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- (71) **Applicant (for all designated States except US):**  
**ETHICON ENDO-SURGERY, INC** [US/US]; 4545  
Creek Road, Cincinnati, Ohio 45242 (US).
- (72) **Inventors; and**
- (75) **Inventors/Applicants (for US only):** **SMITH, Richard**  
C. [US/US]; 1493 Greystone Lane, Milford, Ohio 45150  
(US). **CROPPER, Michael S.** [US/US]; 3232 Charter  
Oak, Edgewood, Kentucky 41017 (US). **SCHWEM-**  
**BERGER, Richard C.** [US/US]; 8250 Eagle Creek Road,

Cincinnati, Ohio 45247 (US). **COE, Jonathan** [US/US];  
3912 St. John Terrace, Cincinnati, Ohio 45236 (US).  
**MEASAMER, John P.** [US/US]; 8780 Weller Station  
Drive, Cincinnati, Ohio 45249 (US).

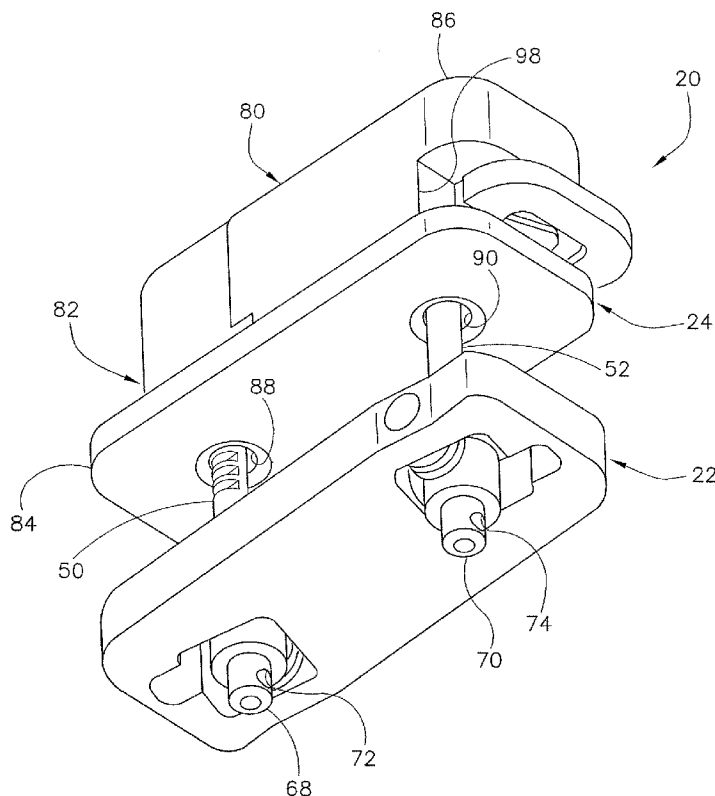
(74) **Agents:** **JOHNSON, Philip S.** et al.; One Johnson & John-  
son Plaza, New Brunswick, New Jersey 08933 (US).

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(54) **Title:** SURGICAL FASTENER



(57) **Abstract:** A surgical fastener for fastening tissue. The fastener includes a first piece having a needle, a second piece having an opening sized for receiving the needle, and a lock for holding the needle of the first piece in the opening of the second piece. At least a portion of the first piece, the second piece and/or the lock comprises a bio-absorbable material so the fastener becomes unfastened from the tissue over time.

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## SURGICAL FASTENER

### Background of the Invention

The present invention relates generally to a surgical fastener, and more particularly to a surgical fastener having absorbable elements.

Gastroesophageal reflux disease or persistent heartburn is caused by an improper relaxation of the lower esophageal sphincter, allowing acidic stomach contents to travel into the esophagus. If left untreated, chronic reflux may cause esophageal stricture, bleeding ulcers, perforation, and scarring. Continued reflux may lead to Barrett's esophagus, involving changes in the esophageal cells and possibly leading to cancer. Antacids and proton pump inhibitors are initially used to treat this condition. If these treatments are unsuccessful, surgical intervention is often recommended.

One interventional surgical method is known as Nissen fundoplication. This procedure involves wrapping a fundus of the stomach around the lower end of the esophagus and fastening it in place to make the lower esophageal sphincter less compliant. Traditionally, this procedure was accomplished by open surgery using sutures to secure the plicated fundus of the stomach around the esophagus without penetrating the stomach. More recently, laparoscopic Nissen procedures have been used. In some laparoscopic procedures, surgical fasteners are used with an endoscopic applicator. Several different fastener designs have been developed. Some of these designs include a two piece fastener. A first of these pieces includes a base having two straight elongate needles extending perpendicularly outward from the base generally parallel to each other. A second piece includes a receiver element having openings positioned for receiving the needles of the first piece and a lock for holding the needles in place once received in the openings. In use, tissue is gathered, the needles of the first piece are pushed through the gathered tissue and the openings of the second piece to hold the tissue and fastener in place. U.S. Patent No. 7,033,378 discloses one such fastener and an applicator used with this fastener.

The tissue held by the fastener grows together of time (e.g., during a period of between about six weeks and about ten weeks). After the tissue has grown together, the fastener becomes unnecessary and can be removed. A subsequent

surgery to remove the fastener is usually undesirable. Thus, there is a need for a fastener made from a bio-absorbable material that will be absorbed over time, allowing the fastener to release the tissue and exit the body.

### Summary of the Invention

Briefly, the present invention includes a surgical fastener for fastening tissue. The fastener comprises a first piece having a needle, a second piece having an opening sized for receiving the needle therein, and a lock for holding the needle of the first piece in the opening of the second piece. At least a portion of an element selected from a group of elements consisting of the first piece, the second piece and the lock comprises a bio-absorbable material so the fastener becomes unfastened from the tissue over time.

In another aspect, the present invention includes a surgical fastener for fastening tissue. The fastener comprises a first piece having a needle and a second piece having an opening sized for receiving the needle and adapted for holding the needle of the first piece in the opening of the second piece. At least a portion of an element selected from a group of elements consisting of the first piece and the second piece comprises a bio-absorbable material so the fastener becomes unfastened from the tissue over time.

In still another aspect, the present invention includes a surgical fastener for fastening tissue. The fastener comprises a first piece having a base and a plurality of needles attached thereto. Each of the needles is adapted for movement between a collapsed position in which the needle extends generally parallel to the base and a deployed position in which the needle extends outward from the base. The fastener further comprises a second piece having a plurality of openings therein. Each of the openings is sized and positioned for receiving one of the needles therein when the needles are in the deployed position. The fastener also includes a lock for holding each of the needles of the first piece in the respective openings of the second piece. At least a portion of an element selected from a group of elements consisting of the first piece, the second piece and the lock comprises a bio-absorbable material so the fastener becomes unfastened from the tissue over time.

Other features of the present invention will be in part apparent and in part pointed out hereinafter.

