(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
20 January 2022 (20.01.2022)

WIPO | PCT

(10) International Publication Number
WO 2022/016101 A3

(51) International Patent Classification:
A61M 25/00 (2006.01) *A61F 2/82* (2013.01)
A61M 25/04 (2006.01) *A61M 25/10* (2013.01)

(21) International Application Number:
PCT/US2021/042049

(22) International Filing Date:
16 July 2021 (16.07.2021)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

63/052,900	16 July 2020 (16.07.2020)	US
63/061,108	04 August 2020 (04.08.2020)	US
63/167,633	29 March 2021 (29.03.2021)	US

(71) Applicant: **INTERVENE, INC.** [US/US]; 415 Grand Avenue, Suite 302, South San Francisco, CA 94080 (US).

(72) Inventor; and
(71) Applicant: **WILSON, Fletcher, T.** [US/US]; c/o Intervene, Inc., 415 Grand Avenue, Suite 302, South San Francisco, CA 94080 (US).

(72) Inventors: **ELKINS, Jeffrey, M.**; c/o Intervene, Inc., 415 Grand Avenue, Suite 302, South San Francisco, CA 94080 (US). **DELL, Kent, D.**; c/o Intervene, Inc., 415 Grand Avenue, Suite 302, South San Francisco, CA 94080 (US). **MENDOZA, Herbert**; c/o Intervene, Inc., 415 Grand Avenue, Suite 302, South San Francisco, CA 94080 (US). **GARRISON, Michi, E.**; c/o Intervene, Inc., 415 Grand Avenue, Suite 302, South San Francisco, CA 94080 (US).

(74) Agent: **DUNHAM, Nicole, S.**; Perkins Coie LLP, P.O. Box 1247, Seattle, WA 98111-1247 (US).

(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, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN,

(54) Title: INTRAVASCULAR DEVICES FOR DELIVERY OF FLUIDS AND THERAPEUTIC AGENTS INTO BLOOD VESSEL WALLS AND INTRAVASCULAR STRUCTURES

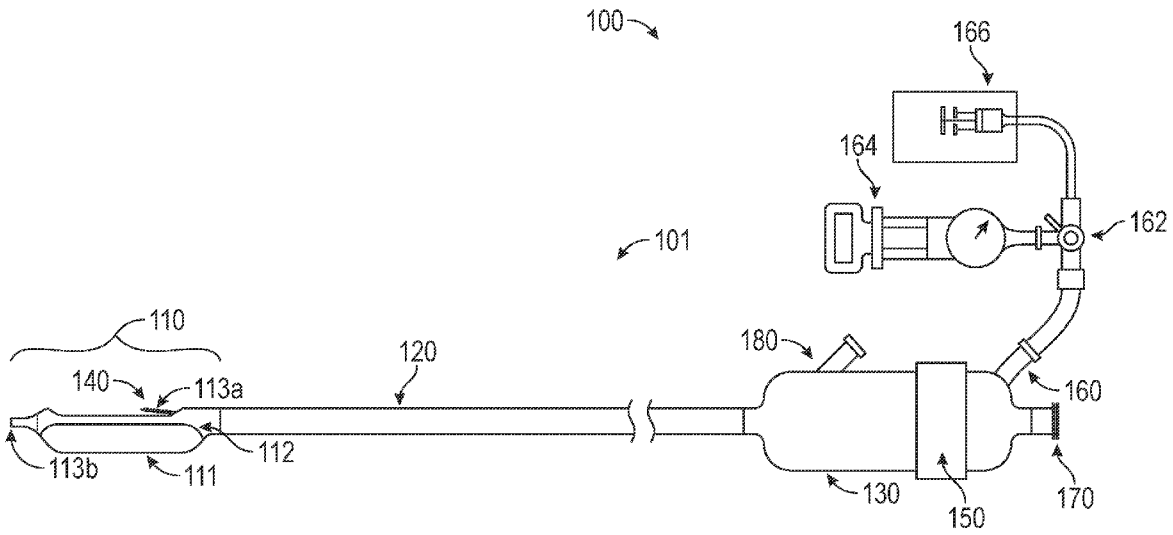


FIG. 1

(57) Abstract: Intravascular devices (100) for intramural delivery of dissection fluids and infusates are disclosed herein. In some embodiments, the systems include an infusion assembly that can access a vessel wall at a depth within a layer of the vessel wall and advance a tissue manipulation component (140) at approximately the same depth within the vessel wall to create an intramural space within the vessel layer. The infusion assembly can further deliver an infusate that includes a therapeutic drug or other agent into the intramural space.

WO 2022/016101 A3

[Continued on next page]

HR, HU, ID, IL, IN, IR, IS, IT, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, 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, ST, 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, KM, 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:
24 February 2022 (24.02.2022)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2021/042049

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M25/00 A61M25/04 A61F2/82 A61M25/10
ADD.

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)
A61M A61F A61B

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 practicable, search terms used)
EPO-Internal, 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 2012/145444 A2 (UNIV LELAND STANFORD JUNIOR [US]; WILSON FLETCHER [US] ET AL.) 26 October 2012 (2012-10-26)	1,2,8-10
Y	paragraphs [0133], [0171], [0192], [0194], [0207], [0208], [0221]; figures 9a,9b,16A-I	4,6,7
Y	WO 2015/148581 A1 (INTERVENE INC [US]) 1 October 2015 (2015-10-01) figures 3A-3D	4,6,7
Y	WO 2017/210656 A1 (INTERVENE INC [US]) 7 December 2017 (2017-12-07) figures 10A-10B	6,7
X	US 2015/112188 A1 (STIGALL JEREMY [US] ET AL) 23 April 2015 (2015-04-23) figures 4A-5B	1

-/--

[X] Further documents are listed in the continuation of Box C.

