Physicians currently use a number of methods to close the arteriotomy, such as localized compression, sutures, collagen plugs, adhesives, gels, foams, clips, and similar materials.

[0005] In performing localized compression, the physician presses down against the vessel to allow the arteriotomy to naturally clot. This method, however, can take a significant amount of time, and requires the patient to remain immobilized and kept in the hospital for observation. Moreover, clots at the puncture site may also be dislodged. The amount of time necessary for the compression can significantly increase depending upon how much heparin, glycoprotein IIb/IIA antagonists, or other anti-clotting agents were used during the procedure. Sutures and collagen plugs can have procedure variability, can require time to close the vessel, and can necessitate a separate deployment device. Adhesives, gels, foams, and clips can have negative cost factors, can necessitate a complicated deployment process, and can have procedure variability.

SUMMARY OF THE INVENTION

[0006] ~~An aspect of the disclosure is directed to a closure device. The closure devices comprises: a distal flexible cap; one or more proximally positioned radial extending elements; a stem positioned between the distal flexible cap and the one or more radial extending element, wherein the distal flexible cap is formable toward an axis. In at least some configurations, thee distal flexible cap can be configured such that it has at least one of a substantially flat distal surface and a substantially flat proximal surface, a substantially flat distal surface and a substantially concave proximal surface, a substantially flat distal surface and a substantially convex proximal surface, a substantially convex distal surface and a substantially flat proximal surface, a substantially convex distal surface and a substantially convex proximal surface, a substantially convex distal surface and a substantially concave proximal surface, a substantially concave distal surface and a substantially flat proximal surface, a substantially concave distal surface and a substantially concave proximal surface, and a substantially concave distal surface and a substantially convex proximal surface. Additionally, the distal flexible cap can have at least one of a uniform thickness in a cross section or a variable thickness in a cross section. In some configurations, the proximal surface of the distal flexible cap has one of more of at least one of anchoring protrusions, nibs or ribs. The distal flexible cap can also be configured to have a shape selected from round, triangular, oval, ovoid, elliptical, square, and saucer. The flexible cap shape can have rounded edges. Additionally, the stem can be positioned on a proximal surface of the flexible cap at least one of centrally and non-centrally. A proximally accessible stem bore can also be provided. Additionally, a clip can be positionable within the proximal bore. The proximally accessible stem bore can also have at least one of internal threads along an interior surface, parallel walls along its length, non parallel walls along its length, an undercut in the bore at a location along its length, and a bent bore along its length. Additionally, the bore can be configured to extend from the proximal end of the device to the proximal end of the flexible cap. A wide variety of configurations for the stem are possible as will be appreciated. A few~~

~~of the configurations include, for example, cross-sectional profile shapes selected from the group comprising square, triangular, arrowhead, trapezoidal, rectangular, J, Y, hook, and bulbous. The stem can further comprise a proximally positioned aperture therethrough, one or more exterior features adapted and configured to achieve anchoring the stem in vivo, one or more slots along at least a portion of its length parallel to a stem longitudinal axis beginning at its proximal end, a configuration which enables it to open away from the longitudinal axis from its proximal end, a proximal end adapted and configured to form a clasp, a socket, a breakable stem, a tearable stem, and/or at least one of the distal flexible cap and stem are in releasable communication with a tether. Additionally, a tether can be provided. The tether can be one or more of a wire, a spring, a thread, a ribbon, and a tube. Wire can at least be one of a bent wire, a curved wire, a wavy wire, and a helical wire.~~According to a first aspect of the present invention, there is provided a tissue closure device comprising: (a) a distal flexible cap; and (b) a stem, wherein the distal flexible cap is formable toward an axis, wherein the stem further comprises a proximally positioned aperture therethrough; wherein the distal cap and the stem are formed from a single integral piece, and wherein the tissue closure device is formed from a bioabsorbable material.

