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(56) Related Art

US 5888223

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Abstract:

The intervertebral implant comprises a three-dimensional body (10) with a top side (1) and an underside (2) that are suitable for application to the end plates of two neighbouring vertebral bodies, a left side surface (3) and a right side surface (4), a front surface (5) and a rear surface (6), a horizontal central level (7) positioned between the top side (1) and underside (2), a vertical central level (12) running from the front surface (5) to the rear surface (6) and a plurality of holes (9) penetrating the body (10) and suitable for receiving longitudinal fixation elements (20); wherein the three-dimensional body (10) is provided on its front surface (5) with a front plate (8), through which the holes (9) run and in which the longitudinal fixation elements (20) can be anchored.

The intervertebral implant is provided with a safety plate (18), which runs generally parallel to the front plate (8) on the body (10) or that can be secured on the front plate (8) in such a way that the holes (9) can be covered at least partially by the safety plate (18).

This permits a permanently rigid, i.e. fixed connection between the intervertebral implant and the longitudinal fixation elements used for securing it.

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Intervertebral implant

The invention relates to an intervertebral implant.

The below discussion of documents, acts, materials, devices, articles and the like is included in this specification solely for the purpose of providing a context for the present invention. It is not suggested or represented that any of these matters formed part of the prior art base or were common general knowledge in the field relevant to the present invention as it existed before the prior date of each claim of this application.

An intervertebral implant is disclosed in GB-A-2 207 607, which is designed in a horseshoe form with a number of cylindrical holes. The holes are designed with smooth insides and provide only an arresting stop for the heads of the bone screws to be inserted therein. The disadvantage of this arrangement is that the positioning screws inserted in the holes can be anchored in the bone only with their shaft, without any rigid connection to the horseshoe-shaped intervertebral implant being created. As soon as any weakening of the anchoring of the screw shaft in the bone occurs, the intervertebral implant will become mobile in relation to the screw and there is then a tendency for the bone screws to migrate, with the attendant dangers for blood vessels. Loosening of the intervertebral implant can also lead to pseudo-arthrosis.

An intervertebral implant is also disclosed in US-A 2000/0010511 MICHELSON, a device that is provided on the front surface with two holes with an internal thread, in which bone screws with a screw head can be inserted. The disadvantage of this implant is that in some circumstances that the bone screws

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can loosen again and are not secured against screwing or falling out once inserted. There is also the further disadvantage that the bone screws are entirely fixed to the implant body itself and the latter accordingly is subject to relatively major strain.

Screws that emerge at the anterior or antero-lateral edge of the vertebral bodies pose a risk of damage to main vessels, such as the aorta, vena calva and supply vessels, such as the lumbar arteries and veins. Damage to the main vessels would lead to death through inner bleeding within a short period. Screws can be more easily loosened when they are not attached with stable angle.

It would be desirable to provide an intervertebral implant that can overcome or at least alleviate one or more of the problems associated with the prior art.

According to the present invention, there is provided an intervertebral implant, including a three-dimensional body with

A) a top side and an underside, suitable for abutting the end plates of two neighbouring vertebral bodies;

B) a left side surface and a right side surface;

C) a front surface and a rear surface;

D) a horizontal central plane positioned between the top side and underside;

E) a vertical central plane running from the front surface to the rear surface;

F) a plurality of holes penetrating the body that are suitable for receiving longitudinal fixation elements; wherein

G) the three-dimensional body is provided at its front surface with a front plate, through which the holes extend and in which the longitudinal fixation elements can be anchored; wherein

H) the intervertebral implant is provided with a securing plate that can be

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secured parallel to the front plate on the body or on the front plate in such a way that the holes can be covered at least partially by the securing plate; whereby

at least one of the plurality of holes in the front plate is designed in such a way that a longitudinal fixation element received therein is rigidly connectable to the front plate.

This rigid connection can be achieved, for example, by having at least one of the holes provided with an internal thread. A corresponding bone screw with a screw head can then be screwed together with the implant to form a rigid connection.

