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<p>(21) International application number: PCT/FR99/01019 (22) International filing date: 29 April 1999 (29.04.99) (30) Data relating to the priority: 98/05,387 29 April 1998 (29.04.98) FR 98/12,662 9 October 1998 (09.10.98) FR (71) Applicant (for all designated States except US): DIMSO (DISTRIBUTION MEDICALE DU SUD-OUEST) [FR/FR]; Zone Industrielle de Marticot, F-33610 Cestas (FR). (72) Inventors; and (75) Inventors/Applicants (US only): ASSAKER, Richard BE/BE; 62, rue du Vert Lion, B-7540 Kain (BE). CONCHY, Frédéric [FR/FR]; 4, chemin des Bouvreuils, F-33650 Saint-Médard-d'Eyrans (FR). LE COUËDIC, Régis [FR/FR]; 7, chemin Lou Sanlié, F-33610 Cestas (FR). (74) Representatives: MARTIN, Jean-Jacques etc.; Cabinet Regimbeau, 26, avenue Kléber, F-75116 Paris (FR).</p>		<p>(81) Designated states: AU, CA, JP KR, MX, US, ZA, European Patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).  Published With the International Search Report.</p>

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(54) Title: BACKBONE OSTEOSYNTHESIS SYSTEM FOR ANTERIOR FIXING

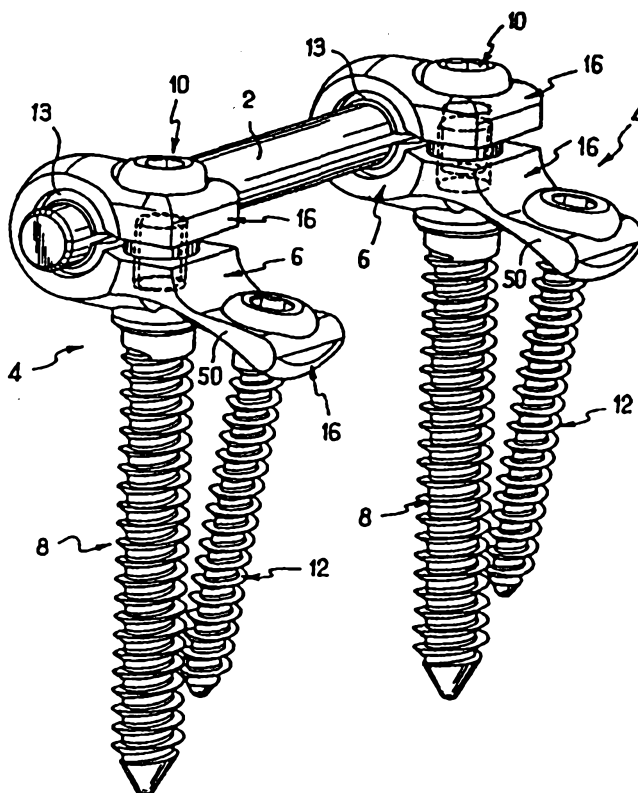
(54) Titre: SYSTEME D'OSTEOSYNTHESE RACHIDIENNE POUR UNE FIXATION ANTERIEURE

(57) Abstract

The invention concerns a backbone osteosynthesis system comprising an elongated element (2), a vertebral screw (8), and a connecting element (6) comprising two branches (16) for clamping between them the linking element (2), at least one first branch (16) being capable of being engaged onto the screw (8). The system comprises a second vertebral screw (12), the first branch (16) having an extension (50) capable of being engaged onto the second screw (12). The system may comprise a second elongated linking element (3).

(57) Abrégé

Le système d'ostéosynthèse rachidienne comprend un élément de liaison allongé (2), une vis vertébrale (8), et un connecteur (6) comportant deux branches (16) aptes à serrer entre elles l'élément de liaison (2), au moins une première des branches (16) étant apte à être engagée sur la vis (8). Le système comprend une deuxième vis vertébrale (12), la première branche (16) présentant un prolongement (50) apte à être engagé sur la deuxième vis (12). Le système peut comprendre un deuxième élément de liaison allongé (3).



SPINAL OSTEOSYNTHESIS SYSTEM FOR ANTERIOR FIXATION

The invention concerns spinal osteosynthesis systems, in particular for anterior fixation.

Spinal osteosynthesis systems for anterior fixation are known in which the connection elements are formed by plates, and others are known in which the connection elements are formed by rods. Because of their bulk, the systems based on plates are difficult to use, if they can be used at all, via the endoscopic route. Moreover, their limited size (length) means that they can only be used for simple vertebrectomies involving a single vertebra, or perhaps two. It is impossible to treat scoliosis with this type of implant. Finally, the plates are difficult to adapt to the morphology of the vertebra in which they are anchored. Moreover, the systems based on rods generally comprise fairly voluminous connectors which cannot always be used via the endoscopic route.

A spinal osteosynthesis device is also known from document FR-2,731,344, the counterpart of WO-96/27340, which device comprises a connector with two branches which can clamp a connection rod between them, the branches being able to be engaged on a vertebral pedicle screw. However, this connector, while well suited for posterior fixation of the spine on the vertebral pedicles, does not ensure sufficient stability with a view to anterior fixation of the spine.

An object of the invention is to make available a spinal osteosynthesis system of a different type, adapted for anterior fixation, easy to fit, ensuring good stability of the system on the spine, and compatible with being fitted via the endoscopic route.

To achieve this object, the invention provides a spinal osteosynthesis system comprising an elongate connection element, a vertebral screw, and a connector including two branches which are able to clamp the

connection element between them, at least a first of  
the branches being able to be engaged on the screw, the  
system comprising a second vertebral screw, the first  
branch having an extension which can be engaged on the  
5 second screw.

Thus, the connector can be rendered less  
voluminous so that it can be put into place via the  
normal or endoscopic route. Moreover, the fixation of  
the connector to the vertebra by means of the two  
10 screws permits precise, stable and reliable positioning  
of the connector and thus of the connection element.  
This connector is easy to join to the connection  
element and to the screws. These advantages make this  
connector particularly well suited to anterior fixation  
15 of the spine. The connector will preferably be in one  
piece.

Advantageously, the extension has an opening  
for receiving the second screw.

Advantageously, the extension has a spherical  
20 recess at one edge of the opening intended to be remote  
from the vertebra.

Thus, it is possible to control the angle of  
the second screw relative to the connector in order to  
better adapt the system to the configuration of the  
25 vertebra.

Advantageously, one of the branches which is  
intended to be remote from the vertebra has an opening  
for receiving the first screw, and a spherical recess  
at one edge of the opening intended to be remote from  
30 the vertebra.

Thus, it is possible to control the angle of  
the first screw relative to the connector in order to  
better adapt the system to the configuration of the  
vertebra.

35 Advantageously, the extended branch can be bent  
manually, in particular using a tool.

Thus, it is possible to adapt the shape of the  
connector to that of the vertebra and in particular to  
position the connector very close to the latter.

Advantageously, the first screw includes a head and a flange distinct from the head and able to cooperate with one of the branches which is intended to be adjacent to the vertebra, in order to immobilize the connector in terms of rotation relative to the first screw.

Thus, upon fitting, prior immobilization of the connector relative to the first screw is obtained, facilitating the positioning of the other elements and making it possible to effect positional corrections, all this before final clamping of the fitted system.

Advantageously, the flange has a face, which is in particular a conical face, able to immobilize the connector by friction.

Advantageously, the first screw has a threaded orifice, the system comprising a clamping screw which can constitute a screw-nut connection with this orifice and is able to bear on one of the branches which is intended to be remote from the vertebra in order to clamp the branches.

Thus, it is possible first to fit the first screw, the connector and the second screw, and only later to install the clamping screw in order to proceed with clamping of the assembly.

Advantageously, the system comprises a ring which can be engaged on the rod and received between the branches, the connector and the ring being designed to permit control of the orientation of the rod in two mutually perpendicular planes before the branches are clamped.

Advantageously, the two branches form part of a single component which is elastically deformable in order for the branches to be closed towards each other.

Advantageously, the connector can be fixed to the vertebral screw and to the first connection element by choosing an angular position of the connection element relative to the connector.

It has also been noted that the device in document FR-2,731,344 mentioned above does not always

afford sufficient rigidity for anterior fixation of the spine.

Consequently, a subsidiary object of the invention is to provide a system suited for anterior  
5 fixation and ensuring a particularly high degree of rigidity.

