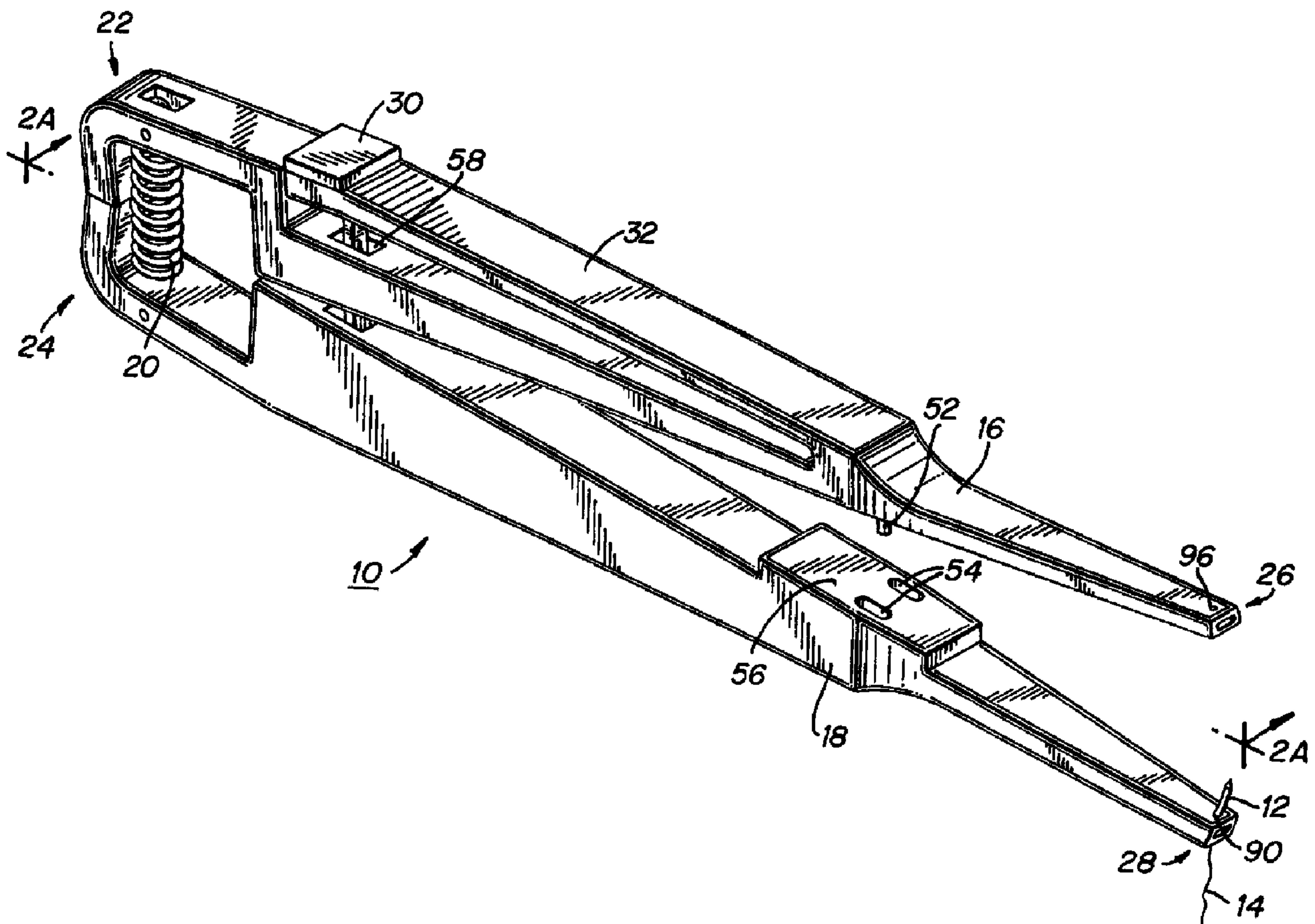




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(57) Abrégé/Abstract:

There is disclosed an apparatus for suturing tissue comprising: a) first and second arms; b) a first jaw supported by the first arm and a second jaw supported by the second arm, the jaws being relatively movable between an open and closed position; c) a first



(57) **Abrégé(suite)/Abstract(continued):**

needle securing member movably positioned in the first jaw and a second needle securing member movably positioned in the second jaw; d) a reciprocating mechanism for moving the first and second needle securing members between a needle securing and a needle release position; and e) a retaining mechanism for preventing separation of the first and second jaws during relative movement of the arms to a closed position.

ABSTRACT

There is disclosed an apparatus for suturing tissue comprising: a) first and second arms; b) a first jaw supported by the first arm and a second jaw supported by the second arm, the jaws being relatively movable between an open and closed position; c) a first needle securing member movably positioned in the first jaw and a second needle securing member movably positioned in the second jaw; d) a reciprocating mechanism for moving the first and second needle securing members between a needle securing and a needle release position; and e) a retaining mechanism for preventing separation of the first and second jaws during relative movement of the arms to a closed position.

VASCULAR SUTURING APPARATUS

This application is a division of copending Canadian Application Serial No. 2,186,077, filed September 20, 1996.

1. Technical Field

The technical field relates generally to surgical suturing instrumentation and, more particularly, to surgical suturing apparatus and method for suturing vascular tissue sections together.

2. Description of Related Art

During many surgical procedures it is often necessary to join or even rejoin portions of vascular tissues or vessels to form an anastomosis. Various methods of joining vascular tissues to create an anastomosis are used, such as, for example, suturing, stapling or clipping the ends of the vessels together. Additionally, various stents may be used to join the vessels together and create the anastomosis. Where vessels are joined open end to open end it is termed an "end to end" anastomosis. In certain surgical procedures it is often desirable to join a free open end of one vessel to an incision in the side of another vessel to create an "end to side" anastomosis or even an incision in the side of another vessel to form "side-to-side" anastomosis.

In some instances suturing of vessels is preferred over stapling or clipping the vessels. Due to the small size of the vessels, a very small suturing needle is used having a length of suture material

attached thereto to suture the vessels together. The suturing needle is typically grasped by a needle holder and passed through one vessel and then the opposite vessel. The procedure is repeated to thread or impart a series of stitches to the vessels to suture them together.

Because of the extremely small size of the suturing needle used, typically on the order of ten thousands of an inch in diameter, handling problems may arise while manipulating the suturing needle through the vascular tissues. For example, upon piercing a vessel, the needle must be pushed through the vessel, released by the needle holder at one end of the needle and subsequently grasped at the opposite end of the needle to draw the needle and suture through the vessel thus requiring the release of the needle and suture during the procedure. Release of the needle is often undesirable and may pose problems in regaining control of the needle. To avoid this, it may become necessary to use two needle holders, one positioned on either side of the vessel, to continually grasp the needle, thereby requiring two hands to perform the operation. Additionally, precise control of the needle is often difficult when using typical needle holders. The small size of the needle also makes it difficult and time consuming to recover if dropped during the surgical procedure.

As noted above, the vascular sections to be sutured are typically extremely small. Suturing of such vascular tissue sections is often performed under magnification by equipping the surgeon with special magnifying glasses. The use of these magnifying glasses, while enlarging the view of the vascular tissues and needle, reduces the field of view within which the surgeon has to operate. Thus, as the needle and suture material are passed through the vessels and pulled to draw the suture material through, it often becomes necessary to move the needle holder and needle from the

field of view. This may require the surgeon to look away from the field of view containing the vessel sections to be sutured and may present problems in repositioning the needle within the magnified field of view to form another stitch in the vascular tissues and increases the time required to suture the vessels together. Even when magnifying glasses are not being used, the surgeon needs to look at the needle as it is moved away from the surgical site to pull the
10 length of suture through the vessel and is passed to his other hand to be re-gripped. Due to the minute size of the vessels, it takes time for the surgeon to refocus on the surgical site to once again pass the needle and suture through the vessel. This repeated change of focus is time consuming and can place a strain on the surgeon's eyes.

Thus, it would be advantageous to have a surgical suturing apparatus and a method of suturing vessels which are particularly suited to suturing vascular tissues in anastomosis procedures. It would further be advantageous to
20 have a surgical suturing apparatus which is operable with a single hand and is capable of maintaining precise and constant control of the needle as it is passed from one needle holding arm of the apparatus to another to avoid release of the needle during the suturing operation. It would also be advantageous to have a surgical suturing apparatus which is capable of suturing vascular tissue sections together with limited hand, apparatus and needle movement in order to maintain the entire suturing operation within a restricted field of view.

30 In accordance with an embodiment of the present invention there is provided an apparatus for suturing tissue comprising: a) a pair of needle holding tweezer like arms pivotably interconnected at a proximal end for movement between open and closed positions; and b) a retaining

mechanism operatively connected to the pair of arms distally of the interconnection and engageable with a surgical needle to secure the surgical needle alternately within each arm of the pair of arms; and c) a cam actuating lever operatively connected to one of the arms such that the retaining mechanism is actuated as the arms are approximated towards one another.

Preferably, the retaining mechanism comprises a
10 retaining arm extending from one of the pair of arms, the retaining arm having a hook portion engageable with a shelf formed in the other of said pair of arms.

Preferably, the apparatus further comprises a ratchet mechanism having a pawl extending from one of the pair of arms and engageable with a rack positioned on the other of said pair of arms.

In a further preferred embodiment, a camming member extends from one of the pair of arms, the camming member camming the hook portion into engagement with the
20 shelf.

There is also disclosed a method of threading a suture through a vascular tissue section which includes the step of providing an apparatus having a first arm with a first needle receiving recess and a second arm with a second needle receiving recess, the first and second arms movable toward and away from each other. The method also includes the steps of holding a surgical needle within the second needle receiving recess, positioning the first and second arms about a first vascular tissue section to be sutured,
30 moving the second arm toward the first arm such that the surgical needle pierces the first vascular tissue section and enters the first needle receiving recess and releasing the surgical needle from the second needle receiving recess and holding the surgical needle within the first needle

receiving recess. The method also includes the step of moving the first arm away from the second arm to draw a suture affixed to the surgical needle at least partially through the first vascular tissue section.

BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments are described herein with reference to the drawings, wherein:

10 FIG. 1 is a perspective view of a first embodiment vascular surgical suturing apparatus with the arms in an open position and holding a surgical suturing needle within one of the arms;

 FIG. 2A is a side cross-sectional view of the suturing apparatus taken along line 2A-2A of Fig. 1;

 FIG. 2B is an enlarged side view, partially shown in section, depicting the reciprocating mechanism of the suturing apparatus of Fig. 1;

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FIG. 3 is a cross-sectional view taken along line 3-3 of Fig. 2B;

FIG. 4 is a perspective view of the toggle wheel;

5 FIG. 5 is a perspective view of the camming lever for moving the toggle wheel;

FIG. 6A is a side cross-sectional view similar to Fig. 2A depicting the arms moved to a closed position;

10 FIG. 6B is an enlarged side view, partially shown in section, of the reciprocating mechanism position corresponding to the position of Fig. 6A;

FIG. 6C is an enlarged side cross-sectional view of the distal end of the suturing apparatus corresponding to the position of 6A;

15 FIG. 7A is a side view of the vascular surgical suturing apparatus of Fig. 1, partially shown in section, illustrating initial actuation of the reciprocating mechanism in a clockwise direction;

20 FIG. 7B is an enlarged side view, partially shown in section, of the reciprocating mechanism position corresponding to the position of Fig. 7A;

FIG. 8 is a view similar to Fig. 7B, illustrating further actuation of the reciprocating mechanism;

25 FIG. 9A is a view similar to Fig. 8, illustrating still further actuation of the reciprocating mechanism;

30 FIG. 9B is an enlarged side cross-sectional view of the distal end of the suturing apparatus of Fig. 1 corresponding to the reciprocating mechanism position of Fig. 9A;

FIG. 10A is a view similar to Fig. 9A, illustrating a final position of the reciprocating mechanism;

35 FIG. 10B is a view similar to Fig. 9B corresponding to the position of Fig. 10A;

FIG. 11A is a cross-sectional view taken along the line 11A-11A of Fig. 9B;

FIG. 11B is a cross-sectional view taken along the line 11B-11B of Fig. 9B;

5 FIG. 12A is a cross-sectional view taken along the lines 12A-12A of Fig. 10B;

FIG. 12B is a cross-sectional view taken along the lines 12B-12B of Fig. 10B;

10 FIG. 13 is a side view of the vascular surgical suturing apparatus, partially shown in section, illustrating the surgical needle positioned in the opposing arm;

FIG. 14 is an enlarged side view, partially shown in section, of the reciprocating mechanism
15 illustrating initial actuation of the reciprocating mechanism in an opposite (counterclockwise) direction;

FIG. 15 is a view similar to Fig. 14, illustrating further actuation of the reciprocating mechanism;

20 FIG. 16A is a perspective view of a pair of vascular tissue sections to be end to end sutured as viewed within a limited field of view under magnification;

FIG. 16B is a view similar to Fig. 16A with the
25 ends of the vessels everted in preparation for suturing;

FIG. 16C is a sectional view of a distal end of the surgical suturing apparatus of Fig. 1 and the pair of everted vessels ready for suturing;

30 FIG. 16D is a view similar to Fig. 16C illustrating the piercing of the everted edges of the vascular sections by the surgical needle;

FIG. 16E is a view similar to Fig. 16D illustrating the surgical needle having been passed to an opposing arm and the suture being drawn through the
35 everted vessel edges;

FIG. 16F is a view similar to view 16E illustrating the surgical needle being passed back to the first arm.

5 FIG. 16G is a view similar to FIG. 16D illustrating the arms being closed again about the everted vessel ends to pierce the vessels and form another stitch;

FIG. 16H is a view of the vessels sutured together to form an end to end anastomosis;

10 FIG. 16I is a view taken along lines I-I of FIG. 16H;

FIGS. 17A and 17B are enlarged views of an alternate suturing apparatus distal end and associated needle engaging member configuration;

15 FIGS. 18A and 18B are enlarged views of another alternate distal end and needle engaging member configuration;

20 FIGS. 19A and 19B are enlarged views of a further alternate distal end and needle engaging member configuration for use with a suturing needle having a hole at least partially therethrough;

FIG. 19C is a side plan view of a double pointed suturing needle having a hole at least partially therethrough;

25 FIGS. 20A and 20B are enlarged views of yet another alternate distal end and needle engaging member arrangement;

30 FIG. 21 is an enlarged view of an alternate suturing apparatus distal end slotted for ease in manipulation of a length of suture affixed to a surgical needle;

35 FIGS. 22A and 22B are enlarged views of another alternate distal end and needle engaging member configuration designed for easy loading of a surgical needle;

FIGS. 23A and 23B are enlarged views of an alternate easy load style distal end and needle engaging member configuration;

5 FIGS. 24A and 24B are enlarged views of still another alternate easy load style distal end and needle engaging member configuration;

FIG. 25 is a perspective view of an alternate embodiment of a vascular suturing apparatus showing the jaws in the closed position;

10 FIG. 26 is an exploded perspective view of the vascular suturing apparatus of FIG. 25;

FIG. 27 is a cross sectional view of the apparatus taken along lines 27-27 of FIG. 25;

15 FIGS. 28 and 29 are perspective views of each side of the toggle wheels of the apparatus;

FIG. 30 is a cross sectional view of a portion of the apparatus showing the jaws in the open position, the surgical needle secured in the lower jaw, and the toggle mechanism in the initial position;

20 FIG. 31 is a cross-sectional view taken along lines 31-31 of FIG. 30;

FIG. 32 is an enlarged cross-sectional view taken along lines 32-32 of FIG. 30 showing securement of the needle in the lower jaw;

25 FIG. 33 is a side view in partial cross section of the apparatus with the jaws in the open position showing the side opposite that shown in FIG. 25 to illustrate the initial position of the jaw retaining mechanism;

30 FIG. 34 is a side view similar to FIG. 33 showing the initial engagement of the jaw retaining mechanism;

FIG. 35 is a cross sectional view similar to Fig. 30 with the jaws in the closed position but prior to actuation of the toggle mechanism and engagement of the ratchet mechanism;

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FIG. 36 is a cross sectional view similar to FIG. 35 illustrating engagement of the ratchet mechanism but prior to reciprocation of the toggle mechanism;

5 FIG. 37 is a broken longitudinal cross sectional view of parts of the apparatus illustrating initial movement of the toggle mechanism to initiate release of the needle from the lower jaw and further showing engagement of the ratchet mechanism;

10 FIG. 37A is an enlarged side view showing the engagement of the jaw retaining mechanism;

FIG. 37B is an enlarged cross sectional view taken along lines 37B-37B of FIG 37 showing securement of the needle in the lower jaw;

15 FIG. 38 is a view similar to FIG. 37 illustrating reciprocation of the toggle mechanism to a second (counterclockwise) position to release the needle from the lower jaw and secure it in the upper jaw, and further showing the release of the ratchet mechanism;

20 FIG. 38A is a view similar to FIG 37A showing movement of the jaw retaining mechanism from an engaged to a release position;

FIG. 38B is a cross sectional view taken along lines 38B-38B of Fig. 38 illustrating release of the needle from the lower jaw;

25 FIG. 39 is a sectional view similar to FIG. 30 illustrating the jaws in the open position and the needle retained in the upper jaw; and

FIG. 40 is an enlarged cross sectional view of the needle release mechanism.

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DESCRIPTION OF PREFERRED EMBODIMENTS

Referring to Fig. 1, there is depicted a first embodiment of a vascular suturing apparatus 10 which is particularly suited to facilitate suturing vascular
35 tissue sections or vessels together. Further, apparatus 10 is specifically designed to repeatedly pass a small surgical needle, having an associated length of suture

material attached thereto, such as, for example, surgical needle 12 and suture 14, through vascular tissue sections while maintaining precise control of needle 12 during all phases of the suturing operation.

5 Apparatus 10 generally includes a first or upper arm 16 movably connected to a second or lower arm 18. Arms 16 and 18 are movable toward and away from each other in order to repeatedly pass needle 12 therebetween in a manner described in detail hereinbelow. Preferably, 10 apparatus 10 is approximately 7 inches long. Apparatus 10 is preferably designed to handle surgical needles 12 having a length of approximately .1 to .5 inches and a diameter of approximately ten thousandths to .025 of an inch which are particularly suited for vascular surgery. 15 Preferably the diameter of the surgical needle and the diameter of the suture are substantially the same to prevent fluid leakage from the vessel between the needle hole and suture.

 Note that the use of the terms "upper" and 20 "lower" herein refers to the orientation of the instrument in Figure 1. Clearly, if the orientation changes, these designations will likewise change.

 In many instances, certain ergonomic and operational advantages may be obtained by biasing a 25 surgical suturing instrument in an initially open position. Thus, in this embodiment there is provided a spring 20 which is affixed to proximal ends 22 and 24 of first and second (or upper and lower in the orientation of Fig. 1) arms 16 and 18, respectively. Spring 20 30 biases apart distal ends 26 and 28 of first and second arms 16 and 18, respectively, in order to facilitate positioning arms 16 and 18 about vascular tissue sections. The biasing action of spring 20 also aids in pulling suture 14 through the tissue sections upon 35 opening of arms 16 and 18.

 Apparatus 10 further includes holding structure to secure needle 12 within either distal end 26 and 28 of

arms 16 and 18, respectively. The holding structure allows surgical needle 12 to be initially held within one of the arms and, upon closure of the arms, to be subsequently passed to the opposite arm. To facilitate
5 single handed use of apparatus 10, a cam actuating lever 30 is provided to automatically actuate the holding structure upon closure of the arms. Cam actuating lever 30 is affixed to an extension arm 32 formed on arm 16. Extension arm 32 is sufficiently stiff to prevent
10 depression of cam actuating lever 30 before arms 16 and 18 have been closed against the bias of spring 20. Thus, after such closure of arms 16 and 18, continued pressure on arms 16 and 18 depresses cam actuating lever 30 to automatically actuate the holding structure to release
15 the surgical needle 12 from one arm for transfer to an opposite arm as described in more detail hereinbelow.

Referring now to Fig. 2A, in order to hold or secure needle 12 within arms 16 or 18, there are provided a pair of needle engaging members or clamping blades 34,
20 36 which are longitudinally movable within arms 16 and 18. A first needle engaging blade 34 is slidably disposed within first arm 16 while a second needle engaging member or second blade 36 is slidably disposed within second arm 18. Distal ends 38 and 40 of first and
25 second blades 34 and 36, respectively, are dimensioned and configured to engage an edge of needle 12 and securely hold needle 12 within recesses 88, 90 formed in first and second arms 16 and 18. To prevent damage to a tip or needle point of surgical needle 12 and to prevent
30 the suture carrying end from sliding through arm 18, there are provided a pair of plates 92 and 94 formed in distal ends 26 and 28, respectively, each of which include a reduced recess area 96 and 98 to prevent surgical needle 12 from sliding completely through
35 recesses 88 and 90 in arms 16 and 18, respectively. Arms 16 and 18 are formed with longitudinally extending channels 100 and 102 which extend from distal ends 38 and

40 to reciprocating mechanism 42. Channels 100 and 102 intersect recesses 88 and 90 to allow members 34 and 36 to engage an edge of surgical needle 12 disposed in the respective recess.

As shown in Fig. 2A, needle engaging members 44, 46 are slightly bowed at regions 44a, 44b, respectively, thereby automatically adjusting to needles of various diameters. That is, as the needle is clamped, the needle engaging member buckles at a predetermined location so that the spring force applied to the needle is constant, regardless of the needle diameter. The needle engaging member is slightly buckled even when the needle is not clamped to ensure that the increased buckling occurs in the same area whenever the needle is clamped.

While the preferred blade engagement structure includes V-notches 106 and 108, it will be appreciated by those skilled in the art that various other configurations at blade distal ends 38 and 40 may be provided to securely hold needle 12 within arms 16 and 18. Thus, alternate structure in either arms 16 or 18 or alternate structure in needle 12 itself such as, for example, notches in an edge of needle 12, or holes completely therethrough, may be provided to accept corresponding engagement structure formed on blades 34 and 36. Thus, for example, a double-pointed surgical needle, or surgical incision member, having suture attachment structure intermediate the points may be utilized.

To repeatedly pass needle 12 between arms 16 and 18, a reciprocating mechanism 42 is affixed adjacent proximal ends 44 and 46 of first and second engaging members 34 and 36, respectively. Reciprocating mechanism 42 alternately advances and retracts engaging members 34

and 36, within arms 16 and 18, respectively, thereby alternately engaging the members 34 and 36 with needle 12. Reciprocating mechanism 42, along with first and second engaging members 34 and 36, provide the
5 aforementioned holding structure for securely and alternately holding needle 12 within needle receiving recesses formed in arms 16 and 18.

Cam actuating lever 30 actuates reciprocating mechanism 42 automatically upon full closure of arms 16
10 and 18. In order to prevent inadvertent release of surgical needle from arms 16 or 18 prior to closure of arms 16 and 18, there is provided a lock member 48 which is flexibly mounted within a recess 50 in lower arm 18. Lock member 48 is engagable with reciprocating mechanism
15 42 to prevent movement of reciprocating mechanism 42, and thus release of needle 12, when arms 16 and 18 are in a open position, i.e., when cam actuating lever 30 has not been depressed.

As noted hereinabove, apparatus 10 is
20 particularly suited to suturing small vessels or vascular tissue sections when viewed under magnification or within a restricted field of view. Further, suturing of vessels requires an extremely small needle 12 and suture 14, typically on the order of ten thousands of an inch in
25 diameter. Thus, in order to ensure precise positioning and transfer of needle 12 between arms 16 and 18 upon closure there are provided a pair of alignment pins 52 which are mounted on first arm 16. Upon closure of arm 16 towards arm 18, alignment pins 52 enter into guide
30 holes 54 formed in lower arm 18. The engagement of alignment pins 52 within guide holes 54 is sufficiently precise to ensure accurate alignment of needle 12 within the recesses 88, 90 formed in distal ends 26 and 28 of arms 16 and 18, respectively. Additionally, to prevent
35 the vascular tissue sections from being compressed or crushed during the suturing operation, there is provided a spacer block 56 which ensures that distal ends 26 and

28 of arms 16 and 18, respectively, do not touch upon closure. However, spacer block 56 does allow arms 16 and 18 to close sufficiently such that needle 12 may be transferred therebetween.

5 Referring now to Fig. 2B, actuation of the reciprocating mechanism 42, is caused by cam actuating lever 30 extending through an aperture 58 formed in arm 16. Reciprocating mechanism 42 preferably includes a rotatable toggle wheel 60 which is provided to
10 alternately advance or retract needle engaging members 34 and 36 in response to depression of cam actuating lever 30 upon full closure of arms 16 and 18, i.e. in response to movement of extension arm 32 with respect to arm 16. Toggle wheel 60 additionally provides recesses (described
15 below) for engagement with lock member 48.

As noted hereinabove, first and second arms 16 and 18 are movably connected together and configured to be operated in a tweezer-like manner if desired. Referring to Fig. 3, arms 16 and 18 are provided with a
20 transverse pivot pin 62 for connecting and pivotally moving arms 16 and 18 with respect to each other. Pivot pin 62 is connected to arms 16 and 18 at a position intermediate proximal ends 22, 24 and distal end 26, 28 of arms 16 and 18, respectively. Thus, pressure on arms
25 16 and 18 distally of pivot pin 62, to close distal ends 26, 28, stretches spring 20, while release of arms 16 and 18 allows spring 20 to bias distal ends 26 and 28 to an open or spaced apart position.

While the preferred position of pivot pin 62, and thus the pivot point of arm 16 and 18, is
30 intermediate the ends of apparatus 10, pivot pin 62 may be positioned at proximal ends 22 and 24. Further, although the preferred method of moving arms 16 and 18 is by pivotal motion, parallel movement of arms 16 and 18 is
35 also contemplated. Parallel movement of arms 16 and 18 is especially desirable when using relatively straight surgical needles and may be accomplished in several ways.

For example, arms 16 and 18 could be mounted with respect to each other to both move perpendicular to their respective longitudinal axes. Alternately, arms 16 and 18 could be mounted to move or slide parallel to their respective longitudinal axes to advance and retract their distal ends. When arms 16 and 18 slide relative to each other, it is preferable to have the distal faces of the arms open to a needle holding recess to facilitate transfer of a surgical needle or surgical incision member therebetween.

Pin 62 further serves as a pivot point for toggle wheel 16 which is rotatable in the clockwise or counterclockwise direction about pin 62. Preferably, proximal ends 44 and 46 of needle engaging members 34 and 36, respectively, are affixed to toggle wheel 60 by means of pins 64 and 66, respectively (see Fig. 3). Thus, rotation of toggle wheel 60 on pivot pin 62 alternately advances and retracts members 34 and 36 within arms 16 and 18, respectively.

Referring to Figs. 2A and 4, toggle wheel 60 is provided with a first angled camming surface 68 having a first ledge 70 which, when engaged by cam actuating lever 30, translates to a clockwise rotation of toggle wheel 60 and thus a distal advancement of needle engaging member 34 and a proximal retraction of needle engaging member 36. Similarly, a second angled camming surface 72 and second ledge 74 are provided, such that when engaged by cam actuating lever 30, toggle wheel 60 is rotated in a counterclockwise direction to advance member 36 and retract member 34.

Toggle wheel 60 is provided with lock notches 76 and 78 which correspond to the distalmost advancement of first and second needle engaging members 34 and 36, respectively. Thus, when toggle wheel 60 is rotated counterclockwise to a position where lock member 48 engages lock notch 78, engaging member 36 is locked into an advanced or distalmost position to securely hold

needle 12 within arm 18. Likewise, when toggle wheel 60 is rotated clockwise to a position where lock member 48 engages lock notch 76, needle engaging member 34 is locked into an advanced or distalmost position to secure
5 needle 12 within arm 16. Thus, lock member 48, in conjunction with lock notches 76 and 78, prevents release and transfer of needle 12 when arms 16 and 18 are not fully closed. Additionally, toggle wheel 60 is provided with a knock off pin 80 to aid lock member 48 in entering
10 lock notches 76 and 78, the operation of which is described in more detail hereinbelow.

Referring now to Figs. 2B and 5, cam actuating lever 30 is provided to automatically perform the dual sequential functions of unlocking toggle wheel 60 from
15 engagement with lock member 48 and rotating toggle wheel 60. Cam actuating lever 30 generally includes a base portion 82 which is preferably affixed to arm extension member 32. Alternatively in a non-automatic version, base 82 may be separately movable with respect to
20 extension member 32. Cam actuating lever 30 includes a flexible release leg 84 which is affixed to base 82 and which is provided to cam lock member 48 out of lock notches 76 or 78 and thus allow toggle wheel 60 to be rotated. Cam actuating lever 30 also includes a flexible
25 toggle leg 86 formed parallel to release leg 84. Toggle leg 86 is engagable with angled camming surfaces 68 and 72 and ledges 70 and 74 in order to rotate toggle wheel 60.

Referring initially to Figs. 1 and 2A, the
30 operation of vascular suturing apparatus 10 will now be described. As noted hereinabove, apparatus 10 is particularly suited to repeatedly pass surgical needle 12 back and forth between arms 16, 18 automatically upon full closure of the arms, i.e. closure of arms 16 and 18
35 with respect to one another and subsequent closure of arm extension 32 with respect to arm 16. In the initial position, distal ends 26 and 28 of arms 16 and 18,

respectively, are biased to an open position by spring 20. Needle 12, having an associated length of suture material 14 attached thereto, is positioned and held within distal end 28 of second (lower) arm 18 by needle engaging member 36. Alignment pins 52 are spaced from guide holes 54 and extension arm 32 is in an unbiased state holding camming lever 30 away from toggle wheel 60 in the initial position. To facilitate transfer of needle 12 between arms 16 and 18, needle 12 preferably has a radius of curvature which is substantially equal to the distance between either needle recess, described hereinbelow, and the pivot point, i.e., pin 62, of apparatus 10. In this manner the radius of curvature of surgical needle 12 matches the arc defined by the closure of arms 16 and 18.

Referring now to Fig. 2B, still in the initial position, toggle wheel 60 is in a counterclockwise most position with lock member 48 in engagement with lock notch 78 of toggle wheel 60 to prevent rotation. Thus, surgical needle 12 is locked into second (lower) arm 18. It will be noted that a portion of angled camming surface 68 of toggle 60 is oriented at a position slightly proximal of a center line c of cam actuating lever 30, and, as best shown in Fig. 3, toggle leg 86 is spaced above toggle wheel 60 while release leg 84 is spaced above lock member 48. When arms 16 and 18 are in an open position, center line c, and thus release leg 84, are not in alignment with lock member 48. Thus any inadvertent depression of cam actuating lever 30 prior to closure of arms 16 and 18 will not result in release of lock member 48 from lock notch 78.

Referring now to Fig. 6A, to actuate vascular suturing apparatus 10, pressure is applied to first and second arms 16 and 18 at a point distal of pivot pin 62 in the direction of arrows X to cause jaws 16 and 18 to come to a closed position where distal ends 26 and 28 are in close cooperative alignment. Arms 16 and 18 are

closed against the bias of spring 20 which now assumes a stressed state. As best shown in Fig. 6B, upon closure of arms 16 and 18, the center line C of cam actuating lever 30 and thus of release leg 84 is rotated into
5 alignment above lock member 48. Note at this point, due to the relative stiffness of extension arm 32, arm 32 has not moved in relation to arm 16.

Referring to Figs. 6B and 6C, when toggle wheel 60 is in a counterclockwise most position with lock
10 member 48 engaging lock notch 78, (corresponding to needle 12 held in the upper arm 16 as viewed in the orientation of Fig. 6C), needle engaging blade 36 is in a distally advanced position such that distal end 40 of member 36 engages an edge of surgical needle 12.
15 Engaging member 34 of lower arm 14 is in a proximalmost position with its distal end 38 disengaged from surgical needle 12.

Referring now to Fig. 7A, continued depression on arm extension 32 of upper arm 16 causes arm extension
20 32 to move because arms 16 and 18 are in abutment. This movement of arm extension 32 moves cam actuating lever 30 attached thereto through aperture 58. As cam actuating lever 30 is moved downwardly through aperture 58, release lever 84 contacts lock member 48 to move it downwardly
25 and out of engagement with lock notch 78 (see Fig. 7B). Thus, toggle wheel 60 is released for rotation. After lock member 48 has been disengaged from lock notch 78, cam actuating lever 30 performs its second function as toggle lever 86 of lever 30 contacts camming surface 68
30 and ledge 70 of toggle wheel 60 to initiate rotation in a clockwise direction. As noted hereinabove, toggle lever 86 will engage angled camming surface 68 due to the positioning of a portion of angled camming surface 68 slightly proximal of a center line C of cam actuating
35 lever 30.

Further pressure on extension member 32 as shown by arrow Y in Fig. 8 causes toggle lever 86 to

further rotate toggle wheel 60 in a clockwise direction. Clockwise rotation of toggle wheel 60 begins to advance upper needle engaging member 34 in a distal direction and retract lower needle engaging member 36 in a proximal
5 direction.

Note that when cam actuating lever 30 is depressed release leg 84 moves lock member 48 out of lock notch 78, and holds it down and away from toggle wheel 60. To allow lock member 48 to spring back up and into
10 engagement with lock notch 76 upon complete rotation of toggle wheel 60, knock off pin 80 is provided to move flexible release leg 84 away from lock member 48. Thus, as shown, when toggle wheel 60 is rotated in a clockwise direction, knock off pin 80 moves into abutment with a
15 lower end of release leg 84.

As cam actuating lever 30 is further depressed (by movement of arm extension 32), with reference to Fig. 9A, toggle leg 86 rotates toggle wheel 60 in a clockwise direction thereby causing knock off pin 80 to move
20 release leg 84 away from and off of lock member 48. Thus as toggle wheel 60 is rotated, lock member 48 now rides along, and is held down by, a lower circumferential surface 104 of toggle wheel 60. Needle engaging members 34 and 36 continue to be advanced and retracted
25 respectively. Referring to Fig. 9B, and as noted above, when jaws 16 and 18 are in a closed position, surgical needle 12 is held within recesses 88 and 90 in distal ends 26 and 28, respectively. Plates 92 and 94 having reduced recess areas 96, 98 prevent surgical needle 12
30 from sliding out of recesses 88 and 90. Thus upon rotation of toggle wheel 60 to cause member 34 to advance and member 36 to retract, surgical needle 12 is securely contained within jaws 16 and 18 although neither of the needle engaging members 34 are in engagement with
35 surgical needle 12. This non-engagement of the needle engaging members 34, 36 is illustrated in Figs. 11A and

11B as the V-shaped camming edges 106, 108, respectively are out of contact with surgical needle 12.

Referring to Fig. 10A, it can be seen that further depression of arm extension 32 and attached cam actuating lever 30 results in toggle wheel 60 rotating to a fully clockwise or final position. As noted above, release lever 84 is held out of alignment with lock member 48 by means of knock off pin 80. Thus, as toggle wheel 60 is rotated to the final position, lock notch 76 assumes a position directly above lock member 48 and lock member 48, being spring biased, moves upward within recess 50 to engage lock notch 76. Thus, toggle wheel 60 becomes locked out from further rotation. Any further depression of cam actuating lever 30 at this time will cause no further rotation of toggle wheel 60.

In Fig. 10B toggle wheel 60 is in a clockwise position, upper needle engaging member 34 is in a distalmost position while lower needle engaging member 36 is in a proximalmost position. Thus, distal end 38 of needle engaging member 34 engages an edge of surgical needle 12 while distal end 40 of member 36 remains disassociated from surgical needle 12. This is shown in Figs. 12A and 12B where V-shaped camming edge 106 of needle engaging member 34 cams or wedges surgical needle 12 within respective recess 88 and V-shaped camming edge 108 of needle engaging member 36 is moved to its proximalmost position spaced from surgical needle 12.

Thus, in this manner, surgical needle 12 has been transferred from arm 18 to arm 16 while containing needle 12 within recesses 88 and 90, thereby accomplishing the transfer of needle 12 from arms 18 to 16 without risk of release or escape of needle 12.

As shown in Fig. 13, pressure is then released from arms 16 and 18, resulting in spring 20 biasing arms 16 and 18 into an open position. Arms 84 and 86 of lever 30 also spring back to their starting positions. Needle engaging member 36 is disengaged from surgical needle 12

while member 34 is engaged and securely holds surgical needle 12 within recess 88 in arm 16. Lock member 48 engagement with lock notch 76 securely locks toggle wheel 60 against rotation to secure surgical needle 12 in arm 16. It should also be noted that depression of cam actuating lever 30 will not cause release of surgical needle 12 as release lever 84 is not in alignment with lock member 48 and thus cannot disengage and free toggle wheel 60 for rotation.

Referring now to Figs. 13-15, to reverse the sequence, i.e. pass surgical needle from arm 16 back to arm 18, arms 16 and 18 are again moved to the closed position and continued pressure on arm 16 causes extension arm 32 to move cam actuating lever 30 through aperture 58. At this stage, at least a portion of camming surface 72 of toggle wheel 60 is located distal to center line C of cam actuating lever 30 and thus of toggle leg 86. Thus, upon depression, as cam actuating lever 30 moves through aperture 58, it again performs the dual sequential functions of causing release leg 84 to contact and disengage lock member 48 from lock notch 76 and cause toggle leg 86 to engage angled cam surface 72 and ledge 74 to initiate rotation of toggle wheel 60 in a counterclockwise direction.

Counterclockwise rotation of toggle 60 retracts needle engaging member 34 out of engagement with surgical needle 12 and advances needle engaging member 36 into engagement with surgical needle 12 in a manner similar to that described above. Knock off pin 80 also cams release leg 84 away from lock member 48 (see Fig. 15). Thus upon complete counterclockwise rotation of toggle wheel 60, lock member 48 will again engage lock notch 78 thereby securing toggle wheel 60 and locking surgical needle 12 back within recess 90 in arm 18. Arms 16 and 18 are then released to return to this open position. The apparatus, reciprocating mechanism and needle 12 are thus returned to the original position shown in Figs. 2A and 2B. In

this manner surgical needle 12 may be repeatedly and passed back and forth between arms 16 and 18 upon closure of arms 16 and 18. Thus, surgical needle 12 is under the total and precise control of an operator during an entire suturing operation without risk of needle 12 being released. It can be appreciated from the discussion above that closure of arms 18 and 16 due to pressure thereon, automatically reciprocates needle securing members 34, 36 to transfer control of surgical needle 12 to the respective arm 16 and 18. Thus, by merely squeezing arms 16 and 18 together, surgical needle 12 is automatically transferred from arm 18 to arm 16 without additional effort or manipulations on the part of the user.

Figs. 16A through 16I illustrate the use of vascular suturing apparatus 10 to attach a pair of vascular tissue sections. The operation of apparatus 10 is best described in terms of suturing open or free ends of vessels to form an end-to-end anastomosis procedure. It will be appreciated by those skilled in the art that a similar procedure and operation of apparatus 10 is readily applicable to suture an open end of a vascular tissue section to an incision in a side of a second vascular tissue section to form an end to side anastomosis or to suture the sides of vascular tissue sections to form a side to side anastomosis.

