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(54) **INTERVERTEBRAL IMPLANT**

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(58) **Field of Classification Search** ... 623/17.11–17.16; 606/90, 293

See application file for complete search history.

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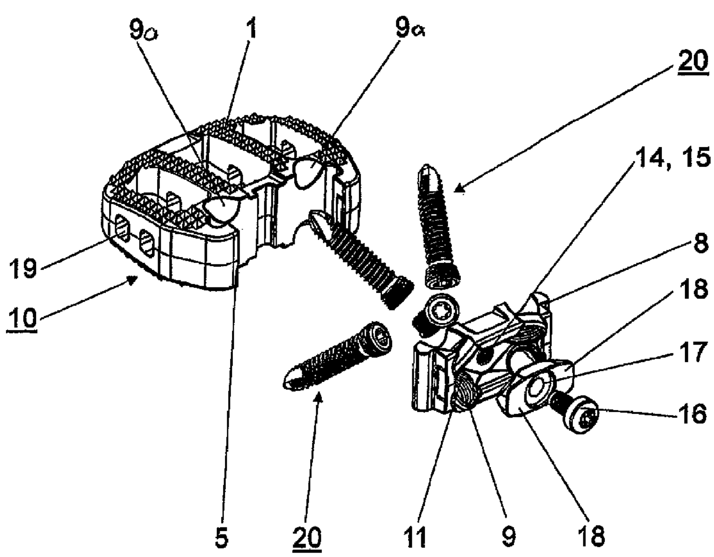
(57) **ABSTRACT**

An intervertebral implant having a three-dimensional body (**10**) and a securing plate (**1**). The three-dimensional body (**10**) includes an upper side (**1**) and an underside (**2**) which are suitable for abutting the end plates of two adjacent vertebral bodies, a left side surface (**3**) and a right side surface (**4**), a front surface (**5**) and a rear surface (**6**), a horizontal middle plane (**7**) between the upper side (**1**) and the underside (**2**), and a vertical middle plane (**12**) extending from the front surface (**5**) to the rear surface (**6**). The three-dimensional body further includes a plurality of boreholes (**9***a*) passing through the body (**10**), which are suitable for accommodating longitudinal fixation elements (**20**). The intervertebral implant also includes a front plate (**8**) displaceably disposed as an insert with the front side (**5**) of the three-dimensional body, the front plate (**8**) having a plurality of boreholes (**9**) in which the longitudinal fixation elements (**20**) can be anchored, and whose openings overlap with the openings of the boreholes of the three-dimensional body (**10**). A securing plate can be fastened essentially parallel to the front plate (**8**) at the three-dimensional body (**10**) in such a manner that the boreholes of the front plate (**9**) are covered at least partly by the securing plate (**18**). By virtue of the configuration of the intervertebral implant, a rigid, firm connection between the intervertebral implant and the longitudinal fixation elements used to fasten it, is possible.

13 Claims, 6 Drawing Sheets



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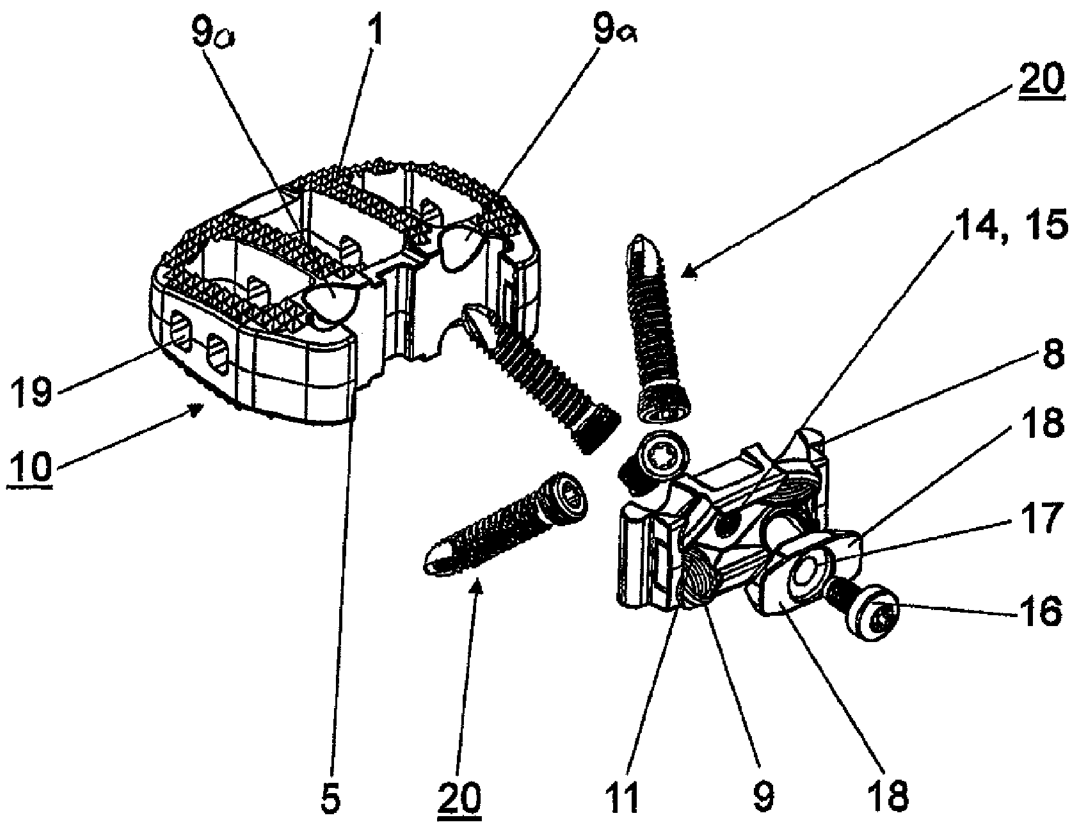