To achieve this object, the system advantageously comprises a second elongate connection element, the connector being able to be fixed  
10 simultaneously to the two connection elements.

Thus, the presence of the two connection elements gives the system very great rigidity, without complicating its assembly, without increasing the volume of its various components (which renders it  
15 compatible with fitting via the endoscopic route), and while maintaining the possibility of controlling the angular position of the connector relative to the first connection element. The system according to the invention does not require identical bending on the two  
20 connection elements. Moreover, the number of connectors can remain small.

Advantageously, the system is designed in such a way that the second connection element can be fixed to the connector only in a single angular position  
25 relative to the connector.

Thus, the shape of the second connection element dictates the relative angular position of the connectors which are fixed to it. This angular position can therefore be chosen in advance depending on the  
30 prior curvature given to this connection element, either at the time of manufacture or, better still, during the surgical intervention.

Advantageously, the second connection element has less resistance to bending than the first  
35 connection element.

Thus, the first connection element has mainly a function ensuring support of the connectors, and the second connection element has mainly a function

ensuring relative angular positioning of the connectors.

Advantageously, the branches can simultaneously clamp the two connection elements.

5 Advantageously, the system is designed in such a way that the second connection element, when fixed to the connector, extends in a trajectory of the second vertebral screw for its disengagement from the connector.

10 Thus, the second screw is prevented from starting to come out at an inopportune moment.

Advantageously, the system comprises a second connector, the two connectors each being able to be fixed simultaneously to the two connection elements.

15 Advantageously, the system is intended to be fixed on the anterior part of the spine.

The invention also provides a connector for a spinal osteosynthesis system, including two branches which can clamp an elongate connection element between  
20 them, at least a first of the branches having an opening which can be engaged on a vertebral screw, and in which the first branch has an extension having an opening which can be engaged on a second vertebral screw.

25 This connector is adapted to form part of the system according to the invention.

Other characteristics and advantages of the invention will become more apparent from the following description of two preferred embodiments given as  
30 nonlimiting examples. In the attached drawings:

- Figure 1 is a perspective view of the system according to a first embodiment of the invention;

- Figure 2 is a partial and exploded perspective view of the system in Figure 1;

35 - Figures 3 and 4 are two perspective views, from above and below, respectively, showing one of the connectors of the system in Figure 1;

- Figure 5 is a view, half in elevation and half in axial section, of a ring of the system in Figure 1;

5 - Figure 6 is a view, partly from above and partly in section, of the connector in Figure 3 receiving the rod;

- Figure 7 is a partial perspective view showing the head of the main screw;

10 - Figure 8 shows the system from Figure 1 fixed on vertebrae;

- Figure 9 is a perspective view of the system according to a second embodiment of the invention;

- Figure 10 is a partial and exploded perspective view of the system in Figure 9;

15 - Figures 11 and 12 are two perspective views, from above and below, respectively, showing one of the connectors of the system in Figure 9; and

- Figure 13 shows the system from Figure 9 fixed on vertebrae.

20 Referring to Figures 1 to 8, the system according to the invention comprises, in the first embodiment, an elongate connection rod 2 of circular cross section and several connector sub-assemblies 4 which can be fixed to the latter. Each of these sub-  
25 assemblies, of which two can be seen in Figure 1 and of which one can be seen in Figure 2, comprises a connector 6, a first vertebral screw or main screw 8, a clamping screw 10, a second vertebral screw or secondary screw 12, and a ring 13.

30 Referring to Figures 3 and 4, the connector 6 includes two branches 16 extending opposite to and at a distance from each other, giving the connector a general U-shaped profile. The connector 6 includes a plane of symmetry S perpendicular to the width of the  
35 branches 16 and parallel to their length. Referring to Figure 6, at the point of origin of the branches 16 the connector has two cylindrical and coaxial inner faces 18, 20 with axis 22 perpendicular to the plane S and with different radii, the face 20 of greater radius

being in two distinct parts and extending on either side of the face 18 of lesser radius, which is traversed by the plane S. At their junctions, the two faces 18, 20 form two circular edges 24 with axis 22.

5           The ring 13 has a cylindrical inner face 26 and a spherical outer face 28 which are coaxial. The cylindrical inner face 26 has a radius about equal to that of the rod 2 in such a way that the ring 13, slotted on one side along its axis, can be received as  
10 a sliding fit on the rod. Moreover, the ring 13 can be lodged between the branches 16 opposite the cylindrical faces 18, 20. The spherical outer face 28 of the ring has a radius which is adapted such that in this position the edges 24 of the connector 6 are in linear  
15 contact with the spherical outer face 28 of the ring 13 and serve as bearings for it. In this position, before clamping of the branches 16, the angular position of the rod 2 engaged in the ring 13 can be controlled in two mutually perpendicular planes over an amplitude of,  
20 for example,  $15^\circ$  on either side of a mean position of the rod in which the rod is perpendicular to the plane S.

          The branches 16 have two respective smooth cylindrical openings which, in this case, are through-  
25 orifices 30 extending coaxially opposite each other. The main screw 8 is a bicortical vertebral screw and has a threaded body for this purpose, in a manner known per se. It has a head 32 having a smooth cylindrical outer face 34. At the junction between the head and the  
30 body, the screw includes an annular flange 36 having a plane lower face perpendicular to a longitudinal axis of the screw and a frustoconical upper face 38 with the narrowest cross section of the frustum situated towards the head 32 of the screw. The head 32 has a threaded  
35 orifice 39 coaxial to the body of the screw and, formed in the threaded face of the orifice 39, a noncircular shape such as a hexagon socket. The clamping screw 10 includes a threaded body 42 which is able to form a screw-nut connection with this orifice 39, and a screw



head 44 in which a hexagon socket is formed. The head 44 has a spherical and convex lower outer face 46 whose narrowest cross section is situated towards the point of the screw.

5           One of the branches 16, which for the sake of clarity we will here call the lower branch, has an extension 50 extending in the direction away from the cylindrical faces 18, 20 of the connector. This is the branch intended to be adjacent to the vertebra. The two  
10 branches 16 are able to be engaged simultaneously on the head 32 of the main screw 8 introduced starting from the lower branch against which the upper face 38 of the flange 36 comes into abutment. The clamping screw 10 is then introduced into the head 32 of the  
15 main screw 8 starting from the upper branch 16. The tightening of the screw 10 in the head 32 of the main screw 8 causes the branches 16 to close towards each other and causes frictional blocking of the rod 2 in the chosen position relative to the connector 6.

20           The orifice 30 of the lower branch 16 has a lower edge, remote from the upper branch and intended to be towards the vertebra, having a concave spherical recess 40 intended to come into contact with the upper face 38 of the flange 36 in order to effect, by  
25 friction, rotational blocking of the connector 6 relative to the axis of the main screw 8. The orifice 30 of the upper branch 16 has an upper edge, remote from the lower branch and intended to be remote from the vertebra, having a concave spherical recess 40  
30 intended to come into contact with the convex and spherical lower face 46 of the head 44 of the clamping screw 10 and making it possible to fix the latter and the main screw 8 by controlling the angular orientation of the main screw 8 relative to the connector.

35           The extension 50 has an opening in the form of a through-orifice 52. The lower branch 16 is curved in the area of the extension 50 in a direction away from the upper branch 16 in such a way that the axes of its orifices 30 and 52 are not quite parallel. The

secondary screw 12 is a vertebral screw, here a monocortical screw, having a threaded body and a head 56 with a spherical and convex lower face 58 whose narrowest cross section is situated towards the body. 5 Its head has a hexagon socket. The orifice 52 of the extension has an upper edge, oriented towards the other branch 16 and intended to be remote from the vertebra, having a spherical and concave recess 60 intended to come into contact with the spherical and convex lower 10 face 58 of the head 56 of the secondary screw 12, making it possible to control the angular orientation of this screw relative to the connector 6.

Certain characteristics of the connector 6 which have not been expanded on in detail here will be 15 found in the abovementioned related documents FR-2,731,344 and WO-96/2730.

The lower branch 16 can be bent in order to accentuate or reduce its curvature for better adaptation to the shape of the anterior part of the 20 vertebra for which it is intended. Once bent, this branch 16 is no longer stressed in flexion since it is fixed to the vertebra by two screws 8, 12 along its length. The two screws, namely the main screw 8 and the secondary screw 12, are self-tapping and include bone 25 threads.

