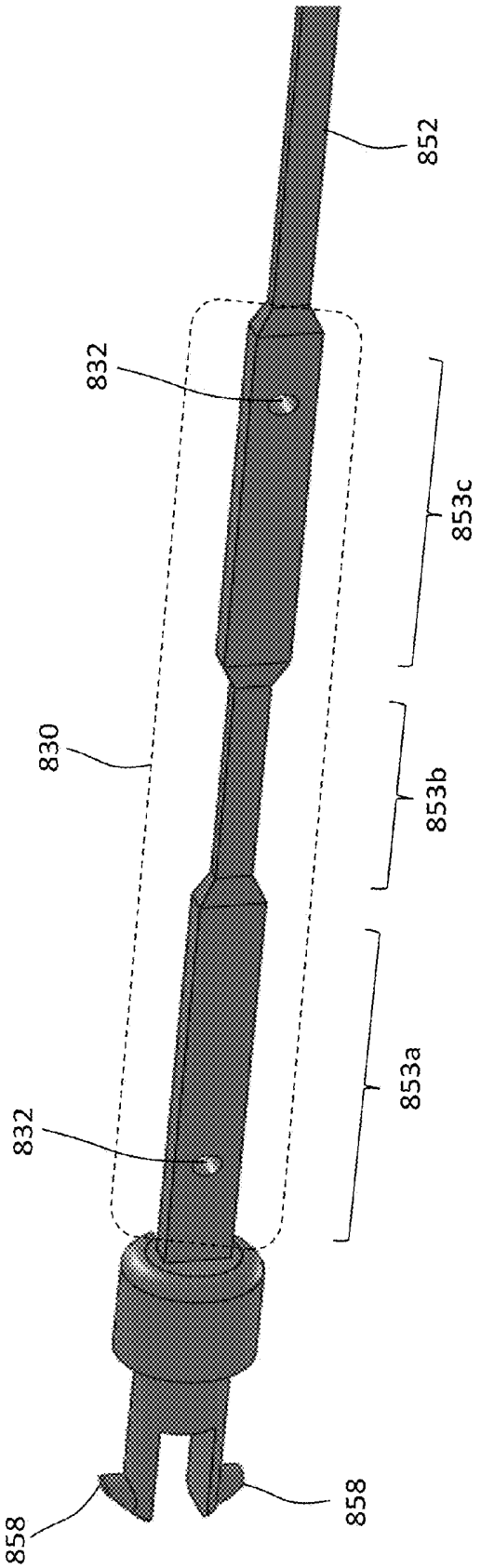

FIG. 8D

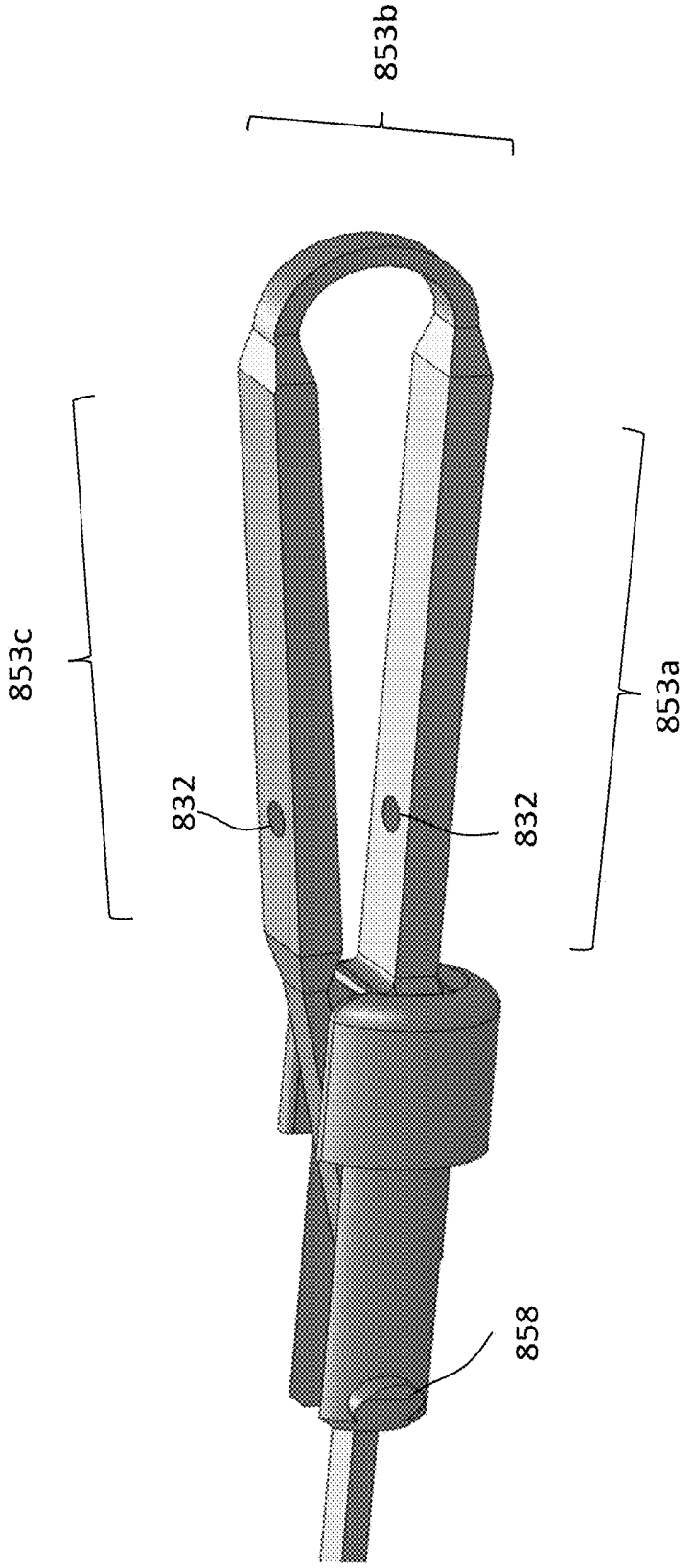

FIG. 8E

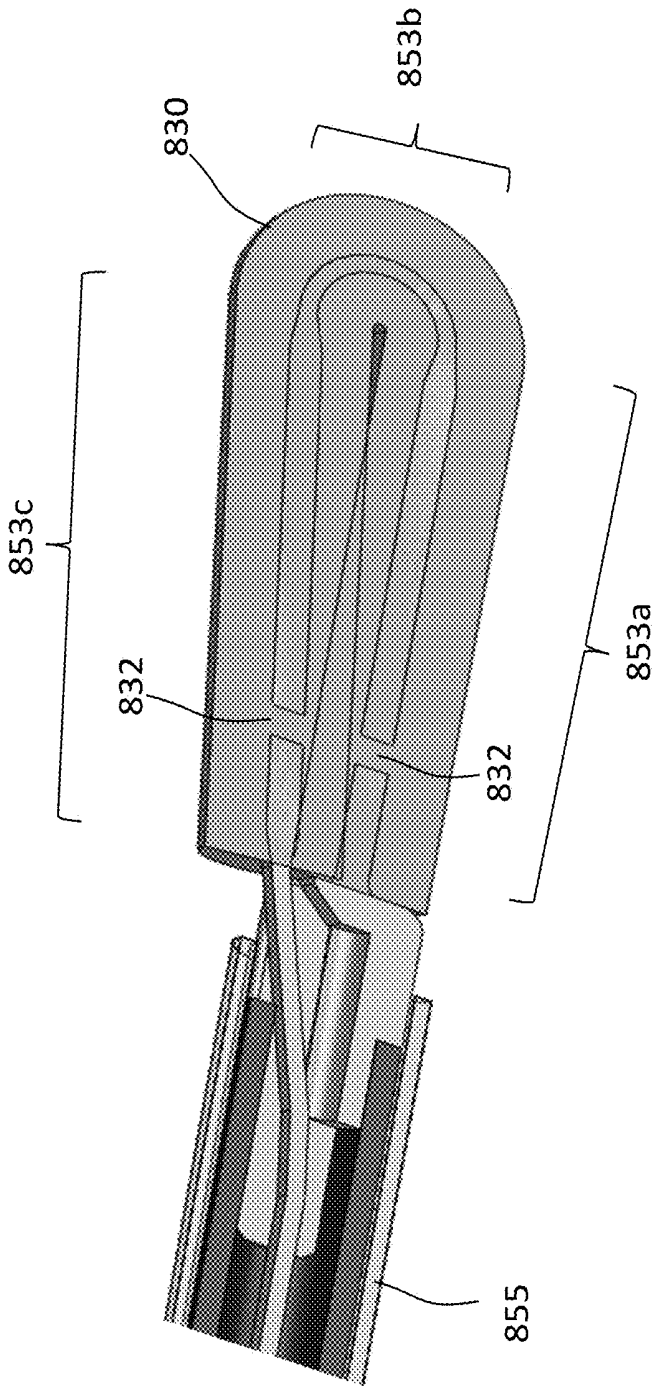

FIG. 8F

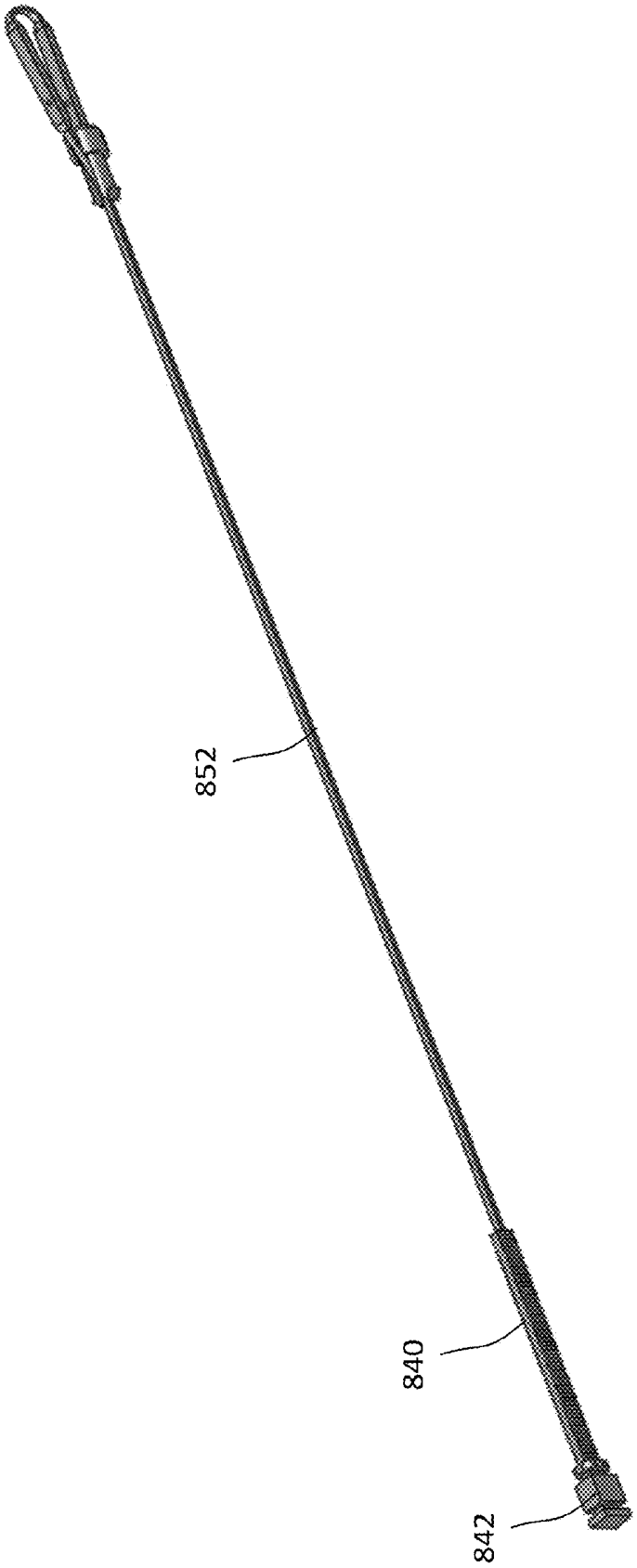

FIG. 8G

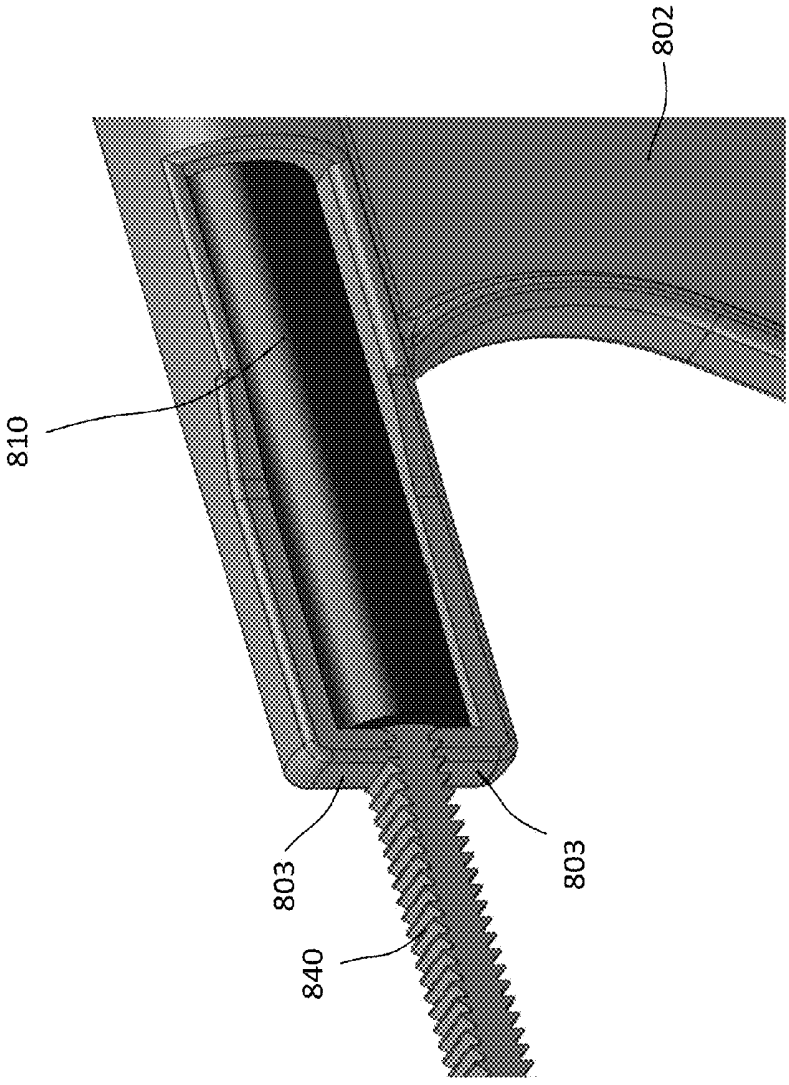

FIG. 8H

METHODS AND DEVICES FOR CONTROLLING HEMORRHAGE DURING MINIMALLY INVASIVE SURGICAL PROCEDURES

RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Application Ser. No. 62/143,861 filed on Apr. 7, 2015, the content of which are hereby incorporated by reference in its entirety.

FIELD

[0002] The teachings herein relate to methods and devices for use in minimally invasive surgical procedures, and more particularly to methods and devices for controlling hemorrhage (e.g., due to rupture of a blood vessel) during minimally invasive surgical procedures.

