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(54) Title: GLAUCOMA TREATMENT DEVICES AND METHODS

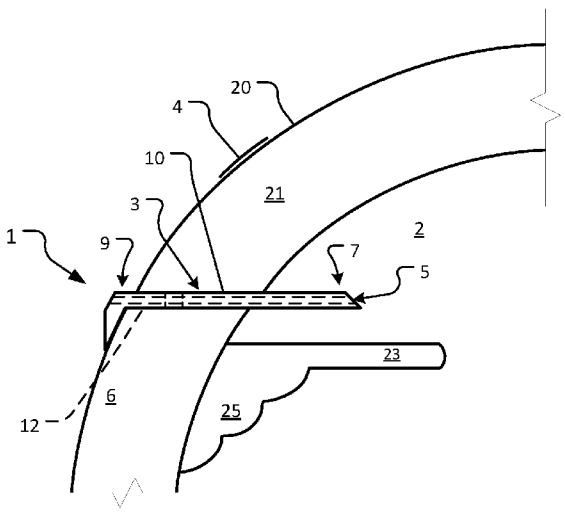


FIG. 1

(57) Abstract: Devices can be implanted in an eye to treat glaucoma. The devices described herein include a body defining a lumen and having first and second ends and external and lumenal surfaces. The body has a length sufficient to provide fluid communication between the anterior chamber and tear film of the eye through the lumen when the device is implanted in the sclera. By the strategic selection of particular materials of construction, and/or by controlling the configuration and size of the lumen, in some embodiments, the device is a filterless construct. In some embodiments, a filter is included. The glaucoma treatment devices as provided herein are designed to prevent bacterial ingress and to provide the required level of outflow resistance to achieve a desired intraocular pressure. Methods of treating glaucoma wherein the device is implanted in the sclera of an afflicted eye are also described.

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INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 9/007 (2016.01)
CPC - A61F 9/00781 (2016.02)
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 2/04, 2/14, 9/007; A61M 5/00, 27/00 (2016.01)
CPC - A61F 9/0017, 9/007, 9/00781, 2009/00891; A61K 9/0051; A61M 2210/0612, 27/002 (2016.02)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 604/8, 9, 294; 606/107, 108; 623/4.1 (keyword delimited)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Patbase, Google Patents, Google Scholar
Search terms used: glaucoma implant lumen channel outflow crosslinker azido nitrobenzoic heterobifunctional suture tear film

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2002/0169468 A1 (BROWN) 14 November 2002 (14.11.2002) entire document	1, 2, 5, 6, 8, 9, 12-17
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Y		7, 10, 11
Y	US 2006/0116626 A1 (SMEDLEY et al) 01 June 2006 (01.06.2006) entire document	7
Y	US 2009/0117166 A1 (MYUNG et al) 07 May 2009 (07.05.2009) entire document	10, 11

☐ 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 application or patent 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	Date of mailing of the international search report
13 April 2016	03 MAY 2016
Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	Authorized officer Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2015/068017

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 supplemental page

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, 2, 5-17

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.
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Continued from Box No. III Observations where unity of invention is lacking

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 must be paid.

Group I, claims 1, 2, and 5-17, are drawn to a device comprising a suture attachment feature.

Group II, claims 3, 5, and 7-17, are drawn to a device configured to maintain a desired intraocular pressure.

Group III, claims 4-6 and 8-17, are drawn to a device including one or more ribs.

Group IV, claims 18-24, are drawn to a two-piece device comprising a collar and a cartridge.

Group V, claims 25-27, are drawn to a system comprising a deployment tool.

The inventions listed as Groups I-V 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 device for treating glaucoma in an eye, the device comprising: a body, the body including a suture attachment feature configured for receiving a suture to attach the body to the eye, are not present in Groups II-V; the special technical features of Group II, a device for treating glaucoma in an eye, the device comprising: a body defining a lumen and having first and second ends, wherein the lumen is open from the first end to the second end and configured to maintain a desired intraocular pressure without having a porous element inside the lumen, are not present in Groups I and III-V; the special technical features of Group III, a device for treating glaucoma in an eye, the device comprising: a body, the body including one or more ribs extending longitudinally through at least a portion of the lumen, are not present in Groups I-II and IV-V; the special technical features of Group IV, a two-piece device for treating glaucoma in an eye, the device comprising: a collar defining a first lumen therethrough; and a cartridge, wherein at least a portion of the cartridge is releasably engageable within the first lumen, the cartridge defining a second lumen therethrough and having a length sufficient to provide fluid communication between an anterior chamber and a tear film of the eye through the second lumen when the device is implanted in a sclera of the eye, are not present in Groups I-III and V; and the special technical features of Group V, a system for treating glaucoma in an eye, the system comprising: a deployment tool, the deployment tool including a distal end; and a body, wherein the distal end of the deployment tool is configured to be releasably engageable with an end of the body, are not present in Groups I-IV.

Groups I-V all share the technical feature of a device for treating glaucoma in an eye, the device comprising: a body defining a lumen, said body having a length sufficient to provide fluid communication between an anterior chamber and a tear film of the eye through said lumen when said device is implanted in a sclera of the eye. However this shared technical feature does not represent a contribution over the prior art. Specifically US 2006/0276739 A1 to Brown discloses a device (device 1; FIG. 1A) for treating glaucoma in an eye (Title; Abstract), the device comprising: a body (body 3; FIG. 1A) defining a lumen (lumen 5; FIG. 1A), said body having a length sufficient to provide fluid communication between an anterior chamber and a tear film of the eye through said lumen when said device is implanted in a sclera of the eye (FIG: 1A; para. [0035] "device is of sufficient length to provide fluid communication between the anterior chamber 2 and tear film 4 when the device is implanted in the sclera 6 of an afflicted eye"; it is noted that FIG. 1A illustrates fluid communication occurring through the lumen 5).

Groups I-III also all share the technical feature of a body having first and second ends and external and lumenal surfaces. However this shared technical feature does not represent a contribution over the prior art. Specifically US 2006/0276739 A1 to Brown discloses a body (body 3; FIG. 1A) having first (first end 7; FIG. 1A) and second (second end 9; FIG. 1A) ends and external (external surface 10; FIG. 1A) and lumenal (lumenal surface 12; FIG. 1A) surfaces.

Since none of the special technical features of the Group I-V inventions are found in more than one of the inventions, unity of invention is lacking.