

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
24 January 2008 (24.01.2008)

PCT

(10) International Publication Number
WO 2008/010240 A1

(51) International Patent Classification:
A61F 2/44 (2006.01)

(21) International Application Number:
PCT/IT2006/000542

(22) International Filing Date: 18 July 2006 (18.07.2006)

(25) Filing Language: Italian

(26) Publication Language: English

(71) Applicant and

(72) Inventor: BINOTTO, Radames [IT/IT]; Via Miramonti,
74, 35038 TORREGLIA (PD) (IT).

(74) Agent: BENETTIN Maurizio; via Sorio, 116, I 35141 -
PADOVA (IT).

CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI,
GB, GD, GE, GH, GM, HN, HR, HU, ID, IL, IN, IS, JP,
KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT,
LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA,
NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD,
SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ,
UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

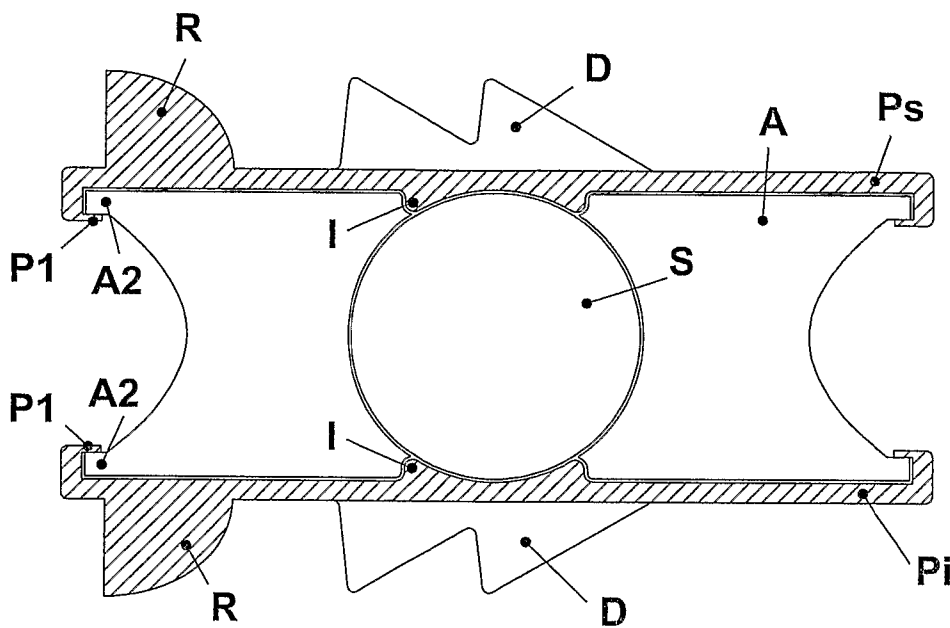
(84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, GH,
GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM,
ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI,
FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT,
RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA,
GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— with international search report

(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,
AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN,

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: BIOCOMPATIBLE INTERVERTEBRAL SPACER



(57) Abstract: A new intervertebral spacer (O) suitable for insertion between two vertebra, characterised in that it comprises two opposite plates (Pi, Ps), having one or more protruding parts (R, D) for immobilisation in the intervertebral space, a shock absorbing element (A) and a rigid spacer element (S) positioned and constrained between said plates (Pi, Ps), and wherein said rigid spacer element (S) permits small relative movements between said plates (Pi, Ps), while said shock absorbing element (A) counters them.

WO 2008/010240 A1

TITLE

BIOCOMPATIBLE INTERVERTEBRAL SPACER

DESCRIPTION

The present patent concerns medical devices for spinal neurosurgery and in particular concerns a new intervertebral spacer.

In the case of patients with vertebral pathologies, for example of degenerative or traumatic origin, it is often necessary to operate to restore or correct the connection between the vertebrae of the spinal column.

In this case the use of interosseus spacers, i.e. elements having form and dimensions such as to be inserted in the intervertebral spaces, in order to restore the correct position and/or distance of the vertebrae, also guaranteeing appropriate mobility and strength, is known.

In surgical operations for implanting one or more intervertebral spacers, the expression primary immobilisation is used, meaning the initial position at the time of the operation, and secondary immobilisation, meaning the intersomatic fusion which guarantees that the implant remains correctly positioned also in the long term.

Many of the known spacers have low mechanical strength and a fairly poor level of intersomatic fusion, consequently their positioning in the intervertebral space is not stable.

In said case, furthermore, there is also the risk of the spacer implanted in the vertebral column moving from the required position, with consequent serious problems for the patient.

