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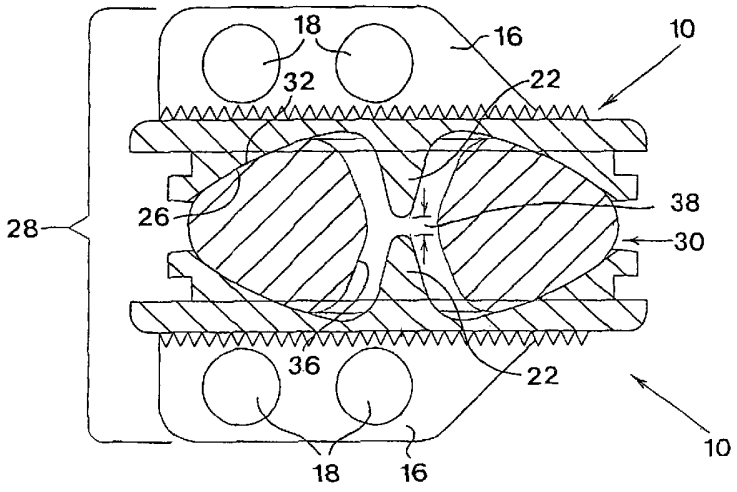
For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: INTERVERTEBRAL PROSTHESIS



(57) Abstract: The invention concerns an intervertebral prosthesis for insertion between adjacent vertebrae. The prosthesis (28) includes upper and lower prosthesis plates (10) which are located against the respective vertebrae and which are formed with concavely curved recesses (20). A core (30) is located between the plates and has opposed, convexly curved surfaces (32) which are received in the recesses of the plates. This allows plates to slide in articulated manner over the core. The recesses of the plates are spherically curved and at least one of them surrounds a locating peg (22) that projects centrally from the base of the recess. The peg locates loosely in a central opening (34) in the curved surface of the core in a manner allowing the plates to slide in all directions over the core while holding the core captive relative to the plates. Other aspects with which the invention is concerned are the prosthesis plates and core.

WO 2004/026187 A1

"INTERVERTEBRAL PROSTHESIS"

BACKGROUND TO THE INVENTION

THIS invention relates to an intervertebral prosthesis.

In the event of damage to a spinal disc it is known practice to implant an intervertebral prosthesis surgically to replace the damaged organ. Several types of prosthesis for this purpose are known and in common use.

One type of known intervertebral prosthesis is sold by Waldemar Link GmbH & Co under the trade mark LINK® SB Charité. This prosthesis includes upper and lower prosthesis plates which locate against and engage the adjacent vertebral bodies, and a low friction core between the plates. The core has upper and lower convexly curved surfaces and the plates have corresponding, concavely curved recesses which cooperate with the curved surfaces of the core. This allows the plates to slide over the core to allow required spinal movements to take place. The curved recesses in the plates are surrounded by annular ridges which locate, at the limit of sliding movement of the plates over the core, in opposing peripheral channels surrounding the curved surfaces of the core.

This type of configuration is also described in EP 0 560 140 and EP 0 560 141 (both Waldemar Link GmbH & Co). However a drawback of such configurations is that the provision of the peripheral ribs and channels limits the areas available for bearing and sliding contact between the plates and core, and accordingly the loads which can be transmitted by the prosthesis. As a result of the relatively small bearing areas, it is believed that at least the core will be subject to rapid wear and have a relatively short life-span.

EP 0 560 141 also describes one alternative arrangement in which the curved surfaces of the core carry opposing, elongate keys that locate in elongate grooves in the plates and another alternative arrangement in which the plates have opposing elongate keys that locate in elongate grooves in the opposite curved surfaces of the core. These key and groove arrangements allow the plates to slide freely over the core, within the limits of the length of the grooves, in one plane only. Although allowance is made for some lateral play of the keys in the grooves, very little sliding movement of the plates over the core can take place in the orthogonal vertical plane, and this is considered to be a serious drawback of this design.

SUMMARY OF THE INVENTION

According to the invention there is provided an intervertebral prosthesis for insertion between adjacent vertebrae, the prosthesis comprising upper and lower prosthesis plates locatable against the respective vertebrae and having opposing, concavely curved recesses therein and a core located between the plates, the core having opposed, convexly curved surfaces received in the recesses of the plates to allow the plates to slide in articulated manner over the core, characterised in that:

- the opposed surfaces of the core and the recesses of the plates have cooperating spherical curvatures,

- the recess of a plate surrounds a locating peg projecting centrally from the base of the recess, and

- the peg locates loosely in an opening located centrally in a curved surface of the core, whereby the plates can slide over the core in all directions while the peg holds the core captive.

