(12) PATENT
(19) AUSTRALIAN PATENT OFFICE

(11) Application No. AU 199720821 B2
(10) Patent No. 733342

(54) Title

A bone fixing device, in particular for fixing to the sacrum during osteosynthesis of the backbone

(51)[6] International Patent Classification(s)
A61B 017/70

(21) Application No: 199720821

(22) Application Date: 1997.05.12

(30) Priority Data

(31) Number	(32) Date	(33) Country
96/05898	1996.05.13	FR

(43) Publication Date : 1997.11.20
(43) Publication Journal Date : 1997.11.20
(44) Accepted Journal Date : 2001.05.10

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(56) Related Art

US 5429639
US 5443467
EP 654249

A B S T R A C T

A bone fixing device, in particular for fixing to the sacrum for osteosynthesis of the backbone, comprises elongate link means receiving at least one bone-fastening screw (2), which passes through an orifice (7) formed in the link means. In the bottom of the link means there is included a bearing surface (7a) of essentially circular cross-section. The head (21) of the screw includes an essentially spherical surface for bearing against said bearing surface. The link means include a first thread (8) in the vicinity of said orifice. The device further includes a plug (3) having a second thread (304) suitable for co-operating with the first thread, the plug being suitable for coming into clamping contact against said screw head (21) to hold it in a desired angular position. According to the invention, the link means are constituted by a single-piece plate-shaped element (5) having the orifice (7) and the first thread (8) formed therein, and said bearing surface (7a) is essentially spherical.

P/00/0011
Regulation 3.2

AUSTRALIA

Patents Act 1990

COMPLETE SPECIFICATION

FOR A STANDARD PATENT

ORIGINAL

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Invention Title: **A BONE FIXING DEVICE, IN PARTICULAR FOR FIXING TO THE SACRUM DURING OSTEOSYNTHESIS OF THE BACKBONE**

The following statement is a full description of this invention, including the best method of performing it known to us

A BONE FIXING DEVICE, IN PARTICULAR FOR FIXING TO THE SACRUM DURING OSTEOSYNTHESIS OF THE BACKBONE

The present invention relates in general to a fixing device, in particular for fixing to the sacrum and usable during osteosynthesis of the backbone.

It is commonplace to perform osteosynthesis of the backbone by using fixing devices that are fastened to the sacrum. This makes it possible to perform reduction movements between the various fixed stages, which movements can be contractions, distractions, or indeed reversals of vertebrae that have slipped forwards relative to the backbone, where the latter condition is known as "spondylolisthesis".

Distraction is often performed for reduction of spondylolisthesis. Partial reduction is thus obtained by putting the fibers of the patient's ligament and disk apparatus back under tension. Reduction is completed by using equipment in accordance with the operating technique associated therewith. Except under exceptional circumstances, the operation is performed bilaterally. Throughout the description below, only one side of the treatment is described.

Most blocks or plates known in the prior art for fixing to the sacrum suffer from certain drawbacks. One of these drawbacks lies in that the orientation of the bone-fastening screws is fixed, which means that the device clearly lacks flexibility in use, given variations from one patient to another concerning the configuration of the sacrum and the neighborhood thereof.

Another drawback of known plates or blocks for fixing to the sacrum lies in the risk of the fastening screws becoming unscrewed, particularly under the effect of relative micromovements that occur between the equipment and the sacrum. This can result in failure of the fixing to the sacrum.

Also, backbone osteosynthesis can be performed by using equipment serving to fix various functional units

of the spinal column, often in a very rigid manner. This gives rise to a sudden change in the distribution of forces, and thus to resulting stress and deformation states for the disks underlying and overlying the fixing. At some stage in the long term, this modification gives rise to degeneration of the disks. This condition is known as the "hinge syndrome".

Document EP-A-0 625 337 discloses a bone fixing device, in particular for fixing the sacrum for osteosynthesis of the backbone, the device comprising elongate link means receiving at least one bone-fastening screw, which screw passes through an orifice formed in the link means, in which the link means include in the bottom region thereof a bearing surface of essentially circular cross-section, in which the head of the screw has a surface that is essentially spherical for bearing against said bearing surface, and in which the link means include a first thread in the orifice, the device also including a plug having a second thread suitable for co-operating with the first thread and for coming into clamping contact with said screw head to hold it in a desired angular position. That device enables the inclination of the screws relative to an elongate link element to be varied, and it also enables the spacing between the screws to be varied.

Nevertheless, that known device is disadvantageous in that the elongate link means are constituted by a plurality of components, specifically an elongate member of cup-shape and a plurality of fixing blocks distributed along the elongate member, each receiving the head of a screw, and at the bottom, a zone corresponding to the elongate member.