#### Brief Description of the Drawings

Fig. 1 is a perspective of a surgical fastener of the present invention;

Fig. 2 is a perspective of a male piece of the fastener of Fig. 1 shown with needles in a deployed position;

Fig. 3 is a perspective of the male piece shown with the needles in a collapsed position;

Fig. 4 is an alternate perspective of the surgical fastener;

Fig. 5 is a perspective similar to Fig. 1 with a latch body cover and base removed to facilitate viewing interior structure;

Fig. 6 is a perspective similar to Fig. 1 with a slide assembly in a locked position;

Fig. 7 is a perspective similar to Fig. 5 with the slide assembly in the locked position;

Fig. 8 is a perspective of a male piece of a fastener of a first alternative embodiment shown in a deployed position; and

Fig. 9 is a cross section taken along line 9-9 of Fig. 8.

Corresponding reference characters indicate corresponding parts throughout the several views of the drawings.

#### Detailed Description of the Preferred Embodiment

Referring now to the drawings and in particular to Fig. 1, a two-piece fastener of the present invention is designated in its entirety by the reference numeral 20. The fastener 20 includes a male piece, generally designated 22, and a female piece, generally designated 24.

As shown in Fig. 2, the male piece 22 includes a base 30 having two openings 32, 34. An elongate channel 36, 38 extends from each opening 32, 34. A recess 40, 42 is positioned adjacent each opening 32, 34, generally opposite one of the channels 36, 38. Two elongate needles or posts 50, 52 are rotatably coupled to the

base 30. Each of the needles 50, 52 is held in position in its corresponding opening 32, 34 by an axle pin 54, 56 so the needle is aligned with its corresponding channel 36, 38. Although the needles 50, 52 are adapted to pierce tissue, in one embodiment they have slightly rounded tips 58, 60 so they displace tissue rather than cut tissue. Torsion springs 62, 64 are fitted over each axle pin 54, 56 so one end is coupled to the corresponding needle 50, 52 and another end is biased against the base 30 in the corresponding recess 40, 42. The torsion springs 62, 64 operate to bias the corresponding needle 50, 52 toward a collapsed position in which the needles lie in the corresponding channel 36, 38 as shown in Fig. 3. Thus, when the male piece 22 and the female piece 24 are unfastened, the needles 50, 52 collapse so the tips 58, 60 are covered and cannot pierce tissue within the patient as the fastener 20 moves through the body. When the needles 50, 52 extend generally perpendicular to the base as shown in Fig. 2, the needles are in a deployed position. Although the needles 50, 52 may have other lengths departing from the scope of the present invention, in one embodiment each needle has a length measured from a center of the axle pin to its respective tip of between about ten millimeters and about twenty millimeters. In one particular embodiment, each needle 50, 52 has a length of at least about twenty millimeters so it can penetrate two full thicknesses of stomach tissue (each full thickness including a mucosal layer, a muscularis layer and a serosal layer). Although the needles 50, 52 may have other shapes and dimensions without departing from the scope of the present invention, in one embodiment each needle has a circular cross section and a diameter of between about one millimeter and about two millimeters. In one particular embodiment, each needle 50, 52 tapers from a diameter of less than about one millimeter at the tip to less than 1.5 millimeters at the base so the needles penetrate tissue easily, so the needles have sufficient strength to maintain alignment during tissue penetration and so the holes made by the needles in the tissue are not prone to leakage. In one embodiment, the needles 50, 52 lie in a common plane.

As further shown in Fig. 3, the channels 36, 38 may be oriented at an angle within the base 30 to accommodate longer needles 50, 52 without increasing a length of the base. Each needle 50, 52 includes a series of notches or grooves 66 near its tip 58, 60. A lower portion 68, 70 of each needle 50, 52 opposite the tip 58, 60

extends beyond the axle pin 54, 56 (Fig. 2) so that the lower portion extends beyond the base 30 when the needles are in the deployed position as shown in Fig. 2. The lower portions 68, 70 may be held by an applicator (not shown) to maintain the needles 50, 52 in the deployed position against the forces applied by the torsion springs 62, 64. The lower portions 68, 70 may also include openings 72, 74 for receiving portions of the applicator. Features of an exemplary applicator are described in detail in U.S. Patent No. 7,033,378.

As shown in Fig. 1, the female piece 24 includes a latch body, generally designated by 80, and a slide assembly, generally designated by 82, slidably connected to the latch body. The latch body 80 includes a base 84 and a cover 86. The base 84 includes two openings or holes 88, 90. These holes 88, 90 are sized and positioned to receive the needles 50, 52 of the male piece 22. Preferably, the holes 88, 90 are chamfered to guide the needles 50, 52 into them to permit modest misalignment of the needles and holes. As illustrated in Fig. 4, in one embodiment the cover 86 of the latch body is U-shaped, having an end portion 92 and two side portions 94 extending from the end portion. Thus, the end portion 92 and side portions 94 define a central opening 98 in the cover 86. The end portion 92 has an opening 98 adjacent the base 84 of the latch body 80 for accommodating a portion of the slide assembly 82 as will be explained in greater detail below.

As illustrated in Fig. 5, the slide assembly 82 includes a body 100, a lock 102, and a cover 104. The body 100 has two elongate slots 106, 108 sized and positioned for receiving the needles 50, 52 when extending through the holes 88, 90 (Fig. 1) in the base 84 of the latch body 80. As will be appreciated by those skilled in the art, the slots 106, 108 permit the slide assembly 82 to move relative to the latch body 80 between an unlocked position shown in Fig. 1 and a locked position shown in Fig. 6. As further shown in Fig. 5, the body 100 also has a recess 110 for receiving the lock 102. The lock 102 includes a central portion 112 sized and shaped for engaging the recess of the body 100 to hold the lock in position relative to the body. As will be appreciated by those skilled in the art, the lock 102 is captured between the slide assembly body 100 and the base 84 of the latch body 80 so the lock is retained in the recess 110. Two arms or catches 114, 116 extend outward in opposite directions from

the central portion 112 of the lock 102. The arms 114, 116 are flexible but biased toward a position in which they overlap the slots 106, 108 in the body 100. As will be described below, each arm 114, 116 selectively engages corresponding slots 66 in the needles 50, 52. Each of the arms 114, 116 includes an angled portion 118, 120 for guiding the respective arm into the corresponding slot. The arms 114, 116 also include stops 122, 124 for preventing the arms from blocking the slots 106, 108 when the needles 50, 52 are not present. During manufacture, the slide assembly cover 104 is attached to the latch slide 100 with pins 130 that are press fit into coupling holes 132, and the lock 102 is inserted into the recess 110. The slide assembly 82 is then captured between the latch body 80 and base 84.

Although the fastener 20 may have other dimensions without departing from the scope of the present invention, in one embodiment the fastener sized for passing through a patient's esophagus. For example, in one embodiment the male piece 22 has a length of about 15 mm, a width of about 6.25 mm, and a height of about 2 mm when the needles are in their collapsed positions. In this embodiment, the female piece 24 has a length of about 15 mm, a width of about 6.25 mm, and a height of about 4 mm. The coupled fastener 20 of this embodiment has a length of about 15 mm, a width of about 6.25 mm, and a height of about 6 mm plus the thickness of the tissue captured between the male and female pieces.

