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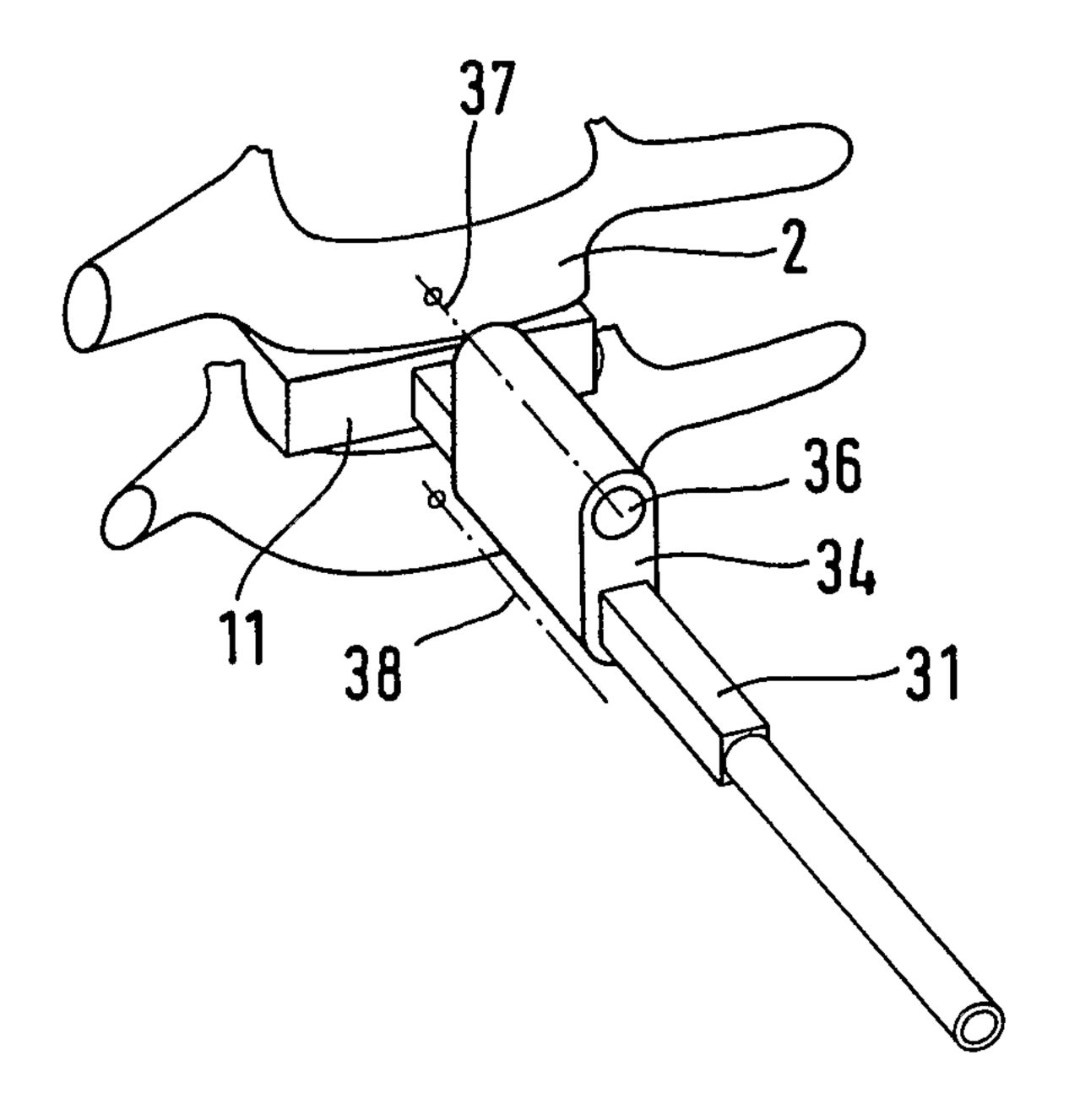
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(54) Titre: INSTRUMENT D'INSERTION D'UNE PROTHESE ARTICULAIRE INTERVERTEBRALE

(54) Title: INSTRUMENT FOR THE INSERTION OF AN INTERVERTEBRAL ARTICULAR PROSTHESIS



#### (57) Abrégé/Abstract:

The invention relates to an instrument for the insertion of an intervertebral articular prosthesis in an intervertebral space between two vertebral bodies. Said inventive instrument comprises; a) an adjusting device which is provided with an intervertebral plate (11) and an adjusting bar (31) which protrudes therefrom, b) a guiding device (34) which is supported, in a detachable manner, by the adjusting device (31), said guiding device forming two guiding axes (37, 38) for a treatment instrument in the vertebral bodies, said guiding axes being arranged above and below the adjusting bar (31) on the median plane, c) two fixing means which can be introduced into the vertebral bodies (2) in the direction of the guiding axes (37, 38) by means of the treatment instrument and d) a distraction instrument which maintains the fixing means in a fixed direction.