It is known that, to partly remedy said drawbacks, particularly in the case of implant of intervertebral spacers on two or more levels, i.e. involving three or more vertebrae, further connection plates between said intervertebral spacers must be used, located in an anterior position with respect to the

vertebral column and fixed to the vertebrae by means of screws.

The operation undergone by the patient is therefore extremely invasive and traumatic and recovery times are very long.

5 Spacers are known made of material of organic or synthetic origin, of material with high biocompatibility, i.e. having characteristics similar to those of human tissue such as not to prevent intersomatic fusion.

Ceramic intervertebral implants are known, used for example to fill the space created in the vertebral column in the case of an operation in which the vertebral disc is removed, as happens in slipped disc operations.

10 Interosseus spacers particularly used for cervical decompression, aimed at correcting vertebral pathologies of the cervical area and correctly re-locating the vertebrae without touching the spinal channel and without preventing natural drainage between adjacent vertebrae, are also known.

15 A further drawback of the known spacers consists in their limited adaptability to the intervertebral spaces of the patient, consequently also limiting mobility of the vertebral column in the vicinity of the implant area.

To remedy all the above drawbacks a new type of biocompatible vertebral spacer has been designed and produced.

20 The object of the new spacer is to guarantee high adaptability in the intervertebral space.

A further object of the present invention is to permit stable initial positioning, i.e. to allow primary immobilisation.

A further object is to permit a high level of spinal intersomatic fusion, i.e. guarantee secondary immobilisation.

25 A further important object of the present invention is not to require the use of plates and/or screws for connection and fixing to the vertebrae, thus making the operation less invasive for the patient.

A further object is to obtain mechanical strength comparable to that of the vertebrae.

The new spacer is particularly suitable for application in the cervical region.

5 These and other objects, direct and complementary, are achieved by the new biocompatible vertebral spacer suitable for insertion in the intervertebral space, i.e. between two vertebrae, and in which the two opposite sides facing said vertebrae comprise protruding parts suitable for permitting and guaranteeing primary and secondary immobilisation of the spacer.

10 In particular, the new spacer comprises two opposing and preferably specular plates, between which at least one shock absorbing element, made of silicone for example, and at least one rigid spacer element are positioned. Said plates, made of biocompatible material with high mechanical strength, comparable to that of the vertebrae, comprise, on the outer side facing said vertebrae, protruding parts suitable for permitting primary and secondary
15 immobilisation of the spacer.

Said protruding parts allow the new spacer to be blocked in a stable manner in the required position also without the aid of plates and screws, particularly in the case of implant of intervertebral spacers on two or more levels, i.e. involving three or more vertebrae.

20 In particular, each of said plates will comprise at least one protruding part suitable for insertion in cavities provided on the vertebrae, to guide correct positioning of the spacer.

Said protruding part, in particular, has a preferably convex surface, for example hemispherical, in order not to obstruct insertion of the spacer in the
25 intervertebral space.

Said plates furthermore comprise, on said outer faces, one or more protrusions or teeth which prevent the spacer from subsequently coming out

of the established position.

Said protrusions or teeth are distributed in corresponding or non-corresponding positions on each of said two plates, so that the spacer is, as a whole, symmetrical or non-symmetrical.

5 For insertion of the new spacer, the surgeon firstly mills the two vertebrae, to create on them the cavities suitable for housing said convex protruding parts of the plates.

The new spacer is then positioned in the intervertebral space so that said convex protruding parts are inserted in the cavities in order to guarantee
10 primary immobilisation.

Said teeth ensure that the spacer does not come out of the required position.

The central shock absorbing element has a substantially parallelepiped shape and is positioned and constrained between said two plates.

Said central shock absorbing element is made of silicone, for example, or of
15 similar medical plastic materials, natural or synthetic polymers, also latest generation, with the possibility of grafting of differentiated cellular material suitable for activating bone growth and/or growth of cartilage or other. It can also be produced using CAT or MIR data with stereolithographic systems, sintering or similar, also imitating the bone trabeculae and can also
20 be custom-made.

Said plates, therefore, if not subject to any type of stress, are arranged parallel, whereas, when constrained in the intervertebral space, they can arrange themselves in a converging manner, thus adapting to the form of the spacer, thanks to said central shock absorbing element which can sustain
25 small deformations.

Said rigid spacer element is constrained between said two plates and is contained for example in said central shock absorbing element.

Said rigid spacer element which, in the preferred solution, has a substantially spherical form, is located in a substantially central position between the two plates and substantially has the function of permitting the relative movements between the two plates, while said shock absorbing element counters said movements.

The material used for construction of all the parts making up the new spacer has mechanical characteristics similar to those of the adjacent vertebrae, so as to integrate perfectly with the human tissue and guarantee adequate mechanical strength.

