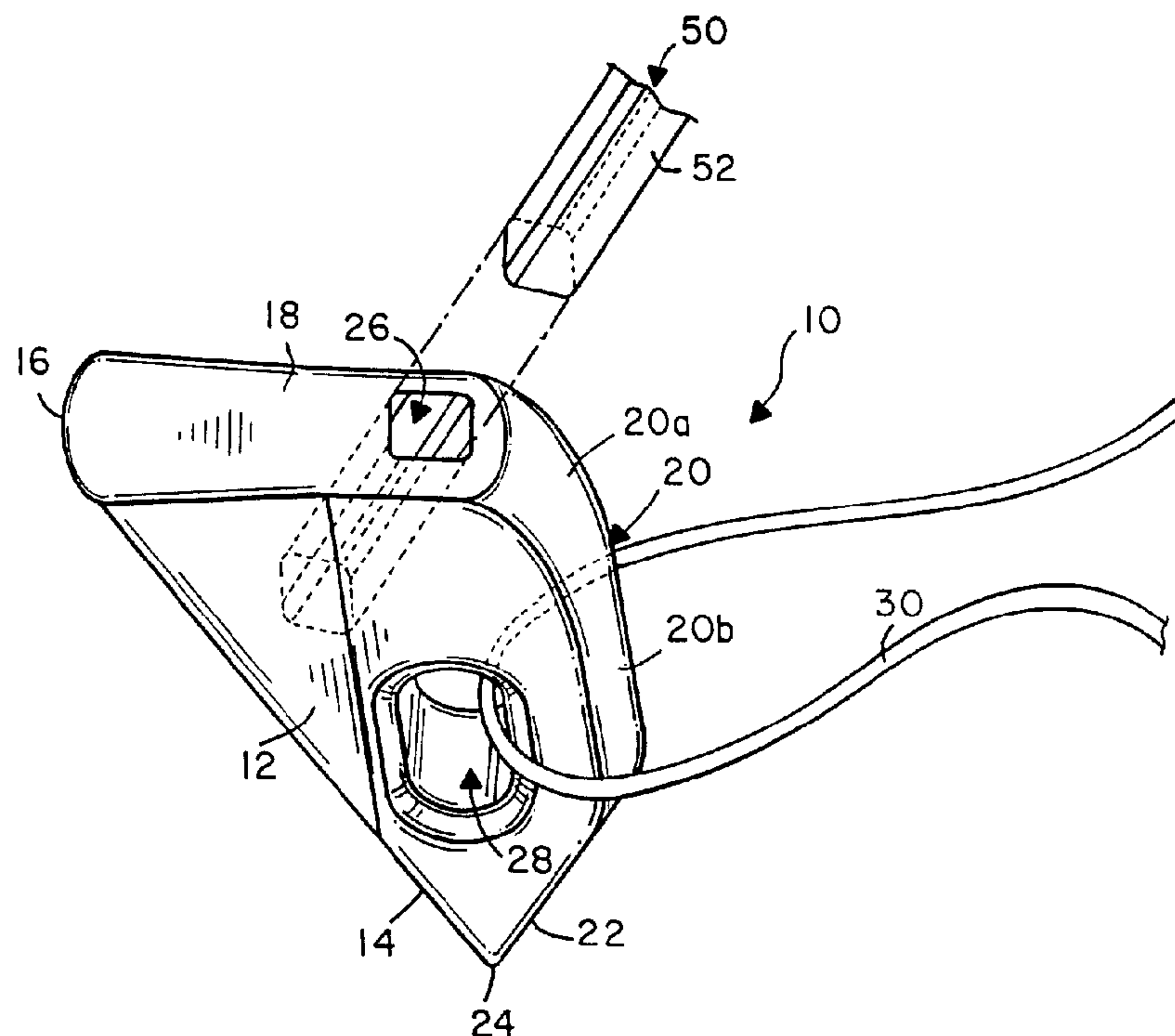




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(57) Abrégé/Abstract:

A suture anchor (10) is provided comprising a generally quadrilaterally shaped body having a bore-abutting surface (14) with a leading gripping edge (16) at one end of the bore-abutting surface (14) a trailing gripping edge (24) at the other end, and a closing surface (20) having an arcuate portion and a linear portion engaging the leading (16) and trailing (24) gripping edges, respectively, generally opposite the bore-abutting surface (14). The body (12) further defines a suture bore (28) extending transversely therethrough and an inserter bore (26) adapted to receive an insertion tool. A suture (30) engages the suture anchor (10) through the bore (28) and is adapted to engage bodily tissue to be secured to the bone. Also provided are a knotless suture anchor configuration, an associated insertion tool, and a suture anchor kit, as well as a method of implanting a suture anchor in a bore in a bone.



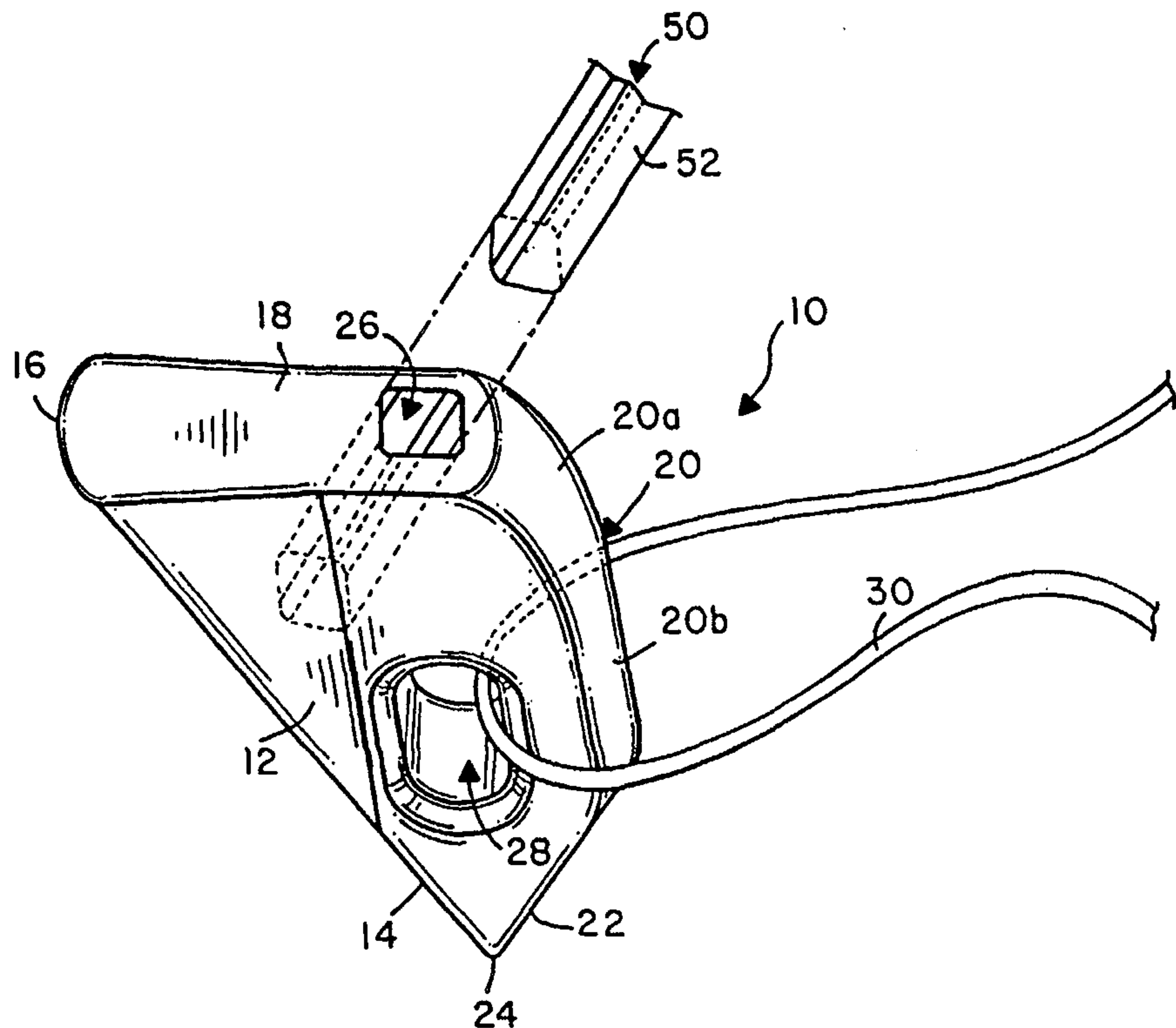
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(54) Title: SUTURE ANCHOR AND ASSOCIATED METHOD OF IMPLANTATION**(57) Abstract**

A suture anchor (10) is provided comprising a generally quadrilaterally shaped body having a bore-abutting surface (14) with a leading gripping edge (16) at one end of the bore-abutting surface (14) a trailing gripping edge (24) at the other end, and a closing surface (20) having an arcuate portion and a linear portion engaging the leading (16) and trailing (24) gripping edges, respectively, generally opposite the bore-abutting surface (14). The body (12) further defines a suture bore (28) extending transversely therethrough and an inserter bore (26) adapted to receive an insertion tool. A suture (30) engages the suture anchor (10) through the bore (28) and is adapted to engage bodily tissue to be secured to the bone. Also provided are a knotless suture anchor configuration, an associated insertion tool, and a suture anchor kit, as well as a method of implanting a suture anchor in a bore in a bone.



SUTURE ANCHOR AND ASSOCIATED METHOD OF IMPLANTATION

FIELD OF THE INVENTION

The present invention relates to surgical implements and, more particularly, to suture anchors for enabling sutures to be attached to bone.

BACKGROUND OF THE INVENTION

5 Certain injuries or conditions within the human body often require that
bodily tissue be firmly affixed to an adjacent bone structure to secure the tissue in a
desired position, for instance, where a ruptured tendon must be reattached to the
corresponding bone. To this end, suture anchors have been developed, providing
an anchor in the bone to which a suture may be secured, wherein the suture is then
10 used to secure the adjacent bodily tissue. Suture anchors generally are inserted
into a bore formed in the bone. There are several types of suture anchors in the
prior art, including a barb-type anchor, a corkscrew type anchor, an insert type
anchor with offset reorienting suture bore, and a wedge-type anchor. Of these
types of suture anchors, the wedge-type anchor has shown good promise.

15 In practice, wedge-type anchors with attached sutures are first introduced
with an insertion tool into a bore drilled into the bone at a location where the
bodily tissue must be affixed. The suture anchor generally includes a first gripping
portion, such as a sharp edge or a point, and is designed to rotate as it enters the
bore or is in the process of being withdrawn therefrom. As the suture anchor
20 rotates, the first gripping portion bites or penetrates the wall of the bore and causes
further rotation of the anchor. At the opposite end of the suture anchor, a second
gripping portion is typically provided. The second gripping portion penetrates into
the wall of the bore generally opposite the first gripping portion as the suture
anchor is rotated, thereby wedging the suture anchor within the bore. When the
25 suture anchor has rotated about the first gripping portion as much as the second
gripping portion will allow with respect to the bone structure surrounding the bore,
the suture anchor is in its seated position where it is anchored in the bore and ready
to have adjacent bodily tissue attached thereto.

30 However, while suture anchors are theoretically designed to work with all
bones, the structure of bone can vary greatly depending on the area of the body in

which the suture anchor is required. Bones generally include a number of trabeculae disposed throughout. The spacing of the trabeculae within the intermedullary canal of the bone is often a good indicator of the density of the bone. Cortical bone is solid bone without visible interstitial spaces and is typical of the midshafts, or diaphyseal regions, of long bones. Metaphyseal and epiphyseal bone, which is the bone around the joints at the opposing ends of the long bones, has a variable amount of cortical shells with a deeper trabecular structure, wherein the amount of cortical shells may vary greatly. Dense bone typically has small and closely spaced trabeculae, resulting in a hard and strong bone. In comparison, less dense or osteoporotic bone has larger and more widely spaced trabeculae, typically resulting in a softer and generally weaker bone. This less dense bone generally comprises a cancellous bone region about the intermedullary canal. A typical bone structure thus typically includes a cortical layer atop cancellous layer where the proportion of both types of bone may vary. Since the structure of bone may vary significantly from one area of the body to another, the specific performance characteristics required of a suture anchor also vary accordingly. Therefore, suture anchors must be able to function as intended when used in all types of bone structure. Where suture anchors are implanted into dense bone structures, well defined strong gripping edges are required for the suture anchor to securely engage the bore in the bone. However, where the suture anchor is implanted into less dense bone, a large surface area engaging the bone is preferred in order to distribute and reduce the stresses on the relatively weak bone.

Examples of wedge-type suture anchors are found in U.S. Patent Nos. 5,540,718 (corresponding to PCT International Publication No. WO-A-95/08295), 5,626,612, 5,782,863, and 5,879,372 to Bartlett which disclose wedge-type suture anchors based on variants of cone, double cone, and combination cone and cylinder configurations. Additionally, U.S. Patent No. 5,683,418 to Luscombe et al. assigned to Mitek Surgical Products, Inc., also the assignee of the present invention, discloses wedge-type suture anchors generally varying in shape from triangle to a quadrilateral.

The Luscombe et al. '418 patent discloses suture anchors which are angularly shaped, generally approximating a triangle to a quadrilateral and having

straight sides. The intersections of major surfaces defining the perimeter of the suture anchor therefore define sharp transitions. Thus, the device disclosed by the '418 patent is generally more useful in dense bone structures where the sharp gripping edges more effectively bite into the bore in the dense bone. However, with the sharp gripping edges biting into the bone, the '418 device generally experiences less rotation in both dense and less dense bone than is desirable to properly seat the anchor. Rotation is further inhibited by the long straight surfaces defining the device.

A possible additional limitation of the '418 device is that the insertion tool used for implanting the suture anchor in the bore is formed from a material having a frangible portion at or near the interface with the anchor which breaks or separates from the anchor after implantation thereof. In the alternative, the '418 device uses a metallic insertion tool which engages a bore in the anchor in a friction fit. Both insertion tools may experience problems in that the tool with the frangible portion may not provide enough strength for manipulating the anchor within the bore, while the friction fit tool may be difficult to separate from the anchor after implantation thereof.

