Office de la Propriété Intellectuelle du Canada
Un organisme d'Industrie Canada

Canadian Intellectual Property Office
An agency of Industry Canada

CA 2510095 C 2008/10/21

(11)(21) 2 510 095

(12) BREVET CANADIEN
CANADIAN PATENT

(13) C

(22) Date de dépôt/Filing Date: 1995/03/22

(41) Mise à la disp. pub./Open to Public Insp.: 1995/09/25

(45) Date de délivrance/Issue Date: 2008/10/21

(62) Demande originale/Original Application: 2 145 249

(30) Priorité/Priority: 1994/03/24 (US08/216,997)

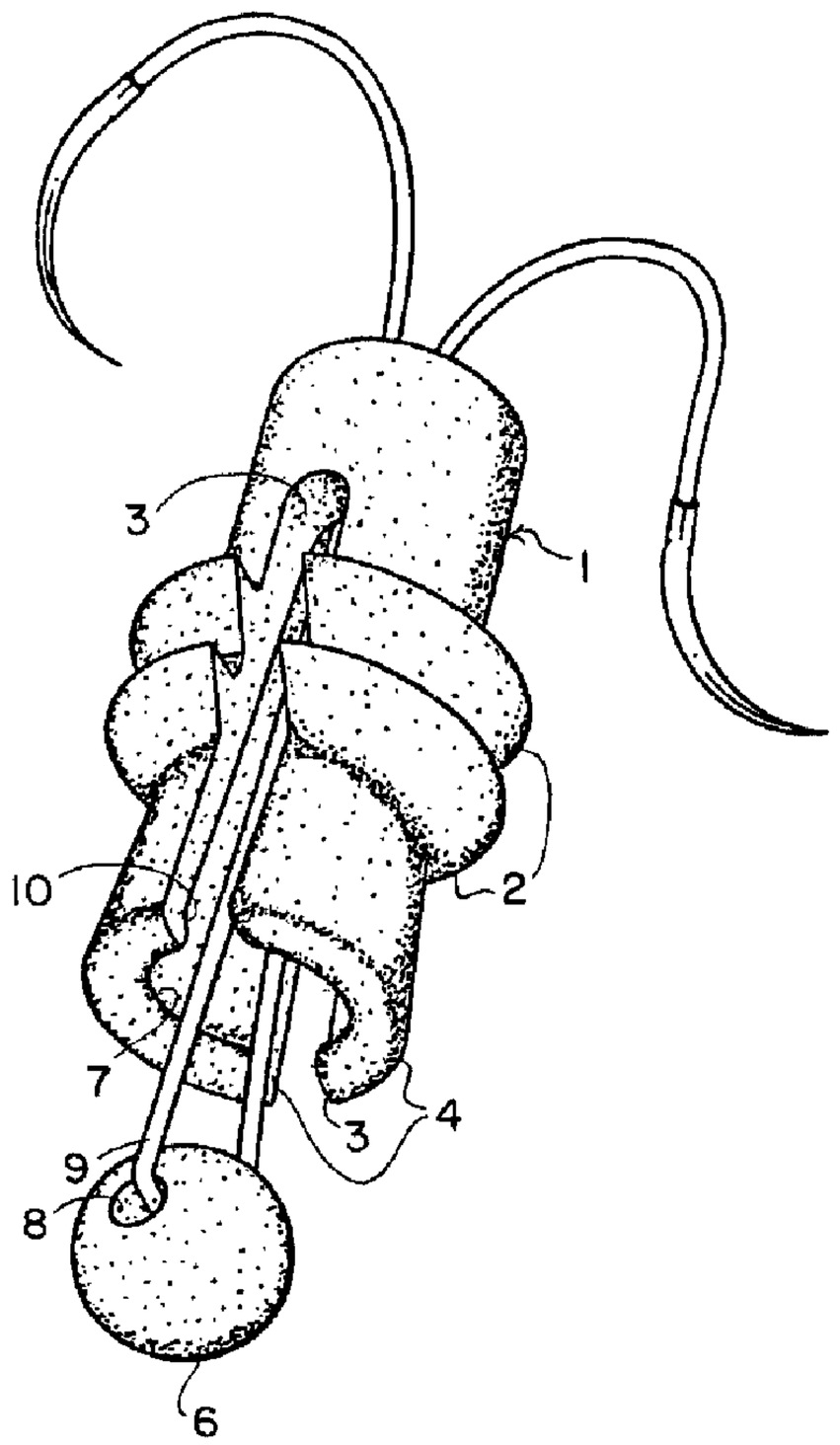
(51) Cl.Int./Int.Cl. *A61B 17/04* (2006.01)

(72) Inventeurs/Inventors:
LE, THU ANH, US;
BRUKER, IZI, US;
LUSCOMBE, BRIAN H., US;
JAMIOLKOWSKI, DENNIS D., US

(73) Propriétaire/Owner:
ETHICON, INC., US

(74) Agent: OGILVY RENAULT LLP/S.E.N.C.R.L.,S.R.L.

(54) Titre : DISPOSITIF D'INSERTION D'ANCRAGE DE SUTURE
(54) Title: INSERTER FOR SUTURE ANCHOR



(57) Abrégé/Abstract:
An inserter for inserting a suture anchor of the type having a stud extending from a head thereof comprising: an elongated section for receipt within a trocar; and a distal tip of said elongated section terminating in a tubular portion for receipt of said stud therein.

Abstract

An inserter for inserting a suture anchor of the type having a stud extending from a head thereof comprising: an elongated section for receipt within a trocar; and a distal tip of said elongated section terminating in a tubular portion for receipt of said stud therein.

INSERTER FOR SUTURE ANCHORS

RELATED APPLICATION

This application is a division of Canadian Patent Application No. 2,145,249 filed March 22, 1995.

TECHNICAL FIELD

The field of art to which this invention relates is surgical implements and more specifically inserters for suture anchors.

BACKGROUND ART

As the treatment of injuries to joints and soft tissue has progressed in the orthopaedic medical arts, there has been a need for medical devices which can be used to attach tendons, ligaments and other soft tissue to bone. When surgically repairing an injured joint, it is preferable to restore the joint by reattaching the damaged soft tissues rather than replacing them with an artificial material. Such restorations typically require the attachment of soft tissue such as ligaments and tendons to bone.

An increase in the incidence of injuries to joints involving soft tissue has been observed. This increased incidence may be due, at least in part, to an increase in participation by the public in various physical activities such as sports and other recreational activities. These types of activities may increase the loads and stress placed upon joints, sometimes resulting in joint injuries with corresponding damage to associated soft tissue. In 1991, for example, there were approximately 560,000 surgical procedures performed in the United States in which soft tissue was attached to a bone in various joints including the shoulder, hip and knee.

One conventional orthopaedic procedure for reattaching soft tissue to bone is performed by initially drilling holes or tunnels at predetermined locations through a bone

in the vicinity of a joint. Then, the surgeon approximates soft tissue to the surface of the bone using sutures threaded through these holes or tunnels. This method, although effective, is a time consuming procedure resulting in the generation of numerous bone tunnels. A known complication of drilling tunnels across bone is that nerves and other soft tissue structures may be injured by the drill bit or orthopaedic pin as it exits the far side of the bone. Also, it may be anatomically very difficult to reach and/or secure a suture/wire that has been passed through a tunnel. When securing the suture or wire on the far side of the bone, nerves and soft tissues can become entrapped and damaged.

In order to overcome some of the problems associated with the use of the conventional bone tunnel procedures, suture anchors have been developed and are frequently used to attach soft tissue to bone. A suture anchor is an orthopaedic, medical device which is typically implanted into a cavity drilled into a bone. Although less frequently, these devices have also been referred to as bone anchors. The cavity is typically referred to as a bore hole and usually does not extend through the bone. This type of bore hole is typically referred to as a "blind hole". The bore hole is typically drilled through the outer cortex layer of the bone and into the inner cancellous layer. The suture anchor may be engaged in the bore hole by a variety of mechanisms including friction fit, barbs which are forced into the cancellous layer of bone, etc. Suture anchors are known to have many advantages including reduced bone trauma, simplified application procedures, and decreased likelihood of suture failure due to abrasion on bone. Suture anchors may be used in the Bankart shoulder reconstruction for repairing

the glenohumeral ligament and may also be used in surgical procedures involving rotator cuff repair and hip replacement.

Suture anchors typically have at least one suture attached. This may be by means of a hole or opening for receiving a suture or sutures. At least one end of the suture extends out from the bore hole and is used to attach soft tissue. The suture anchors presently described in the art may be made of absorbable materials which absorb over time, or they may be made from various non-absorbable, biocompatible materials. Although most suture anchors described in the art are made from non-absorbable materials, the use of absorbable suture anchors may result in fewer complications since the suture anchor is absorbed and replaced by bone over time. In addition, the use of absorbable suture anchors may reduce the likelihood of damage to local joints caused by anchor migration.

Although suture anchors for attaching soft tissue to bone are available for use by the orthopaedic surgeon, there is a constant need in this art for novel suture anchors having improved performance characteristics. There is also a need for inserters for inserting such anchors.

SUMMARY OF THE INVENTION

Copending parent Application No. 2,145,249 filed March 22, 1995 discloses an apparatus for holding one end of a prosthetic element such as a suture, which apparatus comprises a head and an expandable body portion which depends from said head. A wedging means is provided for expanding the body portion by relative movement between the wedging means and expandable body. The expandable body may be comprised of at least two depending

legs and may further include barb means on the outer surface of the legs.

The wedging means may comprise a substantially spherical object which further defines a hole therethrough for receipt of a suture. The spherical object may ride within a passage defined by the depending legs of the body.

The internal passage defined by the depending legs may contain an internal constriction of smaller diameter than the remainder of the passageway to hold the sphere in a predetermined position once actuated or locked. Additionally, this constriction of smaller diameter may provide a tactile as well as an audible indication of the passage of the wedging means from one side of the constriction to the other, thus from an unlocked to a locked position. Preferably the passage contains a constriction which holds the wedging means in a prefired or pre-engaged position prior to spreading the legs. The suture of the suture anchor may pass along side the outside of the head or through an internal opening within the head of the body of the suture anchor. The internal surface of the legs of the suture anchor may further be shaped to partially conform to the shape of the spherical wedge when the sphere is in the seated position above the constriction described. The head may further include a stud extending therefrom for a gripping apparatus to position the suture anchor within an opening.

The present invention provides an inserter for inserting a suture anchor within an opening. The inserter cooperates with a stud extending from the suture anchor and includes an elongated section for receipt within a trocar. A distal tip of the elongated section terminates

in a tubular portion which receives the stud therein. The suture is received by the suture anchor and run along side the inserter in order to hold the suture anchor in the inserter during the insertion process. Alternatively, the tubular portion may be of a diameter to provide a frictional fit with the stud. It may be preferred to have the inserter provided with an outside diameter at its head of the suture anchor to provide a smooth transition between the two objects. Slots may be defined in the outer surface of the inserter in order to receive and protect the suture ends while the insertion process is taking place. The inserter may include an attachment mechanism for receiving and attaching at least one end of the suture to hold the suture anchor on the end of the inserter during the insertion process.

An alternative arrangement provides an inserter which is cannular in nature that allows the suture material to ride within the body of the inserter, thereby protecting it from potential damage during the placement of the suture anchor and/or during the actuation of the locking means.

In one aspect, there is provided an inserter for inserting a suture anchor of the type having a head, an expandable body extending distally from the head and comprising at least two legs, and a wedging means for expanding the body by proximal relative movement of the wedging means within the body, and having a stud extending from the head, the inserter comprising: an elongated section for receipt within a trocar; and a

distal tip of said elongated section terminating in a tubular portion for receipt of said stud therein.

In another aspect, there is provided an inserter, in combination with and for inserting a suture anchor of the type having a head, an expandable body extending distally from the head and comprising at least two legs, and a wedging means for expanding the body by proximal relative movement of the wedging means within the body, and having a stud extending from the head, the inserter comprising: an elongated section for receipt within a trocar; and a distal tip of said elongated section terminating in a tubular portion for receipt of said stud therein.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described with reference to the accompanying drawings wherein:

FIG. 1 is a perspective view of an embodiment of the suture anchor of the present invention in which the actuating ball has not been assembled with the anchor body;

FIG. 2 is an enlarged perspective view of the suture anchor of FIG. 1 after assembly and prior to insertion into the bore hole of the bone;

FIG. 3 is a top plan view of the body of the suture anchor of FIG. 1;

FIG. 4 is a front elevational view of the body of the suture anchor of FIG. 1;

FIG. 5 is a bottom plan view of the body of the suture anchor of FIG. 1;

FIG. 6 is a cross-sectional view taken along line 6-6 of FIG. 3;

FIG. 7 is a plan view of the actuating ball of the suture anchor of FIG. 1;

FIG. 8 is a cross-sectional view along lines 8-8 of FIG. 7;

FIG. 9 is a cross-sectional view showing implantation of the suture anchor of FIG. 1 inserted into the bore hole of the bone prior to actuation;

FIG. 10 is a cross-sectional view of the anchor and bone after actuation of the suture anchor of FIG. 1;

FIG. 11 is a perspective view of an alternate embodiment of the suture anchor;

FIG. 12 is a top plan view of the body of the suture anchor of FIG. 11;

FIG. 13 is a front elevational view of the body of the suture anchor of FIG. 11;

FIG. 14 is a view along lines 14-14 of FIG. 12;

FIG. 15 is a cross-sectional view along lines 15-15 of FIG. 12;

FIG. 16 is a elevational view of the actuating ball of the anchor of FIG. 11;

FIG. 17 is a cross-sectional view along lines 17-17 of FIG. 16;

FIG. 18 is a cross-sectional view of the bone with suture anchor inserted prior to actuation;

FIG. 19 shows the suture anchor of FIG. 11 after actuation;

FIG. 20 is a perspective view of an alternative embodiment of the suture anchor of the present invention;

FIG. 21 is a top plan view of the body of the suture anchor of FIG. 20;

FIG. 22 is a front elevational view of the body of the suture anchor of FIG. 20;

FIG. 23 is a cross-sectional view along lines 23-23 of FIG. 21;

FIG. 24 is a front elevational view of the actuating ball of the suture anchor of FIG. 20;

FIG. 25 is a cross-sectional view along lines 25-25 of FIG. 24;

FIG. 26 is a cross-sectional view of a bone having the suture anchor inserted into a bore hole prior to actuation;

FIG. 27 is a view of the suture anchor of FIG. 26 after actuation;

FIG. 28 is a top plan view of an alternate embodiment of the suture anchor of the present invention;

FIG. 29 is a front elevational view of the suture anchor of FIG. 28;

FIG. 30 is a cross-sectional view taken along lines 30-30 of FIG. 28;

FIG. 31 is a perspective view of the suture anchor of FIGS. 28-30;

FIG. 32 is a top plan view of the most preferred suture anchor of the present invention;

FIG. 33 is a front elevational view of the suture anchor of FIG. 32;

FIG. 34 is a cross-sectional view of the suture anchor of FIG 32 taken along lines 34-34 of FIG. 32;

FIG. 35 is a perspective view of the suture anchor of FIGS. 32-34;

FIG. 36 is a side view of an implantation instrument for the suture anchor of FIG. 35; and

FIG. 37 is a view of the tip of the instrument of FIG. 36.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to FIG. 1 a first embodiment of the suture anchor of the present invention is shown. The anchor has an anchor body 1 which is longitudinally extending and has radially extending fins 2. A pair of diametrically opposed slots are defined by the anchor body and extend longitudinally from one end of the anchor body to a position spaced from the second end of the anchor body. These slots 3 create a pair of legs 4 in opposed positions extending along the anchor body. A ball 6 is received within a passage 7 defined by the legs 4 of the anchor. A suture opening 8 is defined through the ball 6 to receive therein a suture 9. The ball is received within passage 7 and held in place via a radially inward extending rim 10 which causes a constriction of the opening of passage 7. The opening of passage 7 is somewhat narrower than the diameter of the ball 6 such that the ball is held within the suture anchor in the initial condition. The passage 7 extends completely through the body of the anchor as shown in FIG. 6. The suture 9 is threaded through the suture opening 8 of the ball and then both ends of the suture are in turn threaded up through the longitudinal passage 7 and out the top of the anchor through opening 7a defined in the top of the anchor.