#### Abstract

An instrument set for inserting an intervertebral prosthesis into an intervertebral space between two vertebral bodies, comprising:

- an adjustment device consisting of an intervertebral plate (11) and of an adjustment rod (32) projecting from the latter,
- a guide device (34) which is supported in a detachable manner by the adjustment rod (32) and which forms two guide axes (37, 38) for a working instrument, said guide axes (37, 38) lying in the median plane below and above the adjustment rod (32),
- c) two holding means which can be introduced in the direction of the guide axes (37, 38) into the vertebral bodies (2) by means of the working instrument, and
- d) a distraction instrument which maintains the holding means in a fixed direction.

  (Fig. 2)

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# Instrument set for inserting an intervertebral joint prosthesis

When inserting an intervertebral joint prosthesis as a replacement for an intervertebral disk, the operating surgeon is working in an operating site which is very difficult to 10 see and which is in immediate proximity to important nerve paths and blood vessels. This applies in particular to the area of the cervical spine, because here the dimensions of the vertebrae are very small and there is particularly lit-15 tle distance to sensitive adjoining areas. Therefore, in the case of instruments which pose a particular risk of damage or which have to be inserted with particular precision, it is sought to limit their freedom of movement to the necessary range by means of suitable instruments. In doing so, however, visual monitoring must as far as possi-20 ble remain unaffected.

Instruments for inserting intervertebral prostheses into the lumbar spine are known (DE-U-299 16 078, EP-A-0 333 990, FR-A-2737656) in which the cover plates of a prosthesis are first driven into the intervertebral space and spread open, and then the prosthesis core is pushed in between them. In this case, working of the vertebral surfaces can generally be dispensed with. The insertion instruments are relatively large, but this can be tolerated in the area of the lumbar spine. The intervertebral spaces in the area of the cervical spine are so narrow that space for receiving the prostheses must be created by working the adjacent vertebral bodies. In doing so, the access space is so nar-

row and, because of the proximity of vital organs, so sensitive that large instruments cannot be used.

The object of the invention is to make available an instrument set for preparing and/or distracting the cervical spine for insertion of an intervertebral joint prosthesis, said instrument set permitting a high degree of precision and the best possible visual monitoring.

- The solution according to the invention, as set forth in claim 1, proposes an instrument set comprising the following component parts:
  - an adjustment device consisting of an intervertebral plate and of an adjustment rod projecting from the latter,
  - b) a guide device which is supported in a detachable manner by the adjustment rod and which forms two guide axes for a working instrument, said guide axes lying in the median plane below and above the adjustment rod,
  - c) two holding means which can be introduced in the direction of the guide axes into the vertebral bodies by means of the working instrument, and
  - d) a distraction instrument which maintains the holding means in a fixed direction.

When using the instrument set, the intervertebral plate is

first inserted after the intervertebral disk and, if appropriate, the ventral protrusions of the upper vertebral body have been removed. After it has been positioned, it provides an exact indication of the position of the vertebral

body surfaces between which the prosthesis is to be placed. It also ensures that the vertebral bodies are at the predetermined spacing from one another. It is expediently chosen such that it has approximately the same shape and size as the natural intervertebral space or such that its extent is only slightly smaller than that of the intervertebral space. This makes it easier to position since, because of its shape, it automatically adopts a position centered with respect to the intervertebral space and in the same orientation. It can also be provided with X-ray control markers 10 for more accurate positioning. It is held in the intended position by the tensioning generated by the natural ligaments between the vertebral bodies. This tensioning depends on the thickness of the intervertebral plate. A sufficient tensioning is in any case present if this thickness is about as great as the thickness of the intended prosthesis. To ensure that its position can still be corrected later, its surface is essentially smooth, i.e. without elevations which, by sinking into the bone surface or cartilage sur-20 face, make relative movement parallel to the surface direction difficult.