Fig. 1

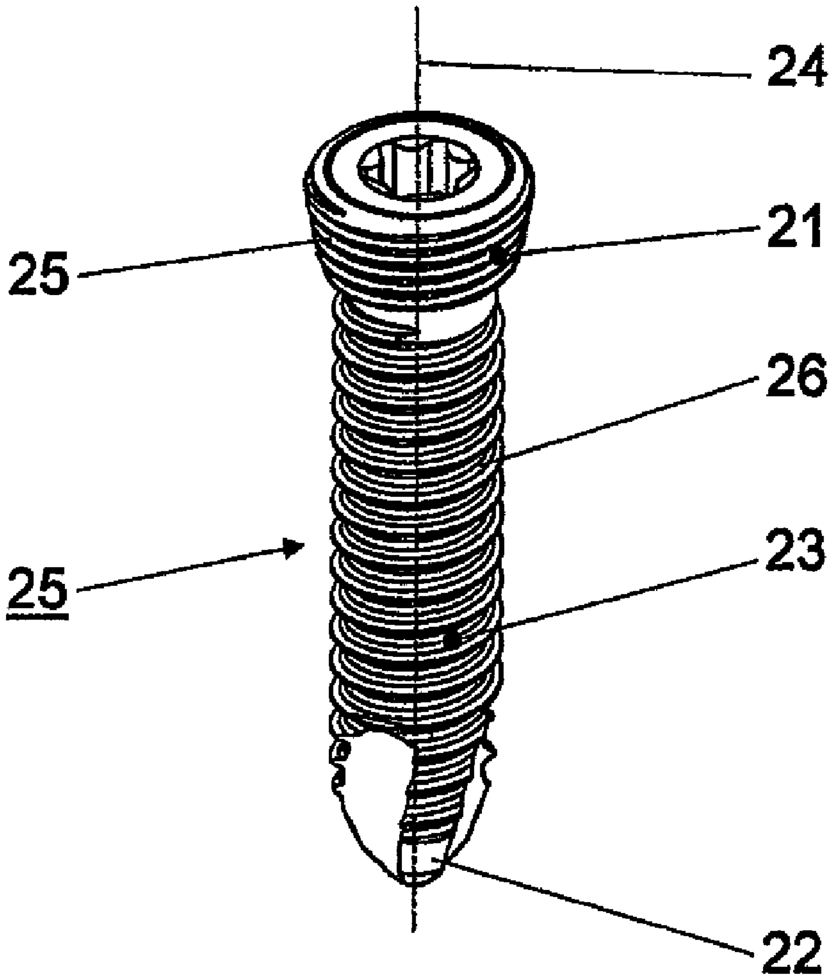

Fig. 2

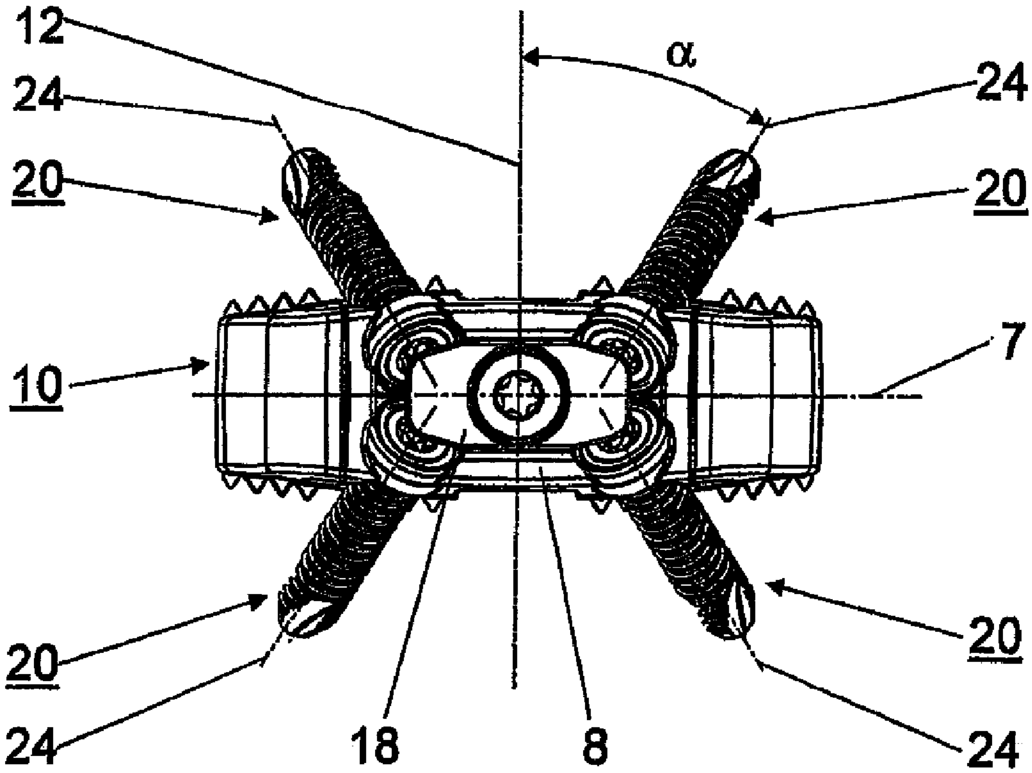

Fig. 3

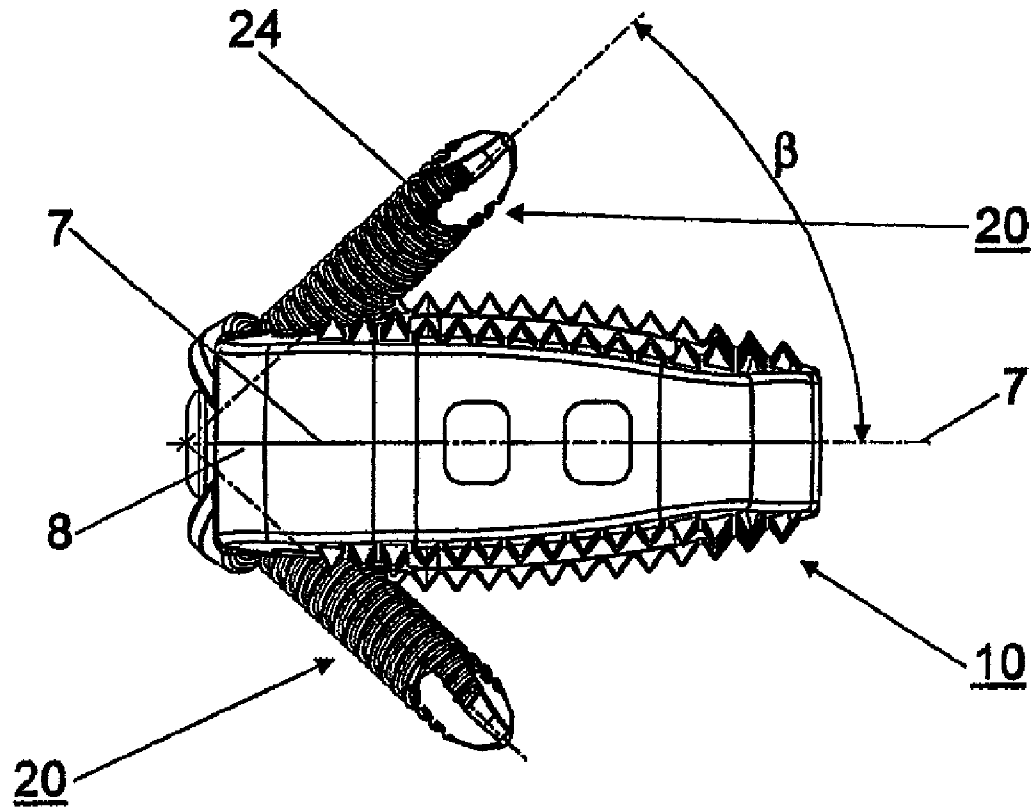

Fig. 4

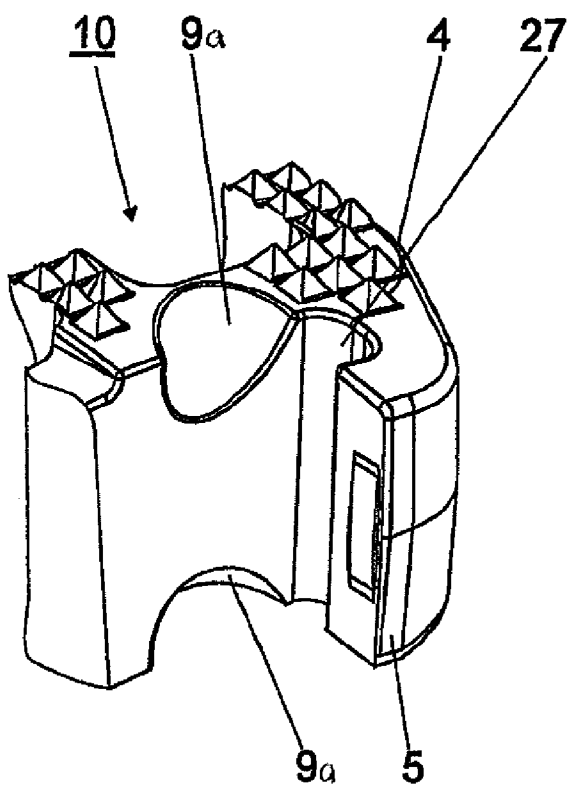

Fig. 5