In order to facilitate discussion of the anastomosis procedure, the operation of vascular suturing apparatus 10 will be described solely in terms of arms 16 and 18, and their respective distal ends 26 and 28 along with surgical needle 12 and associated length of suture material 14. However, it will be appreciated that the working operations of vascular suturing apparatus 10 e.g. the passing of the surgical needle 12 between arms 16 and 18, are performed in the manner described above.

Fig. 16A shows a pair of vascular tissue sections or vessels A and B. As noted above, suturing of

vascular tissue sections is typically accomplished under magnification or within a reduced field of view. Thus the following operation will be described as being performed within a restricted space or field of view indicated by circular line D. Ends A1 and B1 of vascular tissue sections A and B, respectively, are prepared in known fashion to ensure that clean and undamaged tissues are sutured together.

In order to form surfaces through which surgical needle 12 can readily be inserted, ends A1 and B1 are preferably everted or spread open in known fashion to create everted edges A2 and B2 in vessels A and B, respectively, (Fig. 16B).

Vessels A and B are approximated to bring everted edges A2 and B2 into an abutting relationship as shown in Fig. 16C. At this point, vascular suturing apparatus 10 is brought within the field of view by manipulating distal ends 26 and 28 of arms 16 and 18, respectively, adjacent everted edges A2-B2. As shown, preferably surgical needle 12 and associated length of suture material 14 initially contained within arm 18 are positioned adjacent one side of everted edges A2-B2 while distal end 26 of arm 16 is positioned adjacent an opposite edge of everted edges A2-B2.

Arms 16 and 18 are closed together to insert needle 12 through everted edges A2-B2 and enter into distal end 26 on the opposite arm 16 (Fig. 16D). At this point continued operation of vascular suturing apparatus 10 causes control of surgical needle 12 to be automatically transferred from arm 18 to arm 16 in the manner described above. Additionally, as arms 16 and 18 are closed about everted edges A2-B2, spacer block 56 (described above with respect to Figs. 1 and 2A) maintains a working gap E between arms 16 and 18 to prevent undesired compression or possible crushing of everted edges A2-B2 of vascular tissue sections A and B.

Upon opening of arms 16 and 18, (Fig. 16E) surgical needle 12 is securely held within arm 16 and is drawn through the everted edges A2-B2 of vessels A and B along with a portion of length of suture material 14. In
5 this manner, vessels A and B have been pierced and thereby have a suture stitch formed therein.

Referring to Fig. 16F, once length of suture material 14 has been at least partially drawn through both everted edges A2-B2, length of suture material 14
10 may be tied off to form a single stitch in edges A2-B2.

Alternatively, arms 16 and 18 may be closed in a manner described hereinabove to repass or transfer control of surgical needle 12 from arm 16 back to arm 18 and thus reposition the point of surgical needle 12 to
15 again pierce tissue and form another stitch. Thereafter, jaws 16 and 18 may be opened with needle 12 securely held within jaw 18 and again positioned on opposite sides of everted edges A2-B2 to form another stitch (Fig. 16G). Thus, continued repetition of the above described
20 procedure will form a series of overlapping stitches through everted edges A2-B2 as best illustrated in Figs. 16H and 16I.

Thus, it is possible in the above described manner to suture or pass a length of suture material
25 through a vascular tissue section by positioning a surgical needle held within a first arm adjacent the vascular tissue section to be sutured and closing the first arm adjacent a second arm. The needle may then subsequently be transferred to the second arm and opened
30 to draw the surgical needle and length of suture material through the tissue section. This procedure may be repeated to perform a series of stitches in a single vascular tissue section or to join two or more tissue vascular tissue sections together, for example, in side
35 to side or end-to-end in anastomosis procedures. The above described operation occurs automatically upon closure of the arms and no further manipulation on the

part of the operator are required to transfer the surgical needle from one arm to another.

While the discussion above contemplates piercing two vascular tissue sections upon a single closure of apparatus 10, it is well within the knowledge of those skilled in the art to suture vascular tissue sections by piercing a single vascular tissue section with needle 12 at a time and drawing suture material 14 therethrough. Thus, 10 in extremely delicate procedures it is possible to insert a portion of length of suture material 14 within only a single vascular tissue at a time to suture a pair of vascular tissue sections together.

The above description of surgical suturing apparatus 10, its method of operation, and the various methods of suturing vascular tissues best illustrate the preferred embodiments and methods associated with vascular suturing apparatus 10. However, as noted above, a double pointed surgical needle, or surgical incision member having 20 suture attachment structure intermediate the points may be utilized which will allow suturing in both directions without having to repass a single pointed surgical needle and suture back to an opposing arm to form another stitch. Further, as will be appreciated by those skilled in the art, various alternate arm distal end configurations along with alternate blade or needle engaging member configurations may be provided to facilitate suturing of various vascular tissues. The alternate arm and needle engaging member configurations and embodiments discussed below are suitable 30 for use in vascular suturing apparatus 10 and will therefore be described merely in terms of the arm and blade interactions with surgical needle 12.

An alternate embodiment of the vascular suturing apparatus is illustrated in Figs. 25-40. Similar to the apparatus 10 of Fig. 1, the apparatus of this second embodiment provides automatic transfer of

the surgical needle between the two jaws, accomplished with a single hand of the user.

With initial reference to Fig. 25 which shows the apparatus in the closed position in order to transfer the surgical needle 212, apparatus 200 has an upper arm or housing 204 supporting an upper jaw 206 and a lower arm or housing 208 supporting a lower jaw 210. As shown, arms 204, 208 preferably have a knurled gripping surface and are configured to be grasped by the surgeon in a tweezer-like manner to facilitate control of the apparatus for suturing the tissue. Lower arm 208 and lower jaw 210 remain fixed as upper arm 204 and upper jaw 206 move relative thereto to pass the surgical needle 212, with attached suture 214, between jaws 206, 210.

As can be appreciated, the terms "upper" and "lower" as used herein refer to the orientation of the instrument shown in Figure 25; clearly if the orientation of the instrument changes, these designations will change.

Surgical needle 212, like surgical needle 12 of the first embodiment, preferably has a length of approximately .1 to .5 inches and a diameter of approximately ten thousandths to .025 of an inch which are particularly suited for vascular surgery. The needle 212 can be straight as shown, although other needle sizes and configurations, such as curved needles, are also contemplated. As mentioned above with respect to the first embodiment, preferably the surgical needle and suture have substantially equal diameter.

Referring to Figures 26 and 30, upper arm 204 is dimensioned for partial insertion within a cavity 250 formed in lower arm 208 (see also Fig. 31). Cavity 222 of upper arm 204 is dimensioned and configured to receive upper jaw 206. Aperture 220 at the proximal end receives pivot pin 270 of lower jaw 210 to enable pivotal movement of jaw 206 with respect to jaw 10. Upper arm 204 is biased away from upper jaw 206, i.e. biased to the open

position, by spring 232 which has a first end seated within slot 234 of upper arm 204 and a second end abutting surface 231 of upper jaw 206. Spring 232 can alternatively be in the form of a vertically oriented coil spring or other configuration for biasing the arm 204 away from upper jaw 206. Upper arm 204 includes a toggle finger 228 with a flexible release finger 230 for actuation of the wheels 302, 304 of the toggle mechanism to effect transfer of the needle between the jaws 206, 210. The toggle mechanism reciprocates the needle securing blades 330, 350 to alternately secure and release the surgical needle 212 from the respective jaw. Upper arm 204 also includes a ratchet finger 224 having a pawl 226 on its inner surface (not shown in Figure 26) which forms part of a ratchet mechanism for retaining the upper arm 204 and lower jaw 210 together during transfer of the surgical needle between the jaws 206, 210. Thus, jaws 206, 210 cannot be opened until the stroke is completed and the needle is safely secured in one of the jaws, thereby preventing premature opening of the jaws and loss of the needle before it is properly transferred to the opposing jaw. The ratchet and toggle mechanisms are discussed in detail below.

Lower arm 208 of apparatus 200 has a cavity 250 formed between upstanding walls 253, 255 to receive lower jaw 210 as well as a portion of upper arm 204 (see also Fig. 31) when upper arm 204 is squeezed to the closed position. Lower jaw 210 and lower arm 208 remain fixed with respect to each other and with respect to upper arm 204 and upper jaw 206. Both lower and upper arms 204, 208 preferably taper in height towards their proximal end. It is also contemplated that alternately, both arms and jaws could pivot with respect to each other.

Upper jaw 206, as shown in Fig. 26, has a distal end 264 designed to receive surgical needle 212 in recess 266 and cooperates with upper blade 330 to frictionally clamp the needle in a manner described

below. Slot 268 is configured to receive the upper blade 330 which is also described below. A coil spring 325, which biases upper blade 330 proximally to a needle securing position, is seated within upper jaw 206 such
5 that proximal hook 323 wraps around post 282 and distal hook 326 extends through slot 327 in upper blade 330, best shown in Figure 30.

Lower jaw 210 has a pivot pin 270 at its proximal end 284 to engage aperture 220 of upper arm 204
10 to provide for pivotal movement of arm 204. Distal end 286 has a recess 288 for receiving the surgical needle 212 and a slot 290 for the lower blade 350 (Fig. 39). The lower blade 350 is biased proximally by coil spring 352 which, as shown in Fig. 30, has a proximal hook 354
15 wrapped around post 295 of lower jaw 210 and distal hook 356 extending through slot 358 in the lower blade 350. The distal end 286 is preferably configured with an inwardly sloped projecting portion 289. This is similar to the configuration of Fig. 21 which is described below.

20 Support 292 formed in lower jaw 210 has a hole 293 for receiving the mounting pin of the wheels 302, 304 of the toggle mechanism. Aperture 294 and slot 296 are configured to mount release button 500, the function of which is described below.

25 With continued reference to Figures 26 and 30, a support leg 240 extends upwardly from one side of lower jaw 210 and forms part of the ratchet mechanism to prevent separation of the upper arm 204 and lower jaw 210 until the needle 212 is securely held in one of the jaws.
30 More particularly, a rack 244 is positioned within cutout portion 241 of lower jaw 210 and below projection 242 of support leg 240. As upper arm 204 is initially moved towards lower arm 208 to a closed position, ratchet finger 224, carrying pawl 226 on its inner surface, is
35 initially biased distally by projection 242 such that pawl 226 extends into recess 243 of upper jaw 206. When the arms 204, 208 are further closed to a position where

pawl 226 has traveled below projection 242, ratchet finger 224 snaps back in a proximal direction so that pawl 226 engages rack 244 as shown in Figure 36. Once engaged, the upper arm 204, and thus the upper jaw 210, cannot separate from the lower arm 206 and lower jaw 210 until the arms are fully closed and the pawl 226 completes its travel below the rack. (see Fig. 38) This completion of travel occurs only after the toggle mechanism has been fully actuated to release the needle 212 from one of the jaws and to secure the needle in the other jaw. Thus, separation of the jaws 206, 210 until the needle is safely transferred is prevented. The ratchet mechanism and its timing is discussed in more detail below in the description of the sequence of operation of the instrument.

On the side of lower jaw 210 opposite the ratchet finger 224 is retaining arm 401 of the jaw retaining mechanism. Retaining arm 401 extends upwardly and substantially parallel to ratchet finger 224 and as shown in Fig. 33, has a ledge or hook 408 and a projection 403 on its outer surface. When the upper arm 204 is moved toward the lower arm 208, ledge 408 of retaining arm 401 slightly engages a shelf 410 formed in an outer wall of the upper jaw 206 (see Fig. 34). Upon further movement of upper arm 204 towards the lower arm 208, the camming surface 404 of camming projection 402, which is formed in an inner wall of upper arm 204, engages the projection 403 to force retaining arm 401 proximally. Thus, ledge 408 is moved further on shelf 410 and is held in this engaged position as shown in Fig. 37A. This effectively locks the upper and lower jaws 206, 210 together in a parallel position while upper arm 204 can complete its movement to the closed position to actuate the toggle mechanism to effect transfer of the surgical needle 212 to the opposing jaw. Figure 38A illustrates release of the retaining arm 401. As illustrated, when camming projection 402 slides past

projection 403 after the arm 204 has been moved to the closed position, retaining arm 401 springs back to its normal distal position. This disengages retaining arm 401 from shelf 410 to allow the upper jaw 206 to return to the open position.

Turning now to the needle securing (clamping) blades, and referring first to the lower blade 350 and Figures 26, 30 and 32, lower blade 350 is slidably mounted within lower jaw 210 for movement between a proximal position for clamping the surgical needle 212 and a distal position for releasing the needle 212. More specifically, distal end 364 has a recess defined by locking edge 358 which presses needle 212 against surface 269 of the lower jaw 210. When in the proximal clamping position, coil spring 352 biases the lower blade 350 in a proximal direction such that biasing clip 370 (or alternately a biasing pin) engages angled surface 372 of the blade 350 to bias it into engagement with the needle 212 and to force it against surface 269 of lower jaw 210 to securely clamp the needle between the lower blade 350 and the lower jaw 210. When in the distal release position, the angled surface 372 is no longer in contact with biasing clip 370 and therefore the distal end 364 of blade 350 springs into slot 351 of lower jaw 210 and is also pushed into slot 351 by surface 269b. As can be seen in Fig. 38B, when positioned in the slot 351, a sufficient gap 371 is provided to facilitate release of the needle.

A bend 374 is formed in the lower blade 350 to cooperate with release button 500 in the manner described below.

Upper blade 330 functions to retain the surgical needle 212 in the upper jaw 206 in an identical manner as lower blade 350. That is, the distal end 334 of upper blade 330 has a recess defined by a locking edge to clamp the surgical needle against a raised surface (not shown) of upper jaw 206. Upper blade 330 is biased

proximally by coil spring 325 to a needle clamping position. A biasing clip or pin (not shown) biases the blade into engagement with the needle in the same manner as biasing clip 370 of lower needle securing blade 350.
5 Step 336 provides the blade 330 with additional flexibility.

The movement of the upper and lower blades 330, 350 are controlled by the toggle mechanism. The proximal end 362 of lower blade 350 tapers in width and in the
10 illustrated embodiment angles downwardly to abut a portion of wheel 304 of the toggle mechanism. Similarly, the proximal end 332 of upper blade 330 tapers in width and angles downwardly to abut another portion of wheel 304 of toggle mechanism. (It should be appreciated that
15 alternately the downward angle could be eliminated and the proximal end of blades 330, 350 can be straight.) Consequently, as described in detail below, rotation (pivoting) of abutment wheel 304 slides the upper and lower blades 330, 350 between proximal and distal
20 positions to alternately clamp and release the surgical needle 212 from the respective jaw.

Turning now to the reciprocating or toggle mechanism, and with particular reference to Figs. 26-30, the toggle mechanism includes a toggle wheel 302 and a
25 pivotable blade abutment wheel 304, both of which are rotatably mounted on mounting pin 306 within annular cavity 274 of upper jaw 206. Mounting pin 306 is fixedly secured in holes 275 and 293 of upper and lower jaws 206, 210, respectively. Toggle wheel 302 has a first angled
30 camming surface and a first ledge designated by reference numerals 310, 311, respectively, and a second angled camming surface and second ledge designated by reference numerals 312, 313. Toggle wheel 302 further includes first and second locking notches 316, 314 and a knock-off
35 pin 318 positioned therebetween. A locking spring 308 has a perpendicularly extending locking leg 324 engagable with one of the locking notches 314, 316 depending on the

position of the toggle wheel 302. The opposite leg 326 of the locking spring 308 is seated within transverse slot 263 of upper jaw 206. This locking spring 308 prevents (blocks) movement of the toggle wheel 302 if the
5 upper and lower arms 204, 208 are not in the closed position because locking spring 308 is disengaged (unlocked) from the respective locking notch only when upper arm 204 is moved to the closed position. By locking the toggle wheel 302, premature release of the
10 needle 212, i.e. release of the needle before the opposing jaw has secured the needle, is prevented.

Blade abutment wheel 304 has a first V-notch 320 which abuts the proximal end of upper blade 330 and a second V-notch 322 which abuts the proximal end of lower
15 blade 350. As blade abutment wheel 304 rotates clockwise as viewed in Fig 30, it slides upper blade 330 slightly distally, overcoming the force of coil spring 325, to release the surgical needle 212 from the upper jaw 206. Such clockwise movement simultaneously releases the
20 distal force on coil spring 352 and allows coil spring 352 to bias lower jaw blade 350 proximally, thereby clamping the needle against the raised surface 269 of lower jaw 210 in the manner described above. Conversely, counterclockwise movement of abutment wheel 304 allows
25 coil spring 325 to bias upper blade 330 proximally into the needle clamping position and overcomes the force of coil spring 352 to force lower blade 350 distally into a needle release position.

Movement of blade abutment wheel 304 is caused
30 by the pivotal movement of toggle wheel 302. In a manner similar to the toggle wheel of the embodiment of Figures 1-15, when the upper arm 204 is moved to the closed position, toggle finger 228 rides along the camming surface of toggle wheel 302 until it engages the ledge to
35 rotate the wheel 302. As toggle finger rides along the camming surface, flexible release finger 230 engages locking leg 324 of locking spring 308 to force it out of

engagement with the locking notch. More particularly, if the needle 212 is secured in the lower jaw 210 as shown in Fig. 30, sufficient depression of the upper arm 204 will cause toggle finger 228 to ride along first angled camming surface 310 as release finger 230 engages leg 324 of locking spring 308 to force it out of first locking notch 316. This is shown in Fig. 37.

As upper arm 204 is further moved (depressed) to the closed position, toggle finger 228 engages first ledge 311 causing toggle wheel 302 to rotate counterclockwise as shown in Fig. 38. This counterclockwise rotation of toggle wheel 302 causes abutment wheel 304 to rotate in the same direction, thereby sliding upper blade 330 proximally and lower blade 350 distally to clamp the needle 212 in the upper jaw 206 and release it from the lower jaw 210. Note that as toggle wheel 302 is rotated to its counterclockwise position, knockoff pin 318 keeps release finger 230 out of the way so that locking leg 324 of locking spring 308 can engage the second locking notch 314 to retain toggle wheel 302 (and abutment wheel 304) in the second (counterclockwise) position.

When the arms 204, 208 are opened and once again moved to the closed position in order to transfer the needle 212 back to the lower jaw 210, toggle leg 228 engages second camming surface 312 and second ledge 313 to rotate the toggle wheel 302 in a clockwise direction. Release finger 230 will force locking spring 308 out of engagement with the second locking notch 314 to enable it to re-engage the first locking notch 316. Clockwise rotation of toggle wheel 302 will cause clockwise rotation of abutment wheel 304 to slide upper blade 330 to a distal release position and allow lower blade 350 to return to its proximal clamping position.

The operation of the apparatus 200 will now be described. As shown in Fig. 30 the arms 204, 208 and jaws 206, 210 are in the open position with surgical

needle 212 secured in the lower jaw 210 and spring 232 biasing the upper arm 204 away from the upper jaw 206. In this position, toggle wheel 302 and abutment wheel 304 are in the clockwise position such that lower blade 350 is biased proximally by coil spring 352 to clamp the surgical needle 212 in lower jaw 210 and upper blade 330 is forced into a distal (release) position by abutment wheel 304. Also note that locking leg 324 of locking spring 308 is engaged in the first locking notch 316 and release finger 230 is spaced therefrom. Furthermore, in this position, pawl 226 of the ratchet mechanism is spaced from projection 242 and rack 244 of leg 240, thus allowing free movement of the arms. Also, in this position, shown in Fig. 33, shelf 410 of upper jaw 206 is spaced from ledge 408 of retaining arm 401.

When it is desired to initiate suturing of the tissue and transfer of the surgical needle 212 from the lower jaw 210 to the upper jaw 206, arms 204, 208 are squeezed to move upper arm 204 and upper jaw 206 towards fixed lower arm 208 and lower jaw 210. Initially, upper arm 204 and jaw 206 move together towards lower jaw 210, with upper arm 204 remaining spaced from upper jaw 206 due to the biasing force of spring 232 and the engagement of pawl 226 of ratchet finger 224 in recess 243 of upper jaw 206. As the upper and lower jaws 206, 210 are moved to a substantially closed position, parallel to one another as shown in Fig. 35, release finger 230 has moved towards the locking spring 308 but remains out of engagement therewith and toggle finger 228 remains out of engagement with toggle wheel 302. Pawl 226 has almost completed its travel along projection 242 but remains out of engagement with rack 244 as it is biased into recess 243 of upper jaw 206 by projection 242. In this parallel position of the jaws, ledge 408 of retaining arm 401 has engaged shelf 410 of upper jaw 206 but is not securely held thereon because camming projection 402 remains out

of engagement with projection 403 of retaining arm 401, as shown in Fig. 34.

Further depression of upper arm 204 in the direction of the arrow, moves it towards upper jaw 206 as upper jaw 206 has no more room to move and upper arm 204 begins to overcome the biasing force of spring 232. In this position illustrated in Fig. 36, release finger 230 still remains out of engagement with locking spring 308; however toggle finger 228 starts to engage first angled camming surface 310 of toggle wheel 302. Note that toggle wheel is not yet rotated so that surgical needle 212 remains clamped in lower jaw 210. In this position of upper arm 204, the ratchet mechanism is engaged as pawl 226 has completed its travel past projection 242, is no longer forced into recess 243, and has snapped proximally into engagement with the teeth of ratchet 244. Thus, the ratchet mechanism will maintain upper arm 204 and lower jaw 210 together until the completion of the stroke and the transfer of the surgical needle 212 to the opposing jaw. Moreover, when the upper arm 204 is in the position of Fig. 36, camming surface 404 of the camming projection 402 of the jaw retaining mechanism engages the projection 403 of retaining arm 401 to begin to bias retaining arm 401 proximally to hold ledge 408 on shelf 410. This positively locks the upper and lower jaws 206, 210 together to prevent separation during the remainder of the stroke. Note that camming projection 402 is retained in this position due to the engagement of pawl 226 and rack 244 on the other side of the apparatus which locks the upper arm 204 with respect to lower jaw 210.

When upper arm 204 is further squeezed towards lower arm 208, as shown in Fig. 37, release finger 230 forces locking leg 324 of locking spring 308 out of engagement with the first locking notch 316 to free toggle wheel 302 for movement. At this time, toggle leg 228 engages first angled camming surface 310 and begins to slide towards ledge 311. When the toggle mechanism is

in this position, ledge 408 is retained on shelf 410 and pawl 226 is engaged in the lower teeth of rack 244, still maintaining the jaws 206, 210 in the closed position. As the arm 204 moves to the fully closed (depressed) position, toggle finger 228 engages first ledge 311 to rotate the toggle wheel 302 counterclockwise as shown in Fig. 38. As toggle wheel 302 rotates counterclockwise, abutment wheel 304 likewise rotates in the same direction to force lower blade 350 distally (see arrow D) against the force of coil spring 352 to release the surgical needle 212 from lower jaw 210. Simultaneously, upper blade 330 is allowed to return (see arrow E) to its proximal (retracted) position under the force of coil spring 325. Thus, the upper blade 330 is moved to the locking position to clamp the needle 212 in the upper jaw 206 and the lower blade 350 moves into slot 351 to release the needle 212 from the lower jaw 210 (Fig. 38B). As toggle wheel 302 is moved to its counterclockwise position, knock off pin 318 keeps release finger 230 away from locking leg 324 of locking spring 308, thus enabling the locking leg 324 to engage the second locking notch 314. Toggle wheel 302 (and abutment wheel 304) are thereby locked in this second (counterclockwise) position and thus upper blade 330 is locked in the proximal position to retain surgical needle 212. That is, since movement of the toggle wheel 302 is prevented, movement of the upper blade 330 to a release position is also prevented.

As further illustrated in Fig. 38, in this counterclockwise position of the toggle mechanism, i.e. when the toggle wheel 302 is locked in the second position so that the blades 330, 350 are locked, the pawl 226 is disengaged from rack 244 and can travel along the back side of the rack 244 to thereby allow the jaws 206, 210 to move to the open position. The position of arm retaining mechanism 400 at this time is illustrated in Fig. 38A. As shown, the camming projection 402 has moved

from its position of Fig. 37A and slid past the projection 403 on retaining arm 401, thus allowing retaining arm 401 to spring back to its original distal position such that ledge 408 is out of engagement with shelf 410. This allows the upper jaw 206 to return to the open position.

Fig. 39 illustrates the position of the toggle mechanism and the ratchet mechanism when the jaws 206, 210 and arms 204, 208 have returned to the open position with the surgical needle 212 secured in the upper jaw 206. As noted, the pawl 226 of the ratchet mechanism returns to the same position as in Fig. 30 (the jaw retaining mechanism also returns to the original position of Fig. 33). However, the toggle wheel 302 is maintained in the counterclockwise position by the engagement of locking leg 324 of locking spring 308 with second locking notch 314.

If it is desired to transfer the needle 212 back to the lower jaw 210, the arms 204, 210 are closed, causing the jaw retaining mechanism and ratchet mechanism to engage as described above. Furthermore, the toggle finger 228 and release finger 230 will force the toggle wheel 302 and associated abutment wheel 304 to rotate clockwise to move the upper blade 330 distally to a release position and the lower blade 350 proximally to a clamping position to release the needle 212 from the upper jaw 206 and retain it in the lower jaw 210. The locking leg 324 of locking spring 308 will re-engage the first locking notch 316 and when the arms 204, 208 and jaws 206, 210 are open, the apparatus' components will return to the position shown in Fig. 30.

The apparatus 200 may include a quick release mechanism 500 to remove and replace or reload the surgical needle 212. In the illustrated embodiment, the needle 212 needs to be positioned in the lower jaw 210 to use the quick release mechanism, however it is also contemplated that the release mechanism can be positioned

on the upper jaw which would require the needle to be in the upper jaw in order to be replaced. As shown in Figs. 26 and 40, arm 504 extends from pin 503 which is mounted in opening 294 of lower jaw 210. To replace the needle 212, lever 502 is rotated clockwise, causing arm 504 to contact portion 373 of bend 374 of the lower blade 350. This forces the blade 350 distally to release the needle 212 from the jaw 210. With the blade 350 in the distal position (see e.g. Fig. 38B), needle 212 can be removed through gap 371 between the lower blade 350 and lower jaw 210 and a fresh needle and suture can be inserted into gap 371 against raised surface 269 of lower jaw 10. Subsequently, lever 502 is released to return to its initial position of Fig. 30, allowing lower blade 350 to return to the proximal clamping position under the force of coil spring 352.

It should be understood that the apparatus 200 can be used to suture vascular tissue sections in the manner described above with respect to apparatus 10 and illustrated in Figs. 16A through 16I.

Alternate embodiments for clamping the surgical needle, which are applicable to apparatus 10 as well as apparatus 200 will now be described.

Figs. 17A and 17B illustrate an alternate embodiment of a distal end arm configuration 110 and needle engaging member 112. Arm distal end 110 includes an enlarged bore 114 for receipt of a surgical needle 12. Bore 114 aids in positioning and transferring surgical needle 12 between arms especially when pushed through tough tissue sections which may cause deflection of surgical needle 12. Bore 114 includes a V-shaped notch 116 at a distalmost end which cooperates with a V-shaped camming edge 118 on needle engaging member 112. Thus, as shown in Fig. 17B, upon distal movement of engaging member 112, V-shaped camming edge 118 cams surgical needle 12 within bore 114 against notch 116 to securely hold surgical needle 12 therein. As noted above,

surgical needle 12 may be either smooth sided or notched adjacent an edge to receive at least a portion of V-shaped camming edge 118 of needle engaging member 112.

5 Figs. 18A and 18B illustrate an alternate arm 120 and blade or needle engaging member 122 configuration which utilizes proximal retraction, rather than distal advancement, of engaging member 122 to securely hold surgical needle 12 against arm 120. Arm 120 includes a V-
10 shaped engagement notch 124 formed on the distal end while needle engaging member 122 contains an elongated slot 126 for receipt of surgical needle 12 therein. Referring to Fig. 18B, as blade 122 is retracted, surgical needle 12 disposed within slot 126 is cammed
15 against and securely held within notch 124 in arm 120.

Figs. 19A and 19B illustrate yet another alternate embodiment of an arm distal end 128 and needle engaging member 130 configuration best suited for securing a U-shaped, half-circle or otherwise relatively
20 hollow surgical needle 132 which preferably has engagement structure in the form of an engagement hole 134 formed therethrough. Surgical needle 132 (Fig. 19C) may have various cross-sectional configurations while still having suitable engagement structure in the form of
25 hole 134. Arm 128 has a bore 136 formed therein and needle engaging member 130 has a projecting tip 138 which preferably corresponds to the interior shape of the surgical needle 132. Needle engaging member 130 is further formed with a point or finger 140 formed on tip
30 138 and which is specifically designed to engage the engagement structure or hole 134 in surgical needle 132. Thus, upon positioning of surgical needle 132 within recess 136, distal advancement of needle engaging member 130 causes finger 140 to engage hole 134 and securely
35 hold surgical needle 132 within arm 128.

Referring now to Figs. 20A and 20B, an alternate arm 142 and needle engaging member 144 is shown

for securely holding a round or otherwise preferably solid cross-sectional surgical needle 12 which enables easier loading. Arm 142 preferably includes an angled forward edge 146 and a groove or slot 148 proximal to angled forward edge 146. Needle engaging member 144 also includes an angled forward edge 150 and a camming member 152 formed at a distalmost portion of angled edge 150. Thus, referring to Fig. 20B, upon retraction of needle engaging member 144 camming member 152 slides past edge 146 and forces surgical needle 12 into recess slot 148, thereby securing surgical needle 12 within arm 142.

While the above described arm and needle engaging member configurations include enclosed recesses or holes through which surgical needle 12 may be perpendicularly inserted, it may often be desirable to provide open ended or easy loading structure which will allow surgical needle 12 to be inserted parallel rather than perpendicular to the arm structure. Turning first to the embodiment of Figs. 22A, 22B, arm 166 is preferably formed with a V-shaped needle guiding recess 168 having a relatively round or circular needle receiving portion 170 at the apex of the V. Thus, advancement of arm 166 distally towards surgical needle 12 will allow needle 12 to be inserted into recess 160 from the distal end of arm 166, i.e., parallel to its longitudinal axis, rather than moving surgical needle 12 perpendicularly to arm 166 to enter an enclosed recess. Needle engaging member 172 includes an angled surface 174 which, when advanced as shown in Fig. 22B, cams against surgical needle 12 to firmly hold surgical needle 12 within circular recess 170 of arm 166. It will particularly be appreciated that the easy load style of arm distal end configurations and needle engaging member configurations are particularly suited to parallel moving jaw structure which may either move perpendicular to the longitudinal axis of a surgical needle, that is, slide parallel to each other or may move parallel to the

longitudinal axis of a surgical needle, i.e., that is, move perpendicular with respect to each other.

Referring now to Figs. 23A and 23B, there is disclosed a further alternate easy load style arm distal end and needle engaging member configuration. Arm 176 preferably includes a single, distally extending hook 180 having an angled needle guiding front surface 182 and small semi-circular recess 184 disposed distally of angled needle guiding front surface 182. Additionally, a channel 186 for receipt of needle engaging member 178 includes a pair of angled camming surfaces 188 and 190. Needle engaging member 178 includes a distally extending camming finger 192 having a dog leg connecting portion 194 which connects finger 192 to the remainder of needle engaging member 178. Dog leg portion 194 has camming edges 196 and 198 which cooperate with camming edges 188, 190, respectively, in arm 176. As best shown in Fig. 23B, as needle engaging member 178 is retracted, camming edge 196 abuts camming edge 188 to move finger 192 sideways forcing surgical needle 12 to be firmly held within recess 184 in arm 176. Similarly, distal advancement of needle engaging member 178 results in abutting camming edge 190 of arm 178 to engage cam edge 198 to again move finger 192 sideways away from recess 184 thereby releasing surgical needle 12 from arm 176.

Figs. 24A and 24B illustrate a further alternate embodiment of an easy load style arm and needle engaging member configuration. Arm 200 preferably includes a V-shaped needle guiding distal end 202 terminating in an elongated slot or recess 204 for receipt of surgical needle 12 therein. Preferably, arm 200 has an elongated needle engaging member channel 206 having angled edges 208 and 210. Needle engaging member 212 includes a dog leg end portion 214 similar to that described with respect to the embodiment disclosed in Figs. 23A and 23B and contains a hook or recess edge 216 at the distalmost end thereof. Thus, as shown in Fig.

24B, upon proximal retraction of needle engaging member 212, a camming edge 218 on needle engaging member 212 engages angled edge 208 on arm 200 to move needle engaging member 212 sideways thereby capturing surgical
5 needle 12 within recess 204 by curved finger or hook 216. Similarly, distal advancement of needle engaging member 212 within channel 206 causes a camming edge 220 on needle engaging member 212 to engage angled edge 210 on arm 200 to move hook 216 away from recess 204 thereby
10 releasing surgical needle 12 from arm 200.

Referring now to Fig. 21, an arm 154 is illustrated which is particularly suited for use with a single pointed surgical needle 12 having an associated length of suture material 14 extending from an opposite
15 end of the point. Arm 154 is configured to manage and manipulate suture material 14 such that it does not interfere with the transfer of surgical needle 12 from an opposing arm similar to arm 16. Preferably, arm 154 includes angular inwardly sloped projecting portion 156
20 having a recess 158 therethrough. Recess 158 has a slot 160 along one edge thereof to allow suture material 14 to pass therethrough. Additionally, projecting portion 156 is further formed with a chamfered or channeling surface 162 which serves to guide suture material 14 through slot
25 160 and into recess 158. In this manner, when the surgical needle 12 is passed to arm 154, the suture will be prevented from being tangled. Additionally, the channeling surface 162, by guiding the suture material through slot 160, keeps the suture out of the way of the
30 needle engaging member extending through slot 164. By forming the slot through arm 154, a distal end of a needle engaging member may abut surgical needle 12 to hold it within recess 158 or, alternatively, a side edge of needle engaging member may cam against an edge of
35 surgical needle 12 to hold it within recess 158.

It will be understood that various modifications may be made to the embodiments disclosed

herein. For example, as noted hereinabove, parallel movement along or perpendicular to the arm axes is contemplated as well as straight and/of double pointed surgical needles such as surgical incision members.

5 Further, other methods of grasping a surgical needle within a single arm are contemplated. Additionally, modifications within the skill of those knowledgeable in the art may be made to the camming and reciprocating mechanisms to facilitate automatic transfer of a surgical

10 needle from one arm to another. Therefore, the above description should not be construed as limiting, but merely as exemplifications as preferred embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims

15 appended hereto.

THE EMBODIMENTS OF THE INVENTION IN WHICH AN EXCLUSIVE PROPERTY OR PRIVILEGE IS CLAIMED ARE DEFINED AS FOLLOWS:

1. An apparatus for suturing tissue comprising:
 - a) a pair of needle holding tweezer like arms pivotably interconnected at a proximal end for movement between open and closed positions; and
 - b) a retaining mechanism operatively connected to the pair of arms distally of the interconnection and engageable with a surgical needle to secure the surgical needle alternately within each arm of the pair of arms; and
 - c) a cam actuating lever operatively connected to one of the arms such that the retaining mechanism is actuated as the arms are approximated towards one another.
2. The apparatus according to claim 1, wherein the retaining mechanism comprises a retaining arm extending from one of said pair of arms, said retaining arm having a hook portion engageable with a shelf formed in the other of said pair of arms.
3. The apparatus according to claim 1, further comprising a ratchet mechanism comprising a pawl extending from one of said pair of arms and engageable with a rack positioned on the other of said pair of arms
4. The apparatus according to claim 2, further comprising a camming member extending from the one of said pair of arms having the retaining arm, the camming member camming the hook portion into engagement with the shelf.
5. The apparatus according to claim 1, wherein

the retaining mechanism includes first and second needle engaging members and a reciprocating mechanism, wherein the first and second needle engaging members are affixed to the reciprocating mechanism such that the reciprocating mechanism alternately advances and retracts the first and second needle engaging members.

6. The apparatus of claim 5, wherein the reciprocating mechanism is mounted for movement with respect to at least one of the arms, the reciprocating mechanism being movable between a first position, in which the first needle engaging member is moved into engagement with the surgical needle, and a second position, in which the first needle engaging member is disengaged from the surgical needle.

7. The apparatus of claim 6, wherein the cam actuating lever is engageable with the reciprocating mechanism such that the cam actuating lever automatically cams the reciprocating mechanism between the first and second positions in response to closure of the arms.

8. The apparatus according to claim 5, wherein the reciprocating mechanism includes a toggle wheel rotatably mounted to at least one of the first and second arms.

9. The apparatus according to claim 8, wherein a proximal end of each of the first and second needle engaging members is connected to opposite sides of the toggle wheel such that rotation of the toggle wheel simultaneously retracts one of the needle engaging members and advances the other.