In said regard, it is envisaged that said plates will be made of metal, such as titanium, or a plastic polymeric material, for example caprolactone or its derivatives.

More generally, the materials that can be used for said plates are: hydroxylapatite mixed with plasma and gelatins of various origins and growth factors, ceramic bioglass suitable for bone fusion mixed with gelatins of various origins and growth factors, metal implantology products, for example medical steel, ceramic materials etc.

It is preferable for said central shock absorbing element to be made of silicone, whereas it is expedient to make said rigid spacer element of titanium or other biocompatible synthetic material with high mechanical strength, such as synthetic diamond or synthetic ruby.

It is furthermore envisaged that said plates and said central shock absorbing element will be provided with holes for the passage of cells and to permit growth of the bone trabeculae inside them, thus favouring secondary immobilisation of the spacer and fusion with the adjacent bodies.

The characteristics of the new spacer will be better clarified by the following description with reference to the drawings, attached as a non-

limiting example.

Figures 1 and 2 show respectively, in a three-dimensional view, the two plates, upper (Ps) and lower (Pi) of the new spacer (O).

5 Figure 3 shows the spherical rigid spacer element (S) suitable for insertion in the housing (A1) obtained in the central shock absorbing element (A) shown in a three-dimensional view in figure 4.

Figure 5 shows the section of the new spacer (O) completely assembled shown in figure 6, along the vertical central section plane (π).

10 Figure 7 shows a three-dimensional view of a possible embodiment of the new spacer (O).

Figure 8 shows a section of a further possible embodiment of the new spacer (O), with rigid spacer element (S) integral with the upper plate (Ps).

15 According to the preferred solution shown in figures 1-6, the new biocompatible vertebral spacer (O) comprises two opposing and substantially specular plates (Pi, Ps) between which at least one shock absorbing element (A) is positioned, made of silicone for example, and at least one rigid spacer element (S).

20 Said plates (Pi, Ps), made of biocompatible material with high mechanical strength, comparable to that of the vertebrae, comprise on the outer face one or more protruding parts (R, D) suitable for permitting primary and secondary immobilisation of the spacer.

In particular, it is envisaged that each of said plates (Pi, Ps) will comprise at least one protruding part (R), substantially convex in shape, suitable for insertion in cavities provided on the vertebrae for correct positioning of the spacer (O).

25 Said plates (Pi, Ps) comprise furthermore, on said outer faces, one or more teeth (D) suitable for preventing the spacer (O) from subsequently coming

out of the established position.

Said central shock absorbing element (A), positioned between said two plates (Pi, Ps), has a substantially parallelepiped shape, with opposing faces (Ap) substantially flat and lateral surface (Ac) curving inwards. In particular it is envisaged that said lateral wall (Ac) will be concave arcuate or comprising two or more converging faces.

Said central shock absorbing element (A) is connected, at the top and bottom, to said plates (Pi, Ps) as can be seen in figure 5. Said shock absorbing element (A) comprises, at the top and bottom, a protruding perimeter edge (A2) suitable for insertion below the folded-in edge (P1) of said plates (Pi, Ps).

Said rigid spacer element (S) has for example a spherical shape and is inserted in a housing (A1) obtained inside said central shock absorbing element (A).

Said rigid spacer element (S) is furthermore constrained between said plates (Pi, Ps), being housed in concave dome-shaped seats (I), positioned on the surface facing the inside of said plates (Pi, Ps), in a substantially central position and corresponding to said housing (A1) of said shock absorbing element (A).

In the possible embodiment shown in figure 8, the new spacer (O) comprises two opposing and preferably specular plates (Pi, Ps) where said rigid spacer (S) is integral with one of the two plates (Pi, Ps), for example with the upper plate (Ps), and is housed in a seat (I) integral with the opposite plate (Pi).

In this way said plates (Pi, PS) are pivoting with respect to each other, i.e. they can be arranged in a reciprocal non-parallel position.

In the last possible embodiment shown in figure 7, each of said plates (Pi,

Ps) comprises a substantially central seat or hole (F) for the insertion of protruding parts (B) of said central shock absorbing body (A), suitable for guaranteeing assembly of the spacer (O).

Therefore with reference to the preceding description and the illustrations,
5 the following claims are made.

CLAIMS

1. Intervertebral spacer (O) suitable for insertion between two vertebrae, characterised in that it comprises:

- at least two opposing plates (Pi, Ps) in turn comprising, on their outer faces in contact with said vertebrae, one or more protruding parts (R, D);
- at least one shock absorbing element (A) positioned and constrained between said plates (Pi, Ps);
- at least one rigid spacer element (S) positioned and constrained between said plates (Pi, Ps)

and wherein said rigid spacer element (S) permits small relative movements between said plates (Pi, Ps), while said shock absorbing element (A) counters said movements, both acting, wholly or partly, also as a support for said relative movements between the plates (Pi, Ps).

