PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5: A61M 5/142	A3	(11) International Publication Number: WO 89/10149
		(43) International Publication Date: 2 November 1989 (02.11.89)

(21) International Application Number: PCT/US89/01719

(22) International Filing Date: 21 April 1989 (21.04.89)

(30) Priority data:
184,244 21 April 1988 (21.04.88) US

(71) Applicant: THEREX CORPORATION [US/US]; 1600 Providence Highway, Walpole, MA 02081 (US).

(72) Inventors: MELSKY, Gerald, S. ; 2 Dewey Road, Lexington, MA 02173 (US). PROSL, Frank, R. ; 474 Franklin Street, Duxbury, MA 02332 (US).

(74) Agents: McKENNA, John, F. et al.; Nutter, McClennen & Fish, One International Place, Boston, MA 02110-2699 (US).

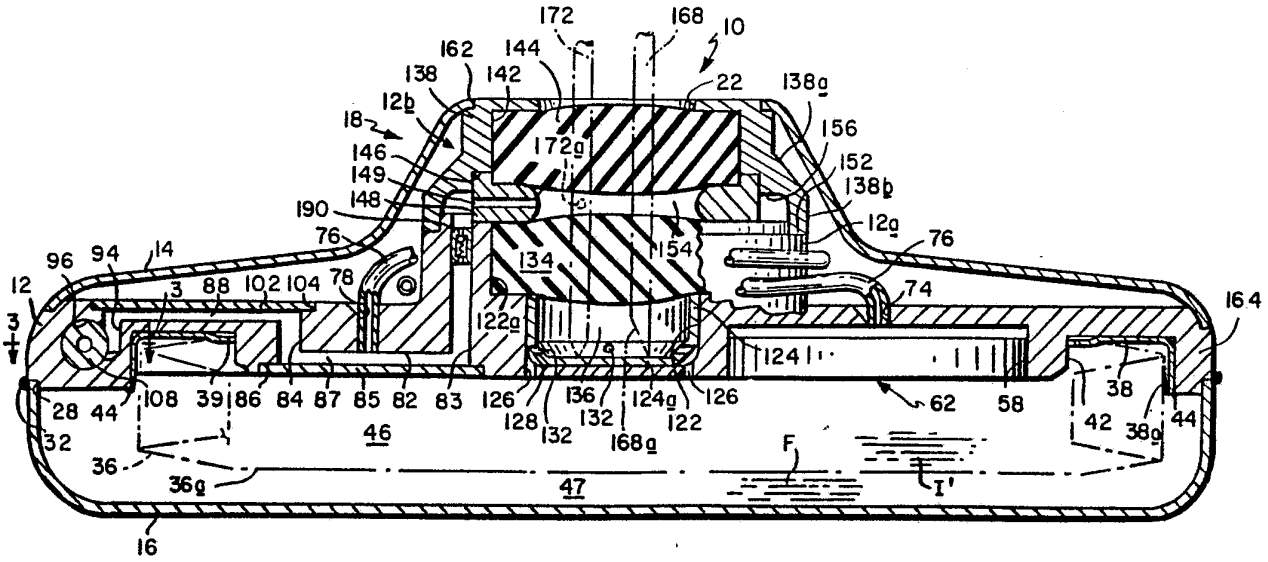
(81) Designated States: AT (European patent), AU, BE (European patent), CH (European patent), DE (European patent), FR (European patent), GB (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent).

Published
With international search report.
With amended claims.

(88) Date of publication of the international search report:
22 February 1990 (22.02.90)

Date of publication of the amended claims:
5 April 1990 (05.04.90)