In an alternative embodiment, the main screw 8 does not have a hexagon socket in its threaded orifice 39, and instead the flange 36 has a hexagonal shape or has two parallel and diametrically opposite flats which 30 can cooperate with a tightening wrench for rotating this screw 8 relative to the connector 6.

In the present example, the connector 6 is made in one piece. The different parts of the system are made of biocompatible metal.

35 Such a device is fitted in the following manner, with reference to Figure 8. After exposing the affected vertebra 70 and the two adjacent vertebrae 72, a vertebrectomy is performed while preserving, if possible, the respective plates of these vertebrae. For

each subassembly, a pilot hole is made on the lateral side of the associated vertebra 72 at an equal distance from the upper and lower plates, and at the limit of the most posterior quarter of the vertebral body. The  
5 main screw 8 is then inserted into this pilot hole as far as the limit flange 36. The connector 6 is then positioned on the said main screw 8, blocked in translation by the conical face 38 of the said main screw 8 matching the recess 40 of the connector 6. The  
10 fit of the connector 6 on the vertebra is then checked and can be adjusted by withdrawing the said connector in order to bend the lower branch 16 which is its most anterior part.

The secondary screw 12 is then screwed relative  
15 to the main screw 8 into the second orifice 52 of the lower branch 16 until the spherical seat 60 of the extension, provided for this purpose, comes into contact with the spherical part 58 of the said secondary screw 12. It is desirable to position the  
20 connector 6 as parallel as possible to the plates.

After the two adjacent vertebrae 72 have been thus equipped, the rod 2 is positioned in the rings of the connectors 6 and its angular position on each sub-assembly is controlled. Final clamping is effected by  
25 virtue of the clamping screw 10 which is inserted into the main screw 8 and thereby compresses the connector 6 in order to clamp the rod.

In the second embodiment illustrated in Figures 9 to 13, the system is very similar to that of the  
30 first embodiment. However, it is distinguished by the presence of a second elongate connection rod 3 or secondary rod of circular cross section, and by the adaptation of the connector 6 for receiving this second rod. The ring 13 is received on the first rod or main  
35 rod 2.

The two connection rods 2, 3 each have a profiled rectilinear shape, the profile here being circular. The secondary rod 3 has a cross section, transverse to its longitudinal axis, having a diameter

smaller than that of the main rod 2. The main rod 2 will, for example, have a diameter of 6 mm. The diameter of the secondary rod 3 will, for example, be between 30% and 80% of the diameter of the main rod 2.

5 This small diameter allows the surgeon to choose the curvature of the secondary rod 3 corresponding to that of the level of the spine which is being operated on. By contrast, since the rings 13 allow relative angular positioning of the two connectors 6, the main rod 2

10 does not have to be bent. It can thus have a substantial diameter in order to be very robust.

The branches 16 of the connector have respective cylindrical recesses or jaws 74 formed in the faces of the branches opposite each other. The

15 recesses 74 extend opposite each other and have axes parallel to each other and perpendicular to the plane of symmetry S.

On the upper branch 16, the recess 74 extends at a free end of the branch such that the orifice 30 is

20 interposed between the faces 18, 20, on the one hand, and the recess 74 on the other. On the lower branch 16, the recess 74 extends between the two orifices 30 and 52, at the origin of the extension 50. It is contiguous with the orifice 52 so that it engages on its edge 60.

25 The secondary rod 3 is intended to be received in the recess 74 of the lower branch 16 in a unique angular position relative to the connector, perpendicular to the plane of symmetry S. When the two branches 16 are clamped in the direction of each other,

30 the recess 74 of the upper branch comes into contact with the secondary rod 3 which is thus in surface contact with each of the two recesses, which effect frictional blocking of the secondary rod 3 relative to the connector 6, which are thereby rigidly fixed to

35 each other.

The secondary rod 3 is placed in the recess 74 of the lower branch after the secondary screw 12 has been introduced into the orifice 52. The position of the recess 74 of the lower branch is such that the

secondary rod 3 then extends in the trajectory of the head of the secondary screw 12 for its disengagement from the connector and its exit from the orifice 52. Consequently, once the secondary rod 3 has been fixed  
5 to the connector, the secondary screw 12 can no longer be separated from the connector.

The upper branch 16 of the connector has at its free end a notch 76 which engages on the recess 74 with which it is contiguous and facilitates manoeuvring of  
10 the secondary screw 12 by means of a tool despite the space occupied by the upper branch.

The system according to the second embodiment is fitted in a similar way to the system of the first embodiment. The placement of the main screw 8 and of  
15 the secondary screw 12 remains unchanged.

After the two adjacent vertebrae 72 have been equipped, the main rod 2 is positioned in the rings 13 of the connectors 6 and the angular position of each sub-assembly 4 relative to this rod 2 is controlled.  
20 The secondary rod 3 is then introduced into the recesses 74 of the connectors 6 after it has first been bent manually to obtain the curvature required for the corresponding level of the spine. In the event of an error, this rod 3 can be removed in order to correct  
25 its curvature and then put back in place. Figure 9 shows the system before the clamping of the branches. Final clamping is effected by virtue of the clamping screw 10 which is inserted into the main screw 8 and thereby compresses the connector 6 in order to clamp  
30 its two branches 16 towards each other. During this clamping, the clamping force is directed first on the main rod 2 via the ring 13, until the recess 74 of the upper branch comes into contact with the secondary rod 3. Thereafter, the clamping force is distributed on the  
35 two rods 2, 3. Thus, the reaction at the level of the pairing of main screw 8 and clamping screw 10 is substantially coaxial to these.

When the system is in place, the connectors 6, of which there are at least two, are each rigidly and

simultaneously fixed to the same main rod and secondary rod.

The characteristics relating to the association of the first screw 8 with the clamping screw 10 will be able to be implemented independently of the presence of the extension 50 and of the second screw 12.

Although less advantageous, the extended branch can be the one which is intended to be farthest from the vertebra.

10 The characteristics relating to the presence of the two vertebral screws on the connector will be able to be implemented independently of those relating to the presence of the main and secondary rods, and vice versa.

CLAIMS

1. Spinal osteosynthesis system, in particular for  
5 anterior fixation, comprising an elongate connection  
element (2), a vertebral screw (8), and a connector (6)  
including two branches (16) which are able to clamp the  
connection element (2) between them, at least a first  
of the branches (16) being able to be engaged on the  
10 screw (8), characterized in that the system comprises a  
second vertebral screw (12), the first branch (16)  
having an extension (50) which can be engaged on the  
second screw (12).
2. System according to Claim 1, characterized in  
15 that the extension (50) has an opening (52) for  
receiving the second screw (12).
3. System according to Claim 2, characterized in  
that the extension (50) has a spherical recess (60) at  
one edge of the opening (52) intended to be remote from  
20 the vertebra.
4. System according to any one of Claims 1 to 3,  
characterized in that one of the branches (16) which is  
intended to be remote from the vertebra has an opening  
(30) for receiving the first screw (8), and a spherical  
25 recess (40) at one edge of the opening intended to be  
remote from the vertebra.
5. System according to any one of Claims 1 to 4,  
characterized in that the extended branch (16) can be  
bent manually, in particular using a tool.
- 30 6. System according to any one of Claims 1 to 5,  
characterized in that the first screw (8) includes a  
head (32) and a flange (36) distinct from the head and  
able to cooperate with one of the branches (16) which  
is intended to be adjacent to the vertebra, in order to  
35 immobilize the connector (6) in terms of rotation  
relative to the first screw (8).
7. System according to Claim 6, characterized in  
that the flange (36) has a face (38), which is in

particular a conical face, able to immobilize the connector (6) by friction.

8. System according to any one of Claims 1 to 7, characterized in that the first screw (8) has a threaded orifice (39), the system comprising a clamping screw (10) which can constitute a screw-nut connection with this orifice and is able to bear on one of the branches (16) which is intended to be remote from the vertebra in order to clamp the branches (16).

9. System according to any one of Claims 1 to 8, characterized in that it comprises a ring (13) which can be engaged on the rod (2) and received between the branches (16), the connector (6) and the ring (13) being designed to permit control of the orientation of the rod (2) in two mutually perpendicular planes before the branches (16) are clamped.

10. System according to any one of Claims 1 to 9, characterized in that the two branches (16) form part of a single component (6) which is elastically deformable in order for the branches to be closed towards each other.