2. Intervertebral spacer (O), according to claim 1, characterised in that one or both of said plates (Pi, Ps) comprise a perimeter edge (P1) partially or totally folded inwards, below which the perimeter edge (A2) of said shock absorbing element (A) is inserted, suitable for guaranteeing the connection between the edge (A2) of said shock absorbing element (A) and the edges (P1) of one or both of said plates (Pi, Ps).

3. Intervertebral spacer (O), according to claim 1, characterised in that said central shock absorbing element (A) has a substantially parallelepiped shape with side wall (Ac) curving inwards.

4. Intervertebral spacer (O), according to claim 1, characterised in that said rigid spacer element (S) is inserted in a housing (A1) obtained in said central shock absorbing element (A) in a substantially central position.

5. Intervertebral spacer (O), according to the preceding claim,

characterised in that said rigid spacer element (S) is housed in at least one seat (I) obtained in a corresponding position on the inner face of one or both of said plates (Pi, Ps).

5 6. Intervertebral spacer (O), according to the preceding claims, characterised in that said spacer element (S) has a substantially spherical shape.

10 7. Intervertebral spacer (O), according to claim 1, characterised in that said rigid spacer element (S) is integral with one of said plates (Pi)/(Ps) and is housed in a seat (I) obtained in a corresponding position on the inner face of the opposite plate (Ps)/(Pi).

15 8. Intervertebral spacer (O), according to claim 1, characterised in that one or both of said plates (Pi, Ps) comprise one or more seats or holes (F) for the insertion of protruding parts (B) of said central shock absorbing element (A) suitable for guaranteeing the connection between said shock absorbing element (A) and one or both of said plates (Pi, Ps).

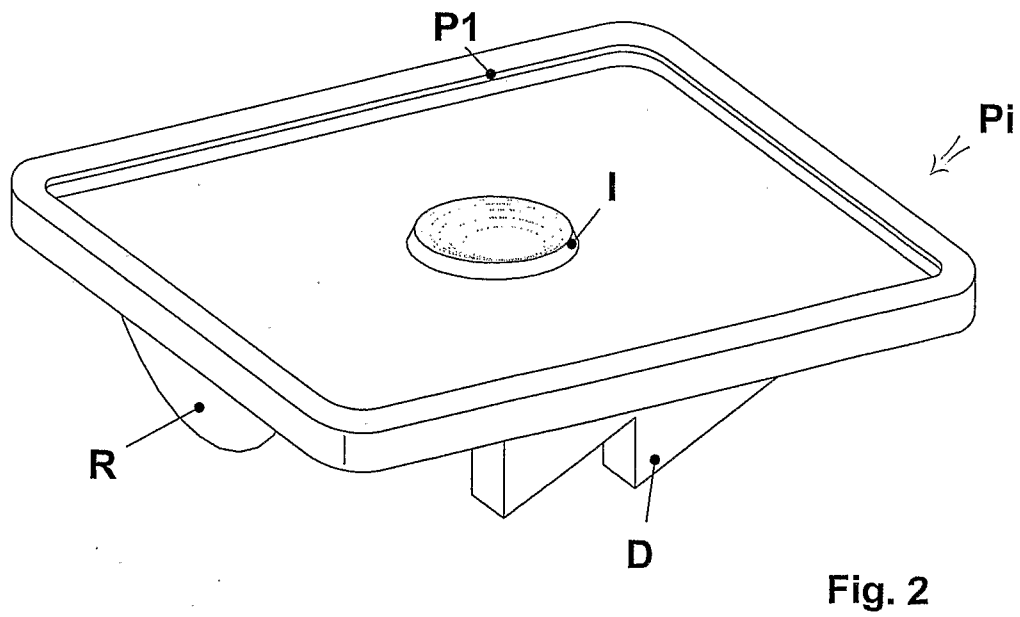
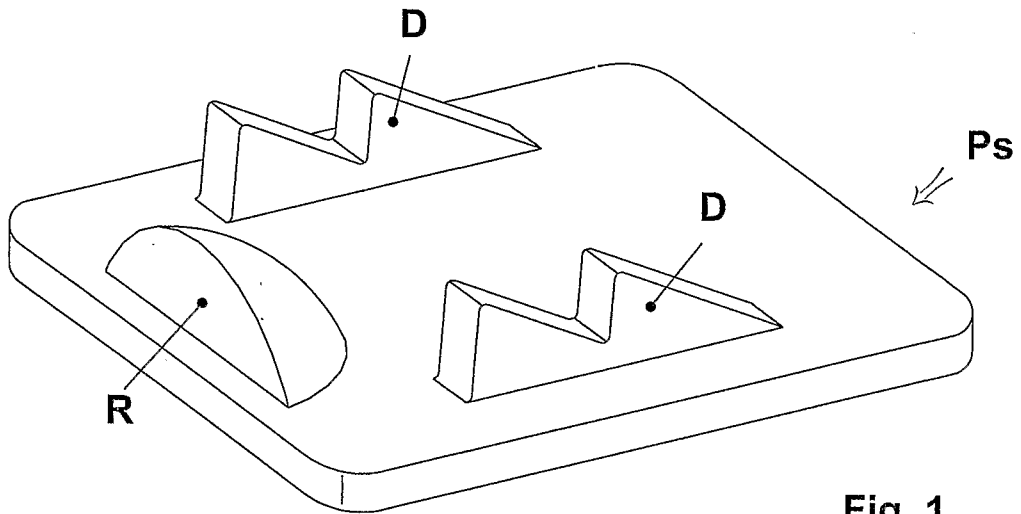
9. Intervertebral spacer (O), according to claim 1, characterised in that one or both of said plates (Pi, Ps) and/or said central shock absorbing element (A) comprises one or more holes or ducts for passage of the cells.

