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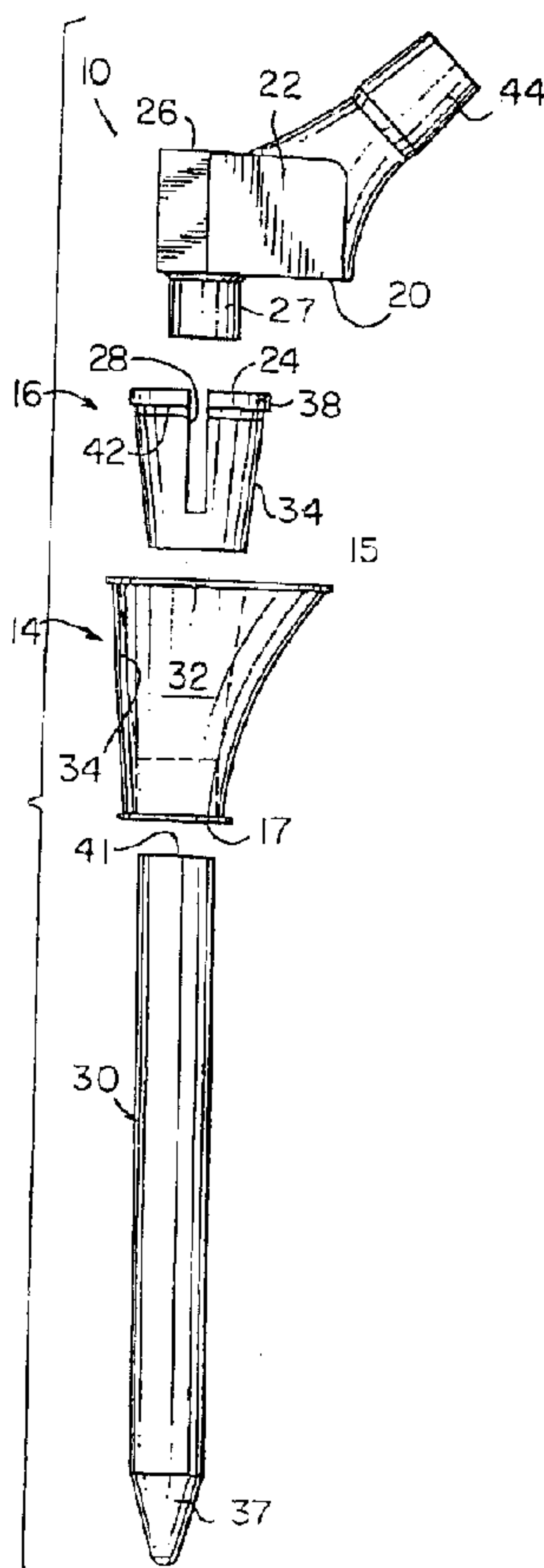
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(54) **PROTHESE POURVUE D'UN CORPS CUNEIFORME**

(54) **PROSTHESIS HAVING WEDGE-SHAPED BODY**



(57) L'invention porte sur une prothèse (10) orthopédique modulaire pourvue d'un corps (14) ayant une section transversale triangulaire près d'une extrémité (20), ce qui permet aux angles de mordre ou d'inciser la cavité osseuse environnante pour obtenir une stabilité de rotation. Une tige (12), pouvant être de structure unitaire ou modulaire, et pourvue d'un col (22) proximal et d'un arbre (30) distal, se loge dans un trou traversant (18) du corps (14). Un manchon (16) de raccordement recevant la tige (12) passe à son tour dans le trou (18) du corps (14), puis est actionné pour se dilater radialement et bloquer la tige et le corps. L'invention porte également sur une hanche (10) modulaire préférée et sur des prothèses humérales (110).

(57) A modular orthopedic prosthesis (10) has a body (14) with a generally triangular cross section near one end (20), allowing its angular corners to bite or incise into the surrounding bone cavity for rotational stability. A stem (12), which may be either unitary or modular in structure, is received within a through-bore (18) of the body (14), having a proximal neck (22) and distal shaft (30). A connecting sleeve (16) receives the stem (12) and is, in turn, received within the bore (18) of the body (14), then actuated to radially expand to lock the stem and body together. Preferred modular hip (10) and humeral (110) prostheses are described.

Abstract

Hygienic water-soluble cleansing paper which has a sufficient wet strength for cleansing human bodies or devices as well as a high solubility in water in a state being impregnated with practically useful cleansing agents with a high moisture content, imparts a good feel in using and can be produced at a high efficiency; and portable packaged water-soluble cleansing paper suitable for cleansing the body after evacuation when being out, preventing inflammation in menstruation and worsening of hemorrhoids, therapeutic uses, etc. The cleansing paper is obtained by interlocking fiber sheets made of a specific water-soluble fiber material with each other under a high-pressure water stream and then impregnating the obtained water-soluble nonwoven fabric with a specific aqueous cleanser. This paper can be enclosed in a steam-impermeable soft packaging material to give a packaged matter conveniently carried out or stored.

1 **PROSTHESIS HAVING WEDGE-SHAPED BODY**

2
3 **TECHNICAL FIELD**

4
5 This invention relates generally to orthopedic prostheses, particularly to those having
6 a modular construction that is assembled from selected components and implanted during
7 re-constructive arthroplastic surgery.

8
9 **BACKGROUND**

10
11 It is known that bone matter that is not stressed/loaded will atrophy and lose viability,
12 a problem which currently persists in present orthopedic implants.

13
14 One approach others have taken is to provide a collar intended to correspond in
15 shape and size to the prepared cavity of a proximal femur, ostensibly to offer rotatory
16 stability to the implanted device. For example, *U.S. Patent No. 4,790,852 to Noiles* shows a
17 modular hip prosthesis including a collar having a shape with a keyhole cross-section and
18 terraces surrounding the outer surface perpendicular to the longitudinal axis of the collar.
19 The collar has a tapered proximal-to-distal contour. However, the shape of the collar is
20 instead dictated by the milling instrumentation used to prepare the proximal femoral cavity.
21 According to the procedure, a surgeon resects the femoral head (ball) with an osteotome,
22 thereby exposing the medial aspect of the cavity, then reams the intramedullary canal to
23 make a space for the collar. The medial bone cavity is then milled to make it fit set criteria
24 of the implant. *U.S. Patent No. 5,002,578 to Luman* also has transverse terraces and a
25 supposed cavity conforming cross-section. However, such terraces, like those of the above
26 Noiles '852 patent, do not counteract rotary motion of the prosthesis, but rather axial motion.
27 *U.S. Patent No. 4,549,319 to Meyer* has an external geometric pattern of elongated
28 projections spaced circumferentially on a hip prosthesis. *U.S. Patent No. 4,624,673 to*
29 *Meyer* discusses a component for use in a prosthetic joint having a hollow tube with a
30 closed end and an open end. The area of the external surface adjacent to the open end is
31 at least twice the area of the external surface adjacent to the closed. A plurality of terraces,
32 oriented orthogonal to a distal shaft, are on the external surface. A female part of self-

1 locking taper is provided to connect the components. *U.S. Patent No. 4,846,839 to Noiles*
2 shows a modular hip with a collar having an oval cross-section and a terraced external
3 surface, connecting with a stem. Products have been marketed generally based upon this
4 approach, e.g., The SROM Hip, of Joint Medical Products, Inc.

5
6 The aforementioned patents seek to provide rotatory stability by circumferential
7 contact between the prepared femoral cavity and an outer surface of a main body or collar
8 member. This type of contact is actually tangential in nature. The use of an oval cross-
9 sectional shape often does not allow the outer surface of the prosthesis collar to effectively
10 engage the intact bone. In many cases, especially in revision patients, healthy bone can be
11 problematic to uniformly contact, for example, in the lateral aspects of the proximal femur,
12 where the greater trochanter is left largely undisturbed by the surgeon during a primary
13 implantation. The lack of rotatory stability, needed for uniform stress on such healthy bone,
14 can cause the intact tissue to weaken and possibly atrophy, unacceptably, at some point
15 following the initial implantation of the prosthesis.

16
17 Others, including some of the above approaches, have further sought to achieve
18 prosthesis-cavity conformance while providing various modular constructions and ways of
19 connecting the components of the prosthesis.

20
21 For example, related *U.S. Patent Nos. 5,370,706 and 5,080,685 to Bolesky* show a
22 body member having a neck with a base defining a neck basal plane. A body member
23 includes an upwardly and inwardly directed portion and a tapered longitudinal bore. A
24 tapered connector engages a head member with the upwardly and inwardly directed portion.
25 A problem experienced with this particular design is its limited strength, due to the location
26 of the interconnecting components. Thus, the point of connection of the shaft must bear a
27 load that is often too great, without being able to distribute that force. In *U.S. Patent No.*
28 *4,878,917 to Kranz, et al.*, there is shown a modular implant with a tensioning connector rod
29 structurally designed to break when loaded a selected amount. *U. S. Patent No. 5,201,882*
30 *to Paxson* discloses indicia for selecting the desired ante-version of a modular hip stem that
31 is connected via tapered fittings to a unitary neck/body member, but the neck is not
32 independently adjustable relative to the body. *U.S. Patent No. 5,725,592*, issued to the

1 present inventor, describes a modular hip prosthesis having a distal stem component that
2 connects with a body component and a neck component both having tapered through-
3 bores.

4
5 Various implant systems have also been proposed for reconstruction of the
6 humerus. *U.S. Patent No. 5,489,309 to Lackey, et al.*, entitled, *A Modular Humeral*
7 *Component System*®, discloses a kit of interchangeable elements each having a variety of
8 sizes said to fit a particular desired patient. A head is assembled proximally to a body by
9 standard tapered connection, the body being affixed to one or more elongated stem portions
10 by conical fittings having hexagonal ends said to prevent anti-rotation. As noted, the stems
11 may further include distal extensions to accommodate the length of the intramedullary canal
12 of the humerus. In *U.S. Patent No. 5,702,486 to Craig, et al.*, another modular humeral
13 prosthesis is described, wherein a unitary humeral stem is assembled to a head by a
14 tapered connection, including a distal extension that can be screwed-in to the stem to fit the
15 given length of a patient's intramedullary canal. It should be noted that these systems rely
16 upon heretofore conventional means for connecting the several components of the
17 prosthesis.

18
19 There is still a need for a modular prosthesis having independently adjustable
20 components, and for a connector mechanism allowing the surgeon to visibly adjust them.
21 Also, a prosthesis is needed, having an adjustable body with a geometry that incisively
22 engages healthy bone, then securely locks with a stem component inter-operatively. The
23 prior patents do not show a body shape capable of adjustably engaging healthy bone tissue
24 in such a manner.

25
26 Other prior unitary implants have had various shapes, but the distal shaft and main
27 body portions of these were not independently adjustable components, allowing surgeons to
28 inter-operatively achieve optimal engagement of the body with healthy bone tissue.

29
30 Moreover, a need exists for a prosthesis that allows the surgeon to independently
31 adjust the implant and realize the aim of engaging intact bone, as well, for an implant
32 geometry that incises the intact bone and stresses it.

1 There is a further need for a modular implant that is infinitely adjustable, rotationally
2 and axially, using a relatively simple array of components, allowing a surgeon flexibility while
3 reducing the cost of carrying a large inventory of sizes. Such a need also exists while
4 continuously delivering desired benefits, via the implant geometry, to a patient's intact bone.
5 A modular implant design is called for, whose components can be readily assembled inter-
6 operatively and securely locked together by the surgeon to achieve these purposes.

8 SUMMARY OF THE INVENTION

9
10 According to the invention, there is provided a modular orthopedic prosthesis
11 including a stem having one end with an elongated portion and another, longitudinally
12 opposed end with a first means presenting a joint motion surface. The prosthesis has a
13 body including a bore defining at least a first axis and having a polygonal cross-section with
14 at least two angular corners adapted to bite or incise into the bone cavity of a patient to
15 prevent rotation of the implanted prosthesis relative to the bone. Means are provided for
16 connecting and locking the stem and body together in a fixed position.

17
18 In a preferred embodiment of this invention, the body has a first end with a generally
19 triangular cross-section in the region of the first end and a generally round cross-section in
20 the region of its second end, presenting a multi-axial wedge shape.

21
22 According to the invention, in another of its aspects, a modular orthopedic prosthesis
23 is provided. The prosthesis comprises a stem component having one end with an elongated
24 portion and another, longitudinally opposed end with a first means presenting a joint motion
25 surface. A body component includes a bore defining at least a first axis. A radially
26 expansible sleeve has opposed ends, one end received within the bore and the other end
27 projecting outwardly from the bore, the sleeve adjustably connecting the stem and body
28 together and locking them in a fixed position.

29
30 In a preferred embodiment of this invention, the joint motion surface is adjustably
31 spaced from the body.

32

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1 In one or more further preferred embodiments of this invention, a modular hip
2 prosthesis is provided and, in one or more still further preferred embodiments, a humeral
3 prosthesis is provided.

4
5 An advantage of the present invention is inventory and manufacturing cost savings,
6 since its modularity allows for economy in manufacturing, as any number of well-known
7 stem types may be selected, and also reduces the inventory of pieces needed on-hand for
8 each surgical procedure.

9
10 Another advantage of the invention is enhanced clinical benefits, as the wedge
11 shape offers enhanced rotatory stability of the prosthesis in use, particularly with revision
12 surgery patients.

13
14 A further advantage of the invention is in providing a connector mechanism that is
15 highly secure once fixed in place, meanwhile providing the surgeon inter-operative flexibility
16 to axially and rotationally adjust the stem independently of the body.

17
18 A still further advantage of the invention gives a surgeon the capability to rotationally
19 "dial" the body in order to have its triangular corners contact and "bite into" or incise as
20 much available healthy bone as possible. By evenly loading/stressing such intact bone,
21 wherever found by the surgeon, particularly in revision patients, it is possible to avoid
22 potential eventual atrophy of the bone tissue.

23
24 Other objects and advantages will become apparent to those skilled in the art by
25 reference to the following Description and Drawings.

