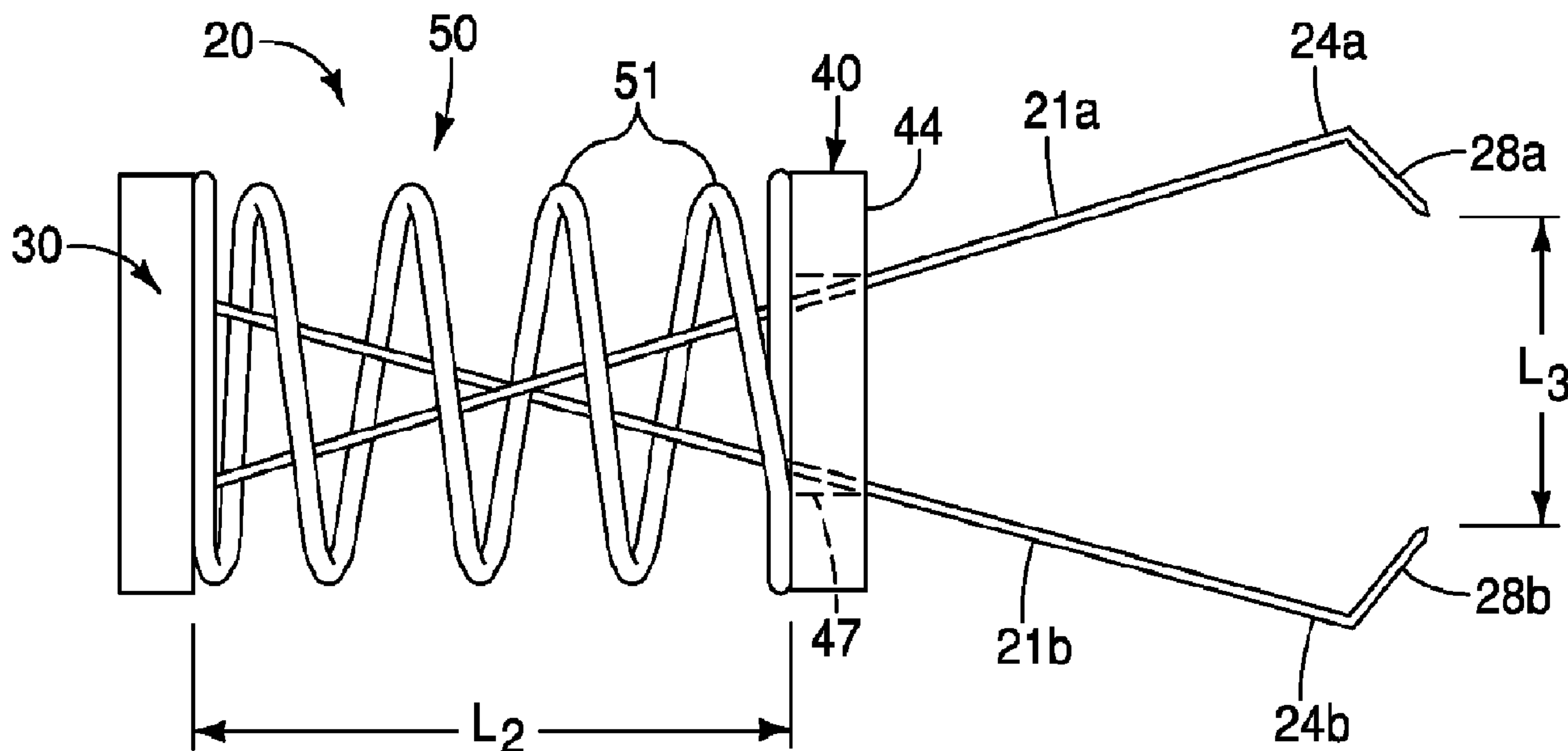




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(57) Abrégé/Abstract:

The present embodiments provide a clip device (20) for engaging tissue. The clip device comprises at least first (21a) and second arms (21b) having proximal (22a, 22b) and distal ends (24a, 24b). The clip device comprises an open state when the spring member (50) is in a compressed state in which the distal end (54) of the spring member is spaced further apart from the distal ends of the first and second arms. In the open state, the distal ends of the first and second arms tend to be spaced apart from each other. Further, the clip device comprises a closed state when the spring member is in a relaxed state in which the spring member is biased to extend distally towards the distal ends of the first and second arms. In the closed state, the distal ends of the first and second arms are adjacent to each other and may engage tissue and promote hemostasis. A delivery system and methods for deploying one or more clip devices also are provided.

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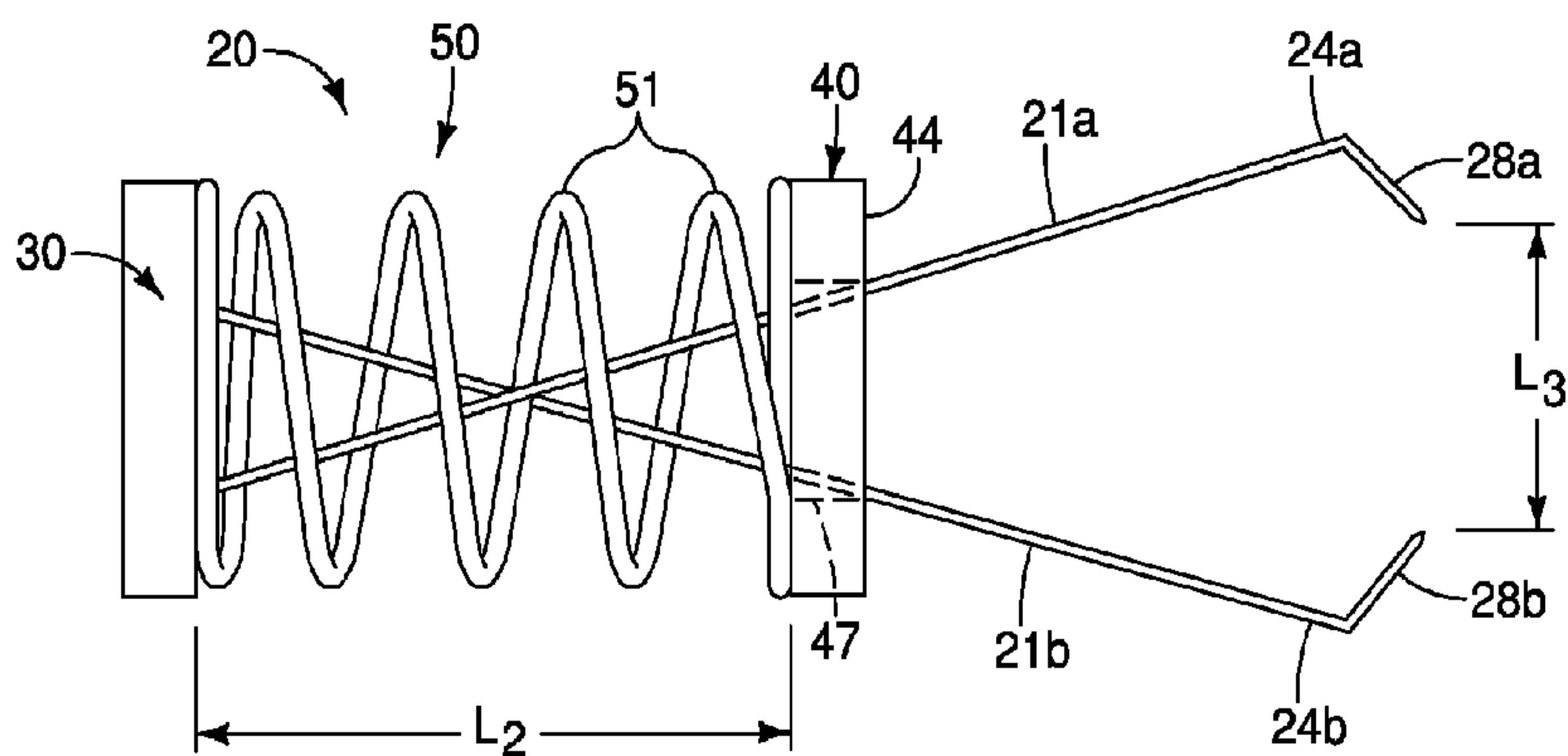


FIG. 2

(57) **Abstract:** The present embodiments provide a clip device (20) for engaging tissue. The clip device comprises at least first (21a) and second arms (21b) having proximal (22a, 22b) and distal ends (24a, 24b). The clip device comprises an open state when the spring member (50) is in a compressed state in which the distal end (54) of the spring member is spaced further apart from the distal ends of the first and second arms. In the open state, the distal ends of the first and second arms tend to be spaced apart from each other. Further, the clip device comprises a closed state when the spring member is in a relaxed state in which the spring member is biased to extend distally towards the distal ends of the first and second arms. In the closed state, the distal ends of the first and second arms are adjacent to each other and may engage tissue and promote hemostasis. A delivery system and methods for deploying one or more clip devices also are provided.

**CLIP DEVICES AND METHODS OF DELIVERY AND DEPLOYMENT****PRIORITY CLAIM**

[0001] This invention claims the benefit of priority of U.S. Provisional Application Serial No. 61/139,141, entitled "Clip Devices and Methods of Delivery and Deployment," filed December 5 19, 2008.