[0007] ~~Another aspect of the disclosure is directed to a delivery capsule. The delivery capsule comprises: a cartridge body; a tapered distal tip; a compressible section; a clear section; a lumen extending therethrough, wherein the clear section is adapted and configured to house a closure device. The delivery capsule can be further adapted and configured to comprise a valve, one or more proximally positioned detent features on an exterior surface of the cartridge body, one or more distally positioned undercuts, an exterior groove in the cartridge body, a one-way snap feature, an undercut central bore, and/or a central aperture adapted and configured to receive a plunger. Where the capsule receives a plunger it can further be configured to permit the plunger to move in a first axial direction and resist movement in a second axial direction different than the first direction. One or more collets can also be provided.~~According to a second aspect of the present invention, there is provided a delivery capsule comprising: a cartridge body; a tapered distal tip; a section adapted for compressing the tissue closure device; a clear section; a lumen extending therethrough, wherein the clear section is adapted and configured to house the tissue closure device as defined in the first aspect.

[0008] ~~Still another aspect of the disclosure is directed to a wound closure delivery system. The wound closure delivery system comprises: an introducer; a wound closure delivery cartridge; a guide and seal assembly; and a plunger wherein the introducer is adapted and configured to releasably engage the wound closure delivery cartridge at a proximal end, the wound closure delivery cartridge is adapted and configured to releasably engage the guide and seal assembly at a proximal end, and the plunger is adapted and configured to be advanced through a lumen in each of the guide and seal assembly, the wound closure delivery cartridge and the introducer. In at least some configurations, thee distal flexible cap can be configured such that it has at least one of a substantially flat distal surface and a substantially flat proximal surface, a substantially flat distal surface and a substantially concave proximal surface, a substantially flat distal surface and a substantially convex proximal surface, a substantially convex distal surface and a substantially flat proximal surface, a substantially convex distal surface and a substantially convex proximal surface, a substantially convex distal surface and a substantially concave proximal surface, a substantially concave distal surface and a substantially flat proximal surface, a substantially concave distal surface and a substantially concave proximal surface, and a substantially concave distal surface and a substantially convex proximal surface. Additionally, the distal flexible cap can have at least one of a uniform thickness in a cross section or a variable thickness in a cross section. In some configurations, the proximal surface of the~~

~~distal flexible cap has one of more of at least one of anchoring protrusions, nibs or ribs. The distal flexible cap can also be configured to have a shape selected from round, triangular, oval, ovoid, elliptical, square, and saucer. The flexible cap shape can have rounded edges. Additionally, the stem can be positioned on a proximal surface of the flexible cap at least one of centrally and non centrally. A proximally accessible stem bore can also be provided. Additionally, a clip can be positionable within the proximal bore. The proximally accessible stem bore can also have at least one of internal threads along an interior surface, parallel walls along its length, non parallel walls along its length, an undercut in the bore at a location along its length, and a bent bore along its length. Additionally, the bore can be configured to extend from the proximal end of the device to the proximal end of the flexible cap. A wide variety of configurations for the stem are possible as will be appreciated. A few of the configurations include, for example, cross-sectional profile shapes selected from the group comprising square, triangular, arrowhead, trapezoidal, rectangular, J, Y, hook, and bulbous. The stem can further comprise a proximally positioned aperture therethrough, one or more exterior features adapted and configured to achieve anchoring the stem in vivo, one or more slots along at least a portion of its length parallel to a stem longitudinal axis beginning at its proximal end, a configuration which enables it to open away from the longitudinal axis from its proximal end, a proximal end adapted and configured to form a clasp, a socket, a breakable stem, a tearable stem, and/or at least one of the distal flexible cap and stem are in releasable communication with a tether. Additionally, a tether can be provided. The tether can be one or more of a wire, a spring, a thread, a ribbon, and a tube. Wire can at least be one of a bent wire, a curved wire, a wavy wire, and a helical wire. The delivery capsule can be further adapted and configured to comprise a valve, one or more proximally positioned detent features on an exterior surface of the cartridge body, one or more distally positioned undercuts, an exterior groove in the cartridge body, a one way snap feature, an undercut central bore, and/or a central aperture adapted and configured to receive a plunger. Where the capsule receives a plunger it can further be configured to permit the plunger to move in a first axial direction and resist movement in a second axial direction different than the first direction. One or more collets can also be provided.~~According to a third aspect of the present invention, there is provided a tissue closure delivery system comprising: an introducer; a tissue closure delivery cartridge having the tissue closure device as defined in the first aspect therein; a guide and seal assembly; and a plunger, wherein the introducer is adapted and configured to releasably engage the tissue closure delivery cartridge at a proximal end, the tissue closure delivery cartridge is adapted and configured to releasably engage the guide and seal assembly at a proximal end, and the plunger is adapted and configured to be advanced through a lumen in each of the guide and seal assembly, the tissue closure delivery cartridge and the introducer.

