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(54) **CERVICAL INTERVERTEBRAL PROSTHESIS**

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(57) **ABSTRACT**

A cervical intervertebral prosthesis includes at least one cover plate that is configured to be connected to one of two adjacent vertebral bodies and an instrument for positioning a fastening device at one of the vertebral bodies in order to secure the intervertebral prosthesis. The instrument is separate from the fastening device and includes a drill gauge and arms with projections for holding the cervical intervertebral prosthesis at a predetermined position relative to the drill gauge. The drill gauge has an orientation pointing towards the cover plates at an oblique angle α.

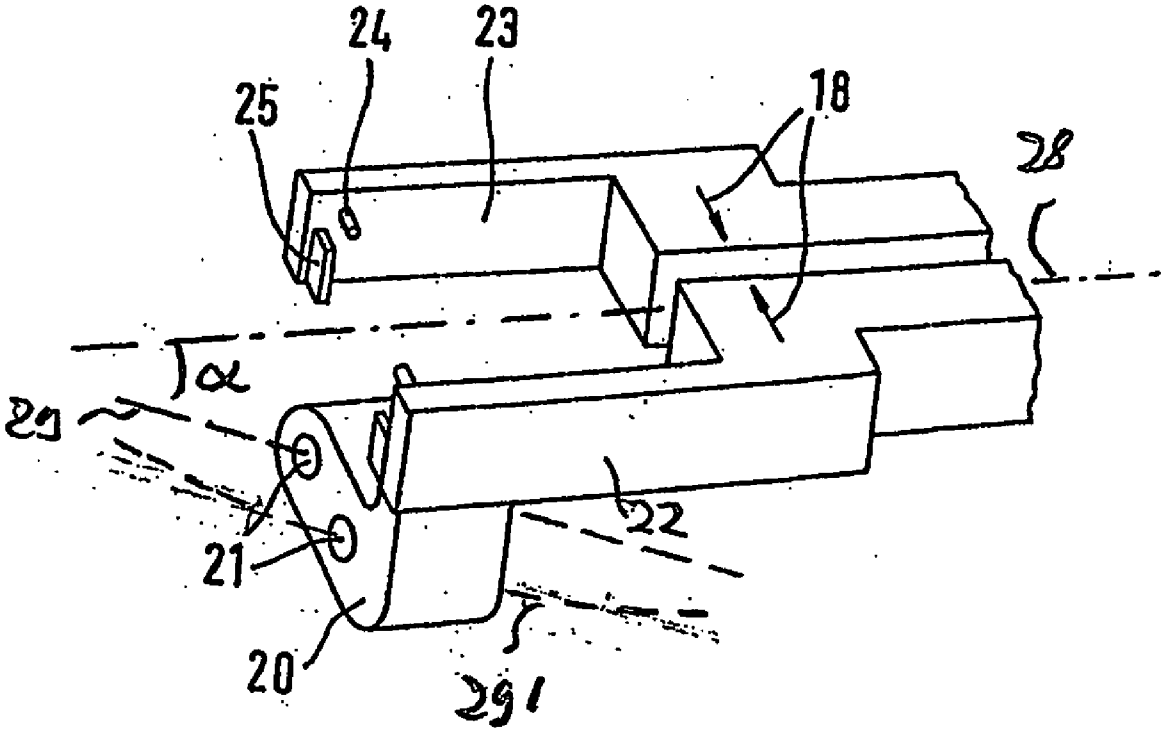
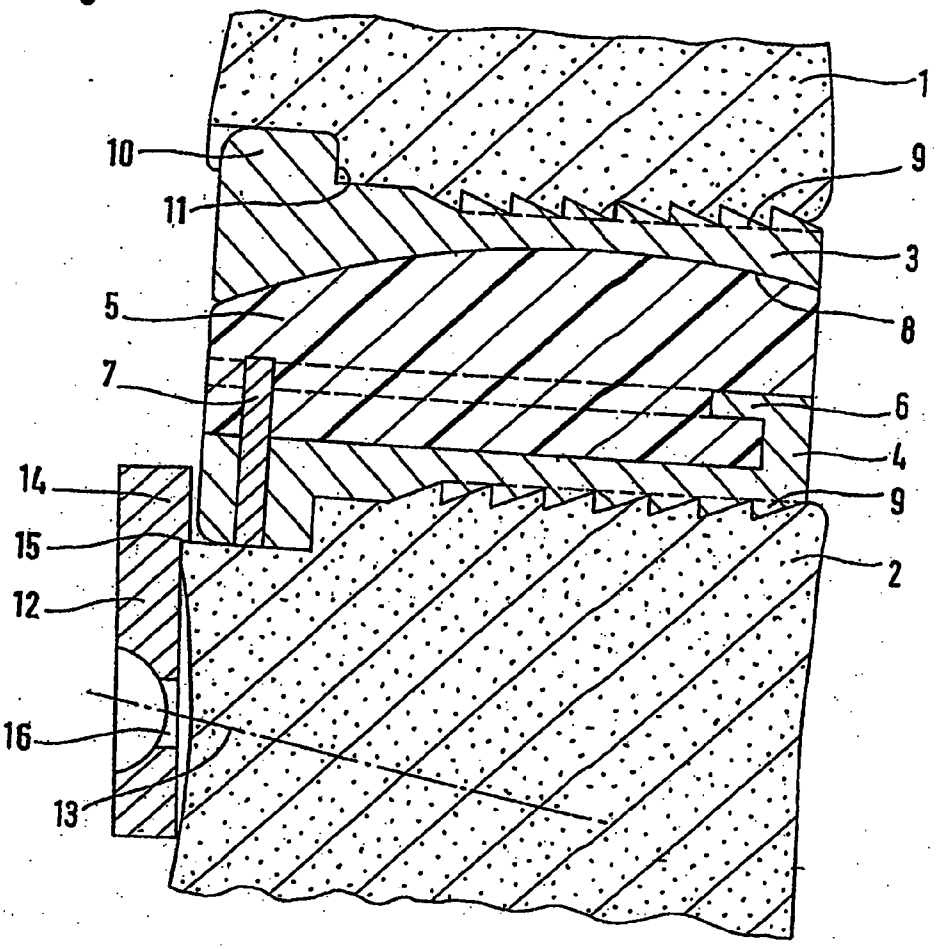