Although the pieces 22, 24 may be made of other materials without departing from the scope of the present invention, in one embodiment some of the pieces are made of bio-absorbable materials such as polydioxanone. Over time, after the fastened tissue grows together and the fastener 20 becomes redundant, portions of the fastener securing it together can be absorbed by the body so the fastener comes apart and passes through the alimentary tract. Although substantially all portions of the of the fastener 20 may be made of bio-absorbable materials, in one embodiment only the female piece 24 and the lock 102 are made of bio-absorbable materials and other components are made of titanium or titanium alloy, and anodized. In other embodiments, the coupled fastener 20, needles 50, 52 and/or axle pins 54, 56 are made of bio-absorbable materials and other components are made of titanium or titanium alloy, and anodized. In one particular embodiment, portions of the pieces 22,

24 are anodized to have a color that is distinct from natural colors of tissue of the stomach cavity so that the pieces may be easily seen during visual inspection during surgery. Preferred colors include purple, blue and black.

A conventional instrument (not shown) such as described in U.S. Patent No. 7,033,378 may be used to install the fastener 20 of the present invention. The male and female pieces 22, 24 of the fastener 20 are positioned on opposite sides of tissue to be fastened. The instrument holds the needles 50, 52 of the male piece 22 in the deployed position as shown in Fig. 2 so the needles can pierce the tissue and extend into the holes 88, 90 of the base 84 of the female piece 24 (Fig. 1). The chamfered openings of the holes 58, 60 guide the needles 50, 52 into the holes if the pieces 22, 24 are slightly misaligned. As will be appreciated by those skilled in the art, the applicator pushes the needles 50, 52 through the tissue and into the holes 88, 90 in the base 84 of the female piece 24. When the needles 50, 52 are inserted in the holes 88, 90 in the base, the slide cover 104 and latch cover 86 cover the sharp points 58, 60 of needles so they will not penetrate or injure adjacent tissue in the patient.

In one embodiment, the needles 50, 52 are straight as shown. However, in an alternative embodiment the needles are curved. As will be appreciated by those skilled in the art, the needles, 50, 52 travel along arcs as the applicator pushes the needles through the tissue and into the holes 88, 90 in the base 84 of the female piece 24. Because the arcs through which the needles 50, 52 travel correspond to their overall shape in this alternative embodiment, the needles follow their respective points 58, 60 and do not stretch or tear the tissue as they travel along their arced path.

Referring now to Figs. 6 and 7, once the fastener 20 is positioned around the tissue with a desired clamping force (or desired pressure), the slide assembly 82 is moved longitudinally relative to the latch body 80 until the body 100 abuts the cover 86 of the latch body 80. As the slide assembly 82 moves relative to the body 80, the arms 114, 116 engage the respective slots 66 of the needles 50, 52, thereby locking the male and female pieces 22, 24 together and clamping the captured tissue between them. The plurality of slots 66 permit the base 30 of the male piece 22 and the base 84 of the latch body 80 to be spaced at several different distances relative to each other when the fastener 20 is fastened to tissue. Moreover, the bases 30, 84 may be angled relative to

each other so that one needle is inserted farther into the latch body than the other needle. This permits the fastener 20 to accommodate various configurations of tissue. As a result of this adjustability, a desired force can be applied to tissue between the pieces 22, 24 whether or not the tissue has a uniform thickness. Accordingly, force can be limited to prevent tissue necrosis. When the slide assembly 82 is moved relative to the latch body 80, the arms 114, 116 will automatically find an appropriate slot 66. Further, the flexibility of the arms 114, 116 compensates for small amounts of misalignment between the arms and slots 66. If an arm 114, 116 of the lock 102 initially contacts a needle 50, 52 at a non-slotted location, the flexibility of the arm will permit it to move into an adjacent slot 66. When locked, a gap 134 is formed between the latch body 80 and the cover 86 of the slide assembly 82 as shown in Fig. 6.

After the male and female pieces 22, 24 have been locked together, they may be unlocked and separated from each other. To unlock the fastener 20, the slide assembly 82 is moved relative to the latch body 80 so the gap 134 closes. As the gap 134 closes, the arms 114, 116 disengage the slots 66 so the pieces 22, 24 can be pulled apart. It is envisioned that the fastener 20 can be unlocked, separated and retrieved from the patient using a standard endoscopic snare device (not shown). The snare device is looped around the slide body 104 and cover 86. As the snare loop is pulled, the snared parts are pulled toward each other by decreasing the size of the snare loop. As discussed above, the needles 50, 52 are spring-biased to collapse into the channels 36, 38 of the base 30 of the male piece 22 when not retained against the bias of the torsion springs 62, 64. This operates to prevent injury to the patient when the pieces 22, 24 are unlocked and separated, or if the male piece 22 inadvertently becomes separated from the applicator or from the female piece 24. Given the size of the pieces 22, 24 and the protection of sharps from exposure to the patient, the pieces may be safely passed through the gastrointestinal system.

It is recognized that various other configurations can be used for locking the female piece 24 relative to the needles 50, 52 of the male piece 22. Examples of alternative configurations are included in U.S. Patent No. 7,033,378.

Fig. 8 illustrates an alternative embodiment of a male piece, generally designated by 140, of the present invention. This male piece 140 includes needles 142,

144 rigidly mounted on a base 146 having a hinge 148 positioned between the needles. Although the base 146 may be made of other materials with departing from the scope of the present invention, in one embodiment the base is made of polydioxanone. Although the needles 142, 144 may be mounted on the base 146 in other ways without departing from the scope of the present invention, in one embodiment the needles are held in position in the base as shown in Fig. 9 by plugs 150, 152 made of a bio-absorbable material such as polydioxanone. Over time, the plugs 150, 152 are absorbed by the patient's body so the fastener comes apart and passes through the alimentary tract. Each of the needles 142, 144 includes a collar 154, 156, respectively, for strengthening the connection between the needles and the plugs 150, 152. In one embodiment, each of the needles 142, 144 has a slot 158, 160 for releasably connecting the male piece 140 to a female piece as described above. In an alternative embodiment, the needles 142, 144 have a series of slots as described above with respect to the first described embodiment. Other features of the needles 142, 144 are similar to those described above with respect to the first embodiment and will not be described in detail. For example, each of the needles 142, 144 has a slightly rounded tip 162, 164, respectively, so they displace tissue rather than cut tissue. In one embodiment, the hinge 148 is biased such as by torsion springs (not shown) so that the hinge folds until the tips 162, 164 of the needles 142, 144 contact. In this folded configuration, the tips 162, 164 are less able to pierce tissue within the patient as the male piece 140 moves through the body.

When introducing elements of the present invention or the preferred embodiment(s) thereof, the articles "a", "an", "the" and "said" are intended to mean that there are one or more of the elements. The terms "comprising", "including" and "having" are intended to be inclusive and mean that there may be additional elements other than the listed elements.

As various changes could be made in the above constructions without departing from the scope of the invention, it is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense.

