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(71) Applicant (for all designated States except US):
SPINE21 LTD. [IL/IL]; PO Box 15054, Matam, Bldg.
No. 30, 31905 Haifa (IL).

(71) Applicant (for GM only): KLEIN, David [US/IL]; Beit
HaRo'fim, 18 Menuha VeNahala Street, Room 27, 76209
Rehovot (IL).

(72) Inventor; and

(75) Inventor/Applicant (for US only): ARNIN, Uri [IL/IL];
1 Ha'amelim Street, 36089 Kiryat Tivon (IL).

(74) Agent: KLEIN, David; Beit HaRo'fim, 18 Menuha Ve-
Nahala Street, Room 27, 76209 Rehovot (IL).

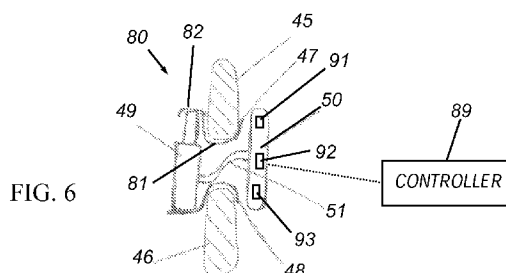
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(54) Title: PROGRAMMABLE FLUID ACTUATED SPINAL IMPLANT HAVING A POST-OPERATIVE ADJUSTABLE DI-
MENSION



(57) Abstract: A spinal implant including first spinal attachment member (47) for attaching to a first spinal portion (45), second spinal attachment member (48) for attaching to a second spinal portion (46), and a fluid actuated (hydraulic or pneumatic) post-implantation variable dimension device (49) disposed between the first and second spinal attachment members (47,48), which is operable after completing surgery in which said spinal implant was installed into a patient, to cause relative movement between the first and second spinal attachment members.

PROGRAMABLE FLUID ACTUATED SPINAL IMPLANT HAVING A POST-
OPERATIVE ADJUSTABLE DIMENSION
FIELD OF THE INVENTION

The present invention relates generally to spinal implants and prostheses, and particularly to a spinal implant having a post-operative adjustable dimension.

BACKGROUND OF THE INVENTION

Spinal stenosis, as well as spondylosis, spondylolisthesis, osteoarthritis, scoliosis and other degenerative phenomena may be the cause of back pain, and may be caused by a narrowing of the spinal canal or foramina that result in stress acting on the spinal cord and/or nerve roots.

One of the methods for resolving back pain involves decompression, the removal of bony elements causing the pain, and fusion of two or more adjacent vertebrae. Unfortunately, fusion tends to have significant shortcoming and may cause the problem to migrate to adjacent vertebral components. Among the non-fusion solutions are disc replacement, dynamic stabilization systems and inter-spinous process implants.

Spinal implants with the capability of height adjustment are known. For example, US Patents 6045579, 6080193 and 6576016 to Hochshuler et al (issued April 4, 2000, June 27, 2000 and June 10, 2003, respectively) describe an adjustable height fusion device for promoting a spinal fusion between neighboring vertebrae. The device is located within the intervertebral disc space and includes a pair of engaging plates for contacting the vertebrae. An alignment device is used to alter the vertical distance between the engaging plates to customize the apparatus to fit a given patient. In one embodiment, the alignment device includes a pair of struts having a predetermined height and extending between the engaging plates from an anterior end to a posterior end of the apparatus. In another embodiment, the alignment device includes a rotatable connector and cam pins for adjusting the distance between the engaging plates. The alignment device is preferably adapted to vary the distance between the engaging plates such that the height of the apparatus proximate the anterior end is greater than that proximate the posterior end whereby the natural lordosis of the spine is maintained after the apparatus is installed.

However, these prior art devices must be adjusted prior to or during the installation and are not capable of post-operative adjustment.

SUMMARY OF THE INVENTION

The present invention seeks to provide an improved spinal implant (or prosthesis, the terms being used interchangeably) having a post-operative adjustable dimension,

fluid-activated (e.g., hydraulically or pneumatically) using an implanted pump, as described in more detail further below.

In one embodiment, at least one of its dimensions of the spinal implant can be modified post-implantation by means of remote control. The adjustable portion (also referred to as a variable dimension mechanism) can have a piston-like configuration hydraulically or pneumatically activated by a small implanted pump. The pump can be electrically powered, such as by an electric motor (powered by a battery or remote induction), and controlled via remote control.