The guide device is supported by an adjustment rod which protrudes from the intervertebral plate. Since the position of the adjustment rod is predetermined by the intervertebral plate, a measure is also obtained for the position of the guide device. The latter can therefore be positioned exactly with the aid of the adjustment instrument, i.e. with the same precision as the adjustment instrument itself. The mutual position of the vertebral bodies is then secured by the intervertebral plate, just as the position of the working tools is secured by the guide device. The working of the vertebral bodies with the aid of the guide

device then takes place as long as the latter is still connected to the adjustment instrument and held by the latter in the exact position.

The guide device can preferably be pushed with a hub onto the adjustment rod from the free end thereof. This allows the operating surgeon to fit together the interacting adjustment surfaces of the rod and of the guide device in a front and clearly visible area of the operating site, instead of doing so at a location deep between the vertebrae and difficult to see. The guide device is then guided along the adjustment rod into the depth of the operating site.

The adjustment rod and the guide device expediently have

interacting surfaces shaped so as to complement one another
and give a non-rotational fit, so that the guide device
cannot turn relative to the adjustment rod. The guide device expediently has a guide for two guide axes arranged in
the median plane parallel to the adjustment rod above and
below the latter. For example, a drill gauge can be arranged below and above the hub of the guide device enclosing the adjustment rod.

Of further advantage is an embodiment in which the hub enclosing the adjustment rod has only one guide, and the interacting surfaces of the hub and of the adjustment rod can
be fitted together in two positions offset 180° in relation
to one another. In this way, the instrument is made smaller
and the view of the operating site is correspondingly improved. In a first of these two positions, the guide device
is used to work a first of the two vertebral bodies and, if
appropriate, to anchor a holding means (preferably a pin)
therein. The guide device is then pulled back along the ad-

justment rod to as far as its round cross-sectional part, turned through 180°, and pushed forward again to permit the same working of the other vertebral body.

A distraction tool can then be applied to the holding means and maintains these in a fixed direction during distraction, i.e. the holding means are connected to the distraction tool in such a way that the holding means and with them the vertebral bodies maintain their mutual orientation. The guide axes of the guides and the accordingly applied holding means or pins are preferably parallel to one another. The seats provided for receiving the holding means or pins on the distraction instrument are then accordingly also arranged parallel to one another.

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In many cases, the natural kyphosis (curvature of the cervical spine with the axis of curvature lying dorsally) is reduced. In these cases, it is expedient not only to distract the vertebral bodies before inserting the intervertebral prosthesis, but also to restore the natural kyphosis. According to the invention, this is achieved by the fact that the intervertebral plate is wedge-shaped, i.e. its thickness decreases from its ventral margin toward its dorsal margin. The instrument set can include intervertebral plates with different wedge angles.

The invention permits a method for inserting an intervertebral prosthesis into the intervertebral space between two vertebral bodies, in which method, in a first step, the intervertebral disk is removed; in a second step, the intervertebral plate of an adjustment instrument is positioned in the intervertebral space and clamped therein; in a third step, the hub of a guide device is pushed onto an adjustment rod projecting from the intervertebral plate in such a way that it defines two guide axes in the median plane above and below the adjustment rod; in a fourth step, the pins are introduced in the direction of the guide axes into the vertebrae; in a fifth step, a distraction forceps is connected to the pins in such a way that they are maintained parallel to one another; and in further steps, the mutual spacing of the vertebral bodies is adjusted, the guide device and the adjustment instrument are removed, the intervertebral space is worked, if desired, and the intervertebral prosthesis is inserted.

The precision with which the instrument set according to the invention can be used depends on the precise positioning of the intervertebral plate in the intervertebral space. It is therefore important that the intervertebral space has a shape matching the intervertebral plate. This is generally also the shape matching the prosthesis that is subsequently to be inserted. To ensure that this condition 20 is met, the instrument set according to the invention is supplemented by a collection of rasps, the largest of these having substantially the shape of the intervertebral plate or prosthesis, while at least one further rasp, which is used for preparatory work, is slightly smaller. If several 25 smaller rasps are provided, their sizes are graded relative to one another.