Fig. 1



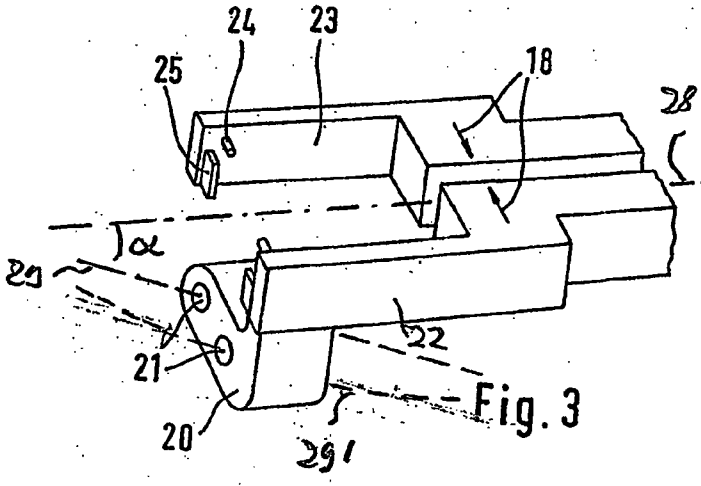


Fig. 3

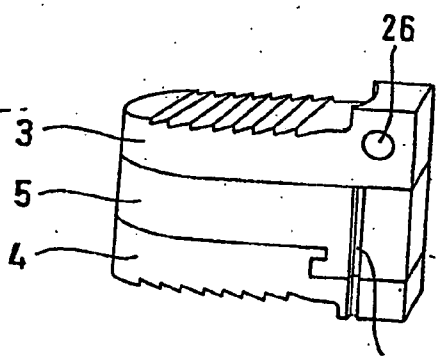


Fig. 2

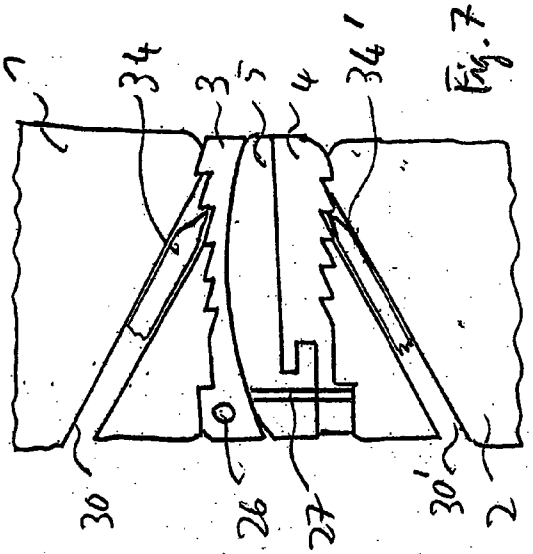


Fig. 7

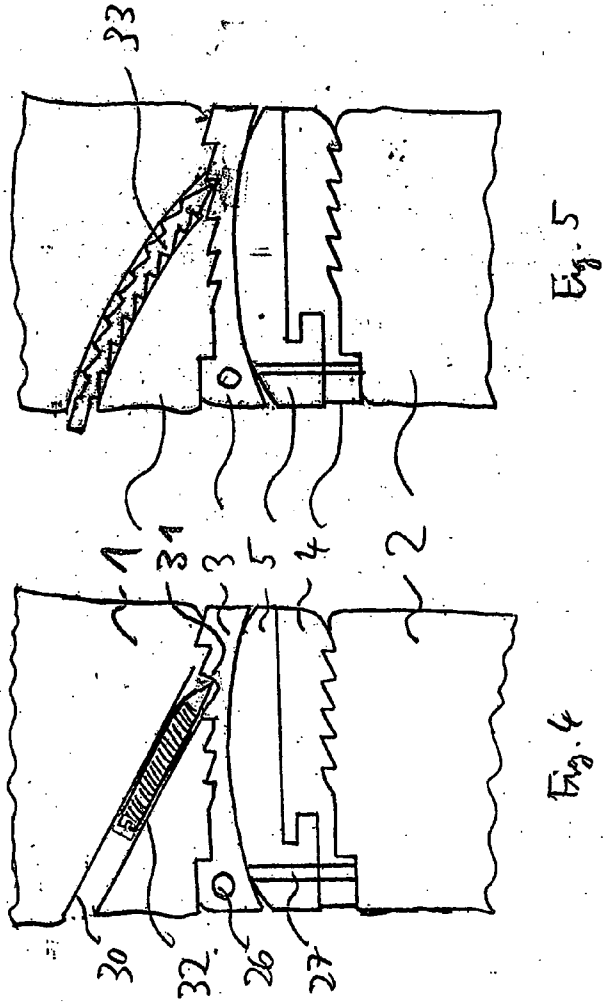


Fig. 5

Fig. 4

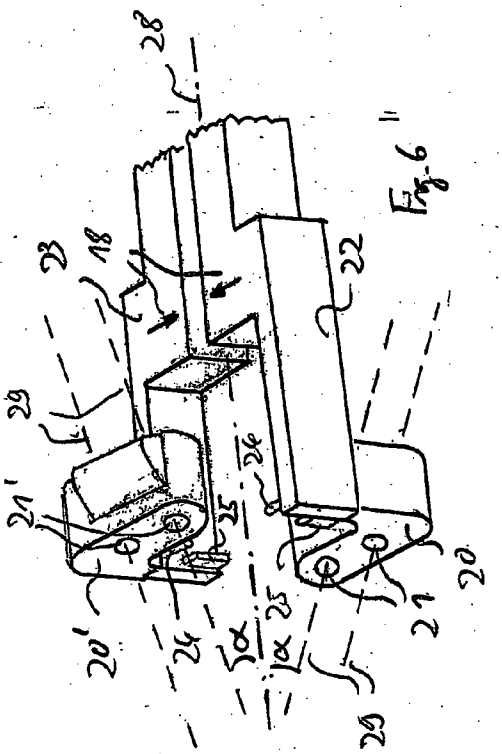


Fig. 6

CERVICAL INTERVERTEBRAL PROSTHESIS

REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation-in-part of Ser. No. 10/814,783, filed Apr. 1, 2004, now U.S. Pat. No. _____.

FIELD AND BACKGROUND OF THE INVENTION

[0002] Cervical intervertebral prostheses are known (EP-A-1 344 508) having two cover plates which are to be connected to the end plates of the adjacent vertebral bodies and between which there is a sliding core which allows the cover plates a relative movement intended to simulate the articulated mobility of the intervertebral disk that has been replaced. To secure the cover plates in their intended position between the vertebral bodies, the cover plates in the known prosthesis are connected to securing plates which extend from the ventral edge of the cover plates, perpendicularly thereto, and are screwed to the ventral surface of the associated vertebral body. It is further known to provide an instrument for positioning an intervertebral prosthesis with a drill guide (U.S. Pat. No. 6,120,503). The drill guide comprises two guide holes arranged parallel to each other on the instrument. A guide orients the instrument in respect to the intervertebral prosthesis in order to ensure a proper parallel orientation between the prosthesis and the guide holes. Fixation screws placed in insertion holes drilled through the guide holes fixate a bracket at the ventral surfaces of the adjacent vertebral bodies, the bracket keeping the prosthesis in place. The ventral surfaces of the vertebral bodies on which the securing plates come to lie do not always extend exactly perpendicular with respect to the end plates of the vertebral bodies. This prevents the securing plates or the bracket from bearing across their entire surface on the vertebral bodies, and it impairs the stability of the fixation.