1
2
3 **BRIEF DESCRIPTION OF THE DRAWINGS**

4 **FIG. 1** is a perspective view of a modular hip prosthesis of the invention, fully
5 assembled and implanted in a proximal femur, with the bone longitudinally cut away;

6 **FIG. 2** is an external side view of the body component of the present invention, taken
7 from an anterior-posterior aspect;

8
9 **FIG. 2A** is a cross-section of the proximal portion of the body of **FIG. 2**, taken
10 substantially along the lines **2A-2A**;

11
12 **FIG. 2B** is a cross-section of the proximal portion of the body of **FIG. 2**, taken
13 substantially along the lines **2B-2B**;

14
15 **FIG. 2C** is a cross-section of the proximal portion of the body of **FIG. 2**, taken
16 substantially along the lines **2C-2C**;

17
18 **FIG. 3** is an external side view of the sleeve component of the present invention,
19 taken from either an anterior-posterior or medial-lateral aspect;

20
21 **FIG. 3A** is a longitudinal section of the body of **FIG. 3**, taken substantially along the
22 lines **3A-3A**;

23
24 **FIG. 3B** is an external top view of the proximal portion of the sleeve of **FIG. 3**;

25
26 **FIG. 4** is a partially exploded perspective view of the invention, showing the sleeve
27 partially seated in the bore of the body, prior to insertion of the stem;

28
29 **FIG. 5A** is a cross-section taken through the proximal femur of a representative
30 cadaver bone;

31

1 **FIG. 5B** is a cross-section of the proximal portion of the body of the invention,
2 implanted in the cadaver bone of **FIG. 5A**, further showing also the cross-section of a
3 representative prior art implant for comparison purposes.
4

5 **FIG. 6** is an exploded perspective view of the stem, body and sleeve of the
6 invention, shown prior to assembly, wherein the stem has a modular shaft construction with
7 separate neck protrusion and distal shaft components;
8

9 **FIG. 7** is an exploded perspective view of the prosthesis of **FIG. 6**, showing the distal
10 shaft component of the modular stem being connected to the body with another
11 independent sleeve;
12

13 **FIG. 8** is an exploded perspective view of the prosthesis of the invention showing a
14 unitary stem with a tapered connection region, a sleeve with a cylindrical outer surface and
15 a tapered internal bore, and a body with a linear through-bore;
16

17 **FIG. 9** is a top view of the body component having a generally triangular shape with
18 two sharp corners and a tapered bore;
19

20 **FIG. 10** is a top view of the body component having a generally polygonal shape,
21 i.e., hemi-hexagonal, with sharp corners, and a tapered bore;
22

23 **FIG. 11** is an external view of the body of a prosthesis of the invention with a medial
24 osteotomy plane;
25

26 **FIG. 12** is a top view of the body component of **FIG. 11**;
27

28 **FIG. 13** is a sectional view, taken substantially along lines 13-13 of **FIG. 12**;
29

30 **FIG. 14** is a perspective view of a modular humeral prosthesis of the invention;

1 first end 15 of body 14 but left proud, i.e., not fully seated in the bore. Then stem 12 is
2 passed through the sleeve 16 until the desired neck height is achieved for restoring the
3 tension of the total articulated joint. Indicia could be added to allow visual recognition of the
4 height adjustment by the surgeon. Once the proper height is achieved, an axial force is
5 applied to the top 24 of sleeve 16, locking it against the bore 18. In a preferred embodiment,
6 axial force can be applied to the top 26 of neck 22 and transmitted indirectly, through the
7 bottom 20 of neck 22, to top 24 of sleeve 16. The components are actuated and locked
8 together in this manner as shown by FIGS. 1 and 4, in the case of a unitary stem 12, and
9 similarly in the case of a modular assembly. As shown in FIGS. 6-7, modular neck 22 has a
10 protrusion 27 extending distally from bottom 20 of the neck for connecting with sleeve 16.
11 Protrusion 27 may be either straight or tapered, depending upon the geometry of its
12 interconnecting member.

13
14 The sleeve 16 will now be more particularly described. Preferably, sleeve 16 is
15 radially flexible by means of a preferred split collet 28, as shown in FIGS. 3 and 3A-3B, to
16 lock the components together. The preferred split collet 28 can be made from titanium,
17 stainless steel or cobalt-chromium alloys. Sleeve 16 has bottom 25 received within bore
18 18. The same locking function is performed by sleeve 16 in the embodiments of FIGS. 6-8
19 that show a modular distal shaft 30. Alternatively, a solid construction could be employed
20 for the sleeve (not shown), using a super-elastic material that is inherently radially flexible
21 under controlled temperature conditions, e.g., a nickel-titanium alloy such as nitinol. Sleeve
22 16 has an outer surface 31 that engages bore 18.

23
24 The body 14 will now be more particularly described. As shown is FIG. 2A, taken
25 through the region of first or proximal end 15 of body 14, the body has an outer surface 32
26 with a "generally polygonal" cross-sectional shape, although the polygon is preferably a
27 triangle. Such a shape affords non-tangential contact with the intact bone, in a plane
28 perpendicular to the longitudinal axis of the bone. Together with the tapered contour in the
29 proximal-distal plane, body 14 functions as a three-dimensional wedge. By the term
30 "generally polygonal", it is meant that one or more of the sides of the polygon could be
31 either linear or slightly bowed, in a concave or convex manner. However, substantially
32 linear sides are preferred. The degree to which the sides may be bowed should not defeat

1 the function of the angular corners 34 shown in FIGS. 1, 2, 2A, 2C and 4-10, as well as in
2 FIGS. 11-12 that will be described below.

3
4 The centroid (not shown) of the proximal polygonal cross-sectional shape of body 14
5 need not coincide with axis A of bore 18. Likewise, the centroid (not shown) of the distal
6 cross-section (FIG. 2B) which could be polygonal or preferably round, need not coincide
7 with the axis A of bore 18, although such coincidence is preferred. Neither of the first 15
8 and second 17 ends of body 14 need be perpendicular to the axis A of bore 18, yet, it is
9 preferred that ends 15, 17 are perpendicular to axis A. As shown in FIGS. 11-13, body 14
10 has a planar osteotomy surface 35, oriented at a selected angle relative to axis A, such that
11 the distance between the axis A and the edge of the outer surface 32 increases in a
12 direction from the first end of the body toward the second end of the body. The planar
13 surface 35 generally corresponds to the location of an osteotomy cut. Either of the surfaces
14 15 or 35 could optionally carry a collar member (not shown) that is meant to rest on the end
15 of the bone, where clinically indicated, to help prevent linear subsidence of the body
16 component axially into the bone cavity. As to the function of the cross-sectional shape,
17 however, the body geometry shown in FIGS. 11-13 has the same function as in the other
18 embodiments previously discussed. That is, the corners 34 incise into the bone to provide
19 rotatory stability to the implanted prosthesis 10, while effectively loading the bone.

20
21 Reference is now made to the three views of sleeve 16 shown in FIG. 3. An outer
22 surface 31 of sleeve 16 contacts bore 18 and creates a lock between stem 12 and body 14,
23 while an inner bore 36 of the sleeve creates a lock between stem 12 and the body, when
24 axial force is applied to the assembled components. Sleeve 16 is radially flexible about axis
25 A of bore 18, by means of collet 28. As with the first 15 and second 17 ends of body 14, the
26 opposed top 24 and bottom 25 of sleeve 16 need not lie in planes that are parallel to one
27 another, although such is preferred. As shown in of FIG. 3A, sleeve 16 may have either a
28 straight or tapered bore 36. Similarly, the outer surface 31 of sleeve 16 could be tapered or
29 straight. The sleeve may have bore 36 of different diameters correspond to the different
30 outer diameters of the stem 12, respectively. The thickness of the wall defined between the
31 inner diameter of the bore 36 and outer diameter to the surface 31 may be varied to
32 accommodate different corresponding diameter sizes of the stem.

1 Although a single through-bore 18 is preferred, separate bores (not shown) could be
2 used to receive each of the distal shaft and neck components, as in the case of a modular
3 stem construction contemplated by FIGS. 6-7. In a modular construction, shaft 30 has a free
4 end or distal tip 37 that is received within the medullary canal of the femur, in the case of hip
5 prosthesis 10.

6
7 In the top and external views of FIG. 3, top 24 of sleeve 16 has an optional upper
8 shoulder 38 that is spaced from surface 15 of body 14. In FIG. 8 an embodiment is shown
9 wherein the optional shoulder 38 stops the sleeve 16 from falling through the bore 18 in
10 body 14 which is necessary since the bore 18 and outer surface 31 of sleeve 16 are both
11 straight rather than tapered. When the stem 12 is passed through the sleeve 16 the taper
12 connection region 40 adjacent the bottom 20 of neck 22 spreads the collet 28 of sleeve 16
13 and locks the components together. Shoulder 38 has an underside 42 that abuts the outer
14 periphery of bore 18 and stops the sleeve 16 from falling through the bore 18. Alternatively
15 instead of the shoulder 38 limiting axial motion of the sleeve relative to the bore, the bore
16 could have a counter-sunk inlet (not shown) that would abut the bottom 25 of sleeve 16 and
17 arrest its downward motion in the bore. The leg length could be adjusted by using different
18 height shoulders 38.

19
20 Referring to FIGS. 1, 4, 6 and 7-8, neck 22 carries a joint motion surface via tapered
21 connector 44 to which a ball (not shown) may be attached having the acetabular fit needed
22 to ensure proper articulation and total joint tension. Distal shaft 30 could be coated, fluted,
23 slotted or the like. The connection region 40, although shown with a tapered diameter in
24 FIG. 8, as well as in a unitary stem 12 or modular neck 22 and shaft 30 configuration, can
25 also have a straight diameter in the other embodiments described. Region 40 is adjacent a
26 fixed or proximal end 41 of modular shaft component 30 (FIGS. 6-7), which is longitudinally
27 opposed from distal tip 37. End 41 is received within sleeve 16.

28
29 Reference is now made to FIG. 5, showing the preferred triangular proximal cross-
30 sections of the invention versus a representative prior art collar (oval and keyhole shapes) in
31 an actual cadaver bone. Superimposed on the prior keyhole shape is the triangular cross-
32 section of the invention. By contrast, the prior art relies upon circumferential and, ultimately

1 tangential contact with the bone and does not present a multi-axial wedged shape that
2 reaches out and incises into intact bone in the lateral regions of the proximal femoral cavity,
3 as does the present design. This structural difference results in a crucial functional
4 distinction.

5
6 In FIGS. 9-10, two preferred polygonal shapes are shown for body 14, taken cross-
7 sectionally in the region of first end 15 adjacent neck 22. In FIG. 12, body 14 has a
8 generally triangular cross-section, with at least two corners 34 on its outer surface 32,
9 whereas, in FIG. 13 there is shown another polygonal shape, i.e., partially hexagonal, which
10 presents such corners 34. The necessity for biting into intact bone, in the case of hip
11 arthroplasty, is most important in the lateral aspect of the femoral cavity, which is less
12 exposed than the medial aspect. This is because the femoral head is resected, exposing
13 the entire proximal medial cavity to the surgeon. This is not so laterally, hence the geometry
14 of the body of the present invention which can reach out and bite into the lateral intact bone.
15 An oval shape does not do this. Bore 18 of body 14 has a tapered portion 46 adjacent the
16 top or proximal end 15, for mating engagement with either sleeve 16 or a tapered stem.

17 Although the invention has been described with reference to a prosthesis 10
18 designed for hip arthroplasty, it must be understood that this invention may be used in other
19 types of arthroplasty, e.g., a shoulder joint, with certain particular adaptations as will be
20 described with reference to FIGS. 14-16 below.

21
22 Referring to FIGS. 14-16, a modular humeral prosthesis is generally shown at 110,
23 including a stem component, generally shown at 112, a body component, generally shown
24 at 114, and a sleeve component, generally shown at 116. Stem 112 has a proximal neck
25 122 and an elongated distal shaft 130 with tip 137 for implantation in the intramedullary
26 canal of a patient. Neck 122 has a first means, in the form of tapered male connector 144,
27 presenting a joint motion surface on which a humeral head component, generally shown at
28 139, is attached by a mating female connector on the underside (not shown) of the head.
29 Body component 114 includes a bore (not shown) defining at least a first axis. Radially
30 expandible sleeve 116 has opposed ends 124, 125, one end 125 received within the bore of
31 body 114 with the other end 124 projecting outwardly from the bore. The sleeve 116
32 adjustably connects stem 112 and body 114 together, radially expanding and locking them

1 in a fixed position when the sleeve is actuated. Body 114 has external surface 132 that
2 contacts the intact bone of the patient. Humeral head 139 is received within the glenoid
3 cavity (not shown) of a patient. This is analogous to the manner in which a ball (not shown)
4 having a desired size would be assembled, i.e., to the proximal connector 44 on stem 12 of
5 hip 10 (FIGS. 1, 6 and 8), for receipt within the acetabulum of a patient.
6

7 The different variations, by which the above-referenced preferred modular system of
8 FIGS. 14, 15 and 16 are constructed and assembled according to the invention, generally
9 follow the scheme shown in FIGS. 1, 6 and 8, respectively. The bore of sleeve 116 may
10 have either a cylindrical or tapered structure, depending upon the desired geometry of body
11 114 or stem 112, respectively. Likewise, the outer surface 131 of sleeve 116 could be
12 tapered or cylindrical, depending upon the desired geometry of body 114 or stem 112,
13 respectively. Neither of these various alternative combinations of geometry (tapered and
14 cylindrical) will be described in detail here, nor will their associated structures and function
15 be further mentioned, as those skilled in the art will appreciate them by careful resort to
16 FIGS. 1-13. In either case, sleeve 116 is provided with collets 128 that radially expand,
17 upon assembly, to lock body 114 and stem 112 together in fixed position, as depicted in
18 FIG. 14.

19 The stem component 112 of humeral prosthesis 110 will now be described, with
20 reference to FIGS. 14-16. Platform 133 is preferably disposed at an angle of generally
21 about 30 degrees, depending upon the patient's anatomy, with respect to the longitudinal
22 axis of distal shaft 130. This angle is generally equal to the angle between the axis of the of
23 the patient's humeral head and the patient's humeral intramedullary canal, that is, the
24 hollow interior of the proximal humerus or humeral shaft. When prosthesis 110 is implanted
25 in a patient, platform 133 acts to prevent subsidence of the implant in the intramedullary
26 canal, and to distribute anatomical loads on the proximal humerus. Neck 122 has a lateral
27 fin 135 extending outwardly therefrom in which suture holes (not shown) may be provided.
28 Tapered male connector 144 projects medially and proximally from neck 122 and mates
29 with a female connector (not shown) located within the underside (not shown) of humeral
30 head component 139 when the prosthesis is fully assembled. Stem 112 may comprise a
31 unitary or modular structure, as shown in FIGS. 15 and 16, respectively. The modular stem
32 112 of FIG. 15 functions similarly to the unitary stem 112 of FIG. 16, with respect to the

1 manner in which the stem is locked together with body 114 and sleeve 116 in fixed position.
2 In FIG. 15, stem further comprises a separate distal shaft 130 and a proximal protrusion 127
3 which components are assembled as in the preferred hip embodiment shown in FIG. 6.
4

5 Sleeve 116 with radially expanding collets 128 is of substantially the same structure
6 and performs the same function as the sleeve 16 with collets 28 described above in relation
7 to FIGS. 1-13.
8

9 Body 114 preferably has a polygonal shape, more preferably has a generally
10 triangular proximal cross-section. The structure and advantages of this geometry are as
11 described with respect to one or more embodiments of the preferred body 14 of hip
12 prosthesis 10 shown in FIGS. 1-13.
13

14 The above Description should not be construed as limiting but rather is given for
15 purposes of illustrating the invention. Obviously, persons skilled in the art could make
16 various modifications to the embodiments shown, without departing from the scope of the
17 present invention, as claimed in those claims appended to this Specification.
18

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CLAIMS:

- 1
2
3 1. A modular orthopedic prosthesis comprising:
4
5 a stem having one end with an elongated portion and another, longitudinally
6 opposed end with a first means presenting a joint motion surface;
7
8 a body including a bore defining at least a first axis and having a generally polygonal
9 cross-section with at least two angular corners adapted to bite into the bone cavity of a
10 patient to prevent rotation of the implanted prosthesis relative to the bone; and
11
12 means for connecting the stem and body together in a fixed position.
13
14 2. The prosthesis of Claim 1 wherein the body has a generally triangular cross-section.
15
16 3. The prosthesis of Claim 1 wherein the body has a single through-bore.
17
18 4. The prosthesis of Claim 1, the body having first and second ends longitudinally
19 opposed from one another along the first axis, the first end being adjacent the first means
20 and the second end being adjacent the elongated portion, the body having a generally
21 polygonal cross-section in the region of the first end of the body.
22
23 5. The prosthesis of Claim 1, the body having a planar osteotomy surface oriented at a
24 selected angle relative to the first axis, such that the distance between the axis and the
25 edge of the surface increases in a direction from the from the first end of the body toward
26 the second end of the body.
27
28 6. The prosthesis of Claim 4, the body having a generally circular cross-section in the
29 region of the second end of the body.
30
31 7. The prosthesis of Claim 1, the first means further comprising a neck operatively
32 connected to the body in the region of the first end.