The invention is explained in more detail below with reference to the drawing, in which:

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Fig 1 shows the adjustment instrument fitted in an intervertebral space,

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shows a corresponding view with a guide de-Fig. 2 vice pushed onto the adjustment rod, show a cross-sectional view and front view, Figs 3 and 4 5 respectively, of the guide device, Fig. 5 shows a partial side view of the adjustment instrument, Fig. 6 shows a drill to be used with the guide device, Fig. 7 shows a screwdriver and screw pin to be used with the guide device, 15 shows a view, corresponding to Fig. 1, with Fig. 8 screw pins inserted into the vertebrae, and Fig. 9 shows a view, corresponding to Fig. 8, with a spreader instrument applied, and 20 Figs 10 - 18 illustrate rasp tools intended for a specific prosthesis, namely: Figs 10 - 15 a set of three different rasps, Fig. 16 the contour of the rasps for comparison, and Figs 17 and 18 the prosthesis for which the rasps are in-

The instrument set shown in Figs 1-9 comprises an adjustment instrument 30 with an intervertebral plate 11. This

tended.

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has a surface area only slightly smaller than the surface area of the intervertebral space, so that it is automatically positioned therein between the raised lateral protrusions. It has approximately the size of the prosthesis that is later to be inserted. Its dimensions in the AP direction and LM direction (LM = lateral-medial, i.e. perpendicular to the median plane) are not significantly smaller than those of the intervertebral space. Its dimension in the LM direction should be at least 70% of the clear distance between the lateral protrusions of the lower vertebral body, preferably at least 80%. Therefore, when it is driven into place, the intervertebral plate assumes a roughly central position. An X-ray apparatus having at least an AP beam path can be used to check the central position of the intervertebral plate and its orientation with respect to the median plane, the position and direction of the outer surfaces of the adjustment rod 32 being critical here. They form the X-ray marker of the instrument for this check. For this purpose, the adjustment rod is made radiopaque, for 20 example of metal. A lateral beam path can also be used to check whether the intervertebral plate has the correct depth setting in the AP direction. In this case, the X-ray marker is formed by those edges of the intervertebral plate which extend in the LM direction, or by a special marker.

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The thickness of the intervertebral plate 11 corresponds approximately to that of the intervertebral prosthesis that is to be inserted. If prostheses of different sizes are available for selection, different intervertebral plates are also accordingly provided in the instrument set. It is at any rate large enough to ensure that it can be pushed into the intervertebral space after removal of the intervertebral disk and is held securely therein by the natu-

ral ligament tension. It can be wedge-shaped in side view, as is shown in Fig. 5. When it has reached its intended position, it has an exactly defined position with respect to the vertebral body surfaces that enclose it.

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This guarantees that the adjustment rod 32 projecting forwardly from the intervertebral plate 11 also has an exactly defined position in relation to the vertebral bodies. It has a square cross section, at least in its area 31 near the intervertebral plate 11, while the portion 33 farther away from this is shown with a round cross section. The adjustment rod 32 is designed as a tube so as to be able to serve as an X-ray marker for an X-ray beam path extending in the AP direction. The tube shape is not necessary, however, because the outer contour of the adjustment rod can also serve as X-ray marker.

The adjustment rod 32 is used for adjusting (positioning) the guide device 34. In Figures 3 and 4, it will be seen that the latter has a bore 35 with a square cross section 20 which matches the portion 31 of the adjustment rod 32. This part of the guide device forms a hub by which it is held on the adjustment rod. It also comprises a bore 36 of round cross section parallel to the bore 35. This bore 36 serves as a drill gauge or more generally for guiding work tools. When the guide device 34 is pushed onto the portion 31 of the adjustment rod, it can assume the position shown in Fig. 2, in which the guide axis 37 defined by the bore 36 is aimed at the center of the upper vertebral body 2. It can also assume a position turned 180° from this, in which 30 the guide axis 38 defined by the bore 36 is aimed at the center of the lower vertebral body. The axes 37 and 38 lie in the same median plane as the adjustment rod 32. Instead

of the square cross section in the portion 31, it is also possible to choose another noncircular shape which permits the possibility of interaction in two positions of the quide device 34 offset 180° in relation to one another.

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The guide device 34 is used first for working one vertebra, and, after it has been pulled back onto the portion 33 of round cross section of the adjustment rod 32, it is then turned through  $180^{\circ}$  in order to work the other vertebra.