SUMMARY OF THE INVENTION

[0003] This shortcoming is remedied by the features of the invention as set forth in this application. According to this, an instrument for positioning a fastening device at a vertebral body in order to secure an intervertebral prosthesis is provided that is separate from the fastening device and comprises two cover plates configured to be connected to adjacent vertebral bodies and a prosthesis core which forms an articular joint with one of the cover plates, the instrument comprising a drill gauge for the fastening device which is configured to be connected to the prosthesis or a prosthesis model in a predetermined relative position, wherein the drill gauge is slanted to point at an oblique angle towards the cover plates. In this way, the slanted drill gauge facilitates creation of a fixation hole that intersects with the cover plate, thus allowing insertion of a fixation device, like a screw or a nail, into the fixation hole interlocking with the cover plate. Hence, the prosthesis is securely held in place.

[0004] It will be appreciated that the fastening device should have a predetermined position in relation to the cover plate. It should be placed such in the vertebral body that it intersects with the cover plate, preferably at a middle portion of its exterior surface, in order to secure the prosthesis in its implanted state. In order to position the fixation device properly in respect to the prosthesis and the adjacent vertebral body, it is therefore expedient to use an instrument having a drill gauge that is slanted to point at an angle towards the cover plates for the fastening device. This drill gauge can be arranged in an orientation pointing towards the cover plates in order to have it at a predetermined position in relation to the prosthesis. Instead of this, it can also interact with, or be fixedly connected to, a prosthesis model which is fitted into the intervertebral space prior to implantation of the prosthesis. The invention thus provides an easy and secure fixation of the prosthesis by using triangulation for optimal positioning of the fixation device. Preferably the drill gauge has an orientation selected such that it intersects with an exterior surface of at least one of the cover plates at a predetermined distance. The exterior surface of a cover plate is its upper or lower surface facing the adjacent upper or lower vertebral bodies, respectively. By virtue of the invention, owing to the slanted arrangement of the drill gauge a surgeon is enabled to create a fixation hole that is optimally positioned in the adjacent vertebral body for fixation of the prosthesis.

[0005] Preferably, the drill gauge comprises a passageway, e.g. an elongated circular hole having a length (depth) greater than its width. Although usually straight, the passageway may have a curvature in order to enable use of a curved fixation device. For an even more secure fastening, two or more parallel passageways could be provided. This enables use of more than one fixation device for each cover plate. Further, a second drill gauge could be provided on the instrument, the drill gauge and the second gauge being oriented towards each other. By virtue of this, the fixation holes created by means of the drill gauges are converging, one intersecting with one of the cover plates and the other intersecting with the other cover plate.

[0006] Preferably, the cover plate of the prosthesis is provided with a recess at the predetermined at which the orientation axis intersects. Owing to the very precise triangulation that is made possible by the drill gauge of this invention, the fastening device inserted in the fastening hole may interlock with the surface of the cover plate, the recess located at this position. Examples for the recess are a receiving hole or a lower part of a serration provided on the exterior surface of the cover plates or of a ridge.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] The invention is explained in more detail below with reference to the drawings which depict an advantageous illustrative embodiment, and in which:

[0008] FIG. **1** shows a sagittal section through the prosthesis in the implanted state,

[0009] FIG. **2** shows a side view of the prosthesis without securing plate,

[0010] FIG. **3** shows an instrument with a drill gauge for the fastening screws of the securing plate according to a first embodiment;

[0011] FIG. **4** shows a cross section of vertebrae with a fixation hole created by the instrument of FIG. **3**;

[0012] FIG. **5** shows a variant of FIG. **4** for a different fixation device;

[0013] FIG. **6** shows a second embodiment of the instrument with dual drill gauges; and

[0014] FIG. **7** shows a cross section of vertebrae with converging fixation hole created by the instrument of FIG. **6**.