As can be seen in FIG. 6 the longitudinal passage 7 tapers towards its top end. Thus, as seen in FIG. 9 the suture anchor may be placed in an appropriate bore hole prepared

in a bone site. The ball is initially held in place by the rim 10 but upon implantation within the opening of the bone, the ball is pulled upward toward the head 5 of the anchor and cooperates with the tapered inner passage to force legs 4 outward. At this point the legs and fins 2 dig into the softer cancellous layer of the bone thus fixing the anchor in place.

An alternate embodiment is shown in FIG. 11. This embodiment is substantially similar to the embodiment previously described, however, it is provided with three fins instead of the two spaced radially extending fins previously described as well as having four slots 3 defined along the longitudinal portion of the anchor such that four separate legs 4 are defined thereby. Again, the central passage is tapered slightly, however, the fins extend to a position further down longitudinally along the legs 4 such that additional gripping force is provided. In this manner as seen in FIG. 18 the device may be inserted into a shallower hole whereby the movement of the ball upward causes the lower fins to dig into the soft cancellous layer of the bone.

A further alternate embodiment is shown in FIG. 20. This embodiment has an anchor body 1 with fins 2 defined thereon similar to the first embodiment. A pair of slots 3 are defined along the anchor body and in turn define a pair of legs 4 extending longitudinally along the anchor body. A cap 11 which may be solid in construction is formed at one end. A ball 6 is received within a passage 7 and defines therethrough a suture opening 8. A suture 9 is received within the suture opening 8 with the ends of the suture extending through the slots and along the

outside of the anchor 11. This distinguishes this anchor from the anchors previously described.

The fins 2 have a top surface 12 and a tapering bottom surface 13. The top surface 12 and the bottom surface 13 meet to form an edge 14 which will bite into the soft cancellous bone of the anchor site.

As is seen in Figs. 26 and 27, an appropriate bore hole is bored through the hard outer cortex of the bone into the soft cancellous layer beneath. The suture anchor is inserted into the opening with the ends of the suture extending through the passage in the ball along the slots and adjacent the cap of the suture. Once inserted within the bore opening, force is applied to the ends of the suture in order to draw the ball upward into the suture anchor. As is seen best in Fig. 23, a small compartment 15 is provided for seating the ball prior to actuation of the device. Upon actuation of the device, the ball is drawn upward along cam surface 16 which initiates the spreading of the legs into narrow passage 17 where the ball rests after implantation of the device.

The preferred device of the invention is shown in Figs. 28-35. This embodiment includes an anchor body 20 which has a pair of depending legs 21 extending downward from the body. The legs 21 define a pair of slots 22 which permit expansion of the legs as will be described below. The legs in part define an inner passage 23 for receipt of an actuation ball as will be described below.

The distal opening of the inner passage 23 has a radially-extending rim 24 which adapts to hold the ball in the holding portion 25 as shown by phantom lines in Fig. 30.

A camming constriction 26 extends radially inward into the inner passage 23. This camming constriction and the remainder of the passage define a seating portion 27.

As may be seen by Fig. 30, the slots 22 extend beyond the seating portion 27. This permits passage of the suture out of the inner passage through the slots and also increases the range of motion of the legs without cracking of the legs.

The embodiment shown in Figs. 32-35 is similar in its definition of its inner passage and camming constriction and slot, however it contains additional fins 28 which help to center the anchor within the bore hole of the bone. The bottom fin 34 actually provides a thickened portion in order to maintain the wall integrity in the area where the ball is initially seated. The ball 30 is received within this seating portion adjacent the bottom fin 34. The ball defines a suture passage 31 which receives a suture 32. The openings of the suture passage 31 are rounded slightly in order to reduce abrasion of the suture.

A stud 33 extends from the anchor body 20 in a longitudinal direction. This assists in the implantation of the device as will be described in connection with the apparatus of Figs. 36 and 37.

The anchors of the present invention may be made from either conventional bioabsorbable materials or conventional non-absorbable materials, combinations thereof and equivalents thereof. Examples of absorbable materials include homopolymers and copolymers of lactide, glycolide, trimethylene carbonate, caprolactone, and p-

dioxanone and blends or other combinations thereof and equivalent thereof. Of particular utility are the polylactides, especially poly[L(-)lactide], and the lactide-rich lactide/glycolide copolymers, especially 95/5 poly[L(-)lactide-co-glycolide].

Examples of non-absorbable materials from which the suture anchors of the present invention may be made include metallic biocompatible materials including stainless steel, Nitinol, titanium, Vitalium and equivalents thereof, polymeric materials such as non-absorbable polyesters, polyamides, polyolefins, polyurethanes, and polyacetals and equivalents thereof, when metallic substances are used, then softer metals are preferred.

The suture anchor devices of the present invention, when made from an absorbable material, are preferably manufactured by molding using conventional injection molding equipment and conventional injection molding processes. A typical molding process includes the steps of (1) injecting a suitable polymer melt into an appropriately designed mold or cavity at process conditions conventionally employed for such polymer systems, (2) releasing from the mold, after the melt cools in the mold, polymer shaped in the proper configuration to meet the design criteria of the device. Additionally the anchor molded from the absorbable polymeric material, may be advantageously subjected to an annealing process to increase its mechanical or biological performance. Thermal annealing can also be used to increase the dimensional stability of molded parts by increasing the crystallinity levels in the parts. One or more surgical sutures, or one or more sutures with surgical needles attached, may be used in combination with the suture

anchor and may be assembled prior to sterilization. The device can then be sterilized using conventional methods to render the anchor suitable for surgical applications.

The bonding of the anchors of the present invention to bone may be advantageously increased by promoting bone growth. This can be accomplished by having a microporous surface into which the bone can rapidly grow to aid fixation. This may be particularly advantageous in the case of a metallic anchor, especially a titanium or titanium alloy anchor, but may also provide benefit in the case of polymeric anchors of the present invention, especially those made of absorbable materials. Other methods include the coating of the anchor's surface with a substance to promote adhesion to the bone. Such coatings include the hydroxyapatite-containing-glass coatings described by Ishikawa, et al., in the article "Effect of Hydroxyapatite Containing Glass Coating on the Bonding between Bone and Titanium Implants" appearing in Clinical Materials, Volume 14, 1993, pages 277-285.

It is further noted that the anchors of the present invention can be made to contain growth factors, especially bone growth factors, that can advantageously increase the effectiveness of the anchors, especially in the area of fixation. This may be accomplished in a number of ways, including via coatings or, in the case of absorbable materials by incorporating the growth factors within the device and allowing them to diffuse out.

The implantation instrument for the preferred device is shown in Fig. 36. The device has a handle 35 which has extending therefrom a shaft 36. The shaft 36 terminates in a narrower holding portion 37 which is adapted to

receive the stud 33 of the suture anchor within a cylindrical seat 38 defined in the tip of the holding portion. A pair of diametrically opposed relief slots 39 are provided for the passage of the suture from the anchor along the shaft. That is, the suture is received within the suture passage defined in the ball and extends outward from the anchor and along the shaft of the apparatus. The suture, as it extends along the shaft of the apparatus, is received within the relief slots 39 and extends upward to the cleats 40 which extend from either side of the handle 35. Thus, in use, the stud of the suture anchor is received within the cylindrical seat 38. An appropriate suture extends through the suture passage of the ball and is laid along the relief slots 39 and attached to the cleats 40 thus holding the anchor in place. In an open procedure or an arthroscopic procedure, the anchor is inserted into a previously bored hole in the bone of the recipient. Once in place in the bored hole the suture is detached from the cleats and upward force is applied to the suture while keeping the anchor in place drawing the ball into the seating portion of the anchor. The action of drawing the ball into the seating portion forces the legs outward as the ball passes the camming constriction and causes the legs and fins to dig into the softer cancellous bone. Thus the suture anchor is implanted within the bore and prepared for attachment of soft tissue to the bone.

The invention has been described with reference to its preferred embodiments, however, it is understood that changes may be made to the invention without departing from the spirit of the disclosure provided herein.

Claims:

1. An inserter for inserting a suture anchor of the type having a head, an expandable body extending distally from the head and comprising at least two legs, and a wedging means for expanding the body by proximal relative movement of the wedging means within the body, and having a stud extending from the head, the inserter comprising:

an elongated section for receipt within a trocar; and

a distal tip of said elongated section terminating in a tubular portion for receipt of said stud therein.

2. The inserter according to claim 1 wherein said tubular portion is of a diameter to provide a frictional fit with said stud.

3. The inserter according to claim 1 wherein said elongated section has an outside diameter substantially the same as the head of the suture anchor.

4. The inserter according to claim 2 wherein the elongated portion has a second outside diameter spaced from the distal tip of said elongated section, said second outside diameter being larger than the outside diameter at said distal tip, and said portion having said second outside diameter further defining longitudinally extending troughs for receipt of a suture extending from said suture anchor during implantation.

5. The inserter according to claim 4 further including means for attaching at least one end of said suture to a handle of said apparatus during the insertion procedure.

6. The inserter according to claim 5 including means for attaching two ends of said suture to said handle during said insertion procedure.

7. An inserter, in combination with and for inserting a suture anchor of the type having a head, an expandable body extending distally from the head and comprising at least two legs, and a wedging means for expanding the body by proximal relative movement of the wedging means within the body, and having a stud extending from the head, the inserter comprising:

an elongated section for receipt within a trocar; and

a distal tip of said elongated section terminating in a tubular portion for receipt of said stud therein.

8. The inserter according to claim 7 wherein said tubular portion is of a diameter to provide a frictional fit with said stud.

9. The inserter according to claim 7 wherein said elongated section has an outside diameter substantially the same as the head of the suture anchor.

10. The inserter according to claim 8 wherein the elongated portion has a second outside diameter spaced from the distal tip of said elongated section, said second outside diameter being larger than the outside diameter at said distal tip, and said portion having said second outside diameter further defining longitudinally extending troughs for receipt of a suture extending from said suture anchor during implantation.

11. The inserter according to claim 10 further including means for attaching at least one end of said suture to a handle of said apparatus during the insertion procedure.

12. The inserter according to claim 11 including means for attaching two ends of said suture to said handle during said insertion procedure.