BACKGROUND

[0003] Minimally invasive surgical procedures such as laparoscopic surgery, endo-assisted procedures, video-assisted thorascopic surgery (VATS), and other similar procedures generally utilize fiber optic cameras and laparoscopic-specific instrumentation delivered to a surgical site (e.g., the abdominal cavity, thoracic cavity, etc.) through cannulas inserted into small incisions in the skin. Over the last several decades, these minimally invasive surgical techniques have become increasingly common due to potential benefits over traditional open techniques, including reduced pain, shorter post-operative recovery time (and decreased duration of hospital stays), and minimal scarring. Recently-introduced robotic systems such as the da Vinci™ Surgical System (marketed by Intuitive Surgical, Inc. of Sunnyvale, Calif., U.S.A.) can further provide improved 3D vision of the operative field and additional degrees of freedom that allow for more complex movements of the surgical instruments in the limited space afforded during minimally invasive surgical procedures.

[0004] Despite major advancements in both minimally invasive surgical procedures and surgeons' skill in utilizing robotic systems for the same, it is inevitable that some minimally invasive surgical procedures must be intra-operatively converted to open surgeries due to surgical complications, technical problems, or oncological conditions. One of the more dreaded instances of intra-operative complications requiring conversion to open surgery (of particular concern during the operation of complex robotic surgical systems) involves intra-operative hemorrhage that can lead to the pooling of blood at the surgical site, thereby occluding the surgeon's field of view so as to make corrective action difficult. With traditional open surgeries, such complications are immediately addressed with the application of direct pressure to the vessel ("tamponade") by a gauze sponge held by a set of ringed clamps (e.g., a sponge stick), while a plan is made to block, occlude, ligate, or otherwise repair the damaged vessel. However, in light of the increasingly smaller access ports that are being utilized in minimally invasive surgeries, it can be difficult to deliver sufficient gauze or other absorptive material through the cannula for tamponade of the hemorrhage site. Because placing a clamp around the bleeding vessel (e.g., with the laparoscopic/robotic surgical tools present at the surgical site) can also be dangerous due to poor visibility and the lack of isolation of the vessel, conversion to an open surgery may therefore be necessary to address the hemorrhage. Conversion to an open surgery can take up to about 10 minutes between the decision to convert and when open surgery resumes (time is required to retrieve open surgery equipment, remove the robotic arms, prepare the patient and the room, and make an incision in the patient to access the surgical site), while continued bleeding from the vascular injury can possibly cause life-threatening blood loss. Though robotic arms may be used to slow the bleeding, the continued presence of the robot in the limited space of the operating room environment can also impede/interfere with the conversion process.

[0005] Accordingly, there remains a critical need for controlling severe hemorrhage during minimally invasive surgical procedures, for example, during conversion to an open procedure.

SUMMARY

[0006] In various aspects, methods and systems in accordance with the present teachings are provided enabling tamponade of an internal hemorrhage site that can occur during a closed, minimally invasive surgical procedure so as to stabilize the hemorrhage site. Because such an acute hemorrhage may need to be addressed by converting to an open surgery, methods and systems in accordance with various aspects of the present teachings can prevent excessive blood loss from the hemorrhaged vessel, while providing the surgeon sufficient time to convert from an endoscopic surgery to an open surgery and, for example, to remove robotic arms. In accordance with various aspects of the present teachings, methods and devices for applying tamponade to an internal hemorrhage site during a laparoscopic procedure are provided in which an absorbent pad coupled to the distal end of an elongate shaft can be delivered through a trocar. During delivery (e.g., through the trocar), the absorbent pad can be disposed in a delivery configuration in which it extends substantially along the longitudinal axis of the elongate shaft. After delivering the absorbent pad to the internal surgical site, the absorbent pad can be actuated into a deployed configuration effective to apply tamponade to the hemorrhage site. In some aspects, for example, the actuation can move the distal end of the absorbent pad toward the proximal end of the elongate shaft (e.g., by bending or folding the absorbent pad) such that the absorbent pad in the deployed configuration has a wider and/or thicker distal portion relative to the distal end of the absorbent pad when in the delivery configuration. In various aspects, this distal portion can then be applied to the hemorrhage site (e.g., compressed against the hemorrhage site) to reduce excess blood loss during conversion or repair.

[0007] In accordance with various aspects of the present teachings, a device for applying tamponade to an internal hemorrhage site during a laparoscopic procedure is provided, the device comprising an elongate shaft extending along a longitudinal axis from a proximal end to a distal end and an absorbent pad disposed at or coupled to the distal end of the elongate shaft, the absorbent pad extending in a delivery configuration along the longitudinal axis from a proximal end to a distal end. The device can also include an actuation mechanism extending from the proximal end of the elongate shaft to the absorbent pad, wherein actuation of the actuation mechanism is configured to move the absorbent pad between the delivery configuration and a deployed configuration for applying tamponade to the hemorrhage

site. For example, in the deployed configuration, the absorbent pad can be folded such that its distal and proximal ends can be disposed adjacent one another.

[0008] The absorbent pad can have a variety of configurations. By way of example, in some aspects, the absorbent pad can exhibit a first length along the central longitudinal axis in the delivery configuration and a second length along the central longitudinal axis in the deployed configuration, the first length being greater than the second length. In some related aspects, the first length is about twice the second length. Additionally or alternatively, a distal portion of the absorbent pad can exhibit an increased thickness in the deployed configuration relative to the proximal end of the absorbent pad in the delivery configuration.

[0009] The actuation mechanism can also have a variety of configurations and can be coupled to the absorbent pad in a variety of manners. In some aspects, for example, the actuation mechanism can be configured to fold the absorbent pad. By way of non-limiting example, the actuation mechanism can be configured to rotate a distal portion of the absorbent pad about the distal end of the elongate shaft. Additionally in some aspects, the distal portion of the elongate shaft can have a reduced diameter relative to a proximal portion of the elongate shaft, wherein the reduced-diameter distal portion of the elongate shaft is disposed within the absorbent pad. In various aspects, the distal portion of the elongate shaft can be more flexible relative to the proximal portion of the elongate shaft (e.g., such that actuation of the actuation mechanism can bend or curve the distal portion of the elongate shaft).

[0010] In accordance with various aspects of the present teachings, the actuation mechanism can comprise a pull lever extending from the absorbent pad to the proximal end of the elongate shaft (e.g., which can be actuated by a user at the proximal end of the elongate shaft). By way of example, the pull lever can be pulled (e.g., via a handle) so as to move the absorbent pad from the delivery configuration to the deployed configuration. After deployment, the absorbent pad can then be compressed against the hemorrhage site to occlude bleeding. In some aspects, the pull lever can be sufficiently rigid to aid delivery of the absorbent pad in the delivery configuration through a trocar extending through a patient's skin surface and/or to enable the distal portion of the absorbent pad to be applied with pressure to a hemorrhage site in the deployed configuration. By way of example, after actuating the pull lever, a distal portion of the absorbent pad in the deployed configuration can have an increased surface area relative to a distal portion of the absorbent pad in the delivery configuration.

[0011] In some aspects, a distal portion of the actuation mechanism can extend through the absorbent pad and be coupled to the distal end of the elongate shaft. In such configurations, the distal portion of the actuation mechanism can be sufficiently rigid to aid delivery of the absorbent pad through the trocar extending through a patient's skin surface. In some related aspects, the distal portion of the actuation mechanism extending through the absorbent pad can comprise at least two segments having different rigidities. For example, a less rigid portion can effectively function as a hinge within the absorbent pad upon actuation of the actuation mechanism. In some aspects, the actuation mechanism can extend through the distal end of the elongate shaft, along an external surface of the absorbent pad, into the distal end of the absorbent pad, through the absorbent pad, out of the proximal end of the absorbent pad, and can be coupled to the distal end of the elongate shaft.