11. System according to any one of Claims 1 to 10, characterized in that the connector (6) can be fixed to the vertebral screw (8) and to the first connection element (2) by choosing an angular position of the connection element relative to the connector.

12. System according to any one of Claims 1 to 11, characterized in that it comprises a second elongate connection element (3), the connector (6) being able to be fixed simultaneously to the two connection elements (2, 3).

13. System according to Claim 12, characterized in that it is designed in such a way that the second connection element (3) can be fixed to the connector (6) only in a single angular position relative to the connector.

14. System according to Claim 12 or 13, characterized in that the second connection element (3)



has less resistance to bending than the first connection element (2).

15. System according to any one of Claims 12 to 14, characterized in that the branches (16) can  
5 simultaneously clamp the two connection elements (2, 3).

16. System according to any one of Claims 12 to 15, characterized in that it is designed in such a way that  
10 the second connection element (3), when fixed to the connector (6), extends in a trajectory of the second vertebral screw (12) for its disengagement from the connector (6).

17. System according to any one of Claims 12 to 16, characterized in that it comprises a second connector,  
15 the two connectors (6) each being able to be fixed simultaneously to the two connection elements (2, 3).

18. Connector (6) for a spinal osteosynthesis system, including two branches (16) which can clamp an elongate connection element (2) between them, at least  
20 a first of the branches (16) having an opening (30) which can be engaged on a vertebral screw (8), characterized in that the first branch (16) has an extension (50) having an opening (52) which can be engaged on a second vertebral screw (12).

