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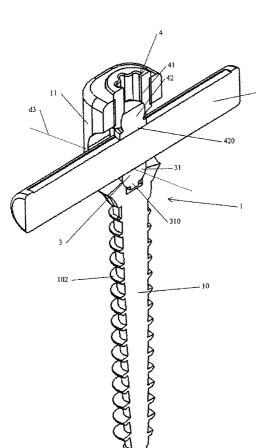
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[Continued on next page]

(54) Title: IMPLANT FOR OSSEOUS ANCHORING WITH POLYAXIAL HEAD



(57) Abstract: The present invention relates to an osseous anchorage implant comprising fixation means capable of receiving and fixing at least one bar, in particular of osteosynthesis, the implant (1) comprising on the one hand osseous anchoring means (10) and on the other hand a fixation head (11) bearing the fixation means, the fixation head being traversed by at least one channel (12) receiving the bar (2), and comprising clamping means (4) capable of clamping the bar against one inside wall, called support wall (32), the implant (1) being characterized in that the fixation means (4) and said support wall (32) enable obtaining, prior to blocking of the fixation, a determined clearance in rotation around at least one first axis (d3) not parallel to the longitudinal axis of the bar, in that the clamping means comprise a face at the contact of the bar, called the moving clamping surface (120), the moving clamping face (420) of the clamping means (4) being borne by a support head (42) articulated at the end of the clamping means (4) by a ball and socket connection, and in that the channel (12) has the form of an open channel having an aperture (120) opening onto one of the lateral faces of the fixation head (11), an edge (124) of said aperture bearing the clamping means (4), the aperture (120) of the channel and the position of the clamping means thus enabling the introduction (i) of the bar by the lateral route.

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### IMPLANT FOR OSSEOUS ANCHORING WITH POLYAXIAL HEAD

The present invention relates to an implant providing osseous anchorage, for example in a vertebra for anchoring an osteosynthesis device. This implant comprises a head capable of receiving a bar linking a plurality of implants in different angular positions.

It is known to fix one or a plurality of implants into one or a plurality of osseous elements in order to connect to the skeleton a device implanted in the human or animal body, said implants being then used to fasten certain elements of said device. For maintaining or correcting the rachis in particular, use of an osteosynthesis device comprising one or a plurality of maintenance bars or plates positioned along the vertebral column and fixed to certain vertebrae by implants is well-known. These implants are fixed on the one hand to the bars and on the other to the vertebrae by an osseous anchoring means comprised of a hook having its support on a vertebra or of a threaded part screwed inside the vertebra, for example, at the pedicle. In the case of an osteosynthesis of the extreme vertebrae one or a plurality of implants can of course be securely fastened to adjacent bone, the sacrum for example.

The FR 0104717 patent discloses for this purpose an implant comprising an osseous anchoring part and a fixation head transversed by a channel where the bar is clamped. This document describes an implant, whose head comprises a lateral opening enabling the introduction of a bar with flat whereas a clamping screw has already been pre-installed in the superior part of said head. In order to assure satisfactory contact of the clamping screw on the flat whatever the angular position of said flat about the axis of the pin, the clamping screw is provided with a tiltable support surface mounted on a ball and socket joint.

By supporting itself on the inside shape of the channel under the effect of the clamping, the bar's position is thus definitively determined by the general position of the implant. At the time of installation of the bar in an implant already anchored in the rachis, if the bar is not in a position

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corresponding to that of the channel, the act of forcing its introduction can induce a certain stress in the bar.

On the one hand, said stress can then make the introduction of the bar into the implant difficult or render its clamping not very accurate. This problem is true more particularly when the bar has already been engaged in a first implant and is being introduced into a second implant. In order to reduce this stress, it is conceivable to anchor the implant according to the position of the bar, but this is not always possible to do nor easy to predict. It would also be conceivable to deform the bar, which could be a problem in the situation and plays against the requirement of a rigid bar to assure an effective hold. This stress can thus make manipulation delicate to execute, in particular in weale intrusion surgical procedures, for example video-assisted or laparoscopic procedures.

On the other hand, even if clamping enables stressing the bar to adopt a position or a shape corresponding to the implant, said stress will persist permanently over a very long time after the procedure. The fact that the bar is under permanent tension poses the risk of a mechanical effect directly on the rachis, for example causing pains or changing or disturbing the correction or the support sought by using the osteosynthesis device.

The object of the present invention is to eliminate at least one drawback of the prior art by providing an osseous anchorage implant capable of adapting itself to a certain extent different orientations of the bar whereas the implant is already anchored in the osseous element.