In some embodiments, only one of the plates, typically the operatively lower plate, includes a peg. In other embodiments, both plates include pegs, the

pegs opposing one another and locating loosely in respective openings located centrally in the opposed curved surfaces of the core. In each embodiment it is preferred that each peg and the opening in which it locates are conical in shape.

According to another aspect of the invention there is provided a prosthesis plate for use in a prosthesis as summarised abvove, the prosthesis plate having a coarse surface locatable against a vertebra, an oppositely facing concavely curved surface which is complemental in shape to a convexly curved surface of a core of the prosthesis, characterised in the concavely curved surface of the plate has a spherical curvature and in that the plate includes a conical locating peg extending centrally from the concavely curved surface, the peg being locatable loosely in a central opening in the convexly curved surface of the core.

According to yet another aspect of the invention there is provided a core for use in the prosthesis, the core comprising a one piece plastics body having operatively upper and lower curved surfaces, characterised in that the curved surfaces of the body are spherically curved and at least one of the surfaces has a central, conical opening therein dimensioned to receive a conical locating peg of a prosthesis plate loosely.

Other features of the invention are set forth in the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described in more detail, by way of example only, with reference to the accompanying drawings in which:

Figure 1 shows a cross-sectional view of a prosthesis plate used in a prosthesis according to the invention;

Figure 2 shows a plan view of the prosthesis plate seen in Figure 1;

Figure 3 shows a cross-sectional view of a core used in a prosthesis according to the invention;

Figure 4 shows a plan view of the core seen in Figure 3;

Figure 5 shows a cross-sectional view of an intervertebral prosthesis according to a first embodiment of the invention in a neutral condition before articulation has taken place; and

Figure 6 shows the prosthesis of Figure 5 articulated to a limit position; and

Figure 7 shows a cross-sectional view of an intervertebral prosthesis according to a second embodiment of the invention.

DESCRIPTION OF PREFERRED EMBODIMENTS

The prosthesis plate 10 seen in Figures 1 and 2 is formed in one piece of grade 5 titanium. It includes a major surface 12 which is machined to a coarse, serrated finish 14. Projecting from the surface 12 is an elongate fin 16 pierced by transverse holes 18. The opposite surface of the plate 10 is formed with a recess 20 surrounding a projecting conical peg 22 of round cross-section at the centre of the recess. The recess is bounded by an annular rim 24. The surface 26 of the recess is concavely, spherically curved and has a titanium nitride finish.

A first embodiment of prosthesis of the invention, indicated generally by the numeral 28 in Figures 5 and 6, includes a pair of identical prosthesis plates 10 arranged in opposition to one another. The prosthesis 28 also includes a core 30 illustrated in Figures 3 and 4. The core is made in one piece of a low friction plastics material, in this case a polyethylene known as Orthosol. The core is generally in the form of a circular, doughnut-shaped toroid and

has identical upper and lower surfaces 32 which are convexly, spherically curved. The upper and lower surfaces 32 are formed centrally with conical openings 34, in this case forming the opposite ends of a circular cross-section passage 36 passing axially and centrally through the body of the core.

The core surfaces 32 and recess surface 26 have the same radius of curvature which is, in this case, 18mm.

In the assembled prosthesis 28, the plates 10 are arranged in opposition to one another with the core 30 located between them. The pegs 22 of the plates locate in the openings 34, i.e. in the ends of the passage 36. The combined length of the pegs is less than the length of the passage 36, so the inner ends of the pegs are spaced apart from one another by a short distance 38, as shown in Figure 5. The transverse dimension of each peg is, at all points along the length of the peg, considerably less than the diameter of the passage 36 at the corresponding point along the length of the passage.

The cooperating spherical surfaces 26 and 32 and the relative dimensions of the pegs 22 and the passage 36 allow the plates 10 to slide or articulate over the core through a fairly large range of angles and in all directions or degrees of freedom, including rotation about the central axis.