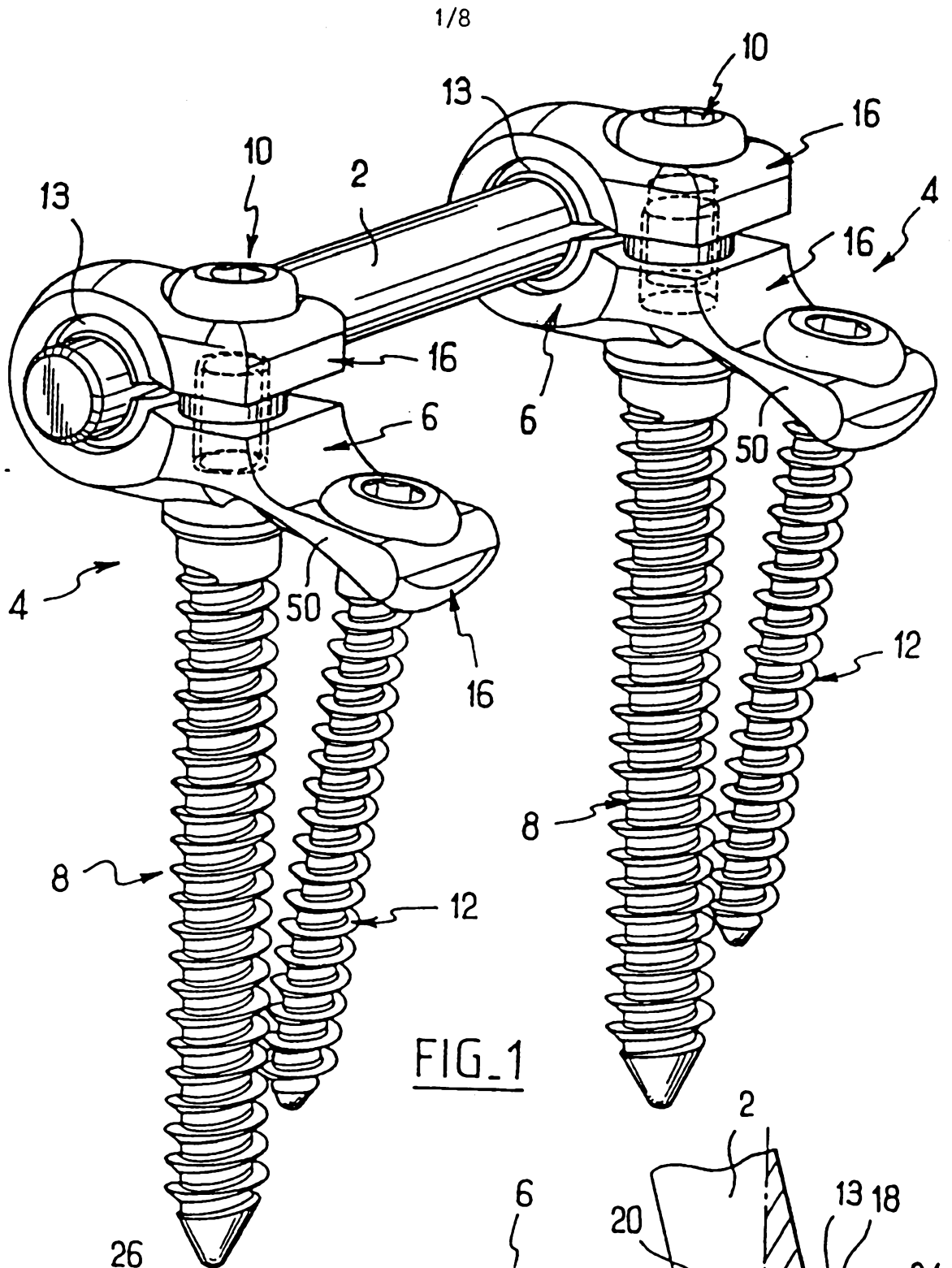


FIG. 1

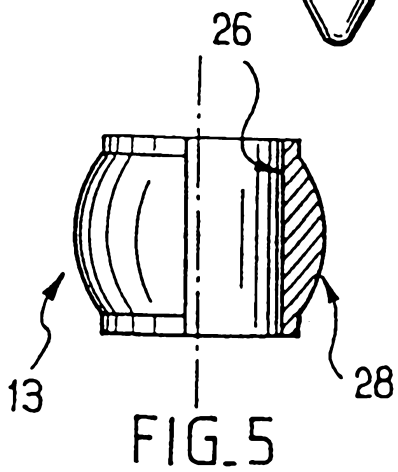


FIG. 5

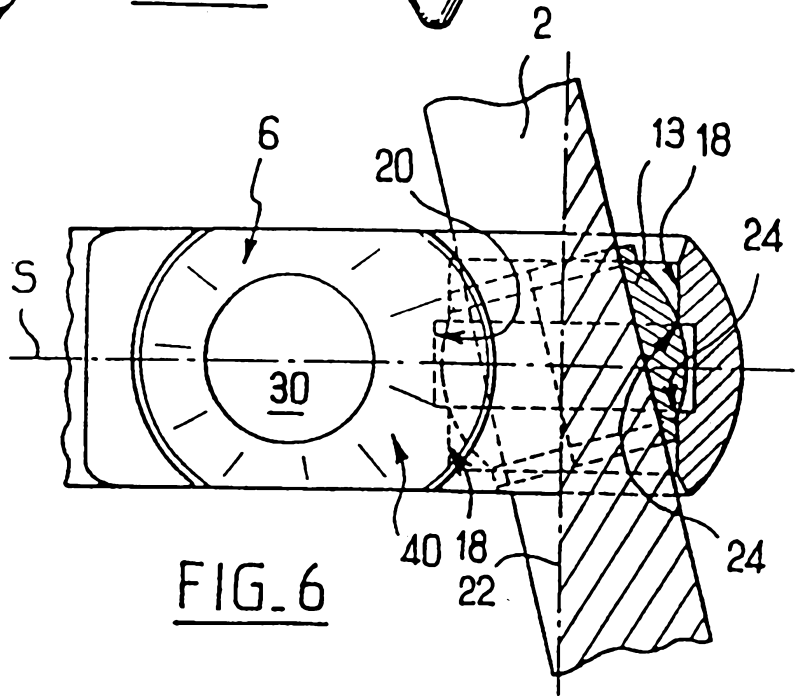
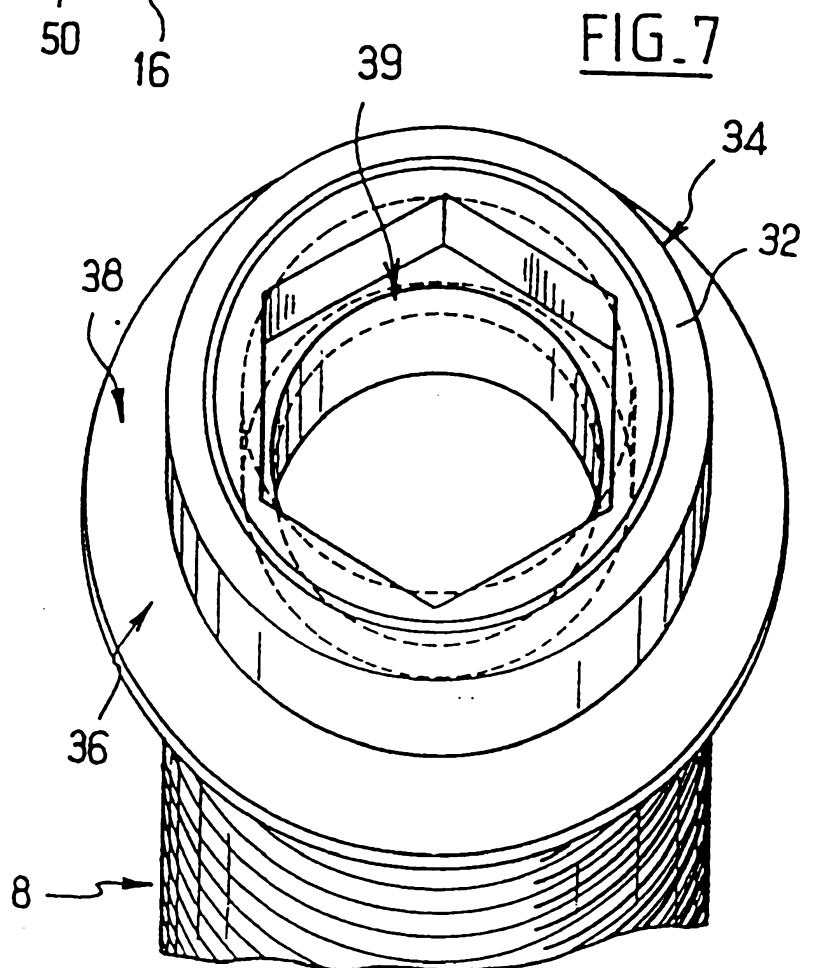
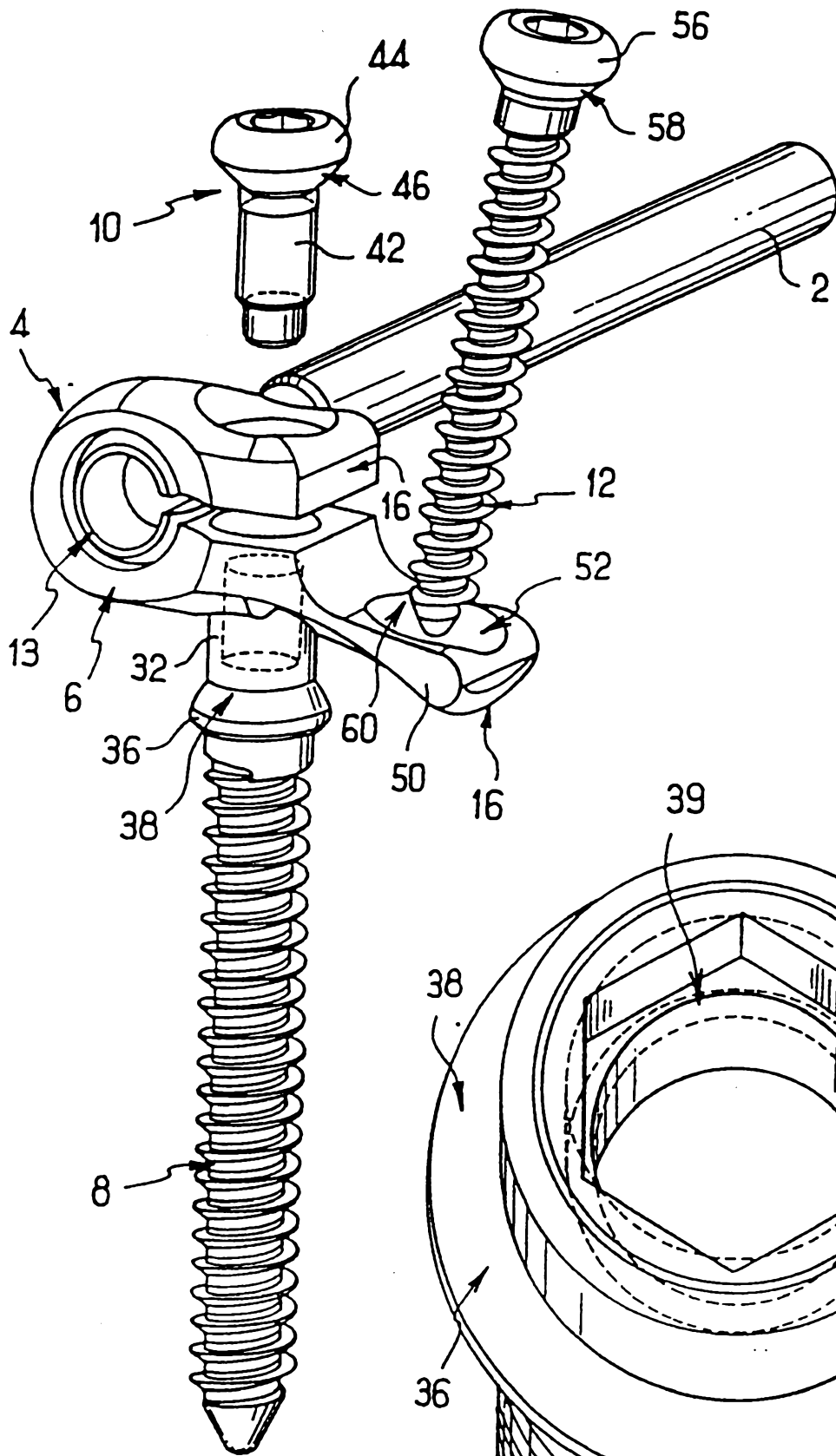