This aim is achieved by an implant for osseous anchoring comprising fixation means capable of receiving and fixing at least one bar, in particular of osteosynthesis, the implant comprising on the one hand osseous anchoring means, and of the other hand a fixation head bearing the fixation means, the fixation head being traversed by at least one channel receiving the bar, and comprising clamping means capable of clamping the bar against one inside wall, called support wall, the implant being characterized in that the fixation means and said support wall enable obtaining, prior to blocking the fixation, a determined clearance in rotation around at least one first axis not parallel to

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the longitudinal axis of the bar, in that the clamping means comprise a face, at the contact with the bar, called the moving clamping face, the moving clamping face of the clamping means being borne by a support head articulated at the end of the clamping means by a ball and socket connection, and in that the channel has the form of an open channel having an aperture opening onto one of the lateral faces of the fixation head, one edge of said aperture bearing the clamping means, the aperture of the channel and the position of the clamping means thus enabling introduction of the bar by the lateral route.

According to one another feature, the fixation means and said support wall enable, prior to blocking the fixation, a determined clearance in rotation around at least one second axis not parallel to the first axis and not parallel to the longitudinal axis of the bar.

According to one another feature, the channel opens at each side of the fixation head through apertures whose disposition and dimensions enable the bar a determined clearance inside the channel in rotation at least about one axis that is substantially perpendicular to the axis the channel and to the support direction of the clamping means.

According to one another feature, the support wall comprises an element, called the moving baseplate, having a clearance in rotation at least about one axis not parallel to the axis of the channel and to the support direction of the clamping means on the bar, the moving clamping face having a determined clearance in rotation around one axis substantially parallel to the axis of rotation of the moving baseplate.

According to one another feature, the moving baseplate has a part in form of a sphere portion leaning by a complementary contact in a housing formed in the fixation head.

According to one another feature, the moving base plate is in contact with the bar by a support face having a shape substantially complementary to the exterior shape of the bar, the moving baseplate having at least one formal irregularity co-operating with a formal irregularity borne by the fixation

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head to form a stop holding the support face of the baseplate turned towards the side of the bar.

According to one another feature, the formal irregularity is a pin formed on the underside, the rear or on the front of the moving baseplate, cooperating with a cavity with a greater dimension borne by the fixation head.

According to one another feature, the formal irregularity is a cylindrical drilling formed on the front of the moving baseplate and co-operating with the cylindrical head of a pin held in drilling formed in the fixation head.

According to one another feature, the clamping means comprise a clamping screw inserted into a drilling traversing one edge of the channel opening and co-operating with said drilling to realize a support upon the bar.

According to one another feature, the osseous anchoring means comprise either a threaded part capable of anchoring in an osseous element by co-operation with the osseous material of said osseous element, or a protruding part capable of anchoring at the surface of an osseous element by co-operating with at least one formal irregularity of said same surface.

According to one feature, the osseous anchoring means are realized by an elongated and threaded part, the axis of the channel being substantially perpendicular to the longitudinal axis of the osseous anchoring means.

According to another feature, the channel has a shape comprising two head to tail truncated cones facing each other with their minor baseplates and joined to each other directly or by means of a cylindrical part.

According to another feature, the bar bears one or a plurality of flats on its external surface, providing a flat contact surface with the support head.

The invention together with its features and advantages will be clearer by reading the description thereafter with reference to the annexed drawings, wherein:

Figures 1, 2, and 3 represent an implant with moving head and osseous anchorage through the reading in section longitudinal to the bar, in side view along the axis of the bar and in a top view, respectively;

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Figure 4 represents a partial side view of an implant with fixed head during introduction of the bar, in section transverse to the bar;

Figures 5 and 6 represent perspective views of an implant with fixed head and osseous anchorage through screw in longitudinal section, along the axis of the bar, and transverse to the bar, respectively;

Figure 7 represents a perspective view of an implant with osseous anchorage by hook and fixed head in longitudinal section along the axis of the bar and represented without its clamping means;

Figures 8 and 9 represent, respectively, a perspective view and a sectional view of an implant with fixed head according to a second embodiment;

Figures 10 and 11 represent, respectively, a perspective view and a sectional view of an implant with fixed head according to a third embodiment;

Figures 12 and 13 represent, respectively, a perspective view and a sectional view of an implant with fixed head according to a fourth embodiment.

The invention described herein relates to an implant comprising on the one hand a means for fixation of a bar and on the other hand means for anchoring to an osseous element.