**BACKGROUND**

[0002] Conventionally, a clip may be introduced into a body cavity through an endoscope to grasp living tissue of a body cavity for hemostasis, marking, and/or ligating. In addition, clips are now being used in a number of applications related to gastrointestinal bleeding such as peptic 10 ulcers, Mallory-Weiss tears, Dieulafoy's lesions, angiomas, post-papillotomy bleeding, and small varices with active bleeding.

[0003] Gastrointestinal bleeding is a somewhat common and serious condition that is often fatal if left untreated. This problem has prompted the development of a number of endoscopic therapeutic approaches to achieve hemostasis such as the injection of sclerosing agents and 15 contact thermo-coagulation techniques. Although such approaches are often effective, bleeding continues for many patients and corrective surgery therefore becomes necessary. Because surgery is an invasive technique that is associated with a high morbidity rate and many other undesirable side effects, there exists a need for highly effective, less invasive procedures.

[0004] Mechanical hemostatic devices have been used in various parts of the body, including 20 gastrointestinal applications. Such devices are typically in the form of clamps, clips, staples and sutures, which are able to apply sufficient constrictive forces to blood vessels so as to limit or interrupt blood flow. One of the problems associated with conventional hemostatic devices, however, is that many devices are not strong enough to cause permanent hemostasis. Further, typically once such, mechanical hemostatic devices are at least partially deployed, they cannot be 25 opened and closed repeatedly before the final release of the device, which may result in possible permanent deployment of the device at an undesirable location.

[0005] Still further, mechanical hemostatic devices typically are loaded, one at a time, within an introducer equipped to deliver and deploy the device. A first hemostatic device may be deployed, but if it becomes desirable to deliver and deploy a second hemostatic device, the introducer typically must be removed from the patient's body in order to load the second hemostatic device. The introducer then is loaded back into the patient's body to deploy the second hemostatic device, and the process is repeated for each subsequent device. However, the process of deploying only one hemostatic device at a time may become very time consuming and inconvenient, causing significant delays when it may be imperative to quickly stop bleeding.

10 **SUMMARY**

[0006] The present embodiments provide a clip device for engaging tissue. The clip device comprises at least first and second arms, each having proximal and distal ends. A spring member is disposed to surround at least a portion of the first and second arms. The clip device comprises an open state when the spring member is in a compressed state in which a distal end of the spring member is spaced apart from the distal ends of the first and second arms. When the spring member is compressed, the distal ends of the first and second arms tend to be spaced apart from each other.

[0007] Further, the clip device comprises a closed state when the spring member is in a relaxed state in which the spring member is biased to extend distally towards the distal ends of the first and second arms. When the spring member is relaxed, the distal ends of the first and second arms are urged adjacent to each other. The distal ends of the first and second arms may penetrate tissue and promote hemostasis when the clip device is in the closed state.

[0008] In one embodiment, the clip device further comprises proximal and distal base members. Proximal and distal ends of the spring member contact the proximal and distal base members, respectively. Further, the spring member is disposed to surround at least a portion of the first and second arms. In this embodiment, the distal base member has an aperture and may slide over the first and second arms. When the spring member is in the relaxed state, the distal base member is advanced distally over the first and second arms and promotes closure of the distal ends of the first and second arms.

[0009] A delivery system for deploying at least one clip device may comprise an outer sheath and a catheter, each having a lumen. The catheter is configured for longitudinal movement within the lumen of the outer sheath, and multiple clip devices are configured to be selectively advanced through the lumen of the catheter. Preferably, at least one wedge member is disposed along a flexible distal region of the catheter. The wedge member is configured to form a constriction at a distal end of the catheter when the outer sheath is positioned over the distal end of the catheter. Distal advancement of a first clip device relative to the constriction is configured to cause the distal base member of the first clip device to engage the constriction, and further configured to cause the distal ends of the first and second arms to extend beyond the constriction to assume the open state. At this time, the spring member may be held in the compressed state near the distal end of the catheter. Subsequent proximal retraction of the outer sheath, beyond the distal end of the catheter and the wedge member, permits radially outward movement of the distal end of the catheter and the wedge member to thereby remove the constriction and permit deployment of the entire clip device from the distal end of the catheter.

[0010] Advantageously, in this manner, any number of clip devices may be sequentially loaded into the lumen of the catheter and deployed, one at a time, without the need to remove the catheter and the outer sheath from the patient's body and individually re-load clip devices, thereby saving important operating time. Further, each of the clip devices advantageously may move between the open and closed states any number of times before final deployment.

[0010a] Provided herein is a clip device for engaging tissue, the clip device comprising a first arm having proximal and distal ends; a second arm having proximal and distal ends; a proximal base member contacting the proximal ends of the first and second arms; and a spring member having proximal and distal ends, wherein the  
5 spring member is disposed to surround at least a portion of the first and second arms, and wherein the proximal end of the spring member is attached to the proximal base member, wherein the clip device comprises an open state when the spring member is in a compressed state in which the distal end of the spring member is spaced apart from the distal ends of the first and second arms, and wherein the distal ends of the  
10 first and second arms tend to be spaced apart from each other when the clip device is in the open state, wherein the clip device comprises a closed state when the spring member is in a relaxed state in which the spring member is biased to extend distally towards the distal ends of the first and second arms, wherein the distal ends of the first and second arms are adjacent to each other when the clip device is in the closed state,  
15 wherein the relaxed state of the spring member causes the arms to close.

[0010b] Also provided herein is a clip device for engaging tissue, the clip device comprising a first arm having proximal and distal ends; a second arm having proximal and distal ends; a proximal base member contacting the proximal ends of the first and second arms; and a spring member having proximal and distal ends, wherein  
20 the spring member is disposed to surround at least a portion of the first and second arms, and wherein the proximal end of the spring member is attached to the proximal base member, wherein the clip device comprises an open state when the spring member is in a compressed state in which the distal end of the spring member is spaced apart from the distal ends of the first and second arms, and wherein the distal  
25 ends of the first and second arms tend to be spaced apart from each other when the clip device is in the open state, wherein the compressed state of the spring member allows the arms to move to the open state, wherein the clip device comprises a closed state when the spring member is in a relaxed state in which the spring member is biased to extend distally towards the distal ends of the first and second arms, wherein  
30 the distal ends of the first and second arms are adjacent to each other when the clip device is in the closed state.

[0010c] Further provided herein is a clip device for engaging tissue, the clip device comprising a first arm having proximal and distal ends; a second arm having proximal and distal ends; a proximal base member contacting the proximal ends of the first and

second arms; and a spring member having proximal and distal ends, wherein the spring member is disposed to surround at least a portion of the first and second arms, and wherein the proximal end of the spring member extends from the proximal base member, wherein the clip device comprises an open state when the spring member is  
5 in a compressed state in which the distal end of the spring member is spaced apart from the distal ends of the first and second arms, and wherein the distal ends of the first and second arms tend to be spaced apart from each other when the clip device is in the open state, wherein the clip device comprises a closed state when the spring member is in a relaxed state in which the spring member is biased to extend distally  
10 towards the distal ends of the first and second arms, wherein the distal ends of the first and second arms are adjacent to each other when the clip device is in the closed state, wherein the first and second arms each extend in generally straight configurations and are angled with respect to one another between their respective proximal ends and tips, wherein the first and second arms crisscross relative to one another between their  
15 respective proximal ends and tips, and wherein the tips are bent in radially inward directions and configured to penetrate tissue.

[0011] Other systems, methods, features and advantages of the invention will be, or will become, apparent to one with skill in the art upon examination of the following figures and detailed description. It is intended that all such additional systems,  
20 methods, features and advantages be within the scope of the invention, and be encompassed by the following claims.

#### **BRIEF DESCRIPTION OF THE DRAWINGS**

[0012] The invention can be better understood with reference to the following  
25 drawings and description. The components in the figures are not necessarily to scale, emphasis instead

being placed upon illustrating the principles of the invention. Moreover, in the figures, like referenced numerals designate corresponding parts throughout the different views.

[0013] FIG. 1 is a side view of a clip device of a first embodiment in a closed state.

[0014] FIG. 2 is a side view of the clip device of FIG. 1 in an open state.

5 [0015] FIGS. 3-5 are side-sectional views illustrating an exemplary delivery system and sequence of deployment for at least one clip device provided in accordance with FIGS. 1-2.

[0016] FIG. 6 is a perspective view illustrating features of a distal region of a catheter of a delivery system.

[0017] FIGS. 7-8 are side-sectional views of an alternative embodiment of a delivery system.

10 [0018] FIG. 9 is a side view of an alternative clip device in a closed state.

[0019] FIG. 10 is a side view of the clip device of FIG. 9 in an open state.

#### **DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS**

[0020] In the present application, the term “proximal” refers to a direction that is generally towards a physician during a medical procedure, while the term “distal” refers to a direction  
15 that is generally towards a target site within a patient’s anatomy during a medical procedure.

[0021] Referring now to FIG. 1, a first embodiment of a clip device 20 is shown. In this embodiment, the clip device 20 comprises a first arm 21a and a second arm 21b. The first arm 21a has a proximal end 22a and a distal end 24a, while the second arm 21b has a proximal end 22b and a distal end 24b. The clip device 20 further comprises a proximal base  
20 member 30 having proximal and distal surfaces 32 and 34. Optionally, the clip device 20 may comprise a distal base member 40 having proximal and distal surfaces 42 and 44, and an aperture 47 formed therein, as shown in FIG. 1.

