



- (51) **International Patent Classification:**
A61M 39/08 (2006.01) *A61M 39/10* (2006.01)
- (21) **International Application Number:**
PCT/EP2012/004718
- (22) **International Filing Date:**
14 November 2012 (14.11.2012)
- (25) **Filing Language:** English
- (26) **Publication Language:** English
- (30) **Priority Data:**
11009454.7 30 November 2011 (30.11.2011) EP
61/564,980 30 November 2011 (30.11.2011) US
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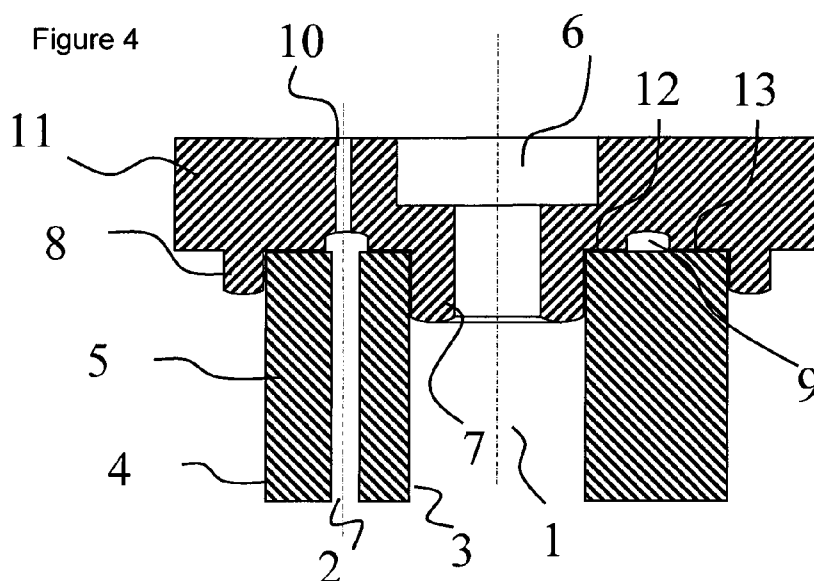
(81) **Designated States** (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, 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, PA, 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))

(54) **Title:** CONNECTOR WITH DOUBLE LUMEN TUBE



(57) **Abstract:** The present invention relates to an assembly of a dual lumen tubing as described above and a dual bore connector as described above having a first flow conduit along the first lumen and the first bore, and having a second flow conduit from the second bore, via a circumferential groove and along the second lumen. Such an assembly may be used in connection with an extracorporeal circuit of a haemodialysis machine or an infusion set.

CONNECTOR WITH DOUBLE LUMEN TUBE

Description

5 The present invention relates to a double lumen tubing set and connector. This tubing set is intended for use with infusion bags or vials. In particular the tubing set is intended to be used with haemodialysis machines or an infusion set.

Background

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In haemodialysis treatments which require an extracorporeal circulation it is often necessary to administer different drugs or therapeutic substances to the patient. The presence of the tubing set advantageously makes it possible to avoid the administering of the drug taking place through puncture carried out directly on the
15 patient himself.

During the haemodialysis treatments it often becomes necessary to administer different drugs or therapeutic substances, like iron, heparin, erythropoietin, vitamins and antibiotics. The infusion of such substances in the extracorporeal circuit is
20 currently carried out through conventional syringes. The substance is drawn from a vial or ampoul in which it is supplied by the manufacturer and is then injected into a special puncturable access point provided along the tubing set. Thus there is a double transfer of the substance: firstly from the vial to the syringe and then from the syringe to the circuit. Such an operation therefore requires the use of disposable
25 materials, such as the syringe and the respective needle, just to transfer the substance from the vial to the tubing set. Moreover, the use of needles always carries the risk of the service staff being pricked. In case the drug is supplied in ampouls, these have to be broken with risk of injuries (sharp edges) or to suck possible glass fragments into the syringe.

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Finally, some of the quoted substances need to be administered slowly, over a few minutes. Therefore it can easily be understood how the administering of various substances to more than one patient represents a considerable workload for the nursing staff responsible for the treatment.

