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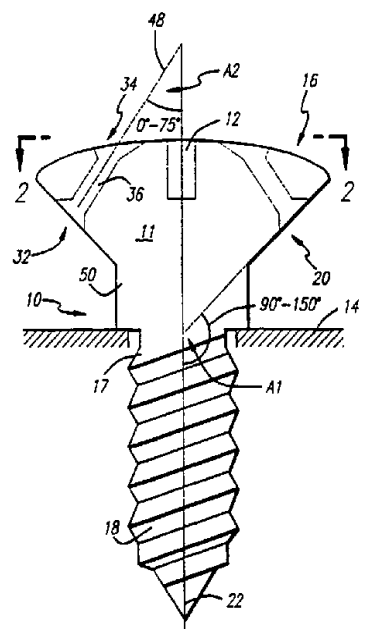
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(54) Title: SOFT TISSUE SECURING ANCHOR

(57) Abstract

A surgical anchor is provided with one or more anchor holes distributed around the head of the anchor. Each anchor hole is inclined to allow attachment of one or more sutures to the anchor either before, during or after the anchor is seated in a bone. The upper and lower apertures of each anchor hole are chamfered, and the chamfered areas from the anchor hole to the outside edge shall be polished or somehow smoothed to remove sharp edges and rough areas which may cause friction and abrasion to soft tissue or suture material. The lower surface of the anchor head may be angled to further simplify the task of feeding a surgical needle through the anchor hole after the anchor is seated into bone.



*(Referred to in PCT Gazette No. 13/1999, Section II)

Soft Tissue Securing Anchor

Related Applications

This invention claims priority of copending United States
5 provisional patent application Serial No. 60/048,284.

Background of the Invention

1. Field of the Invention

The present invention relates generally to the field of
10 surgical devices. In particular, this invention relates to anchors
for attaching soft tissue to bone, and or to other soft tissue.

2. Background of the Invention

Conventional devices are generally metal, plastic or
absorbable anchors which are screwed or press fit into pre-drilled
15 holes in a bone. The conventional anchors have a suture-securing
hole transverse to the long axis of the anchor. The suture-
securing hole is generally located in the shank of the anchor which
is therefore at or near the surface of the bone when the anchor is
properly seated in the bone. The orientation of the suture
20 securing hole in conventional anchors typically requires that the
anchor have the suture threaded through the suture-securing hole,
before the anchor is secured to the bone. A surgeon has little or
no choice of the angle or position of tissue approximation, that is
of attachment, when using such conventional anchors. Once a
25 conventional anchor is secured in place, a surgeon is generally not
able to rethread a suture through the suture-securing hole if the
suture should break or otherwise come loose. Usually, a new anchor
kit needs to be opened if the suture breaks. This leads to the
inefficient use of the patient's operative time as well as the
30 surgeon's time. Conventional anchors also only accommodate one
suture per anchor and surgeons have little or no choice of suture

Two-piece soft tissue securing devices such as shown in United States Patent No. 4,988,351 (D1) have added multiple suture attachment points to a washer secured to a bone. These devices are limited by the use of the two pieces and the inherent difficulty of managing more than one workpiece at a time. Additionally, washers as shown in D1 may be broken during attachment leading to all the problems described above.

Such conventional anchors require a surgeon to follow many steps and use special tools to successfully load and use the conventional anchors. First, the surgeon must gather the special tools necessary to use the conventional anchor. Second, the surgeon must thread the suture provided with the conventional anchor using a specialized threading tool. Third, the surgeon must drill an anchor hole into the bone which will secure the conventional anchor. Fourth, the surgeon must attach a conventional anchor to a special insertion tool. Fifth, the surgeon must secure the conventional anchor into the hole prepared in step three. Sixth, the surgeon must apply an appropriate surgical needle to an end of the free suture. Seventh, the surgeon must approximate the soft tissue to the conventional anchor using the needle and suture.

Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is solely for the purpose of providing a context for the present invention. It is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present invention as it existed in Australia before the priority date of each claim of this application.

Summary of the Invention

In accordance with the present invention, a soft tissue securing anchor is provided with two or more anchor holes distributed around the perimeter of the head of the anchor in a variety of orientations.