[0022] The clip device 20 further comprises a spring member 50 having a proximal end 52, a distal end 54, and a plurality of turns 51 disposed therebetween. The spring member 50  
25 circumferentially surrounds at least a portion of the first and second arms 21a and 21b. In the embodiment of FIGS. 1-2, the spring member 50 is disposed between the proximal and distal base members 30 and 40. In particular, the proximal end 52 of the spring member 50 contacts the distal surface 34 of the proximal base member 30, while the distal end 54 of the spring member 50 contacts the proximal surface 42 of the distal base member 40. The spring  
30 member 50 may be secured to the proximal and distal base members 30 and 40 using an

adhesive, solder, weld, mechanical attachment device, or any other suitable mechanism. Alternatively, the spring member 50 may be disposed in an abutting relationship with the proximal and distal base members 30 and 40.

5 [0023] As shown in FIG. 1, the proximal end 22a of the first arm 21a contacts the proximal base member 30 at a location spaced apart from the proximal end 22b of the second arm 21b. The first and second arms 21a and 21b are angled with respect to one another and crisscross between their respective proximal and distal ends. By crisscrossing one another, the arms 21a and 22b may be more inclined to move radially outward and apart from one another in an open state, as shown in FIG. 2. However, as will be explained in FIGS. 9-10 below, the arms  
10 alternatively may not cross paths with respect to each other.

[0024] The distal ends 24a and 24b of the arms 21a and 21b are preferably bent in radially inward directions to form tips 28a and 28b, respectively, as shown in FIGS. 1-2. The tips 28a and 28b are configured to grasp and/or pierce tissue. While two arms 21a and 21b are depicted in the embodiment of FIGS. 1-5, it is contemplated that fewer or greater arms may  
15 be used. For example, as explained in FIGS. 9-10 below, an alternative clip device 120 comprises three arms 121a-121c.

[0025] The first and second arms 21a and 21b may be made from any suitable resilient material such as stainless steel, nitinol, plastic, and the like. In addition, the arms may have a cross-sectional shape that is round, square, rectangular, triangular, pie-shaped, truncated  
20 cone, and the like. The proximal and distal base members 30 and 40 also may be formed from stainless steel, nitinol, plastic, and the like, although the proximal and distal base members 30 and 40 preferably comprise an enhanced rigidity relative to the first and second arms 21a and 21b.

[0026] The clip device 20 may be moved between closed and open states by selectively  
25 actuating the spring member 50 between relaxed and compressed states, as shown in FIGS. 1-2, respectively. The spring member 50 comprises a first length  $L_1$  in the relaxed state, as shown in FIG. 1. In the relaxed state, the spring member 50 is longitudinally expanded and the distal base member 40 may engage the distal ends 24a and 24b of the arms 21a and 21b, thereby urging the distal ends 24a and 24b of the arms 21a and 21b adjacent to one another.  
30 At this time, the clip device 20 is in a closed state, in which the arms 21a and 21b are configured for delivery within a lumen 78 of a catheter 70, as shown below. Further, in the

closed state of FIG. 1, the tips 28a and 28b are configured to grasp tissue and facilitate tissue closure and hemostasis.

[0027] It should be noted that the aperture 47 of the distal base member 40 may be sized so that it will not slide distally over the distal ends 24a and 24b of the arms 21a and 21b when the spring member 50 is relaxed and the clip device 20 is in the closed state of FIG. 1. 5 Optionally, distal stop members, such as a solder, may be disposed on the arms 21a and 22b at a location proximal to the tips 28a and 28b, to limit distal advancement of the distal stop member 40.

[0028] The spring member 50 further comprises a second length  $L_2$  in the compressed state, 10 as shown in FIG. 2. The second length  $L_2$  is less than the first length  $L_1$  due to compression of the spring member 50, and therefore, the distal base member 40 is spaced further apart from the distal ends 24a and 24b of the arms 21a and 21b. When the spring member 50 is in the compressed state of FIG. 2, the clip device 20 is in an open state in which the distal ends 24a and 24b of the first and second arms 21a and 21b, and more specifically the tips 28a and 15 28b, are spaced apart a distance  $L_3$  that is configured to at least partially surround one or more desired tissue segments prior to closure of the first and second arms 21a and 21b. In particular, since the distal ends 24a and 24b of the arms 21a and 21b are not radially constrained by the spring member 50 and/or the distal base member 40, the distal ends 24a and 24b of the arms 21a and 21b may move in a radially outward direction, as shown in FIG. 20 2. The arms may move in a radially outward direction due to inherent resilient properties of the material forming the arms 21a and 21b, or alternatively, the arms 21a and 21b may be heat-set to assume the deployed configuration shown in FIG. 2.

[0029] While the distal base member 40 is depicted as approximately halfway between the proximal base member 30 and the distal ends 24a and 24b of the arms 21a and 21b in the 25 open state of FIG. 2, the distal base member 40 may be positioned closer to or further from the proximal base member 30 when the spring member 50 is in a compressed state. For example, if the spring member 50 is further compressed, the second length  $L_2$  will be shortened and the spacing  $L_3$  may be increased. By contrast, if the spring member 50 is further expanded, the second length  $L_2$  will be increased and the spacing  $L_3$  may be reduced.

[0030] The spring member 50 may comprise any suitable material, such as stainless steel. 30 Further, the spring member 50 may comprise a shape and configuration that may be tailored based on a given application. In particular, the diameter, wire thickness, stiffness and/or

other features of the spring member 50 may be varied as needed for a particular procedure to meet anatomical constraints and/or vary the force imposed on tissue segments. For example, a substantially stiff spring member 50 may provide an increased force upon the distal ends 24a and 24b of the arms 21a and 21b to reduce the likelihood of the clip device 20 becoming  
5 disengaged from tissue after deployment.

[0031] In the embodiment of FIGS. 1-2, the proximal and distal base members 30 and 40 comprise generally cylindrical shapes, which may facilitate insertion through a lumen 78 of a catheter 70, as explained further below. However, the proximal and distal base members 30 and 40 alternatively may comprise different shapes. Further, as will be explained further  
10 below, the distal base member 40 preferably comprises an outer diameter sized to selectively engage a constriction 79 of the catheter 70, but the proximal base member 30 and the spring member 50 may comprise reduced diameter profiles relative to the distal base member 40.

[0032] Referring now to FIGS. 3-5, an exemplary system is described for delivery and deployment of at least one of the clip devices 20 of FIGS. 1-2. The delivery system  
15 comprises a catheter 70 having a lumen 78, and further comprises an outer sheath 80 having a lumen 88. In the embodiment of FIGS. 3-5, first and second clip devices 20a and 20b are provided for sequential deployment.

[0033] The catheter 70 comprises an outer diameter that is less than an inner diameter of the outer sheath 80, thereby allowing the catheter 70 to be longitudinally advanced within the  
20 lumen 88 of the outer sheath 80. The catheter 70 further comprises an inner diameter that is generally larger than an outer diameter of the first and second clip devices 20a and 20b, thereby allowing the first and second clip devices 20a and 20b to be loaded within the lumen 78 of the catheter 70, as shown in FIG. 3.

[0034] The catheter 70 comprises a distal end 74 and a flexible distal region 75. The flexible  
25 distal region 75 may be selectively moved in radially inward and outward directions, for purposes described further below. Preferably, a plurality of slits 77 are formed in the distal end 74, as shown in FIG. 6, to permit the radial flexibility along the distal region 75.

[0035] At least one wedge member 92 may be used to form a constriction 79 at the distal end  
30 74 of the catheter 70. In the embodiment of FIGS. 3-5, the at least one wedge member 92 has a triangular shape and is disposed between the catheter 70 and the outer sheath 80, causing the flexible distal region 75 of the catheter 70 to move radially inward to form the constriction 79, as shown in FIGS. 3-4. The wedge member 92 may comprise a biocompatible glue,

plastic, metal or other suitable material, and may comprise other shapes besides the triangular shape depicted to accomplish the objectives described below. Alternatively, one or more wedge members 92 may be formed as an integral portion of the catheter 70 at the distal region 75.

5 [0036] The outer sheath 80 may comprise a rigid or substantially rigid material, such as stainless steel or plastic materials, which substantially prohibits radial outward movement of the wedge member 92 and the flexible distal region 75 of the catheter 70, when a distal end 84 of the outer sheath 80 covers these regions, as shown in FIGS. 3-4. However, when the distal end 84 of the outer sheath 80 is retracted proximally beyond the wedge member 92 and  
10 the flexible distal region 75 of the catheter 70, the flexible distal region 75 may move radially outward and the constriction 79 may be removed, as depicted in FIG. 5 below.

[0037] In one exemplary method, the first and second clip devices 20a and 20b may be loaded sequentially such that the first clip device 20a is loaded distal to the second clip device 20b within the lumen 78 of the catheter 70, as shown in FIG. 3. A stylet 90 may be  
15 positioned in the lumen 78 at a location proximal to the second clip device 20b. It should be noted that while two clip devices are shown in this example, any number may be used and sequentially loaded into the catheter 70 in an abutting manner distal to the stylet 90.

[0038] The outer sheath 80 is positioned over the catheter 70 such that the constriction 79 is formed via the wedge member 92, as shown in FIG. 3. The constriction 79 forms an inner  
20 diameter that is less than an outer diameter of the distal base member 40, as shown in FIG. 3. Accordingly, the distal base member 40 cannot be advanced through the distal end 74 of the catheter 70. When the spring member 50 of the first clip device 20a is in the relaxed state shown in FIG. 3, the distal ends 24a and 24b of the arms 21a and 21b may extend partially into the constriction 79, but preferably do not extend beyond the distal end 74 of the catheter  
25 70 to reduce the likelihood of inadvertent piercing.