At a predetermined limit of articulated movement of the plates relative to the core, the rims 24 of the plates contact with one another as indicated by the numeral 40 in Figure 6. Further articulation of the prosthesis 28 beyond this point is not possible. At the limit of articulation, the pegs 22 also come into abutment with the side of the passage 36, as also illustrated in Figure 6.

It will also be noted in Figure 6 that the openings 34 at the ends of the passage 36 are defined by similar cone angles to the pegs 22, so that

contact between the pegs and the sides of the openings takes place complementally over virtually the entire length of each peg.
Throughout the range of possible articulation, the pegs 22 remain in the passage 36 and prevent the core from separating laterally from the plates 10. In other words, the core is held captive by the pegs during all possible articulations which can take place. In the illustrated embodiment, the plates 10 are limited to 12° of articulation before the rims 24 abut one another, i.e. 12° is the maximum articulation which can take place.

In the prosthesis 28 described above, the pegs 22 locate in a passage 32 which passes right through the core 30. It will however be understood that in other embodiments, the pegs could merely locate in blind recesses or openings in the opposite surfaces of the core without such openings actually being joined to one another to form a continuous passage.

Figure 7 illustrates a prosthesis according to a second embodiment of the invention in a view similar to that of Figure 5. In Figure 7, components corresponding to components illustrated in the earlier Figures are indicated by the same reference numerals.

The lower prosthesis plate 10 in Figure 7 is identical to the prosthesis plates of the first embodiment. However, the upper prosthesis plate, designated 10.1, has no central peg. Instead, the surface 26 is continuously, spherically curved. In all other respects the plate 10.1 is identical to the plate 10.

In the assembled prosthesis 50, the core is held captive by the action of the single peg 22 carried by the lower prosthesis plate 10. The core 30 is identical to the core described previously but once again it will be appreciated that core could have a blind recess in its downwardly facing, curved surface 32 only to receive the single peg 22.

The prosthesis 28, 50 is surgically implanted between adjacent spinal vertebrae in place of a damaged disc. Those skilled in the art will

understand that the adjacent vertebrae are forcibly separated from one another to provide the necessary space for insertion. The plates 10, 10.1 are slipped laterally into place between the vertebrae with their fins 16 entering slots cut in the opposing vertebral surfaces to receive them.

After insertion of the core between the opposing plates, the vertebra are allowed to move together to hold the assembled prosthesis in place.

The surfaces 12 of the plates 10, 10.1 locate against the opposing vertebrae and, with passage of time, firm connection between the plates and the vertebrae will be achieved as bone tissue grows over the serrated finish. Bone tissue growth will also take place about the fins 16 and through the holes 18 therein, further enhancing the connection which is achieved.

Referring to Figures 3 and 4, the core 30 used in the embodiments described above is formed with narrow, angularly spaced, blind passages which accommodate titanium pins 42. The core itself is transparent to X-radiation and so would normally be invisible in a post-operative X-ray examination. The pins 42 serve as radiographic markers and enable the position of the core 30 to be ascertained during such examination.

Annular grooves 44 are provided in the plates 10, 10.1 to facilitate holding and manipulation of the prosthesis by appropriate instruments during placement into the intervertebral disc space.

Compared to known prostheses, the prostheses 28, 50 described above have a number of advantages, as follows:

1. The peg or pegs 22 hold the core captive and prevent it from slipping out sideways.

2. At a predetermined maximum limit of articulation, the rims 24 contact one another to prevent further articulation. At the same time,

the peg or pegs 22 contact the sides of the openings 34, also preventing further articulation.

3. An acceptable bearing area of the plates on the core is obtained with the central peg/central opening configurations described above. This is particularly advantageous compared to prior art prostheses where the core has peripheral channels on its upper and lower surfaces to receive peripheral rims on the plates at the limit of articulation.

In practice, it may happen that there is imperfect alignment of the prosthesis plates. In the case of very poor alignment, the dual peg configuration of Figures 5 and 6 gives rise to the possibility that the pegs 22 are laterally offset from one another by a substantial distance. This can in turn lead to the undesirable consequence that the range of articulation which can be accommodated is unduly limited, and attempts to articulate past the limit could result in damage to the core by the misaligned pegs. In the embodiment of Figure 7 the single peg can be received centrally by the core, thereby avoiding this potential problem.

The principles of the invention are applicable to prosthetic disc implants for lumbar vertebrae as well as cervical vertebrae. In the latter case, the fins 16 will typically be omitted.