This means that it is extremely fiddly for the surgeon to handle the device and put it into place, and in particular it is necessary to slide a series of fixing blocks along the elongate member, and to hold them in position thereon.

A first object of the present invention is to mitigate that drawback.

To this end, the invention provides a bone fixing device, in particular for fixing the sacrum for osteosynthesis of the backbone, the device including an integral link member receiving at least one bone-fastening screw, which screw passes through an orifice directly formed in the link member, wherein the link member includes in the bottom region thereof an essentially spherical bearing surface, wherein the head of the screw has a surface that is essentially spherical and complementary to the hearing surface of the link member for surface contact therebetween, and wherein the link member includes a first thread in the orifice, the device further including a plug having a second thread suitable for cooperating with the first thread and for coming into clamping contact with said screw head to hold it in a desired angular position.

Preferred, but non-limiting aspects of the device of the invention are the following:

the first thread is a tapping formed internally in the orifice at a distance from said bottom, and the plug has an outside thread;

the screw head also has a generally spherical top, and the plug has a complementary internal spherical cavity;

said link member includes a series of orifices in alignment that are interconnected by a slot enabling a bone-fastening screw to be moved from one orifice to another before tightening;

said screw head and said plug have identical tightening sockets;

said link member is designed to be fixed to a first bone and forms an integral portion of an element that also includes an eyelet for another bone-fastening screw for fastening to a second bone, together with a rod interconnecting said plate and said eyelet;

the device further includes a bone-fastening device for fastening to another bone, to which said rod is fixed;

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the device includes at least two bone-fastening screws passing through respective orifices formed in said plate, and the two screws are suitable for taking up two different angular positions;

the device further includes means for attenuating the stiffness of the assembly between at least one of the bone-fastening screws and said element;

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- said means for attenuating stiffness comprise at least one piece of flexible material interposed and compressed between said screw head and the associated plug;
- the device is associated with a plurality of pieces of flexible material having different flexibilities, thereby enabling different degrees of stiffness attenuation to be provided without requiring action to be taken on the torque with which the plug is tightened;
- said piece is an O-ring;
- said piece is a pellet;
- said stiffness attenuation means comprise a thixotropic fluid interposed between and compressed between the plug and said screw head;
- said spherical bearing surface of said orifice is formed by deforming an O-ring placed in a bottom region of said orifice;
- said spherical bearing surface of said orifice is constituted by a surface of a rigid ring fitted in a bottom region of said orifice;
- said rigid ring is made of a material selected from the group comprising: ceramic-coated titanium alloys, titanium alloys treated by ion bombardment, and solid ceramics;
- the stiffness attenuation means further include a surface coating suitable for reducing friction between said essentially spherical bearing surface and said complementary surface of the screw head; and
- said surface coating is made by nitrogen ion bombardment.

Other aspects, objects, and advantages of the present invention appear more clearly on reading the following detailed description of preferred embodiments thereof given by way of example and made with reference to the accompanying drawings, in which:

• Figure 1 is a mid longitudinal section view through a fixing element of the invention;

• Figure 2 is a front view of the Figure 1 element;

• Figure 3 is a side view of the element together with three bone-fastening screws and the associated plugs;

• Figure 4 is a front view of the element provided with screws and plugs;

• Figure 5 is a side view in elevation of a plug for co-operating with the screw of Figure 6 and the element of Figures 1 and 2;

• Figure 6 is a side view in elevation of a bone-fastening screw for co-operating with the element of Figures 1 and 2;

• Figure 7 is a cross-section view of the fixing element, a bone-fastening screw, and the associated plug, after assembly;

• Figure 8 is a view partially in elevation and partially in section through an auxiliary bone-fastening screw designed to co-operate with another portion of the fixing element of Figures 1 and 2;

• Figures 9 to 12 are cross-section views analogous to Figure 4, through four variant embodiments of the invention;

• Figure 13 is a cross-section view through the various components of a fifth variant embodiment of the invention; and

• Figure 14 is a cross-section view through the fifth variant in the assembled state.

As a preliminary point, it should be observed that elements or portions that are identical or similar from one figure to another are designated, wherever possible, by the same reference symbols, and are not described again on each occasion.

With reference now to Figures 1 and 2, there can be seen a sacrum-fixing element given overall reference 1 and made up of three portions: an upper eyelet 4, a

sacrum plate 5, and a rod 6, e.g. a cylindrical rod, interconnection the eyelet and the plate. In profile, the overall shape of the element 1 is curved to comply with lordosis, as can be seen in Figure 1.

