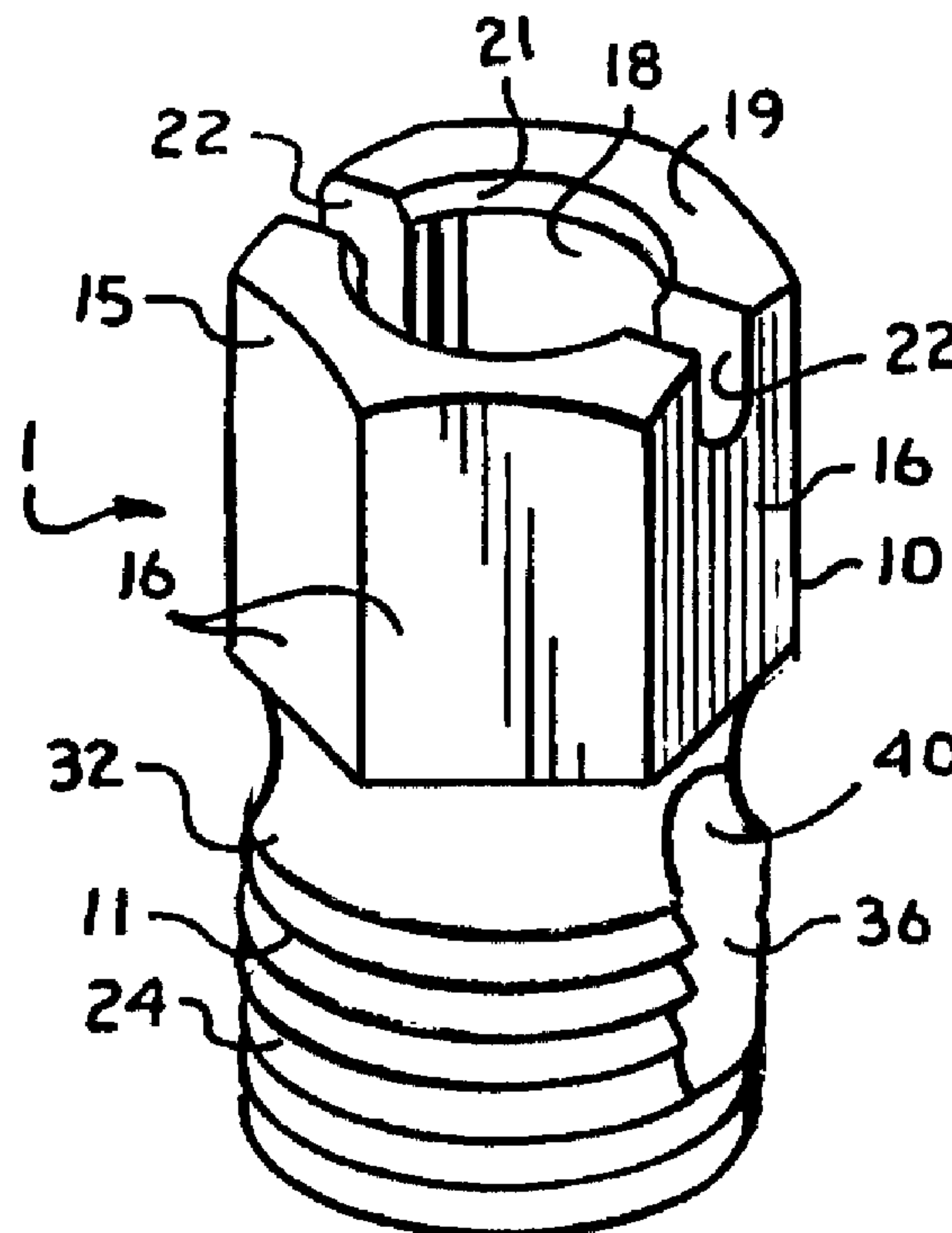




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(54) Titre : VIS DE FIXATION POUR IMPLANTS MEDICAUX  
(54) Title: SET SCREW FOR MEDICAL IMPLANTS



(57) Abrégé/Abstract:

This invention is a low profile removable set screw (1) for use in connecting one medical implant to another, and for similar uses. The set screw has a base (11), and a head (10) that is breakable from the base in a breakaway region (12) at a preselected torque, such that the head allows rotation of the screws and torquing of a tip of the base against one of the implants during installation. The screw includes a groove (32) or a notch at the breakaway region to trigger breaking. The screw also includes a pair of slots (35, 36) extending radially from an outer threaded surface (24) of the base part way into the base. The slots intersect with the breakaway region, but not with each other leaving a center core in the base. A tool (4) is provided for removing the base after the head is broken away. The tool includes a pair of spaced ears (54, 55) that are received in the slots, and provide for rotation of the base by rotating the tool. A bore of larger width than the slots is centered on each slot at the breakaway region providing relief for metal adjacent to the bores during torquing, and breaking.



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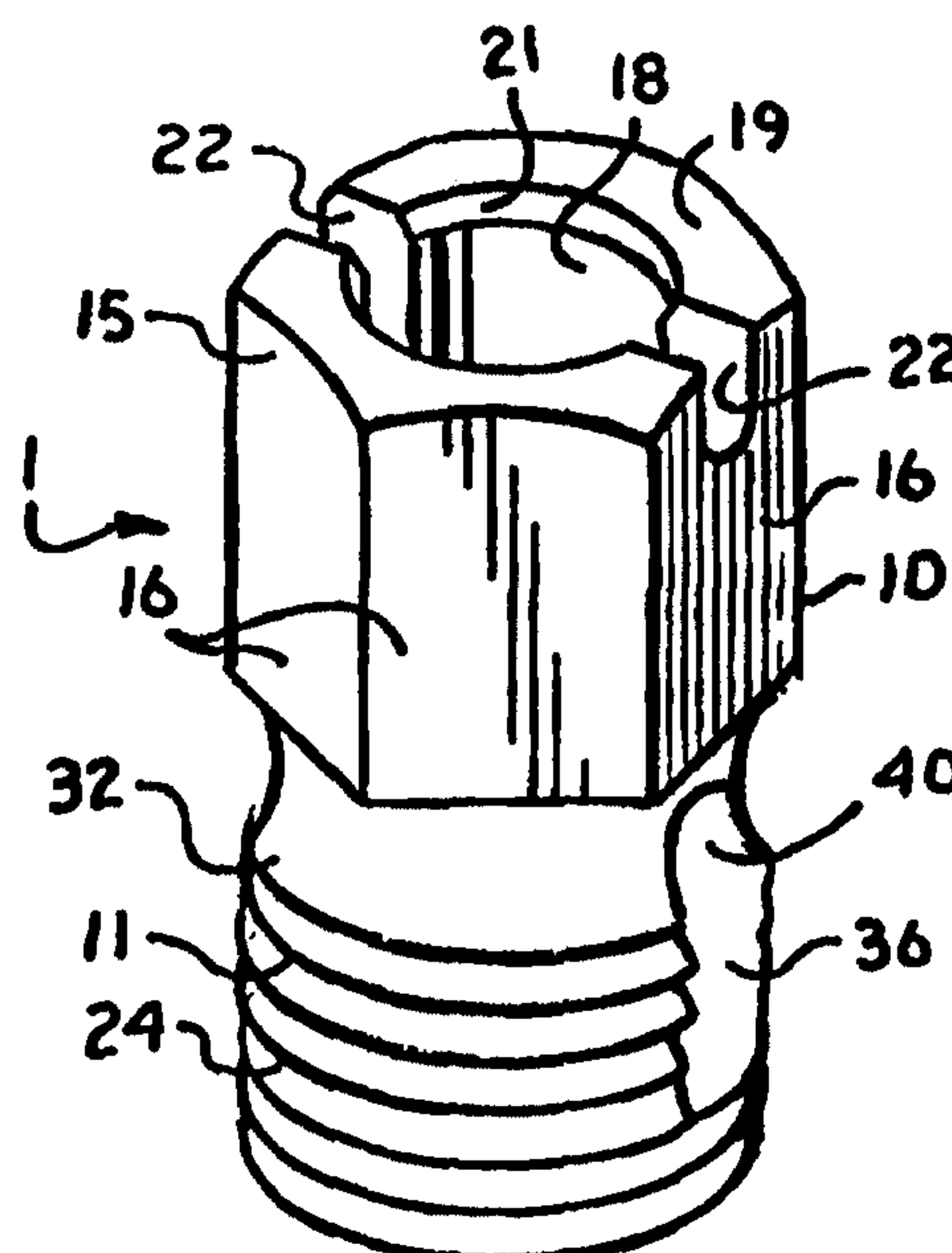
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(54) Title: SET SCREW FOR MEDICAL IMPLANTS

## (57) Abstract

This invention is a low profile removable set screw (1) for use in connecting one medical implant to another, and for similar uses. The set screw has a base (11), and a head (10) that is breakable from the base in a breakaway region (12) at a preselected torque, such that the head allows rotation of the screws and torquing of a tip of the base against one of the implants during installation. The screw includes a groove (32) or a notch at the breakaway region to trigger breaking. The screw also includes a pair of slots (35, 36) extending radially from an outer threaded surface (24) of the base part way into the base. The slots intersect with the breakaway region, but not with each other leaving a center core in the base. A tool (4) is provided for removing the base after the head is broken away. The tool includes a pair of spaced ears (54, 55) that are received in the slots, and provide for rotation of the base by rotating the tool. A bore of larger width than the slots is centered on each slot at the breakaway region providing relief for metal adjacent to the bores during torquing, and breaking.



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## SET SCREW FOR MEDICAL IMPLANTS

3

4

Background of the Invention

5

6       The present application is directed to a set screw for  
7 use in applications where it is important for the head of  
8 the set screw to break away to leave a clean profile, but  
9 for the set screw to be removable, especially set screws for  
10 use in conjunction with medical implants.

11       Over recent years, medical implants for support of and  
12 correction of defects in various portions of the body,  
13 especially the spine, have improved dramatically. It is  
14 desirable to continue to improve these implants, so that the  
15 implants provide greater strength and durability and so that  
16 the implants are effective for the life of the patient.  
17 Furthermore, it is very desirable to provide such an implant  
18 which is low profile and interferes as little as possible  
19 with tissues surrounding the implant. Because the set screw  
20 which holds together various parts of the implant,  
21 especially spinal implants, has often been a limiting factor  
22 with respect to such implants, current attention has been  
23 directed to improving the set screw.

24       Set screws of the type used in medical implants have  
25 among other problems two somewhat conflicting requirements.  
26 It is important to be able to grasp the set screw and apply



1 rotational force to it until it is torqued to a particular  
2 preselected amount. Because the torque applied to such set  
3 screws is comparatively high, this normally requires a  
4 protruding head with an external surface which can be  
5 grasped by a driving tool to set the screw at the  
6 preselected torque.

7 On the other hand, if the head sticks outwardly from  
8 the set screw after installation, then this presents a  
9 problem, since the head will interfere with surrounding  
10 tissue, such as muscle, ligament and the like.

11 Consequently, set screws have been developed recently that  
12 have a break off head that is designed to break away from a  
13 base of the set screw upon the application of the preselect  
14 torque.

15 While the break away head satisfies the two above and  
16 noted requirements, it presents a problem of its own. That  
17 is, once the head breaks away, it is then quite difficult to  
18 grasp the remaining set screw base to remove it, should the  
19 implant need to be adjusted during installation or should  
20 later work on the implant require removal of the set screw.