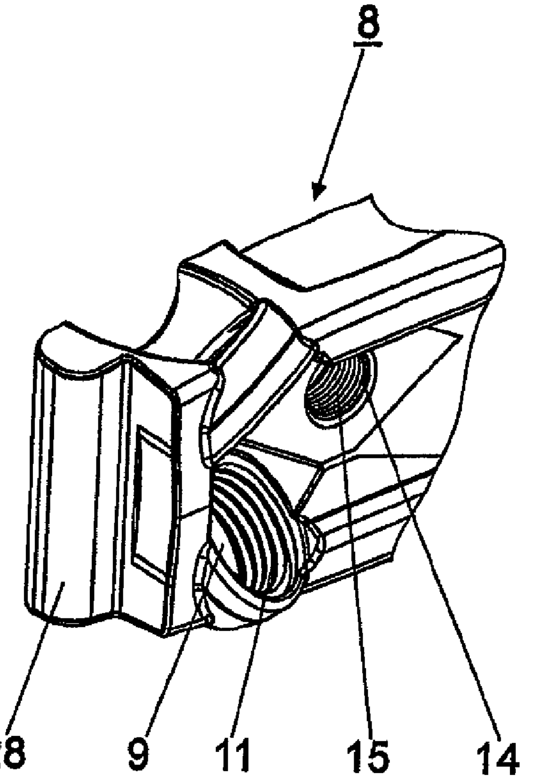

Fig. 6

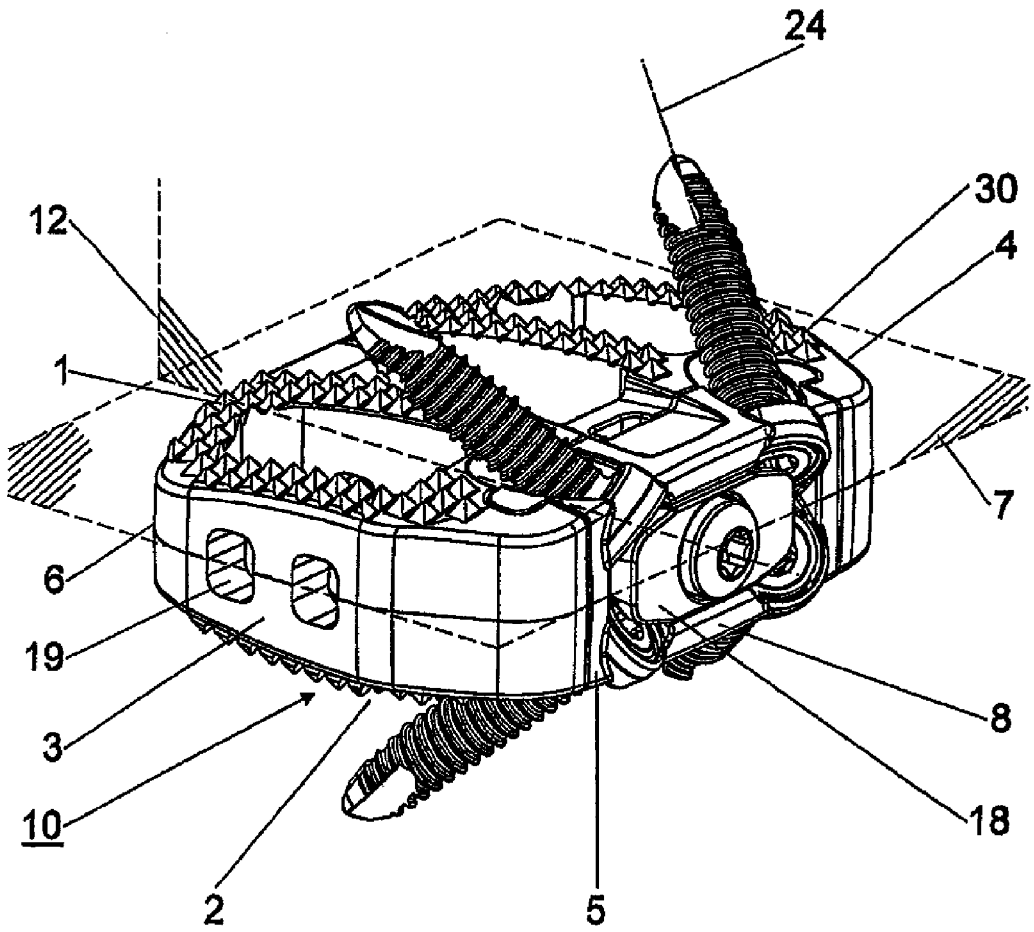

Fig. 7

INTERVERTEBRAL IMPLANT

CROSS REFERENCE TO RELATED APPLICATION

This application is a continuation of U.S. patent application Ser. No. 11/199,599, filed Aug. 8, 2005, which is a continuation of International Patent Application No. PCT/CH2003/000089, filed Feb. 6, 2003, the entire contents of which are expressly incorporated herein by reference thereto.