The Bartlett '718, '612, '863, and '372 patents disclose wedge-type suture anchors based on variants of cone, double cone, and combination cone and cylinder configurations. These devices use the tip of the cone, or a truncation thereof, to form the edge which first bites into the bone and then provides the point about which the anchor rotates. However, with the reduced cross-sectional area at or near the tip of the cone, this main biting edge may be weaker and prone to breaking in high stress situations, such as where the anchor is being implanted in a dense bone structure. In addition, wedge-type suture anchors generally use a suture, engaged with the anchor through a bore therein, to assist in rotating and seating the anchor within the bone. The wedge-type suture anchors generally have the bore located between the main biting edge and the bore in which the insertion tool is inserted, thereby providing a small moment arm for rotating the suture anchor using the suture. Thus, the suture may be less helpful in assisting the suture anchor to rotate within the bore in the bone, especially in a dense bone structure where the anchor is more difficult to rotate. On the other hand, the Bartlett devices may be more effective in less dense bone where the main biting edge does not

experience as high a stress during the seating process for the anchor. Further, the anchor may be able to rotate to a greater extent within the bore in a less dense bone, thus allowing the suture to be more effective in rotating and seating the anchor. Accordingly, since the Bartlett devices are able to rotate more extensively in less dense bone, the anchor can be more effectively seated, thus providing the greater surface area which is desirable for a suture anchor used in less dense bone.

PCT International Publication No. WO-A-97/37595 to Pedlick et al., assigned to Mitek Surgical Products, Inc., the assignee of the present invention, also discloses a wedge shaped suture anchor. Such suture anchors include, for example, a blind hole for receiving the distal end of an installation tool. The blind hole "opens on the suture anchor's proximal end surface and extends distally into the suture along an axis." The blind hole also "serves as a mounting opening to receive the distal end of [the] installation tool," and "is disposed closer to [the] abutment surface than to [the] biting edge." In addition, "the axis is preferably set at a slight intersecting angle relative to the longitudinal axis of [the] abutment surface." When driving the suture anchor into the bore hole, "the suture anchor's plow surface will first tend to engage [the] rim of [the] bore hole, causing the distal end of [the] shaft tip to flex as the suture anchor pivots to enter the bore hole." Thus, the Pedlick device includes a blind hole for receiving the installation tool, wherein the blind hole is configured such that the suture anchor is essentially used to flex the tip of the installation tool as the suture anchor is being inserted in the bore hole. In this configuration, the installation tool may impart high stresses to the suture anchor upon installation thereof in the bone hole and/or may result in the rotation of the suture anchor about the shaft tip.

Thus, there exists a need for a suture anchor which will effectively anchor a suture within a bore in a bone while also preferably functioning equally in bones of differing densities, from hard dense bone to softer, less dense bone.

SUMMARY OF THE INVENTION

The above and other needs are met by embodiments of the present invention which provide a suture anchor particularly adapted for effectively anchoring sutures in all types of bone structures from hard dense cortical bone to softer, less dense cancellous bone. In one embodiment, the suture anchor comprises a body having a bore-abutting surface with a leading gripping edge at one end of the bore-abutting

surface, a trailing gripping edge at the other end thereof, and a closing surface engaging the leading and trailing gripping edges generally opposite the bore-abutting surface. The body further defines a suture bore extending transversely therethrough and an inserter bore adapted to receive an insertion tool. A suture engages the suture anchor through the bore such that it is adapted to engage bodily tissue to be secured to the bone.

The suture anchor is preferably quadrilaterally shaped with the side having the longest dimension comprising the bore-abutting surface. A leading surface intersects one end of the bore-abutting surface at an acute angle to form the leading gripping edge. A trailing surface intersects the other end of the bore-abutting surface at an acute angle to form the trailing gripping edge. The configurations of both the leading and trailing gripping edges may be varied according to the structure of the bone in which the anchor is to be inserted. A closing surface having an arcuate portion and a substantially linear portion engages the ends of the leading and trailing surfaces, respectively, opposite the bore-abutting surface, to form a generally quadrilaterally shaped body. The body further defines a suture bore extending transversely therethrough and disposed adjacent the trailing

gripping edge, wherein the suture bore may vary in size. The suture bore also engages a suture, wherein the suture passes through the suture bore and is adapted to engage bodily tissue adjacent the bore. In addition, in order to facilitate insertion of the suture anchor within the bore in the bone, the body defines an
5 inserter bore adapted to receive an insertion tool. The inserter bore preferably extends through the leading surface such that it is angularly disposed with respect to the bore-abutting surface. More preferably, the inserter bore is disposed between the leading gripping edge and the suture bore and has a uniform cross-sectional shape along its length. The inserter bore preferably has a non-circular
10 cross-section, where a generally square shape is most preferred.

The suture anchor may also be varied in size and configuration according to characteristics and structure of the bone in the affected area of the body and the performance characteristics required of the suture anchor. Preferably, the body of the suture anchor is comprised of a biocompatible material, with a bioabsorbable
15 material being particularly desirable. The body may be comprised of, for instance, polylactic acid, polydioxanone, polyglycolic acid, or the like, with polylactic acid being most preferred.

A further advantageous aspect of the present invention comprises an alternate embodiment of a suture anchor configured to permit knotless sutures to
20 be used to secure bodily tissue to the adjacent bone structure. The alternate knotless embodiment of the present invention comprises generally the same suture anchor configuration as the embodiments previously described, but further including a notch in the bore-abutting surface and a suture forming a loop through the suture bore. Preferably, the suture is adapted to engage the bodily tissue to be
25 secured to the bone. Once the bodily tissue is engaged, the suture wraps back about the body and engages the notch. The body is then implanted into the bore in the bone to secure the bodily tissue thereto without requiring further knotting of the suture.

Still another advantageous aspect of the present invention comprises an
30 insertion tool for inserting a suture anchor within a bore in a bone. The insertion tool generally comprises a rigid shaft having opposed ends with a tip engaged with one end of the shaft. The tip further has a proximal end operably engaged with the shaft and a distal end adapted to be engaged with an inserter bore in a suture

anchor. The tip is preferably comprised of a shape memory material, such as a nickel-titanium alloy, with a non-circular cross-section corresponding to the cross-sectional shape of the inserter bore in the body. In addition, it is further advantageous for the tip to have a uniform cross-sectional shape along its length to facilitate ease of separation from the inserter bore. Further, a non-circular or, more particularly, a generally square shape of the tip minimizes rotation of the suture anchor about the axis of the tip. Thus, the use of a shape memory material for the tip, and a shape for the tip which inhibits rotation of the anchor with respect thereto, allows the tip to be small in size. The small size of the tip thereby allows the tool and the suture anchor to be more easily manipulated within the bore and allows for small-sized suture anchors.

Yet a further advantageous aspect of the present invention comprises a kit for anchoring a suture in a bore in a bone. According to one embodiment, the kit comprises at least one insertion tool and at least one suture anchor according to the previously described embodiments thereof. At least one boring bit may also be included, with the bit capable of forming a bore of sufficient size in a bone to accommodate a provided suture anchor.

Another advantageous aspect of the present invention comprises a method of implanting a suture anchor within a bore in a bone. A suture anchor is first urged into engagement with the bore using an insertion tool angled with respect to the bore such that a bore-abutting surface of the suture anchor is engaged with the wall of the bore. The insertion tool is then elastically deformed to urge the suture anchor into the bore such that the bore-abutting surface remains engaged with the wall of the bore as the suture anchor is inserted. The suture anchor is then manipulated within the bore by moving the insertion tool to the diametrically opposite side of the bore such that the suture anchor rotates about a leading gripping edge thereof. After the insertion tool is removed from the suture anchor, the suture anchor is further rotated into a seated position within the bore by the exertion of a tensile force on the suture passing through the suture bore. The suture anchor thus further rotates about the leading gripping edge, for example, up to about 90 degrees from its insertion angle, such that both the leading gripping edge and a trailing gripping edge are engaged with the wall of the bore. The suture

anchor attains a seated position when the engagement of the trailing gripping edge with the wall of the bore prevents further rotation of the suture anchor.

Therefore, according to embodiments of the present invention, the leading gripping edge formed by the intersection of two surfaces provides a more robust structure than the tip of a cone, thereby providing a stronger suture anchor for high stress situations such as implantation of the anchor in high density bone. Further, the arcuate transition between the leading and trailing gripping edges facilitates rotation of the suture anchor in a bore in various bone structures, from dense cortical structures to less dense cancellous structures, thereby improving the seating ability of the suture anchor and requiring less effort to achieve the necessary rotation. In addition, the trailing gripping edge formed by the intersection of two surfaces provides a sharp gripping edge which is desirable in a dense bone structure. However, when included with the closing surface having an arcuate portion, the sharp trailing gripping edge permits the suture anchor to engage the bore in a less dense bone structure after the anchor has been rotated to provide the high seating surface area which is desirable for a less dense bone structure. Thus, the suture anchor according to embodiments of the present invention provides a mechanism for effectively anchoring a suture within a bore in a bone while also functioning equally in bones of differing densities, from hard dense bone to softer, less dense bone. Further, the uniform non-circular configuration of the inserter bore/insertion tool interface minimizes rotation of the suture anchor about the axis of the tip while facilitating a robust and easily connectable/disconnectable interface between the insertion tool and the suture anchor.

BRIEF DESCRIPTION OF THE DRAWINGS

Some of the advantages of the present invention having been stated, others will appear as the description proceeds, when considered in conjunction with the accompanying drawings, which are not necessarily drawn to scale, in which:

FIG. 1 is a perspective view of one embodiment of the present invention showing a suture anchor engaging a suture and corresponding insertion tool.

FIG. 2 is a lateral view of the embodiment of the present invention as shown in **FIG. 1**.

FIG. 3 is a rear view of one embodiment of the present invention as shown in **FIG. 1**.

FIG. 4 is a perspective view of an alternate embodiment of the present invention showing a suture anchor engaging a suture and corresponding insertion
5 tool.

FIG. 5 is a lateral view of the alternate embodiment of the present invention as shown in **FIG. 4**.

FIG. 6 shows multiple views of still another alternate embodiment of the present invention.

10 **FIG. 6A** shows multiple views of yet another alternate embodiment of the present invention.

FIGS. 7 – 14 show a cross-sectional sequence of insertion of a suture anchor into a bore in a bone in accordance with embodiments of the present invention.

15 **FIG. 15** is a cross-sectional view of bodily tissue being attached to the bone by a suture anchored within the bone by a suture anchor in accordance with an embodiment of the present invention.

FIG. 16 shows an insertion tool for inserting a suture anchor into a bore in a bone according to one embodiment of the present invention.

20 **FIG. 17** shows a boring tool for forming a bore in a bone in which a suture anchor is implanted according to one embodiment of the present invention.

FIG. 18 shows an alternate embodiment of the present invention comprising a knotless suture anchor.

25 DETAILED DESCRIPTION OF THE INVENTION

The present invention now will be described more fully hereinafter with reference to the accompanying drawings, in which preferred embodiments of the invention are shown. This invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein;
30 rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art. Like numbers refer to like elements throughout.

FIGS. 1 - 3 disclose one embodiment of the suture anchor according to the present invention, indicated generally by the numeral **10**. The suture anchor **10** is preferably biocompatible and comprised of a bioabsorbable material, such as polylactic acid, polydioxanone, polyglycolic acid, and similar materials or blends thereof. Such materials should preferably be recognized by the appropriate regulatory authority as being suitable for use in humans. Additionally, it is desirable that the material strengthen the bone into which the anchor is inserted. It is further desirable for the material to be translucent or transparent to noninvasive examinations such as radiographs (e.g., X-rays). Accordingly, the suture anchor may also be comprised of cortical bone, where the bone may further be autologous or autogenous bone. Generally, the suture anchor may be comprised of a suitable biocompatible polymer, biocompatible metal, or other biocompatible material (see, e.g., U.S. Patent Nos. 5,540,718, 5,626,612, 5,782,863, and 5,879,372 to Bartlett and U.S. Patent No. 5,683,418 to Luscombe et al.). The suture anchor **10** is generally quadrilaterally shaped and comprises a body **12** having a bore-abutting surface **14**, a leading gripping edge **16**, a leading surface **18**, a closing surface **20**, a trailing surface **22**, a trailing gripping edge **24**, an inserter bore **26**, and a suture bore **28**. The bore-abutting surface **14** and the leading surface **18** intersect at an acute angle to form the leading gripping edge **16**. At the other end, the bore-abutting surface **14** intersects with the trailing surface **22** at an acute angle to form the trailing gripping edge **24**. The leading surface **18** and the trailing surface **22** are further connected by the closing surface **20**, dispose generally opposite the bore-abutting surface **14** and comprising an arcuate portion **20a** and a substantially linear portion **20b**. The body **12** further defines an inserter bore **26** in the leading surface **18** and a transverse suture bore **28** therethrough and through which a suture **30** is passed.

According to one embodiment of the present invention, the bore-abutting surface **14** may be a flat surface in both the longitudinal and lateral directions, but is preferably flat in the longitudinal direction and curved or radiused in the lateral direction along the edge of the body **12**. The body **12** may also widen as it approaches the leading gripping edge **16** such that the leading gripping edge **16** is generally the widest portion of the body **12**. Accordingly, both the bore-abutting surface **14** and the leading surface **18** are wider approaching the leading gripping

edge 16. The leading gripping edge 16 is preferably wide in order to distribute the anchoring stress over a greater surface area, as well as to strengthen the suture anchor 10, as is further explained herein. The leading surface 18 is generally a flat surface and defines the inserter bore 26. The inserter bore 26 is preferably located
5 in the leading surface 18 in the vicinity where the leading surface 18 meets the arcuate portion 20a of the closing surface 20. The inserter bore 26 extends into the body 12 towards the bore-abutting surface 14, thereby forming an acute angle with the leading surface 18.