In a general fashion, in the field of surgery, an implant is defined as an object intended for being implanted in the human or animal body and to remain there continuously after the surgical procedure, at least over a certain period of time. More precisely, one speaks of a prosthesis to designate a device realizing a function, for example a movement or an articulation. Although not comprising a prosthesis *per se*, it must be understood that the implant described herein can comprise part of a prosthesis device or can be used for fixation on such a device.

By way of example, the implant according to the invention is described herein in the form of an implant incorporated in an osteosynthesis device, such as used to hold, prop, or straighten the rachis. This function is thus assured by one or a plurality of rigid bars or similar elements, connecting a plurality of rachis elements with each other, such as the sacrum, the

vertebrae or parts of vertebrae. In the same sense, such a bar can obviously be used also to connect another implant or prosthesis to the skeleton such as, for example, an artificial vertebra, an arthrodesis frame, or an intervertebral disc prosthesis.

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It its part affixed to an osseous element, said bar is anchored to said osseous element by means of one or a plurality of implants comprising osseous anchoring means such as, for example, a screw or one or a plurality of hooks. The implants thus comprise fixation means capable of receiving the bar before or in the course of the surgical procedure, then fixing said bar to the implant.

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In one embodiment represented in Figures 1 to 6, said anchoring means are realized by an elongated part having a thread and capable of being screwed into the osseous material, for example at the pedicle or body of a vertebra or into the sacrum.

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In one embodiment represented in Figure 7, said osseous anchoring means comprise a hook intended for being engaged to a formal irregularity in the osseous element, such as a pedicle or a vertebral or sacral protrusion, or a transverse apophysis.

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In the course of the surgical procedure, when an implant is anchored in an osseous element and that a bar is to be fixed to it, the position in which the bar can be introduced does not always correspond to that, which would be the easiest for assembly to the fixation means of the implant. Said position can be restricted, for example, by the anatomical environment or by the fact that said bar is already assembled in another implant.

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Moreover, when the bar is inserted into the fixation means, if the latter are not properly aligned with the axis of the bar, the arrangement of the contact or fixation surfaces can be the cause of poor fixation, not being sufficiently rigid or secure.

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In particular, if the bar must be forced at the time of fixation to be adapted to the relative position of the implants, said force can result in residual stresses in the structure of the osteosynthesis device. Such

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persisting stresses can consequently impair the patient's daily comfort or perturb or change the desired effect of the device.

In order that the fixation means can be better adjusted to the position of the bar, the fixation means according to the invention comprise at least one element having a certain moveability. Said element can be adjusted by a rotation around one or a plurality of axes not merged with the longitudinal axis of the bar and, for example, perpendicular to said longitudinal axis. Said rotation can be executed according to a determined clearance capable of comprising maximal angular positions or according to predetermined angular positions or capable of being unlimited, that is completely free. According to the embodiments, said fixation means can comprise an element moving along one or a plurality of axes or they may comprise a plurality of elements themselves moving along one or a plurality of axes.

The bar can thus be assembled in a plurality of angular positions relative to the anchoring means or to the osseous element. These variations in angular position can particularly comprise an adjustable tilt relative to the osseous surface where the implant is anchored or a rotation around an axis extending from said osseous surface or a combination of the two.

In the embodiments represented herein, the implant (1) is rigidly connected to the bar (2) by fixation means comprising a channel (12) housed in one part of the implant, said part being designated as the fixation head (11). The channel (12) can exhibit the shape of a channel opening at its two ends and open on one of its sides. Such a lateral opening (120) thus enables introduction (i; Figure 4) of the bar (2) through the side of the channel without the necessity of having to thread the bar through an end.

Once inserted into the channel (12), fixation of the bar is assured by clamping means (4) that are supported by means of at least one side of said bar to make contact and block it against one wall, called the support wall, of the channel (12). Said clamping means comprise, for example, a clamping screw (41) mounted in a drilling (14) borne by one part of the fixation head (11) constituting one edge (124) of the lateral opening (120) of the channel (12). Said clamping screw (41) has an external threading that co-operates

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with an internal threading of said drilling (14) to displace the screw (41) along a clamping axis (d4) and bring it into contact against the bar, thus clamping clamping screw (41) can comprise formal irregularities, for example an internal mark, enabling the use of a clamping tool to realize blocking the bar (2). The bar can advantageously have one or a plurality of flats upon its external surface to enable obtaining a flat contact surface with the clamping screw (41) and thus enhanced reliability of blocking than with a punctal or linear contact.