TECHNICAL FIELD

The present invention relates generally to intervertebral implants.

BACKGROUND OF THE INVENTION

GB-A-2 207 607 discloses an intervertebral implant, which has a horseshoe-shaped configuration with a plurality of cylindrical holes. The holes are smooth on the inside and only have a stop for the heads of the bone screws, which are to be introduced therein. A disadvantage of this arrangement is that the fastening screws, introduced therein, can be anchored only with their shaft in the bone. This does not result in a rigid connection with the horseshoe-shaped intervertebral implant. When the anchoring of the screw shaft in the bone is weakened, the intervertebral implant becomes movable with respect to the screw and the bone screws tend to migrate, endangering the blood vessels. Moreover, the loosening of the intervertebral implant can lead to a pseudoarthrosis.

U.S. Patent Publication US-A 2000/0010511 (Michelson) discloses an intervertebral implant, which, at its front surface, has two boreholes with an internal thread, into which bone screws with a threaded head can be introduced. A disadvantage of this implant is that the bone screws can become loose and are not secured against being screwed out or falling out. A further disadvantage is that the bone screws are fastened completely to the implant body itself and that therefore the latter experiences a relatively large stress.

Screws which emerge at the anterior or anterolateral edge of the vertebral body because of loosening run the risk of injuring main vessels such as the aorta and Vena calva, as well as supply vessels such as lumbar arteries and veins. Injury to these main vessels may result in internal bleeding possibly causing death within a very short time. Loosening of screws is more likely when they are not mounted angularly firmly.

SUMMARY OF THE INVENTION

The present invention is to provide a remedy for the above-discussed disadvantages. The present invention is directed to an intervertebral implant which can enter into a permanent, rigid connection with bone fixation means, so that, even if the bone structure is weakened, there is no loosening between the intervertebral implant and the bone fixation means. Moreover, over a separately constructed front plate, there is tension chording for the bone fixation elements, so that the implant body experiences less stress, that is, superimposed tensions. Moreover, a securing plate enables all bone fixation elements to be secured simultaneously.

The present invention accomplishes the objective set out above with an intervertebral implant, comprising a three-dimensional body having an upper side and an under side which are suitable for abutting the end plates of two adjacent vertebral bodies. The three-dimensional body further includes a left side surface and a right side surface, a front

surface and a rear surface, a horizontal middle plane between the upper side and the under side, and a vertical middle plane extending from the front surface to the rear surface. The three-dimensional body further comprising a plurality of boreholes, having openings at least at or near the front surface, passing there through and being suitable for accommodating longitudinal fixation elements. The intervertebral implant further including a front plate displaceably disposed as an insert with the front side of the three-dimensional body, where the front plate includes a plurality of boreholes having openings and in which the longitudinal fixation elements can be anchored, and whose openings overlap with the openings of the boreholes of the three-dimensional body. The intervertebral implant has a securing plate fastened substantially parallel to the front plate in such a manner that the boreholes of the front plate are covered at least partly by the securing plate. An advantage achieved by the present invention, arises essentially from the solid connection between the intervertebral implant and the longitudinal fixation elements, used to fasten it.

Compared to the two-part implants of the state of the art, for which a front plate is implanted in a separate step, the present invention has the advantage that the implantation of the intervertebral implant may be carried out in one step and, with that, can be carried out more easily and more quickly. A further advantage is that the intervertebral implant is fixed as frontally as possible at the body of the vertebra. That is, at a place where good bone material usually is present. The result is an anterior movement limitation without a greater risk to the surrounding structures. The load is still absorbed under compression by the intervertebral implant and not by the front plate or the fixation screws (longitudinal fixation elements).

A method for implanting an intervertebral implant of the present invention between two adjacent vertebral bodies includes introducing the intervertebral implant, having a three-dimensional body, a front plate, and one or more boreholes, between two adjacent vertebral bodies, attaching longitudinal fixation elements with heads through the boreholes into the vertebral bodies, and attaching a securing plate by means of a fastening agent over the heads of the longitudinal fixation elements to the front plate, such that the heads of the longitudinal fixation elements are captured between the front plate and the securing plate wherein the longitudinal fixation elements are secured against being shifted relative to the intervertebral implant.