[0012] In some aspects of the present teachings, the elongate shaft can define one or more lumen extending therethrough. By way of example, the elongate shaft can comprise a sidewall disposed about a lumen through which the longitudinal axis extends, wherein the sidewall defines an opening proximal to the distal end of the elongate shaft. In various aspects, the actuation mechanism can extend through this opening of the sidewall and couple to at least one of the distal end of the absorbent pad and the distal end of the elongate shaft. By way of non-limiting example, in some aspects the absorbent pad can comprise a distal cap to which the actuation mechanism is coupled.

[0013] In accordance with various aspects of the present teachings, the actuation mechanism can be configured to pull the distal end of the absorbent pad toward the proximal end of the absorbent pad substantially along the longitudinal axis. By way of example, the actuation mechanism can extend through the absorbent pad and can be coupled to a distal end thereof. In some aspects, the absorbent pad can comprise a distal cap to which the actuation mechanism is coupled.

[0014] The absorbent pad can have a variety of configurations and can be made of a variety of materials. The absorbent pad can be gauze or a sponge formed in the shape of a cylinder or gauze rolled into a cylinder to ease passage through the trocar.

[0015] Devices in accordance with the present teachings can additionally include one or more additional features to aid in the treatment of an internal hemorrhage. By way of non-limiting example, one or more lumen can extend through the elongate shaft and can be in fluid communication with the absorbent pad. In various aspects, the lumen can be coupled to a negative pressure source for application of suction through the absorbent pad and/or to a fluid source for application of hemostatic agents to the hemorrhage site through the absorbent pad.

[0016] In accordance with various aspects of the present teachings, methods of applying tamponade to an internal hemorrhage site during a laparoscopic procedure are provided that comprise delivering an absorbent pad (e.g., gauze, sponge) in a first configuration through a trocar extending through a skin surface to an internal hemorrhage site, the absorbent pad being coupled to a distal end of an elongate shaft extending along a longitudinal axis from a proximal end to the distal end, wherein the absorbent pad extends substantially along the longitudinal axis from a proximal end to a distal end in the first configuration. The method can also comprise deploying the absorbent pad by moving the absorbent pad from the first configuration to a second configuration in which the distal end of the absorbent pad is disposed adjacent to the proximal end of the absorbent pad. Thereafter, pressure can be applied to the internal hemorrhage site with the absorbent pad in the second configuration. In various aspects, the absorbent pad exhibits a first length along the central longitudinal axis in the first configuration and a second length along the central longitudinal axis in the second configuration, the first length being greater than the second length. For example, the first length can be about twice the second length. Additionally, a distal portion of the absorbent pad can have an increased thickness in the second configuration relative to the proximal end of the absorbent pad in the first configuration. In various

aspects, methods in accordance with the present teachings can further comprise converting the laparoscopic procedure to an open procedure while maintaining pressure to the internal hemorrhage site with the absorbent pad in the second configuration. In some aspects, the laparoscopic procedure can be a robot-assisted laparoscopic procedure, wherein the method further comprises disengaging the robot from the patient prior to making a conversion incision.

[0017] In some aspects, deploying the absorbent pad comprises pulling a pull lever extending from the distal end of the absorbent pad to the proximal end of the elongate shaft. Additionally or alternatively, deploying the absorbent pad comprises folding the absorbent pad. By way of example, a distal portion of the absorbent pad can be rotated about the distal end of the elongate shaft. In related aspects, the distal portion of the elongate shaft can have a reduced diameter relative to a proximal portion of the elongate shaft, and the reduced-diameter distal portion of the elongate shaft can extend at least partially through the absorbent pad. In some related aspects, the distal portion of the elongate shaft can be more flexible relative to the proximal portion of the elongate shaft such that the distal portion bends while deploying the absorbent pad. Additionally or alternatively, in some aspects, the elongate shaft comprises a sidewall disposed about the longitudinal axis, the sidewall defining an opening proximal to the distal end of the elongate shaft, wherein deploying the absorbent pad comprises pulling a pull lever coupled to the distal end of the absorbent pad through the opening. In some aspects, the method can further comprise locking the pull lever to maintain the absorbent pad in the second configuration.

[0018] In various aspects of the present teachings, deploying the absorbent pad can comprise pulling the distal end of the absorbent pad toward the proximal end of the absorbent pad substantially along the longitudinal axis.

[0019] In some aspects, the methods described herein can additionally comprise coupling a lumen extending through the elongate shaft and in fluid communication with the absorbent pad to a negative pressure source so as to apply suction through the absorbent pad. Additionally or alternatively, a lumen extending through the elongate shaft can be coupled to a fluid source, for example, to deliver a hemostatic agents to the hemorrhage site through the absorbent pad.

[0020] These and other features of the applicant's teaching are set forth herein.

BRIEF DESCRIPTION OF THE DRAWINGS

[0021] The foregoing and other objects and advantages of the invention will be appreciated more fully from the following further description, with reference to the accompanying drawings. The skilled person in the art will understand that the drawings, described below, are for illustration purposes only. The drawings are not intended to limit the scope of the applicant's teachings in any way.

[0022] FIG. **1**, in schematic diagram, illustrates an exemplary device for applying tamponade to an internal hemorrhage site in a delivery configuration in accordance with various aspects of the applicant's teachings.

[0023] FIG. **2**, in schematic diagram, illustrates the device of FIG. **1** in a deployed configuration.

[0024] FIGS. **3**A, **3**B, and **3**C schematically depict the delivery, deployment, and tamponade of an internal hemorrhage site through a trocar, respectively, using the device of FIG. **1** in accordance with various aspects of the present teachings.

[0025] FIG. **4** depicts another exemplary device for applying tamponade to an internal hemorrhage site in accordance with various aspects of the applicant's teachings.

[0026] FIG. **5** depicts another exemplary device for applying tamponade to an internal hemorrhage site in accordance with various aspects of the applicant's teachings.

[0027] FIGS. **6**A and **6**B schematically depict another exemplary device for applying tamponade to an internal hemorrhage site in accordance with various aspects of the present teachings.

[0028] FIGS. **7**A-E schematically depict another exemplary device for applying tamponade to an internal hemorrhage site in accordance with various aspects of the present teachings.

[0029] FIGS. **8**A-H schematically depict another device for applying tamponade to an internal hemorrhage site in accordance with various aspects of the present teachings.

DETAILED DESCRIPTION

[0030] It will be appreciated that for clarity, the following discussion will explicate various aspects of embodiments of the applicant's teachings, while omitting certain specific details wherever convenient or appropriate to do so. For example, discussion of like or analogous features in alternative embodiments may be somewhat abbreviated. Well-known ideas or concepts may also for brevity not be discussed in any great detail. The skilled person will recognize that some embodiments of the applicant's teachings may not require certain of the specifically described details in every implementation, which are set forth herein only to provide a thorough understanding of the embodiments. Similarly it will be apparent that the described embodiments may be susceptible to alteration or variation according to common general knowledge without departing from the scope of the disclosure. The following detailed description of embodiments is not to be regarded as limiting the scope of the applicant's teachings in any manner.

[0031] In various aspects, methods and systems in accordance with the present teachings are provided that enable the tamponade of an internal hemorrhage site that can potentially occur during a closed, minimally invasive surgical procedure. In the unfortunate instance that an acute hemorrhage requires unscheduled conversion to an open surgery, the exemplary methods and systems described herein can enable the surgeon to prevent excessive blood loss from the hemorrhaged vessel during the conversion or repair process. Whereas in open surgeries hemorrhage is typically provided by a gauze sponge held by a set of ringed clamps (e.g., a sponge stick), the small diameter access ports through the trocars typically used in minimally invasive surgeries can make it difficult to deliver sufficient gauze or other absorptive material to properly, temporarily occlude the hemorrhaged vessel. Moreover, because placing a clamp around the bleeding vessel (e.g., with the laparoscopic/robotic surgical tools present at the surgical site) can be dangerous due to poor visibility and the lack of isolation of the vessel, devices in accordance with the present teachings can be placed in compression with the hemorrhage site to slow blood loss during the conversion to an open surgery.