One alternative to the above embodiment includes at least one of the holes being tapered to a cone towards the underside, so that a bone screw with corresponding conical head can be anchored therein with rigid connection. The conical hole preferably includes a conical angle that is smaller than the resulting friction angle. The conicity of the conical hole preferably measures 1:3.75 to 1:20.00, and more preferably 1:5 to 1:15.

In a preferred embodiment, the front plate in the three-dimensional body is designed as an insert and slidably arranged.

According to the present invention, there is also provided a process for the implantation of an intervertebral implant between two neighbouring vertebral bodies, including the following operation steps:

a) an intervertebral implant with a front plate having several holes is inserted between two neighbouring vertebral bodies;

b) at least two longitudinal fixation elements with heads are screwed into the vertebral bodies through the holes of the front plate;

c) a securing plate is secured to the front plate over the heads of the longitudinal fixation elements by means of a securing device, wherein the heads of the longitudinal fixation elements between the front plate and the securing plate are held and secured against shifting relative to the intervertebral implant.

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It is preferable to provide an intervertebral implant that can establish a permanently rigid connection to bone fixation devices, so that loosening between the intervertebral implant and the bone fixation means can be reduced or eliminated if the bone structure is ever weakened. It is further preferable to provide a tension bond for the bone fixation elements by means of a separately formed front plate, so that the implant body is subject to less strain, i.e. combined tension forces. A safety plate furthermore also permits simultaneous securing of all bone fixation elements.

The advantages that can be provided by the invention generally result from the permanently rigid, i.e. fixed, connection between the intervertebral implant and the longitudinal fixation elements used for securing this.

At the front surface of the three-dimensional body, a front plate is attached in a position vertical to the horizontal central level of the intervertebral implant through which the holes run and in which the longitudinal fixation elements can be anchored. This has the advantage, compared to two-part implants known to the Applicant in which a front plate is implanted in a separated operation step, that the implantation of the intervertebral implant can be carried out in a single step and thus more easily and quickly. A further advantage results from the above in that the fixation of the intervertebral implant can be carried out closer to the front of the vertebral body, i.e. at a position where there is generally good bone material. This can result in an anterior restriction of movement, without, however, any greater risk being thereby incurred for the surrounding structures than is the case when an intervertebral implant such as those known to the Applicant is used. The burden under compression can still be borne by the intervertebral implant and not by the front plate or the fixation screws.

A safety plate can be secured parallel to the front plate, preferably by means of a screw connection, a bayonet joint or click catch. The safety plate can be provided with a central hole, which can in turn be provided with an internal

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thread. The front plate can be provided advantageously with a central hole for receiving a securing means.

The bone fixation elements can have either a smooth head, with the result that there will not be a rigid connection to the implant, or a screw head, conical head or expansion head, so that there will be a rigid connection to the implant. In both cases, however, the bone fixation elements can be secured by the safety plate against being turned out, pressed out or falling out at some later time.

In a special embodiment, the front plate in the three-dimensional body can be arranged as an insert and arranged with sliding movement and preferably vertical to the horizontal central level, so that it can slide in a vertical direction in relation to the three-dimensional body. This leads to so-called "stress shielding" (protection or neutralisation of mechanical stress forces), which can permit the end plates to gradually adapt to the intervertebral implant in the course of the healing process.

In a further embodiment, the front plate can be manufactured from a material

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different from the three-dimensional body, preferably from a metallic material. Preferable metallic materials are titanium or titanium alloys. The complete tension bond arrangement (front plate and screws) can be manufactured from implant steel or high-alloy metallic materials such as CoCrMo of CoCrMoC. The advantage of titanium lies in its tissue compatibility and its favourable bone merging characteristics. The advantage of the high-alloy metallic materials lies in their high mechanical strength properties, which allow filigree constructions.

The top side and/or the underside of the intervertebral implant are preferably not planar, but preferably are of convex form. This can allow better adjustment to fit the end plates of the neighbouring vertebral bodies. In a further embodiment, the side surfaces of the intervertebral implant are preferably all generally of convex form.