21 Therefore, there needs to be some mechanism provided to  
22 allow the set screw to be removed. While the force or  
23 torque required to remove the base of the set screw after it  
24 has been installed is less than the installation torque, it  
25 is normally only approximately 70% of that required to

1 install the set screw. Thus, a relatively large torque must  
2 be applied to the set screw base to remove it. Because it  
3 is imbedded in the implant and because it is low profile,  
4 there is little surface to grasp to allow the surgeon to  
5 remove the set screw, once installed.

6 Applicant, in a manner described in prior patent  
7 applications of applicant, and others have tried to develop  
8 different ways to effectively remove the set screw base once  
9 it has been broken away from the driving head. One of  
10 applicant's prior concepts was to provide an internal bore  
11 in the base of the set screw which may be a smooth wall bore  
12 or which may include some structure for assisting in the  
13 gripping of the wall by a tool and then utilizing a easy out  
14 tool or the like to try to grasp the interior of the bore  
15 for removal. Such structure was designed to try to provide  
16 sufficient torque to remove the base and in some cases  
17 functioned satisfactorily for this purpose, but in other  
18 cases did not. Because of the high torque applied to the  
19 base, it is not an easy process to remove the screw in this  
20 manner. In addition, the leverage radius that can be used  
21 on the interior wall is substantially less than can be  
22 applied to the exterior wall of the set screw.

23 Consequently, applicant foresaw a need for a set screw  
24 that would have a break away head to allow a preselected  
25 torque to be applied to the set screw and then have the head

1 break away leaving a lower section and further that provided the surgeon with structure near  
2 the radial exterior of the screw base that could be accessed by a tool that would allow the  
3 surgeon to apply removal torque to remove the set screw with substantially greater grip and  
4 with substantially greater mechanical advantage as compared to use of a tool in a central bore.

5  
6 Summary of the Invention

7 One aspect of the invention is a set screw for operably joining a first element to a  
8 second element comprising:

- 9 a) a base having an axis of rotation, a threaded outer surface adapted to be  
10 rotatably received in a mating threaded bore in the first element, a bottom adapted to  
11 engage the second element and a top;  
12 b) said base having a pair of slots extending radially inward from said threaded  
13 outer surface and communicating with said base top; and  
14 c) a center core positioned between said slots and extending to near said base top.

15 Another aspect of the invention is a set screw for operably joining a first element to a  
16 second element comprising:

- 17 a) a head having a surface for gripping, rotating and applying torque to said set  
18 screw;  
19 b) a base initially joined to said head and having a threaded outer surface adapted  
20 to be received into a threaded bore of the first element;  
21 c) said head and said base being joined at a breakaway region adapted to break  
22 upon the application of a preselected torque such that said head separates from  
23 said base; and



- 1 d) a slot located in said base and extending radially inward from said base threaded  
2 surface; said slot intersecting with said breakaway region; and said slot being  
3 adapted to receive a removal tool inward of said threaded surface subsequent to  
4 said head being broken from said base to allow application of torque to said base  
5 and rotate said base counterclockwise.

6 Another aspect of the invention is a set screw comprising:

- 7 a) a base having a threaded surface adapted to be threadedly received in a threaded  
8 bore;
- 9 b) a head originally joined to said base at a breakaway region determined by  
10 location of a reduced cross-sectional area in a plane perpendicular to an axis of  
11 rotation of said screw as compared to surrounding regions to the breakaway  
12 region; said head being shaped and configured to receive a driving tool for  
13 rotating and applying torque to said set screw; said head breaking from said set  
14 screw at a preselected torque at said breakaway region; and
- 15 c) a removal slot that extends radially inward from said threaded surface and is  
16 adapted to receive a removal tool, when said set screw is operably received in a  
17 threaded bore; said slot being non-accessible by a removal tool when said head  
18 is joined to said base; and said slot is accessible by a removal tool after said  
19 head has broken from said base.

1 Another aspect of the invention is a set screw comprising:

- 2 a) a base having an axis of rotation and a threaded outer surface adapted to be  
3 operably received in a threaded bore; said base having a bottom and a top;  
4 b) a grippable head initially joined to the top of said base for driving said base into  
5 a bore; said head being breakable from said base; and  
6 c) said base top including a non planar removal structure sized and shaped to be  
7 adapted to receive and provide purchase to a removal tool for removing said  
8 base from a bore receiving said base; said removal structure being inaccessible  
9 when said base is in a bore and said head is joined to said base and said removal  
10 opening being accessible by a removal tool when said base is in a bore and said  
11 head is broken from said base.

12 Another aspect of the invention is a set screw comprising:

- 13 a) a base having a threaded surface adapted to be received in a threaded bore;  
14 b) a head originally joined to said base at a breakaway region; said head being  
15 shaped and configured to receive a driving tool for rotating and applying torque  
16 to said set screw; said head breaking from said set screw at a preselected torque  
17 at said breakaway region; and  
18 c) a removal slot that extends radially inward from said threaded surface; said slot,  
19 when said base is received in a bore, being non-accessible by a removal tool  
20 while said head is joined to said base; and said slot, when said base is received  
21 in a bore, being accessible by a removal tool after said head has broken from  
22 said base.



1 Another aspect of the invention is a medical implant system comprising:

2 a) a first implant having a first bore and a second threaded bore intersecting with  
3 said first bore;

4 b) a second implant operably received in said first implant first bore;

5 c) a removable set screw for operably securing said first implant to said second  
6 implant; said screw being threadably receivable in said first implant second  
7 threaded bore, abutted against said second implant and thereafter torqued to a  
8 preselected torque;

9 d) said set screw having:

10 1) a base with an external threaded surface sized and shaped to be  
11 threadably received in said first implant threaded bore, a bottom having a  
12 tip operably sized and shaped to frictionally engage said second implant  
13 and a top opposite said tip;

14 2) a head breakably attached to said base top and adapted to receive an  
15 installation tool to drive said set screw base into said first implant  
16 threaded bore; said head breaking from said base upon the application of  
17 said preselected torque; subsequent to said head breaking from said base,  
18 said base being relatively low profile with respect to said first implant  
19 threaded bore;

20 3) said base also including a pair of slots; each of said slots extending  
21 radially inward from said base threaded surface and intersecting with  
22 said base top; said slots being diametrically opposed to each other and  
23 spaced by a center core of said base; when said base is in said first

1                    implant threaded bore, said slots are accessible to a removal tool when  
2                    said head is broken from said base and are non-accessible to a removal  
3                    tool when said head is attached to said base; and

- 4                    4)        a break initiating region of comparatively less cross-section in a plane  
5                    perpendicular to said screw axis of rotation and positioned between said  
6                    head and said base.

7                    Another aspect of the invention is a set screw for operably joining a first element to a  
8                    second element comprising:

- 9                    a)        a base having an axis of rotation, a threaded outer surface adapted to be  
10                    rotatably received in a mating threaded bore in the first element, a bottom  
11                    adapted to engage the second element and a top;  
12                    b)        said base having a pair of slots extending radially inward from said threaded  
13                    outer surface and communicating with said base top;  
14                    c)        a center core positioned between said slots and extending to near said base top;  
15                    d)        a breakaway head originally joined to said base; and wherein  
16                    e)        said head blocks access to said slots when said base is in a bore and when said  
17                    head is joined to said base, but said slots are accessible after said head breaks  
18                    from said base.

19                    Another aspect of the invention is a set screw for operably joining a first element to a  
20                    second element comprising:

- 21                    a)        a head having a surface for gripping, rotating and applying torque to said set  
22                    screw;

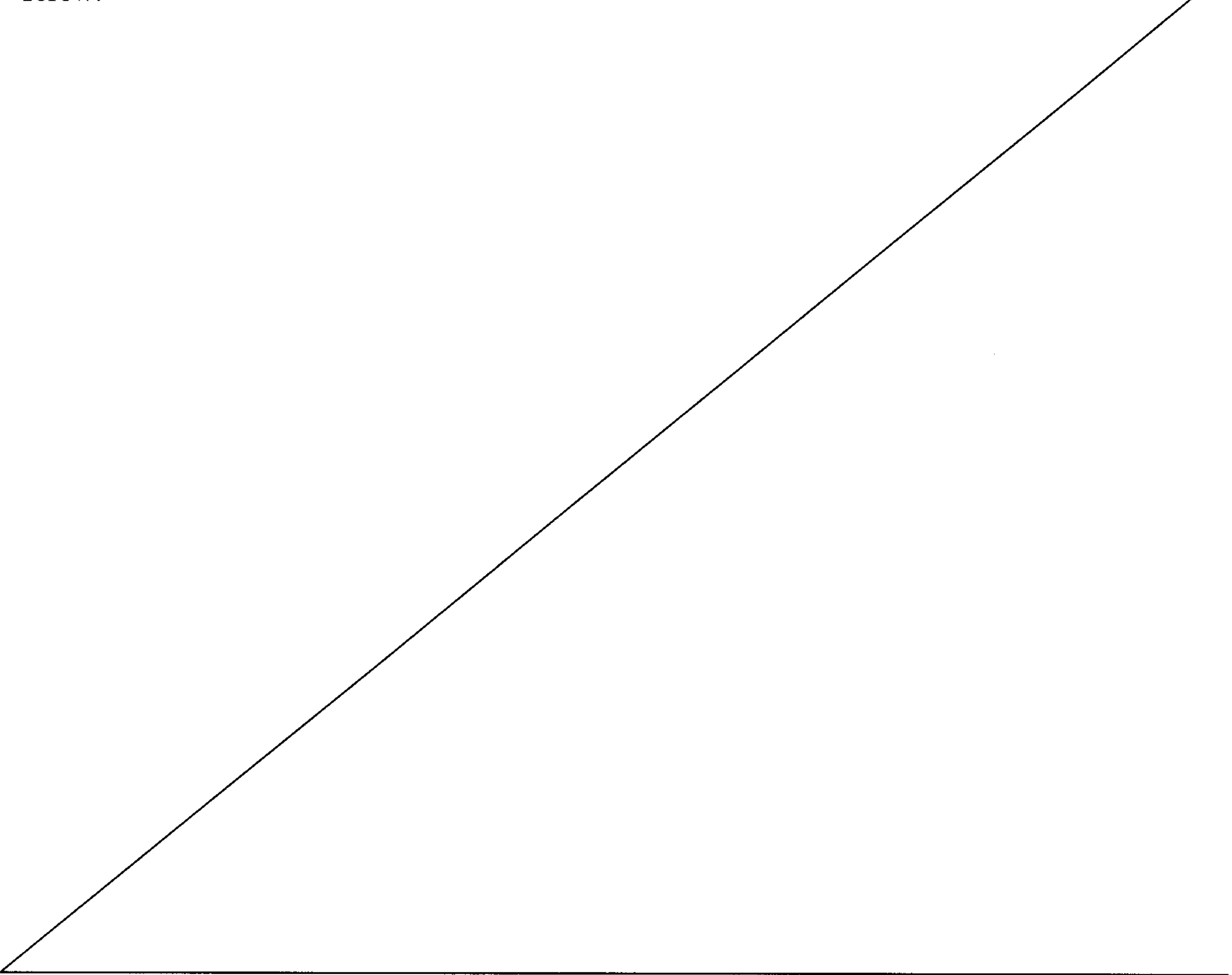
- 1           b)     a base initially joined to said head and having a threaded surface adapted to be  
2                 received into a threaded bore of the first element;
- 3           c)     said head and said base being joined at a breakaway region adapted to break  
4                 upon the application of a preselected torque such that said head separates from  
5                 said base; and
- 6           d)     a pair of slots that do not pass through an axial center of rotation of the set screw  
7                 base; said slots being located in and extending radially inward from said base  
8                 threaded surface; said slots each intersect with said breakaway region; and said  
9                 slots being adapted to receive a removal tool inward of said threaded surface  
10                subsequent to said head being broken from said base to allow application of  
11                torque to said base and rotate said base counterclockwise.