1 8. The prosthesis of Claim 1, the elongated portion further comprising a shaft having a
2 free end with a tip and a fixed end opposite the tip wherein the bore of the body is adapted
3 to receive the fixed end for assembly with the body.

4

5 9. The prosthesis of Claim 1 wherein the stem further comprises a neck, carrying the
6 joint motion surface, and a shaft opposite the neck, the shaft being adapted for receipt
7 within the medullary canal of a bone, the stem passing through the bore and being attached
8 to the body in a fixed position along the first axis.

9

10 10. The prosthesis of Claim 1, wherein the neck and shaft each comprise separate
11 modular articulating components of the stem.

12

13 11. The prosthesis of Claim 10, the stem further comprising a neck attached to the body
14 along the first axis.

15

16 12. The prosthesis of Claim 10 wherein the elongated portion is attached to the body
17 along the first axis.

18

19 13. The prostheses of Claim 1 wherein the sleeve comprises a super-elastic material.

20

21 14. The prostheses of Claim 13 wherein the super-elastic material is nitinol.

22

23 15. The prosthesis of Claim 1 wherein the bore of the body and an outer surface of the
24 sleeve have mating tapers which, when seated together, activate the stem and body to lock
25 together in fixed relative position.

26

27 16. The prosthesis of Claim 1, the sleeve having an inner bore that is tapered and the
28 stem having at least one corresponding outer surface that is tapered wherein the mating
29 tapers, when engaged, activate the stem and body to lock together in fixed relative position.

30

31 17. A modular orthopedic prosthesis comprising;

32

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1 a stem component having one end with an elongated portion and another,
2 longitudinally opposed end with a first means presenting a joint motion surface;

3
4 a body component including a bore defining at least a first axis; and

5
6 a radially expansible sleeve having opposed ends, one end received within the bore
7 and the other end projecting outwardly from the bore, the sleeve connecting the stem and
8 body together in a fixed position.

9
10 18. The prosthesis of Claim 17 wherein the body has a polygonal cross-section with at
11 least two angular corners adapted to bite or incise into the bone cavity of a patient to
12 prevent rotation of the implanted prosthesis relative to the bone.

13
14 19. The prosthesis of Claim 17, the sleeve further comprising a collet having a bore
15 wherein the stem is received within the bore of the collet, the stem and collet together being
16 further received within the bore of the body to lock them together.

17
18 20. The prosthesis of Claim 19, the sleeve further comprising a split collet.

19
20 21. The prosthesis of Claim 19 wherein the collet has a distal insertion end for receipt
21 within the bore along the first axis and an opposed, proximal end including an annular
22 flange.

23
24 22. The prosthesis of Claim 19 wherein the annular flange comprises a spacer shoulder
25 having a selected thickness.

26
27 23. The prosthesis of Claim 17 wherein the stem comprises a unitary member.

28
29 24. The prosthesis of Claim 17, the first means further comprising a neck wherein the
30 receives the neck for assembly with the body.

31

1 25. The prosthesis of Claim 17, the elongated portion further comprising a shaft having a
2 free, distal end with a tip and a fixed, proximal end opposite the tip wherein the receives the
3 fixed end for assembly with the body.

4
5 26. The prosthesis of Claim 17 wherein the stem further comprises a neck, carrying the
6 joint motion surface, and a shaft opposite the neck, the shaft having a distal tip adapted for
7 receipt within the medullary canal of a bone, the stem passing through the bore and being
8 attached to the body in a fixed position along the first axis.

9
10 27. The prosthesis of Claim 26, the stem further comprising a neck attached to the body
11 along the first axis.

12
13 28. The prosthesis of Claim 27 wherein the elongated portion is attached to the body
14 along the first axis.

15
16 29. The prostheses of Claim 17 wherein the neck and the shaft comprise separate
17 modular components of the stem.

18
19 30. The prostheses of Claim 17 wherein the body has an upper face defining an outer
20 periphery of the bore, the sleeve having an end received within the bore and an opposite
21 end with an annular flange juxtaposed with the outer periphery.

22
23 31. The prostheses of Claim 17 wherein the annular flange has a shoulder with an upper
24 surface and the first means includes a neck with an abutment surface contacting the upper
25 surface of the shoulder as the stem is locked within the body.

26
27 32. The prostheses of Claim 17 wherein the first means of the stem comprises a
28 separate neck component and the elongated portion a separate shaft component, the neck
29 having means adjacent the body for connecting within the bore of the sleeve, the shaft
30 having a free end and a fixed end, the fixed end passing through the bore of the body and
31 into the bore of the sleeve.

32

1 33. The prostheses of Claim 17 wherein the sleeve comprises an annular collet made of
2 a super-elastic material.

3

4 34. The prostheses of Claim 33 wherein the super-elastic material is nitinol.

5

6 35. The prosthesis of Claim 17 wherein the bore of the body and an outer surface of the
7 sleeve have mating tapers which, when seated together, activate the stem and body to lock
8 together in fixed relative position.

9

10 36. The prosthesis of Claim 17, the sleeve having an inner bore that is tapered and the
11 stem having at least one corresponding outer surface that is tapered wherein the mating
12 tapers, when engaged, activate the stem and body to lock together in fixed relative position.

13

14 37. A modular orthopedic prosthesis comprising:

15

16 a stem having one end with an elongated portion and another, longitudinally
17 opposed end with a first means presenting a joint motion surface;

18

19 a body including a bore defining at least a first axis and having a polygonal cross-
20 section with at least two angular corners adapted to bite into the bone cavity of a patient to
21 prevent rotation of the implanted prosthesis relative to the bone; and

22

23 a radially expansible sleeve having opposed ends and a bore, one end of the sleeve
24 being received within the bore of the body and another end projecting outwardly from the
25 bore of the body, wherein the stem is received within the bore of the sleeve, the stem and
26 sleeve together being further received within the bore of the body to connect the stem and
27 body together in a fixed position.

28

29 38. The prosthesis of Claim 37, the first means of the stem comprising a neck and the
30 elongated portion comprising a shaft, the bore of the body being a through-bore, wherein
31 the neck and shaft are a unitary member received in the through-bore.

32

- 1 **39.** The prosthesis of Claim 37, the first means of the stem comprising a neck and the
2 elongated portion comprising a shaft, the bore of the body being a through-bore, wherein
3 the neck and shaft are separate members each received within the through-bore.
4
- 5 **40.** The prosthesis of Claim 37, the body having first and second ends longitudinally
6 opposed from one another along the first axis, the first end being adjacent the first means
7 and the second end being adjacent the elongated portion, the body having a generally
8 triangular cross-section in the region of the first end of the body.
9
- 10 **41.** The prosthesis of Claim 40, the body having a generally circular cross-section in the
11 region of the second end of the body.
12
- 13 **42.** The prosthesis of Claim 37 wherein the sleeve comprises a split collet.
14
- 15 **43.** The prosthesis of Claim 37, the body having a pair of ends longitudinally opposed
16 from one another along the first axis of the bore with one of the ends presenting a top
17 surface adjacent the first means and another end being adjacent the elongated portion,
18 wherein the collet further has an end received within the bore of the body and an opposed
19 end spaced from the top of the body.
20
- 21 **44.** The prosthesis of Claim 37, wherein the collet has an annular flange on the end of
22 the collet that is spaced from the top surface of the body, the flange being of a larger size
23 than the bore of the body and limiting motion of the collet within the bore.
24
- 25 **45.** The prosthesis of Claim 37 wherein the sleeve comprises an annular collet made of
26 a super-elastic material.
27
- 28 **46.** The prosthesis of Claim 45 wherein the super-elastic material is nitinol.
29
- 30 **47.** The prosthesis of Claim 37 wherein the bore of the body and an outer surface of the
31 sleeve have mating tapers which, when seated together, activate the stem and body to lock
32 together in fixed relative position.

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1 48. The prosthesis of Claim 37, the sleeve having an inner bore that is tapered and the
2 stem having at least one corresponding outer surface that is tapered wherein the mating
3 tapers, when engaged, activate the stem and body to lock together in fixed relative position.
4

5 49. A modular orthopedic prosthesis comprising:
6

7 a stem having one end with a neck presenting a joint motion surface and another,
8 longitudinally opposed end having a shaft;
9

10 a body including a through-bore having at least a tapered portion, defining a first
11 axis, the body having first and second ends longitudinally opposed from one another along
12 the first axis, the first end being adjacent the neck and presenting an upper face, the second
13 end being adjacent the shaft, the body having a generally triangular cross-section in the
14 region of its first end with at least two angular corners adapted to bite and incise into the
15 bone cavity of a patient to prevent rotation of the implanted prosthesis relative to the bone,
16 the body having a generally circular cross-section in the region of the second end; and
17

18 a radially expansible collet having opposed ends including an internal bore and a
19 tapered external surface mating with the tapered portion of the bore, the collet being
20 received within the bore of the body and projecting outwardly from the bore of the body,
21 wherein the stem is received within the bore of the sleeve, the stem and sleeve together
22 being further received within the bore of the body to lock the stem and body together in a
23 fixed position as the mating tapers are engaged.
24

25 50. The prosthesis of Claim 49 wherein the stem comprises a unitary member.
26

27 51. The prostheses of Claim 49 wherein the neck and the shaft comprise separate
28 modular components of the stem.
29

30 52. A modular humeral prosthesis comprising:
31

1 a humeral stem having a proximal neck, carrying a joint motion surface, and a shaft
2 opposite the neck, the shaft having a distal tip adapted for receipt within the medullary canal
3 of the humerus;

4
5 a body including a bore defining at least a first axis, the shaft being received by the
6 body; and

7
8 a radially expansible sleeve having opposed proximal and distal ends, the distal end
9 received within the bore and the proximal end projecting outwardly from the bore, the sleeve
10 connecting the stem and body together in a fixed position.

11
12 53. The humeral prosthesis of Claim 52, the neck having a platform and a connector
13 projecting proximally from the platform, with a fin extending laterally from the neck.

14
15 54. The humeral prosthesis of Claim 53 further comprising a humeral head component
16 having an outer hemispherical surface, adapted to be received within the glenoid cavity,
17 the head further including a connector that mates with the connector of the neck.

18
19 55. The humeral prosthesis of Claim 54, the sleeve further comprising a split collet.

20
21 56. The humeral prosthesis of Claim 55 wherein the shaft and neck further comprise
22 separate, modular components of the stem.

23
24 57. The humeral prosthesis of Claim 55 wherein the shaft and neck further comprise a
25 unitary structure.

26
27 58. The humeral prosthesis of Claim 52 wherein the sleeve comprises an annular collet
28 made of super-elastic material.

29
30 59. The humeral prosthesis of Claim 55 wherein the super-elastic material is nitinol.

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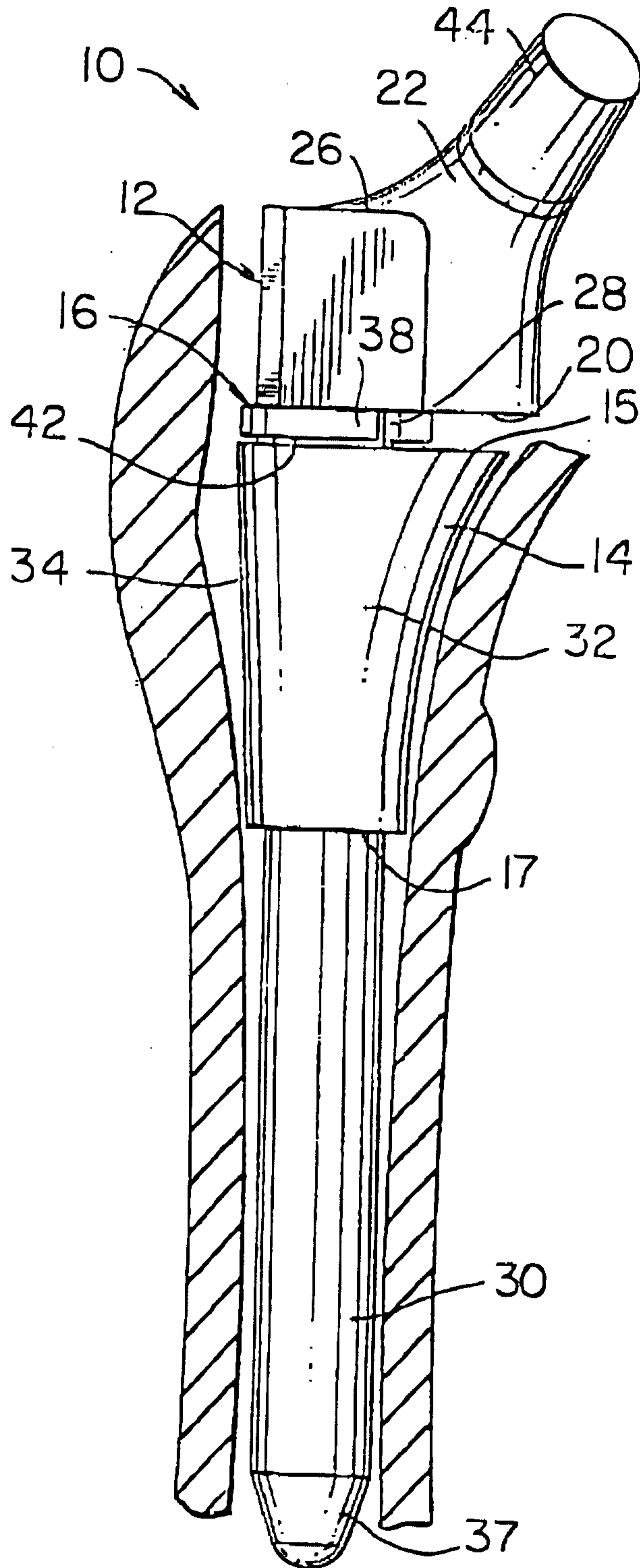