In a preferred embodiment, the holes advantageously do not penetrate the left and the right side surface of the intervertebral implant. The front surface can also have the advantage of not being penetrated by the holes.

In a further preferred embodiment, at least two of the holes run parallel. This can facilitate insertion of the intervertebral implant during the implantation process.

In a further preferred embodiment, at least two of the holes run in divergent direction when seen from the front side. In this way, the bone screws can be inserted in an area of the vertebral body where bone quality is better than in the centre.

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In one special embodiment, the axes of the holes in relation to the horizontal central level form an angle beta in the range 20° to 60°, preferably 36° to 48°. The axes of the holes in relation to the vertical central level preferably form an angle alpha in the range 10° to 45°, and more preferably 27° to 33°. This can ensure better access when the screws are being inserted.

In a further embodiment, the horizontal central level is not penetrated by the holes.

In one special embodiment, the top side and underside of the body are provided with a structuring, preferably in the form of teeth.

The intervertebral implant can be arranged as a hollow body, the jacket surfaces of which are preferably provided with perforations.

According to the circumstances of the case being treated, it is possible to connect two, three, four or more longitudinal fixation elements to the intervertebral implant to form a rigid connection. Preferably, at least one fixation element should advantageously penetrate the top side and at least one fixation element penetrate the underside of the intervertebral implant.

The longitudinal fixation elements used are preferably in the form of bone screws with a head and a shaft, where the head is preferably provided with an external thread, which corresponds to the internal thread of the hole of the intervertebral implant. A second possible rigid connection means can preferably make use of a bone screw in which the head is tapered to a cone in the

direction of the shaft, wherein the conicity of the head corresponds to the conicity of the hole of the intervertebral implant.

In a further embodiment, at least two longitudinal fixation elements penetrate the top side and at least two longitudinal fixation elements penetrate the underside. This can provide the intervertebral implant with optimal anchoring in the neighbouring vertebral bodies.

The longitudinal fixation elements provided in the form of bone screws have preferably a self-boring and cutting external thread. The longitudinal fixation elements can also be designed as plain, non-threaded straight pins that are provided with a drill bit, preferably in the form of a trepan.

A further variation consists of the longitudinal fixation elements being formed as spiral screws, and, finally, the longitudinal fixation elements can also be designed as single-wing or multi-wing spiral blades.

The intervertebral implant can be manufactured from any material that has no adverse effects on the body, such as a body-compatible plastic, preferably a non-reinforced plastic. The advantage which can be gained thereby in comparison to the fiber-refinforced plastics that are already known from implantology is that no reinforcement fibres are released, which represents a clinical advantage. In such a body composed of non-reinforced plastic, bone screws can be used, the external thread of which can be provided with a load flank angle in the range 11° to 14°, preferably in the range 12° to 13°. The comparably low inclination of the load flank leads to a

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high clamping force, which in turn leads to a reduction in radial expansion and danger of tearing in the plastic. The external thread of the bone screws can be provided with an angle of inclination in the range 6° to 10°, preferably 7° to 9°. This special angle of inclination can generate an automatic locking mechanism in the screw thread and thus can secure the bone screw against loosening by itself.

In order to improve the anchoring of the bone screw in the plastic body, the hole can be in the form of a metal sleeve with internal thread. The intervertebral implant can also be composed only partially of a plastic permeable to x-rays and - in the area of the holes - consist of metal, e.g. of titanium or titanium alloy. This can ensure an overall improved guiding and anchoring of the bone screws in the intervertebral implant.

In a further preferred embodiment, the holes can be provided with a smooth interior wall, in which the screw head of a metallic, longitudinal fixation element can be cut in or moulded.

The invention and embodiments of the invention are explained in more detail below on the basis of a partially schematic illustration of an embodiment.