CLAIMS

1.

An intervertebral prosthesis for insertion between adjacent vertebrae, the prosthesis comprising upper and lower prosthesis plates locatable against the respective vertebrae and having opposing, concavely curved recesses therein and a core located between the plates, the core having opposed, convexly curved surfaces received in the recesses of the plates to allow the plates to slide in articulated manner over the core, characterised in that:

- the opposed surfaces of the core and the recesses of the plates have cooperating spherical curvatures,

- the recess of a plate surrounds a locating peg projecting centrally from the base of the recess, and

- the peg locates loosely in an opening located centrally in a curved surface of the core, whereby the plates can slide over the core in all directions while the peg holds the core captive.

2.

A prosthesis according to claim 1 wherein the recesses of the plates are bounded by annular rims arranged to contact one another at a predetermined limit of sliding movement of the plates over the core.

3.

A prosthesis according to claim 2 wherein the plates are formed with annular grooves, adjacent the rims, to facilitate handling thereof by instruments used to place the prosthesis in use.

4.

A prosthesis according to any one of claims 1 to 3 wherein only the operatively lower plate includes a locating peg.

5.

A prosthesis according to claim 4 wherein the peg and the opening in which it locates are conically shaped.

6.

A prosthesis according to claim 5 wherein the core is a doughnut-shaped body and the central opening therein is provided by an end of a central passage extending axially through the body

7.

A prosthesis according to any one of claims 1 to 3 wherein each plate includes a locating peg, the pegs opposing one another and locating loosely in respective openings located centrally in the opposed convexly curved surfaces of the core.

8.

A prosthesis according to claim 7 wherein the core is a doughnut-shaped body and the central openings therein are provided by opposite ends of a central passage extending axially through the body.

9.

A prosthesis according to claim 8 wherein the pegs are arranged to abut the side of the openings at the predetermined limit of sliding movement of the plates over the core.

10.

A prosthesis according to any one of claims 7 to 9 wherein the pegs and openings are complementally, conically shaped.

11.

A prosthesis according to any one of the preceding claims wherein the core is transparent to X-radiation and carries radiographic markers.

12.

A prosthesis according to claim 11 wherein the core is formed with angularly spaced, radial passages accommodating radially oriented pins serving as the radiographic markers.

13.

A prosthesis according to any one of the preceding claims wherein the plates have coarse surfaces to locate in use against the vertebrae.

14.

A prosthesis according to claim 14 wherein the plates carry upstanding, elongate fins locatable in slots in the vertebrae.

15.

A prosthesis according to claim 15 wherein holes are formed transversely through the fins.

16.

A prosthesis plate for use in a prosthesis according to any one of the preceding claims, the prosthesis plate having a coarse surface locatable against a vertebra, and an oppositely facing concavely curved surface which is complemental in shape to a convexly curved surface of a core of the prosthesis, characterised in the concavely curved surface of the plate has a spherical curvature and in that the plate includes a conical locating peg extending centrally from the concavely curved surface, the peg being locatable loosely in a central opening in the convexly curved surface of the core.

17.

A prosthesis plate according to claim 16 wherein the plate includes an upstanding, elongate fin, locatable in a slot in a vertebra, extending from the coarse surface.

18.

A prosthesis plate according to claim 17 comprising one or more holes formed transversely through the fin.

19.

A core for use in a prosthesis according to any one of claims 1 to 15, the core comprising a one piece plastics body having operatively upper and lower convexly curved surfaces, characterised in that the convexly curved surfaces of the body are spherically curved and at least one of the surfaces has a central, conical opening therein dimensioned to receive a conical locating peg of a prosthesis plate loosely.

20.

A core according to claim 19 wherein the core is doughnut-shaped and the upper and lower spherically curved surfaces each have a central conical opening therein, the openings forming opposite ends of a central passage extending longitudinally through the core.

21.

A core according to claim 19 or claim 20 wherein the core is transparent to X-radiation and carries radiographic markers.

22.

A core according to claim 21 wherein the core is formed with spaced, radial passages accommodating radially oriented pins serving as the radiographic markers.

