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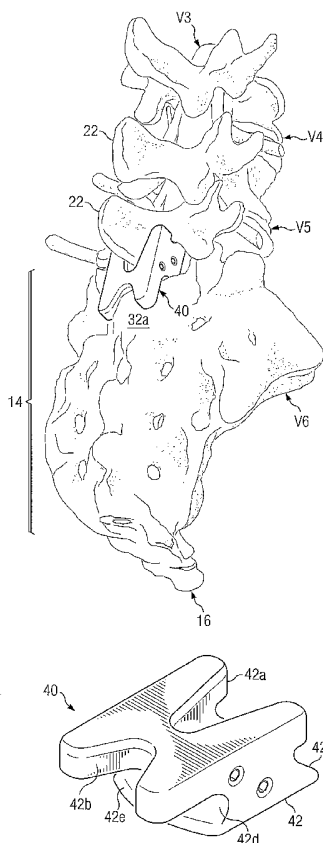
Declarations under Rule 4.17:

— as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))

[Continued on next page]

(54) Title: INTERVERTEBRAL DEVICE FOR SPINAL STABILIZATION AND METHOD IMPLANTING SAME

(57) Abstract: An intervertebral prosthetic device for spinal stabilization and a method of using same according to which a body member is implanted between two adjacent vertebrae so that a spinous process of a vertebra extends into a notch formed in the body member. A groove is also formed in the body member that engages one of the vertebrae. The device is particularly adapted to give support between the sacrum (V6, 14) and the lowest lumbar vertebra (V5).



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— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

Published:

— *with international search report*

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.

INTERVERTEBRAL DEVICE FOR SPINAL STABILIZATION AND METHOD IMPLANTING SAME

Background

The present invention relates to an intervertebral prosthetic device for stabilizing the human spine, and a method of implanting same.

Spinal discs that extend between adjacent vertebrae in vertebral columns of the human body provide critical support between the adjacent vertebrae. These discs can rupture, degenerate, and/or protrude by injury, degradation, disease, or the like, to such a degree that the intervertebral space between adjacent vertebrae collapses as the disc loses at least a part of its support function, which can cause impingement of the nerve roots and severe pain.

In these cases, intervertebral prosthetic devices have been designed that can be implanted between the adjacent vertebrae, both anterior and posterior of the column, to prevent the collapse of the intervertebral space between the adjacent vertebrae and thus stabilize the spine.

However, many of these devices have less than optimum biomechanics, are relatively difficult to insert, have insufficient strength, and often do not provide an optimum fit with the anatomy.

Summary

Therefore, the intervertebral prosthetic device according to an embodiment of the invention overcomes the above deficiencies by providing improved biomechanics and increased strength, in addition to being relatively easy to insert, yet provides an improved fit with the anatomy.

Various embodiments of the invention may possess one or more of the above features and advantages, or provide one or more solutions to the above problems existing in the prior art.

Brief Description of the Drawings

Fig. 1 is a side elevational view of an adult human vertebral column.

Fig. 2 is a posterior elevational view of the column of Fig. 1.

Fig. 3 is an enlarged, front elevational view of one of the vertebrae of the column of Figs. 1 and 2.

Fig. 4 is an enlarged, partial, isometric view of a portion of the column of Figs. 1 and 2, including the lower three vertebrae of the column, and depicting an intervertebral prosthetic device according to an embodiment of the invention inserted between two adjacent vertebrae.

Fig. 5 is an enlarged, isometric, view of the prosthetic device of Fig. 3.

Fig. 6 is an enlarged, top plan view of the prosthetic device of Fig. 5.

Figs. 7 is a cross-sectional view taken along the line 7-7 of Fig. 6.

Detailed Description

With reference to Figs. 1 and 2, the reference numeral 10 refers, in general, to a human vertebral column 10. The lower portion of the vertebral column 10 is shown and includes the lumbar region 12, the vertebrae V6, and the coccyx 16. The flexible, soft portion of the vertebral column 10, which includes the thoracic region and the cervical region, is not shown.