FIG. 6



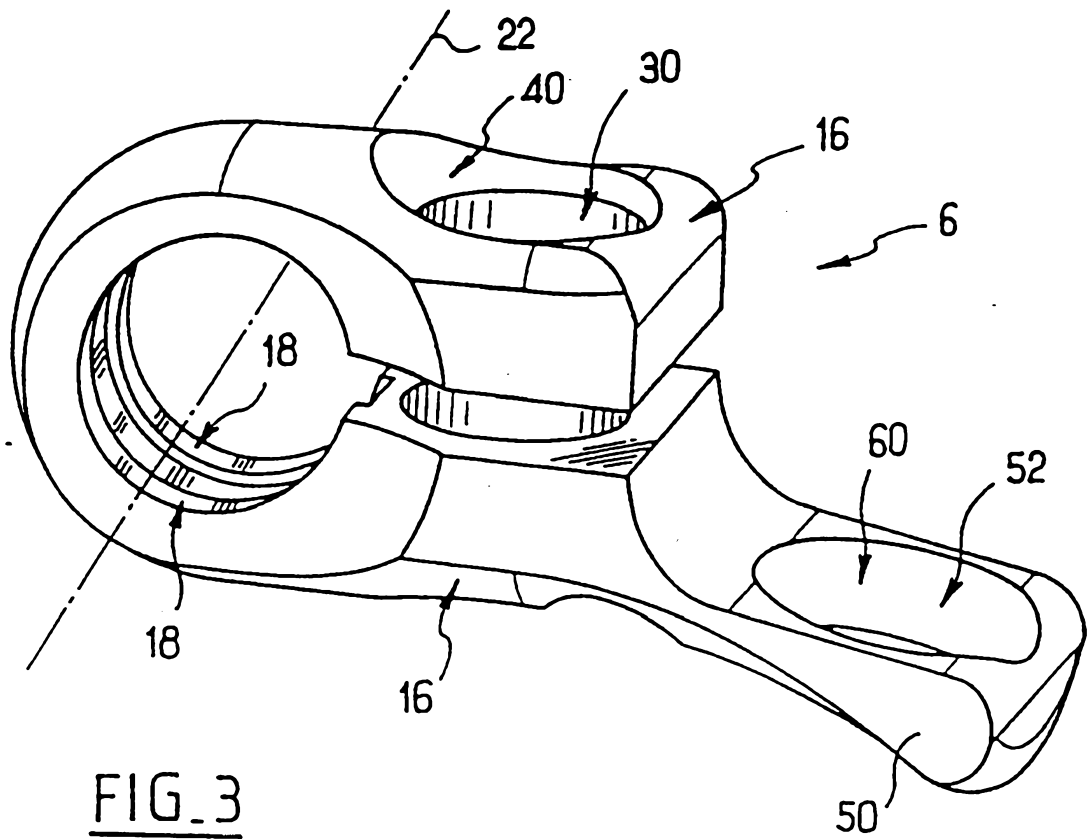


FIG. 3

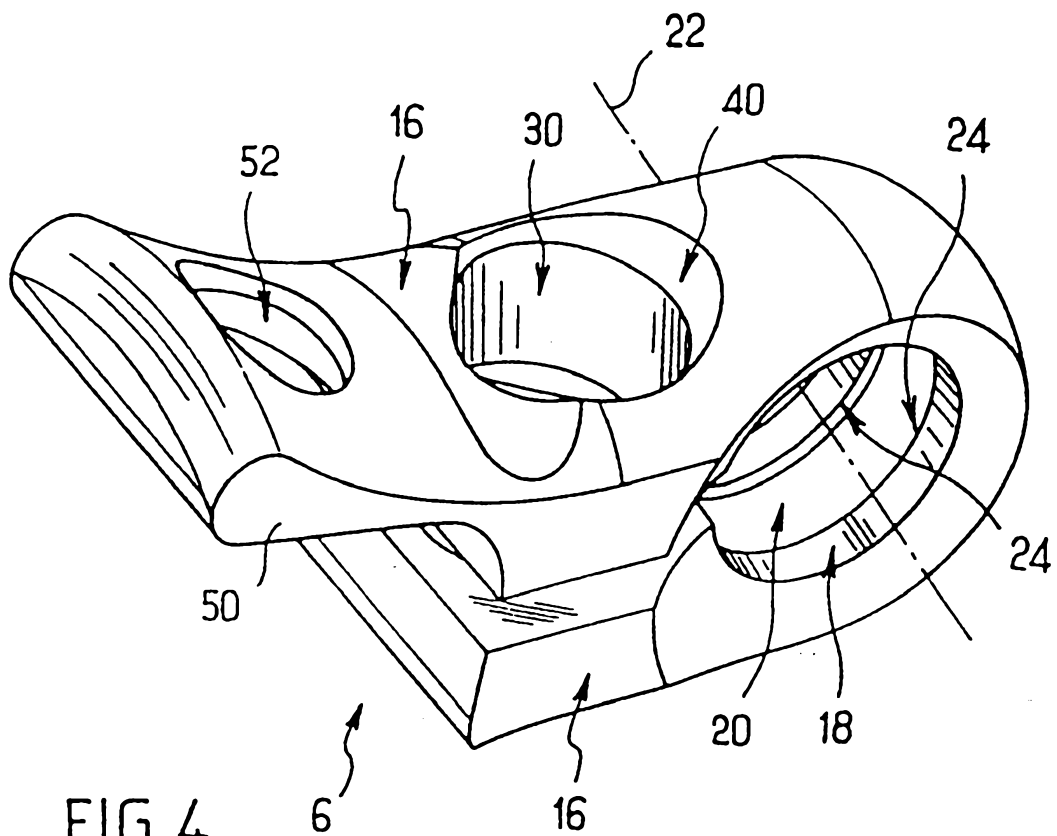


FIG. 4

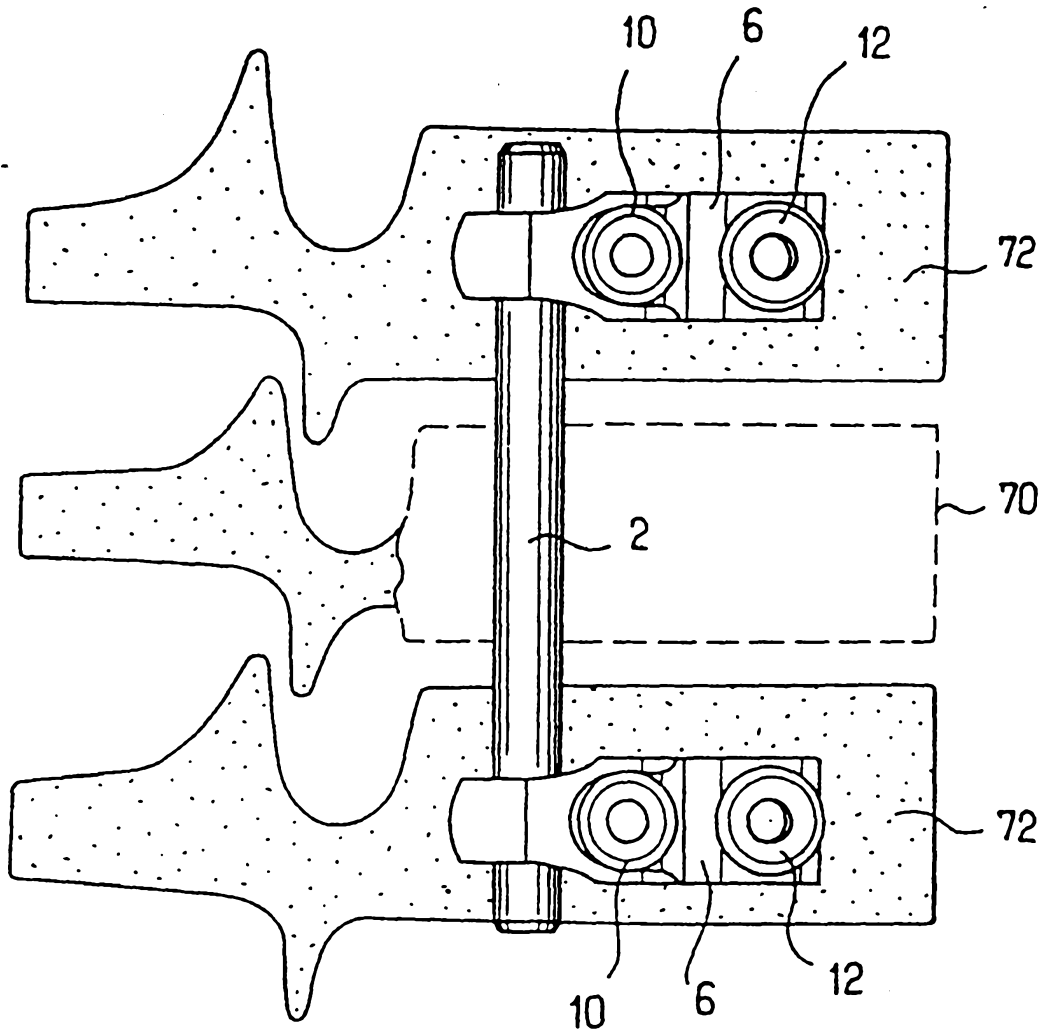


FIG. 8

