



(51) International Patent Classification:

A61L 31/08 (2006.01) A61L 31/16 (2006.01)

(21) International Application Number:

PCT/US2009/040964

(22) International Filing Date:

17 April 2009 (17.04.2009)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

61/047,002 22 April 2008 (22.04.2008) US

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(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, BR, BW, BY, BZ, CA, CH, 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, IS, JP, KE, KG, KM, 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, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, 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, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (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, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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:

- 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:  
23 December 2010

(54) Title: MEDICAL DEVICES HAVING A COATING OF INORGANIC MATERIAL

(57) Abstract: In one aspect, a medical device has a first configuration and a second configuration, a reservoir containing a therapeutic agent, and a barrier layer disposed over the reservoir, wherein the barrier layer comprises an inorganic material. In another aspect, a medical device has a reservoir containing a therapeutic agent, a barrier layer disposed over the reservoir, wherein the barrier layer comprises an inorganic material, and a swellable material disposed between the barrier layer and a surface of the medical device, wherein the swellable material is a material that swells upon exposure to an aqueous environment. In yet another aspect, a medical device has a multi-layered coating having alternating reservoir layers and barrier layers, and a plurality of excavated regions penetrating through at least a partial thickness of the multi-layered coating. In yet another aspect, a medical device has a polymer layer comprising a block co-polymer, wherein the polymer layer contains a therapeutic agent, and a barrier layer disposed over the polymer layer, wherein the barrier layer comprises an inorganic material, and wherein the barrier layer has a plurality of discontinuities. Methods of forming coatings on medical devices and methods of delivering therapeutic agents to body sites are also disclosed.



## INTERNATIONAL SEARCH REPORT

International application No

PCT/US2009/040964

## A. CLASSIFICATION OF SUBJECT MATTER

INV. A61L31/08 A61L31/16

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

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, WPI Data, COMPENDEX, EMBASE

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2006/127443 A1 (HELMUS MICHAEL N [US]) 15 June 2006 (2006-06-15)  claims 1,3,4	1-24, 40-52, 66-69, 72,73
X	US 2007/198081 A1 (CASTRO DANIEL [US] ET AL) 23 August 2007 (2007-08-23)  paragraph [0025] - paragraph [0028] paragraph [0030] - paragraph [0032]	1-7, 10-24, 66-69
Y	paragraph [0041] - paragraph [0042] paragraph [0066] - paragraph [0069]  ----- -/--	8,9, 40-52, 72,73



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.
- \* & \* document member of the same patent family

Date of the actual completion of the international search

25 October 2010

Date of mailing of the international search report

29/10/2010

Name and mailing address of the ISA/

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# INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2009/040964

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2006/029364 A2 (ADVANCED BIO PROSTHETIC SURFAC [US]) 16 March 2006 (2006-03-16) paragraph [0012] - paragraph [0014] paragraph [0048] - paragraph [0049] -----	1
Y	US 2008/057103 A1 (ROORDA WOUTER [US]) 6 March 2008 (2008-03-06) paragraph [0028] - paragraph [0032] figure 1 -----	8,9
Y	US 2006/093643 A1 (STENZEL ERIC B [IE]) 4 May 2006 (2006-05-04) paragraph [0050] - paragraph [0052] figures 5A, 5B -----	40-52, 72,73

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US2009/040964

## 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 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.:
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.:  
1-24, 40-52, 66-69, 72, 73

### 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: 1-24, 40-52, 66-69, 72, 73

Medical device comprising a reservoir containing a therapeutic agent and a barrier layer comprising an inorganic material, wherein the barrier layer gets cracks or openings during the expansion from the unexpanded to expanded configuration.

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2. claims: 25-39, 70, 71

Medical device comprising a reservoir containing a therapeutic agent, a barrier layer comprising an inorganic material, and a swellable material disposed between the barrier layer and a surface of the medical device.

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3. claims: 53-65, 74-77

Medical device comprising a block copolymer layer with microphase separated domains which form a textured surface, wherein the block copolymer contains a therapeutic agent, and a barrier layer comprising an inorganic material, wherein the barrier layer has discontinuities caused by the underlying textured surface.

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# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2009/040964

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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