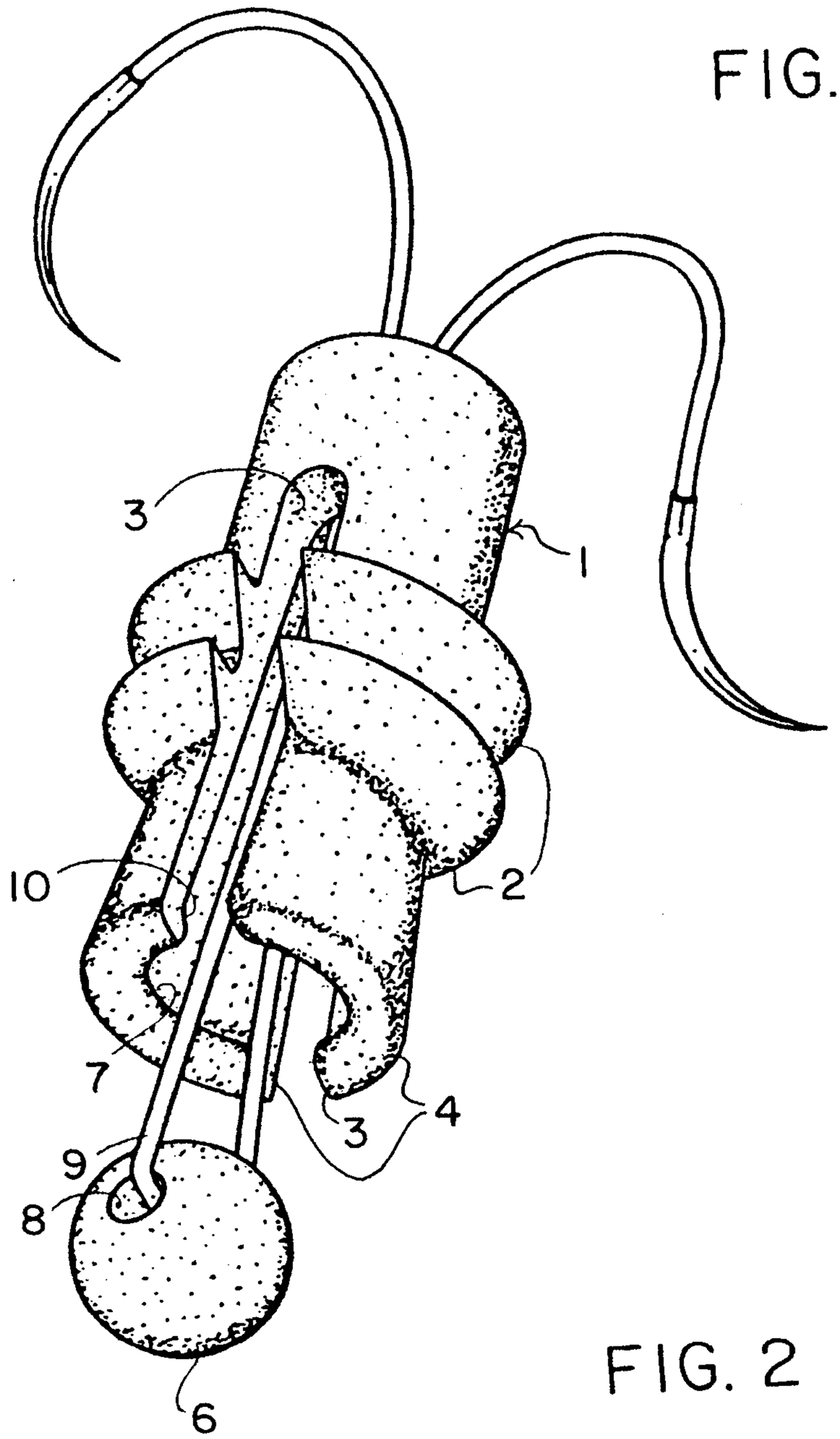


FIG. 1

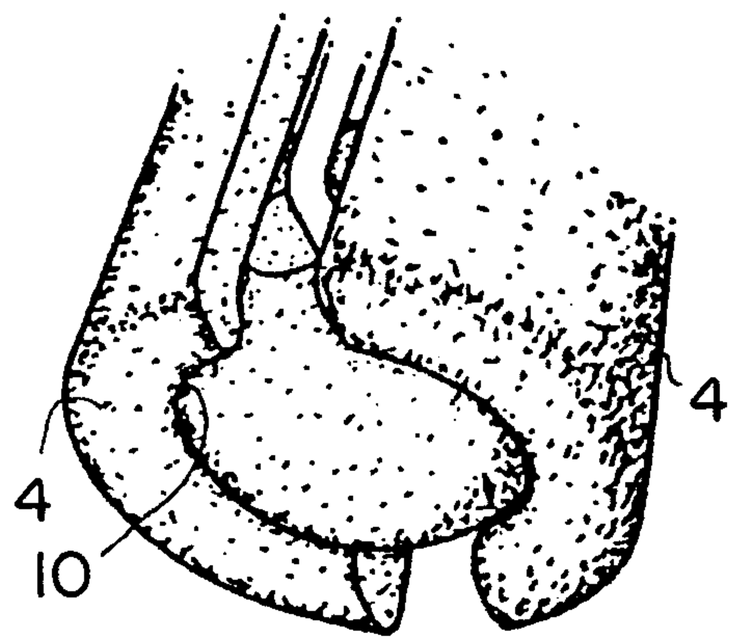


FIG. 2

FIG. 6

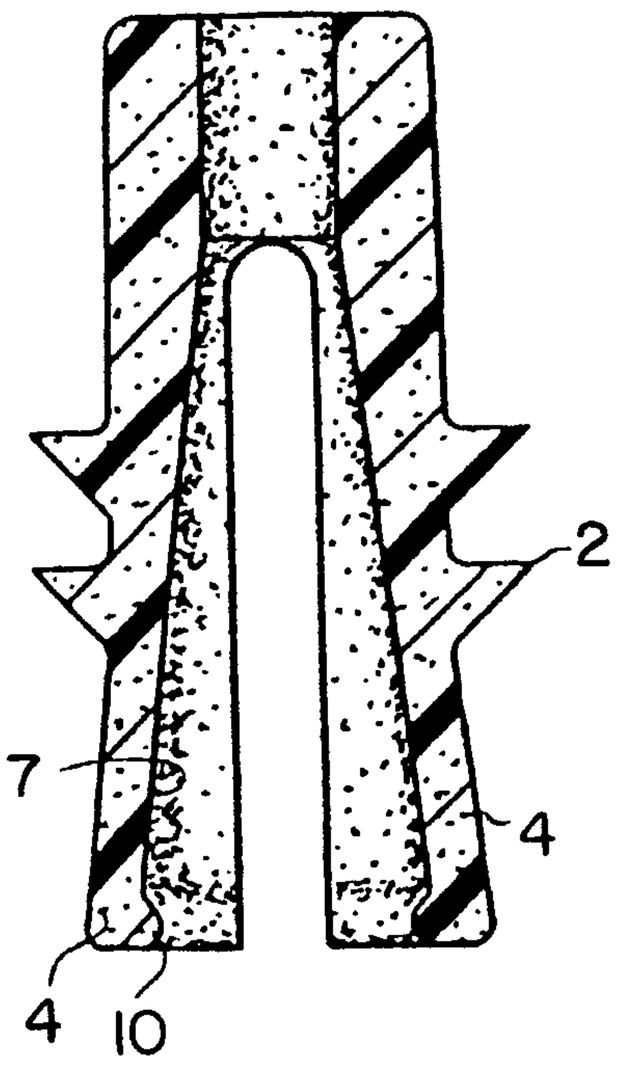


FIG. 7

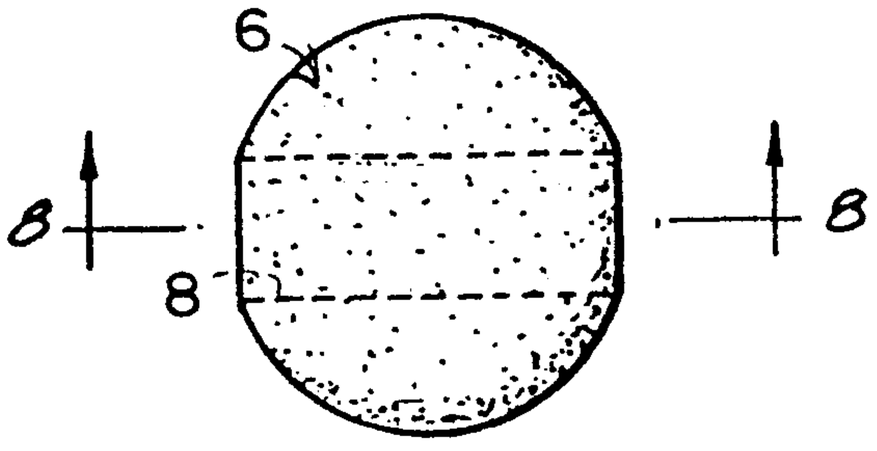


FIG. 8

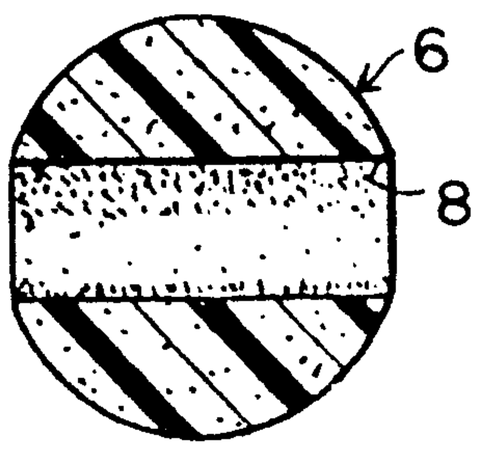


FIG. 3

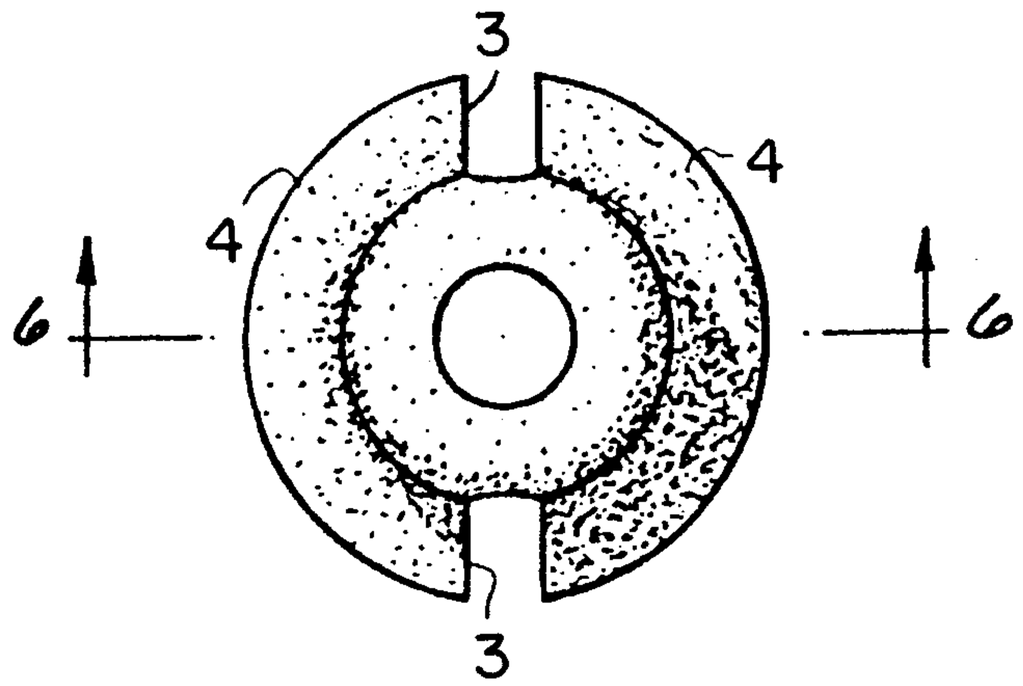


FIG. 4