[0039] Referring to FIG. 4, in a next step, the stylet 90 is advanced distally, relative to the catheter 70 and the outer sheath 80, to cause distal advancement of the second clip device 20b and corresponding distal advancement of the first clip device 20a in an abutting manner. The stylet 90 is advanced while the outer sheath 80 continues to cover the distal end 74 of the  
30 catheter 70, thereby retaining the constriction 79. As the first clip device 20a is advanced distally, the distal base member 40 of the first clip device 20a is retained by the constriction 79. However, the proximal base member 30 and the arms 21a and 21b of the first clip device

20a are advanced distally relative to the constriction 79, and the spring member 50 becomes compressed between the proximal and distal base members 30 and 40, as depicted in FIG. 4. At this time, the distal ends 24a and 24b of the arms 21a and 21b of the first clip device 20a are advanced distally beyond the distal end 74 of the catheter 70, and when unconstrained, tend to bow in a radially outward direction spaced apart from one another. The spacing  $L_3$  shown in FIG. 2 therefore is formed between the distal ends 24a and 24b of the first and second arms 21a and 21b. The length of the spacing  $L_3$  may be varied based on the amount of distal advancement of the stylet 90 and corresponding compression of the spring member 50. Further, the length of the spacing  $L_3$  may be sufficient to capture one or more desired segments of tissue between the distal tips 28a and 28b of the arms 21a and 21b.

[0040] In accordance with one aspect, a physician need not deploy the first clip device 20a at this time, even though the first clip device 20a is in the open state. Rather, the first clip device 20a may be moved between the open and closed states, shown in FIGS. 3-4, any number of times before final deployment. For example, if it becomes desirable to recapture the distal ends 24a and 24b of the arms 21a and 21b when in the open state of FIG. 4, a physician may proximally retract the stylet 90, which reduces the force upon the spring member 50 of the first clip device 20a. The spring member 50 assumes the relaxed state shown in FIG. 3, and the proximal base member 30 and the arms 21a and 21b move in a proximal direction, causing the distal ends 24a and 24b of the arms 21a and 21b to move in radially inward directions back into the catheter 70. Advantageously, in this manner, each of the individual clip devices may move between the open and closed states any number of times before final deployment.

[0041] Referring now to FIG. 5, in a next step, if the physician wishes to proceed with deployment of the first clip device 20a in the open state of FIG. 4, the outer sheath 80 is proximally retracted with respect to the catheter 70, such that the distal end 84 of the outer sheath 80 is positioned proximal to the wedge member 92. At this time, the wedge member 92 is no longer radially constrained and may move in a radially outward direction, as shown in FIG. 5. The flexible distal region 75 of the catheter 70 also may move radially outward and the constriction 79 may be removed, as depicted in FIG. 5. In this configuration, an inner diameter at the distal end 74 of the catheter 70 is equal to or greater than the outer diameter of the first clip device 20a. Therefore, the first clip device 20a may be ejected from the distal end 74 of the catheter 70. It should be noted that, when no longer constrained by the

constriction 79, the spring member 50 is biased towards the relaxed state of FIG. 1 and the distal base member 40 is advanced towards the distal ends 24a and 24b of the arms 21a and 21b, causing the tips 28a and 28b to securely engage tissue, e.g., to promote hemostasis. The second clip device 20b then is positioned for deployment near the distal end 74 of the catheter

5 70.

[0042] After deployment of the first clip device 20a, but before deployment of the second clip device 20b, the outer sheath 80 may be distally advanced with respect to the catheter 70, thereby urging the wedge member 92 in a radially inward direction and causing the flexible distal region 75 to move radially inward and form the constriction 79, as shown in FIG. 3

10 above. Subsequently, the same sequence of deployment for the first clip device 20a, as explained with respect to FIGS. 3-5, may be used to deploy the second clip device 20b. Advantageously, in this manner, any number of clip devices may be sequentially loaded into the lumen 78 of the catheter 70 and deployed, one at a time, without the need to remove the catheter 70 and outer sheath 80 from the patient's body and individually re-load clip devices

15 thereby saving important operating time.

[0043] It should be noted that the distal base member 40 optionally may be omitted. In this case, substantially identical method steps may be used to deploy the first and second clip devices 20a and 20b, however, the distal end 54 of the spring member 50 would be configured to be retained by the constriction 79 of the catheter 70, and further configured to

20 directly apply a compressive force directly upon the distal ends 24a and 24b of the arms 21a and 21b in the closed state of FIG. 1.

[0044] Referring to FIG. 6, and as noted above, the flexible distal region 75 of the catheter 70 may be selectively moved in a radially inward and outward direction by providing a plurality of slits 77 formed in the flexible distal region 75. In the embodiment shown, four slits 77 are

25 formed in the distal end 74 of the catheter 70 and extend in tapered manner in a distal to proximal direction. The four slits 77 may be radially spaced apart around the circumference of the catheter 70. One or more of the wedge members 92 may be attached to the flexible distal region 75 at one or more locations between the slits 77. While four illustrative tapered slits 77 are shown in FIG. 6, it will be appreciated that greater or fewer slits may be

30 employed, and they may comprise different shapes and configurations than depicted.

[0045] Referring now to FIGS. 7-8, the clip device 20 is deployed in the same manner as FIGS. 3-5, with the main exception that one or more alternative wedge members 92' are

disposed internal to the catheter 70. Preferably, the alternative wedge members 92' comprise a triangular shape and are attached to an inner surface of the catheter 70 along the flexible distal region 75, or are formed integrally with the distal region 75. When the outer sheath 80 is distally advanced to cover the distal end 74 of the catheter 70, the wedge member 92' is moved radially inward to form the constriction 79, as shown in FIG. 7. At this time, the spring member 50 of the clip device 20 may be compressed by distal advancement of the stylet 90, as explained in FIG. 4 above.

[0046] When it becomes desirable to release the clip device 20, the outer sheath 80 may be proximally retracted with respect to the catheter 70 to a location proximal to the wedge member 92'. At this time, the wedge member 92' is no longer radially constrained and may move in a radially outward direction to form a substantially flush extension to the catheter 70, while the flexible distal region 75 moves radially outward, as shown in FIG. 8. At this time, the constriction 79 is removed and the clip device 20 may be ejected from the distal end 74 of the catheter 70.

[0047] Referring now to FIGS. 9-10, an alternative clip device 120 is shown. The clip device 120 is substantially identical to the clip device 20 of FIGS. 1-5, with the main exceptions that the clip device 120 comprises three arms 121a-121c having proximal ends 122a-122c and distal ends 124a-124c, respectively. Unlike the embodiment of FIGS. 1-5, the arms 121a-121c do not cross paths with each other between their respective proximal and distal ends. Distal tips 128a-128c of the three arms 121a-121c tend to be radially spaced apart when the clip device 120 is in the open state, as shown in FIG. 10. The distal ends 124a-124c of the arms 121a-121c may be biased to assume the open state of FIG. 10, either due to the inherent resilient properties of the material forming the arms 121a-121c, or alternatively, the arms 121a-121c may be heat-set to assume the deployed configuration shown in FIG. 10. Preferably, the alternative clip device 120 is deployed in an identical manner to the clip device 20, as described with respect to FIGS. 3-5 above.

[0048] In further alternative embodiments, the apparatus and methods described herein may be used for engaging a layer of material, and are not restricted to methods for treatment of a human or animal body by surgery or therapy. For example, first and second clip devices may be provided and loaded within a lumen of a catheter, as described above. The first clip device may be positioned to engage a layer of material at a desired location in the open state, and then a compressive force is removed to allow the first spring member to be biased

towards the relaxed state and cause the distal ends of the first and second arms of the first clip device to be adjacent to each other and engage the layer of material, as generally described above.

[0049] While various embodiments of the invention have been described, the invention is not  
5 to be restricted except in light of the attached claims and their equivalents. Moreover, the advantages described herein are not necessarily the only advantages of the invention and it is not necessarily expected that every embodiment of the invention will achieve all of the advantages described.

## WHAT IS CLAIMED IS:

1. A clip device for engaging tissue, the clip device comprising:
  - a first arm having proximal and distal ends;
  - a second arm having proximal and distal ends;
  - a proximal base member contacting the proximal ends of the first and second arms; and
  - a spring member having proximal and distal ends, wherein the spring member is disposed to surround at least a portion of the first and second arms, and wherein the proximal end of the spring member is attached to the proximal base member,
    - wherein the clip device comprises an open state when the spring member is in a compressed state in which the distal end of the spring member is spaced apart from the distal ends of the first and second arms, and wherein the distal ends of the first and second arms tend to be spaced apart from each other when the clip device is in the open state,
    - wherein the clip device comprises a closed state when the spring member is in a relaxed state in which the spring member is biased to extend distally towards the distal ends of the first and second arms, wherein the distal ends of the first and second arms are adjacent to each other when the clip device is in the closed state, wherein the relaxed state of the spring member causes the arms to close.
2. The clip device of claim 1 further comprising a distal base member having an aperture configured to permit movement of the distal base member at least partially over the first and second arms, wherein the distal end of the spring member contacts a proximal surface of the distal base member.
3. The clip device of claim 1, wherein the distal ends the first and second arms are bent in radially inward directions to form tips configured to penetrate tissue.

