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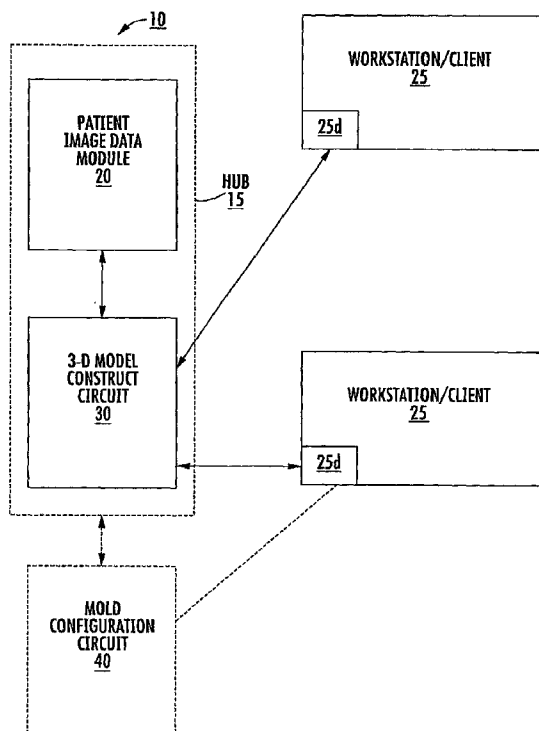
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[Continued on next page]

(54) Title: PATIENT-SPECIFIC SPINAL IMPLANTS AND RELATED SYSTEMS AND METHODS

(57) Abstract: Methods and systems for generating custom implants by programmatically analyzing a patient's image data to electronically obtain shapes and dimensions of relevant anatomical features of a target region of the patient; and fabricating a patient-specific replacement implant for the patient using the analyzed patient image data. Related patient-specific spinal implants are also described.





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INTERNATIONAL SEARCH REPORT

International application No
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A. CLASSIFICATION OF SUBJECT MATTER

INV. A61F2/30 A61F2/44 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)
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)

EP0-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>WO 2004/043305 A (IMAGING THERAPEUTICS INC [US]; TSOUGARAKIS KONSTANTINOS [US]; STEINES) 27 May 2004 (2004-05-27)</p> <p>claims 1,2,5,6,8,12-14,45,60,62,65,68-70,81,82 paragraphs [0001], [0002], [0005], [0006], [0008], [0012] - [0014], [0045], [0060], [0062], [0065], [0068] - [0070], [0081], [0082]</p> <p style="text-align: center;">----- -/--</p>	<p>1-4,7, 10-13, 17-19, 22-25, 28,30, 33-35, 39,40, 43-45</p>



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
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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
- *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/US2007/012517

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 6 146 419 A (EATON L DANIEL [US]) 14 November 2000 (2000-11-14)	1-3,5,6, 10,12, 17-19, 22-24, 30,31, 33,39, 40,44,45
A	claims 1,2,5,7; figures column 4, line 12 - line 22	35
X	WO 01/85040 A (NANYANG POLYTECHNIC [SG]; LOH KWOK WENG LEONARD [SG]; ONG ENG HOO TEDD) 15 November 2001 (2001-11-15)	1,17,18, 22,23, 28,30, 31,44
A	claims 1-6,8; figures 1,4a,4b page 3, line 3 - line 5 page 4, line 19 - page 5, line 1 page 5, line 13 - page 7, line 18	3-6, 8-15,25, 26,33-36
X	US 5 370 692 A (FINK DAVID J [US] ET AL) 6 December 1994 (1994-12-06)	1,17,22, 23,43
A	claims 1-5; figures column 6, line 10 - line 66	3,4,33, 35
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A	claims 1-4,13-15; figures column 2, line 31 - column 3, line 14	1,5-7,45
A	EP 1 430 852 A (BIOGENIE PROYECTOS LTDA [BR]) 23 June 2004 (2004-06-23)	
X	WO 03/059211 A (ANDERSSON MATTS [SE]; HOLM STEN [SE]) 24 July 2003 (2003-07-24)	1-4, 7-16, 22-30, 33-36, 39,40, 43,44
A	claims 1-4,6,8,9; figure 1 page 3, line 37 - page 4, line 32	
	US 5 514 180 A (HEGGENESS MICHAEL H [US] ET AL) 7 May 1996 (1996-05-07)	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2007/012517

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.: 42
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(vi) PCT - Program for computers
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 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 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.:
1-19, 22-31, 33-36, 39, 40, 43-45
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 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.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

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

1. claims: 1-7 10-13 17-19 22-25 28 30 31 33-35 39 40 43-45

A method for generating custom spinal implants, comprising: programmatically analyzing a patient's image data to electronically obtain shapes and dimensions of relevant anatomical features of a target region of the patient; and fabricating a patient-specific replacement implant for the patient using the analyzed patient image data, the method further comprises, before the fabricating step, electronically generating a 3-D model of at least one level of a target disc space of each patient using respective patient image data, then generating a 3-D model of the total disc replacement spinal implant based on data from the 3-D model of the target disc space and wherein the programmatically analyzing step comprises analyzing patient image data of superior and inferior vertebral endplates associated with the at least one target disc space; and wherein the fabricating step comprises molding an intervertebral disc spinal implant shape with superior and inferior surfaces substantially matching the analyzed superior and inferior vertebral endplate surfaces.

2. claims: 8, 9, 14-16, 26, 27 29, 36

A method for generating custom spinal implants, comprising: programmatically analyzing a patient's image data to electronically obtain shapes and dimensions of relevant anatomical features of a target region of the patient; and fabricating a patient-specific replacement implant for the patient using the analyzed patient image data, the method further comprises, before the fabricating step, electronically generating a 3-D model of at least one level of a target disc space of each patient using respective patient image data, then generating a 3-D model of the total disc replacement spinal implant based on data from the 3-D model of the target disc space and electronically displaying a virtual representation of the 3-D model of the replacement disc implant in an electronic anatomical graphic model of a spinal column of the patient; and electronically graphically simulating a post-surgical affect on posture, height and/or wedge angle on the patient's spinal column using the virtual representation of the generated disc.

3. claims: 20, 21, 32, 37, 38, 41

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

A method for generating custom spinal implants, comprising: programmatically analyzing a patient's image data to electronically obtain shapes and dimensions of relevant anatomical features of a target region of the patient; and fabricating a patient-specific replacement implant for the patient using the analyzed patient image data, further comprising accepting clinician input to adjust stiffness and/or flexibility of the custom implant at local bone interface regions of the device.

4. claims: 46, 47

A medical arthroplasty implant in a sterile package, the implant in the package comprising a body with a shape and dimensions customized to match local bone structure in a target joint space of a respective patient.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2007/012517

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