12        Another aspect of the invention is a set screw comprising:

- 13           a)     a base having a threaded surface adapted to be received in a threaded bore;
- 14           b)     a head originally joined to said base at a breakaway region located by an exterior  
15                 notch; said head being shaped and configured to receive a driving tool for  
16                 rotating and applying torque to said set screw; said head breaking from said set  
17                 screw at a preselected torque at said breakaway region; and
- 18           c)     a removal slot that extends radially inward from said threaded surface and is  
19                 adapted to receive a removal tool, when said set screw is operably received in a  
20                 threaded bore; said slot being non-accessible by a removal tool when said head  
21                 is joined to said base; and said slot is accessible by a removal tool after said  
22                 head has broken from said base.



1           A set screw is provided that is especially suited for use in medical implants and the like  
2 wherein it is desired to have a low profile set screw preferably that is installed at a preselected  
3 torque and is then removable should removal be required. In different embodiments, the set  
4 screw includes a threaded lower section or base and a breakoff head. In particular, the base and  
5 the head are originally joined at a location having a partial or circumferential notch or groove in  
6 the circumference of the screw between the head and bore, such that as torque is increasingly  
7 applied to the head, the torque on the head reaches a preselected amount and the head breaks  
8 from the base at the groove generally in a plane perpendicular to an axis of rotation of the  
9 screw.



1       The base includes a threaded surface that is radially  
2 spaced from an axis of rotation and that is received in a  
3 similarly and matingly threaded bore in a first medical  
4 implant or the like. The bottom of the base includes an  
5 axially projecting tip that may be a point, a ring, both or  
6 another similar structure for engaging a second implant so  
7 as to secure the second implant relative to the first.

8       The head includes an outer grippable surface for  
9 gripping and applying torque and an internal bore to receive  
10 tools for gripping during installation.

11       Located along the outer wall of the screw and extending  
12 partially along the base and partially along the head are a  
13 pair of non-intersecting or spaced slots. The slots extend  
14 radially part way into the screw and are preferably  
15 positioned opposite or diagonally with respect to each  
16 other. The slots extend through the threads on the base.  
17 The slots provide for removal of the base after the set  
18 screw is installed and the head broken away.

19       A tool is provided to remove the base utilizing the  
20 slots. The tool includes a manipulative handle operably  
21 connected to a pair of ears adapted to be received in the  
22 base slots. The ears are spaced, sized and positioned to be  
23 received in the slots radially inward of the threads so that  
24 the tool can be inserted into the slots without engaging or  
25 interfering with the threads of the first implant bore to

1 allow counterclockwise rotational force to be applied to the  
2 base through the ears by rotation of the tool by a user and  
3 in this way remove the base from the implants.

4 Also associated with the slots is a circular bore that  
5 is of slightly greater diameter than the side to side width  
6 of the slots, the bore is preferably positioned to be  
7 centered on the notch or groove along which breakage between  
8 the head and base occurs. The bore provides relief at the  
9 location of breakage. That is, normally when breakage  
10 between the head and base occur, some of the metal adjacent  
11 to the slots may be twisted into the slot opening, thereby  
12 preventing easy access of the tool to the slot. With the  
13 bore, adjacent metal that is twisted is received in the  
14 portion of the bore outside the slot, thereby allowing the  
15 tool to be easily received in the slot.

16

17

18 Objects and Advantages of the Invention

19

20 Therefore, the objects of the present invention are: to  
21 provide a set screw for use in conjunction with medical  
22 implants and the like wherein the set screw has a low  
23 profile after installation, provides for installation to a  
24 preselected torque and is removable from the implant after  
25 installation; to provide such a set screw having a breakoff



1 head and a region of reduced cross-section produced by a  
2 notch or groove that is centered in a plane perpendicular to  
3 the axis of installation so as to trigger breakage at a  
4 preselected location; to provide such a set screw having  
5 axially extending and radially penetrating slots that extend  
6 along the outer surface of the screw and intersect with the  
7 location whereat the head breaks from the base, the slots  
8 being positioned and shaped to receive a tool to apply  
9 counterclockwise rotation to the base to remove the set  
10 screw from the implant; to provide such a set screw  
11 including a relief region adjacent to the slots to receive  
12 twisted metal upon breakage of the head from the base so as  
13 to allow full access of the slots to the tool; to provide  
14 such a screw that has such slots that are positioned to  
15 provide a mechanical advantage to removal of the base over  
16 that provided by mechanisms and systems that remove the base  
17 through internal structure; to provide a tool having ears  
18 adapted to be received in the slots for applying a removal  
19 torque; to provide such a tool wherein the ears include  
20 gripping cleats; to provide such a set screw in combination  
21 with medical implants to secure a first implant to a second  
22 implant; and to provide such a set screw, tool and overall  
23 implant system that is comparatively easy to use, easy to  
24 produce, and especially well adapted for the intended usage  
25 thereof.

1        Other objects and advantages of this invention will  
2        become apparent from the following description taken in  
3        conjunction with the accompanying drawings wherein are set  
4        forth, by way of illustration and example, certain  
5        embodiments of this invention.

6        The drawings constitute a part of this specification  
7        and include exemplary embodiments of the present invention  
8        and illustrate various objects and features thereof.

9

10                    Brief Description of the Drawings

11

12        Figure 1 is a perspective view of a removable set screw  
13        with a break off head and a base in accordance with the  
14        present invention.

15        Figure 2 is a front elevational view of the set screw.

16        Figure 3 is a side elevational view of the set screw.

17        Figure 4 is a cross sectional view of the set screw,  
18        taken along line 4-4 of Figure 3.

19        Figure 5 is a fragmentary side elevational view of the  
20        set screw on a reduced scale positioned in an implant with a  
21        head of the set screw broken away from a lower section  
22        thereof and having portions removed to show detail thereof.

23        Figure 6 is an enlarged fragmentary top plan view of  
24        the set screw and implant of Figure 5 after breakaway of the  
25        set screw head.

1           Figure 7 is a side elevational view of a tool to remove  
2 the set screw base from the implant.

3           Figure 8 is a fragmentary side elevational view of the  
4 implant of Fig. 5 with the set screw base being removed by  
5 the removal tool.

6           Figure 9 is an enlarged and cross sectional view of the  
7 set screw base and tool, taken along line 9-9 of Fig. 8.

8           Figure 10 is an enlarged fragmentary view of the  
9 removal tool, taken within circle 10 of Fig. 7.

10           Figure 11 is an enlarged fragmentary front elevational  
11 view of the removal tool.

12



1                   Detailed Description of the Invention

2  
3           As required, detailed embodiments of the present  
4 invention are disclosed herein; however, it is to be  
5 understood that the disclosed embodiments are merely  
6 exemplary of the invention, which may be embodied in various  
7 forms. Therefore, specific structural and functional  
8 details disclosed herein are not to be interpreted as  
9 limiting, but merely as a basis for the claims and as a  
10 representative basis for teaching one skilled in the art to  
11 variously employ the present invention in virtually any  
12 appropriately detailed structure.

13           The reference numeral 1 generally designates a set  
14 screw in accordance with the present invention used in  
15 conjunction with a medical implant system 3 (Fig. 5) and  
16 having an associated removal tool 4 (Fig. 7).

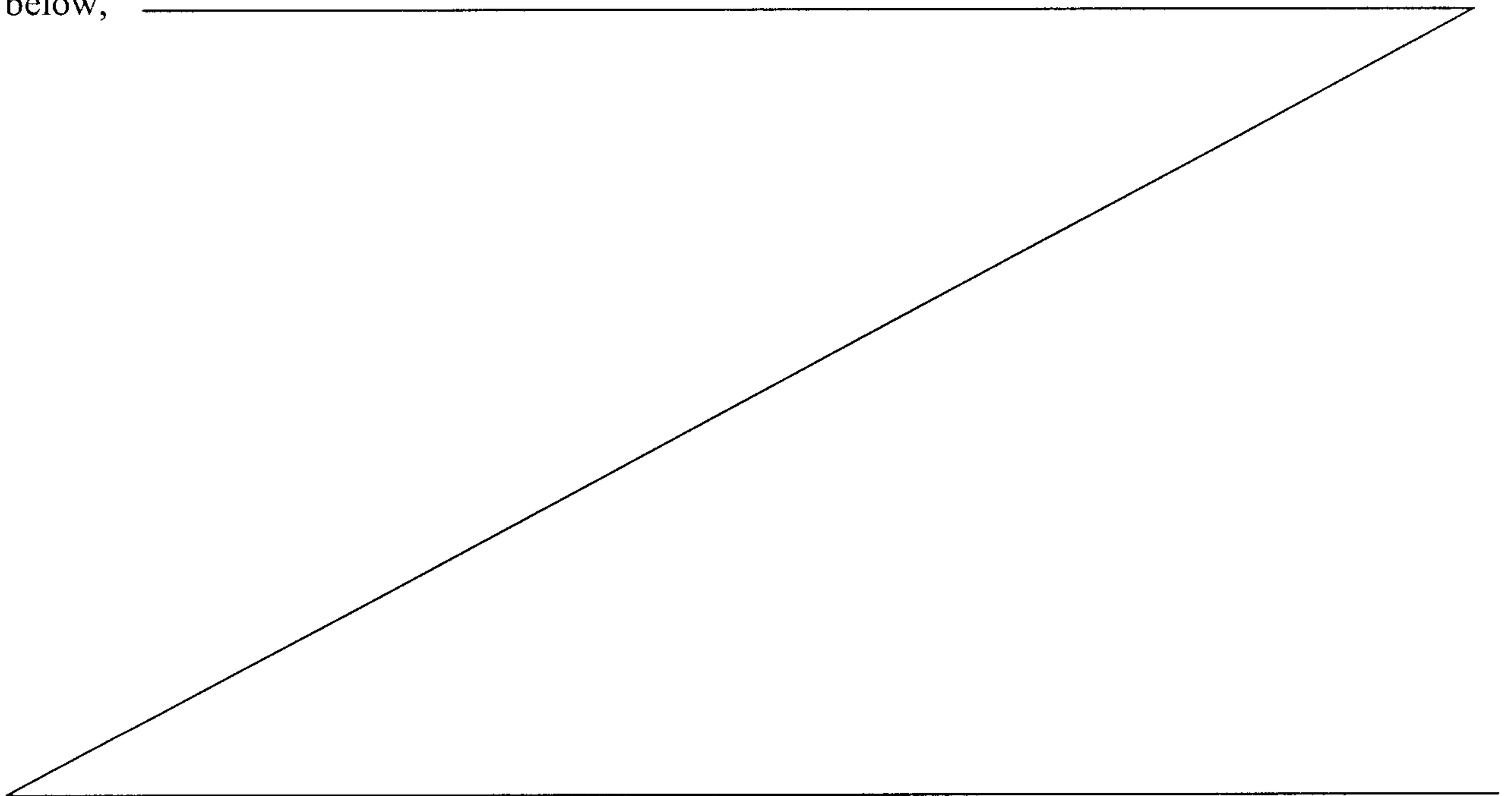
17           The set screw 1 has an upper section or head 10 and a  
18 lower section or base 11 originally joined together along a  
19 planar breakaway zone or region 12. The set screw 1 is  
20 rotatable about a central axis A that passes longitudinally  
21 through the center of the screw 1.