In one embodiment represented in Figures 4 to 13, the channel (12) has a support wall providing an element, called a moving baseplate (3), said baseplate being moving relative to the fixation head (11). Said moving baseplate (3) has a part (31) in form of a sphere portion, leaning by a complementary contact in a housing formed in the wall of the channel (12). By virtue of said spherical contact, the moving baseplate (3) disposes of a certain freedom of rotation around the center of its spherical part (31). Said moving baseplate has in particular a certain clearance (a3) in rotation around an axis (d3) substantially perpendicular to the longitudinal axis (d12) of the channel and to the direction of support of the clamping means. On its face, said support face (32), in contact with the bar, the moving baseplate has a shape complementary to the external surface of said bar, for example in the form of a cylindrical portion, that provides a good contact surface when clamping.

On its part (31) in form of a sphere portion the moving baseplate (3) can have one or a plurality of formal irregularities (310) co-operating with one or a plurality of formal irregularities of the housing of the fixation head (11) to form a stop limiting the clearance in rotation of the moving baseplate. Said formal irregularities (310) can be, for example, a pin protuding from the moving baseplate and co-operating with a larger dimensioned cavity formed on the complementary contact surface. Said stop, for example, allows avoiding excessive turning of the moving baseplate and assuring that it properly presents its support facing the bar. Thus, in the embodiment represented in Figures 4 to 7, the formal irregularity (310) is a pin realized

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under the spherical part (31) of the moving baseplate (3), and in the embodiment represented in Figures 8 and 9, the formal irregularity (310) is a pin realized on the rear of the moving baseplate (3). Likewise, in the embodiment represented in Figures 12 and 13, the formal irregularity (310) is a pi, having an oblong cross-section, realized on the front of the moving baseplate. The dimensions of the cavities co-operating with the formal irregularities (310) in the form of a pin exceed from at least 20 to 30 mm the dimensions of said formal irregularities (310) at least along the axis of rotation (d3) of the moving baseplate (3) so as to enable an angular clearance of the moving baseplate without enabling a complete rotation of same.

In the embodiment represented in Figures 10 and 11, the formal irregularities (310) are a cylindrical drilling realized in the front of the moving baseplate (3) and co-operating with the cylindrical head of a pin held in a drilling formed on the fixation head, the dimensions of the cylindrical drilling being greater than those of the head of the pin by at least 20 to 30 mm, at least along the axis of rotation (d3) of the moving baseplate (3). In this fashion, the pin enables the moving baseplate (3) to turn around said axis (d3) while holding it in the complementary cavity housed in the wall of the channel (12).

With regard to the bar (2), the inside surface of the channel (12) is of sufficient dimensions to enable the bar a certain clearance (a2) in rotation around one or a plurality of axes not parallel to the longitudinal axis of the bar or, in particular, perpendicular to this longitudinal axis.

At its end on the bar side, the clamping screw (41) exhibits a moving element, called the support head (42), articulated by a ball and socket connection. The screwing of the clamping screw (41) provokes the leaning of said support head (42) on the flat of the bar (2) through one moving clamping face (420) of the moveable clamping system. Said ball and socket connection allows a certain clearance of the support head (42) relative to the clamping screw (41) in rotation around the center of said ball and socket connection. By a rotation around at least one axis parallel to the axis of rotation (d3) of

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the moving baseplate (3), the moving support face (420) can thus be permanently adjusted to the position of the bar and the moving baseplate. Said ball and socket connection also enables the support face to remain in contact with the bar without sliding over it, which avoids deterioration of the surfaces in contact, assures the blockage, and reduces the risk of residual stresses.

Thus, it can be understood, that the bar can be inserted and blocked in different angular positions inside the channel (12), while providing a flat contact surface both with the clamping means and with the wall of the channel by means of the moving baseplate (3). Said polyaxial angular clearance thus allows inserting the bar more easily and obtaining a clamping of the bar in its most natural position relative to the implants, which reduces or eliminates the stresses that could subsist in the device after clamping. Furthermore, the clamping forces concur directly with blocking without necessarily opposing the rigidity of the bar and the reliability of the blocking is thus improved.

In an embodiment represented in Figures 1 to 3, the fixation head (11) is moving relative to the osseous anchoring part (10) according to an articulation enabling freedom in rotation around at least two axes not merged with the longitudinal axis of the bar.