FIG. 1

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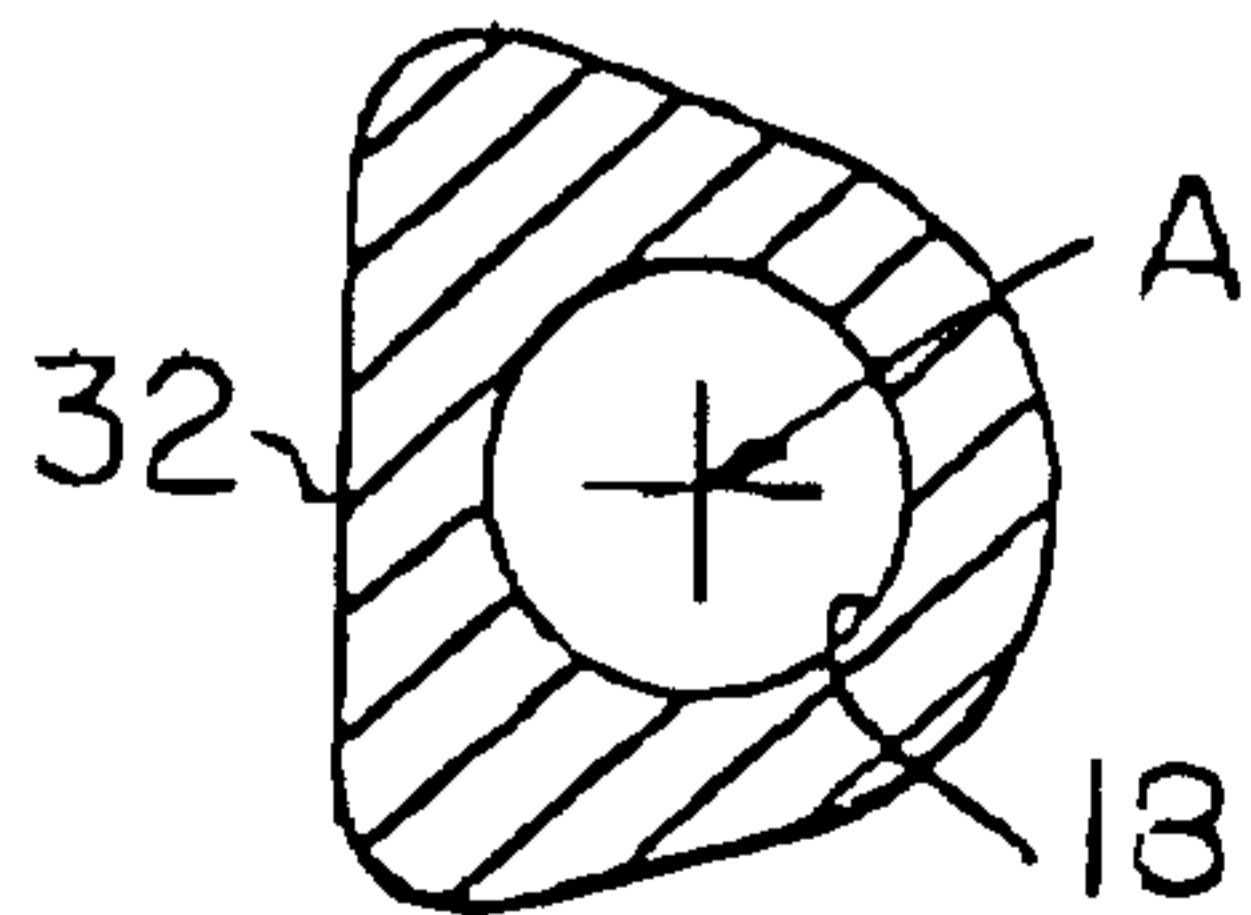
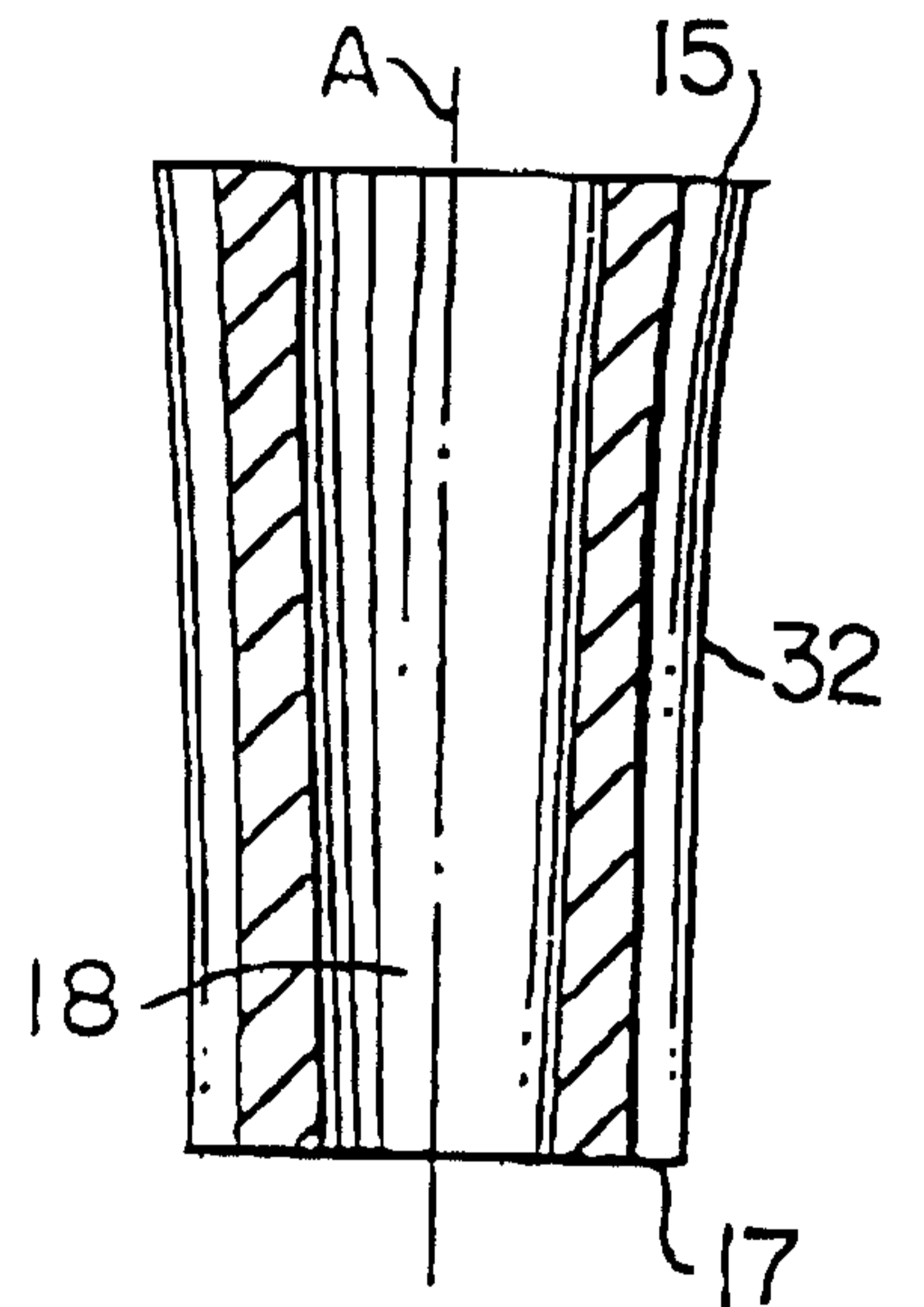
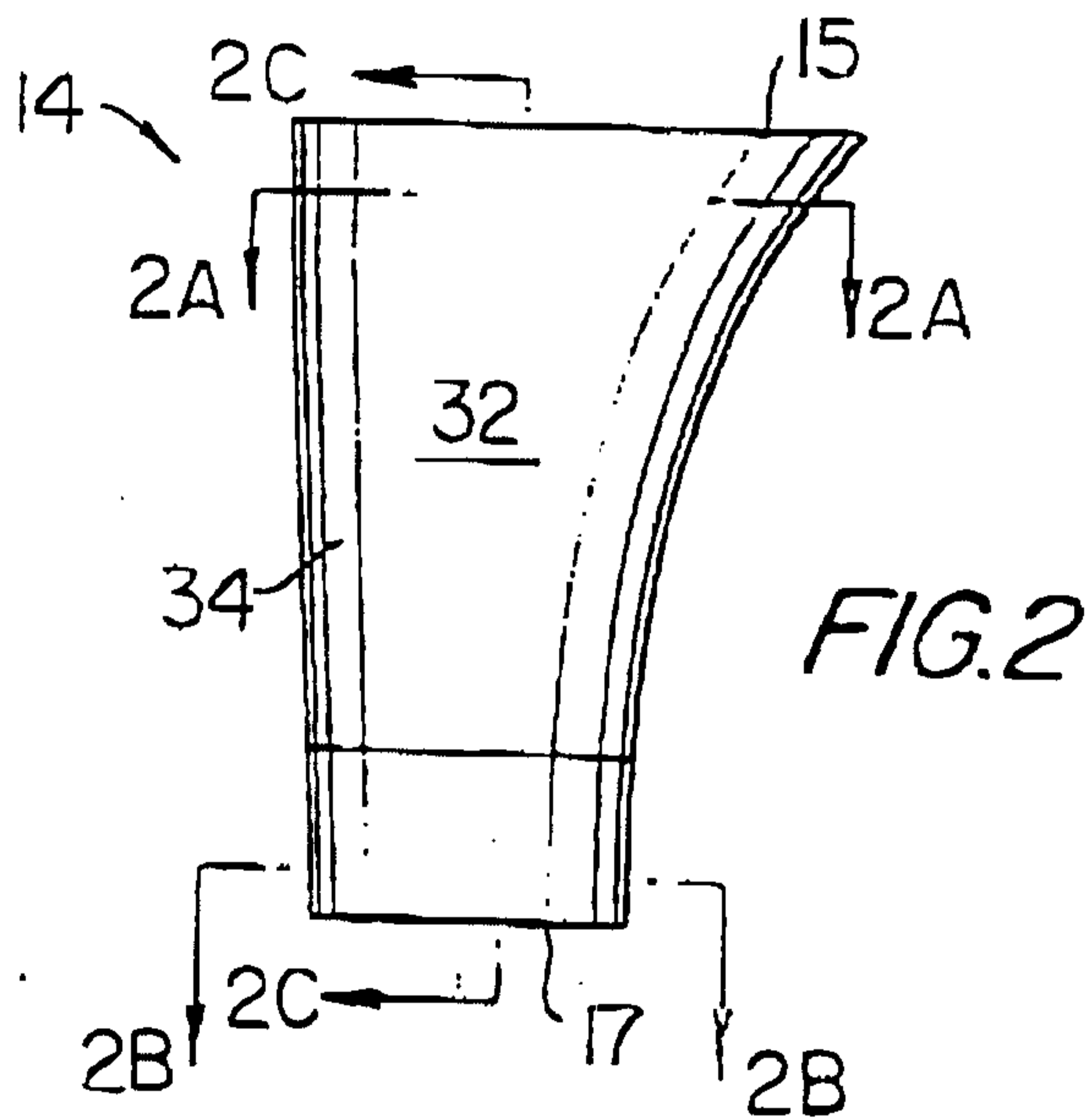
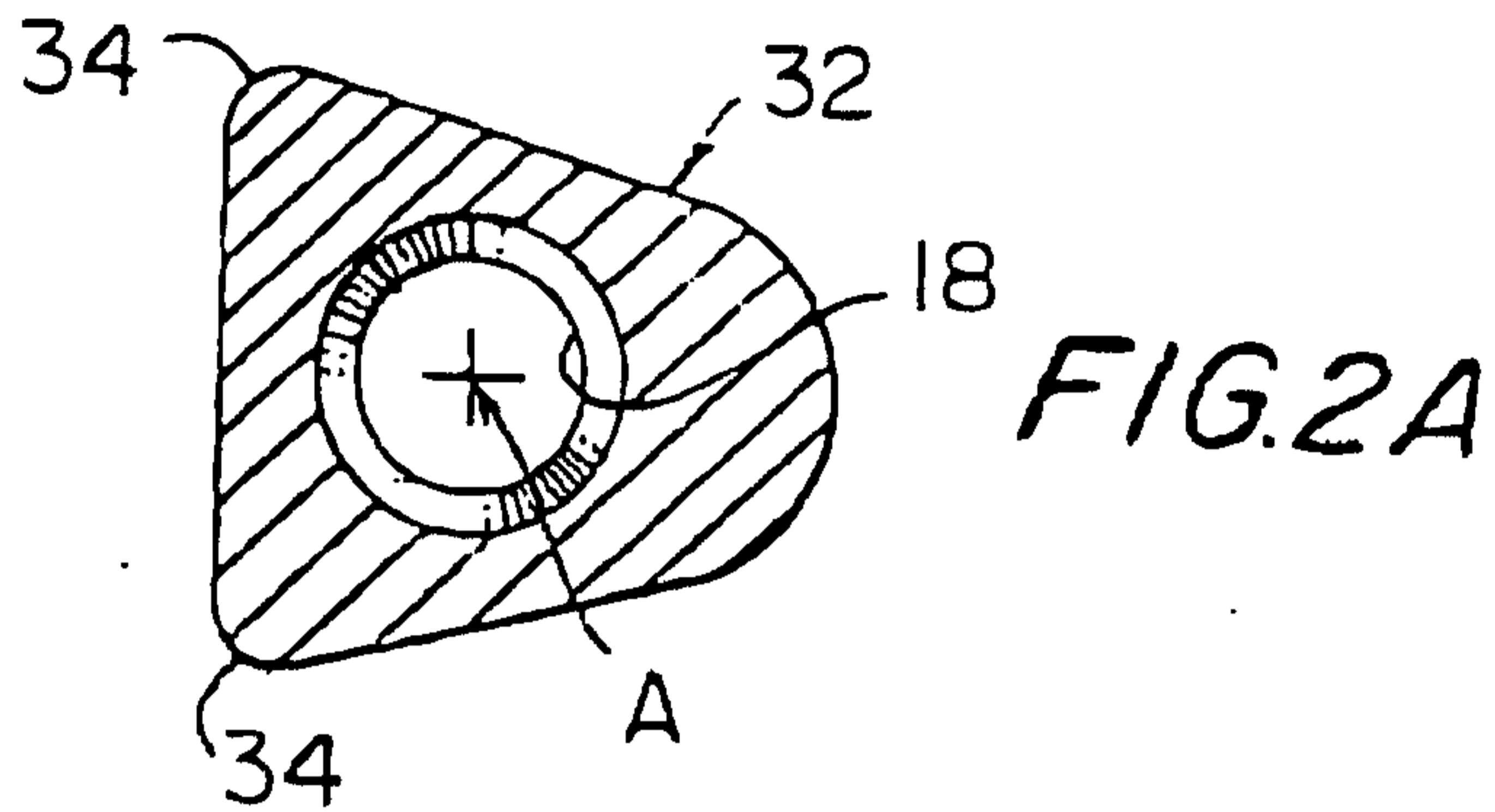