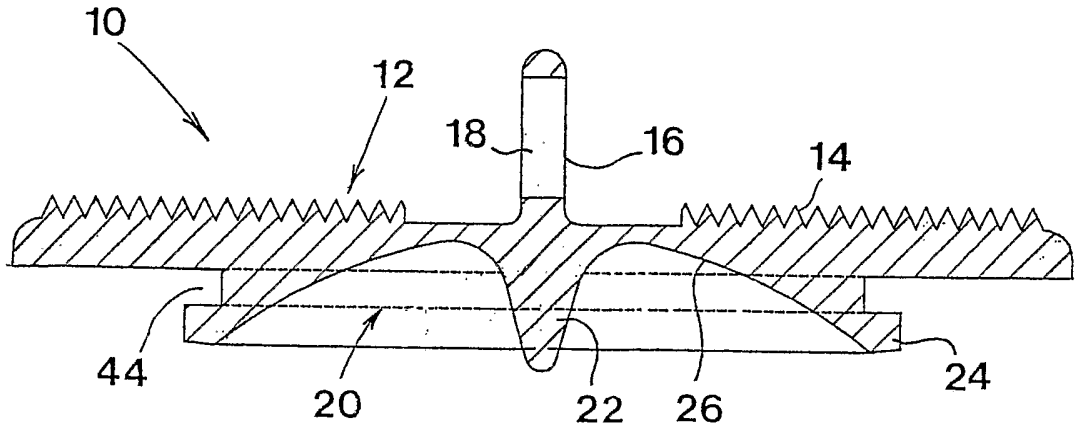


Fig.1

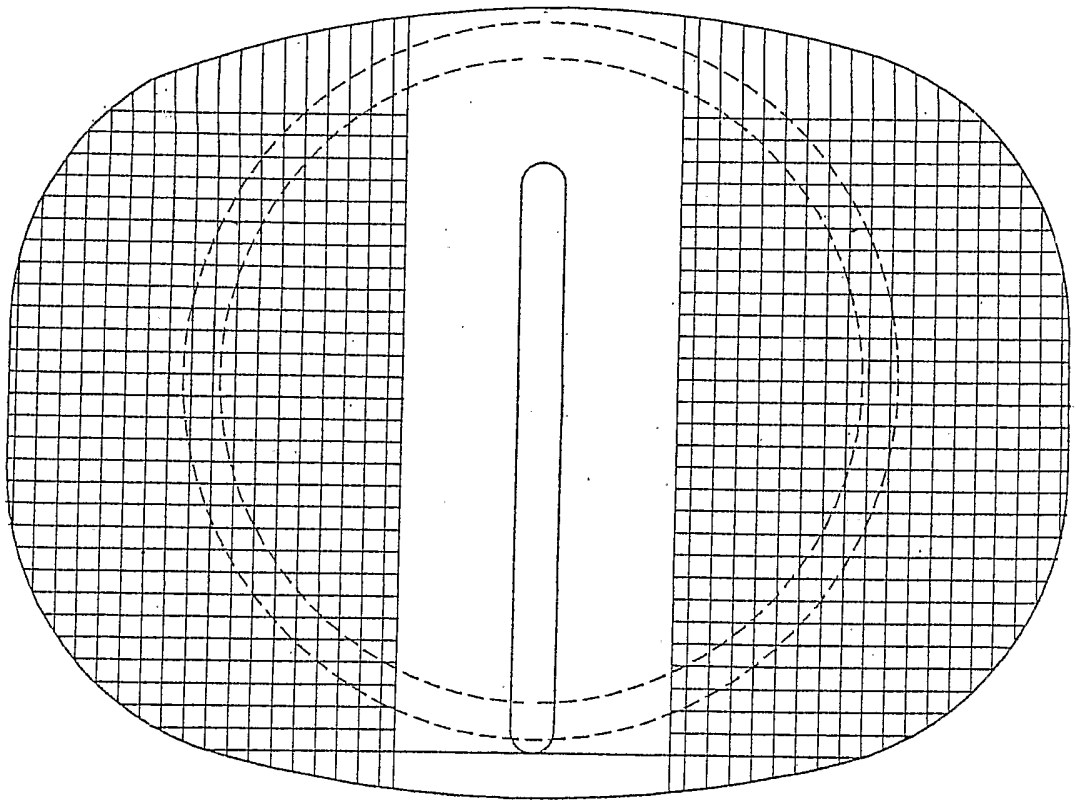


Fig.2

