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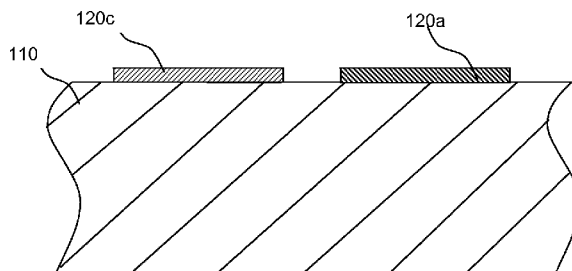


Fig. 1

(57) Abstract: The present invention pertains to implantable or insertable medical devices which comprise a substrate and one or more therapeutic-agent-containing regions contain one or more therapeutic agents. In various aspects of the invention, one or more characteristics of such therapeutic-agent-containing regions are controlled. Further aspects of the invention relate to methods of forming such devices and to methods of using such devices.



WO 2009/158276 A3

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2009/047899

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61L31/02 A61L31/08 A61L31/14 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

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, BIOSIS, EMBASE, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 00/32238 A1 (SCIMED LIFE SYSTEMS INC [US]) 8 June 2000 (2000-06-08) page 2, lines 15-28 page 4, lines 2-12 page 7, lines 26-30 examples 1-4 claims 1-26	23
X	US 2007/212394 A1 (REYES PRISCILLA [US] ET AL) 13 September 2007 (2007-09-13) paragraphs [0010] - [0014], [0 39], [0 40], [0 41], [0 80], [0 85] - [0087], [161] claims 1-20	1-23
A	EP 1 810 665 A1 (CORDIS CORP [US]) 25 July 2007 (2007-07-25) the whole document	1-23



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

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Name and mailing address of the ISA/

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INTERNATIONAL SEARCH REPORT

International application No
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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2006/134168 A1 (CHAPPA RALPH A [US] ET AL) 22 June 2006 (2006-06-22) the whole document -----	1-23
A	US 2007/224235 A1 (TENNEY BARRON [US] ET AL) 27 September 2007 (2007-09-27) the whole document -----	1-23

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/047899

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.:

1-23

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: 1-23

Medical device comprising a substrate, a first region comprising a first therapeutic agent in predominantly crystalline form and a second region comprising a second therapeutic agent in predominantly amorphous form, wherein the first and second therapeutic agents may be the same or different.

2. claim: 24

A metallic stent comprising a plurality of crystals of an antirestenotic agent disposed over the stent surface and a release regulating layer disposed over and contacting said crystalline particles and said surface, wherein said release regulating layer is a porous inorganic layer.

3. claims: 25, 26

A method of forming crystals of a therapeutic agent on a medical device substrate comprising forming nucleation sites on said substrate followed by crystallizing said therapeutic agent on said substrate, wherein crystals of the therapeutic agent are formed at the nucleation sites.

4. claim: 27

A method of forming crystals of a therapeutic agent on a medical device substrate comprising contacting a substrate with a suspension of therapeutic agent crystals in a solvent in which the therapeutic agent crystals are insoluble, and removing the solvent.

5. claim: 28

A method of forming multiple regions comprising a therapeutic agent in predominantly crystalline form on a medical device substrate, said method comprising contacting a substrate with droplets containing said therapeutic agent, wherein the droplets have a volume of 1 femtoliter or less.

6. claims: 29-36

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

A medical device comprising an inorganic substrate, a discontinuous layer of therapeutic-agent-containing material that comprises a therapeutic agent, said discontinuous layer comprising a first area corresponding to a plurality of regions of said therapeutic-agent-containing material which cover the substrate and a second area which does not cover the substrate, and an inorganic nanoporous layer disposed over the therapeutic-agent-containing layer, said inorganic nanoporous layer being in contact with said therapeutic-agent-containing material in said first area and in contact with said substrate in said second area.

7. claims: 37-41

A method of changing the morphology of a therapeutic-agent-containing region on a medical device surface, said method comprising exposing said medical device surface to a vapor that comprises a solvent within which the therapeutic-agent-containing particles are soluble under conditions such that the solvent wets the therapeutic-agent-containing particles and such that the therapeutic-agent-containing particles flow along the surface of the medical device.

8. claims: 42-45

A medical device comprising a substrate and a discontinuous therapeutic-agent containing region comprising a group of non-connected therapeutic-agent-containing particles in which 100% of particles are less than 100 micrometer in length and width, whereby between 20% and 90% of the medical device surface in the discontinuous therapeutic-agent containing region is covered by the particles.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

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