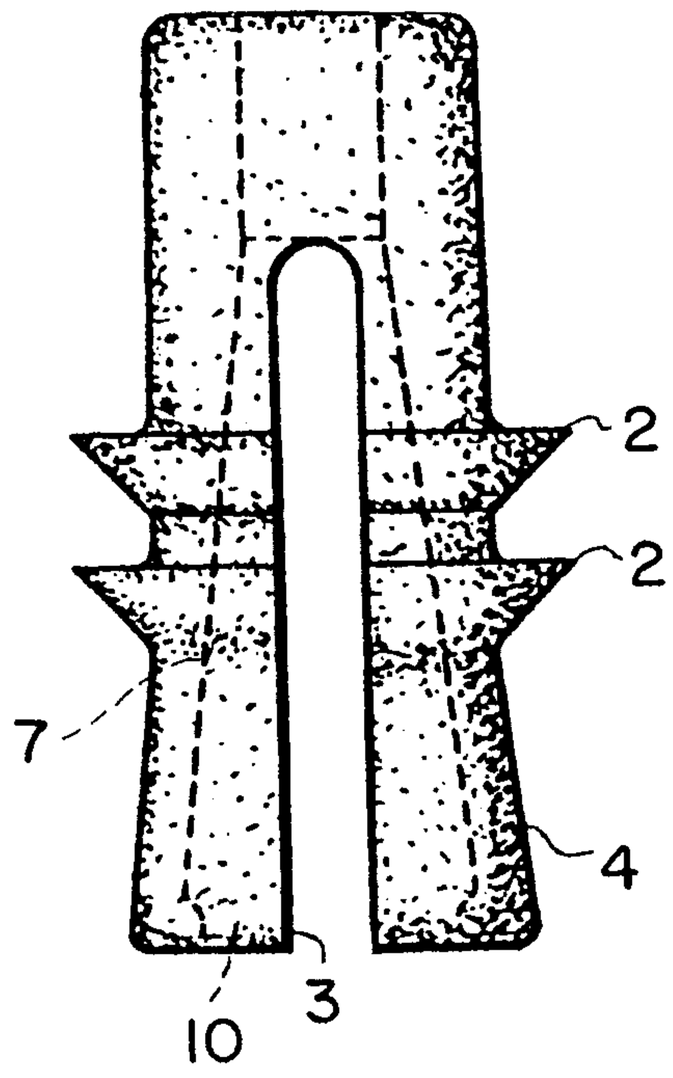


FIG. 5

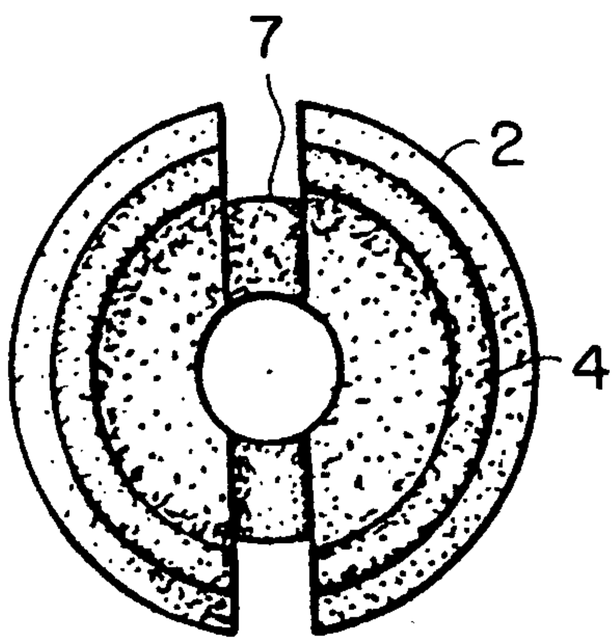


FIG. 9

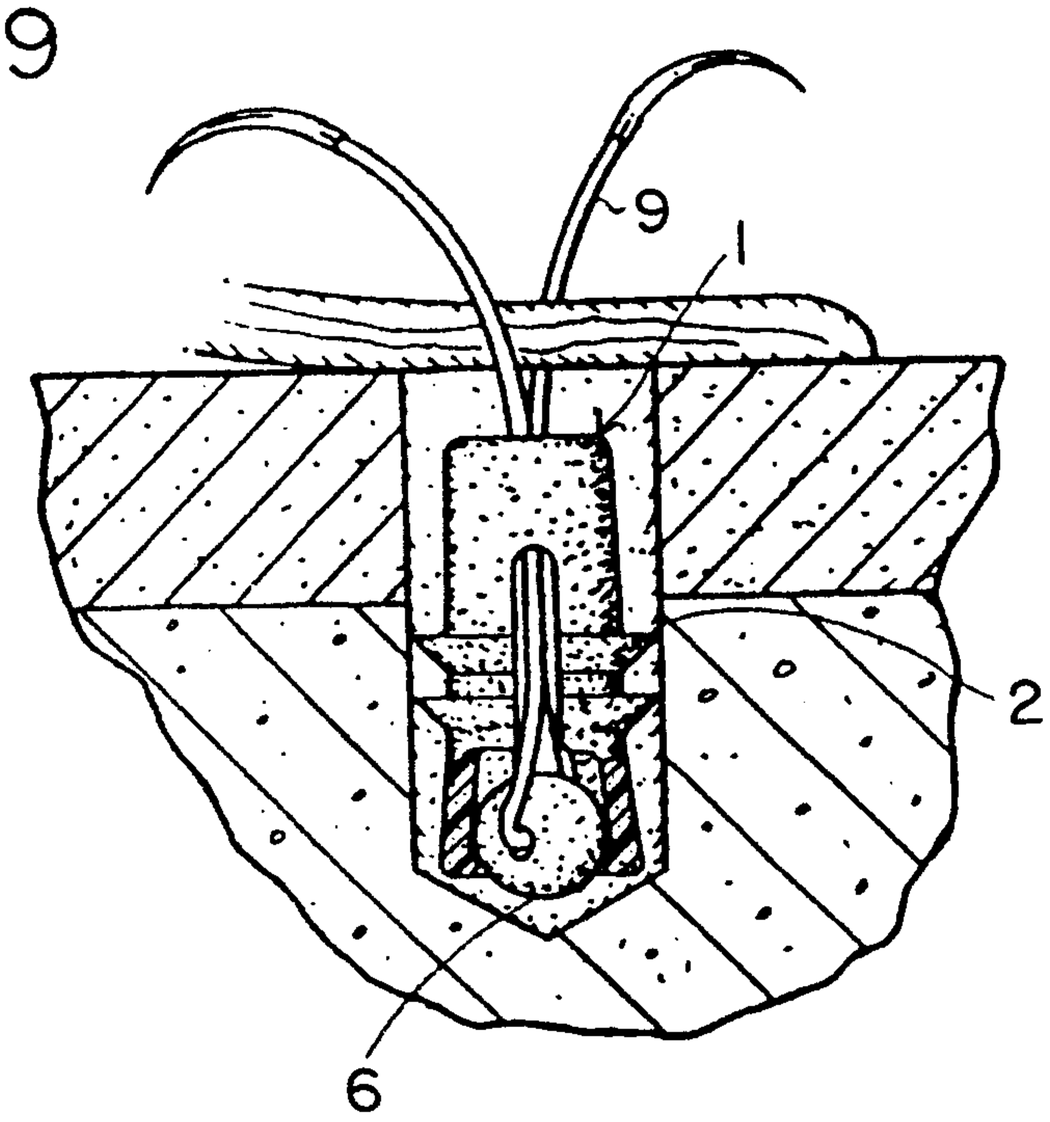


FIG. 10

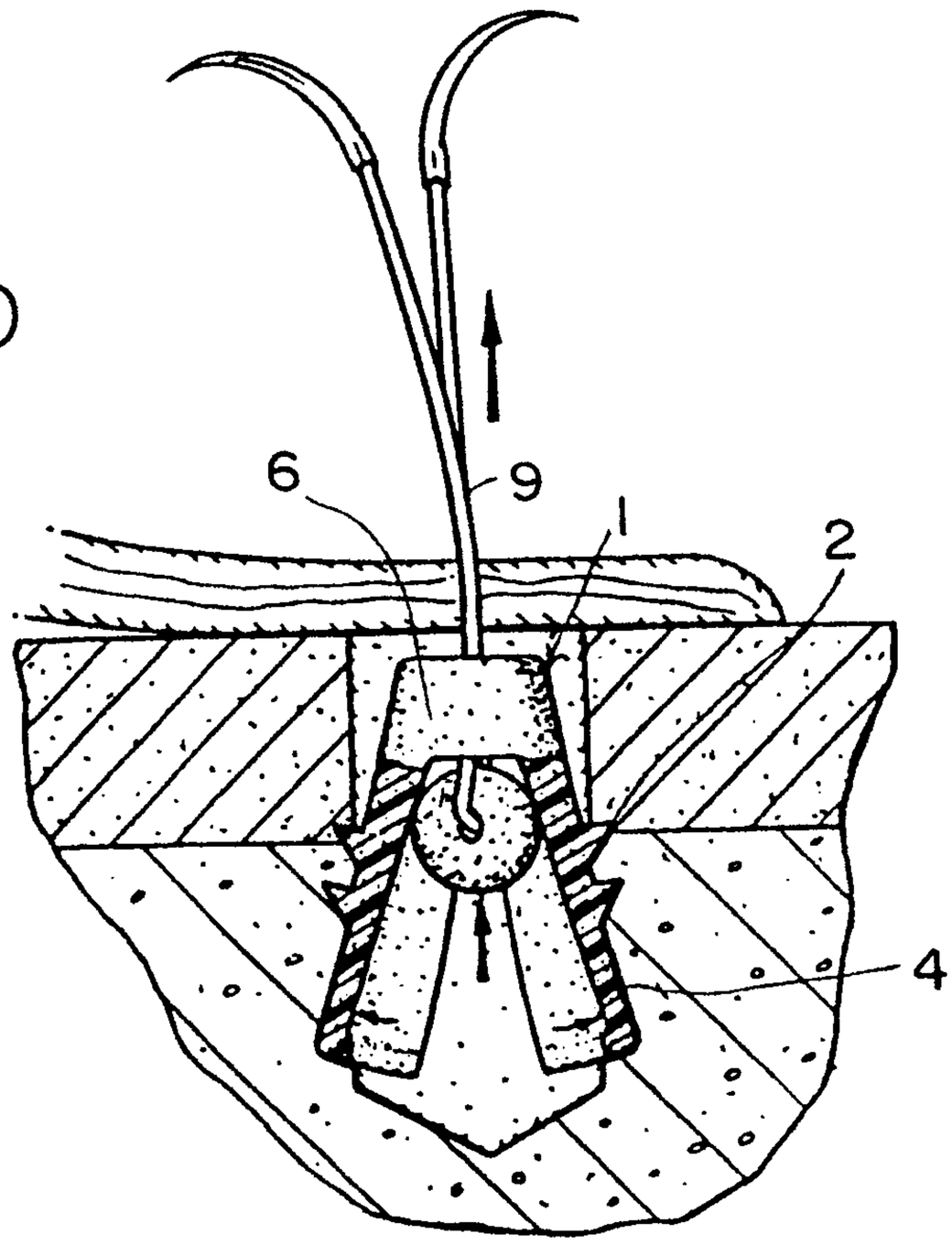


FIG. 11

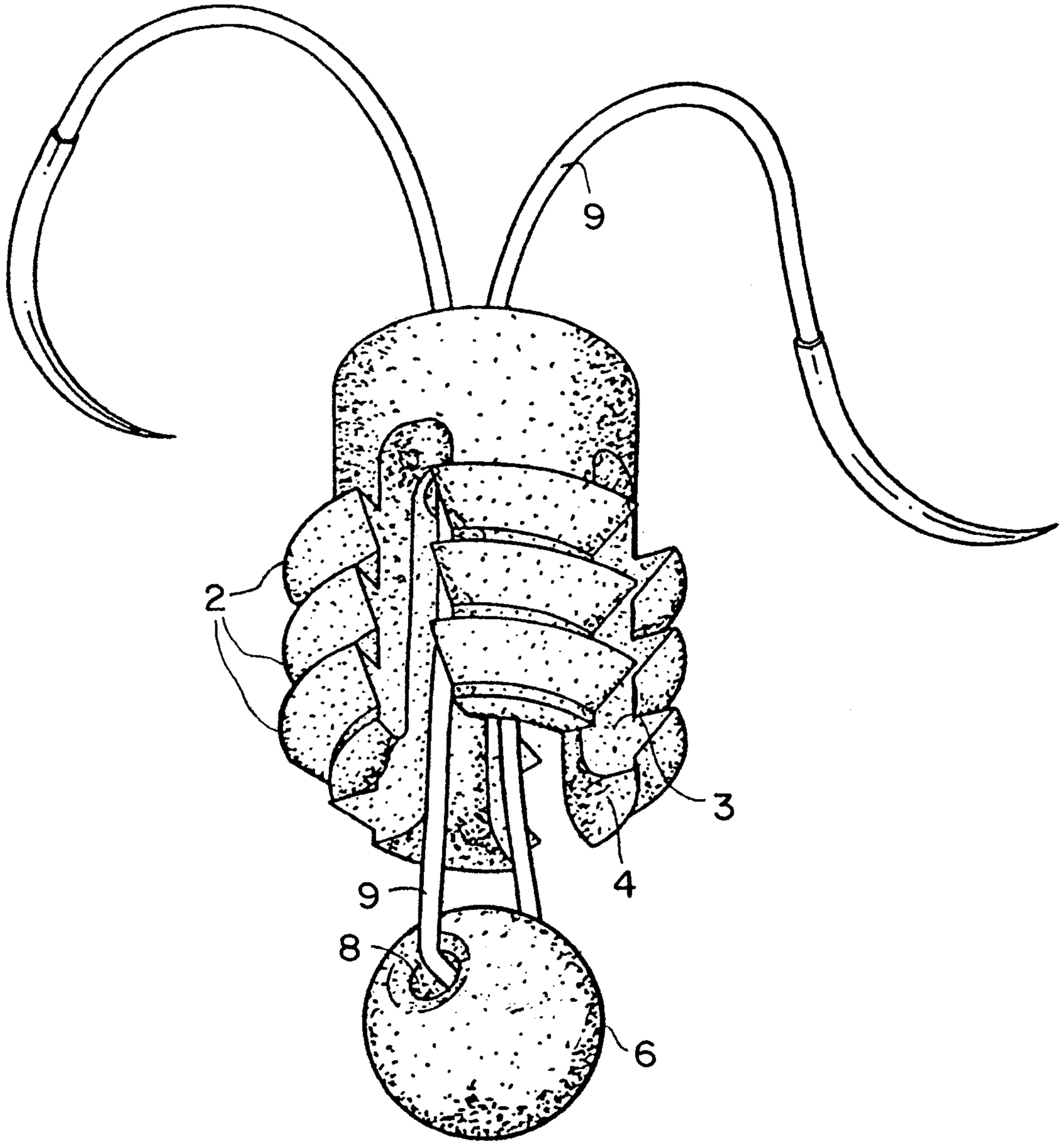


FIG. 12

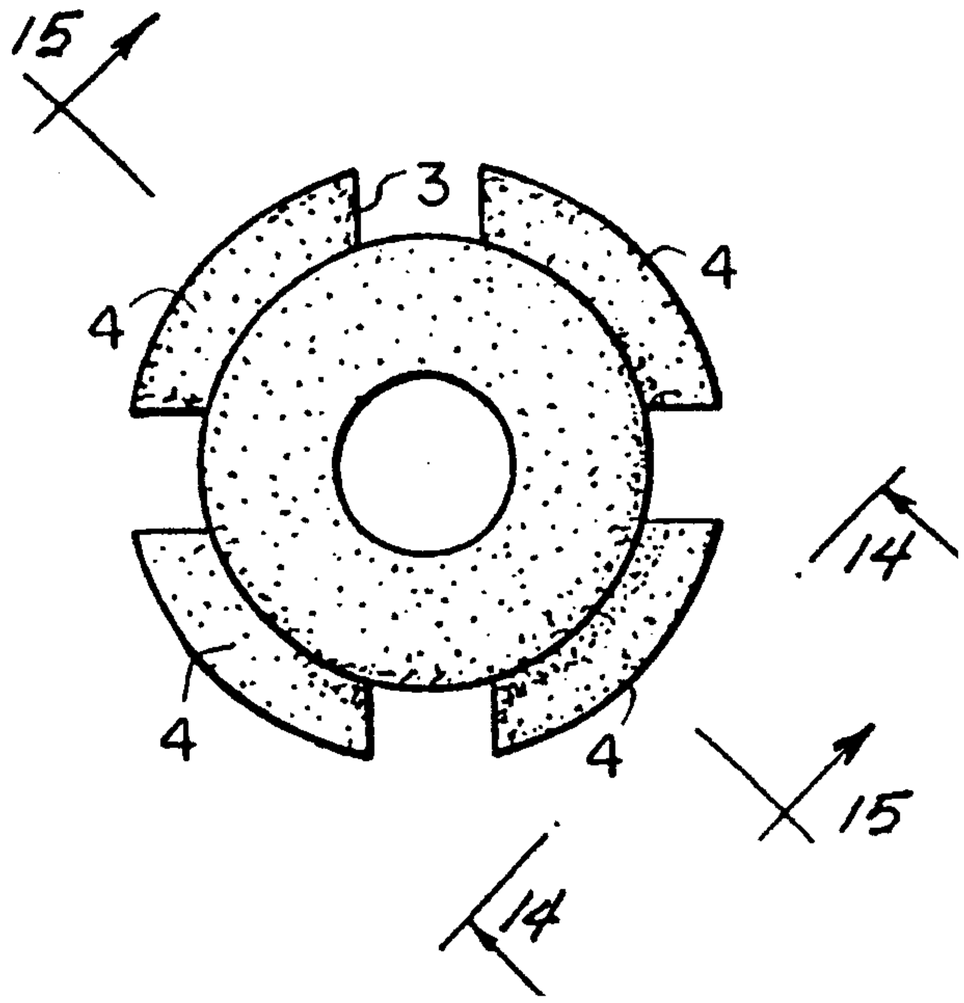


FIG. 13