Fig. 1 shows an explosion diagram of the intervertebral implant;

Fig. 2 shows a longitudinal bone fixation device in the form of a screw;

Fig. 3 shows a front view of the intervertebral implant according to Fig. 1;

Fig. 4 shows a side view of the intervertebral implant according to Fig. 1;

Fig. 5 shows a three-dimensional detail view of the body of the intervertebral implant, showing the connection elements to the front plate according to Fig. 6;

Fig. 6 shows a three-dimensional detail view of the front plate of the intervertebral implant, showing the connection elements to the body according to Fig. 5; and

Fig. 7 shows a complete assembled intervertebral implant with front plate and safety plate.

The intervertebral implant illustrated in figures 1 - 7 comprises a three-dimensional body 10 in the form of a cage with a top side 1 and an underside 2, suitable for application to the end plates of two neighbouring vertebral bodies, a left side surface 3 and a right side surface 4, a front surface 5 and a rear surface 6, a horizontal central level 7 lying between the top side 1 and underside 2, a vertical central level 12 running from the front surface 5 to the rear surface 6, four holes 9 penetrating the body 10, which holes are suitable for receiving the longitudinal fixation elements 20.

The body 10 is designed as a hollow body, the jacket surfaces of which are provided with perforations 19.

The three-dimensional body 10 is provided with a front plate 8 on its front surface 5, through which the holes 9 run and in which the longitudinal fixation elements 20 can be anchored.

The intervertebral implant is furthermore provided with a safety plate 18, which can be secured to the front plate 8 by means of a screw connection parallel to the front plate 8 in such a way that the holes 9 can be covered partially by the safety plate 18. The safety plate 18 is provided for this purpose with a central hole 17. The front plate 8 is correspondingly provided with a central hole 15 with internal thread 14 for receiving a securing means 16 in the form of a screw.

The four holes 9 in the front plate 8 are provided with an internal thread 11, so that the longitudinal fixation elements 20 received therein can be connected in the form of

screws with the front plate 8 to form a rigid joint.

The front plate 8 consists of titanium, and the three-dimensional body 10 consists of a non-reinforced plastic permeable to x-rays. The front plate 8 is, as illustrated in figures 5/6, formed as an insert for the body 10 and arranged with sliding movement and vertical to the horizontal central level 7. The body 10 is provided for this purpose a semi-circular cylindrical groove 27, running parallel to the vertical central level 12. at the transition points of the left side surface 3 or the right side surface 4 (Fig. 5) to the front surface 5. The front plate 8 is accordingly provided on the right and left sides (Fig. 6) with a similarly oriented and similarly dimensioned, semi-circular cylindrical rail 28. In this way, the front plate can be very easily inserted and positioned - during the manufacture of the intervertebral implant - with its two lateral rails 28 in the relevant grooves 27 of the body 10.

The side surfaces 1, 2, 3, 4, 5 and 6 the body 10 are all designed with convex form.

The holes 9 penetrate neither the left side surface 3 nor the right side surface 4; the front surface 5 is also not completely penetrated by the holes 9.
The four holes 9 all run in divergent directions from the perspective of the front surface 5 (Fig. 7).
The axes 24 of the holes 9 form in relation to the horizontal central level 7 an angle beta of 42° and in relation to the vertical central level 12 an angle alpha of 30°.

The holes 9 do not penetrate the horizontal central level 7, only the axes 24 of the longitudinal fixation elements 20 inserted therein intersect the horizontal central level 7

of the body 10.

As illustrated in Fig. 7, the top side 1 and underside 2 of the body 10 are provided with structuring in the form of teeth 30.

The longitudinal fixation elements 20 are formed as bone screws. As illustrated in Fig. 2, the longitudinal fixation elements 20 inserted in the holes 9 are provided with a head 21, a tip 22, a shaft 23 and an axis 24. The head 21 is provided with an external thread 25, corresponding to the internal thread 11 of the hole 9, so that the heads 21 can be anchored in the holes 9 to form a rigid connection. The shaft 23 is provided with a thread 26, which is self-drilling and cutting. The load flank angle of the tread 26 measures 12.5° and the angle of inclination 8°.