20 10. Intervertebral spacer (O), according to claim 1, characterised in that at least one of said protruding parts (R) has a substantially convex and at least partially rounded shape.

11. Intervertebral spacer (O), according to claim 1, characterised in that one or more of said protruding parts (D) are substantially triangular teeth.

25 12. Intervertebral spacer (O), according to the preceding claims, characterised in that it is made wholly or partly of one of the following materials or in a combination of the same: hydroxylapatite mixed with plasma and gelatins of various origins and growth factors, ceramic bioglass

suitable for bone fusion mixed with gelatins of various origins and growth factors, metal implantology products, titanium, steel, ceramic materials, elastic medical plastic silicone materials, synthetic and natural polymers, tissues, resins, polyethylene and/or other materials suitable for stimulating
5 bone and/or cartilage fusion and acting also wholly or partly as spacers and/or shock absorbers with the possibility of pivoting.



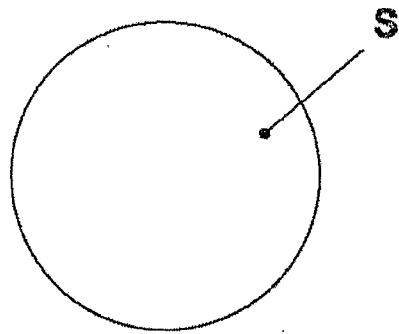


Fig. 3

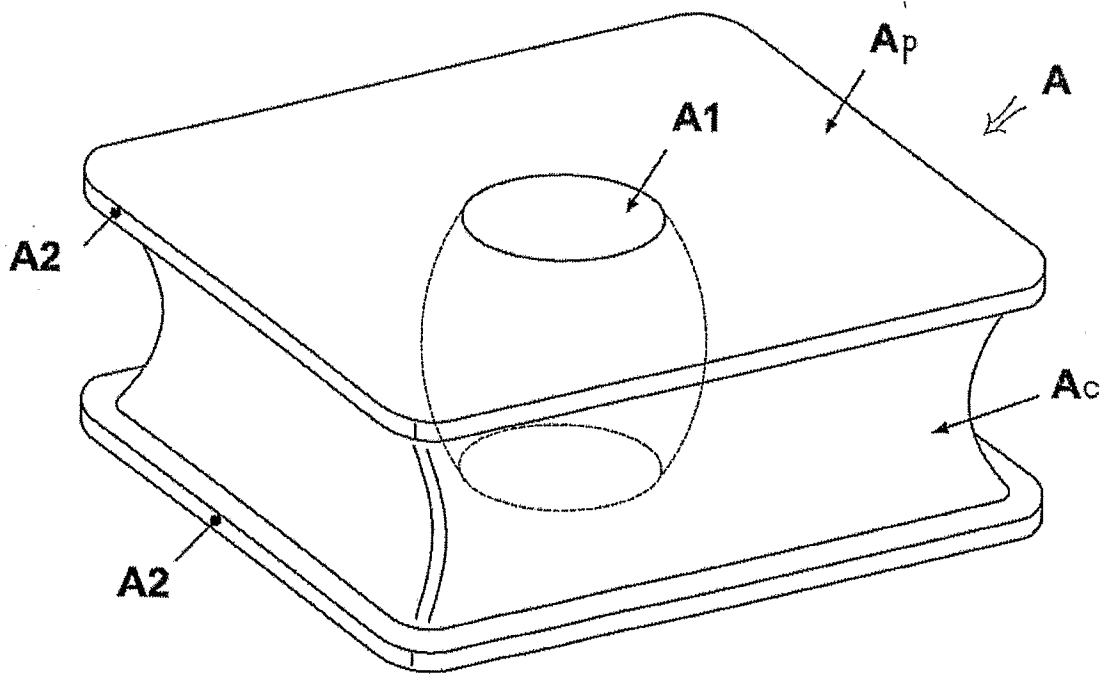
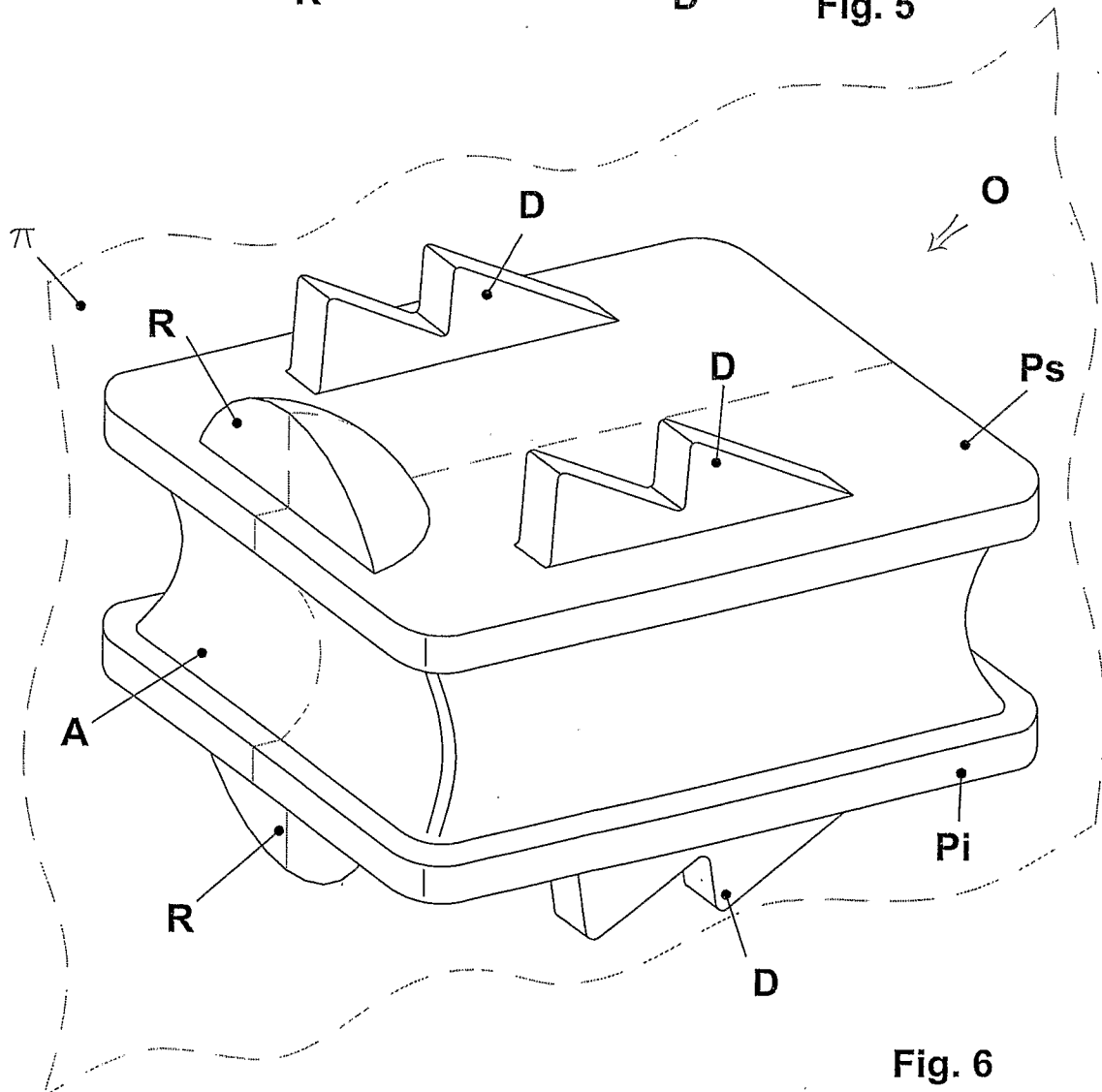
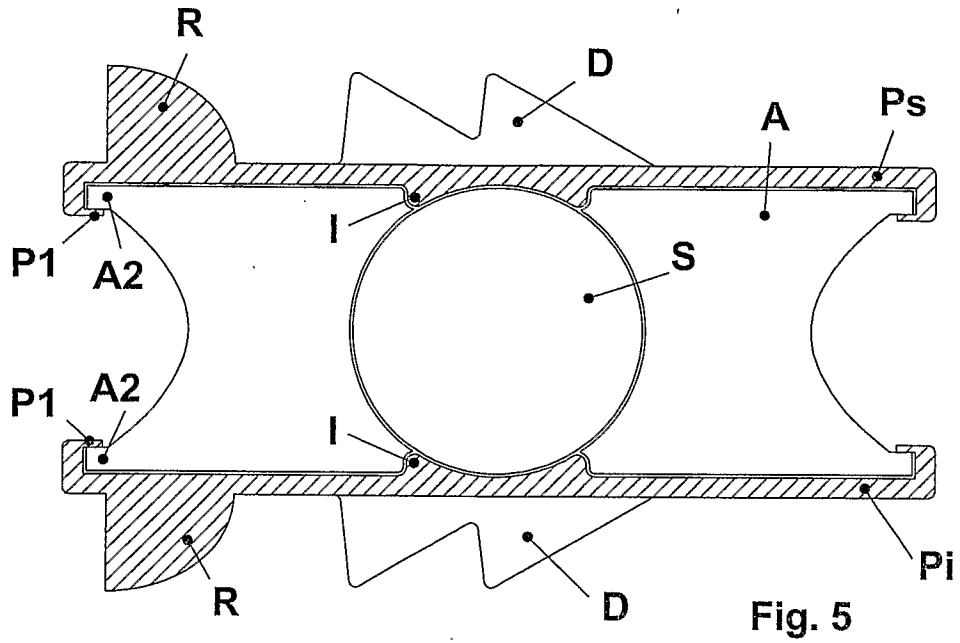