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The work involves first making a hole in a vertebra by means of a drill 39 whose shaft is designed to match the bore 36, into which hole a screw pin 41 is then introduced by means of the screwdriver 40 whose shaft likewise matches the bore 36. The pin 41 fits exactly into a bore provided in the screwdriver 40, and this ensures that it is screwed into the respective vertebra flush with the screwdriver 40 and thus also flush with the axes 37, 38 and parallel to the adjustment rod 32. After this has been done on both vertebrae, the picture shown in Fig. 8 is reached. By virtue of the guide device and its adjustment by the adjustment instrument, the screw pins 41 protrude ventrally from both vertebrae 2 exactly in the median plane and parallel to one another.

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A distraction instrument can now be applied to the pins 41, said instrument having two arms 42, each of them with a receiving part 43 for the pins 41, and the arms 42 can be positioned on an instrument body 44 and distracted parallel to one another in arrow direction 45. Distraction instruments of this kind are known and therefore do not need to be described here.

With the aid of this instrument, the vertebrae 2 can, if necessary, be distracted slightly further so that the intervertebral plate 11 can be removed. If so desired, the intervertebral space can be worked in the state in which the vertebrae are held by the instrument 42 to 44 and the pins 41, in order to prepare to receive the intervertebral prosthesis. Finally, the prosthesis is inserted into the intervertebral space and obtains its final position by the distraction of the vertebrae 2 with the instrument 42 to 44 being reversed.

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The instrument set also comprises a collection of rasps which prepare the surface shape of the vertebrae for receiving the prosthesis. They are shown in Figs 10 to 16. The examples shown are suited for the illustrative embodiment of the prosthesis shown in Figs 17 and 18. It has an oval to rectangular contour designed to extensively utilize the area of the intervertebral space. It is so flat that it can be fitted without deep reaming of the cover plates of 20 the vertebral bodies. It has outer surfaces which face the cover plates of the vertebral bodies and which are approximately level and serrated across their greater part 50. Their dorsolateral corners 51 are beveled so that the surface in these areas is set back from the plane of the sur-25 face portion 50.

A complementary shape of the intervertebral space is prepared using a collection of rasps 52, 53 and 54 which are shown in Figures 10 to 15. Fig. 16 shows the graded sizes 30 of the rasps. The smallest rasp 52 is first pushed into the intervertebral space, using a grip (not shown in detail), in order to open up the access. This is followed by rasp 53 which has a trapezoid shape, roughly corresponding to the trapezoid shape of the level surface portion of the prosthesis surface. Finally, rasp 54 shapes the intervertebral
space substantially to the shape of the prosthesis that is
to be fitted. The height of all the rasps is the same as
that of the prosthesis. All the rasps are designed without
teeth in those surfaces corresponding to the level part 50
of the prosthesis. This means that they effect an abrasion
of the cartilage and a trimming of the bone mainly with
their front edge 55, without removing any appreciable material from the end face of the vertebral bodies. All the
rasps are provided with an abutment piece 56 which ensures
that they can penetrate into the intervertebral space only
to the intended depth.

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### Patent Claims

- 1. An instrument set for inserting an intervertebral prosthesis into an intervertebral space (1) between two vertebral bodies (2), comprising:
  - an adjustment device (30) consisting of an intervertebral plate (11) and of an adjust-ment rod (32) projecting from the latter,
  - b) a guide device (34) which is supported in a detachable manner by the adjustment rod (32) and which forms two guide axes (37, 38) for a working instrument (39, 40), said guide axes (37, 38) lying in the median plane below and above the adjustment rod (32),
  - two holding means (41) which can be introduced in the direction of the guide axes (37, 38) into the vertebral bodies (2) by means of the working instrument (39, 40), and
  - d) a distraction instrument (42, 43, 44) which maintains the holding means (41) in a fixed direction.
- 2. The instrument set as claimed in claim 1, characterized in that a hub of the guide device (34) can be pushed onto the adjustment rod (32) from the free end thereof, and the adjustment rod (32) and the hub have interacting surfaces (31, 35) shaped so as to complement one another and give a non-rotational fit.