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WO 201 1/054693 discloses a tubing set having a gate for the connection of vials to an extra-corporeal circuit of a haemodialysis machine.

WO 87/07159 discloses a medical fluid administration set which is intended for infusions related to an intravenous therapy; such set is not suitable for use in cooperation with a haemodialysis machine.

GB 1432105 discloses a medical drain comprising an elongate tube having a central first lumen and a peripheral outer wall, a second lumen integral with and lying within the peripheral outer wall in spaced parallel relation to the central first lumen.

15

US 3,495,595 discloses a medico-surgical tube comprising a double lumen tube.

US 5,401,241 discloses a duodenal intubation catheter comprising a double lumen tube.

20

US 5,868,717 discloses a dual-lumen catheter and method of use.

Problem of the invention

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Conventional tubing sets for infusion comprise a single lumen line connecting a vial and a drip chamber. The single lumen line serves two functions. Firstly, it acts as a delivery lumen, suitable for delivering the drug from the vial to the drip chamber. And secondly, it acts as a vent lumen, suitable for providing air inside the vial in order to replace the delivered drug. In other words, the liquid infusion flows down to the drip chamber, while air returns through the same line to vent the vial for pressure compensation. This counter-current flow may lead to an unsteady flow of the

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medicament to the drip chamber. It is one task of the present invention to provide a steady flow of a liquid medicament from a vial to a patient infusion line or to an extracorporeal circuit of a haemodialysis machine.

5 Alternatively, two separate lumen may be used to achieve a steady flow of medicament and air. While single lumen tubes are readily available, an assembly of two tubes may in some cases be time-consuming and the correct connection of each tube has to be assured. In some cases two tubes cannot be connected due to spatial
10 constrains in the design of a haemodialysis machine.

10

Dual or multi lumen tubes have two or more lumen running parallel. Dual lumen tubing sets are known from prior art. They are frequently used for a multitude of applications. In one typical embodiment a dual lumen tubing comprises two parallel lumen attached to each other having a cross section with a shape of a figure 'eight'
15 or two connected semicircles forming an overall circular shape.

15

One drawback of conventional dual lumen tubing is that the assembly requires high precision. At both ends of the tubing each lumen has to be connected to its respective port. Furthermore, a high angular precision is necessary in order to
20 achieve a tight connection between the tubing and a connector. Even a minor axial rotation of the tube may lead to an insufficient connection of one or both lumen. A rotation of 180° will result in a mix-up of both lumen.

20

Tubing sets for use in infusion and/or haemodialysis are commonly single use items,
25 which will be disposed of after use. As the price for disposable articles is typically low such items require low cost manufacturing. This is normally achieved by a highly automated production process. It is economically advantageous to limit the number of manual production steps or even completely eliminate them from the production process. Thus, it is another task of the present invention to provide a tubing set which
30 can be manufactured in a highly automated production process.

30

Summary of the invention

In one aspect, the invention relates to a dual lumen tubing comprising a first circular lumen and a second lumen wherein said first lumen has a circular inner cross section with radius r_1 and an outer circular cross section with radius r_2 and wherein the second lumen is located in the wall of the tubing having a diameter d_3 with $d_3 < (r_2 - r_1)$.

In another aspect, the invention relates to a dual bore connector comprising a first bore, two circular contact surfaces and a circumferential groove between the inner radius r_1 and the outer radius r_2 and embedding the second bore. In yet another embodiment, the dual bore connector may, optionally, comprise an inner cylindrical connection means with an outer radius r_1 and/or an outer cylindrical connection means with an inner radius r_2 .

In yet another aspect, the invention relates to an assembly of a dual lumen tubing as described above and a dual bore connector as described above having a first flow conduit along the first lumen and the first bore, and having a second flow conduit from the second bore, via the circumferential groove and along the second lumen.

Such an assembly may be used in connection with an extracorporeal circuit of a haemodialysis machine or an infusion set.

The invention is also directed to a process for manufacture of an assembly as described above comprising the step of glueing, and, optionally, simultaneously or consecutively blowing a gas through the second bore, via the circumferential groove and along the second lumen.