Other objectives and advantages in addition to those discussed above will become apparent to those skilled in the art during the course of the description of a preferred embodiment of the invention which follows. In the description, reference is made to accompanying drawings, which form a part thereof, and which illustrate an example of the invention. Such example, however, is not exhaustive of the various embodiments of the invention, and therefore, reference is made to the claims that follow the description for determining the scope of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** shows an exploded drawing of the intervertebral implant,

FIG. **2** shows a longitudinal fixation element in the form of a screw,

FIG. **3** shows an elevation of the intervertebral implant of FIG. **1**,

FIG. **4** shows a side view of the intervertebral implant of FIG. **1**, FIG. **5** shows a three-dimensional detailed representation of the body of the intervertebral implant, which shows the connecting elements to the front plate of FIG. **6**,

FIG. **6** shows a three-dimensional detailed representation of the front plate of the intervertebral implant and the connecting elements to the body of FIG. **5** and

FIG. **7** shows a completely installed intervertebral implant with front plate and securing plate.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The intervertebral implant, shown in FIG. **1**-**7**, includes a three-dimensional body **10** in the form of a cage with an upper side **1** and an underside **2**, which are suitable for abutting the end plates of two adjacent vertebral bodies, a left side surface **3** and a right side surface **4**, a front surface **5** and a back surface **6**, a horizontal middle plane **7** located between the upper side **1** and the underside **2**, a vertical middle plane **12** extending from the front surface **5** to the rear surface **6** and four boreholes **9***a*, which pass through the body **10** and are suitable for accommodating longitudinal fixation elements **20**. The body **10** may be constructed as a hollow body, the mantle surfaces of which are provided with perforations **19**. The upper side **1** and/or under side **2** of the intervertebral implant may preferably be convex in shape, not planar. A convex shape to the upper side **1** and the underside **2** allows for an improved fit with the end plates of the adjacent vertebral bodies by the intervertebral implant. Further, the side surfaces **1**-**6** of the intervertebral implant may be essentially convex, as well.

As shown in FIG. **7**, the upper side **1** and the underside **2** of the three-dimensional body **10** are provided with structuring in the form of teeth **30**.

At the front surface of the three-dimensional body **10**, a front plate **8** may be mounted, which is disposed perpendicular to the horizontal central plane of the intervertebral implant and through which four boreholes **9** pass and in which the longitudinal fixation elements **20** can be anchored. The front plate **8**, as shown in FIGS. **5** and **6**, is constructed as an insert for the three-dimensional body **10**. The three-dimensional body **10** has a semicircular groove **27** extending parallel to the vertical middle plane **12** at the transitions of the left side surface **3** and the right side surface **4** (FIG. **5**) to the front surface **5**. Correspondingly, the front plate **3** has right and left (FIG. **6**) similarly extending and similarly dimensioned, semicircular rail **28**. As a result, the front plate can be pushed and positioned easily with its two lateral rails **28** into the corresponding grooves **27** of the body **10** during the production of the intervertebral implant.

In one embodiment at least one of the boreholes **9** in the front plate is constructed so that a longitudinal fixation element **20**, accommodated therein, can be connected rigidly with the front plate. A rigid connection may be accomplished, for example, owing to the fact that at least one of the boreholes **9** of the front plate **8** has an internal thread. A corresponding longitudinal fixation element **20**, bone screw, with a threaded end can then be screwed together rigidly with the implant. In an alternative embodiment, the four boreholes **9** in the front plate may have an internal thread **11**, so that longitudinal fixation elements **20** can be connected rigidly with the front plate **8**.

As discussed, the front plate **8** may be disposed, preferably vertically to the horizontal central plane, so that it can be displaced vertically with respect to the three-dimensional body **10**. By these means, "stress shielding" (protection and neutralization of mechanical stresses) is attained, which permits the end plates to be adapted to the intervertebral implant during the healing process.

The intervertebral implant may have a securing plate **18**, which can be fastened by means of a screw connection parallel to the front plate **8** at the front plate **8** in such a manner that the boreholes **9** of the front plate **3** are partly covered by the securing plate **18**. The securing plate **18** may have a central borehole **17** provided, preferably, with an internal thread. Corresponding thereto, the front plate **8** has a central borehole **15** for accommodating fastening means **16**. Preferably, the central borehole **15** has an internal thread **14** for accommodating a fastening means **16** in the form of a screw. The securing plate **18** may also be fastened by a bayonet catch or a click catch. By fastening the securing plate **18** to the front plate **8**, the heads **21** of the longitudinal fixation elements **20** (discussed later) are contacted by the securing plate **18**, so that they are secured against being ejected or screwed out.

Preferably, the boreholes **9***a* of the three-dimensional body **10** do not pass either through the left side surface **3** or the right side surface **4** or completely through the front surface **5**. The front surface **5**, preferably, is also not crossed by the boreholes **9***a*. Further, the horizontal middle plane **7** is not pierced by the boreholes **9***a*. Only the axes **24** of the longitudinal fixation elements **20**, introduced therein, intersect the horizontal middle plane **7** of the body **10**. As seen from the front surface **5**, the boreholes of the three-dimensional body **10** and the front plate diverge. The axes **24** of the boreholes of the three-dimensional plate **10** and the front plate **8** enclose an angle β ranging from 20° to 60°, specifically from 36° to 48°, and more preferably an angle β of 42° with the horizontal middle plane **7** (FIG. **4**) and an angle α ranging from 10° to 45°, specifically from 27° to 33°, and more preferably an angle α of 30° with the vertical middle plane **12** (FIG. **3**). Thus, better access for introducing the screws is achieved.