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15 3. The instrument set as claimed in claim 2, character-ized in that the guide device (34) has one guide above

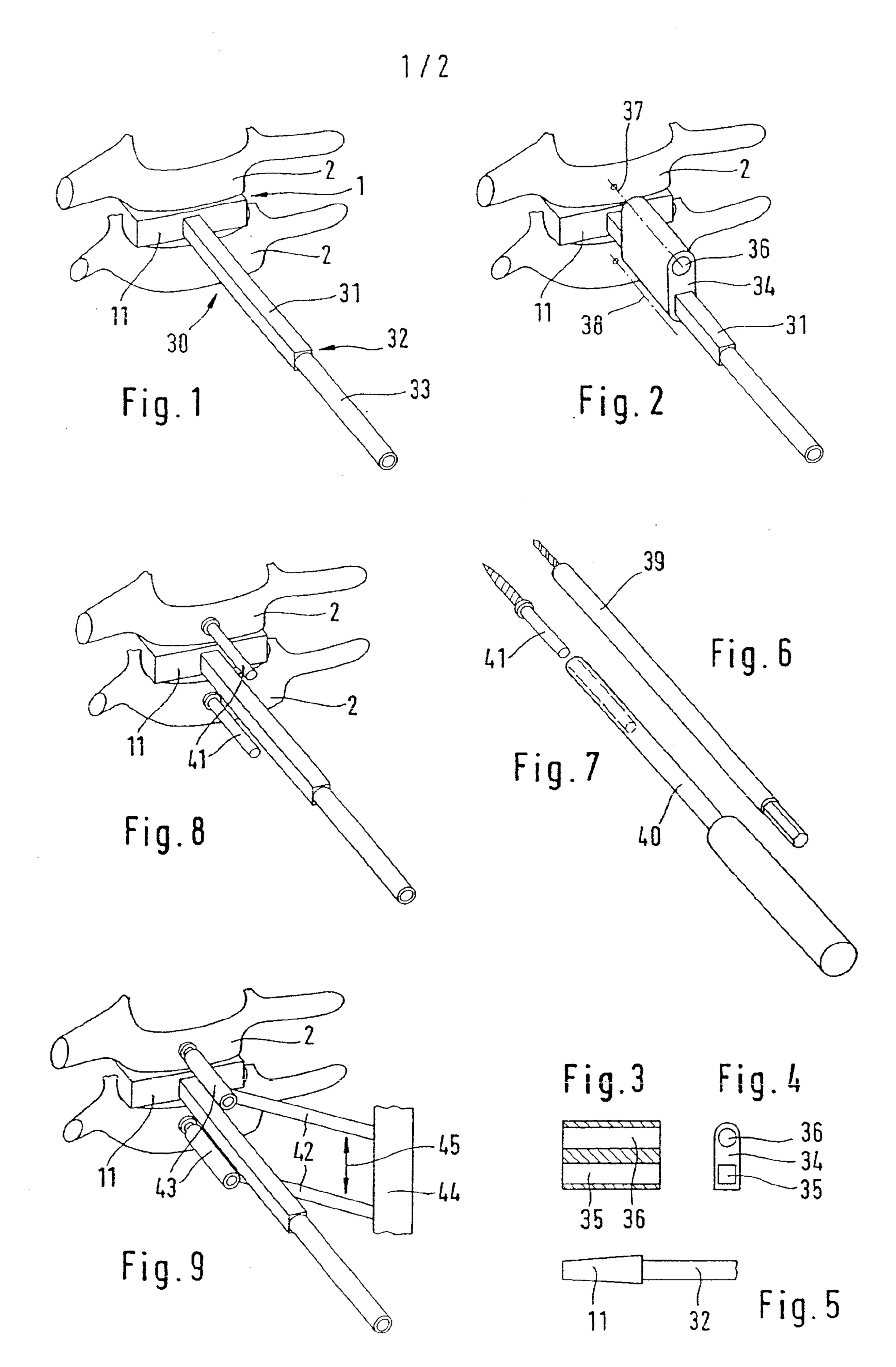
the adjustment rod and one guide below the adjustment rod.

4. The instrument set as claimed in claim 2, characterized in that the guide device (34) has only one guide
(36), and the complementary interacting surfaces (31,
35) of the adjustment rod (32) and of the hub can be
fitted together in positions offset 180° in relation
to one another.