Claims

## WHAT IS CLAIMED IS:

1. A surgical fastener for fastening tissue, said fastener comprising:  
a first piece having a needle;  
a second piece having an opening sized for receiving said needle therein;  
and  
a lock for holding the needle of said first piece in the opening of said second piece;  
wherein at least a portion of an element selected from a group of elements consisting of the first piece, the second piece and the lock comprises a bio-absorbable material so the fastener becomes unfastened from the tissue over time.
2. A surgical fastener as set forth in claim 1 wherein said first piece includes a base and said needle extends from said base.
3. A surgical fastener as set forth in claim 2 wherein said needle is pivotally attached to said base for movement between a collapsed position in which the needle extends generally parallel to the base and a deployed position in which the needle extends outward from the base.
4. A surgical fastener as set forth in claim 3 wherein said needle is biased toward the collapsed position.
5. A surgical fastener as set forth in claim 4 wherein the base includes a channel for receiving the needle when in the collapsed position.
6. A surgical fastener as set forth in claim 3 further comprising a pin pivotally attaching the needle to said base, the pin comprising the bio-absorbable material.

7. A surgical fastener as set forth in claim 2 further comprising a plug joining the needle to the base, said plug comprising the bio-absorbable material.

8. A surgical fastener as set forth in claim 2 wherein the needle comprises the bio-absorbable material.

9. A surgical fastener as set forth in claim 2 wherein the lock comprises the bio-absorbable material.

10. A surgical fastener as set forth in claim 1 wherein said needle includes a groove and said lock engages the groove to hold the needle of said first piece in the opening of said second piece.

11. A surgical fastener as set forth in claim 10 wherein said lock includes an arm that engages the groove in the needle to hold the needle of said first piece in the opening of said second piece.

12. A surgical fastener as set forth in claim 11 wherein said arm is biased toward the needle when the needle of said first piece is inserted in the opening of said second piece.

13. A surgical fastener for fastening tissue, said fastener comprising:  
a first piece having a needle; and  
a second piece having an opening sized for receiving said needle and adapted for holding the needle of said first piece in the opening of said second piece;  
wherein at least a portion of an element selected from a group of elements consisting of the first piece and the second piece comprises a bio-absorbable material so the fastener becomes unfastened from the tissue over time.

14. A surgical fastener for fastening tissue, said fastener comprising:  
a first piece having a base and a plurality of needles attached thereto, each of said plurality of needles being adapted for movement between a collapsed

position in which the needle extends generally parallel to the base and a deployed position in which the needle extends outward from the base;

a second piece having a plurality of openings therein, each of said plurality of openings being sized and positioned for receiving one of said plurality of needles therein when said needles are in the deployed position; and

a lock for holding each of said plurality of needles of said first piece in the respective openings of said second piece;

wherein at least a portion of an element selected from a group of elements consisting of the first piece, the second piece and the lock comprises a bio-absorbable material so the fastener becomes unfastened from the tissue over time. .

15. A surgical fastener as set forth in claim 14 wherein each of said plurality of needles is pivotally attached to said base for movement between the collapsed position and the deployed position.

16. A surgical fastener as set forth in claim 15 wherein each of said plurality of needles is biased toward the collapsed position.

17. A surgical fastener as set forth in claim 16 wherein the base includes a plurality of channels for receiving each of said plurality of needles when in its collapsed position.

18. A surgical fastener as set forth in claim 15 further comprising a plurality of pins, each of said plurality of needles being pivotally attached to said base by one of said plurality of pins, each pin of said plurality of pins comprising the bio-absorbable material.

19. A surgical fastener as set forth in claim 14 further comprising a plug joining at least one of said needles to the base, said plug comprising the bio-absorbable material.

20. A surgical fastener as set forth in claim 14 wherein each of said needles comprises the bio-absorbable material.

21. A surgical fastener as set forth in claim 14 wherein the lock comprises the bio-absorbable material.

22. A surgical fastener as set forth in claim 14 wherein at least one of said plurality of needles includes a groove and said lock engages the groove to hold the grooved needle in the opening of said second piece.

23. A surgical fastener as set forth in claim 22 wherein each of said needles includes a groove and said lock engages the groove to hold the grooved needle in the opening of said second piece.

24. A surgical fastener as set forth in claim 23 wherein each of said needles includes a plurality of grooves including said aforesaid groove and said lock engages at least one of said plurality of grooves to hold the needle in the opening of said second piece.

25. A surgical fastener as set forth in claim 22 wherein said lock includes an arm that engages the groove in the grooved needle to hold the grooved needle of said first piece in the opening of said second piece.

26. A surgical fastener as set forth in claim 25 wherein said arm is biased toward the grooved needle when the grooved needle of said first piece is inserted in the opening of said second piece.