In one embodiment, at least one of the boreholes **9** of the front plate **8** may taper conically towards the underside **2**, so that a bone screw, with a corresponding conical head, can be anchored rigidly therein. The conical borehole preferably has a conical angle, which is smaller than the resulting frictional angle. Advisably, the conicity of the conical borehole is 1:3.75 to 1:20.00 and preferably 1:5 to 1:15.

In another configuration, at least two of the boreholes **9** of the front plate **8** extend parallel to each other. This makes insertion of the intervertebral implant easier. In another embodiment, at least two of the boreholes **9** of the front plate **8** diverge when viewed from the front side. By these means, a region of the vertebral body, which has a better bone quality than does the center of the vertebral body, is reached by the bone screws.

To improve the anchoring of the bone screw in a plastic body of the intervertebral implant (discussed later), a metal sleeve with an internal thread (not shown) may be inserted in the boreholes of the front plate and three-dimensional body. The intervertebral implant may also consist only partially of an x-ray transparent plastic and, in the region of the boreholes consist of a metal, such as titanium or a titanium alloy. Improved guidance and anchoring of the bone screws in the intervertebral implant may be achieved. Further, the boreholes **9** may have a smooth internal wall, into which the threaded head of a metallic, longitudinal fixation element may cut or be molded.

Depending on circumstances, two, three, four or more longitudinal fixation elements may be connected rigidly with the intervertebral implant. Preferably, at least one fixation element should pierce the upper side and at least one fixation element the underside of the intervertebral implant. The longitudinal fixation elements **20** may have either a smooth head, so that there will not be a rigid connection with the implant or a threaded, conical or expendable end, so that there will be a rigid connection with the implant. In both cases, however, the longitudinal fixation elements **20** are secured by the securing plate against rotating out, being ejected out or falling out at a later time.

The longitudinal fixation elements **20** are preferably constructed as bone screws. As shown in FIG. **2**, the longitudinal fixation elements **20**, introduced into the boreholes **9**, have a head **21**, a tip **22**, a shaft **23** and an axis **24**. The head **21** may preferably be provided with an external thread **25**, which corresponds to the internal thread **11** of the borehole **9**, so that the heads **21** can be anchored in the boreholes **9** in a rigid manner. The shaft **23** may be provided with a thread **26**, which is self-drilling and self-cutting. The load thread angle of the thread **26** has a range of between 11° to 14°, preferably between 12° and 13°, and more preferably a load thread angle of 12.5°. The pitch angle of the thread may have a range of between 6° and 10°, preferably between 7° and 9°, and more preferably have a pitch angle of 8°. The special pitch angle produces a self-retardation in the thread, thus ensuring that the bone screw will not automatically become loose.

In the case of a second, possibly rigid type of connection, a longitudinal fixation element **20**, bone screw, may preferably be used, the head of which tapers conically towards the shaft, the conicity of the head corresponding to the conicity of the borehole of the intervertebral implant. The longitudinal fixation elements may also be constructed as threadless cylindrical pins, which are provided with a drilling tip, preferably in the form of a trocar. A further variation consist therein that the longitudinal fixation elements are constructed as spiral springs. Finally, the longitudinal fixation elements may also be constructed as single-vaned or multi-vaned spiral blades.

As shown in FIG. **7**, two longitudinal fixation elements **20** pierce the upper side **1** and two longitudinal fixation elements **20** pierce the underside **2** of the body **10**, thereby anchoring the intervertebral implant to the adjacent vertebral bodies.

The intervertebral implant may be produced from any material which is compatible with the body. Preferably, the three-dimensional body **10** may consist of a body-compatible plastic which has not been reinforced and which may be transparent to x-rays. The advantage over fiber-reinforced plastics, which are already known in implant technology, is that no reinforcing fibers are exposed. Such exposure may be disadvantageous clinically. In such a three-dimensional body **10** constructed of a plastic that has not been reinforced, the use bone screws may be preferable. As discussed previously, the external thread of the bone screw(s) may have a load thread angle range of 11° to 14°, and preferably between 12° to 13°. A comparatively slight inclination of the load flank brings about a high clamping force. As a result, radial expansion and the danger of forming cracks in the plastic are reduced. Furthermore, the external thread of the bone screw(s) may preferably have a pitch angle between 6° and 10° and preferably between 7° and 9°.

The front plate **8** may be made from materials different than the three-dimensional body **10**. The front plate **8** is preferably made from a metallic material. Titanium or titanium alloys are particularly suitable as metallic materials. The complete tension chord arrangement (front plate and screws) may also be made from implant steel or highly alloyed metallic materials, such as CoCrMo or CoCrMoC. The advantage of titanium lies in that there is good tissue compatibility and the good ingrowing behavior of bones. The advantage of highly alloyed metallic materials lies in their high-strength values, which permit filigree constructions.

A brief description of a surgical procedure follows in order to explain the invention further.

