



- (51) International Patent Classification:
A61F 2/82 (2006.01)
- (21) International Application Number:
PCT/US2014/041267
- (22) International Filing Date:
6 June 2014 (06.06.2014)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
61/831,800 6 June 2013 (06.06.2013) US
- (71) Applicant: **FORT WAYNE METALS RESEARCH PRODUCTS CORP.** [US/US]; 9609 Ardmore Avenue, P.O. Box 9040, Fort Wayne, IN 46899 (US).
- (72) Inventors: **SCHAFFER, Jeremy, E.**; 13034 Cherry Street, Leo, IN 46765 (US). **GRIEBEL, Adam, J.**; 7415 Maples Road, Fort Wayne, IN 46816 (US).
- (74) Agent: **BAILEY, Brian, S.**; Faegre Baker Daniels LLP, 111 East Wayne Street, Suite 800, Fort Wayne, IN 46802 (US).
- (81) Designated States (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM,

DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

- (84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

- with international search report (Art. 21(3))
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))

- (88) Date of publication of the international search report:
2 April 2015

(54) Title: BIODEGRADABLE WIRE FOR MEDICAL DEVICES

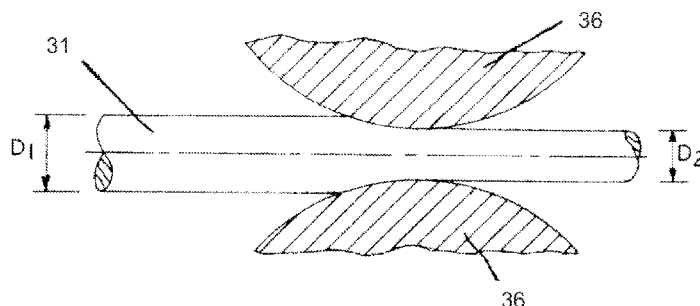


FIG. 3A

(57) Abstract: A bioabsorbable material composition includes magnesium (Mg), lithium (Li) and calcium (Ca). Lithium is provided in a sufficient amount to enhance material ductility, while also being provided in a sufficiently low amount to maintain corrosion resistance at suitable levels. Calcium is provided in a sufficient amount to enhance mechanical strength and/or further influence the rate of corrosion, while also being provided in a sufficiently low amount to preserve material ductility. The resultant ductile base material may be cold-worked to enhance strength, such as for medical applications. In one application, the material may be drawn into a fine wire, which may be used to create resorbable structures for use in vivo such as stents.



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/041267

A. CLASSIFICATION OF SUBJECT MATTER
 IPC(8) - A61F 2/82 (2015.01)
 CPC - A61L 31/148 (2014.12)
 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(8) - A61F 2/82; A61K 9/00 (2015.01)
 CPC - A61L 31/022, 31/088, 31/14, 31/148 (2014.12) (keyword delimited)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
 USPC- 623/1.15, 11.11 (keyword delimited)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
 Orbit, Google Patents, Google Scholar.
 Search terms used: Alloy, wire, stent, ductility, calcium, lithium, magnesium

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2012/0143227 A1 (STECKEL et al) 07 June 2012 (07.06.2012) entire document	1, 2, 6, 11-13, 15-20, 22, 23, 25
---		-----
Y		3-5, 7-10, 14, 21, 24
Y	US 2011/0319978 A1 (SCHAFFER) 29 December 2011 (29.12.2011) entire document	3-5, 7-9, 21
Y	US 2009/0081313 A1 (AGHION et al) 26 March 2009 (26.03.2009) entire document	10, 14, 24
A	US 4,149,882 A (UNSWORTH et al) 17 April 1979 (17.04.1979) entire document	1-25

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	"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
"E" earlier application or patent but published on or after the international filing date	"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
"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)	"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	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search 13 January 2015	Date of mailing of the international search report 29 JAN 2015
--	--

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774
---	---

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/041267

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.:
1-25

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.

PCT/US2014/041267

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 need to be paid.

Group I: Claims 1-25 are drawn to a magnesium-based alloy wire.

Group II: Claims 26-31 are drawn to a method of manufacturing a wire.

The inventions listed in Groups I and II 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 features of Group I, a magnesium-based alloy wire, are not present in Group II; the special technical features of Group II, a method of manufacturing a wire, are not present in Groups I.

Groups I and II share the technical features of bimetal composite wire, comprising: an outer shell formed of a first biodegradable metallic material; and an inner core formed of a second biodegradable metallic material, said first and second biodegradable metallic materials being different from one another whereby said first and second biodegradable metallic materials have differing biodegradation rates, and one of said first and second biodegradable materials comprising a magnesium-based alloy selected from the group consisting of: a Mg-Li-Ca alloy having between 3.0 wt.% and 7.0 wt.% Li and between 0.10 wt. % and 1.0 wt. %; a Mg-Li-Ca-RE alloy having between 3.0 wt.% and 7.0 wt.% Li, between 0.10 wt. % and 1.0 wt. % Ca, and between 0.25 wt. % and 7.0 wt.% RE, wherein "RE" is at least one rare earth element; a Mg-Li-Ca-Al alloy having between 3.0 wt. % and 7.0 wt. % Li and between 1.0 wt. % and 6.0 wt. % combined Al and Ca including 0.10 to 1.0 wt. % Ca and 0.9 wt. % to 5.0 wt. % Al; and a Mg-Li-Al-Ca-RE alloy having between 3.0 wt. % and 7.0 wt. % Li, between 1.0 wt. % and 6.0 wt. % combined Al and Ca including 0.10 to 1.0 wt. % Ca and 0.9 wt. % to 5.0 wt. % A, and between 0.25 wt. % and 7.0 wt. % RE, wherein "RE" is at least one rare earth element.

Specifically, US 2012/0143227 A1 to Steckel et al. teach a bimetal composite wire (Para. [0034], ...bioabsorbable implant...elongated metallic element...; Para. [0075]), comprising: an outer shell formed of a first biodegradable metallic material; and an inner core formed of a second biodegradable metallic material (Fig. 8; Paras. [0075];[0077], ...magnesium alloy and high-purity Fe...the core may include iron with layers 810 including magnesium...), said first and second biodegradable metallic materials being different from one another whereby said first and second biodegradable metallic materials have differing biodegradation rates (Para. [0075], ...layers of magnesium alloy and high purity Fe.; Para. [0073]), and one of said first and second biodegradable materials comprising a magnesium-based alloy is: a Mg-Li-Ca alloy having between 3.0 wt.% and 7.0 wt.% Li and between 0.10 wt. % and 1.0 wt. % Ca (Para. [0038], Li 2.0-5.0% by weight, with the balance Mg...; Para. [0046], ...Mg—Li alloys...include less than 10%..calcium...).

The inventions listed in Groups I through II therefore lack unity under Rule 13 because they do not share a same or corresponding special technical feature.