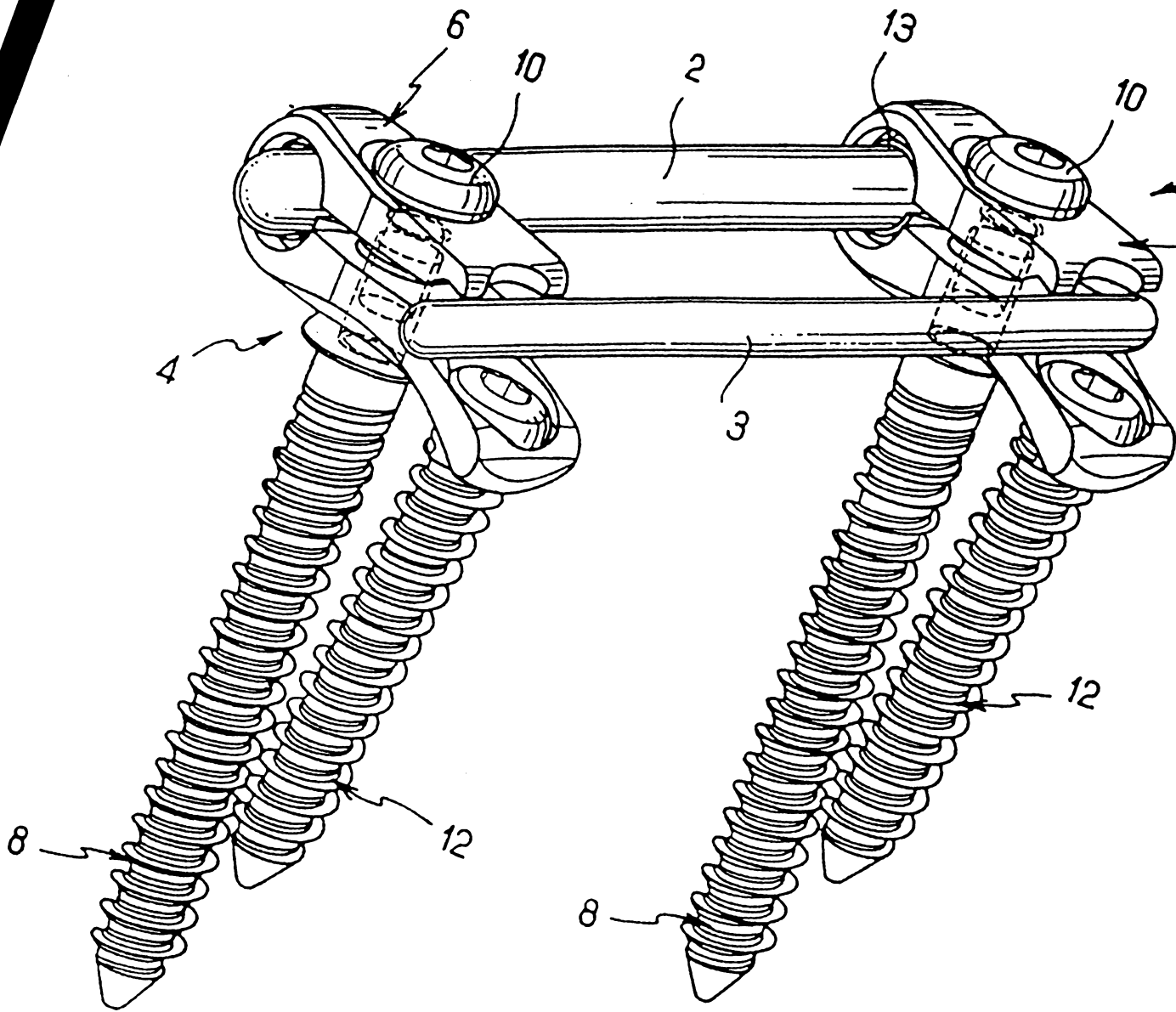


FIG. 9

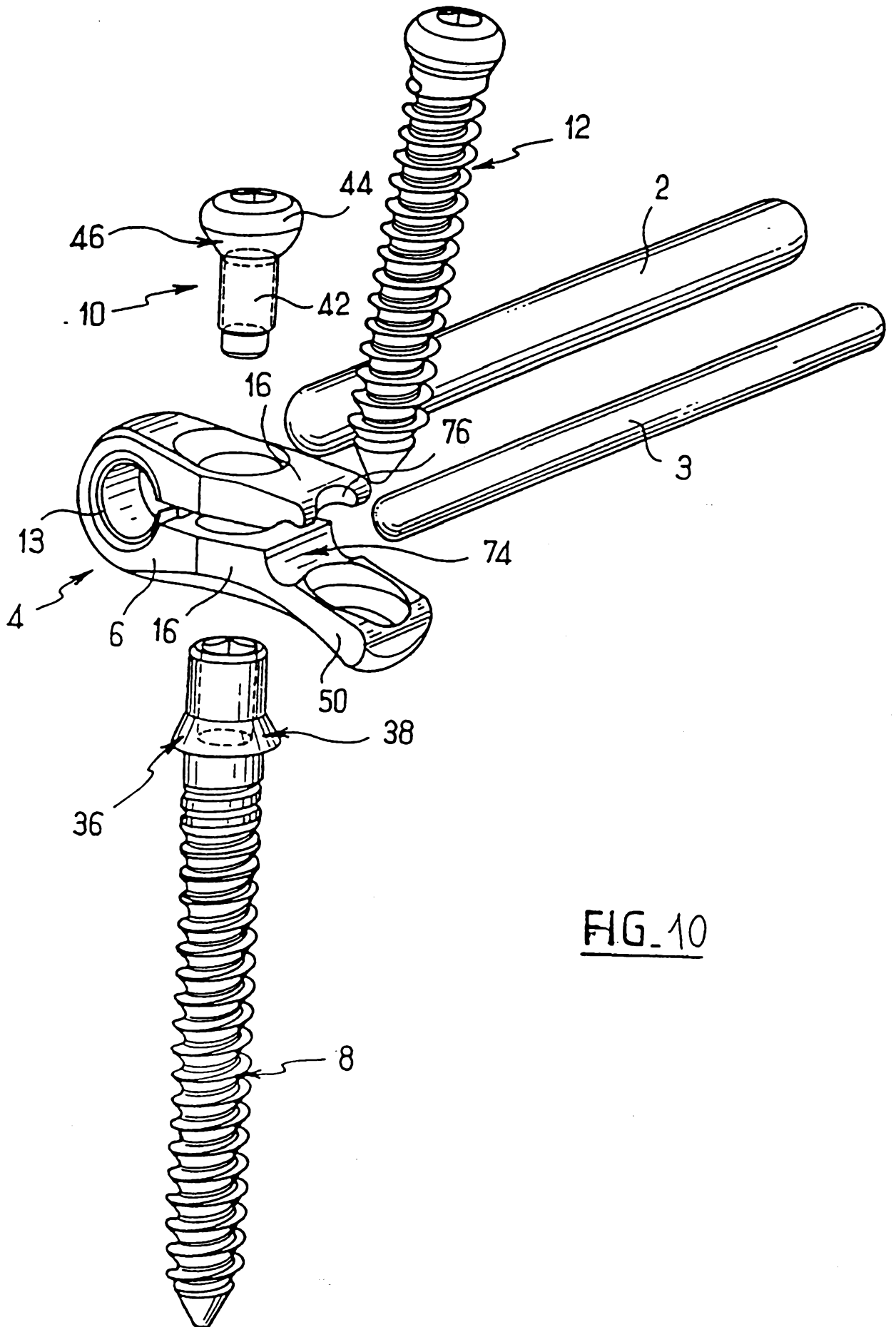


FIG. 10

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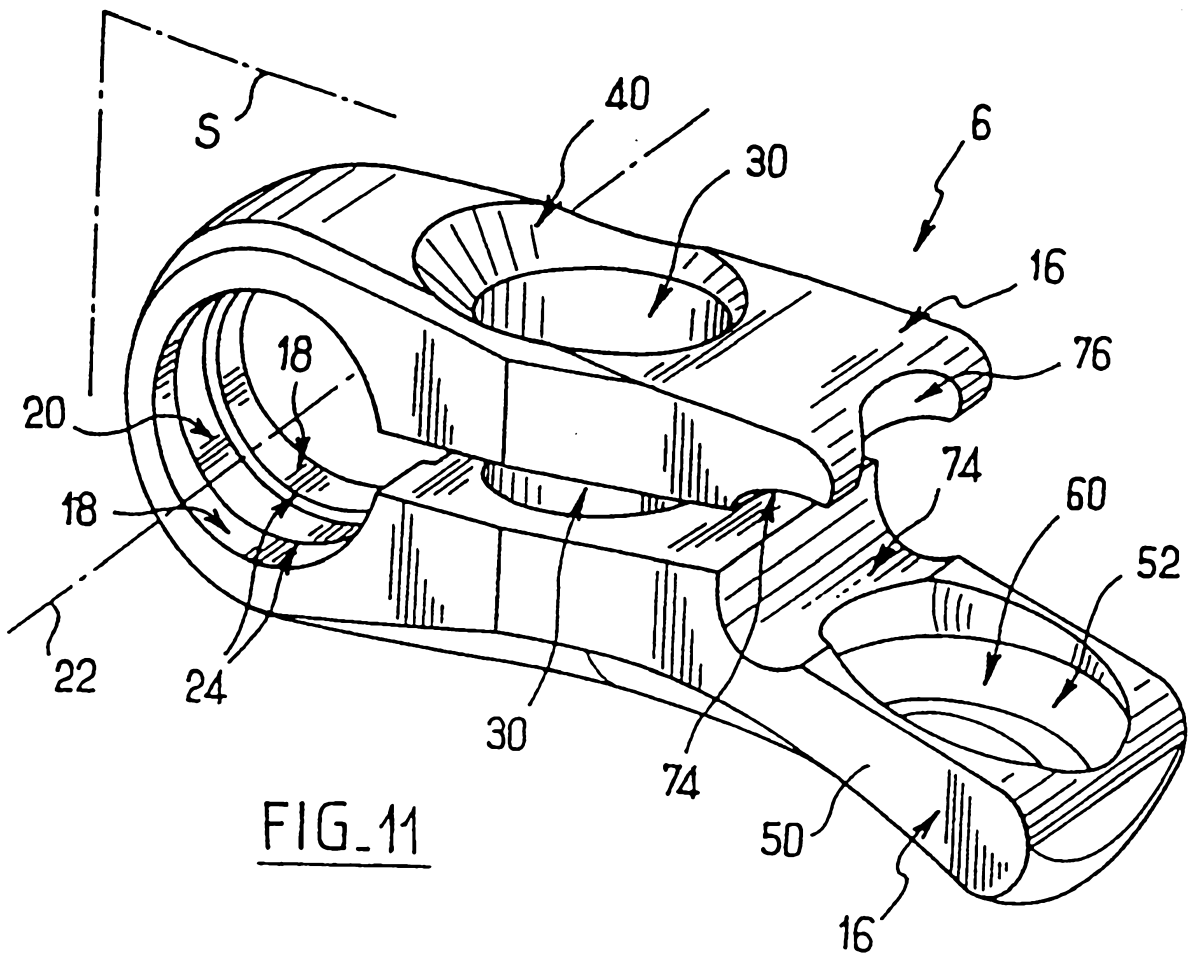