A soft tissue securing anchor according to the present invention maybe used to secure soft tissue to bone, or to reapproximate a plurality of soft tissue points to a single bone site or to approximate soft tissue to soft tissue. The materials from which a soft tissue securing anchor are fabricated may be the same as conventional anchors, i.e., an inert material. Specific materials that may be used include plastics, stainless steel, titanium alloys, or absorbable materials. Thus a soft tissue securing anchor according to the present

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invention has the same effect on a body in which it is surgically secured as conventional anchors. Additionally, all types of conventional absorbable or non-absorbable sutures may be used with the present invention.

In a first aspect, the present invention is an improved soft tissue
5 securing anchor having multiple suture securing points and attached to a bone by a screw wherein the improvement is characterized by:

an attachment means having along axis and a head at a first end of the long axis;

means to accommodate a securing or drive tool; and

10 two or more anchor holes through the head, each of the two or more anchor holes having an upper aperture and a lower aperture, each of the two or more anchor holes oriented to cause a line through the center of the anchor hole to intersect an extension of the long axis beyond the head forming an angle.

15 In a second aspect of the present invention, the anchor holes are inclined so that with the soft tissue securing anchor seated in the bone, the upper and lower apertures of each anchor hole are accessible to attach separate sutures to each of the anchor holes using conventional surgical techniques, i.e., curved needles. Any other variety of surgical needles may
20 also be used. Additionally, free sutures, without attached needles may be threaded through these holes. The inclined anchor holes allow a surgeon to efficiently attach soft tissue to the soft tissue securing anchor using preferred surgical tools without the necessity of using a multiplicity of specialized tools. Thereby making any given surgery more efficient and cutting down on
25 costly operative time as well as time that the patient is exposed to potentially life-threatening anaesthesia. The presence of a plurality of anchor holes in a single soft tissue securing anchor permits a surgeon to secure a plurality of soft tissue points with fewer soft tissue securing anchors than would have been required using conventional anchors that only accommodate a single
30 suture.

In another aspect of the present invention, the lower surface of the anchor head is angled relative to the long axis of the soft tissue securing anchor. The angle chosen is dictated by the surgeon's choice of needle and suture for a particular application. The angle of the lower surface of the
35 anchor head combined with the



angle of the anchor holes allows the surgeon to efficiently attach one or more sutures to a single soft tissue securing anchor. This minimizes the amount of foreign bodies that are surgically placed in a patient's body. Foreign body tissue reaction may lead to an
5 increased rate of infection and, therefore, with the present invention, the patient would benefit with a lowered rate of foreign body tissue reaction. Additionally, since the suture to anchor body interface is very important with respect to operative stability, the possibility of now securing multiple soft tissue
10 points to one anchor via the present invention means that if a single suture were to break, the operative approximation of soft tissue to bone or soft tissue to soft tissue would not be lost, as it is with the breaking of a suture attached to a conventional anchor.

15 In a further aspect of the present invention, each aperture of each anchor hole is chamfered to accommodate surgical needles. The chamfered aperture simplifies the surgeon's task of introducing the surgical needle into the anchor hole by widening the entry and exit apertures, and thus funneling the surgical needle point to the
20 center of the anchor hole. The chamfer also lessens the angle of approximation the surgeon must achieve with a surgical needle to successfully pass the surgical needle and suture through the anchor hole. The chamfered areas, from the anchor hole to the outside edge, shall be polished or somehow smoothed to remove sharp edges
25 and rough areas which may cause friction and abrasion of the tissue-approximating suture or the soft tissue itself. The chamfered aperture also minimizes acute edges in contact with the suture to minimize abrading of the suture thus allowing the liberal use of sliding knots on sutures passing through the present
30 invention.

In a still further aspect of the present invention, an anchor for securing soft tissue to bone or soft tissue to soft tissue includes a conventional attachment means having a long axis and a head at a first end of the long axis, a means to accommodate a
5 securing or drive tool, and an anchor hole through the head, the anchor hole has an upper aperture and a lower aperture. The anchor hole is oriented to cause a line through the center of the anchor hole to intersect an extension of the long axis beyond the head.