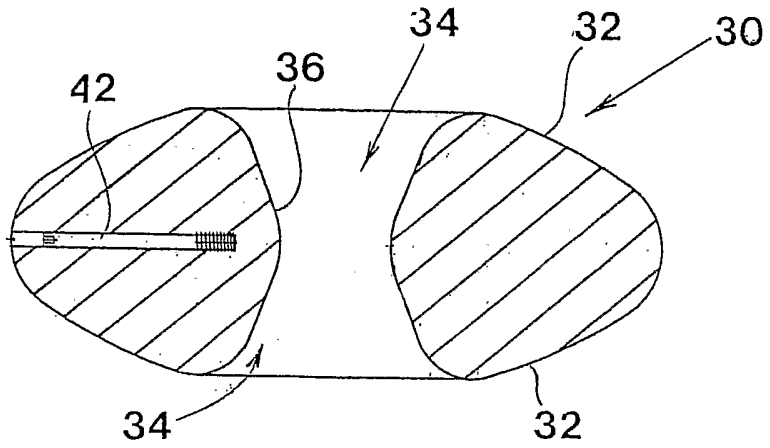


Fig.3

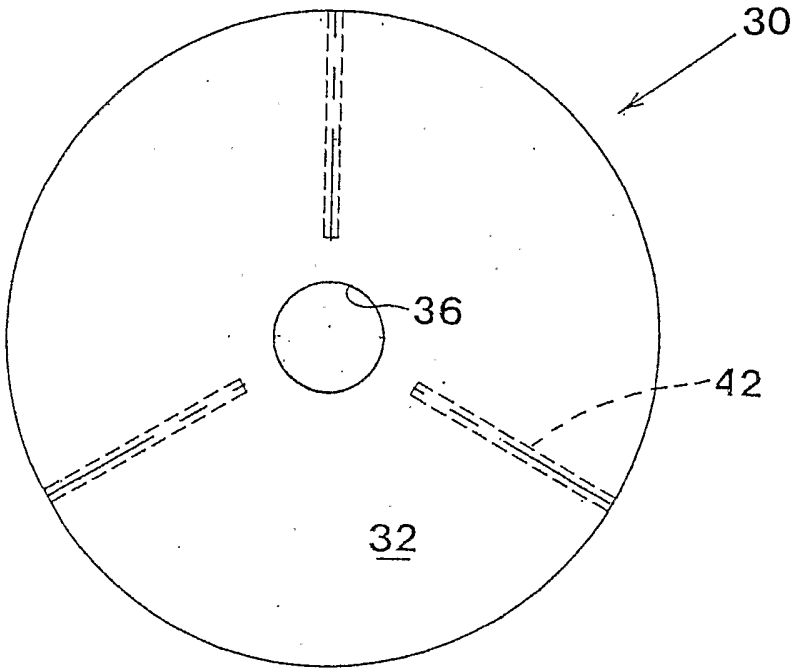


Fig.4

Fig.5