FIG. 11

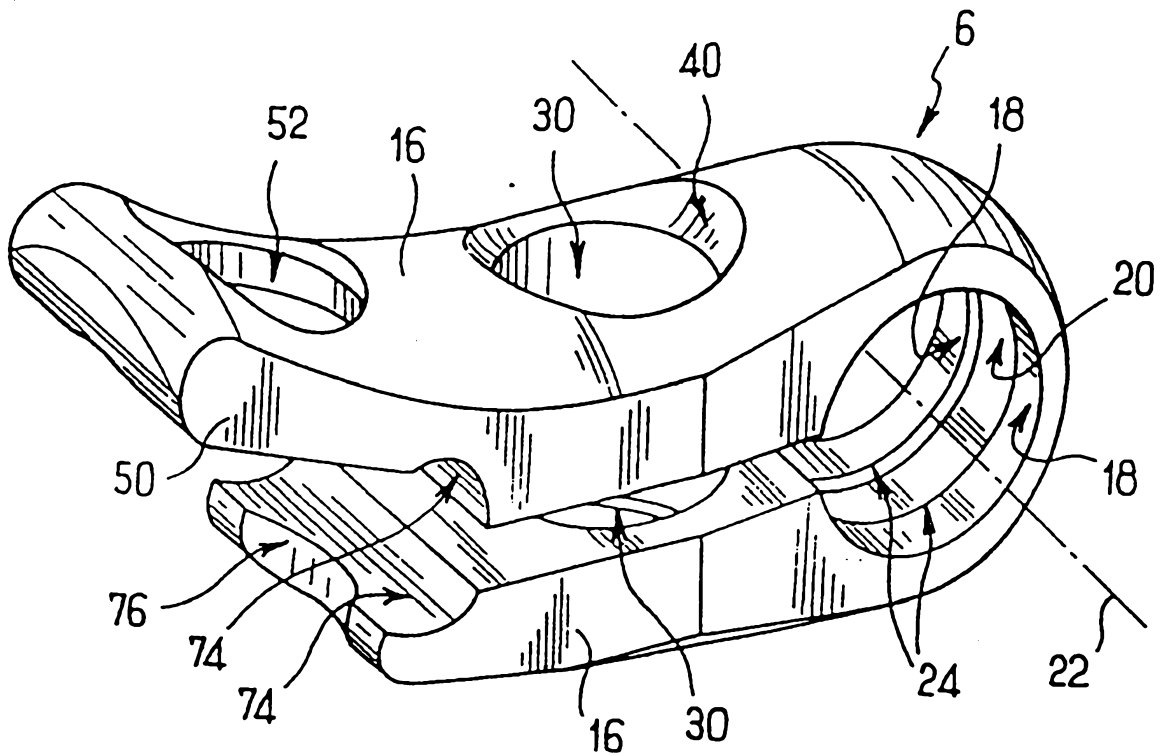


FIG. 12



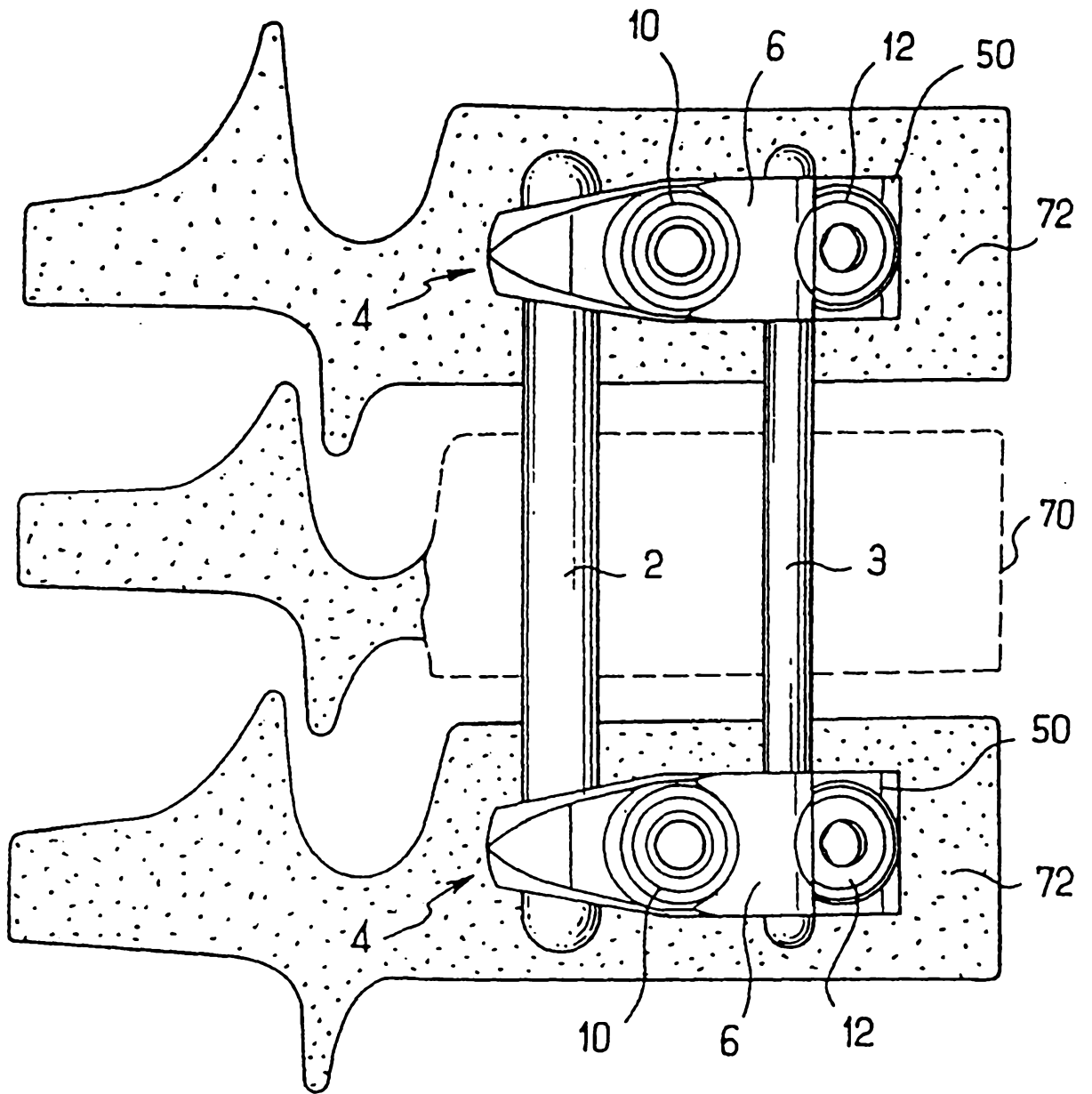


FIG. 13