(54) Title: IMPLANTABLE INFUSION APPARATUS



(57) Abstract

Implantable infusion apparatus (10) includes a housing (14, 16) with an inlet passage (22) extending into the housing at a pronounced promontory (18) on the housing wall. The passage has an outer end at the top of the promontory and an inner end defined by a needle stop (124) positioned inside the housing. Self-sealing septa (134, 144) mounted in the passage at selected spacings from the needle stop divide the passage into a plurality of aligned inlet ports (136, 154) each of which has its own fluid outlet (132, 149). One of the outlets (132) leads to a pumpable infusate reservoir (46) having an outlet conduit (76) connected to a catheter (24) that extends outside the housing; another (149) leads directly to the outlet conduit (83) so that while a first fluid is being pumped from the reservoir to the catheter, a second fluid can be introduced into the other inlet port for mixing with the first fluid flowing to the catheter. Several different infusate flow configurations are also disclosed.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria
AU	Australia
BB	Barbados
BE	Belgium
BF	Burkina Faso
BG	Bulgaria
BJ	Benin
BR	Brazil
CA	Canada
CF	Central African Republic
CG	Congo
CH	Switzerland
CM	Cameroon
DE	Germany, Federal Republic of
DK	Denmark
ES	Spain
FI	Finland
FR	France
GA	Gabon
GB	United Kingdom
HU	Hungary
IT	Italy
JP	Japan
KP	Democratic People's Republic of Korea
KR	Republic of Korea
LI	Liechtenstein
LK	Sri Lanka
LU	Luxembourg
MC	Monaco
MG	Madagascar
ML	Mali
MR	Mauritania
MW	Malawi
NL	Netherlands
NO	Norway
RO	Romania
SD	Sudan
SE	Sweden
SN	Senegal
SU	Soviet Union
TD	Chad
TG	Togo
US	United States of America

AMENDED CLAIMS

[received by the International Bureau on 9 March 1990 (09.03.90)
original claims 7, 18-34,37-46 cancelled; claims 1,6,14,15,16,35 and 36 amended
claims 8-17, 35 and 36 renumbered as claims 7-16 and 17-18 (7 pages)]

1. Implantable infusion apparatus comprising

a hermetically sealed housing, said housing including a pronounced outwardly projecting promontory positioned at or near the center of the housing away from the periphery thereof;

a passage into said housing at said promontory;

needle stop means at the end of said passage inside said housing;

a first needle-penetrable, self-sealing septum mounted in said passage at a selected spacing from said needle stop means, said first septum being located at the outer surface of said housing at the top of said promontory;

a second septum mounted in said passage at a selected spacing from said first septum thereby to divide said passage into a first segment extending between said needle stop means and said first septum and a second aligned segment extending between said first septum and said second septum;

first and second fluid outlets from said first and second passage segments;

a pumpable infusate reservoir inside said housing in fluid communication with one of said fluid outlets, the other of said fluid outlets being in fluid communication with fluid flow means extending within said housing;

a catheter extending from the housing for conducting fluid from said apparatus to an infusion site; and

a conduit in said housing for conducting fluid from said reservoir to said catheter.

2. The apparatus defined in claim 1 wherein the other of said fluid outlets is also in fluid communication with said catheter.

3. The apparatus defined in claim 2 wherein

said catheter is a dual lumen catheter;

said conduit is in fluid communication with one lumen of said catheter; and

said other of said outlets conducts fluid to the other lumen of said catheter.

4. The infusion apparatus defined in claim 2 wherein said conduit from said reservoir to said catheter includes a filter and a fluid flow restrictor.

5. The infusion apparatus defined in claim 4 wherein the flow restrictor comprises a length of glass capillary tubing.

6. The infusion apparatus defined in claim 4 wherein

said conduit also includes a mixing chamber downstream from said flow restrictor; and

the other of said fluid outlets leads to said mixing chamber, so that while a first fluid is being expelled from said pumpable reservoir to said mixing chamber, a second fluid introduced into said second passage segment will flow to and be mixed in said mixing chamber with said first fluid so that a fluid mixture will be conducted to the catheter.

7. The apparatus defined in claim 1 wherein said pumpable infusate reservoir includes

a collapsible infusate chamber; and

means for collapsing the chamber to force infusate from the chamber through said conduit to said catheter.

8. The apparatus defined in claim 7 wherein the collapsing means comprise a two-phase fluid confined inside said housing adjacent to said chamber, said fluid exerting sufficient vapor pressure at physiological temperatures to collapse said chamber.

9. The apparatus defined in claim 1 wherein said housing is generally circular and said catheter exits said housing substantially tangentially.

10. The apparatus defined in claim 1 and further including

a second catheter, said second catheter exiting said housing substantially tangentially and collinearly to said catheter; and

means for conducting fluid from the other of said fluid outlets to said second catheter.

11. The apparatus defined in claim 1 wherein said pumpable infusate reservoir comprises

rigid manifold means inside the housing;

a collapsible metal bellows capsule having an open end mounted to the manifold means, the opposite end of the capsule being closed; and

means in the housing for collapsing the bellows capsule.

12. The apparatus defined in claim 11 wherein

said passage, said outlets and at least a portion of said conduit are formed in said manifold means; and

said needle stop, septa and catheter are all mounted to said manifold means adjacent to the open end of said bellows capsule.

13. The apparatus defined in claim 12 wherein the open end of the bellows capsule is recessed into a circular groove with an open edge formed in said manifold means.