4. The clip device of claim 1, wherein the first and second arms are angled with respect to one another and crisscross between their respective proximal and distal ends.
5. The clip device of claim 1 further comprising a third arm having proximal and distal ends, wherein the first, second and third arms tend to be spaced apart from each other when the clip device is in the open state, wherein the distal ends of the first, second and third arms are adjacent to each other when the clip device is in the closed state, and wherein the first, second and third arms do not cross paths with respect to each other when the clip device is in the open state.
6. The clip device of claim 1 further comprising:
  - a catheter having a lumen, wherein the clip device is configured to be selectively advanced through the lumen of the catheter; and
  - a constriction formed at a distal end of the catheter, wherein the constriction facilitates selective deployment of the clip device through the distal end of the catheter.
7. The clip device of claim 6, wherein multiple clip devices are configured to be loaded in a sequential manner within the lumen of the catheter at the same time, and further are configured to be individually and selectively deployed from the distal end of the catheter.
8. The clip device of claim 6 further comprising:
  - an outer sheath having a lumen, wherein the catheter is configured for longitudinal movement within the lumen of the outer sheath; and
  - at least one wedge member disposed along a flexible distal region of the catheter, wherein the wedge member forms the constriction at the distal end of the catheter when the outer sheath is positioned over the distal end of the catheter.
9. The clip device of claim 8, further comprising:
  - a distal base member having an aperture configured to permit movement of the distal base member at least partially over the first and second arms, wherein

the distal end of the spring member contacts a proximal surface of the distal base member, and

wherein the constriction comprises a diameter smaller than an outer diameter of the distal base member, such that distal advancement of the clip device relative to the constriction is configured to cause the distal base member to engage the constriction, and further configured to cause the distal ends of the first and second arms to extend distally beyond the distal end of the catheter and assume the open state, and further cause the spring member to assume the compressed state.

10. The clip device of claim 9, wherein proximal retraction of the outer sheath, beyond the distal end of the catheter and the wedge member, is adapted to permit radially outward movement of the distal end of the catheter and the wedge member to thereby remove the constriction and permit deployment of the entirety of the clip device from the distal end of the catheter.

11. A clip device for engaging tissue, the clip device comprising:

a first arm having proximal and distal ends;

a second arm having proximal and distal ends;

a proximal base member contacting the proximal ends of the first and second arms; and

a spring member having proximal and distal ends, wherein the spring member is disposed to surround at least a portion of the first and second arms, and wherein the proximal end of the spring member is attached to the proximal base member,

wherein the clip device comprises an open state when the spring member is in a compressed state in which the distal end of the spring member is spaced apart from the distal ends of the first and second arms, and wherein the distal ends of the first and second arms tend to be spaced apart from each other when the clip device is in the open state, wherein the compressed state of the spring member allows the arms to move to the open state,

wherein the clip device comprises a closed state when the spring member

is in a relaxed state in which the spring member is biased to extend distally towards the distal ends of the first and second arms, wherein the distal ends of the first and second arms are adjacent to each other when the clip device is in the closed state.

12. The clip device of claim 11 further comprising a distal base member having an aperture configured to permit movement of the distal base member at least partially over the first and second arms, wherein the distal end of the spring member contacts a proximal surface of the distal base member.
13. The clip device of claim 11, wherein the distal ends the first and second arms are bent in radially inward directions to form tips configured to penetrate tissue.
14. The clip device of claim 11, wherein the first and second arms are angled with respect to one another and crisscross between their respective proximal and distal ends.
15. The clip device of claim 11 further comprising:
  - a catheter having a lumen, wherein the clip device is configured to be selectively advanced through the lumen of the catheter; and
  - a constriction formed at a distal end of the catheter, wherein the constriction facilitates selective deployment of the clip device through the distal end of the catheter.
16. A clip device for engaging tissue, the clip device comprising:
  - a first arm having proximal and distal ends;
  - a second arm having proximal and distal ends;
  - a proximal base member contacting the proximal ends of the first and second arms; and
  - a spring member having proximal and distal ends, wherein the spring member is disposed to surround at least a portion of the first and second arms, and wherein the proximal end of the spring member extends from the proximal base

member,

wherein the clip device comprises an open state when the spring member is in a compressed state in which the distal end of the spring member is spaced apart from the distal ends of the first and second arms, and wherein the distal ends of the first and second arms tend to be spaced apart from each other when the clip device is in the open state,

wherein the clip device comprises a closed state when the spring member is in a relaxed state in which the spring member is biased to extend distally towards the distal ends of the first and second arms, wherein the distal ends of the first and second arms are adjacent to each other when the clip device is in the closed state,

wherein the first and second arms each extend in generally straight configurations and are angled with respect to one another between their respective proximal ends and tips, wherein the first and second arms crisscross relative to one another between their respective proximal ends and tips, and wherein the tips are bent in radially inward directions and configured to penetrate tissue.

17. The clip device of claim 16 further comprising a distal base member having an aperture configured to permit movement of the distal base member at least partially over the first and second arms, wherein the distal end of the spring member contacts a proximal surface of the distal base member.
18. The clip device of claim 16 further comprising:
  - a catheter having a lumen, wherein the clip device is configured to be selectively advanced through the lumen of the catheter; and
  - a constriction formed at a distal end of the catheter, wherein the constriction facilitates selective deployment of the clip device through the distal end of the catheter.
19. The clip device of claim 18, wherein multiple clip devices are configured to be loaded in a sequential manner within the lumen of the catheter at the same time,

and further are configured to be individually and selectively deployed from the distal end of the catheter.

20. The clip device of claim 18 further comprising:

an outer sheath having a lumen, wherein the catheter is configured for longitudinal movement within the lumen of the outer sheath; and

at least one wedge member disposed along a flexible distal region of the catheter, wherein the wedge member forms the constriction at the distal end of the catheter when the outer sheath is positioned over the distal end of the catheter.

21. The clip device of claim 20, further comprising:

a distal base member having an aperture configured to permit movement of the distal base member at least partially over the first and second arms, wherein the distal end of the spring member contacts a proximal surface of the distal base member, and

wherein the constriction comprises a diameter smaller than an outer diameter of the distal base member, such that distal advancement of the clip device relative to the constriction is configured to cause the distal base member to engage the constriction, and further configured to cause the distal ends of the first and second arms to extend distally beyond the distal end of the catheter and assume the open state, and further cause the spring member to assume the compressed state.