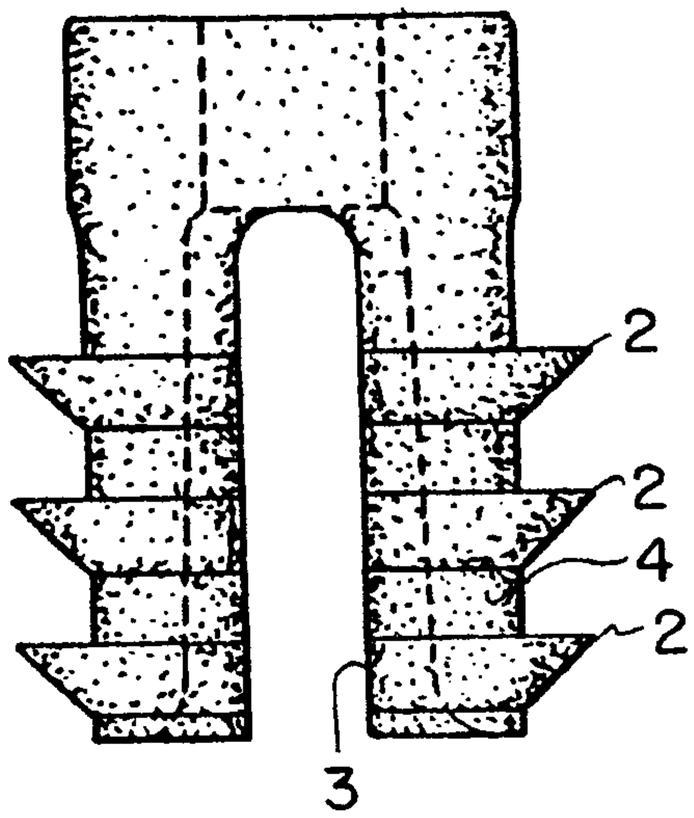


FIG. 14

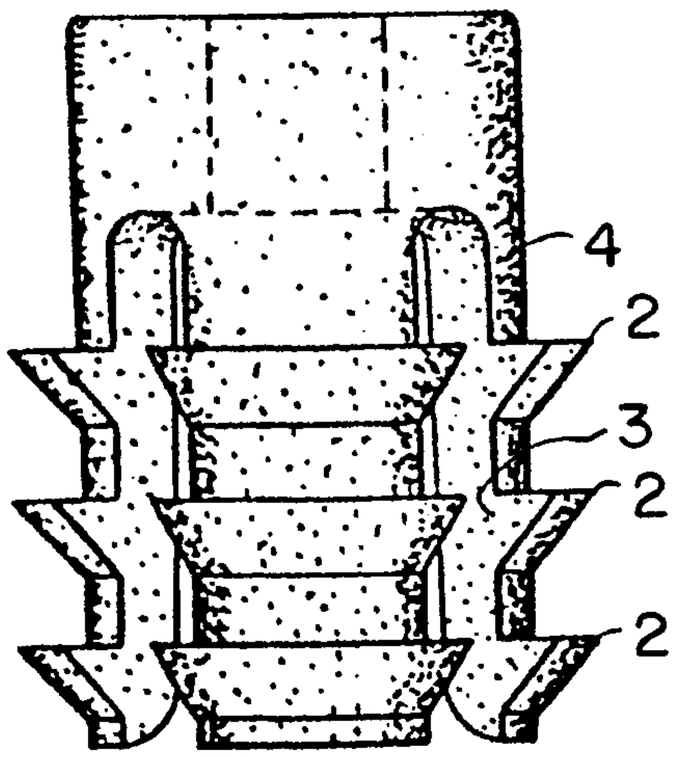


FIG. 15

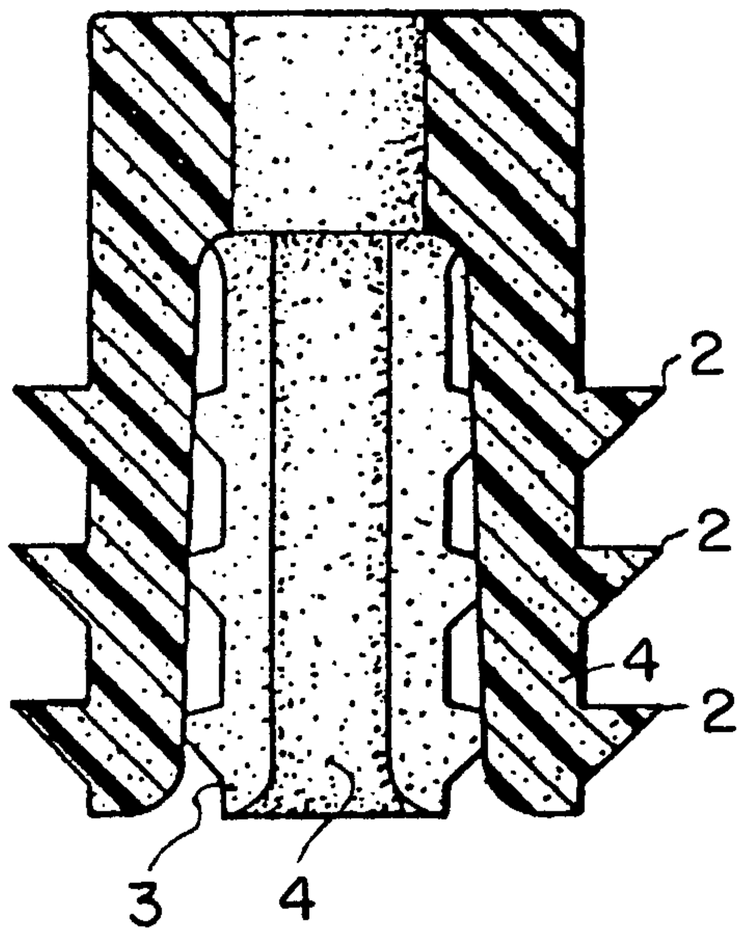


FIG. 16

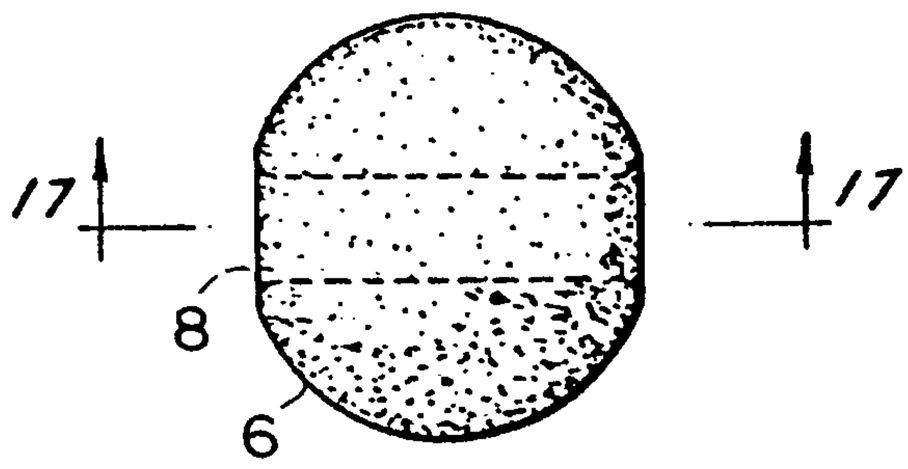


FIG. 17

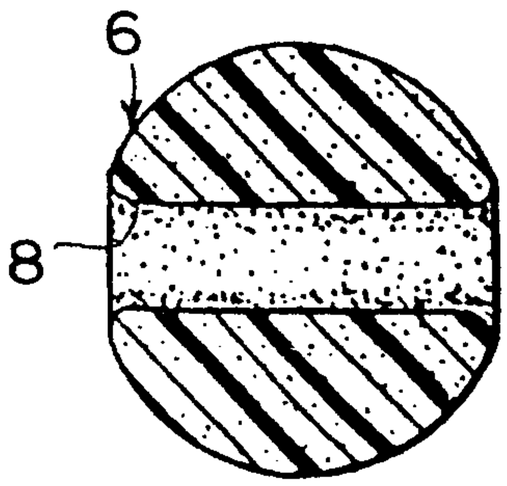


FIG. 18

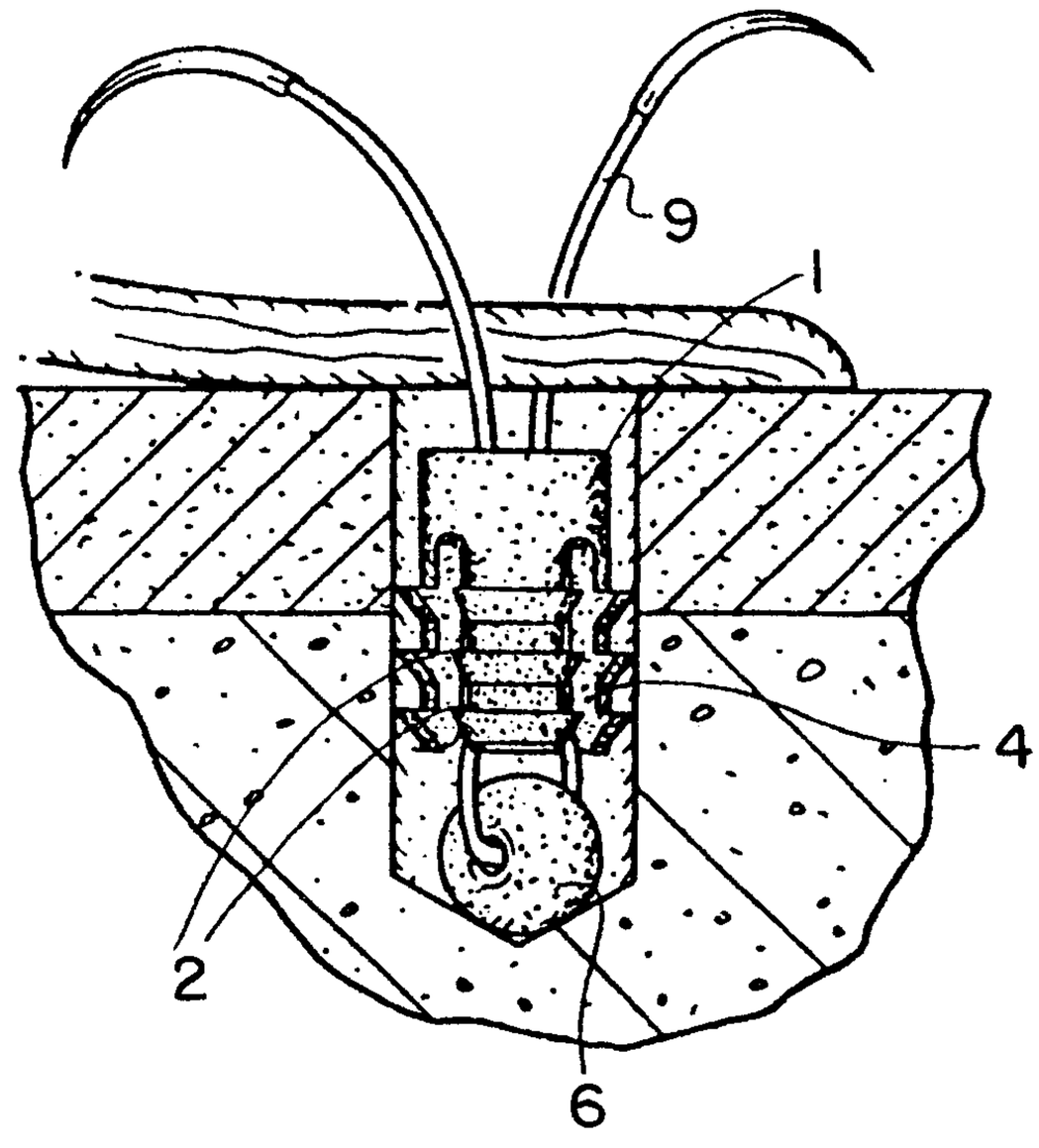


FIG. 19

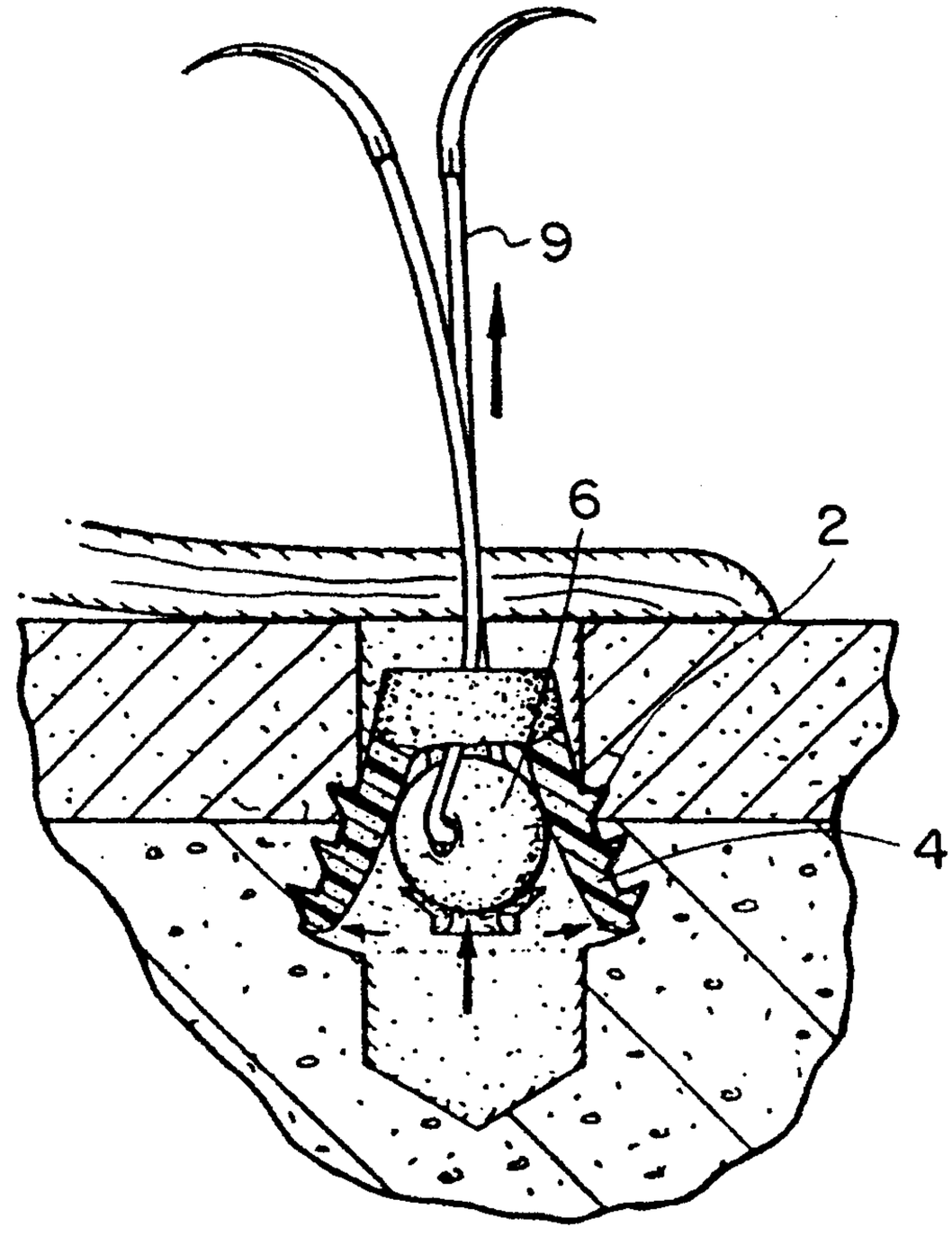