FIG. 1

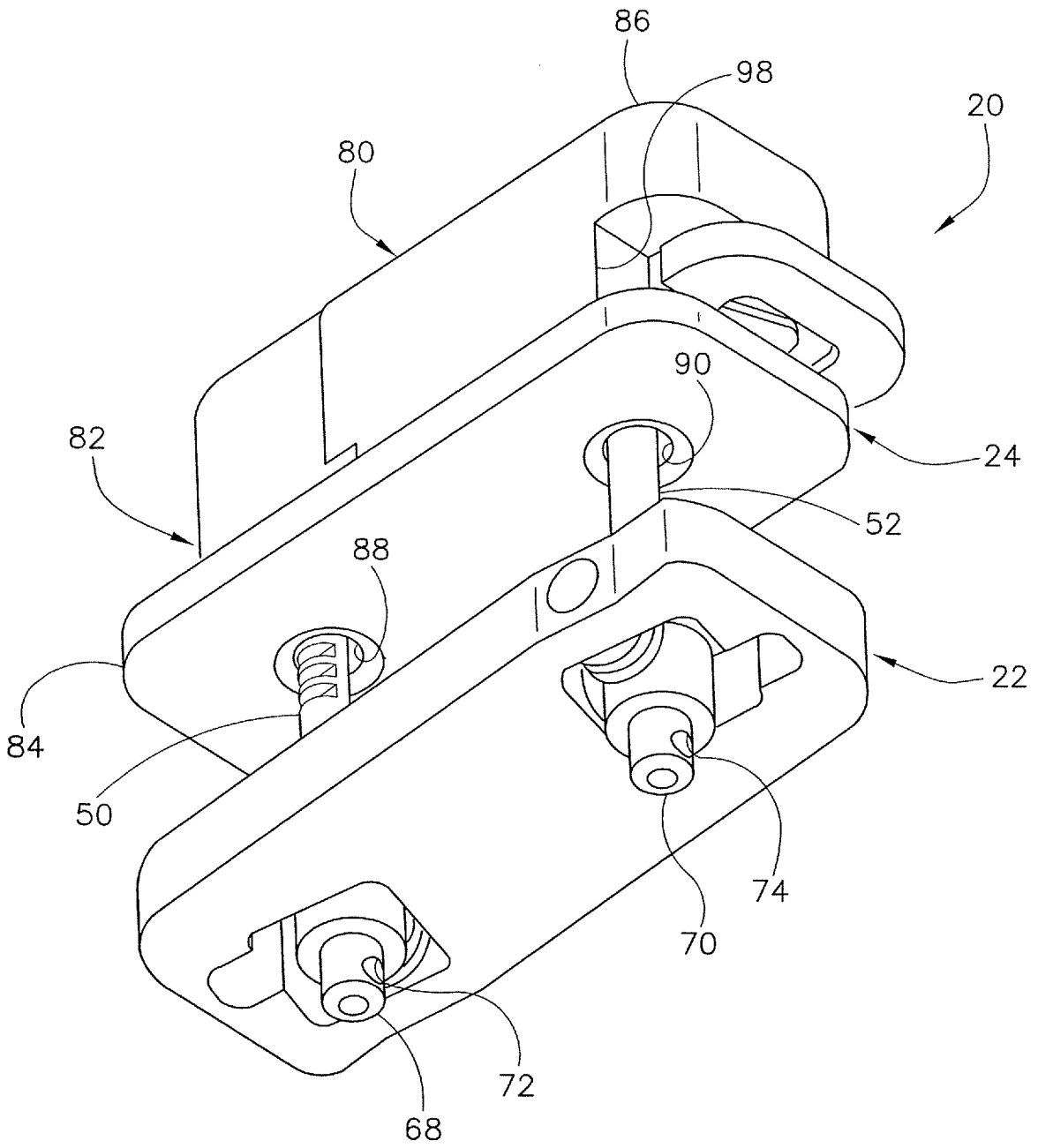


FIG. 2

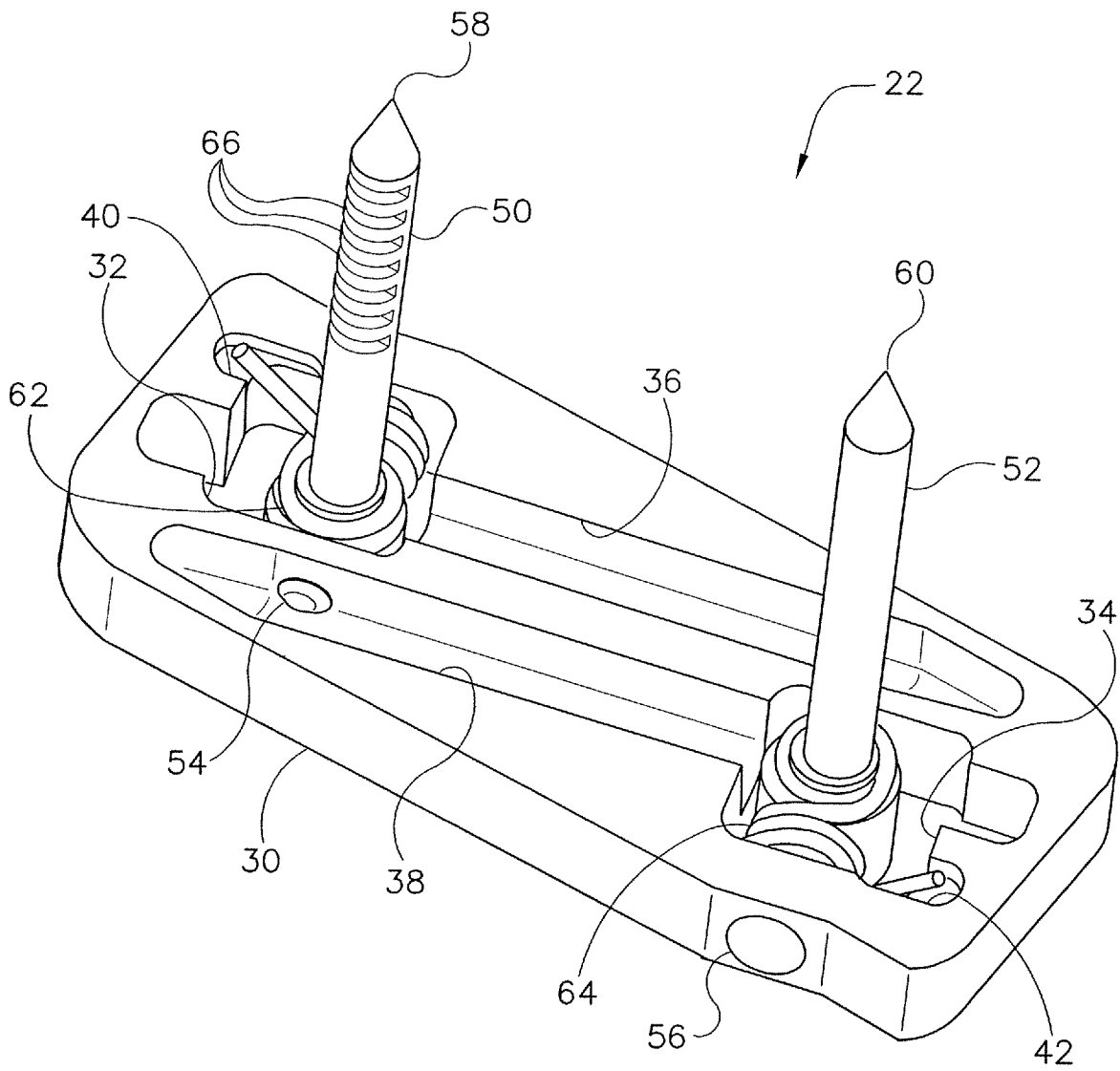
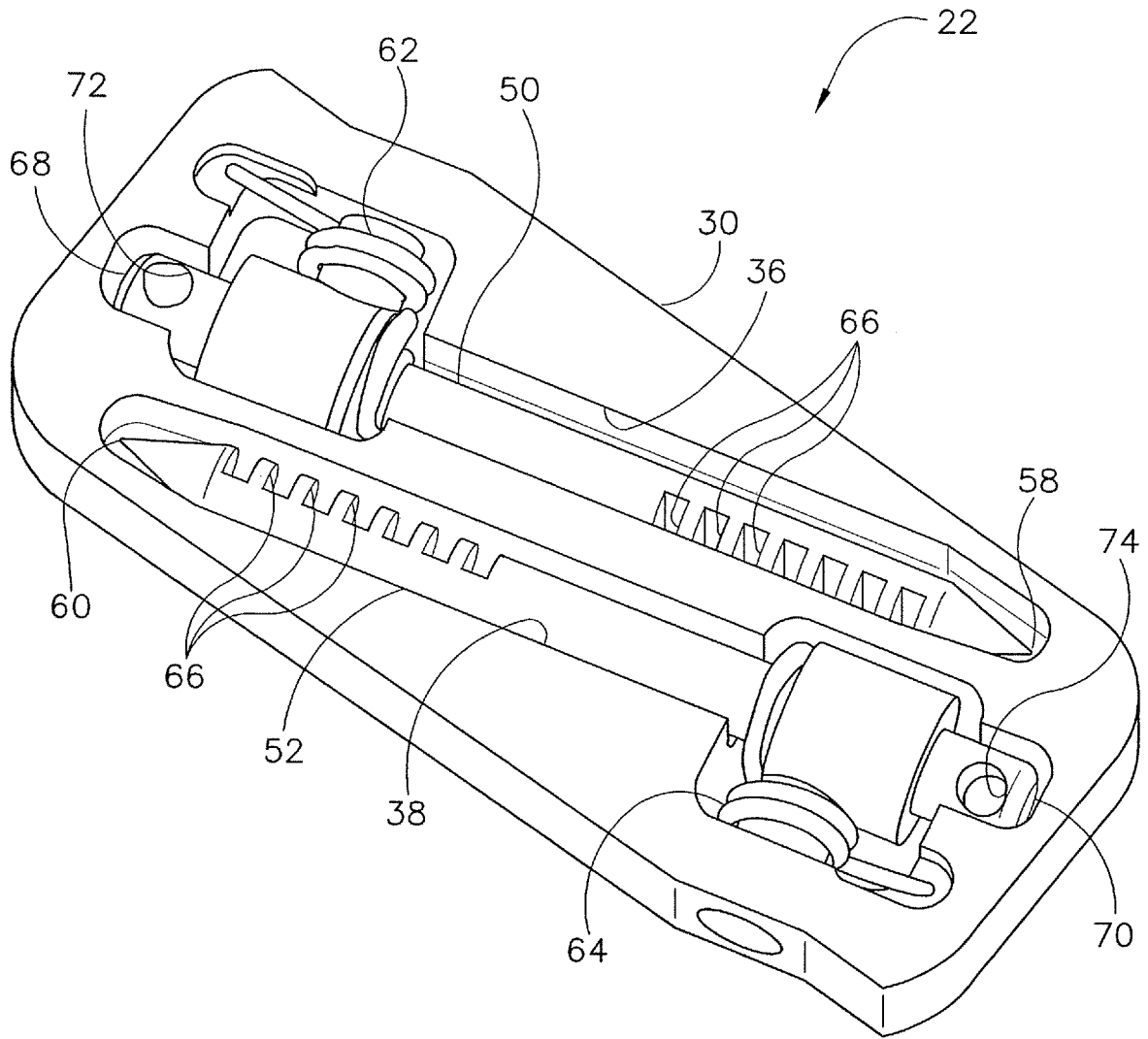


