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[Continued on next page]

(54) Title: SYSTEM AND METHOD TO INCREASE THE OVERALL DIAMETER OF VEINS AND ARTERIES

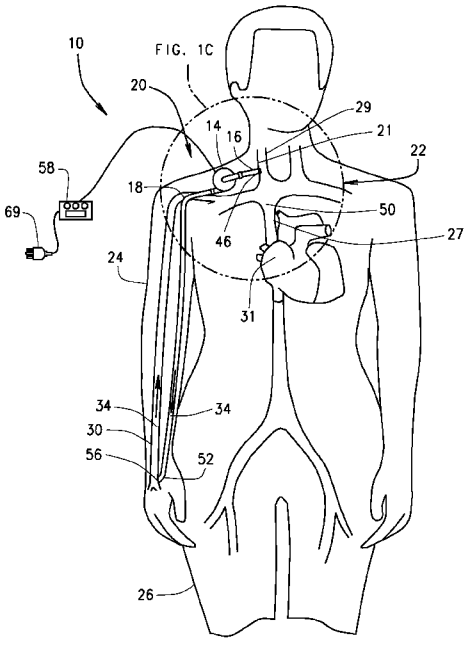

FIG. 1B

(57) Abstract: A system and method for increasing the speed of blood and the wall shear stress in a peripheral artery or peripheral vein to a sufficient level and for a sufficient period of time to result in a persistent increase in the overall diameter and lumen diameter of the artery or vein is provided. The method includes systems and methods to effect the movement of blood at the desired rate and in the desired direction. The movement of blood is monitored and adjusted, as necessary, to maintain the desired blood speed and wall shear stress in the peripheral artery or vein in order to optimize the rate and extent of persistent diameter increase of the peripheral artery or peripheral vein.

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INTERNATIONAL SEARCH REPORT

International application No.
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A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 5/00 (2013.01)
USPC - 604/8
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) - A61M 1/00, 1/10, 1/36, 5/00, 39/00, 39/02 (2013.01)
USPC - 210/634, 644, 645; 604/4.01, 8, 9

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
CPC - A61M 1/00, 1/10, 1/36, 5/00, 39/00, 39/02 (2013.01)

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	PRIES et al. REMODELING OF BLOOD VESSELS: Responses of Diameter and Wall Thickness to Hemodynamic and Metabolic Stimuli. Hypertension Journal of the American Heart Association. 46: 725-731, 2005. [retrieved on 11.04.2011]. Retreived from the Internet. <http://hyper.ahajournals.org/cgi/content/full/46/4/725>. entire document	1-47, 97-133
Y	US 2005/0113631 A1 (BOLLING et al) 26 May 2005 (26.05.2005) entire document	1-47, 97-133
A	US 5,178,603 A (PRINCE) 12 January 1993 (12.01.1993) entire document	1-47, 97-133

☐ 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
29 January 2013	08 FEB 2013
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.
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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 Continuation Sheets Attached)

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.:
claims 1-47, 97-133

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.

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CONTINUATION FROM BOX III

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 1-47, 97-133 are drawn to a method for increasing an overall diameter and a lumen diameter of a donating artery (Paras. [0096], [0097]).

Group II, claims 48-96 are drawn to a method for increasing an overall diameter and the lumen diameter of a donating vein (Paras. [0073], [0100]).

Group III, claims 134-181 are drawn to a method for increasing an overall diameter and a lumen diameter of an accepting vein from a donating artery (Paras. [0028], [0101]).

Group IV, claims 182-225 are drawn to a method for increasing an overall diameter and the lumen diameter of an accepting vein from a donating vein (Para. [0112]).

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 pump-conduit assembly to remove oxygenated blood from the donating artery and pump blood into an accepting location, the pump-conduit assembly including: a pump having an inlet and an outlet, the pump able to move oxygenated blood into the accepting location at a flow rate sufficient to cause a persistent increase in the overall diameter and the lumen diameter of the donating artery; a first conduit having a first inlet to fluidly connect to the donating artery and a first outlet fluidly connected to the inlet of the pump; the first conduit for removing oxygenated blood from the donating artery; a second conduit having a second outlet to fluidly connect to the accepting location and a second inlet fluidly connected to the outlet of the pump, the second conduit for moving oxygenated blood into the accepting location; and, a control unit configured to control the pump, are not present in Groups II-IV;

the special technical features of Group II, a pump-conduit assembly to remove deoxygenated blood from a donating vein and pump blood into an accepting location, the pump-conduit assembly including: a pump having an inlet and an outlet, the pump able to move deoxygenated blood into the accepting location at a flow rate sufficient to cause a persistent increase in the overall diameter and lumen diameter of the donating vein; a first conduit having a first inlet to fluidly connect to the donating vein and a first outlet fluidly connected to the inlet of the pump; the first conduit for removing deoxygenated blood from the donating vein; a second conduit having a second outlet to fluidly connect to the accepting location and a second inlet fluidly connected to the outlet of the pump, the second conduit for moving deoxygenated blood into the accepting location; and, a control unit configured to control the pump, are not present in Groups I, III-IV;