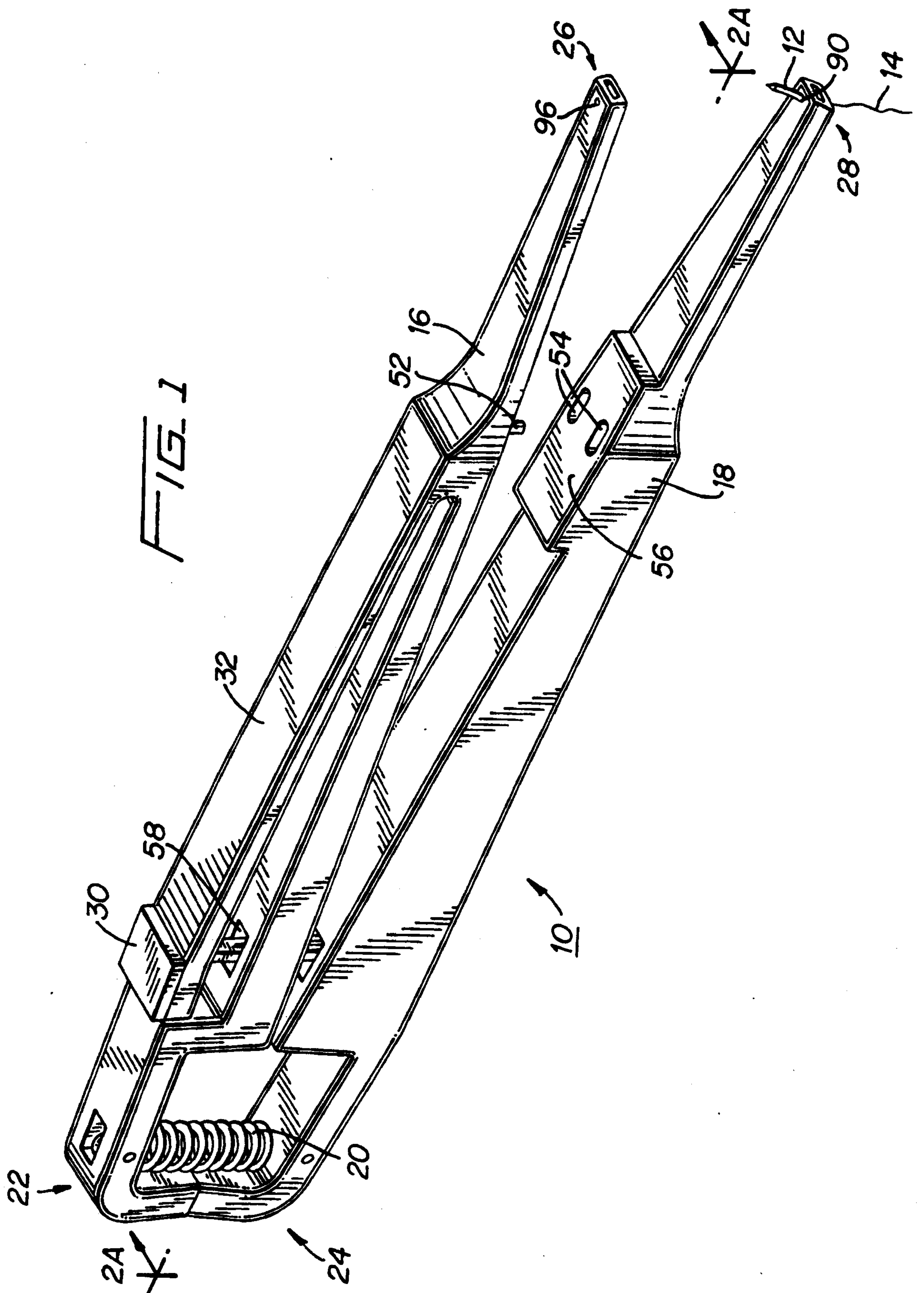
10. The apparatus according to claim 1, further comprising a lockout member mounted to at least one of the first and second arms such that the lockout member is movable between a locked position, in which movement of the reciprocating mechanism is substantially prevented, and an unlocked position, in which movement of the reciprocating mechanism is allowed.

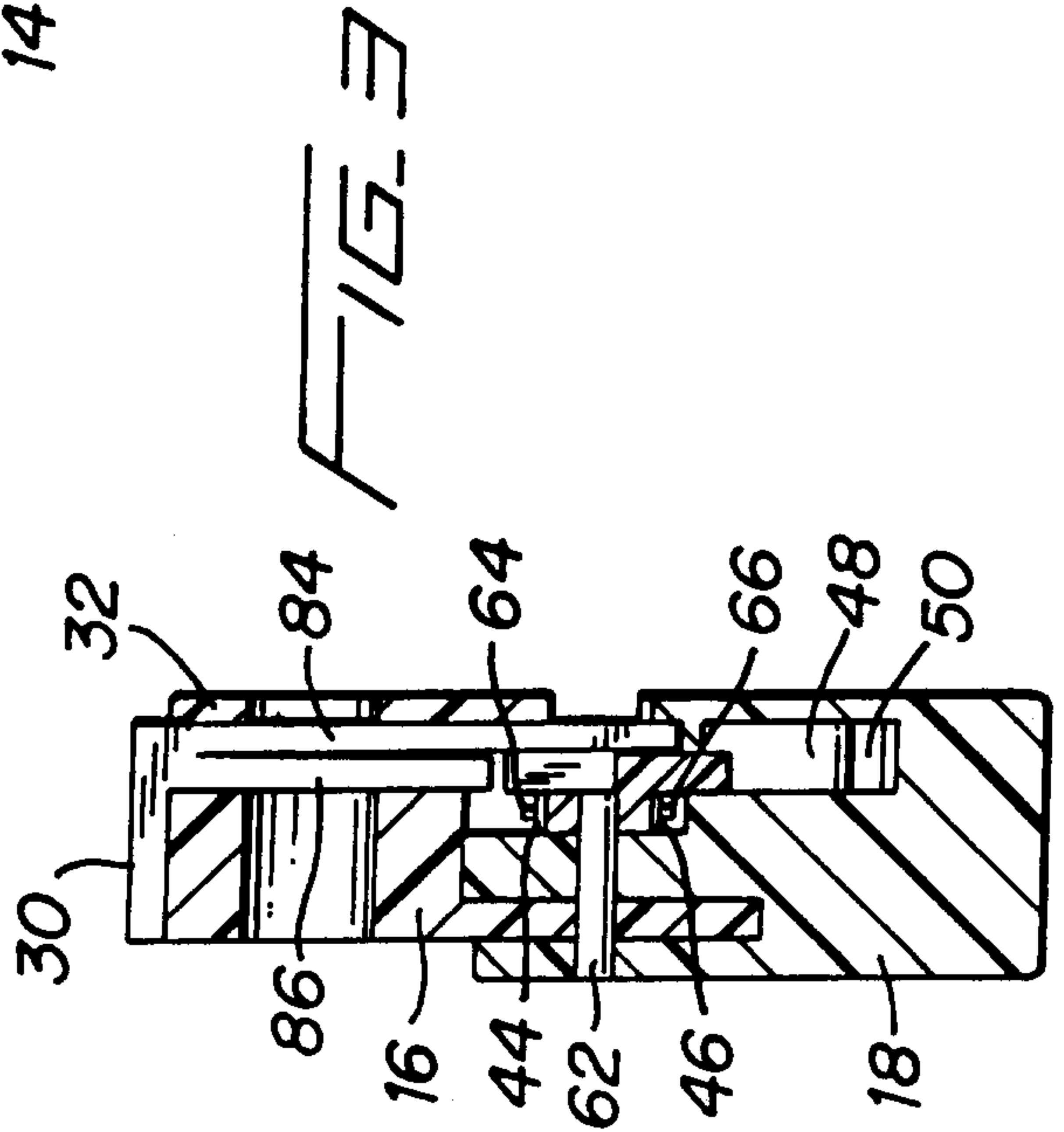
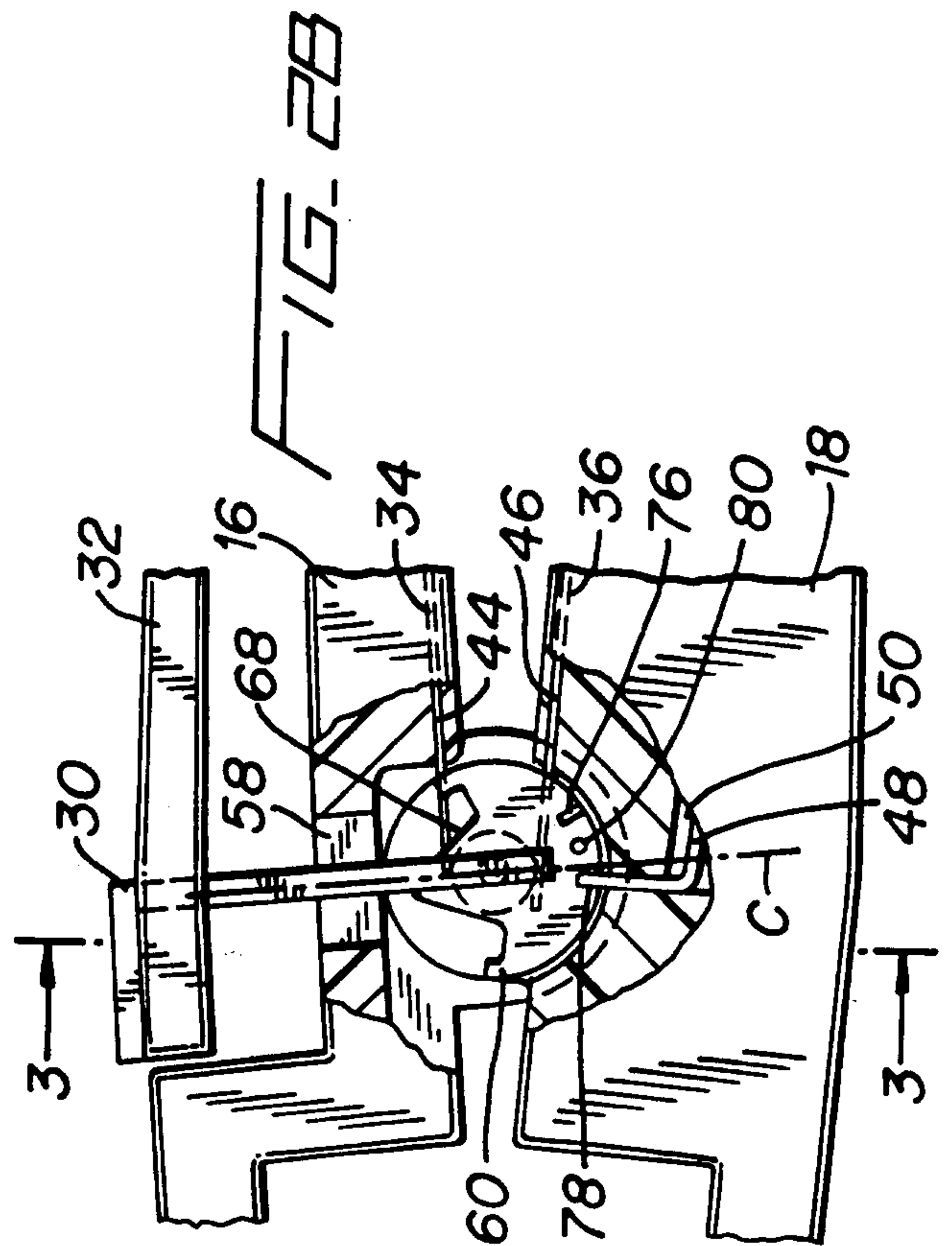
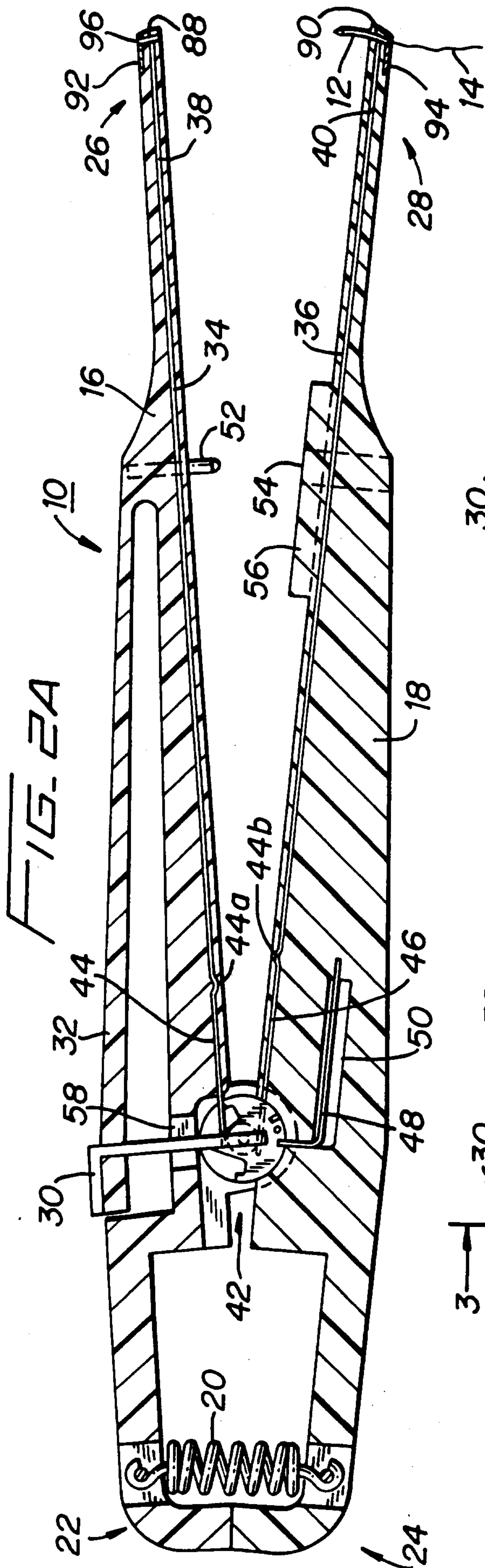
11. The apparatus according to claim 10, wherein the cam actuating lever includes a release leg, the release leg moving the lockout member from the locked position to the unlocked position upon closure of the arms.

12. The apparatus according to claim 1, further comprising a spring member mounted between the first and second arms to bias distal ends of the first and second arms into the open position.

13. The apparatus according to claim 1, wherein the first arm has a first recess configured to receive at least a portion of the surgical needle therein, the first needle engaging member being movable into a position wherein the first needle engaging member is disposed adjacent the first recess to engage the surgical needle disposed therein.

14. The apparatus according to claim 13, wherein the first arm has a longitudinal channel therein for receipt of the first needle engaging member, the first channel at least partially intersecting the first recess in the first arm.





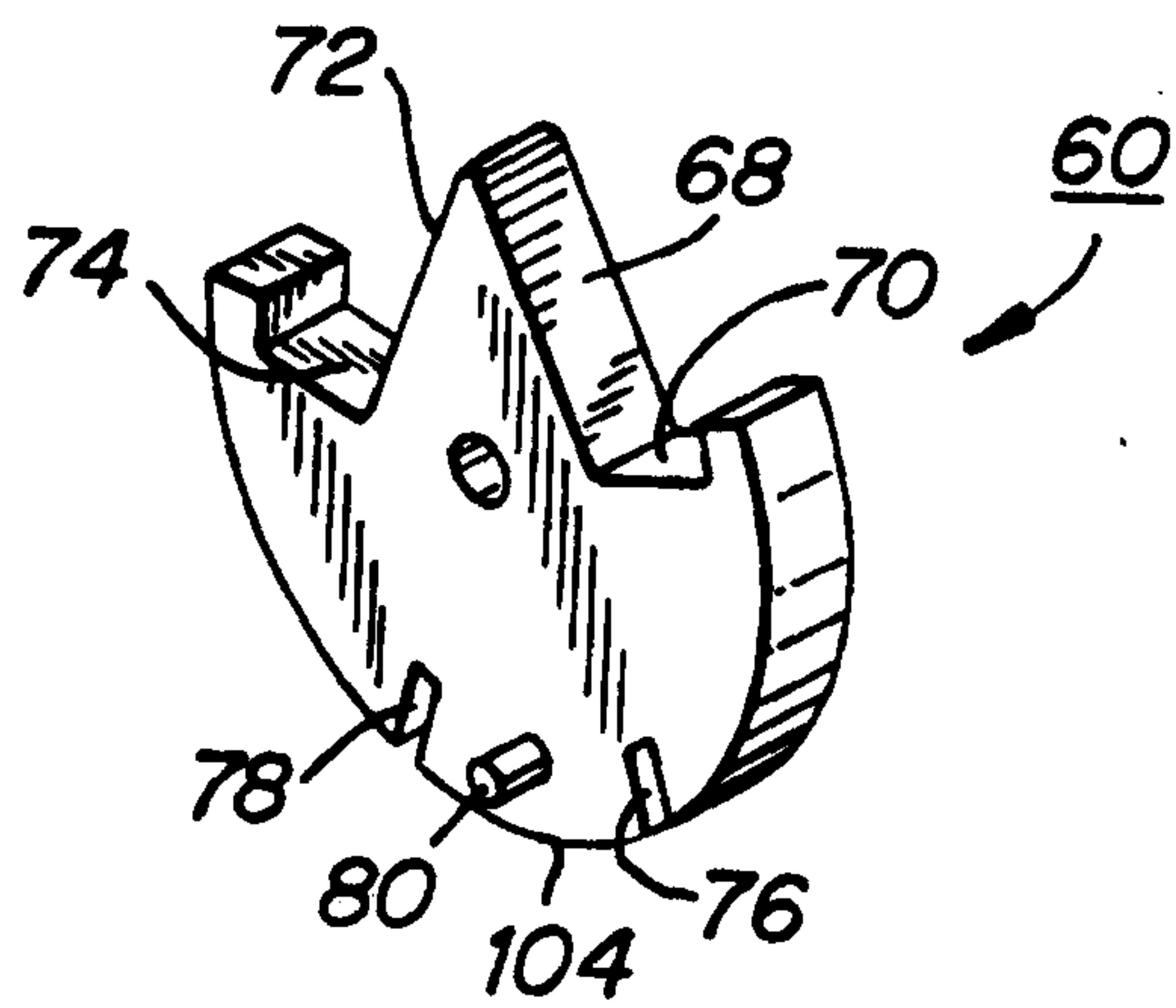


FIG. 4

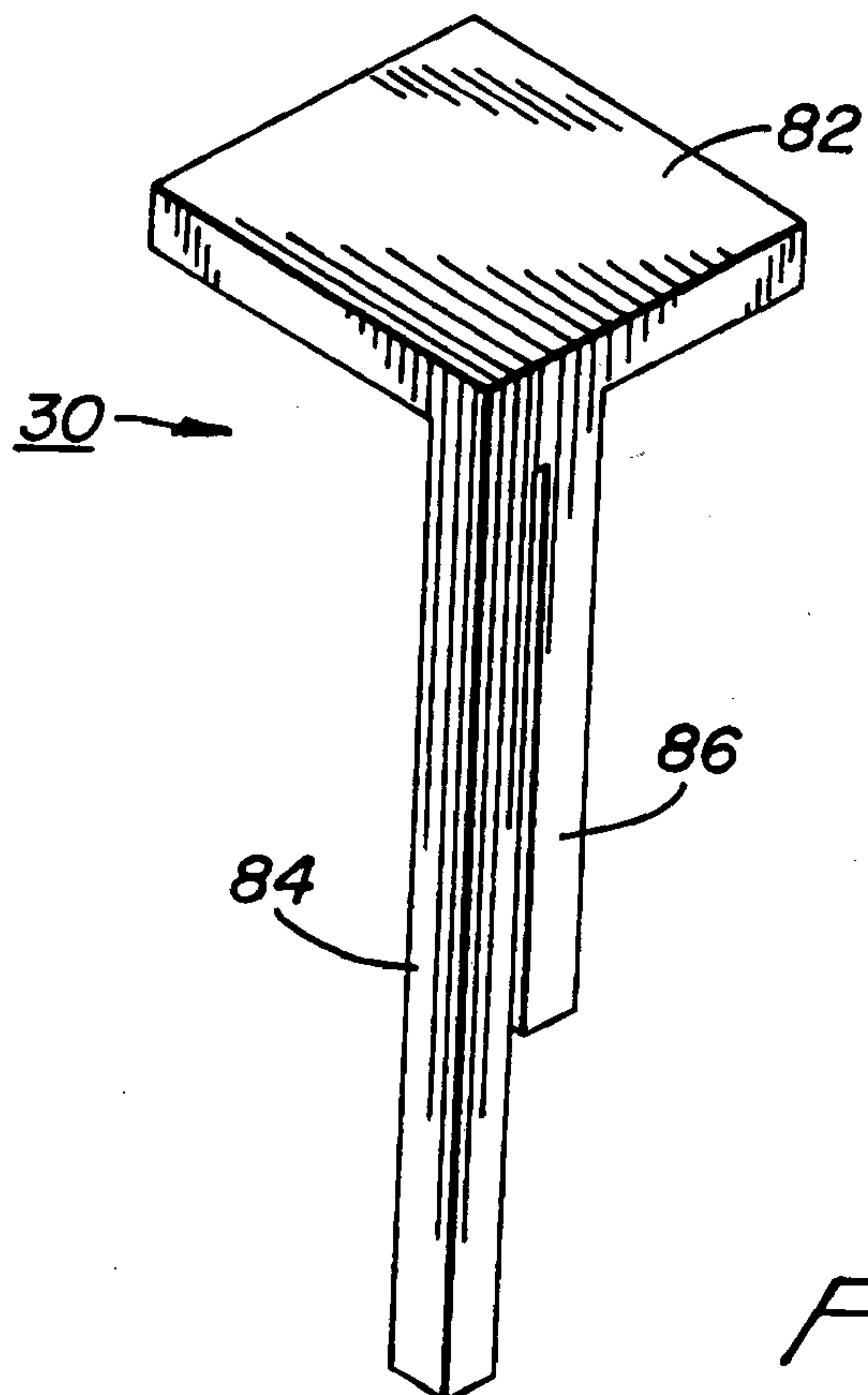
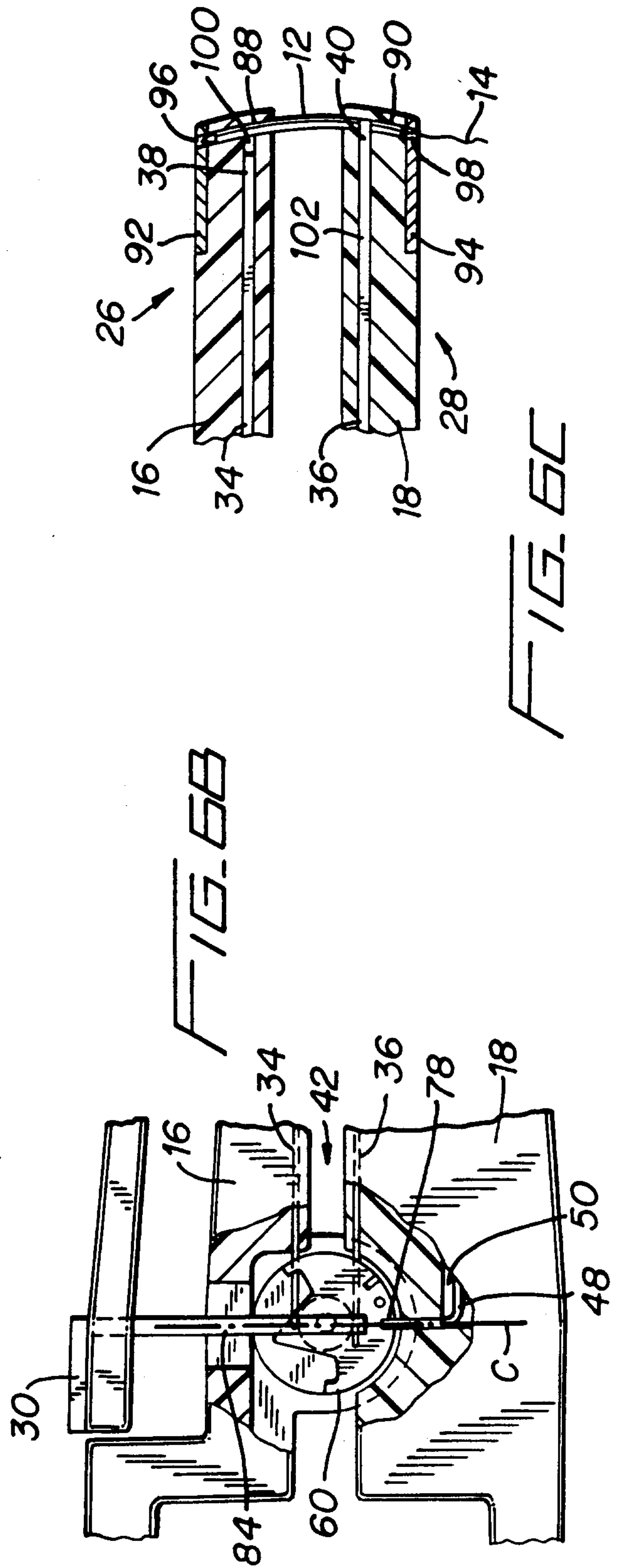
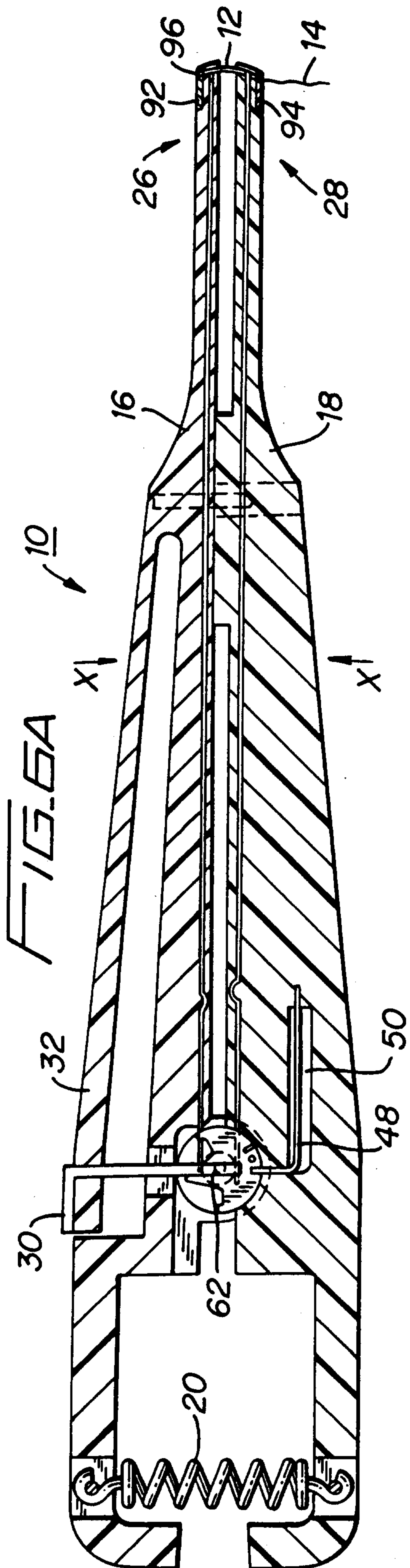
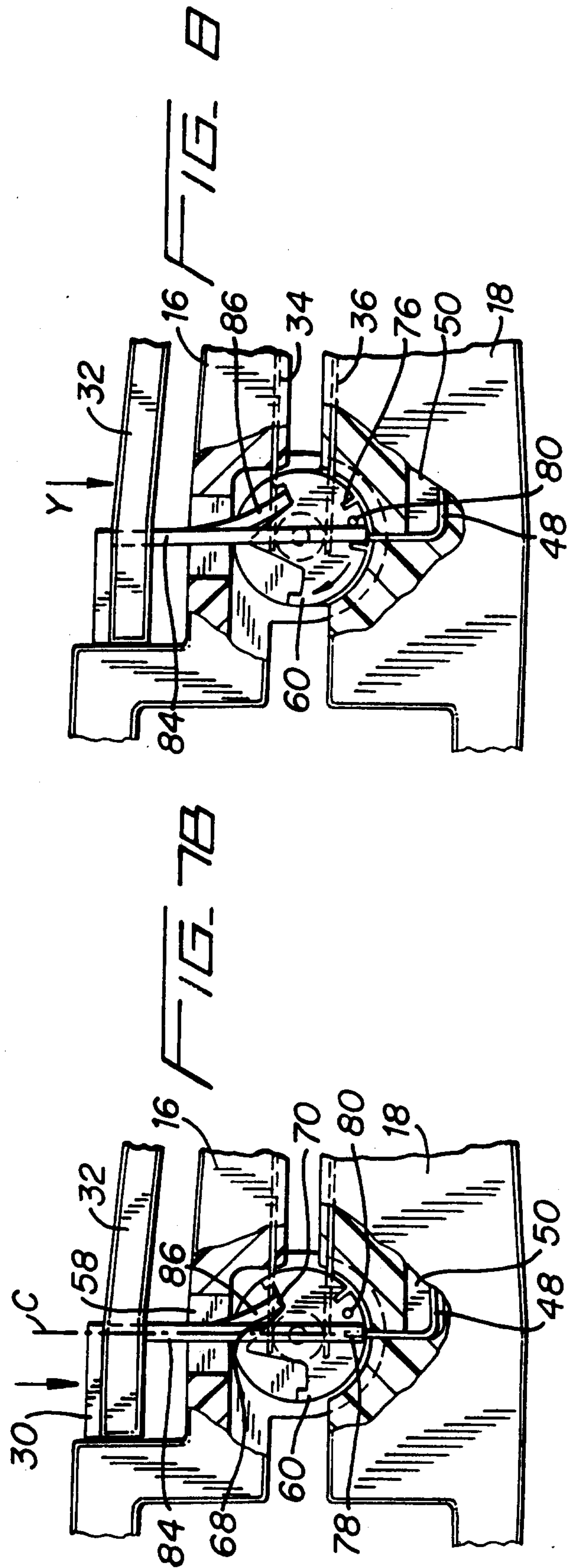
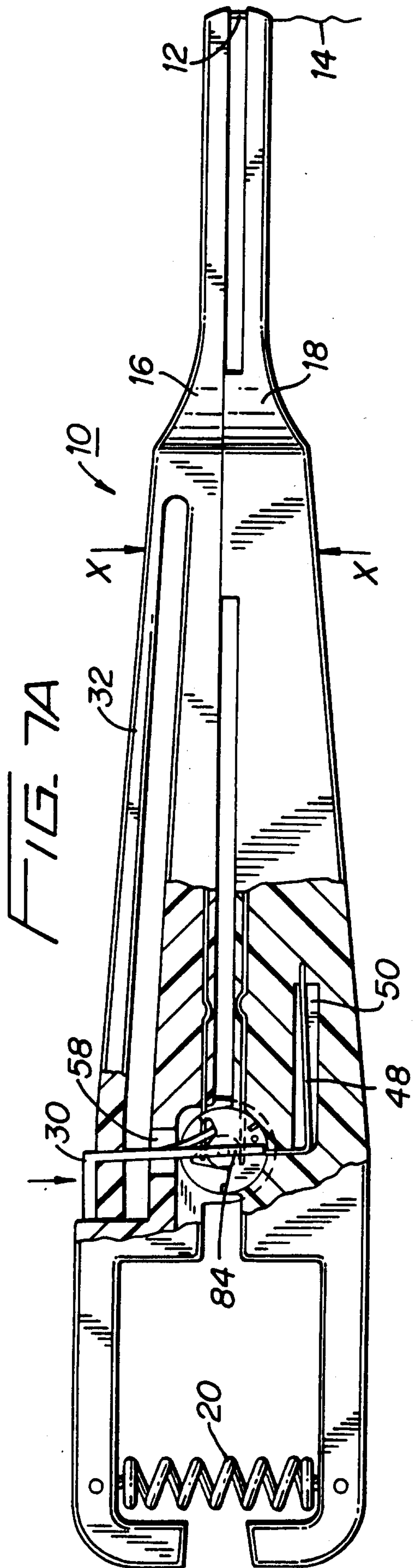


FIG. 5





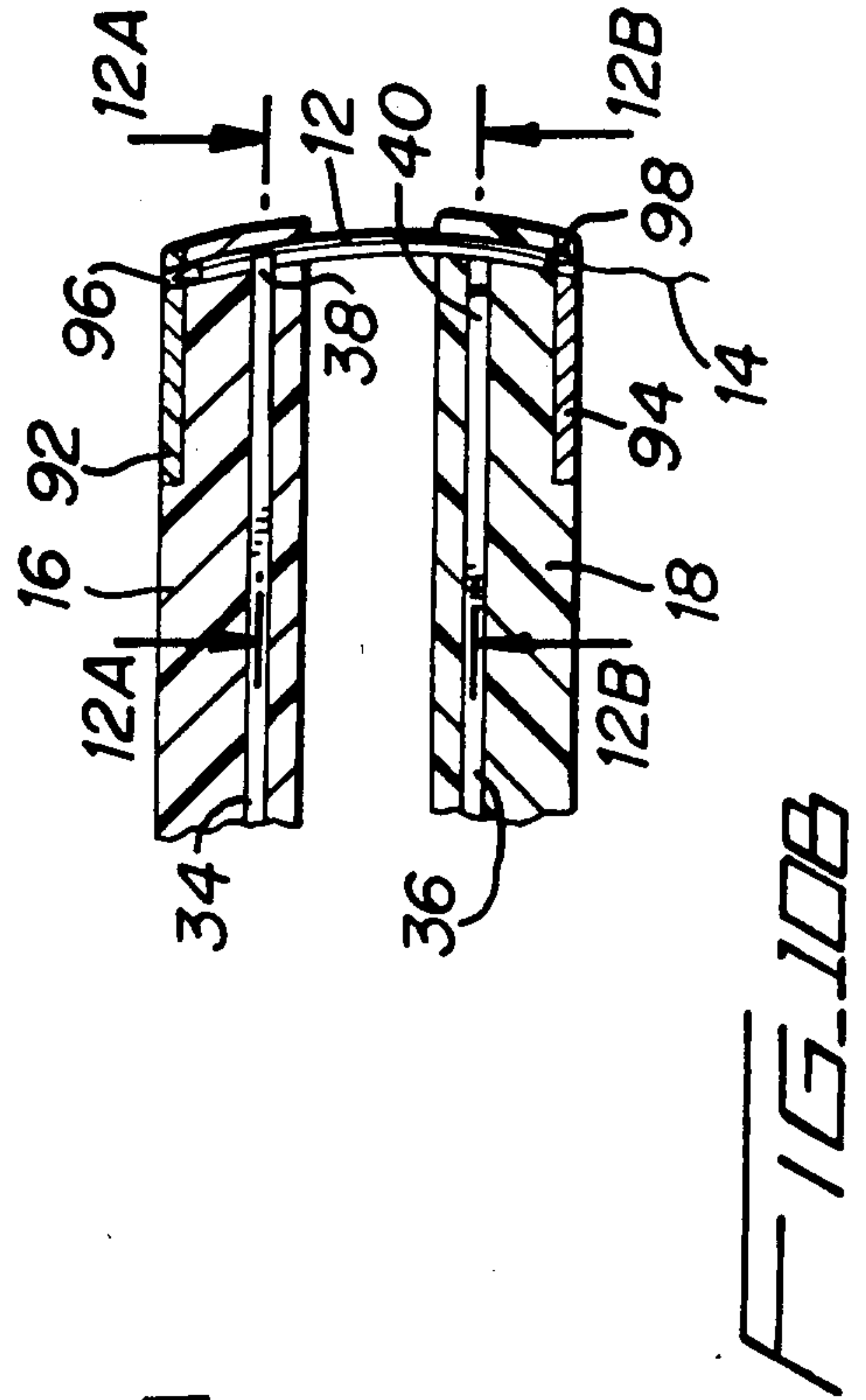
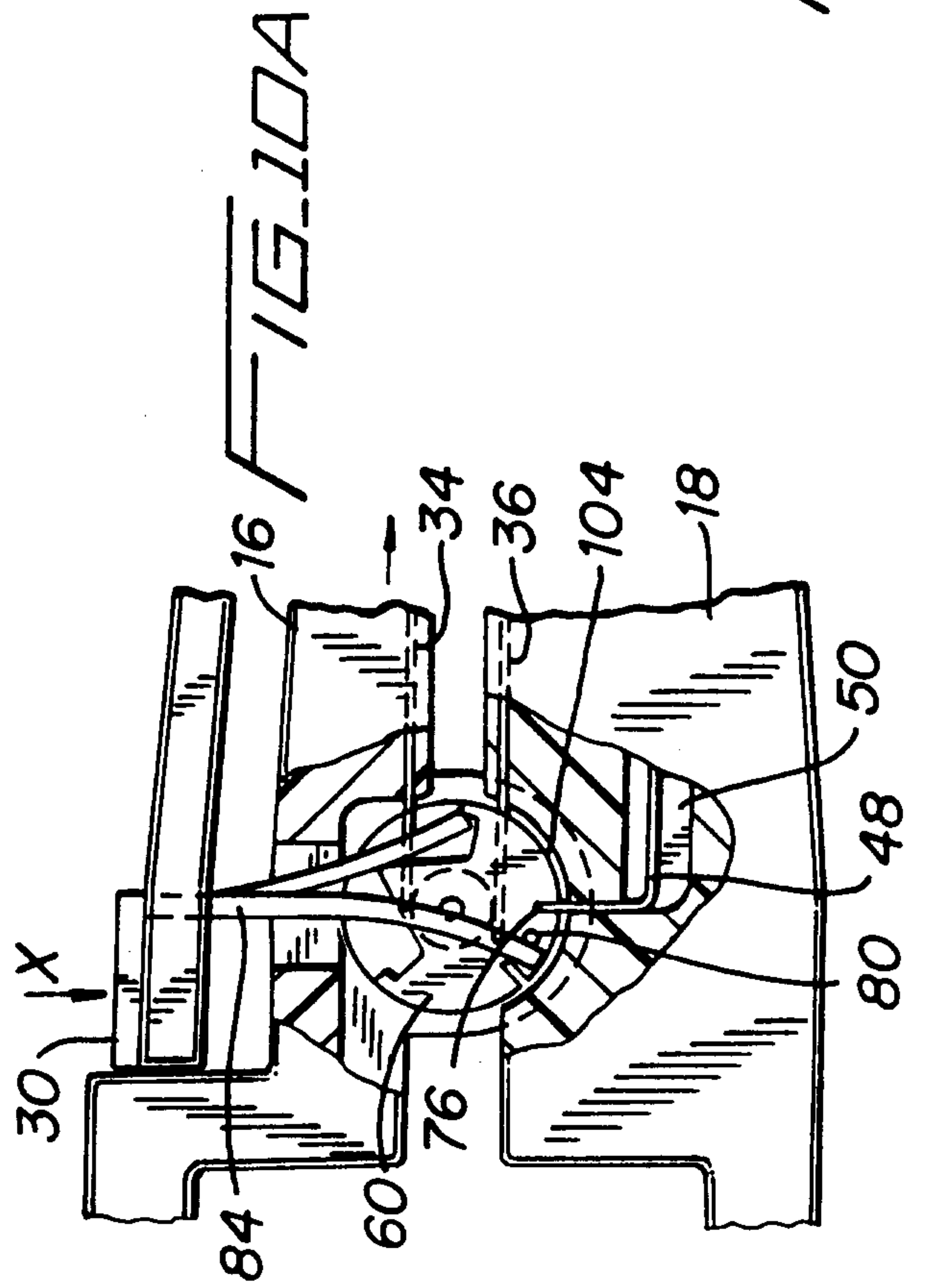
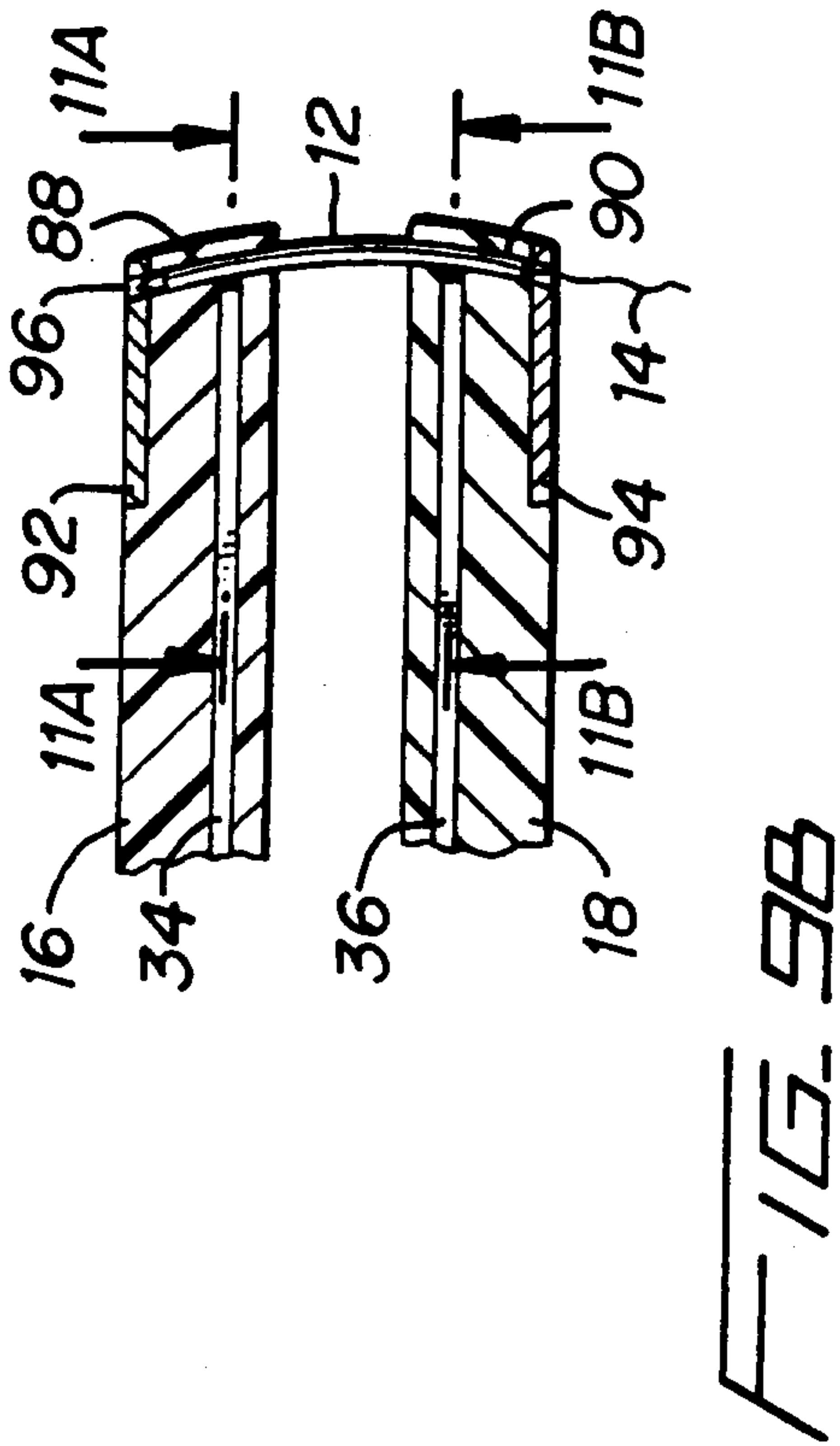
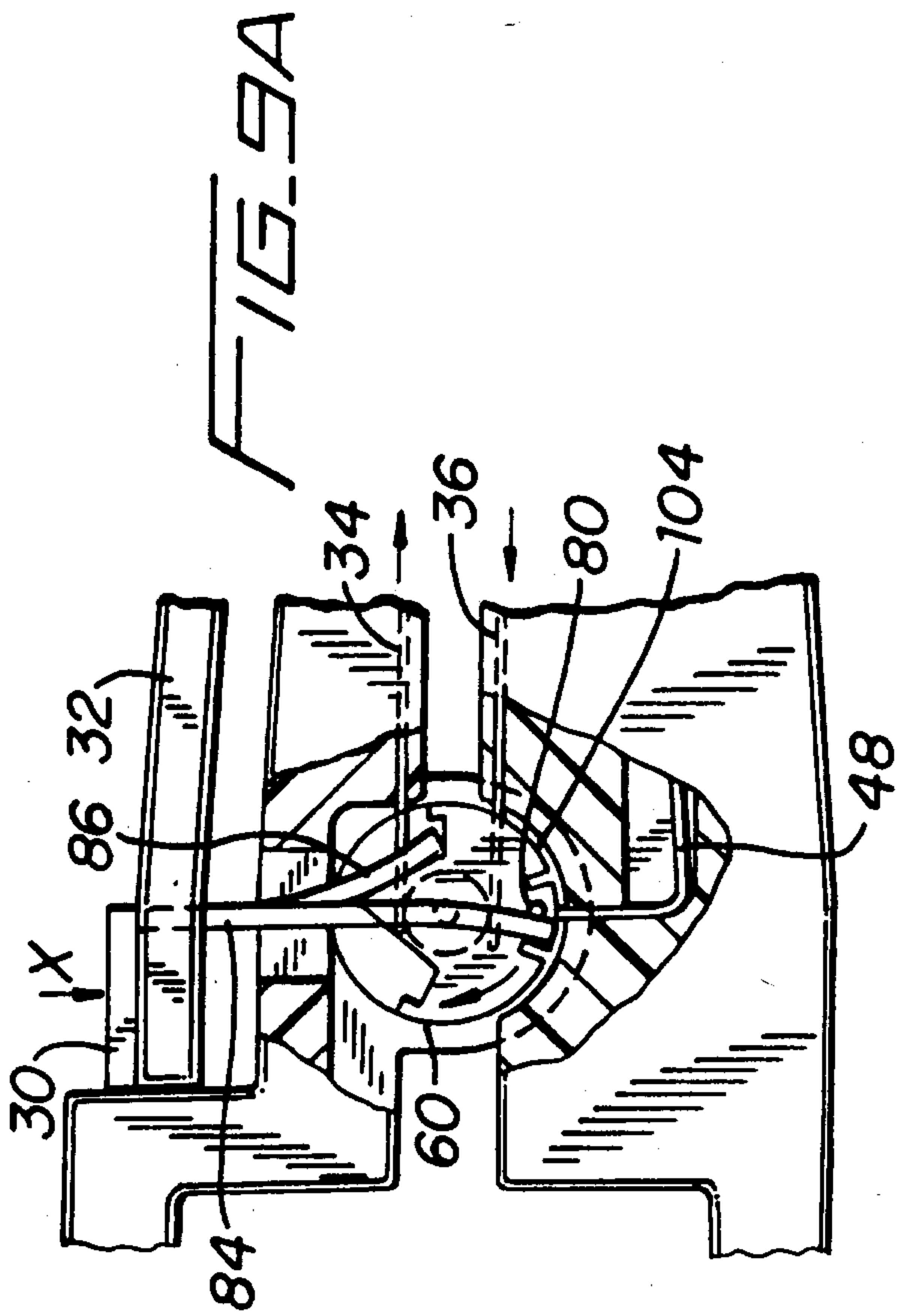