DETAILED DESCRIPTION OF THE INVENTION

[0015] Between the vertebrae **1** and **2** of the cervical spine there is an intervertebral space into which is inserted the intervertebral prosthesis consisting of an upper cover plate **3**, a lower cover plate **4**, and a prosthesis core **5**. The prosthesis core **5** is held on the lower cover plate **4** by profiles **6** and a catch **7**. With the upper cover plate **3**, it forms a slide surface pairing **8**. The cover plates **3** and **4** have a sawtooth formation **9** by means of which they are held on the associated end plates of the vertebral bodies **1**, **2**. Short flanges **10** with dorsally facing limit stop surfaces **11** ensure that the cover plates **3**, **4** cannot move farther than is wanted in the dorsal direction relative to the vertebral bodies **1**, **2**. An undesired movement in the ventral direction is generally prevented by the sawtooth formation of the profiles **9**. This at least applies several months after the operation, when the bone tissue has grown into the surface of the cover plates and has connected firmly to them. Details of this construction are described in the publication WO 03/075804 A1.

[0016] There are cases where, because of special physiological circumstances, a risk of ventral displacement of the prosthesis must be taken into account. This risk may also arise for a period until the abovementioned connection between the cover plates and the bone tissue is secure. In these cases, one approach is to combine the cover plate in question with a securing plate **12** which, in the example in FIG. **1**, is attached to the ventral surface of the caudal vertebral body **2** by means of screws **13**. A part of the securing plate **12** designated as limit stop part **14** extends above the vertebral body **2** in such a way that it lies in front of part of the associated prosthesis cover plate **4**. If the latter has a tendency to move out of the intervertebral space in the ventral direction, it will strike against the limit stop part **14** of the securing plate **12** and thus be prevented from moving any farther in this direction.

[0017] The securing plate **12** is shown on the caudal vertebral body **2**. However, a securing plate could be attached, in addition or instead, to the cranial vertebral body **1**.

[0018] The way in which the securing plate is attached is not important as regards the invention. The most obvious way is to use bone screws, expediently provided with a means (not shown) to secure them against loosening. They can be screwed in substantially parallel to the main plane of the prosthesis in the vertebral body. It is particularly advantageous for them to be inclined away from the prosthesis in the dorsal direction, as is depicted.

[0019] The securing plate **12** does not have to be positioned with great precision. It suffices if it is placed at a suitable location, preferably over a large part of the width of the prosthesis, and extends into the path which the prosthesis would take in the event of an undesired movement in the ventral direction. For this, it suffices if it extends 1 or 2 mm above the edge **15** of the vertebral body **2**. It should not extend any more than about 2.5 to 3 mm above it, so as not to impede the relative flexion movement of the vertebral bodies **1**, **2** and of the prosthesis parts.

[0020] To make the positioning easier, the securing plate **12** can be provided with an edge **15** which corresponds to the edge, designated by the same reference number, of the vertebral body **2** and separates the limit stop part **14** of the securing plate from that part which is to be fastened to the front surface of the vertebral body. When the limit stop part **14** has the desired height of about 2 mm, the surgeon proceeds by placing the securing plate on the vertebral body **2** in such a way that the edges **15** of the securing plate and vertebral body lie on one another. He then drills the holes for receiving the fastening screws **13** by using the screw holes **16** in the securing plate as drill gauges. In this way, he achieves a secure positioning.

[0021] A still more secure positioning is achieved by using another approach, with fixation devices like nails or screws inserted by means of the instrument shown in FIG. **3**. A drill gauge **20** with bore holes **21** as passageways for guiding the drill is arranged on a forceps-like instrument having two arms **22**, **23** which, by means not shown, can be moved toward one another in the direction of arrow **24** and can be fixed in the approximated position. On their flanks facing one another, the arms **22**, **23** have projections **24**, **25** which are of a configuration that matches the corresponding recesses **26**, **27** of the prosthesis, and, in the example shown, these projections are specifically pins **24**, which correspond with bores **26**, and blades **25** which correspond with slits **27**. After the prosthesis **3**, **4**, **5** has been inserted into the intervertebral space, as is shown in FIG. **1**, the instrument is applied to the prosthesis and adjusted thereon with the aid of the elements **24** to **27**. The bore holes **21** of the drill gauge **20** are slanted such that they have an orientation pointing towards the cover plates **3**, **4** at an oblique angle. This slanting is shown by an angle α between an orientation axis **29** of the bore holes **21** and a longitudinal axis **28** of the instrument. A preferred range for the angle **2** is between 15 and 60 degrees, in particular between 35 and 45 degrees. Fixation holes **30** created by drilling through the bore holes **21** are intended to end at a predetermined position that corresponds to a recess **31** being arranged at a predetermined distance on the exterior surface of the cover plate **3** of the prosthesis. Into the fixation hole **30** a screw **32** may be inserted as a fixation device, its tip interlocking with the recess **31**. Alternatively, nails may be employed as fixation devices. The fixation device as well as the drill guide may even have a curvature (illustrated by curved orientation line **29'**), for fastening of the prosthesis with a Steffee nail **33** (FIG. **5**). The prosthesis is thus secured even against rather large pull-out forces (FIGS. **4** and **5**).