the special technical features of Group III, a pump-conduit assembly to remove oxygenated blood from a donating artery and pump blood into an accepting vein, the pump-conduit assembly including: a pump having an inlet and an outlet, the pump able to move oxygenated blood into the accepting vein at a flow rate sufficient to cause a persistent increase in the overall diameter and lumen diameter of the accepting vein; a first conduit having a first inlet to fluidly connect to the donating artery and a first outlet fluidly connected to the inlet of the pump; the first conduit for removing oxygenated blood from the donating artery; a second conduit having a second outlet to fluidly connect to the accepting vein and a second inlet fluidly connected to the outlet of the pump, the second conduit for moving oxygenated blood into the accepting vein; and, a control unit configured to control the pump, are not present in Groups I-II, IV;

and the special technical features of Group IV, a pump-conduit assembly to remove deoxygenated blood from a donating vein and pump blood into an accepting vein, the pump-conduit assembly including: a pump having an inlet and an outlet, the pump able to move deoxygenated blood into the accepting vein at a flow rate sufficient to cause a persistent increase in the overall diameter and lumen diameter of the accepting vein; a first conduit having a first inlet to fluidly connect to the donating vein and a first outlet fluidly connected to the inlet of the pump; the first conduit for removing deoxygenated blood from the donating vein; a second conduit having a second outlet to fluidly connect to the accepting vein and a second inlet fluidly connected to the outlet of the pump, the second conduit for moving deoxygenated blood into the accepting vein; and, a control unit configured to control the pump, are not present in Groups I-III.

Groups I through IV share the technical features of a pump-conduit assembly to remove blood from a donating artery/vein and pump blood into an accepting location, the pump-conduit assembly including: a pump having an inlet and an outlet, the pump able to move blood into the accepting location at a flow rate sufficient to cause a persistent increase in the overall diameter and lumen diameter of the accepting/donating artery/vein; a first conduit having a first inlet to fluidly connect to the donating artery/vein and a first outlet fluidly connected to the inlet of the pump; the first conduit for removing blood from the donating artery/vein; a second conduit having a second outlet to fluidly connect to the accepting location and a second inlet fluidly connected to the outlet of the pump, the second conduit for moving blood into an accepting location; and a control unit configured to control the pump.

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
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However, these shared technical features do not represent a contribution over the prior art, specifically, US 2005/0113631 A1 to Bolling et al. in view of Remodeling of Blood Vessels: Responses of Diameter and Wall Thickness to Hemodynamic and Metabolic Stimuli to Pries et al. (http://hyper.ahajournals.org/content/46/4/725.full).

Bolling et al. teach a pump-conduit (32, 50, 52, Fig. 1) assembly to remove blood from a donating artery/vein (26; Para. [0061]; Para. [0072] regarding from one peripheral blood vessel to another) and pump blood into an accepting location (24; Para. [0061]; Para. [0072] regarding from one peripheral blood vessel to another), the pump-conduit assembly (32, 50, 52) including: a pump (32) having an inlet (34) and an outlet (36), the pump able to move blood into the accepting location at a flow rate (Para. [0063]; Para. [0069] regarding the controller may also be autoregulating to permit automatic regulation of the speed, and/or regulation of the synchronous or asynchronous pulsation of the pump 32, based upon feedback from ambient sensors monitoring parameters, such as pressure); a first conduit (50) having a first inlet (at 60) to fluidly connect to the donating artery/vein (26; Para. [0061]; Para. [0072] regarding from one peripheral blood vessel to another) and a first outlet (at 56) fluidly connected to the inlet (34) of the pump (32); the first conduit for removing blood from the donating artery/vein (26; Para. [0061]; Para. [0072] regarding from one peripheral blood vessel to another); a second conduit (52) having a second outlet (at 68) to fluidly connect to the accepting location (24; Para. [0061]; Para. [0072] regarding from one peripheral blood vessel to another) and a second inlet fluidly (at 66) connected to the outlet (36) of the pump (32), the second conduit for moving blood into an accepting location (24; Para. [0061]; Para. [0072] regarding from one peripheral blood vessel to another); and a control unit (42) configured to control the pump (32). Bolling et al. do not explicitly disclose moving blood into the accepting location at a flow rate sufficient to cause a persistent increase in the overall diameter and lumen diameter of the accepting/donating artery/vein. However, Pries et al. teach structural adaptation of blood vessels (Abstract) and further teach moving blood into the accepting location at a flow rate sufficient to cause a persistent increase in the overall diameter and lumen diameter of the accepting/donating artery/vein (Abstract regarding an increase in vessel diameter with increasing wall shear stress and Page 726, Col. 2, line 26-Page 728, Col. 1, line 3 regarding flow and pressure are physically related to wall shear stress....increased shear stress leads to increase in structural diameter; Fig. 2A).
Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the method of Bolling et al. to include the limitations above, as taught by Pries et al. for the purpose of monitoring and remodeling a blood vessel.

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.