Securing the safety plate 18 to the front plate 8 ensures that the heads 21 of the longitudinal fixation elements 20 come in contact with the safety plate 18, which secures them against being pushed or twisted out subsequently.

As illustrated in Fig. 7, two longitudinal fixation elements 20 penetrate the top side 1 and two longitudinal fixation elements 20 penetrate the underside 2 of the body 10.

A brief description of operation is provided here by way of further explanation of the invention:

a) The intervertebral implant in the form of a three-dimensional body (10) is inserted between two neighbouring vertebral bodies by means of suitable Instruments;

b) four longitudinal fixation elements 20 in the form of bone screws are screwed through the holes 9 of the front plate 8 into the vertebral bodies by means of a suitable target device;

c) the safety plate 18 is fixed to the front plate by means of the securing means 16 in the form of a screw over the heads 21 of the longitudinal fixation elements 20, which results in the heads 21 of the longitudinal fixation elements 20 - and thus also the screws themselves - being held between the front plate 8 and the safety plate 18 and being secured against relative shifting towards the body 10 (e.g. by falling or being twisted out). The securing means 16 in the form of a screw is preferably provided with a thread, which is characterised by its strong automatic locking properties.

The invention described herein is susceptible to variations, modifications and/or additions other than those specifically described and it is to be understood that the invention includes all such variations, modifications and/or additions which fall within the spirit and scope of the above description.

Throughout the description and claims of this specification the word "comprise" and variations of that word, such as "comprises" and "comprising", are not intended to exclude other additives or components or integers.

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THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. An intervertebral implant, including a three-dimensional body having

A) a top side and an underside, suitable for abutting the end plates of two neighbouring vertebral bodies;

B) a left side surface and a right side surface;

C) a front surface and a rear surface;

D) a horizontal central plane positioned between the top side and underside;

E) a vertical central place running from the front surface to the rear surface;

F) a plurality of holes penetrating the three dimensional body that are suitable for receiving longitudinal fixation elements; wherein

G) the three-dimensional body is provided at the front surface with a front plate, through which the plurality of holes extend and in which the longitudinal fixation elements can be anchored; wherein

H) the intervertebral implant is provided with a securing plate that can be secured parallel to the front plate on the three-dimensional body or on the front plate in such a way that the plurality of holes can be covered at least partially by the securing plate; wherein

at least one of the plurality of holes in the front plate is designed in such a way that a longitudinal fixation element received therein is rigidly connectable to the front plate.

2. An intervertebral implant according to claim 1, wherein the front plate in the three-dimensional body is designed as an insert and slidably arranged.

3. An intervertebral implant according to claim 1 or 2, wherein the securing plate can be secured parallel to the front plate, preferably by means of a screw connection, a bayonet joint or click lock.

4. An intervertebral implant according to any one of claims 1 to 3, wherein the securing plate is provided with a central hole.

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5. An intervertebral implant according to claim 4, wherein the front plate is provided with a central hole for receiving a securing means, which is preferably provided with an internal thread.

6. An intervertebral implant according to any one of claims 1 to 5, wherein at least one of the plurality of holes is provided with an internal thread.

7. An intervertebral implant according to claim 6, wherein at least one hole of the plurality of holes tapers conically towards the underside.

8. An intervertebral implant according to claim 7, wherein the conical hole has a conical angle which is smaller than a resulting friction angle.

9. An intervertebral implant according to any one of claims 1 to 8, wherein the front plate is formed as an insert and is preferably arranged vertically to the horizontal central plane.

10. An intervertebral implant according to any one of claims 1 to 9, wherein the plurality of holes do not penetrate the left side surface and the right side surface.

11. An intervertebral implant according to any one of claims 1 to 10, wherein the plurality of holes do not totally penetrate the front surface.

12. An intervertebral implant according to any one of claims 1 to 11, wherein at least two holes of the plurality of holes run parallel.