This articulation is realized by a complementary spherical contact between the fixation head (11) and the end of the osseous anchorage part (10) remote from the osseous element, said end being designated as the rotation head (101). The rotation head comprises a part (1011) in form of a hemispherical portion widening in the direction of the fixation head (11); that is, by moving away from the osseous element. Said hemispherical portion(1011) is retained on the inside of the fixation head (11) by a complementary contact in a housing formed in said fixation head and narrowing itself towards the osseous anchorage part. Said housing communicates with the channel (12) where it opens in its part situated opposite to the clamping means. The spherical nature of these contact surfaces thus enable a rotation of the fixation head and the osseous

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anchorage part relative to each other, in rotation about the center of said surface (1011) in a hemispherical form.

Said rotations enable, in particular, unlimited clearance (a1) of the fixation head relative to the osseous anchorage part, in rotation around an axis (d11), called the axis of rotation of the head, non parallel, indeed even perpendicular to the longitudinal axis of the bar or of the channel and passing through the center of the hemisphere (1011) of the rotation head (101).

These rotations also enable a certain clearance (a4) of the fixation head relative to the osseous anchorage part, in rotation around an axis substantially perpendicular to the axis (d11) of rotation of the head and passing through the center of the hemisphere (1011) of the rotation head (101).

In this embodiment, a mobile base (3) similar to that hereinbefore described is borne by the rotation head (101) in a housing formed on the face opposite to the bar.

At the time of clamping of the clamping means, the clamping screw (41) co-operates by its threading with the drilling (14) of the fixation head (11) to the lean on the bar (2). The bar leans on the moving baseplate (3). The moving baseplate (3) leans on the rotation head (101), which is retained by the housing of the fixation head (11). Clamping of these surfaces among themselves which produces a blocking of the set of these parts relative to each other.

It is well understood that in this manner an implant is provided, whose fixation head, prior to blocking of the clamping means, is moving relative to the osseous anchoring part, while being fixed to the bar after said blockage. The fixation head (11) can thus be tilted according to a certain clearance relative to the exterior surface of the osseous element and can pivot freely around an axis extending from said osseous surface.

Once the implant is anchored in the osseous element, it is thus still possible to adjust the position of the fixation head in order to enable the bar to keep or to resume its shape, which reduces the risks of residual stresses and permits easy introduction of the bar into diverse positions of this bar and

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implants. Once the bar is introduced and the whole device assembled, it is thus possible to block said positions by virtue of the clamping means. As clamping can be achieved in the most natural position of the pin, the clamping forces are concentrated at the best on the blocking reliability. In particular, these clamping forces do not risk, or the risk thereof is minimal, introducing in the device residual stresses or movements relative to the position selected by the surgeon.

In this embodiment, the clamping means (4) need not comprise a support head (42) on the ball and socket connection, in particular if the tilting of the fixation head (11) is sufficiently close to that of the bar (2) to assure a planar contact between the clamping screw (41) and the flat of the bar.

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In the embodiments represented in the figures, the fixation head (11) of the implant (1) has a square external section which enables easy implantation of the implant (1) into a vertebra using a suitable tool. In other respects, the head passing above the channel (12), it is also easy to subsequently reposition the implant (1) in the vertebra after the bar (2) has been introduced into the channel (12).

It should be clear to the specialist in the art that the present invention enables embodiments in many specific forms without moving it away from the field of application of the invention as claimed. Consequently, the present embodiments must be considered illustrative, but can be modified in the field defined by import of the attached claims and the invention should not be limited to the details provided above.

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#### **CLAIMS**

- 1. An implant (1) for osseous anchoring comprising fixation means capable of receiving and fixing at least one bar (2), in particular of osteosynthesis, the implant (1) comprising on the one hand osseous anchoring means (10) and on the other hand a fixation head (11) bearing the fixation means, the fixation head being traversed by at least one channel (12) receiving the bar (2) and comprising clamping means (4) capable of clamping the bar against one inside wall, called support wall (32), the implant (1) being characterized in that the fixation means (4) and said support wall (32) enable obtaining, prior to blocking of the fixation, a determined clearance in rotation around at least one first axis (d3) not parallel to the longitudinal axis of the bar, in that the clamping means comprise a face at the contact with the bar, called the moving clamping face (120), the moving clamping face (420) of the clamping means (4) being borne by a support head (42) articulated at the end of the clamping means (4) by a ball and socket connection, and in that the channel (12) has the form of an open channel having an aperture (120) opening onto on of the lateral faces of the fixation head (11), one edge (124) of said aperture bearing the clamping means (4), the aperture (120) of the channel and the position of the clamping means thus enabling the introduction (i) of the bar by the lateral route.
- 2. An implant according to Claim 1, wherein the fixation means (4) and said support wall (32) enable obtaining, prior to blocking of the fixation, a determined clearance in rotation around at least one second axis (d4) not parallel to the first axis (d3) and not parallel to the longitudinal axis of the bar.
- 3. An implant according to Claim 1 or 2, wherein the channel (12) opens at each side of the fixation head (11) through apertures, whose disposition and dimensions enable the bar a determined clearance (a2) inside the channel (12) in rotation at least around one axis substantially perpendicular to the axis (d12) of the channel and to the support direction (d4) of the clamping means.