FIG. 2B

FIG. 2C

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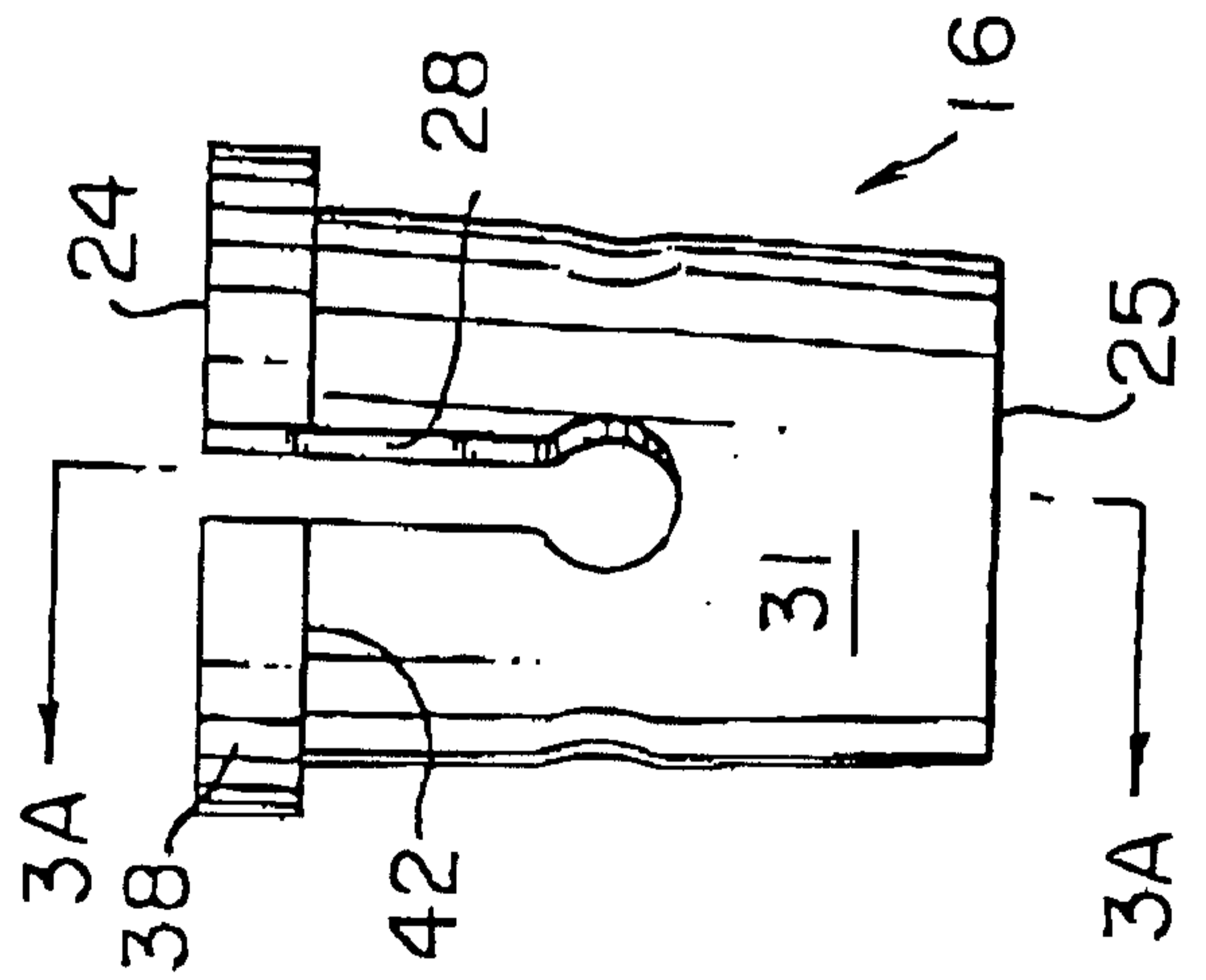
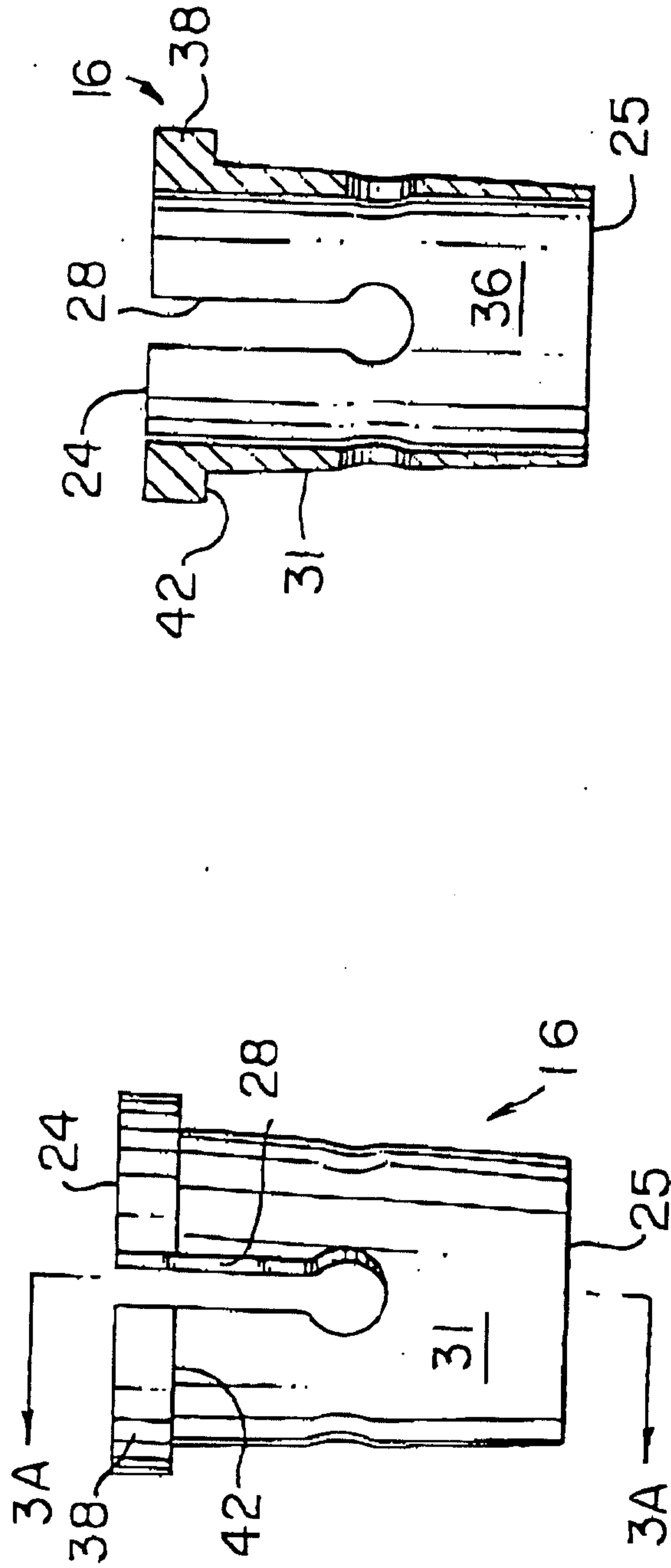
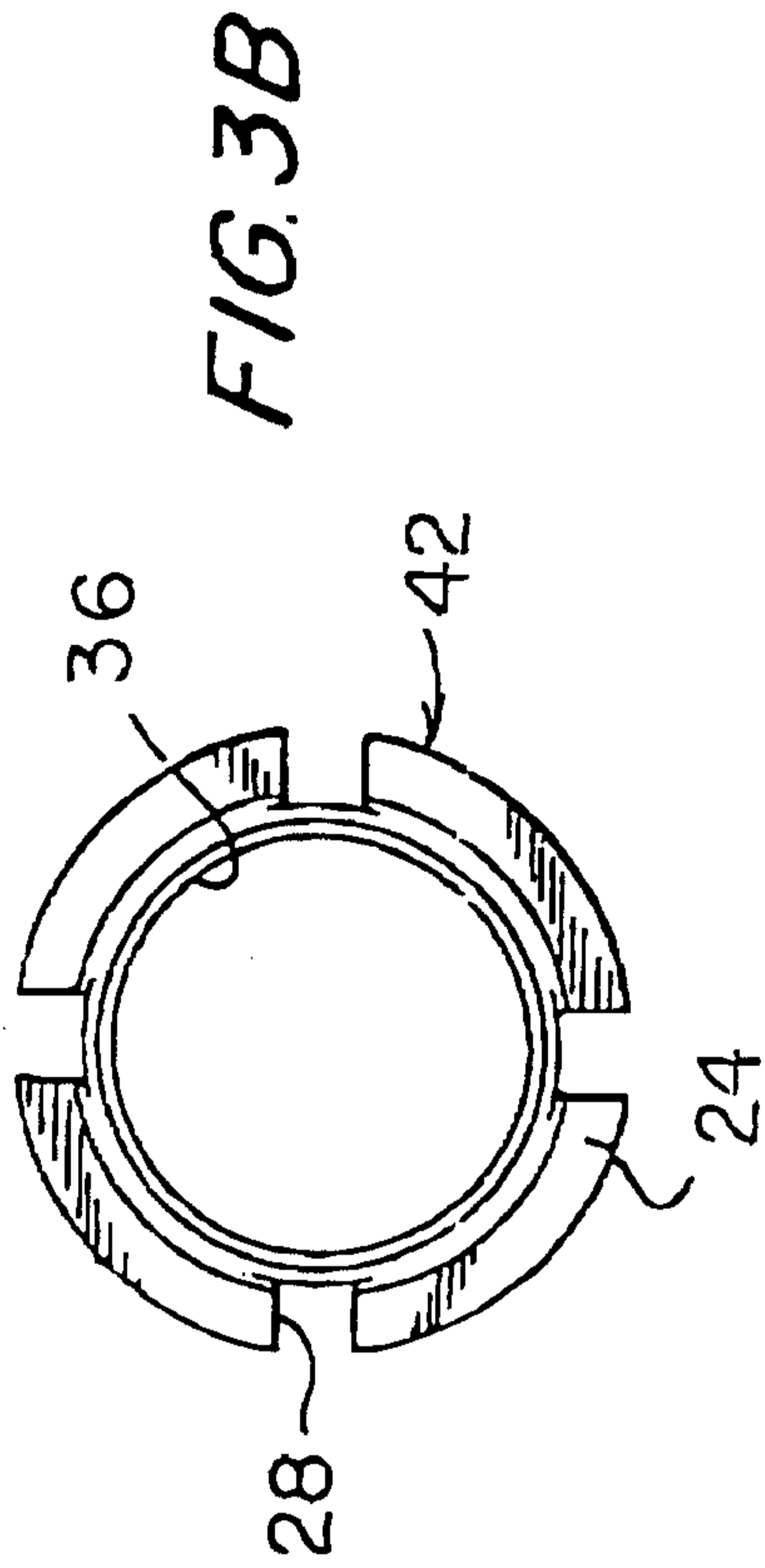


FIG. 3A

FIG. 3

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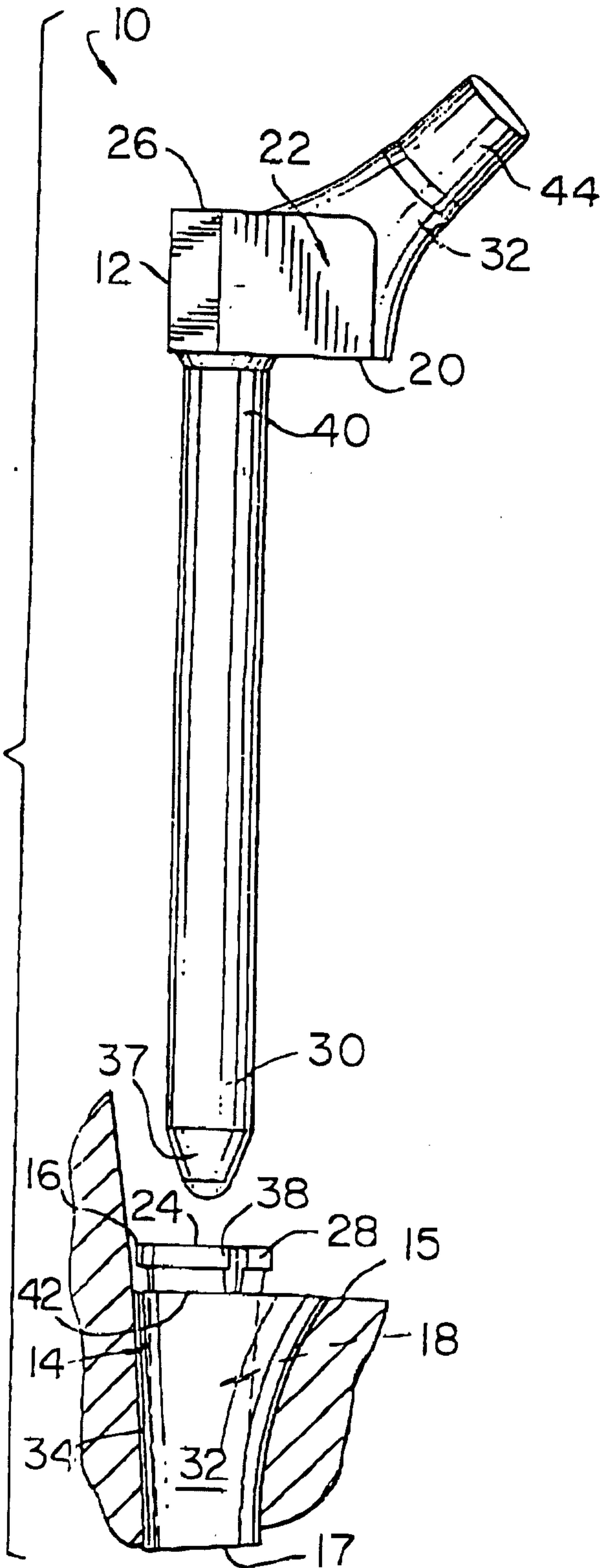