FIG. 20

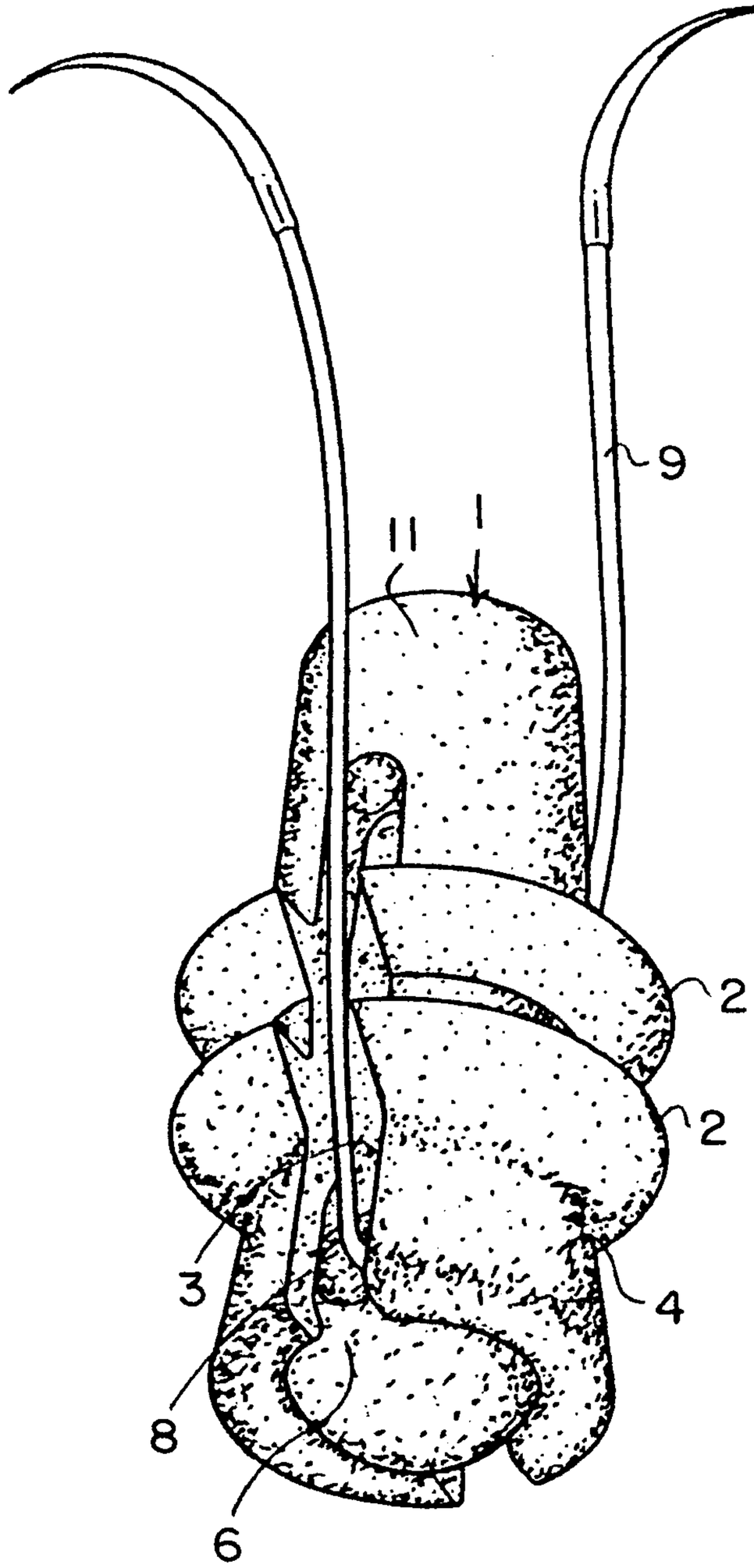


FIG. 21

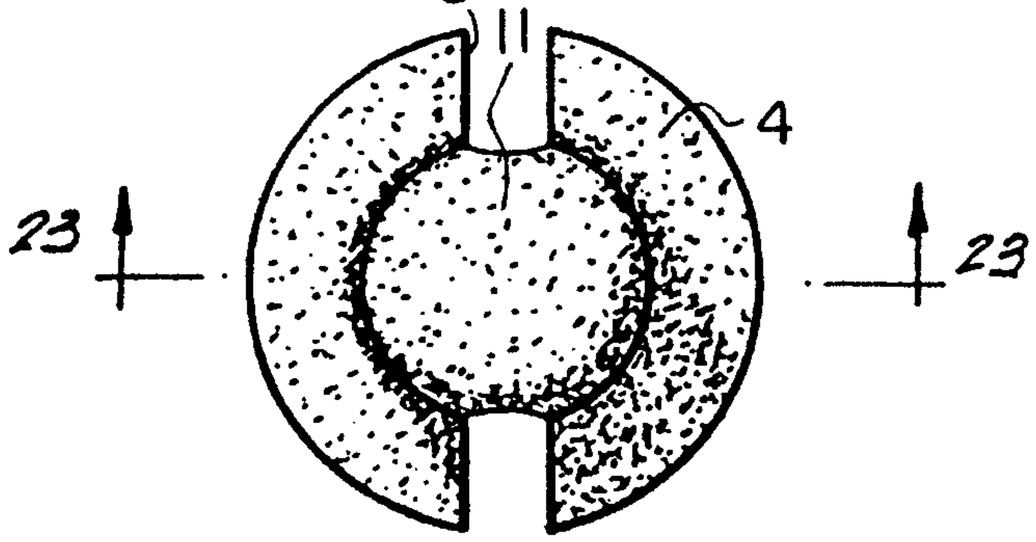


FIG. 22

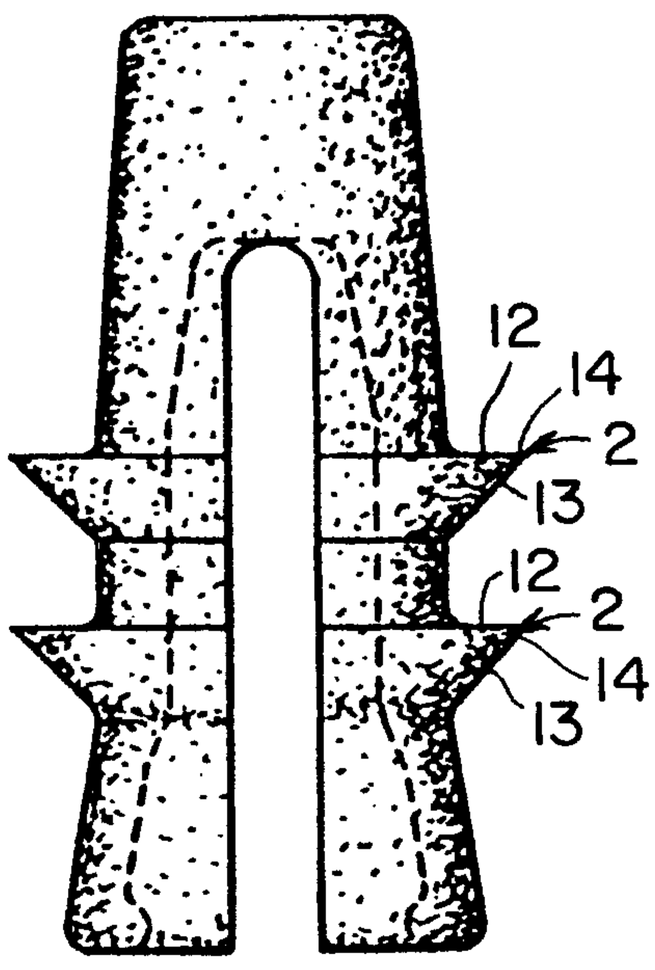


FIG. 23

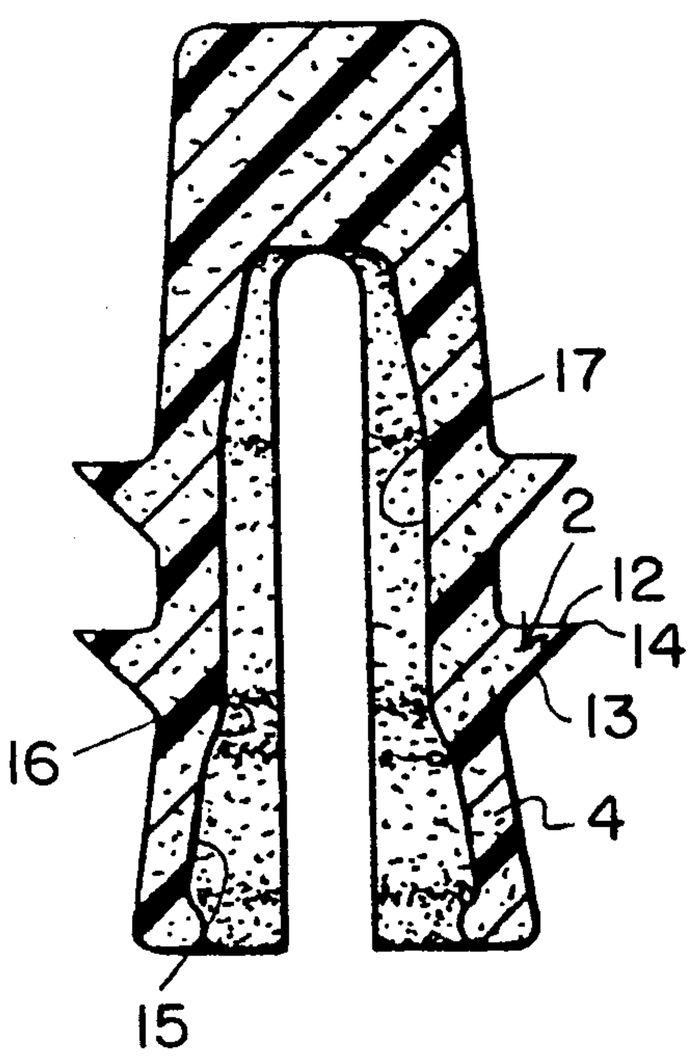


FIG. 24

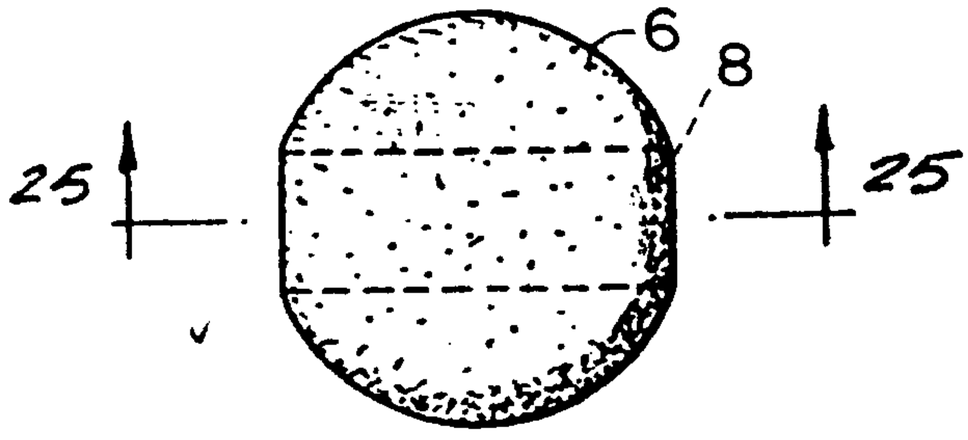


FIG. 25

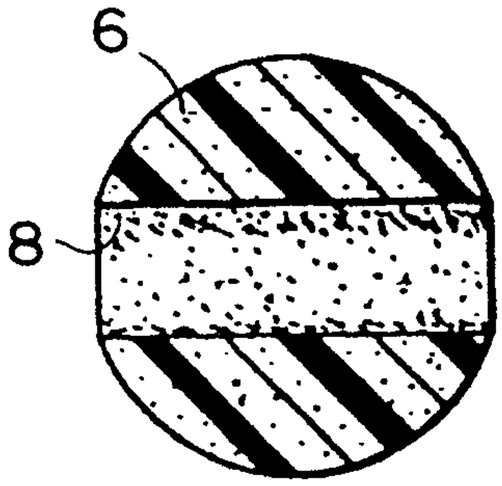