[0032] In accordance with various aspects of the present teachings, methods and devices for applying tamponade to

an internal hemorrhage site during a laparoscopic procedure are provided in which an absorbent pad coupled to the distal end of an elongate shaft can be delivered through a trocar in a first configuration Upon being ejected from the trocar (e.g., to a location adjacent the surgical site), the absorbent pad can be reconfigured into a second configuration such that the absorbent pad has a distal portion exhibiting sufficient surface area of absorbent material for applying direct pressure to the hemorrhage site (e.g., compression against the hemorrhage site). With reference now to FIGS. **1** and **2**, an exemplary embodiment of a device for applying tamponade to an internal hemorrhage site is depicted. As shown in the figures, the exemplary device **100** generally comprises an elongate shaft **110**, an absorbent pad **130**, and an actuation mechanism **150** configured to move the absorbent pad **130** between a delivery configuration as shown in FIG. **1** and a deployed configuration as shown in FIG. **2**.

[0033] It will be appreciated by a person skilled in the art that the elongate shaft **110** can have a variety of lengths but is generally configured to extend along a central longitudinal axis from a proximal end **110***a* that can be disposed external to a patient (e.g., for gripping by the operator or coupled to a handle) to a distal end **110***b* that can be disposed within the patient. In accordance with various aspects of the present teachings, the elongate shaft can have a length in a range of about 12 inches to about 22 inches, though longer or shorter shafts can also be suitable depending for example on the depth of the surgical site to which the absorbent pad **130** is to be delivered. Likewise, though the exemplary shaft **110** is depicted as having a circular cross-sectional shape, it will be appreciated that the elongate shaft **110** can have a variety of cross-sectional shapes (e.g., round, square, oval) and sizes. In various aspects, however, it may be preferable that the elongate shaft **110** is circular in cross-section so as to ease insertion through a trocar having a circular seal and/or cannula. Similarly, the elongate shaft **110** can have a variety of cross-sectional dimensions but is generally configured to be able to extend through the cannula to the surgical site (e.g., the shaft **110** has a smaller diameter than the cannula through which the shaft **110** is inserted). In accordance with various aspects of the present teachings, the exemplary elongate shaft can have a substantially constant cross-sectional diameter (e.g., less than or equal to 15 mm, about 15 mm, about 12 mm, about 11 mm, in a range of about 5 mm to about 8 mm).

[0034] In accordance with various aspects of the present teachings, the elongate shaft **110** can comprise one or more lumens that extend at least partially along the length of the elongate shaft **110** (e.g., a hollow cylindrical body). By way example, as shown in FIG. **1**, the elongate shaft can include a first lumen through which the actuation mechanism **150** can extend from the proximal end **110***a* of the elongate shaft **110** to a distal opening **112** in the sidewall of the elongate shaft **110**, as discussed in detail below. Further, the elongate shaft **110** can additionally include one or more additional lumens that extend through the distal end **110***b* of the elongate shaft so as to be in fluid communication with the absorbent pad **130**. It will be appreciated by a person skilled in the art in light of the present teachings that these one or more additional lumens can be coupled (e.g., via port **114**) to a fluid supply (not shown) to enable a fluid (e.g., a solution containing a hemostatic agent) to be delivered to the absorbent pad (e.g., to be exuded therefrom at the hemorrhage site) and/or a negative pressure source (not shown) such that suction can be applied to the hemorrhage site.

[0035] As shown in FIGS. **1** and **2**, the elongate shaft **110** can be formed from a variety of materials that are of sufficient rigidity and strength to push the absorbent pad **130** through and eject the absorbent pad **130** from the distal end of a trocar as otherwise discussed herein. It will further be appreciated that the shaft **110** can comprise a plurality of sections formed from the same or different materials as one another so as to provide the elongate shaft **110** with different rigidities along its length. In accordance with one aspect of the present teachings, the elongate shaft **110** can comprise a hollow carbon fiber or steel shaft having an external diameter less than about 15 mm and an internal diameter in a range of from about 5 mm to about 8 mm. In accordance with various aspects of the present teachings, the sidewall of the elongate shaft can also be reinforced with additional materials (the same or different) from the remainder of the material of the elongate shaft **110** or different, stronger materials so as to provide for increased strength at various stress points of the elongate shaft. As noted above, for example, the actuation mechanism can extend through an opening **112** in the sidewall of the elongate shaft **110**. To avoid failure of the shaft **110** at this opening **112**, the shaft can be reinforced in proximity to the opening **112** with an additional layer of steel, for example.

[0036] As shown in FIGS. **1** and **2**, the device **100** also generally comprises an absorbent pad **130** that is disposed at and/or coupled to and extends distally from the distal end **110***b* of the elongate shaft **110**. The absorbent pad **130** can comprise a variety of absorbent materials, which are typically compliant, compressible, and/or flexible in accordance with the present teachings such that the absorbent pad **130** can be compressed against the damaged vessel without causing damage thereto, while nonetheless being effective to stop and/or slow the hemorrhage. Exemplary materials suitable for use in accordance with the present teachings include without limitation compressible porous materials, compressed cellulose sponge, natural sponge, synthetic sponge, polyurethane foam, collagen, and compacted gauze or other natural fibrous materials (e.g., cotton). In accordance with various aspects of the present teachings, the absorbent pad **130** can contain one or more radio-opaque markers so as to prevent any gauze from being left behind following the surgery.

[0037] The absorbent pad **130** can have a variety of shapes and sizes, but is generally limited by the dimensions of the trocar through which the absorbent pad **130** is delivered to the surgical site. By way of non-limiting example, the absorbent pad **130** can be cylindrical and can be sized so as to pass through a 15 mm trocar, a 12 mm trocar, or an 11 mm trocar. In the exemplary embodiment shown in FIGS. **1** and **2**, the absorbent pad **130** generally comprises several layers of gauze sheets that have been rolled into a cylinder and secured, for example, with retaining member **132** (e.g., thread or suture). It will be appreciated that such gauze rolls can purchased pre-rolled (e.g., a Kittner roll marketed by Carefree Surgical Specialties, Inc.) or can be assembled, for example, by surgical staff. As shown in phantom in FIGS. **1** and **2**, the absorbent pad **130** can surround a distal portion of the elongate shaft **110** such that the distal end **110***b* of the elongate shaft **110** partially extends within the absorbent pad **130** and such that the distal end **110***b* of the elongate shaft

110 is disposed between the proximal end **130***a* and distal end **130***b* of the absorbent pad **130**.

[0038] As shown in FIGS. **1** and **2**, a device in accordance with the present teachings additionally includes an actuation mechanism configured to move the absorbent pad from a first configuration (e.g., as shown in FIG. **1**) to a folded or bent deployed configuration (as shown in FIG. **2**). With specific reference to the exemplary device **100**, the actuation mechanism **150** generally comprises a pull lever **152** that extends from the proximal end **110***a* of the elongate shaft **110**, through an inner lumen thereof, out of the opening **112**, and can be coupled to the distal end **130***b* of the absorbent pad **130**. In some embodiments, the actuation mechanism **150** can additionally comprise a pull lever handle **154** to ease grasping thereof during deployment. It will also be appreciated that though the actuation of the actuating mechanism is generally described herein with reference to a manual force (e.g., by pulling), actuation can alternatively be accomplished through motor-driven means. Moreover, actuation can be accomplished by any other actuating mechanism known in the art and modified in accordance with the present teachings (e.g., via a scissor-type trigger handle, via rotation, etc.).