13. An intervertebral implant according to any one of claims 1 to 12, wherein the axes of the plurality of holes in relation to the horizontal central plane form an angle beta in the range 20° to 60°, preferably 36° to 48°.

14. An intervertebral implant according to any one of claims 1 to 13, wherein the axes of the plurality of holes in relation to the vertical central plane form an angle alpha in the range 10° to 45°, preferably 27° to 33°.

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15. An intervertebral implant according to any one of claims 1 to 14, wherein the plurality of holes do not penetrate the horizontal central plane.

16. An intervertebral implant according to any one of claims 1 to 15, wherein the plurality of holes are provided with a smooth interior wall, in which the screw head of a metallic, longitudinal fixation element can be cut in or moulded.

17. An intervertebral implant according to any one of claims 1 to 16, with at least two longitudinal fixation elements that can be inserted into the plurality of holes wherein,

the at least two longitudinal fixation elements inserted into the holes are provided with a head, a tip, a shaft and an axis and wherein the heads can be anchored in the holes.

18. An intervertebral implant according to claim 17, wherein the heads of the longitudinal fixation elements come in contact with the securing plate secured to the three-dimensional body or to the front plate.

19. An intervertebral implant according to claim 17 or 18, wherein at least one longitudinal fixation element penetrates the top side and at least one longitudinal fixation element penetrates the underside.

20. A process for the implantation of an intervertebral implant between two neighbouring vertebral bodies, including the following operation steps:

a) an intervertebral implant with a front plate having several holes is inserted between two neighbouring vertebral bodies;

b) at least two longitudinal fixation elements with heads are screwed into the vertebral bodies through the holes of the front plate;

c) a securing plate is secured to the front plate over the heads of the longitudinal fixation elements by means of a securing device, so that the heads of the longitudinal fixation elements between the front plate and the securing

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plate are held and secured against shifting relative to the intervertebral implant.