In a still further aspect of the present invention, an anchor
10 for securing soft tissue to bone or soft tissue to soft tissue includes an attachment means having a long axis and a head at a first end of the long axis, a means to accommodate a securing or drive tool, and an anchor hole through the head, the anchor hole having an upper aperture and a lower aperture, the anchor hole
15 oriented to cause a line through the center of the anchor hole to be skew to the long axis.

In another still further aspect of the present invention, a surgical anchor for reapproximating soft tissue to bone or soft tissue to soft tissue includes a screw having a head, a shank and a
20 threaded end, a shoulder between the body and the shank to provide a visual and tactile reference for proper head height above the bone, a means to accommodate a securing or drive tool, and a plurality of generally radial anchor holes disposed about the circumference of the head and extending through the head, each
25 anchor hole describing an angle between 0 and 75 degrees from the shank to a line through the anchor hole.

These and other features and advantages of this invention will become further apparent from the detailed description and accompanying figures that follow. In the figures and description,

threads, barbs, fingers, toggle or molly bolts, and rivets. Suture anchor 10 may be secured into bone by any conventional means such as the application of torque or press-fit. The currently preferred embodiment of the present invention is a threaded, self tapping

5 screw having a shoulder 50 which delineates head 11 from shank 17. Shoulder 50 provides a visual and physical indication to the surgeon to stop inserting soft tissue securing anchor 10 when shoulder 50 contacts bone 14. The size of shoulder 50 and the shape of head 11 are selected to permit access by surgical needle

10 to both upper and lower apertures such as upper aperture 34 and lower aperture 32. Raising lower aperture 32 above bone 14 permits easy access to lower aperture 32. Head 11 may include a means for accommodating a drive tool such as a shaped head, tabs, flanges, channels, or one or more drive sockets such as drive socket 12 for

15 securing anchor 10. A shaped head or drive socket such as drive socket 12 may be any conventional configuration compatible with surgical drive tools such as slotted, star, square, hex or allen shaped. Upper surface 16 of head 11 may be flat, convex or other conventional screw shape as shown in Fig. 2.

20 In accordance with one aspect of the present invention, lower surface 20 of head 11 may describe an angle A_1 between 90° and 150° from long axis 22. The angle of lower surface 20 may be determined by a surgeon's choice of needle and suture for a particular application. In the currently preferred embodiment of the present

25 invention, the angle of lower surface 20 for a soft tissue securing anchor appropriate for cranial cosmetic surgery is about 40° - 50° from long axis 22.

Referring now to both Fig.'s 1 and 3, soft tissue securing anchor 10 includes anchor points 24, 26, 28 and 30. Each anchor

point has an upper aperture and a lower aperture. Anchor hole 36 includes upper aperture 34 and lower aperture 32. Anchor holes 25, 29, 36 and 46 may be inclined at an angle A_1 (or A_3 of Fig 5B) between 0° and 75° from long axis 22. The angle of inclination, the diameter of the anchor holes, and the shape of head 11 are selected to accommodate the surgical task and a surgeon's choice of needle. The object is to secure the anchor, leaving sufficient space between lower aperture 32 and bone 14 for the surgeon to easily secure a suture through the anchor holes such as anchor hole 36. In a preferred embodiment of the present invention, soft tissue securing anchor 10 is appropriate for cranial cosmetic surgery and anchor holes 25, 29, 36 and 46 are inclined in the range of about 35° - 50° from long axis 22.

In a further aspect of the present invention, each aperture of each anchor hole is chamfered to accommodate surgical needles. Referring now to Fig. 2, anchor hole 36 connects upper aperture 34 and lower aperture 32. Chamfer 38 widens lower aperture 32, and chamfer 40 widens upper aperture 34. In a preferred embodiment of the present invention appropriate for cranial cosmetic surgery, the chamfers 38 and 40 of anchor hole 36 are about 45° from center line 48. The chamfers may be cut to a depth of 5% to 50% of the total length of an anchor hole. In a preferred embodiment of the present invention, chamfers 38, 40, 39 and 41 are cut to 25% of the total length of anchor holes 36 and 46 respectively. Chamfers 38 and 39 shall be polished or somehow smoothed, from anchor hole 36 and 46 respectively to lower surface 20 to remove sharp edges and rough areas which may cause friction and abrasion of soft tissue or suture material. Chamfers 40 and 41 shall be polished or somehow smoothed, from anchor hole 36 and 46 respectively to upper surface

16 to remove sharp edges and rough areas which may cause friction and abrasion of soft tissue or suture material.