FIG. 3



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FIG. 4

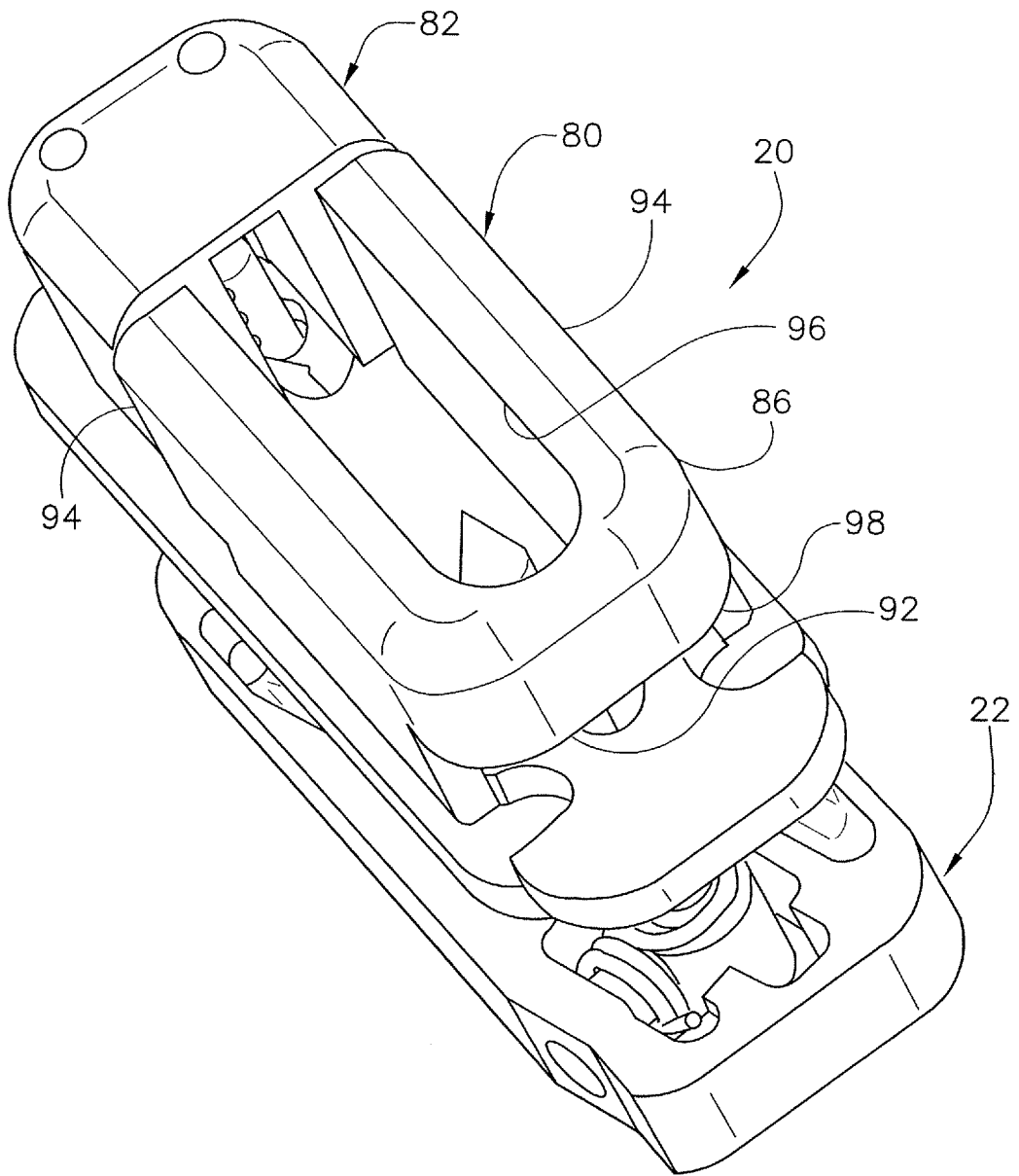


