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

Published:

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6 December 2012

(54) Title: TRANSPEDICULAR ACCESS TO INTERVERTEBRAL SPACES AND RELATED SPINAL FUSION SYSTEMS AND METHODS

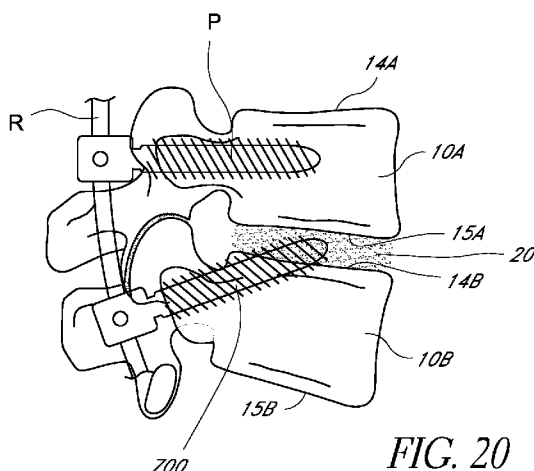


FIG. 20

(57) Abstract: According to some embodiments, a method of accessing an intervertebral space of a patient's spine in a minimally invasive manner comprises creating a passage from a posterior end of a pedicle of a vertebral member using a probe, advancing the probe through the pedicle and to a main body portion of the vertebral member, advancing the probe through a superior endplate of the vertebral member and into the intervertebral space and enlarging the passage using at least one tap to create an enlarged passage from a posterior of the pedicle to the intervertebral space. In some embodiments, the enlarged passage traverses at least three cortical layers of the vertebral member.



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 12/29535

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 17/88 (2012.01)

USPC - 606/279

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: A61B 17/88 (2012.01)

USPC: 606/279

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

IPC: A61B 17/88 (2012.01)

USPC: 604/523; 606/79, 80, 246, 247, 248, 279

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

PubWEST (PGPB,USPT,EPAB,JPAB), Google (Scholar, Patents); Keywords: drill\$4, ream\$4, pedicle, upper\$2, top, superior\$2, endplate, vertebra\$2, plate, up, upward\$2, remov\$5, excis\$4, cut\$4, disc, disk, curette, brush, ribbon, expans\$6, head, screw, rasp, inflat\$4, coil\$4, spiral\$4, helix, helical\$4, implant\$4, expans\$4, spin\$2, replac\$6

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2009/0312764 A1 (Marino) 17 December 2009 (17.12.2009) para [0067]-[0071]; Fig. 7A-7E	1-19
Y	US 2007/0055276 A1 (Edidin) 08 March 2007 (08.03.2007) para [0033], [0034], [0041], [0042], [0061], [0062]; Fig. 1, 2, 5, 6	1-19
Y	US 2009/0248159 A1 (Aflatoon) 01 October 2009 (01.10.2009) para [0058]; Fig. 7	5, 6
Y	US 2009/0187191 A1 (Carl et al.) 23 July 2009 (23.07.2009) para [0140]; Fig. 16B, 16C	12-14
Y	US 2010/0145391 A1 (Kleiner) 10 June 2010 (10.06.2010) Abstract; para [0010], [0072], [0080]	15-19
A	US 2009/0062807 A1 (Song) 05 March 2009 (05.03.2009); entire document	1-19
A	US 2008/0243249 A1 (Kohm et al.) 02 October 2008 (02.10.2008); entire document	1-19

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


* 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 application or patent 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

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 12/29535

Box No. 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.:
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 No. 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:
See extra 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 additional fees, this Authority did not invite payment of additional fees.
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.:
1-19

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

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Box III. Unity of Invention

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-19; directed to methods for vertebral fusion

Group II: Claims 20-29; directed to methods for vertebral fusion

Group III: Claim 30-42; directed to methods and systems for vertebral fusion

The inventions listed as groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of group I is removing native tissue, which is not present in groups II-III. The special technical feature of group II is inserting a second bone screw, which is not present in groups I or III. The special technical feature of group III is a facet implant, which is not present in groups I-II.

The only elements of commonality between groups I-III are those of fusing a first vertebra to a second vertebra, said second vertebra being immediately adjacent and above the first vertebra, which is known in the prior art (ref. US 2010/0114098 A1 to Carl; para [0083]--"the flexible drilling assembly 550 is advanced over the now bent wire 530 and second access hole is drilled into the inferior endplate of the vertebral body 600. As shown in FIG. 6, the wire 530 could then be pushed into and across the intervertebral disc space 555 so that the drill bit can be extended to the superior endplate of the adjacent vertebral body 600"; para [0084]--"device 500 could simply be rotated 180 degrees to perform a similar procedure on the superior endplate of vertebral body 600"; para [0086]--"Implant 900 is a single-piece rod which could be used in a rigid fusion"; Fig. 6, 9), creating a passage from a posterior end of a pedicle of the first vertebra through a superior endplate of the first vertebra, such that the passage extends into an intervertebral space located generally between the first and second vertebrae, which is known in the prior art (ref. US 2010/0114098 A1 to Carl; para [0082]--"A representative method for using device 500 for transpedicular access to the intervertebral disc space includes performing open or closed surgery to the posterior portion of a selected vertebral body to expose a pedicle 580. Then, an access hole is drilled into the patient's vertebral body 600 which extends from the pedicle 580 into the marrow 550' of the vertebral body 600' to a first depth. Next the outer cannula 510 is inserted into the access hole up to the first depth and the wire 530, with or without the drill assembly operatively associated therewith, is then slidably inserted into the passageway of the outer cannula 510"; para [0083]--"the flexible drilling assembly 550 is advanced over the now bent wire 530 and second access hole is drilled into the inferior endplate of the vertebral body 600. As shown in FIG. 6, the wire 530 could then be pushed into and across the intervertebral disc space 555 so that the drill bit can be extended to the superior endplate of the adjacent vertebral body 600"; para [0084]--"device 500 could simply be rotated 180 degrees to perform a similar procedure on the superior endplate of vertebral body 600"), and advancing a first bone screw through the passage, such that a distal end of the first bone screw extends at least partially into the intervertebral space, which is known in the prior art (ref. US 2009/0312764 A1 to Marino; para [0070]--"vertebrae pair 20, 21 having a cannulated compression-distraction screw 70 advanced over the offset guide pin or wire 56 through the disc space into the superior vertebra via an offset transpedicular channel"; Fig. 7A-7E).

The only element of commonality between groups I and II is that of delivering an implant, which is known in the prior art (ref. US 2009/0312764 A1 to Marino; para [0071]--"other instrumentation can be inserted into the superior vertebra 21 via the transpedicular channel. FIG. 7F is a simplified sagittal view of the vertebrae pair 20, 21 having a fusion construct advanced through the inferior vertebra 20 and disc space 22 into the superior vertebra 23 via the second transpedicular channel"; Fig. 7F).

Accordingly, unity of invention is lacking under PCT Rule 13.1.