22           The head 10 has an outer grippable surface 15, which in  
23 the illustrated embodiment includes six planar faces 16  
24 joined together in a hexagonal shape, such that the faces 16

lie in planes that are parallel to but are spaced from the axis A.

The surface 15 is sized and shaped to receive a driving or installation tool (not shown) of any conventional type for torquing or clockwise (as viewed from a top 19 of the head 10) rotating the set screw 1. A bore 18 extends from the top 19 of the head 10 partially through the head 10 and is coaxial with axis A. The bore 18 preferentially receives a nipple from a driving tool during insertion. Near the top of the bore 18 is a relief 21. A pair of tool receivers 22 and 23 extend between the bore 18 and the surface 15 near the head top 19. The receivers 22 operably receive a portion of a driving tool during installation of the set screw. A suitable driving tool for use with the set screw 1 of the present invention is illustrated in U.S. Patent No. 5,941,885, TOOLS FOR USE IN INSTALLING OSTEOSYNTHESIS APPARATUS UTILIZING SET SCREW WITH BREAK-OFF HEAD.

The purpose of the head 10 is to allow a surgeon or other user to apply a driving tool to grip the surface 15 and apply rotational force or torque to the screw 1. The head surface 15 allows good leverage about the axis A and mechanical advantage. As discussed in greater detail below,



1 the head 10 breaks away from the base 11 at a preselected  
2 torque.

3 Although the illustrated surface 15 is hexagonal in  
4 cross section, surfaces of other shapes including non  
5 polyhedral shapes may be utilized for the grippable surface  
6 15.

7 The base 11 has a radially outer surface 24 that is  
8 threaded and which is coaxial with but spaced from the axis  
9 A.

10 The thread of the threaded surface 24 is sized and  
11 shaped to be received in an implant as described below. A  
12 bottom 26 of the base 11 has an axially projecting tip 27  
13 that provides frictional engagement and preferably .  
14 penetration into an object against which the screw 1 is  
15 operably set. The tip 27 that extends outward parallel to  
16 the axis A. The tip 27 operably engages a structure against  
17 which the set screw 1 is set, also as described further  
18 below. The tip 27 of the illustrated embodiment includes a  
19 point 29 and sharp edged ring 30 that is radially spaced  
20 from the point 29. Although the point 29 and ring 30 are  
21 shown in the illustrated embodiment, it is foreseen that  
22 other types of projecting tips may be used in accordance  
23 with the present invention.

24 Located between the head 10 and base 11 is the  
25 breakaway region 12. The location 12 is in a plane that is



1 typically perpendicular to the axis A. When the head 10  
2 breaks from the base 11, as shown in Fig. 5, an upper  
3 surface 31 is left on the base 11. The region 12 has a  
4 reduced cross sectional area perpendicular to the axis A, as  
5 compared to the surrounding regions of the screw 1.  
6 Preferably, the breaking of the head 10 from the bore 11  
7 leaves the base upper surface 31 relatively smooth and free  
8 from burrs, although the metal will deform slightly sideways  
9 due to twisting. The region 12 in the illustrated invention  
10 is produced by a circumferential groove 32 that has a center  
11 line 33 that lies in a plane perpendicular to the axis A.  
12 Although a circumferential uniform groove 32 is used to  
13 trigger breakage in the present embodiment, it is foreseen  
14 that other structures such as a non-uniform notch may also  
15 be used for this purpose.

16 Extending radially inward from the head surface 15 and  
17 the base surface 24 is a pair of spaced and non-intersecting  
18 slots 35 and 36. Each of the slots 35 and 36 is elongate  
19 with the greatest length being aligned parallel to the axis  
20 A. Each of the slots 35 and 36 is formed by milling or  
21 drilling and extends perpendicular to or radially inward  
22 toward the axis A. Each slot 35 and 36 is positioned in  
23 opposed relationship or diametrically relative to the other.

24 Each slot 35 and 36 extends substantially along the  
25 base outer surface 24 and in the illustrated embodiment each

1 slot 35 and 36 extends along about two thirds of the surface  
2 24. The slots 35 and 36 extend through the breakaway region  
3 12 and in the illustrated embodiment extend partly along the  
4 head surface 15. The depth of each slot 35 and 36 may vary  
5 somewhat, but must accommodate the removal tool 4. In the  
6 illustrated embodiment the slots 35 and 36 each extend  
7 approximately 60% of the distance between the lowest part of  
8 the threaded surface 24 and the axis A. The width of each  
9 of the slots 35 and 36 in the illustrated embodiment is  
10 about one third of the diameter of the base 11, but it is  
11 foreseen that slots of other size may be used in accordance  
12 with the invention, especially considering the size and  
13 shape of the tool 4 and the overall diameter of the set  
14 screw 1.

15 Relief bores 40 and 41 are positioned to be centered  
16 over each respective slot 35 and 36 relative to the minor  
17 axes of the slots 35 and 36, as shown in Fig. 3. The bores  
18 40 and 41 are also centered on the breakaway region 12.  
19 Each bore 40 and 41 is somewhat larger than the associated  
20 slot 35 and 36 so as to form a relief area 43 and 44  
21 therebetween. The relief areas 43 and 44 receive deformed  
22 metal due to twisting and breaking at the breakaway region  
23 12 to prevent such metal from entering and blocking the  
24 slots 35 and 36. The bores 43 and 44 are cylindrical and in

1 the illustrated embodiment have the same depth as the slots  
2 35 and 36.

3 The illustrated set screw removal tool 4 is T-shaped  
4 and includes an elongate shaft 50 with a handle 51 extending  
5 perpendicularly in opposite directions from one end thereof.  
6 At an end opposite the handle 51 is a set screw engaging  
7 tool head 52. As is best seen in Figures 10 and 11, the  
8 tool head 52 includes a pair of axially projecting and slot  
9 receiving tabs, lugs or ears 54 and 55. The ears 54 and 55  
10 are separated or spaced by a slot or channel 56. The ears  
11 54 and 55 are sized and shaped to be received inward of the  
12 thread and within the slots 35 and 36 once the head 10 has  
13 been broken from the base 11 and the channel 56 spans a  
14 center core 57 of the set screw 11 between the slots 35 and  
15 36. The ears 54 and 55 adapted to be positioned or set in  
16 the slots 35 and 36, as is illustrated in Figures 8 and 9.  
17 The channel 56 is sufficiently large in size to receive the  
18 center core 57 of the set screw located between the slots 35  
19 and 36. The ears 54 and 55 are also sized to not extend  
20 outwardly into the thread of either the base 11 or mating  
21 thread of the implant system 3.

22 Located near a lower end of each of the ears 54 and 55  
23 is a cleat 58. The cleats 58 are positioned on the sides of  
24 the ears 54 and 55 that engage the slots 35 and 36 when the  
25 tool is rotated counterclockwise to remove the base 11. As



1 a substantial amount of torque is applied to the tool 4 to  
2 remove set screw base 11 once it has been secured to the  
3 implant system 3, the cleats 58 serve to grip the sidewalls  
4 of the slots 35 and 36 and reduce the likelihood of  
5 slippage. If one of the ears 54 or 55 should break during  
6 removal of the base 11, the broken ear is simply removed and  
7 a new tool 4 is utilized for the purpose.

8 Shown in Figures 5, 6 and 8 is the set screw 1 in  
9 combination with the medical implant system 3. The medical  
10 implant system 3 that is illustrated includes a bone screw  
11 60 and a rod 61. In the illustrated embodiment the bone  
12 screw 60 is implanted in a vertebral bone 62. In  
13 conventional medical implant systems of the type illustrated  
14 herein, there are a wide range of parts that are utilized  
15 including hooks, connectors, bars, plates and numerous other  
16 elements that are all interconnected together by means of  
17 set screws. The set screw 1 of the present invention may be  
18 used for interconnecting together any of the various  
19 elements.

20 In the illustrated embodiment, the bone screw includes  
21 a first bore 62 that is sized and shaped to slideably  
22 receive the rod 61 and is often perpendicular to the central  
23 elongate axis of the bone screw 60. The rod 61 is  
24 positioned in a first rod receiving bore 64 in the  
25 illustration. The bone screw 60 includes a second threaded

1 bore 65 which intersects with the first bore 64 and which is  
2 generally aligned to be coaxial with the bone screw 60. The  
3 thread of the thread bore 65 is sized and shaped to receive  
4 the thread on the base outer surface 24 of the set screw 1.

5 The set screw 1 is, thus, first threaded into the  
6 threaded bore 65 until the projecting tip 19 engages the rod  
7 61. Thereafter, clockwise rotation producing an increasing  
8 torque is applied to the set screw 1 to set the set screw 1  
9 both within the threaded bore 65 and against the rod 61. As  
10 the set screw 1 is rotated, the set screw point 29 and ring  
11 30 engage and partially penetrate into the rod 61. As  
12 increasing torque is applied to the set screw 1, the torque  
13 finally reaches a preselected torque where the head 10  
14 breaks from the base 11, as is illustrated in Figure 5.

15 The torque can be substantially varied according to the  
16 system and set screw, but has been found that a torque of 90  
17 inch pounds is highly effective when setting the set screw  
18 so as to prevent relative motion between the various  
19 elements of the system 3, including the bone screw 60 and  
20 rod 61.

21 Subsequent to the head 10 breaking from the base 11,  
22 the upper surface 31 of the base 11 is preferably beneath or  
23 substantially even with a top 67 of the bone screw 63. In  
24 this manner the set screw 1 does not have a projecting head  
25 10 and is comparatively low profile.

1           Consequently, in operable use, the set screw base 11  
2   secures a first implant such as the bone screw 60 to a  
3   second implant such as the rod 61 by means of the set screw  
4   1 being threadably held in the first implant bore 65 and set  
5   against the second implant or rod 61 by rotation and  
6   application of torque thereto.

7           Subsequent to the set screw base 11 being set, it is  
8   sometimes necessary to remove the base 11. This occurs when  
9   the implant system 3 must be adjusted during installation or  
10  at a later time when original parts of the system must be  
11  removed for some reason. When this occurs, the removal tool  
12  4 is utilized. In particular, the removal tool ears 54 and  
13  55 are placed in the slots 35 and 36. Thereafter the user  
14  applies counterclockwise rotation to the handle 51 to urge  
15  the ears 54 and 55 against respective sides of the slots 35  
16  and 36. Sufficient torque is applied in this manner to  
17  unseat the base 11. The ears 54 and 55 are sufficiently  
18  radially inward so as not to interfere with the threads on  
19  the interior of the bone screw threaded bore 65. This  
20  allows a subsequent set screw 1 to be utilized in the bore  
21  65 to reset the bone screw 60 relative to the rod 61.

22           While the torque required to unseat the set screw base  
23  11 varies from system to system and with the type of metal  
24  used, it has been found that the torque required to unseat



1 the base 11 is often approximately 70% of the torque  
2 required to seat the screw.

3 It is foreseen that the set screw 1 of the present  
4 invention can be constructed of many different types of  
5 materials. When the set screw 1 is to be utilized for  
6 medical implants, the material construction should be as  
7 compatible as possible with implantation and it has been  
8 found that stainless steel and titanium are typically  
9 preferred as materials of construction for such uses.

10 Although the set screw of the present invention is  
11 described and illustrated in conjunction with mainly medical  
12 implants, as it advantageously provides for many of the  
13 requirements peculiar to such implants as opposed to other  
14 types of set screws, it is foreseen that the set screw of  
15 the present invention may also be used with other types of  
16 systems.