FIG. 5

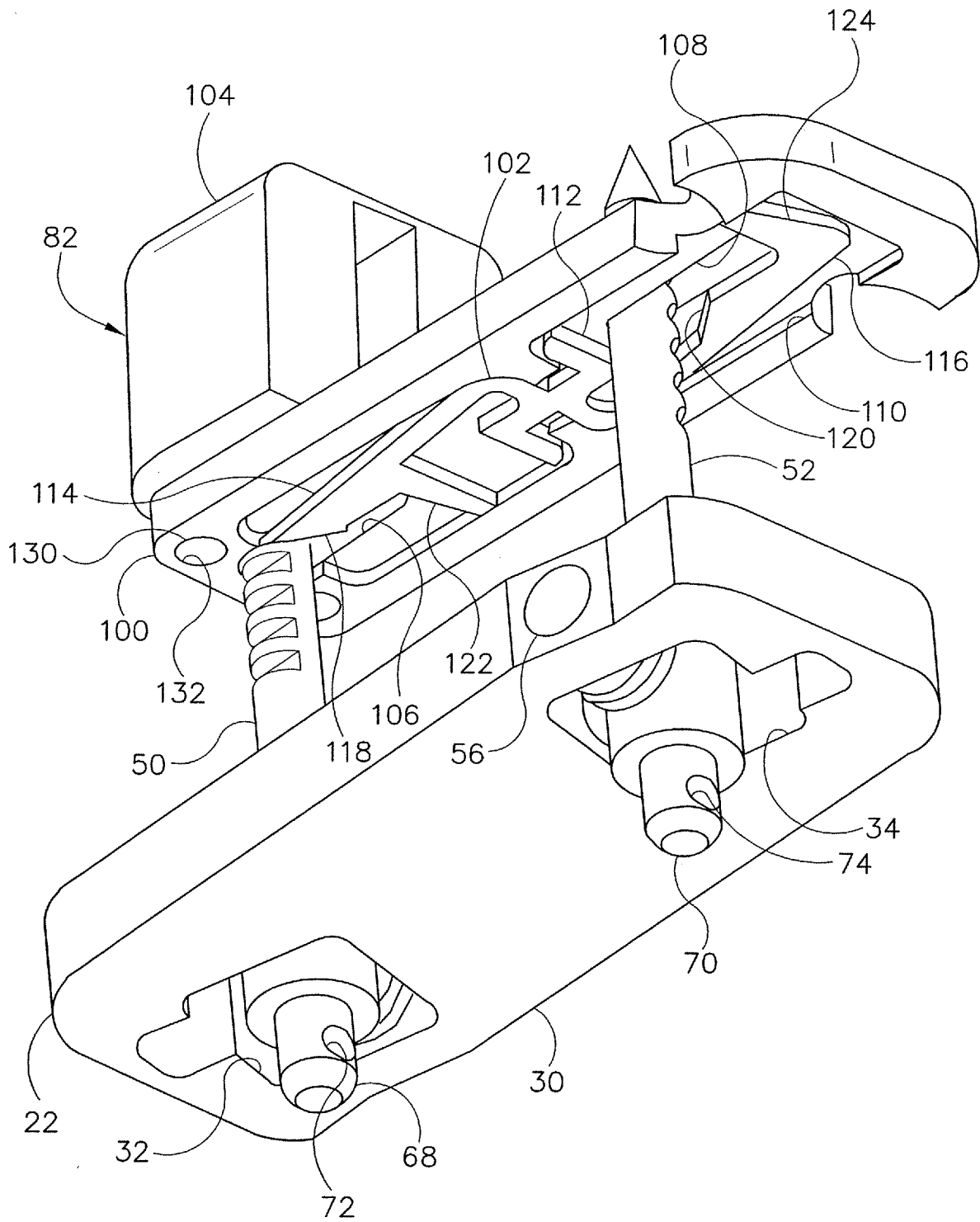


FIG. 6

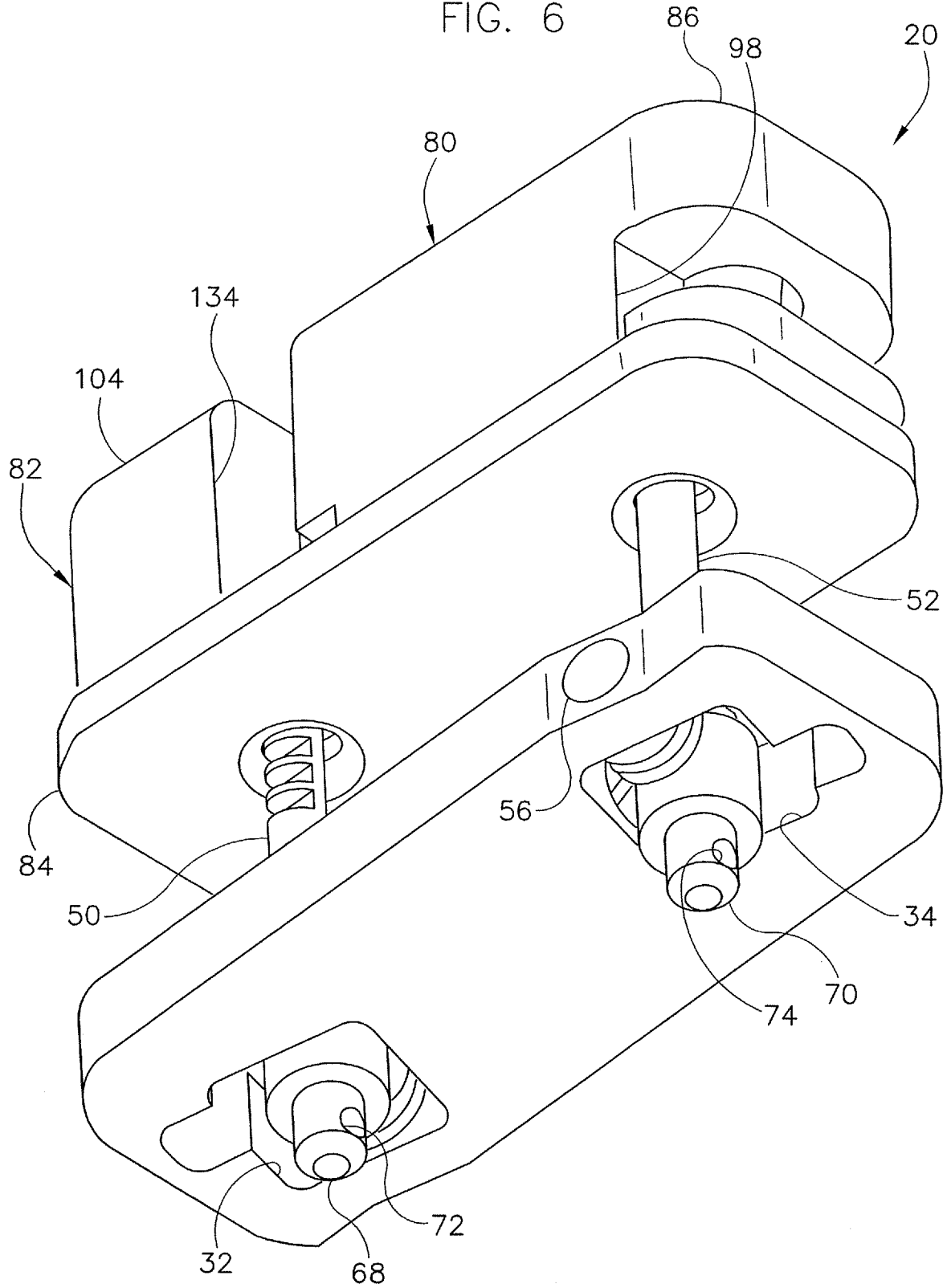