FIG. 11A

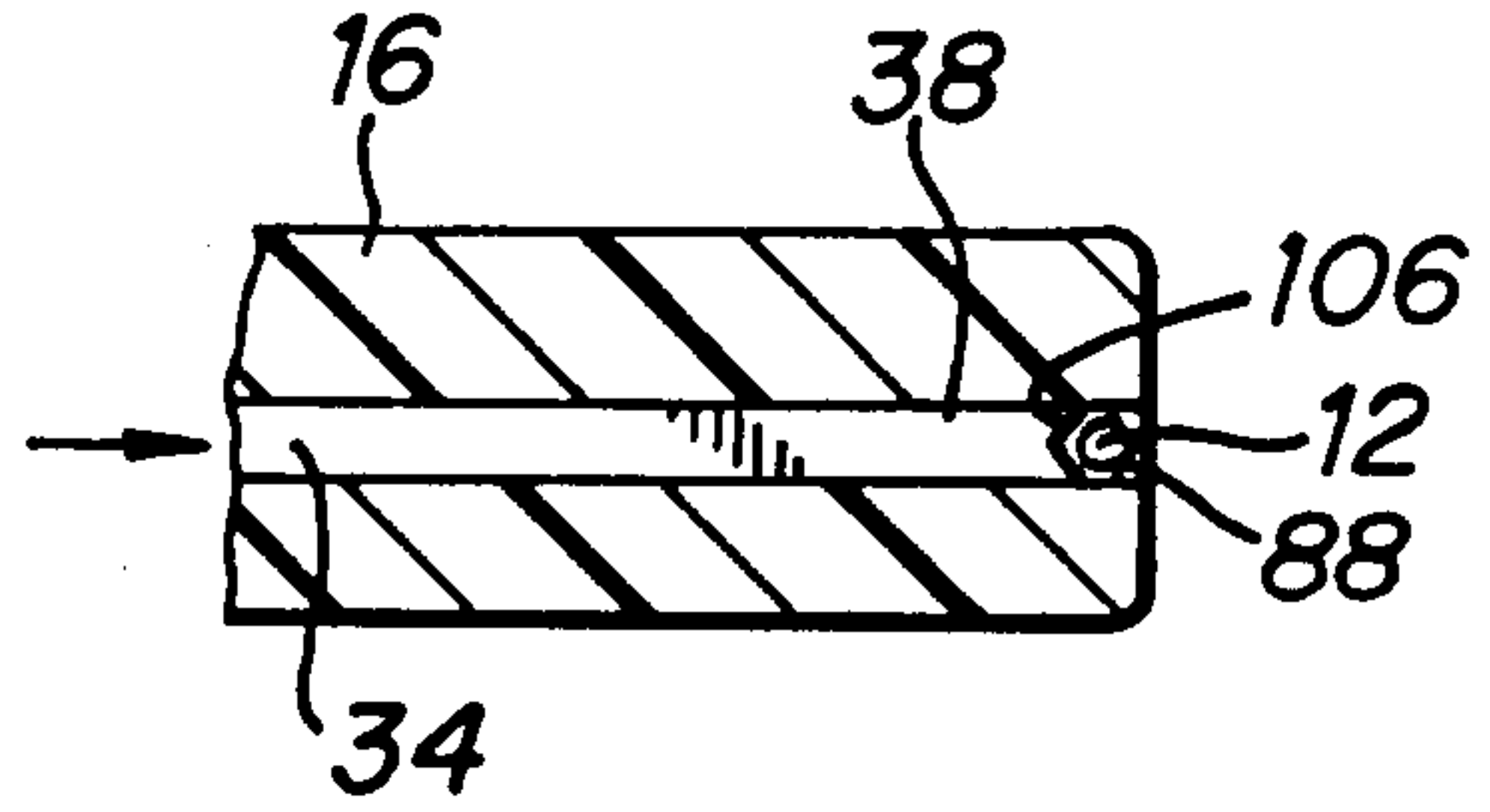


FIG. 11B

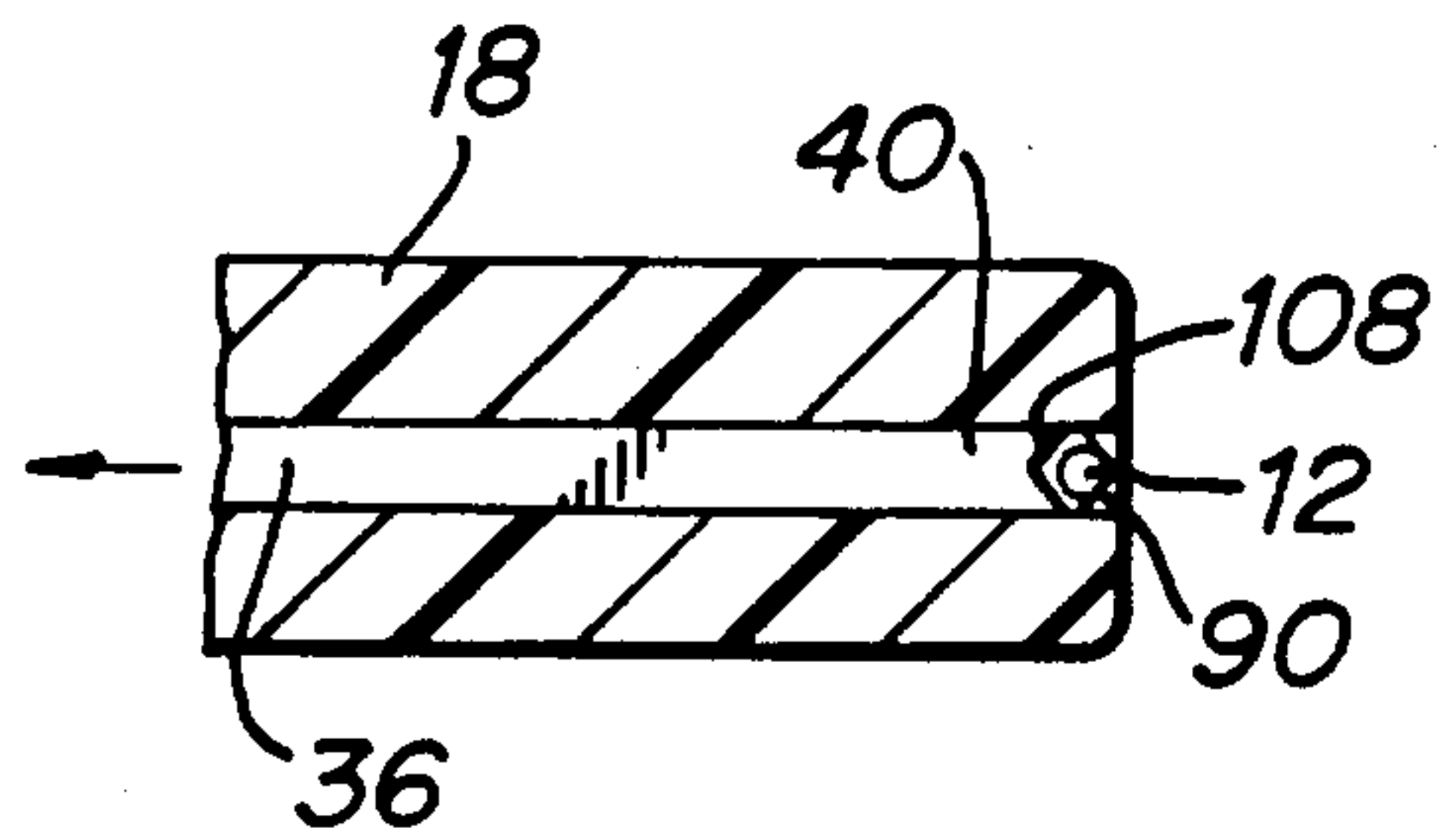


FIG. 12A

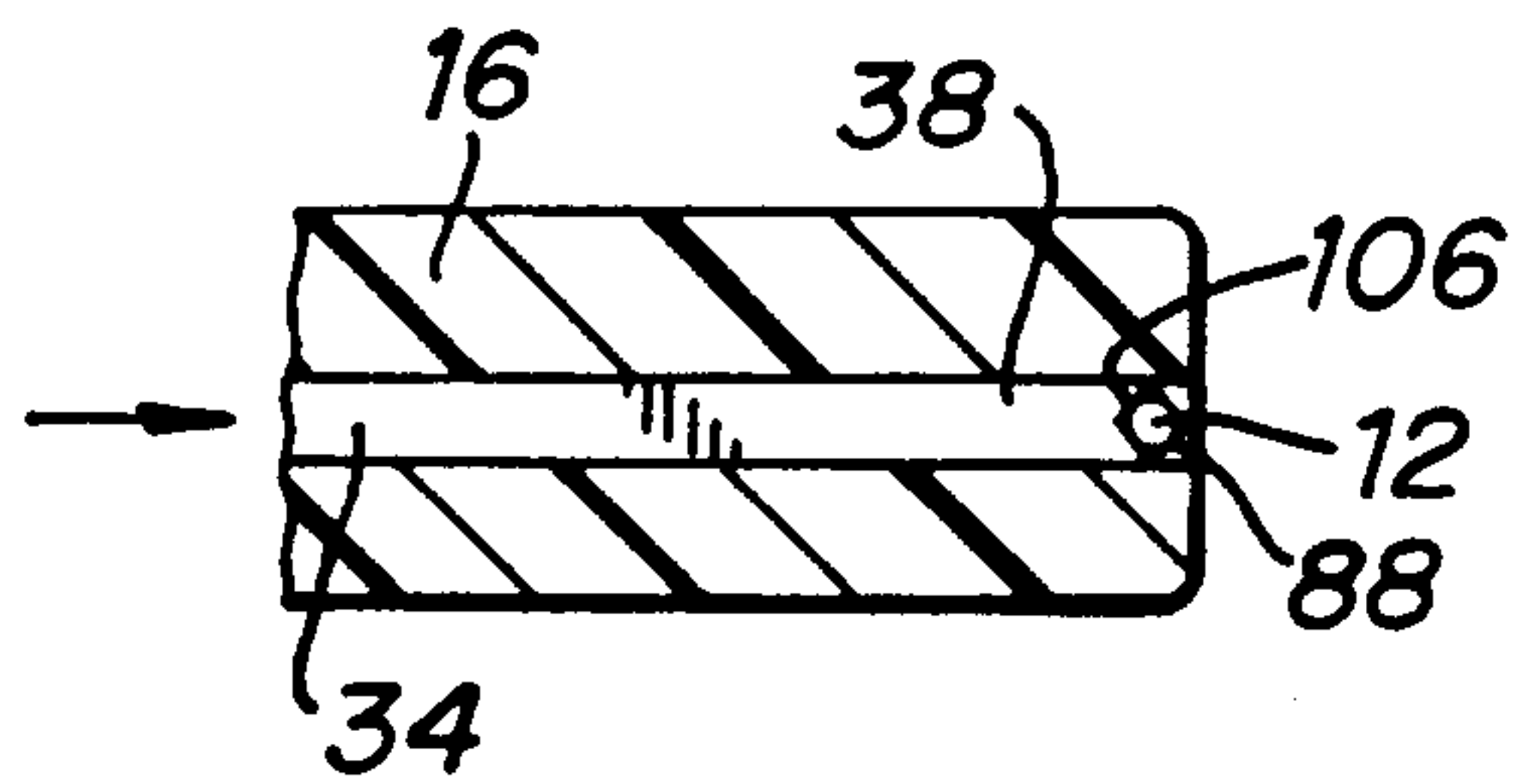
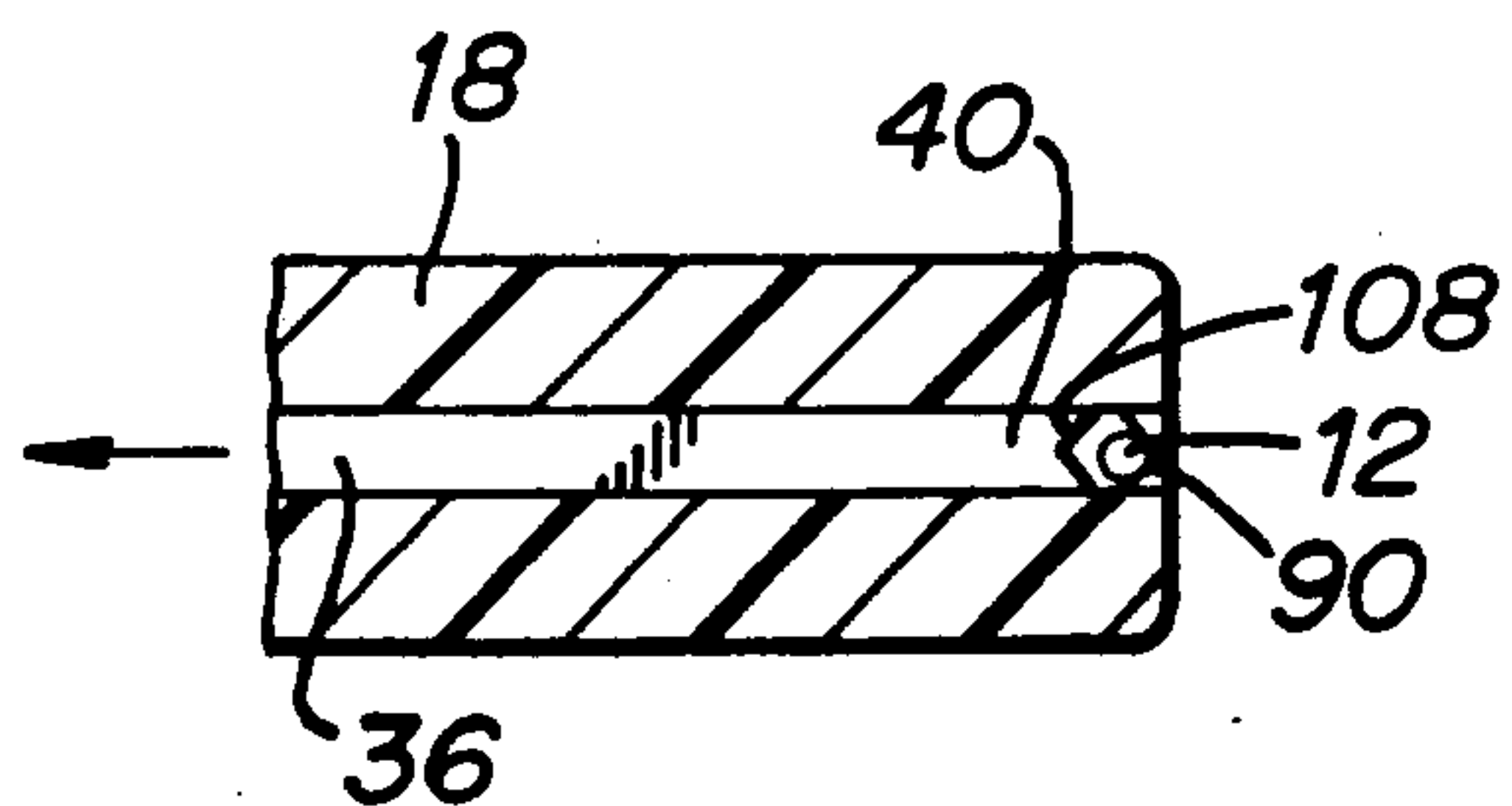
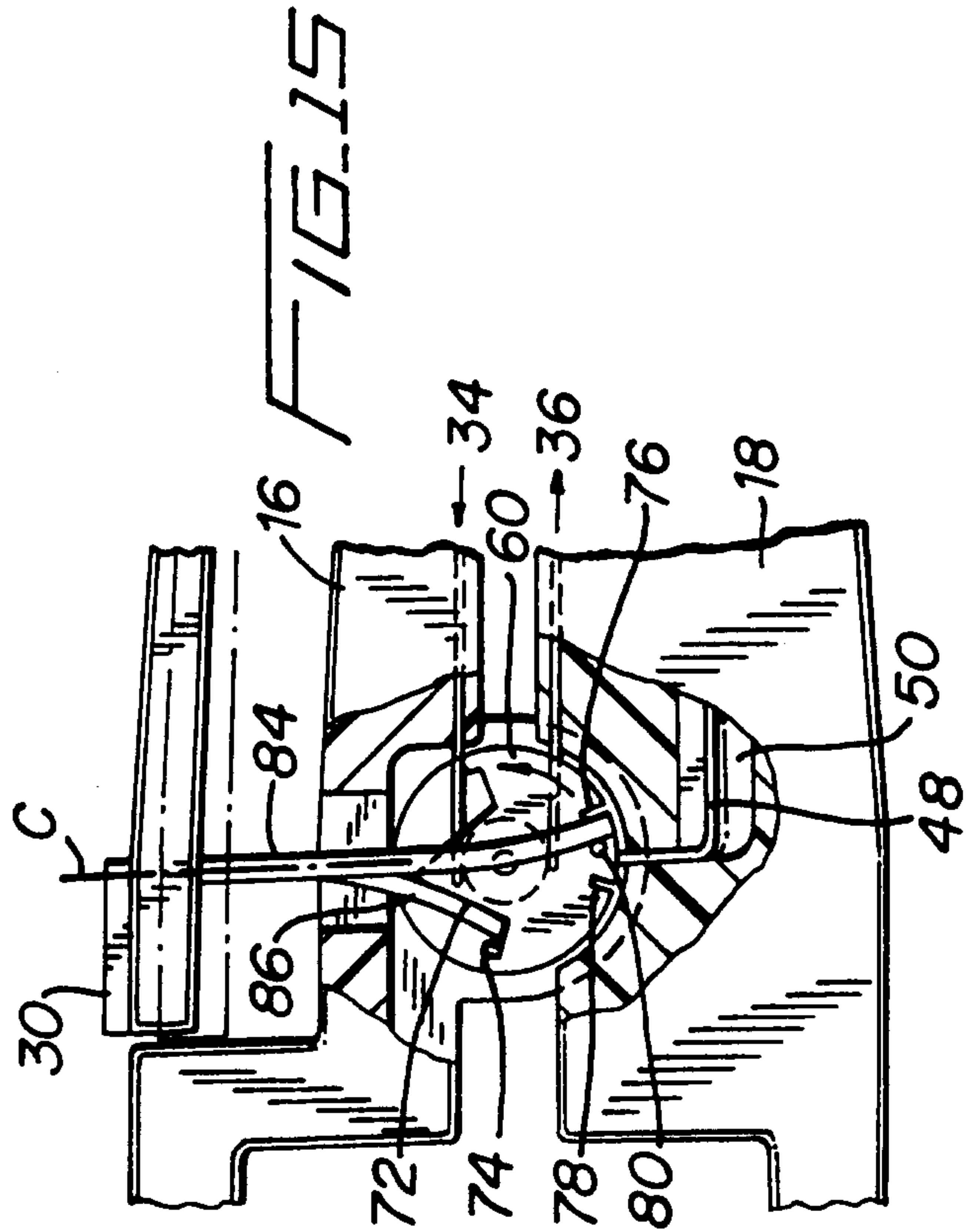
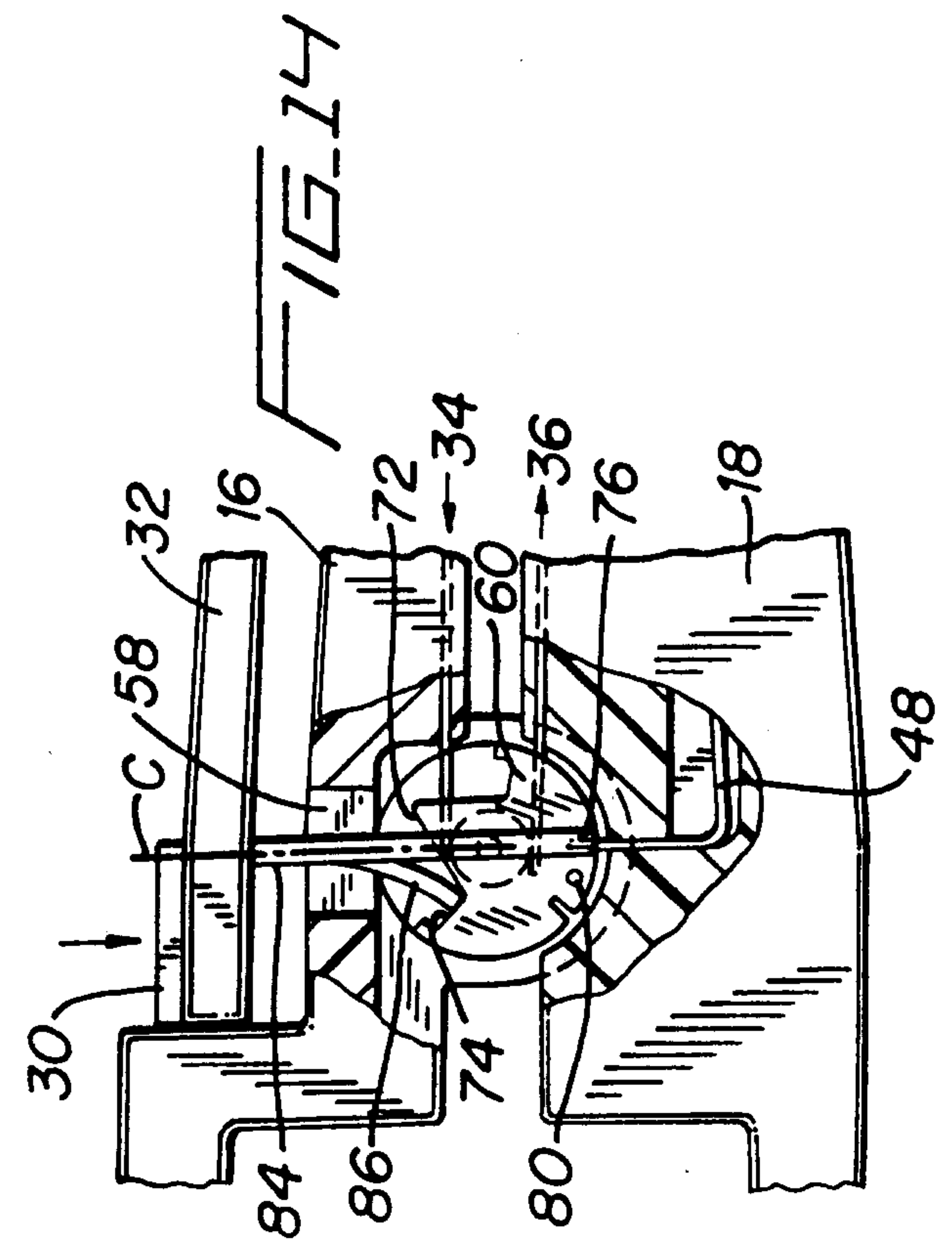
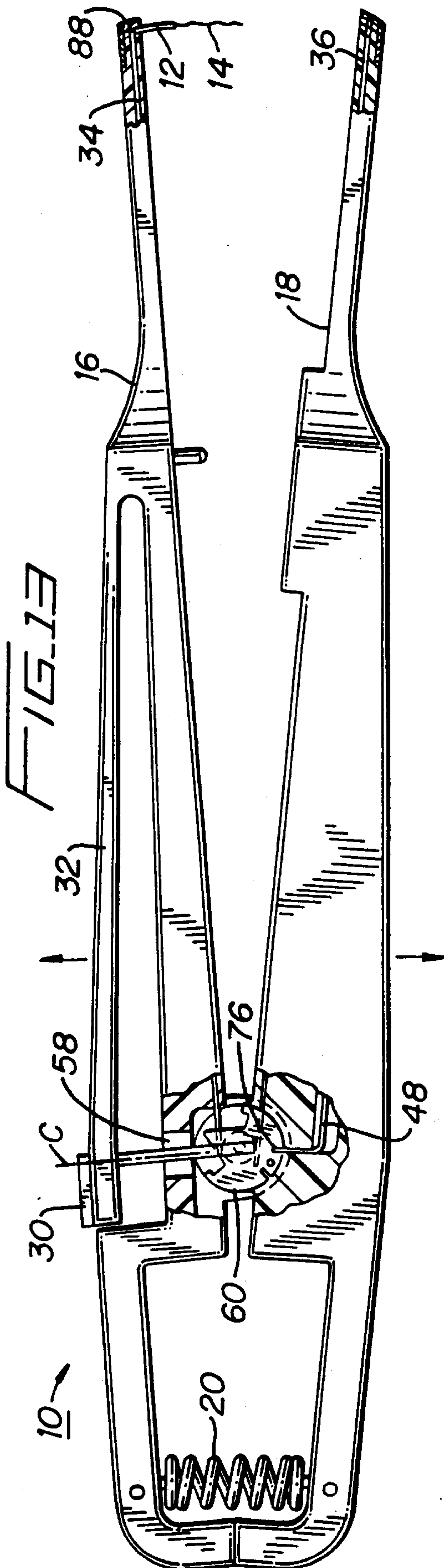