The prosthesis is configured to bridge between two vertebrae, most preferably but not limited to, adjacent vertebrae. The prosthesis includes a plurality of attachment members (end features) configured to be attached to a plurality of bone attachment points, such as but not limited to, spinous process, vertebral end plates or pedicles (via pedicle screws).

There is thus provided in accordance with a non-limiting embodiment of the present invention a spinal implant including first spinal attachment member for attaching to a first spinal portion, second spinal attachment member for attaching to a second spinal portion, and a fluid actuated (hydraulic or pneumatic) post-implantation variable dimension device disposed between the first and second spinal attachment members, which is operable after completing surgery in which said spinal implant was installed into a patient, to cause relative movement between the first and second spinal attachment members.

In accordance with an embodiment of the present invention the first and second spinal attachment members include pedicle screws.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be understood and appreciated more fully from the following detailed description, taken in conjunction with the drawings in which:

Fig. 1 is a simplified pictorial illustration of a spinal implant including a post-implantation variable dimension device, constructed and operative in accordance with an embodiment of the invention, implanted between two adjacent spinous processes;

Fig. 2 is a simplified pictorial illustration of a spinal implant including a post-implantation variable dimension device, constructed and operative in accordance with another embodiment of the invention, connected to pedicle screws so that actuating the variable dimension mechanism can change the distance between the screws;

Fig. 3 is a simplified pictorial illustration of a spinal implant including a post-implantation variable dimension device, constructed and operative in accordance with yet another embodiment of the invention, inserted in between two adjacent vertebrae;

Fig. 4 is a simplified pictorial illustration of a fluid-operated (hydraulically or pneumatically operated) post-implantation variable dimension device, constructed and operative in accordance with an embodiment of the invention;

Fig. 5 is a simplified pictorial illustration of a fluid-operated (hydraulically or pneumatically operated) post-implantation variable dimension device, constructed and operative in accordance with another embodiment of the invention; and

Fig. 6 is a simplified pictorial illustration of a fluid-operated (hydraulically or pneumatically operated) post-implantation variable dimension device, constructed and operative in accordance with yet another embodiment of the invention.

DETAILED DESCRIPTION OF EMBODIMENTS

Reference is now made to Fig. 1, which illustrates a spinal implant 10, constructed and operative in accordance with an embodiment of the invention.

Spinal implant 10 is shown implanted between two adjacent spinous processes of the lumbar spine (in this example, spinal implant 10 is an interspinous process device). Spinal implant 10 includes a post-implantation variable dimension device 12 disposed between a first (upper) support end plate (spinal attachment member) 14 and a second (lower) support end plate (spinal attachment member) 16. The post-implantation variable dimension device 12 may include a post arranged for linear motion (slightly tilted from vertical in the sense of the drawing), such as by means of a miniature linear actuator which is remote controlled. In general, post-implantation variable dimension device 12 may be constructed in accordance with any of the embodiments described below with reference to Figs. 4-6.

Reference is now made to Fig. 2, which illustrates a spinal implant 20, constructed and operative in accordance with another embodiment of the invention. Spinal implant 20 includes a post-implantation variable dimension device 22, and is connected to pedicle screws 24 (spinal attachment members 24). Actuation of variable dimension device 22 changes the distance between screws 24. Here too, post-implantation variable dimension device 22 may include a post arranged for linear motion, such as by means of a miniature linear actuator which is remote controlled. In general, post-implantation variable dimension device 22 may be constructed in accordance with any of the embodiments described below with reference to Figs. 4-6.

Reference is now made to Fig. 3, which illustrates a spinal implant 30 including a post-implantation variable dimension device 32, constructed and operative in accordance with yet another embodiment of the invention, inserted in between two adjacent vertebrae (e.g., L4 and L5). Spinal implant 30 includes a first (upper) support plate 34 connected to and supporting an upper vertebra, and a second (lower) support plate 36 connected to and supporting a lower vertebra. The variable dimension device 32 is installed between first and second support plates (spinal attachment members) 34 and 36. Actuation of variable dimension device 32 changes the distance between first and second support plates 34 and 36, and can change the location between the two adjacent vertebrae both in the vertical and the sagittal planes. In general, post-implantation variable dimension device 32 may be constructed in accordance with any of the embodiments described below with reference to Figs. 4-6.