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- 4. An implant according to anyone of claims 1 to 3, wherein the support wall comprises an element, called the moving baseplate (3), having a clearance (a3) in rotation at least around one axis (d3) not parallel to the axis (d12) of the channel (12) and to the support direction (d4) of the clamping means on the bar (2), the moving clamping face (420), having a determined clearance in rotation around one axis substantially parallel to the axis (d3) of rotation of the moving baseplate.
- 5. An implant according to Claim 4, wherein the moving baseplate (3) has part in form of a sphere portion (31) leaning by a complementary contact in a housing formed in the fixation head (11).
- 6. An implant according to claim 4 or 5, wherein the moving baseplate (3) is in contact with the bar (2) by a support face (32) having a shape substantially complementary shape to the exterior of the bar, the moving baseplate having at least one formal irregularity (310) co-operating with a formal irregularity borne by the fixation head (11) to form a stop holding the support face (32) of the base turned towards the side of the bar (2).
- 7. An implant according to Claim 6, wherein the formal irregularity (310) is a pin formed on the underside, the rear or on the front of the moving baseplate (3), co-operating with a cavity with a greater dimension borne by the fixation head.
- 8. An implant according to Claim 6, wherein the formal irregularity (310) is a cylindrical drilling formed on the front of the moving baseplate (3) and co-operating with the cylindrical head of a pin held in the drilling formed in the fixation head (11).
- 9. An implant according to any one of Claims 1 to 8, wherein the clamping means (4) comprise a clamping screw (41) inserted into a drilling (14) traversing one edge (124) of the channel opening and co-operating with said drilling to realize a support upon the bar (2).
- 10. An implant according to any one of Claims 1 to 9, wherein the osseous anchoring means comprise either a threaded part (102) capable of

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anchoring in an osseous element by co-operating with the osseous material of said osseous element, a protruding part (103) capable of anchoring at the surface of an osseous element by co-operating with at least one formal irregularity of said same surface.

- 11. An implant according to Claim 10, wherein the osseous anchoring means are realized by an elongated and threaded part, the axis (d12) of the channel (12) being substantially perpendicular to the longitudinal axis of the osseous anchoring means.
- 12. An implant according to any one of claims 1 to 11, wherein the channel (d12) has a shape comprising two head to tail truncated cones facing each other with their minor bases plates and joined to each other directly or by means of a cylindrical part.
- 13. An implant according to anyone of Claims 1 to 12, wherein the bar (2) bears one or a plurality of flats on its external surface, providing a flat contact surface with the support head (42).