FIG. 26

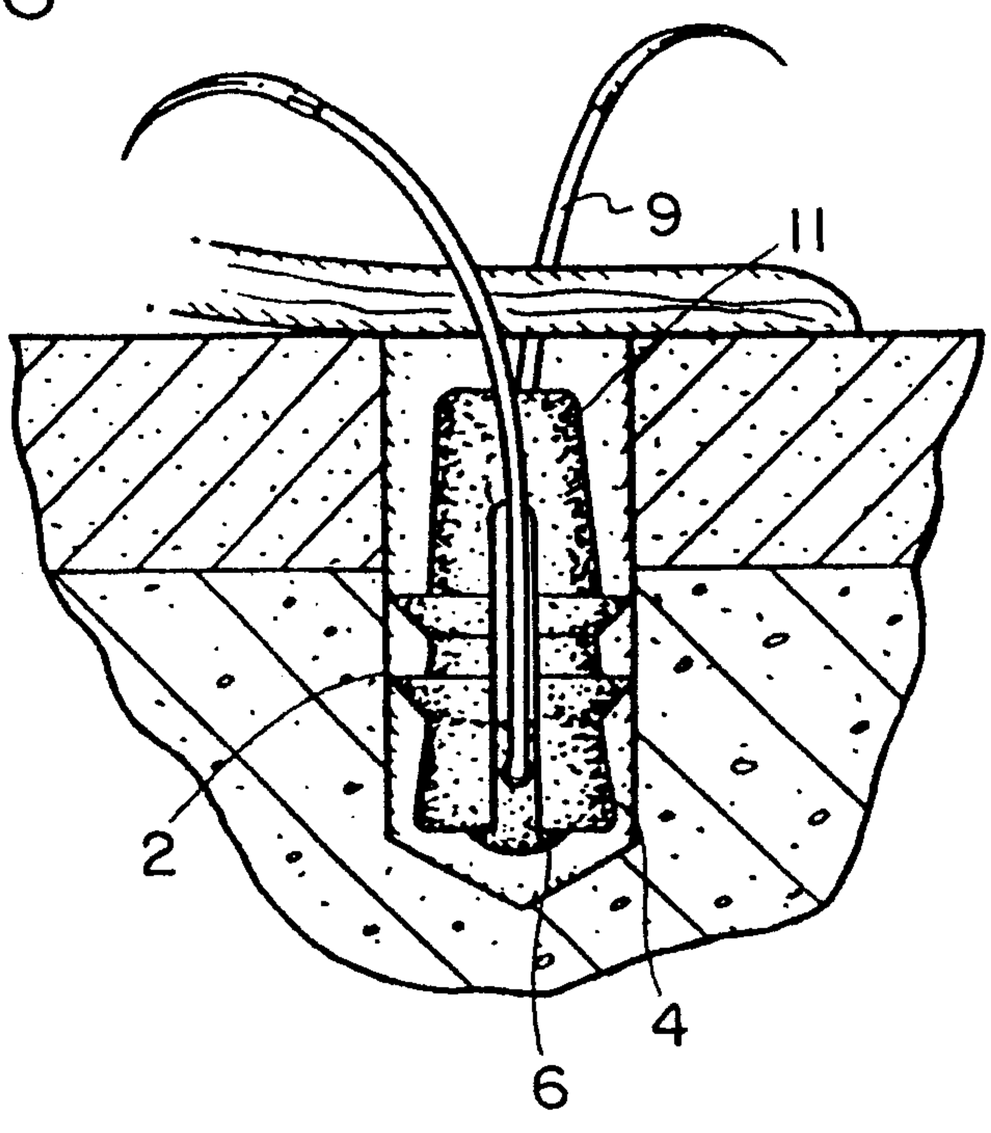


FIG. 27

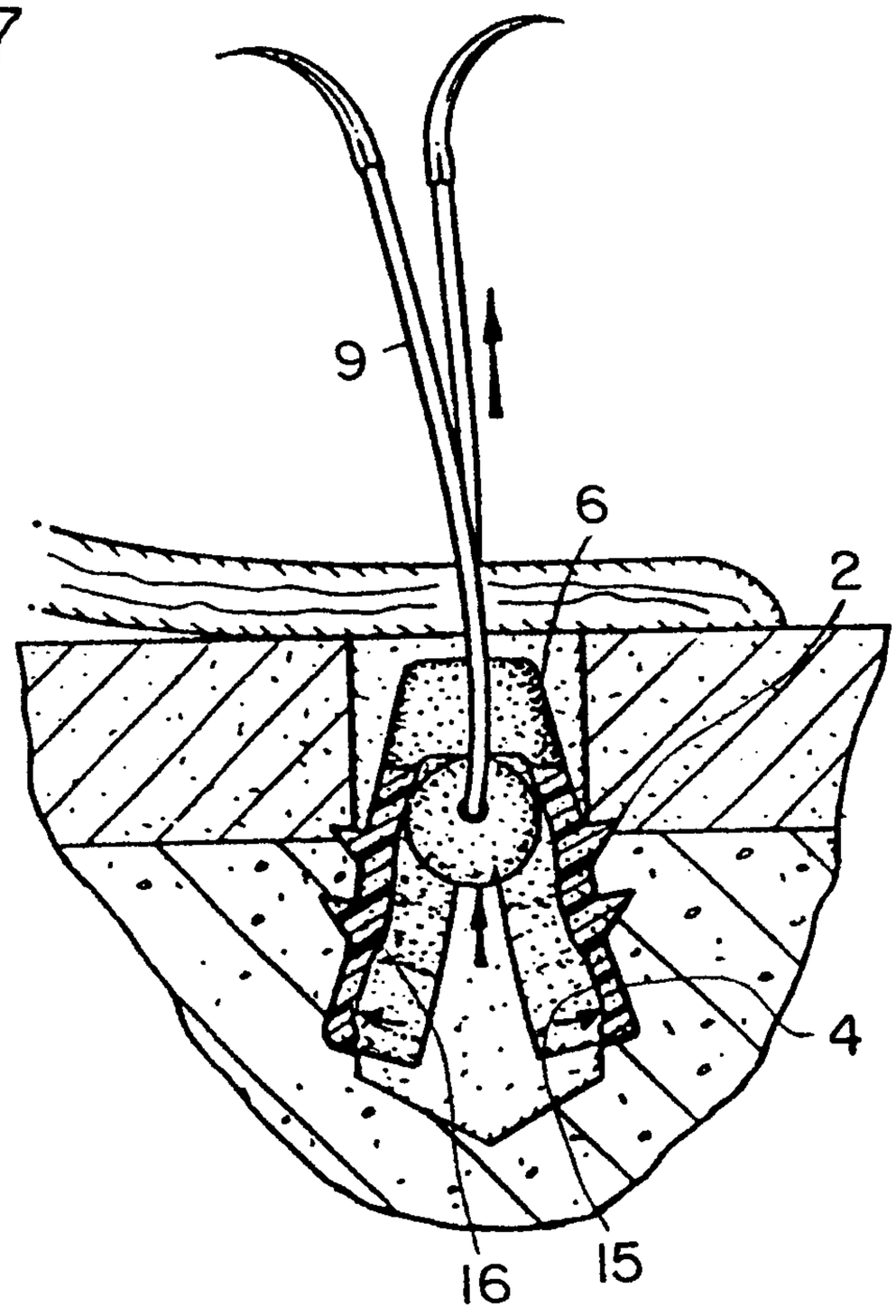


FIG. 28

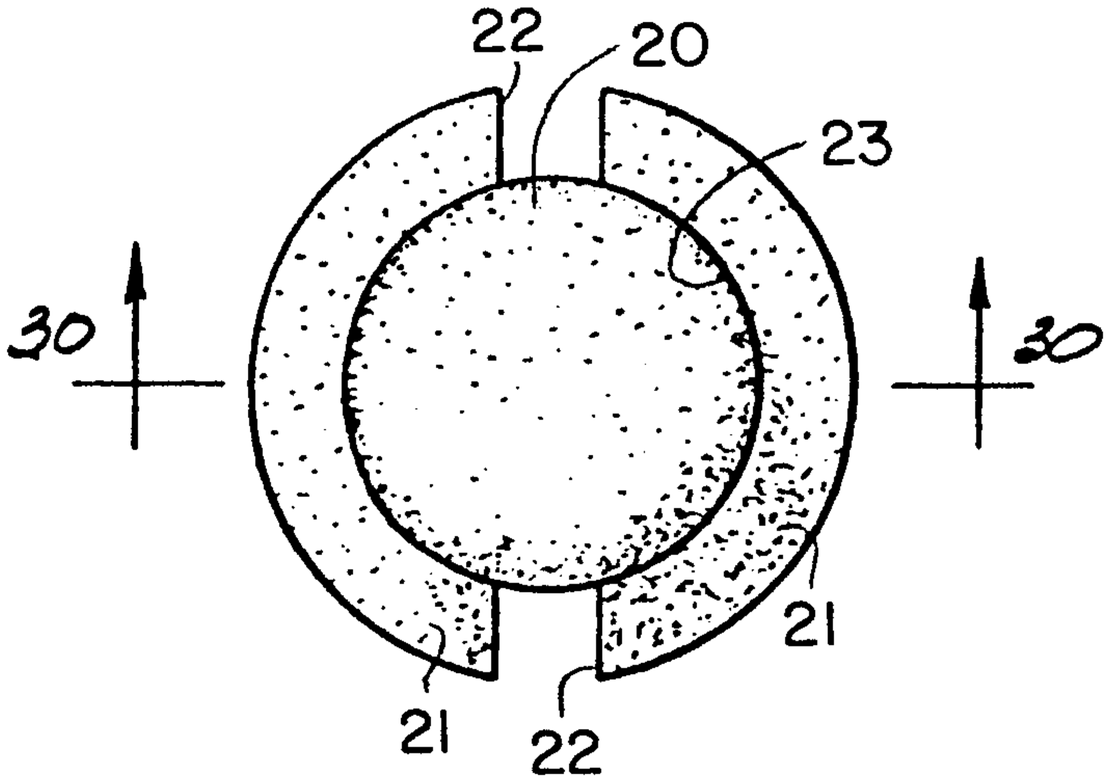


FIG. 29

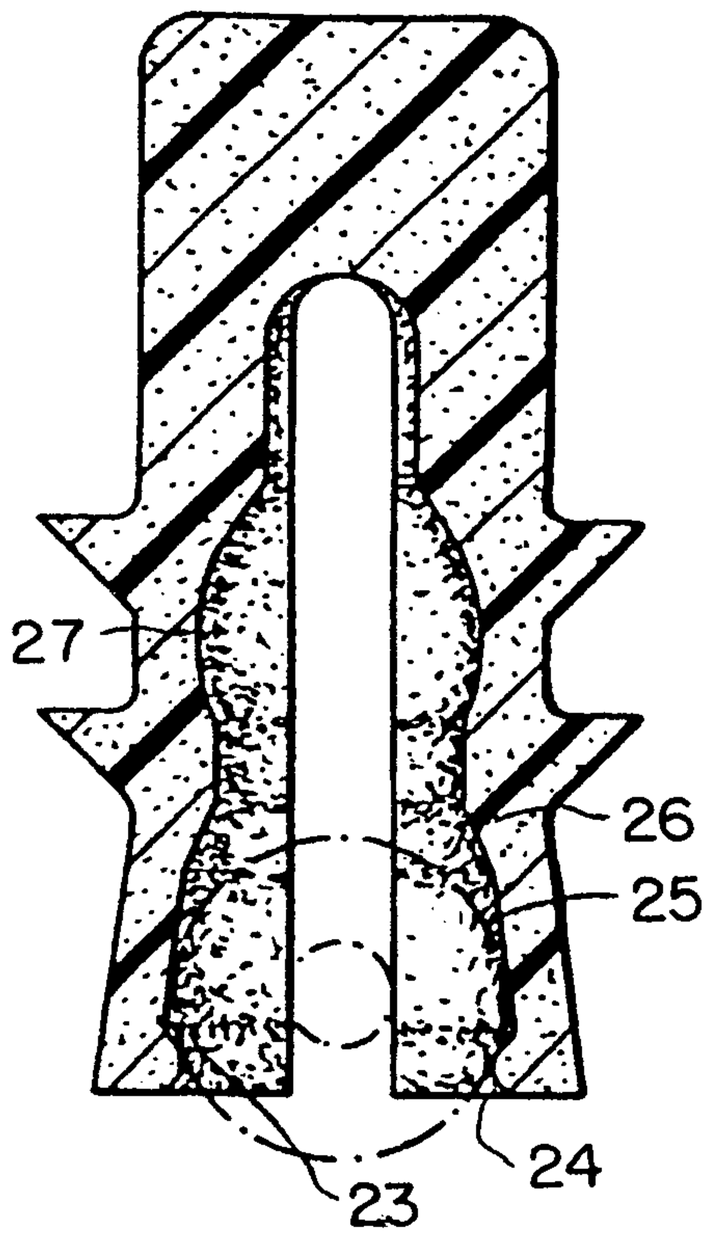


FIG. 30

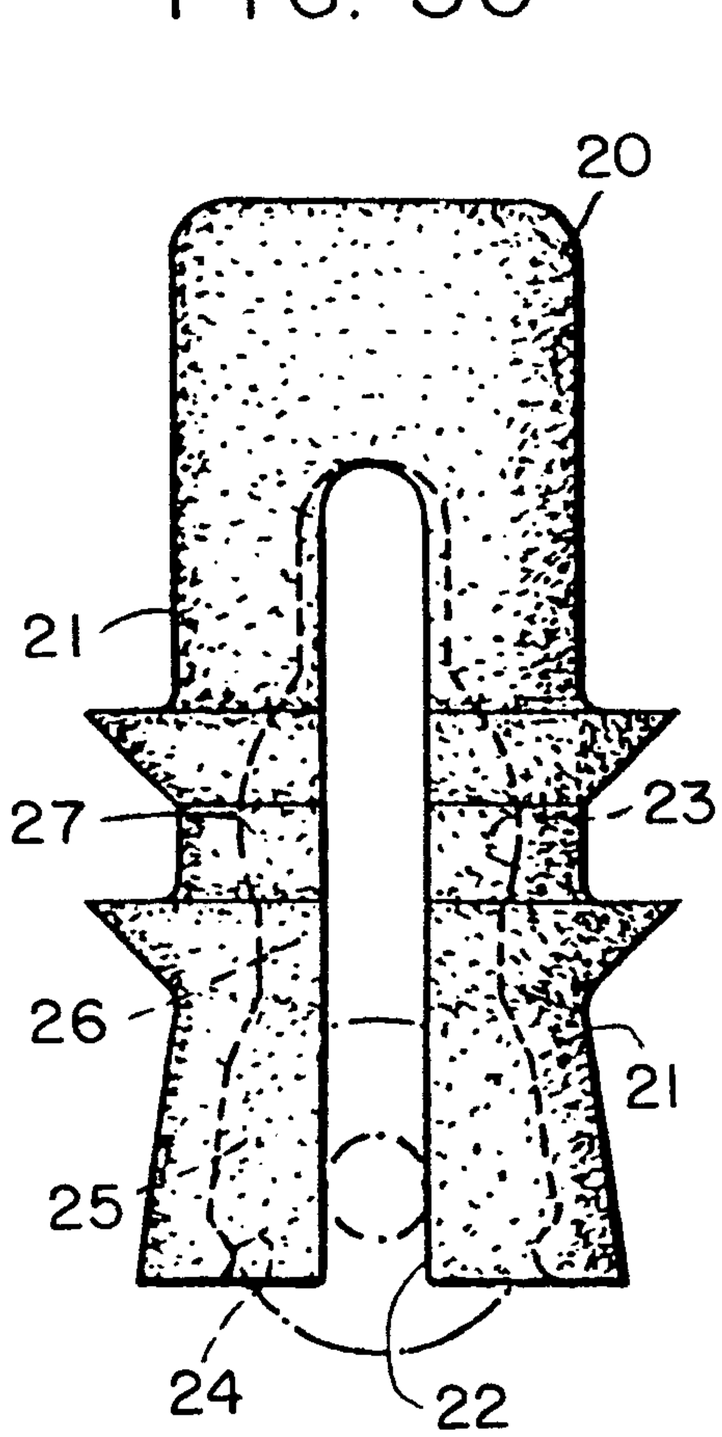


FIG. 31

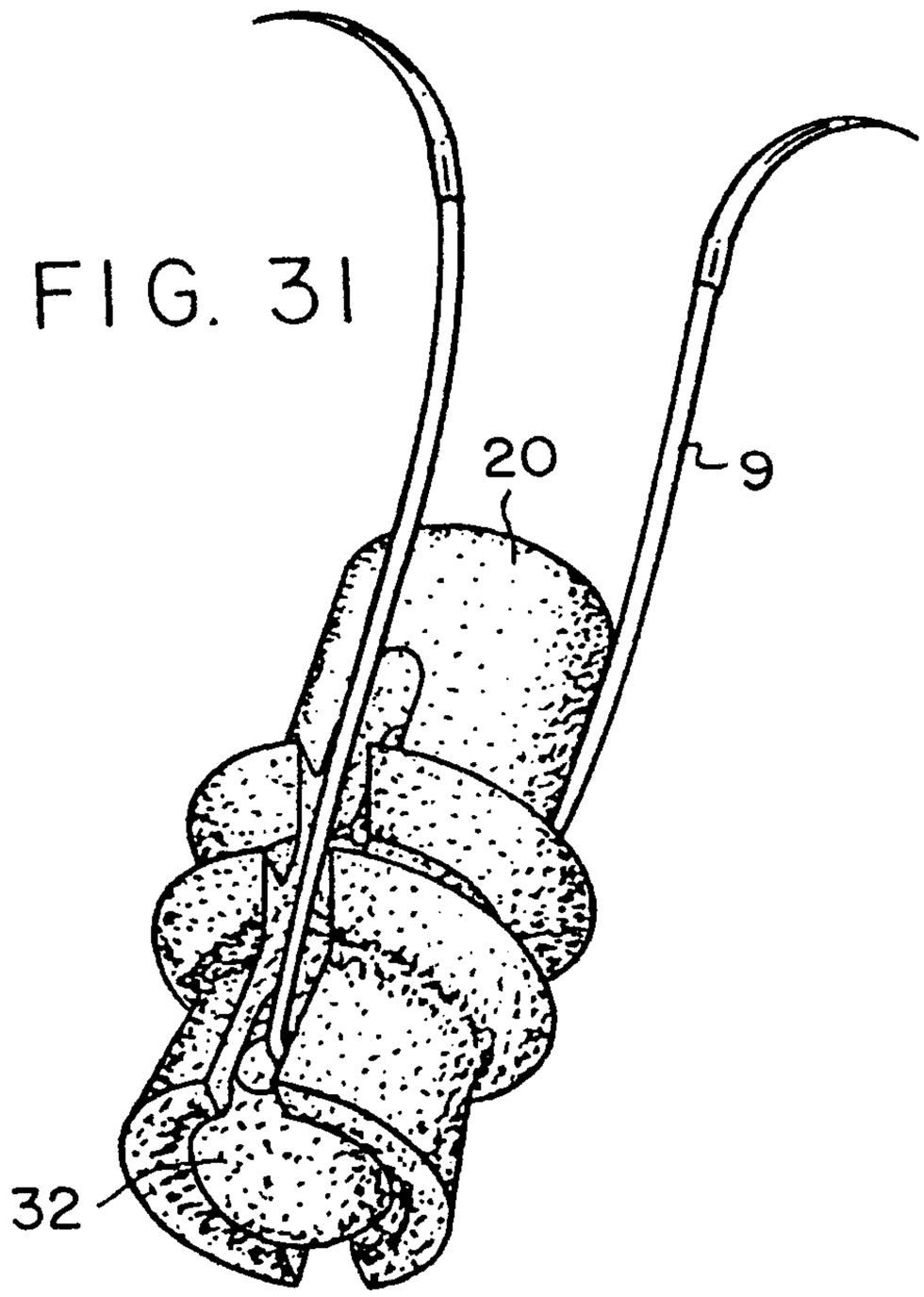


FIG. 32