Reference is now made to Fig. 4, which illustrates a fluid-operated (hydraulically or pneumatically operated) post-implantation variable dimension device 60, constructed and operative in accordance with an embodiment of the invention. Variable dimension device 60 includes two end plates (spinal attachment members) 61 and 62, both attached to a piston 63. Piston 63 is fluidly actuated (that is, either hydraulically or pneumatically), such as by means of compressed liquid (e.g., water) or gas (e.g., air). The compressed fluid is introduced to piston 63 by means of a tube 64 which is connected to a fluid inlet 65.

Reference is now made to Fig. 5, which illustrates a fluid-operated (hydraulically or pneumatically operated) post-implantation variable dimension device 70, constructed and operative in accordance with another embodiment of the invention. Device 70 includes a piston 41 located between two spinal elements 37 and 38 supported by two attachment members 39 and 40. In contrast with the flat plates 61 and 62 of the embodiment of Fig. 4, in this embodiment, attachment members 39 and 40 have a curved cross-sectional shape (e.g., U-shaped, half-circle, half-ellipse, etc.). A pump unit 42, which may contain an internal or external fluid reservoir, is connected to piston 41 via a tube 43. In contrast with the embodiment of Fig. 4, the pump unit 42 is implanted in the body as well.

Reference is now made to Fig. 6, which illustrates a fluid-operated (hydraulically or pneumatically operated) post-implantation variable dimension device 80, constructed and operative in accordance with yet another embodiment of the invention. Device 80 includes a piston 49 located between two spinal elements 45 and 46 supported by two

attachment members 47 and 48. In contrast with the previous embodiments, in this embodiment, piston 49 is not located between the spinal elements 45 and 46; instead it is located adjacent spinal elements 45 and 46. An implanted pump unit 50, which may contain an internal or external fluid reservoir, is connected to piston 49 via a tube 51. The pump unit 50 and the piston 49 may straddle (and may or may not abut) outer portions of the spinal elements 45 and 46. The attachment members 47 and 48 each include a first portion 81, which contacts the spinal elements 45 and 46, from which extends a second portion 82 not located between the spinal elements 45 and 46 upon which piston 49 acts to vary the distance between spinal elements 45 and 46.

An external (i.e., external to the patient's body) controller 89, shown in Fig. 6 and applicable for any of the embodiments of the invention, operates the implanted pump units of any of the embodiments of the invention. External controller 89 may include a control panel, a processor, an RF transmitter/emitter, a magnetic power source, an electric coil, a cellular communication device and any combination thereof. (Accordingly, the pump may be actuated electronically, magnetically, by RF signals, etc.) The communication between the external control portion and the implanted pump may be controlled by a code or password to protect against undesired operation of the internal device.

As seen in Fig. 6 (again applicable for any of the embodiments of the invention), the implanted pump unit 50 may include a microprocessor 91, transceiver 92, and/or battery 93 built into the unit. The microprocessor 91 may be used to process instructions or any other kind of information sent to pump unit 50 by the external controller 89 or received therefrom via the transceiver 92.

It will be appreciated by persons skilled in the art that the present invention is not limited by what has been particularly shown and described hereinabove. Rather the scope of the present invention includes both combinations and subcombinations of the features described hereinabove as well as modifications and variations thereof which would occur to a person of skill in the art upon reading the foregoing description and which are not in the prior art.

CLAIMS

What is claimed is:

1. A spinal implant comprising:
 - a first spinal attachment member (39, 47) for attaching to a first spinal element (37, 45);
 - a second spinal attachment member (40, 48) for attaching to a second spinal portion (38, 46); and
 - a post-implantation variable dimension device (70, 80) disposed between said first and second spinal attachment members (39, 47, 40, 48), which is operable after completing surgery in which said spinal implant was installed into a patient, to cause relative movement between said first and second spinal attachment members (39, 47, 40, 48);characterized in that said post-implantation variable dimension device (70, 80) comprises a fluid-operated piston (41, 49) in fluid communication with an implanted pump unit (42, 50) via a tube (43, 51), said implanted pump unit (42, 50) being remotely controlled by an external controller (89) external to the patient's body.
2. The spinal implant according to claim 1, wherein said first and second spinal attachment members (39, 47, 40, 48) comprise pedicle screws.
3. The spinal implant according to claim 1, wherein said attachment members (39, 40) have a curved cross-sectional shape.
4. The spinal implant according to claim 1, wherein said attachment members (47, 48) each comprise a first portion, which contacts said spinal elements (45, 46), from which extends a second portion, not located between said spinal elements (45, 46), upon which said piston (49) acts to vary a distance between said spinal elements (45, 46).
5. The spinal implant according to claim 1, wherein said piston (41) is located between the spinal elements (37, 38).
6. The spinal implant according to claim 1, wherein said pump (49) is not located between the spinal elements (45, 46).
7. The spinal implant according to claim 1, wherein said pump unit (50) and said piston (49) straddle outer portions of the spinal elements (45, 46).
8. The spinal implant according to claim 1, wherein said implanted pump unit (42, 50) comprises a microprocessor (91) therein.
9. The spinal implant according to claim 1, wherein said implanted pump unit (42, 50) comprises a transceiver (92) therein.