The lumbar region 12 of the vertebral column 10 includes five vertebrae V1, V2, V3, V4 and V5 separated by intervertebral discs D1, D2, D3, and D4, with the disc D1 extending between the vertebrae V1 and V2, the disc D2 extending between the vertebrae V2 and V3, the disc D3 extending between the vertebrae V3 and V4, and the disc D4 extending between the vertebrae V4 and V5.

The vertebrae V6 includes five fused vertebrae, one of which is a superior vertebrae V6 separated from the vertebrae V5 by a disc D5. The other four fused vertebrae of the sacrum 14 are referred to collectively as V7. A disc D6 separates the vertebrae V6 from the coccyx 16 which includes four fused vertebrae (not referenced).

With reference to Fig. 3, the vertebrae V5 includes two laminae 20a and 20b extending to either side (as viewed in Fig. 2) of a spinous process 22 that extends posteriorly from the juncture of the two laminae. Two transverse processes 24a and 24b extend laterally from the laminae 20a and 20b, respectively. Two articular processes 26a and 26b extend superiorly from the

laminae 20a and 20b, respectively, and two articular processes 28a and 28b extend inferiorly from the laminae 20a and 20b, respectively. The inferior articular processes 28a and 28b rest in the superior articular process of the vertebra V2 to form a facet joint. Since the other vertebrae V1-V4 are similar to the vertebrae V5, they will not be described in detail.

Referring again to Fig. 2, the vertebrae V6 of the sacrum 14 includes two laminae 30a and 30b extending to either side (as viewed in Fig. 2) of a median sacral crest, or spinous process, 32a that extends inferiorly from a ridge 34 and posteriorly from the juncture of the two laminae. The vertebrae V6 also includes a pair of sacral wings 36a and 36b that extend laterally from the laminae 30a and 30b, respectively. Four additional axially-spaced sacral crests, or spinous processes, 32b-32d are associated with the fused vertebrae V7 of the sacrum 14 and extend inferiorly from the spinous process 32a.

Referring to Fig. 4, it will be assumed that, for one or more of the reasons set forth above, the vertebrae V5 and V6 are not being adequately supported by the disc D4 and that it is therefore necessary to provide supplemental support and stabilization of these vertebrae. To this end, an intervertebral disc prosthetic device 40 according to an embodiment of the invention is implanted between the spinous processes 22 of the vertebrae V5 and the crest, or spinous process 32a, of the vertebrae V6.

The device is shown in detail in Figs. 5-7 and includes a solid body member 42 having a generally rectangular cross section in each plane with the exception of several notches and cuts to be described.

In particular, two curved grooves, or notches, 42a and 42b are formed in the upper portions of the respective end portions of the body member, as viewed in the drawings. A laterally extending angled cut, or groove 42c, having a curved cross section, is formed in the underside of the body member 42 below the notch 42a, as viewed in Fig. 5 and 7. Similarly, a laterally extending cut, or groove 42d, also having a curved cross section, is formed in the underside of the body member 42 below the notch 42b. The shape of the cut 42d is such that a tab, or hook, 42e (Fig. 7) is defined on the underside of the body member.

Two laterally extending, through openings 42f are formed through the body member 42 for receiving cables, or the like, to tether the device to the vertebrae V5 and V6 when the device 40 is implanted between the vertebrae V5 and V6 in the position shown in Fig. 4.

Referring to Fig. 4, the device 40 is inserted between the vertebrae V5 and the vertebrae V6 with the spinous process 22 of the vertebrae V5 extending in the notch 42a of the body member 42, and the crest, or spinous process, 32a of the vertebrae V6 extending in the notch 42b of the body member. The groove 42c (Figs. 5 and 7) thus extends superiorly and extends around the corresponding edges of the laminae 30a and 30b (Fig. 2) of the vertebrae V5, and the groove 42d extends inferiorly and fits around the ridge 34 (Fig. 2) of the vertebrae V6, with the tab 42e extending under the latter ridge.