17 It is to be understood that while certain forms of the  
18 present invention have been illustrated and described  
19 herein, it is not to be limited to the specific forms or  
20 arrangement of parts described and shown.

21

C L A I M S

What is claimed and desired to be secured by Letters Patent is as follows:

1. A set screw for operably joining a first element to a second element comprising:

- a) a base having an axis of rotation, a threaded outer surface adapted to be rotatably received in a mating threaded bore in the first element, a bottom adapted to engage the second element and a top;
- b) said base having a pair of slots extending radially inward from said threaded outer surface and communicating with said base top; and
- c) a center core positioned between said slots and extending to near said base top.

2. The set screw according to Claim 1 including:

- a) a breakaway head originally joined to said base.

3. A set screw for operably joining a first element to a second element comprising:

- a) a head having a surface for gripping, rotating and applying torque to said set screw;
  - b) a base initially joined to said head and having a threaded outer surface adapted to be received into a threaded bore of the first element;
  - c) said head and said base being joined at a breakaway region adapted to break upon the application of a preselected torque such that said head separates from said base; and
  - d) a slot located in said base and extending radially inward from said base threaded surface; said slot intersecting with said breakaway region; and said slot being adapted to receive a removal tool inward of said threaded surface subsequent to said head being broken from said base to allow application of torque to said base and rotate said base counterclockwise.
4. The set screw according to Claim 3 wherein:  
said slot is a first slot that does not pass through the axis of rotation of said screw



and including a second slot;

- a) said slots are diametrically opposed and are separated by a center core.

5. The set screw according to Claim 4 wherein:

- a) said slots are elongate and have a major length parallel to an axis of rotation of said set screw.

6. The set screw according to Claim 3 including:

- a) a circular bore having a center located in a plane perpendicular to the axis of rotation of said set screw and defining said breakaway region whereat the widest cross-section thereof in a plane perpendicular to the set screw axis of rotation overlaps said breakaway region; said bore intersecting with said slot; and
- b) said bore operably reducing the cross-section of said screw in said breakaway region compared to surrounding regions, so as to trigger breakage in the breakaway region.

7. The set screw according to Claim 4 further in

combination with a removal tool; said removal tool comprising:

- a) an elongate shaft;
- b) an operator grip for operably rotating said shaft; and
- c) a pair of ears projecting from said shaft; said ears being sized and positioned so as to be receivable in respective slots of said base after said head is broken from said base such that removal torque may be operably applied to said base through said ears by said removal tool.

8. A set screw according to Claim 4 wherein:

- a) said slots are positioned, sized and shaped to be available for entry of a removal tool after said head is broken from said base and are not accessible by a removal tool prior to said head being broken from said base when said set screw base is located within a threaded bore.

9. A set screw according to Claim 3 in combination with the first and second elements wherein:

- a) said first element is an elongate member

- portion of a first medical implant; and
- b) said second element is a second medical implant having a first bore for operably receiving said elongate member portion and a second threaded bore for receiving said set screw; said first and second bores intersecting.
10. The combination according to Claim 4 wherein:
- a) said set screw is sized and shaped such that as said base engages and becomes set against said elongate member portion and further torque is applied to said head, said head breaks from said base at a preselected torque such that said break-away region is entirely within said second threaded bore and thereby low profile.
11. A set screw comprising:
- a) a base having a threaded surface adapted to be threadedly received in a threaded bore;
- b) a head originally joined to said base at a breakaway region determined by location of a reduced cross-sectional area in a plane



perpendicular to an axis of rotation of said screw as compared to surrounding regions to the breakaway region; said head being shaped and configured to receive a driving tool for rotating and applying torque to said set screw; said head breaking from said set screw at a preselected torque at said breakaway region; and

- c) a removal slot that extends radially inward from said threaded surface and is adapted to receive a removal tool, when said set screw is operably received in a threaded bore; said slot being non-accessible by a removal tool when said head is joined to said base; and said slot is accessible by a removal tool after said head has broken from said base.

12. The set screw according to Claim 11 wherein:

- a) said slot is a first slot and including a second slot.

13. The set screw according to Claim 12 wherein:

- a) said first and second slots are diametrically opposed from each other and are spaced by a

center core.

14. The set screw according to Claim 13 wherein:
  - a) said slots are longer parallel to a rotational axis of said set screw than wide and open onto an upper surface of said base after said head breaks from said base.
15. The set screw according to Claim 11 wherein:
  - a) said breakaway region is produced by placement of a radially smaller outer surface in the breakaway region as compared to the outer threaded surface of said base.
16. The set screw according to Claim 15 wherein:
  - a) said breakaway region is defined by a combination of said outer surface and said slots.
17. The set screw according to Claim 15 wherein:
  - a) said breakaway region is defined by a combination of said outer surfaces, said slots and at least one radial bore extending partway into said base from said threaded

surface and overlapping said breakaway region.

18. A set screw comprising:

- a) a base having an axis of rotation and a threaded outer surface adapted to be operably received in a threaded bore; said base having a bottom and a top;
- b) a grippable head initially joined to the top of said base for driving said base into a bore; said head being breakable from said base; and
- c) said base top including a non planar removal structure sized and shaped to be adapted to receive and provide purchase to a removal tool for removing said base from a bore receiving said base; said removal structure being inaccessible when said base is in a bore and said head is joined to said base and said removal opening being accessible by a removal tool when said base is in a bore and said head is broken from said base.

19. The set screw according to Claim 18 wherein:



- a) said removal structure comprises a pair of spaced slots extending radially inward from said base threaded outer surface and opening onto said top of said base.
20. The set screw according to Claim 19 wherein:
- a) said slots are diagonally opposed and spaced by a center core.
21. A set screw comprising:
- a) a base having a threaded surface adapted to be received in a threaded bore;
  - b) a head originally joined to said base at a breakaway region; said head being shaped and configured to receive a driving tool for rotating and applying torque to said set screw; said head breaking from said set screw at a preselected torque at said breakaway region; and
  - c) a removal slot that extends radially inward from said threaded surface; said slot, when said base is received in a bore, being non-accessible by a removal tool while said head is joined to said base; and said slot, when

said base is received in a bore, being accessible by a removal tool after said head has broken from said base.

22. The set screw according to Claim 21 wherein:

a) said slot is a first slot and including a second slot.

23. The set screw according to Claim 22 wherein:

a) said first and second slots are diametrically opposed from each other and are spaced by a center core.

24. A medical implant system comprising:

a) a first implant having a first bore and a second threaded bore intersecting with said first bore;

b) a second implant operably received in said first implant first bore;

c) a removable set screw for operably securing said first implant to said second implant; said screw being threadably receivable in said first implant second threaded bore, abutted against said second implant and thereafter torqued to a preselected torque;

- d) said set screw having:
- 1) a base with an external threaded surface sized and shaped to be threadably received in said first implant threaded bore, a bottom having a tip operably sized and shaped to frictionally engage said second implant and a top opposite said tip;
  - 2) a head breakably attached to said base top and adapted to receive an installation tool to drive said set screw base into said first implant threaded bore; said head breaking from said base upon the application of said preselected torque; subsequent to said head breaking from said base, said base being relatively low profile with respect to said first implant threaded bore;
  - 3) said base also including a pair of slots; each of said slots extending radially inward from said base threaded surface and intersecting with said base top; said slots



being diametrically opposed to each other and spaced by a center core of said base; when said base is in said first implant threaded bore, said slots are accessible to a removal tool when said head is broken from said base and are non-accessible to a removal tool when said head is attached to said base; and

- 4) a break initiating region of comparatively less cross-section in a plane perpendicular to said screw axis of rotation and positioned between said head and said base.

25. The system according to Claim 24 wherein:

- a) said set screw includes a pair of radially extending bores in said screw; each of said bores being positioned adjacent to and intersecting with a respective slot and with the base top; a central axis of each of said bores being centered within said breakaway region.

26. The system according to Claim 24 wherein:
- a) each of said slots is elongated parallel to the axis of rotation of said base.
27. A set screw for operably joining a first element to a second element comprising:
- a) a base having an axis of rotation, a threaded outer surface adapted to be rotatably received in a mating threaded bore in the first element, a bottom adapted to engage the second element and a top;
  - b) said base having a pair of slots extending radially inward from said threaded outer surface and communicating with said base top;
  - c) a center core positioned between said slots and extending to near said base top;
  - d) a breakaway head originally joined to said base; and wherein
  - e) said head blocks access to said slots when said base is in a bore and when said head is joined to said base, but said slots are accessible after said head breaks from said base.