The intervertebral implant, in the form of a three-dimensional body **10**, is introduced between two adjacent vertebral bodies by means of a suitable instrument. Longitudinal fixation elements **20**, in the form of bone screws, securing the three-dimensional body **10** are screwed/inserted by means of a suitable aiming device through the boreholes **9** of the front plate **8** into the vertebral bodies. The front plate **8** may be displaced vertically with respect to the three-dimensional body **10**, such that the openings of the boreholes **9***a* of the three-dimensional plate **10** and the boreholes **9** of the front plate **8** overlap, to obtain stress shielding. The securing plate **18** is fastened by means of the fastening agent **16** in the form of a screw over the heads **21** of the longitudinal fixation elements **20** at the front plate **8**, so that the heads **21** of the longitudinal fixation elements **20** and, with that, the screws themselves, are captured between the front plate **8** and the securing plate **18** and secured against being shifted relative to the three-dimensional body **10** (for example, by falling out or by turning out). The fastening agent **16**, in the form of a screw, preferably is provided with a thread, which is distinguished by a large self-retardation.

The invention claimed is:

1. An intervertebral implant for implantation between two adjacent vertebral bodies, the implant comprising:

a plurality of bone fixation elements each including a head and a shaft, the shaft having a thread for engaging one of the adjacent vertebra;

a three dimensional body having a left side surface, a right side surface, a front surface, a back surface, an upper side and an underside, the upper side and the underside being sized and configured to contact the one of the two adjacent vertebral bodies, respectively, the three dimensional body further including at least one partial borehole in communication with the front surface and the upper side of the body and at least one partial borehole in communication with the front surface and the underside of the body;

a plate having an upper surface and a lower surface, the plate contacting the front surface of the three dimensional body, the plate including a plurality of boreholes, at least one of the plurality of boreholes formed in the plate aligning with the at least one partial borehole in communication with the upper side of the body and at least one of the plurality of boreholes formed in the plate aligning with the at least one partial borehole in communication with the underside of the body when the three dimensional body is coupled to the plate so that one of the plurality of bone fixation elements is insertable through one of the plurality of boreholes formed in the plate, through one of the plurality of partial borehole formed in the three dimensional body and into one of the adjacent vertebral bodies, respectively, wherein the three dimensional body further includes a first height as defined by the upper side and the underside and the plate includes a second height as defined by the upper and lower surfaces of the plate, the first height being substantially equal to the second height so that the three dimensional body and the plate are contained between the adjacent vertebral bodies when the implant is inserted between the adjacent vertebral bodies;

wherein the plate is made from a biocompatible metallic material and the three dimensional body is made from a biocompatible non-metallic material.

2. The intervertebral implant of claim **1**, further comprising:

a semicircular groove extending parallel to a vertical middle plane at transitions of the left and right side surfaces to the front surface.

3. The intervertebral implant of claim **1**, wherein the three dimensional body is made from a biocompatible plastic.

4. The intervertebral implant of claim **1**, wherein the plurality of bone fixation elements are bone screws and the plurality of boreholes formed in the plate include internal threads, at least a portion of the heads of the bone screws being externally threaded for engaging the internal threads of the plurality of boreholes to anchor the plurality of bone screws to the plurality of boreholes in a rigid manner.

5. The intervertebral implant of claim **1**, wherein the three dimensional body includes at least one through hole extending from the upper side to the underside.

6. The intervertebral implant of claim **1**, wherein the body includes a horizontal middle plane and a vertical middle plane, the plurality of partial borehole formed in the body comprise four body partial borehole, the plurality of boreholes formed in the plate comprise four plate boreholes and the plurality of bone fixation elements comprise four bone fixation elements, two of the bone fixation elements passing through the upper side of the body and two of the bone fixation elements passing through the underside of the body, the four partial borehole formed in the body and the four boreholes formed in the plate being arranged such that the heads of the four bone fixation elements are located between the upper side and an underside in an assembled configuration.

7. The intervertebral implant of claim **6**, wherein the two of bone fixation elements passing through the upper side diverge with respect to one another and the two bone fixation elements passing through the underside diverge with respect to one another.

8. The intervertebral implant of claim **1**, wherein the plate may be pushed and placed easily with respect to the front surface of the body.

9. The intervertebral implant of claim **1**, further comprising:

a securing plate fastenable to the plate, the securing plate at least partially covering each of the plurality of boreholes formed in the plate so that, once implanted, the head of the bone fixation elements are located between the plate and the securing plate.

10. The intervertebral implant of claim **9**, wherein the plate includes an internally threaded central borehole for receiving a central screw for fastening the securing plate to the plate.

11. The intervertebral implant of claim **1**, wherein the body is convex in shape.

12. The intervertebral implant of claim **1**, wherein the body includes a horizontal middle plane and a vertical middle plane, the plurality of partial borehole formed in the body and the plurality of boreholes formed in the plate define borehole axes, the borehole axes defining a first angle β relative to the horizontal middle plane and a second angle α relative to the vertical middle plane, the first angle ranging from twenty to sixty degrees (20-60°) and the second angle ranging from ten to forty-five degrees (10-45).

13. The intervertebral implant of claim **1**, further comprising:

a securing mechanism operatively engaging the plate, the securing mechanism at least partially covering each of the plurality of boreholes formed in the plate to inhibit the bone fixation elements from falling out.

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