The inserter bore 26 is preferably configured to receive the tip 52 of an
10 insertion tool 50 for implanting the suture anchor 10 within the bone. Preferably, the inserter bore 26 and the tip 52 have corresponding non-circular lateral cross-sections, wherein the cross-sectional shapes are uniform along the lengths thereof. Preferably, the tip 52 of the insertion tool 50 is generally square, but may have beveled or radiused corners, and the inserter bore 26 is accordingly shaped to
15 receive the tip 52. Generally, the tip 52 of the insertion tool 50 may be any shape or configuration which minimizes rotation of the suture anchor 10 about the longitudinal axis of the tip 52. In addition, at least the tip 52 of the insertion tool 50 is preferably formed from a material having elastic properties and, more preferably, superelastic properties, such as a shape memory material. The elastic
20 or superelastic properties of the material should be such that the tip 52 is not substantially permanently deformed during insertion and implantation of the suture anchor 10, thereby allowing the tip 52 to substantially return to an initial configuration (generally the configuration of the tip 52 as it is initially inserted into the inserter bore 26). Preferably, at least the tip 52 of the insertion tool 50 is
25 comprised of a nickel-titanium alloy, such as is commercially available under the names NITINOL™ (Raychem), TINEL™ (Raychem), or SENTINOL™ (GAC International Inc.). Such shape memory alloys having superelastic properties are well known in the art; however, any other shape retaining material sufficient for properly implanting the suture anchor 10 of the present invention in a bore in a
30 bone may be used. The use of a shape memory material and the shape of the tip 52 which minimizes rotation of the suture anchor 10 about the tip 52 engaged therewith further allows a smaller sized tip 52 to be used to effectively implant the suture anchor 10 within a bone. In addition, a smaller sized tip 52 further allows a

smaller suture anchor **10** to be used in situations where such is necessary or desired.

According to one embodiment of the present invention, the suture anchor **10** may include a suture **30** engaged therewith through the suture bore **28**. The suture bore **28** is disposed intermediate the bore-abutting surface **14** and the linear portion **20b** of the closing surface **20**, adjacent the trailing surface **22** and the trailing gripping edge **24**. The suture bore **28** may vary in size and is preferably rounded or beveled around the openings in the body **12** in order to avoid abrasion of the suture **30**. Most preferably, the suture bore **28** is disposed in the body **12** on the opposing side of the inserter bore **26** from the leading gripping edge **16**. That is, the inserter bore **26** is most preferably disposed intermediate the leading gripping edge **16** and the suture bore **28**. Since, as will be described further herein, the leading gripping edge **16** provides a point about which the suture anchor **10** is rotated by a tensile force applied to the suture **30** threaded through the suture bore **28**, disposing the suture bore **28** adjacent the trailing gripping edge **24** provides a larger moment arm for exerting the necessary rotational force on the suture anchor **10** via the suture **30**. Thus, more turning torque may be exerted on the suture anchor **10** as compared to a suture anchor **10** having the suture bore **28** disposed on the opposite side of the inserter bore **26** and closer to the leading gripping edge **16**. The suture anchor **10** is typically rotated within the bore in the bone until a seated position is attained, wherein the seated position is preferably up to about ninety degrees from the orientation in which the suture anchor **10** was initially inserted into the bore. The degree of rotation depends, at least in part, on the structure of the bone into which the suture anchor **10** is implanted.

The closing surface **20** and the trailing surface **22** may be flat surfaces, but preferably are curved or radiused in the lateral direction for the lengths thereof. As described further herein in accordance with a preferred method of the present invention, the inserter bore **26** cooperates with an insertion tool **50** to introduce the suture anchor **10** into a bore in a bone. As the suture anchor **10** is introduced into the bore, the bore-abutting surface **14** lies flush with the wall of the bore, with the insertion tool **50** forcing it thereagainst. The closing surface **20** and, more specifically, the arcuate portion **20a** defining the maximum width of the suture anchor **10** as measured perpendicularly from the bore-abutting surface **14**, is

disposed adjacent the wall of the bore diametrically opposite the leading gripping edge 16. Thereafter, moving the insertion tool 50 to the diametrically opposite side of the bore or applying a tensile force on the suture 30 outwardly of the bore tends to cause the suture anchor 10 to rotate such that the leading gripping edge 16 is driven into the wall of the bore. Thus, the rotation of the suture anchor 10 is preferably initiated by moving the insertion tool 50 to the diametrically opposite side of the bore from which the insertion tool 50 initially introduced the anchor 10 into the bore. Once the insertion tool 50 is removed from the inserter bore 26, tensile force on the suture 30 is used complete the rotation of the anchor 10 into a seated position.

The arcuate portion 20a of the closing surface 20 facilitates rotation of the suture anchor 10 about the leading gripping edge 16 as the insertion tool 50 is moved to the opposite side of the bore and/or a tensile force is applied to the suture 30. As the suture anchor 10 is further rotated by the insertion tool 50 and/or the tensile force applied to the suture 30, the rotation of the suture anchor 10 continues until the intersection of the linear portion 20b of the closing surface 20 and the trailing surface 22 and/or the trailing gripping edge 24 begins to penetrate the wall of the bore opposite the leading gripping edge 16. However, once the insertion tool 50 is removed from the inserter bore 28, the rotation of the suture anchor 10 into the seated position is accomplished solely by exerting tensile force on the suture 30.

An alternate embodiment of the present invention is shown in **FIGS. 4 and 5**. While generally similar to the embodiments as described above, this alternate embodiment differs in the configuration of the leading surface 118. Here, the leading surface 118 further comprises a concave depression 119 therein immediately prior to intersection of the leading surface 118 and the bore-abutting surface 14. The concave depression 119 thus redefines the leading gripping edge 16 as a scoop since it forms a more acute angle between the bore-abutting surface 14 and the leading surface 118.

Further alternate embodiments of the present invention are shown in **FIGS. 6 and 6A**. As shown in **FIG. 6**, the leading surface 218 is downwardly stepped between the inserter bore 26 and the leading gripping edge 216. Further, the bore-abutting surface 214 varies in width as it intersects the leading surface 218, thereby

forming a reduced width leading gripping edge **216**. A reduced width leading gripping edge **216** may be advantageous, for example, in dense bone structures where biting of the leading gripping edge **216** into the wall of the bore may be facilitated by a smaller and sharper structure. As further shown in **FIG. 6A**,
5 various dimensions of the suture anchor **10** may be varied according to the performance characteristics desired for the particular application. For example, the increased dimensions **BW** and **OW** produce a larger and more robust suture anchor **10**, which further requires a larger bore in the bone into which it is inserted. These characteristics may be advantageous where, for instance, larger bone structures are
10 involved and/or it is anticipated that the bodily tissue to be fastened to the bone will experience higher stresses at the attachment thereto. In this instance, a larger and stronger suture anchor **10** may be desirable. Thus, in embodiments of the present invention, the dimensions and configurations of the suture anchor **10** may be varied to adapt the suture anchor **10** to the requirements of the particular
15 application.

In accordance with embodiments of the present invention, a method of implanting the suture anchor **10** in a bore in a bone is shown in **FIGS. 7 - 14**. As shown in **FIG. 7**, a bore is first drilled in the bone using a boring bit **54**. The bore generally passes through an outer layer of dense bone (cortical layer) and into an
20 inner layer of a less dense or osteoporotic bone (cancellous layer) further therein. Once the bore is formed, the boring bit **54** is removed. A suture anchor **10** is then prepared for insertion by inserting the tip **52** of an insertion tool **50** into the inserter bore **26**. In addition, the suture anchor **10** typically includes a suture **30** threaded through the suture bore **28**. After the tip **52** is inserted into the inserter bore **26**, the
25 loose ends of the suture **30** are attached to the insertion tool **50** in order to secure the suture **30** and prevent it from becoming tangled or damaged during the insertion process. As shown in **FIG. 8**, the suture anchor **10** is then introduced into the bore such that the bore-abutting surface **14** is engaged with the wall of the bore. In this position, the insertion tool **50** is in its original configuration (substantially
30 straight), with the tip **52** inserted in the inserter bore **26** and angled with respect to the axis of the bore. Further, as shown, the diameter of the bore roughly corresponds to the maximum width of the suture anchor **10**, defined as the maximum perpendicular dimension from the bore-abutting surface **14**. This

maximum width of the suture anchor **10** is roughly along the portion of the body **12** corresponding to the arcuate portion **20a** of the closing surface **20**. Thus, when the suture anchor **10** is introduced into the bore in the bone, the bore-abutting surface **14** is preferably contacting the wall of the bore, while the point defining the maximum width of suture anchor **10** (the arcuate portion **20a**) is at least within close proximity to the wall of the bore diametrically opposite the bore-abutting surface **14**.

As shown in **FIG. 9**, a force directed inwardly with respect to the bore is then exerted on the insertion tool **50** such that the suture anchor **10** is urged into the bore. When the insertion tool **50** encounters the outer layer of cortical bone, the force causes the insertion tool **50** to bend such that distal end of the tip **52** remains in the inserter bore **26**, but the portion of the tip **52** outside of the suture anchor **10** bends or deforms to conform to the wall of the bore. At this point, a portion of the bore-abutting surface **14** is still in contact with the dense cortical bone layer since suture anchor **10** has not been inserted far enough into the bore for the leading gripping edge **16** to pass by this bone layer. The bore-abutting surface **14**, aided by the force provided by the tip **52** of the insertion tool **50**, remains flush against the wall of the bore.

FIG. 10 shows the suture anchor **10** after further force has been exerted on the insertion tool **50** inwardly with respect to the bore. Once the suture anchor **10** has been inserted into the bore for a sufficient distance to clear the dense cortical surface layer of bone, it enters a less dense inner portion of the bone (the cancellous layer). Since the cancellous layer is less dense and weaker than cortical bone, the suture anchor **10** may begin to turn or rotate within the bore in response to force exerted by the tip **52** of the insertion tool **50** returning to its original shape due to the effect of the shape memory material from which it is comprised. As the rotation of the suture anchor **10** occurs, the leading gripping edge **16** is forced into the cancellous layer forming this portion of the wall of the bore. Diametrically opposed the leading gripping edge **16**, the arcuate portion **20a** is urged against the wall of the of the bore, wherein engagement with the wall proceeds along the arcuate portion **20a** to the linear portion **20b** and then to the trailing surface **22** as the suture anchor **10** rotates. Thus, the suture anchor **10** generally begins to rotate about the point where the leading gripping edge **16** engages the wall of the bore.

As further shown in **FIG. 11**, the rotation of the suture anchor **10** may continue until the tip **52** of the insertion tool **50** has returned to its original shape such that the insertion tool **50** rests against the wall at the entrance to the bore. The suture anchor **10** has been illustrated in this method of implantation as interacting with a bone structure having a cancellous layer underlying a cortical layer, such as that found, for example, in the “rotator cuff” area of the human shoulder (also known as the greater tuberosity of the humerus). However, a suture anchor **10** according to embodiments of the present invention may also be used in areas of dense bone, predominantly comprised of a cortical layer with little or no underlying cancellous layer, such as, for example, at the “cup” or glenoid area of the shoulder. While the suture anchor **10** according to embodiments of the present invention may tend not to rotate as freely or extensively within a cortical bone layer as within a cancellous layer, it contains features further described herein which render the suture anchor **10** generally adapted for application to both dense cortical bone and less dense cancellous bone structures.

As shown in **FIG. 12**, further rotation of the suture anchor **10** may be obtained by exerting axial force on the suture **30** outwardly with respect to the bore and/or urging the insertion tool **50** to the diametrically opposite side of the bore. The forces exerted through the suture **30** and/or the insertion tool **50** causes the leading gripping edge **16** to bite or penetrate further into the wall of the bore and the suture anchor **10** to rotate thereabout. At the wall on the opposite side of the bore, the trailing gripping edge **24** begins to penetrate into the wall of the bore. **FIG. 13** shows that rotation of the suture anchor **10** due to the force exerted on the suture **30** and/or the insertion tool **50** further brings the insertion tool **50** into contact with the wall on generally the opposite side of the bore from which the insertion tool **50** initially entered the bore. At this point, the insertion tool **50** is removed from the inserter bore **26** of the suture anchor **10** by a tensile force applied outwardly with respect to the inserter bore **26**.

As shown in **FIG. 14**, once the insertion tool **50** is removed, further tensile force may be exerted on the suture **30** to complete the rotation of the suture anchor **10** within the bore to a seated position. In a seated position, the suture anchor **10** preferably may have rotated up to about ninety degrees from the orientation in which it was inserted into the bore. As shown in **FIG. 14**, in a cancellous bone

layer, the suture anchor **10** in a seated position will preferably be disposed such that the bore-abutting surface **14** is substantially perpendicular to the axis of the bore. Both the leading gripping edge **16** and the trailing gripping edge **24** will have penetrated into the wall of the bore. Further, the divergence of the leading surface **18** from the trailing surface **22**, as both approach the bore-abutting surface **14**, increases the surface area of the suture anchor **10** engaging the bone in a seated position. Thus, in a less dense cancellous bone layer, the suture anchor **10**, according to embodiments of the present invention, provides a large surface area over which a force exerted outwardly with respect to the bore can be distributed.

10 Preferably, the size and configuration of the suture anchor **10** may be varied to provide an optimally effective surface area for the particular bone structure in which the suture anchor **10** is to be implanted. This feature is particularly advantageous where the cortical bone layer is relatively thin and does not significantly contribute to the strength of the bone. A suture anchor **10** having a

15 large effective surface area in the seated position will distribute the stresses on a cancellous bone layer over a relatively larger area, thereby lowering the risk of the bone failing in the vicinity of the bore and thus the risk of the suture anchor **10** pulling out of the bone.

Where the suture anchor **10** is to be implanted in a bone having a dense

20 cortical structure, the suture anchor **10** will not be able to rotate as extensively as in a cancellous bone structure since it is more difficult for the leading and trailing gripping edges **16** and **24** to penetrate the walls of the bore. In this situation, the suture anchor **10** according to embodiments of the present invention may be slightly smaller than the diameter of the bore. Thus, after the suture anchor **10** is

25 inserted into the bore in the bone in the same manner as previously described, a tensile force applied to the suture **30**, or a force resulting from the insertion tool **50** being urged toward the opposite side of the bore, causes rotation of the suture anchor **10**. Since the bore is larger than the maximum width of the suture anchor **10**, rotation of the suture anchor **10** within the bore is facilitated and the leading

30 and trailing gripping edges **16** and **24** are better able to penetrate the wall of the bore to secure the suture anchor **10**. Once the insertion tool **50** is removed from the suture anchor **10**, a tensile force exerted on the suture **30** causes further rotation of the suture anchor **10** into a seated position within the bore in the cortical bone

structure, where the degree of rotation is preferably up to about ninety degrees from the orientation in which the suture anchor **10** was inserted into the bore.