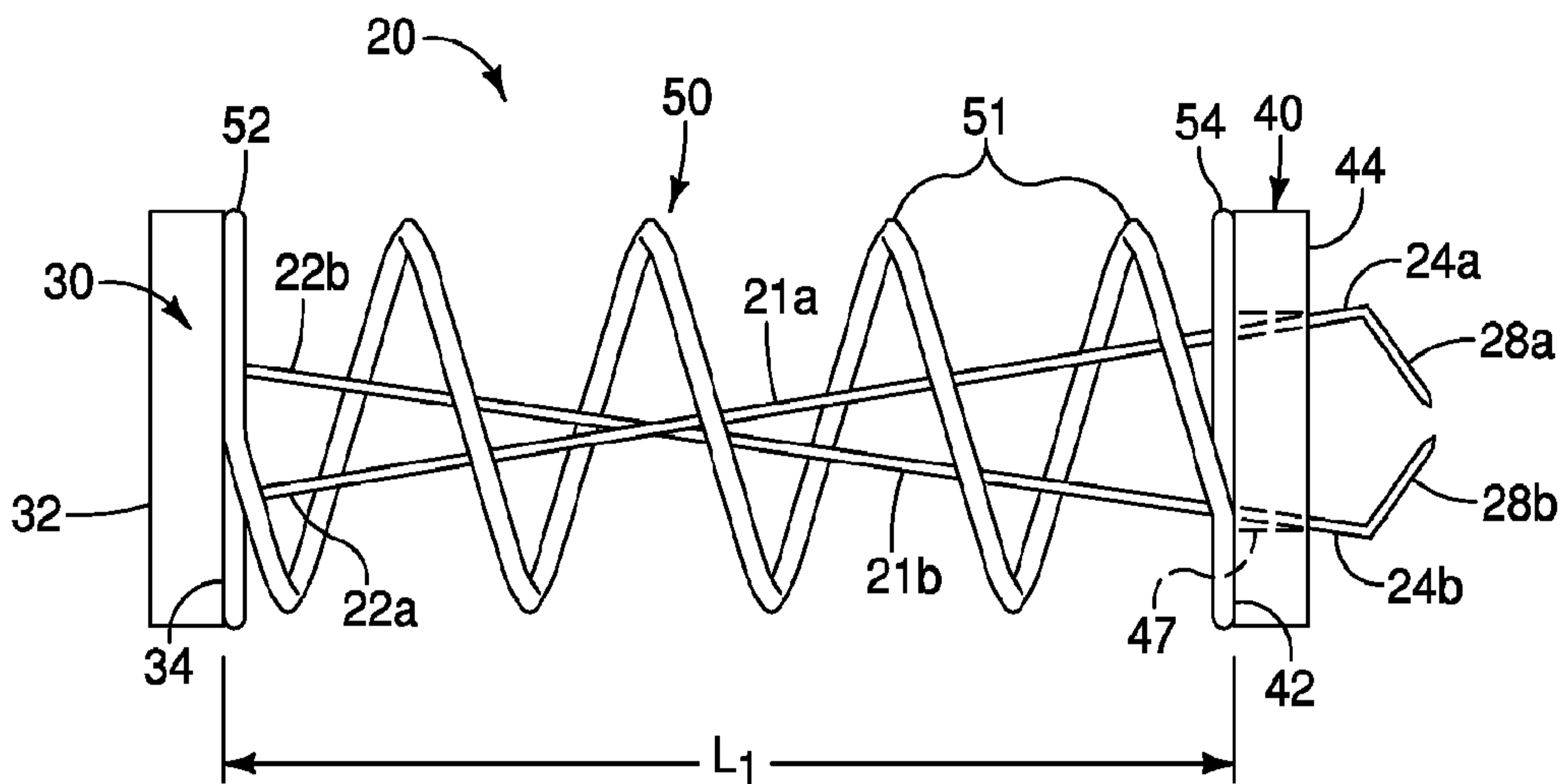


FIG. 1

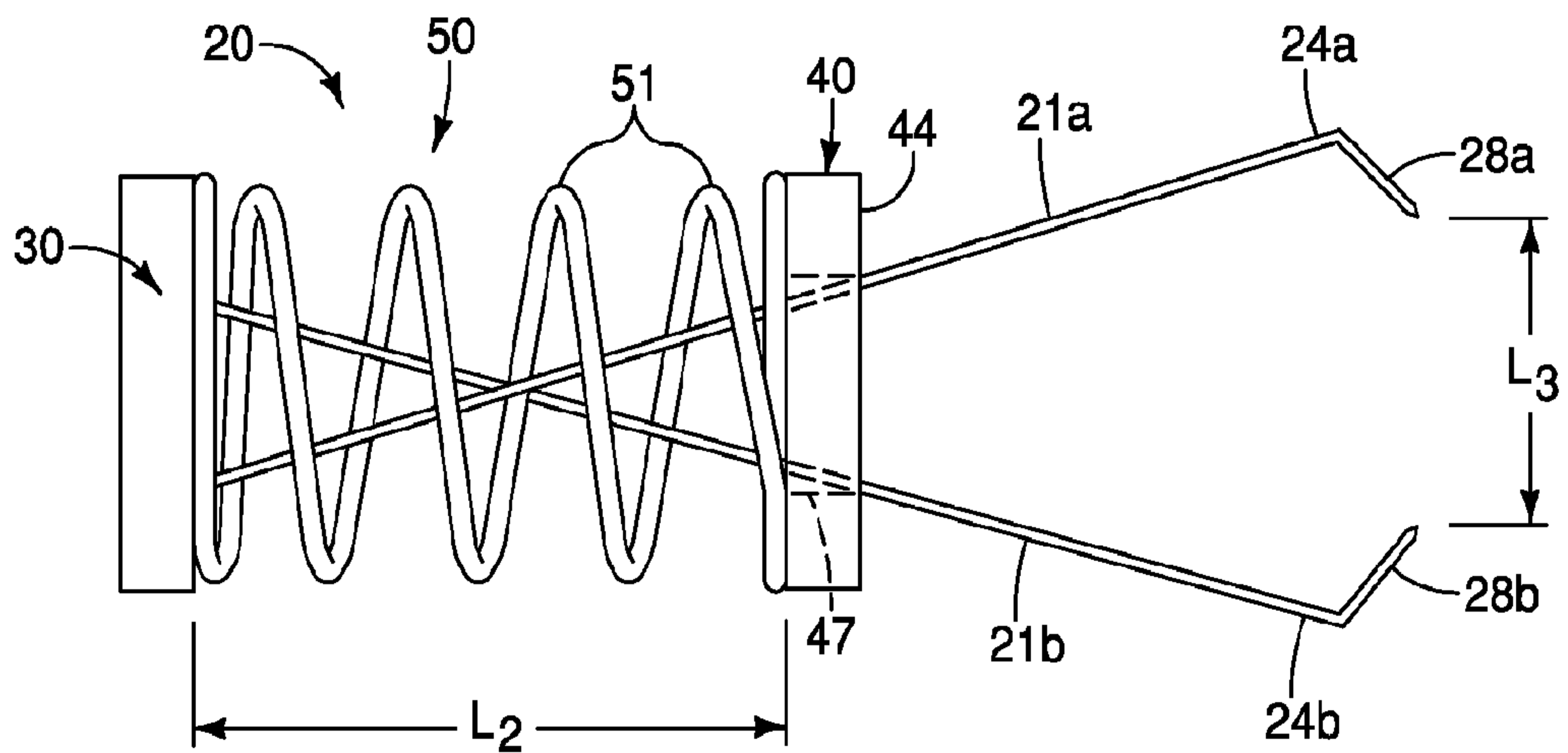


FIG. 2

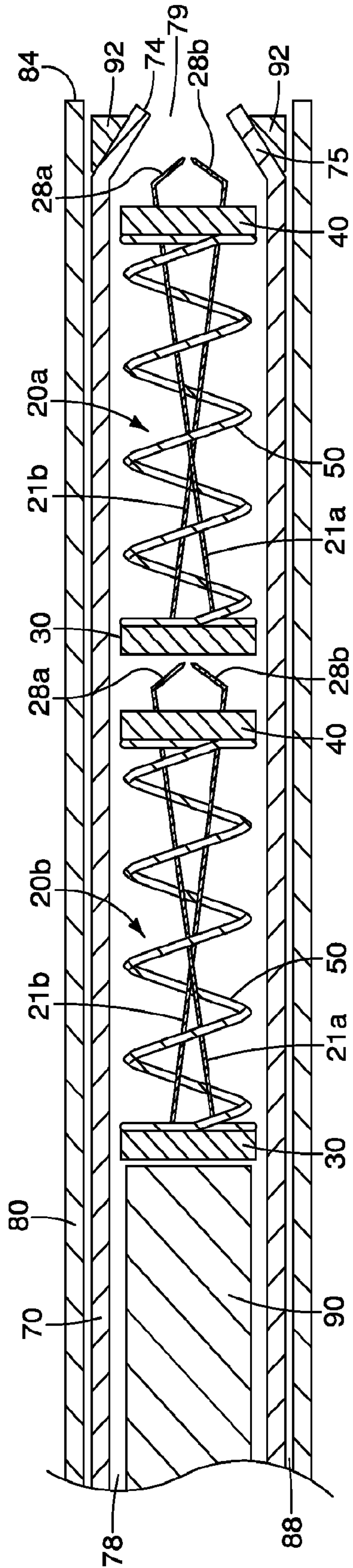


FIG. 3