28. A set screw for operably joining a first element to a second element comprising:

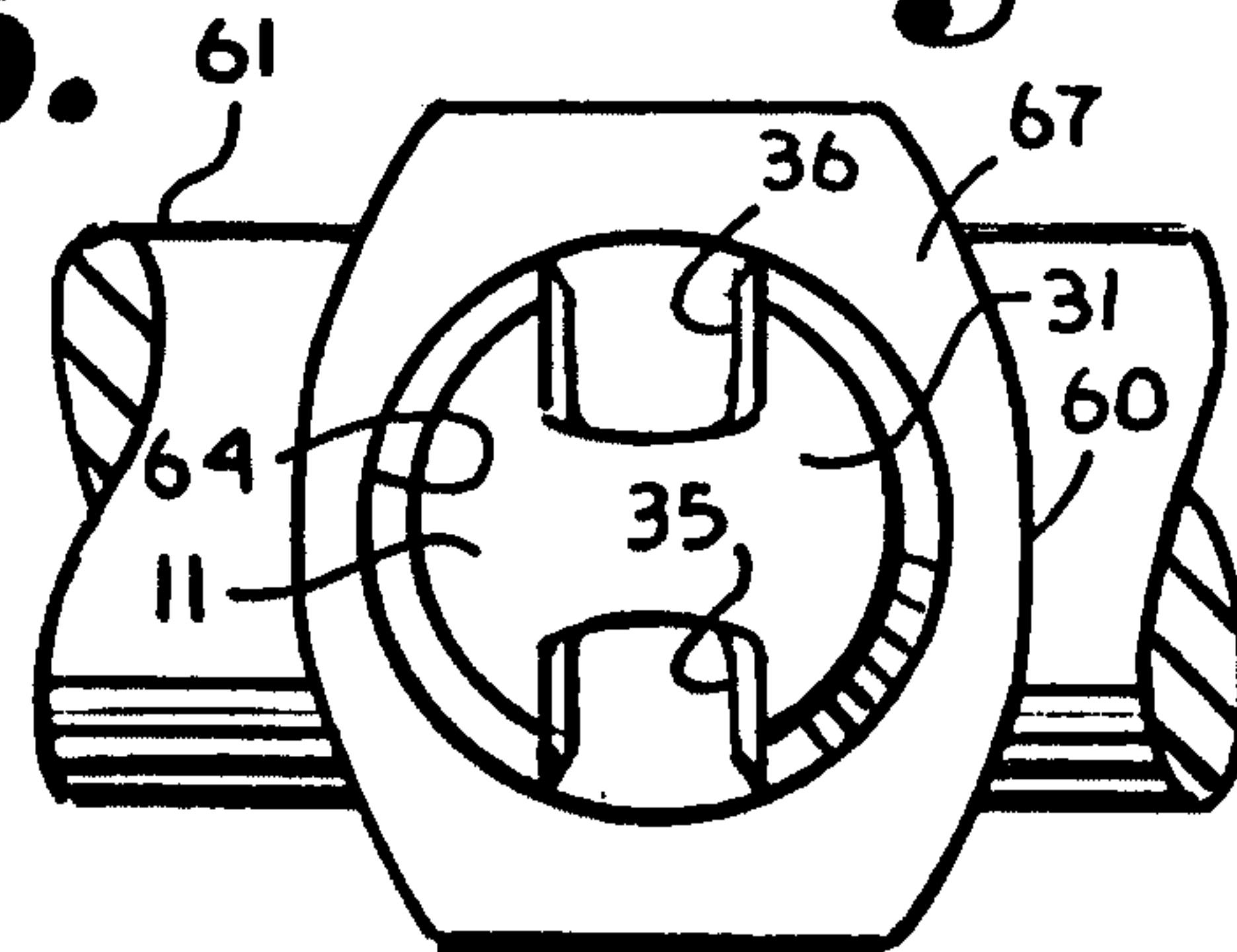
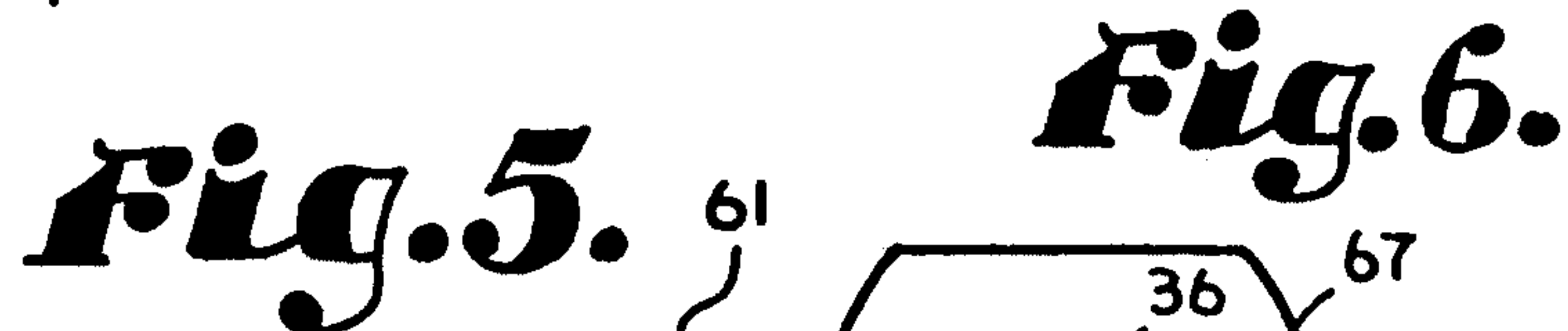
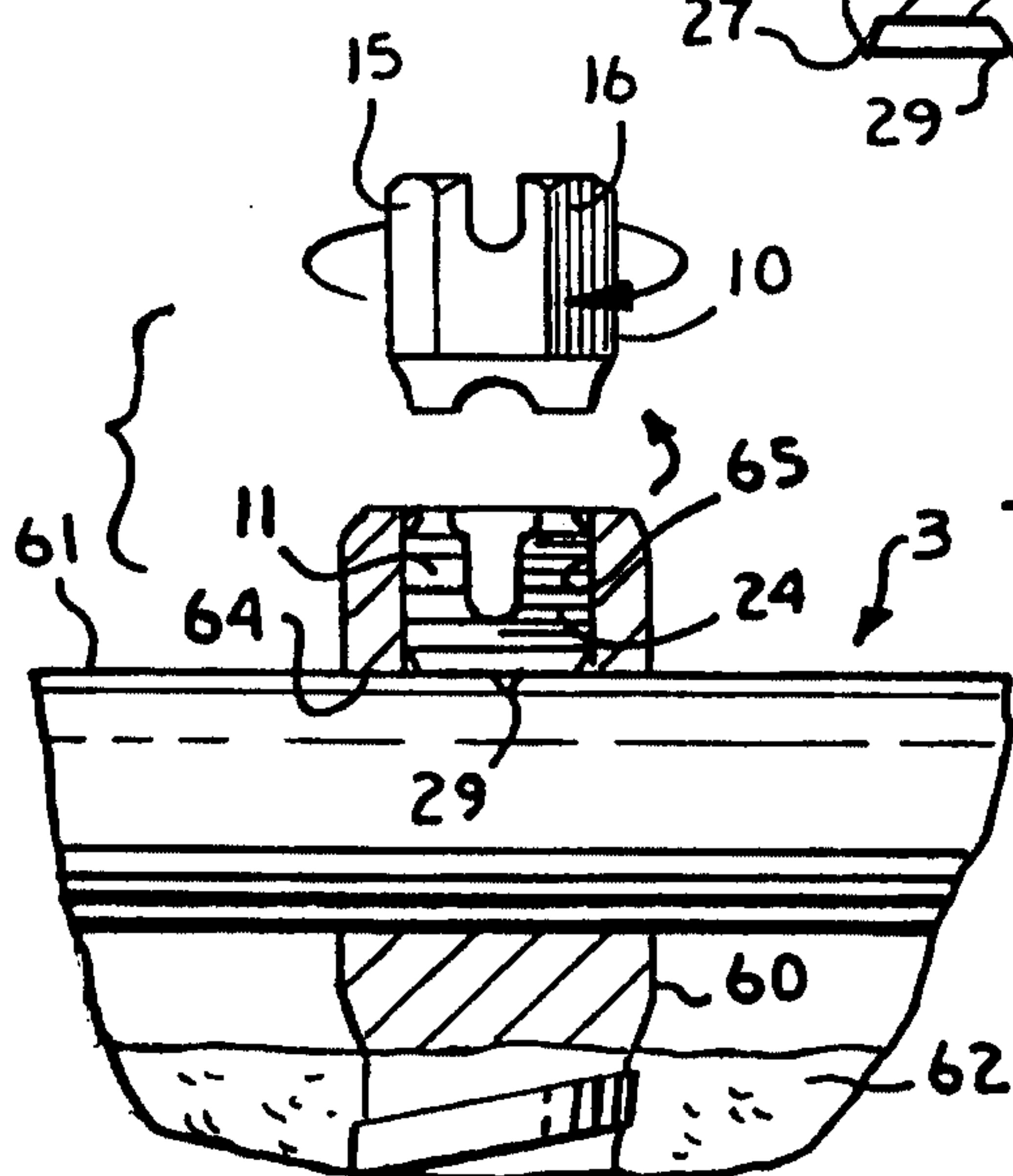
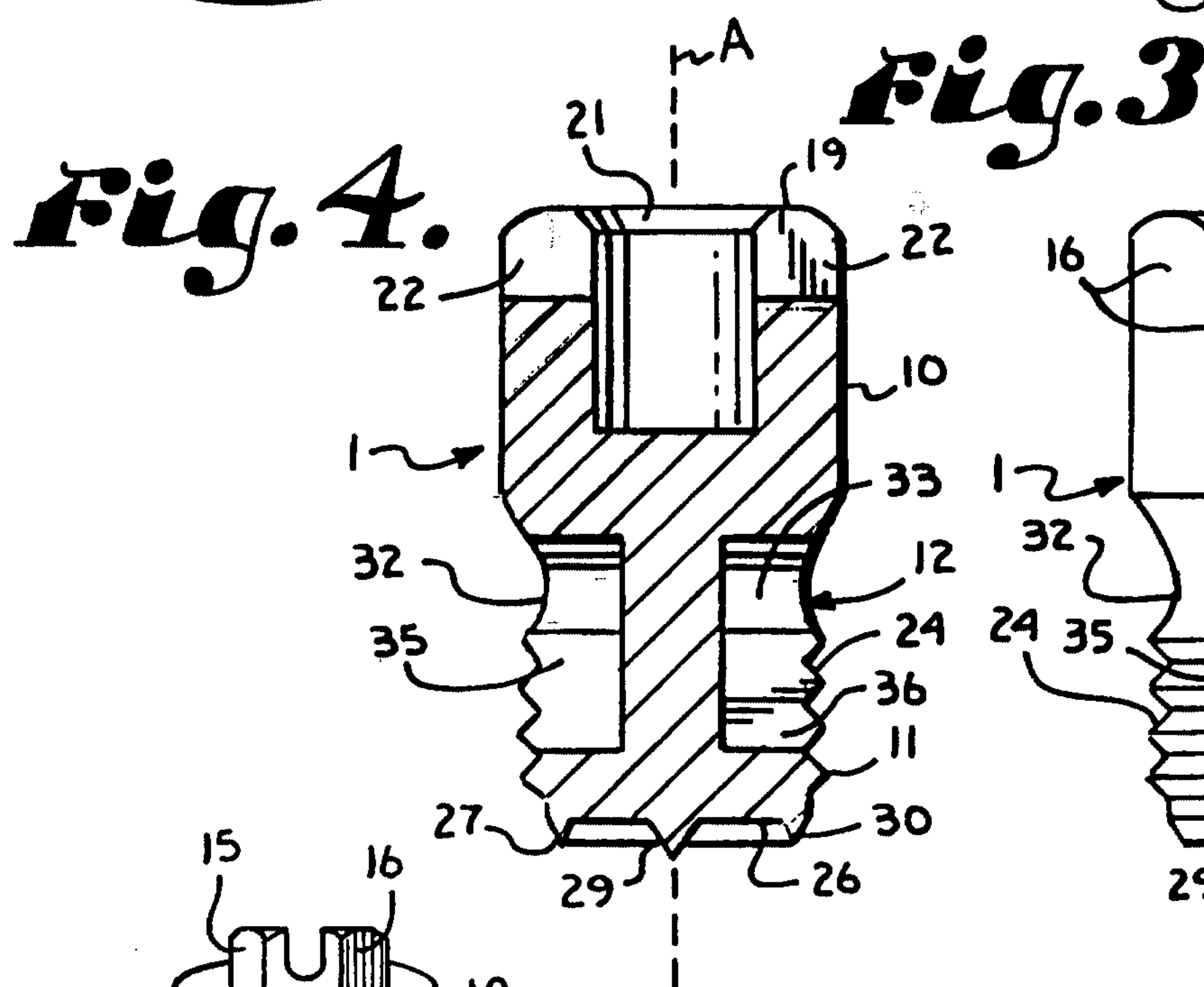
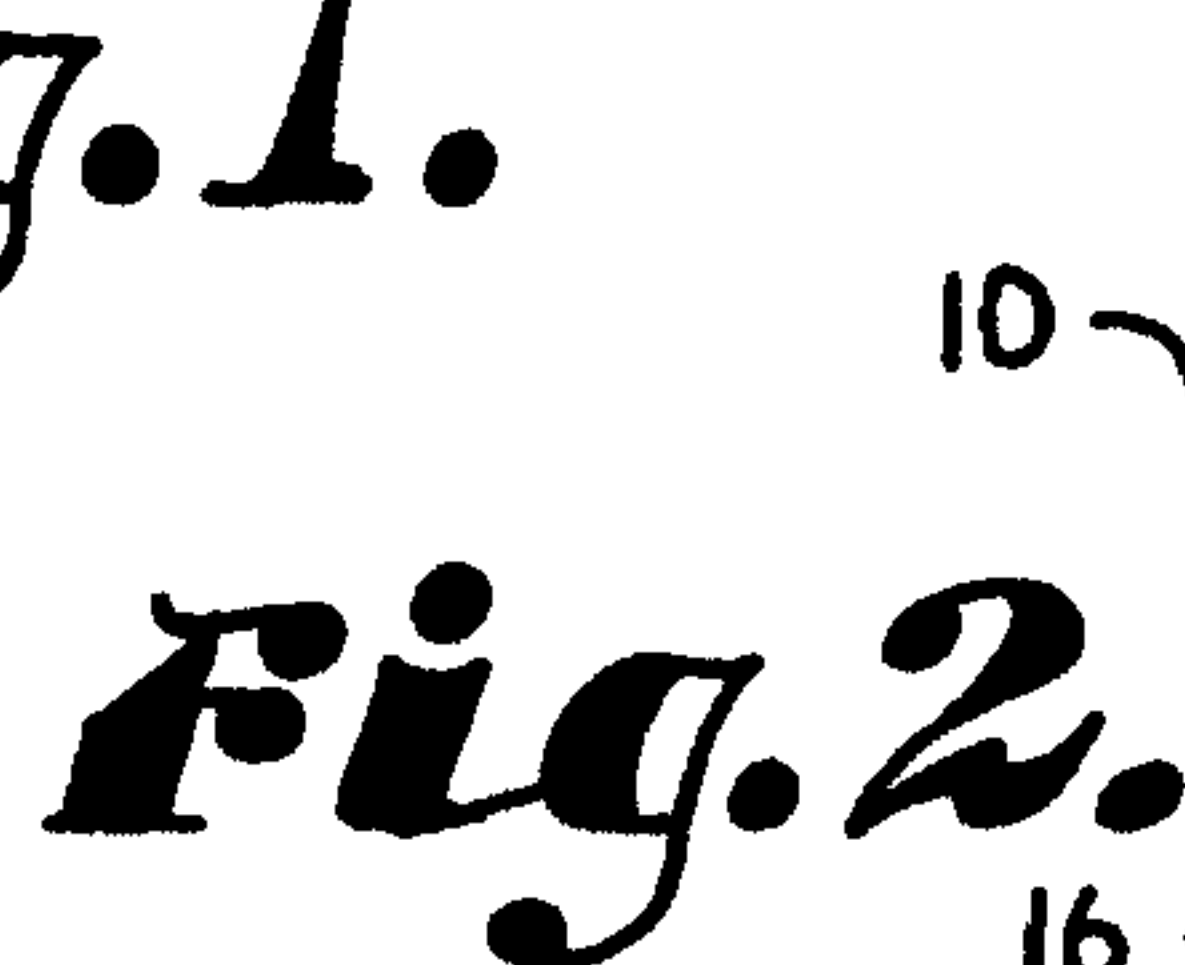
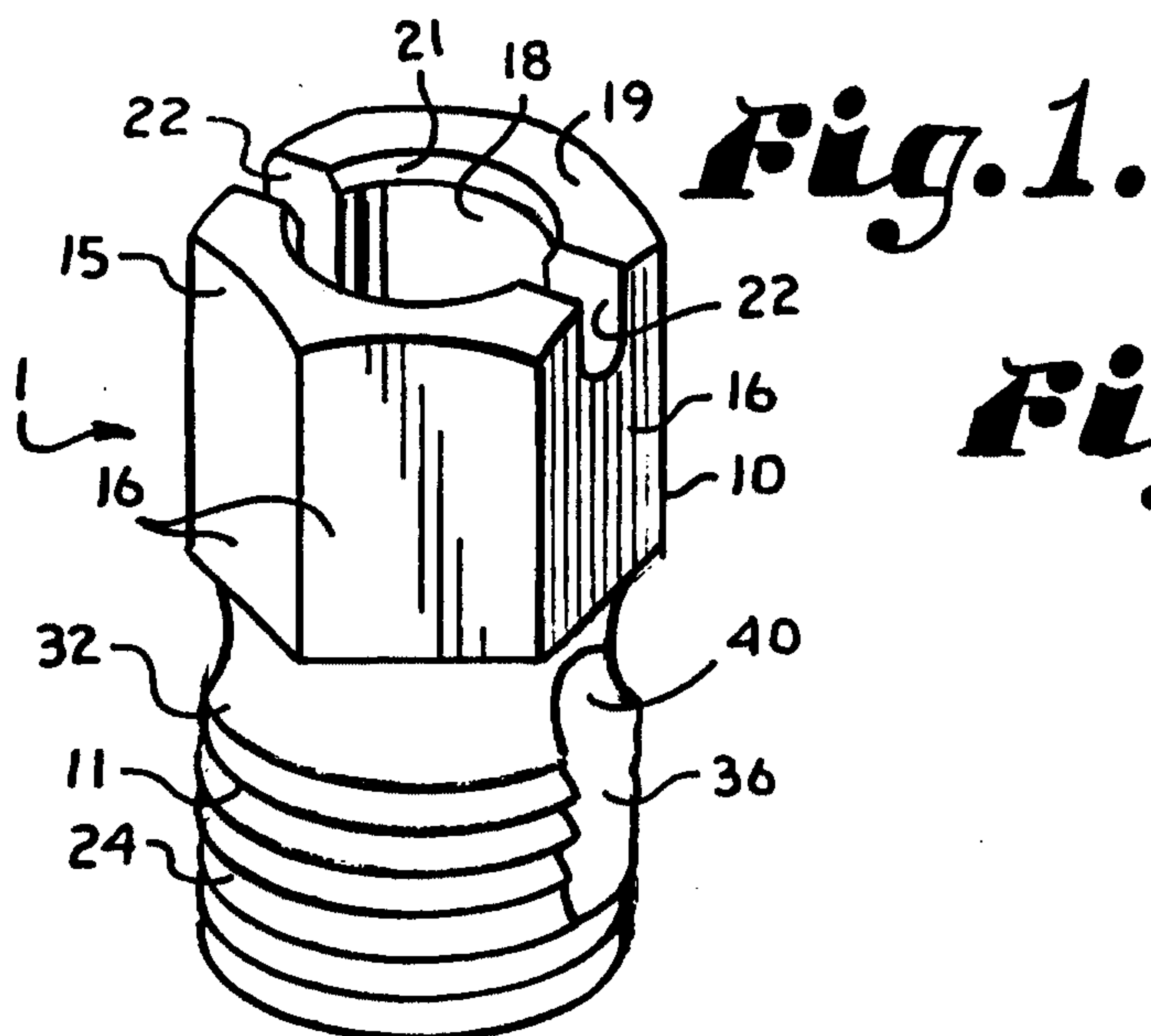
- a) a head having a surface for gripping, rotating and applying torque to said set screw;
- b) a base initially joined to said head and having a threaded surface adapted to be received into a threaded bore of the first element;
- c) said head and said base being joined at a breakaway region adapted to break upon the application of a preselected torque such that said head separates from said base; and
- d) a pair of slots that do not pass through an axial center of rotation of the set screw base; said slots being located in and extending radially inward from said base threaded surface; said slots each intersect with said breakaway region; and said slots being adapted to receive a removal tool inward of said threaded surface subsequent to said head being broken from said base to allow application of torque to said base and rotate said base counterclockwise.



