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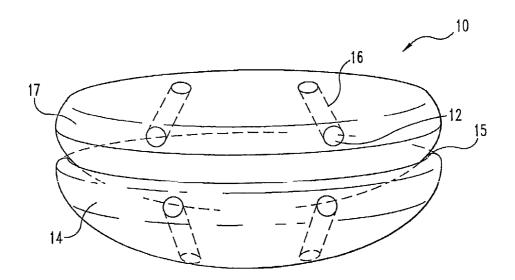
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[Continued on next page]

(54) Title: IMPLANTS BASED ON ENGINEERED METAL MATRIX COMPOSITE MATERIALS HAVING ENHANCED IMAGING AND WEAR RESISTANCE



(57) Abstract: This invention relates to an implantable medical device to treat a patient. The implantable device can be an orthopedic device such as a spinal implant including, but not restricted to, a disc or nucleus pulposus prosthesis, a spinal rod assembly, or a bone fixation plate. The orthopedic device can be formed to include a metal matrix composite that provides enhanced wear and diagnostic imaging techniques. In other forms, the present invention provides an implantable medical device that includes a porous metal matrix composite that can deliver a therapeutic composition to a patient. In still other forms, the present invention provides an implantable electrical device or lead formed to include a metal matrix composite that provides lower polarization and interfacial impedance and allows enhanced sensing of the physiological signals.

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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)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)

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

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INTERNATIONAL SEARCH REPORT

Internal al Application No PCT/US2004/016772

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61F2/44 A61F A61F2/06 A61L27/42 A61L27/40 A61L27/56 A61N1/05 A61L31/12 A61L31/14 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) A61L A61F A61M A61B A61N 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 Belevant to claim No. Category ° Citation of document, with indication, where appropriate, of the relevant passages Y DE 196 41 023 A (UNIV SINGAPORE) 1-4.6-18,10 April 1997 (1997-04-10) 21-28, 33-43. 53-58. 62-64 the whole document WO 03/013396 A (WU XINHUA; BLUNN GORDON 9,10,16, Υ (GB); UNWIN PAUL (GB); ASHWORTH MARK 17, 26-28, ANDREW () 20 February 2003 (2003-02-20) 33,41, 42,62,64 page 1, line 4 - page 3, line 19 page 7, line 4 - line 17 table 4 -/--Further documents are listed in the continuation of box C. Patent family members are listed in annex. ΙXΙ ° Special categories of cited documents: *T* later document published after the international filling date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the *A* document defining the general state of the art which is not considered to be of particular relevance invention "E" earlier document but published on or after the international "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to "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) 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. "O" document referring to an oral disclosure, use, exhibition or other means in the art. *P* document published prior to the international filing date but later than the priority date claimed "&" document member of the same patent family Date of mailing of the international search report Date of the actual completion of the international search 0 8, 12, 2004 26 November 2004 Authorized officer 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 Buchmann, G

INTERNATIONAL SEARCH REPORT

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PCT/US2004/016772									
C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT Category Citation of document, with indication, where appropriate, of the relevant passages Relevant to claim No.									
Challon of document, with indication, where appropriate, of the following passages									
WO 93/01771 A (CALCITEK INC) 4 February 1993 (1993-02-04) page 7, line 14 - line 21	11-13, 43,63								
WO 00/23015 A (SDGI HOLDINGS INC) 27 April 2000 (2000-04-27)	1-4, 6-10, 14-18, 21-28, 33,38, 53-58, 62,64								
figures									
EP 0 955 021 A (LINK WALDEMAR GMBH CO) 10 November 1999 (1999-11-10) figures	34-42								
DE 298 22 563 U (AESCULAP AG & CO KG) 18 February 1999 (1999-02-18) page 1 - page 2	1								
FR 2 806 918 A (MEDTRONIC INC) 5 October 2001 (2001-10-05) page 4, line 6 - line 20	65–73								
WO 02/083234 A (MICKSI EVA ; ST JUDE MEDICAL (SE)) 24 October 2002 (2002-10-24) page 3, line 15 - page 4, line 36	74-84								
WO 00/71083 A (UNIV BOSTON) 30 November 2000 (2000-11-30) page 2, line 1 - page 4, line 6	85,86, 88,90,92								
FR 2 412 300 A (SEROLE MICHELLE) 20 July 1979 (1979-07-20) page 2, line 26 - line 31	85,86,88								
US 2003/049149 A1 (LANDINGHAM RICHARD L) 13 March 2003 (2003-03-13) paragraph '0032!	1–92								
US 2003/060873 A1 (GERTNER MICHAEL E ET AL) 27 March 2003 (2003-03-27) paragraph '0011! - paragraph '0017!	1–92								
	### Citation of document, with indication, where appropriate, of the relevant passages ### W0 93/01771 A (CALCITEK INC) 4 February 1993 (1993-02-04) page 7, line 14 - line 21 ### W0 00/23015 A (SDGI HOLDINGS INC) 27 April 2000 (2000-04-27) ### ### ### ### ### ### ### ### ### #								