Once the suture anchor **10** has been implanted, the suture **30** engaged therewith through the suture bore **30** allows adjacent bodily tissue to be affixed to the bone, as shown in **FIG. 15**. For example, suture anchors **10** may be used in the pelvic region to provide attachment points for bladder suspension procedures, in the shoulder area for reattachment of the rotator cuff, or in the feet and/or knees to assist in reattaching tendons. Preferably, the suture anchor **10**, according to embodiments of the present invention, is seated in the bore in the bone such that the anchoring force (the force required to extract a seated suture anchor **10** from the bore) approaches the tensile strength of the suture **30** threaded therethrough. Thus, according to one particularly advantageous embodiment, the suture anchor **10** and attached suture **30** may withstand a force of up to about 30 pounds without the suture anchor **10** pulling out of the bore or the suture **30** breaking. Generally, a minimum amount of tools are required for applying the suture anchors **10** according to embodiments of the present invention. As shown in **FIGS. 16 and 17**, typical tools used for applying the suture anchor **10** include an insertion tool **50** having a tip **52** comprised of a shape memory material as shown in **FIG. 16** and a boring bit **54** as shown in **FIG. 17**. Accordingly, an advantageous aspect of the present invention may comprise a kit having at least one of a suture anchor **10**, at least one of a corresponding boring bit **54**, and at least one of a corresponding insertion tool **50**, thus facilitating selection of an appropriate configuration of a suture anchor **10** for the particular bone structure in which it is to be implanted.

A further advantageous aspect of the present invention is shown in **FIG. 18** and comprises an alternate embodiment of the present invention. While being similar to the embodiments previously described, the suture anchor **10** shown in **FIG. 18** further includes a notch **60** angularly disposed in the bore-abutting surface **14** and extending into the body **12**, wherein the location of the notch **60** along the bore-abutting surface **14** may vary. Where the suture anchor **10** also includes a suture **330** configured in the form of a loop, a knotless suture anchor **10** is provided. That is, the suture **330** may be wrapped about or otherwise engaged with the bodily tissue to be secured by the suture anchor **10** before it is wrapped about the suture anchor **10** to engage the notch **60**. Once the suture **330** is engaged with

the notch 60, the suture anchor 10 may be implanted into a bore in an adjacent bone according to the method previously described. On completion of the suture anchor 10 implantation procedure, the suture 330 is preferably not required to be further knotted since the bodily tissue is already secured to the adjacent bone.

5 Thus, embodiments of the present invention provide distinct advantages over the prior art. The leading gripping edge formed by the intersection of two surfaces provides a more robust structure than the tip of a cone, thereby providing a stronger suture anchor for high stress situations such as implantation of the anchor in high density bone. Further, the arcuate portion of the closing surface
10 between the leading and trailing gripping edges facilitates rotation of the suture anchor in a bore in various bone structures, from dense cortical structures to less dense cancellous structures, thereby improving the seating ability of the suture anchor and requiring less effort to achieve the necessary rotation. In addition, the trailing gripping edge formed by the intersection of two surfaces provides a sharp
15 gripping edge which is desirable in a dense bone structure. However, when included with the arcuate portion of the closing surface, the sharp trailing gripping edge permits the suture anchor to engage the bore in a less dense bone structure after the anchor has been rotated to provide the high seating surface area which is desirable for a less dense bone structure. Thus, the suture anchor according to
20 embodiments of the present invention provides a mechanism for effectively anchoring a suture within a bore in a bone while also functioning equally in bones of differing densities, from hard dense bone to softer, less dense bone. Further, the uniform non-circular configuration of the inserter bore/insertion tool interface minimizes rotation of the suture anchor about the axis of the tip while facilitating a
25 robust and easily connectable/disconnectable interface between the insertion tool and the suture anchor.

Many modifications and other embodiments of the invention will come to mind to one skilled in the art to which this invention pertains having the benefit of the teachings presented in the foregoing descriptions and the associated drawings. Therefore, it is to be
30 understood that the invention is not to be limited to the specific embodiments disclosed and that modifications and other embodiments are intended to be included within the scope of the appended claims. Although specific terms are employed herein, they are used in a generic and descriptive sense only and not for purposes of limitation.

THAT WHICH IS CLAIMED:

1. An implantable suture anchor (10) for wedging within a bore formed in a bone to secure a suture to the bone, characterized by:

a body (12) having a generally quadrilaterally shaped lateral cross-section, said body comprising:

a bore-abutting surface (14) having opposed ends;

a leading gripping edge (16) at one end of the bore-abutting surface (14), the leading gripping edge (16) comprising an intersection of a leading surface (18) with the bore-abutting surface (14) at an acute angle;

a trailing gripping edge (24) at the end of the bore-abutting surface (14) opposite the leading gripping edge (16), the trailing gripping edge (24) comprising an intersection of a trailing surface (22) with the bore-abutting surface (14) at an acute angle; and

a closing surface (20) having an arcuate portion (20a) and a substantially linear portion (20b), the arcuate portion (20a) engaging the leading surface (18) and the substantially linear portion (20b) engaging the trailing surface (22) so as to generally form a quadrilateral, the closing surface (20) being disposed generally opposite the bore-abutting surface (14) for facilitating the rotation of the body (12) about the leading gripping edge (16) within the bore;

said body further defining:

a suture bore (28) extending transversely therethrough adjacent the trailing gripping edge (24); and

an inserter bore (26) adapted to receive an insertion tool and defining an axis extending toward the bore-abutting surface (14) between the leading gripping edge (16) and the suture bore (28).

2. A suture anchor according to Claim 1 wherein the inserter bore (26) extends through the leading surface (18) such that it is angularly disposed with respect to the bore-abutting surface (14).
3. A suture anchor according to Claim 1 wherein the body (12) is comprised of a biocompatible material.
4. A suture anchor according to Claim 3 wherein the body (12) is comprised of a bioabsorbable material.
5. A suture anchor according to Claim 4 wherein the body (12) is comprised of at least one of polylactic acid, polydioxanone, and polyglycolic acid.
6. A suture anchor according to Claim 1 wherein the body (12) is comprised of polylactic acid.
7. A suture anchor according to Claim 1 wherein the inserter bore (26) is uniformly shaped along its length.
8. A suture anchor according to Claim 7 wherein the inserter bore (26) is non-circular.
9. A suture anchor according to Claim 8 wherein the inserter bore (26) is generally square.
10. An insertion device (50) for implanting a suture anchor (10) within a bore in a bone, characterized by:
 - a rigid shaft having opposed ends; and
 - a tip (52) on one end of said shaft, said tip (52) comprised of a shape memory material and having a proximal end operably engaged with the shaft and a distal end adapted to be engaged with an inserter bore (26) defined by a suture anchor (10), the distal end of the tip (52) having a non-circular cross-section corresponding to the cross-section of the

inserter bore (26) to minimize rotation of the suture anchor (10) about the axis of the tip (52) when the distal end of the tip (52) is engaged with the inserter bore (26).

11. An insertion device according to Claim 10 wherein the tip (52) is comprised of a nickel-titanium alloy.

12. An insertion device according to Claim 10 wherein the tip (52) is uniformly shaped along its length.

13. An insertion device according to Claim 10 wherein the tip (52) is generally square.

14. A kit for anchoring a suture (30) in a bore in a bone, characterized by: at least one suture anchor (10) comprising:

a body (12) having a generally quadrilaterally shaped lateral cross-section, said body (12) further having a bore-abutting surface (14) having opposed ends and at least one gripping edge (16); said body (12) further defining:

a suture bore (28) extending transversely therethrough; and
an inserter bore (26) adapted to receive an insertion tool and defining an axis extending toward the bore-abutting surface (14) between the leading gripping edge (16) and the suture bore (28);

at least one suture (30) operably engaged with the suture bore (28), the suture (30) passing through the suture bore (28) and adapted to engage bodily tissue to be secured to the bone; and

at least one insertion device (50) for inserting the suture anchor (10) in the bore in the bone, comprising:

a rigid shaft having opposed ends; and

a tip (52) at one end of said shaft, the tip (52) comprised of a shape memory material and having a proximal end operably engaged with the shaft and a free distal end capable of engagement with

the inserter bore (26), the distal end of the tip (52) having a non-circular cross-section corresponding to the cross-section of the inserter bore (26) to minimize rotation of the suture anchor (10) about the axis of the tip (52) when the distal end of the tip (52) is engaged with the inserter bore (26).

15. A kit according to Claim 14 further comprising a leading surface (18) operably engaged with an end of the bore-abutting surface (14) at an acute angle to form a leading gripping edge (16).

16. A kit according to Claim 15 further comprising a trailing surface (22) operably engaged with the end of the bore-abutting surface (14) opposite the leading gripping edge (16), at an acute angle, to form a trailing gripping edge (24).

17. A kit according to Claim 16 further comprising a closing surface (20) having an arcuate portion (20a) and a substantially linear portion (20b), the arcuate portion (20a) engaging the leading surface (18) and the substantially linear portion (20b) engaging the trailing surface (22) so as to generally form a quadrilateral, the closing surface (20) being disposed generally opposite the bore-abutting surface (14) for facilitating the rotation of the body (12) about the leading gripping edge (16) within the bore.

18. A kit according to Claim 15 wherein the inserter bore (26) extends through the leading surface (18) such that it is angularly disposed with respect to the bore-abutting surface (14) and located between the leading gripping edge (16) and the suture bore (28).

19. A kit according to Claim 14 further including at least one boring bit (54) for forming a circular bore in the bone.

20. A kit according to Claim 14 wherein the body (12) is comprised of polylactic acid.

21. A kit according to Claim 14 wherein the inserter bore (26) is uniformly shaped along its length.
22. A kit according to Claim 14 wherein the inserter bore (26) is generally square.
23. A kit according to Claim 14 wherein the tip (52) is comprised of a nickel-titanium alloy.
24. A kit according to Claim 14 wherein the tip (52) is uniformly shaped along its length.
25. A kit according to Claim 14 wherein the tip (52) is generally square.
26. A method of implanting a suture anchor (10) within a bore in a bone, characterized by:
urging the suture anchor (10) into engagement with the bore using an insertion tool (50) angled with respect to the bore;
elastically deforming the insertion tool (50) externally to the suture anchor (10) to urge the suture anchor (10) into the bore;
rotating the suture anchor (10) within the bore;
removing the insertion tool (50) from the suture anchor (10); and
rotating the suture anchor (10) into a seated position within the bore.
27. A method according to Claim 26 further including the step of boring a circular bore in a bone with a boring bit (54) before the urging step.
28. A method according to Claim 26 wherein the urging step further comprises urging the suture anchor (10) into engagement with the bore such that a bore-abutting surface (14) of the suture anchor (10) is engaged with the wall of the bore.

29. A method according to Claim 28 wherein the deforming step further comprises deforming the insertion tool (50) externally to the suture anchor (10) such that the bore-abutting surface (14) of the suture anchor (10) remains engaged with the wall of the bore as the suture anchor (10) is inserted into the bore.

30. A method according to Claim 29 wherein the step of rotating the suture anchor (10) within the bore further comprises moving the insertion tool (50) to the diametrically opposite side of the bore to thereby rotate the suture anchor (10) about a leading gripping edge (16) thereof.

31. A method according to Claim 30 wherein the step of rotating the suture anchor (10) into a seated position within the bore further comprises exerting a tensile force on a suture (30) passing through a suture bore (28) in the suture anchor (10) to further rotate the suture anchor (10) about the leading gripping edge (16) and into a seated position within the bore.

32. An implantable knotless suture anchor (10) for wedging within a bore formed in a bone to secure a suture (330) to the bone, characterized by:

a body (12) having a generally quadrilaterally shaped lateral cross-section, said body comprising:

a bore-abutting surface (14) having opposed ends;

a leading gripping edge (16) at one end of the bore-abutting surface (14), the leading gripping edge (16) comprising an intersection of a leading surface (18) with the bore-abutting surface (14) at an acute angle;

a trailing gripping edge (24) at the end of the bore-abutting surface (14) opposite the leading gripping edge (16), the trailing gripping edge (24) comprising an intersection of a trailing surface (22) with the bore-abutting surface (14) at an acute angle; and

a closing surface (20) having an arcuate portion (20a) and a substantially linear portion (20b), the arcuate portion (20a) engaging the leading surface (18) and the substantially linear

portion (20b) engaging the trailing surface (22) so as to generally form a quadrilateral, the closing surface (20) being disposed generally opposite the bore-abutting surface (14) for facilitating the rotation of the body (12) about the leading gripping edge (16) within the bore;

said body further defining:

a suture bore (28) extending transversely therethrough adjacent the trailing gripping edge (24); and

an inserter bore (26) adapted to receive an insertion tool (50) and disposed between the leading gripping edge (16) and the suture bore (28);

a notch (60) in the bore-abutting surface (14); and

a suture (330) operably engaged with the suture bore (28), the suture (330) forming a loop and passing through the suture bore (28), the suture (330) further adapted to engage bodily tissue to be secured to the bone and then to wrap about the body (12) to engage the notch (60) before the suture anchor (10) is inserted into the bore in the bone.