A preferred embodiment of the present invention is shown in Fig.'s 1 and 3. Soft tissue securing anchor 10 is a stainless steel, pan-head, self-tapping screw having four anchor points 24, 26, 28 and 30 equally spaced around head 11. The preferred technique for using a soft tissue securing anchor according to the present invention is for the surgeon to expose bone 14 which will secure soft tissue securing anchor 10 using conventional surgical techniques. A hole is drilled into bone 14 by conventional means using either a hand or power drill. Soft tissue securing anchor 10 is screwed into bone 14 by applying a torque to soft tissue securing anchor 10 using a conventional surgical drive tool inserted into drive socket 12. When shoulder 50 contacts bone 14 soft tissue securing anchor 10 is seated. The surgeon may remove the drive tool from soft tissue securing anchor 10 and reapproximate soft tissue to the area of bone 14 which secures soft tissue securing anchor 10 by using conventional surgical techniques and sewing suture to anchor points 24, 26, 28 and 30.

In alternative techniques, sutures may be secured to anchor points 24, 26, 28 and 30 before, during or after the process of seating soft tissue securing anchor 10 in bone 14. These techniques are suited to bone sites which limit access to head 11 after soft tissue securing anchor 10 is seated. Thus the suture may be secured to soft tissue securing anchor 10 before, during or after soft tissue securing anchor 10 is fully seated into bone 14. This allows the surgeon to adopt her technique to a variety of securing sites for soft tissue securing anchors.

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Referring now to Fig.'s 4(a) and (b), an alternate embodiment of the present invention is shown in which anchor holes 52 and 54 are oriented skew to long axis 58. Each anchor hole has an upper aperture and a lower aperture. Anchor hole 52 includes upper
5 aperture 52U and lower aperture 52L. Each aperture is chamfered. Upper aperture 52U includes aperture 52N. With anchor holes 52 and 54 oriented as shown in Fig.'s 4(a) and (b), the angle formed between the anchor holes and a plane perpendicular to long axis 58 may be from 0° to 90°.

10 Referring now to Fig.'s 5(a) and (b), an alternate embodiment of the present invention is shown in which lower surface 20 Anchor holes 74, 78, 80, 82, 84, 86, 88 and 90 are oriented generally parallel to drive socket 76. In Fig. 5(b) only anchor holes 74 and 90 are shown for clarity. With the anchor holes 74 and 90 oriented
15 as shown in Fig.'s 5(a) and (b), the angle formed between the anchor holes and a plane perpendicular to long axis 92 may be from 0° to 90°.

Referring now to Fig.'s 6(a) and (b), anchor holes 60, 68, 70 and 72 form an angle of 0° with a plane perpendicular to long axis
20 62. The embodiment of the present invention shown in Fig.'s 6(a) and (b) allows a surgeon to obtain an adequate angle of approximation to successfully secure one or more sutures to soft tissue anchor 64 by maintaining the surgical needle with the plane of its curve parallel to the plane of the surface of bone 66 as the
25 surgical needle is passed through anchor hole 60, 68, 70 or 72 of soft tissue securing anchor 64. This embodiment of the present invention also presents a low profile above the surface of the bone in which it is secured.

Having now described the invention in accordance with the requirements of the patent statutes, those skilled in this art will understand how to make changes and modifications in the present invention to meet their specific requirements or conditions.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:-

1. An improved soft tissue securing anchor having multiple suture securing points and attached to a bone by a screw wherein the improvement is characterized by:

5 an attachment means having a long axis and a head at a first end of the long axis;

means to accommodate a securing or drive tool; and

10 two or more anchor holes through the head, each of the two or more anchor holes having an upper aperture and a lower aperture, each of the two or more anchor holes oriented to cause a line through the center of the anchor hole to intersect an extension of the long axis beyond the head forming an angle.

2. The anchor of claim 1 further characterized by:

15 a shoulder displaced about the attachment means near the head to provide a visual and tactile reference for maintaining proper head height above the bone.

