



(51) International Patent Classification:
A61B 18/04 (2006.01)

(21) International Application Number:
PCT/US2012/040639

(22) International Filing Date:
3 June 2012 (03.06.2012)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/493,344 3 June 2011 (03.06.2011) 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, CL, 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, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD,
SE, SG, SK, SL, SM, ST, SV, SY, TH, 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, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ,
UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ,
TM), European (AL, 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, RS, SE, SI, SK, SM,
TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW,
ML, MR, NE, SN, TD, TG).

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:
28 February 2013

(54) Title: METHOD AND APPARATUS FOR TISSUE ABLATION

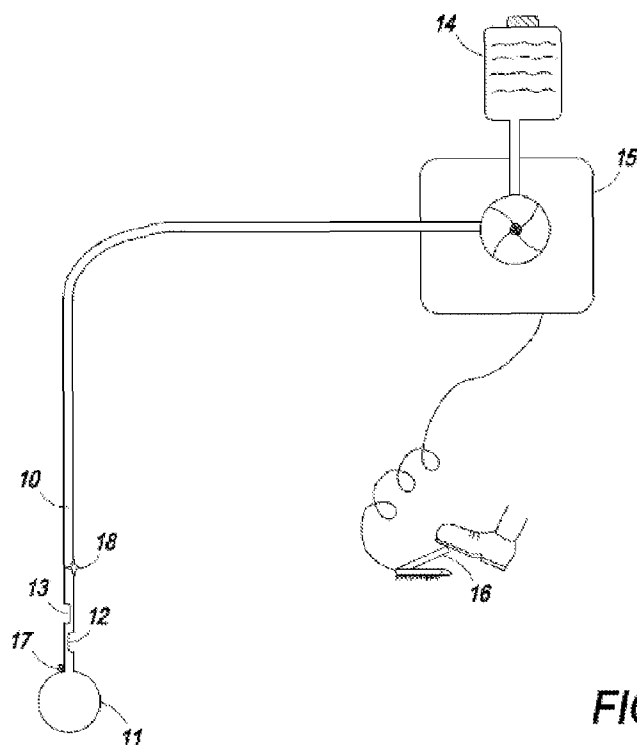


FIG. 1

(57) **Abstract:** The present application discloses devices that ablate human tissue. The device comprises a catheter with a shaft through which an ablative agent can travel, a liquid reservoir and a heating component, which may comprise a length of coiled tubing contained within a heating element, wherein activation of said heating element causes said coiled tubing to increase from a first temperature to a second temperature and wherein the increase causes a conversion of liquid within the coiled tubing to vapor, a reusable cord connecting the outlet of the reservoir to the inlet of the heating component, and a single use cord connecting a pressure-resistant inlet port of a vapor based ablation device to the outlet of the heating component.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 12/40639

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 18/04 (2012.01)

USPC - 606/27

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)

USPC: 606/27

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC: 606/28, 29, 30, 31, 32, 39, 41, 42, 45 (keyword limited; terms below)

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

PatBase; Google

Search Terms Used: ablat*, steam, copper, tub*, heat*, reservoir, container, liquid, fluid, water, coil*, luer lock, generator, power, power supply, surgical

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2008/0281267 A1 (MEHIER) 13 November 2008 (13.11.2008) fig 1, para [0043]-[0044], [0047]-[0049], [0051]	1, 3
Y		2, 4-7
Y	US 6,905,496 B1 (ELLMAN et al) 14 June 2005 (14.06.2005) fig 1, col 2, ln 60-63, col 4, ln 13-17	2
Y	US 2006/0036237 A1 (DAVISON et al) 16 February 2006 (16.02.2006) para [0048]	4
Y	US 2003/0216729 A1 (MARCHITTO et al) 20 November 2003 (20.11.2003) para [0101]	5
Y	US 2010/0114083 A1 (SHARMA) 06 May 2010 (06.05.2010) fig 1, para [0070]	6-7

☐ 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

04 December 2012 (04.12.2012)

Date of mailing of the international search report

18 DEC 2012

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:

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PCT Helpdesk: 571-272-4300

PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 12/40639

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:
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 1-7) is drawn to a tissue ablation device comprising:
a liquid reservoir, wherein said reservoir includes an outlet connector that can resist at least 1 atm of pressure for the attachment of a reusable cord; a heating component;
a cord connecting the outlet of said reservoir to the inlet of the heating component;
a single use cord connecting a pressure-resistant inlet port of a vapor based ablation device to the outlet of said heating component.

-----Continued on 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.:
1-7

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
Information on patent family members

International application No.

PCT/US 12/40639

Continuation of Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

Group II (Claim 8-13) is drawn to a vapor ablation device system comprising: a container with a sterile liquid; a pump; a first filter; a heating component; a valve; a catheter in fluid communication with said heating component, said catheter comprising at least one opening at its operational end; and a microprocessor.

Group III (Claims 14-20) is drawn to a tissue ablation system comprising: a catheter comprising a handle housing a fluid heating chamber, a wire leading to a controller; an insulating sheath; at least one opening proximate the distal end of said catheter for the passage of vapor; a controller operably connected to said heating element via said wire, wherein said controller is capable of modulating energy supplied to said heating element and further wherein said controller is capable of adjusting a flow rate of liquid supplied to said catheter; wherein liquid is supplied to said heating chamber and then converted to vapor within said heating chamber by a transfer of heat from said heating element to said chamber.

The inventions listed as Groups I-III 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:

Groups I and II share the technical feature of a tissue ablation system comprising: a liquid reservoir and a heating component as shown by US 2009/0301483 A1 to Barry et al. (hereinafter Barry). Barry teaches a tissue ablation system (para[0021]) comprising: a liquid reservoir and a heating component (para[0059]).

Groups II and III share the technical feature as taught by Barry, of a catheter having at least one opening proximate the distal end of said catheter for the passage of vapor (para[0059]-[0060], [0063]; Figs. 1-5); wherein said controller is capable of adjusting a flow rate of liquid supplied to said catheter (para[0061]; wherein water is converted to vapor (0059)).

The inventions of Groups I-III each recite a special technical feature above and beyond the shared technical feature and method. In particular:

The special technical feature of Group I is a liquid reservoir, wherein said reservoir includes an outlet connector that can resist at least 1 atm of pressure for the attachment of a reusable cord; a cord connecting the outlet of said reservoir to the inlet of the heating component; a single use cord connecting a pressure-resistant inlet port of a vapor based ablation device to the outlet of said heating component; not required by the inventions of Groups II and III.

The special technical feature of Group II is a pump in fluid communication with said container; a first filter disposed between and in fluid communication with said container and said pump;; not required by the inventions of Groups I and III.

The special technical feature of Group III is a catheter comprising a handle housing a fluid heating chamber, a wire leading to a controller; an insulating sheath; a controller operably connected to said heating element via said wire, wherein said controller is capable of modulating energy supplied to said heating element, not required by the inventions of Group I and II.

None of these technical features are common to the other groups, nor do they correspond to a special technical feature in the other groups. Therefore, unity of invention is lacking because the groups do not share a same or corresponding special technical feature making a contribution over the prior art. Therefore, unity of invention is lacking.