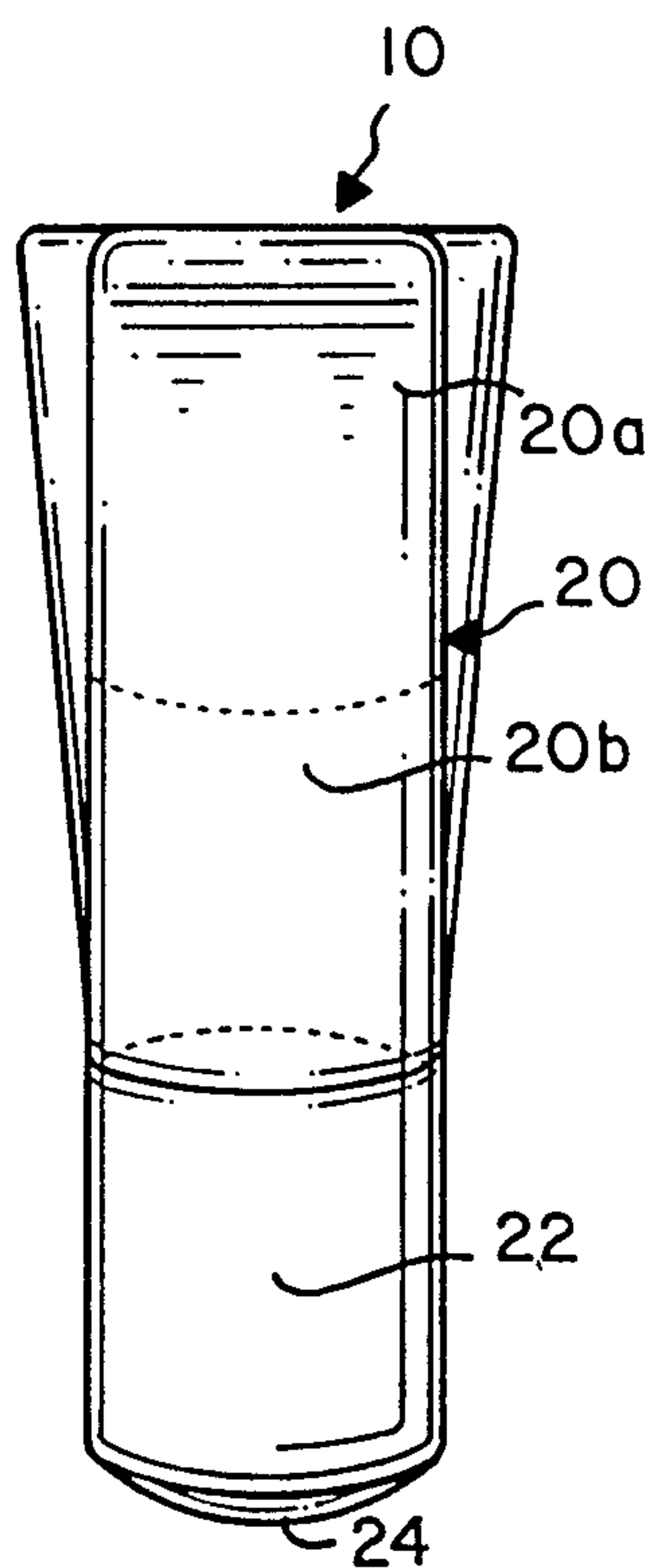
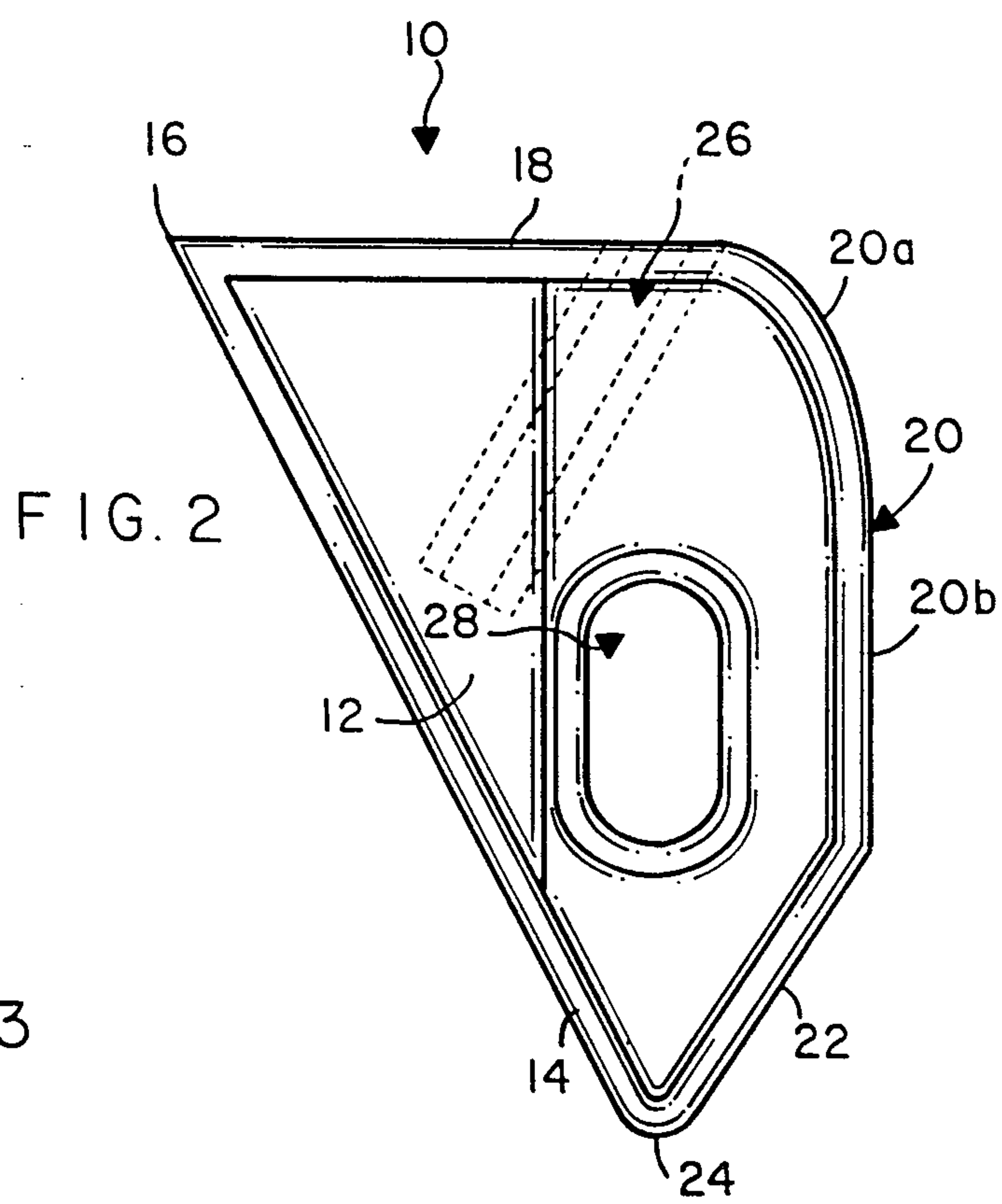
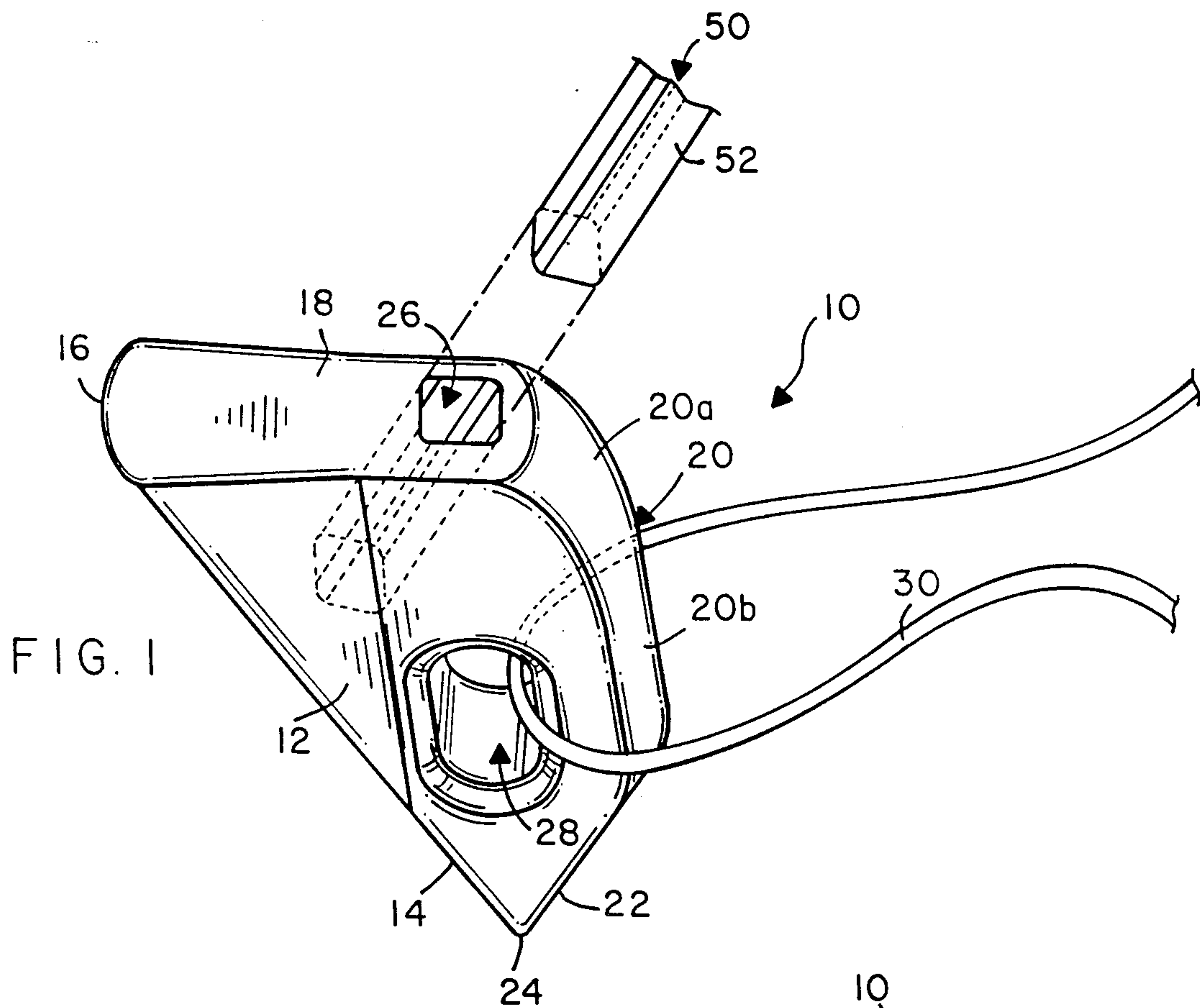
33. A knotless suture anchor according to Claim 32 wherein the inserter bore (26) extends through the leading surface (18) such that it is angularly disposed with respect to the bore-abutting surface (14).

34. A knotless suture anchor according to Claim 32 wherein the body (12) is comprised of polylactic acid.

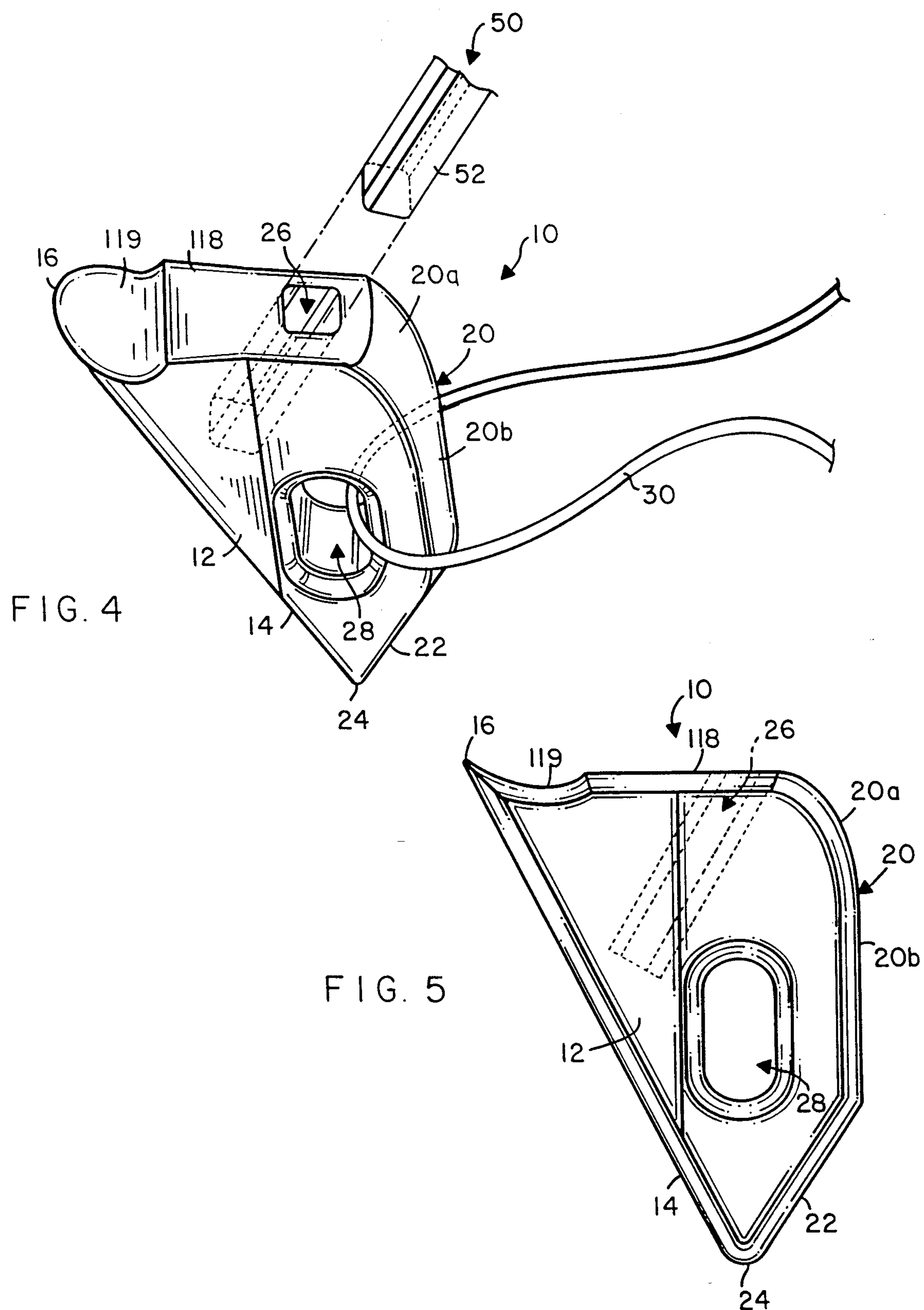
35. A knotless suture anchor according to Claim 32 wherein the inserter bore (26) is uniformly shaped along its length.