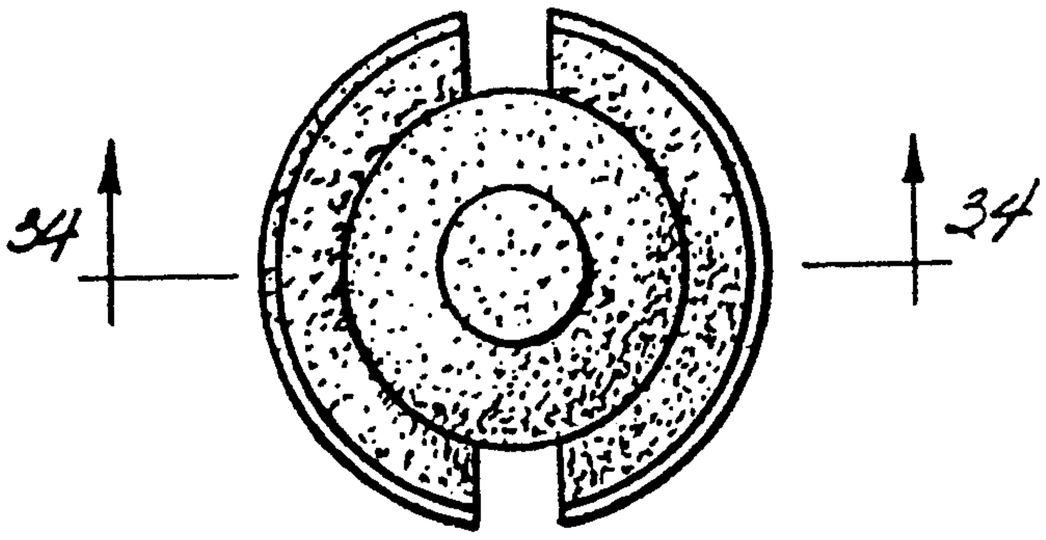


FIG. 33

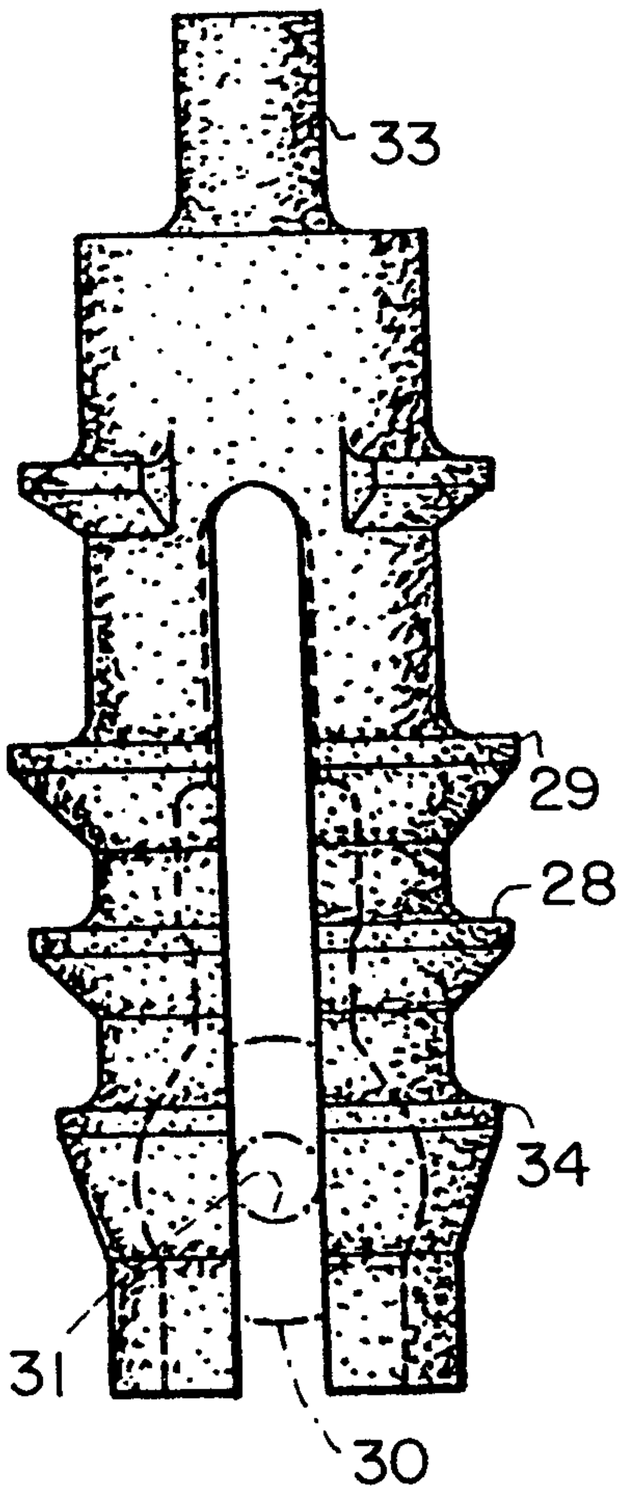


FIG. 34

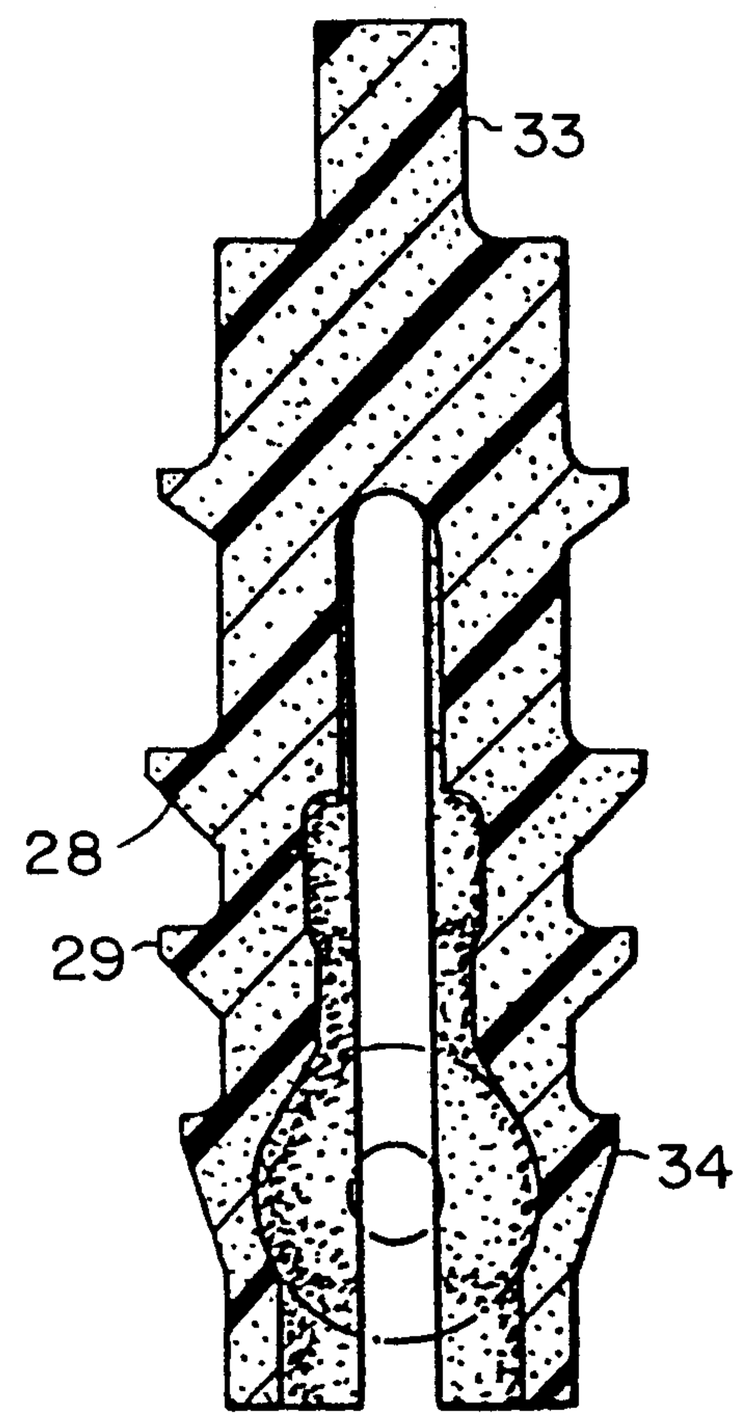


FIG. 35

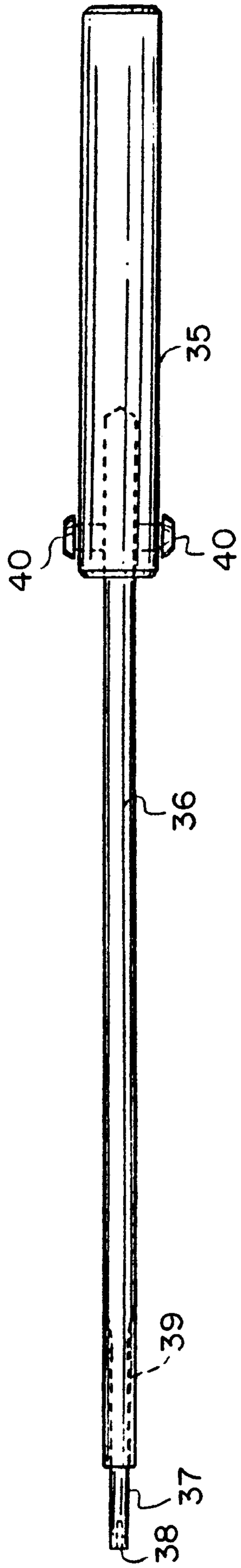


FIG. 36

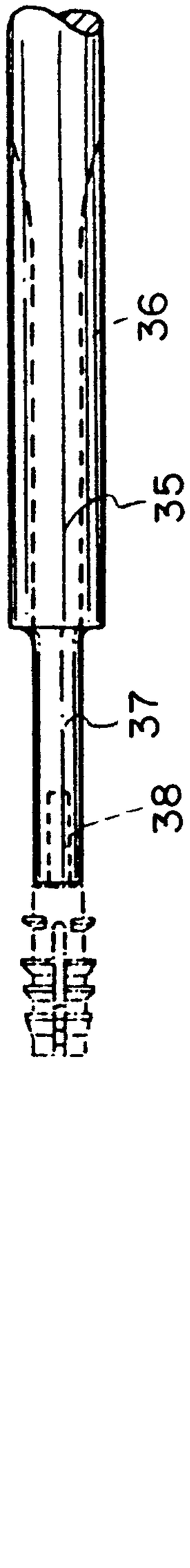
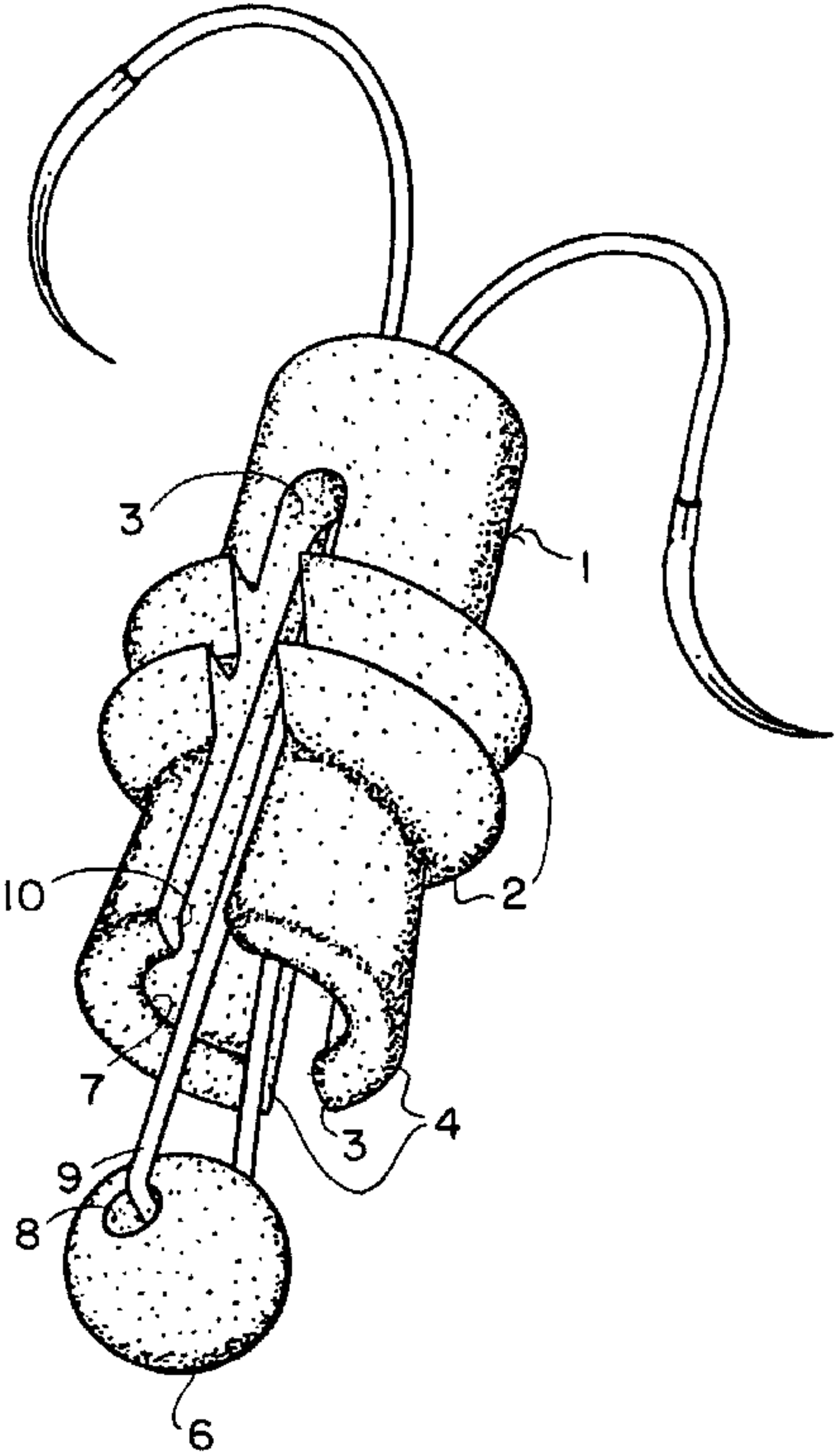


FIG. 37


3
1
10
2
7
4
3
9
8
6