[0039] The pull lever **152** can have a variety of configurations and can be formed from a variety of materials (e.g., metal, plastic, nylon, thread) but generally is sufficiently strong such that a proximally directed force (e.g., on the pull lever handle **154**) can be effective to manipulate the absorbent pad **130** as otherwise discussed herein. Moreover, as will be appreciated by a person skill in the art in light of the present teachings, the exemplary pull lever **152** exhibits relatively little stretch such that tension can be maintained on the absorbent pad **130** during deployment. Though the pull lever **152** can have a substantially uniform cross section along its entire length, in various aspects of the present teachings the pull lever **152** can have one or more features for locking the absorbent pad **130** in a deployed configuration. For example, as shown in FIGS. **1** and **2**, for example, a portion of the pull lever **152** can be formed as a stop **156** having an increased diameter relative to the adjacent portions of the pull lever **152**.

[0040] An exemplary deployment of the device **100** will now be described. In various aspects of the present teachings, a user of the device **100** can push the absorbent pad **130** through a trocar in the exemplary delivery configuration shown in FIG. **1**. As shown, in this delivery configuration, the absorbent pad maintains a minimum cross-sectional area to ease insertion through the trocar. By way of example, the absorbent pad **130** is coupled to the distal end **110**b of the shaft **110** such that the major dimension (length L) of the absorbent pad **130** is substantially aligned with the central axis of the elongate shaft **110**, while the minor dimension (width W) is transverse to the longitudinal axis. Upon ejection of the absorbent pad **130** from the distal end of the trocar (e.g., through a distally directed force on the elongate shaft), the pull lever **152** can be actuated through a deployment force shown in FIG. **2**. By pulling on the pull lever handle **154**, the pull lever **152** will translate through the shaft **110**, thereby pivoting or rotating the distal portion of the absorbent pad **130** in the direction of the arrow about the distal end **110***a* of the elongate shaft **110**, thereby folding the absorbent pad **130** substantially on itself into the deployed configuration exemplified in FIG. **2**. As indicated in FIG. **2**, the absorbent pad has a reduced length (e.g., ½ L) in the deployed configuration and an increased width at the folded distal end **134**. In various aspects, the pull force can be applied until the stop **156** enters into a compression fit engagement with the opening **112** of the elongate shaft **110**, or alternatively, the entire stop **156** is pulled into the opening **112** with the distal shoulder **156***b* of the stop **156** abutting the inner surface of the opening **112**. In this manner, tension on the absorbent pad can be maintained even after release of tension on the pull lever handle **154**. Additionally or alternatively, it will be appreciated that one or more stops can be formed on a portion of the pull lever **152** (e.g., on the portion within the inner lumen) that can move proximally and be locked into a groove or cleat formed within the inner lumen.

[0041] With reference now to FIGS. **3**A-C, another exemplary device **300** in accordance with various aspects of the present teachings is schematically depicted being inserted through a trocar **360**, which extends through a patient's skin surface. As shown in FIGS. **3**A-C, the device **300** is substantially similar to that discussed above with reference to FIGS. **1** and **2**, and generally includes an elongate shaft **310**, an absorbent pad **330** disposed at a distal end thereof, and an actuation mechanism **350** for moving the absorbent pad **330** from the delivery configuration (FIG. **3**A) to the deployment configuration (FIG. **3**B). The device **300** differs, however, in that the actuation lever **352** includes a series of teeth **356** that are configured to engage with a locking mechanism **358**, e.g., as with a ratchet and pawl. In this manner, upon proximal actuation of the pull lever **352**, the engagement of the teeth **356** with a corresponding engagement feature of the locking mechanism **358** can be effective to maintain tension on the pull lever **352**, thereby keeping the absorbent pad **330** in the deployed configuration. Though not shown, it will be appreciated by a person skilled in the art that the locking mechanism **358** can additionally include a release mechanism that can release the engagement with the teeth **356**, thereby releasing tension on the absorbent pad **330** (e.g., for withdrawal).

[0042] As shown in FIGS. **3**A-C, the elongate shaft **310** additionally includes elongated shaft handles **318** which can aid in the delivery of the absorbent pad **330** through the trocar **360**, for example, until the absorbent pad is ejected out the distal end **360***b* thereof. For example, following the discovery of a hemorrhage in a blood vessel **302** that arose during a closed surgical procedure (e.g. laparoscopic or robot-assisted minimally invasive surgery), a user (e.g., surgeon, surgeon's assistant) can insert the device **300** into the proximal end of the trocar **360** (e.g., which can already be in place to aid in viewing the surgical site or can be inserted through the skin surface **304** upon discovery of the hemorrhage). The user can press, for example, on the elongated shaft handles **318** to move the distal end **310***a* of the elongate shaft distally, thereby pushing the absorbent pad **330** out of the distal end **360***b* of the trocar **360**. Upon ejection of the absorbent pad **330**, the pull lever **352** can be actuated through an upward (proximal) deployment force as shown in FIG. **3**B, iteratively engaging the teeth. As above, by pulling on the pull handle **354**, the pull lever **352** will translate through the shaft **310**, thereby pivoting or rotating the distal portion of the absorbent pad **330** in the direction of the arrow about the distal end **310***a* of the elongate shaft **310** and folding the absorbent pad **330** substantially on itself into the deployed configuration exemplified in FIG. **3**B. After manipulating the absorbent pad into the deployed configuration, an additional distally directed force on the

elongated shaft handles **318** can maneuver the folded absorbent pad **330** (now with increased surface area) into contact with the vessel **302** at the hemorrhage site to slow or prevent blood loss therefrom. As shown, the absorbent pad has a reduced length along the central axis of the elongate shaft in the deployed configuration and an increased width at the folded distal end **334**, thereby providing increased surface area (and additional absorptive material) relative to the distal end **330***b* in the delivery configuration. In various aspects, with the hemorrhage thus occluded, the surgeon can thus begin the conversion process, for example, by removing the robotic arms and making a conversion incision. It will be appreciated that though robotic arms may be used to slow the bleeding, the use of the exemplary devices and methods described herein can free both hands of the surgeon, for example, by having an assistant apply the tamponade.

[0043] With reference now to FIG. **4**, another exemplary device **400** in accordance with various aspects of the present teachings is depicted. FIG. **4** is substantially similar to the device **100** shown in FIGS. **1** and **2**, but differs in that the pull lever **452** instead extends over the distal most end **430***b* of the absorbent pad **430** to couple to a portion of the absorbent pad **430** on an opposed side of the central axis (A) from the opening **412** in the elongate shaft **410**.

[0044] With reference now to FIG. **5**, another exemplary device **500** in accordance with various aspects of the present teachings is depicted. FIG. **5** is substantially similar to the device **100** shown in FIGS. **1** and **2**, but differs in that the distal end or end area **530***b* of the absorbent pad **530** further comprises a distal cap **536** to which the pull lever **552** is coupled. It will be appreciated that the distal cap **536** can be formed from a different material from the remainder of the absorbent pad, for example, to provide a more rigid connection point for the pull lever **552** and/or to ease insertion of the absorbent pad **530** through a trocar.

[0045] With reference now to FIGS. **6**A and **6**B, another exemplary device **600** in accordance with various aspects of the present teachings is depicted. The device **600** is similar to the device **500** discussed above with reference to FIG. **5** in that the device **600** also includes an elongate shaft **610**, an absorbent pad **630** disposed at a distal end thereof and terminating distally in a distal end cap **636**, and an actuation mechanism **650** for manipulating the absorbent pad **630**. The device **600** differs, however, from the exemplary devices discussed above in that the pull lever **652** extends along the central axis of the elongate shaft **610** and out of the distal end **610***b* of the elongate shaft **610**, and through the absorbent pad **630**, terminating in a coupling with the distal end cap **636**. In other words, unlike in the exemplary devices discussed above with reference to FIGS. **1-5**, there is no proximal opening in the sidewall of the elongate shaft **610** through which the actuation lever **652** extends). Rather, by applying a proximally directed force via the pull lever **652** on the end cap **636** along the central axis of the elongate shaft **610**, the end cap **636** is moved proximally thereby compressing the absorbent member **630** axially. In this manner, the absorbent member **630** can bunch about the distal end **610***b* of the elongate shaft, thereby radially expanding to provide an increased distal surface area for tamponade of the hemorrhaged vessel.