Figures

The characteristics and the further advantages of the present invention shall become clear from the following description of some embodiments, given for indicating and not limiting purposes with reference to the attached drawings.

Figure 1 schematically represents a cross sectional view of a dual lumen tubing according to the present invention.

Figure 2 schematically represents a cross sectional view of a dual bore connector according to the present invention.

Figure 3 schematically represents a cross sectional view of an assembly of a dual lumen tube and a dual bore connector according to the present invention.

Figures 4 - 6 schematically represent cross sectional views of assemblies of a dual lumen tube and a dual bore connector according to further embodiments of the present invention.

Detailed description of the invention

The problems described above are solved by the present invention by providing a dual lumen line having two separate lumina comprising a first circular lumen (1) and a second lumen (2) wherein said first lumen (1) has a circular inner (3) cross section and a circular outer cross section (4) and wherein the second lumen is located in the wall (5) of the tubing and wherein this double lumen tube is connected to a dual bore connector comprising a first bore (6) and a second bore (10) and having a circumferential groove (9) around the first bore (6) embedding the second bore (10).

The two lumina of the dual lumen tube are connected to the two bores of the dual bore connector facilitating two flow conduits. A first conduit is formed by the circular lumen (1) and the first bore (6). The second conduit is formed by the second lumen

(2) and the second bore (10) via the circumferential groove (9). A permanent flow connection between the second lumen (2) and the second bore (10) is facilitated by the circumferential groove (9), which is independent of an axial rotation of the dual lumen tube during assembly or use.

5

In the description of the present invention the term "dual lumen tube" refers to a tube having two lumina running parallel and with one lumen embedded in the wall of a first lumen. More specifically, the term "dual lumen tube" refers to a tube comprising a first circular lumen (1) and a second lumen (2) wherein said first lumen (1) has a circular inner cross section (3) with radius r_1 and an outer circular cross section (4) with radius r_2 and wherein the second lumen is located in the wall (5) of the tubing having a diameter d_3 with $d_3 < (r_2 - r_1)$.

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In the description of the present invention the term "dual bore connector" refers to a connecting means having two bores and a circumferential groove around a first bore and embedding the second bore. More specifically, the term "dual bore connector" refers to a connecting means (11) comprising

15

- a first bore (6),
- a circular contact surface (12) with an inner radius r_1 and a circular contact surface (13) with an outer radius r_2 surrounding said first bore (6), and
- a circumferential groove (9) between the inner radius r_1 and the outer radius r_2 and embedding the second bore (10).

20

In the description of the present invention the term "assembly" refers to a combination of a "dual lumen tube" and a "dual bore connector" as defined above.

25

Embodiments of the present invention will be disclosed in detail, with specific reference to figures 1 - 6. In such embodiments the liquid medicament flows - either by gravity or pressure difference, e.g., generated by a pump or pneumatic pressure - from a fluid reservoir (e.g. a vial or an IV bag) through the delivery port (10) via the

30

circumferential groove (9) to the delivery lumen (2). In return, air flows through the vent lumen (1) and the bore (6) to the fluid reservoir.

One aspect of the invention is depicted in figure 1 and relates to a dual lumen tubing comprising a first circular lumen (1) and a second lumen (2) in the wall (5) of the tubing forming said first lumen (1) and having a circular inner (3) and a circular outer cross section (4).

One further aspect of the present invention is depicted in figure 2 and relates to a dual bore connector comprising

- a first bore (6),
- a circular contact surface (12) with an inner radius r_1 and a circular contact surface (13) with an outer radius r_2 surrounding said first bore (6), and
- a circumferential groove (9) between the inner radius r_1 and the outer radius r_2 and embedding the second bore (10).