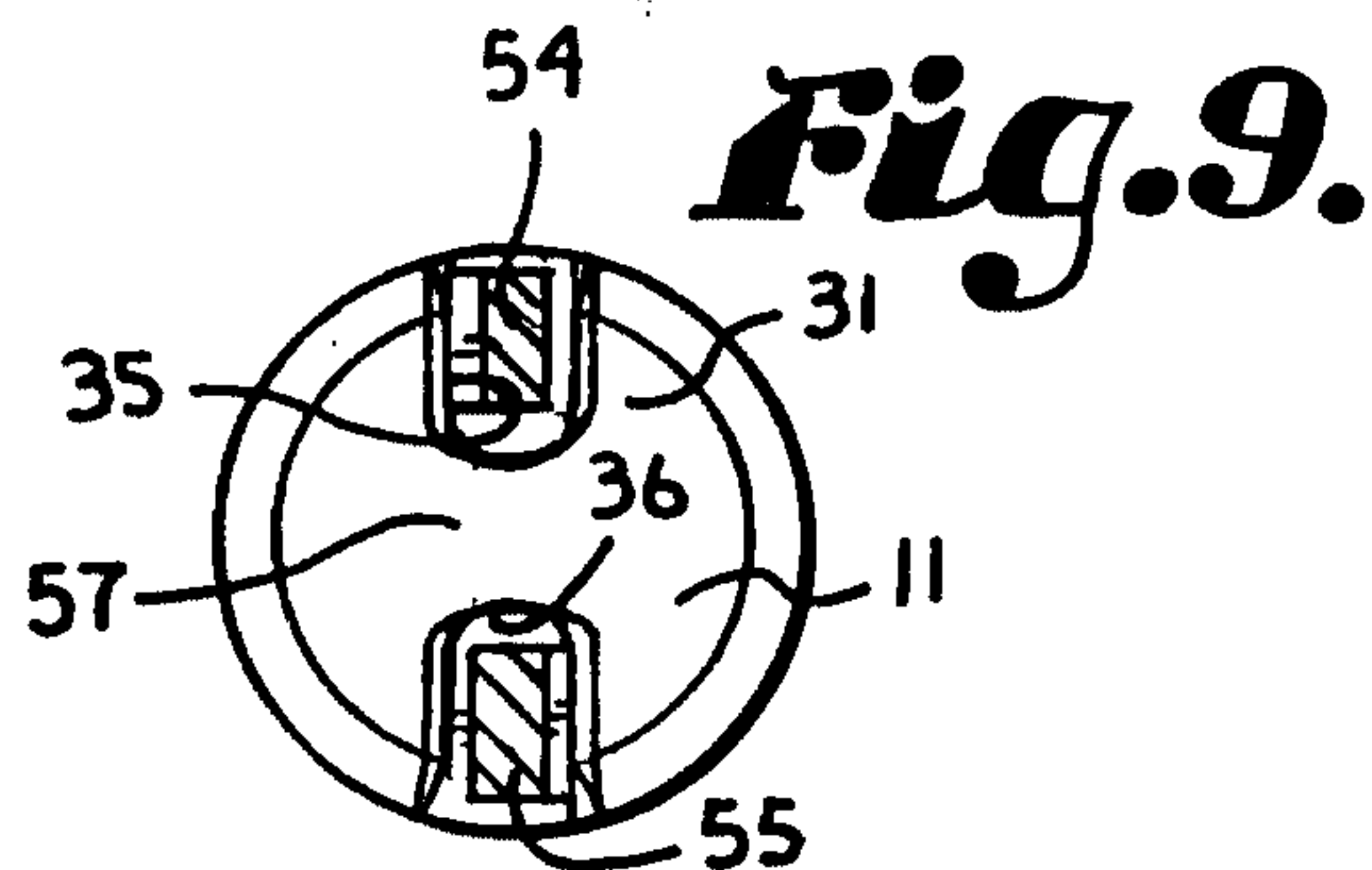
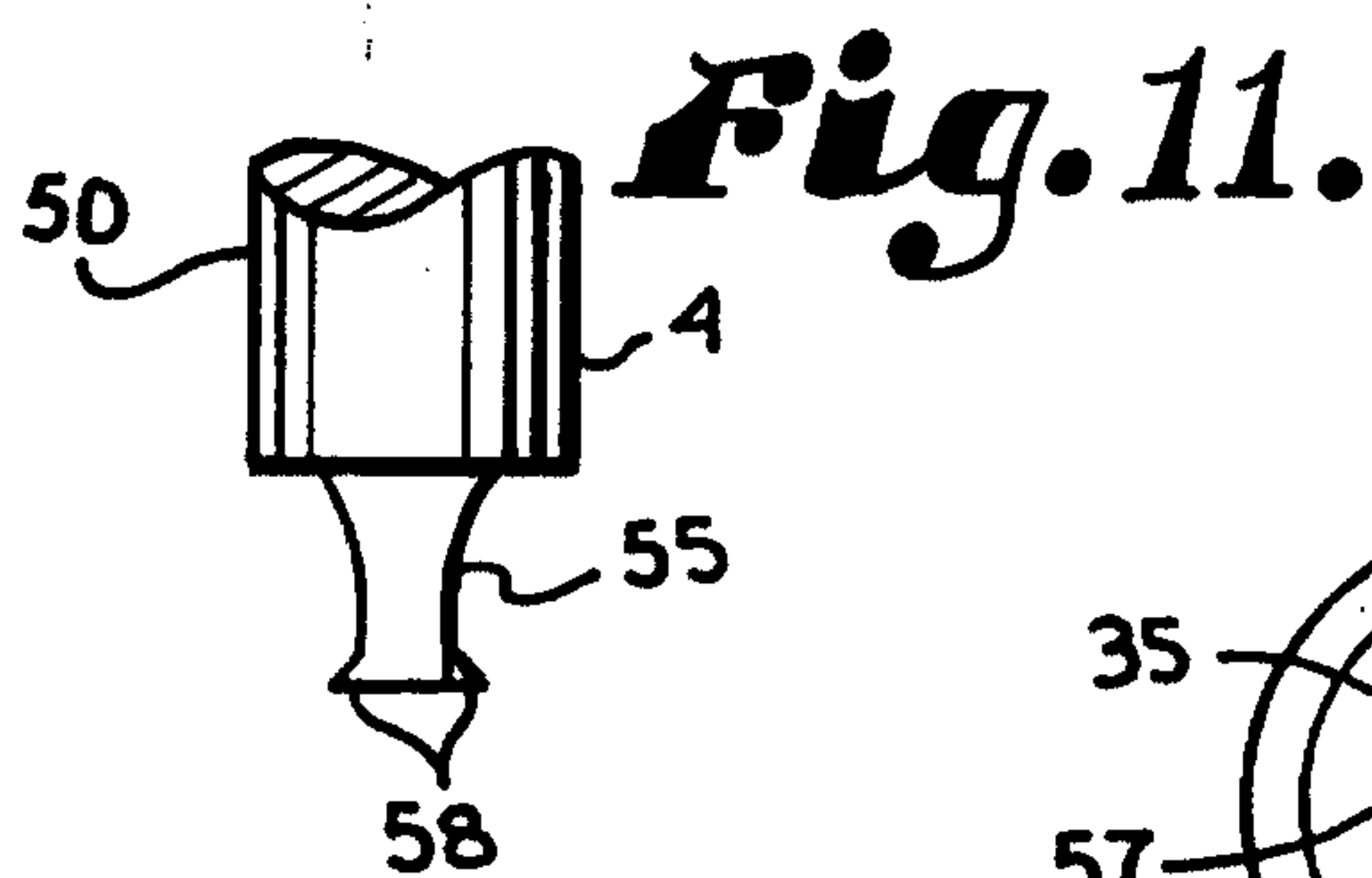
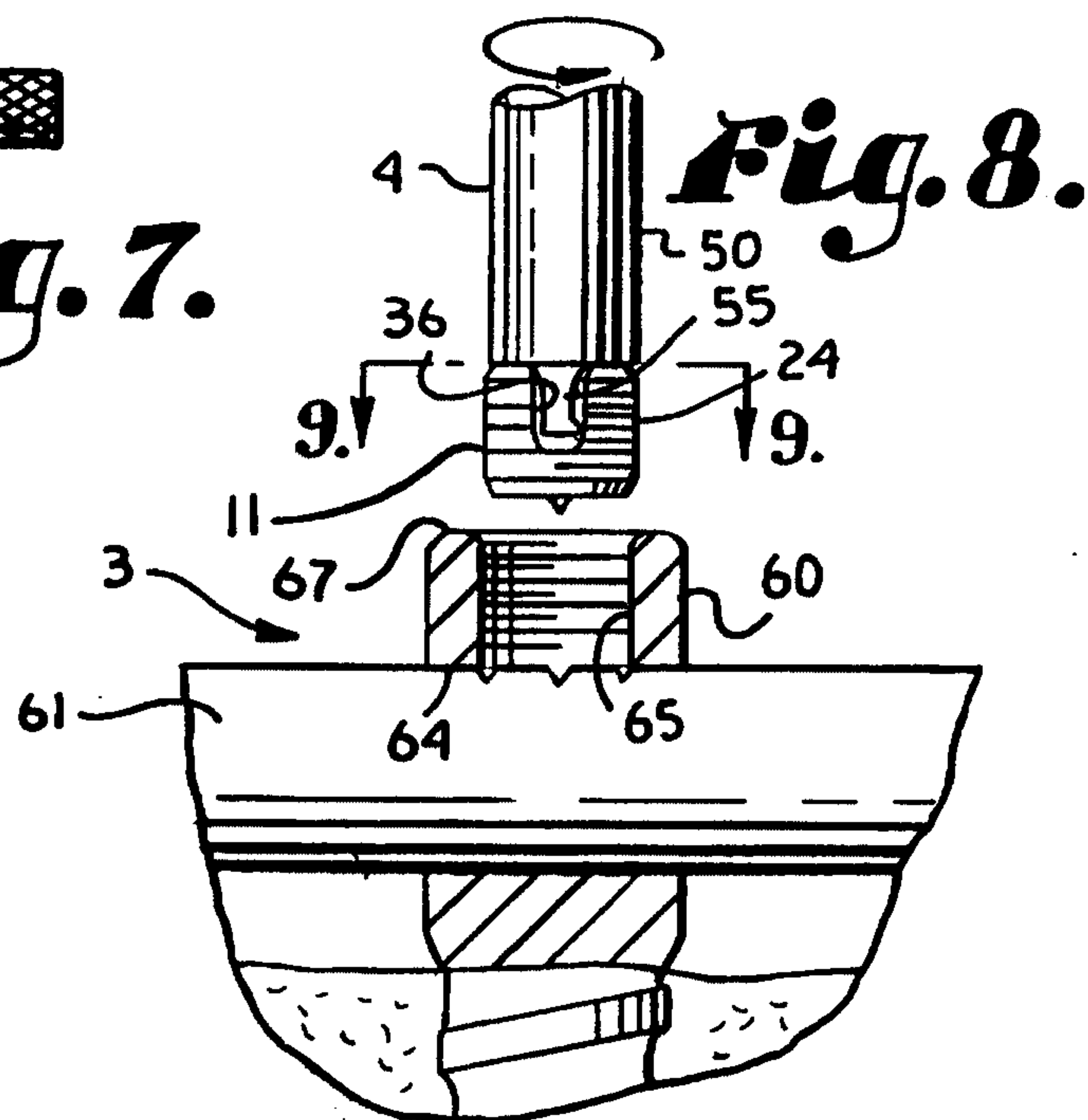
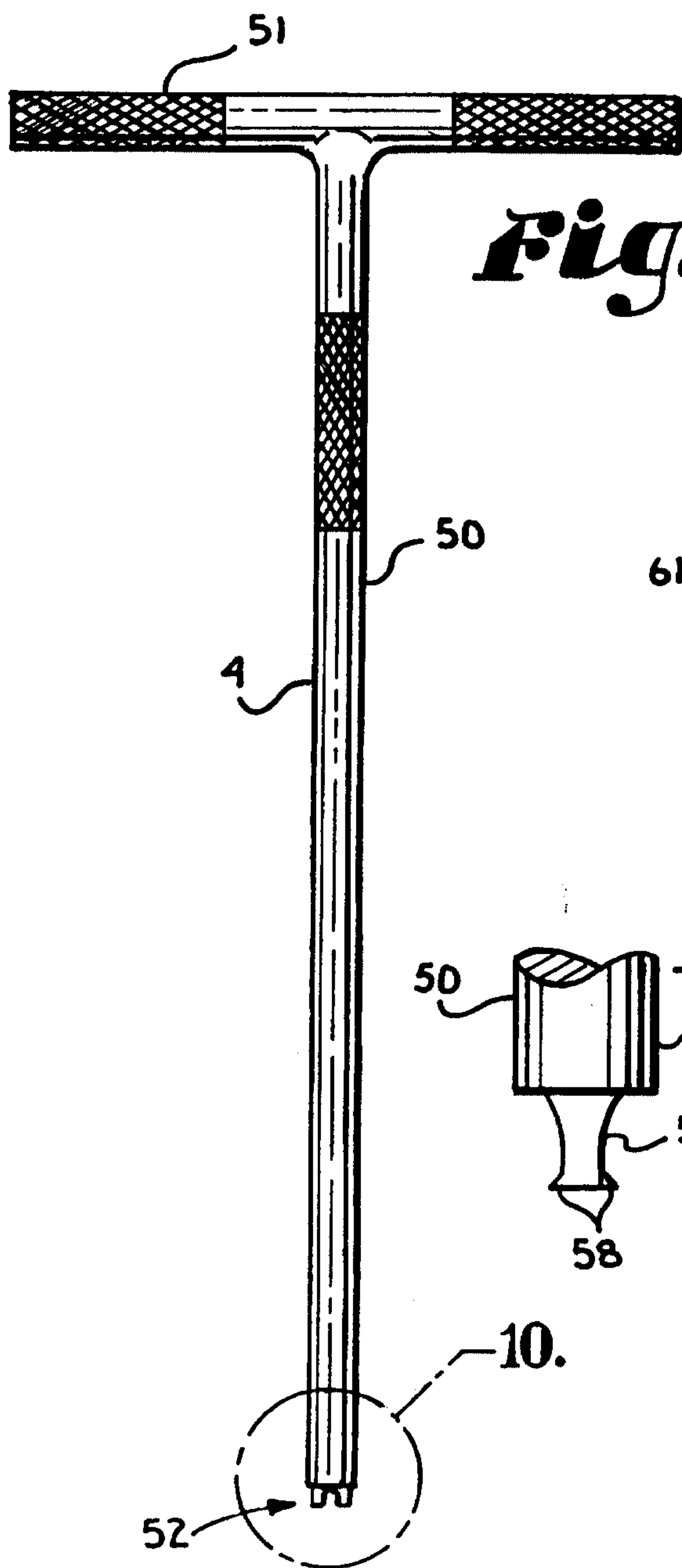
29. The set screw according to Claim 28 wherein:
- a) said slots are diametrically opposed and are separated by a center core.
30. A set screw according to Claim 28 wherein:
- a) said slots are positioned, sized and shaped to be available for entry of a removal tool after said head is broken from said base and are not accessible by a removal tool prior to said head being broken from said base when said set screw base is located within a threaded bore.
31. A set screw comprising:
- a) a base having a threaded surface adapted to be received in a threaded bore;
  - b) a head originally joined to said base at a breakaway region located by an exterior notch; said head being shaped and configured to receive a driving tool for rotating and applying torque to said set screw; said head breaking from said set screw at a preselected torque at said breakaway region; and
  - c) a removal slot that extends radially inward from said threaded surface and is adapted to

receive a removal tool, when said set screw is operably received in a threaded bore; said slot being non-accessible by a removal tool when said head is joined to said base; and said slot is accessible by a removal tool after said head has broken from said base.

32. The set screw according to Claim 31 wherein:
- a) said slot is a first slot and including a second slot; and
  - b) said first and second slots are diametrically opposed from each other and are spaced by a center core.







**Fig. 10.**