14. Implantable infusion apparatus comprising:

a hermetically sealed housing;

a passage into said housing;

needle stop means at the end of said passage inside said housing;

a first needle-penetrable, self-sealing septum mounted in said passage at a selected spacing from said needle stop means;

a second septum mounted in said passage at a selected spacing from said first septum thereby to divide said passage into a first segment extending between said needle stop means and said first septum and a second aligned segment extending between said first septum and said second septum;

first and second fluid outlets from said first and second passage segments;

a pumpable infusate reservoir inside said housing in fluid communication with one of said fluid outlets, said reservoir including rigid manifold means inside the housing, means defining a circular groove with an open edge in said manifold means, a collapsible metal bellows capsule-having an open end recessed into said groove, the opposite end of said capsule being closed, and means for mounting said bellows open end to said manifold means, said mounting means comprising a bracket including an annular body having an inner edge seated in said groove and a cylindrical flange having a free edge extending from the periphery of said body to the open edge of said groove,

the inner edge of said body being connected by continuous weld to the open end of said bellows capsule and

the free edge of said flange being connected by a continuous weld to said open edge of said groove in the manifold means,

means in said housing for collapsing the bellows capsule;

a catheter extending from the housing for conducting fluid from said apparatus to an infusion site, and

a conduit in said housing for conducting fluid from said reservoir to said catheter, said passage, said outlets and at least a portion of said conduit being formed in said manifold means, and said needle stop, septa and catheter all being mounted to said manifold means adjacent to the open end of said bellows capsule.

15. Implantable infusion apparatus comprising:

a hermetically sealed housing;

a passage into said housing;

needle stop means at the end of said passage inside said housing;

a first needle-penetrable, self-sealing septum mounted in said passage at a selected spacing from said needle stop means;

a second septum mounted in said passage at a selected spacing from said first septum thereby to divide said passage into a first segment extending between said needle stop means and said first septum and a second aligned segment extending between said first septum and said second septum;

first and second fluid outlets from said first and second passage segments;

a pumpable infusate reservoir inside said housing in fluid communication with one of said fluid outlets, said reservoir including rigid manifold means inside the housing, means defining a circular groove with one open edge in said manifold means, a collapsible metal bellows capsule having an open end recessed into said groove, the opposite end of the capsule being closed, and means for mounting said bellows open end to said manifold means at said groove;

means in the housing for collapsing the bellows capsule;

a catheter extending from the housing for conducting fluid from said apparatus to an infusion site,

said manifold means being disk-shaped and

said circular groove being located eccentric to the circular periphery of said manifold means so that the groove is displaced away from said catheter,

and a conduit in said housing for conducting fluid from said reservoir to said catheter, said passage, said outlets and at least a portion of said conduit being formed in said manifold means and said needle stop, septa and catheter all being mounted to said manifold means adjacent to the open end of said bellows capsule.

16. The apparatus defined in claim 1 and further including flow check means for preventing fluid flow from said other of said fluid outlets to said second passage segment.

17. Implantable infusion apparatus comprising

a rigid manifold having opposite first and second surfaces and a pronounced outwardly projecting mesa positioned at or near the center of said second surface away from the periphery thereof, said mesa having a central perpendicular axis;

a collapsible fluid-tight infusate chamber having a closed end and an open end;

means for mounting the chamber open end in a fluid-tight manner to the manifold first surface opposite said mesa;

a self-sealing inlet port in said manifold mesa, said inlet port being accessible from the manifold second surface at the top of said mesa;

fluid conduit means extending between said inlet port and the interior of said chamber; and

a first outlet conduit communicating between said manifold first surface inside said chamber and the manifold periphery.

18. Implantable infusion apparatus comprising

a rigid manifold having opposite first and second surfaces and a central mesa at said second surface, said mesa having a central perpendicular axis;

a collapsible fluid-tight infusate chamber having a closed end and an open end;

means for mounting the chamber open end in a fluid-tight manner to the manifold first surface opposite said mesa;

a self-sealing inlet port in said manifold mesa, said inlet port being accessible from the manifold second surface at the top of said mesa;

fluid conduit means extending between said inlet port and the interior of said chamber;

a first outlet conduit communicating between said manifold first surface inside said chamber and the manifold periphery;

a second self-sealing inlet port in said manifold mesa, said second inlet port being in alignment along said axis with said first inlet port and accessible from the manifold second surface at the top of said mesa; and

a second outlet conduit in said manifold communicating between said second inlet port and the periphery of said manifold.