Fig. 4



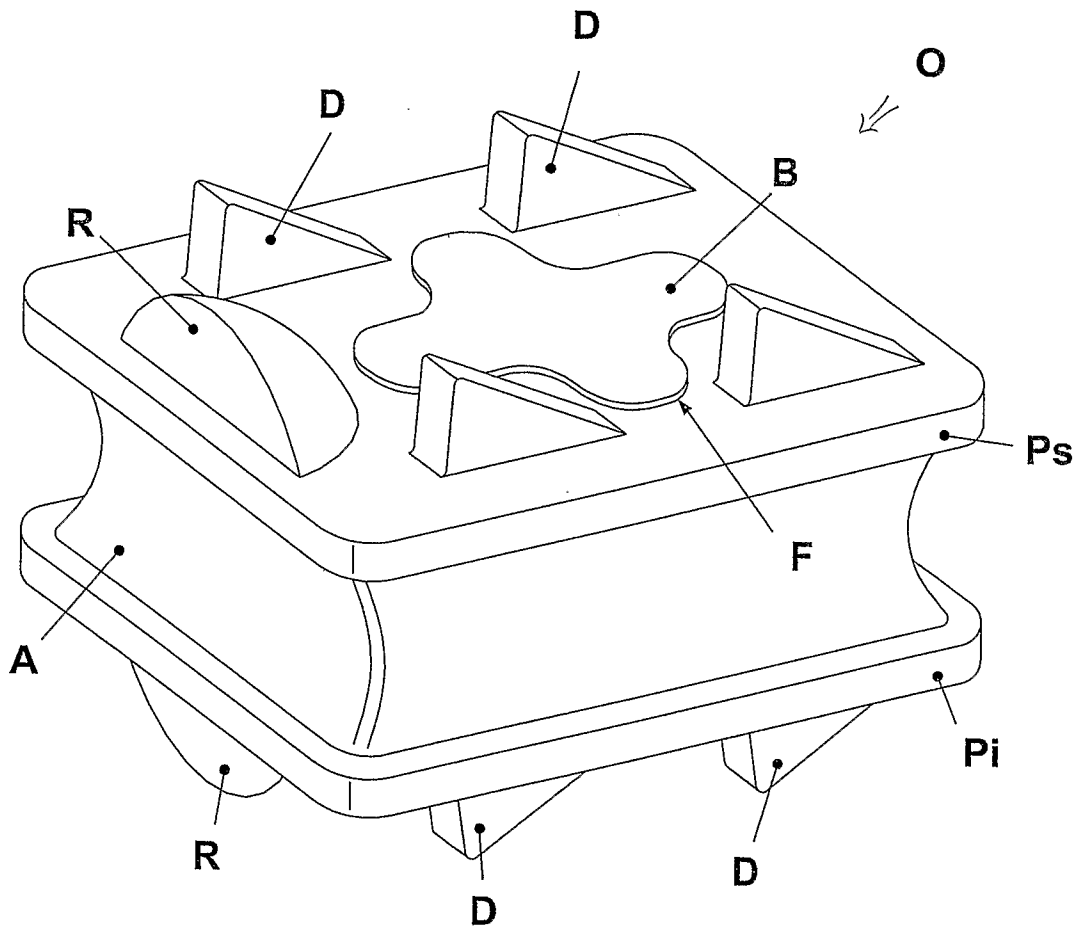


Fig. 7

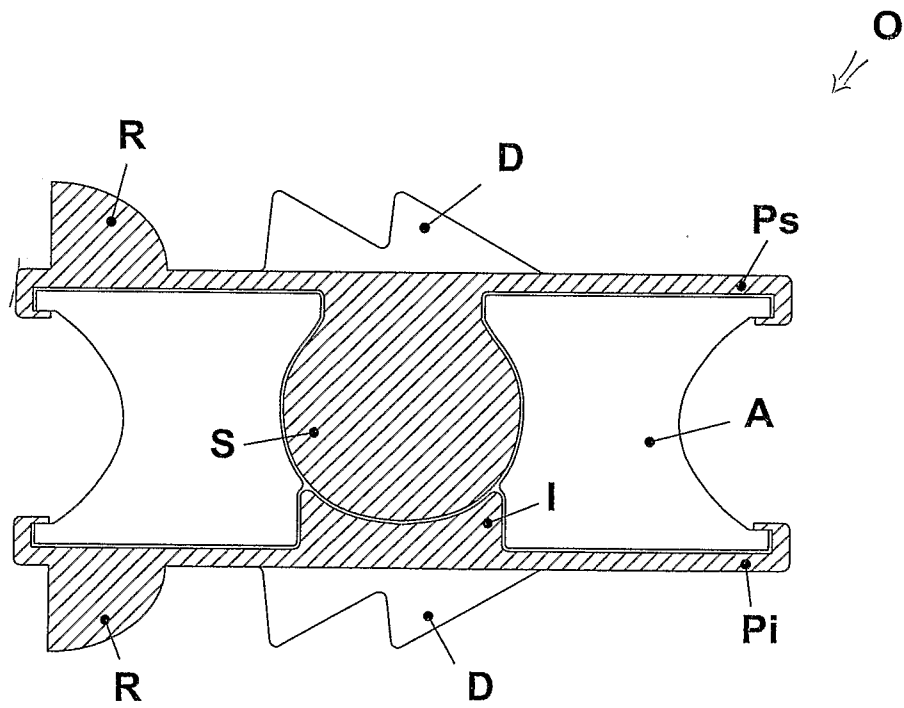


Fig. 8

INTERNATIONAL SEARCH REPORT

International application No
PCT/IT2006/000542

A. CLASSIFICATION OF SUBJECT MATTER
INV. 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)
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	US 2005/203626 A1 (SEARS WILLIAM [AU] ET AL) 15 September 2005 (2005-09-15) figures 3a-7,12,13,20-22,27-33 paragraphs [0017] - [0025], [0032], [0039], [0041]	1-5,7-9,12
X	WO 2005/037028 A (SDGI HOLDINGS INC [US]; EISERMANN LUKAS [US]) 28 April 2005 (2005-04-28) figures 1a-8 page 4, line 3 - page 6, line 17	1,4-6,8-10
X	WO 94/04100 A (SOFAMOR [FR]; MAZDA KEYVAN [FR]) 3 March 1994 (1994-03-03) claims 1,2,6,7,11,12; figures	1,4,5,7,10-12

Further documents are listed in the continuation of Box C.

See patent family 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.
- *Z* document member of the same patent family

Date of the actual completion of the international search

29 March 2007

Date of mailing of the international search report

05/04/2007

Name and mailing address of the ISA/

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

Authorized officer

Stach, Rainer

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IT2006/000542

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2005203626 A1	15-09-2005	AU 2005222651 A1	29-09-2005
		CA 2560064 A1	29-09-2005
		EP 1740131 A1	10-01-2007
		WO 2005089680 A1	29-09-2005
WO 2005037028 A	28-04-2005	AU 2004281785 A1	28-04-2005
		CA 2542144 A1	28-04-2005
		CN 1867303 A	22-11-2006
		EP 1691730 A2	23-08-2006
		KR 20060118485 A	23-11-2006
		US 2005085909 A1	21-04-2005
WO 9404100 A	03-03-1994	AU 4964593 A	15-03-1994
		CN 1090485 A	10-08-1994
		FR 2694882 A1	25-02-1994
		MX 9305071 A1	29-04-1994
		TR 26927 A	24-08-1994
		ZA 9306156 A	19-09-1994