FIG. 12B





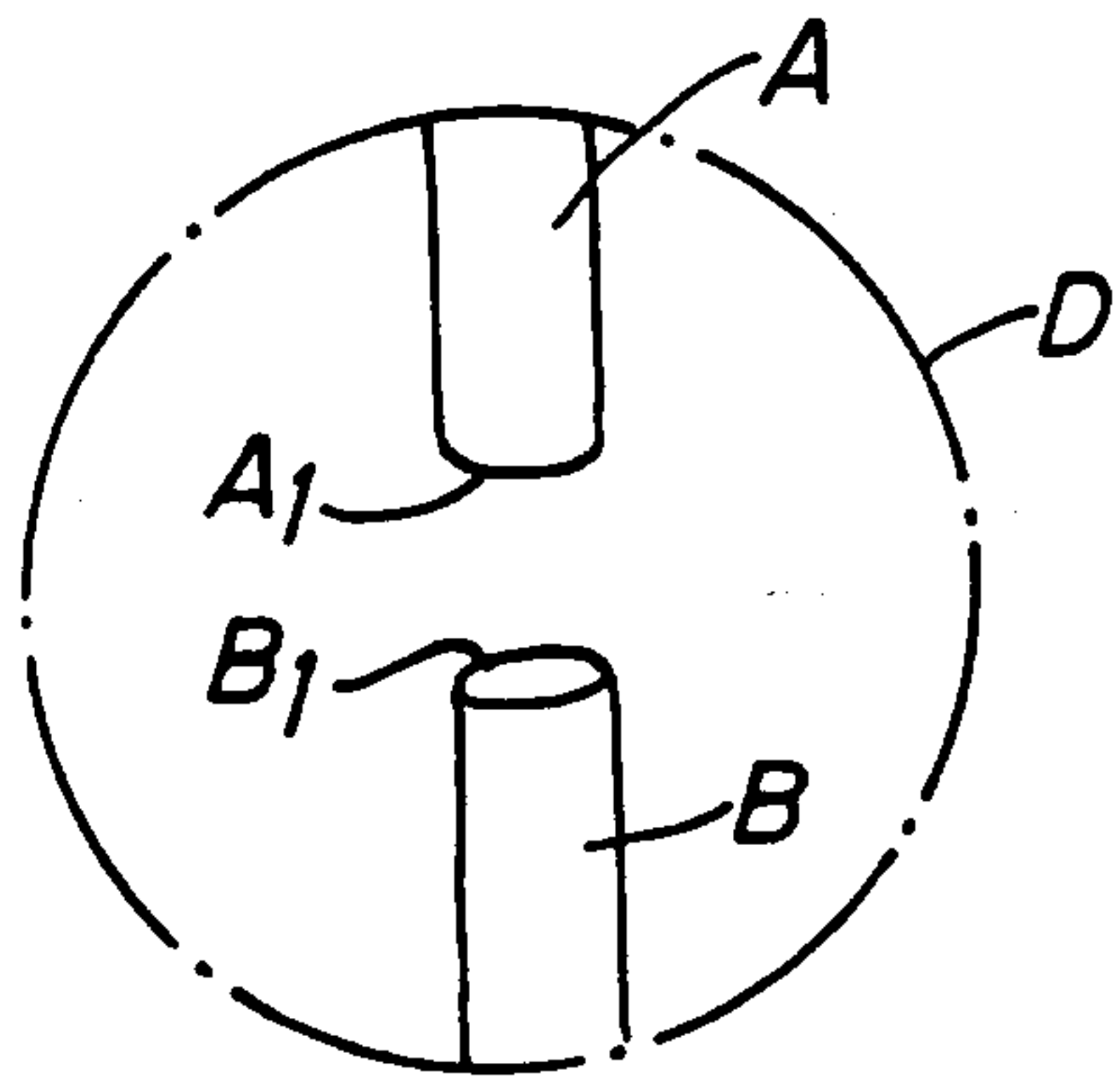


FIG. 16A

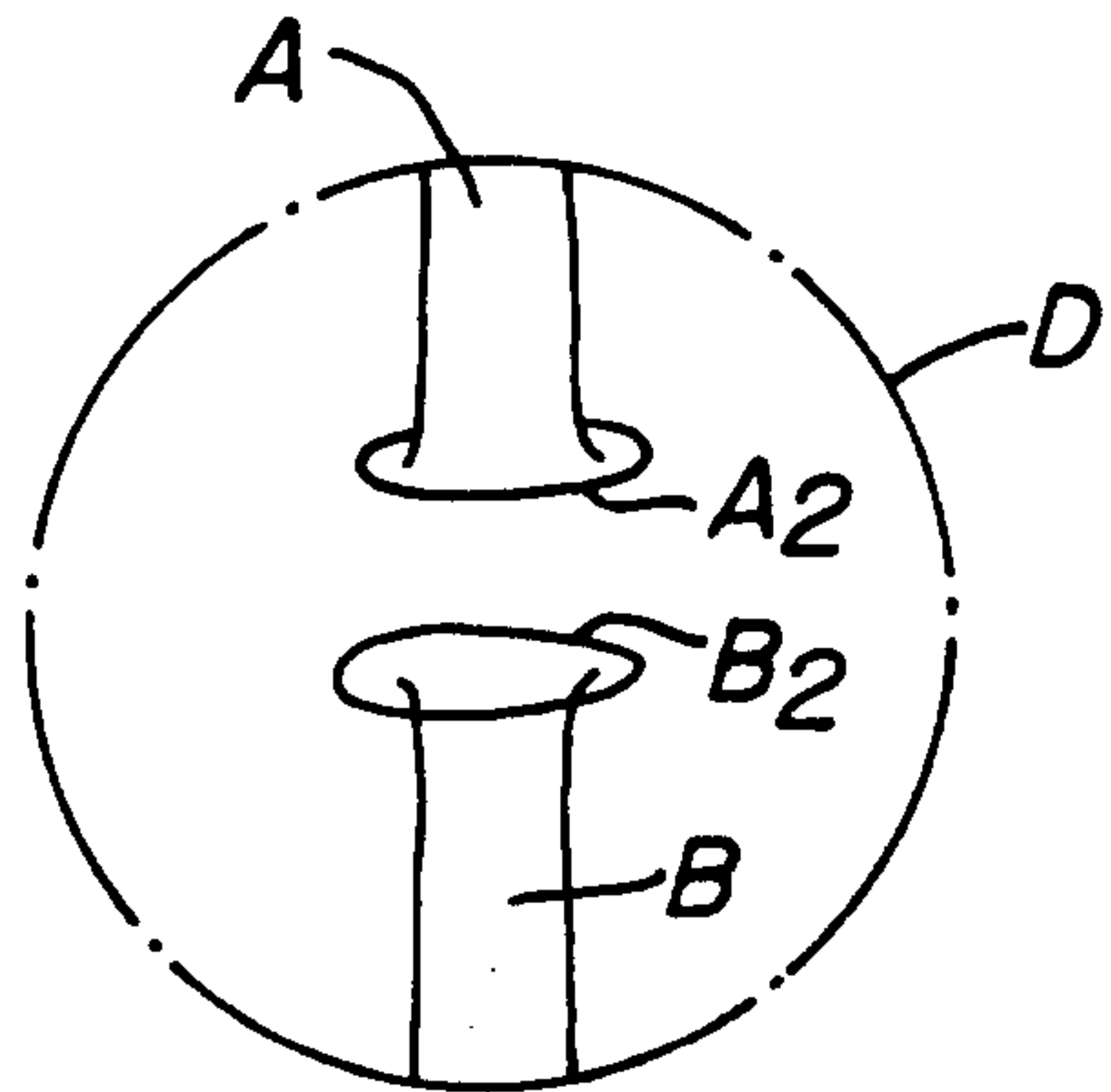


FIG. 16B

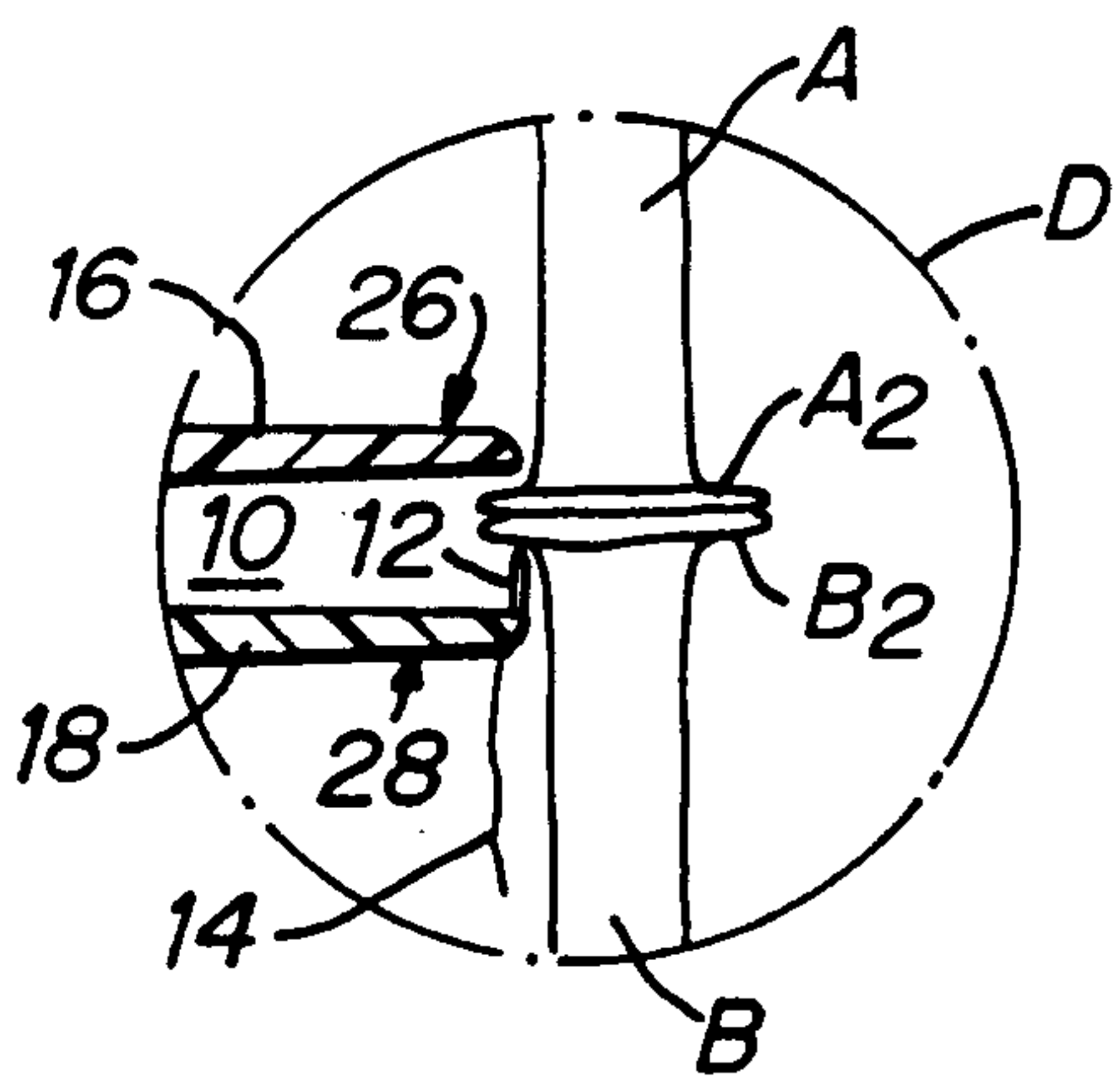


FIG. 16C

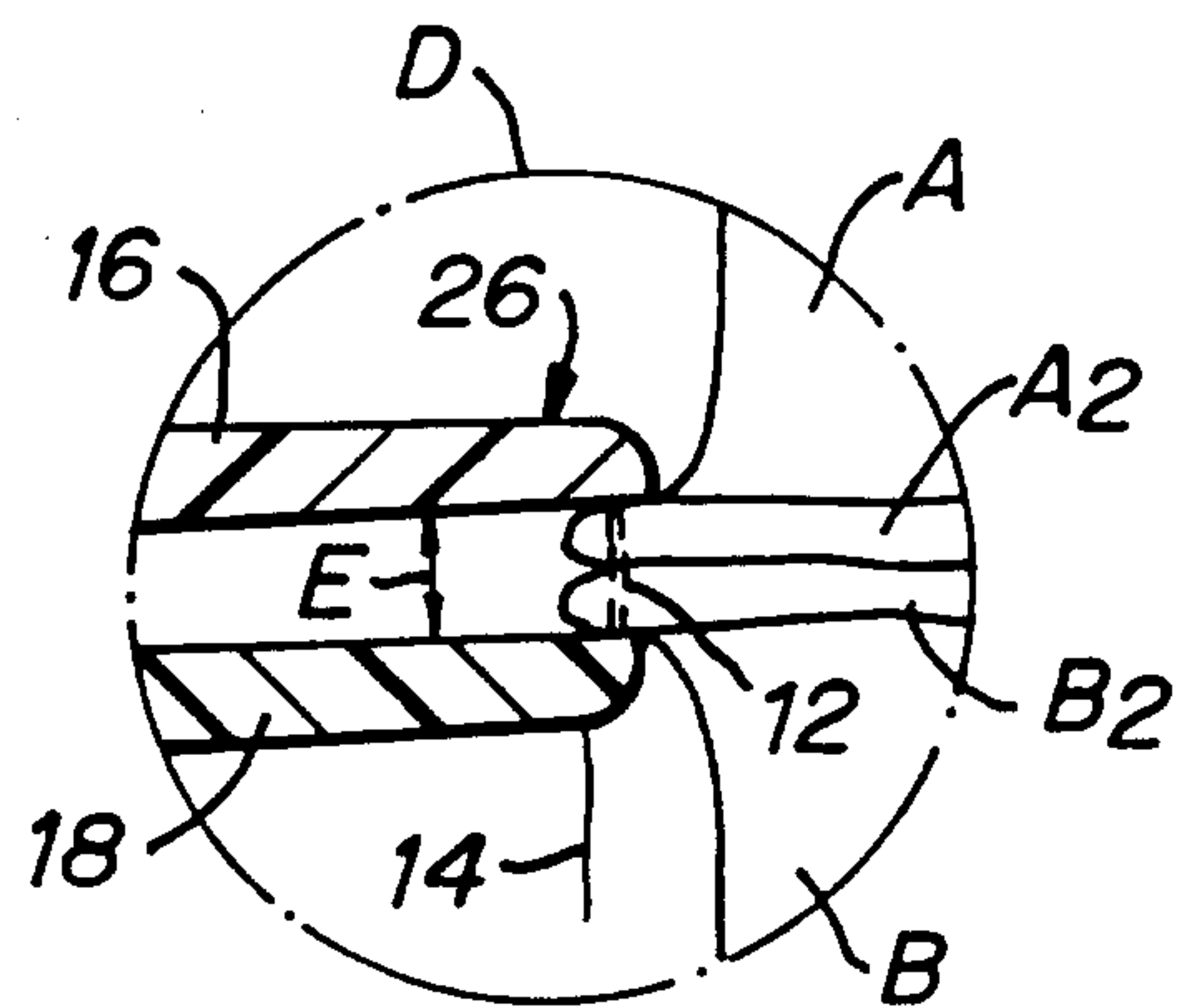


FIG. 16D

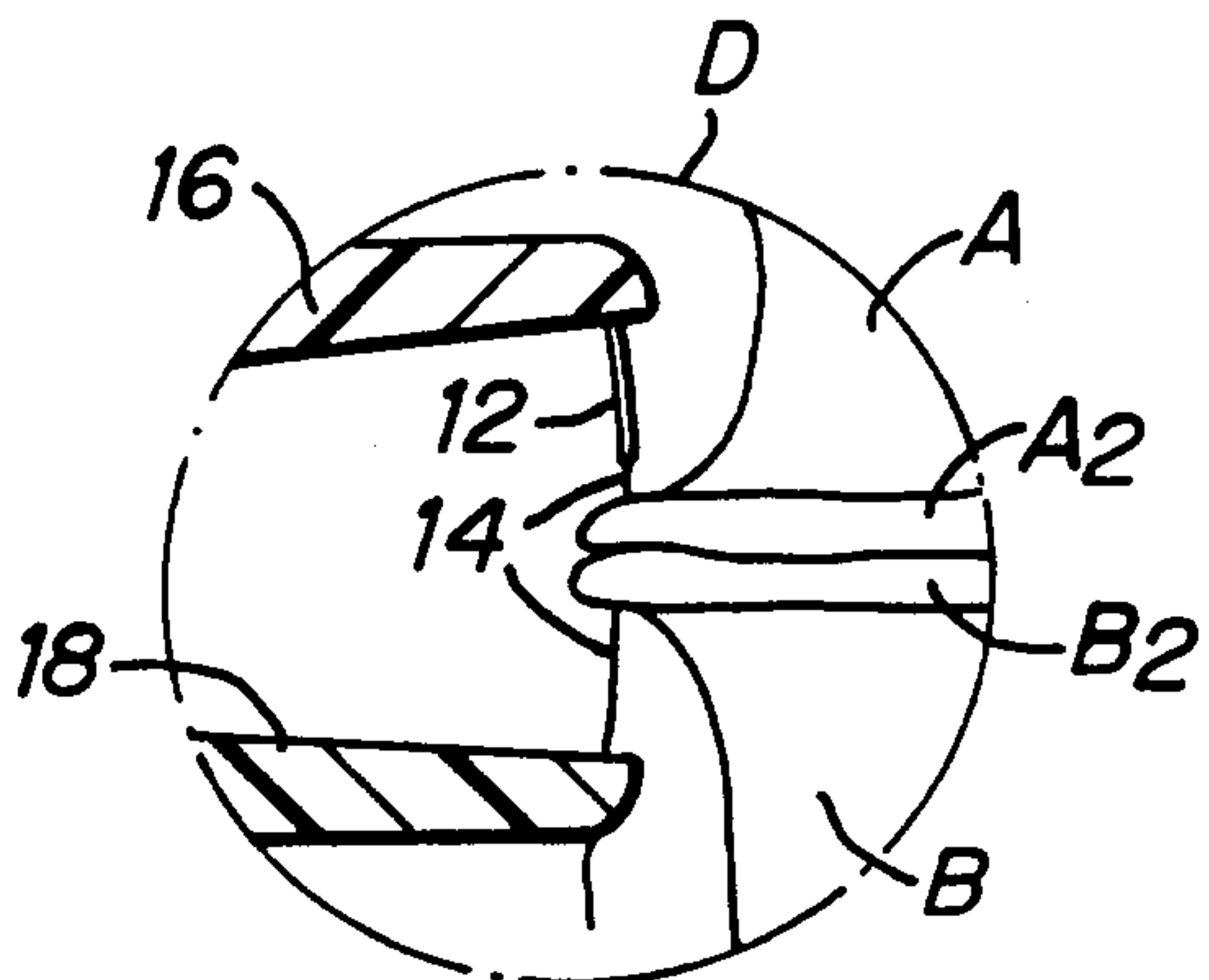


FIG. 16E

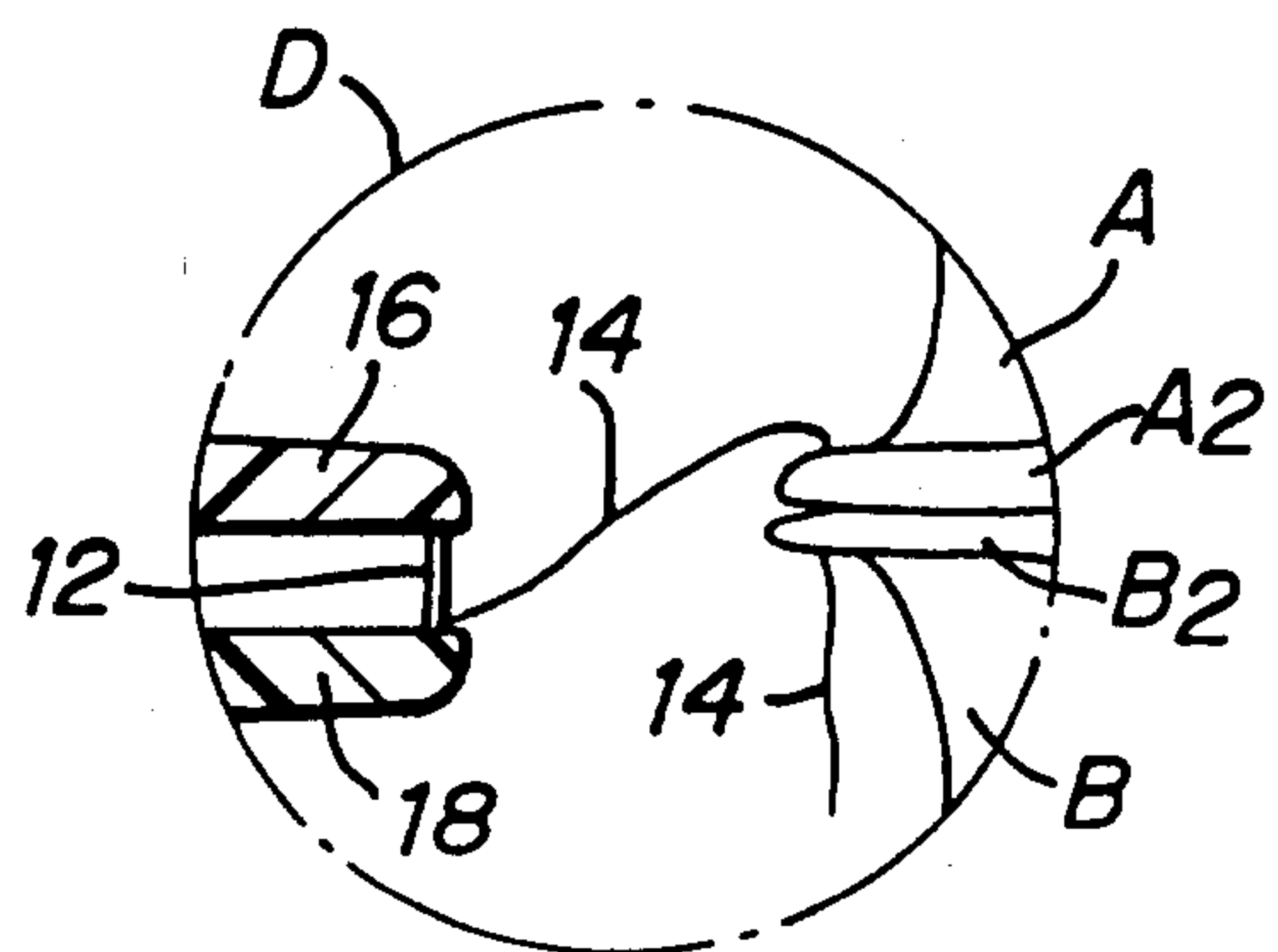


FIG. 16F

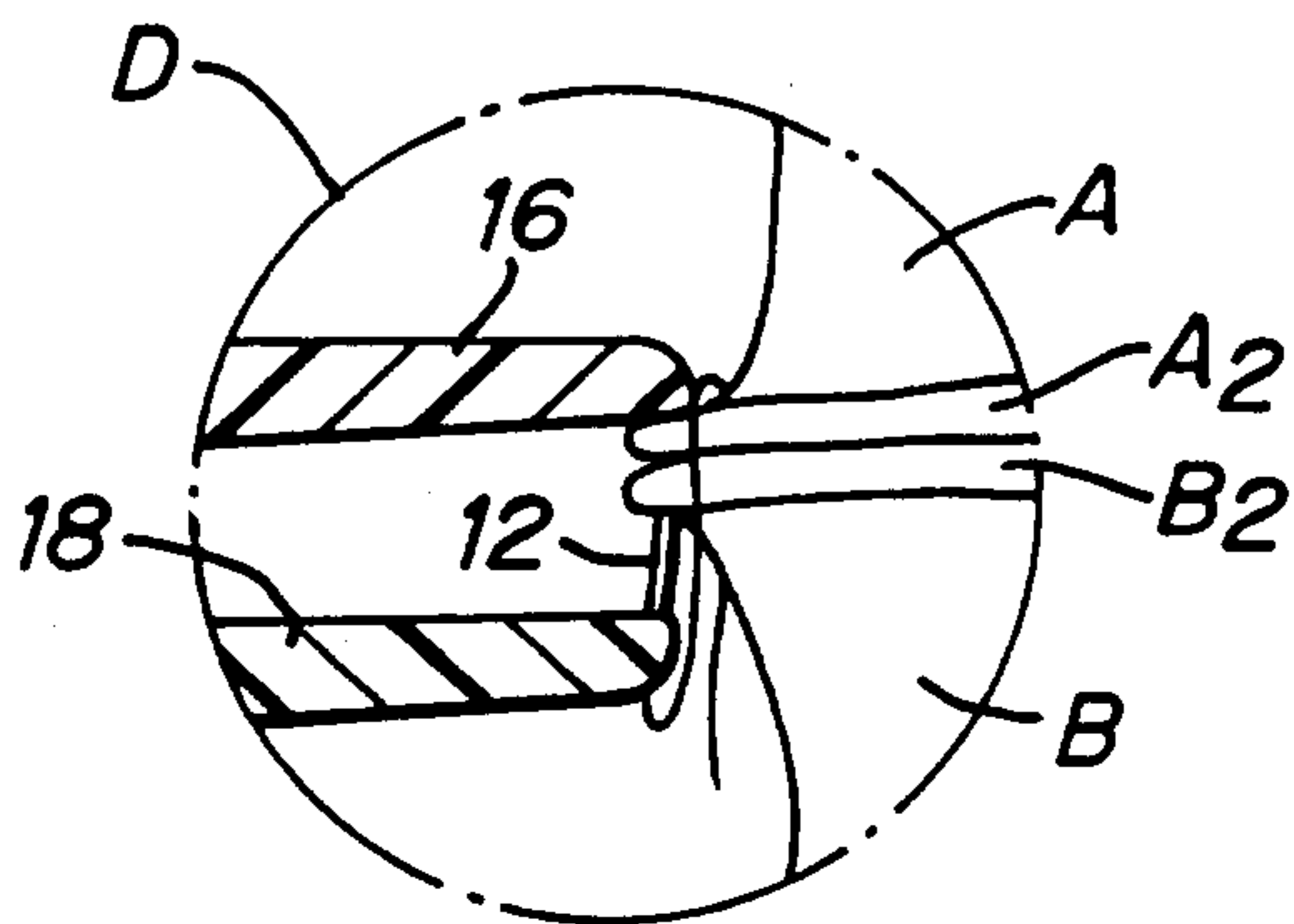


FIG. 16G

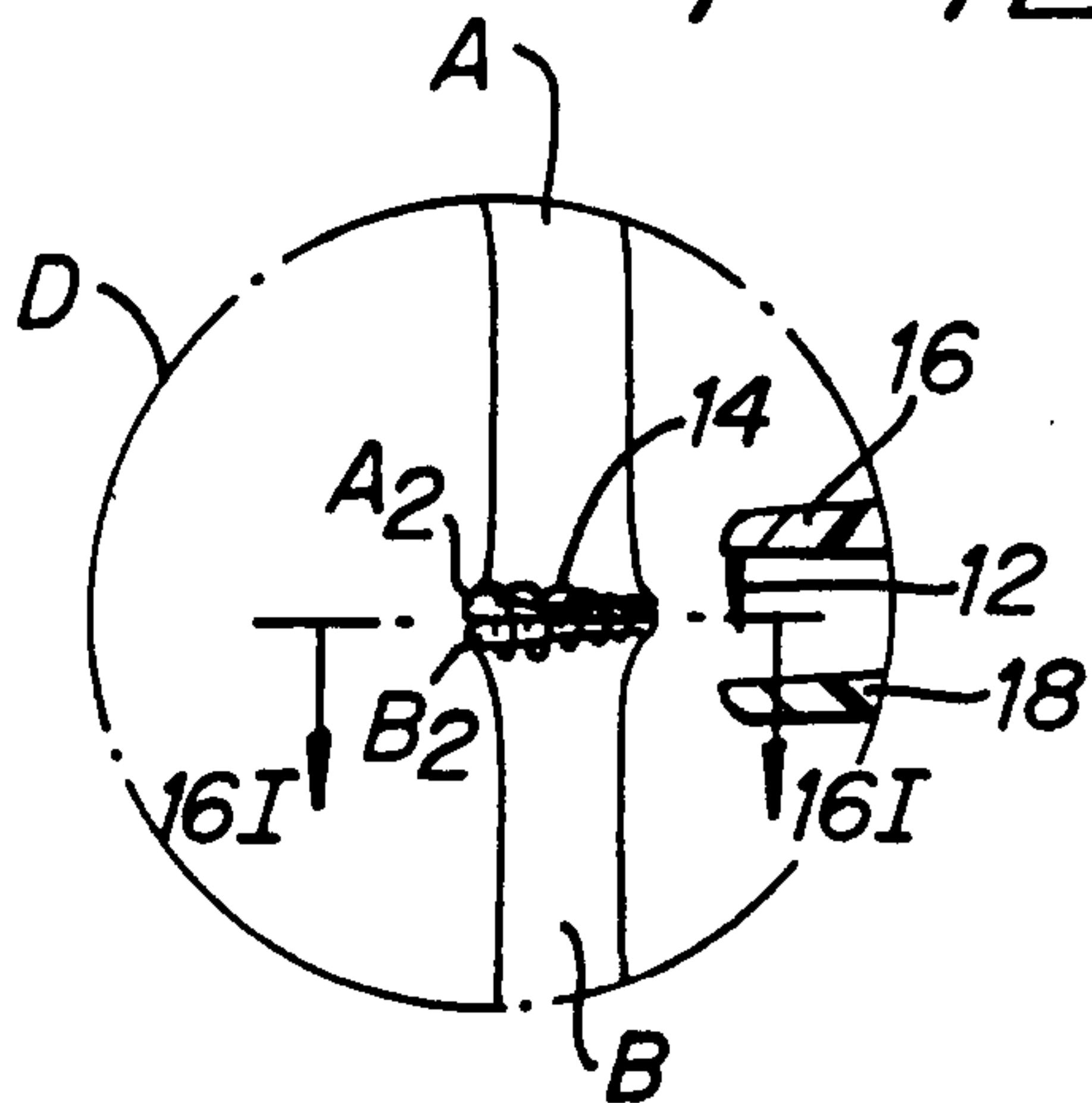


FIG. 16H

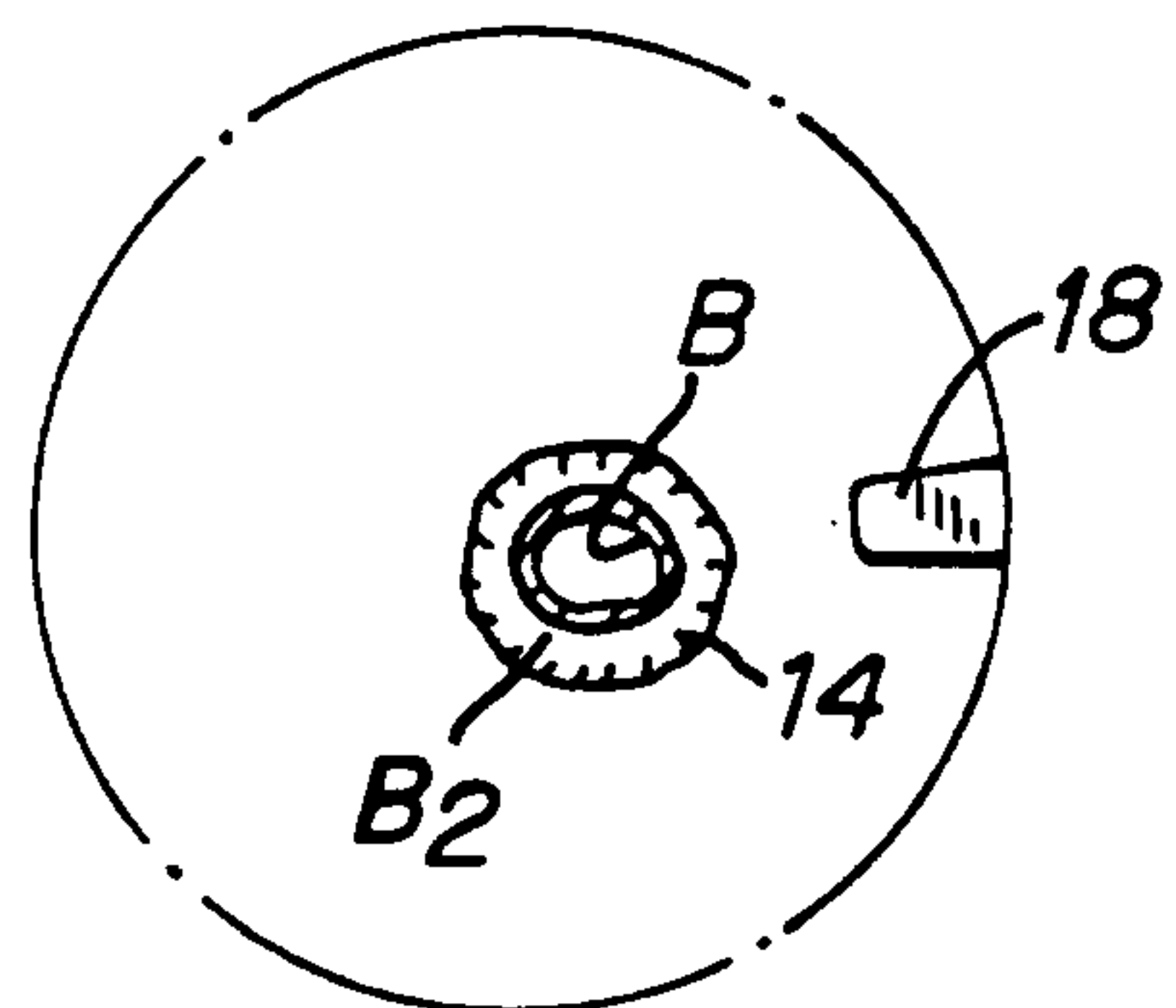


FIG. 16I

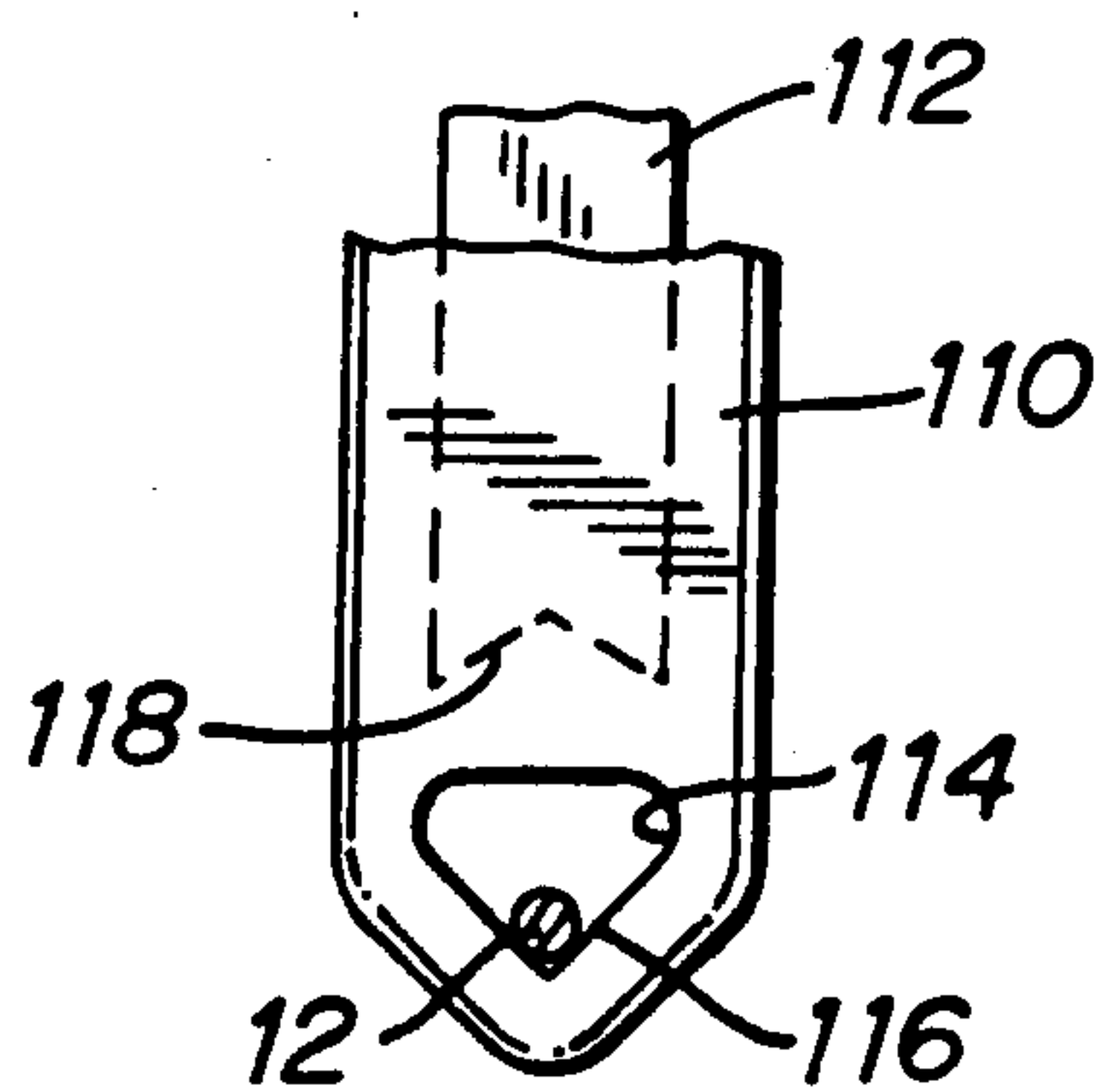