One embodiment of the present invention is depicted in figure 3 and relates to an assembly of a dual lumen tube (1-5) and a dual bore connector (6-13) comprising a first bore (6), a circular contact surface (12) with an inner radius r_1 and a circular contact surface (13) with an outer radius r_2 surrounding said first bore (6), a circumferential groove (9) between the inner radius r_1 and the outer radius r_2 and embedding the second bore (10), and a dual lumen tube being attached to the contact surfaces (12) and (13) of the dual bore connector. The dual lumen tube can be attached to the contact surfaces (12) and (13) of the dual bore connector by means of, e.g., welding or glueing.

In further embodiments of the present invention the dual bore connector optionally comprises one or two circular connection means (7) and (8) having a cylindrical or tubular shape. A dual lumen tube as defined above can be attached to the dual bore connector by fitting it onto the tubular connection means (7) and (8). Examples of

further embodiments comprise one or two circular connection means (7) and/or (8) are depicted in figures 4 - 6.

One further embodiment of the present invention is depicted in figure 4 and relates to an assembly of a dual lumen tube (1-5) and a dual bore connector (6-13). The assembly comprises a dual bore connector having two cylindrical connection means [(7) and (8)] around a first bore (6) and having two contact surfaces [(12) and (13)], and a circumferential groove (9) embedding the second bore (10) in between the two cylindrical connection means [(7) and (8)]. The dual lumen tube (1-5) is attached to the dual bore connector (6-13) by fitting it in between the two cylindrical connection means [(7) and (8)], and, optionally, glueing or welding it to the contact surfaces (12) and (13).

One further embodiment of the present invention is depicted in figure 5 and relates to an assembly of a dual lumen tube (1-5) and a dual bore connector (6-13). The assembly comprises a dual bore connector having one cylindrical connection means (7) around a first bore (6) and having two contact surfaces (12) and (13), and a circumferential groove (9) embedding the second bore (10) around the cylindrical connection means (7). The dual lumen tube (1-5) is attached to the dual bore connector (6-13) by fitting the first lumen (1) onto the cylindrical connection means (7), and, optionally, glueing or welding it to the contact surfaces (12) and (13).

One further embodiment of the present invention is depicted in figure 6 and relates to an assembly of a dual lumen tube (1-5) and a dual bore connector (6-13). The assembly comprises a dual bore connector having one cylindrical connection means (8) around a first bore (6) and having two contact surfaces (12) and (13), and a circumferential groove (9) embedding the second bore (10) in between the first bore (6) and the cylindrical connection means (8). The dual lumen tube (1-5) is attached to the dual bore connector (6-13) by fitting it into the cylindrical connection means (8), and, optionally, glueing or welding it to the contact surfaces (12) and (13).

In a second embodiment of the present invention, the allocation of the two lumen (1) and (2) is swapped. Again, reference is made to figures 1 - 6. In such a second embodiment the liquid medicament flows - either by gravity or pressure difference, e.g., generated by a pump or pneumatic pressure - from a fluid reservoir (e.g. a vial or an intravenous infusion bag) through the delivery port (6) to the delivery lumen (1). In return, air flows through the vent lumen (2) via the circumferential groove (9) and the bore (10) to the fluid reservoir.

Dual lumen tubes can be made from one or a combination of different materials.

Without limitation such materials include, e.g., polyamide (Nylon), polyurethane, polyethylene (HDPE, LDPE or LLDPE), polypropylene, PVC, PTFE (Teflon), synthetic or natural rubbers, silicone, stainless steel and other metal material or combinations thereof.

Dual lumen tubes are obtainable using processes known to those skilled in the art. Without limitation such processes include, e.g., extrusion, welding, winding rotary piercing, drawing over a mandrel and sewing. A preferred process is extrusion.

The dual bore connector can be made from one or a combination of different materials. Without limitation such materials include, e.g., nylon, polyesters, polyurethane, polypropylene, polystyrene, polyethylene (HDPE, LDPE or LLDPE), polycarbonate, ABS, PVC, PTFE (Teflon), styrene-acrylonitrile resin stainless steel and other metal material or combinations thereof.

The dual bore connector can be manufactured by, e.g., injection moulding, turning or milling.

The dual lumen tube as described above is attached to the dual bore connector.