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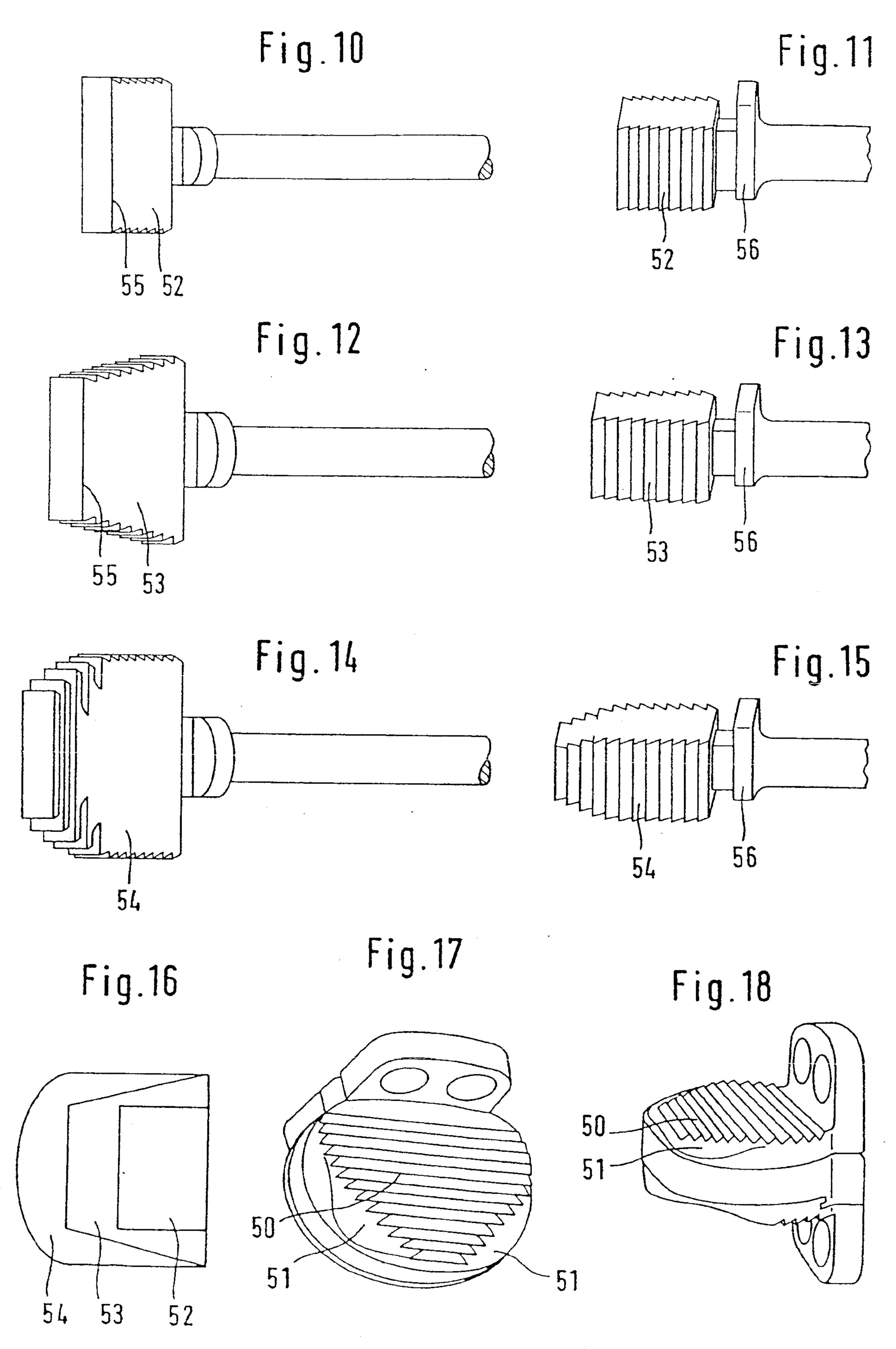
- 5. The instrument set as claimed in claim 2, characterized in that the guide axes (37, 38) run parallel to the adjustment rod (32).
- 15 6. The instrument set as claimed in claim 5, character-ized in that the holding means are pins (41).
- 7. The instrument set as claimed in claim 1, characterized in that the surface area of the intervertebral plate (11) is slightly smaller than the surface area of the intervertebral space.
- 8. The instrument set as claimed in claim 1, characterized in that the surface of the intervertebral plate
  (11) is designed such that it is displaceable in the transverse direction and positionable in the intervertebral space (1) under X-ray control.
- 9. The instrument set as claimed in claim 1, characterized in that the intervertebral plate (11) is wedgeshaped.

10. An instrument set for inserting an intervertebral prosthesis into the intervertebral space between two vertebral bodies, characterized in that it comprises material-removing tools (52, 53, 54) for shaping the intervertebral space so that it matches the shape of the prosthesis, one set of material-removing tools being assigned in each case to a prosthesis shape, the largest of these tools being substantially the same as the prosthesis shape, and the other tools being smaller in stages.



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