[0022] A second embodiment of the instrument having dual drill guides **20**, **21'** is shown in FIG. **6**. It comprises a drill guide **20**, **21'** at either side (top and bottom) of the arms **22**, **23** of the instrument. Thus fixation holes **30**, **30'** may be drilled at once in both adjacent vertebral bodies **1**, **2**. Both cover plates **3**, **4** of the prosthesis can thus be secured with fixation devices, e.g. pins **34**, **34'** as shown in FIG. **7**. Hence, a further improvement in fixation of the prosthesis can be achieved.

[0023] The securing plate or the fixation devices can be made of metal or of a sufficiently resistant plastic. If the cover plate interacting with it is made of metal, a plastic is

preferably chosen, or a plastic insert which forms the dorsally oriented surface of the limit stop part **14**.

[**0024**] If the securing function of the securing plate or the fixation devices is needed only temporarily, for example until the cover plates of the prosthesis have fused sufficiently with the adjoining bone tissue, the securing plate and the fixation device, for example the screw, can be made of biodegradable material. Such material is known and, therefore, does not have to be explained here. It is attacked and somehow broken down by the body. The time it takes for this to happen can be influenced by the choice of material. It is chosen such that the securing plate and the fixation device can exert a sufficient securing force for as long as is necessary, for example for a period of four months after the operation.

What is claimed is:

1. An instrument for positioning a fastening device at a vertebral body in order to secure an intervertebral prosthesis that is separate from the fastening device and comprises two cover plates configured to be connected to adjacent vertebral bodies and a prosthesis core which forms an articular joint with one of the cover plates,

the instrument comprising a drill gauge for the fastening device which is configured to be connected to the prosthesis or a prosthesis model in a predetermined relative position, wherein the drill gauge is configured for connection so as to be slanted to point at an oblique angle towards the cover plates.

2. The instrument of claim 1, wherein the drill gauge has a passageway formed therein.

3. The instrument of claim 2, wherein the passageway has a length greater than its width.

4. The instrument of claim 2, wherein the passageway is curved.

5. The instrument according to claim 1, 2**3** or **4**, further comprising a second drill gauges, the drill gauge and the second drill gauge being oriented towards each other.

6. A cervical intervertebral prosthesis system, comprising

two cover plates having a first dimension in an anterior-posterior direction and being configured to be connected to adjacent vertebral bodies,

a prosthesis core which forms an articular joint with one of the cover plates, a fastening device and

an instrument separate from the fastening device for positioning the fastening device at one of the adjacent vertebral bodies in order to secure the intervertebral prosthesis,

the instrument comprising a drill gauge and arms with projections for holding the cervical intervertebral prosthesis at a predetermined position relative to the drill gauge, the drill gauge having a direction of orientation pointing towards the cover plates at an oblique angle.

7. The system of claim 6, wherein the direction of orientation of the drill gauge is selected so such that the direction intersects with an exterior surface of at least one of the cover plates at a predetermined distance from the drill gauge.

8. The system of claim 7, wherein the predetermined distance is between one third and two thirds of the first dimension.

9. The system of claim 7, wherein the at least one of the cover plates has a recess on its exterior surface at the predetermined distance.

10. The system of claim 6, wherein the drill gauge has a passageway formed therein.

11. The system of claim 10, wherein the passageway has a length greater than its width.

12. The system of claim 10, wherein the passageway is curved.

13. The system of claim 6, wherein the drill gauge comprises at least two parallel passageways formed therein.

14. The system of claim 6, 7, **8**, **9**, **10**, **11**, **12** or **13**, further comprising a second drill gauges, the drill gauge and the second drill gauge being oriented towards each other.

15. The system of claim 6, wherein the fixation device is a screw.

16. The system of claim 6, wherein the fixation device is a wire.

17. The system of claim 6, wherein the fixation device is a Steffee nail.

18. The system of claim 15, 16 or **17**, wherein the fixation device is curved.

* * * * *