21. An intervertebral implant according to any one of the embodiments substantially as herein described and illustrated.

22. A process according to any one of the embodiments substantially as herein described and illustrated.

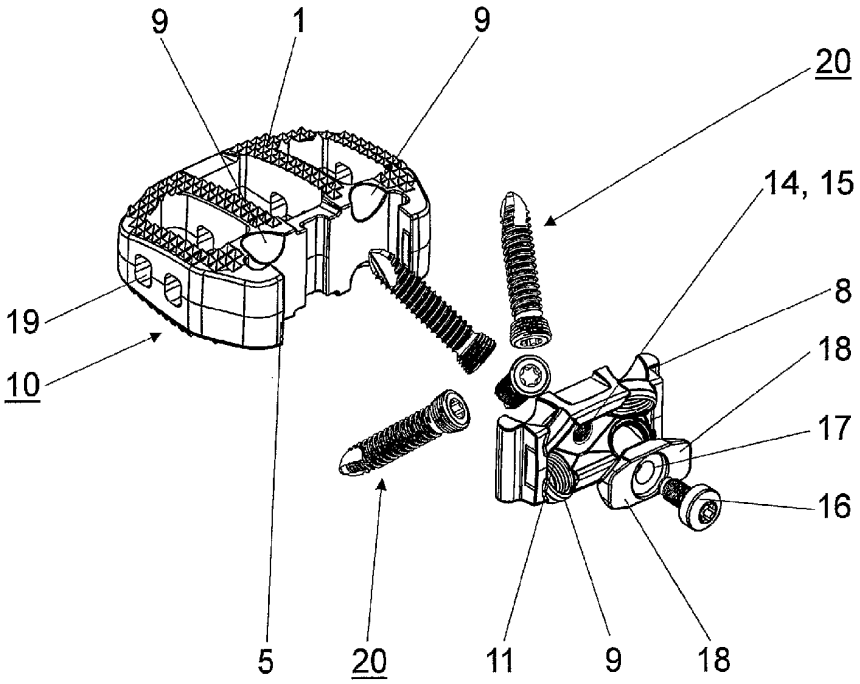

Fig. 1