A series of holes 7 is formed through the plate 5 in alignment with the long direction of the element 1 and for receiving bone-fastening screws 2.

Preferably, a range of models for the element 1 is offered to the surgeon, different models having, in particular, different lengths of rod 6, and within the plate 5, different numbers of holes for bone-fastening screws.

As shown in Figure 3, in a three-hole version, the plate 5 may receive two bone-fastening screws 2, while in a five-hole version (not shown), it may receive three bone-fastening screws 2.

The holes 7 are in communication with one another via an oblong section through slot 9 as can be seen in Figure 2. This slot makes it easy to pass a screw 2 from one position to another while performing reduction. In the region of its bottom, each of these holes includes a spherical cup 7a for co-operating with a complementary bottom portion of the head 21 of the screw 2, said head 21 being generally spherical in shape and having a tightening socket 211, e.g. of the hexagonal type.

This shape for each hole 7 and for the associated screw head 21 allows each screw to move within a solid angle where the half-angle at the apex is, for example, of the order of 30°.

In addition, since each screw is stabilized in its housing while it is being installed, two screws that are distant from each other are suitable for maintaining bone distraction without requiring the use of a distractor instrument.

As shown in particular in Figures 1 and 7, each hole 7 possesses internally, at a distance from the cup 7a, a thread in the form of a tapping 8 which enables it to

receive a plug 3, shown in detail in Figure 5. The outside face of the plug includes a tightening socket 302 which is preferably identical to that in the screw head 21 so that the same tightening tool can be used, and a spherical cup-shaped housing 301 co-operating with the similarly spherical top of the screw head 21. The periphery of the plug is threaded at 304 in order to co-operate with the tapping 8 in the hole 7. The purpose of the plug 3, after being screwed into place and tightened, is to lock the screw 2 in an angular position as determined by the surgeon.

The plate 5, the screw 2, and the plug 3, once assembled together, are shown in Figure 7. The threaded plug 3 performs a non-return function preventing any accidental unscrewing of the associated bone-fastening screw 2, particularly under the conditions explained in the preamble of the present application.

Also, by means of the device of the present invention, spondylolisthesis can be reduced by implanting in the pedicle of the vertebra concerned either an intermediate screw fixed on the intermediate link rod 6, or a screw placed in the eyelet 4.

In the first case, the intermediate rod 6 can thus be used to reverse the vertebra. To this end, and as shown in Figure 8, it can be associated with a top-loading screw, given overall reference 10 and known per se, and which is previously implanted in the vertebra in question.

It is also possible to secure the vertebra that is to be moved to the intermediate rod 6 by means of a different type of device that is not shown, but that is likewise known per se, in which the screw is offset relative to the axis of the rod 6 but is connected thereto by a holding system.

In the second case, it is the top eyelet 4 of the element 1 which is used to receive the bone-fastening screw 2 engaged in the vertebra that is to be treated,

said screw 2 being preferably of the same type as described above. To this end, a hole 7 identical to that described with reference to the plate 5, is formed through said eyelet, so as to allow the screw 2 to be moved angularly and so as to provide a non-return function by means of a plug 3, thus preventing the screw becoming loose.

In order to avoid giving rise to the hinge syndrome as described in the preamble, it is possible to avoid locking firmly the screw 2 that is inserted through the top eyelet 4. Under such circumstances, the screw 2 retains a certain amount of mobility relative to the eyelet 4.

In this way, the position of the vertebra in which the screw 2 inserted through the eyelet 4 is engaged is indeed fixed, but the underlying intervertebral disk continues to function, to some extent. A rigidity gradient is thus established in the fixing which has the effect of attenuating the sudden change of stress state at the overlying disk.

This relative mobility between the screw 2 and the eyelet 4 can be provided in various ways.

A first technique, not shown, consists in using the same principle as that shown in Figure 7, i.e. using a threaded plug 3 and providing a shoulder in the hole 7 in the eyelet that prevents the plug 3 from reaching a position in which it locks the angular position of the screw 2.

In a variant, also not shown, such a shoulder may be formed on the threaded plug 3.

Also, or alternatively, it is possible to reduce friction between the plug 3 and the head 21 of the screw 2 to a negligible quantity by applying a thin layer of a low coefficient of friction coating, e.g. of ceramic type or of diamond like carbon, on one or more of the various surfaces in contact, i.e. the head of the screw 21, the

cup 7a of the hole 7 in the eyelet 4, and the cup 301 in the threaded plug 3.

For example, such a coating may be applied solely to the head 21 of the screw 2.