FIG. 17A

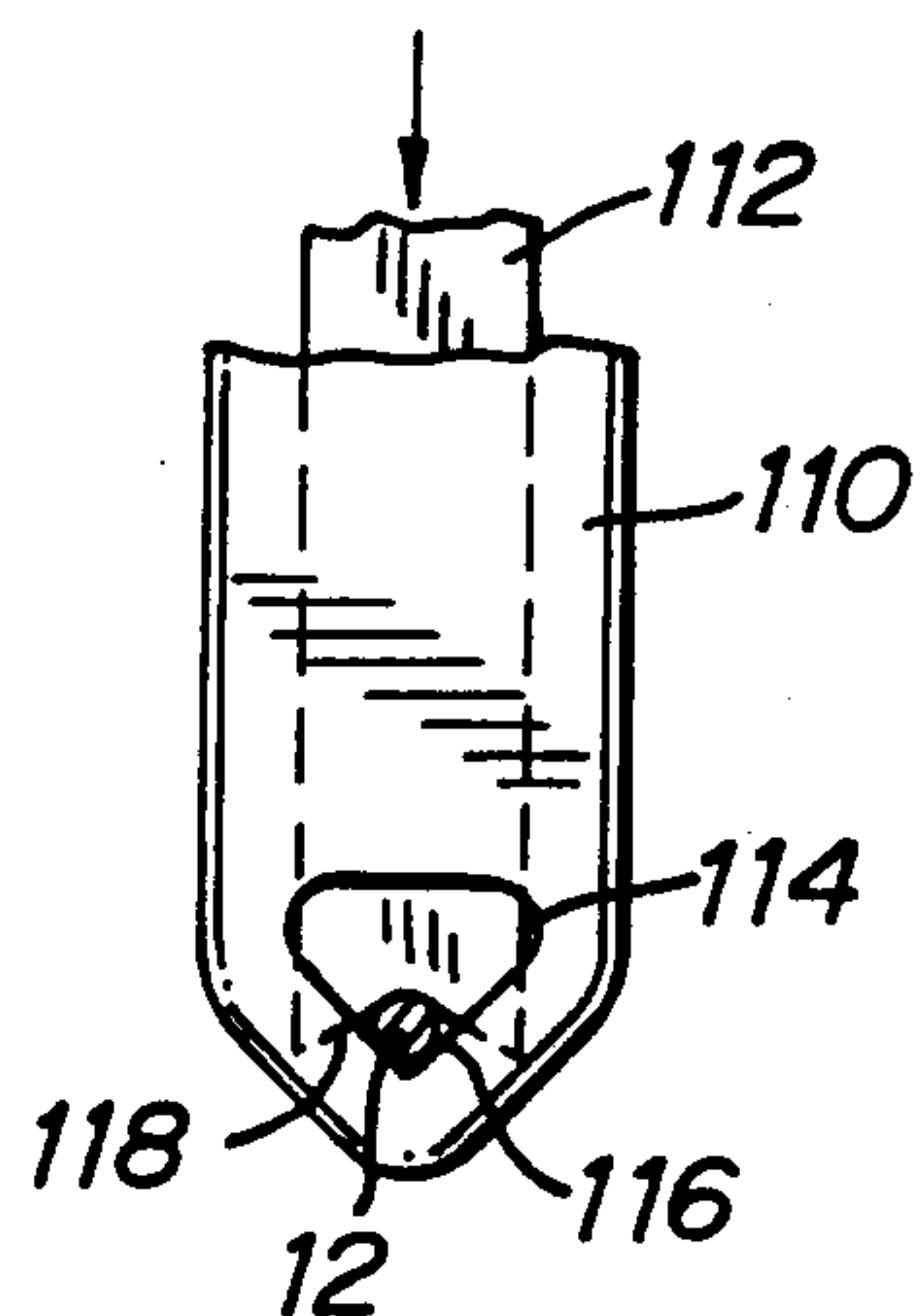


FIG. 17B

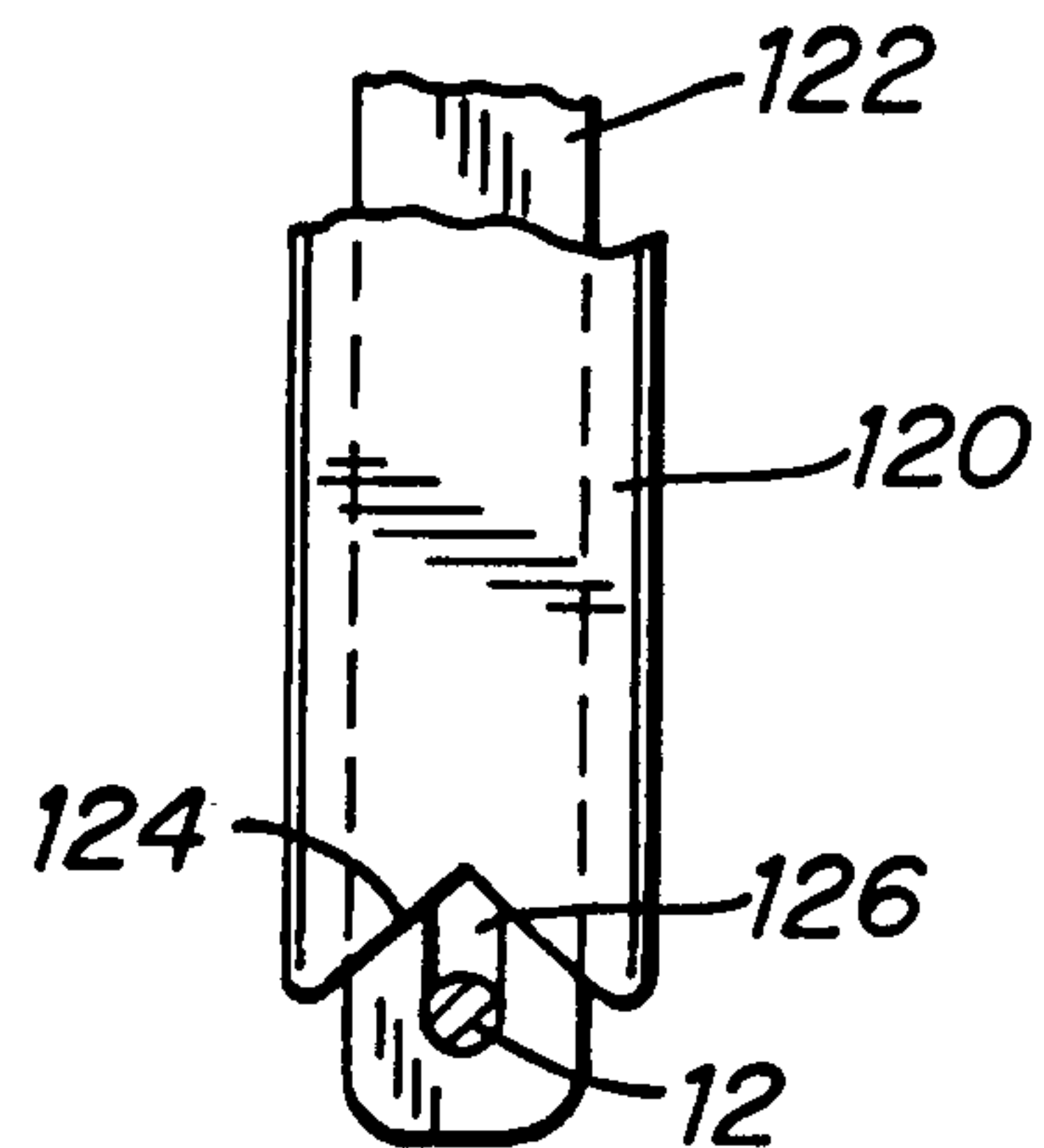


FIG. 18A

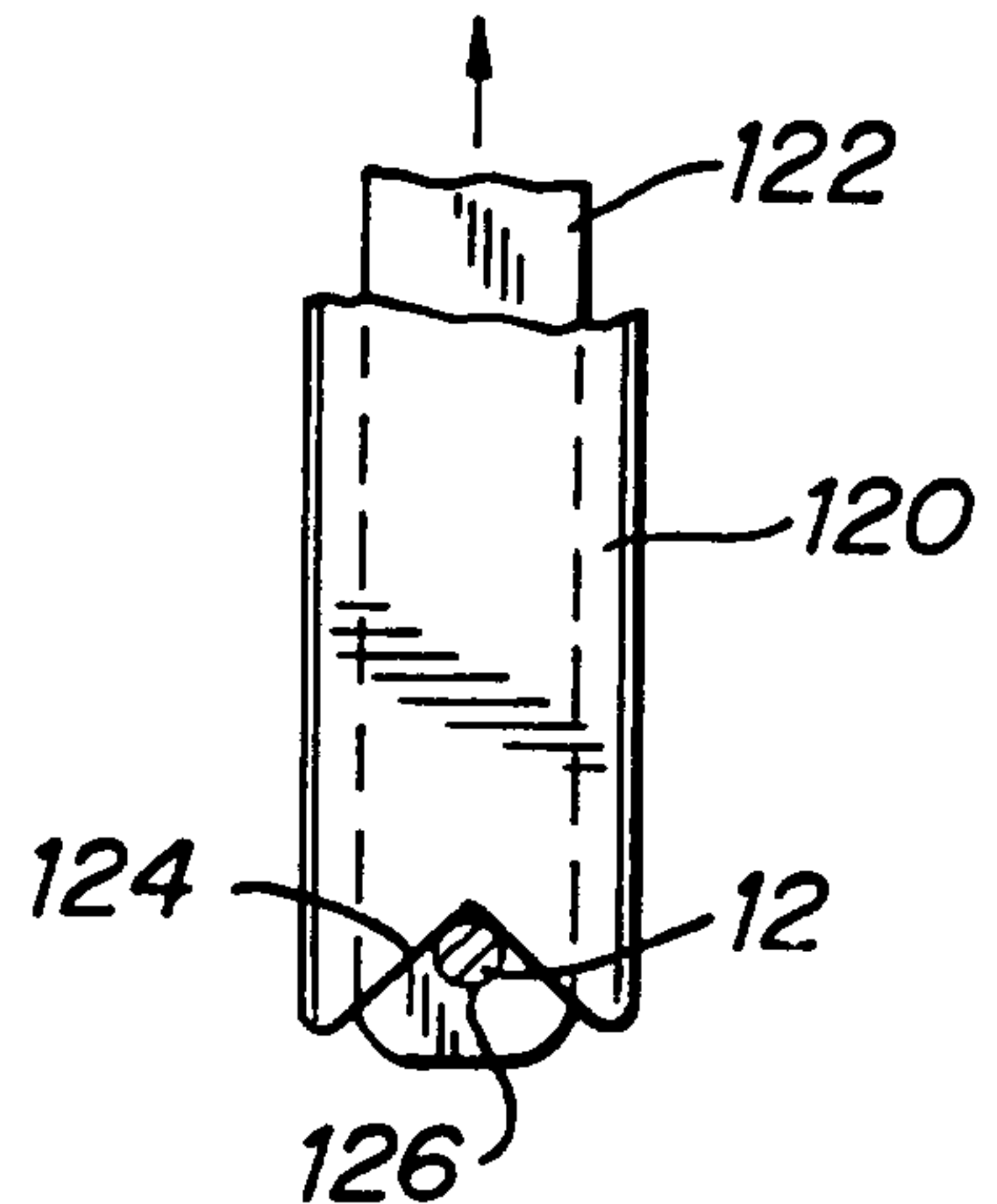


FIG. 18B

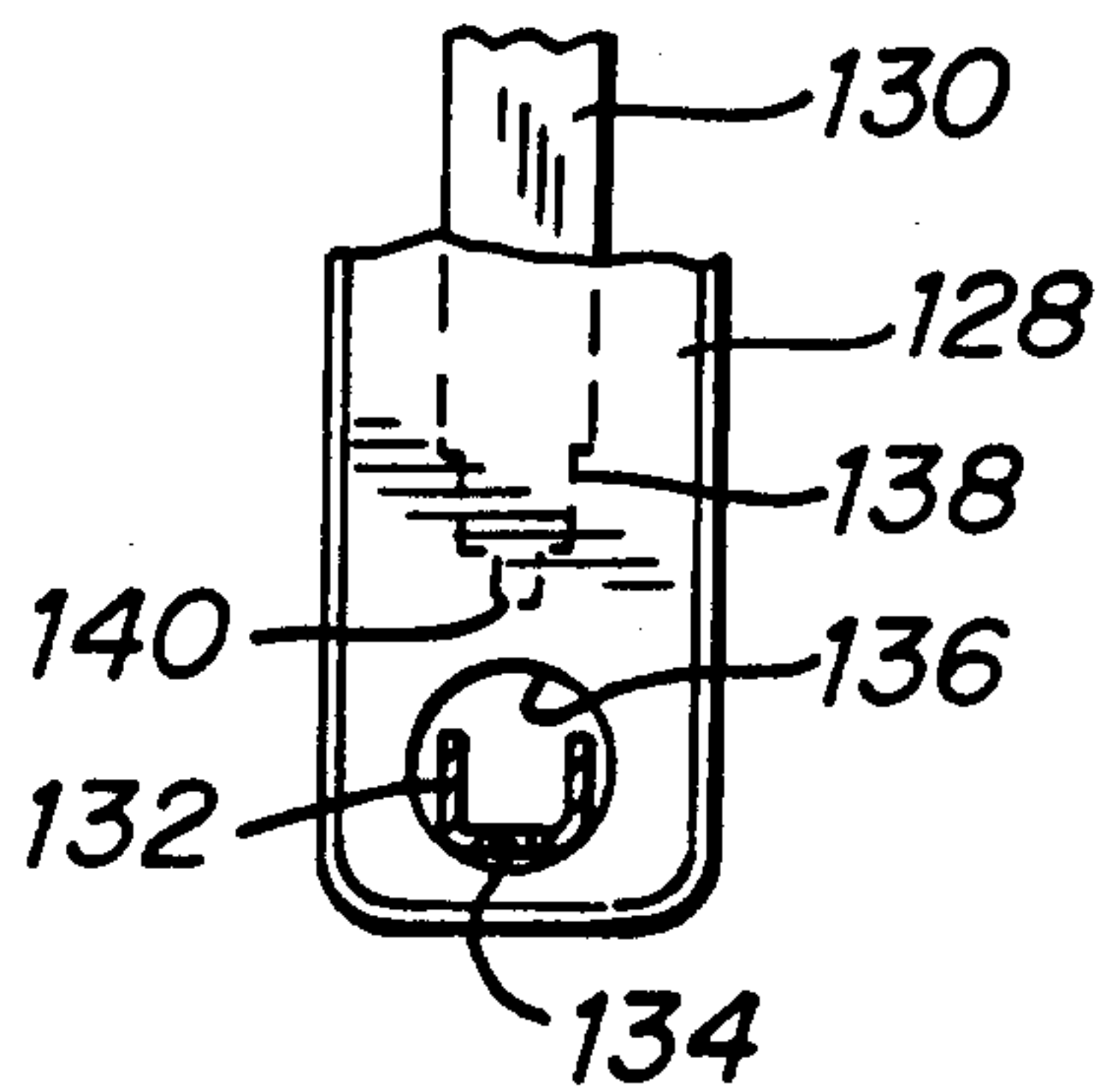


FIG. 19A

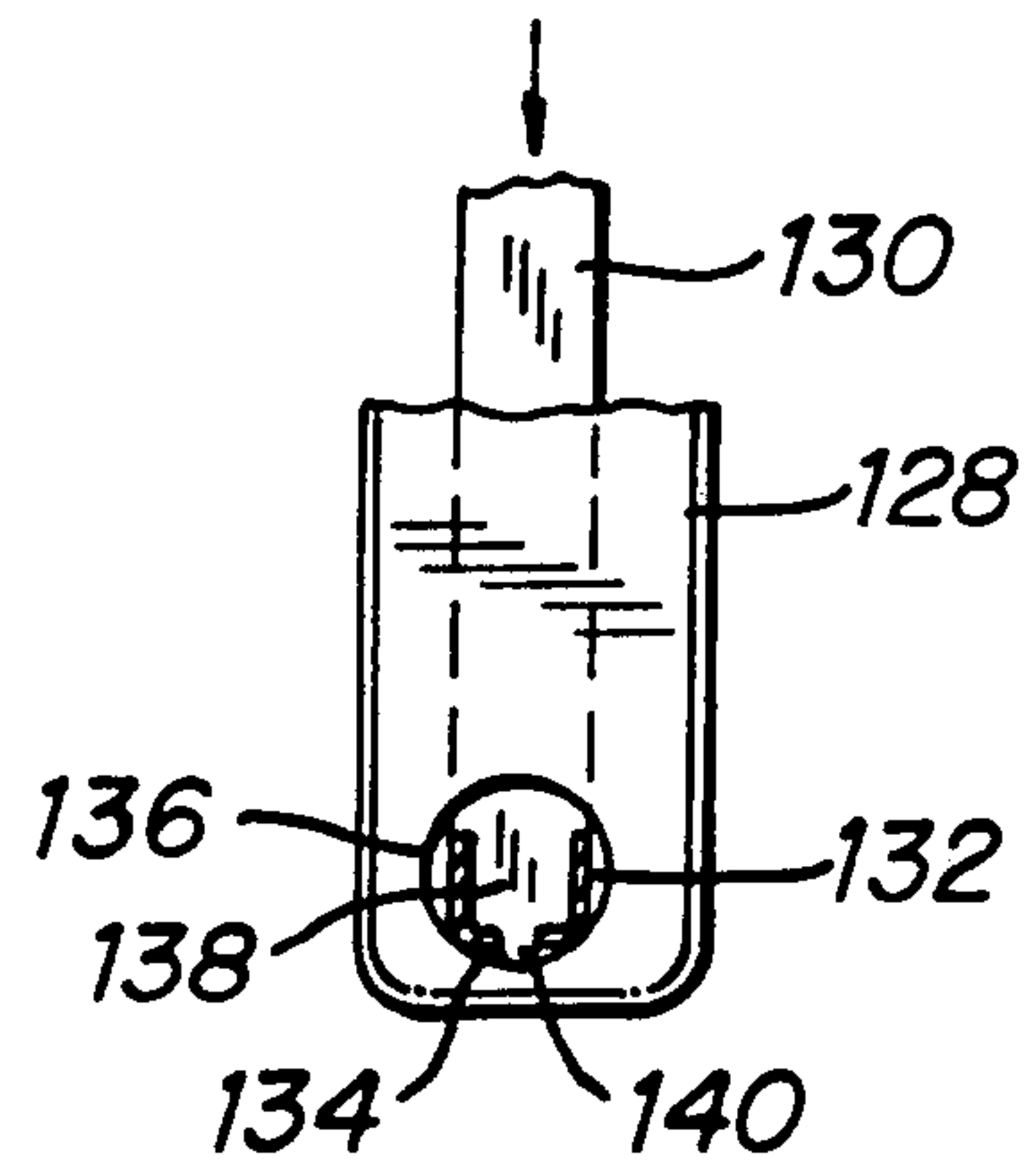


FIG. 19B

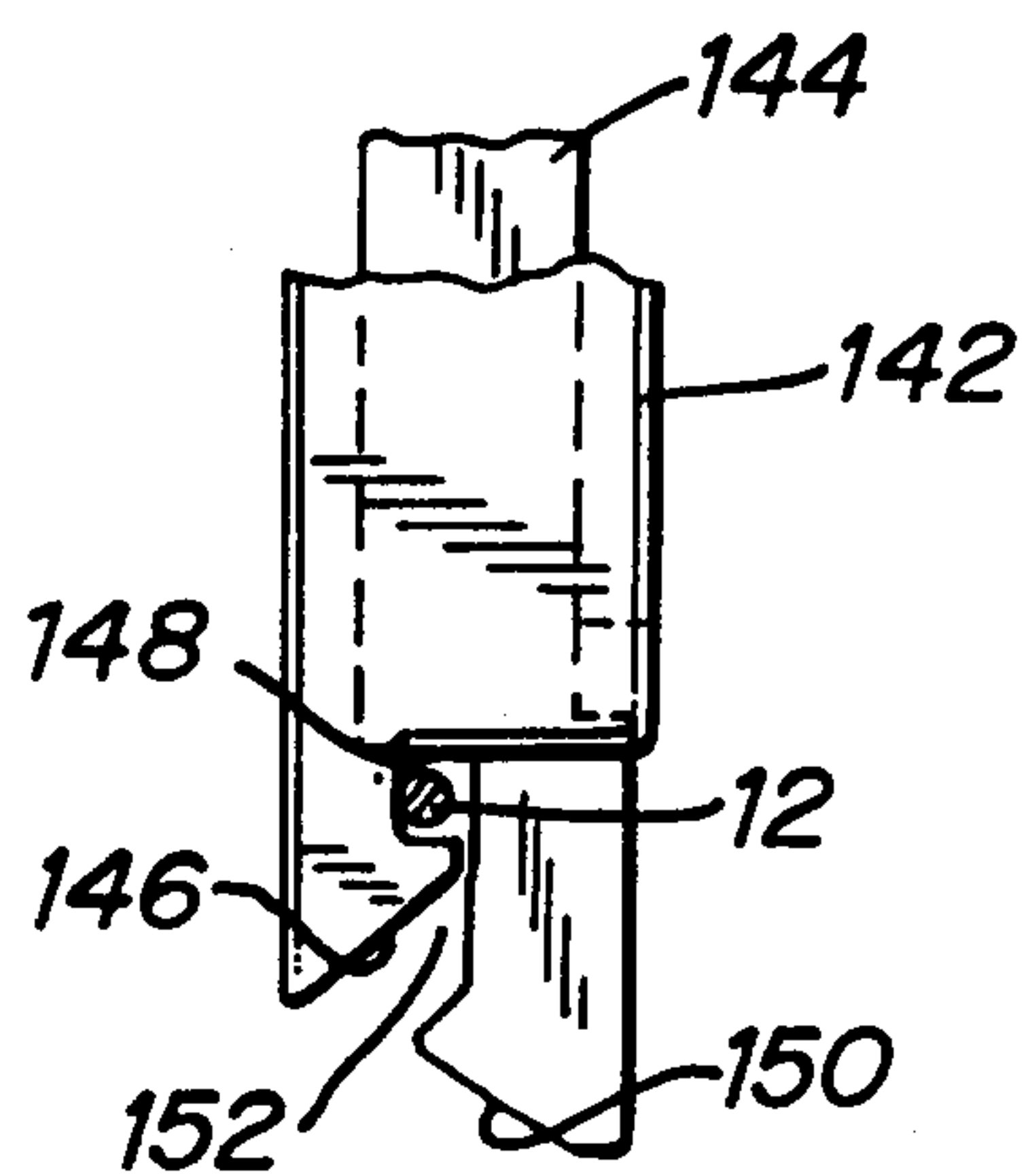


FIG. 20A

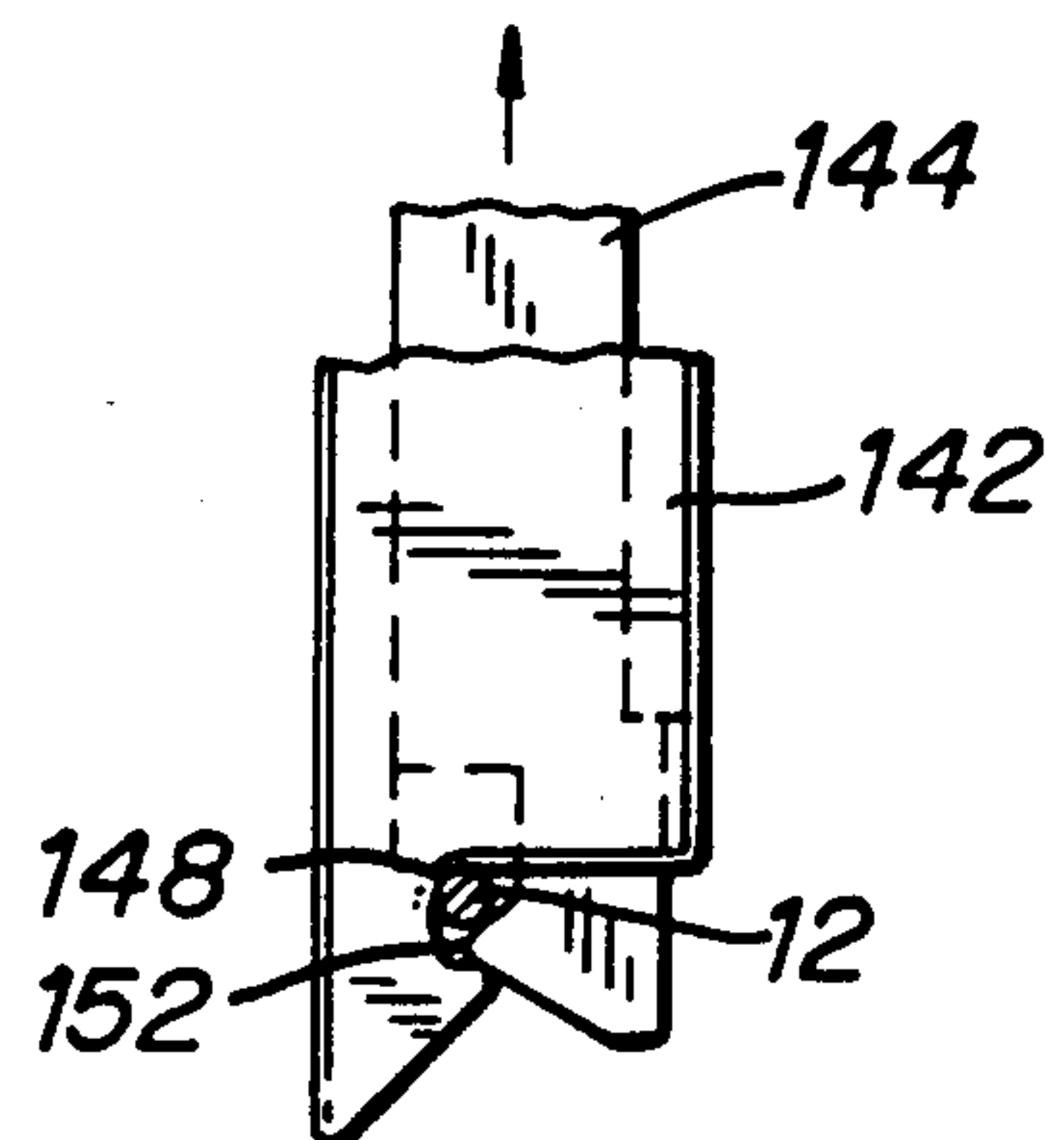


FIG. 20B

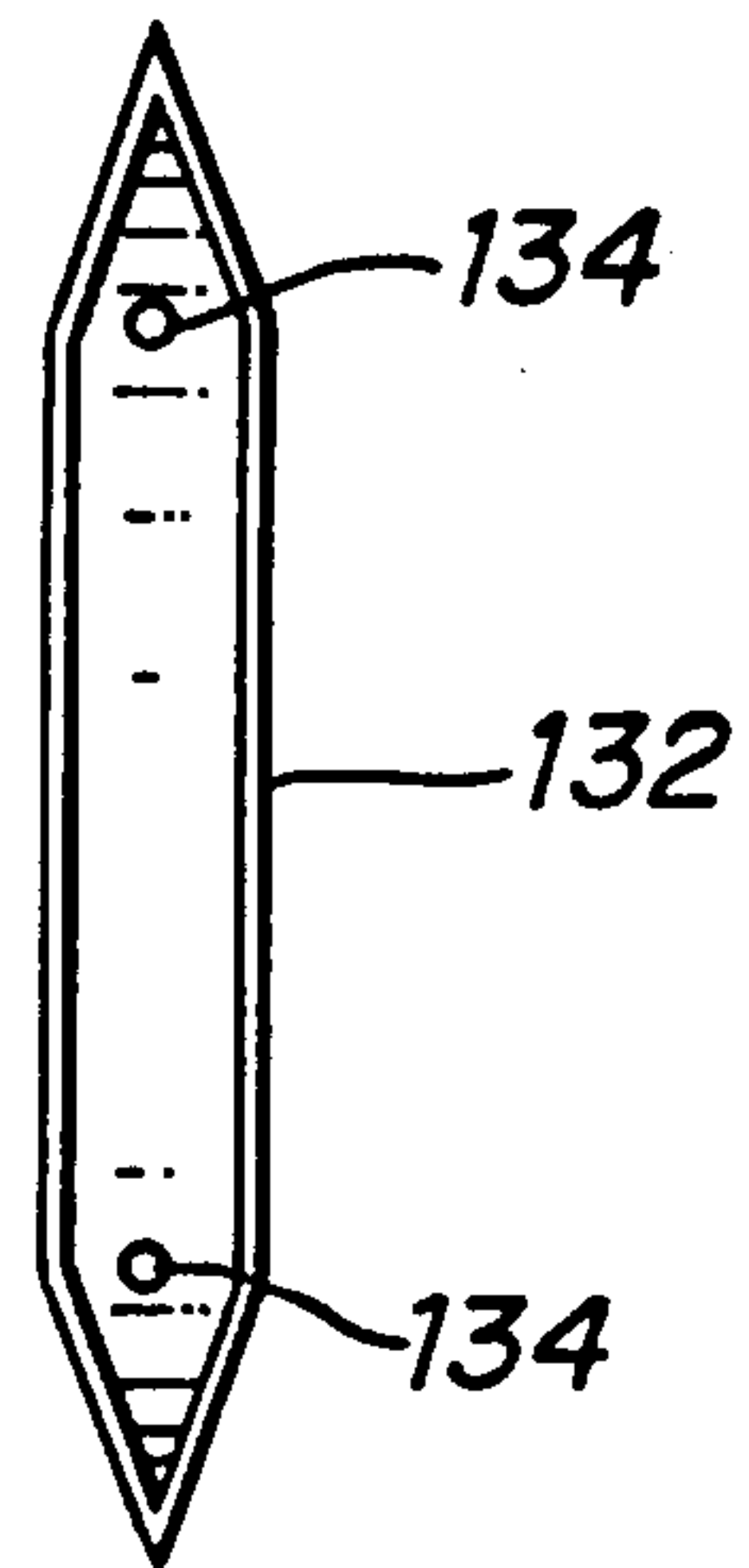


FIG. 19C

FIG. 21

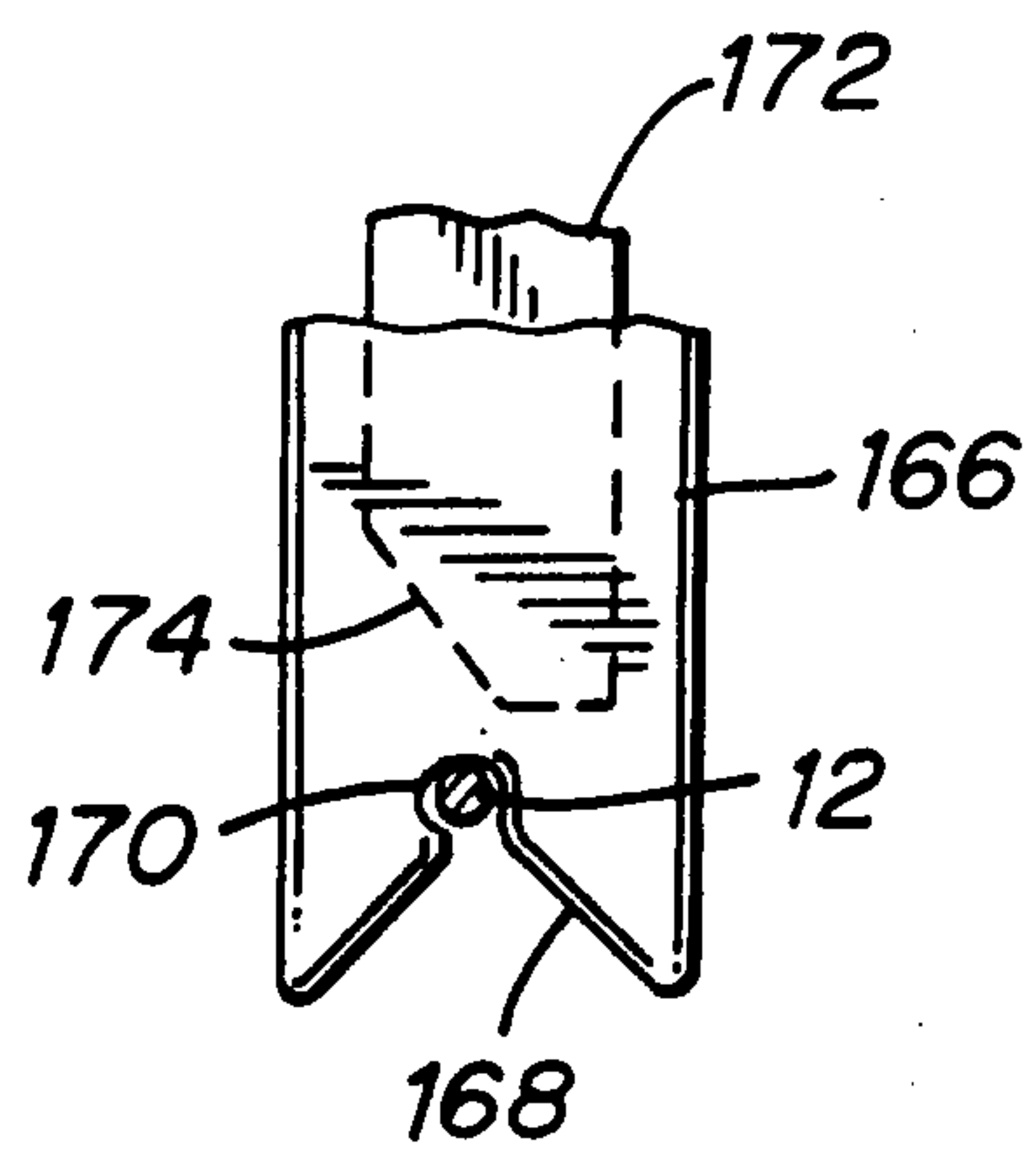
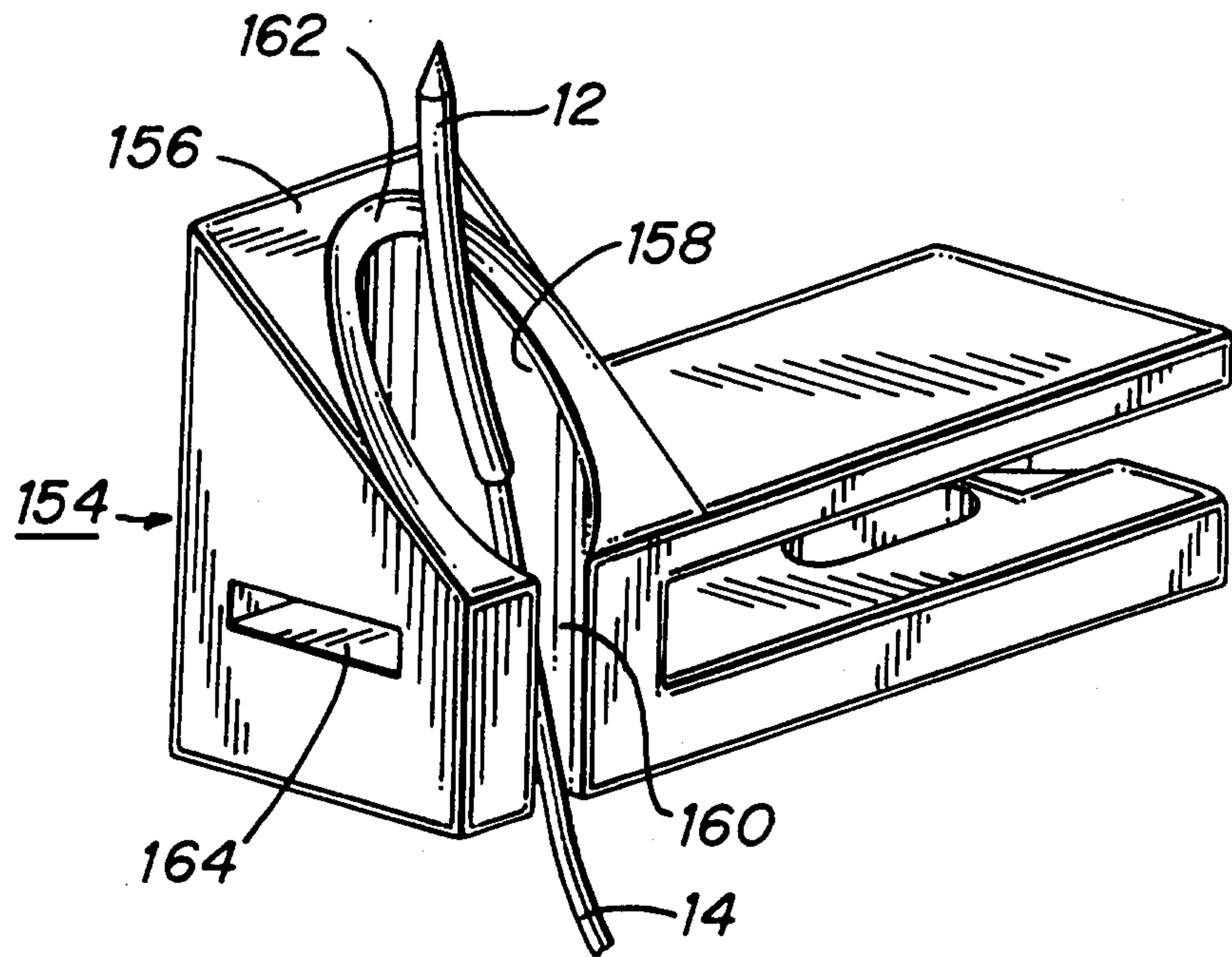