Figure 1

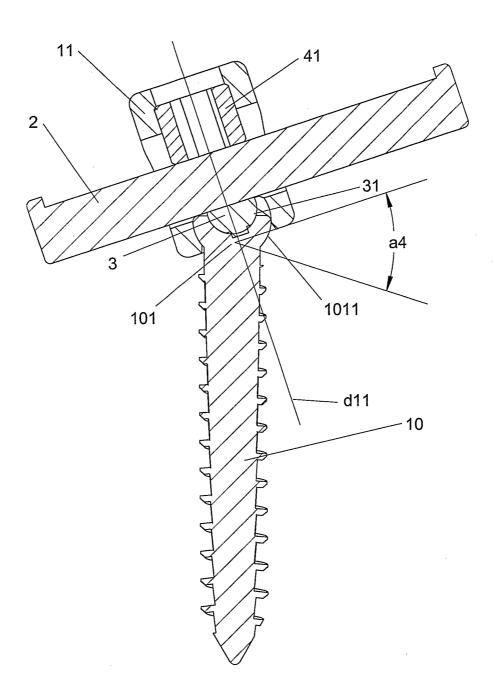


Figure 2

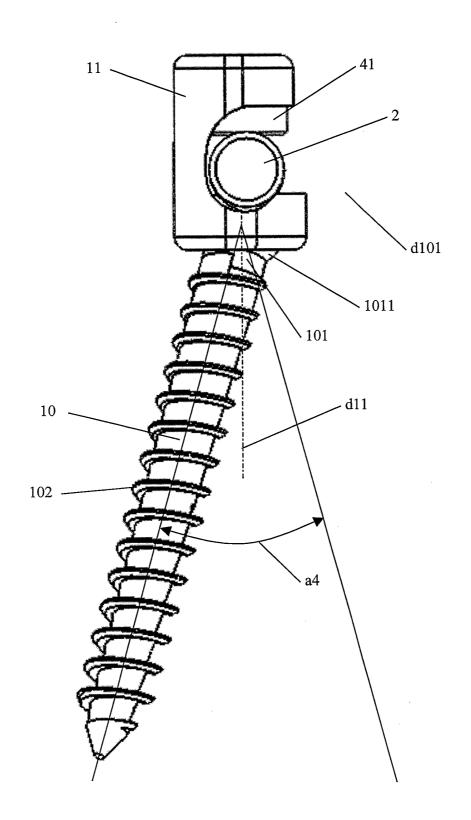
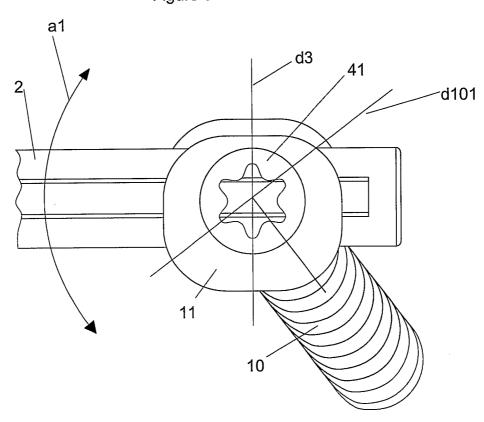


Figure 3



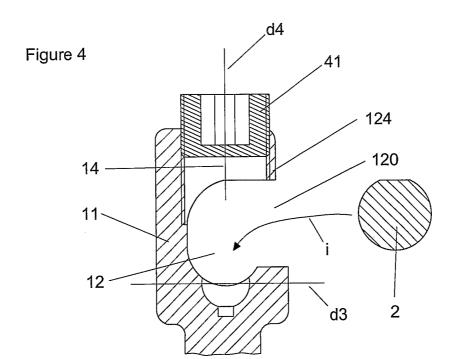


Figure 5

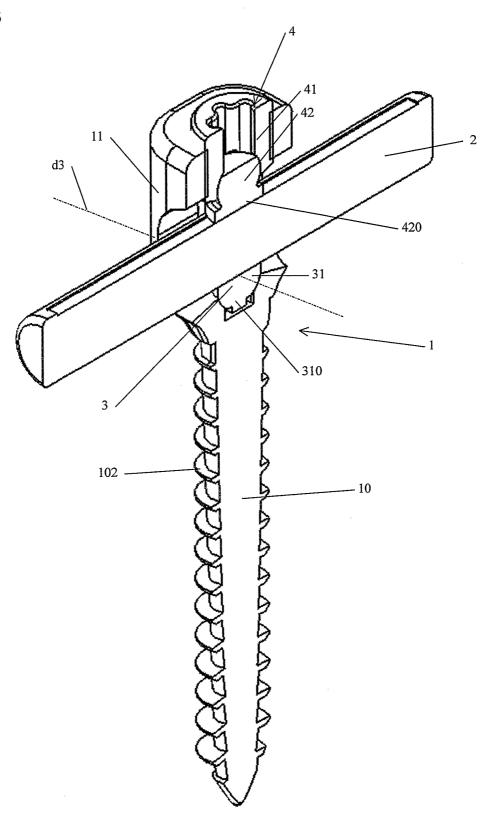
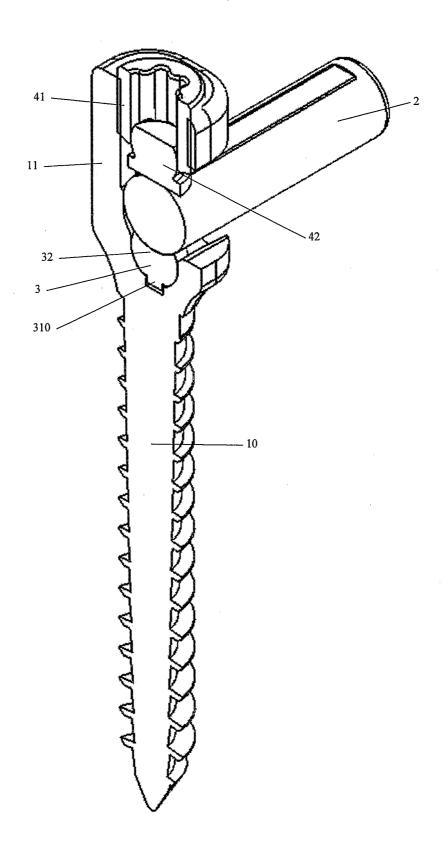