With reference now to Figures 9 to 14, several variant embodiments are described that serve to attenuate the stiffness of the assembly between the screw 2 and the eyelet in which it is engaged, likewise for the purpose of avoiding the hinge syndrome.

Thus, Figure 9 shows a technique in which all contact is avoided between the rigid parts that need to move relative to one another by using a bottom, first O-ring 401 and a top, second O-ring 402. These two rings are preferably made of a damping material such as silicone, and they are shown in Figure 9 in the deformed state after the plug has been tightened.

Thus, when the rings 401 and 402 are compressed and deformed during tightening, they provide a connection of attenuated stiffness between the screw 2 and the eyelet 4.

Advantageously, rings having different hardness characteristics but all having the same dimensions, are made available to the surgeon, thereby enabling the surgeon to vary the stiffness of the assembly without having to adapt the extent to which the threaded plug 3 is tightened, since that can be very difficult to implement in reliable manner.

Also, in order to minimize friction between the rings 401 & 402 and the head 21 of the screw, it may be advantageous to apply surface treatment to the screw by nitrogen ion bombardment, thereby improving the tribological characteristic of the head of the screw.

Still with reference to Figure 9, it can be seen that in this case the plug 3 continues to have a spherical cup 303 that is intended solely to enable the angle of the screw 2 to be varied but without applying locking thrust against the head 21 of said screw.

Figure 10 shows a variant in which the plug 31 differs from that of Figure 5 in that its cup, referenced 311 is no longer complementary to the spherical head 21 of the screw 2, but is more flared, so that a pellet 411 of damping material can be interposed between the cup 311 and said head 21, and can be compressed and deformed when tightening the plug.

This also provides attenuation of the overall stiffness of the assembly.

Figure 11 shows a variant in which the threaded plug 32 has a plane working surface and in which direct contact between the plug 32 and the head of the screw 21 is avoided by using an O-ring 412 made of a damping material, which is compressed and deformed when the plug is tightened.

Figure 12 shows a variant in which the plug, given reference 33, has a conical recess 331 in its working face, and in which contact between the plug 33 and the screw head 21 is avoided by injecting a thixotropic fluid 412 while the appliance is being installed, thereby likewise performing the damping function.

In addition, in the three variant embodiments of Figures 10, 11, and 12, contact friction between the spherical head 21 and the cup 7a of the hole 7 formed in the eyelet 4 can also be reduced by using a coating of the kind mentioned above. In this respect, the coating used in the variant of Figure 12 should be selected so that contact between the base of the spherical head 21 and the cup 7a seals the thixotropic fluid even when compressed by tightening the plug.

Figures 13 and 14 show another variant embodiment in which the eyelet is modified. More precisely, the eyelet 4 has a generally cylindrical cup 421 in which the portion remote from the bottom is tapped at 8 to receive the threaded plug 3, identical to that of Figure 5.

A ring 422 is interposed between the cup 421 and the screw head 21. It may either be a rigid ring, e.g. made

of a ceramic-coated titanium alloy, or of titanium alloy treated by ion bombardment, or indeed of solid ceramic, or else it may be an O-ring identical to the ring 401 used in the variant embodiment of Figure 9, likewise made of a damping material, e.g. silicone.

When the ring 422 is rigid, it may be advantageous for the radius of curvature of its internal spherical bearing surface to have a value that is slightly smaller than the radius of the screw head 21, so as to ensure that said screw head is stressed on tightening. In which case the version of Figures 13 and 14 can advantageously also be used when it is desired to lock the screw fully.

In another variant, the ring 422 can be split, there again with the head 21 being put under stress and with the option of locking.

Naturally, the parts such as the element 1, the screws 2, and the plugs 3 are all made of biocompatible materials having appropriate mechanical properties, e.g. a titanium alloy.

Various additional remarks are given below to finish off.

Firstly, the shape and the dimensions of the element 1 are selected so as to enable it to withstand twisting stresses, by means of the plane bearing surface generated between the base of the plate-shaped portion 5 and the adjacent bone.

This shape also makes it possible to limit movement in longitudinal translation on the intermediate screws.

Thereafter, the above-described means for attenuating stiffness provide such attenuation both in the sagittal plane and in the transverse plane.

Finally, the invention makes it possible to offer an osteosynthesis system that is highly modular: thus, for example, different versions of the ring 422 can be offered to the practitioner for adjusting the anterior contact zone (adjacent to the vertebra), whereas one of the above-described damping means can be offered with

various different degrees of stiffness so as to adapt damping in the posterior portion (adjacent to the plug). In practice, this makes it possible to cover the entire range between flexible links and rigid links.