FIG. 22A

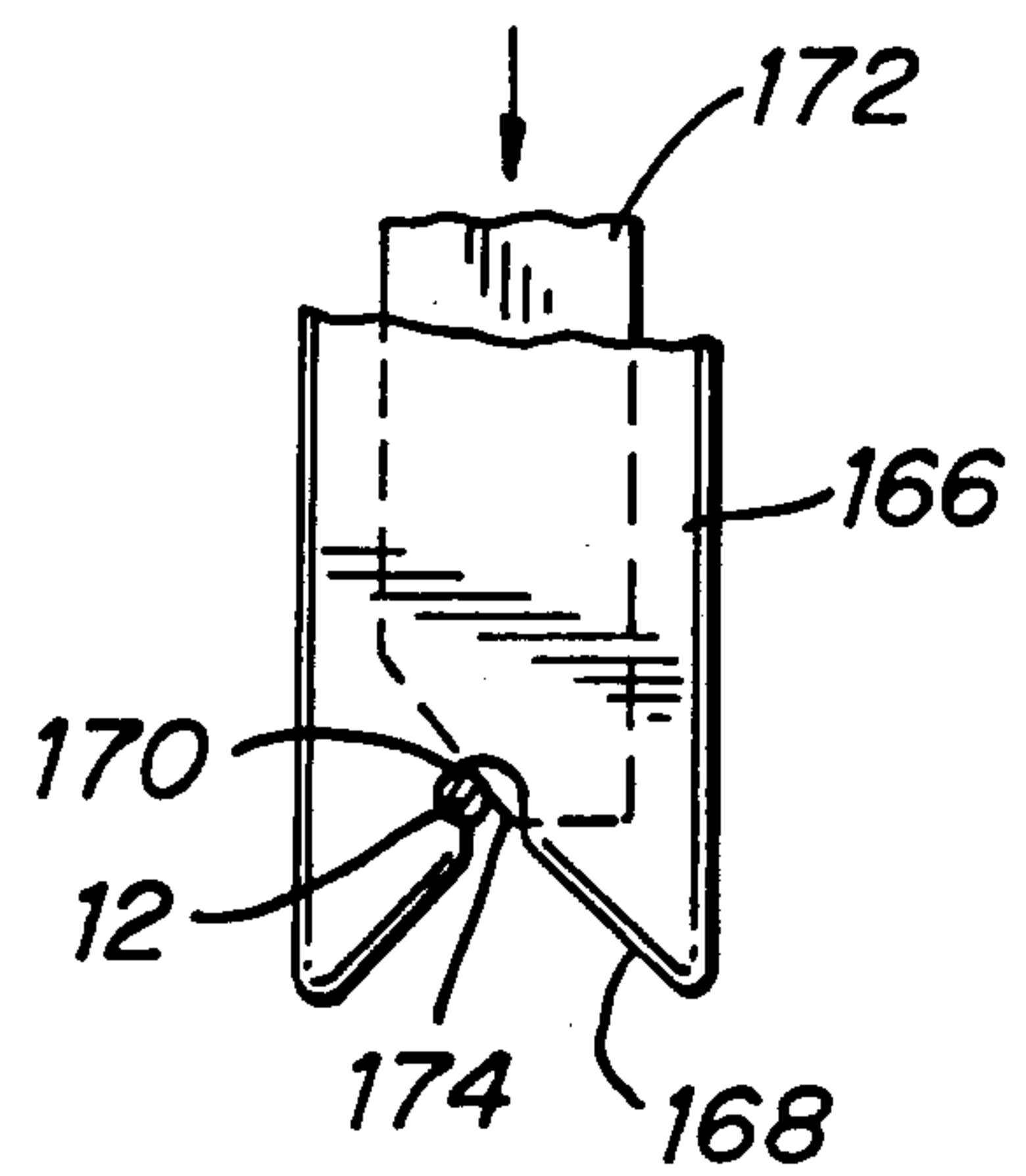


FIG. 22B

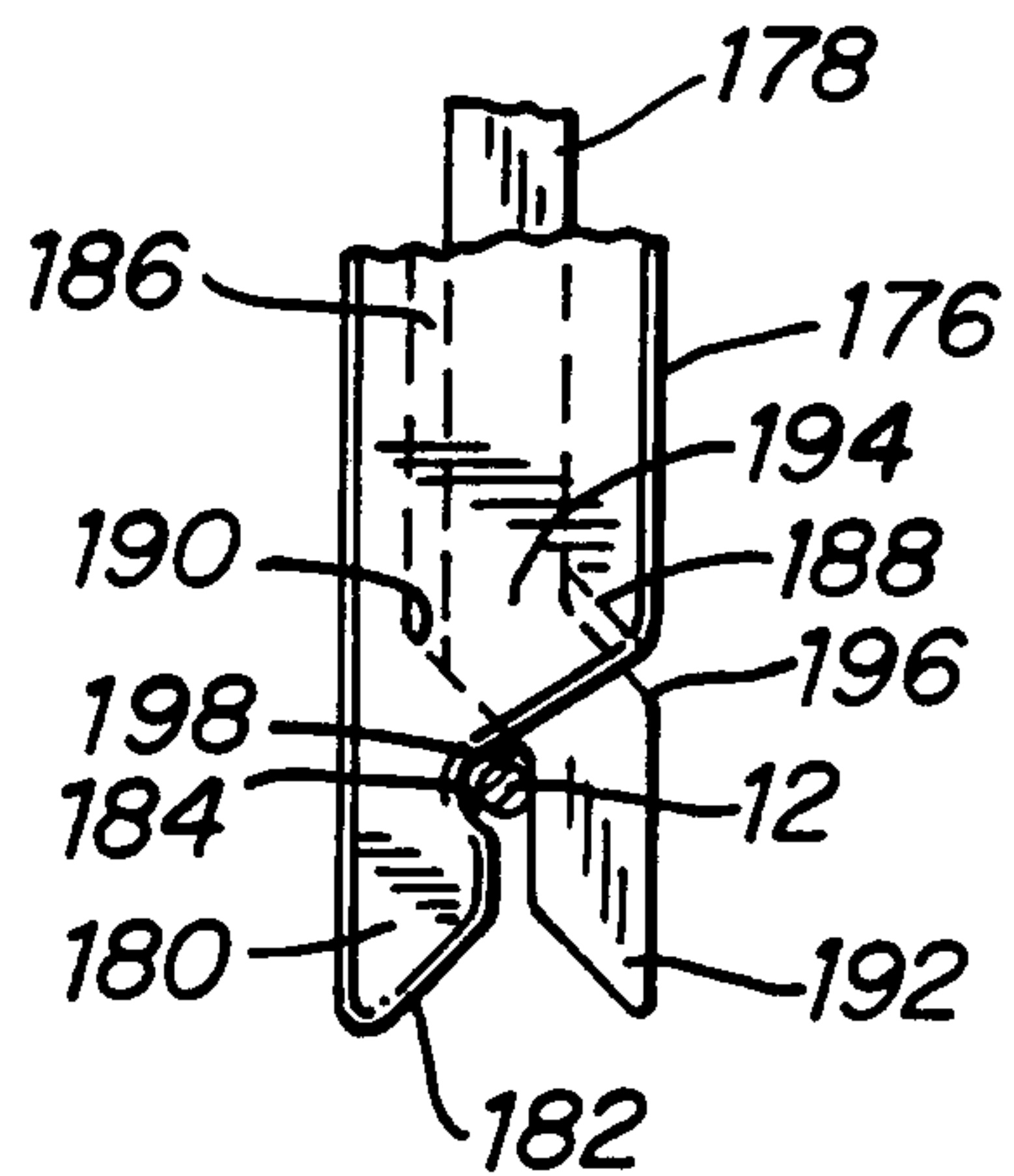


FIG. 23A

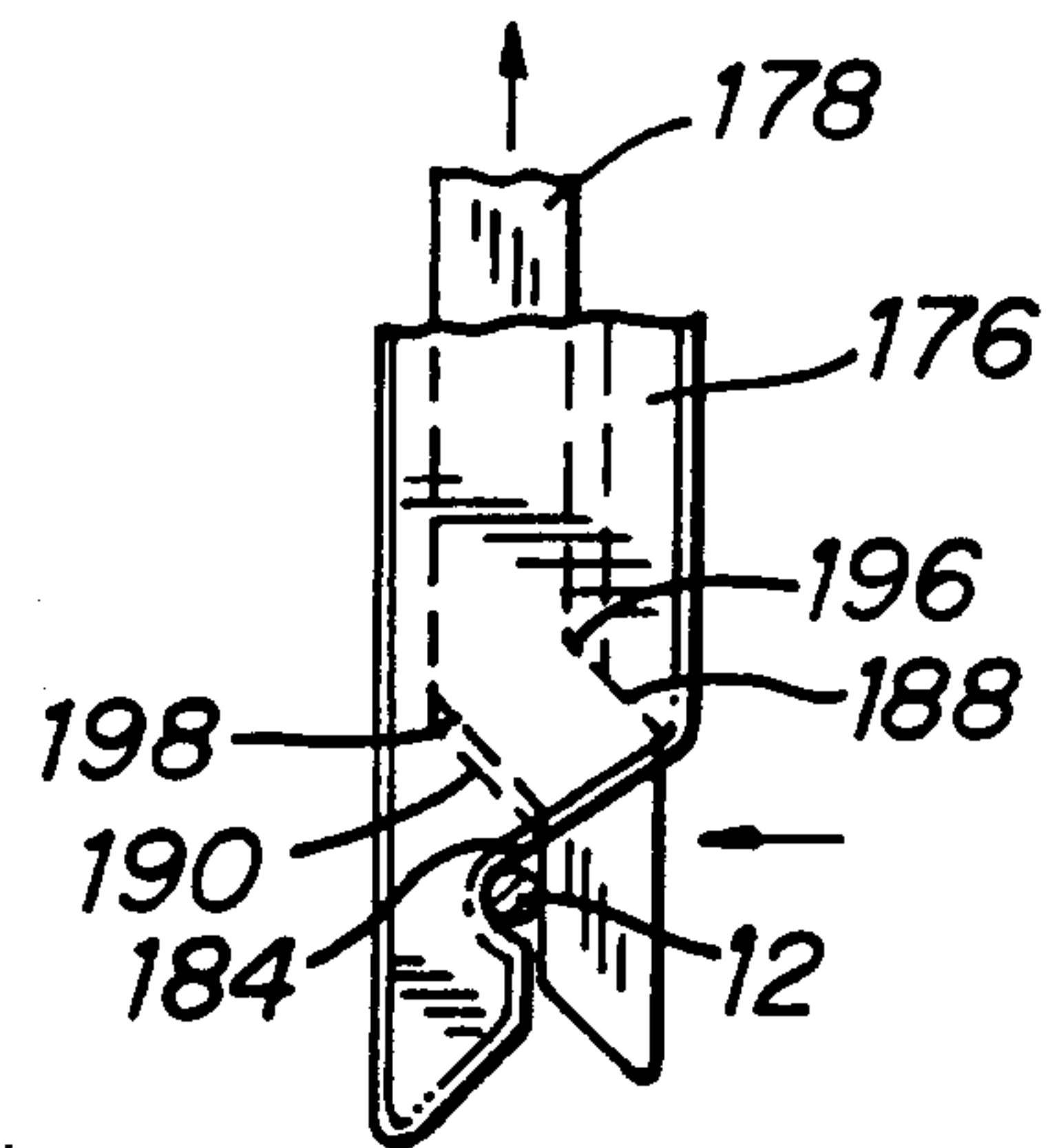


FIG. 23B

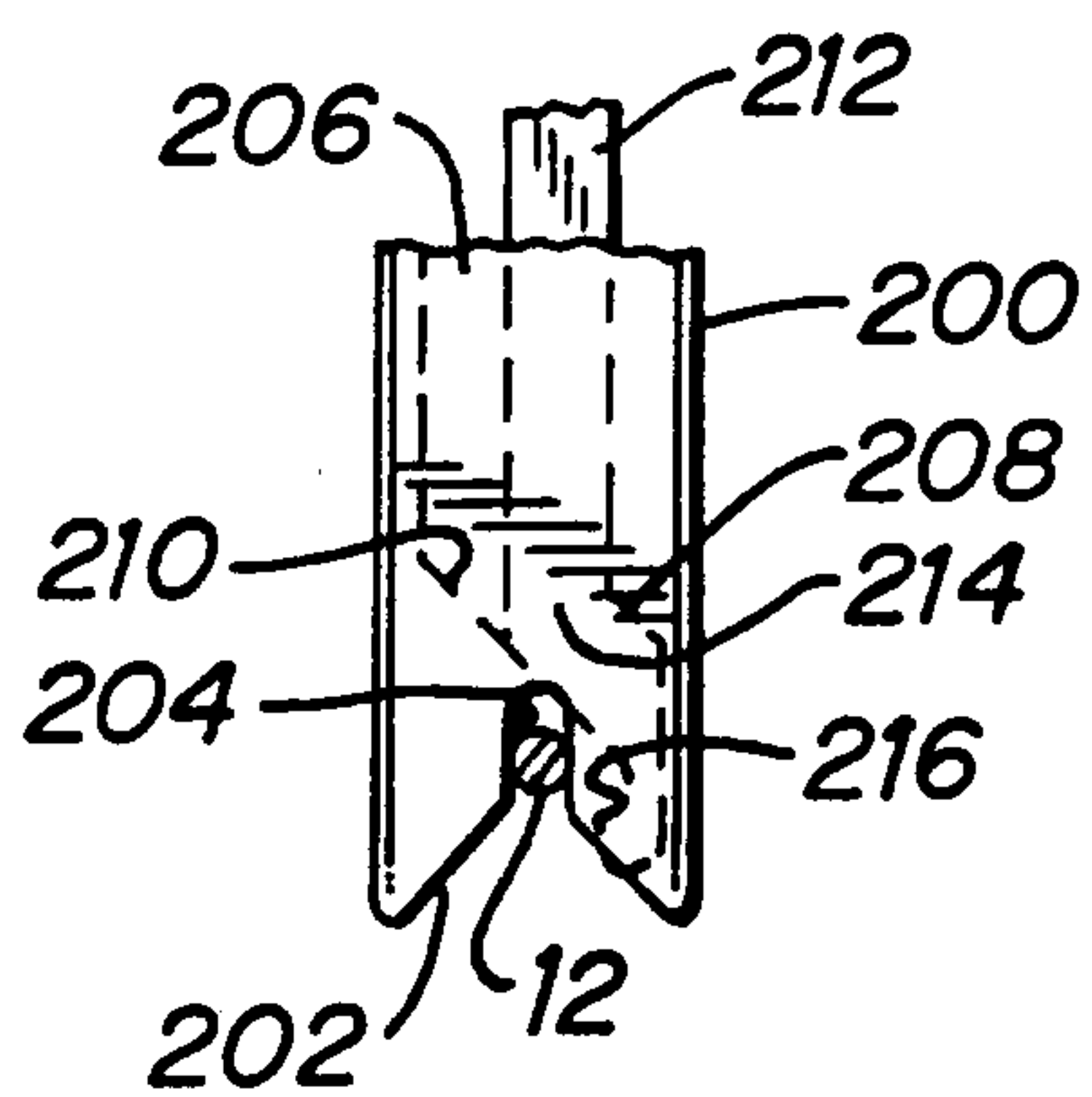


FIG. 24A

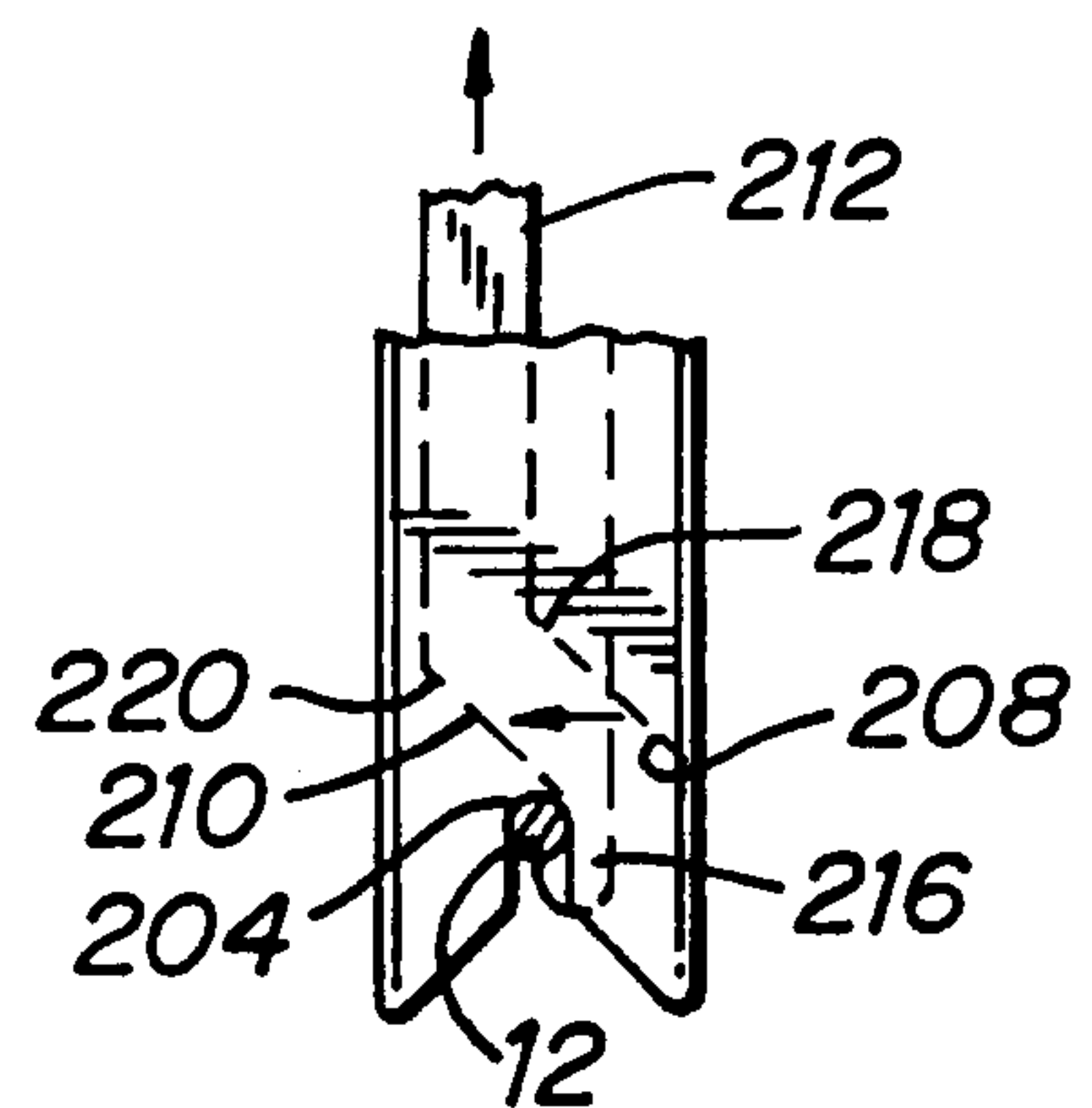


FIG. 24B

FIG. 25

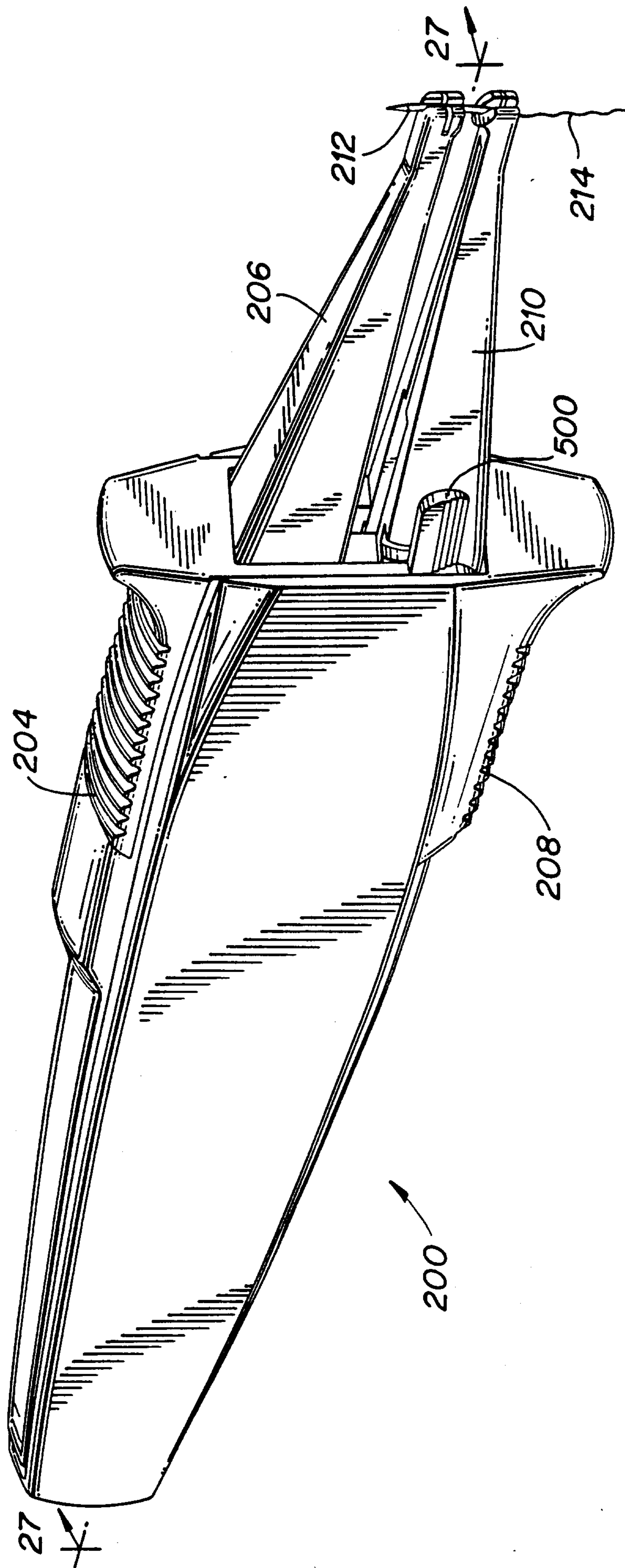
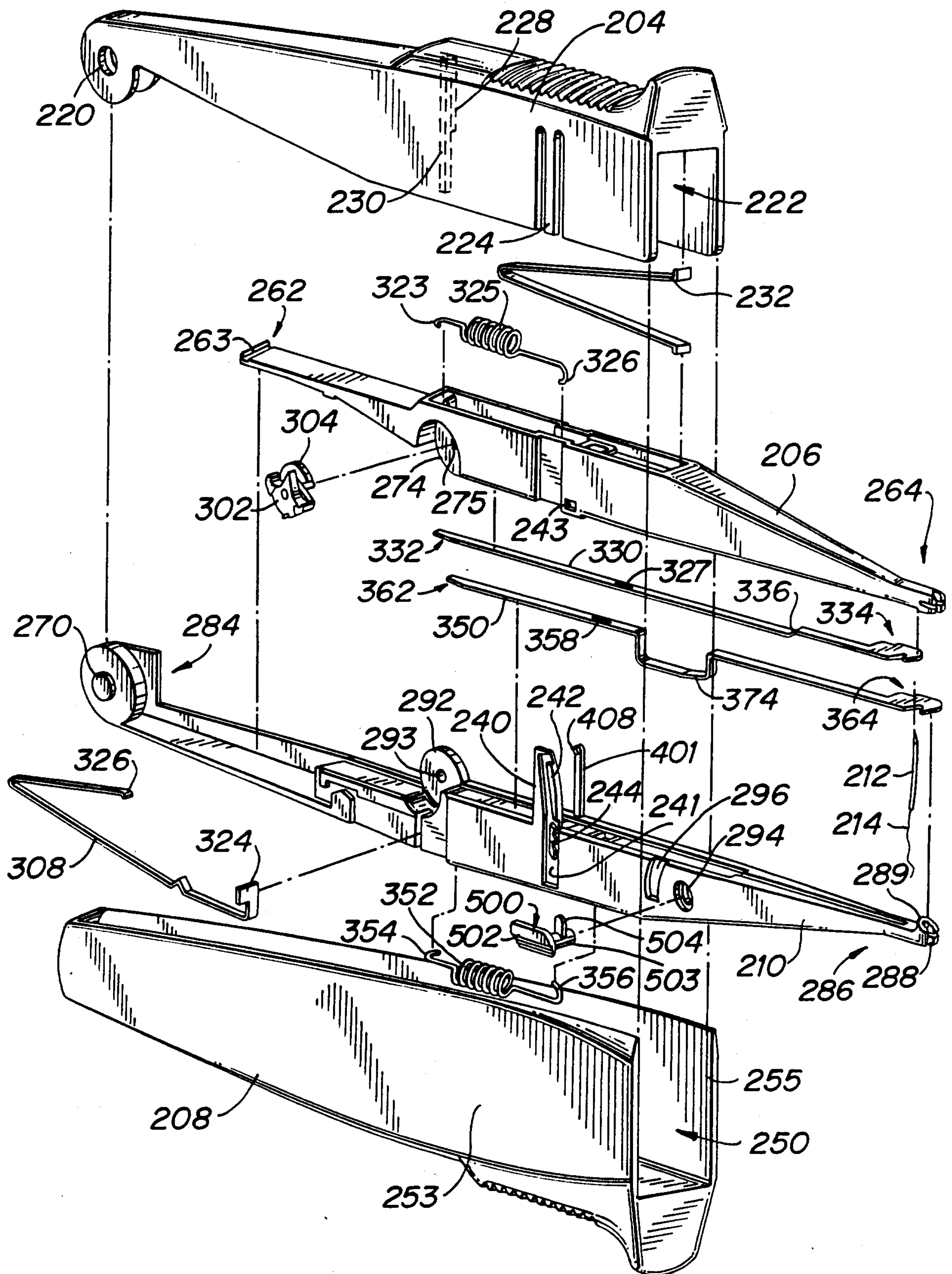
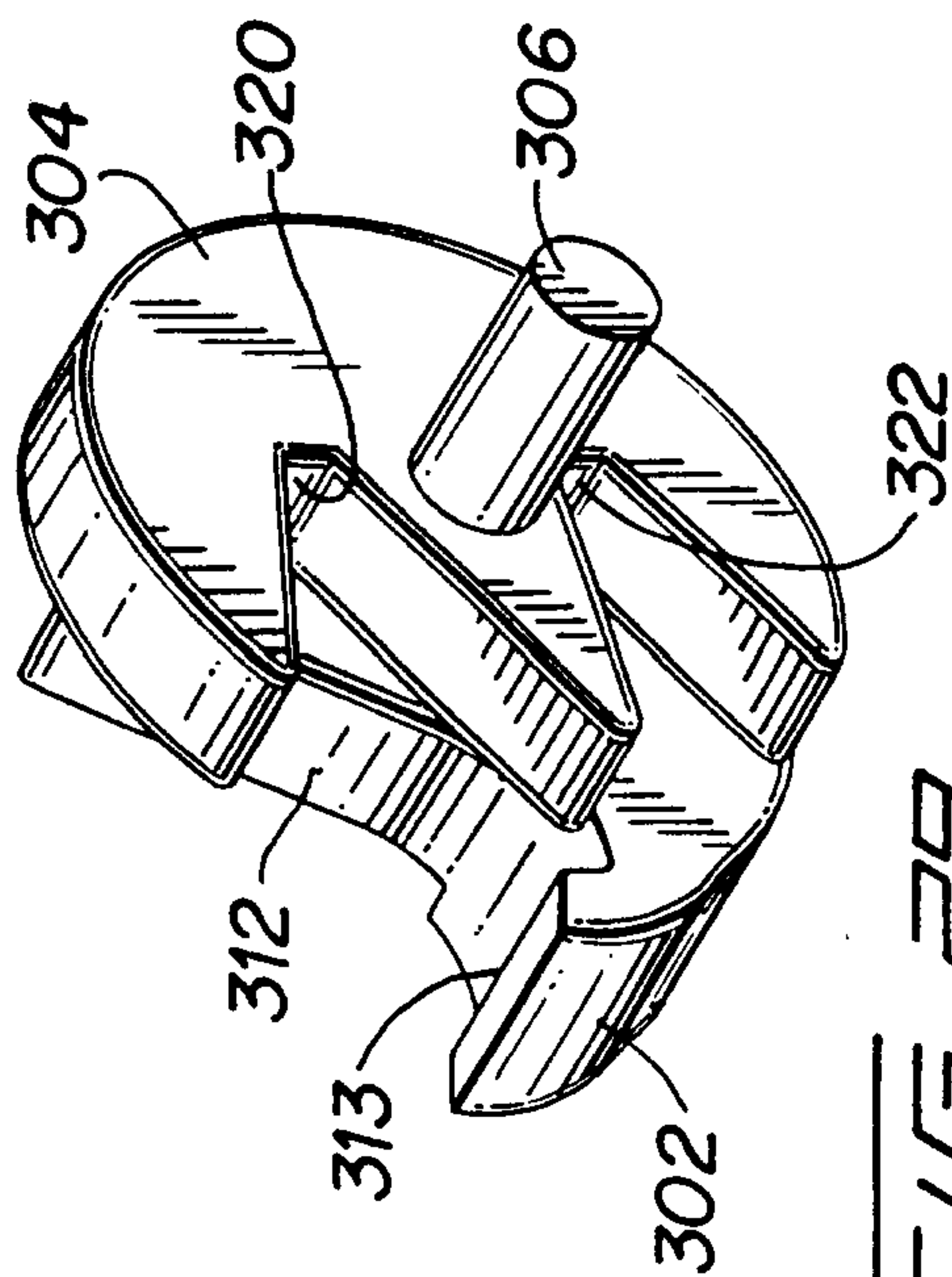
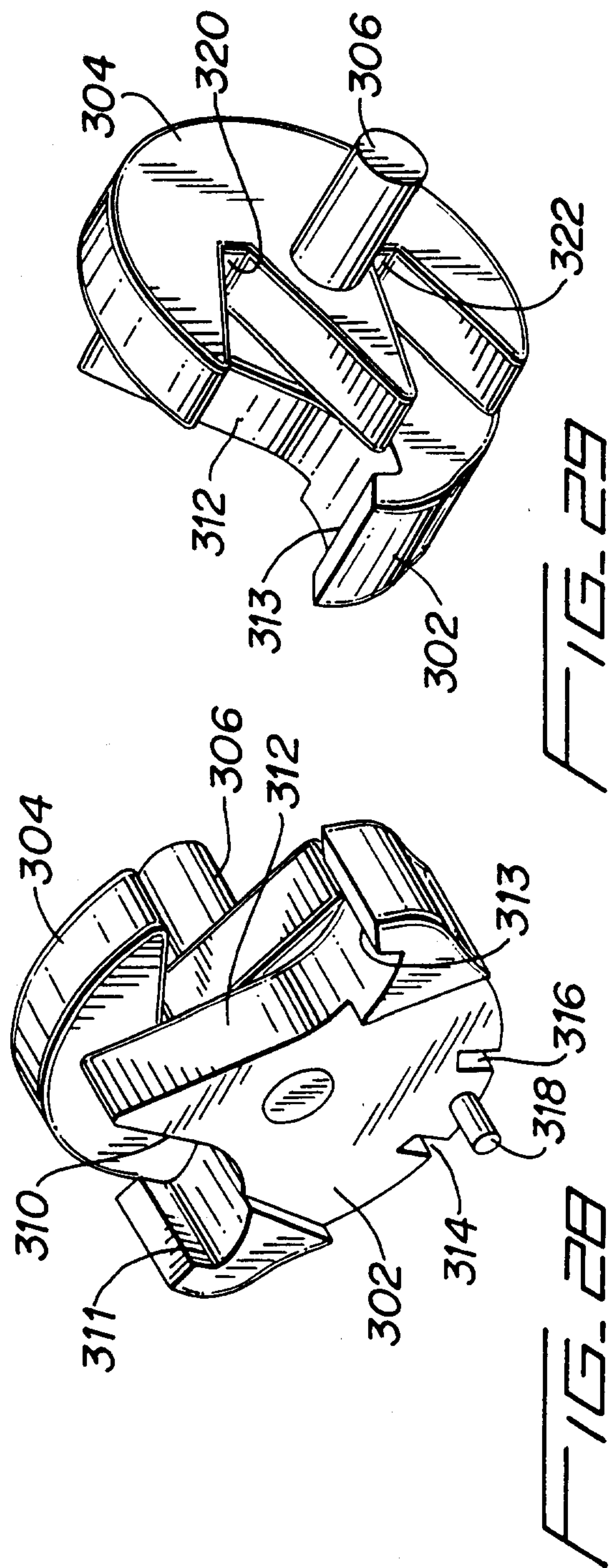
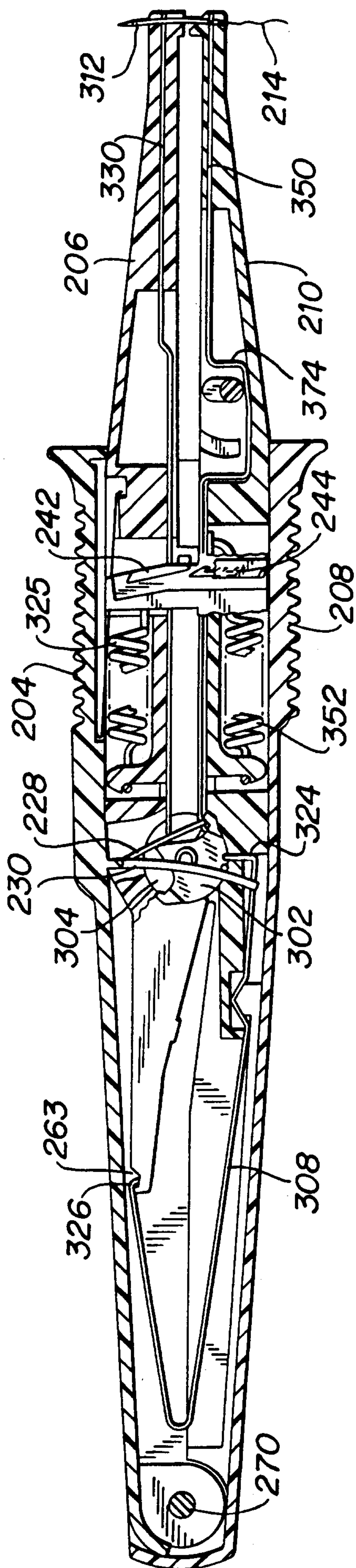


FIG. 26





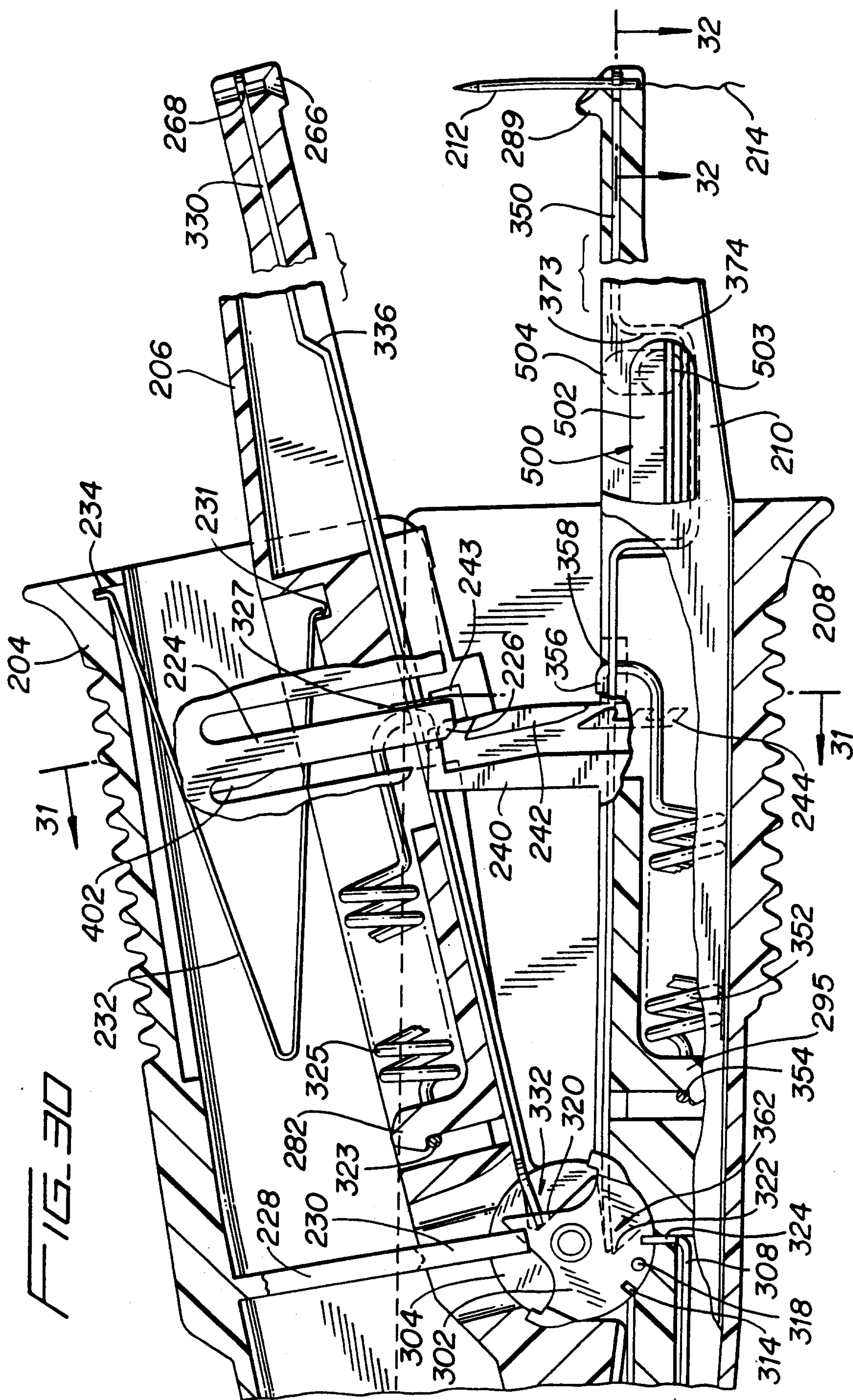


FIG. 31

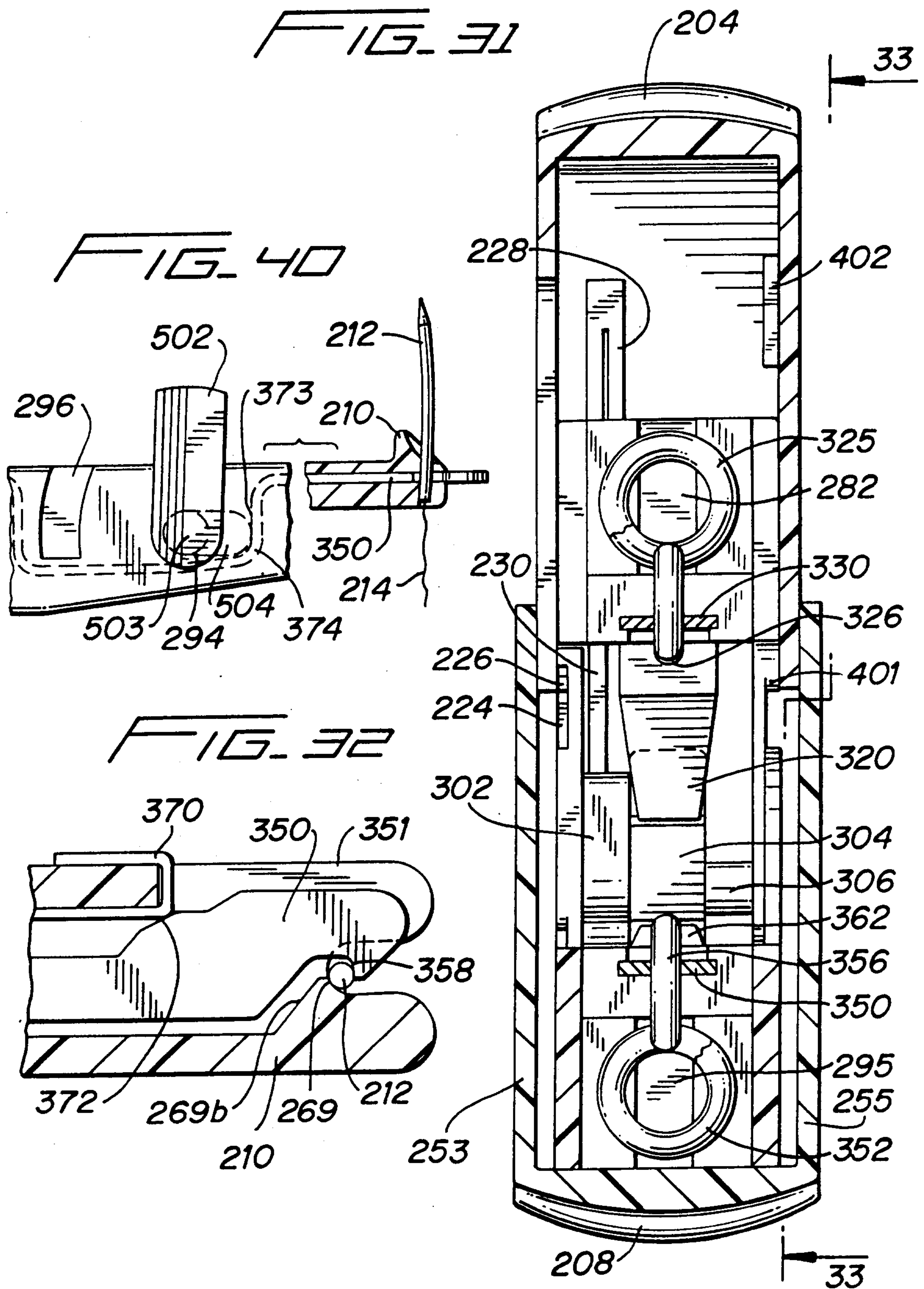


FIG. 40

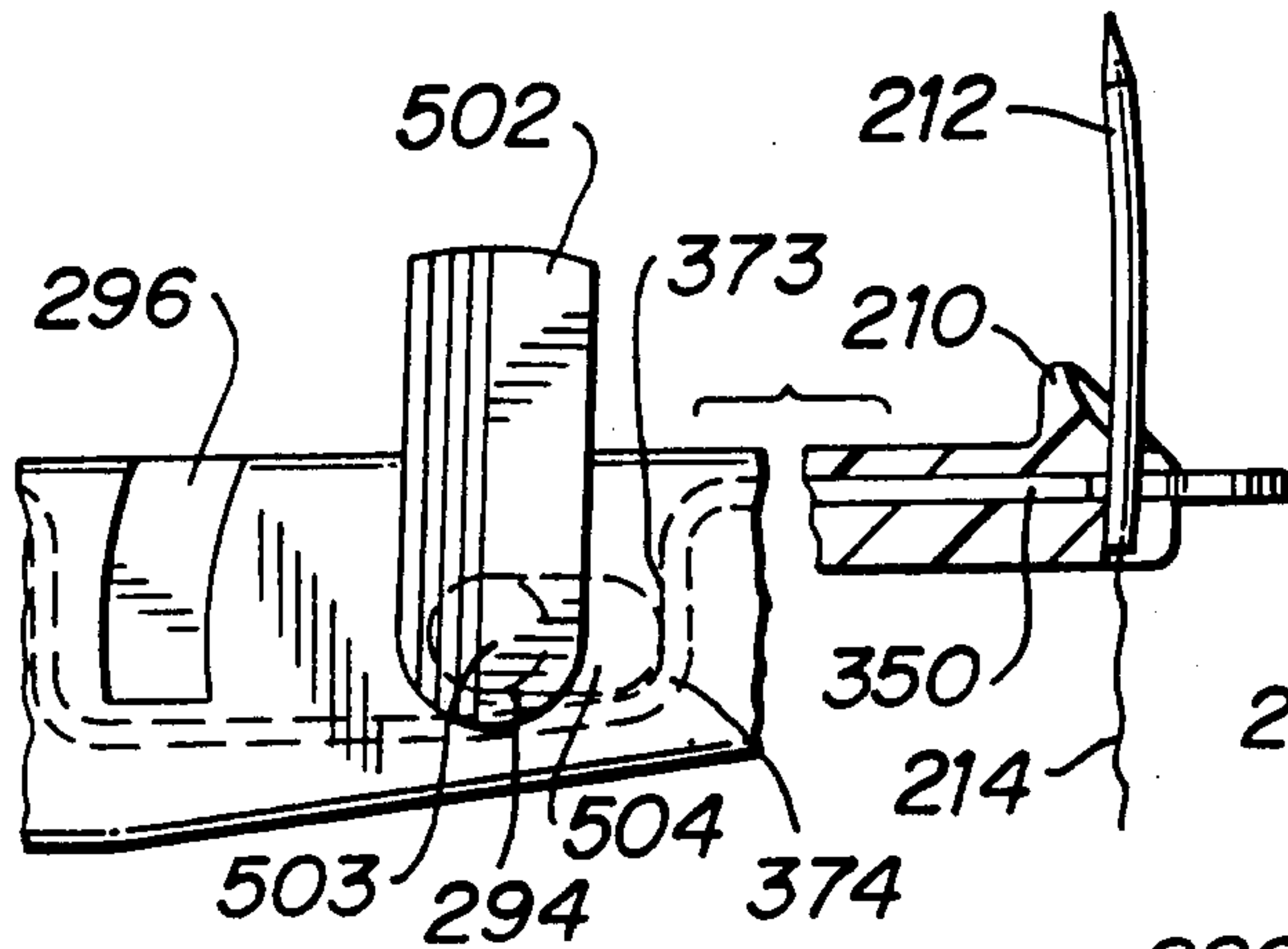
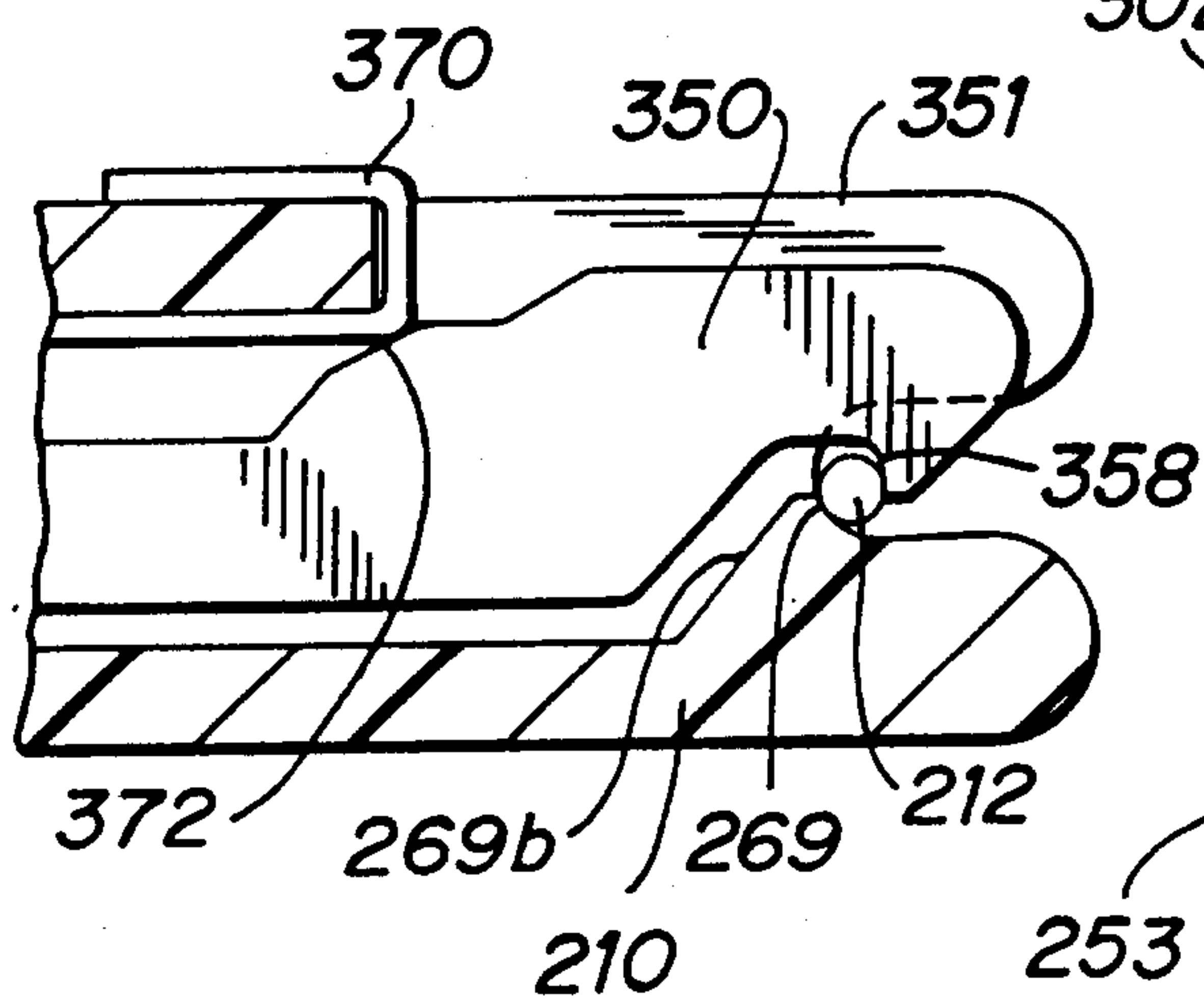