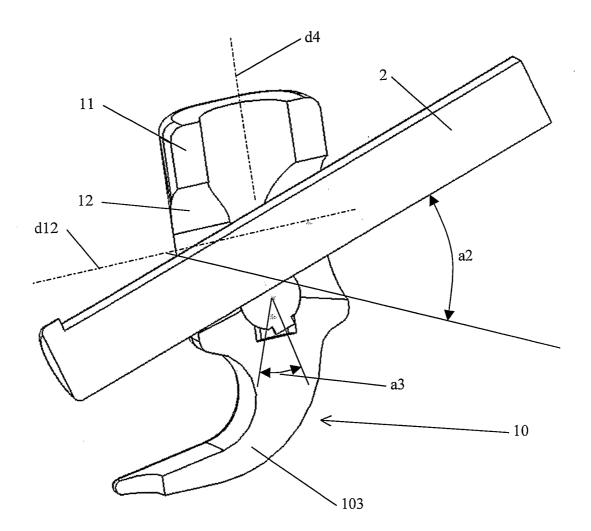
Figure 6



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Figure 7



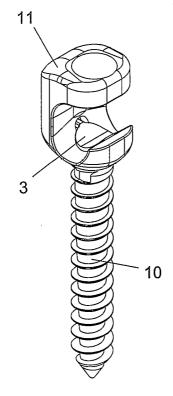


Figure 8

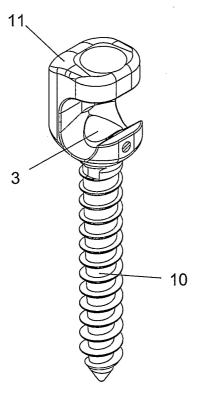


Figure 10

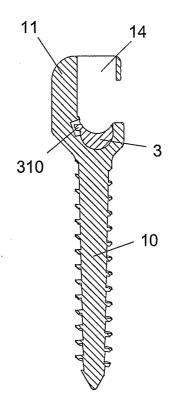


Figure 9

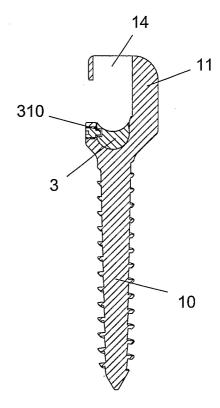


Figure 11

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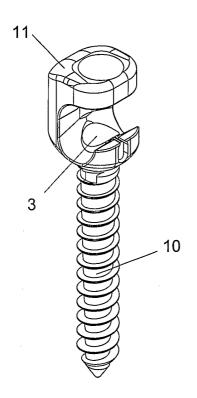


Figure 12

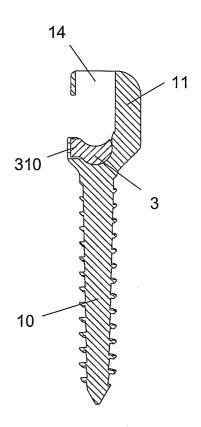


Figure 13

#### INTERNATIONAL SEARCH REPORT

al Application No PCT/IB 02/05302

# A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61B17/70

According to International Patent Classification (IPC) or to both national classification and IPC

#### B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols) IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

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Υ	abstract; figures 3-5,7 page 2, line 50-57	6-8,12
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Further documents are listed in the continuation of box C.	χ Patent family members are listed in annex.
Special categories of cited documents:      A* document defining the general state of the art which is not considered to be of particular relevance      E* earlier document but published on or after the international filing date      L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)      O* document referring to an oral disclosure, use, exhibition or other means      P* document published prior to the international filing date but later than the priority date claimed	<ul> <li>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</li> <li>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</li> <li>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</li> <li>"&amp;" document member of the same patent family</li> </ul>
Date of the actual completion of the international search  17 March 2003	Date of mailing of the international search report 25/03/2003
Name and mailing address of the ISA  European Patent Office, P.B. 5818 Patentlaan 2  NL – 2280 HV Rijswijk  Tel. (+31–70) 340–2040, Tx. 31 651 epo nl,  Fax: (+31–70) 340–3016	Authorized officer  Macaire, S

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