In this respect, it will be observed that the above-described stiffness-attenuating means can be used both with the screw in the eyelet 4 and with the screws in the plate 5.

Naturally, the present invention is not limited in any way to the various embodiments described and shown, and the person skilled in the art will be able to make variations or modifications within the spirit of the invention.

The claims defining the invention are as follows:

1. A bone fixing device, in particular for fixing the sacrum for osteosynthesis of the backbone, the device including an integral link member receiving at least one bone-fastening screw, which screw passes through an orifice directly formed in the link member, wherein the link member includes in the bottom region thereof an essentially spherical bearing surface, wherein the head of the screw has a surface that is essentially spherical and complementary to the hearing surface of the link member for surface contact therebetween, and wherein the link member includes a first thread in the orifice, the device further including a plug having a second thread suitable for cooperating with the first thread and for coming into clamping contact with said screw head to hold it in a desired angular position.

2. A device according to claim 1, wherein the first thread is a tapping formed internally in the orifice at a distance from said bottom region, and the plug has an outside thread.

3. A device according to claim 1 or 2, wherein the screw head also has generally spherical top, and the plug has a complementary internal spherical cavity.

4. A device according to claim 1 or 2, wherein said link member includes a series of orifices in alignment that are interconnected by a slot enabling a bone-fastening screw to be moved from one orifice to another before tightening.

5. A device according to any one of claims 1 to 4, wherein said screw head and said plug have identical tightening sockets.

6. A device according to any one of claims 1 to 5, wherein said link member is adapted to be fixed to a first bone and forms an integral portion of a member that also includes an eyelet for another bone-fastening screw for fastening to a second bone, together with a rod interconnecting said plate and said eyelet.

7. A device according to claim 6, wherein it further includes a bone-fastening device for fastening to another bone, to which said rod is fixed.

8. A device according to any one of claims 1 to 7, wherein it includes at least two bone-fastening screws passing through respective orifices formed in said link member, and the two screws are suitable for taking up two different angular

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positions.

9. A device according to any one of claims 1 to 8, wherein it further includes means for attenuating the stiffness of the assembly between at least one of the bone-fastening screws and said element.

10. A device according to claim 9, wherein said means for attenuating stiffness comprises at least one piece of flexible material interposed and compressed between said screw head and the associated plug.

11. A device according to claim 10, wherein it is associated with a plurality of pieces of flexible material having different flexibilities, thereby enabling different degrees of stiffness attenuation to be provided without requiring action to be taken on the torque with which the plug is tightened.

12. A device according to claim 10 or 11, wherein said piece is an O-ring.

13. A device according to claim 10 or 11, wherein said piece is a pellet.

14. A device according to claim 9, wherein said stiffness attenuation means comprises a thixotropic fluid interposed between and compressed between the plug and said screw head.

15. A device according to any one of claims 1 to 14, wherein said spherical bearing surface of said orifice is formed by deforming an O-ring placed in a bottom region of said orifice.

16. A device according to any one of claims 1 to 14, wherein said spherical bearing surface of said orifice is constituted by a surface of a rigid ring fitted in a bottom region of said orifice.

17. A device according to claim 16, wherein said rigid ring is made of a material selected from the group comprising: ceramic-coated titanium alloys, titanium alloys treated by ion bombardment, and solid ceramics.

18. A device according to any one of claims 1 to 14, wherein the stiffness attenuation means further include a surface coating suitable for reducing friction between said essentially spherical bearing surface and said complementary surface of the screw head.

19. A device according to claim 18 wherein said surface coating is made by nitrogen ion bombardment.

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20. A bone fixing device substantially as hereinbefore described with reference to figures 1 to 5, or 6 and 7 or 8 and 9 or 10 or 11 or 12 or 13 and 14 of the accompanying drawings.

DATED: 20 March 2001

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Patent Attorneys for the Applicant:

STRYKER FRANCE SA & FRANCK GANEM

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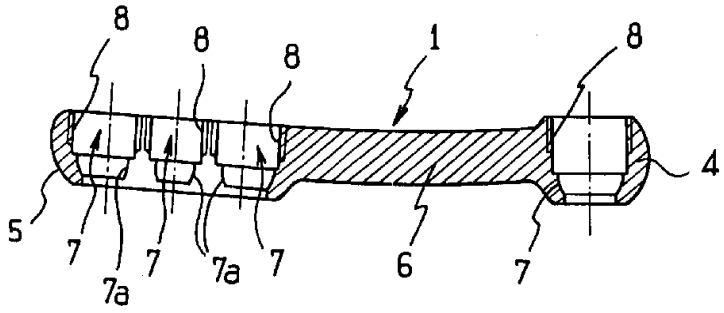