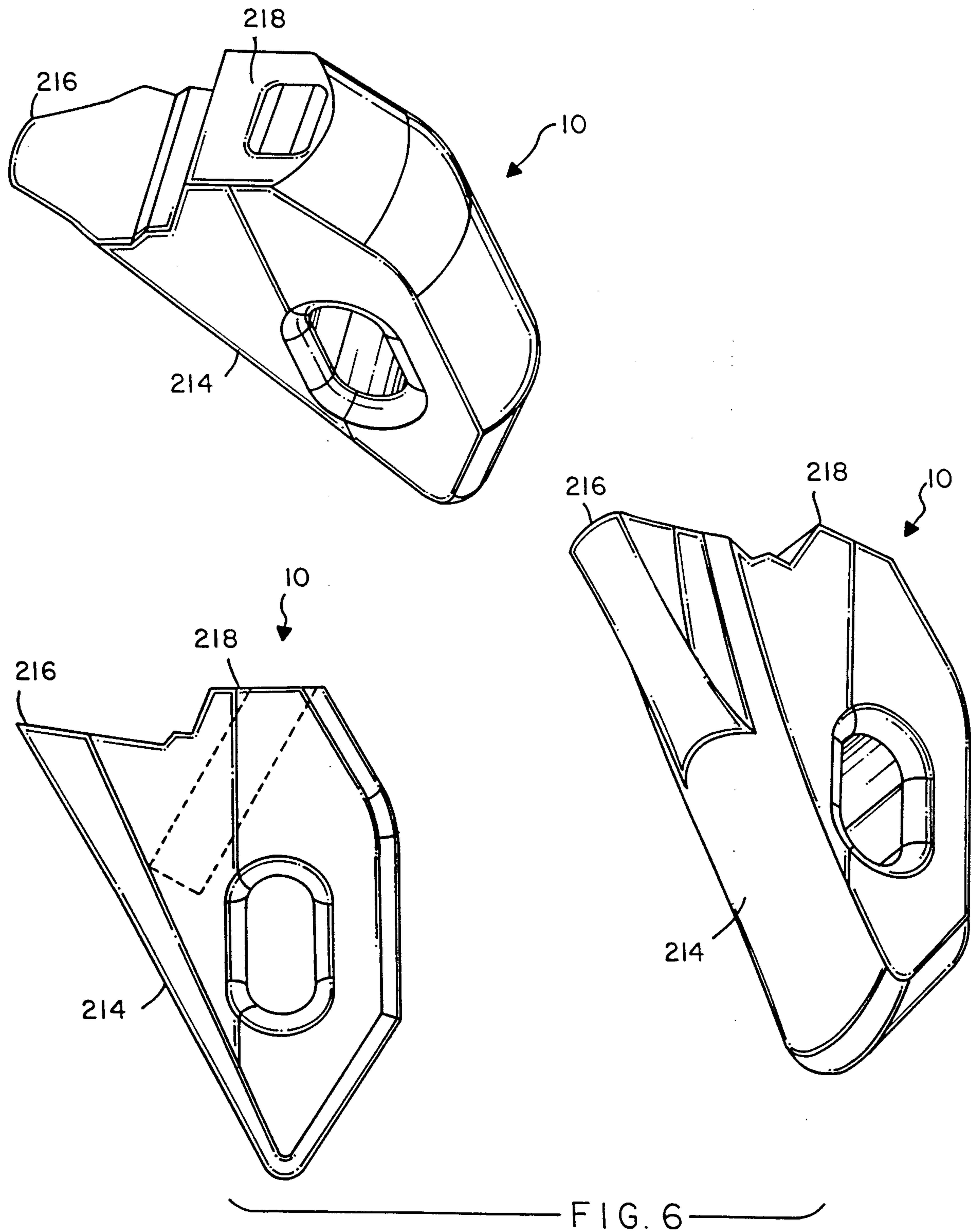
36. A knotless suture anchor according to Claim 35 wherein the inserter bore (26) is non-circular.

37. A knotless suture anchor according to Claim 36 wherein the inserter bore (26) is generally square.



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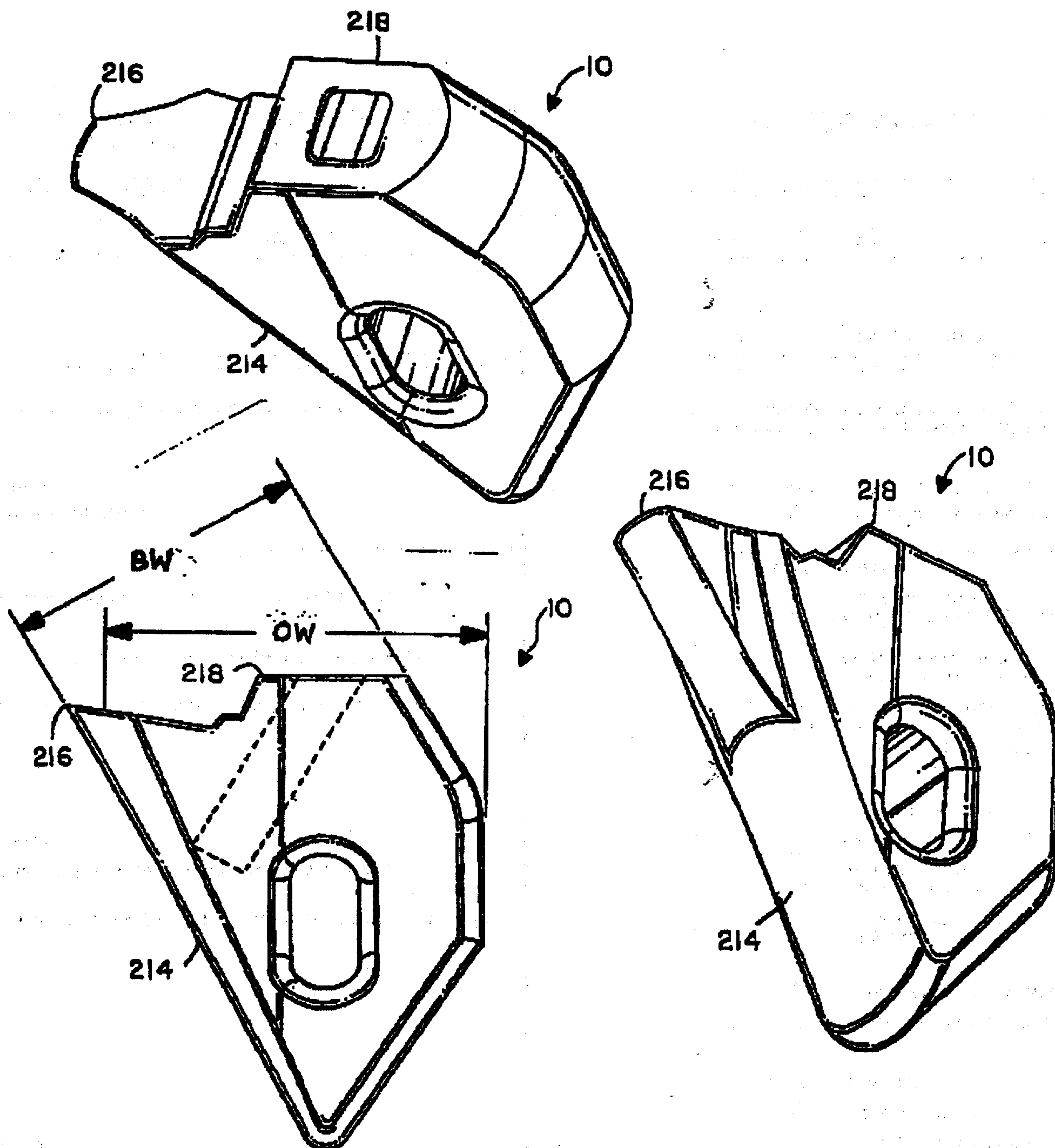


FIG. 6A

SUBSTITUTE SHEET

AMENDED SHEET

FIG. 7

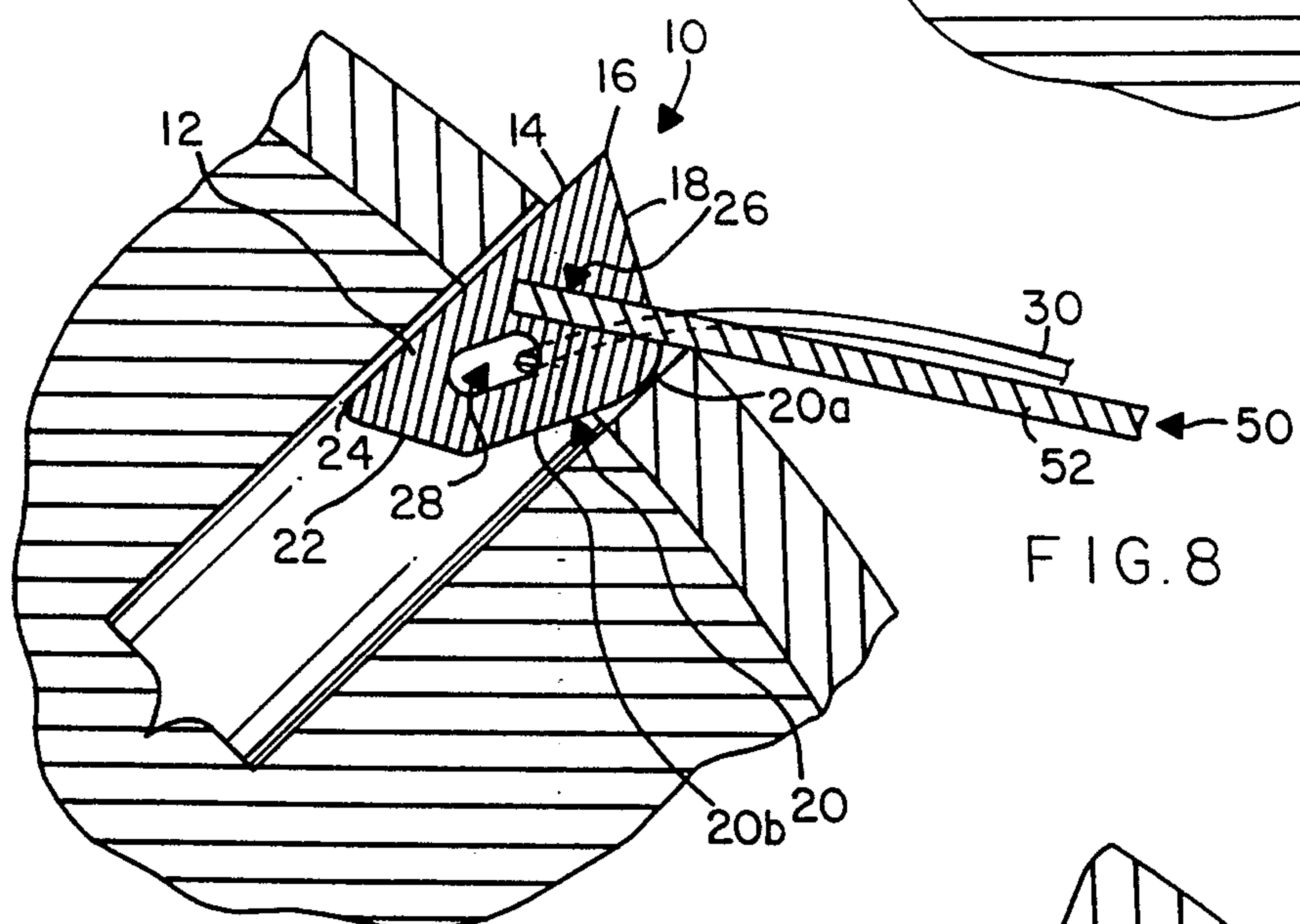
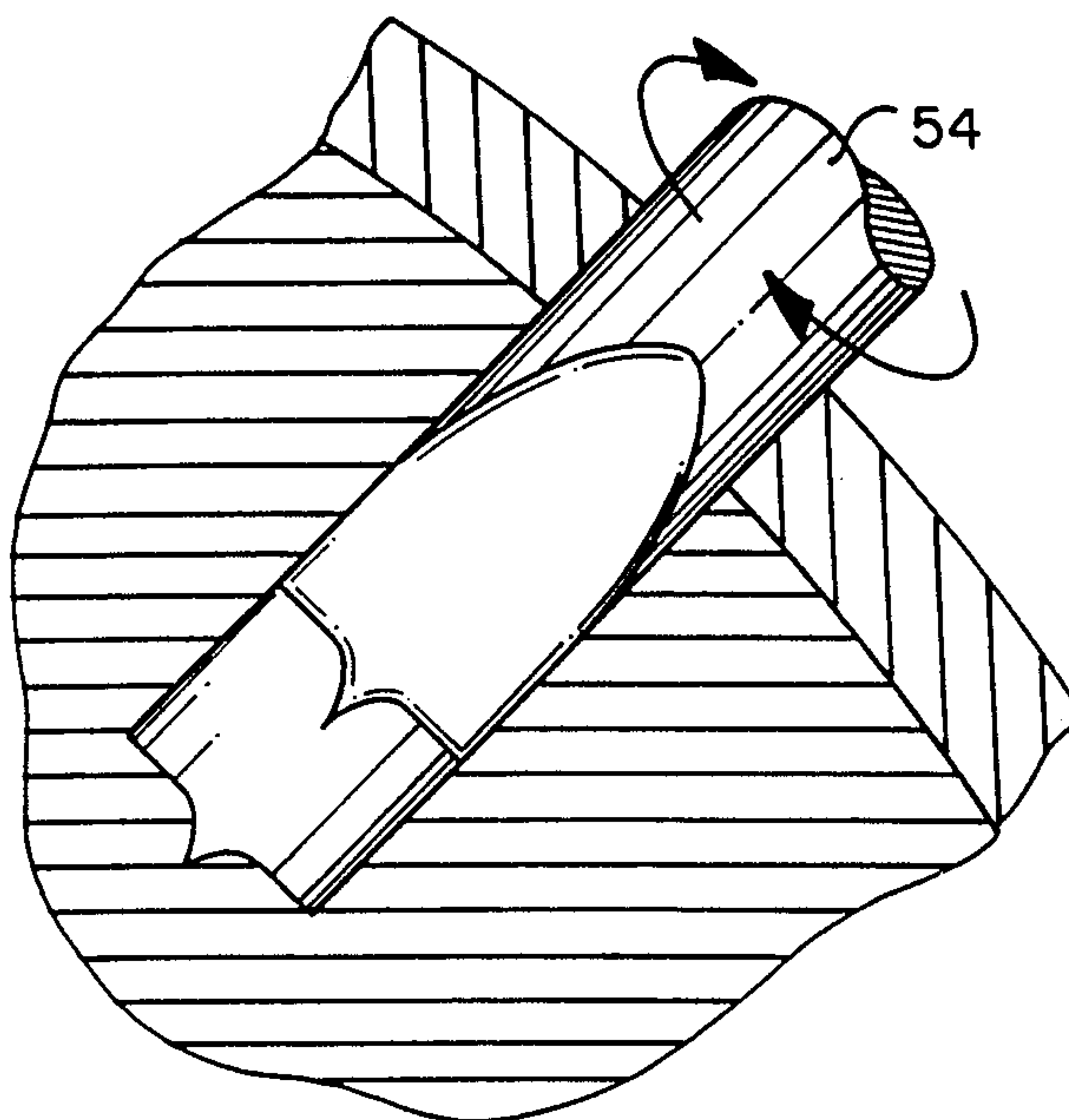