FIG. 4

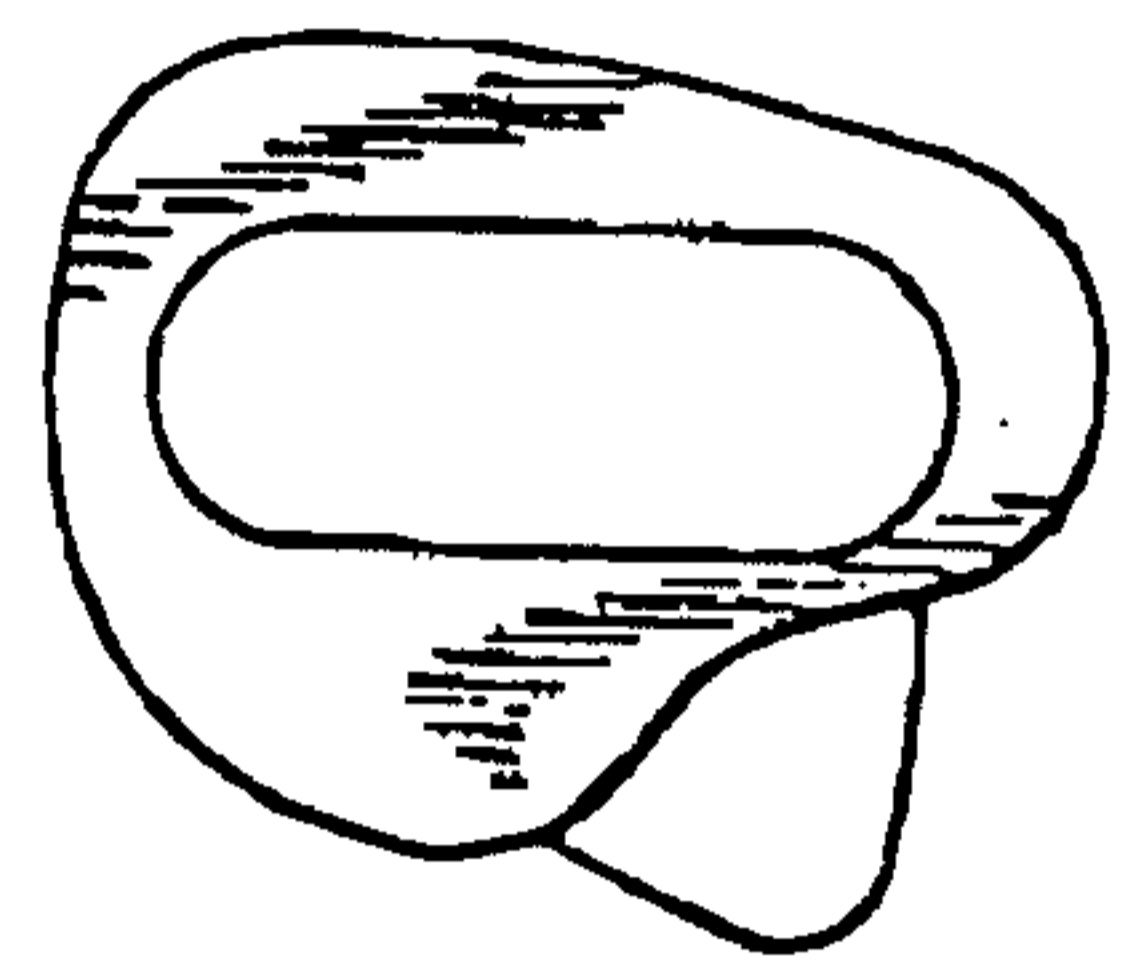


FIG. 5A

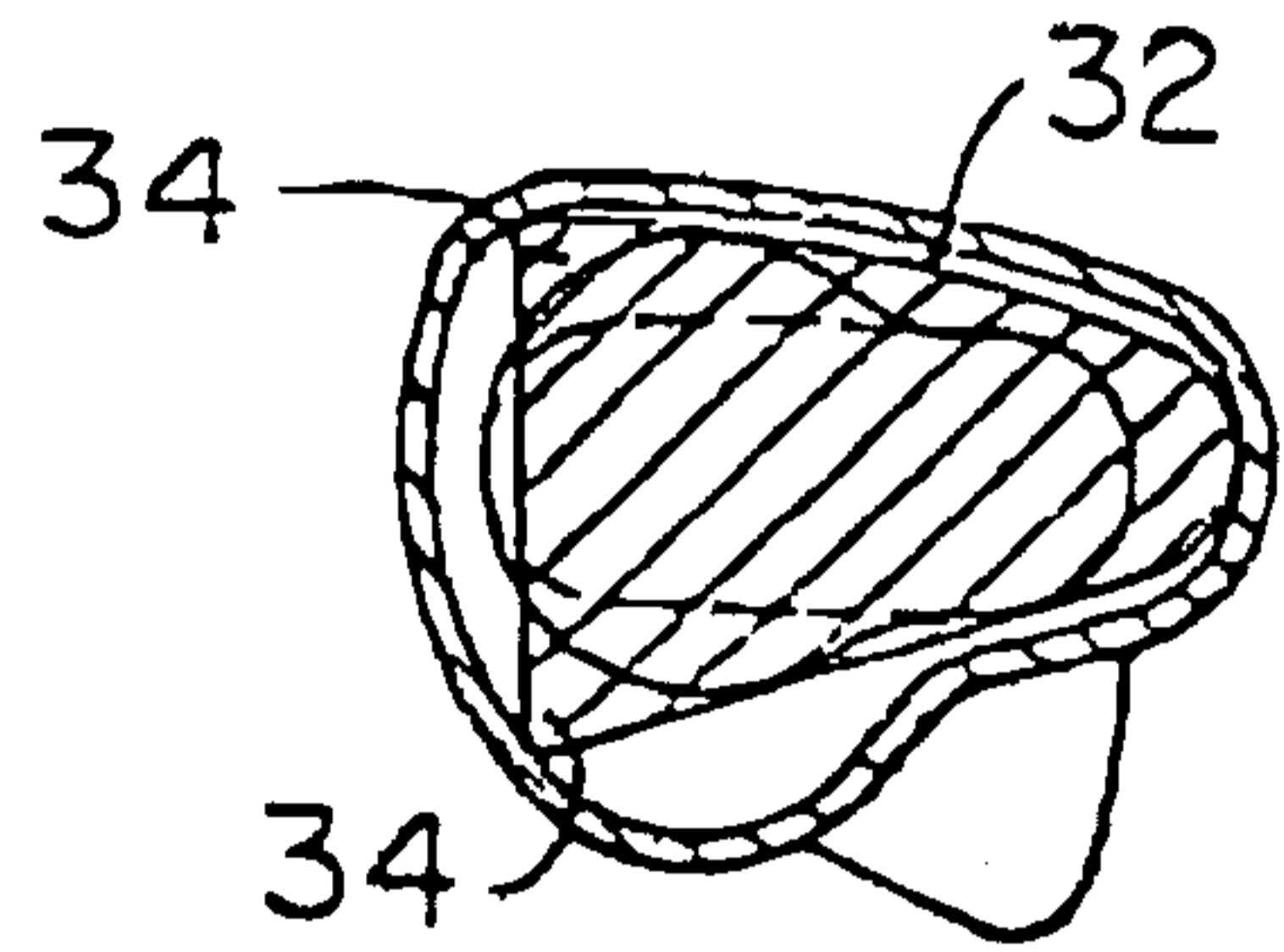


FIG. 5B

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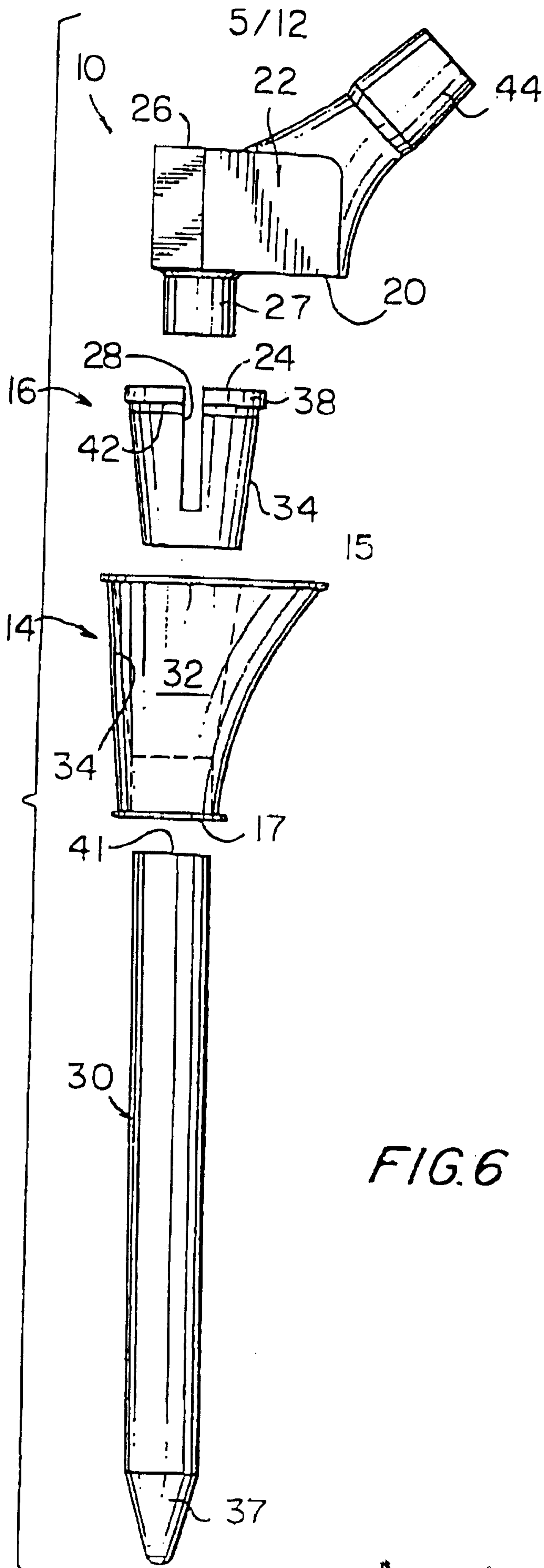


FIG. 6

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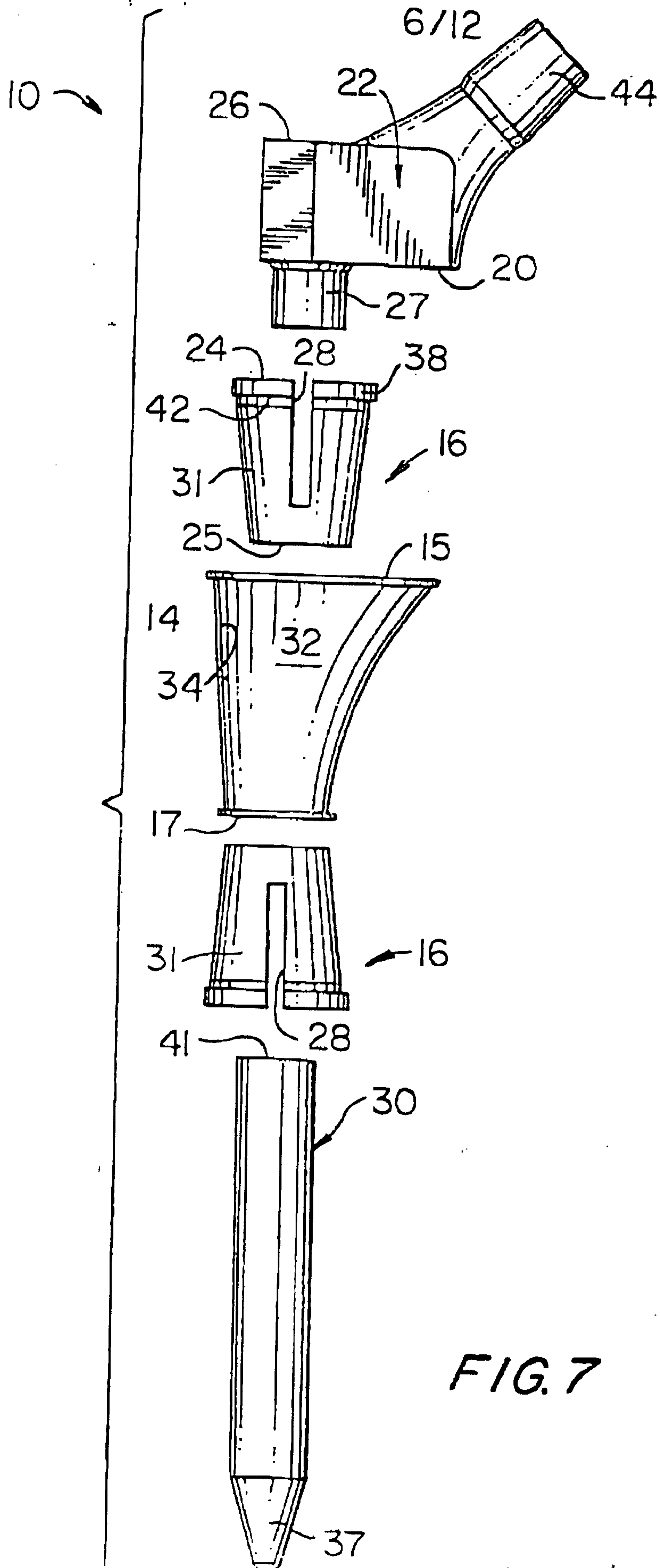


FIG. 7

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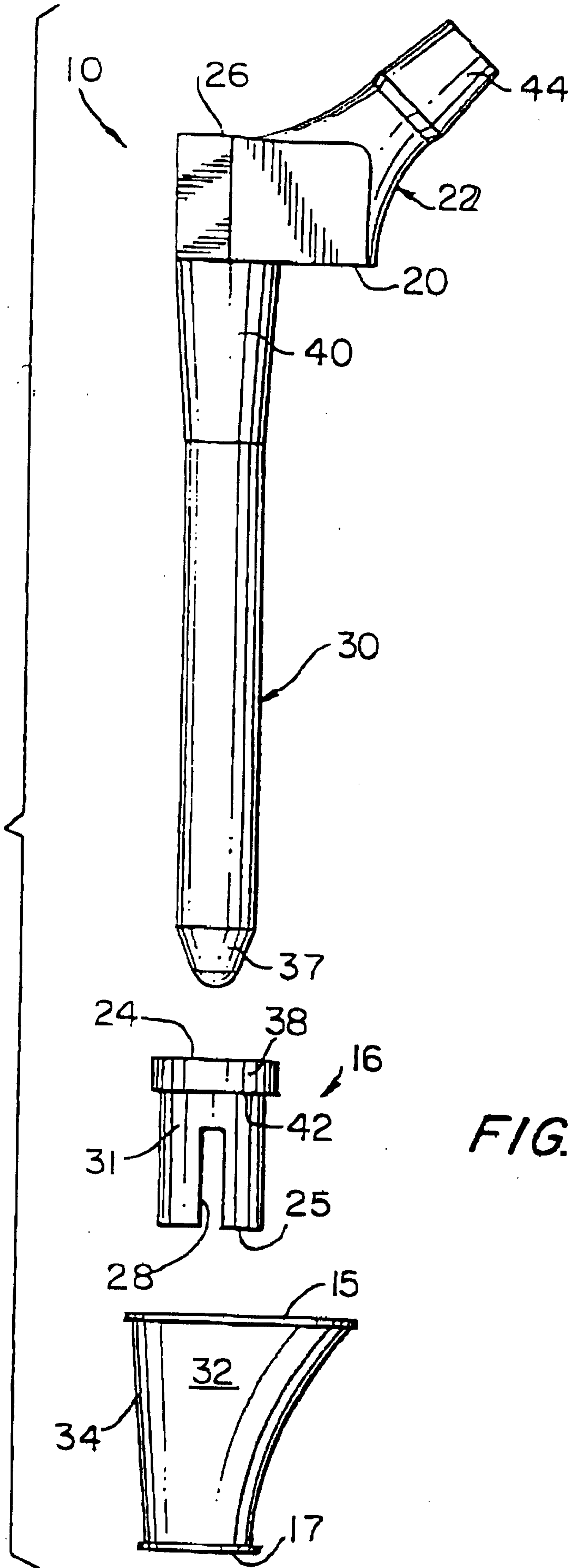


FIG. 8

AMENDED SHEET (ARTICLE 19)