FIG.1

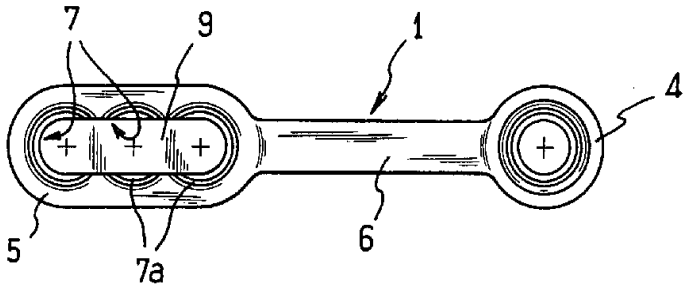

FIG.2

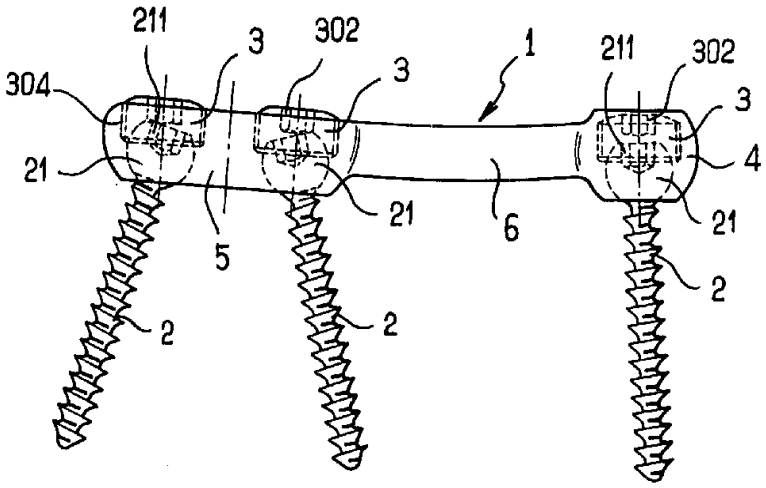

FIG.3

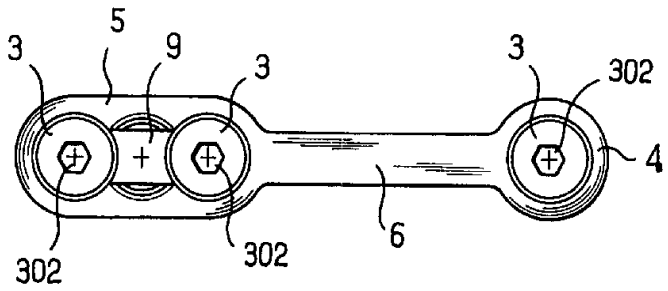

FIG.4

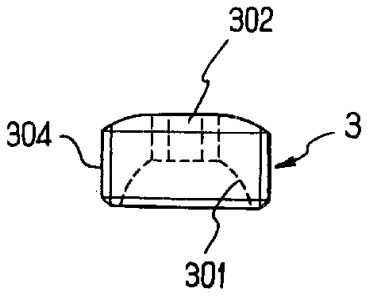

FIG_5