FIG. 8

FIG. 9

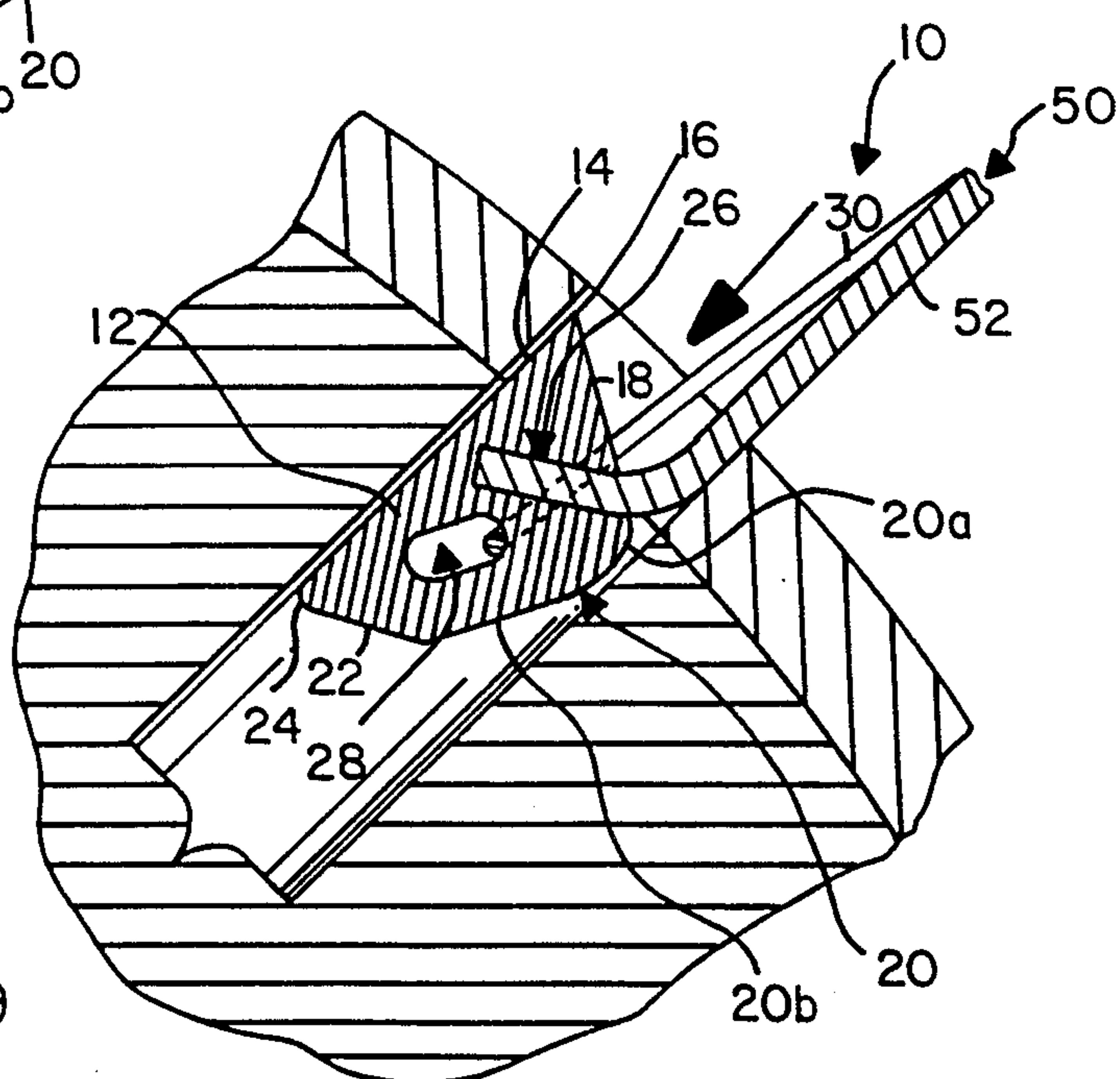


FIG. 10

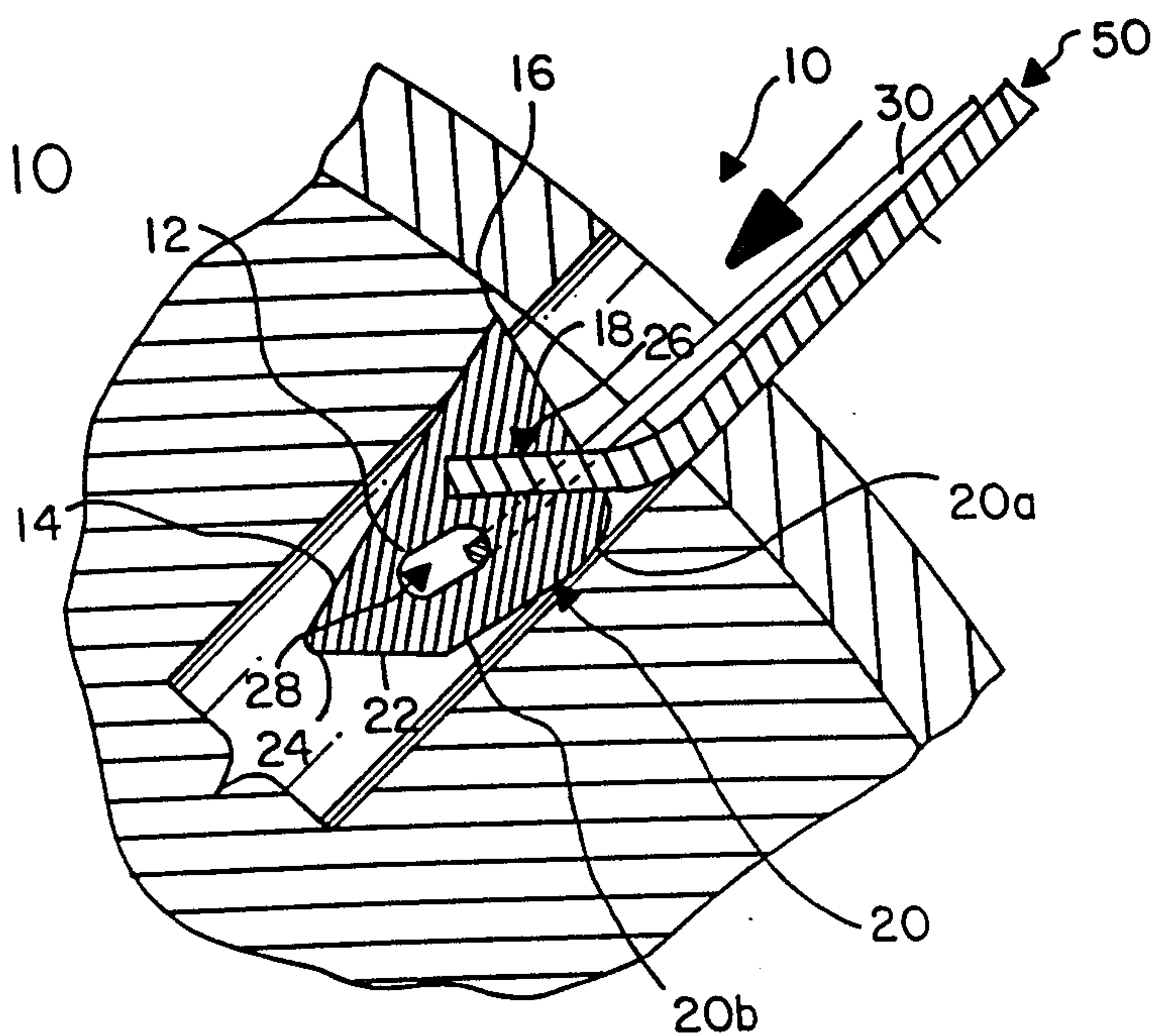


FIG. 11

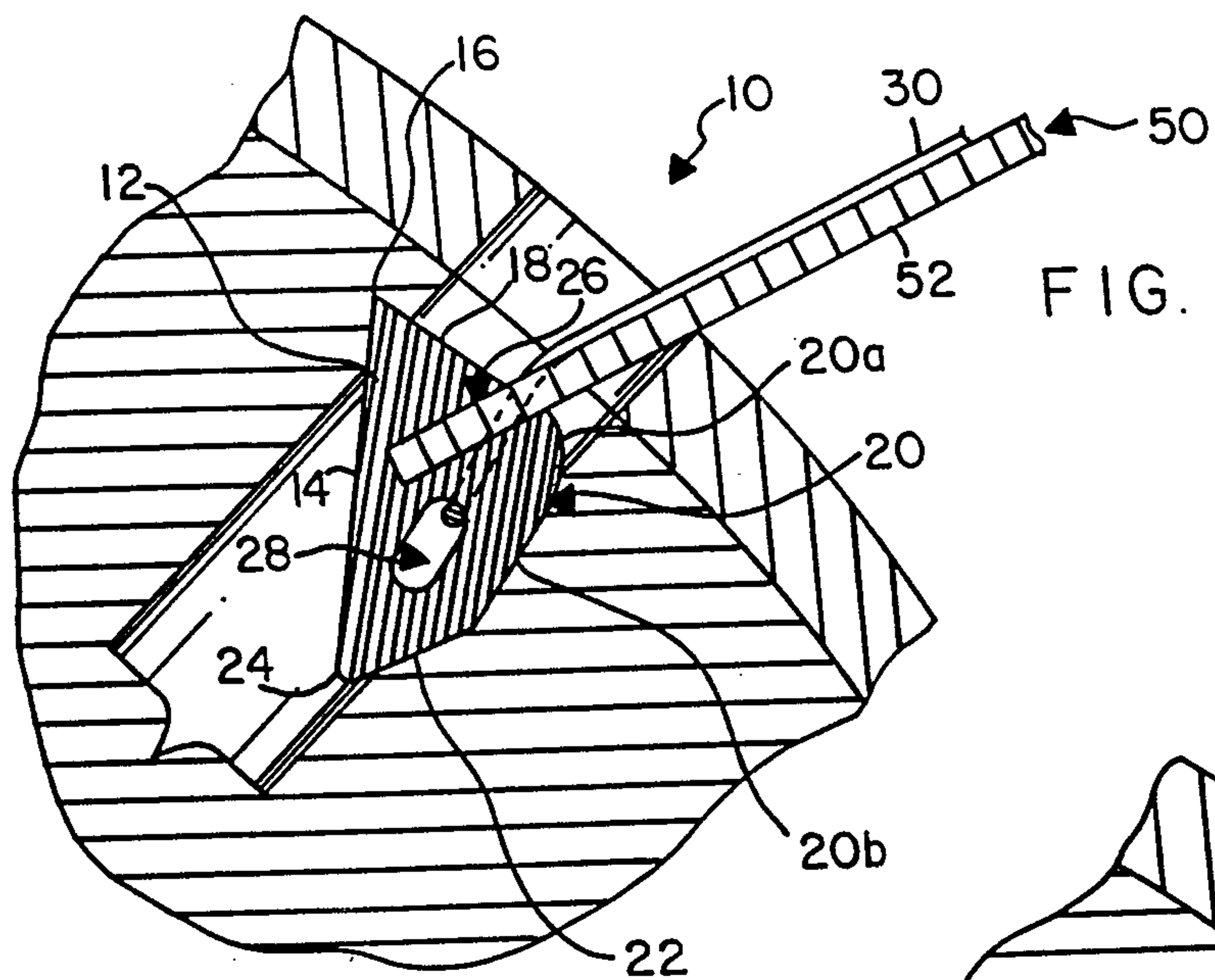
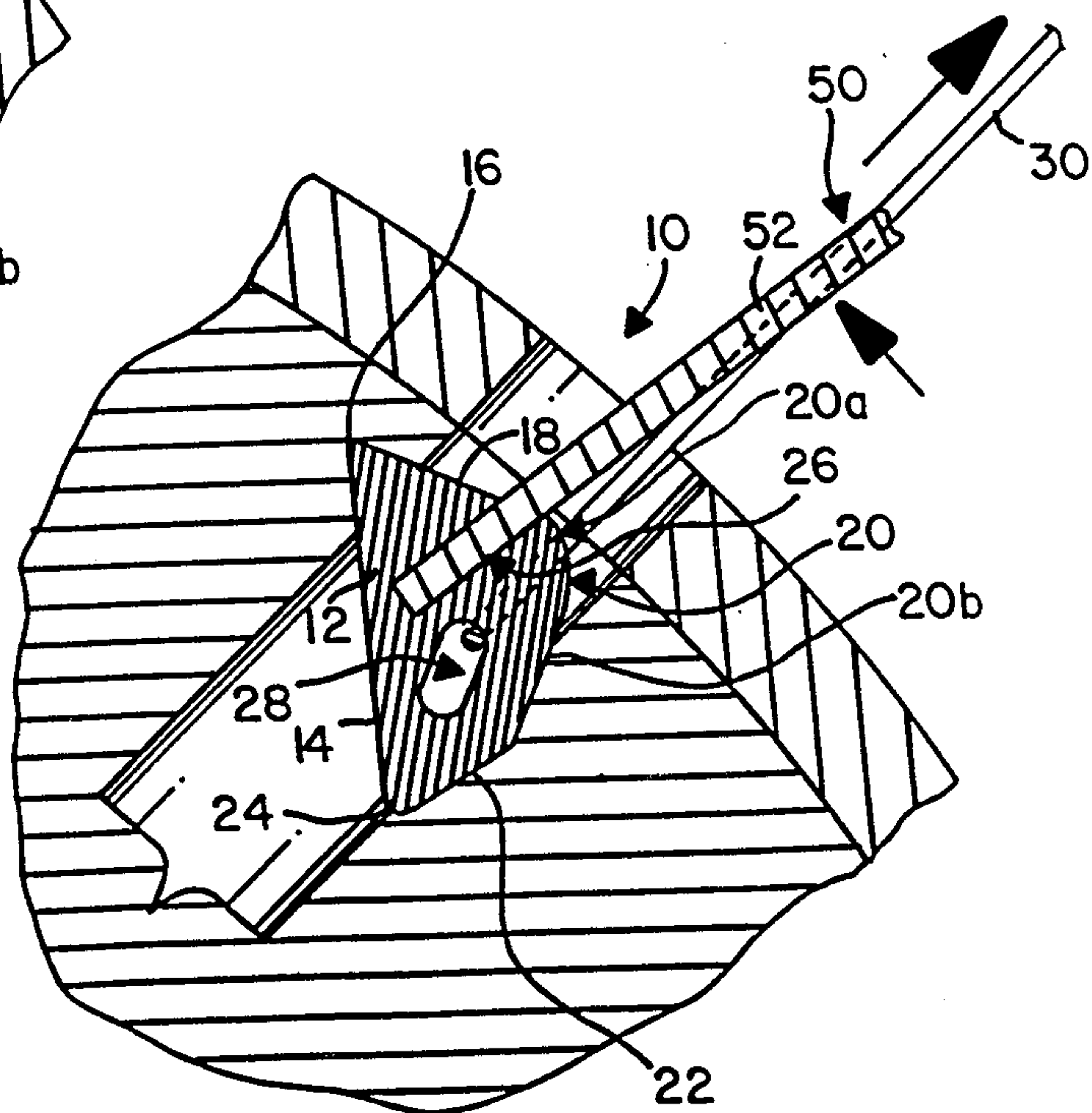
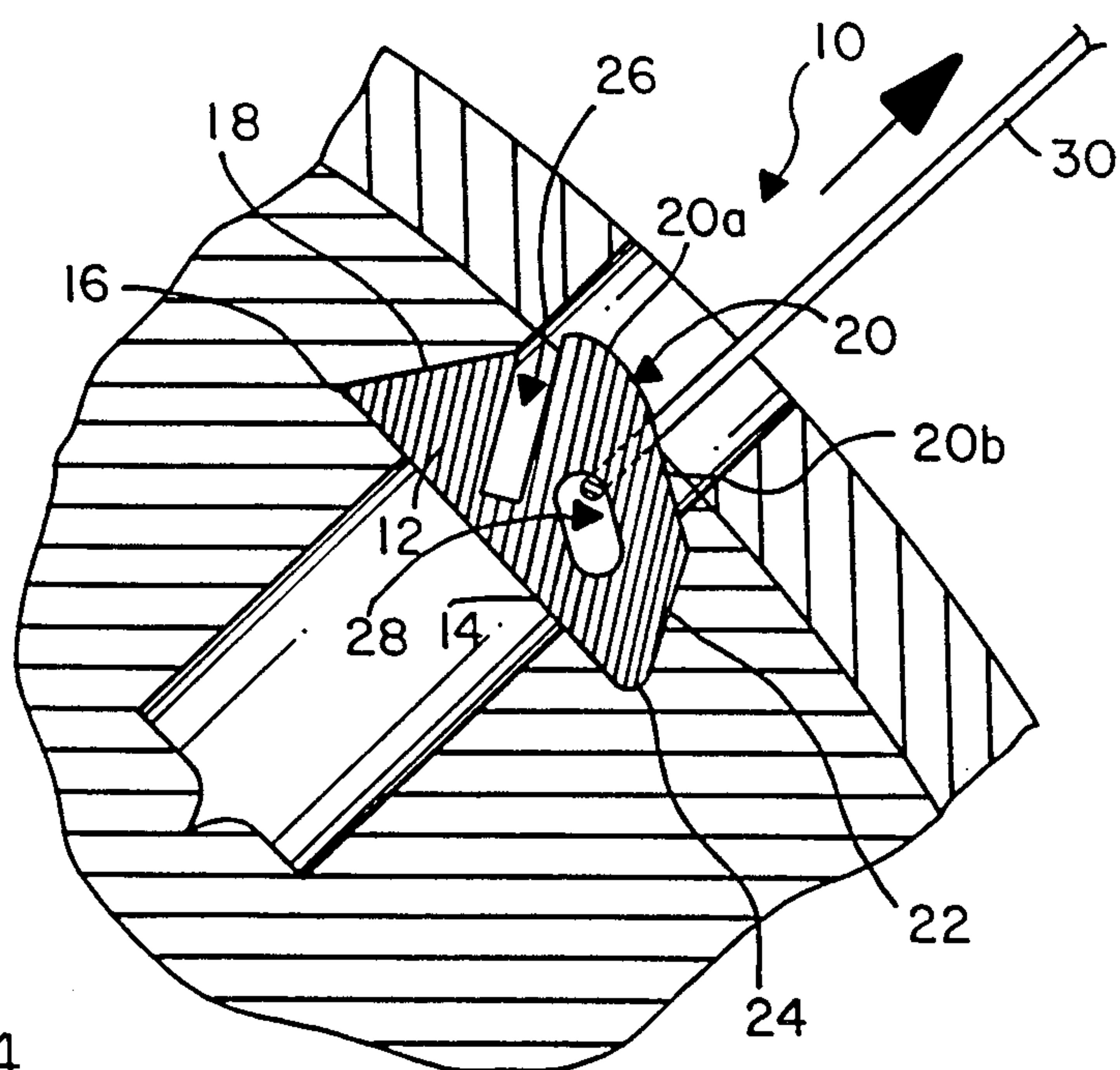