10. The spinal implant according to claim 1, wherein said implanted pump unit (42, 50) comprises a battery (93) therein.

11. A spinal implant comprising:

a first spinal attachment member (47) for attaching to a first spinal element (45);

a second spinal attachment member (48) for attaching to a second spinal portion (46); and

a post-implantation variable dimension device (80) disposed between said first and second spinal attachment members (47, 48), which is operable after completing surgery in which said spinal implant was installed into a patient, to cause relative movement between said first and second spinal attachment members (47, 48);

characterized in that said post-implantation variable dimension device (80) comprises a fluid-operated piston (49) in fluid communication with an implanted pump unit (50) via a tube (51), said implanted pump unit (50) being remotely controlled by an external controller (89) external to the patient's body, and wherein said piston (49) is not located between the spinal elements (45, 46), and wherein said attachment members (47, 48) each comprise a first portion (81), which contacts the spinal elements (45, 46), from which extends a second portion (82) not located between the spinal elements (45, 46) upon which said piston (49) acts to vary a distance between the spinal elements (45, 46).

12. The spinal implant according to claim 11, wherein said pump unit (50) and said piston (49) straddle outer portions of the spinal elements (45, 46).

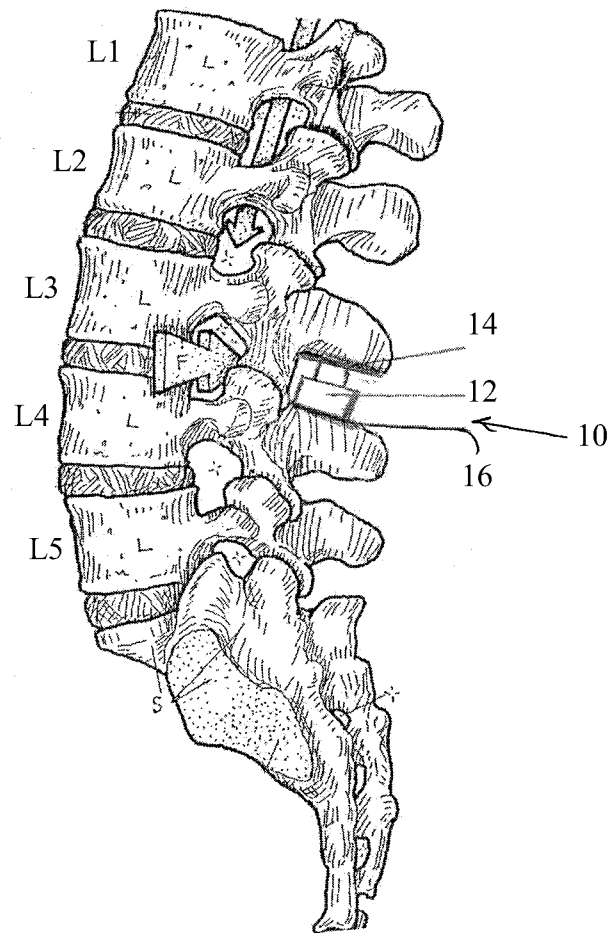


FIG. 1

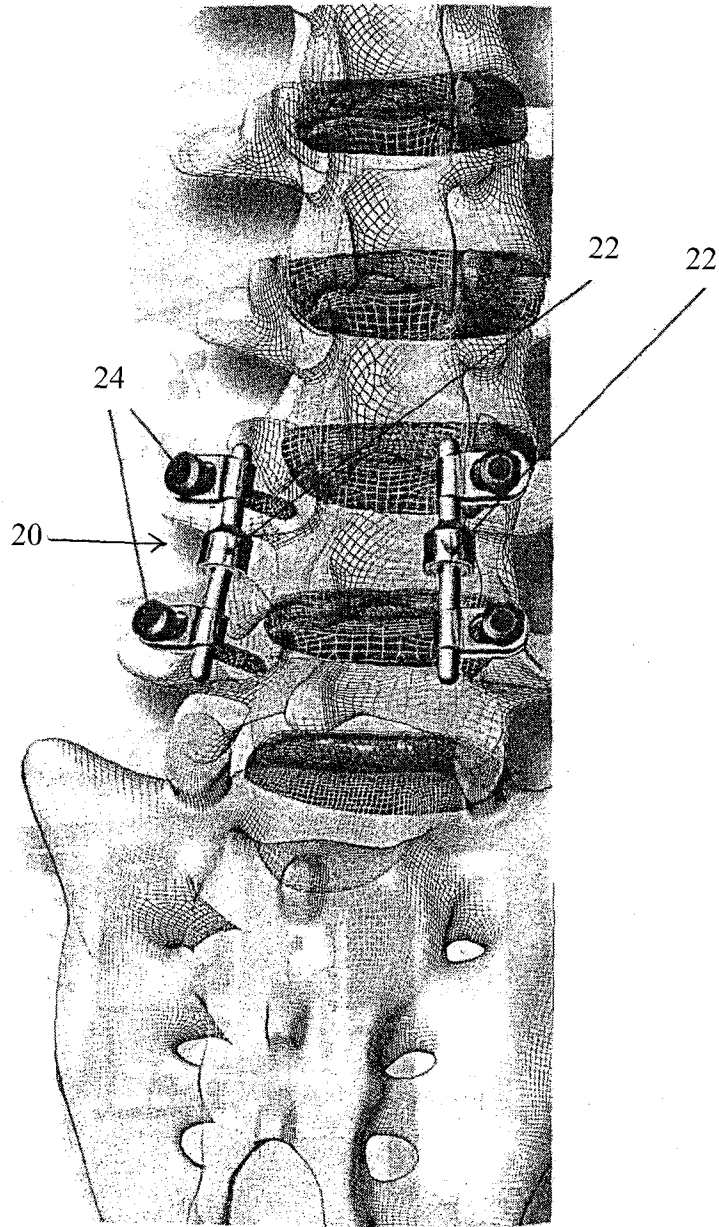


FIG. 2

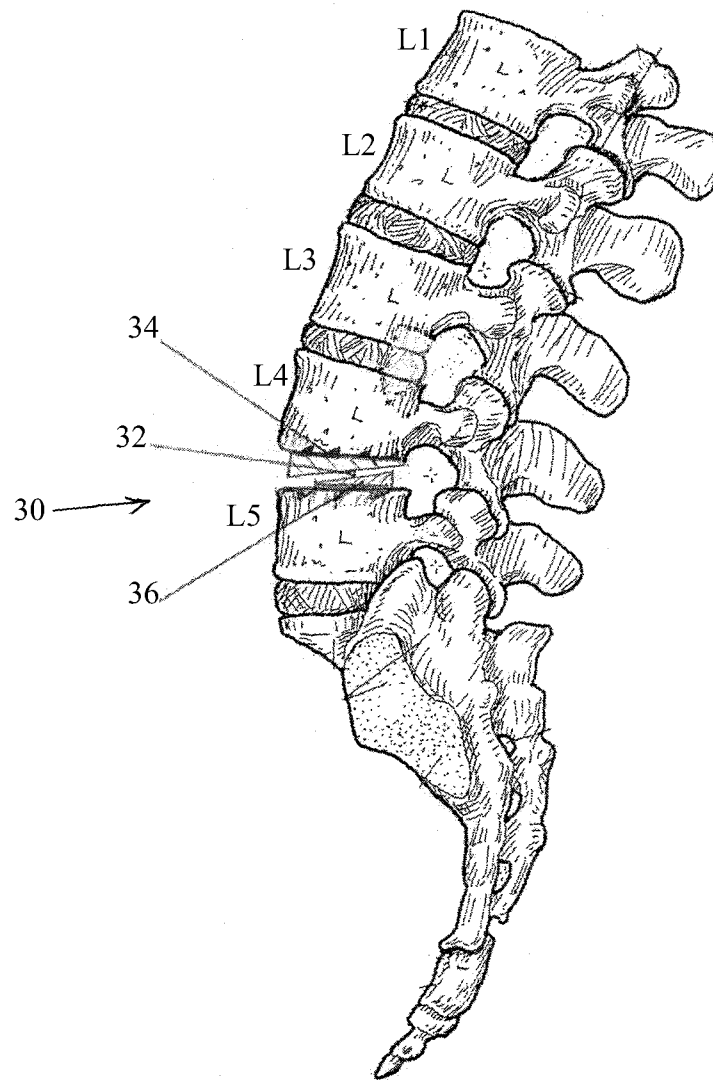


FIG. 3

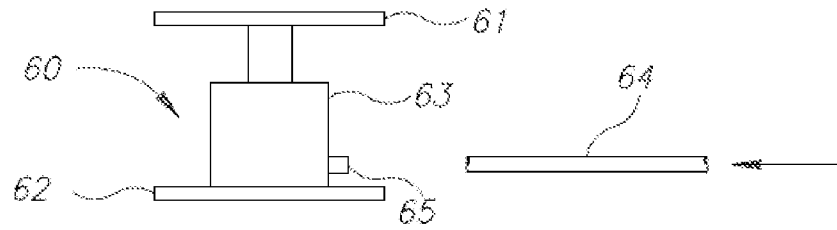


FIG. 4

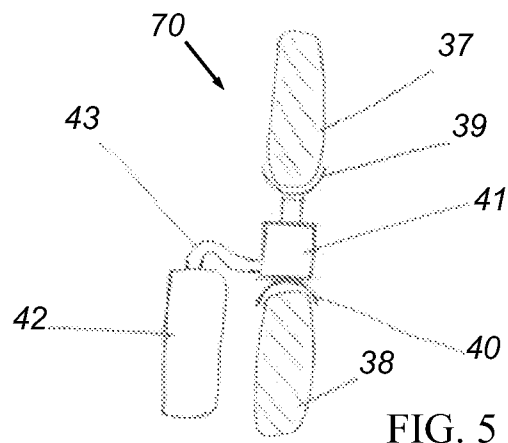


FIG. 5

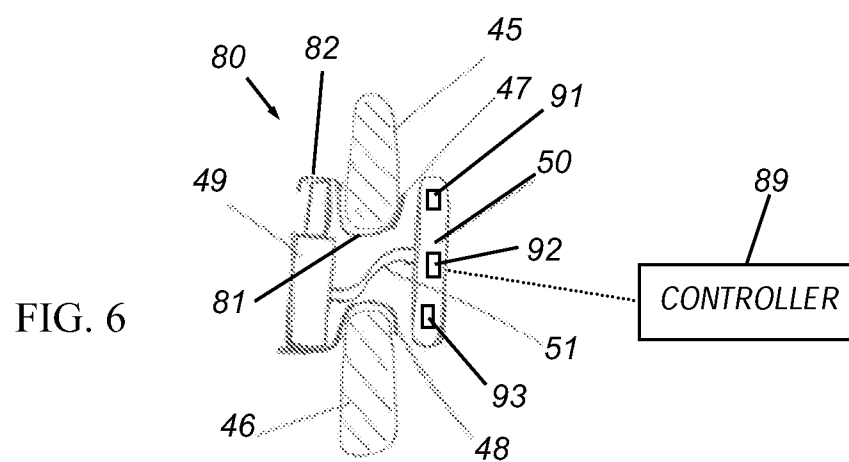


FIG. 6

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2010/036804

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/44
ADD.

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 A61B

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, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2007/276369 A1 (ALLARD RANDALL N ET AL) 29 November 2007 (2007-11-29) paragraphs [0022] - [0050], [0098] - [0116]; claims; figures 5-6,14	1-12
A	US 2002/151978 A1 (ZACOUTO FRED [FR] ET AL) 17 October 2002 (2002-10-17) paragraphs [0259], [0304] - [0331], [0344] - [0415]; claims; figures 13,23-32,40-64	1-12
A	US 2007/173855 A1 (WINN BRAD ET AL) 26 July 2007 (2007-07-26) paragraphs [0004], [0012] - [0034]; claims; figures ----- -/--	1-12

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

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

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"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

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Date of the actual completion of the international search

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Name and mailing address of the ISA/
European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Kühne, H

INTERNATIONAL SEARCH REPORT

International application No
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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2007/250045 A1 (TRIEU HAI H) 25 October 2007 (2007-10-25) paragraphs [0057] - [0079], [0089] - [0103]; claims; figures 8,25-32 -----	1-12
A	US 2007/276337 A1 (TRIEU HAI H) 29 November 2007 (2007-11-29) paragraphs [0056] - [0066], [0086] - [0099]; claims; figures 6,24-28 -----	1-12
A	US 2009/093890 A1 (GELBART DANIEL) 9 April 2009 (2009-04-09) paragraphs [0004] - [0018]; claims; figures -----	1-12

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

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