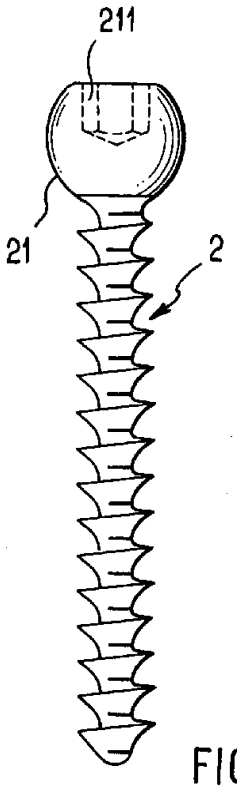

FIG_6

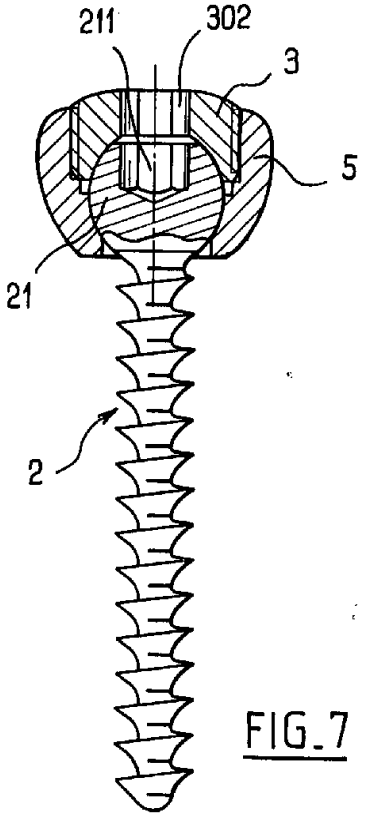

FIG_7

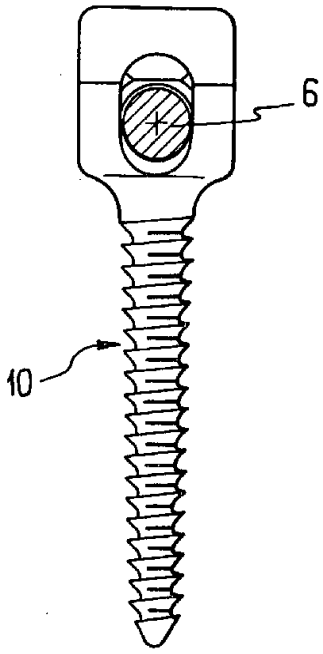

FIG_8

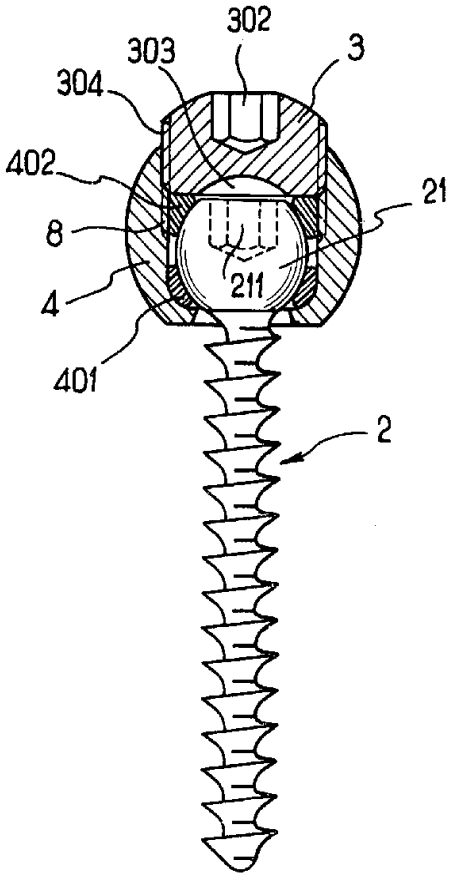

FIG_9

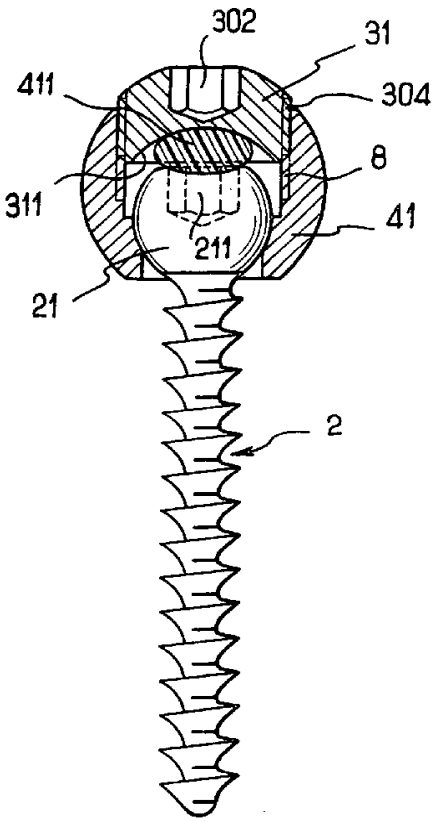