It is understood that the body member 42 can be fabricated from any conventional material or combination of materials. For example, it could have an inner core of a relatively hard material, such as hard rubber or plastic, which is surrounded by a relatively soft material such as silicone, which can be molded around the core.

The device 40 is relatively easy to insert between the vertebrae V5 and V6 in the manner described above, and readily fits the vertebrae. The grooves 42c and 42d, as well as the tab 42e, aid in retaining the device 40 in the implanted position, and the core 42f adds strength to the device 40, while the soft material surrounding the core minimizes damage to the processes 22 and 30a of the vertebrae V5 and V6, respectively.

Variations

It is understood that variations may be made in the foregoing without departing from the invention and examples of some variations are as follows:

Any conventional substance that promotes bone growth, such as HA coating , BMP, or the like, can be incorporated in the body member 42;

The body member 42 may have through holes formed therein to improve integration of the bone growth;

The body member 42 may vary in shape, size, composition, and physical properties;

The number and location of the notches and grooves formed in the body member 42 can vary;

The prosthetic device 40 can be placed between two vertebrae in the vertebral column 10 other than the ones described above;

The body member 42 can be fabricated from materials other than those described above;

Bilateral extrusions, or the like, can be provided on the body member 42 to enable a tethering device to be attached to the component;

The prosthetic device 40 can be implanted between body portions other than vertebrae;

The prosthetic device 40 can be inserted between two vertebrae following a discectomy in which a disc between the adjacent vertebrae is removed, or corpectomy in which at least one vertebrae is removed;

The spatial references made above, such as "under", "over", "between", "flexible, soft", "lower", "top", "bottom", etc. are for the purpose of illustration only and do not limit the specific orientation or location of the structure described above.

The preceding specific embodiments are illustrative of the practice of the invention. It is to be understood, therefore, that other expedients known to those skilled in the art, or disclosed herein, may be employed without departing from the invention or the scope of the appended claims, as detailed above. In the claims, means-plus-function clauses are intended to cover the structures described herein as performing the recited function and not only structural equivalents but also equivalent structures. Thus, although a nail and a screw may not be structural equivalents in that a nail employs a cylindrical surface to secure wooden parts together, whereas a screw employs a helical surface, in the environment of fastening wooden parts a nail and a screw are equivalent structures.

Claims

What is claimed is:

1. A prosthetic device for insertion between two vertebrae of a spine to stabilize the spine, the device comprising;
a body member;
at least one notch formed in the body member for receiving the spinous process of at least one of the vertebrae; and
at least one groove formed in the body member for engaging one of the vertebrae.
2. The device of claim 1 wherein the groove extends around the corresponding edges of the one vertebrae.
3. The device of claim 2 wherein the groove extends around the corresponding edges of the laminae of the one vertebrae.
4. The device of claim 2 wherein the groove extends around the ridge of the one vertebrae.
5. The device of claim 4 wherein the groove defines a tab that extends underneath the ridge.
6. The device of claim 1 wherein there are two grooves that engage the respective vertebrae.
7. The device of claim 6 wherein one of the grooves extends around the corresponding edges of the one vertebrae.

8. The device of claim 7 wherein the one groove extends around the corresponding edges of the laminae of the one vertebrae.
9. The device of claim 7 wherein the other groove extends around the ridge of the other vertebrae.
10. The device of claim 9 wherein the other groove defines a tab that extends underneath the ridge.
11. The device of claim 1 wherein two notches are provided at the respective ends of the body member to receive the spinous processes from the two vertebrae, respectively.
12. The device of claim 11 wherein two grooves are provided that are also formed at the respective ends of the body member.
13. The device of claim 12 wherein the notches are formed on the upper side of the body member and the grooves are formed on the lower side of the body member.
14. The device of claim 1 wherein the at least one notch extends longitudinally relative to the body member and the at least one groove extends laterally relative to the body member.
15. A method of implanting a prosthetic device between two vertebrae of a spine to stabilize the spine, the method comprising:
 - positioning the device so that the spinous process of at least one of the vertebrae extends into a notch formed in the device; and
 - positioning the device relative to the ridge of the one of the vertebrae so that a portion of the device extends underneath the ridge.