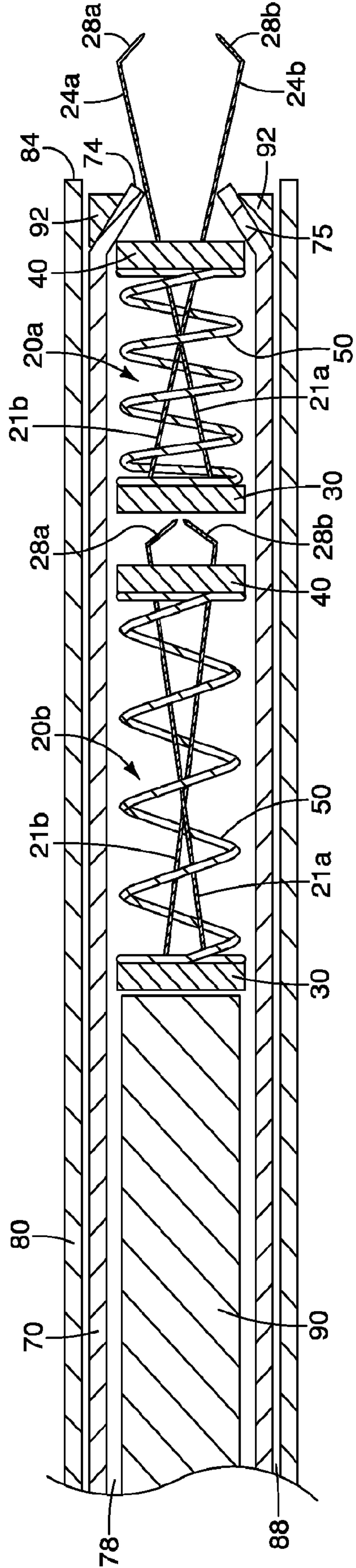


FIG. 4

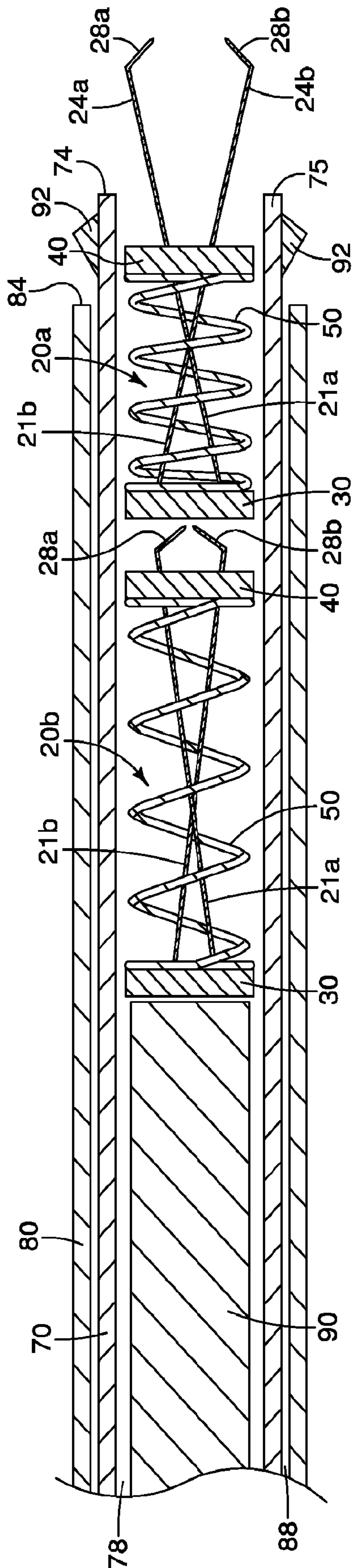


FIG. 5

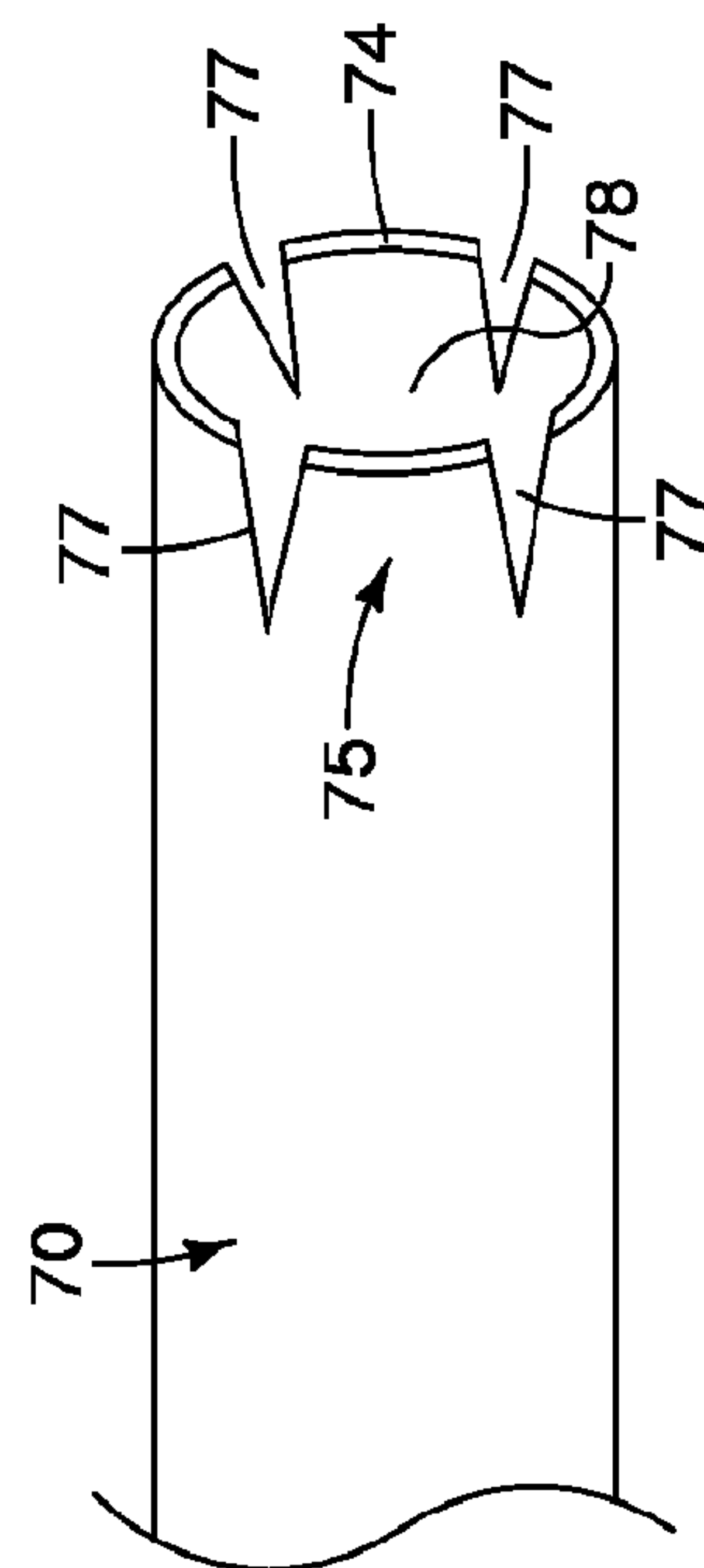


FIG. 6

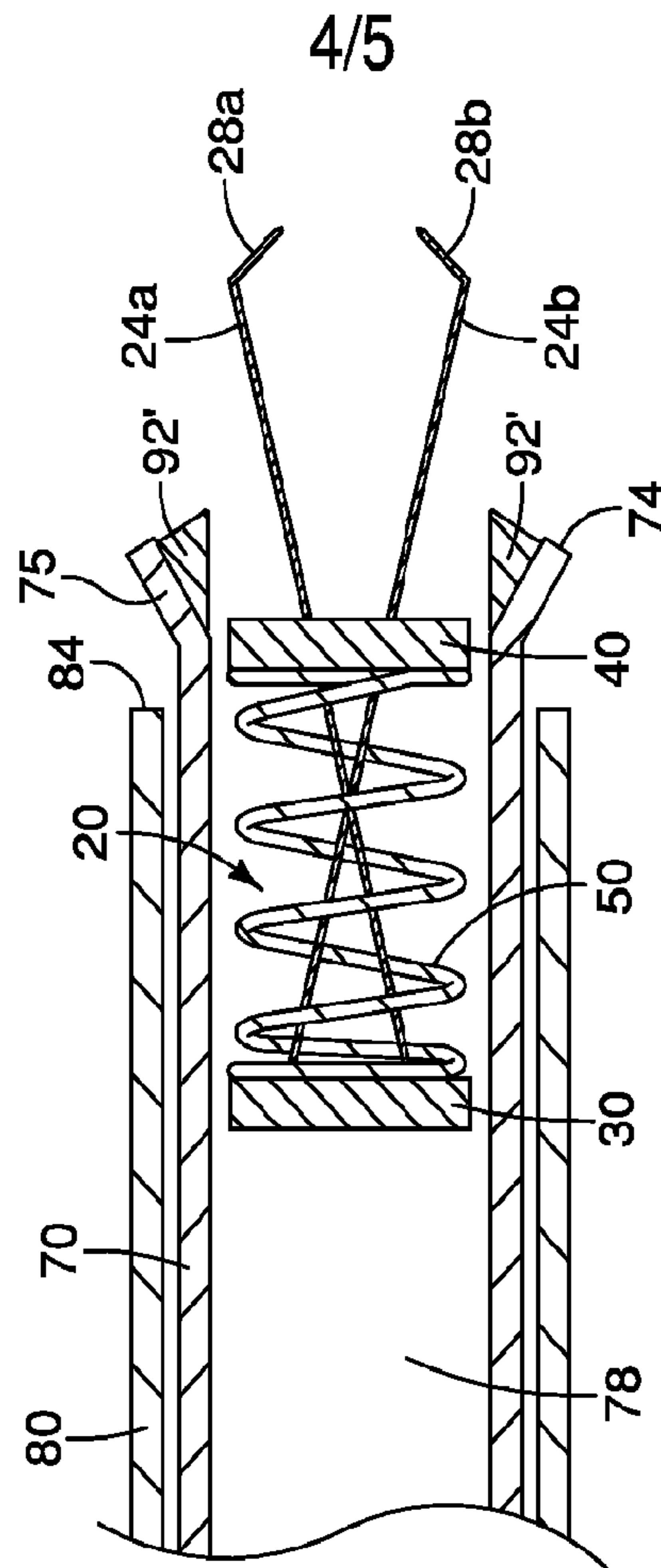