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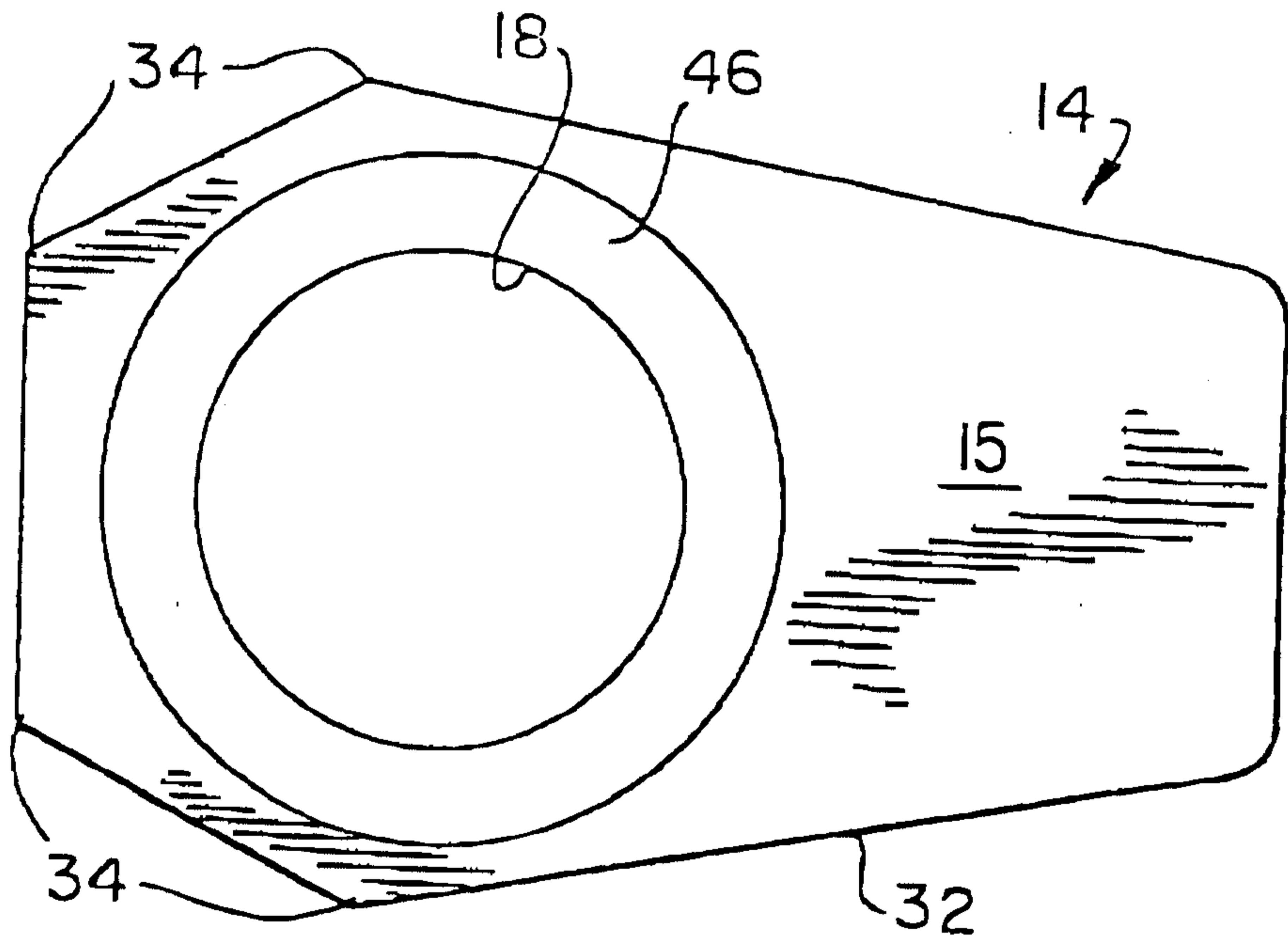
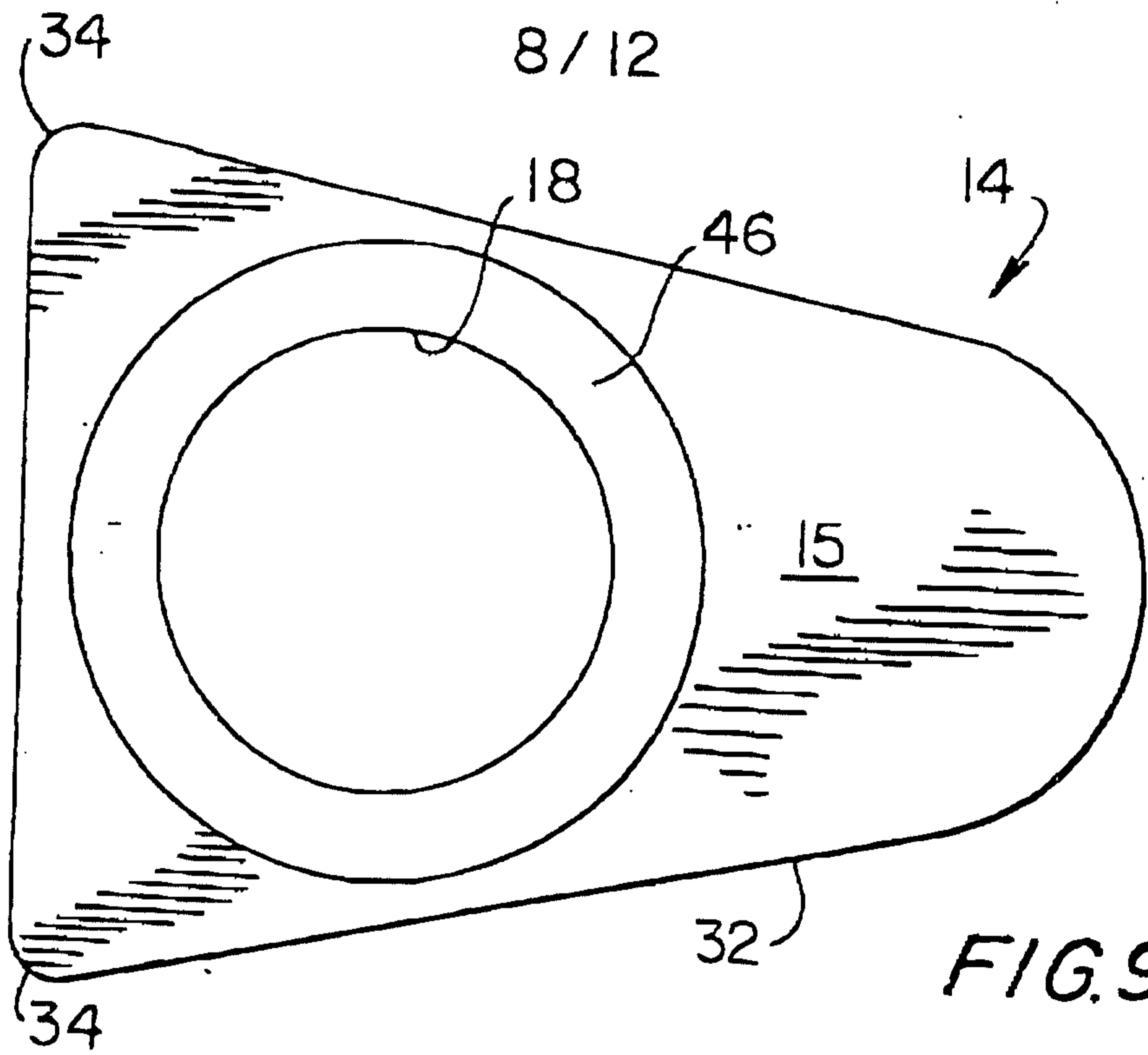


FIG. 10

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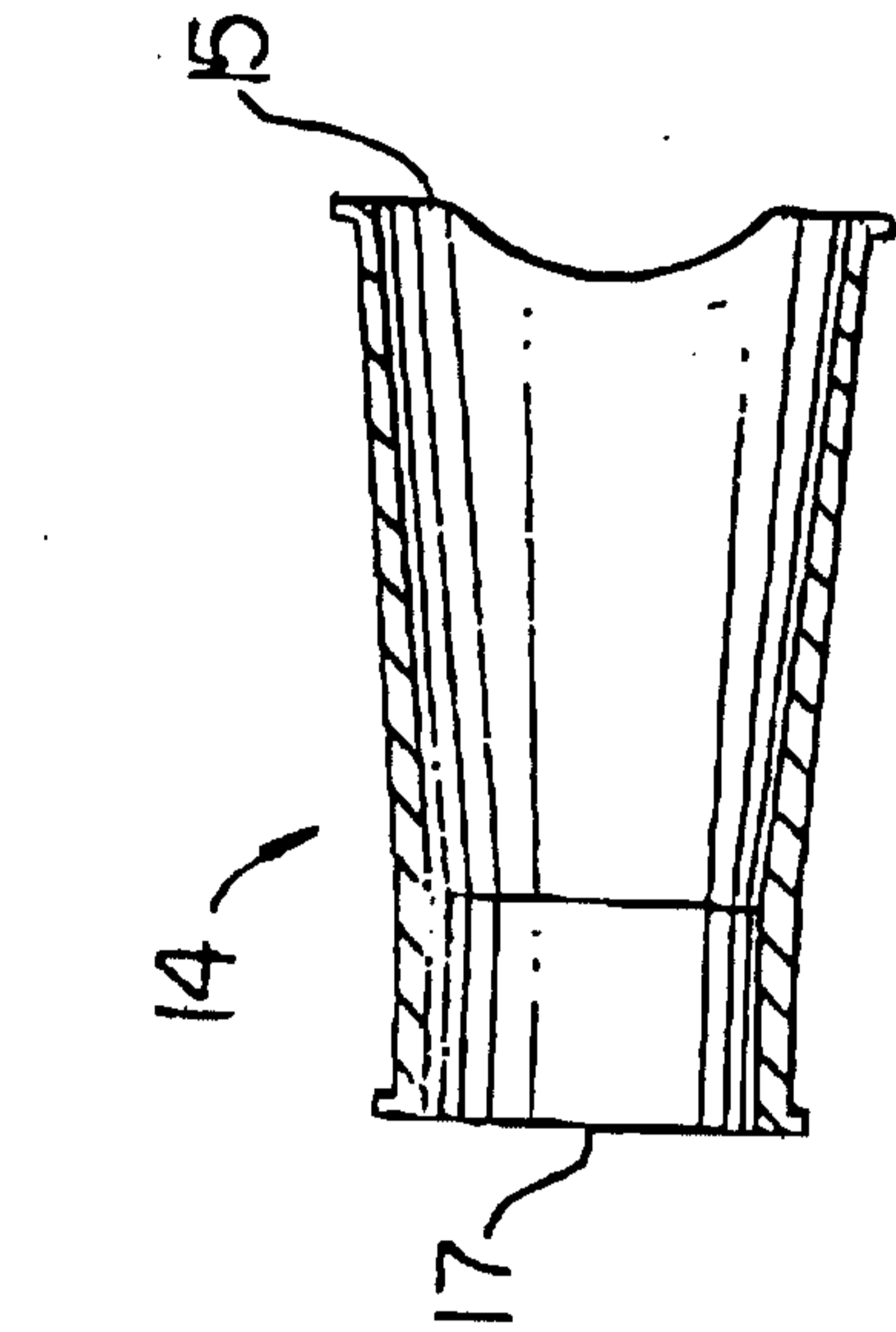