The dual lumen tube can be attached to the connector by any means of fastening known to those skilled in the art. Without limitation, examples for means of fastening are ferrules, clamps or tube clips. The tube may in addition or alternatively be

fastened to the connector by welding or by use of an adhesive or glue. The adhesives can be solvent-type glues, synthetic monomer glues or synthetic polymer glues.

- 5 In one preferred embodiment the tube is attached to the connector by glueing. During the process of glueing a gas is preferably blown through the lumen (1) and/or (2) or through the ports (6) and/or (10) of the connector to prevent glue from blocking the fluid flow paths of the assembly. Without limitation the gas may include nitrogen, oxygen, noble gases or air. Air is the preferred gas.

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In another preferred embodiment the tube is attached to the connector by mechanical interference and glueing. (see Figure 4) The tube is attached to the connector by mechanical interference with the cylindrical connection means (7) and glueing the tube to the cylindrical connection means (8). Glue is applied to the outer surface (4)
15 of the tube, while no glue is applied to the front end and the inner surface (3) of the tube.

- Examples for solvent-type glues are polystyrene cement/butanone or dichloromethane, which by welding bond the material together. Examples for
20 synthetic monomer glues are acrylonitrile, cyanoacrylate ("Superglue"), acrylic or resorcinol glue. Examples for synthetic polymer glues are epoxy resins, ethylene-vinyl acetate (a hot-melt glue), phenol formaldehyde resin, polyamide, polyester resins, polyethylene (a hot-melt glue), polypropylene, polysulfides, polyurethane, polyvinyl acetate (PVA), polyvinyl alcohol, polyvinyl chloride (PVC), polyvinyl chloride
25 emulsion (PVCE), polyvinyl pyrrolidone (PVP), rubber cement, silicones and styrene acrylic copolymer.

Claims

1. Tubing comprising a first circular lumen (1) and a second lumen (2) wherein said
5 first lumen (1) has a circular inner cross section (3) with radius r_1 and an outer
circular cross section (4) with radius r_2 and wherein the second lumen is located
in the wall (5) of the tubing having a diameter d_3 with $d_3 < (r_2 - r_1)$.
2. Tubing according to claim 1 wherein the second lumen (2) has a circular cross
10 section.
3. Dual bore connector (11) comprising
 - a) a first bore (6),
 - 15 b) a circular contact surface (12) with an inner radius r_1 and a circular contact
surface (13) with an outer radius r_2 surrounding said first bore (6), and
 - c) a circumferential groove (9) between the inner radius r_1 and the outer radius
 r_2 and embedding the second bore (10).
- 20 4. Dual bore connector according to claim 3 comprising
 - a) an inner cylindrical connection means (7) with an outer radius r_1 and / or
 - b) an outer cylindrical connection means (8) with an inner radius r_2 .
- 25 5. Assembly comprising a tubing according to claim 1 or 2 and a dual bore
connector according to claim 3 or 4.
6. Assembly according to claim 5 having a first flow conduit along the first lumen (1)
and the first bore (6), and having a second flow conduit from the second
30 bore (10), via the circumferential groove (9) and along the second lumen (2).

7. Process for manufacture of an assembly according to claim 5 comprising the step of glueing the dual lumen tube onto the dual bore connector.
8. Process according to claim 6 comprising the step of blowing a gas through
5 lumen (2) or port (10).
9. Use of a tubing set according to claim 5 in connection to an extracorporeal circuit of a haemodialysis machine or an infusion set.
- 10 10. Use of a tubing set according to claim 5 in connection to an extracorporeal circuit of a haemodialysis machine or an infusion set.