16. The method of claim 15 further comprising forming a groove in the device to define a tab that extends underneath the ridge.

17. The method of claim 16 wherein the groove extends around the ridge.

18. The method of claim 16 further comprising forming another groove in the device that extends around the corresponding edge of the other vertebrae.

19. The method of claim 1 wherein two notches are provided at the respective ends of the device to receive the spinous processes from the two vertebrae, respectively.

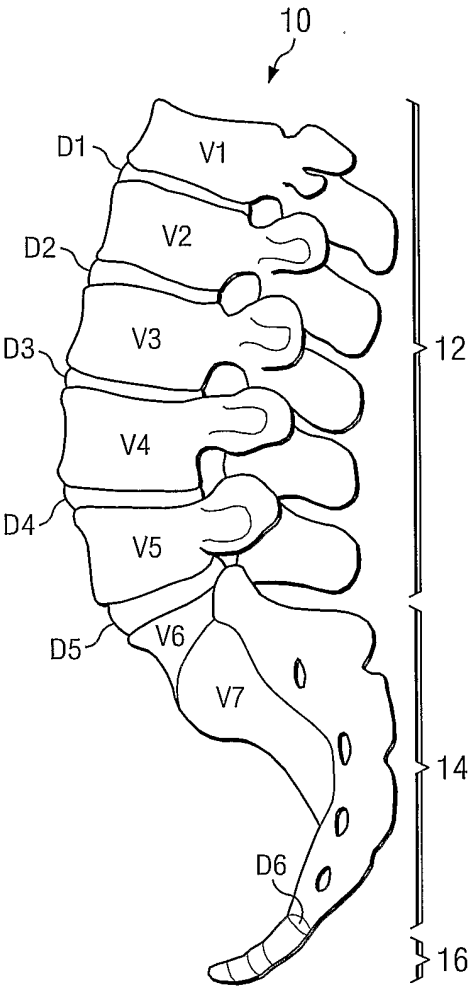


FIG. 1

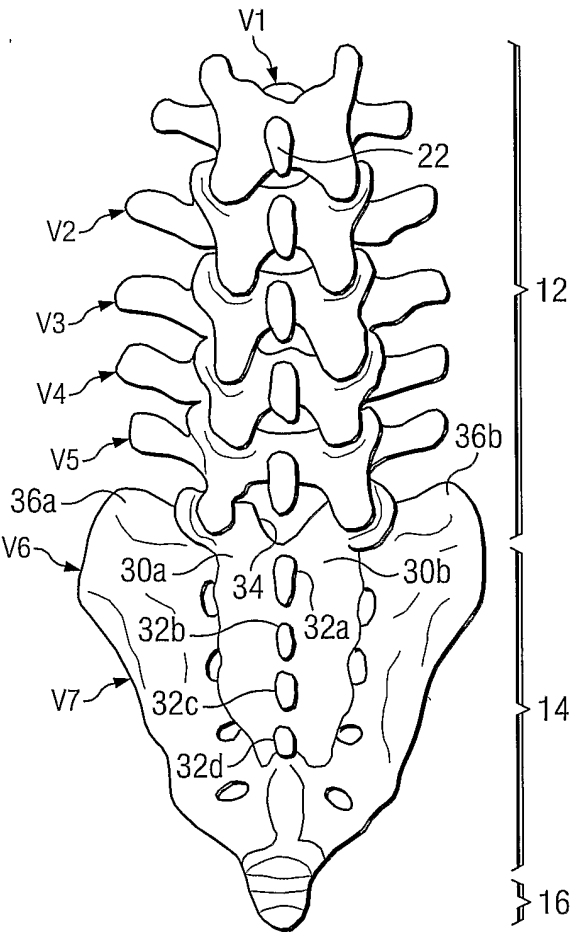


FIG. 2

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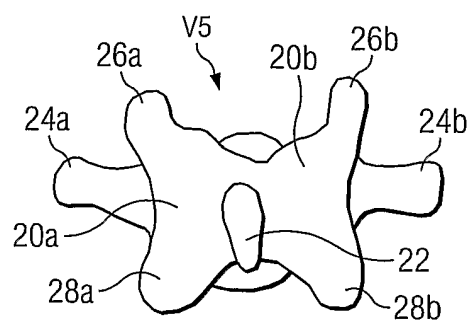