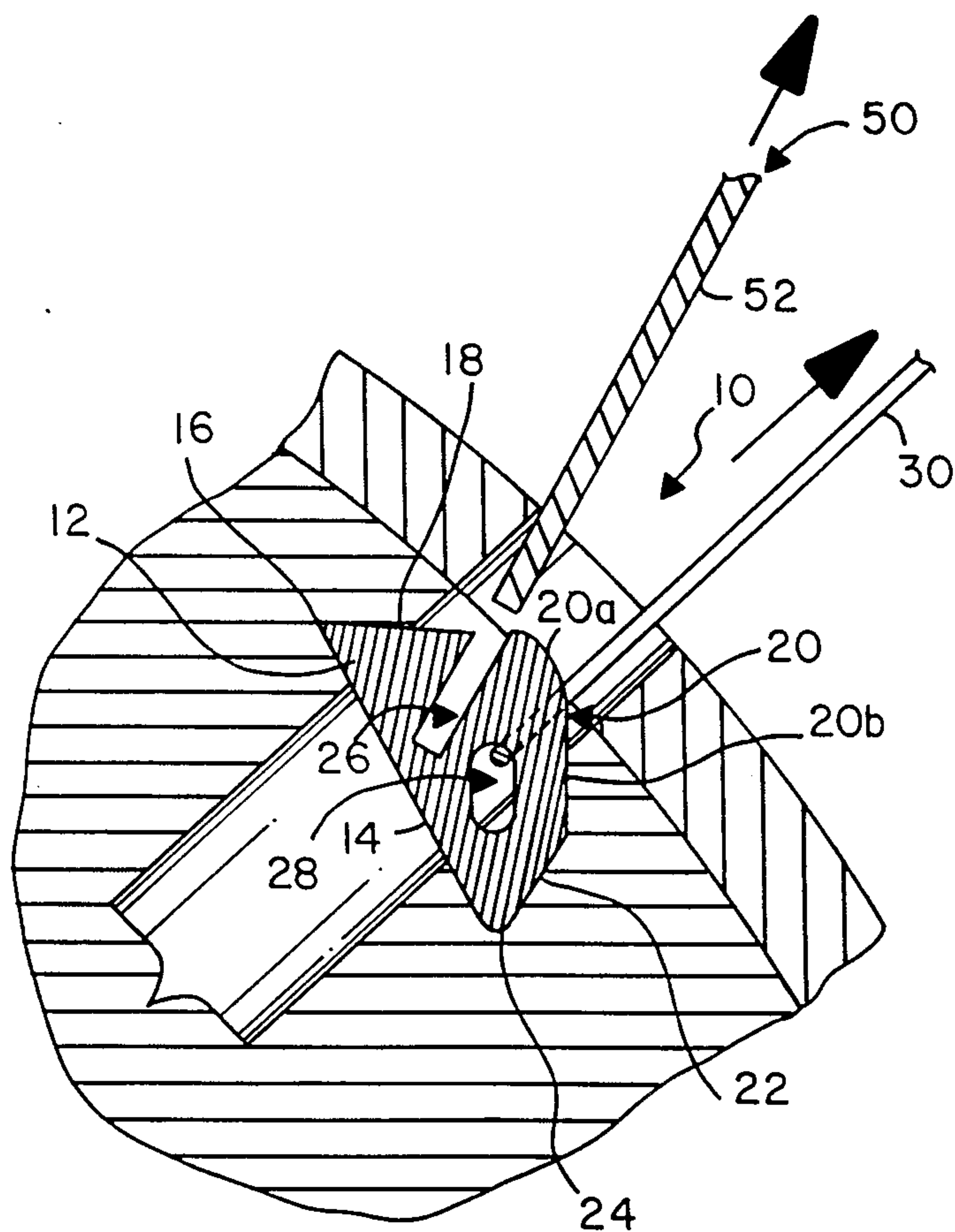


FIG. 12



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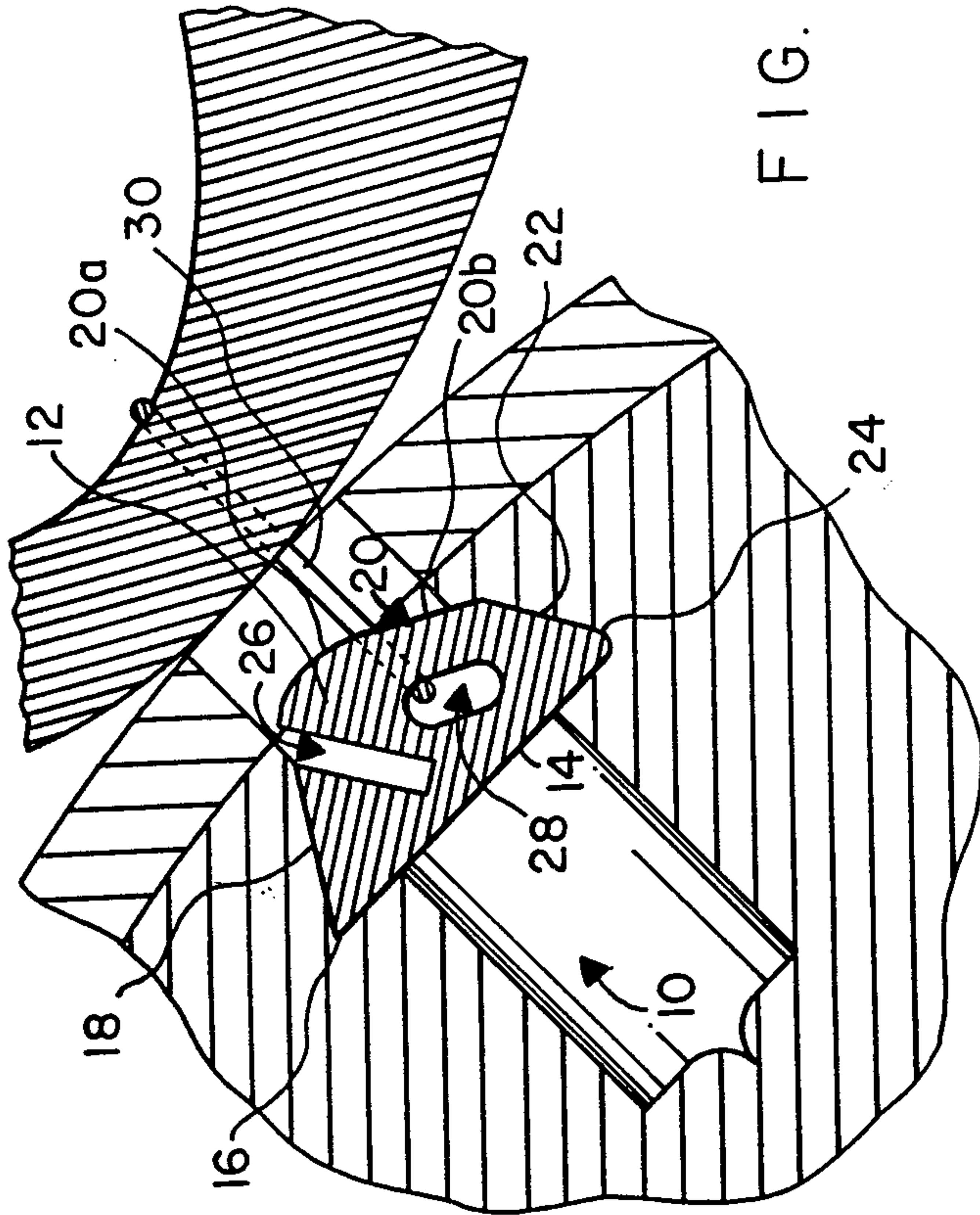


FIG. 15

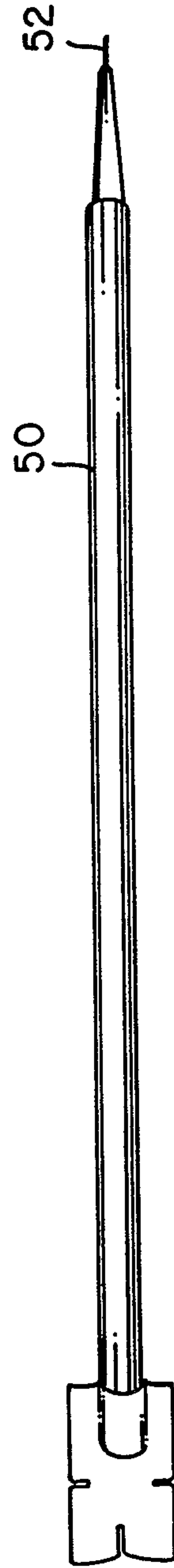


FIG. 16

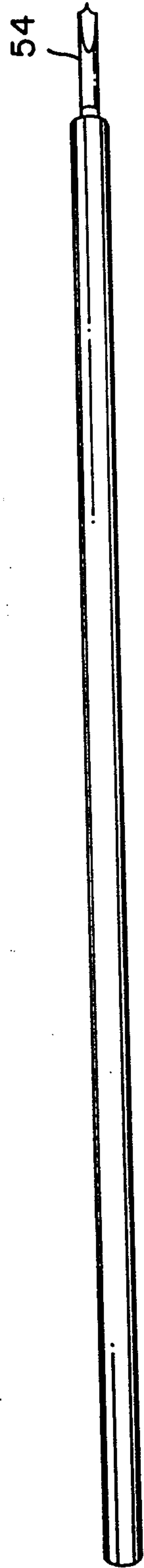


FIG. 17