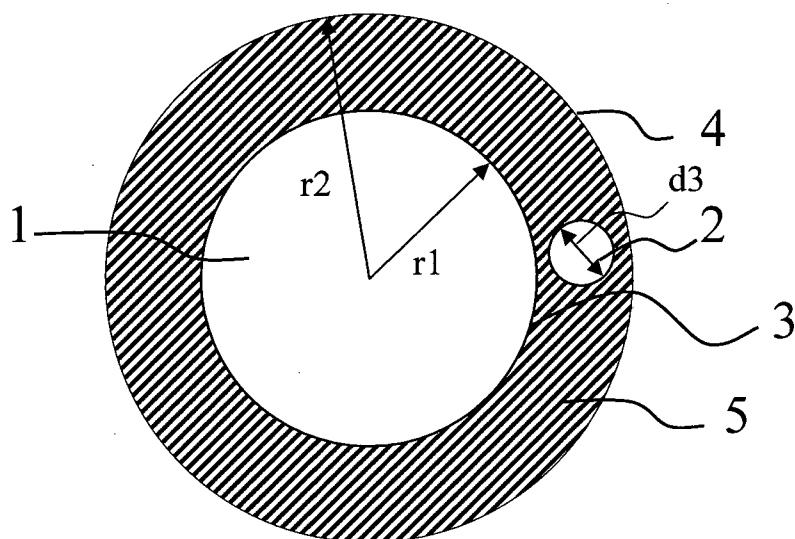


Figure 1

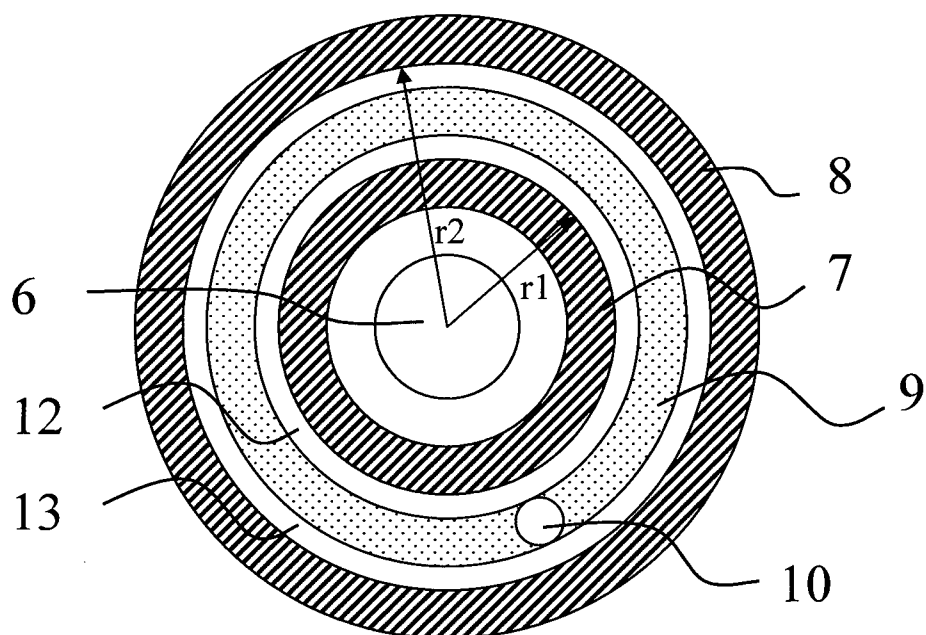


Figure 2

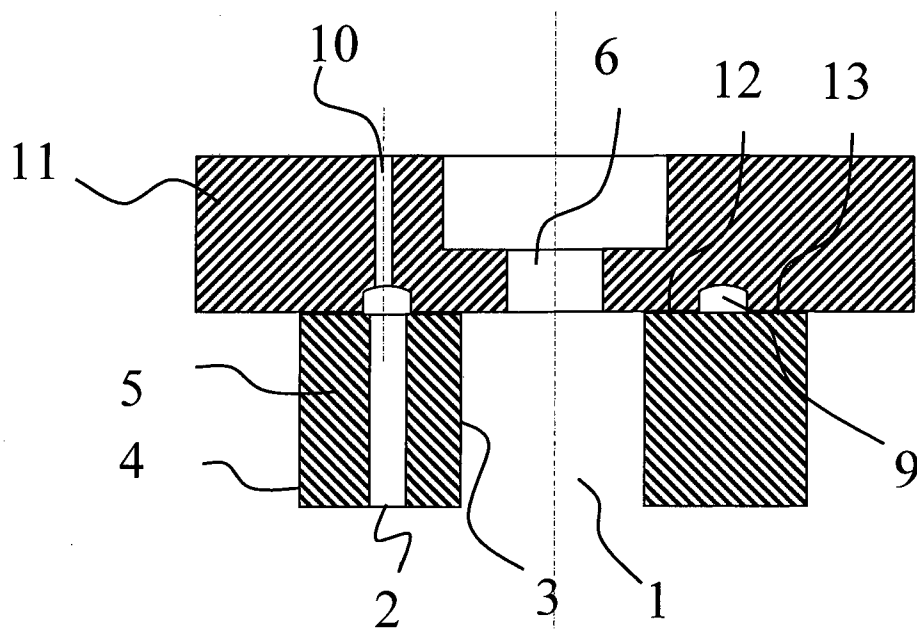


Figure 3

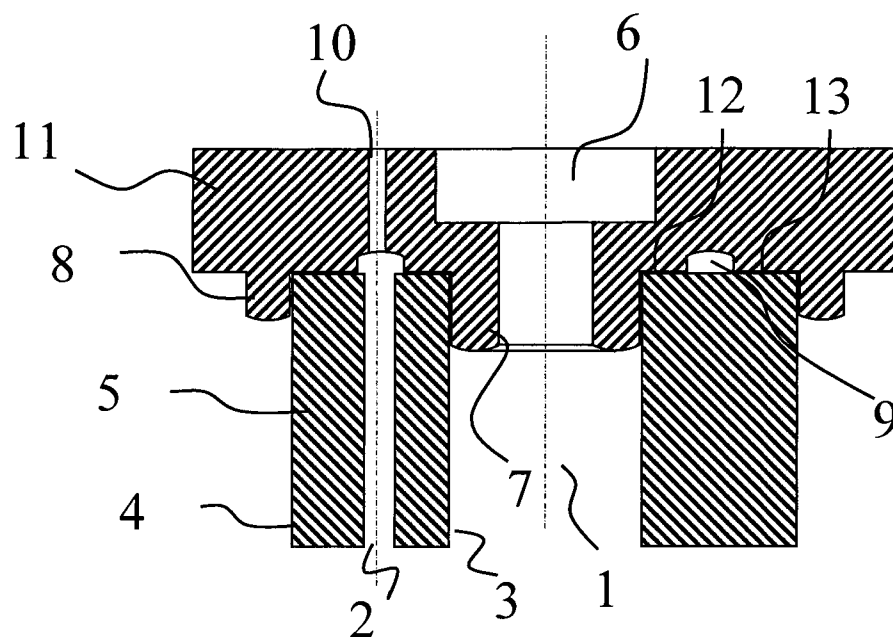


Figure 4

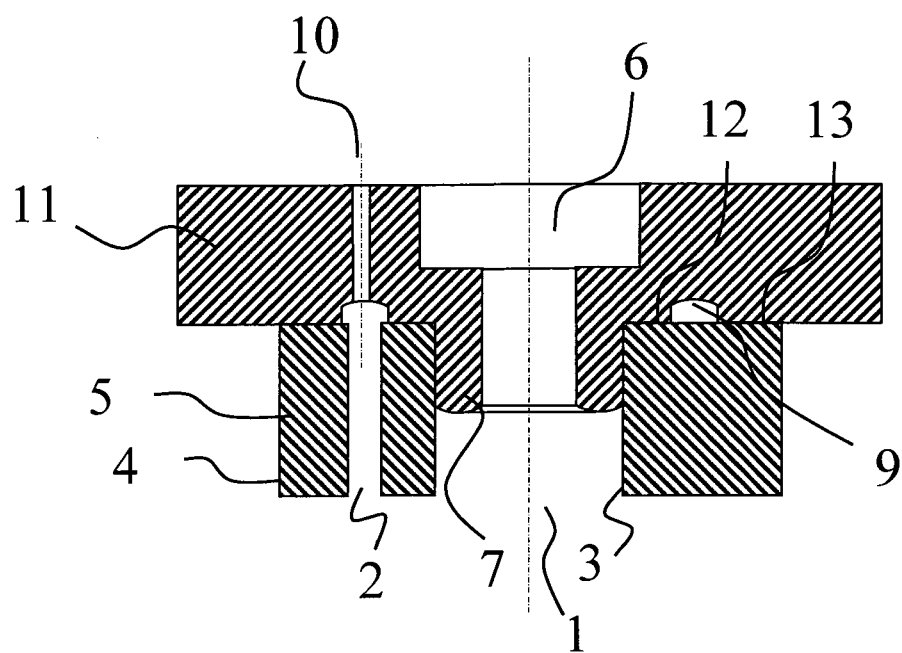


Figure 5

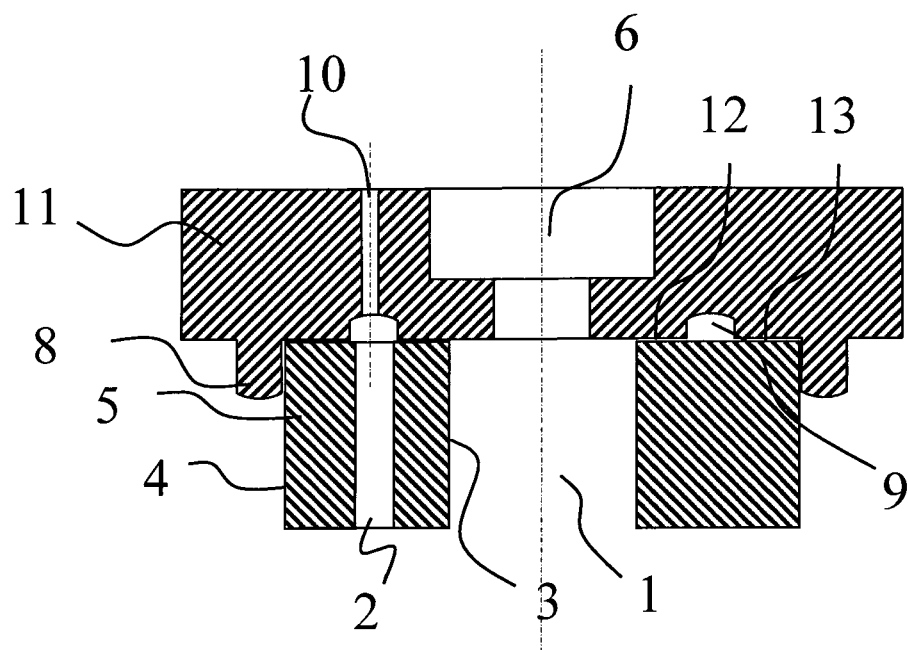


Figure 6

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2012/004718

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M39/08 A61M39/10
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

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	US 2007/088218 AI (MCINTYRE JOHN [US] ET AL) 19 April 2007 (2007-04-19) figure 6b -----	1,2
X	US 2008/011368 AI (SINGH VINAY K [US] ET AL) 17 January 2008 (2008-01-17) figure 3b -----	3,4
X	GB 2 307 180 A (KCI MEDICAL LTD [GB]) 21 May 1997 (1997-05-21) figure 6e -----	1,2
X,P	US 2011/315147 AI (WOOD LOCKETT E [US] ET AL) 29 December 2011 (2011-12-29) paragraph [0035] ; figure 3 ----- -/- .	1,2



Further documents are listed in the continuation of Box C.



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

12 December 2012

Date of mailing of the international search report

19/12/2012

Name and mailing address of the ISA/

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NL - 2280 HV Rijswijk
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Fax: (+31-70) 340-3016

Authorized officer

Nei l l er, Frederi c

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2012/004718

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P	<p>WO 2012/0 10322 A2 (FRESNIUS MEDICAL CARE DE GMBH [DE] ; HAECKER JUERGEN [DE] ; NOACK JOACH) 26 January 2012 (2012-01-26) the whole document</p> <p>-----</p>	3,4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2012/004718

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.: **9. 1^Q**
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
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:

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. ☐ 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. :

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/EP2012/004718

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