FIG. 13

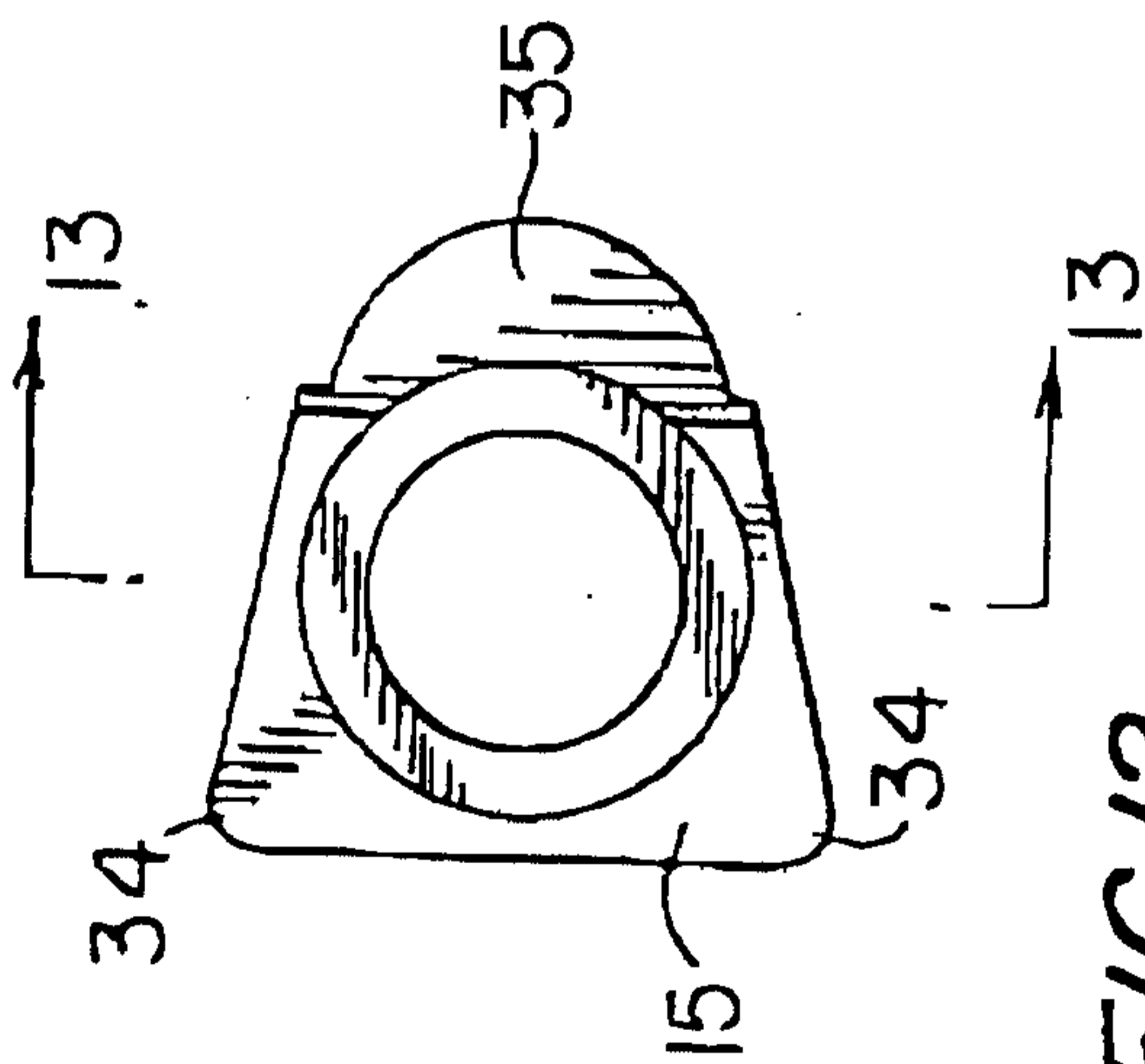


FIG. 12

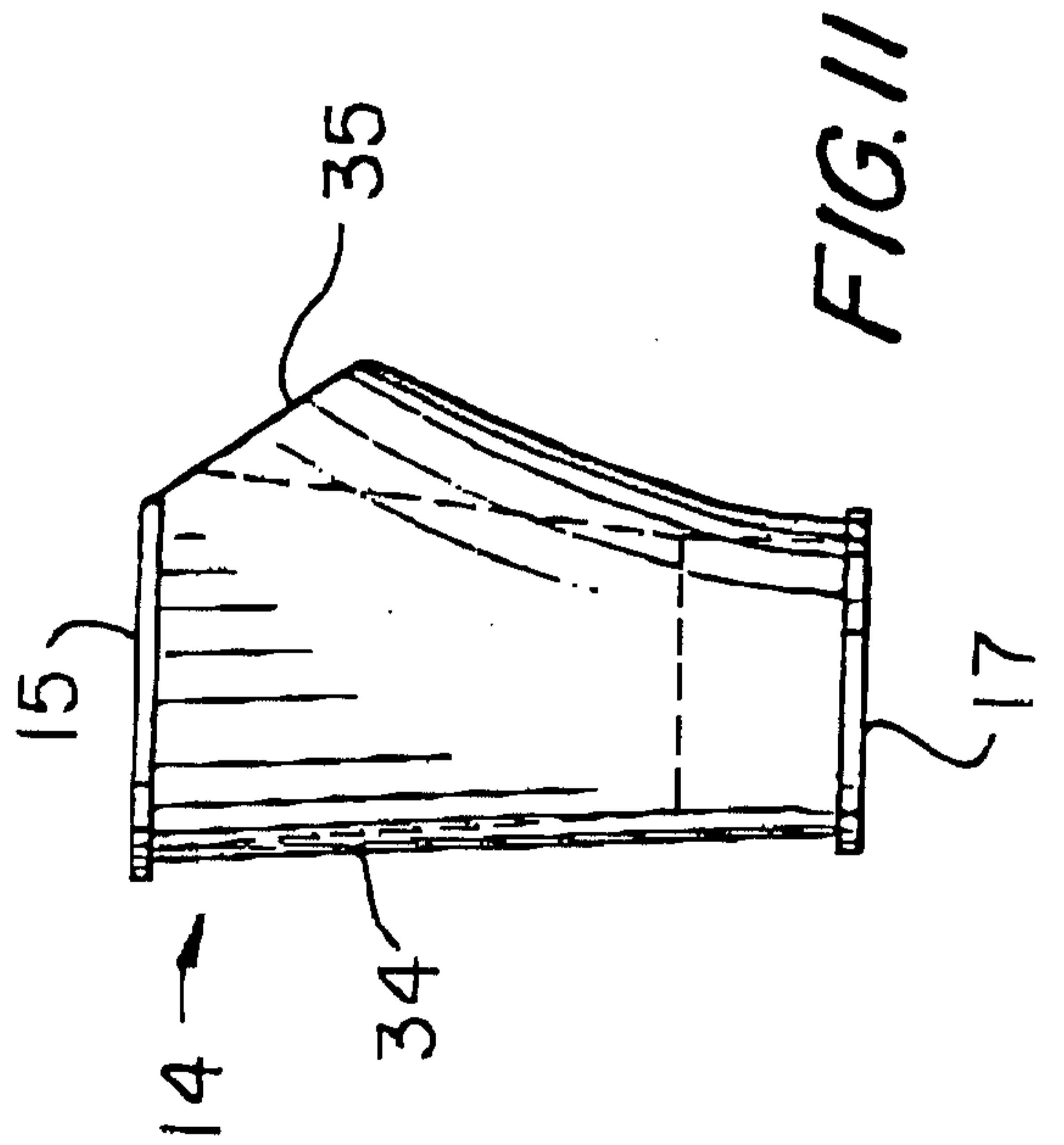


FIG. 11

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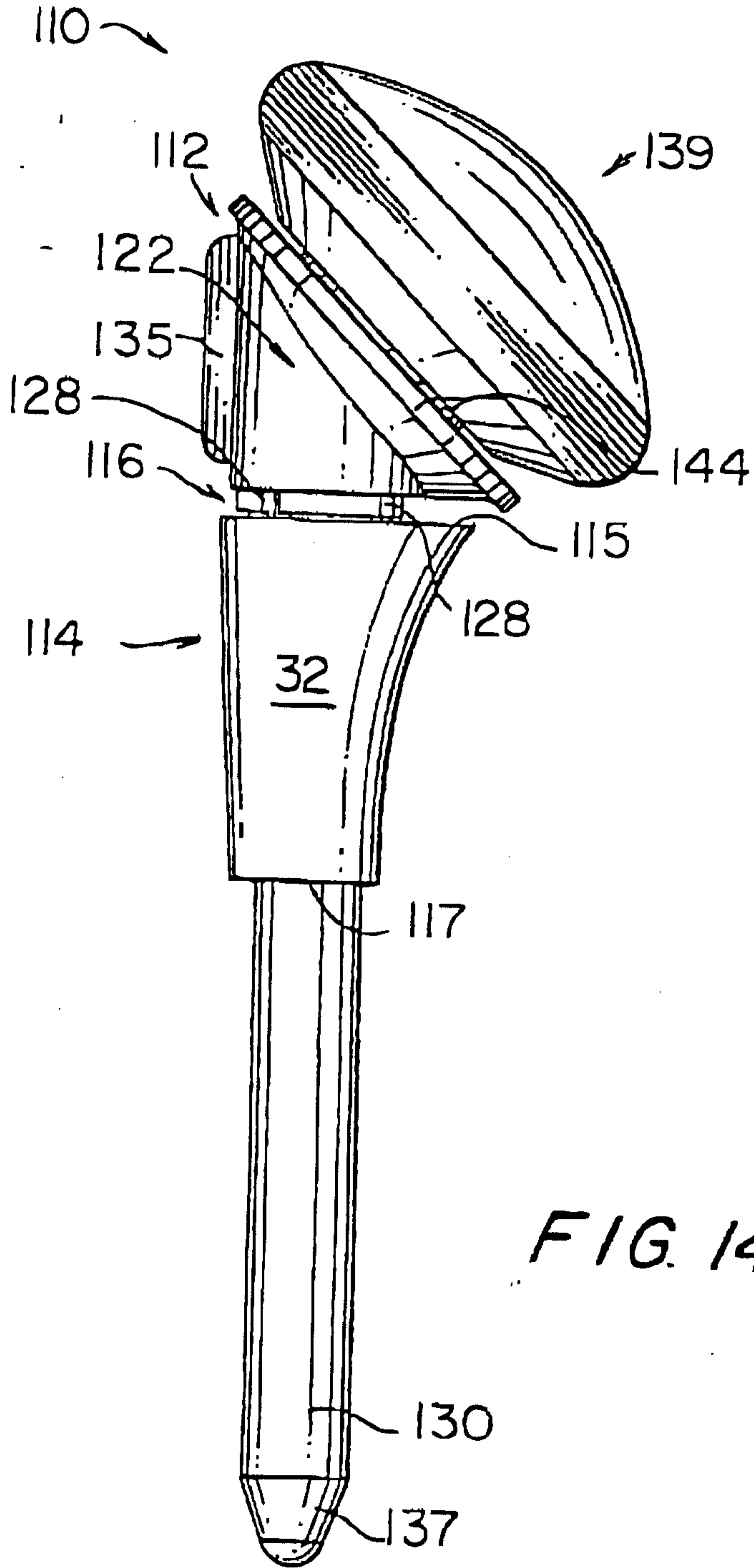


FIG. 14

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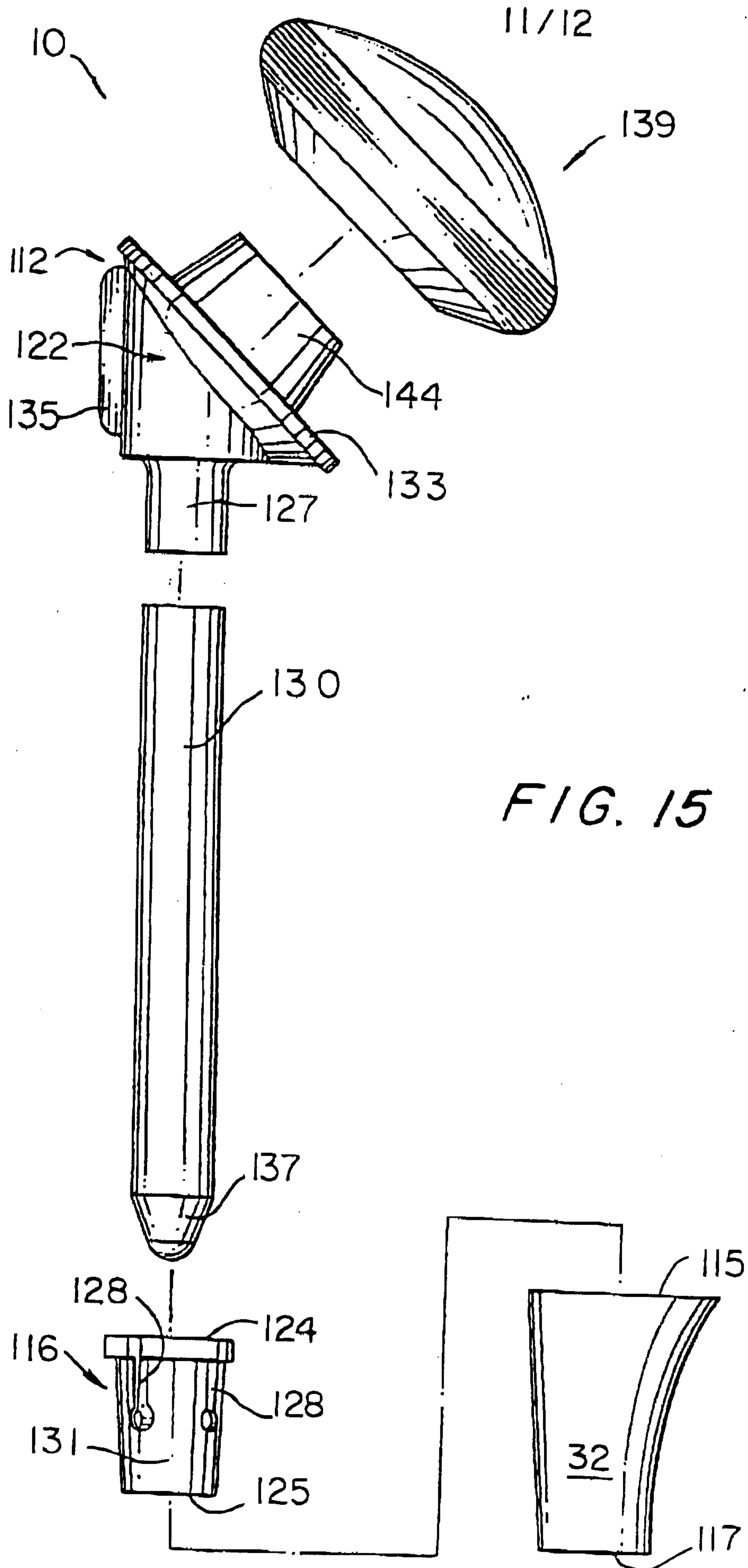


FIG. 15

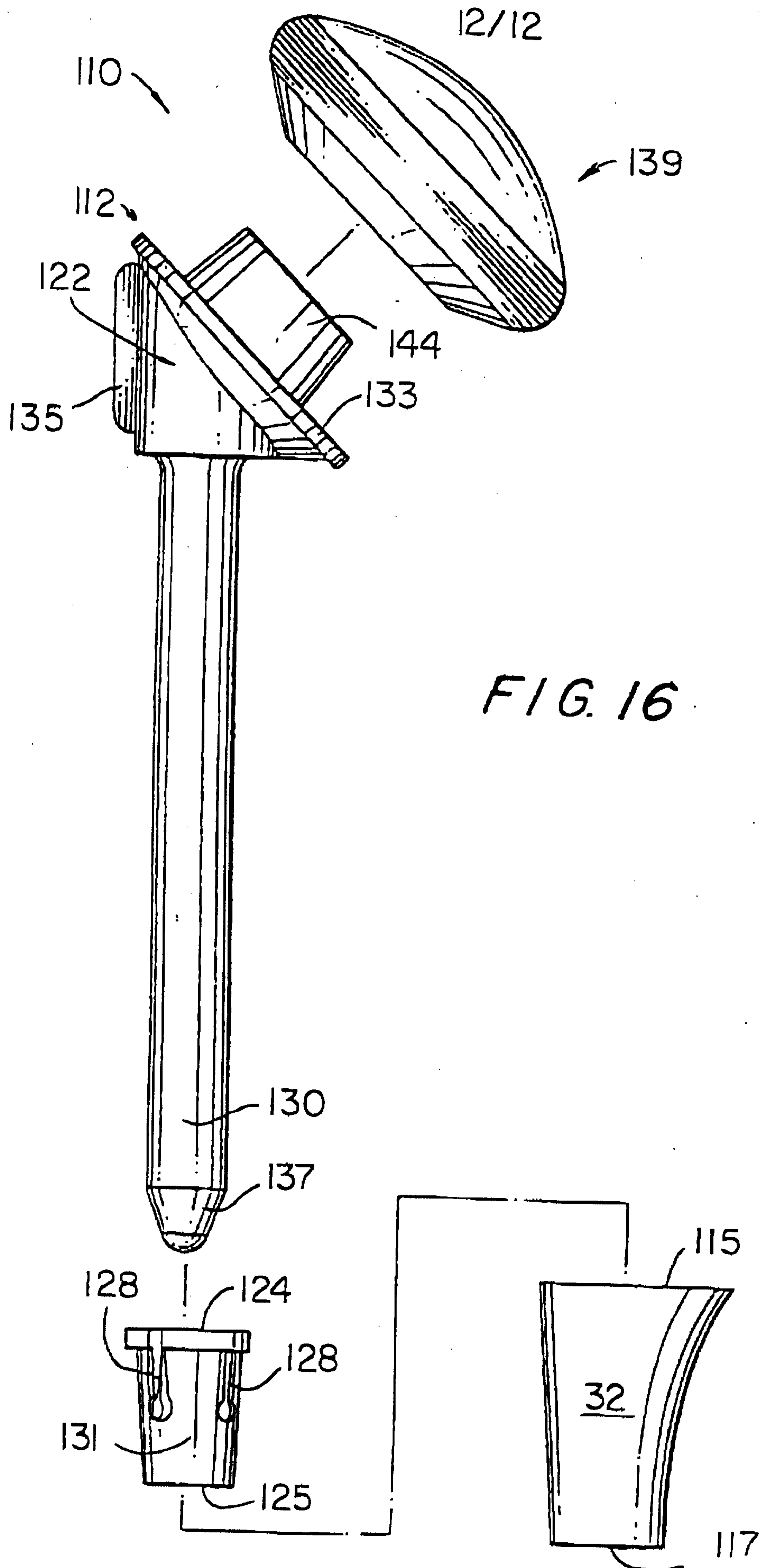


FIG. 16

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