[X] 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
8 November 2021	10/01/2022

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Wilson, Mark

1

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2021/042049

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2013/119849 A1 (INTERVENE INC [US]) 15 August 2013 (2013-08-15) figures 14-17	1
A	WO 2015/077515 A1 (NAUMANN MICHAEL T [US]; BRANNIGAN THOMAS J [US]) 28 May 2015 (2015-05-28) figures 9a-9b	3
A	WO 2012/030587 A1 (SALIENT SURGICAL TECH INC [US]; BLOOM ELIOT F [US]) 8 March 2012 (2012-03-08) figures 4-5	3
A	US 8 177 748 B1 (BEYERLEIN DAGMAR [US]) 15 May 2012 (2012-05-15) figure 7	3
A	US 6 458 098 B1 (KANESAKA NOZOMU [US]) 1 October 2002 (2002-10-01) figure 2	1,3
A	WO 2013/159066 A1 (FRACTYL LAB INC [US]; CAPLAN JAY [US] ET AL.) 24 October 2013 (2013-10-24) figures 6-12	1

1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2021/042049

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. [X] Claims Nos.: 16-21
because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210

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. [X] 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.:
1-4, 6-10

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: 1-4, 6-10

The height adjustment component comprises: a rotatable guide component positioned within the lumen; and a track carried by the rotatable guide component, wherein the tissue penetrating component is slidably positioned within the track (claim 3);
The tissue penetrating component comprises a distal opening and a plug at least partially blocking the distal opening, wherein the plug is configured to offset the distal opening at least partially from a central axis of the tissue penetrating component (claim 4);
A protective tube coaxially surrounds the needle, wherein the needle is configured to advance distal to the protective tube to penetrate a surface of the tissue wall, and wherein the protective tube is configured to advance distal to the needle (claim 6).

---

2. claims: 5, 11-15

The handle assembly comprises a valve in fluid communication with the tissue penetrating component, and wherein the valve is controllable between a dissection fluid supply and an infusate supply (claims 5 and 11).

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 16-21

According to Article 17(2)(a)(i) PCT and Rule 39.1(iv) PCT no international search is required to be carried out on claims 16-21 of the present application, because their subject-matter relates to a method for treatment of the human or animal body by surgery. Particular reference is made to the wording of claim 16: "A method of intravascularly delivering a therapeutic agent to a target site, the method comprising: positioning a distal portion of a catheter shaft of an infusion device at a target site within a vein of a patient..." and of claim 20: "...A method of intravascularly delivering a therapeutic agent to a patient diagnosed with deep vein thrombosis, the method comprising:positioning a distal portion of a catheter device at a target site within a vein of the patient...".

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2021/042049

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2012145444 A2	26-10-2012	CN 103826543 A	28-05-2014
		EP 2699169 A2	26-02-2014
		EP 3388005 A1	17-10-2018
		EP 3777727 A1	17-02-2021
		JP 6157007 B2	05-07-2017
		JP 2014518657 A	07-08-2014
		US 2012289987 A1	15-11-2012
		US 2017035450 A1	09-02-2017
		US 2017035455 A1	09-02-2017
		US 2018333166 A1	22-11-2018
		WO 2012145444 A2	26-10-2012
WO 2015148581 A1	01-10-2015	EP 3122266 A1	01-02-2017
		US 2015265263 A1	24-09-2015
		US 2015265302 A1	24-09-2015
		US 2016235428 A1	18-08-2016
		US 2019282259 A1	19-09-2019
		US 2019321064 A1	24-10-2019
		WO 2015148581 A1	01-10-2015
WO 2017210656 A1	07-12-2017	AU 2017272363 A1	06-06-2019
		EP 3463120 A1	10-04-2019
		US 2020337726 A1	29-10-2020
		WO 2017210656 A1	07-12-2017
US 2015112188 A1	23-04-2015	NONE	
WO 2013119849 A1	15-08-2013	EP 2811923 A1	17-12-2014
		EP 3628247 A1	01-04-2020
		US 2015359630 A1	17-12-2015
		US 2019298510 A1	03-10-2019
		US 2021068941 A1	11-03-2021
		WO 2013119849 A1	15-08-2013
WO 2015077515 A1	28-05-2015	CA 2967788 A1	28-05-2015
		EP 3071112 A1	28-09-2016
		JP 6591415 B2	16-10-2019
		JP 6603821 B2	06-11-2019
		JP 2016537137 A	01-12-2016
		JP 2019177161 A	17-10-2019
		US 2015141836 A1	21-05-2015
		US 2019282203 A1	19-09-2019
		WO 2015077515 A1	28-05-2015
WO 2012030587 A1	08-03-2012	US 2012053485 A1	01-03-2012
		WO 2012030587 A1	08-03-2012
US 8177748 B1	15-05-2012	US 8177748 B1	15-05-2012
		US 2005004513 A1	06-01-2005
US 6458098 B1	01-10-2002	NONE	
WO 2013159066 A1	24-10-2013	AU 2013249043 A1	30-10-2014
		CA 2869904 A1	24-10-2013
		EP 2838598 A1	25-02-2015
		EP 3711810 A1	23-09-2020
		IL 234948 A	25-03-2021
		JP 6235559 B2	22-11-2017

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2021/042049

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
		JP 6409111 B2	17-10-2018
		JP 6654228 B2	26-02-2020
		JP 2015516859 A	18-06-2015
		JP 2018029996 A	01-03-2018
		JP 2018202207 A	27-12-2018
		JP 2020062538 A	23-04-2020
		KR 20140147118 A	29-12-2014
		US 2015045825 A1	12-02-2015
		US 2017007324 A1	12-01-2017
		WO 2013159066 A1	24-10-2013