Internal application No. PCT/US2004/016772

INTERNATIONAL SEARCH REPORT

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. X Claims Nos.: 93-96 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
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:
see additional sheet
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. X 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.:
1-33,34-43,53-64,65-73,74-84,85-92
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. X 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: 1-33,34-43,53-64

A spinal implant comprising a metal matrix composite including a metallic matrix and a reinforcing component dispersed within the metallic matrix.

2. claims: 44-52

A medical device comprising a metal matrix composite including a metallic matrix and a reinforcing component dispersed within the metallic matrix.

3. claims: 65-73

A catheter comprising a metal matrix composite including a metallic matrix and a reinforcing component dispersed within the metallic matrix.

4. claims: 74-84

A pacemaker lead comprising a metal matrix composite including a metallic matrix and a reinforcing component dispersed within the metallic matrix.

5. claims: 85-92

A bone plate comprising a metal matrix composite including a metallic matrix and a reinforcing component dispersed within the metallic matrix.

INTERNATIONAL SEARCH REPORT

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Internal Application No
PCT/US2004/016772

	tent document in search report		Publication date		Patent family member(s)		Publication date
DE	19641023	A	10-04-1997	SG DE GB	49564 19641023 2305938	A1	15-06-1998 10-04-1997 23-04-1997
				JP	9165632		24-06-1997
				US	5758253		26-05-1998
 WO	03013396	Α	20-02-2003	BR	0211843	A	24-08-2004
				CA	2457048		20-02-2003
				EP	1414376		06-05-2004
				WO	03013396	A1 	20-02-2003
WO	9301771	Α	04-02-1993	US	5306307		26-04-1994
				EP	0612230		31-08-1994 27-04-1995
				JP WO	7503864 9301771		04-02-1993
					. 		
ΜO	0023015	Α	27-04 - 2000	EP	1124508		22-08-2001
				MO	0023015		27-04-2000 08-05-2000
				AU EP	1116799 1459712		22-09-2004
				JP	2002508679		19-03-2002
ΕP	0955021	Α	10-11-1999	EP	0955021		10-11-1999 15-10-2001
				AT DE	205691 59801514		25-10-2001
				ES	2163216		16-01-2002
				HK	1023496		18-01-2002
DE	29822563	U	18-02-1999	DE	29822563	U1	18-02-1999
FR	2806918	Α	05-10-2001	US	6551290		22-04-2003
				DE	10113983		20-12-2001
				FR	2806918		05-10-2001
				IE US	20010197 2004199128		20-03-2002 07-10-2004
					2004199120		
WO	02083234	A	24-10-2002	WO	02083234	A1	24-10-2002
WO	0071083	Α	30-11-2000	AU	5025000		12-12-2000
				CA	2371914		30-11-2000
				EP	1178769		13-02-2002
				JP WO	2003500112 0071083		07-01-2003 30-11-2000
				US	6605293		12-08-2003
				US	2004024470		05-02-2004
	2/12200	A	20-07-1979	 FR	2412300		20-07-1979
	2412300 						
US 	2003049149	A1 	13-03-2003	US	2003050707	A1 	13-03-2003
US	2003060873	A1	27-03-2003	EP	1461165		29-09-2004
				WO	03045582	Al	05-06-2003