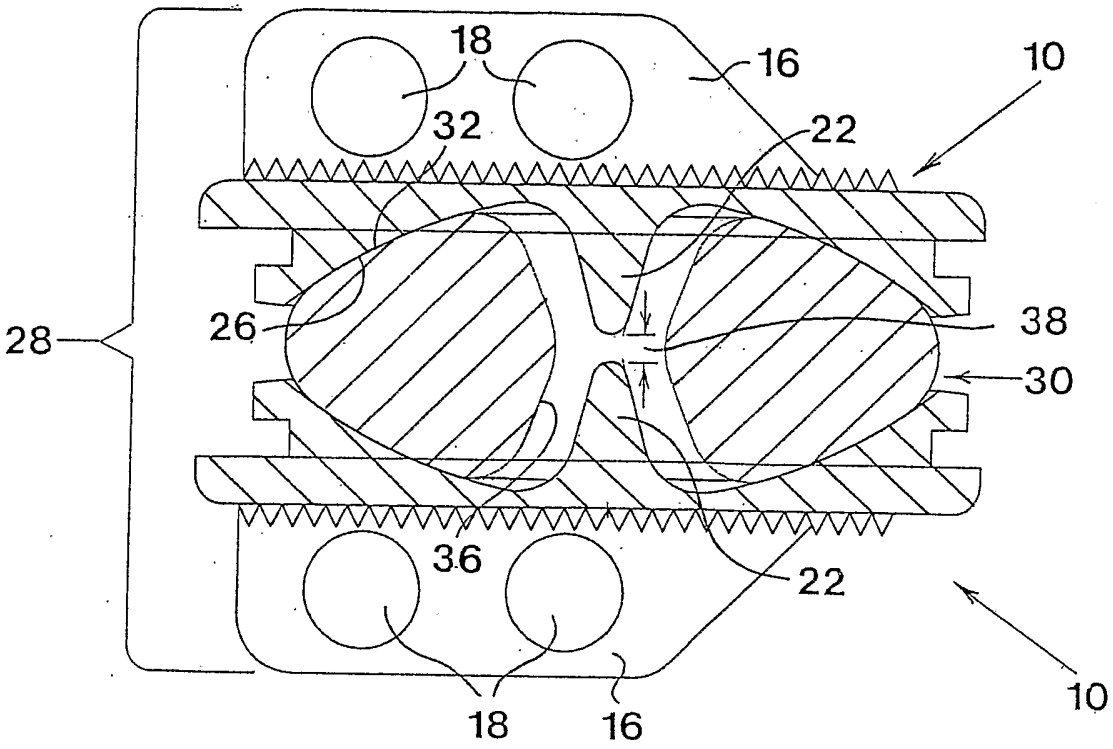


Fig.6

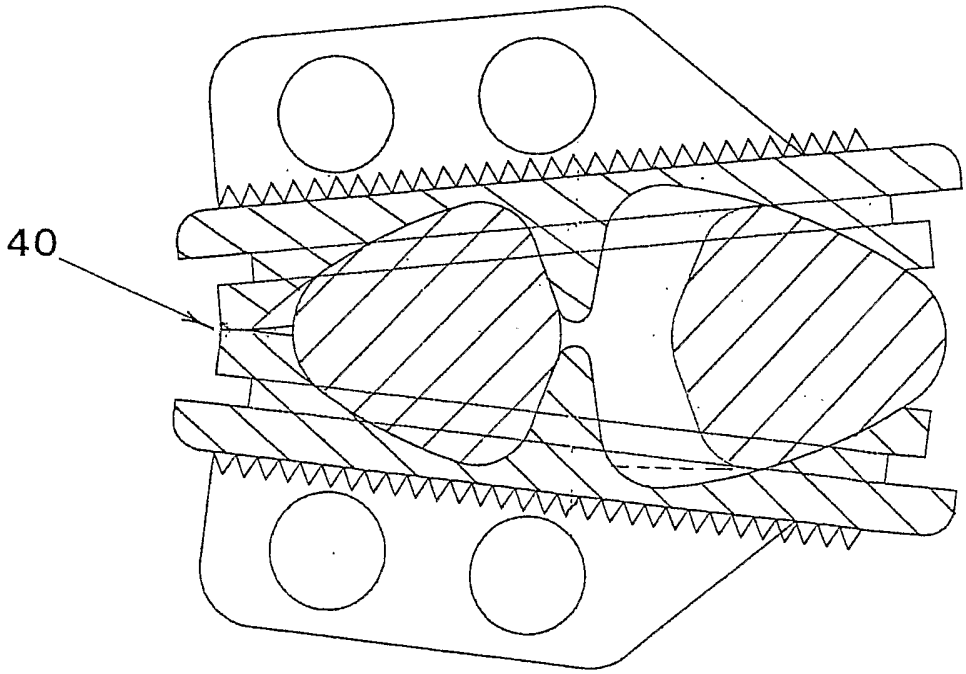
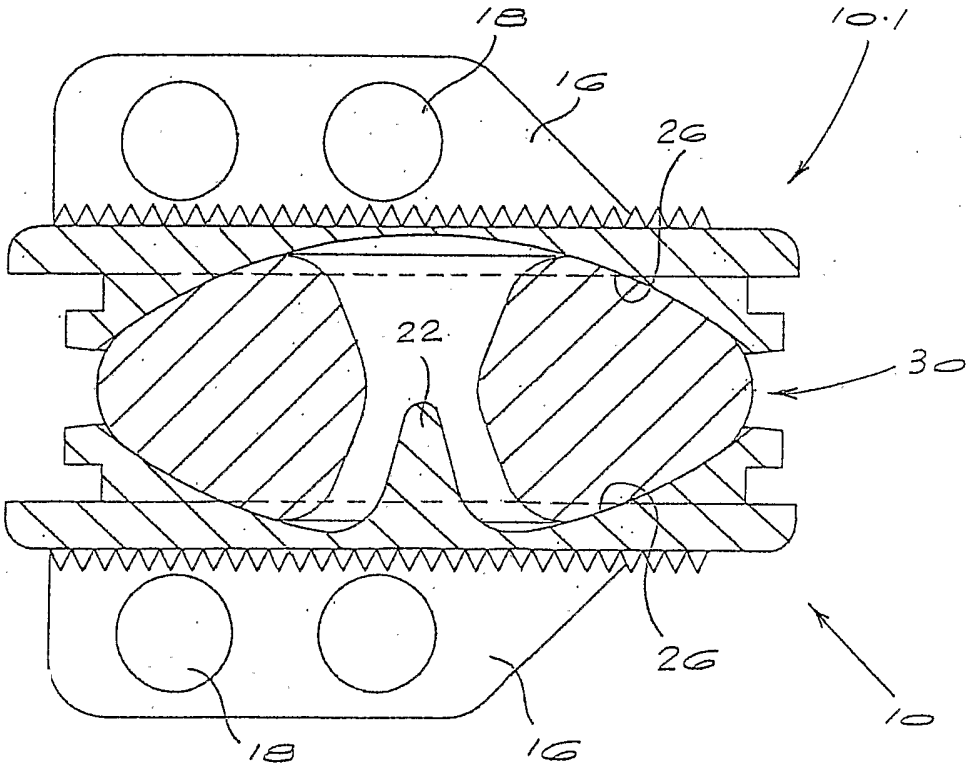