FIG. 3

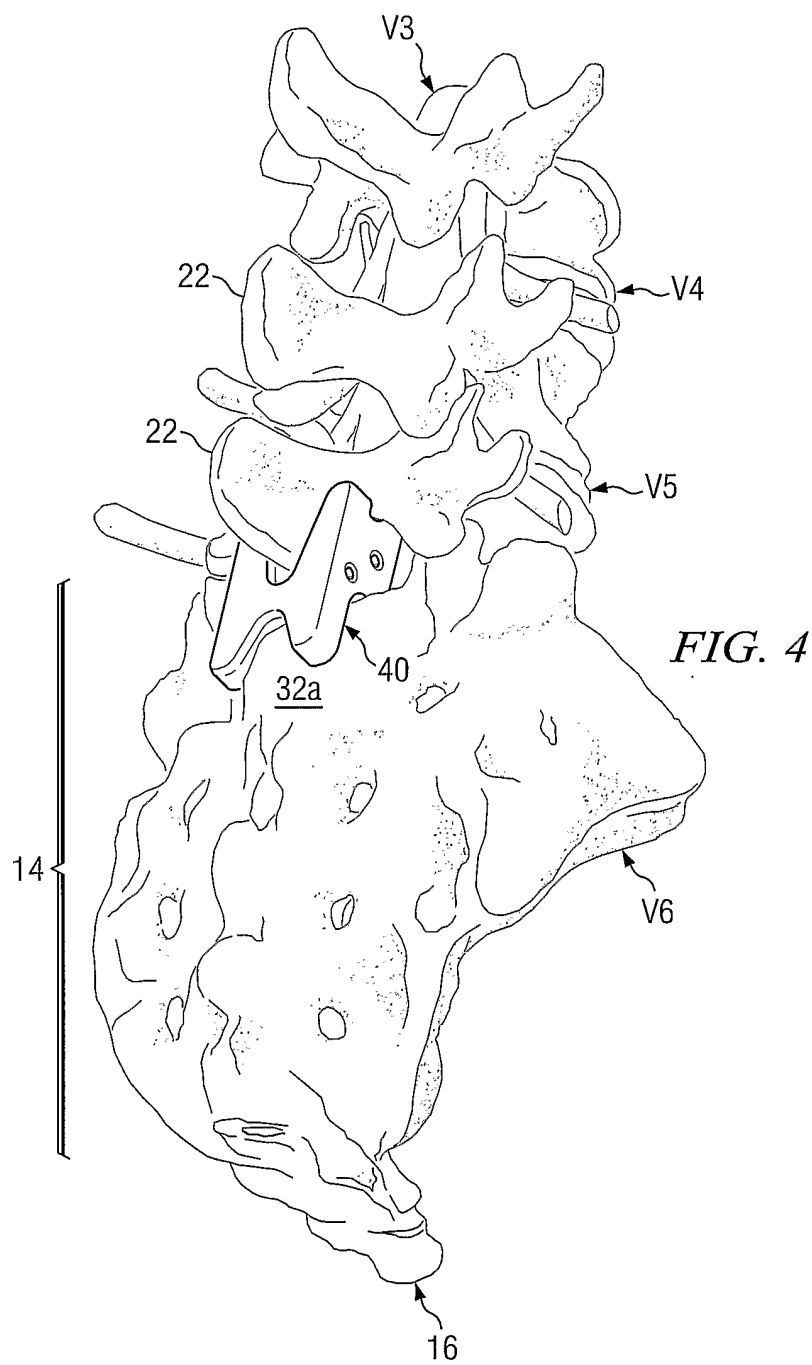


FIG. 4

FIG. 5

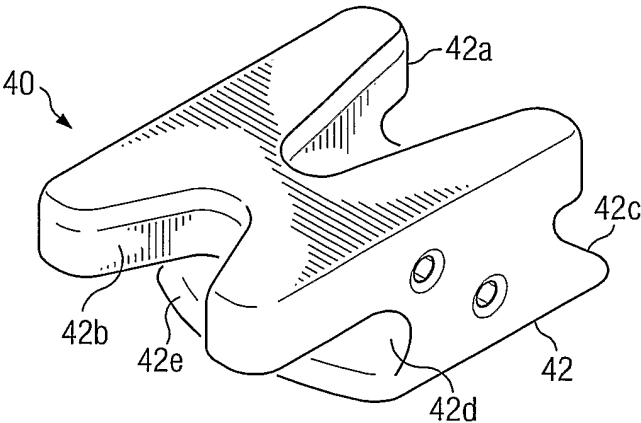


FIG. 6

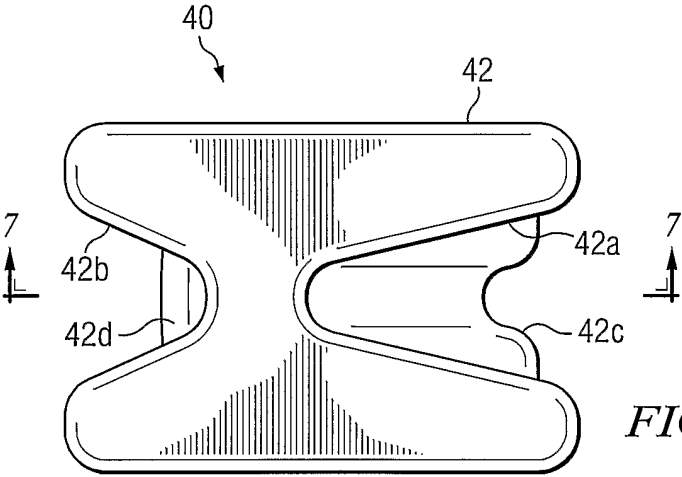
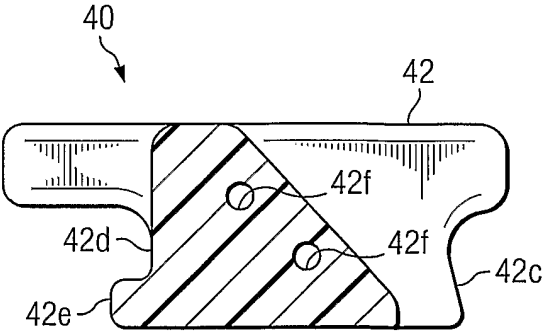


FIG. 7



INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/009173

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/70

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)
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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR 2 858 929 A (SPINE NEXT) 25 February 2005 (2005-02-25) page 5, line 22 - page 10, line 32 -----	1-5, 11, 14
X	EP 1 138 268 A (COUSIN BIOTECH ; TAYLOR, JEAN) 4 October 2001 (2001-10-04) paragraph [0022]; figure 6 -----	1-5, 14
A	WO 02/051326 A (SPINE NEXT; SENEGAS, JACQUES; PASQUET, DENIS; LE COUEDIC, REGIS) 4 July 2002 (2002-07-04) the whole document -----	1-14

☐ 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.
- *G* document member of the same patent family

Date of the actual completion of the international search

13 July 2006

Date of mailing of the international search report

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INTERNATIONAL SEARCH REPORT

International application No.
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Box II Observations where certain claims were found unsearchable (Continuation of item 2 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.: 15-19
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
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 III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

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

Information on patent family members

International application No

PCT/US2006/009173

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