[0046] As noted above, actuation mechanisms in accordance with the present teachings can have a variety of configurations for moving an absorbent pad between a delivery configuration and a deployment configuration (e.g., folding the absorbent pad after positioning the absorbent pad within the surgical cavity). With reference now to FIGS. **7**A and **7**B, another exemplary device **700** in accordance with various aspects of the present teachings is schematically depicted. Like the devices discussed above, the device **700** includes an elongate shaft **710**, an absorbent pad **730** disposed at a distal end thereof, and an actuation mechanism **750** for manipulating the absorbent pad **730**. The device **700** differs, however, in that an actuation lever **752** of the actuation mechanism **750** extends from the distal end **710***b* of the elongate shaft **710** and through the absorbent pad **730**, emerging therefrom at the distal end **730***b* of the pad. As best shown in FIGS. **7**A and **7**B, the pull lever **752** includes a terminal end **752***b* that can be secured to the hollow elongate shaft **710** adjacent its distal end **710***b* or a more proximal location. It will likewise be appreciated that the elongate pull lever **752** can be integrally formed with the elongate shaft **710** so as to extend from the distal end of the shaft through the absorbent pad **730** in accordance with various aspects of the present teachings. In use, the pull lever **752** can be pulled to cause bending of a distal portion of the pull lever and thus the surrounding absorbent pad **730** so as to provide a deployed configuration of the absorbent pad for the tamponade of a hemorrhage.

[0047] As noted above, in some embodiments, pull lever used in device according to the present teachings, can have a substantially uniform cross section along its entire length, and similarly can exhibit substantially constant rigidity along its length. In some embodiments, the thickness and/or rigidity of the pull lever can vary, e.g., in a continuous or discontinuous manner, along its length. By what of example, with specific reference to FIGS. **7**A and **7**B, the end of the pull lever **752** coupled to and/or extending from the distal end **710***b* of the elongate shaft can have various thicknesses and/or rigidities in order to facilitate the bending or folding of the absorbent pad **730** in accordance with various aspects of the present teachings. By way of example, a distal portion **753** of the pull lever **752** around which an absorbent pad **730** can be wrapped, secured, or disposed can have a segment **753***a* made of a stiffer material and/or can have an increased thickness relative to the material and/or thickness of the segment **753***b*. For example, the thickness of segment **753***a* can be at least 10% greater than segment **753***b*. It will be appreciated in light of the present teachings that actuation of the pull lever **752** will thus be more effective to bend the segment **753***b* relative to the segment **753***a* such that the folded absorbent pad **730** obtains its desired shape. In some aspects, by having the pull lever **752** extend through the entire length of the absorbent pad **730**, the pull lever **752** can add to the rigidity and aid the delivery of the absorbent pad **730** through a trocar in the delivery configuration.

[0048] With specific reference now to FIGS. **7**C-E, a thin sheath **755** can further be provided around the absorbent pad **730** and elongated shaft **710** to ease the insertion and/or deployment of the device. The thin sheath **755** can be used to cover absorbent pad **730** and at least a portion of the pull lever **752** and the elongated shaft **710** when the device is in the loaded configuration as illustrated in FIG. **7**C. In this configuration, the thin sheath **755** can reduce frictional forces as the absorbent pad **730** and the elongated shaft **710** are inserted through the trocar. In some embodiments, the thin sheath **755** can be used to cover partially or completely the elongated shaft **710** when the device is in the delivery and deployment configurations as illustrated in FIGS. **7**D

and **7**E, respectively, while leaving the thin sheath **755** proximally withdrawn from the thin sheath **755**. In these configurations, the thin sheath **755** can reduce the frictional forces as the absorbent pad **730** is compressed radially as it passes through the trocar. Furthermore, the absorbent pad **730** can be actuated into its deployed configuration by bending it so that its proximal and distal ends meet. As a result, in the deployed configuration the absorbent pad can have a reduced length (e.g., ½ L) and an increased width (e.g., 2 W), providing a larger surface area to cover the hemorrhage.

[0049] With reference now to FIGS. **8**A-H, another exemplary device **800** for applying tamponade to an internal hemorrhage site in accordance with various aspects of the present teachings is schematically depicted. As shown, the device **800** includes a pistol grip **802**, an elongate shaft **810**, an absorbent pad **830** disposed at a distal end of the shaft **810**, a pull lever **852** extending through the shaft **810**, and a pull lever handle **854** for moving the absorbent pad **830** between a delivery configuration and a deployed configuration, as discussed otherwise herein. As shown in FIG. **8**A and **8**B, the device **800** additionally includes a sheath **855** and a sheath handle **804** coupled to the proximal end thereof, the sheath **855** configured to be disposed to surround the elongate shaft **810** and the absorbent pad **830** during insertion through a trocar (as in FIG. **8**A). As shown in FIG. **8**B, the sheath handle **804** can then be actuated (e.g., by pulling the sheath handle proximally) to withdraw the sheath from around the absorbent pad **830** when a user is ready to deploy the absorbent pad **830**. As best shown in FIG. **8**B, the sheath handle **804** can be engaged by locking mechanism **806** so as to maintain the sheath **855** in the withdrawn position.

[0050] Once the thin sheath handles **810** are locked, an actuation mechanism can then be actuated so as to move the absorbent pad **830** from its delivery configuration (extending along longitudinal axis of the elongate shaft **810** (as in FIG. **8**B) to its deployed configuration (as in FIG. **8**C). As shown in FIG. **8**C, for example, pull lever handle **854** can be pulled proximally to fold the absorbent pad **830**. In some embodiments, the pull lever **852** can have a substantially uniform cross section along its length. In other embodiments, the pull lever **852** can have regions exhibiting different thickness or rigidity. It will be appreciated in light of the present teachings that the pull lever **852** can be formed of a single material or can include different regions formed of materials exhibiting different rigidities. By way of example and with specific reference to FIGS. **8**D-**8**F, the distal portion of the pull lever **852** (which extends through the absorbent pad **830** as shown in phantom) includes two sections **853***a* and **853***c* that are thicker and/or more rigid than section **853***b* disposed therebetween, in order to facilitate the folding of the absorbent pad **830**. In this manner, the section **853***b* can function as a hinge such that a proximally-directed force on the pull lever **852** selectively bends the pull lever **852** at section **853***b*, thereby folding the absorbent pad **830** disposed thereabout, as illustrated in FIGS. **8**E and **8**F. In various aspects, the absorbent pad can have a length in the range of about 4 to about 10 centimeters, with the hinge portion **830** having a length in a range of about 1 to about 4 centimeters, by way of non-limiting example.

[0051] Referring again to FIGS. **8**D-**8**F, the distal portion of the pull lever **852** comprises one or more throughholes **832** that can be utilized to couple the absorbent pad thereto (e.g., by sewing the pad to the pull lever **852**). For example, as shown in FIG. **8**D, after wrapping or disposing the absorbent pad **830** about the distal portion of the pull lever, the absorbent pad **830** can be firmly coupled to the pull lever by threading a suture through the absorbent pad and the throughholes **832** in sections **853***a* and **853***b*. Referring still to FIG. **8**D, the distal-most end of the pull lever **852** can also comprise a coupling mechanism **858** to couple the distal-most end of the pull lever **852** to the distal end of the elongated shaft **810**. By way of example, an internal surface of the elongated shaft **810** can comprise recesses configured to receive the coupling mechanism **858** (e.g., pins). The coupling between the elongated shaft **810** and the coupling mechanism **858** of the distal end of the pull lever **852** is illustrated in the FIG. **8**F, which depicts a cross section of the distal end of the device **800** in the deployed configuration. It will be appreciated that in its delivery configuration, the pull lever **852** would therefore extend through the distal end of the elongate shaft **810**, along an external surface of the absorbent pad **830** (e.g., between the absorbent pad **830** and the sheath **855**), into the distal end of the absorbent pad **830**, through the absorbent pad **830**, out of the proximal end of the absorbent pad **830**, and is coupled to the distal end of the elongate shaft **810** via coupling mechanism **858**. As with the hinge section **853***b*, the connection between section **853***c* and the thinner/less rigid section of the pull lever **852** is configured to allow the pull lever **852** to bend thereat such that the pull lever **852** emerges from the distal end of the absorbent pad **830** in the delivery configuration and reverses direction to extend proximally through the elongate shaft **810**.