FIG. 32



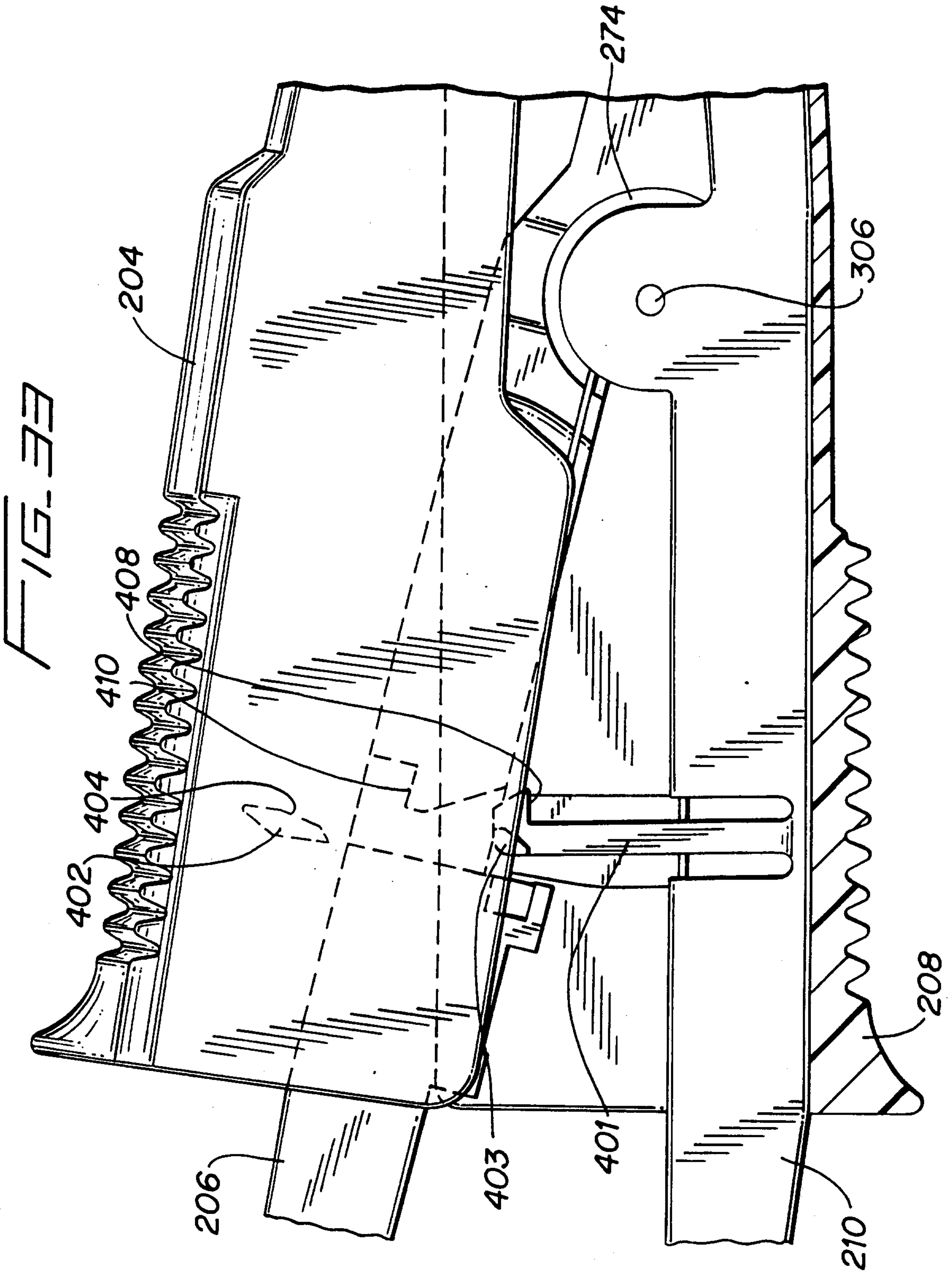
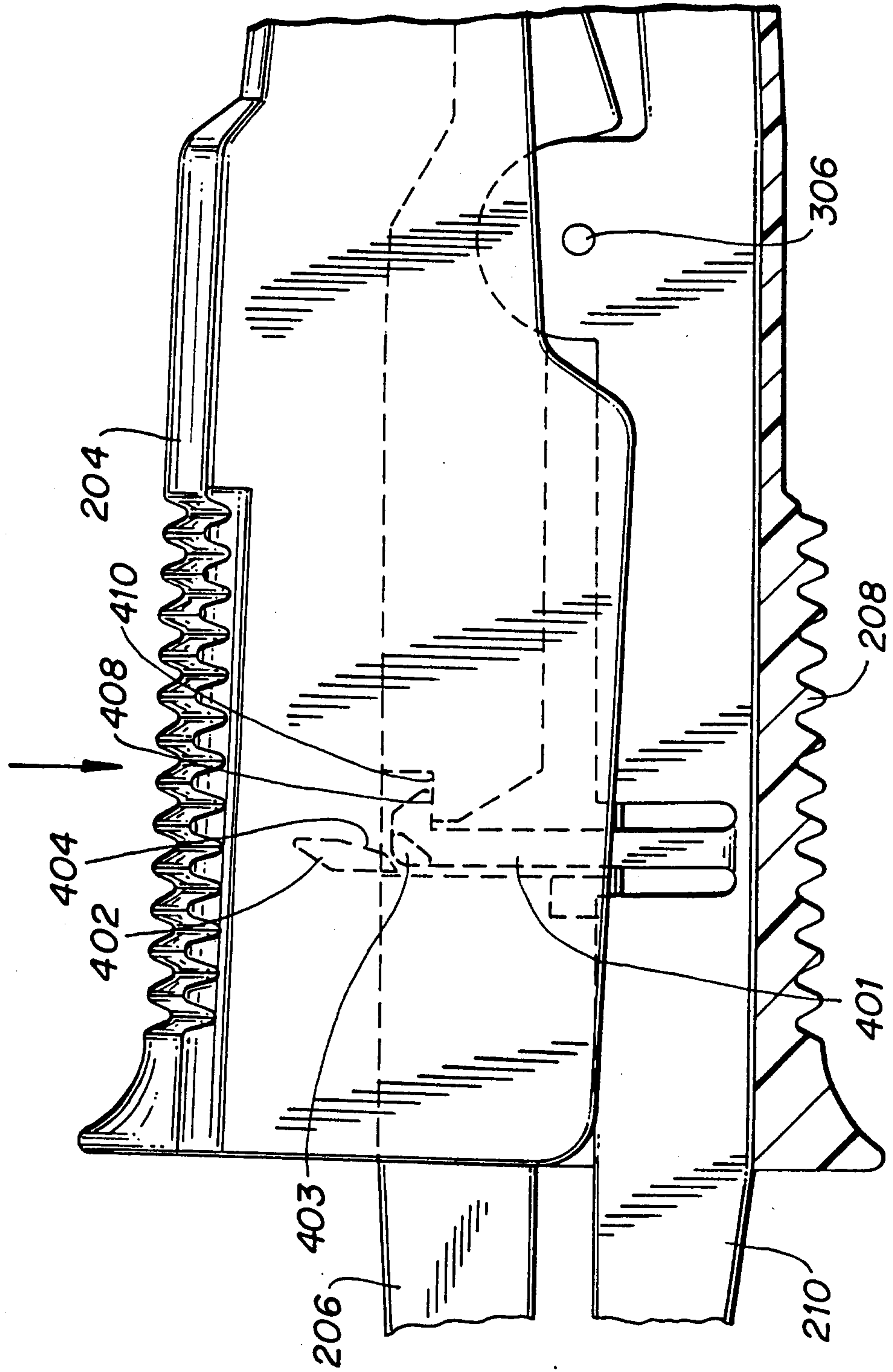


FIG. 34



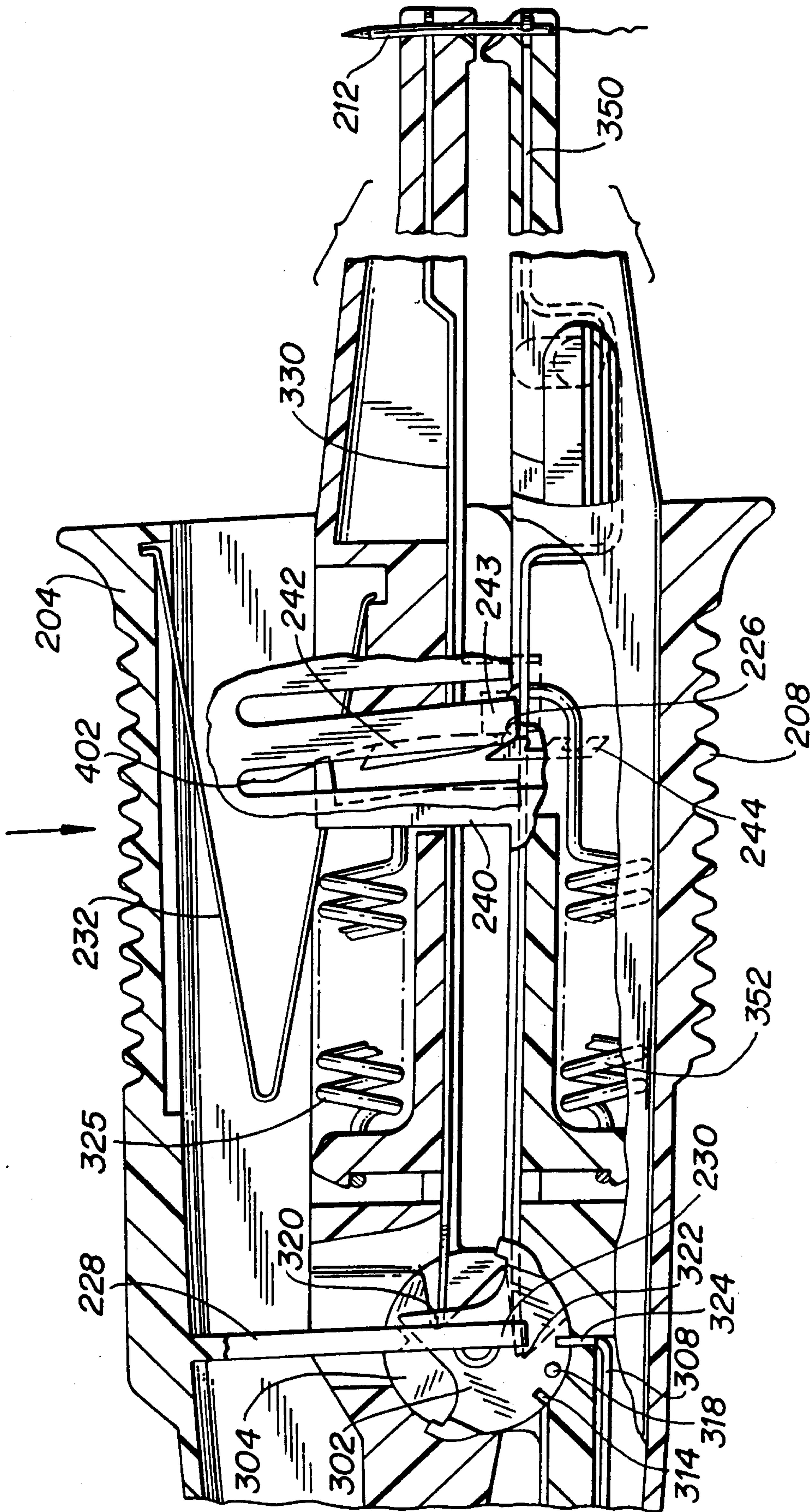
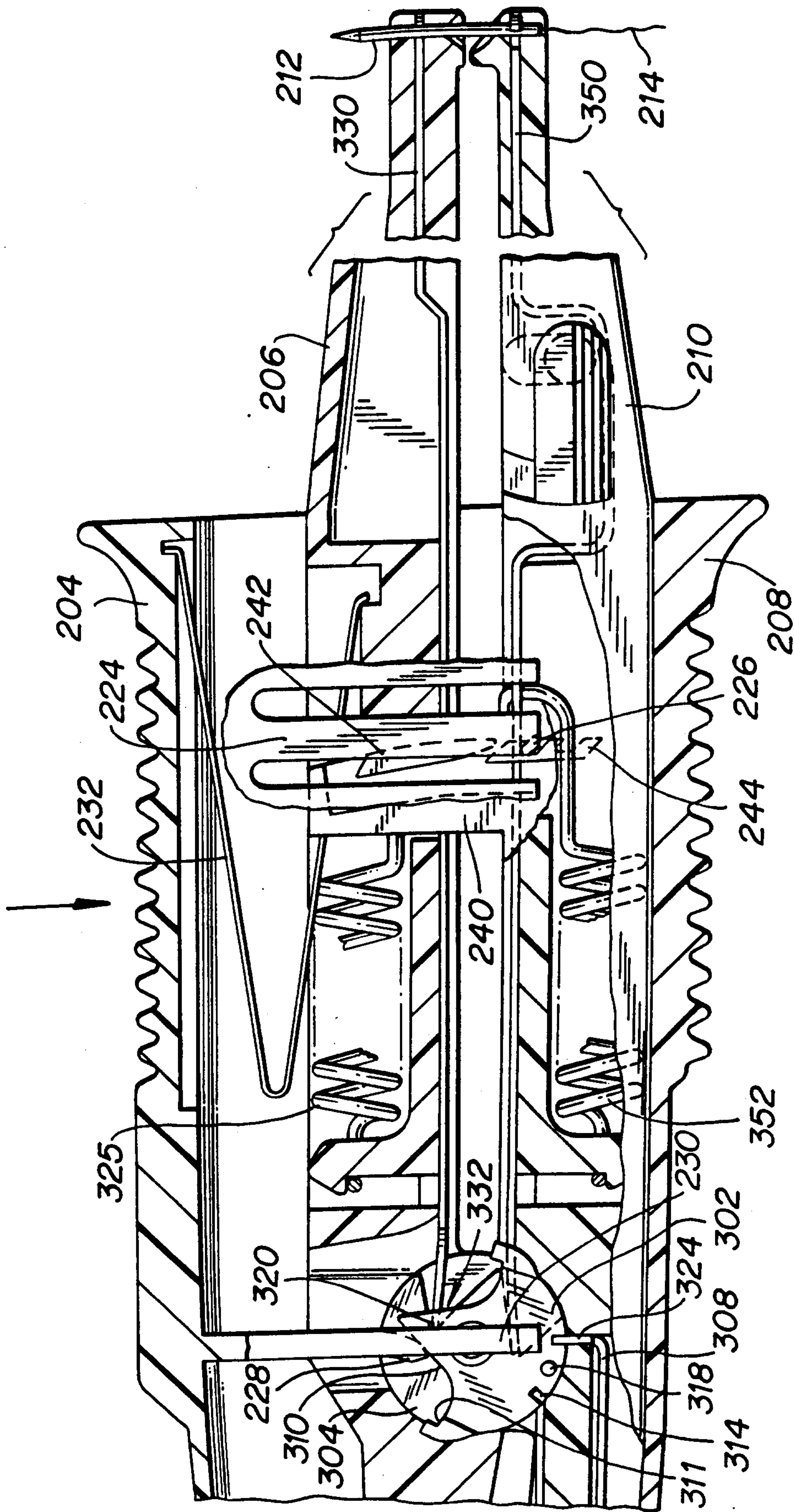


FIG. 35



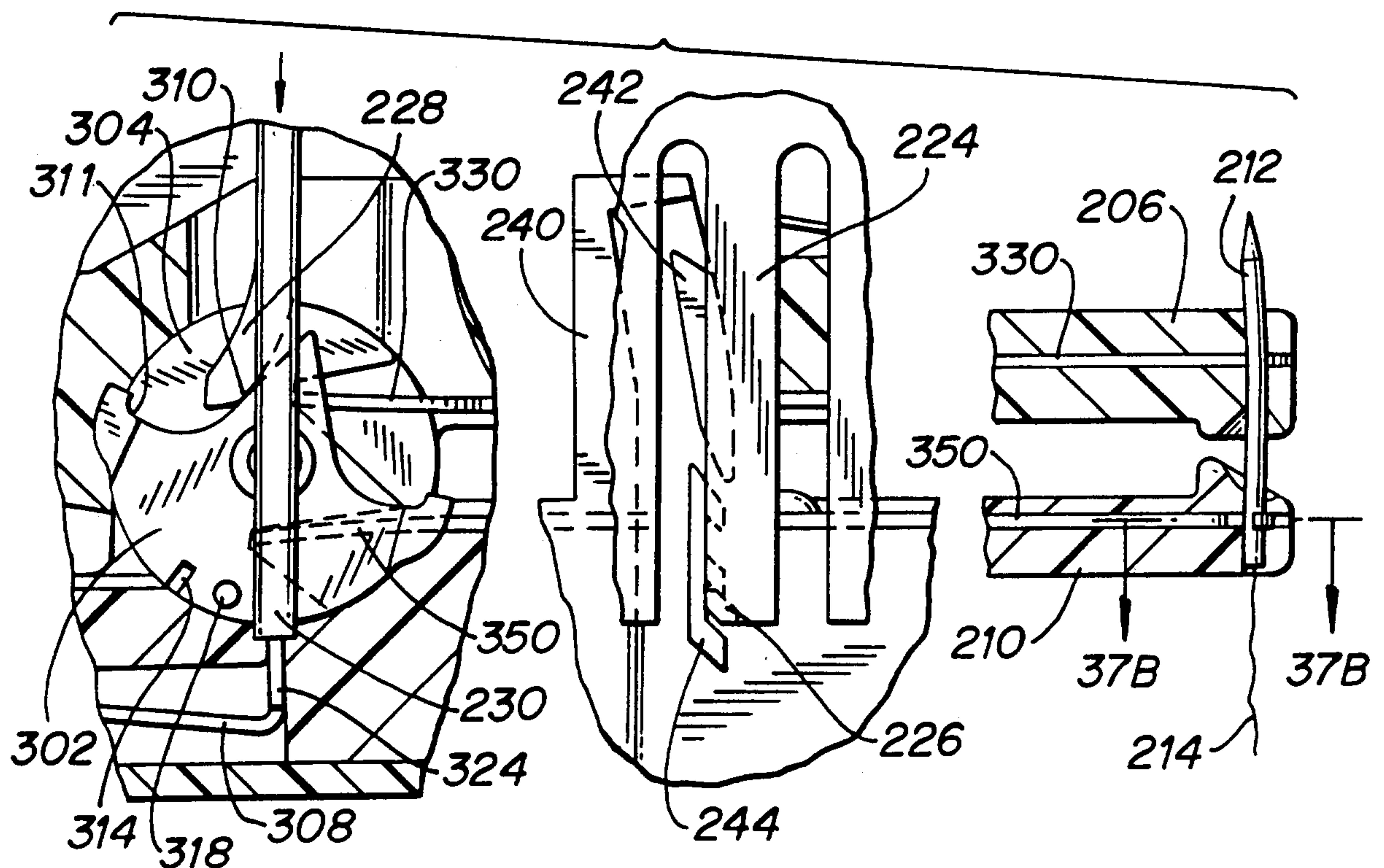


FIG. 37

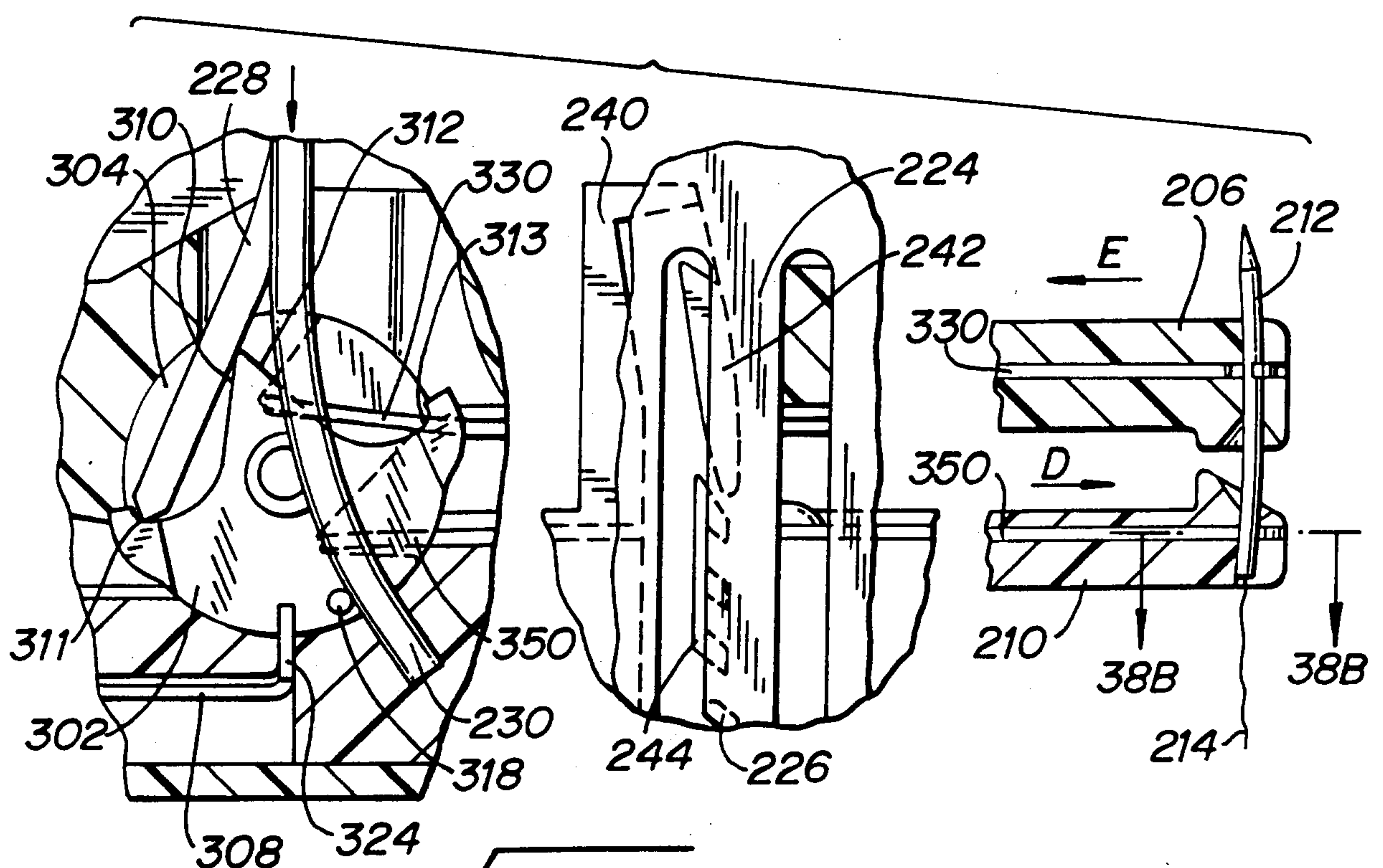


FIG. 38

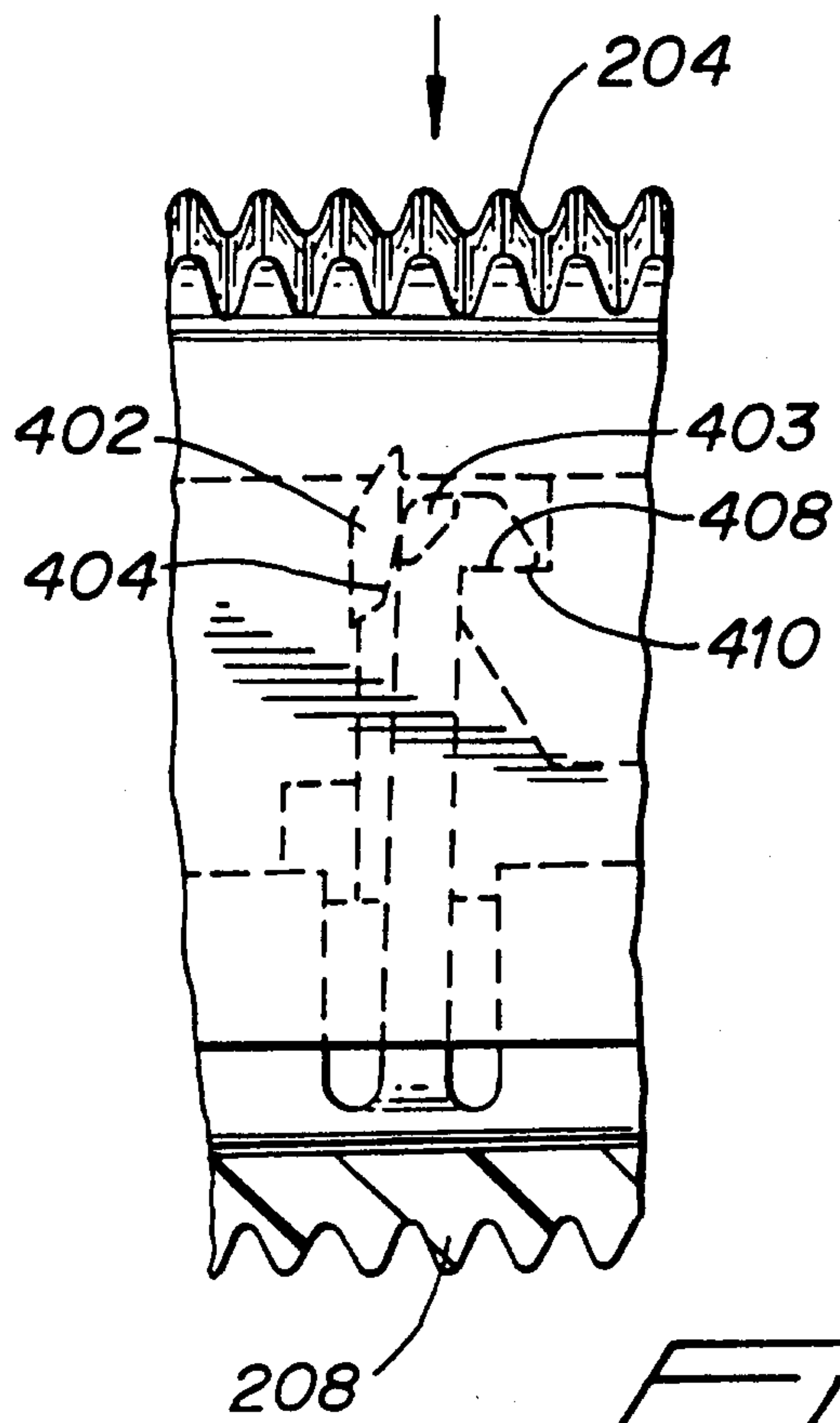


FIG. 37A

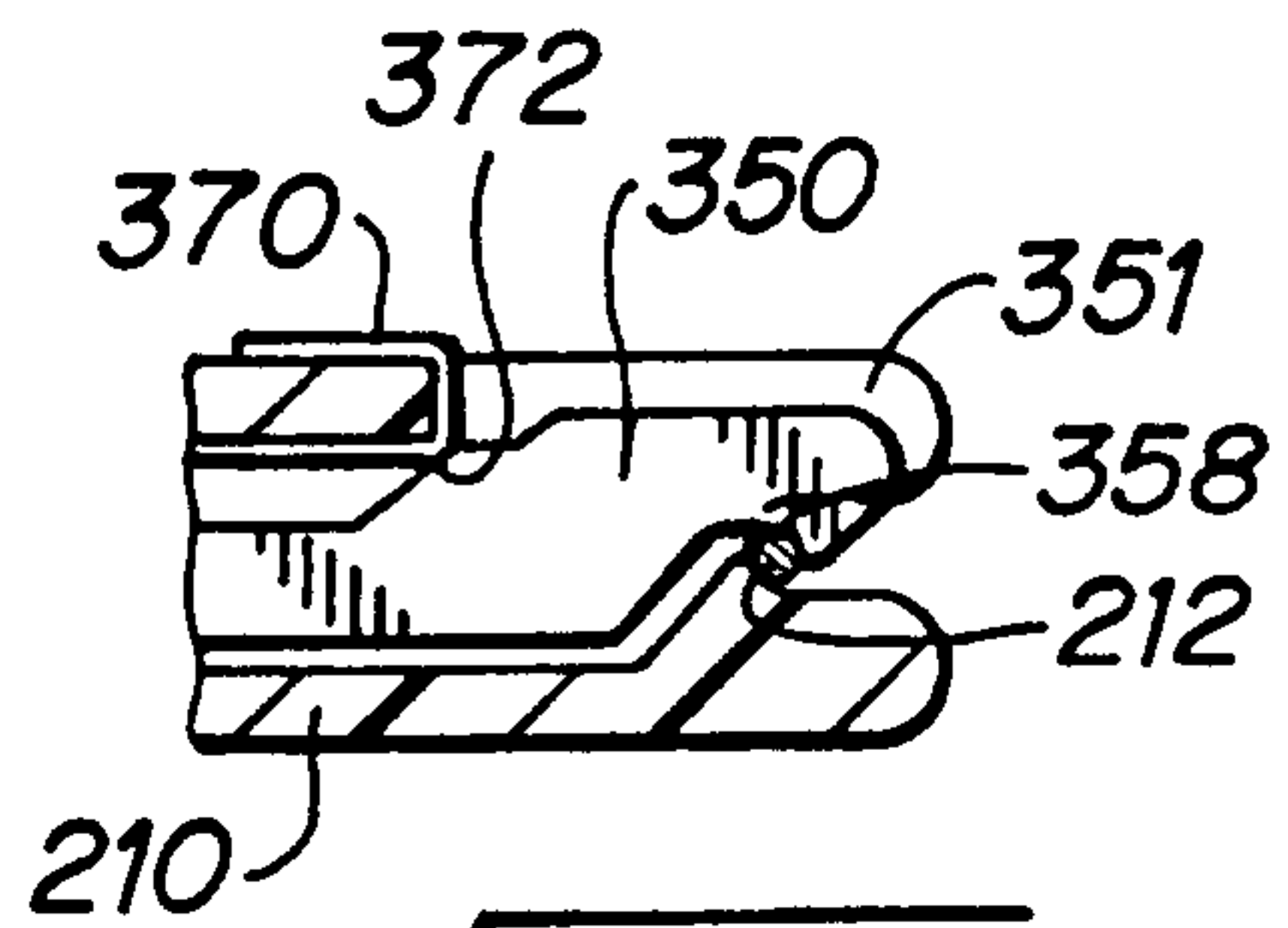


FIG. 37B

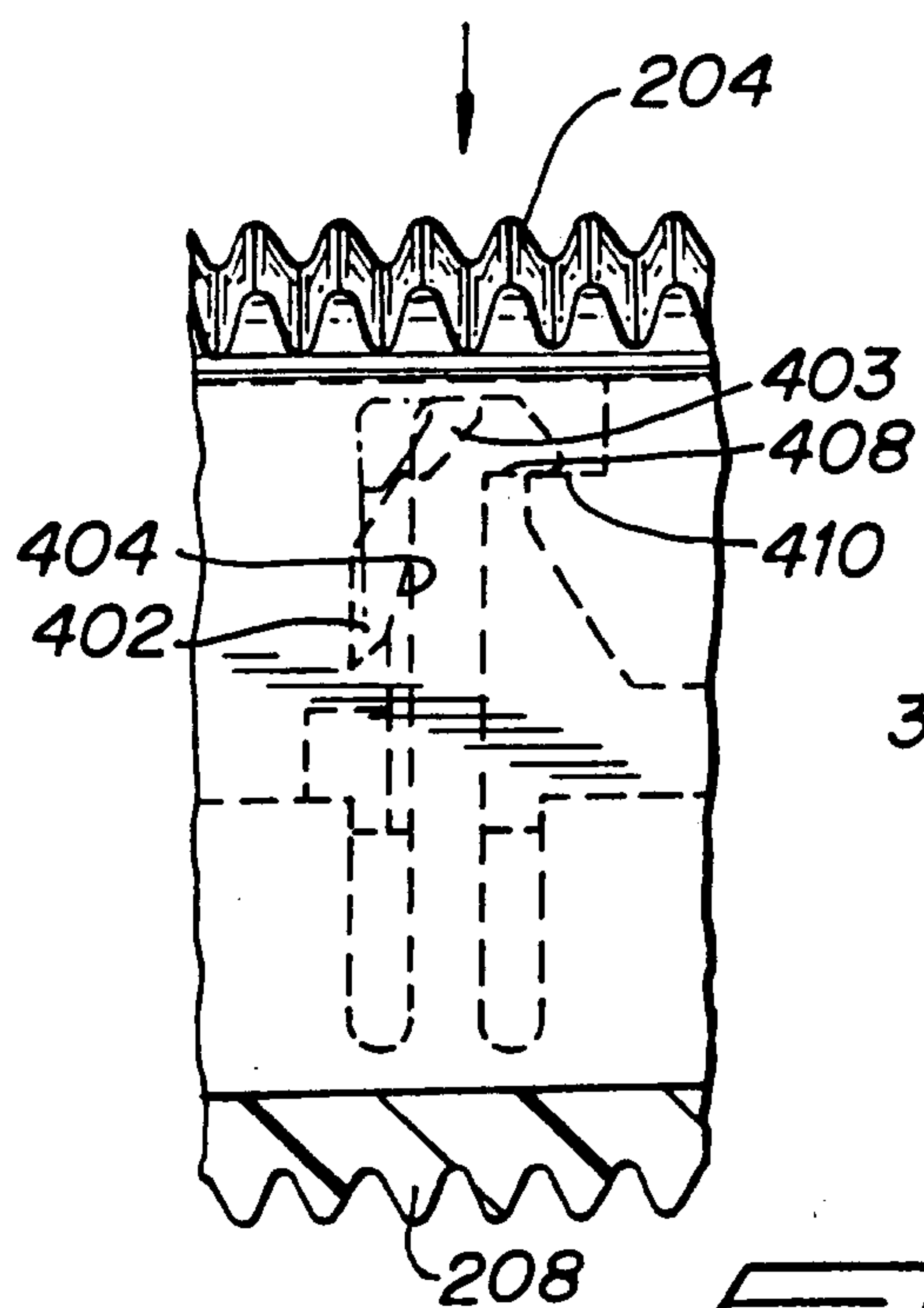


FIG. 38A

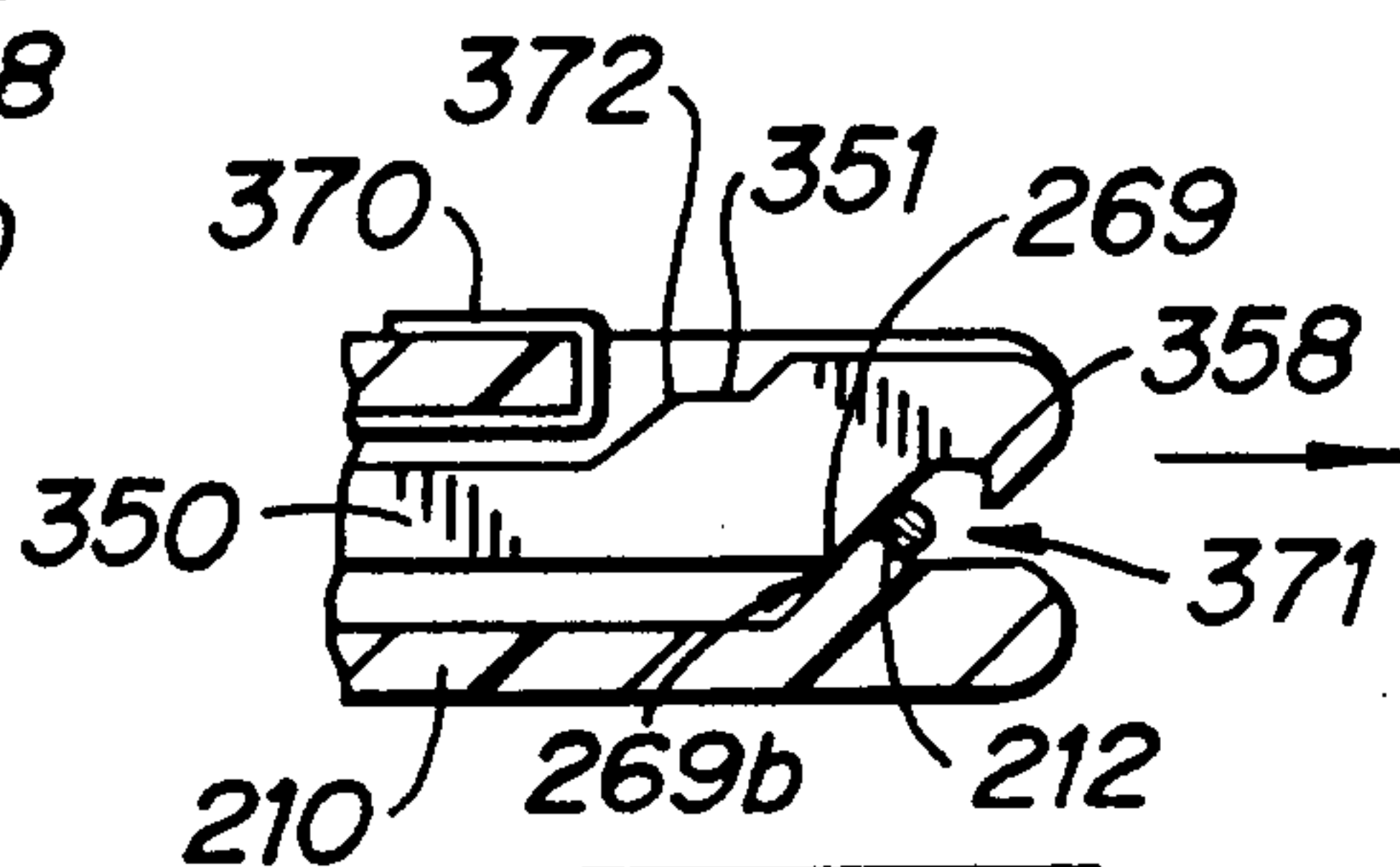


FIG. 38B