FIG. 7

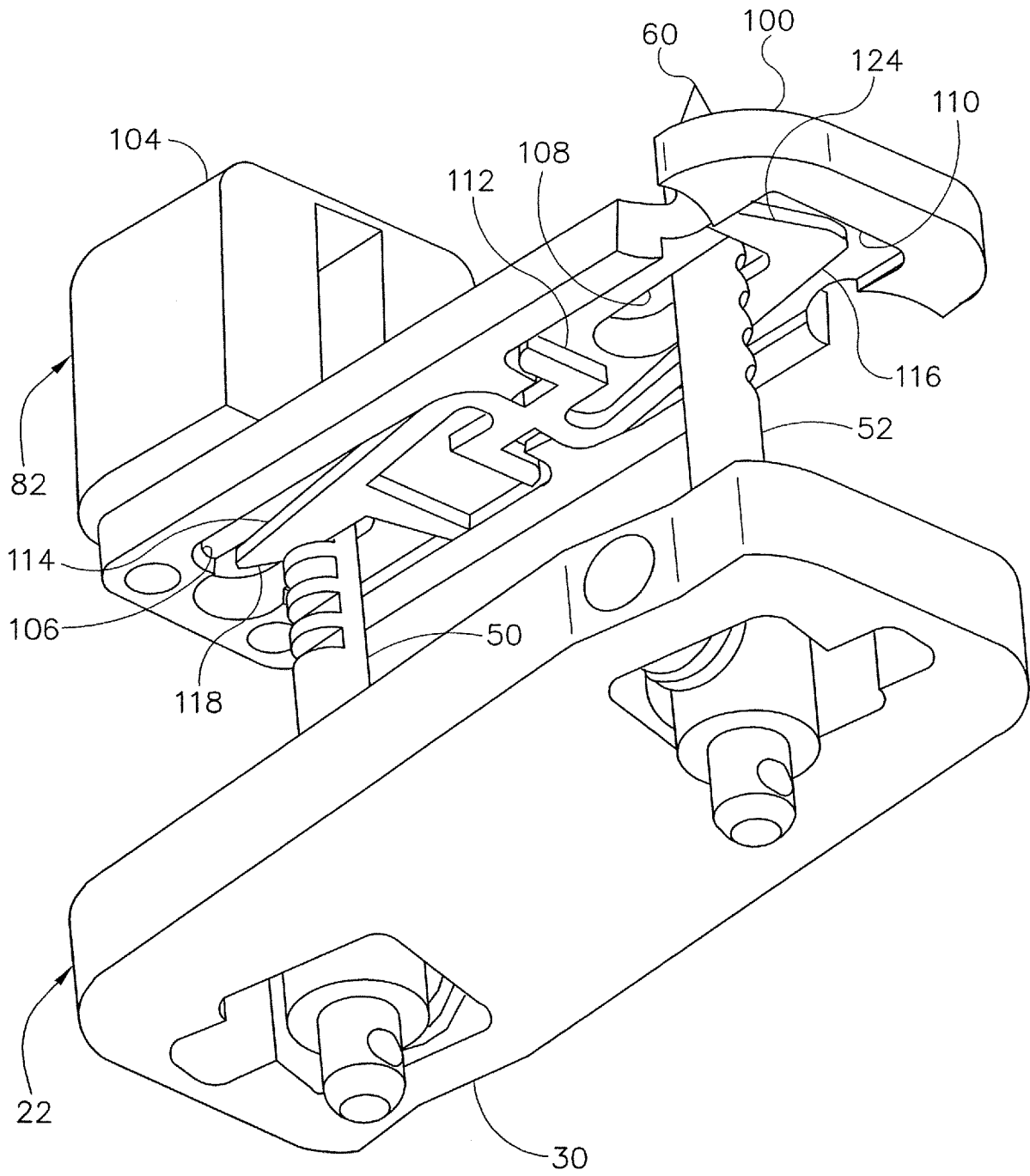


FIG. 8

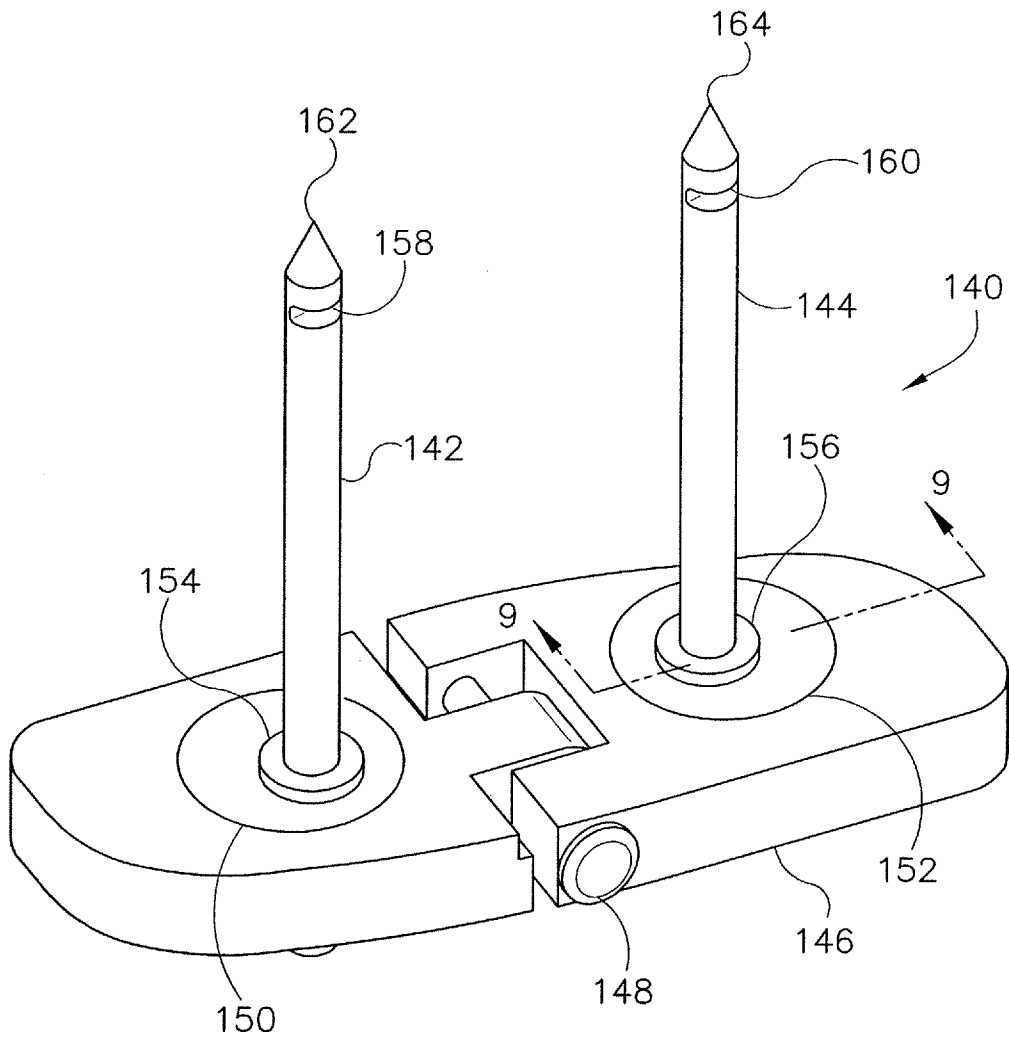


FIG. 9