[0052] With reference now referring to FIGS. **8**G and **8**H, the proximal end of the pull lever **852** is shown in additional detail. As shown, the proximal portion of the pull lever **852** can comprise a plurality of teeth **840** and proximally terminate in a pull lever handle hook **842** that can be coupled to pull lever handle **854** for actuating the pull lever **852**. As best shown in FIG. **8**H, the plurality of teeth **840** can be configured to couple with a ratchet mechanism **803** of the handle **802** so as to maintain the pull lever **852** in place when the absorbent pad **830** is in its deployment configuration. It will be appreciated that the ratchet mechanism **803** can include release mechanism (not shown) to release the pull lever **852**, for example, to straighten the absorbent pad for extraction.

[0053] Those skilled in the art will know or be able to ascertain using no more than routine experimentation, many equivalents to the embodiments and practices described herein. Accordingly, it will be understood that the invention is not to be limited to the embodiments disclosed herein, but is to be understood from the following claims, which are to be interpreted as broadly as allowed under the law.

[0054] The section headings used herein are for organizational purposes only and are not to be construed as limiting. While the applicant's teachings are described in conjunction with various embodiments, it is not intended that the applicant's teachings be limited to such embodiments. On the contrary, the applicant's teachings encompass various alternatives, modifications, and equivalents, as will be appreciated by those of skill in the art.

What is claimed:

1. A device for applying tamponade to an internal hemorrhage site during a laparoscopic procedure, comprising:

an elongate shaft extending along a longitudinal axis from a proximal end to a distal end;

an absorbent pad disposed at the distal end of the elongate shaft, the absorbent pad extending in a delivery configuration along the longitudinal axis from a proximal end to a distal end; and

an actuation mechanism extending from the proximal end of the elongate shaft to the absorbent pad, wherein actuation of the actuation mechanism is configured to move the absorbent pad from the delivery configuration to a deployed configuration for applying tamponade to a hemorrhage site.

2. The device of claim **1**, wherein the actuation mechanism is configured to fold the absorbent pad.

3. The device of claim **2**, wherein, in the deployed configuration, the absorbent pad is folded such that the distal and proximal ends of the absorbent pad are disposed adjacent one another.

4. The device of claim **1**, wherein the absorbent pad exhibits a first length along the central longitudinal axis in the delivery configuration and a second length along the central longitudinal axis in the deployed configuration, the first length being greater than the second length.

5. The device of claim **1**, wherein a distal portion of the absorbent pad has an increased thickness in the deployed configuration relative to the proximal end of the absorbent pad in the delivery configuration.

6. The device of claim **1**, wherein a proximal portion of the absorbent pad is disposed about the distal end of the elongate shaft and wherein the actuation mechanism is configured to rotate a distal portion of the absorbent pad about the distal end of the elongate shaft. The device of claim **1**, wherein a distal portion of the actuation mechanism extends through the absorbent pad and is coupled to the distal end of the elongate shaft.

8. The device of claim **7**, wherein the distal portion of the actuation mechanism is sufficiently rigid to aid delivery of the absorbent pad through a trocar extending through a patient's skin surface.

9. The device of claim **7**, wherein the distal portion of the actuation mechanism extending through the absorbent pad comprises at least two segments having different rigidities.

10. The device of claim **9**, wherein the at least two segments having different rigidities function as a hinge within the absorbent pad upon actuation of the actuation mechanism.

11. The device of claim **1**, wherein the actuation mechanism extends through the distal end of the elongate shaft, along an external surface of the absorbent pad, into the distal end of the absorbent pad, through the absorbent pad, out of the proximal end of the absorbent pad, and is coupled to the distal end of the elongate shaft.

12. The device of claim **1**, wherein the actuation mechanism extends through the absorbent pad and is coupled to a distal end thereof, and wherein the actuation mechanism is configured to pull the distal end of the absorbent pad toward the proximal end of the absorbent pad substantially along the longitudinal axis.

13. The device of claim **1**, wherein the absorbent pad comprises gauze rolled to form a cylinder.

14. The device of claim **1**, wherein the absorbent pad comprises sponge.

15. The device of claim **1**, further comprising a lumen extending through the elongate shaft and in fluid communication with the absorbent pad, wherein the lumen is configured to couple to a negative pressure source for application of suction through the absorbent pad.

16. The device of claim **1**, further comprising a lumen extending through the elongate shaft and in fluid communication with the absorbent pad, wherein the lumen is configured to couple to a fluid source for application of hemostatic agents to the hemorrhage site through the absorbent pad.

17. A device for applying tamponade to an internal hemorrhage site during a laparoscopic procedure, comprising:

an elongate shaft extending along a longitudinal axis from a proximal end to a distal end;

an absorbent pad coupled to the distal end of the elongate shaft, the absorbent pad extending in a delivery configuration along the longitudinal axis from a proximal end to a distal end; and

an actuation mechanism extending from the proximal end of the elongate shaft to the absorbent pad, wherein actuation of the actuation mechanism is configured to move the distal end of the absorbent pad toward the proximal end of the elongate shaft.

18. A method of applying tamponade to an internal hemorrhage site during a laparoscopic procedure, comprising:

delivering an absorbent pad in a first configuration through a trocar extending through a skin surface to an internal hemorrhage site, the absorbent pad being disposed at a distal end of an elongate shaft extending along a longitudinal axis from a proximal end to the distal end, wherein the absorbent pad extends substantially along the longitudinal axis from a proximal end to a distal end in the first configuration;

deploying the absorbent pad by moving the absorbent pad from the first configuration to a second configuration; and

applying pressure to the internal hemorrhage site with the absorbent pad in the second configuration.

19. The method of claim **18**, wherein deploying the absorbent pad comprises folding the absorbent pad such that the distal and proximal ends of the absorbent pad are disposed adjacent one another.

20. The method of claim **18**, wherein deploying the absorbent pad comprises actuating a pull lever coupled to the distal end of the elongate shaft so as to bend a portion of the pull lever extending through the absorbent pad.

21. The method of claim **18**, further comprising converting the laparoscopic procedure to an open procedure while maintaining pressure to the internal hemorrhage site with the absorbent pad in the second configuration.

22. The method of claim **21**, wherein the laparoscopic procedure comprises a robot-assisted laparoscopic procedure, wherein the method further comprises disengaging the robot from the patient prior to making a conversion incision.

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专利名称(译)	在微创手术过程中控制出血的方法和装置		
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摘要(译)

在各个方面，提供了根据本教导的方法和系统，其能够实现在闭合的微创外科手术过程中可能发生的内部出血部位的填塞。在不幸的情况下，急性出血需要不定期转换为开放手术，本文所述的示例性方法和系统可使外科医生能够防止在转换或修复过程中从出血血管中过多的血液流失。在开放手术中，通常由由一组环状夹具（例如，海绵棒）保持的纱布海绵提供出血，通过微创外科手术中使用的套管针的小直径进入端口可能使得难以递送足够的纱布或其他吸收性材料适当，暂时堵塞出血的血管。此外，因为在出血血管周围放置夹子（例如，腹腔镜/机器人手术工具存在于手术部位）可能由于可见性差和血管没有隔离而是危险的，根据本教导的装置可以与出血部位压迫，以减缓转换为开放手术期间的失血。