[0009] ~~Yet another aspect of the disclosure is directed to a method of closing a wound. Suitable methods comprise: assembling a wound closure system comprising a guide and seal assembly, a closure device delivery capsule, and an introducer; inserting the assembled would closure system percutaneously; centering a mammalian vessel with a distal tip of a tubular sheath of the introducer; and inserting a plunger into a proximal aperture in the guide and seal assembly; advancing the plunger through the guide and seal assembly into the closure device delivery capsule; engaging the closure device at the tip of the plunger; advancing the closure device into a tapered tip and reducing a profile of the closure device in at least one plane; advancing the closure device beyond the distal tip of the tubular sheath of the introducer and into the vessel; and withdrawing the system until a proximal surface of a face plate of the closure device comes in contact with an interior surface of the mammalian vessel; disengaging the closure device from the interior of the introducer. Additionally, at~~

~~least one of the steps of pulling a tether connected to a proximal end of the closure device , and releasing the tether connected to the proximal end of the closure device.~~

[0010] ~~Still other aspects are directed to a kit for a percutaneous procedure comprising a closure device delivery capsule housing a closure device; an introducer; a guide and seal assembly; and a plunger. The kit can further comprise one or more items selected from the group consisting of needles, hypo tubes, guidewires, electrode wires, intravenous wires, vascular introducers, catheters, laparoscopes, endoscopes, trocars, and cannulas, one or more compounds for delivery to a tissue, and/or one or more items selected from the group consisting of a pair of scissors, a scalpel, a swab, a syringe, a hemostat, a lubricant, a needle, a snare, an antiseptic, and an anesthetic. Suitable compounds include, for example, one or more of a sclerosing agent, an antibiotic, and an anti-inflammatory agent.~~

INCORPORATION BY REFERENCE

[0011] All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are used, and the accompanying drawings of which:

[0013] **FIG. 1** shows a perspective view of an embodiment of a vessel closure system;

[0014] **FIG. 2** shows a perspective view of an embodiment of a vascular closure clip in an open or pre-deployed configuration;

[0015] **FIG. 3** shows a perspective view of the clip of **FIG. 2** in a closed or deployed configuration;

[0016] **FIG. 4** shows a side view of the clip of **FIG. 2** in an open configuration;

[0017] **FIG. 5** shows a side view of the clip of **FIG. 2** in a closed configuration;

[0018] **FIG. 6** shows a bottom view of the clip of **FIG. 2** in a closed configuration;

[0019] **FIG. 7** shows a perspective view of a deployment instrument preloaded with a vascular closure clip;

[0020] **FIG. 8** shows a close-up view of the distal end of the deployment instrument of **FIG. 7**;

[0021] **FIG. 9** shows a perspective view of an inner tubular member portion of the deployment instrument of **FIG. 7**;

[0022] **FIG. 10** shows a side view of the inner tubular member of **FIG. 9**;