3. The anchor of claim 1 or claim 2 wherein the upper aperture and lower aperture are chamfered.

20 4. The anchor of claim 3 wherein the chamfer extends from 5 to 50 percent of the total length of an anchor hole.

5. The anchor of any one of the preceding claims further characterized by: a plurality of anchor holes disposed about the circumference of the head.

25 6. The anchor of any one of the preceding claims wherein the anchor is characterized by an inert material.

7. The anchor of any one of the claims 1-5 wherein the anchor is characterized by plastics, stainless steel, titanium alloy or absorbable material or a combination thereof.

30 8. The anchor of any one of the preceding claims wherein the attachment means is characterized by a screw.

9. The anchor of claim 8 wherein the means to accommodate a securing or drive tool is characterized by a drive aperture on the head to accept a tool for imparting torque to the anchor.

35 10. The anchor of claim 3, wherein the head is generally conical having a vertex, an upper surface and a lower surface, the vertex of the cone attached to the attachment means forming an angle between the lower surface and the

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24. The anchor of any one of claims 14 to 23 wherein the head is generally conical having a vertex, an upper surface and a lower surface, the vertex of the cone attached to the attachment means forming angle between the lower surface and the long axis and the primary axis of the cone collinear with the long axis of the attachment means.
- 5
25. The anchor of claim 24 wherein the angle between the lower surface and the long axis is between 90 and 150 degrees.
26. The anchor of claim 24 wherein the angle between the anchor holes and the long axis is between 5 and 75 degrees.
- 10
27. The anchor of claim 24 wherein the angle between the anchor holes and the long axis is between 35 and 50 degrees, and the chamfers are 45 degrees from a centerline through each anchor hole.
28. A soft tissue securing anchor substantially as described with reference to the accompanying figures.

Dated this 30th day of January 2001

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Patent Attorneys for the Applicant:

F B RICE & CO

SECRET



FIG. 1

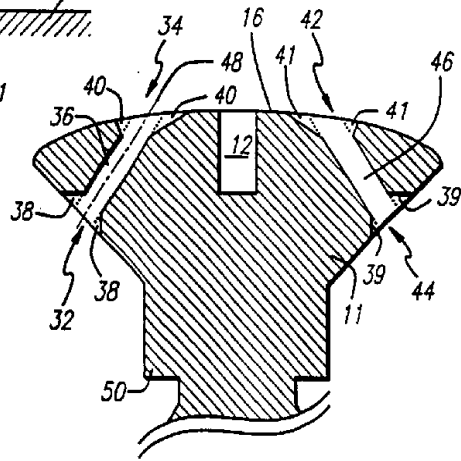
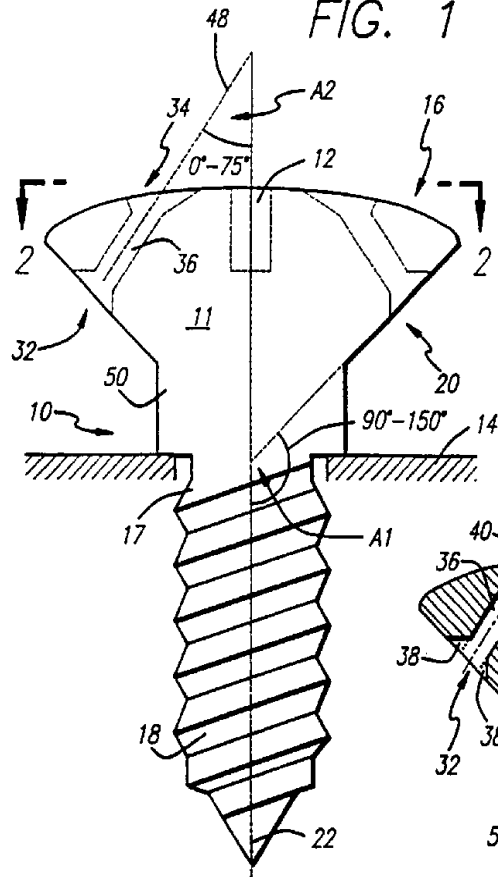