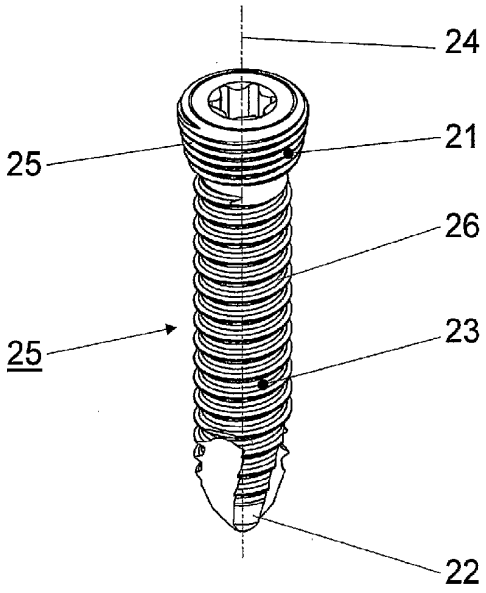

Fig. 2

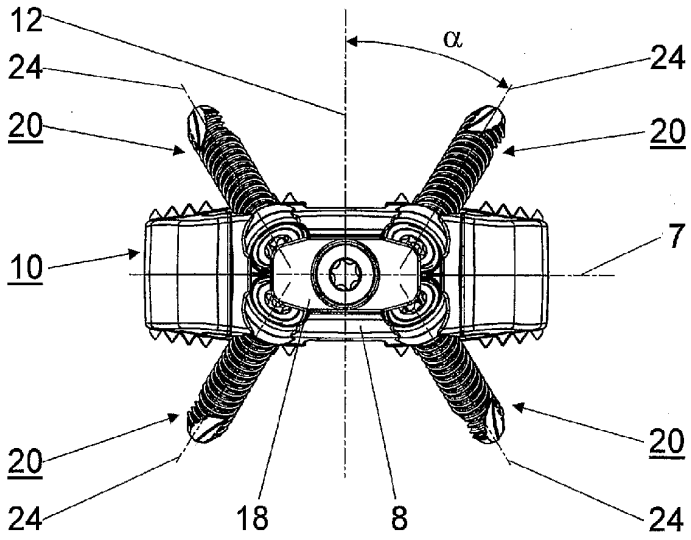

Fig. 3

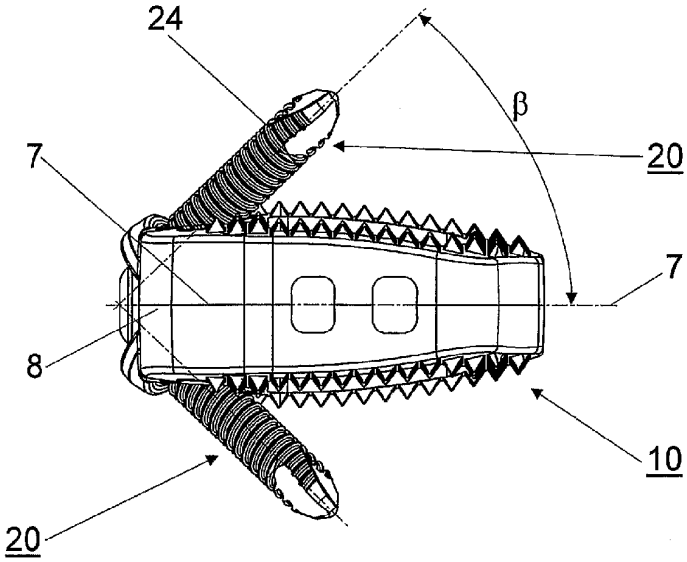

Fig. 4

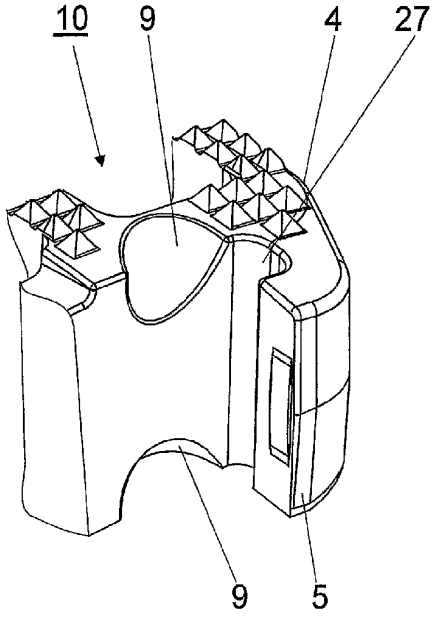

Fig. 5

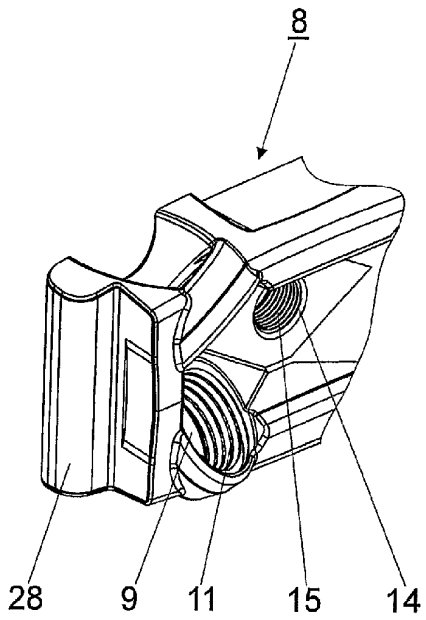

Fig. 6

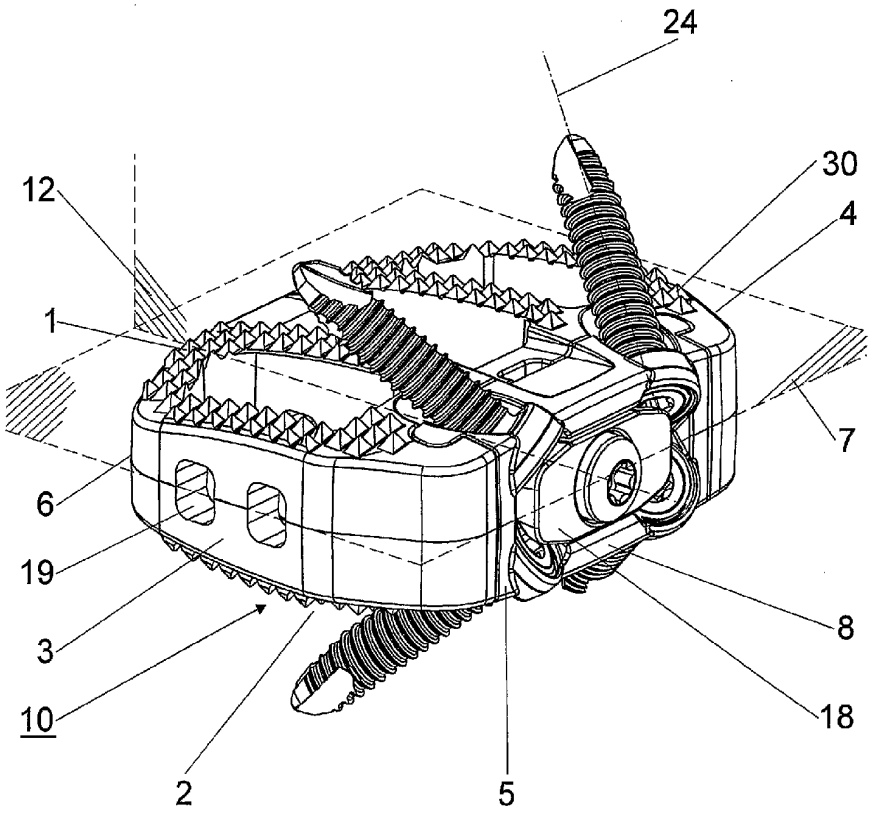

Fig. 7