FIG_10

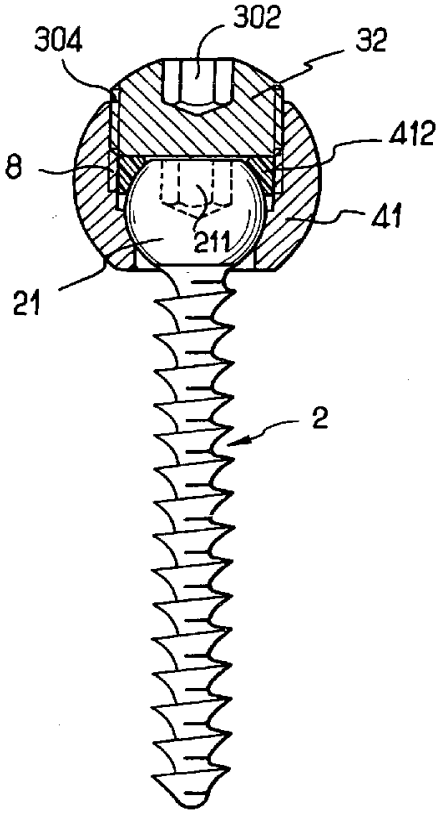

FIG_11

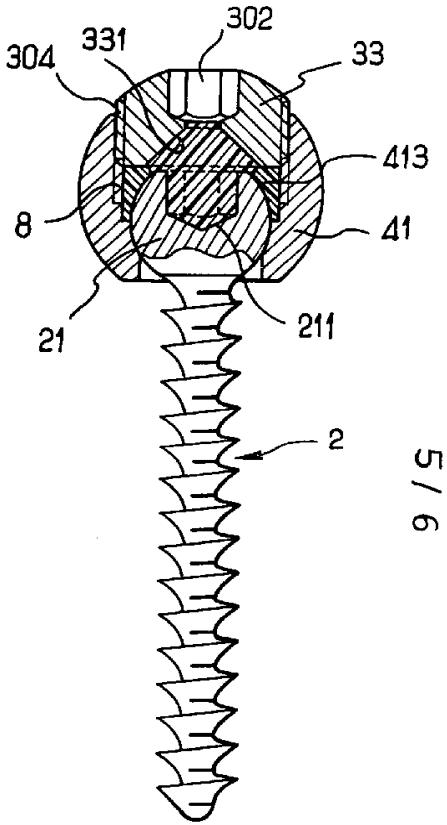

FIG_12

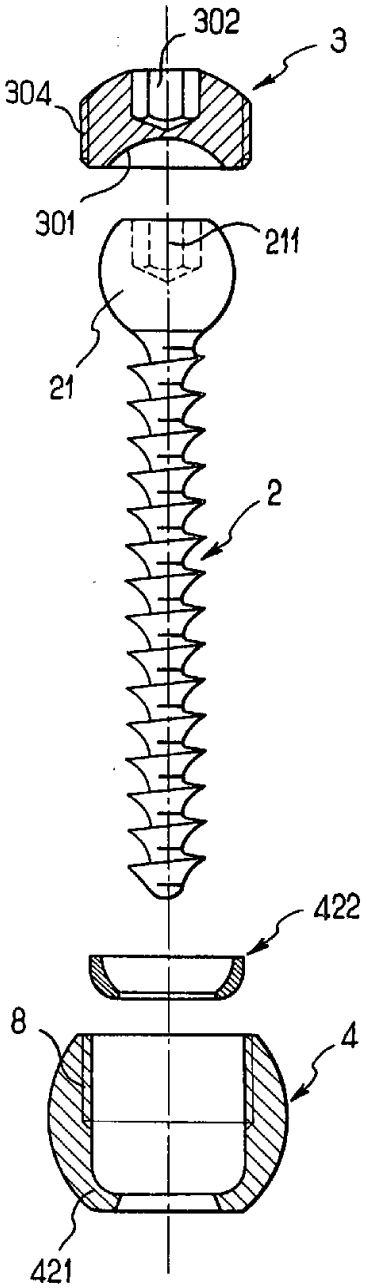

FIG_13

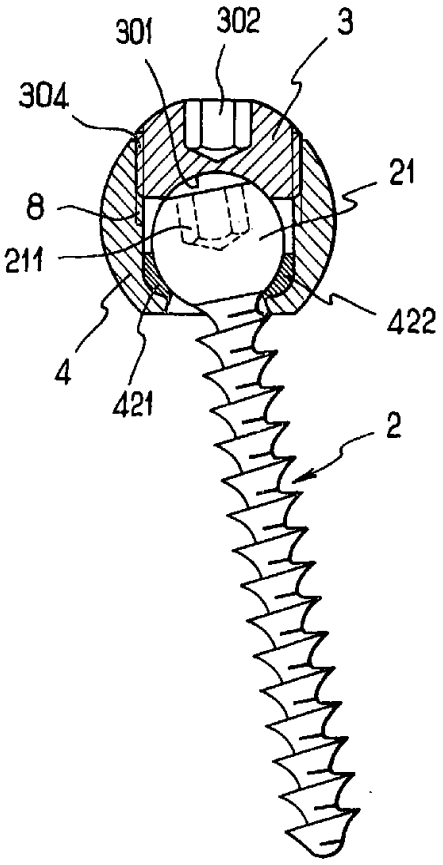

FIG_14