FIG. 8

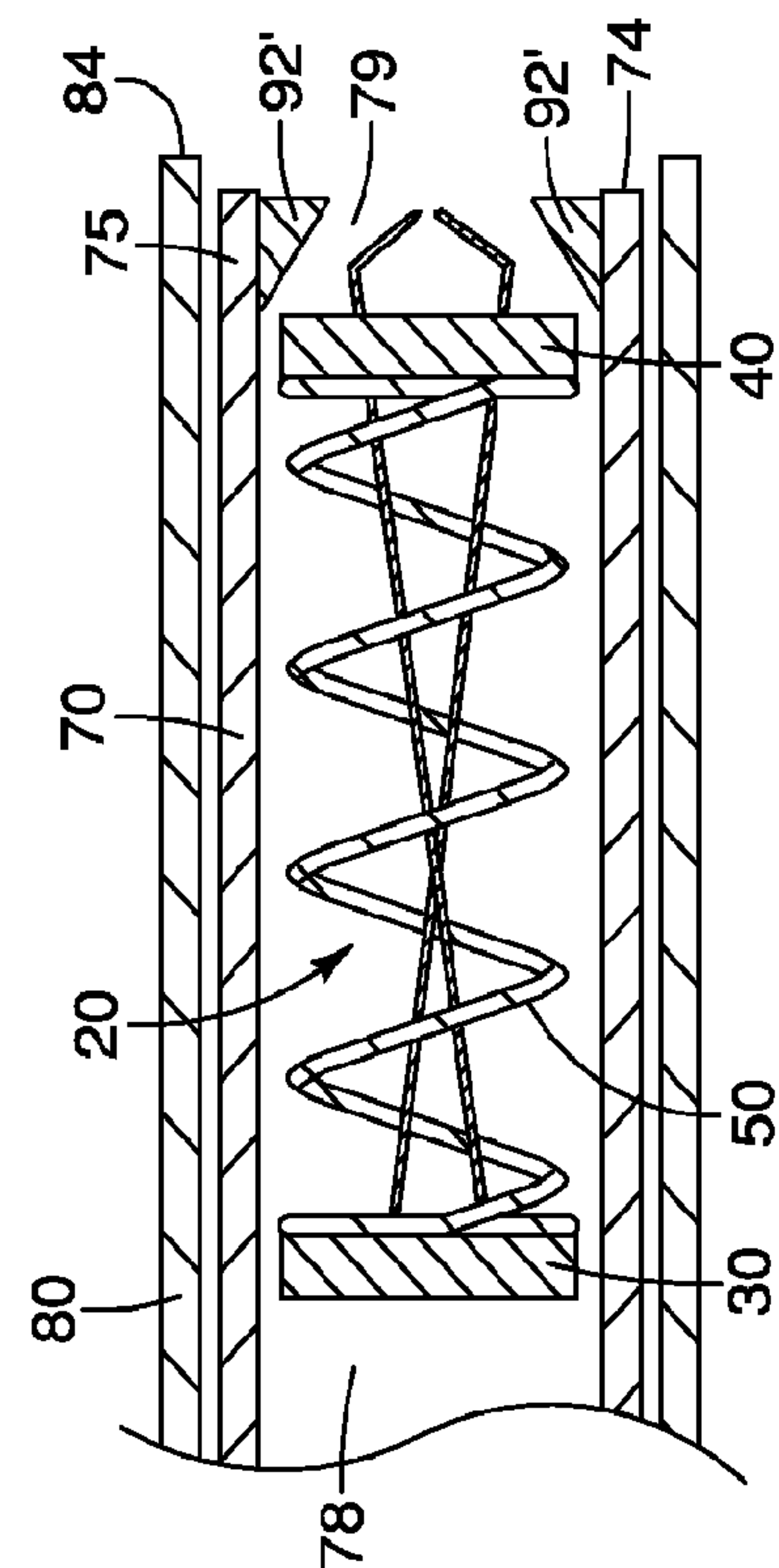


FIG. 7

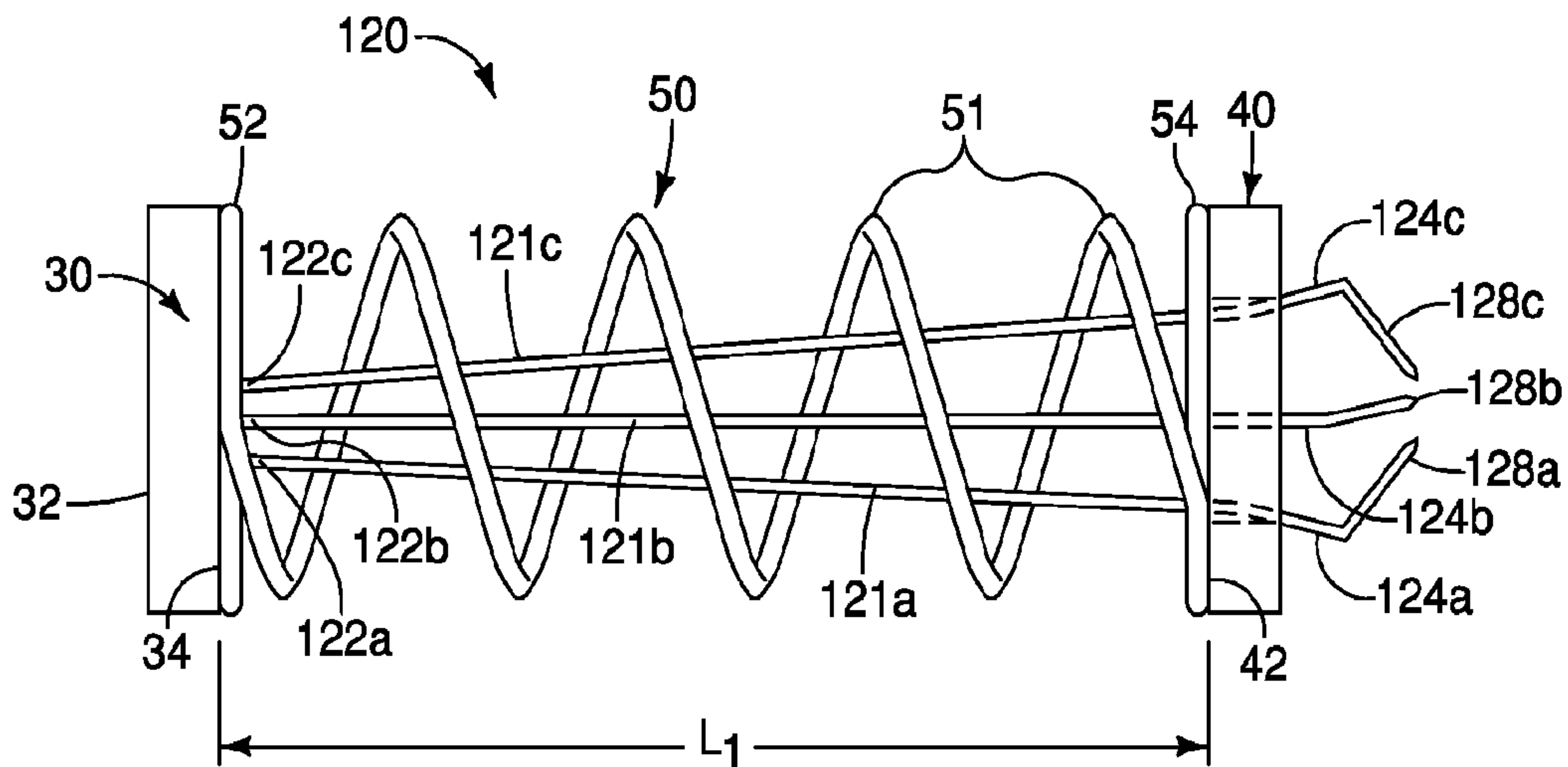


FIG. 9

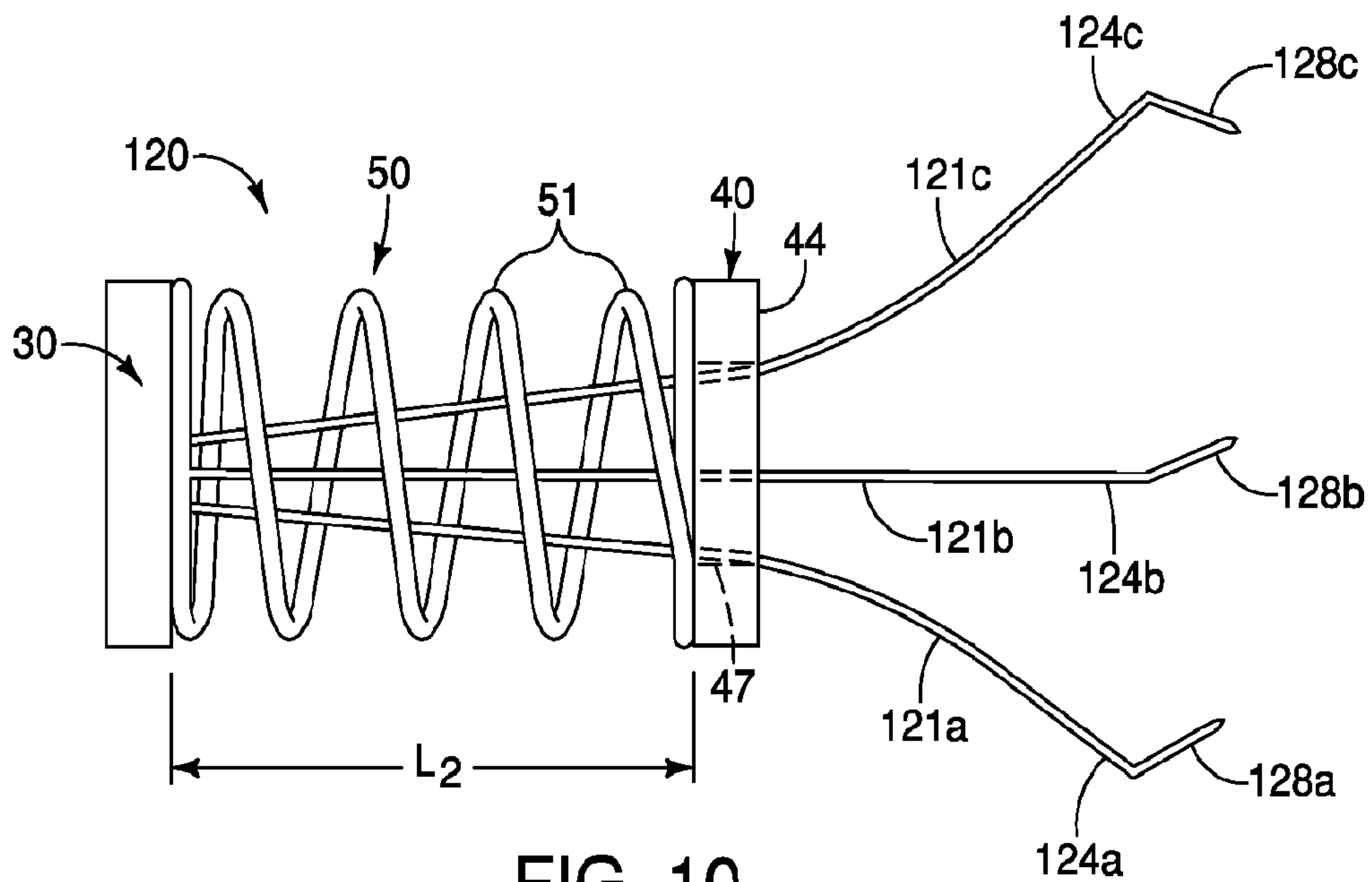


FIG. 10