FIG. 2

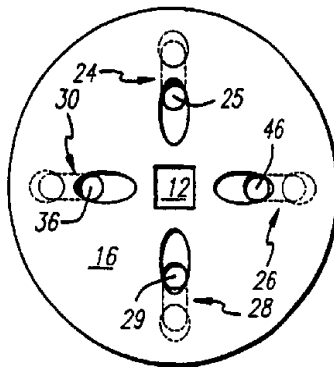


FIG. 3

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FIG. 4A

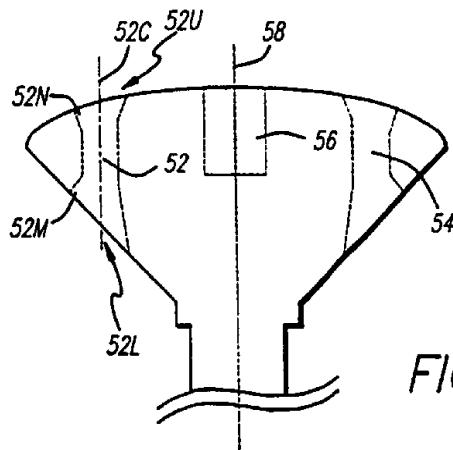
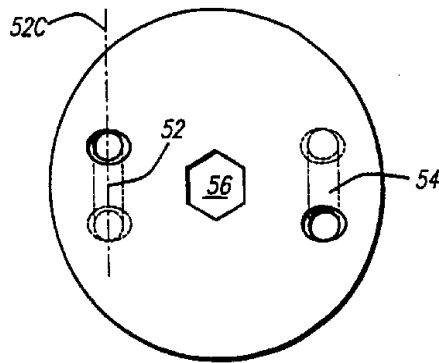


FIG. 4B

FIG. 5A

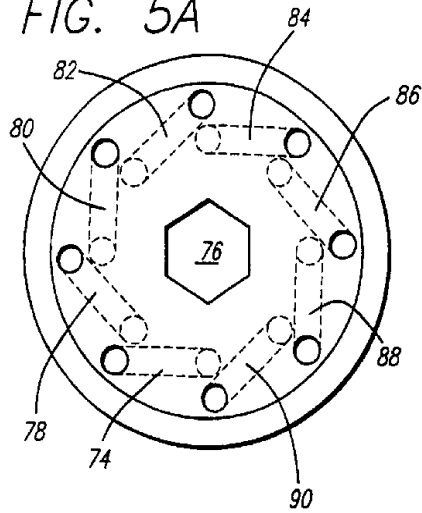


FIG. 5B

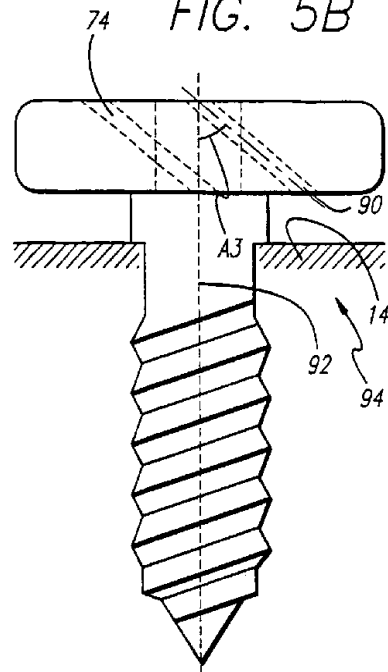


FIG. 6B

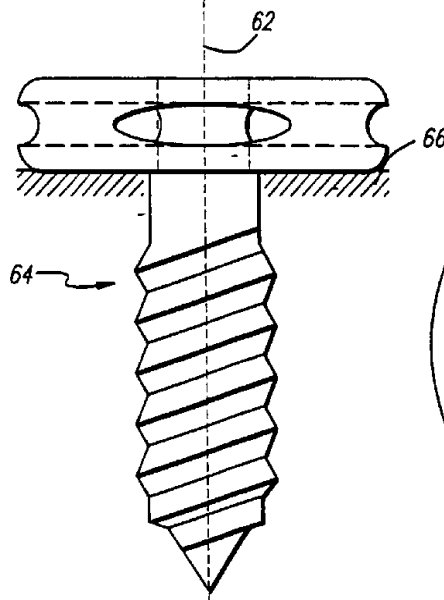


FIG. 6A