Fig.7



INTERNATIONAL SEARCH REPORT

PCT/IB 03/01529

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 00 04851 A (BRYAN VINCENT ;KUNZLER ALEX (US); SPINAL DYNAMICS CORP (US)) 3 February 2000 (2000-02-03) figures page 4, line 13 - line 18 page 5, line 8 - line 12	1,7-10, 13,16, 19,20
Y		14,17,21
A		18
X	EP 0 560 141 A (LINK WALDEMAR GMBH CO) 15 September 1993 (1993-09-15) cited in the application claim 6; figures 2,4,8-15 column 4, line 10 - line 21 column 5, line 5 - line 49	1,2,7, 13,16,19

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
10 July 2003	18/07/2003

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Stach, R

INTERNATIONAL SEARCH REPORT

PCT/IB 03/01529

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 759 766 A (BUETTNER-JANZ KARIN ET AL) 26 July 1988 (1988-07-26) figures 1-8,13-21,23,25 examples 6-8 column 3, line 53 - line 55	1,7,11, 13
Y		21
A		16,19
Y	WO 01 01893 A (BEYERSDORFF BORIS ;MARNAY THIERRY (FR); SPINE SOLUTIONS INC (US)) 11 January 2001 (2001-01-11) figures 1-3	14,17
A		1,2,4, 13,16
A	US 6 368 350 B1 (GRIFFITH STEVEN L ET AL) 9 April 2002 (2002-04-09) figures 8-28	1,2,4,9, 23
A	US 6 447 548 B1 (RALPH JAMES D ET AL) 10 September 2002 (2002-09-10) figures	3
A	FR 2 805 985 A (EUROSURGICAL) 14 September 2001 (2001-09-14)	

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-15

An intervertebral prosthesis comprising upper and lower plates locatable against the respective adjacent vertebrae and having opposing concavely curved recesses therein and a core located between the plates having opposed convexly curved surfaces received in the recesses characterised in that:
the opposed surfaces of the core and the recesses of the plates have cooperating spherical curvatures,
the recess of a plate surrounds a locating peg projecting from the base of the recess, and
the peg locates loosely in an opening located in a curved surface of the core.

2. Claims: 16-18

A prosthesis plate having a coarse surface locatable against a vertebra and an oppositely concavely curved surface characterised in that said surface has a spherical curvature and that a conical locating peg extends from that surface

3. Claims: 19-22

A core comprising a one piece plastic body having upper and lower convexly curved surfaces characterized in that said surfaces are spherically curved and at least one of the surfaces has a central opening therein.

PCT/IB 03/01529

INTERNATIONAL SEARCH REPORT

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

PCT/IB 03/01529

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