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(54) Title: SYSTEMS AND METHODS FOR CROSSING AND TREATING AN OCCLUSION

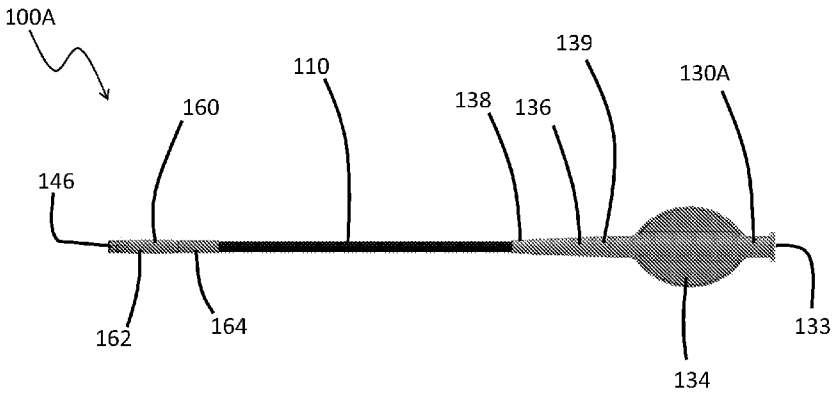

Figure 2A

(57) Abstract: A device and method for treating a patient with total or near total occlusion is provided. The device can be positioned in a blood vessel at a treatment site. An occlusion at the treatment site is enlarged by a catheter. The catheter can be advanced over a guidewire into the occlusion. One or more of [a] compression or torsion applied to the guidewire or [b] compression or torsion applied to the catheter body expands or creates a path through the occlusion. The expansions or creation of the access path can be by cutting or abrading the occlusion or by a shoe-horn effect.

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/056162

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 17/32 (2015.01)
CPC - A61B 17/320758 (2015.01)
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) - A61B 17/22, 17/32; A61M 25/09 (2015.01)
CPC - A61B 17/320758, 17/320725, 17/320783, 2017/22001; A61M 2025/09090 (2015.01)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC- 606/108, 606/158, 606/159 (keyword delimited)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PatBase, Orbit, Google Patents, Google Scholar, Google.
Search terms used:guide, wire, catheter, occlusion, blood, vessel, balloon, large, outer, diameter, crossing profile, abrasive surface

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4,842,579 A (SHIBER) 27 June 1989 (27.06.1989) entire document	1-8
Y		9
Y	US 2010/0274270 A1 (PATEL et al) 28 October 2010 (28.10.2010) entire document	9
A	US 2005/0021002 A1 (DECKMAN et al) 27 January 2005 (27.01.2005) entire document	1-9
A	US 8,021,330 B2 (MCANDREW) 20 September 2011 (20.09.2011) entire document	1-9

☐ 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
"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
04 March 2015	19 MAR 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

Form PCT/ISA/210 (second sheet) (July 2009)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/056162

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.:
1-9

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/US2014/056162

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 1-9 are drawn to a system comprising an implement having a distal face, a side surface with at least one opening extending inwardly from the side surface and a proximal end engaged with the distal end of the elongate body.

Group II, claims 10-14 are drawn to a catheter comprising an occlusion clearing implement having a rigid distal face and a cylindrical body extending proximally therefrom, the cylindrical body configured to by juxtaposed relative to a distal portion of the elongate flexible body over an interface.

Group III, claims 15-22 are drawn to a catheter comprising a lesion clearing implement having a ring structure.

Group IV, claims 23-27 are drawn to a method of treating a patient.

The inventions listed in Groups I-IV 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 catheter device having a lumen extending therethrough with an inner diameter larger than the outer diameter of a guidewire; an implement having a distal face, a side surface with at least one opening extending inwardly from the side surface and a proximal end engaged with the distal end of the elongate body, the distal end of the implement configured to act upon a portion of the occlusion; and a handle disposed at the proximal end of the elongate body; wherein the system is configured such that distal pressure on the handle urges the implement distally to firmly engage the occlusion; and wherein the system is configured such that actuating the handle causes the elongate body and the implement to be actuated to enlarge a passage through the occlusion are not present in Groups II-IV; the special technical feature of Group II, an occlusion clearing implement having a rigid distal face and a cylindrical body extending proximally therefrom, the cylindrical body configured to by juxtaposed relative to a distal portion of the elongate flexible body over an interface; wherein the occlusion implement retains a minimum transverse dimension of at least about 90% of its at rest diameter upon action against a lesion whereby deformation of an inner passage thereof is minimal during interaction with the lesion are not present in Groups I, III and IV; the special technical feature of Group III, a lesion clearing implement having a ring structure; and an interface disposed between the ring structure and the elongate catheter assembly, the interface providing a protrusion disposed on one of the elongate catheter assembly and the ring structure and a recess disposed on the other of the elongate catheter assembly and the ring structure; wherein the interface is at least partially in a radial direction such that an axial load can be transmitted across the interface are not present in Groups I, II and IV; the special technical feature of Group IV, a method of treating a patient with a total or near total occlusion comprising: accessing a blood vessel of a patient at an access location using a catheter technique; advancing a guidewire into the patient and to a treatment site, the treatment site having a total or near total occlusion; advancing a catheter over the guidewire into apposition with a proximal portion of the occlusion, the catheter having a lumen therethrough and an anchor face at a distal end thereof; and applying one or more of [a] compression or torsion to the guidewire or [b] compression or torsion to the catheter body to expand or create an access path through the occlusion are not present in Groups I-III.

Groups I -IV share the technical feature of providing access across an occlusion and a catheter comprising an elongate flexible body extending between a proximal end and a distal end and an occlusion/lesion clearing implement. However, this shared technical feature does not represent a contribution over the prior art. Specifically US 2008/0033423 A1 to Peacock, III discloses providing access across an occlusion (abstract regarding providing vascular access across chronic total occlusions) and a catheter comprising an elongate flexible body extending between a proximal end and a distal end (Fig. 1 sheath 40; para. 0084) and an occlusion/lesion clearing implement (Fig. 1 distal end 36; para 0083-0084 regarding enlargement 30, starting with distal tip 36, to preferentially find and propagate along paths of least resistance to such motion, which is believed to most often occur at natural tissue planes between at least two amorphous tissues in the CTO.)

Groups I, II and IV share the technical feature of advancing a catheter over a guidewire within the vasculature. However, this shared technical feature does not represent a contribution over the prior art. Specifically, US 2008/0033423 A1 to Peacock, III discloses of advancing a catheter over a guidewire within the vasculature (para. 0086 regarding a separate delivery sheath 60 (shown in shadow in Fig. 1) may be first advanced to the lesion over a first guidewire (not shown), which first guidewire is then removed and replaced with the sheathed wire assembly 10 of the present embodiment which tracks through the proximally positioned delivery sheath 60 and against the target CTO lesion).

Groups I and IV share the technical feature of a catheter device having a lumen extending therethrough. However, this shared technical feature does not represent a contribution over the prior art. Specifically discloses a catheter device (Fig. 1 sheath 40) having a lumen extending therethrough (Fig. 1 housing wire 20; para. 0084 regarding sheath 40 is designed to be tightly toleranced over the internally housed wire 20 such that the sheath 40 and wire 20 advance together through a CTO).

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